MEASURING TRANSITIONAL PATIENT SAFETY

TIPPs AND TRIQs AND TRACEs

MARIJE ANNELIEKE VAN MELLE

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MEASURING TRANSITIONAL PATIENT SAFETY

TIPPs, TRIQs AND TRACEs

Evaluatie van transmurale patiëntveiligheid; over TIPPs, TRIQs en TRACEs
(met een samenvatting in het Nederlands)

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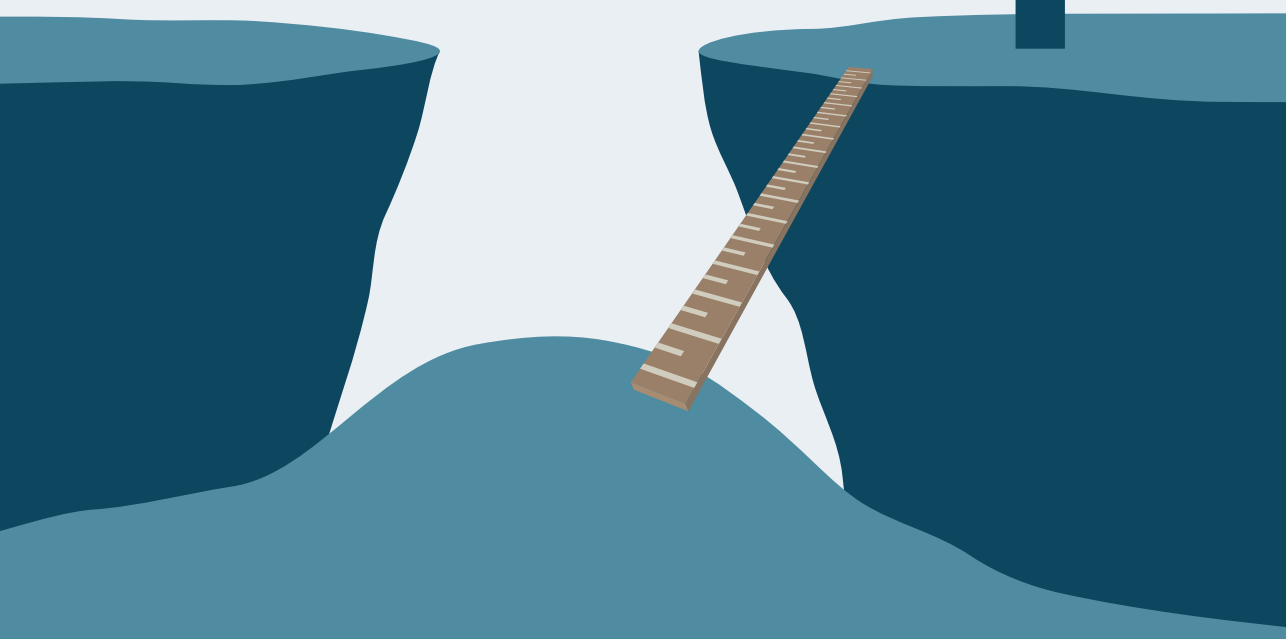

GENERAL INTRODUCTION

An elderly patient is referred to the geriatrician by the general practitioner who suspects him of dementia. In hospital, the geriatrician detects a suboptimal kidney function, which was known to the general practitioner, who deemed it as acceptable for the patient's age. Yet, the geriatrician stops the metformin that was prescribed for his diabetes. Also, the geriatrician requests a colonoscopy for the patient. For this procedure, the family decides to bring the patient to another hospital because of its shorter waiting time. After the colonoscopy, a resident of this hospital calls the general practitioner to inform him that the patient's blood glucose level was elevated and suggests further treatment in general practice. With this call the general practitioner is indirectly informed on the colonoscopy. When the patient is seen in general practice, his blood glucose and the glycated hemoglobin (HbA1c) are very high. Only at this point, the general practitioner notices that the metformin prescription has been stopped by the geriatrician. The general practitioner remains uninformed about the reason for the colonoscopy, and on the outcome of the diagnostic process for dementia.

Transitional patient safety

Every clinician will recognize the flaws in this real-life patient case as quite familiar in current daily practice. The geriatrician appears not to have pursued the general practitioner's (GP) question for dementia diagnostics. Was the GPs referral letter absent, or maybe unclear? Also, the geriatrician diagnoses and treats already known healthcare issues without first consulting the GP. Wouldn't this violate a non-treatment decision that has been consciously taken, maybe even in shared decision with the patient? Furthermore, communication and correspondence between the subsequent professionals involved seems lacking. And lastly, is the transitional process further muddled by the fact that the patient and his family chose to go to different hospitals for different healthcare complaints, creating more transitions and risking lack of coordination? Evidently, this case reveals patient harm due to these transitional incidents, and the consequences could have been even worse for this patient. Indeed, patient transitions between primary and secondary care are potentially harmful.

The number of transitions is expected to increase because of the ageing population and current health policy. Elderly patients with more complex health issues will often be simultaneously treated by several physicians. This demands close collaboration between the physicians involved. In addition, health policy stimulates low-complex hospital care to be substituted to primary care in order to control healthcare costs.[1] These developments lead to further increase of patient transitions between different levels of healthcare worldwide, which, with current practice, will likely result in increased patient harm. Hence, improving communication and logistics of care transitions, or improving so-called 'transitional patient safety' is key for the quality and safety in healthcare.[2]

Transitional patient safety concerns any patient transition in the healthcare system. Yet, this thesis focuses on the patient transition between primary and

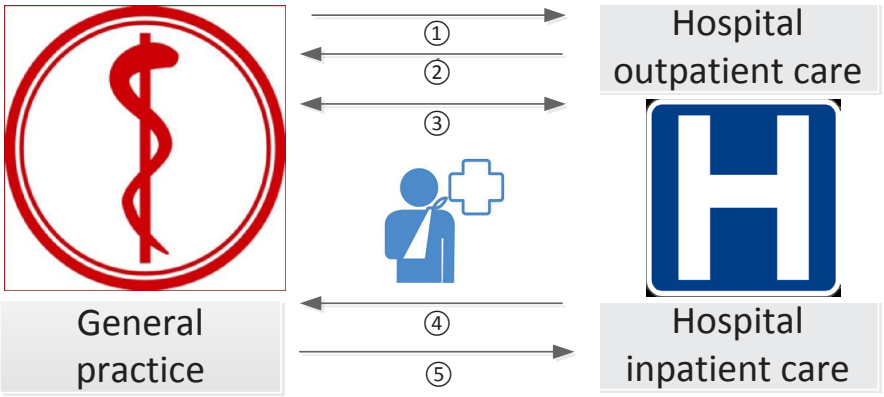

Figure 1.1 Patient movements between general practice and hospital
1=referral to specialty outpatient care, 2=discharge from specialty care to general practice, 3= concurrent care at specialty outpatient clinic and general practice, 4= discharge after hospital admission, 5=referral to emergency department

secondary healthcare settings, such as referral, discharge, and visits to the Emergency Department and Outpatient Department (see Figure 1.1).

All these care transitions include handover of responsibility for the patient's care between health professionals. For this, adequate exchange of vital information is key.[3] When handover processes between the professionals involved are not well aligned, and hampered by poor or even lacking communication, transitional safety incidents occur.[4] A transitional safety incident (TSI) is defined as "any unintended or unexpected event in patient care between different healthcare settings which could have led or did lead to harm for one or more patients receiving care."[5] TSIs can be subdivided, according to impact and severity, in unsafe situations (circumstances or events that enhance the risk for error), near misses (an act of commission or omission that could have harmed the patient but did not do so as a result of chance, prevention or mitigation) and adverse events (any injury to a patient caused by medical care).

Internationally, 20-30% of the discharged patients experiences an adverse event causing patient harm.[6,7,8] Of the readmitted patients, 20% attributed their readmissions to too early discharge, poor quality of hospital care, or inadequate discharge instructions for follow-up .[9] Errors in communication, medication errors, incomplete provision of care, and incomplete patient instructions are found to be main causes of TSI around hospital discharge. For instance, in the US, only half of discharge summaries were sent within four weeks, and none met the quality criteria such as timeliness, addressing the appropriate physician, and completeness of content.[7,10] Also, approximately 40% of discharge summaries contained medication discrepancies,[11,12] and 27% of the drugs that were stopped in the hospital because of adverse drug events were found to be re-prescribed after discharge by the general practitioner.[13] Furthermore, in up to 43% of discharge summaries, relevant

information on post-discharge management was missing and only 16-35% of the pending tests were communicated to the follow-up provider.[7,14] In the Netherlands, Roorda et al. found that after outpatient treatment for breast cancer, in only half of patients referred back to the GP for follow-up care this transfer was adequately communicated.[15] Altogether, there is overwhelming evidence that the transfer of patients from hospital to home is a high risk event. On the other end of the patient's journey, the quality of the GP's referral is also often suboptimal. Hospital specialists considered only one out of six referral letters as "relatively good"[16,17]. Other research showed that approximately 80% of referral letters contain medication discrepancies.[18]

When applying these international results to the Dutch situation, we urgently need to tackle transitional safety problems in order to improve healthcare, to reduce patient harm and avoid unnecessary healthcare costs.

Causes of transitional safety incidents

Problems with unsafe patient transitions between different care settings are not new, and have been reported for decades.[19] The persistence of transitional unsafety is striking, yet probably a result of fragmentation in the healthcare system.[20,21,22] Different healthcare settings act as separate entities, working independently.[22,23] Because of discontinuity between these settings, gaps occur. Good collaboration and communication is needed to bridge these gaps.[24] Presently , healthcare providers are focused on the provision of healthcare within their organisation, and do not feel a shared responsibility when patients move to a different setting.[25,26,27] In 2012, the Dutch Healthcare Inspection concluded that healthcare providers were not fully aware of their responsibilities in handover situations between primary and secondary care.[28] Patient information was not always forwarded to the next 'link in the healthcare chain' in a timely manner, nor was the information necessarily complete or adequate.[28] Healthcare professionals reported barriers for good communication, such as the lack of personal contact between providers and insufficient knowledge on each other's working processes.[29] Groene and Gobel et al describe general practice and the hospital environment as being two separate worlds.[25,26] In each of these two worlds, many professionals are involved in the transitional handover process, but they do not have shared protocols, nor are they trained in transitional handovers. As a result, handovers are often inefficient and vulnerable for process failures. Despite efforts and best intentions of the stakeholders at both sides, handovers remain 'high risk' situations for transitional safety incidents.

Interventions to improve transitional patient safety

Many interventions have been designed and tested to improve transitional patient's safety. The Care Transition Intervention (Coleman et al) combined a patient held

healthcare record to promote an active patient role and a transfer nurse at discharge.[30] Project Red (Jack et al), redesigned the discharge procedure, which resulted in the implementation of a transfer nurse ('a discharge advocate') who ensured improved patient education with an 'After Hospital Care Plan' and medication review at discharge.[31] In the Transitional care model Naylor et al implemented a transitional care nurse who was responsible for discharge planning protocol and all home follow-up[32], while project Boost (Hansen et al) focused on improving the discharge process within hospitals.[33] All of these interventions focused on improving the discharge process from hospital to home, and did not address other parts of the patients' journey such as referrals or simultaneous care in both general practice and hospital.

According to a systematic review by Laugaland et al., discharge interventions can be divided into 1) interventions aimed at improving professional behavior, such as education and training; 2) process interventions, such as implementation of transfer nurses or medication reconciliation, redesigning discharge protocols, discharge planning, standardized discharge letters or electronic discharge tools; and 3) patient or family-orientated interventions, such as education, coaching or discharge support.[23] In Laugaland's review, as well as in reviews by Rennke and Eklund, over one in three of the included interventions were shown to improve outcomes of transitional patient safety.[23,34,35] Successful interventions reduced readmission rates, decreased the number of adverse drug events, increased satisfaction of patients and relatives or decreased healthcare consumption and costs.[23]

However, the quality of most of these studies was low.[34,35] Outcome measures were heterogeneous and the validity of measurement instruments mostly unclear.[35] Only few studies provided information on contextual factors, costs, and the fidelity of transitional care strategies. Overall, the intervention effects appeared to be very context specific.[34] Furthermore, most interventions published were solely aimed at one healthcare setting, mainly in-hospital. Although transitions of care do not only involve different settings but also different professionals, only few studies took a multidisciplinary approach. In addition, most of these single setting interventions seemed to have a short-term effect. Intervening on multiple levels potentially results in a more sustained effect. Therefore, multi-component interventions are recommended.[7,23]

In conclusion, although there is a fair amount of evidence for the unsafety of patient transitions and the background processes causing them, evidence for successful improvement strategies is scarce. Interventions that proved to work in one setting seem difficult to scale up, and evidence on their potential to actually improve safety during patient transitions is contradictory.[7,23,34]

Stakeholders' involvement

So far, most interventions aim at process improvement only, i.e. the procedures involved when patients are handed over. These describe actions that professionals are expected to undertake when transferring a patient between settings, such as

writing referral letters, making follow up appointments, reviewing medication and preparing discharge information. However, for optimal implementation of these procedures, professionals need to change their behaviour too, i.e., they need to adjust 'the way they normally do things' around patient transitions. This requires a constructive transitional patient safety culture[36], comprising of values, attitudes, competencies, and behavioural patterns of the organisations and professionals.[37] A transitional patient safety culture concerns the way professionals working in different healthcare settings think about and act towards each other in case of patient transitions.[38] The incident described in the introduction is an example of a failing transitional patient safety culture. When internally referring the patient for a colonoscopy without informing the general practitioner, the medical specialist does not adequately value the longstanding relationship that the general practitioner has with the patient, which could have rendered vital information for the diagnostic decision making. Furthermore, although the diagnostics and treatment had not finished yet, a letter to inform the GP about the medication changes would have benefitted continuity of pharmacotherapy for the patient.

Interestingly, the fact that the patient in the example consulted a different hospital because of shorter waiting times has put the continuity of care even more at risk. The role of the patient in healthcare safety is of vital importance. The patient is the central and consistent factor and the only one who experiences the entire healthcare journey. With every transition, the patient crosses the gap between the two worlds of primary and secondary care. However, many patients do not appreciate the risks during their healthcare journey, and do not actively participate in safeguarding their own patient safety.[26,39] Getting the patient involved may boost awareness and outcomes of transitional safety. The ability of patients to understand and participate depends on both individual and contextual factors, which should be taken into account in clinical practice .[30,39] Actions of professionals to safeguard patients' safety should be tailored to the individual needs and competencies of patients. But first, to optimally involve patients, we need to gain more insight in the role that patients play in transitions and in the opportunities that occur to empower the patient.

Summarising, for the development of effective strategies to improve transitional safety we need to develop a comprehensive approach, based on a constructive safety culture, with improvement of the processes around patient transitions, as well as better involvement of patients and professionals. Valid measurement instruments are required to monitor the safety culture, for assessment of patients and professionals' perceptions, and to evaluate the effect of interventions.

Transitional Incident Prevention Programme (TIPP)

Following the Intervention mapping approach, we designed a pragmatic complex intervention programme, based on the comprehensive approach of transitional safety, involving healthcare processes as well as professionals' safety culture and

patients' participation.[40,41] The overall aim was to develop a strategy and tools for improving transitional safety between hospitals and their regional partnering general practices. For this, we needed further understanding of the current practice of care transitions in the Netherlands, and we needed to develop measurement tools assessing background and outcomes of transitional safety.

The TIPP study consisted of three phases:

1) a diagnostic phase in which we further explored the current status of transitional patient safety in the different settings (frequency, type, and severity of transitional safety incidents, transitional safety culture and patients' perceptions) to determine the main challenges and the required instruments,
2) a developmental phase in which we used the information we collected in the first phase to develop measurement instruments and an intervention program to improve transitional patient safety,
3) an intervention phase in which we implemented and evaluated the developed interventions in a pragmatic trial.

Our exploration of transitional patient safety was guided by the concept by Donabedian, who discerned three dimensions in the evaluation of quality of care, namely *structure* (how care is organised), *process* (what healthcare professionals do to maintain or improve health, either for healthy people or for those diagnosed with a healthcare condition) and *outcome* (what ultimately happens to the patient).[42] Measuring structure gives patients a sense of a healthcare provider's capability, systems and processes to provide high-quality care. Examples are the presence of an electronic medical record and a medication prescription system, or the presence of a safety incident reporting system. Process measures indicate what a provider does to maintain or improve healthcare, i.e. the adherence to guidelines and checklists. Outcome measures reflect the impact of the healthcare service on the health status of patients. Examples are the percentage of patients who died as a result of surgery, infection rates, functional status, wellbeing, or experienced patient harm or safety incidents. Later, Pronovost et al. expanded the quality of care model by adding patient safety culture as a precondition for the provision of high quality care.[43] Frequently used strategies to measure patient safety within organisations are retrospective chart review incident reporting systems, audits, and patient reports.[44,45] These measurement strategies could also be used in monitoring transitional patient safety.

The objectives and outline of this thesis

This thesis focuses on the exploration of transitional patient safety, on the development of new measurement tools and on the evaluation of an intervention program for transitional patient safety.

The main objectives are:

1) To explore the frequency, type and severity of transitional incidents
2) To map existing measurement tools and outcomes that are used in transitional patient safety, assess their quality and identify knowledge gaps,
3) To develop and validate new measurement tools to measure different aspects of transitional patient safety, such as processes, culture and patients' perceptions.
4) To implement and evaluate a multifaceted intervention program to improve transitional patient safety.

The outline of this thesis is visualized in Figure 1.2. To provide an insight into transitional patient safety and its problems, we first collected number and background of transitional incidents as experienced by healthcare professionals from primary and hospital care, and patients, through focus groups, interviews, and transitional incident reporting procedures. In Chapter 2, we provide an overview of all the collected transitional incidents throughout this first phase of TIPP. In Chapter 3, we systematically assessed existing outcomes and measurement tools used in transitional patient safety. Chapter 4 describes the concept of transitional patient safety culture and the development and validation of the TRAnsitional patient safety Climate Evaluation (TRACE) instrument. Chapter 5 describes the development and validation of the Transitional Risk and Incident Questionnaire (TRIQ), measuring patient perception of transitional patient safety. To facilitate measurement of TSIs, we developed a transitional medical record database, linking medical records of general practice and hospitals. In Chapter 6 we describe the comparison of transitional patient safety incidents as identified in the medical records with the patients' stories. In Chapter 7, we describe the validation of the newly developed transitional medical record review procedure. In Chapter 8, we present the results from a medication review study on the transfer of prescription changes from hospital to general practice as measured in the transitional database. In Chapter 9, we describe the protocol for the evaluation of the multifaceted TIPP intervention program to improve transitional safety. Finally, in Chapter 10 we present the results of the evaluation of the of the TIPP programme. In Chapter 11, the main findings of this thesis are discussed. Also, recommendations regarding measurement, clinical practice and improvement of transitional patient safety, and possible directions for future research are provided.

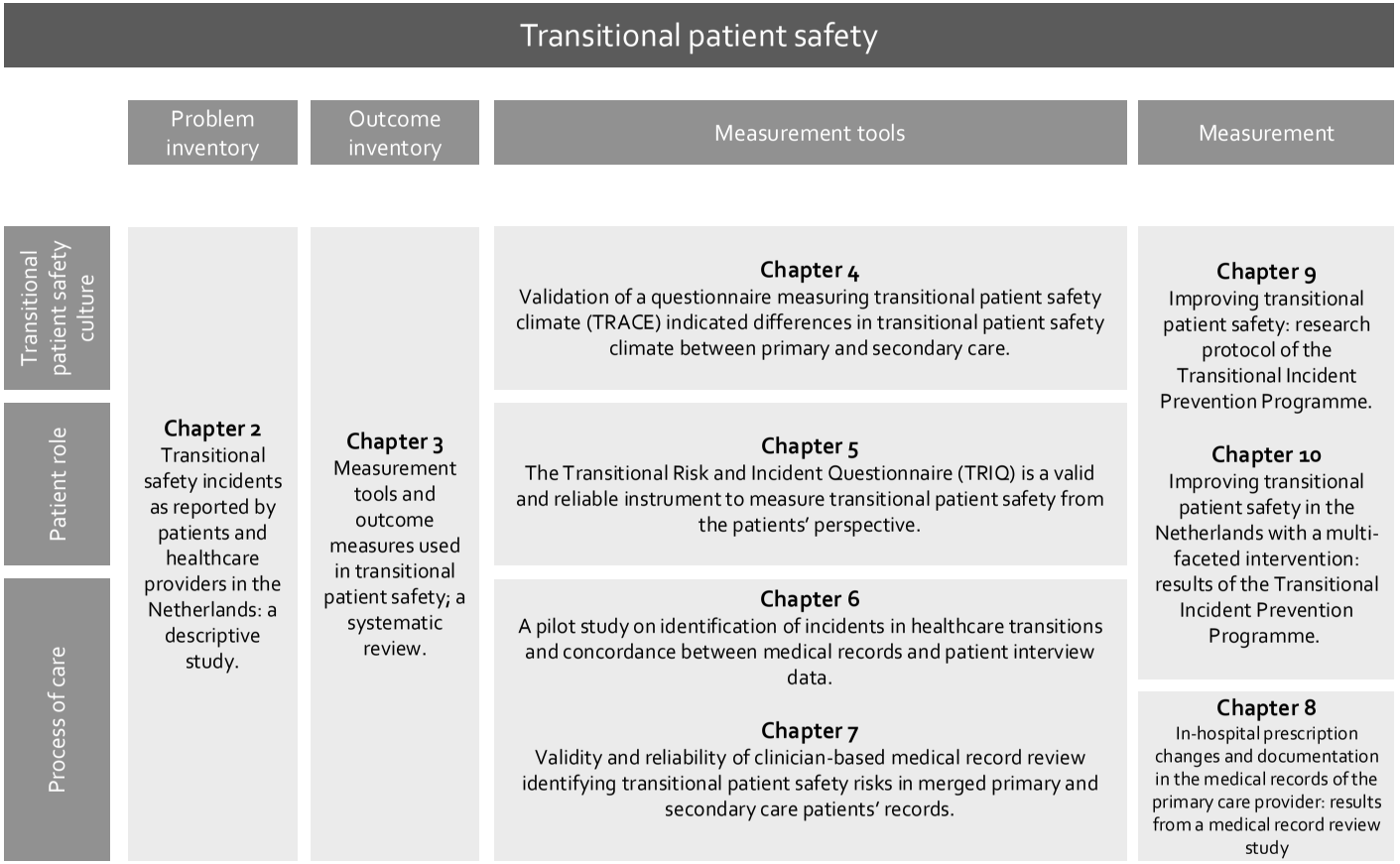

Figure 1.2 Schematic outline of the thesis

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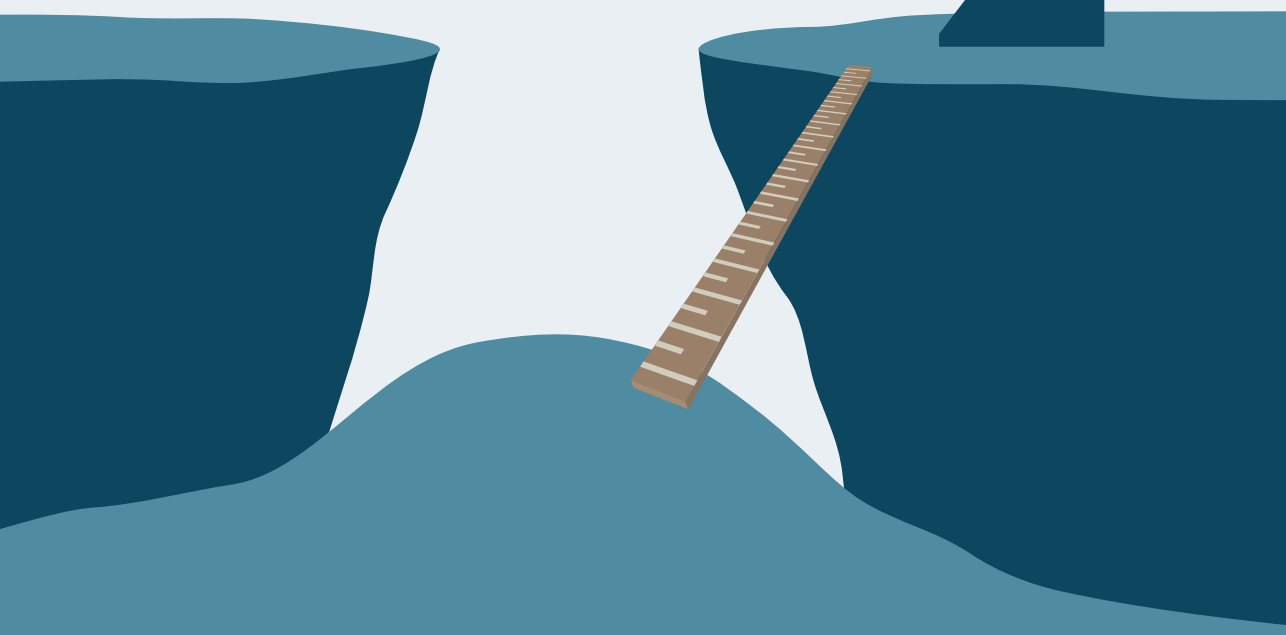


TRANSITIONAL SAFETY INCIDENTS AS REPORTED BY PATIENTS AND HEALTHCARE PROVIDERS IN THE NETHERLANDS: A DESCRIPTIVE STUDY

Poldervaart JM, van Melle MA, Reijnders LR, de Wit NJ, Zwart DLM.

ABSTRACT

Introduction

Care transitions between primary and secondary care are hazardous in terms of patient safety. For developing an improvement strategy, understanding of type and potential causes of transitional safety incidents (TSIs) is needed. As this knowledge was not available in the Netherlands, we aimed to provide an overview of the nature of TSIs reported by patients and healthcare professionals.

Methods

We collected data (2013-2015) from patients, through a survey, interviews and incident reporting weeks, and healthcare providers (general practitioners and hospital specialists) through incident reporting systems, surveys, interviews and focus group discussions. We classified all reported TSIs according to type, cause and severity.

Results

In total, 548 TSIs were reported by 411 patients and 137 healthcare providers. 368 of 548 TSI reports contained sufficient information to be classified for aspects of the transitional process, 191 of 548 for cause, and 149 of 548 for severity. Most TSIs concerned handover correspondence from hospital to general practitioner (26%), referral (14%) and communication/collaboration (14%). Concerning cause, reported TSIs could be attributed to organisational (48%) and human factors (43%). Twenty-four percent concerned unsafe situations, 45% near misses and 31% adverse events. Three lethal incidents were reported. Patients and healthcare providers reported differently on referral (17% vs. 9%), repeated diagnostic testing (20% vs. 1%), and uncertainty about the first responsible physician (10% vs. 3%).

Discussion

Reported TSIs typically concerned informational discontinuity. One third caused harm to the patient. Patients report different TSIs than healthcare providers, suggesting a different view on transitional patient safety. Interventions to improve transitional patient safety should focus on information exchange to bridge the gap between hospital and general practice.

INTRODUCTION

While general practitioners (GPs) adequately manage more than 90% of all medical problems, still ten million patients are referred to the specialty outpatient clinic annually in the Netherlands, and per year two million patients are admitted to the hospital.[1,2,3] During these transitions in health care, patients are known to be at increased risk for safety incidents [4,5] because of several hazards across the interface. Examples are inadequate transfer of medical information, such as diagnoses or test results, or changes in medication, to the next care level.[6,7,8] Internationally, research has shown that many transitional safety incidents (TSI) were linked to miscommunication during the discharge process.[9] Furthermore, after referral from the GP to the hospital information needs to be up to date and complete in order to guarantee a safe transition. However, hospital care providers consider only a minority of referral letters to be adequate.[10,11,12] Moreover, unfortunately the electronic medical records of primary and hospital care are not linked, which impedes direct electronic information transfer between settings.

In the Netherlands, little is known about the number or nature of TSIs. To improve transitional patient safety, we need to understand better 'what goes wrong'; profound knowledge about the content of incidents will guide future solutions and help to prioritize action. Moreover, feedback to stakeholders on both parts supports creating a sense of urgency necessary for improvement.[13] Within the context of the Transitional Incident Prevention Programme (TIPP) study, which aimed to evaluate a multifaceted intervention program to prevent TSIs in the Netherlands.[14,15]

We aimed to explore type, causes and severity of TSIs as reported by patients and health care providers in the Netherlands

METHODS

As safety incidents differ depending on source as well as reporting method, we purposefully collected TSIs through different methods.[16-18] Using both qualitative and quantitative methods, we collected reports on TSIs from both healthcare providers in primary and hospital care, as well as from patients.

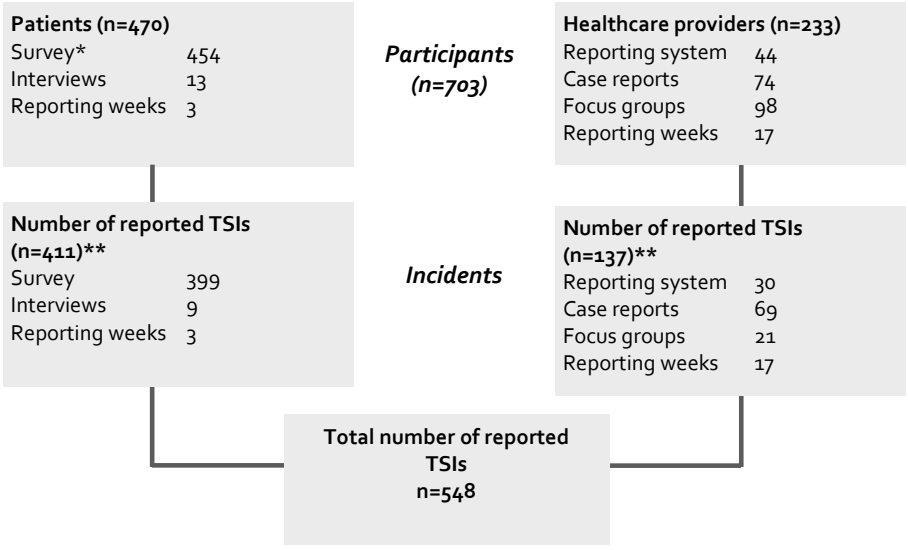
Setting and study population

Between 2013 and 2015 we collected data on TSIs from three hospitals and affiliated general practices from two regions in the Netherlands. In the urbanized area of Utrecht, data was collected in the departments of cardiology and gastroenterology of two hospitals, the University Medical Center Utrecht and the Diakonessenhuis Utrecht. In the rural region of Hardenberg, data was collected in the departments of cardiology, gastroenterology and internal medicine of the Röpcke-Zweers hospital. In addition, 56 general practices referring to one of these three hospitals

participated. Additionally, data was collected from patients visiting the outpatient departments of the hospitals and general practices that participated.

Data collection

First, we collected retrospective data from the incident reporting systems in the three hospitals. In addition, we prospectively collected patient data, quantitatively using the Transitional Risk and Incidence Questionnaire (TRIQ) questionnaire, and qualitatively through interviews. For healthcare providers, we prospectively collected data quantitatively through a case report form, and qualitatively through focus group discussions. Finally, we collected data on TSIs reported by patients or healthcare providers in the participating hospitals and general practices during so called "incident reporting weeks" (See Figure 2.1 for flow chart). For the final classification, we pooled all the TSIs reported by patients and healthcare providers.



* Survey concerned the TRIQ (Transitional Risk and Incidence Questionnaire)
** one participant could report on more than one TSI.
TSI: transitional safety incident

Figure 2.1. Flowchart of data sources and number of reported TSIs by patients and healthcare providers

Incident reporting systems
We retrospectively collected safety incidents reported through the existing internal "incident reporting systems" of the participating hospitals and general practices between 2011 and 2014, and assessed whether these incidents were TSIs or not.

Patient survey
Between November 2014 and January 2015, patients visiting the outpatient clinics of participating hospital departments were asked to digitally fill in the TRIQ questionnaire. The TRIQ is a validated questionnaire developed to measure both experienced TSIs as well as perceptions of patients on transitional patient safety.[19] Data from the TRIQ questionnaire were collected through Net Questionnaire. On request, patients were assisted by a medical student, trained to guide patients through the questionnaire without influencing their answers.[19] We considered all events as reported by the patient a possible TSI, and asked patients to explain the background and details of the event. The research team subsequently assessed these reported events and classified them as TSI or not.

Patient interviews
Semi-structured interviews were conducted between October 2013 and June 2014 with patients that either had experienced a TSI or reported to have been at safety risks. Patients were approached for the interview by their treating physician. After patients consented, they were approached by phone by a nurse to receive additional information and given an interview date. The interviews were conducted by one of three researchers (IM, LR, MM) and took 36-104 minutes. The interviews focused on patients' experiences during their transitional patient journey that preceded the safety incident.

Case reports by GPs and hospital care providers
In April 2014, GPs and hospital care providers from both regions were asked to report one recently experienced TSI and provide additional information on the circumstances preceding the TSI, using a digital anonymous incident reporting system.

Focus group discussions of GPs and hospital care providers
In April and May 2014 focus group discussions were held with both GPs and hospital specialists. Key themes of the focus group discussions were individual experiences and perceptions of transitional patient safety, perceived culture differences between primary and secondary care regarding the safety climate as well as suggestions for improvement. For the current study, we used the examples of TSIs brought up by participants during the focus group discussions.

Incident reporting weeks
During two separate weeks in November 2014 and March 2015 both patients and healthcare providers were asked to report any TSIs they encountered. Patients

could report incidents on paper forms, which were available in waiting rooms of the participating general practices and outpatient clinics of hospitals. Healthcare providers were asked to report incidents through their existing (hospital) or specially designed (GPs) electronic incident reporting system.

Classification of reported TSIs
According to the literature we defined a TSI as: "any unintended or unexpected event in patient care between different healthcare organisations which could have led or did lead to harm to a patient"[20]

Classification according to aspects of care transition's process
We adjusted an existing safety taxonomy of the World Health Organisation with sixteen categories to transitional patient safety. Two researchers (MM, VS) independently classified all reported TSIs according to aspects of the transitional process in which the TSI occurred (Table 2.1).[21] In case of disagreement, the incident was discussed with three members of the research team (VS, MM, DZ) until consensus was reached.

Classification of cause
Dependent on the information available, reported TSIs were systematically classified according to cause using the Eindhoven Classification Model (ECM) (Appendix 2.1).[22] This method classifies root causes in five separate categories: technical, organisational, human, patient-related and others.[23]

Classification of severity
To classify TSI 'severity', we used the categories of the National Coordinating Council for Medication Error Reporting and Prevention index (NCC MERP index) (Appendix 2.2).[24] This index distinguishes four main categories of severity: (1) no error, but the capacity to cause error (unsafe situation, category A); (2) error, no harm (near miss, category B to D); (3) error and harm (adverse event, category E to H); and (4) error, death (adverse event, category I).

Statistical analysis

All data were descriptively analysed in Excel for Windows.

Ethics

According to Dutch law, the TIPP study was exempted from formal medical-ethical approval by the medical ethical committee University Medical Center Utrecht, The Netherlands (METC decision 13/142).

Table 2.1 Classification according to aspects of the transitional process in which the TSI reports occurred

Transitional process	Examples of collected TSIs
Handover correspondence from the hospital to the GP Information after outpatient clinic visits or discharge letters can be delayed*, incomplete or absent.	A patient with (normally perfectly regulated) diabetes visits the GP with repeated high glucose levels. A change in medication by the GP does not control the blood glucose levels. After 4 weeks, the GP receives a letter from the pulmonologist; the patient started with prednisone over a month ago because of his exacerbated chronic obstructive pulmonary disease.
Referral information from the GP to the hospital (correspondence) Information from the GP to the hospital can be delayed, incomplete or absent.	A patient is referred to the emergency department for complaints of chest pain. However, the referral letter lacks information on medical history, although the patient tells the physician at the emergency department to have a cardiac disease, although he does not know what specifically.
Diagnostic testing Diagnostic testing can be omitted, or may be performed twice redundantly.	A GP measures lipid levels of a patient. In the hospital, the lipid levels are measured again in the same week by the internal medicine hospital care provider.
Medication prescription Incorrect or absent communication between healthcare providers on type, dosage, frequency.	The GP prescribes bumetanide to a patient with heart failure and complaints of fluid retention. However, the patient already used furosemide which was prescribed by the cardiologist, but not communicated to the GP. The patient uses both diuretics and then visits the heart failure nurse because of complaints of dehydration, who discovers the double medication.
Communication/collaboration This concerns all communication or signs of collaboration apart from the information through written communication	A GP receives a euthanasia request by telephone from a patient's family. The patient was diagnosed with terminal cancer in hospital of which the GP was not yet informed. He recently referred the patient to hospital because of a back ache.
Registration/administration	A patient goes into cardiac arrest during an endoscopic procedure and is successfully resuscitated. However, afterwards it turned out the patient had requested a do-not-resuscitate policy, which was not communicated by the GP.
Diagnostic error The GP does not (timely) recognize complaints, and referral is delayed or misdirected.	Patient was referred to the emergency department by the GP with suspicion of cerebrovascular accident. However, it turned out the patient had a simple urinary tract infection and was no emergency case at all, and the GP had not visited the patient first.
Discharge process from the hospital to the GP (other than correspondence)	A patient is discharged from the outpatient clinic of the cardiologist but this is not communicated to the GP. The patient then does not receive controls for his cardiovascular risk management for the next 5 years.
Self-care advice No or inadequate communication to patient to manage condition at home	The patient did not receive adequate advice when at home, and makes an appointment with the GP to answer all his questions after discharge.
Triage	A patient was referred to the ophthalmologist (OP) with complaints of vision loss and swelling of the right eye. The hospital secretary booked a consultation with an optometrist instead, who diagnosed tear film insufficiency. When the patient returned after several weeks to the GP with persistent complaints, the GP referred the patient to the OP in a different hospital. Here, the OP diagnosed an orbital meningioma for which the patient had neurosurgical treatment.

Table 2.1 Continued

Transitional process	Examples of collected TSIs
Accessibility	A patient is referred to a tertiary care hospital, but is refused because the nature of his complaints is considered not complex enough.
After-hours care This concerns care between 17:00h and 8:00h and during the weekends	*During an out-patient clinic visit, a patient is coincidentally diagnosed with an abdominal aneurysm, which is not communicated to the GP. After an emergency visit to the GP with a backache, the patient dies at the GP out-of-hours service, because the GP does not recognize the ruptured aneurysm in time.*
Responsible physician It can be unclear who is the first responsible physician for managing patient's current disease episode; or no responsible physician is assigned at all.	A patient with kidney failure is treated in the hospital. The GP does not know whether the hospital care provider also performs the diabetes controls for this patient.
Multiple medical specialties involved	Both the cardiologist and internal medicine hospital care provider treat the patient, but because they do not report to each other, they are not aware of each other and both perform a cardiac stress test. The patient complaints about this to the GP.
Internal referral	A patient is known at the GP with a thyroid disorder, for which she is adequately treated by the GP for several years now. Because of an acute problem, she was referred to the ear-nose-throat-(ENT) specialist. The ENT-specialist internally refers her to the internal medicine for her (stable) thyroid problem.
Multiple hospitals involved	Patient is being referred by GP for complaints of back pain with radiation to the neurologist. However, after multiple tests it turned out the patient was already known with these complaints in another hospital, and wanted a second opinion.

* *Delayed communication in our study was defined as 14 days*

RESULTS

Reported TSIs

In total, 548 TSI reports were collected: 470 patients reported 411 incidents, and 233 healthcare providers reported 137 incidents (Figure 2.1).

Data collected from incident reporting systems: In total, 44 safety incidents were reported through the incident reporting systems. Of these, 14 (32%) did not concern transitional safety and were excluded, leaving 30 TSI reports for analysis.

Patient survey: In total, 239 of the 454 patients (53%) completing the TRIQ, questionnaire reported 399 TSIs.

Patient interviews: 19 patients signed up for an interview, and 13 patients were actually interviewed. Reasons for non-response (N=-6) were: deemed too sick; language barrier; no incident; living too far away; not able to reach patient. Patients' age ranged from 6 (of whom the parents were interviewed) to 82 years, the median

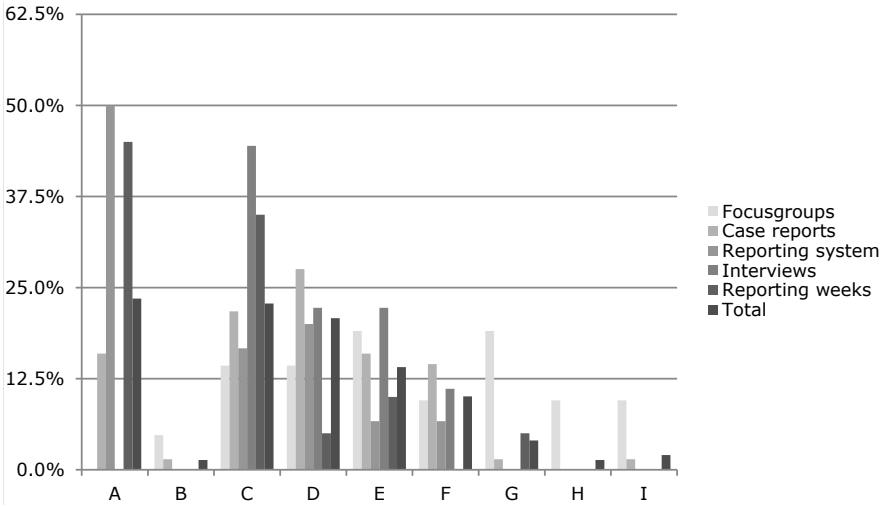


Figure 2.2 Classification by severity of TSIs according to NCC-MERP index.
TSI: transitional safety incident

age was 60 years. Of the 13 patients, eight reported a single TSI, and one patient reported two incidents. Thus, nine TSIs could be analysed.

Focus group discussions of GPs and hospital care providers: In total, 12 focus group discussions were held with 98 healthcare providers; seven with GPs and five with hospital specialists. The focus groups discussions revealed 21 TSIs.

Case reports by GPs and hospital care providers: In total, 74 of the 300 healthcare providers from the participating organisations reported an incident, five of which concerned intramural incidents.

Incident reporting weeks: During the two incident reporting weeks, 21 incidents were reported by patients (n=4) and healthcare providers (n=17). Of patient reported incidents, one was not considered as a TSI. Thus, 20 TSIs were used for analysis.

Classification of TSIs

Classification according to aspects of transitional process

For 368 out of 548 (67%) reported TSIs sufficient information was available for classification. In particular, data from the patient survey (TRIQ) often missed sufficient information; of 399 TSI reported through the TRIQ, 180 (45%) contained insufficient information for classification. The 368 TSI reports often occurred in more than one aspect of transitional care, resulting in 672 classifications. In total, 171 TSI reports (26% of 672, range 22-50% within the different data sources) were attributed to a problem in either handover of information from the hospital to the GP or vice versa (97 of 672 classifications, 14%, range 0-19%), or failing communication/collaboration between healthcare providers (93 of 672 classifications, 14%, range 0-22%) (Table 2.2).

Table 2.2 Classification into aspects of the transitional process in which the 548 TSIs occurred, stratified for the different data sources

	Total		TRIQ		Interviews		Reporting weeks		Focus groups		Case reports		Reporting system	
Total number of classifications#	N=672		N=420		N=22		N=37		N=45		N=110		N=38	
1. Handover correspondence to GP	172	25.6%	99	23.6%	6	27.3%	12	32.4%	12	26.7%	24	21.8%	19	50.0%
2. Referral from GP to hospital	97	14.4%	78	18.6%	0	0%	2	5.4%	5	11.1%	12	10.9%	0	0%
3. Communication/collaboration	93	13.8%	57	13.6%	0	0%	8	21.6%	6	13.3%	17	15.5%	5	13.2%
4. Diagnostic testing	91	13.5%	87	20.7%	1	4.5%	0	0%	1	2.2%	2	1.8%	0	0%
5. Medication prescription	72	10.7%	33	7.9%	2	9.1%	4	10.8%	7	15.6%	22	20.0%	4	10.5%
6. Responsible physician	52	7.7%	45	10.7%	1	4.5%	1	2.7%	1	2.2%	3	2.7%	1	2.6%
7. Discharge process*	23	3.4%	7	1.7%	2	9.1%	2	5.4%	1	2.2%	7	6.4%	4	10.5%
8. Diagnostic error	22	3.3%	2	0.5%	3	13.6%	3	8.1%	7	15.6%	6	5.5%	1	2.6%
9. Accessibility	14	2.1%	8	1.9%	1	4.5%	2	5.4%	0	0%	2	1.8%	1	2.6%
10. Multiple hospitals involved	10	1.5%	2	0.5%	2	9.1%	1	2.7%	1	2.2%	3	2.7%	1	2.6%
11. Triage	7	1.0%	0	0%	2	9.1%	0	0%	1	2.2%	2	1.8%	2	5.3%
12. After-hours care	6	0.9%	0	0%	1	4.5%	0	0%	0	0%	5	4.5%	0	0%
13. Multiple specialties involved	6	0.9%	0	0%	1	4.5%	1	2.7%	1	2.2%	3	2.7%	0	0%
14. Internal referral	4	0.6%	1	0.2%	0	0%	1	2.7%	0	0%	2	1.8%	0	0%
15. Registration (administration)	2	0.3%	1	0.2%	0	0%	0	0%	1	2.2%	0	0%	0	0%
16. Self-care advice	1	0.1%	0	0%	0	0%	0	0%	1	2.2%	0	0%	0	0%

* *other than correspondence*

\# *one incident could be classified into more than one aspects of the transitional process, for example handover correspondence to the GP and medication prescription.*

TRIQ: Transitional Risk and Incidence Questionnaire

GP: general practitioner

TSI: transitional safety incident

Differences of TSI reports between patients and healthcare providers

Healthcare providers reported (n=223) flaws in "handover of correspondence to GP" as the most frequent background of a TSI (30%), followed by flaws in "communication/collaboration" (16%) and in "medication prescription" (16%) (Table 2.3). Patients' reported TSIs (n=449) concerned incidents in "handover of correspondence to GP" (24%) followed by "repeated diagnostic testing" (20%) and "referral" (17%).

Compared to healthcare providers, patients more often reported "omission of referral information" (17% vs. 9%) and "repeated diagnostic testing" (20% vs. 1%) (Table 2.3). Concerning coordination of simultaneous care ("who is the first responsible physician, the GP or hospital care provider"), 10% of the patients' reports indicated that they did not know who was coordinating their care, which was less frequently reported as a problem by healthcare providers (3%). On the other hand, healthcare providers reported TSIs more often concerned problems with medication (16% vs. 8%). (See Table 2.3 for a description of all differences).

Table 2.3 Classification into transitional process in which the 548 TSIs occurred, stratified for patients and healthcare providers

	Patients		Healthcare providers	
Transitional process	N=449#		N=223	
1. Handover correspondence to GP	106	23.6%	66	29.6%
2. Referral from GP to hospital	78	17.4%	19	8.5%
3. Communication/collaboration	58	12.9%	35	15.7%
4. Diagnostic testing	88	19.6%	3	1.3%
5. Medication prescription	37	8.2%	35	15.7%
6. Responsible physician	46	10.2%	6	2.7%
7. Discharge process*	10	2.2%	13	5.8%
8. Diagnostic error	6	1.3%	16	7.2%
9. Accessibility	9	2.0%	5	2.2%
10. Multiple hospitals involved	5	1.1%	5	2.2%
11. Triage	2	0.4%	5	2.2%
12. After-hours care	1	0.2%	5	2.2%
13. Multiple specialties involved	1	0.2%	5	2.2%
14. Internal referral	1	0.2%	3	1.3%
15. Registration (administration)	1	0.2%	1	0.4%
16. Self-care advice	0	0%	1	0.4%

* *other than correspondence*

\# *A TSI could be classified into more than one aspects of the transitional process.*

GP: general practitioner

TSI: transitional safety incident

Classification of cause

In total, 191 of the 548 (35%) TSI reports contained sufficient information for identifying at least one cause, using the ECM criteria (Table 2.4). "Organisational factors" (48%) and "human factors" (43%) were the two most frequently identified categories for causes, followed by "patient-related factors" (5%).

Table 2.4 Classification by cause according to the Eindhoven Classification Model (ECM), stratified for the different data sources

	Total		TRIQ		Interviews		Reporting weeks		Focus groups		Case reports		Reporting system	
Causes	N=493		N=299		N=34		N=88		N=37		N=11		N=24	
Technical	4	0.8%	0	0%	0	0%	1	1.1%	2	5.4%	0	0.0%	1	4.2%
Organisational	104	21.1%	11	3.7%	14	41.2%	40	45.5%	22	59.5%	5	45.5%	12	50.0%
Human	93	18.9%	6	2.0%	17	50.0%	41	46.6%	12	32.4%	6	54.5%	11	45.8%
Patient-related	9	1.8%	4	1.3%	2	3.1%	2	2.3%	1	1.4%	0	0%	0	0%
Unclassifiable	283	57.4%	278	93.0%	1	1.5%	4	4.5%	0	0%	0	0%	0	0%

TRIQ: Transitional Risk and Incidence Questionnaire

Classification of severity

Of the 548 TSIs, 149 (27%) could be classified according to the NCC-MERP (Figure 2.2). In total, 35 of 149 (24%) TSI reports were classified as unsafe situations (NCC-MERP category A), 45% as near misses (NCC-MERP category B to D) and 31% as adverse events (NCC-MERP categories E to I).

Different data sources revealed different TSI severity. The focus group discussions revealed the most harmful incidents with two third of incident reports in the main category of adverse events (categories E to I). In the focus groups, none of the TSI reports were classified as unsafe situation (category A), as opposed to the incident reporting weeks and the reporting system, in which half of the TSI reports were classified as unsafe situation.

Severe incidents

In our TSI dataset, three incidents (2.0%; 3 of 149) had fatal consequences (category I). Two of them were revealed in the focus group discussions and one was a case report. One concerned a hip fracture not recognized during the diagnostic process and one concerned a carcinoma diagnosed after failure of follow-up of a suspicious test result. Both regarded vulnerable patients (elderly or cognitively impaired). The third concerned a patient with a newly diagnosed abdominal aneurysm, of whom the hospital had provided no handover correspondence to the GP. When the patient presented with back pain at the out-of-hours primary care services, the presented symptoms were not linked to the aneurysm and the patient died.

DISCUSSION

Main findings

We identified a total of 548 TSIs reported by patients or healthcare providers through six different data sources. Correspondence and communication between hospital and GP, during referral, discharge, and simultaneous care at the outpatient hospital care were the most vulnerable aspects of the transitional healthcare process, and TSIs were mainly caused by organisational factors. Healthcare professionals and patients differed in types of TSIs they reported, whereas healthcare professionals noted more medication discrepancies, and patients noted redundant testing and uncertainty about the first responsible physician more frequently. Although the majority of TSIs did not cause patient harm, one third actually did, of which a minority with fatal consequences. Many of the reported TSIs provide opportunities for prevention of adverse health outcomes.

Comparison to literature

In our study, inadequate information exchange between the GP and the hospital was most frequently mentioned as a cause of TSIs. This is in line with to the literature: a survey among 4720 physicians demonstrated that only 35% of hospital care providers always received referral information, and only 62% of GPs received handover correspondence.[25] Kripalani et al. reported that in the United States 51-77% of the discharge summaries were not received by GPs within four weeks.[26]

Interestingly, in our study 20% of patients reported that diagnostic testing was repeated in the hospital, while only 1% of the healthcare providers mentioned this. Although it can be difficult for patients to assess whether repeated testing is truly redundant, the patient is the only one being present in all phases of the healthcare process. Therefore, patients might be able to reveal issues that healthcare providers are simply unaware of.[16,27,28] Little is known in literature on repeated diagnostic testing in transitional care. A study from 1983 estimated that 11-14% of diagnostic testing was repeated without justification.[29] A more recent study demonstrated that that a 50% reduction in redundant laboratory testing was possible with better sharing of information.[30] Scrutinizing patient's reports on redundant testing may be another fruitful source to uncover unnecessary diagnostics that threaten transitional safety.

As to the causes of TSIs we mainly found organisational and human factors to be involved. This in contrast to a large Dutch medical record review study, which found 43% of all in-hospital incidents to be patient-related, followed by 32% due to human factors.[31] Smits et al. found human factors (61%) to be the main cause in adverse events in the hospitalized patients, followed by 39% by patient-related factors.[32] The discrepancy between the patient-related and organisational factors involved might be caused by the different processes involved in transitional as compared to

in-hospital patient safety. In transitional patient safety, communication between settings is vital. A large part of the communication-process comprises of written correspondence and medication reconciliation, which should be organised within the medical record system. So, we considered all TSI reports concerning these subjects as caused by organisational flaws. The low percentage of patient-related causal factors is probably explained by the fact that the patient often has a fairly inactive role in transitional patient safety.[33,34]

Regarding severity, the distribution of the reported TSIs in unsafe situations (24%), near misses (45%) and adverse events (31%) was in line with earlier studies. Forster et al. found adverse events in 19% of the patients after discharge.[35] The TSIs reported in our focus group discussions were more severe than those identified through other data sources. A focus group setting is likely to provoke discussion on events that are vividly memorised because they had major impact on the physician. These are inherently those with severe patient harm. The same is true for the case reports. Furthermore, we identified many minor incidents and unsafe situations that have the capacity to cause harm, such as inadequate correspondence. Additional literature on these minor TSIs is scarce. Tam et al. demonstrated unsafe situations in 10-67% of patients related to incomplete medication histories on admission to the hospital.[36] Although these unsafe situations may seem harmless and futile, they require time and effort of the healthcare provider to be corrected, and may escalate to patient harm in the presence of other risk factors.[37]

Limitations

Our approach has some limitations. We have used different data sources, each with their own logistics and methodology. Although the different approaches have provided a rich and heterogeneous spectrum of TSIs, we are not able to draw final conclusions on the generalizability of our findings. Undoubtedly, the presented overview is an underrepresentation of the actual occurrence of TSIs during the study period, as underreporting of safety issues is common. For instance, patients are unlikely to report unsafe situations that they do not notice and healthcare providers are known to underreport minor incidents.[38] In addition, patients tend to be quite forgiving to their healthcare providers in case of TSIs because of their dependent relationship.[19,39] Although we are not certain that all types of TSIs are equally represented in our study, we believe that our results provide a face valid overview of TSIs' as occurring in clinical practice and can guide future steps to improve transitional safety. Of course, we cannot draw any conclusions on the incidence of subtypes of TSIs, as our methods were not suited for any judgment on frequencies.[40]

Additionally, often we could not classify the TSI reports because of insufficient details in the reports. As this mainly concerned patient reported TSIs from the TRIQ survey the findings on patient reported TSIs should be interpreted with caution.

Conclusion

TSIs typically occur in the transitional processes of information continuity such as handover from hospital to the GP, referral and communication. One third of TSIs causes harm to the patient. Patients report different TSIs than healthcare providers, suggesting a different view on transitional patient safety. Improvement strategies should focus on the exchange of information between hospital and the GP.

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COMPETING INTERESTS

Authors declare to have no competing interests.

Authors' contributions

DZ, MM and JP designed the study. LR and MM acquired the data. MM and JP analysed the data. JP, MM, LR, NW and DZ drafted the manuscript. All authors read and approved the final manuscript.

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APPENDIX 2.1

Classification by causes of reported TSIs: the Eindhoven Classification Model (ECM): Medical Version

1. Technical	
External	Any technical failures beyond the control and responsibility of the investigating organisation
Design	Failures due to poor design
Construction	Correct design which was not followed accurately during construction aspects
2. Organisational	
External	Any failures at an organisational level beyond the control and responsibility of the investigating organisation
Transfer of Knowledge	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff
Protocols	Failures related to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent, poorly presented)
Management priorities	Failures resulting from management decisions in which safety is delegated to an inferior position when faced with conflicting demands or objectives
Culture	Failures resulting from a collective approach and its attendant modes of behavior to risks in the investigating organisation
3. Human	
External	Human failures originating beyond the control and responsibility of the investigating organisation
Knowledge	Inability of an individual to apply their existing knowledge to manage novel situations
Qualifications	Incorrect fit between an individual's qualifications, training or education and a task
Coordination	Lack of task coordination within the organisation or team
Verification	Failures in the correct and complete assessment of a situation including relevant conditions of the patient and materials to be used before starting the intervention
Intervention	Failures that result from faulty task planning and execution
Monitoring	Failures during monitoring of process or patient status during or post-intervention
Slips	Failures in the performance of fine motor skills
Tripping	Failures in whole body movements
4. Patient-related	
Patient-related factor	Failures related to patient characteristics which are beyond the control of staff and influence treatment
5. Unclassifiable	
Unclassifiable	For failures that cannot be classified in any other category

TSI: transitional safety incidents

APPENDIX 2.2

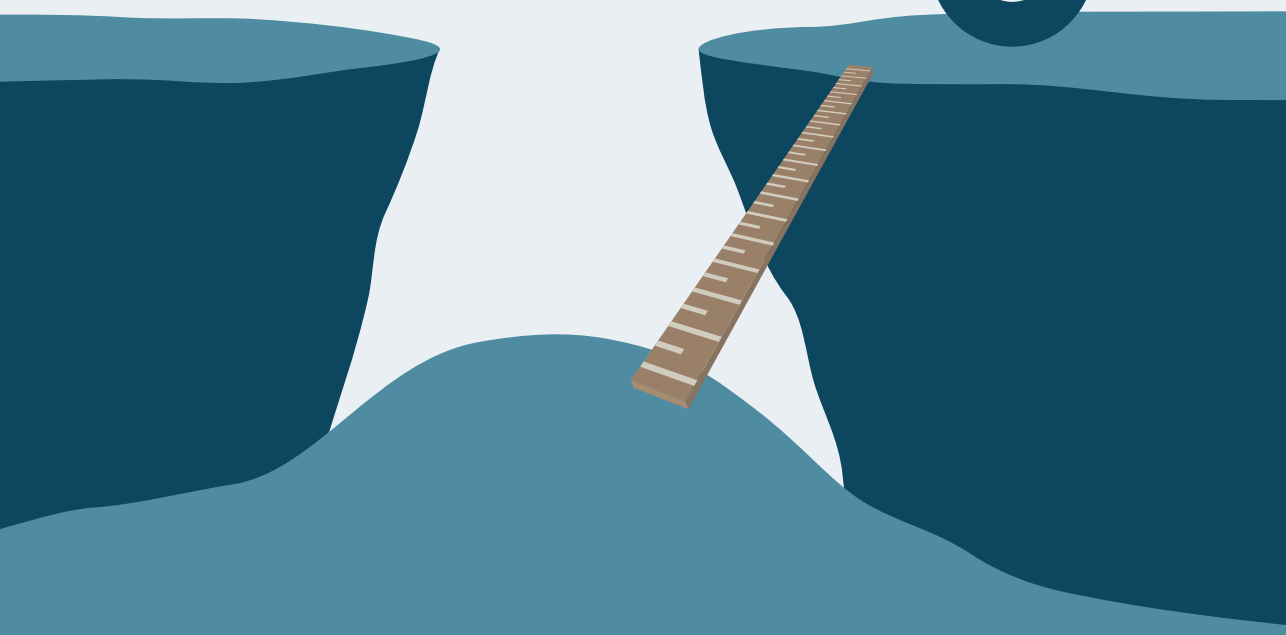
Classification of reported TSIs by severity: the NCC-MERP Index

Category	Error/Harm	Description	
A	Unsafe situation	No error	Events that have the capacity to cause error
B	Near miss	Error no harm	An error occurred but did not reach the patient
C	Near miss	Error no harm	An error occurred that reached the patient but no harm was caused
D	Near miss	Error no harm	An error occurred, reached the patient & required monitoring/intervention to preclude harm
E	Adverse event	Error & harm	Error that may have contributed/resulted in temporary harm and required intervention
F	Adverse event	Error & harm	Error that may have contributed to or resulted in temporary harm and required initial or prolonged hospitalization
G	Adverse event	Error & harm	Error that may have contributed to or resulted in permanent harm
H	Adverse event	Error & harm	Error that required intervention necessary to sustain life
I	Adverse event	Error & death	Error that may have contributed to or resulted in patient's death

TSI: transitional safety incidents

Under review

3



MEASUREMENT TOOLS AND OUTCOME MEASURES USED IN TRANSITIONAL PATIENT SAFETY; A SYSTEMATIC REVIEW

van Melle MA, van Stel HF, Poldervaart JM, de Wit NJ, Zwart DLM.

ABSTRACT

Background

Patients are at risk for harm when treated simultaneously by healthcare providers from different healthcare organisations. To assess current practice and improvements of transitional patient safety, valid measurement tools are needed.

Methods

PubMed, Cinahl, Embase and Psychinfo were systematically searched to identify and appraise all measurement tools and outcomes that measure aspects of transitional patient safety. Two researchers performed the title and abstract and full-text selection. First, publications about validation of measurement tools were appraised for quality following COSMIN criteria. Second, we inventoried all measurement tools and outcome measures found in our search that assessed current transitional patient safety or the effect of interventions targeting transitional patient safety.

Results

The initial search yielded 8288 studies, of which 17 assessed validity of measurement tools of different aspects of transitional safety, and 191 assessed current transitional patient safety or effect of interventions. In the validated measurement tools, the overall quality of content and structural validity was acceptable; other COSMIN criteria, such as reliability, measurement error and responsiveness, were mostly poor or not reported. In our outcome inventory, the most frequently used validated outcome measure was the Care Transition Measure (n=9). The most frequently used non-validated outcome measures were: medication discrepancies (n=98), hospital readmissions (n=55), adverse events (n=34), emergency department visits (n=33), (mental or physical) health status (n=28), quality and timeliness of discharge summary, and patient satisfaction (n=23).

Conclusions

Although no validated measures exist that assess all levels of transitional patient safety, we found validated measurement tools on specific aspects. Reporting of validity of transitional measurement tools was incomplete. Numerous outcome measures with unknown measurement properties are used.

BACKGROUND

Incidents frequently occur when patients transfer between different healthcare levels,[1] so improving transitional patient safety is an important objective in healthcare. Recently, international patient safety experts have called to widen the safety scope across multiple healthcare levels. Accordingly, the need arises for valid and reliable measurement tools for transitional patient safety.[2]

Transitional patient safety comprises several levels, ranging from patient safety culture to patient outcomes. This is reflected in the 'values-behaviour-outcomes' continuum as presented by the Health Foundation (figure 3.1).[3] This continuum covers safety culture, climate, initiatives and outcomes. Safety culture is a broad term representing the organisation's values and actions related to safety, whereas safety climate focuses on perceptions of professionals about the way in which safety is managed in the organisation.[3] Initiatives are the actual measures in the organization that are developed and implemented to improve patient safety.

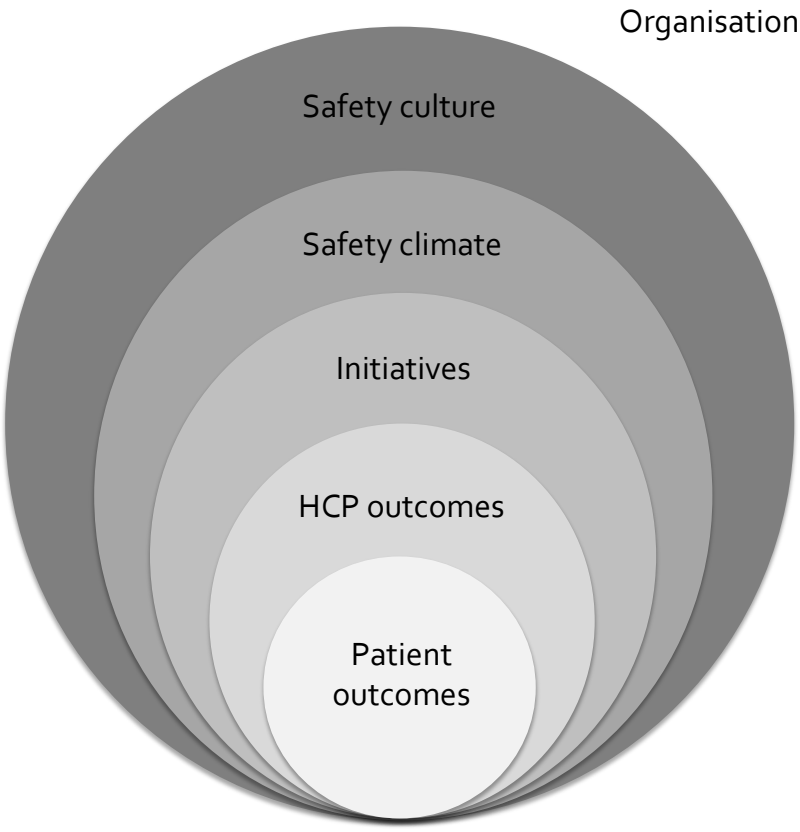


Figure 3.1 The culture-behaviour-patient outcome continuum in patient safety. *HCP= healthcare professional.*[3]

Outcomes encompass transitional patient safety incidents from the healthcare professionals' (HCP) perspective, and safety related patient outcomes from the patients' perspectives (Figure 3.1). All levels are supposed to interact with each other.[3]

In line with this conceptual model, transitional patient safety should be measured from both the perspective of the HCP and the patient (figure 3.1).[4] HCPs do oversee the process of care, but only within their own organisation. The patient experiences the entire journey across different healthcare levels, but does not oversee the organisational aspects.[5,6] Therefore, instruments measuring both the perception of the patient and the HCP on transitional patient safety are needed.

Previous research covered either a single transition, such as discharge or referral, or related concepts like "continuity of care".[7-15] However, the patient's journey often entails several transitions per episode of illness. Focusing only on a single transition does not appreciate the complex reality of multiple communications, transitions and handovers between the different healthcare professionals and settings involved. In contrast, the domain of 'continuity of care' is broader than that of transitional patient safety. Transitional patient safety focusses on the prevention or reduction of harm associated with patient transitions, while continuity of care covers other quality aspects like efficiency, effectiveness, equity, and timeliness.[16] Additionally, continuity of care is primarily studied within one organisation, while transitional patient safety focuses on safety between distinct healthcare settings.

At present, there is no overview of either the available instruments for measuring transitional patient safety, their validity and reliability, or the outcomes used in transitional patient safety. Therefore, we aimed to systematically identify all measurement tools and outcomes that are used to assess aspects of transitional patient safety, to appraise the reported quality of the validated measurement tools.

METHODS

Search strategy and data sources

We conducted a systematic literature search in Pubmed (including MEDLINE), EMBASE, PsychINFO and CINAHL (January 1st 2017). We used a combination of the following search strategies: 1) transitional care, including various terms and keywords synonymous and related to transitional care, i.e. continuity of care, transitional, cross-boundary, seamless, integrated; 2) measurement, for which we used an existing filter by Terwee et al.[17,18]; and 3) patient safety, for which we used an existing filter by Tanon et al.[19] Both filters were adjusted for PsychInfo. Detailed search strategies are available online in Appendix 3.1. We also reviewed the reference lists of the identified studies and checked previously published systematic reviews.[7-15]

The systematic review was registered in the PROSPERO database (nr 42016037311).

Study selection

Electronic citations, including available abstracts, were independently screened by two researchers (JP and MM). If the title and abstract did not clearly indicate whether the inclusion criteria were met, full-text was obtained and reviewed. As the aim of this systematic review was twofold, we included studies that: 1) assessed the quality of validated measurement tools on aspects of transitional patient safety (hereinafter referred to as "validity assessment", and 2) used an outcome measure to report the effect of interventions to improve or cross-sectional evaluations of aspects of transitional patient safety (hereinafter referred to as "outcome inventory"). We included all quantitative studies focusing on the transition between primary and hospital care, addressing all levels of patient safety (according to the Health Foundation)[3], from both the patients' as well as the professionals' perspectives. No limits were set on the design of the study or on the target population (patients and HCPs). Studies addressing organisational concepts like integrated care were excluded (Appendix 3.2). The full-text publications were reviewed by two independent reviewers (JP and MM) using the same in- and exclusion criteria. If necessary, a third reviewer (HS) was consulted for a final decision.

Data extraction

Validity assessment

Data extraction, and the assessment of measurement properties and methodology were performed by two reviewers (HS and MM) independently. Consensus was reached in consensus meetings. Data were collected on the characteristics of the included publications, namely country and language of development, type of transition, outcome level in the culture-behaviour-outcome continuum, the construct that was measured, the target population (including mean age and gender, number of respondents and response rate), the number of items, and dimensions after factor analysis. Transitions were divided into three categories: from primary care to hospital (referral or admission), from hospital to primary care (discharge after hospital admission or outpatient clinic visit) and two-way transitions (admission and discharge, overall continuity and simultaneous care at hospital outpatient clinic and primary care practice).

The methodological quality of studies was assessed according to the "COnsensus-based Standards for the selection of health Measurement INstruments" (COSMIN) criteria.[20] This checklist evaluates internal consistency, reliability, measurement error, content validity, structural validity, hypothesis testing, cross-cultural validity, criterion validity, responsiveness, interpretability, and generalizability. Each item was rated on a 4-point scale (poor, fair, good or excellent). The overall score for each criterion was determined by taking the lowest rating of the items. As no optimal reference standard is present in transitional patient safety, many items of the COSMIN were not applicable. Therefore, we excluded Box G (cross-cultural validity), Box H (criterion validity) and items D3, F7, F8 from the assessment. As

Box C (measurement error) and Box I (responsiveness) were never assessed in all included publications, it was therefore not reported.

Outcome inventory

Data extraction was performed by MM, and data was collected on year, country and language of development, type of transition, level of outcome in the culture-behaviour-outcome continuum, measured construct, target population, study design, perception, and outcomes measured to assess current state or improvement of transitional patient safety. As in some studies multiple outcomes were used, each study could describe multiple levels of outcomes and perceptions.

RESULTS

Our search identified 8288 unique, potentially relevant published scientific papers, of which 628 were selected for full-text selection (figure 3.2). From these, 422 papers were excluded, because they did not meet inclusion criteria, the paper could not be

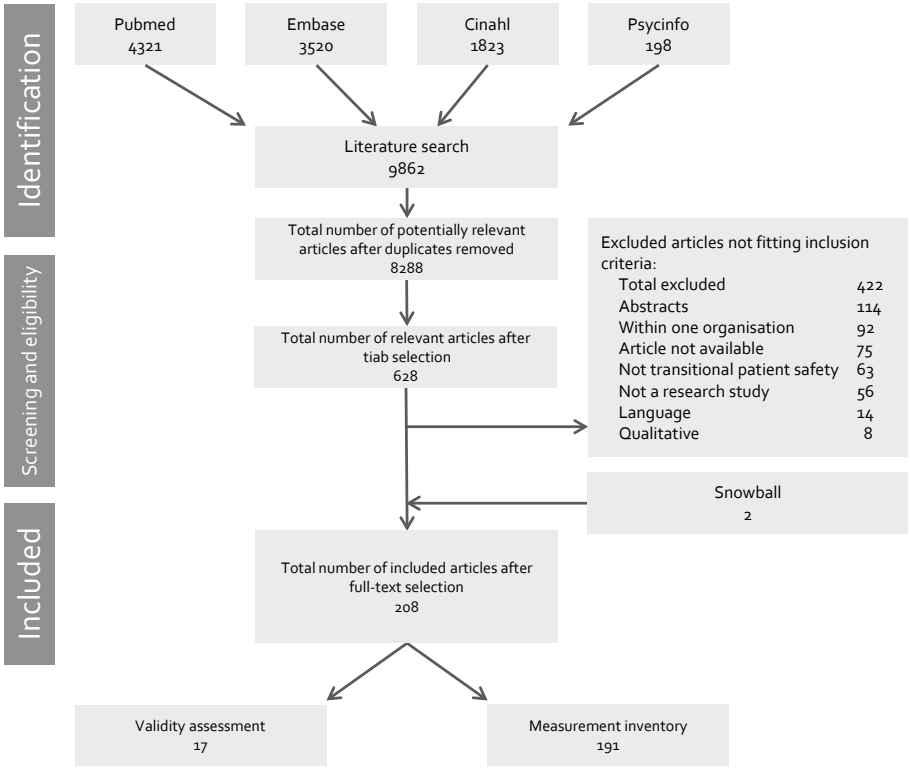


Figure 3.2 Flowchart of article selection procedure.

found or did not report original research. Reference lists of included publication and related literature rendered two more publications on validated measurement tools. In total 208 publications remained, of which 17 concerned publications validating instruments measuring transitional patient safety and 191 publications concerned studies reporting outcomes used in transitional patient safety.

Characteristics of studies in validity assessment

Table 3.1 presents the characteristics of the 17 included studies validating measurement tools on aspects of transitional patient safety; 11 studies considered seven distinct questionnaires measuring transitional patient safety from a patient's perspective and six studies measured transitional patient safety from a HCP's perspective.[21-37] Six measurement tools involved all transitions between primary care practice (PCP) and hospital, five concerned only hospital discharge and three only referrals. Considering the outcome level, three measurement tools measured (aspects of) safety climate, 11 measured HCP outcomes, and five measured patient outcomes. All but two validated measurement tools were questionnaires. Most patient-reported questionnaires were targeted at adult or elderly patients. A complete list of all characteristics is available online (Appendix 3.3).

Quality of studies on validity assessment

The 17 included publications were published between 2001 and 2013. The quality of Forster et al. and Smith at al. could not be assessed using the COSMIN, for they did not validate a questionnaire, but reported on diagnostic tools for adverse events and medication discrepancies, respectively.[33,37] The methodological quality of the studies was overall acceptable for the COSMIN items internal consistency, content validity, structural validity, and hypothesis testing (Table 3.2). Reliability was only assessed by Uijen et al., and measurement error and responsiveness were not assessed at all.[31] In 13 of the 17 publications we identified methodological flaws in the validation: 1) after extensive item reduction, the resulting item set did not fully cover the original content, and objectives and content validity were not re-assessed,[21,22,30,] 2) not reporting important design choices and characteristics, such as number of items in the measurement tool, total respondents, or respondent characteristics,[23,25,26,35] 3) not describing statistical analysis,[35] treating a multi-dimensional construct as a unidimensional questionnaire in the analysis[24] and performing an exploratory factor analysis instead of a confirmatory analysis in one sample[24,31,32,36] and 4) ignoring strikingly low factor loadings (Appendix 3.3)[26,35]. Graumlich et al. chose a very selective group of patients and therefore their validation is not generalizable beyond their study population.[25]

Table 3.1 Characteristics of the publications in the validity assessment of measurement tools on aspects of transitional patient safety
Level of outcome = the level of outcome in culture-behaviour-outcome continuum.

Authors	N	Country	Measurement tool	Transition	Level of outcome	Subject of questionnaire	Target population	Response rate
Patient perspective								
Aller 2013	1500	SP	Continuity of care between care Levels (CCAENA)	Hospital<->PCP	HCP	Continuity of care	Patients that have experienced a transition	23%
Berendsen **2009**	1404	NL	Consumer Quality Index Continuum of Care (CQI-COC)	PCP referral and relational continuity	HCP	Collaboration between GP and hospital	Referred patients	65%
Coleman 2002	60	USA	Care Transition Measure (CTM)	Discharge from hospital to home/nursing home	HCP	Care transition	Patients ≥65 years who were recently discharged from hospital and received subsequent skilled nursing care in facility/home.	NR
Coleman 2005	200	USA	Care Transition Measure (CTM)	Discharge from hospital to home/nursing home	HCP and patient	Care transition	Adult patients discharged with primary diagnosis of chronic obstructive pulmonary disease, congestive heart failure, stroke, or hip fracture	100%
Graumlich **2008**	460	USA	B-prepared	Hospital discharge	HCP	Patient preparedness on hospital discharge	All adult patients discharged by internal medicine hospitalists	NR
Grimmer 2001	500 (patients), 31 (carers)	AUS	PREPARED	Hospital discharge	HCP and patient	Discharge	Patients ≥65 years, recently discharged from hospital	60% (patients), 52% (care givers)
Haggerty 2011	236-427	CAN	4 questionnaires with dimension management continuity: PCAS, PCAT-S, CPCI, VANOCSS	PCP<-> other specialists	HCP	Management continuity	Primary care patients who had seen more than one provider in the previous month	54-99%*

Table 3.1 Continued

Authors	N	Country	Measurement tool	Transition	Level of outcome	Subject of questionnaire	Target population	Response rate
Patient perspective								
Haggerty 2012	256	CAN	Patient Perceived Continuity from Multiple Clinicians	Hos<->PCP	HCP and patient	Continuity of care	Adult patients in primary care seeing other clinicians in a variety of settings	80%
Kollen 2010	1404	NL	Consumer Quality Index Continuum of Care (CQI-COC)	PCP referral and relational continuity	HCP	Continuity of care	Adult patients who had been referred and visited a specialist	65%
Uijen 2011	288	NL	Nijmegen Continuity Questionnaire	Hos<->PCP	HCP	Continuity of care	Patients with comorbidity	72%
Uijen 2012	268	NL	Nijmegen Continuity Questionnaire	Hos<->PCP	HCP	Continuity of care	Patients with comorbidity	76%
Healthcare professional perspective								
Berendsen 2010	496	NL	Doctors' opinions on collaboration (DOC) questionnaire	Hos<->PCP	HCP and climate	Interprofessional collaboration	PCPs and specialists	45%
Forster 2012	**	CAN	Peer review process of adverse outcome	Hospital discharge	Patient	Adverse events at discharge	NA	NA
Graumlich **2008**	417	USA	Modified Physician-PREPARED	Hospital discharge	HCP	Discharge	Community physicians	76%
Hess 2009	12212	USA	CRP-PIM: Communication with Referring Physicians Practice Improvement Module	PCP referral to secondary care consultants (hospital and private groups)	HCP and climate	Communication of consultants	Referring physicians	?

Table 3.1 Continued

Authors	N	Country	Measurement tool	Transition	Level of outcome	Subject of questionnaire	Target population	Response rate
Patient perspective								
Nuno-solinis 2013	187	SP	No name reported	Hos<->PCP	Climate	Interprofessional collaboration	Physicians and nurses-working in integrated healthcare organisations	16%
Smith **2004**	***	USA	Medication discrepancy tool	Hospital discharge	Patient	Medication discrep-ancies	Practitioners across the continuum of care	NA

SP: Spain; NL: the Netherlands; USA: United States of America; AUS: Australia; CAN: Canada; HOS: hospital; PCP: Primary care provider; NA= not applicable; NR=not reported

* *PCAS:79%, PCAT-S:91%, CPCI:99%, VANOCCS:64+54%*

** *Vignette study on 319 case report, 30 physicians*

*** *Vignette study on 20 cases, 6 clinicians*

Table 3.2 Quality of the studies in validity assessment; validation of measurement tools on aspects of transitional patient safety, according to the COSMIN criteria.

Author	Year	Measurement tool	Box A: Internal consistency	Box B: Reliability	Box D: Content validity	Box E: Structural validity	Box F: Hypothesis testing
Patient perspective							
Aller	2013	Continuity of care between careLevels (CCAENA)	excellent	–	unknown*	good	good
Berendsen	2009	Consumer Quality Index Continuum of Care (CQI-COC)	fair	–	fair	good	good
Kollen	2010		–	–	–	–	fair
Coleman	2002	Care Transition Measure (CTM)	–	–	excellent	–	poor
Coleman	2005		good	–	–	excellent	poor

Table 3.2 Continued

Author	Year	Measurement tool	Box A: Internal consistency	Box B: Reliability	Box D: Content validity	Box E: Structural validity	Box F: Hypothesis testing
Patient perspective							
Grimmer	2001	(B-)prepared	poor	–	excellent	fair	fair
Graumlich	2008		poor	–	excellent/ previ-ously	fair	fair
Haggerty	2011	Several existing questionnaires with a single dimension on management continuity: PCAS, PCAT-S, CPCI, VANOCSS	good	–	NA	good	fair
Haggerty	2012	Patient Perceived Continuity from Multiple Clinicians	good	–	excellent	good	poor**
Uijen	2011	Nijmegen Continuity Questionnaire	good	–	poor	good	good
Uijen	2012		poor	fair		good	fair
Healthcare professional perspective							
Berendsen	2010	Doctors' opinions on collaboration (DOC) questionnaire	fair	–	excellent	fair	fair
Forster	2012	Peer review process of adverse outcome	NA	NA	NA	NA	NA
Graumlich	2008	Physician-PREPARED	poor		excellent	fair	fair
Hess	2009	Communication with Referring Physicians Practice Improvement Module (CRP-PIM)	poor	–	poor	poor	fair
Nuno-Solinis	2013	(unnamed)	poor	–	excellent	poor	fair
Smith	2004	Medication discrepancy tool	NA	NA	NA	NA	NA

– = not assessed in this paper; NA=not applicable

** Referred to a Spanish article on the development and first steps of validation*

*** Driven by of the lack of a reference standard, the researchers used an alternative reference standard that we judged not applicable as a reference standard*

We excluded Box G (cross-cultural validity), Box H (criterion validity) and items D3, F7, F8 from the assessment. Box C (measurement error) and Box I (responsiveness) were not assessed in any of the included publications and therefore omitted from the table

Results of the outcome inventory

We identified 191 publications, of which 76 reported evaluation of current transitional patient safety and 115 outcomes of interventions for improving transitional patient safety. Of the latter group, 39 were designed as a randomized controlled trial, 16

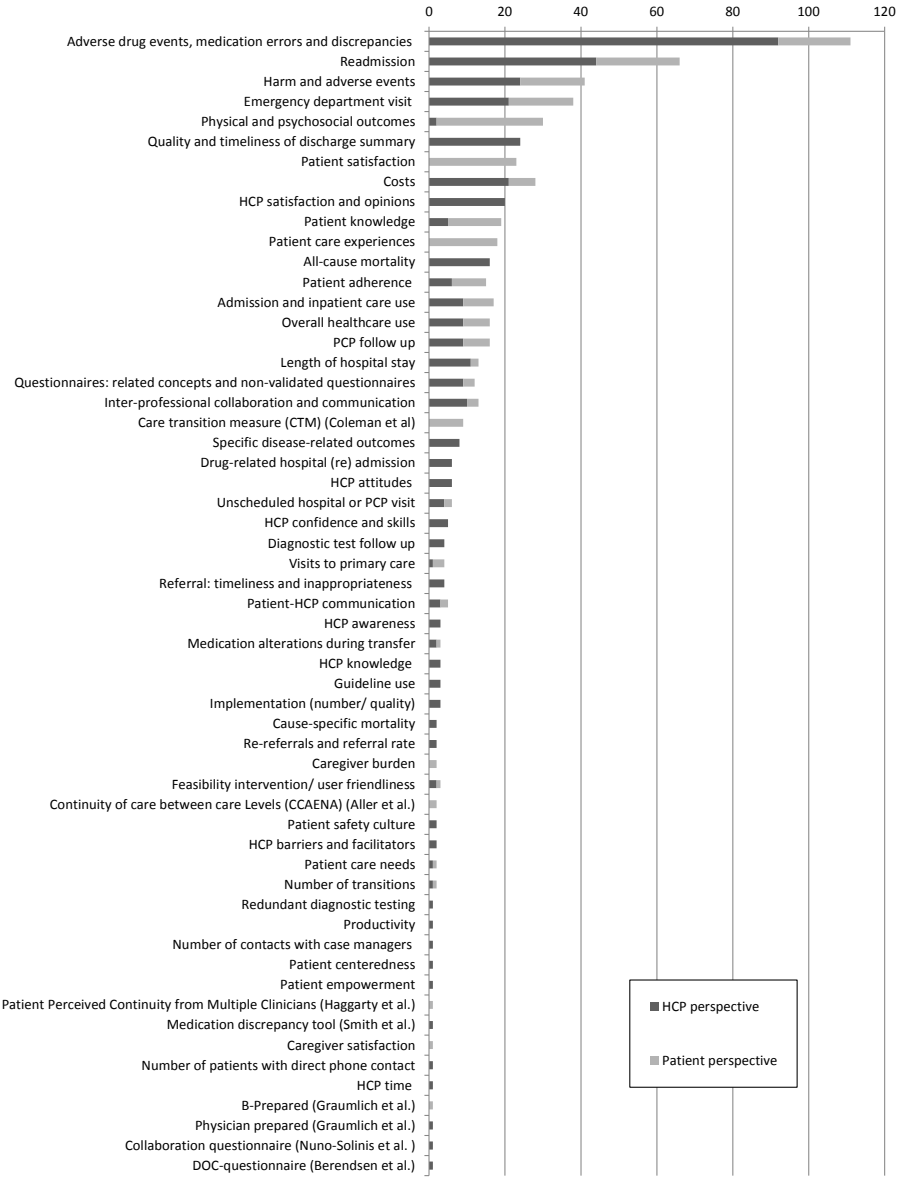


Figure 3.3 Outcomes used in transitional patient safety evaluation according to perspective
HCP=healthcare professional, PCP= primary care provider.

as a non-randomized controlled trial, 29 as a before-after study and 31 had an observational design. In total, the 191 publications used 56 different outcome measures, of which the most frequently used ones were: medication discrepancies (n=98), hospital readmissions (n=55), adverse events (n=34), emergency department visits (n= 33), (mental or physical) health status (n=28), quality and timeliness of discharge summary (n=24), patient satisfaction (n=23), and costs (n=21). Additionally, the way these outcomes were assessed was very divers; e.g. medication errors were measured using either medical records, trained pharmacists, or patient interviews, PCP questionnaires and incident reports and were assessed at different moments in the healthcare process. Hundred-and twenty-five publications assessed transitional patient safety only from a HCPs' perspective, 17 only from the patients' perspective and 49 from both perspectives (Figure 3.3 and Appendix 3.4).

Of all 191 publications in this outcome inventory, 43 measured two-way patient transitions between hospital to primary care, 13 from primary care to hospital and 135 from hospital to primary care. Regarding the outcome level, 15 studies measured an organisational outcome, 9 measured culture, 7 initiatives, 68 a HCP outcome and 154 a patient outcome, respectively (Figure 3.4). A complete list of all the instruments in the outcome inventory, their sources, and characteristics is available in Appendix 3.5.

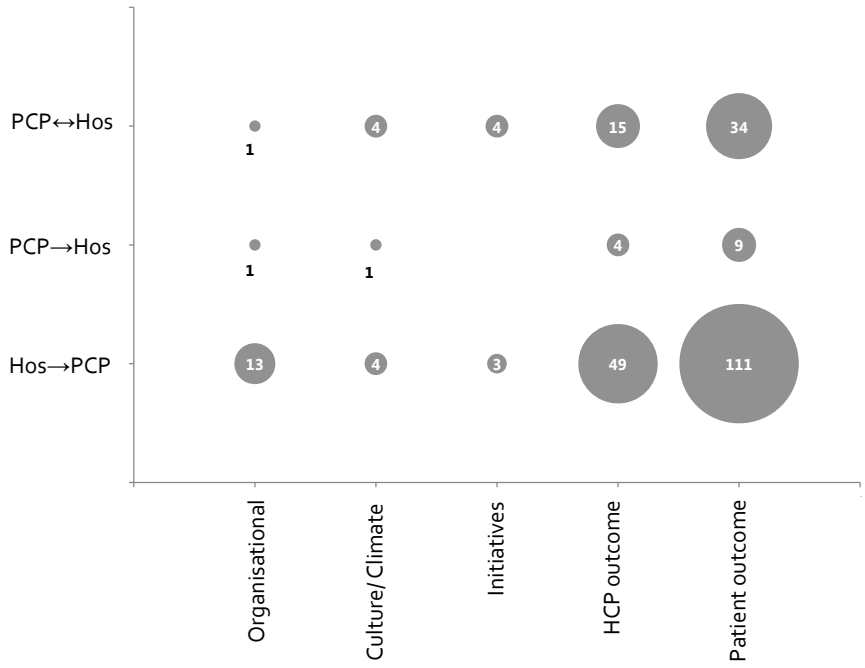


Figure 3.4 Outcome inventory: Which transitions and which outcome level (mentioned in figure 1) do the selected publications include? *PCP=Primary care provider, Hos=hospital, HCP=healthcare professional; number=absolute number of publications*

DISCUSSION

Although our systematic review did not identify any measurement tool that measured the full scope of transitional patient safety, we identified 17 validation studies of 13 different instruments for measuring relevant aspects of transitional patient safety. According to the COSMIN criteria, the quality of these measurement tools was generally acceptable on the items internal consistency, content validity and structural validity. Measurement tools from the patients' perspectives performed somewhat better (quality: moderate to good) than tools from the healthcare professionals' perspective (quality: moderate). The methodological quality of other criteria was generally poor or not addressed at all. For example, by leaving out minimal important change, test-retest reliability and responsiveness, instruments are not sufficiently validated to measure change over time or the effect of a transitional patient safety intervention.

Only few recent publications on patient safety used validated outcomes. The most often used validated instrument was the Care Transition Measure by Coleman et al., which measures only the patient preparedness for discharge .[23,24] In total, over 45 different non-validated outcomes were used in our literature review, and most were not used consistently.

Comparison to the literature

Our results may overlap with systematic reviews on continuity of care (Schultz et al. and Uijen et al.), or integrated care (Strandberg-Larsen et al.).[7,8,13] However, both assess coordination of care, while our review focuses on transitional patient safety. Transitional patient safety encompasses the prevention of errors or reduction of adverse effects associated with transitions of care potentially causing harm to patients and is focused more on the safety outcome instead of the organisational aspects. These transitional patient safety outcomes are specifically of interest because we need to be able to measure if an intervention is actually effective on all levels: from patient safety culture to patient outcomes. In our systematic review, we also disregarded instruments that assessed other quality aspects such as efficiency and effectiveness[38] and measurement tools that focused on continuity within healthcare organisations instead of transitional patient safety. [39-46]

Interpretations of findings

Although we found an acceptable methodological quality of several aspects of validity according to the COSMIN criteria, the ratings should be viewed with caution.[20] The most important step in development of a measurement tool is content validity, which scored high in the included studies. However, the majority of studies excluded items after factor analysis. In 3 of the studies Aller et al., Berendsen et al., and Uijen et al., up to half of all items were excluded, as well as entire transitions

(e.g. excluding all items concerning referral, while the questionnaire was developed for overall continuity back and forth). [21,22,30] This discarded the initial development and item generation process, and potentially undermined the initial content validity. This may have been induced by the common practice in current medical literature to validate measurement tools as being reflective concepts (the construct is reflected by the items, for example anxiety).[47] Transitional patient safety, however, is a formative concept , in which the construct is the result of the presented items, for example socio-economic status.[47] Therefore, the majority studies conducted item generation in a formative way, with the intention to assemble a set of items that all together would capture the construct of transitional safety. Up to now there is no consensus among experts on the optimal way to assess validity of formative measurement tools, and therefore construction of domains is usually performed 'as usual', i.e. in a reflective way using exploratory factor analysis.[48,49] As a result of this approach, many items relevant for transitional safety were excluded from final versions of measurement tools.

Many instruments in our review could not be adequately validated because of the absence of a valid comparator or reference standard. This aspect of validation is often ignored, and solved by using an internal comparator question, single outcomes such as the number of emergency department visits, or other proxies that only poorly relate to transitional patient safety. This was reflected in poor quality scores in the boxes "hypothesis testing" and "criterion validity", thus lowering the overall rating. In contrast, other important aspects of validity such as reliability and measurement error which could have been assessed were not performed.

The outcome inventory showed that the large majority of studies only measured transitional patient safety from one perspective, presenting a limited view. Most studies approached transitional patient safety from the HCP perspective which covers only part of the transition. Fifteen studies measured transitional patient safety from the patients' perspective, underlining the importance of the patients' perspective as being the only stakeholder that fully experiences the healthcare transitions.[4] However, 42 of the 191 studies combined the patients' and HCPs' perspectives, leading to a more complete view.

The outcome inventory also demonstrated that the majority of studies focused on single directional transitions, specifically on discharge. This leaves referral from primary care to hospital underrepresented. On the outcome level, the majority of studies measured HCP and patient outcomes, leaving especially culture and climate unmeasured. These gaps provide insight into the niches to fill by future research on interventions and measurement tools needed for transitional patient safety.

Strengths and limitations

We combined a very broad search strategy on transitional care with validated search filters on patient safety and measurement tools. This resulted in a broad range of papers and a wide selection of validated measurement tools. The broad search

strategy also provided a wide range of publications measuring either the current state of transitional patient safety or improvement of transitional patient safety in intervention studies. We included all types of research design as often patient safety is assessed in observational studies.[50] Including only randomised controlled trials would have limited the overview and subsequently the generalizability of the results.

A limitation may have been that the concept of transitional patient safety that we used is relatively new, moving away from the traditional single organisation safety concept to a more patient-centered view across multiple healthcare settings. Therefore, the specific term "transitional patient safety" is not yet commonly used in literature. This might have led to omission of relevant publications in our article selection for both the validity assessment and the outcome inventory.

In addition, the COSMIN criteria are originally designed for patient reported outcome measurements, which did not match all the instruments we included.[20] The COSMIN criteria, however, are frequently used in other types of measurement tools, such as HCP-reported measurement tools. However, the absence of a reference standard in transitional patient safety limits the applicability of COSMIN criteria (e.g. criterion validity, hypothesis testing). And importantly, as we intended to identify all validated measurement tools developed for transitional patient safety, we also identified two studies validating review methods for transitional safety incidents (Smith et al. and Forster et al.). [33,37] Even though quality could not be assessed using the COSMIN criteria, these measurement tools are useful, as they could help other healthcare organisations identify and improve their identified weaknesses.

Conclusion

We provided an overview of the available validated measurement tools. Although their quality was generally acceptable, the validation process could be improved considerably, specifically for their use in intervention studies. As none measures all levels of transitional patient safety, the identified measurement tools could be used as a base for a more comprehensive set of measurement tools. Furthermore, our outcome inventory shows that the available validated measurement tools are infrequently used. The range of outcome measures used in current literature is fragmented and gaps exist in available measurement tools and outcome measures. Especially measurement tools for transitional patient safety culture and the referral process are needed.

The concept of transitional patient safety is evolving, resulting in the use of a wide variety of outcome measures and measurement tools. Adequate monitoring of transitional patient safety in future requires standardised measurements, to be used in different healthcare settings in order to identify best practices and to assess the effectiveness of safety interventions.

ACKNOWLEDGEMENTS

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APPENDIX 3.1 SEARCH STRATEGY

Pubmed (including medline)

1. Transitional care
((Continuity[tiab] OR Continuum[tiab] OR Integration[tiab] OR Integrated[tiab] OR Integrating[tiab] OR Integral[tiab] OR "Patient-centered"[tiab] OR Transitional[tiab] OR Transition[tiab] OR Transmural[tiab] OR Seamless[tiab] OR Crossboundary[tiab] OR "Cross-boundary"[tiab]) AND (care[tiab] OR healthcare[tiab])) OR (Continuity[tiab] AND service[tiab]) OR "continuity of patient care"[Mesh]

2. Measurement (Terwee et al.)
(instrumentation[sh] OR methods[sh] OR Validation Studies[pt] OR Comparative Study[pt] OR psychometrics[MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment (health care)"[MeSH] OR outcome assessment[tiab] OR outcome measure*[tw] OR "observer variation"[MeSH] OR observer variation[tiab] OR "Health Status Indicators"[Mesh] OR "reproducibility of results"[MeSH] OR reproducib*[tiab] OR "discriminant analysis"[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR coefficient[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR "internal consistency"[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tiab] OR precision[tiab] OR imprecision[tiab] OR "precise values"[tiab] OR test–retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intra-observer[tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant[tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR repeatab*[tiab] OR ((replicab*[tiab] OR repeated[tiab]) AND (measure[tiab] OR measures[tiab] OR findings[tiab] OR result[tiab] OR results[tiab] OR test[tiab] OR tests[tiab])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR factor analysis[tiab] OR factor analyses[tiab] OR dimension*[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR item discriminant[tiab] OR interscale correlation*[tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR (variability[tiab] AND

(analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR ((minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR meaningful change[tiab] OR "ceiling effect"[tiab] OR "floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab])

3. Patient safety (Tanon et al.)
(Safe*[tiab] OR Safety[Mesh] OR Err*[tiab] OR Adverse[tiab]) AND ("Risk Management"[Mesh] OR "Quality of Health Care"[Mesh] OR "Medical Errors"[Mesh] OR "Safety Management"[Mesh] OR "Medical Audit"[Mesh]) OR "patient safety"[Mesh]

Embase

1. Transitional care
((‘Continuity’:ab,ti OR ‘Continuum’:ab,ti OR ‘Integration’:ab,ti OR ‘Integrated’:ab,ti OR ‘Integrating’:ab,ti OR ‘Integral’:ab,ti OR ‘Patient-centered’:ab,ti OR ‘Transitional’:ab,ti OR ‘Transition’:ab,ti OR ‘Transmural ‘:ab,ti OR ‘Seamless’:ab,ti OR ‘Crossboundary’:ab,ti OR ‘Cross-boundary’:ab,ti) AND (‘care’:ab,ti OR ‘healthcare’:ab,ti)) OR (‘Continuity’:ab,ti AND ‘service’:ab,ti) OR ‘integrated health care system’/exp AND [embase]/lim

2. Measurement (Terwee et al.)
('intermethod comparison'/exp OR 'data collection method'/exp OR 'validation study'/exp OR 'feasibility study'/exp OR 'pilot study'/exp OR 'psychometry'/exp OR 'reproducibility'/exp OR reproducib*:ab,ti OR 'audit':ab,ti OR psychometr*:ab,ti OR clinimetr*:ab,ti OR clinometr*:ab,ti OR 'observer variation'/exp OR 'observer variation':ab,ti OR 'discriminant analysis'/exp OR 'validity'/exp OR reliab*:ab,ti OR valid*:ab,ti OR 'coefficient':ab,ti OR 'internal consistency':ab,ti OR (cronbach*:ab,ti AND ('alpha':ab,ti OR 'alphas':ab,ti)) OR 'item correlation':ab,ti OR 'item correlations':ab,ti OR 'item selection':ab,ti OR 'item selections':ab,ti OR 'item reduction':ab,ti OR 'item reductions':ab,ti OR 'agreement':ab,ti OR 'precision':ab,ti OR 'imprecision':ab,ti OR 'precise values':ab,ti OR 'test-retest':ab,ti OR ('test':ab,ti AND 'retest':ab,ti) OR (reliab*:ab,ti AND ('test':ab,ti OR 'retest':ab,ti)) OR 'stability':ab,ti OR 'interrater':ab,ti OR 'inter-rater':ab,ti OR 'intrarater':ab,ti OR 'intra-rater':ab,ti OR 'intertester':ab,ti OR 'inter-tester':ab,ti OR 'intratester':ab,ti OR 'intra- tester':ab,ti OR 'interobeserver':ab,ti OR 'inter-observer':ab,ti OR

'intraobserver':ab,ti OR 'intra- observer':ab,ti OR 'intertechnician':ab,ti OR 'inter-technician':ab,ti OR 'intratechnician':ab,ti OR 'intra- technician':ab,ti OR 'interexaminer':ab,ti OR 'inter-examiner':ab,ti OR 'intraexaminer':ab,ti OR 'intra-examiner':ab,ti OR 'interassay':ab,ti OR 'inter-assay':ab,ti OR 'intraassay':ab,ti OR 'intra-assay':ab,ti OR 'interindividual':ab,ti OR 'inter-individual':ab,ti OR 'intraindividual':ab,ti OR 'intra-individual':ab,ti OR 'interparticipant':ab,ti OR 'inter-participant':ab,ti OR 'intraparticipant':ab,ti OR 'intra- participant':ab,ti OR 'kappa':ab,ti OR 'kappas':ab,ti OR 'coefficient of variation':ab,ti OR repeatab*:ab,ti OR (replicab*:ab,ti OR 'repeated':ab,ti AND ('measure':ab,ti OR 'measures':ab,ti OR 'findings':ab,ti OR 'result':ab,ti OR 'results':ab,ti OR 'test':ab,ti OR 'tests':ab,ti)) OR generaliza*:ab,ti OR generalisa*:ab,ti OR 'concordance':ab,ti OR ('intraclass':ab,ti AND correlation*:ab,ti) OR 'discriminative':ab,ti OR 'known group':ab,ti OR 'factor analysis':ab,ti OR 'factor analyses':ab,ti OR 'factor structure':ab,ti OR 'factor structures':ab,ti OR 'dimensionality':ab,ti OR subscale*:ab,ti OR 'multitrait scaling analysis':ab,ti OR 'multitrait scaling analyses':ab,ti OR 'item discriminant':ab,ti OR 'interscale correlation':ab,ti OR 'interscale correlations':ab,ti OR ('error':ab,ti OR 'errors':ab,ti AND (measure*:ab,ti OR correlat*:ab,ti OR evaluat*:ab,ti OR 'accuracy':ab,ti OR 'accurate':ab,ti OR 'precision':ab,ti OR 'mean':ab,ti)) OR 'individual variability':ab,ti OR 'interval variability':ab,ti OR 'rate variability':ab,ti OR 'variability analysis':ab,ti OR ('uncertainty':ab,ti AND ('measurement':ab,ti OR 'measuring':ab,ti)) OR 'standard error of measurement':ab,ti OR sensitiv*:ab,ti OR responsive*:ab,ti OR ('limit':ab,ti AND 'detection':ab,ti) OR 'minimal detectable concentration':ab,ti OR interpretab*:ab,ti OR (small*:ab,ti AND ('real':ab,ti OR 'detectable':ab,ti) AND ('change':ab,ti OR 'difference':ab,ti)) OR 'meaningful change':ab,ti OR 'minimal important change':ab,ti OR 'minimal important difference':ab,ti OR 'minimally important change':ab,ti OR 'minimally important difference':ab,ti OR 'minimal detectable change':ab,ti OR 'minimal detectable difference':ab,ti OR 'minimally detectable change':ab,ti OR 'minimally detectable difference':ab,ti OR 'minimal real change':ab,ti OR 'minimal real difference':ab,ti OR 'minimally real change':ab,ti OR 'minimally real difference':ab,ti OR 'ceiling effect':ab,ti OR 'floor effect':ab,ti OR 'item response model':ab,ti OR 'irt':ab,ti OR 'rasch':ab,ti OR 'differential item functioning':ab,ti OR 'dif':ab,ti OR 'computer adaptive testing':ab,ti OR 'item bank':ab,ti OR 'cross-cultural equivalence':ab,ti OR 'outcome assessment'/exp OR 'medical record':ab,ti) AND [embase]/lim

3. Patient safety (Tanon et al.)

((Safety/exp OR Safe*:ti,ab OR Err*:ti,ab OR Adverse:ti,ab) AND ('Health Care Quality'/exp OR 'Risk assessment'/exp) OR 'patient safety'/exp) AND [embase]/lim

Cinahl (ebsco)

1. Transitional care
TI (("Continuity" OR "Continuum" OR "Integration" OR "Integrated" OR "Integrating" OR "Integral" OR "Patient-centered" OR "Transitional" OR "Transition" OR "Transmural " OR "Seamless" OR "Crossboundary" OR "Cross-boundary" AND ("care" OR "healthcare")) OR AB (("Continuity" OR "Continuum" OR "Integration" OR "Integrated" OR "Integrating" OR "Integral" OR "Patient-centered" OR "Transitional" OR "Transition" OR "Transmural " OR "Seamless" OR "Crossboundary" OR "Cross-boundary" AND ("care" OR "healthcare")) OR TI (continuity of patient care OR continuity of care) OR AB (continuity of patient care OR continuity of care) OR (MH "Continuity of Patient Care+")

2. Measurement (Terwee et al.)
TI psychometr* OR TI observer variation OR TI reproducib* OR TI reliab* OR TI unreliab* OR TI valid* OR TI coefficient OR TI homogeneity OR TI homogeneous OR TI "internal consistency" OR AB psychometr* OR AB observer variation OR AB reproducib* OR AB reliab* OR AB unreliab* OR AB valid* OR AB coefficient OR AB homogeneity OR AB homogeneous OR AB "internal consistency" OR (TI cronbach* OR AB cronbach* AND (TI alpha OR AB alpha OR TI alphas OR AB alphas)) OR (TI item OR AB item AND (TI correlation* OR AB correlation* OR TI selection* OR AB selection* OR TI reduction* OR AB reduction*)) OR TI agreement OR TI precision OR TI imprecision OR TI "precise values" OR TI test-retest OR AB agreement OR AB precision OR AB imprecision OR AB "precise values" OR AB test-retest OR (TI test OR AB test AND (TI retest OR AB retest)) OR (TI reliab* OR AB reliab* AND (TI test OR AB test OR TI retest or AB retest)) OR TI stability OR TI interrater OR TI interrater OR TI intrarater OR TI intra-rater OR TI intertester OR TI inter-tester OR TI intratester OR TI intra-tester OR TI interobserver OR TI inter-observer OR TI intraobserver OR TI intra-observer OR TI intertechnician OR TI inter-technician OR TI intratechnician OR TI intra-technician OR TI interexaminer OR TI inter-examiner OR TI intraexaminer OR TI intra-examiner OR TI interassay OR TI inter-assay OR TI intraassay OR TI intra-assay OR TI interindividual OR TI inter-individual OR TI intraindividual OR TI intra-individual OR TI interparticipant OR TI inter-participant OR TI intraparticipant OR TI intra-participant OR TI kappa OR TI kappa's OR TI kappas OR TI repeatab* OR AB stability OR AB interrater OR AB inter-rater OR AB intrarater OR AB intra-rater OR AB intertester OR AB inter-tester OR AB intratester OR AB intra-tester OR AB interobserver OR AB inter-observer OR AB intraobserver OR AB intra-observer OR AB intertechnician OR AB inter-technician OR AB intratechnician OR AB intra-technician OR AB interexaminer OR AB inter-examiner OR AB intraexaminer OR AB intra-examiner OR AB interassay OR AB inter-assay OR AB intraassay OR AB intra-assay OR AB interindividual OR AB inter-individual OR AB intraindividual OR AB intra-individual OR AB interparticipant OR AB inter-participant OR AB intraparticipant OR AB intra-participant OR AB kappa OR AB

kappa's OR AB kappas OR AB repeatab* OR ((TI replicab* OR AB replicab* OR TI repeated OR AB repeated) AND (TI measure OR AB measure OR TI measures OR AB measures OR TI findings OR AB findings OR TI result OR AB result OR TI results OR AB results OR TI test OR AB test OR TI tests OR AB tests)) OR TI generaliza* OR TI generalisa* OR TI concordance OR AB generaliza* OR AB generalisa* OR AB concordance OR (TI intraclass OR AB intraclass AND (TI correlation* or AB correlation*)) OR TI discriminative OR TI "known group" OR TI factor analysis OR TI factor analyses OR TI dimension* OR TI subscale* OR AB discriminative OR AB "known group" OR AB factor analysis OR AB factor analyses OR AB dimension* OR AB subscale* OR (TI multitrait OR AB multitrait AND (TI scaling OR AB scaling) AND (TI analysis OR AB analysis OR TI analyses OR AB analyses)) OR TI item discriminant OR TI interscale correlation* OR TI error OR TI errors OR TI "individual variability" OR AB item discriminant OR AB interscale correlation* OR AB error OR AB errors OR AB "individual variability" OR (TI variability OR AB variability AND (TI analysis OR AB analysis OR TI values OR AB values)) OR (TI uncertainty OR AB uncertainty AND (TI measurement OR AB measurement OR TI measuring OR AB measuring)) OR TI "standard error of measurement" OR TI sensitiv* OR TI responsive* OR AB "standard error of measurement" OR AB sensitiv* OR AB responsive* OR ((TI minimal OR TI minimally OR TI clinical OR TI clinically OR AB minimal OR AB minimally OR AB clinical OR AB clinically) AND (TI important OR TI significant OR TI detectable OR AB important OR AB significant OR AB detectable) AND (TI change OR AB change OR TI difference OR AB difference)) OR (TI small* OR AB small* AND (TI real OR AB real OR TI detectable OR AB detectable) AND (TI change OR AB change OR TI difference OR AB difference)) OR TI meaningful change OR TI "ceiling effect" OR TI "floor effect" OR TI "Item response model" OR TI IRT OR TI Rasch OR TI "Differential item functioning" OR TI DIF OR TI "computer adaptive testing" OR TI "item bank" OR TI "cross-cultural equivalence" OR TI outcome assessment OR AB meaningful change OR AB "ceiling effect" OR AB "floor effect" OR AB "Item response model" OR AB IRT OR AB Rasch OR AB "Differential item functioning" OR AB DIF OR AB "computer adaptive testing" OR AB "item bank" OR AB cross-cultural equivalence" OR AB outcome assessment

3. Patient safety (Tanon et al.)
((TX Health* OR TX Care* OR TX Prevent*) AND (TX Safe* OR TX Err*) AND (MH "Child" OR TX Patient* or TX Human)) OR MH "Health Care Errors+".

Psychinfo (ovid)

Transitional care
((Continuity.ti OR Continuum.ti OR Integration.ti OR Integrated.ti OR Integrating.ti OR Integral.ti OR Patient-centered.ti OR Transitional.ti OR Transition.ti OR Transmural.ti OR Seamless.ti OR Crossboundary.ti OR Cross-boundary.ti) AND

(care.ti OR healthcare.ti OR care.ab OR healthcare.ab)) OR ((Continuity.ab OR Continuum.ab OR Integration.ab OR Integrated.ab OR Integrating.ab OR Integral.ab OR Patient-centered.ab OR Transitional.ab OR Transition.ab OR Transmural.ab OR Seamless.ab OR Crossboundary.ab OR Cross-boundary.ab) AND (care.ti OR healthcare.ti OR care.ab OR healthcare.ab))

2. Measurement (Terwee et al.)

psychometr*.ti OR observer variation.ti OR reproducib*.ti OR reliab*.ti OR unreliab*.ti OR valid*.ti OR coefficient.ti OR homogeneity.ti OR homogeneous.ti OR internal consistency.ti OR psychometr*.ab OR observer variation.ab OR reproducib*.ab OR reliab*.ab OR unreliab*.ab OR valid*.ab OR coefficient.ab OR homogeneity.ab OR homogeneous.ab OR internal consistency.ab OR (cronbach*.ti OR cronbach*.ab AND (alpha.ti OR alpha.ab OR alphas.ti OR alphas.ab)) OR ((item.ti OR item.ab) AND (correlation*.ti OR correlation*.ab OR selection*.ti OR selection*.ab OR reduction*.ti OR reduction*.ab)) OR agreement.ti OR precision.ti OR imprecision.ti OR precise values.ti OR test-retest.ti OR agreement.ab OR precision.ab OR imprecision.ab OR precise values.ab OR test-retest.ab OR (test.ti OR test.ab AND retest.ti OR retest.ab) OR (reliab*.ti OR reliab*.ab AND (test.ti OR test.ab OR retest.ti or retest.ab)) OR stability.ti OR interrater.ti OR interrater.ti OR intrarater.ti OR intra-rater.ti OR intertester.ti OR inter-tester.ti OR intratester.ti OR intra-tester.ti OR interobserver.ti OR inter-observer.ti OR intraobserver.ti OR intra-observer.ti OR intertechnician.ti OR inter-technician.ti OR intratechnician.ti OR intra-technician.ti OR interexaminer.ti OR inter-examiner.ti OR intraexaminer.ti OR intra-examiner.ti OR interassay.ti OR inter-assay.ti OR intraassay.ti OR intra-assay.ti OR interindividual.ti OR inter-individual.ti OR intraindividual.ti OR intra-individual.ti OR interparticipant.ti OR inter-participant.ti OR intraparticipant.ti OR intra-participant.ti OR kappa.ti OR kappa-s.ti OR kappas.ti OR repeatab*.ti OR stability.ab OR interrater.ab OR inter-rater.ab OR intrarater.ab OR intra-rater.ab OR intertester.ab OR inter-tester.ab OR intratester.ab OR intra-tester.ab OR interobserver.ab OR inter-observer.ab OR intraobserver.ab OR intra-observer.ab OR intertechnician.ab OR inter-technician.ab OR intratechnician.ab OR intra-technician.ab OR interexaminer.ab OR inter-examiner.ab OR intraexaminer.ab OR intra-examiner.ab OR interassay.ab OR inter-assay.ab OR intraassay.ab OR intra-assay.ab OR interindividual.ab OR inter-individual.ab OR intraindividual.ab OR intra-individual.ab OR interparticipant.ab OR inter-participant.ab OR intraparticipant.ab OR intra-participant.ab OR kappa.ab OR kappa-s.ab OR kappas.ab OR repeatab*.ab OR ((replicab*.ti OR replicab*.ab OR repeated.ti OR repeated.ab) AND (measure.ti OR measure.ab OR measures.ti OR measures.ab OR findings.ti OR findings.ab OR result.ti OR result.ab OR results.ti OR results.ab OR test.ti OR test.ab OR tests.ti OR tests.ab)) OR generaliza*.ti OR generalisa*.ti OR concordance.ti OR generaliza*.ab OR generalisa*.ab OR concordance.ab OR (intraclass.ti OR intraclass.ab AND correlation*.ti or correlation*.ab) OR discriminative.ti OR known group.ti OR factor analysis.ti OR factor analyses.ti OR dimension*.ti OR subscale*.

ti OR discriminative.ab OR known group.ab OR factor analysis.ab OR factor analyses.ab OR dimension*.ab OR subscale*.ab OR (multitrait.ti OR multitrait.ab AND scaling.ti OR scaling.ab AND (analysis.ti OR analysis.ab OR analyses.ti OR analyses.ab)) OR item discriminant.ti OR interscale correlation*.ti OR error.ti OR errors.ti OR individual variability.ti OR item discriminant.ab OR interscale correlation*.ab OR error.ab OR errors.ab OR individual variability.ab OR (variability.ti OR variability.ab AND (analysis.ti OR analysis.ab OR values.ti OR values.ab)) OR (uncertainty.ti OR uncertainty.ab AND (measurement.ti OR measurement.ab OR measuring.ti OR measuring.ab)) OR standard error of measurement.ti OR sensitiv*.ti OR responsive*.ti OR standard error of measurement.ab OR sensitiv*.ab OR responsive*.ab OR ((minimal.ti OR minimally.ti OR clinical.ti OR clinically.ti OR minimal.ab OR minimally.ab OR clinical.ab OR clinically.ab) AND (important.ti OR significant.ti OR detectable.ti OR important.ab OR significant.ab OR detectable.ab) AND (change.ti OR change.ab OR difference.ti OR difference.ab)) OR (small*.ti OR small*.ab AND (real.ti OR real.ab OR detectable.ti OR detectable.ab) AND (change.ti OR change.ab OR difference.ti OR difference.ab)) OR meaningful change.ti OR ceiling effect.ti OR floor effect.ti OR Item response model.ti OR IRT.ti OR Rasch.ti OR Differential item functioning.ti OR DIF.ti OR computer adaptive testing.ti OR item bank.ti OR cross-cultural equivalence.ti OR outcome assessment.ti OR meaningful change.ab OR ceiling effect.ab OR floor effect.ab OR Item response model.ab OR IRT.ab OR Rasch.ab OR Differential item functioning.ab OR DIF.ab OR computer adaptive testing.ab OR item bank.ab OR cross-cultural equivalence.ab OR outcome assessment.ab OR psychometrics/ OR exp Measurement/ OR exp Interrater Reliability/ exp OR Test Reliability/ OR exp Test Validity/

3. Patient safety (Tanon et al.)
((Safe*.ti OR Err*.ti OR Adverse.ti) OR (Safe*.ab OR Err*.ab OR Adverse.ab) OR exp Safety/) AND (risk management/ OR exp "Quality of Care"/ OR exp Errors/ OR exp Accident Prevention/ OR exp Clinical Audits/) OR patient safety.ti OR patient safety.ab

APPENDIX 3.2 IN- AND EXCLUSION CRITERIA

Inclusion criteria:

- Quantitative measurements
- Patients of all ages
- Physical and mental health
- No limits on study design
- Research assessing transitional patient safety:
  Group 1: Validity assessment: Research regarding measurement properties (development, validation or evaluation) of measurement tools in transitional patient safety
  Group 2: Outcome inventory: Research regarding the current state of, or interventions on transitional patient safety and measuring their effect
- Studies on transitional patient safety between general practitioner/ primary care practitioner/ family medicine and hospital. A transition of patient responsibility from a healthcare professional (general practice/primary care or hospital) to another healthcare professional in the other level (general practice/primary care or hospital) is essential.
- Studies on patient safety culture/ climate (definition: the norm, values and assumptions of healthcare professionals on transitional patient safety or "How do healthcare professionals think about transitional patient safety")
- Studies on initiatives and staff outcomes: behaviour of healthcare professionals ("How do healthcare professionals behave in transitional care", e.g. referral, discharge, simultaneous care, medication reconciliation, quality indicators, discharge/ referral letters or other communication)
- Studies on patient outcomes: transitional patient safety incidents and mortality/ morbidity outcomes and patient-reported outcome measures (PROMs): patients perspectives ("How does the patient perceive transitional patient safety")
- Measurements from both the perspectives of the healthcare professional (process and culture) and patient
- Studies on a medical home (which includes a primary care team)

Exclusion criteria:

- Qualitative measurements
- Measurement tools addressing more organisational concepts such as integral care
- Research regarding transitions between other healthcare organisations in primary and secondary care (e.g. ambulance, obstetric health center, nursing homes)
- Models and frameworks
- Electronic health record implementation
- Relational continuity of care
- Home healthcare (only included if a general practitioner is clearly involved)

APPENDIX 3.3 VALIDITY ASSESSMENT: CHARACTERISTICS INCLUDED STUDIES

Author/Year *Country* Response rate Mean age Gender	Measurement tool	N	Transition	Level of Outcome	Domain	Number of items	Dimensions	Target population	Methodological observations
					Patient perception				
Aller, 2013 Spain Response rate 23% Mean age 56 Gender (% female) 56%	Continuity of care between care levels (CCAENA)	1500	HOS<->PCP	HCP	Continuity of care	29	1) Patient-PCP relationship (Relational Continuity (7 items), 2) Patient-SCP relationship (Relational Continuity) (7 items), 3) Continuity across care levels (IC and MC) (11 items), 4) Accessibility across care levels (MC) (4 items)	Patients that have experienced a transition	▪ Relevant items excluded after factor analysis undermining initial content validity ▪ More details of validation in Spanish publication
Berendsen, 2009 The Netherlands Response rate 65% Mean age 54 Gender (% female) 60%	Consumer Quality Index Continuum of Care (CQI-COC)	1404	PCP->HOS	HCP	Collaboration between PCP and hospital	22	1) PCP approach (6 items), 2) PCP referral (5 items), 3) Specialist (9 items), 4) Collaboration (2 items)	Referred patients	▪ Many items excluded ▪ After extensive item reduction, the resulting item set did not fully cover the original content
Coleman, 2002 USA Response rate NR Mean age NR Gender (% female) NR	Care Transition Measure (CTM)	60	HOS->PCP	HCP	Quality of care transition	NR	1) Information transfer 2) Patient and caregiver preparation, 3) Support for self-management, 4) Empowerment to assert preferences	Patients ≥65 years recently discharged from hospital and who received subsequent skilled nursing care in a facility/home	▪ No reported total of items ▪ No reported number and characteristics of respondents

Appendix 3.3 *Continued*

Author/Year Country Response rate Mean age Gender	Measurement tool	N	Transition	Level of Outcome	Domain	Number of items	Dimensions	Target population	Methodological observations
Coleman, 2005 USA Response rate 99.5% Mean age 67 Gender (% female) 60%	Care Transition Measure (CTM)	200	HOS->PCP	HCP + patient	Quality of care transition	15	1) Critical understanding (6 items), 2) Preferences important (3 items), 3) Management preparation (4 items), 4) Care plan (2 items)	Adult patients discharged with primary diagnosis of chronic obstructive pulmonary disease, congestive heart failure, stroke, or hip fracture	▪ Sequel to Coleman, 2002 ▪ All items treated as unidimensional measurement tool, although the questionnaire was developed with 4 dimensions
Graumlich, 2008 USA Response rate NR Mean age 54 Gender (% female) 58%	B-prepared	460	HOS->PCP	HCP	Patient perceptions of preparedness for hospital discharge	11	1) Self-care information for medication and activity (4 items), 2) Equipment and services (4 items), 3) Confidence (3 items)	Adult patients discharged by internal medicine hospitalists	▪ Sequel to Grimmer, 2001 ▪ Very selective group of patients, limiting generalizability
Grimmer, 2001 Australia Response rate patients 60%; carers 52% Mean age NR Gender (%female) NR	PREPARED	Patients 500, Carers 431	HOS->PCP	HCP + patient	Quality of discharge planning activities	21	1) Information exchange (5 items), 2) Receipt of medication information (4 items), 3) Preparation for coping post dis-charge (3 items), 4) Control of post-discharge circumstances (2 items), 4) Patient outcomes (3 items), 5) Cost and service usage (4 items)	Patients ≥65 years, recently discharged from hospital	▪ No patient characteristics reported ▪ Low factor loadings ignored in conclusion

Appendix 3.3 *Continued*

Author/Year ***Country*** Response rate Mean age Gender	Measurement tool	N	Transition	Level of Outcome	Domain	Number of items	Dimensions	Target population	Methodological observations
Haggerty, 2011 Canada Response rate 54-99%* Mean age 48 Gender (% female) 65%	Several existing (validated) questionnaires on continuity of care with a dimension on management continuity: PCAS, PCAT-S, CPCI, VANOCCS#	236-427¥	HOS<->PCP	HCP	Management continuity	28 in 4 questionnaires	1) PCAS: Integration (6 items), 2) PCAT-S: Coordination (4 items), 3) CPCI: Coordination of care (8 items), 4) VANOCCS: overall coordination (6 items), specialty access (4 items)	Primary care patients who had seen more than one provider in the previous month	▪ Compared single dimensions on management continuity of related questionnaires, so COSMIN not applicable
Haggerty, 2012 Canada Response rate 80% Mean age 53 Gender (% female) 71%	Patient Perceived Continuity from Multiple Clinicians	256	HOS<->PCP	HCP + patient	Continuity of care	37	1) Coordinator role (5 items), 2) Comprehensive knowledge of patient (4 items), 3) Confidence and partnership (3 items), 4) Confidence in team (2 items), 5) Role clarity and coordination (6 items), 6) Information between clinicians (6 items), 7) Evidence of a care plan (7 items), 8) Self-management information provided (4 items)	Adult patients in primary care seeing other clinicians in a variety of settings	▪ Sequel to Haggerty 2011 ▪ Use of a reference standard not applicable in transitional patient safety
Kollen, 2010 The Netherlands Response rate 65% Mean age 56 Gender (% female) 60%	Consumer Quality Index Continuum of Care (CQI-COC)	1404	PCP->HOP	HCP	Quality of continuum of care	22	1) PCP approach (6 items), 2) PCP referral (5 items), 3) Specialist (9 items), 4) Collaboration (2 items)	Adult patients who had been referred and visited a specialist	▪ Sequel to Berendsen 2009

Appendix 3.3 *Continued*

Author/Year *Country* Response rate Mean age Gender	Measurement tool	N	Transition	Level of Outcome	Domain	Number of items	Dimensions	Target population	Methodological observations
Uijen, 2011 The Netherlands Response rate 72% Mean age 65 Gender (% female) 54%	Nijmegen Continuity Questionnaire	288	HOS<->PCP	HCP	Continuity of care	28	1) Personal continuity: care provider knows me (10 items), 2) Personal continuity: care provider shows commitment (6 items), 3) Team/cross boundary continuity (12 items)	Patients with comorbidity	▪ Relevant items excluded after factor analysis, undermining initial content validity
Uijen, 2012 The Netherlands Response rate 76% Mean age in PCP 66, in hos 58 Gender (% female) in PCP 54%, in hos 49%	Nijmegen Continuity Questionnaire	268	HOS<->PCP	HCP	Continuity of care	28	1) Personal continuity: care provider knows me (10 items), 2) Personal continuity: care provider shows commitment (6 items), 3) Team/cross boundary continuity (12 items)	Patients with comorbidity	▪ Sequel to Uijen, 2011 ▪ Assessing discriminative validity ▪ Confirmatory factor analysis would be more appropriate than exploratory factor analysis
HCP perspective									
Berendsen, 2010 The Netherlands Response rate 45% (PCP 47%, spec 44%) Mean age PCP 50, hospital specialist 51 Gender (% female) PCP 33%, spec 21%	Doctors' opinions on collaboration (DOC-) Questionnaire	496	HOS<->PCP	Climate + HCP outcome	Quality of interprofessional collaboration	20	1) Organisation (7 items), 2) Communication (3 items), 3) professional expertise (4 items), 4) image (3 items), 5) knowing each other (3 items)	PCPs and specialists	▪ Confirmatory factor analysis would be more appropriate than exploratory factor analysis
Forster, 2012 Canada Response rate NA Mean age NA Gender (% female) NA	Peer review process of adverse outcome	§	HOS->PCP	Patient outcome	Adverse events at discharge	NA	NA	NA	▪ COSMIN not applicable

Appendix 3.3 Continued

Author/Year *Country* Response rate Mean age Gender	Measurement tool	N	Transition	Level of Outcome	Domain	Number of items	Dimensions	Target population	Methodological observations
Graumlich, 2008 USA Response rate 76% Mean age NR Gender (% female) NR	Modified Physician-PREPARED	417	HOS->PCP	HCP outcome	Quality of hospital discharge	8	1) Adequacy of discharge plan/Transmission (6 items), 2) Timeliness of communication (2 items)	Community physicians	▪ No characteristics of respondents reported ▪ Relevant items excluded after factor analysis, undermining initial content validity
Hess, 2009 USA Response rate NR Mean age 46 Gender (% female) 20%	CRP-PIM: Communication with Referring Physicians Practice Improvement Module	12212	PCP->HOS	Climate + HCP	Communication of consultants	13	1) contacting/ communication with the consultant (10 items), 2) consultant office staff (3 items)	Referring physicians	▪ No characteristics of respondents reported ▪ Generalizability theory used, but not described in publication
Nuno-solinis, 2013 Spain Response rate 16% Mean age 45 Gender (% female) 77%	Unnamed	187	HOS<->PCP	Climate	Interprofessional collaboration	10	1) personal relationship (4 items), 2) organisational setting (6 items)	Clinical professionals (doctors and nurses) working in integrated healthcare organisations	▪ Based on a theoretical model ▪ Exploratory and confirmatory factor analysis used in the same sample
Smith, 2004 USA Response rate NA Mean age NA Gender (% female) NA	Medication discrepancy tool	‡	HOS->PCP	Patient	Medication discrepancies	27	1) patient level (8 items), 2) system level (11 items), 3) resolution (8 items)	Practitioners across the continuum of care	▪ COSMIN not applicable

SP: Spain; NL: the Netherlands; USA: United States of America; AUS: Australia; CAN: Canada; HOS: hospital; PCP=primary care provider, NA= not applicable, NR=not reported, GP=general practitioner

* *PCAS:79%, PCAT-S:91%, CPCI:99%, VANOCCS:64+54%*

¥ *PCAS:342, PCAT-S:392, CPCI:427, VANOCCS:278+136*

§ *Vignette study on 319 case reports, 30 physicians*

‡ *Vignette study on 20 cases, 6 clinicians*

\# *Primary Care Assessment Survey (PCAS), the Primary Care Assessment Tool – Short Form (PCAT-S), the Components of Primary Care Instrument (CPCI) and the Veterans Affairs National Outpatient Customer Satisfaction Survey (VANOCSS)*

APPENDIX 3.4 OUTCOME INVENTORY: USED OUTCOMES FROM HEALTHCARE PROFESSIONALS' AND PATIENTS' PERSPECTIVES INVENTORIED IN 191 PUBLICATIONS THAT MEASURED TRANSITIONAL PATIENT SAFETY: WHICH ARE USED AND HOW OFTEN.

As some publications measured more than one outcome or one outcome from both the perspective of the healthcare professional and the patient, the added numbers can exceed the total.

Used outcomes in 191 publications	Total (n)	HCP perspective (n)	Patient perspective (n)
Medication total	**98**	**92**	**19**
Adverse drug events, medication errors and discrepancies	97	92	18
Medication alterations during transfer	3	2	1
Admissions and readmission total	**66**	**53**	**30**
Readmission	55	44	22
Admissions and inpatient care use	13	9	8
Drug-related hospital (re) admission	7	7	0
Patient and caregiver total	**58**	**16**	**46**
Physical and psychosocial outcomes	28	2	28
Patient satisfaction	23	0	23
Patient care experiences	18	0	18
Patient knowledge	19	5	14
Patient adherence	15	6	9
Patient- HCP communication	4	3	2
Caregiver burden	2	0	2
Patient care needs	2	1	1
Caregiver satisfaction	1	0	1
Patient empowerment	1	1	0
Unscheduled visits total	**40**	**28**	**20**
Emergency department visit	33	21	17
PCP follow up	13	9	7
Unscheduled hospital or PCP visit	5	4	2
Healthcare use total	**33**	**24**	**13**
Overall healthcare use	13	9	7
Length of hospital stay	12	11	2
Visits to general practice	4	1	3
Number of contacts with case managers	1	1	0
Number of transitions	1	1	1
Redundant diagnostic testing	1	1	0
Number of patients with direct phone contact	1	1	0

Used outcomes in 191 publications	Total (n)	HCP perspective (n)	Patient perspective (n)
HCP total	**37**	**36**	**3**
HCP satisfaction and opinions	20	20	0
Interprofessional collaboration and communication	11	10	3
HCP attitudes	6	6	0
HCP confidence and skills	5	5	0
HCP knowledge	4	4	0
HCP awareness	3	3	0
Guideline use	3	3	0
HCP: barriers and facilitators	2	2	0
Patient safety culture	2	2	0
Productivity	2	2	0
Patient centeredness	1	1	0
Harm and adverse events	**34**	**24**	**17**
Discharge communication total	**26**	**26**	**0**
Quality and timeliness of discharge summary	24	24	0
Diagnostic test follow up	4	4	0
Costs	**21**	**21**	**7**
Mortality total	**17**	**17**	**0**
All-cause mortality	16	16	0
Cause-specific mortality	2	2	0
Questionnaires on transitional patient safety	**16**	**4**	**13**
Care transition measure (CTM) (Coleman et al.)	9	0	9
Continuity of care between care Levels (CCAENA) (Aller et al.)	2	0	2
Collaboration questionnaire (Nuno Solinis et al.)	1	1	0
DOC-questionnaire (Berendsen et al.)	1	1	0
B-prepared (Graumlich et al.)	1	0	1
Physician prepared (Graumlich et al.)	1	1	0
Patient Percieved Continuity from Multiple Clinicians (Haggerty et al.)	1	0	1
Medication discrepancy tool (Smith et al.)	1	1	0
Questionnaires: related concepts and non-validated questionnaires	**15**	**10**	**6**
Specific disease-related outcomes*	**9**	**9**	**0**
Referrals total	**5**	**5**	**0**
Referral: timeliness and inappropriateness	4	4	0
Re-referrals and referral rate	2	2	0
Intervention total	**5**	**5**	**1**
Implementation (number/ quality)	3	3	0
Feasibility intervention/ user friendliness	2	2	1

*HCP= healthcare professional, PCP=Primary care provider. Many studies used more than one outcome, and from different perspectives. Therefore, the sub-totals can add up to more than the total outcomes. *Brain natriuretic peptide (BNP), Hemoglobine A1c, lipid levels, volume status, renal function, weight, International Normalized Ratio (INR), haemorrhagic events, thromboembolic events, post referral colonoscopy delay.*

APPENDIX 3.5

Appendix table 3.5.1 Outcome invenory: characteristics of included studies

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Ahmed 2005 [1] UK N=208	PCP<->HOS Overall continuity	Patient outcome	Medication safety	To bridge the information gap that exists between the primary and secondary care continuum with regard to the swift transfer of accurate patient medication details using the interventions of an intervention pharmacist.	Patients visiting hospital	Intervention study: before-after design	Medication compared between primary care and secondary care.	HCP	ADEs, medication errors and discrepancies; Medication alterations during transfer
Akbarov 2015 [2] UK N= 205,519	PCP<->HOS Overall continuity	Patient outcome	Medication safety	To investigate the feasibility of linked primary and secondary care electronic health record data for surveillance of medication safety, examining not only prescribing but also monitoring, and associations with patient- and general practice-level characteristics. The objectives of this study included assessing the prevalence of 22 medication safety indicators, investigating associations with patient and practice characteristics, and investigating variation between general practices.	All adult patients of general practices	Observational study: cross-sectional design		HCP	ADEs, medication errors and discrepancies
Alassaad 2011 [3] Sweden N=290	HOS->PCP Discharge	Patient outcome	Medication safety	To investigate the frequency, type and severity of prescribing and transcribing errors for drugs dispensed in multidose plastic packs when patients are discharged from the hospital. The secondary objective was to correct identified errors and suggest measures to promote safe prescribing.	Adult patients with Multi drug dosage = baxter	Intervention study: prospective design	All multi drug dosage orders were reconciled and transcribing errors communicated to the prescribing physician.	HCP	ADEs, medication errors and discrepancies
Alex 2016 [4] USA Intervention N=145, Control N=134	HOS<->PCP Admission and discharge	Patient outcome	Medication reconciliation	To determine whether collaboration between a clinical pharmacist and inpatient physicians can improve the discharge process and resolve medication discrepancies at discharge.	All patients admitted to a veteran hospital	Intervention study: non-randomized controlled trial	A pharmacist assisted with medication management, medication reconciliation, and medication education upon discharge.	HCP	ADEs, medication errors and discrepancies

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Alidina 2016 [5] USA N=13 practices	HOS<->PCP Overall continuity	HCP outcome	Coordination of care	To explore how patient centred medical homes use coordination mechanisms to build and optimize their medical neighbourhoods.	Patient-centred medical home physicians	Intervention study: before-after design	Implementation of a patient centred medical home	HCP	HCP: barriers and facilitators; HCP satisfaction and opinions; HCP attitudes
Aller 2012 [6] Spain N=1500	PCP<->HOS Overall continuity	HCP outcome	Continuity of care	To analyse patient's reported elements of relational, informational and managerial (dis)continuity between primary and outpatient secondary care and to identify associated factors.		Observational study: cross-sectional design		Patient	Patient care experiences; Patient satisfaction; Continuity of care between care Levels (CCAENA) (Aller et al.)
Aller 2013 [7] Spain N= 1405	PCP<->HOS Overall continuity	HCP outcome	Continuity of care	To determine the patients' perceived degree of continuity of care between primary and secondary care and to identify contextual and individual factors that influence patients' perceptions of continuity of care.	Adult patients who had received primary care and secondary care for the same condition	Observational study: cross-sectional design		Patient	Patient care experiences; Patient satisfaction; Continuity of care between care Levels (CCAENA) (Aller et al.)
Anderson 2013 [8] USA N= 470	HOS->PCP Discharge	HCP & patient outcome	Medication reconciliation	To examine the feasibility and characteristics that define successful implementation of a Clinical Pharmacy Specialist telephonic hospital discharge follow-up quality improvement initiative, as well as the impact of this initiative.	Adult patients with a PCP and discharged from the hospital medical and surgical services	Intervention study: retrospective design	Telephonic discharge follow-up by residency-trained Clinical Pharmacy Specialists within 48 to 96 h of hospital discharge.	Patient	Readmission; PCP follow up
Armor 2016 [9] USA N=43	HOS->PCP Discharge	Patient outcome	Medication reconciliation	To evaluate ADEs, potential ADEs and medication discrepancies occurring between hospital discharge and primary care follow-up.	Adult patients recently discharged from the hospital	Observational study: retrospective design	Medication reconciliation conducted by a pharmacist after discharge.	HCP	ADEs, medication errors and discrepancies; Readmission; Harm and adverse events
Arora 2010 [10] USA Patient N=64, PCP n=40	HOS->PCP Discharge	HCP outcome	Discharge safety and experience	To report older patients' experiences with problems after hospital discharge and investigate whether PCP were aware of their hospitalization.	Frail, older patients hospitalized patients and their primary care practitioners.	Observational study: prospective design		HCP & patient	HCP awareness; Interprofessional collaboration and communication; Patient care experiences

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Atkinson 2005 [11] USA N=1006	PCP<->HOS Overall continuity	Patient outcome	Medicati-on safety	To describe a successful initiative to im-plement a pharmacist-centred medication management program into the existing care practices at Home Care Plus.	Elderly patients: with one or more of four risk factors for ADES	Observati-onal study: prospective design	A pharmacist conducted a drug regimen review, assessing the patient for potential inappropriate medications, ADES, and negative health outcomes potentially related to medication use.	HCP	ADEs, medication er-rors and discrepancies
Azzi 2014 [12] Australia N=300	PCP->HOS Referral	Patient outcome	Medicati-on safety	To identify, classify and determine the factors associated with medication discrepancies for type 2 diabetes mellitus patients, referred from primary care to a tertiary ambulatory clinic.	Adult type 2 diabetes mel-litus patients first refereed to the Diabetes Centre.	Observati-onal study: retrospective design		HCP	ADEs, medication er-rors and discrepancies
Balaban 2015 [13] USA N=1510	HOS->PCP Discharge	Patient outcome	Case manage-ment at discharge	To determine if an intervention by patient navigators, hospital-based Community Health Workers, reduces readmissions among high risk, low socioeconomic status patients.	High risk patients of general medi-cine with at least one readmission risk factors	Intervention study: RCT	Patient navigators provided coaching and assistance in the transition from hospital to home (discharge prepara-tion, telephone outreach, supporting medication management, scheduling of follow-up appointments, communication with pri-mary care, and symptom management).	HCP & patient	Readmission; PCP follow up; ED visits
Baldo 2014 [14] Italy N=3568	PCP<->HOS Overall continuity	Patient outcome	Continuity of diabetes care (care chain)	To assess mortality of patients with type2 diabetes by type of healthcare delivery system, i.e. through specialist centres or generalist doctors, or integrated care.	Adult patients with diabetes treated at either a diabetes clinics, the PCP, or recei-ving integrated care	Observati-onal study: retrospective design		HCP	All-cause morta-lity; Cause-specific mortality
Balling 2015 [15] USA N=1011	HOS->PCP Discharge	Patient outcome	Medica-tion recon-ciliation	To assess the impact of a transition-of-care pharmacist during hospital discharge.	Patients dischar-ged from two inpatient units (adult medical/ surgical) with high readmission rates.	Observati-onal study: prospective design	A transition-of-care pharmacist to provided discharge medication reconciliation and patient education on discharge medications.	HCP	ADEs, medication er-rors and discrepancies; Readmission

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Balogun 2015 [16] USA N=251	PCP<->HOS Overall continuity	HCP outcome	Interprofessional communication	To enable students to discuss the roles of physicians and nurses in transitioning patient care from one clinical setting to another and to demonstrate competence in interprofessional communication skills and strategies in transitions of care.	Medical and nursing students	Intervention study: before after design	An interprofessional workshop on transitions in geriatric care.	HCP	HCP knowledge; HCP confidence and skills
Bauer 2015 [17] Germany Sample size calculation: N=370	HOS->PCP Discharge	Patient outcome	Care transitions in colorectal care	To increase the proportion of patients achieving a clinical relevant improvement of their health-related quality of life.	Adults with colorectal cancer in curative therapy conditions	Intervention study: RCT (protocol)	Additional support by specialized oncology nurses after discharge by telephone, consisting of symptom monitoring, counselling on self-assessment and self-management and dealing with individual resources for coping and psychosocial well-being.	Patient	Physical and psychosocial outcomes; Patient care needs
Belda-Rustarazo 2015 [18] Spain N=814	PCP<->HOS Admission and discharge	Patient outcome	Medication safety	To examine the frequency/type of reconciliation errors at hospital admission and discharge and to report on the drugs involved, associated risk factors and potential to cause harm in a healthcare setting with comprehensive digital health records.	Elderly patients with polypharmacy, admitted to the Internal Medicine Department	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies; Harm and adverse events
Berendsen 2009 [19] the Netherlands N=491 (259 PCPs, 232 Hos spec)	PCP<->HOS Overall continuity	Climate & HCP outcome	Communication between PCP and hospital	To address the following research question. How do PCPs and specialists assess their mutual communication through telephone, letters and postgraduate courses?	PCPs and specialists in the Netherlands	Observational study: cross-sectional design		HCP	Interprofessional collaboration and communication; DOC-questionnaire (Berendsen et al.)
Bergkvist 2009 [20] Sweden N=172	HOS->PCP Discharge	Patient outcome	Medication safety and quality of discharge communication	To investigate whether the process improves the quality of the discharge summary and if this process development also reduces medication errors when patients are discharged from hospital.	Elderly patients admitted to the Department of Internal Medicine	Intervention study: non-randomized controlled trial	Medication reconciliation by a pharmacist at admission and discharge. Based on identified problems, a systematic medication care plan was created.	HCP	ADEs, medication errors and discrepancies; Quality and timeliness of discharge summary

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Biese 2014 [21] USA N=120	HOS->PCP Discharge form ED	Patient outcome	Case management at discharge from ED	To investigate whether a post-discharge telephone call–mediated intervention by a nurse would improve discharge care plan adherence, specifically by expediting post–ED visit physician follow-up appointments and/or compliance with medication changes. The second objectives were to determine if this telephone call intervention would reduce return ED visits and/or hospitalizations within 35 days of the index ED visit and to determine potential cost savings of this intervention.	Elderly patients discharged from an academic Level I trauma center ED	Intervention study: RCT	A telephone call from a trained study nurse between 1 and 3 days after ED discharge to review and facilitate compliance with patient-specific discharge instructions.	Patient	Medication alterations during transfer; PCP follow up; admission and inpatient care use; ED visits; Costs; Patient adherence; Patient satisfaction; Patient knowledge
Bishop 2015 [22] USA N=104	HOS->PCP Discharge	Patient outcome	Medication reconciliation	To determine whether integration of pharmacist review in the process of medication reconciliation at discharge identifies and corrects discrepancies.	Adult patients admitted and discharged with medication for Internal Medicine	Observational: study: prospective design	Discharge medication reconciliation by a pharmacist.	HCP	ADEs, medication errors and discrepancies
Bloom-Feshback 2016 [23] USA N=101	HOS->PCP Discharge	HCP outcome	Discharge safety in patients with low health literacy	To develop an Objective Structured Clinical Examination for medical students to demonstrate communication skills to be used during the hospital discharge process with patients of low health literacy.	Medical students	Observational study: prospective design	A health literacy workshop.	HCP	HCP knowledge; HCP confidence and skills
Bonnet-Zamponi 2012 [24] France N=639	HOS->PCP Discharge	Patient outcome	Medication safety	To assess the effect of an intervention on drug-related problem (DRP; adverse drug reactions, adherence problems, underuse)-related readmission rates in older adults.	Elderly patients admitted emergently to hospital	Intervention study: RCT	Multimodal discharge planning intervention: prescription review, patient education on disease self-management, enhanced Transition-of-Care Communication.	HCP	Readmission; Drug-related hospital (re) admission
Braund 2014 [25] New Zealand N=1374	HOS->PCP Discharge	Patient outcome	Medication safety	To identify the types and quantities of drug related problems that community pharmacies detect within a single district health board in New Zealand.	All patients discharged with medication	Observational study: cross-sectional design		HCP	ADEs, medication errors and discrepancies; Harm and adverse events

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Bray-Hall 2010 [26] USA N=136	HOS->PCP Discharge	Climate & HCP outcome	Education in transitional safety and skills	To develop a sustainable and effective Transition in Care Curriculum (TICC). Specific goals were to increase student confidence in and knowledge of skills necessary during care transitions at the time of hospital discharge, and to quantify the frequency of student-identified medication discrepancies during a post-discharge home visit.	Third year medical students	Intervention study: before-after design	Multiple instructional modalities, including didactics, self-study, experiential learning, and small group discussion.	HCP	ADEs, medication errors and discrepancies; HCP knowledge; HCP satisfaction and opinions; HCP confidence and skills
Brener 2016 [27] Canada N= 164,059	HOS->PCP Discharge	Patient outcome	Discharge safety	To determine the frequency of supportive-care visits by PCPs to hospitalized patients and to identify the association between these visits, patient outcomes, and health services utilization.	Adults hospitalized between 2008 to 2009	Observational study: retrospective design		HCP	All-cause mortality; Readmission; Visits to primary care; ED visit; Patient care needs
Burns 2014 [28] USA N=423	HOS->PCP Discharge	HCP & patient outcome	Case management at discharge	To pilot-test the feasibility and preliminary effect of a community health worker intervention to reduce hospital readmissions.	Adult patients with one or more risk factors for readmission	Intervention study: RCT	A community health worker facilitated the transitions from hospital to home and back to the primary care provider. Including: introductory visits with patients in the hospital; community health worker participation in the hospital discharge process; semi-structured community health worker outreach to elicit patient concerns; and liaison calls, as needed, to primary care nurses to assist in scheduling or to respond to patient concerns.	HCP	Readmission; Visits to primary care; Admission and inpatient care use; ED visits; Number of contacts with case managers; HCP: barriers and facilitators
Callen 2008 [29] Australia N=245	HOS->PCP Discharge	HCP outcome	Discharge safety	To study the hospital discharge summaries, which were either handwritten or electronic, of a population of inpatients, with regard to documentation of information required for ongoing care; and to compare the electronic with the handwritten summaries concerning documentation of this information.	Discharge summaries (handwritten or electronic) of elderly patients hospitalised for at least two days.	Observational study: prospective design	An electronic discharge summary system with training.	HCP	Quality and timeliness of discharge summary

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Callen 2009 [30] Australia N=1808	HOS->PCP Discharge	Patient outcome	Medi-cation safety at discharge	To quantify and compare the medication transcription error rate from handwritten medications on manual discharge sum-maries to typed medications on electronic discharge summaries, and to examine the quality of medication documentation according to the level of medical training of the doctors who created the discharge summaries.	Discharge summaries of elderly patients with polypharma-cy discharged to private homes or a nursing home	Intervention study: before-after design	An electronic discharge summary system.	HCP	ADEs, medication er-rors and discrepancies
Carter 2008 [31] USA Sample size calculation: N=1000	PCP<->HOS Admis-sion and discharge	Patient outcome	Medica-tion recon-ciliation	To determine the effects of hospital pharmacists' enhanced communication with patients and their community providers are described.	Adult patients admitted with a diagnosis of hypertension, hyperlipidaemia, heart failure, coronary artery disease, myocar-dial infarction, stroke, transient ischemic attack, asthma, chronic obstructive pul-monary disease, or diabetes or receives oral anti-coagulation.	Intervention study: RCT	A pharmacist case mana-ger provided admission medication verification with the patients' com-munity pharmacists, medication teaching, and discharge counselling.	HCP & patient	ADEs, medication er-rors and discrepancies; Readmission; Visits to primary care; Admission and inpatient care use; Unscheduled hospital or PCP visit; ED visits; Costs; Guideline use; Patient adherence; Harm and adverse events
Cavanaugh 2015 [32] USA N=124	HOS->PCP Discharge	Patient outcome	Case manage-ment at discharge	To compare the transitions of care, mea-sured by hospital readmission rates and medication interventions, in a multidisci-plinary team visit coordinated by a clinical pharmacist with those conducted by a physician-only team in a hospital follow-up program.	Discharged patients	Observati-onal study: retrospective design	A multidisciplinary team visit coordinated by a pharmacist in a hospital follow-up program.	HCP	ADEs, medication er-rors and discrepancies; Medication alterations during transfer; Read-mission; Patient adherence

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Chan 2015 [33] USA N=685	HOS->PCP Discharge	Patient outcome	Discharge safety	To assess the effect of the support from hospitalization to home for elders intervention on the patient experience.	Patients 55 years and older, admitted to the internal medicine, family medicine, cardiology, or neurology services and discharged home	Intervention study: RCT	Intervention participants received inpatient visits by a language-concordant study nurse and post-discharge phone calls from a language-concordant nurse practitioner to reinforce the care plan and to address acute complaints.	HCP & patient	Patient- HCP communication; Patient care experiences; Patient knowledge; Implementation (number/ quality); Care transition measure (CTM) (Coleman et al.)
Chevalier 2006 [34] Canada N=39	HOS->PCP Discharge	Climate & HCP outcome	Medication safety at discharge	To measure nurses' perceptions of patient safety, medication safety and current medication reconciliation practice at transition points in a patient's hospital stay. This study provided baseline information on nurses' perceptions of patient safety culture and medication safety at transition points in a patient's hospital stay.	Nursing staff in three general medicine units	Observational study: cross-sectional design		HCP	ADEs, medication errors and discrepancies; Patient safety culture; Questionnaires: related concepts and non-validated questionnaires
Coleman 2004a [35] USA N=1393	HOS->PCP Discharge	HCP & patient outcome	Patient empowerment	To test whether an intervention designed to encourage older patients and their HCPs to assert a more active role during care transitions can reduce rehospitalisation rates.	Community dwelling elderly patient	Intervention study: non-randomized controlled trial	A personal health record and a series of visits and telephone calls with a transition coach.	HCP % patient	Admission and inpatient care use; ED visits; Patient care experiences
Coleman 2004b [36] USA N=1404	HOS->PCP Discharge	Patient outcome	Discharge safety	To describe patterns of post hospital care transitions; characterize these patterns as uncomplicated or complicated; identify those at greatest risk for complicated transitions.	Elderly patients discharged from an acute care hospital	Observational study: cross-sectional design		HCP & patient	Number of transitions; Overall healthcare use; Patient care experiences; Patient satisfaction; Physical and psychosocial outcomes; Questionnaires: related concepts and non-validated questionnaires

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Coleman 2005 [37] USA N=375	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To determine the prevalence and contributing factors associated with post hospital medication discrepancies.	Elderly, community dwelling adults admitted to the hospital	Observational: study prospective design		HCP	ADEs, medication errors and discrepancies; Medication discrepancy tool (Smith et al.)
Coleman 2006 [38] USA N=750	HOS->PCP Discharge	Patient outcome	Case management at discharge and patient empowerment	To tests whether this same intervention, designed to encourage older patients and their HCPs to assert a more active role in their care transitions, can reduce rates of rehospitalisation.	Community dwelling, elderly patients admitted for a non-psychiatric condition	Intervention study: RCT	Tools for patients to promote cross-site communication and encouragement to take a more active role in their care and to assert their preferences and guidance from a "transition coach."	HCP	Readmission
Dalal 2014 [39] USA N=441	HOS->PCP Discharge	HCP outcome	Post-discharge test continuity	To evaluate the impact of our automated email notification system on physician awareness of a tests pending at discharge results and assess overall satisfaction with this strategy.	Adult patients, discharged from general medicine or cardiology	Intervention study: RCT	An email system that emailed the hospital and network PCP when a patient's test was pending at discharge	HCP	HCP awareness; HCP satisfaction and opinions
Daley 2010 [40] USA Intervention N=89, Control N=375	HOS->PCP Discharge	Patient outcome	Medication reconciliation	To test the effect of a transitional heart failure programme.	Patients with heart failure, who were admitted with a diagnosis of heart failure and are at high risk for readmission.	Intervention study: non-randomized controlled trial	Health literacy screening, medication reconciliation upon hospital admission and discharge, communication of discharge medication to all healthcare providers, and a follow-up appointment with the patient's cardiologist post-discharge	HCP	All-cause mortality; Readmission; Length of hospital stay; Costs
Dichmann Sorknaes 2016 [41] Denmark N=266	HOS->PCP Discharge	Patient outcome	Discharge safety	To investigate the effect of one week of daily real-time telemedicine video consultations (teleconsultation) between hospital-based nurses specialized in respiratory diseases (telenurses) and patients with severe Chronic obstructive pulmonary disease discharged in addition to conventional treatment compared to the effect of conventional treatment.	Patients discharged after admission with acute exacerbation of chronic obstructive pulmonary disease	Intervention study: RCT	One week of daily real-time telemedicine video consultations (teleconsultation) between hospital-based nurses specialized in respiratory diseases (telenurses)	HCP	Readmission

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Donaho 2015 [42] USA N=114	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To reduce 30-day readmission rates to the hospital.	Patients recently admitted to the hospital with a diagnosis of HF	Observational study: prospective design	Providing timely, protocol-driven post-discharge evaluation and management, including a discharge plan, medication education and reconciliation, education on symptom recognition and reporting, and coordination of outpatient health care resources. Care coordination services included communications with the primary care provider, other specialist providers, and/or home health services.	HCP	ADEs, medication errors and discrepancies; Readmission; Volume status; Costs
Douglas 2013 [43] Canada N=47	HOS->PCP Discharge	Patient outcome	Discharge safety	To determine whether two pre discharge functional measures were valid for predicting time to incident or harm after discharge.	Elderly patients recruited from a geriatric rehabilitation unit and referred to occupational therapy and undergoing functional or cognitive assessment	Observational study: prospective design		HCP & patient	Visits to primary care; Admission and inpatient care use; Harm and adverse events; Physical and psychosocial outcomes; Questionnaires: related concepts and non-validated questionnaires
Dunn 2015 [44] USA N=797	HOS->PCP Discharge	HCP outcome	Continuity of anticoagulant care (care chain)	To develop a concise report to improve the timeliness of international normalized ratio (INR) testing and quality of warfarin management post hospitalization.	Patients who were discharged on warfarin	Intervention study: before-after design	Safe Transitions Anticoagulation Report (STAR), which contains essential information on anticoagulation and is embedded in the discharge summary.	HCP	Diagnostic test follow up; Specific disease-related outcomes; HCP satisfaction and opinions

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Dutton 2003 [45] UK N=1247	PCP->HOS Admission	Patient outcome	Medication reconciliation	To quantify prescribing errors to pre-admission medication in patients admitted to hospital. It also assesses the impact of a hospital pharmacies in identifying and correcting these errors	Patients admitted to hospital	Intervention study: before-after design	Medication reconciliation	HCP	ADEs, medication errors and discrepancies; Harm and adverse events
Elliot 2012 [46] Australia N=428	PCP<->HOS Admission and discharge	HCP & patient outcome	Medication reconciliation	To test the impact of a hospital pharmacist-prepared interim residential care medication administration chart (IRCMAC) on medication administration errors and use of locum medical services after discharge from hospital to residential care.	Patients discharged with medication changes	Intervention study: before-after design	Medication reconciliation using software	HCP	ADEs, medication errors and discrepancies; HCP satisfaction and opinions
Ellit 2010 [47] Australia N=76	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To reconcile patients' medicines and to classify drug related problems identified during medication review conducted after discharge from hospital.	Patients discharged home from the cardiology unit with cardiac medication	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; Questionnaires: related concepts and non-validated questionnaires
Eskildsen 2011 [48] USA N=121	HOS->PCP Discharge	Climate & HCP outcome	Education in transitional safety and skills	To give medical students the fund of knowledge and skills to develop and implement a safe discharge plan.	Fourth-year medical students	Intervention study: before-after design	A care transitions curriculum: discussion of an online case highlighting care transitions issues; preparation of a discharge summary based on online templates; and a post-discharge phone call to one of their patients.	HCP	Quality and timeliness of discharge summary; HCP knowledge; HCP satisfaction and opinions; HCP confidence and skills; HCP attitudes
Farris 2014 [49] USA N=945	HOS->PCP Discharge	Patient outcome	Medication reconciliation	To determine if a pharmacist case manager providing a faxed discharge medication care plan from a tertiary care institution to primary care could improve medication appropriateness and reduce adverse events, rehospitalisation and ED visits.	Discharged patients	Intervention study: RCT	Medication reconciliation on admission and discharge, patient education.	HCP	ADEs, medication errors and discrepancies; Readmission; Overall healthcare use; Unscheduled hospital or PCP visit; ED visits; Harm and adverse events

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Fertig 1993 [50] UK N=31 practices	PCP->HOS Referral	Patient outcome	Referral safety	To determine the extent to which variation in rates of referral among PCPs may be explained by inappropriate referrals and to estimate the effect of implementing referral guidelines.	General practices in the UK	Observational study: prospective design		HCP	Re-referrals and referral rate; Referral: timeliness and inappropriateness
Flink 2015 [51] Sweden N=76 medical records of 22 patients	PCP<->HOS Overall continuity	Climate & HCP outcome	Continuity of care	To explore patient handovers between primary and secondary care by assessing the levels of patient-centeredness of medical records used for communication between care settings and by assessing continuity of patient care.	Adult patients with chronic diseases and/or polypharmacy	Observational study: retrospective design		HCP	Patient centeredness
Forster 2003 [52] Canada N=400	HOS->PCP Discharge	Patient outcome	Discharge safety	To describe the incidence, severity, preventability, and "ameliorability" of adverse events affecting patients after discharge from the hospital and to develop strategies for improving patient safety during this interval.	Adult hospital patients	Observational study: retrospective design		HCP & patient	Harm and adverse events
Forster 2004 [53] Canada N=361	HOS->PCP Discharge	Patient outcome	Discharge safety	To determine the risk, severity and type of adverse events after discharge from 2 campuses of a Canadian teaching hospital.	Patients discharged home or to residential living from general internal medicine	Observational study: retrospective design		HCP & patient	Harm and adverse events
Forster 2005 [54] Canada N=400	HOS->PCP Discharge	Patient outcome	Discharge safety	To describe the incidence of ADEs, preventable ADEs, and ameliorable ADEs occurring after hospital discharge and their associated risk factors.	Patients discharged home from general internal medicine	Observational study: retrospective design		HCP & patient	ADEs, medication errors and discrepancies
Forster 2007 [55] Canada N=408	HOS->PCP Discharge	Patient outcome	Discharge safety from the ED	To describe the types of adverse events in patients discharged home from an ED.	Patients who were sent home directly from the ED	Observational study: retrospective design		HCP & patient	All-cause mortality; Readmission; ED visits; Harm and adverse events; Physical and psychosocial outcomes

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Foust 2011 [56] USA N=198 hospital discharge medical records, representing 162 patients	HOS->PCP Discharge	Patient outcome	Medi-cation safety at discharge	To examine the rates and types of medica-tion reconciliation problems among older adults hospitalized for acute episodes of heart failure who were discharged home.	Adult patients hospitalized for acute episodes of heart failure who were discharged home	Observati-onal study: retrospective design		HCP	ADEs, medication er-rors and discrepancies
Frydenberg 2012 [57] Norway N=30	PCP<->HOS Admis-sion and discharge	Patient outcome	Medica-tion recon-ciliation	To explore whether such inadequate communication leads to errors in patients' medication on admission, during hospital stay, and after discharge, and whether these errors were potentially harmful.	Patients urgently admitted to the medical ward, and using three or more drugs	Observati-onal study: prospective design		HCP & patient	ADEs, medication er-rors and discrepancies
García-Molina Sáez 2016 [58] Spain N=321	HOS->PCP Discharge	Patient outcome	Medica-tion recon-ciliation	To analyse the effectiveness of a compute-rized pharmaceutical intervention to reduce reconciliation errors at discharge in Spain.	All patients admit-ted for at least 48 hours	Intervention study: before after design	Before patient discharge, the pharmacist included the pre-admission medication in a computerized tool integrated into the electronic clinical history of the patient and designed to facilitate the task of medication reconciliation/ prescription, and adding recommendations for discharge.	HCP	ADEs, medication er-rors and discrepancies

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Gardella 2012 [59] USA N= 8586	PCP<->HOS Admission and discharge	HCP & patient outcome	Medication safety and patient education of medication safety	To produce an accurate preadmission medication list within 24 hours of admission, and to provide post-discharge education of complex patients by pharmacists	Hospital patients	Intervention study: non-randomized controlled trial	Medication reconciliation at discharge and communication of discharge medication to the next provider. The reconciliation team included a hospitalists, non-hospitalist physicians, pharmacists, nurses, and personnel from marketing, information technology, and administration.	HCP	ADEs, medication errors and discrepancies; Readmission; Drug-related hospital (re) admission; PCP follow up; ED visits; Harm and adverse events; Patient knowledge; Patients with Direct Phone Contact
Gardner 2014 [60] USA N=1240	HOS->PCP Discharge	Patient & organisational outcome	Cost effectiveness of care transition intervention	To evaluate the cost avoidance associated with implementation of the Care Transitions Intervention (CTI).	Patients with planned discharges home	Intervention study: non-randomized controlled trial	A patient-centred coaching intervention to empower individuals to better manage their health. It begins in-hospital and continues for 30 days post-discharge, including one home visit and one to two phone calls.	HCP	Overall healthcare use; Costs
Ghatnekar 2013 [61] Sweden N=NA	PCP<->HOS Admission and discharge	HCP & patient outcome	Medication reconciliation	To evaluate the cost effectiveness of a multidisciplinary team including a pharmacist for systematic medication review and reconciliation from admission to discharge at hospital among elderly patients (the Lund Integrated Medicines Management (LIMM)) in order to reduce drug-related readmissions and outpatient visits.	Patients admitted to and discharged from hospital	Cost effectiveness model	Medication reconciliation by pharmacists at admission, during hospital stay, and after discharge including communication with the patient, and the primary and/or community care provider at discharge.	HCP	ADEs, medication errors and discrepancies; Overall healthcare use; Costs
Gilbert 2012 [62] Australia N=77	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To compare the number and clinical significance of medication errors and omission in discharge medicines information, and the timeliness of delivery of this information to community-based health practitioners, between the existing Hospital Discharge Summary (HDS) and a pharmacist prepared Medicines Information Transfer Fax (MITF).	Patients at high risk of medication errors	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Glintborg 2007 [63] Denmark N=200	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To estimate whether hospitals succeed in making accurate medication lists congruent with patients' actual medication use. Subsequently, the authors evaluated where errors were introduced and the possible implications of incongruent medication lists.	Patients scheduled for discharge (medical and surgical ward)	Observational study: prospective design		HCP & patient	ADEs, medication errors and discrepancies
Graumlich 2009a [64] USA Physicians N=70, Patients: N=631	HOS->PCP Discharge	HCP & patient outcome	Transitional communication	To measure patient and physician perceptions after discharge with computerized physician order entry (CPOE) software.	Hospital physicians and their patients discharged home	Intervention study: RCT	Discharge software facilitating communication at the time of hospital discharge to patients, retail pharmacists, and community physicians.	HCP & patient	HCP satisfaction and opinions; Interprofessional collaboration and communication; Patient care experiences; Patient satisfaction; B-prepared (Graumlich et al.); Physician prepared (Graumlich et al.); Questionnaires: related concepts and non-validated questionnaires
Graumlich 2009b [65] USA Physicians N=69, Patients: N=631	HOS->PCP Discharge	Patient outcome	Transitional communication	To measure effects of a discharge software application of computerized physician order entry (CPOE).	Hospital physicians and their patients discharged home	Intervention study: RCT	Discharge software facilitating communication at the time of hospital discharge to patients, retail pharmacists, and community physicians.	Patient	Readmission; ED visits; Harm and adverse events
Gray 2008 [66] UK N=86	HOS->PCP Discharge	HCP outcome	Medication reconciliation	To investigate the effect of sharing information about patients' medication between the hospital and practice-based primary care pharmacists. It also sought to assess whether this led to improved implementation of treatment plans after discharge from hospital and could be integrated into the current workload of the practice-based pharmacists.	Discharged elderly patients	Intervention study: before-after design	Information sharing about patients' medication between hospital and primary care pharmacists.	HCP	Quality and timeliness of discharge summary

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Grimes 2008 [67] Ireland N=139	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To investigate the quality and consistency of medication details generated for such transfer from an Irish teaching hospital.	Adult cardiology patients admitted to hospital	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies
Grimes 2011 [68] Ireland N=1200	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To investigate the factors contributing to medication reconciliation on discharge, and identify the prevalence of non-reconciliation.	Adult patients discharged and prescribed at least one medicine	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; Quality and timeliness of discharge summary; Interprofessional collaboration and communication
Hamar 2016 [69] USA Intervention N=560, Control N=3340	HOS->PCP Discharge	Patient outcome	Discharge safety	To evaluate the Care Transition Solution as means to improve quality through reduction of preventable hospital readmissions among patients with readmission-sensitive conditions subject to penalties imposed by the Affordable Care Act.	Admitted patients with readmission-sensitive conditions	Observational study: retrospective design	A nurse transition coach assessing risks at discharge, reconciliation of medications, a patient-oriented Care Transition Record, with documented discharge plan; coordination of medical providers and service agencies for post-discharge patient care; and a post-discharge telephonic follow-up	HCP	Readmission
Hanlon 2006 [70] USA N=808	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To examine the incidence and predictors of all and preventable ADEs in frail elderly persons after hospital discharge, a highly vulnerable but rarely studied population.	Frail elderly persons discharged home.	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; Harm and adverse events
Hansen 2013 [71] USA Patient N=NR Hospitals: Intervention N=11, Control=19	HOS->PCP Discharge	Patient outcome	Discharge safety	To determine the effect of Project BOOST (Better Outcomes for Older adults through Safe Transitions) on rehospitalisation rates and length of stay.	All patients admitted to a clinical acute-care unit of 11 hospitals	Intervention study: non-randomized controlled trial	Hospitals receive expert mentoring and peer support to aid in improving the care of patients as they transition from hospital to home including map ping current processes and creating and implement action plans for organizational change.	HCP	Readmission; Length of hospital stay; Implementation (number/ quality)

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Hastings 2011 [72] USA N=92	HOS->PCP Discharge	Patient outcome	Discharge safety from ED	To describe older patients' understanding of ED discharge information and to explore the relationship between understanding of ED discharge information and adverse outcomes.	Patients 65 years and older discharged home from the ED	Observational study: prospective design		Patient	All-cause mortality; Readmission; ED visits; Harm and adverse events; Physical and psychosocial outcomes; Patient knowledge
Hawes 2013 [73] USA N=61	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To evaluate the impact of a transitional care clinic visit conducted by a pharmacist compared with usual care on the resolution of medication discrepancies and incidence of rehospitalisation's and ED visits.	Admitted patients with risk factors for rehospitalisation who also received primary care	Intervention study: RCT	A care transitions clinic visit with a clinical pharmacist approximately 72 hours post-discharge, and prior to the post hospitalization PCP visit, including a complete medication history, identifying and resolving medication discrepancies, creating a current medication list for both the medical record and the patient, and counselling on appropriate medication use.	HCP	ADEs, medication errors and discrepancies; Readmission; ED visits
Hazen 2015 [74] the Netherlands Sample size calculation: 2850 per arm (three arms)	PCP<->HOS Overall continuity	Patient outcome	Medication safety	To evaluate the effect of integration of a non-dispensing pharmacist in general practice on the safety of pharmacotherapy in the Netherlands.	Elderly patients with multimorbidity and polypharmacy	Intervention study: non-randomized controlled trial	An assessment by a pharmacist of the patient's drug-related needs, a care plan to meet the specific needs of the patient, and a follow-up evaluation to determine the impact of the decisions made and actions taken.	HCP	ADEs, medication errors and discrepancies; Drug-related hospital (re) admission; Costs
Hellstrom 2012 [75] Sweden N=670	PCP->HOS Admission	Patient outcome	Medication safety at admittance	To describe the frequency, type and predictors of errors in medication history, and to evaluate the extent to which standard care corrects these errors.	All patients admitted to two internal medicine wards	Observational study: prospective design	Clinical pharmacists conducted medication reconciliations	HCP	ADEs, medication errors and discrepancies

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Heyworth 2013 [76] USA N=60	HOS->PCP Discharge	Patient outcome	Medication reconciliation	To pilot test a medication reconciliation tool delivered via a web portal to improve medication safety among patients recently discharged from hospital.	Hospitalized (adult) veteran patients	Observational study: prospective design	Medication reconciliation by a multidisciplinary team, including physicians, a pharmacist and a nurse informaticist using interactive software so that patients could perform medication reconciliation independently at home	HCP	ADEs, medication errors and discrepancies; Patient care experiences; Harm and adverse events
Hohmann 2014 [77] Germany Patient N= 310 PCP N= 111	HOS->PCP Discharge	HCP & patient outcome	Medication safety at discharge	To develop a structured medication report as part of the discharge letter, to evaluate the impact of the medication report in ischaemic stroke patients and to identify the most important issues in the transitional care process of stroke patients.	Adult patients with either a diagnosis of transient ischaemic attack or ischaemic stroke taking two or more drugs during hospital stay and at discharge	Intervention study: before-after design	Medication reconciliation during hospital stay and a structured medication report created by a pharmacist, as part of the discharge letter.	HCP	Quality and timeliness of discharge summary; HCP satisfaction and opinions; Patient adherence
Holland 2011 [78] USA N=371	HOS->PCP Discharge	HCP & patient outcome	Discharge safety and experience	To report how we evaluated a change in DP practice from the perspective of recently discharged patients.	Adult patients recently discharged from a medical or surgical nursing unit	Intervention study: non-randomized controlled trial	Discharge planning decision support tool.	Patient	Patient care experiences; Patient knowledge; Care transition measure (CTM) (Coleman et al.)
Horwitz 2013 [79] USA N=377	HOS->PCP Discharge	HCP outcome	Quality of discharge letter	To conduct a comprehensive quality assessment of discharge summaries.	Patients discharged home after hospitalization for acute coronary syndrome, heart failure, or pneumonia.	Observational study: retrospective design		HCP	Quality and timeliness of discharge summary; Questionnaires: related concepts and non-validated questionnaires
Hu 2012 [80] USA N=82	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To examine, in older Chinese Americans, the prevalence of both potential inappropriate medications (PIMs) and medication discrepancies (MDs); the relationship between PIMs and MDs; and the patient and hospitalization characteristics associated with them during care transitions from hospital discharge to home care.	Elderly Chinese Americans receiving home after hospital discharge and taking at least one prescribed medication at hospital discharge.	Observational study: prospective design		HCP & patient	ADEs, medication errors and discrepancies; Questionnaires: related concepts and non-validated questionnaires

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Huynh 2016 [81] UK N=142	HOS->PCP Discharge	Patient outcome	Medication reconciliation	To investigate the incidence, nature and potential clinical severity of medication discrepancies at the point of hospital discharge in a paediatric setting.	Paediatric patients discharged from hospital	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies
Jack 2009 [82] USA N=749	HOS->PCP Discharge	Patient outcome	Discharge safety	To test the effects of an intervention designed to minimize hospital utilization after discharge.	English-speaking hospitalized adults	Intervention study: RCT	A nurse discharge advocate to arrange follow-up appointments, confirm medication reconciliation, and conduct patient education and a medication review post-discharge by a clinical pharmacist.	HCP & patient	Readmission; Overall healthcare use; PCP follow up; ED visits; Physical and psychosocial outcomes; Patient knowledge
Julian 2007 [83] UK N=193	PCP->HOS Referral	Patient outcome	Continuity of care and referral safety	To examine the outcomes of an integrated model that lends weight to PCP-led evidence based care.	Women with menstrual disorders	Intervention study: non-randomized controlled trial	Facilitate patients' access to diagnostic and therapeutic facilities within secondary care, by shared evidence based guidelines for the management of patients in both primary and secondary care, which determined timing for investigations and surgical treatment.	HCP & patient	Overall healthcare use; Patient care experiences; Physical and psychosocial outcomes
Kanaan 2013 [84] USA N=1000	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To characterize ADEs occurring within the high-risk 45-day period after hospitalization in older adults.	Elderly hospitalized patients discharged home.	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; Harm and adverse events
Kantelhardt 2016 [85] Germany Control N=149, Intervention N=163	PCP<->HOS Admission and discharge	Patient outcome	Medication reconciliation	To investigate medication-related errors in spinal instrumentation patients and apply current medication reconciliation strategies.	All patients 18 years and older, who underwent spinal instrumentation	Intervention study: before-after design	A medication list at admission and which was stopped before surgery, and discharge, to remind the discharging physician of home medication. A special focus was on anticoagulants	HCP	ADEs, medication errors and discrepancies; Patient adherence

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Karapinar-Carkit 2010 [86] The Netherlands Sample size calculation N= 360 patients per group	HOS->PCP Discharge	HCP, patient & organisational outcome	Discharge safety	To determine the effect of the COACH program (Continuity Of Appropriate pharmacotherapy, patient Counselling and information transfer in Healthcare) on readmission rates in patients discharged from the internal medicine department.	Patients admitted to an internal medicine ward with at least one prescribed drug intended for chronic use	Intervention study: before-after design	Medication reconciliation, patient counselling and communication between the hospital and primary care healthcare providers.	HCP & patient	ADEs, medication errors and discrepancies; Readmission; Costs; HCP satisfaction and opinions; Patient adherence; Patient satisfaction; Physical and psychosocial outcomes
Keers 2015 [87] UK N=274	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To investigate the quality and safety of discharge prescriptions written at mental health hospitals.	Patients admitted to acute adult and later life inpatient wards	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies; Quality and timeliness of discharge summary
Kennedy 2014 USA [88] Sites N=7 Pharmacists N=8	PCP<->HOS Overall continuity	HCP & organisational outcome	Medication reconciliation	To determine the impact of integrating pharmacists into patient-centred medical homes, with a focus on population management.	Primary care patients	Observational study: prospective design	A pharmacist in the primary care practice providing direct patient care, educating prescribers, and using an approach to identify population-based opportunities to improve prescribing.	HCP	ADEs, medication errors and discrepancies; Costs
Kind 2012 [89] USA N= 708	HOS->PCP Discharge	Patient outcome	Discharge safety	To provide a detailed outline of the program's clinical protocols and feasibility and an assessment of its impact on thirty-day rehospitalisation.	Elderly, community-dwelling veterans at high risk of poor posthospital outcomes, hospitalized on medical or surgical wards and discharged home	Intervention study: before-after design	A registered nurse case manager to coordinate the veteran's transitional care through active participation in inpatient multidisciplinary discharge rounds, a single brief protocol-driven inpatient encounter, and one to four protocol-driven post hospital telephone calls with the veteran and, if available, the veteran's hcp.	Patient	ADEs, medication errors and discrepancies; Readmission

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
King 2008 [90] USA N=46	HOS->PCP Discharge	Patient & organisational outcome	Discharge safety	To determine if implementation of a nurse-driven discharge planning protocol for patients undergoing cardiac implant would result in improved organizational efficiencies, higher medication reconciliation rates, and higher patient satisfaction scores.	Patients scheduled for a cardiac implant procedure	Intervention study: RCT	A physical assessment, review of the post procedure chest radiograph, and examination of the cardiac implant device function by an intervention nurse. The intervention nurse also provided patient education, discharge instructions, and conducted medication reconciliation and conducted a scripted follow-up phone call to answer questions and monitor for post procedure complications.	HCP & patient	ADEs, medication errors and discrepancies; Length of hospital stay; Costs; Patient satisfaction; Physical and psychosocial outcomes; Questionnaires: related concepts and non-validated questionnaires
Knez 2011 [91] Slovenia N=101	PCP<->HOS Admission and discharge	Patient outcome	Medication reconciliation	To evaluate the need for medication reconciliation.	Adult patients with at least one drug discharged from hospital	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies; Questionnaires: related concepts and non-validated questionnaires
Koehler 2009 [92] USA N=41	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To assess the impact of a supplemental care bundle targeting high-risk elderly inpatients implemented by hospital-based staff compared to usual care on a composite outcome of hospital readmission and/or ED visitation at 30 and 60 days following discharge.	Elderly medical inpatients predisposed to unplanned readmission or post-discharge ED visitation	Intervention study: RCT	A multicomponent intervention following hospital discharge by a care coordinator and clinical pharmacist including: education, identifying discharge barriers, medication reconciliation at admittance and discharge, personal health record, fax with information to PCP and follow up phone call after discharge.	HCP	ADEs, medication errors and discrepancies; Readmission; Length of hospital stay; ED visits; Physical and psychosocial outcomes

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Lai 2008 [93] USA N=79	HOS->PCP Discharge	Initiatives & HCP outcome	Discharge safety	To determine whether a discharge curriculum would improve students' attitudes and self-assessed skills in interdisciplinary collaboration and transitional care for chronically ill patients.	Third-year medical students and fourth-year pharmacy students	Intervention study: before-after design	An interdisciplinary curriculum on transitional care including a post-discharge visit to a patient	HCP	HCP: satisfaction and opinions; confidence and skills; attitudes
Lalonde 2008 [94] Canada N=83	HOS->PCP Discharge	HCP & patient outcome	Medication reconciliation	To assess the effect of a medication discharge plan (MDP) on the rate of medication discrepancies between hospital and outpatient settings.	Adult patients, discharged from a geriatric, family medicine, or psychiatric ward with at least two pharmacotherapeutic changes	Intervention study: RCT	A medication discharge plan containing medication at admittance, mutations and medication at discharge.	HCP & patient	ADEs, medication errors and discrepancies
Lassere 2015 [95] USA Sample size calculation: N=792	PCP<->HOS Overall continuity	Patient outcome	Continuity of care	To assess the acceptability and long-term clinical outcomes of an electronic and paper patient-held portable health files (PHF).	Community-dwelling patients, 60 years or older, who have two or more chronic medical conditions that require prescription medication and regular care by at least three medical practitioners (general and specialist care)	Intervention study: RCT	A patient-held portable health file	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Overall healthcare use; Admission and inpatient care use; Unscheduled hospital or PCP visit; Redundant diagnostic testing; Patient adherence; Harm and adverse events; Physical and psychosocial outcomes; Feasibility intervention/ user friendliness
Lee 2009 [96] USA N=241	HOS->PCP Discharge	Patient outcome	Medication safety; analgesics	To describe the epidemiology of controlled substance prescription errors by physicians-in-training for children being discharged from the hospital.	Discharged paediatric patients	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies; Harm and adverse events; Questionnaires: related concepts and non-validated questionnaires

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Lesselroth 2009 [97] USA N=111	PCP->HOS Outpatient clinic visit	HCP & patient outcome	Medication reconciliation	To describes how we developed and implemented a process for patients in the waiting room to use kiosk technology in providing their own medication histories.	Patients of a chemotherapy administration unit	Observational study: prospective design	Automated patient history intake device using reconciliation software program accessed by the patient using a computer terminal kiosk located in the clinic lobby.	HCP & patient	ADEs, medication errors and discrepancies; Productivity; Patient- HCP communication
Lindpaintner 2013 [98] Switzerland N=60	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To improve patient outcomes following hospital discharge and on reducing barriers to continuity and provider efficiency.	Patients at high risk for adverse events	Intervention study: RCT	An individualized discharge plan was formulated by a nurse case manager in collaboration with the physician team (multicomponent: pt education on self-management, fax with information to PCP, evaluating telephone call within 24 hours of discharge, availability for questions, home visit).	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; PCP follow up; ED visits; Quality and timeliness of discharge summary; Costs; HCP satisfaction and opinions; Patient satisfaction; Physical and psychosocial outcomes; Caregiver burden
Lindquist 2013 [99] USA N=114	HOS->PCP Discharge	Patient outcome	Discharge safety	To determine whether PCP contact with patients at hospital discharge impacts the frequency of medication discrepancies at 24 hours post-discharge.	Community dwelling adults, admitted to acute medicine services on at least 5 medications	Intervention study: before-after design	When the patient was nearing discharge from the hospital, hospitalists were asked to phone the PCP to discuss the patient's discharge plan and facilitate clinical handoffs to the outpatient setting. Primary care providers were asked to speak with treating hospitalists and contact patients within 24 hours of hospital discharge to discuss any hospital medication changes.	Patient	ADEs, medication errors and discrepancies; PCP follow up

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Lingaratnam 2012 [100] Australia Control N=223, intervention N= 348	HOS->PCP Discharge	Initiatives, HCP & patient outcomes	Medication reconciliation	To design and test the effectiveness of a consumer–healthcare professional partnership model towards effective medication reconciliation.	Patients admitted to a surgical ward (intervention), and an oncology ward (control)	Intervention study: non-randomized controlled trial	Medication reconciliation including education of the patient, a medication list from the pharmacist at discharge, telephone call after patient discharge.	HCP & patient	ADEs, medication errors and discrepancies; Patient satisfaction; Harm and adverse events; Patient knowledge; Patient empowerment
Linsky 2012 [101] USA N=106	PCP<->HOS All transitions	Patient outcome	Medication reconciliation	To determine the prevalence of discrepancies within a national healthcare system with electronic health records –pharmacy linkage to characterise the medications involved and to identify factors associated with discrepancies.	Patients from ambulatory care clinics (including Primary Care, Rheumatology and Heart Failure clinics)	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; Questionnaires: related concepts and non-validated questionnaires
Manning 2007 [102] USA N=138	HOS->PCP Discharge	HCP & patient outcome	Medication reconciliation	To establish of in terms of patient satisfaction, understanding and safety, 3D is better than the Medication Discharge Worksheet (MDW), (3D=custom software enabling semi-automatic 3D form generation)	Adult patients, with more than three discharge medications, and returning home	Intervention study: RCT	Custom software creating an automatic medication form at discharge	Patient	ADEs, medication errors and discrepancies; Harm and adverse events; Patient knowledge
Martinussen 2013 [103] Norway N=1298	PCP->HOS Referral	Climate & HCP outcome	Referral quality	To investigate how hospital physicians view the general quality of patient referrals received from PCPs, and the extent to which insufficient information in referrals and inappropriate referrals is considered a problem for cooperation with PCPs.	Publicly employed hospital physicians	Observational study: cross-sectional design		HCP	HCP satisfaction and opinions; Interprofessional collaboration and communication

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Maslove 2009 [104] Canada PCP N=119, Patients N=209, Housestaff N=12	HOS->PCP Discharge	HCP outcome	Discharge safety	To assess PCP satisfaction with an electronic discharge summary (EDS) program as compared to conventional dictated discharge summaries.	Patients discharged home from General Internal Medicine department	Intervention study: RCT	An electronic discharge summary to improve the quality of a discharge summary including preadmission information, hospital course, and discharge and follow-up plans.	HCP	Readmission; ED visits; Diagnostic test follow up; Quality and timeliness of discharge summary; HCP satisfaction and opinions; Patient adherence; Patient care experience; Patient knowledge; Care transition measure (CTM) (Coleman et al.)
Mazor 2016 [105] USA N=297	PCP->HOS referral	HCP outcome	Timely referral	To examine the extent to which primary care practitioners' perceptions of event-level, physician-level and organisation-level factors influence a physician's intent to disclose a medical error in stressful situations.	PCPs from an integrated healthcare delivery systems	Observational study: cross-sectional design		HCP	Patient-HCP communication; Referral: timeliness and inappropriateness
McCormick 2015 [106] USA N=220	HOS->PCP Discharge	Patient outcome	Home care after discharge (tracheostomy)	To report patient/family experiences and outcomes after tracheostomy.	Parents of children with a tracheostomy tube but also adolescents and adults with a tracheostomy tube themselves	Observational study: cross-sectional design		Patient	Overall healthcare use; Patient care experiences; Harm and adverse events; Patient knowledge
McMillan 2006 [107] New zealand N=200	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To audit discharge summaries at Auckland Hospital to determine the frequency and nature of any medication errors. We have attempted to identify factors that contribute to these errors.	Patients discharged from hospital	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; Quality and timeliness of discharge summary
McMillan 2013 [108] USA N=120	PCP<->HOS Admission and discharge	Patient outcome	Medication reconciliation	To evaluate communication and medication discrepancies on admission and discharge between PCPs without admitting privileges and hospitalist physicians.	All patients admitted from primary care practices	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; Referral: timeliness and inappropriateness

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Meran 2010 [109] UK N=88	HOS->PCP Discharge from oupatient clinic	HCP & patient outcome	Safety of substitution/ discharge to PCP	To determine if patients discharged from nephrology clinic were appropriately discharged and adequately monitored in primary care. In addition, we prospectively follow-up the discharged patients' renal parameters and determine whether they were appropriately re-referred to nephrology services.	All patients discharged from a renal outpatient clinic	Observational study: prospective design	A renal patient care pathway.	HCP	All-cause mortality; Re-referrals and referral rate; Specific disease-related outcomes
Mesteig 2010 [110] Norway N=131	HOS->PCP Discharge	Patient outcome	Discharge safety	To describe unwanted incidents registered by the ambulatory team among patients discharged from a geriatric evaluation and management unit (GEMU) by character, frequency and stage in the transitional process. Only unwanted incidents with a severity making contact with the primary health care necessary were registered.	All patients planned to be discharged from a geriatric evaluation and management unit to their homes	Observational study: prospective design	An ambulatory team as part of the geriatric evaluation and management unit to improve the transitional process from hospital to the patients' homes.	HCP & patient	ADEs, medication errors and discrepancies; Quality and timeliness of discharge summary; Harm and adverse events
Meyers 2014 [111] USA Sample size calculation: N=3000	HOS->PCP Discharge	Patient outcome	Discharge safety	To enhance understanding of how health literacy and other patient factors affect the quality of care transitions and outcomes after hospitalization.	Adult patients hospitalized with acute coronary syndromes or acute decompensated heart failure	Observational study: prospective design		HCP & patient	All-cause mortality; Readmission; Overall healthcare use; ED visits; Physical and psychosocial outcomes
Mishra 2009 [112] Nepal N=130	HOS->PCP Discharge	HCP outcome	Quality of discharge letter	The study aims to assess the adequacy of medical records in Bir Hospital, a central hospital.	Patients admitted to a Liver Unit of a central tertiary care hospital	Observational study: cross-sectional design		HCP	Quality and timeliness of discharge summary
Misky 2010 [113] USA N=65	HOS->PCP Discharge	Patient outcome	Discharge safety	To evaluate characteristics and outcomes of discharged patients lacking timely PCP follow-up, defined as within 4 weeks of discharge.	Adult patients admitted to internal medicine	Observational study: prospective design		Patient	Readmission; PCP follow up; Length of hospital stay; ED visits
Moore 2003 [114] USA N=86	HOS->PCP Discharge	Patient outcome	Discharge safety and medication safety at discharge	To determine the prevalence of medical errors related to the discontinuity of care from an inpatient to an outpatient setting, and to determine if there is an association between these medical errors and adverse outcomes.	Patients discharges who had subsequent visit with an outpatient primary care provider within 2 months of discharge	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; Readmission; Diagnostic test follow up

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Moore 2011 [115] UK N=377	PCP<->HOS Admission and discharge	Initiatives & patient outcome	Medication reconciliation	To evaluate the use of a shared electronic primary health care record (EHR) to assist with medicines reconciliation in the hospital from admission to discharge.	Patients admitted to the elderly care admissions ward	Observational study: prospective design	Medication reconciliation using a shared electronic primary health record	HCP	ADEs, medication errors and discrepancies; Harm and adverse events
Moyer 2014 [116] USA N=229	HOS->PCP Discharge	HCP & patient outcome	Discharge safety and experience	To test whether a multifaceted intervention that included a health coach to assist families and an enhanced personal health record to improve the quality of information available to parents and community professionals would decrease adverse events and improve family assessment of the transition.	The families of all newborn infants admitted for at least 2 weeks to a newborn center, also registered with a primary care provider	Intervention study: non-randomized controlled trial	A transition coach and a personal health record.	HCP & patient	All-cause mortality; Readmission; Patient adherence; Patient care experiences; Patient knowledge; Caregiver burden; Caregiver satisfaction; Care transition measure (CTM) (Coleman et al.)
Murphy 2009 [117] USA N=760	PCP<->HOS Admission and discharge	Patient outcome	Medication reconciliation	To implement a comprehensive medication reconciliation program to reduce errors in admission and discharge medication orders at an academic medical centre is described.	Every inpatient admitted to hospital	Observational study: prospective design	Medication reconciliation by a pharmacist at admission and discharge: a discharge medication report was developed for patients to take home.	HCP	ADEs, medication errors and discrepancies
Musgrave 2013 [118] USA N=192	HOS->PCP Discharge	Patient outcome	Medication reconciliation at discharge	To critically evaluate the discharge process for solid-organ transplant recipients in order to determine if a transplant pharmacists' formalized involvement with the discharge medication reconciliation process would improve medication safety by decreasing the rate and severity of medication errors.	Patients discharged from an abdominal transplant surgery service	Intervention study: non-randomized controlled trial (historical control)	Medication reconciliation verified by a transplant pharmacist.	HCP	ADEs, medication errors and discrepancies
Nana 2012 [119] USA N=102	PCP<->HOS Admission and discharge	Patient, initiatives & HCP outcome	Medication reconciliation	To describe the initiation of a medication reconciliation program and other pharmacy services in the ED of a community and to address errors and inconsistencies in ED admission and discharge medication reconciliations.	ED patients	Observational study: prospective design	An ED pharmacist performing admission medication, entering ED pharmacy orders, facilitating medication delivery, and providing drug information	HCP	ADEs, medication errors and discrepancies; HCP satisfaction and opinions

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Naylor 1990 [120] USA N=40	HOS->PCP Discharge	Patients & organisational outcome	Discharge safety	To examine the effects of a comprehensive discharge planning protocol implemented by a gerontological nurse specialist as compared to the hospital's general discharge planning procedure.	Community-dwelling hospitalized elders, admitted to a medical or surgical unit	Intervention study: RCT	A discharge planning protocol including: assessment of unique needs of elderly patients which were communicated to their primary nurses and documented, validation of patients and healthcare professionals understanding, two visits during hospitalization, possibility of contact and two telephone-contacts post-discharge.	HCP	Readmission; Length of hospital stay; Specific disease-related outcomes; Costs
Naylor 1994 [121] USA Patients N=276, HCP N=125	HOS->PCP Discharge	Patient & organisational outcome	Discharge safety	To study the effects of a comprehensive discharge planning protocol, designed specifically for the elderly and implemented by nurse specialists, on patient and HCP outcomes and cost of care.	Hospitalised patients, 70 years and older	Intervention study: RCT	A comprehensive discharge planning and home follow-up protocol designed specifically for elders at high risk for poor post-discharge outcomes	HCP	Readmission; Length of hospital stay; Costs
Naylor 1999a [122] USA N=363	HOS->PCP Discharge	Patient & organisational outcome	Discharge safety	To examine the effectiveness of an advances practice nurses-centred comprehensive discharge planning and home follow-up protocol for elders hospitalized.	Elderly patients at risk for readmissions	Intervention study: RCT	Comprehensive discharge planning and home follow-up protocol designed for elders at risk for poor outcomes after discharge and implemented by advanced practice nurses.	HCP & patient	Readmission; ED visits; Costs; Patient satisfaction; Physical and psychosocial outcomes
Naylor 1999b [123] USA N=202	HOS->PCP Discharge	Patient outcome	Discharge safety	To examine the effectiveness of a discharge planning and home follow-up management program for elders hospitalized with common medical and surgical cardiac conditions.	Community-dwelling, elderly patients, admitted with heart failure, angina, myocardial infarction, coronary artery bypass graft surgery, or cardiac valve replacement	Intervention study: RCT	A comprehensive discharge planning and home follow-up protocol designed specifically for elders at high risk for poor post-discharge outcomes.	HCP	Readmission; Physical and psychosocial outcomes

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Naylor 2004 [124] USA N=239	HOS->PCP Discharge	Patient &or-ganisational outcome	Discharge safety	To examine the effectiveness of a transi-tional care intervention delivered by advanced practice nurses to elders hospitalized with heart failure.	Elderly patients hospitalized with heart failure	Intervention study: RCT	A 3-month discharge plan-ning and home follow-up protocol by advanced practice nurses.	HCP & patient	All-cause mortality; Readmission; Overall healthcare use; Costs; Patient satisfaction; Physical and psychoso-cial outcomes
Naylor 2011 [125] USA N=172	HOS->PCP Discharge	Patients, HCP & or-ganisational outcome	Discharge safety	To evaluate the impact of translating into a large US health plan, the Transitional Care Model (TCM), an evidence-based approach to address the needs of chronically ill older adults throughout acute episodes of illness.	Chronically ill older adults throughout acute episodes of illness	Intervention study: before-after design	An advanced practice nurse comprehensive in-hospital planning and home follow-up.	HCP & patient	Overall healthcare use; Costs; HCP satisfaction and opinions; Patient satisfaction; Physical and psychoso-cial outcomes
Nuñez 2006 [126] Spain N=500	HOS->PCP Discharge	Patient outcome	Discharge safety from ED	The causes of unscheduled returns to the ED within 72 hours of discharge are unclear. A study was undertaken to identify factors associated with this quality care indicator.	Patients over 14 years, presenting to the ED	Observati-onal study: retrospective design		HCP	ADEs, medication er-rors and discrepancies; Readmission; PCP follow up; ED visits
Nuno-Solinis 2013 [127] Spain N=146	PCP<->HOS Overall continuity	Climate & HCP outcome	Interpro-fessional coopera-tion	To assess the change in the degree of interprofessional collaboration across two different levels of care, before and after the establishment of the Bidasoa Integrated Healthcare Organisation, based on the perceptions of two groups of health profes-sionals (doctors and nurses).	Clinical profes-sionals at different levels of care	Intervention study: before-after design	Organisational integration of the clinical processes between different care levels.	HCP	Interprofessional col-laboration and commu-nication; Collaboration questionnaire (Nuno Solinis et al.)

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Okoniewska 2012 [128] Canada Sample size calculation: N= 1400	HOS->PCP Discharge	Patient & organisational outcome	Discharge safety/ communication at discharge	To examine whether a transfer-of-care communication tool is efficacious and cost-effective for reducing hospital readmission, adverse events and ADEs as well as reducing death.	Adult, community-dwelling patients admitted to hospital	Intervention study: RCT	Patient's discharge summaries generated by a computer-enabled communication tool providing a standardized template for communicating all relevant clinical information on patients who are leaving hospital, is immediately available at time of leaving and is accessible through the web by community-based providers (family physicians, specialists, home care nurses, and community pharmacists).	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Harm and adverse events; Physical and psychosocial outcomes
Ong 2016 [129] USA Intervention N=715, Control N=722	HOS->PCP Discharge	Patient outcome	Discharge safety	To evaluate the effectiveness of a care transition intervention using remote patient monitoring in reducing 180-day all-cause readmissions among a broad population of older adults hospitalized with heart failure.	Older adults hospitalized with heart failure	Intervention study: RCT	The intervention combined health coaching telephone calls and telemonitoring. Telemonitoring used electronic equipment that collected daily information about blood pressure, heart rate, symptoms, and weight. Centralized registered nurses conducted telemonitoring reviews, protocolized actions, and telephone calls.	HCP & patient	All-cause mortality; Readmission; Physical and psychosocial outcomes

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Ouchida 2009 [130] USA N=103	HOS->PCP Discharge	Climate & HCP outcome	Transitio-nal care	To assess the effect of a new curriculum on transitional care on participants' knowledge, attitudes, and self-reported behaviours in these domains.	Third-year medical students completing their required internal medicine rotations	Intervention study: before-after design	A new curriculum emp-hasizing transitional care, functional assessment, interdisciplinary team, community resources, and reimbursement. The curriculum consists of two 90-minute sessions that in-corporate interdisciplinary lectures, an educational digital video disc (DVD), small-group discussion, and a team-based learning exercise.	HCP	ADEs, medication er-rors and discrepancies; All-cause mortality; Readmission; Costs
Parrish 2009 [131] USA N=791	HOS->PCP Discharge	Initiatives, HCP & patient outcomes	Discharge safety and self-ma-nagement	To identify factors that promote sustainabi-lity of the intervention by assessing features of each site's implementation and the site's likelihood of continuing the program; solici-ting feedback from the sites; and analysing site and patient characteristic data and data from the Care Transitions Intervention measurement instruments (the 3-Item Care Transition Measure [CTM-3) and the Patient Activation Assessment [PAA) tool).	Elderly discharged patients	Observati-onal study: prospective design	The Care Transitions Intervention: a self-management program designed to provide patients discharged from the acute care setting with skills, tools, and the sup-port of a transition coach to ensure that their health and self-management needs are met.	HCP & patient	ADEs, medication er-rors and discrepancies; All-cause mortality; Readmission; Costs; Physical and psychoso-cial outcomes; Imple-mentation (number/ quality); Care transition mea-sure (CTM) (Coleman et al.); Medication discrepancy tool (Smith et al); Questionnaires: related concepts and non-validated question-naires

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Paulino 2004 [132] Europe: Austria, Denmark, Germany, The Netherlands, Portugal and Spain. N=435	HOS->PCP Discharge	Patient outcomes	Medication discharge safety	To examine the nature and frequency of drug related problems in community pharmacies among patients discharged from hospitals in several countries, and to examine several variables related to these drug related problems.	Patients discharged with a medication prescription	Observational study: prospective design	A systematic medication review by community pharmacists in discharged patients.	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Phatak 2016 [133] USA Intervention N=137, Control N=141	HOS->PCP Discharge	Patient outcomes	Discharge safety	To evaluate the impact of intensive pharmacist involvement during the acute care admission as well as for a 30-day time period post-discharge on both ADEs and readmissions.	Patients admitted to an internal medicine unit on high-risk medications or with greater than three prescription medications upon discharge home	Intervention study: RCT	Medication reconciliation at admission, a patient-specific pharmaceutical care plan, discharge counselling, and post-discharge phone calls.	HCP & patient	ADEs, medication errors and discrepancies; Readmission; Drug-related hospital (re) admission; ED visit; Patient satisfaction; Harm and adverse events; Patient knowledge; Questionnaires: related concepts and non-validated questionnaires
Pourrat 2014 [134] France Sample size calculation: N=1176	HOS->PCP Discharge	Patient outcome	Medication discharge safety	To assess the impact of a complex intervention comprising of medication reconciliation performed at discharge by a hospital pharmacist (HP) with communication between the HP and community pharmacist on drug related problems during the seven days following discharge.	Adult patients discharged home, and visiting the same community pharmacist for at least three months.	Intervention study: RCT	The hospital pharmacist will perform a medications reconciliation that will be communicated to the patient and their community pharmacist	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Redmond 2016 [135] Ireland N=949	PCP<->HOS All transitions of care	Climates & HCP outcome	Medication reconciliation and communication	To survey PCPs and community pharmacists in Ireland regarding current practices of medication management, specifically medication reconciliation, communication between health care providers and medication errors as patients transition in care.	PCPs and community pharmacists in Ireland	Observational study: cross-sectional design		HCP	Patient safety culture; HCP satisfaction and opinions; Interprofessional collaboration and communication; HCP attitudes
Reese 2003 [136] USA N=15	HOS->PCP Discharge	Patient outcome	Discharge safety and medication reconciliation at discharge	To examine feasibility of implementing a hospitalist home visit programme.	Elderly, poor, and minority patients discharged home	Observational study: prospective design	Home visit after discharge by a hospital physician including a focused history and physical, a review of medications, and a home safety evaluation.	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Rice 2016 [137] USA N= not reported	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To describe the development, implementation, and refinement of the transitional care bundle and its effect on readmission rates, patient satisfaction, time to follow-up care after discharge, and discharge medication list errors.	Inpatients on the internal medicine service	Observational study: prospective design	A transitional care bundle that crosses care settings and organizational functions was developed to meet needs expressed by patients. It comprises 5 elements: risk stratification, a specialized phone number for discharged patients, timely post-discharge follow-up, standardized patient discharge instructions and same-day discharge summaries, and pharmacist-supported medication reconciliation.	HCP & patient	ADEs, medication errors and discrepancies; PCP follow up; Visits to primary care; Questionnaires: related concepts and non-validated questionnaires
Riordan 2016 [138] Ireland N=83	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	To explore the relationship between discharge prescribing error and post-discharge medication error.	All adult inpatients discharged alive to home from any adult department	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Roorda 2013 [139] the Netherlands N=502	HOS->PCP Discharge	HCP outcome	Discharge safety	The present study explored the discharge of breast cancer patients to primary care by specialists, at the end of hospital follow-up and the experiences and views of PCPs regarding transfer of follow-up to the primary care setting.	PCPs of patients discharged to primary care of at the end of hospital follow-up after breast cancer	Observational study: cross-sectional design		HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Roughead 2009 [140] Australia N= 109,860	HOS->PCP Discharge	Patient outcome	Discharge safety	This study aimed to determine length of time from hospital discharge until a general practice, pharmacy or specialist visit, or care planning service.	Hospitalized veteran patients	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Russel 2014 [141] Australia N=106	HOS->PCP Discharge	HCP outcome	Discharge safety/ quality of discharge letter	To assess effectiveness of an intervention on accurateness of synopsis in a discharge letter.	Discharged patients whose charts and discharge summaries were written by a general medical team	Intervention study: before-after design	A training session on discharge summaries emphasising the need (i) for a structured problem-based synopsis rather than one that is a free ranging narrative; (ii) for a brief discussion of each problem; (iii) to be clear about the principal diagnosis; and (4) in the list of secondary diagnoses, to list only the problems relevant to this admission.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Santel 2006 [142] USA Incidents N=2022	PCP<->HOS Admission and discharge	Patient outcome	Medication safety	To evaluate 2,022 medication errors that involved a reconciliation issue and were reported to an incident reporting program.	All patients	Observational study: prospective design	An incident reporting system.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Scales 2016 [143] Canada N=1,014,891	HOS->PCP Discharge	Patient outcome	Discharge safety	To evaluate rates of and risk factors for potentially unintentional medication continuation following hospitalization.	All individuals aged ≥ 66 years who were discharged alive from an acute care hospital	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Schnipper 2006 [144] USA N= 178	HOS->PCP Discharge	HCP & patient outcome	Medication safety at discharge	To identify drug-related problems during and after hospitalization and to determine the effect of patient counselling and follow-up by pharmacists on preventable ADEs.	Patients discharged home from the general medicine service at a large teaching hospital	Intervention study: RCT	Pharmacist counselling at discharge and a follow-up telephone call 3 to 5 days later.	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Harm and adverse events
Schnipper 2009 [145] USA N=322	PCP<->HOS Admission and discharge	Patient outcome	Medication reconciliation	To measure the impact of an information technology– based medication reconciliation intervention on medication discrepancies with potential for harm.	Patients admitted to a general medicine department	Intervention study: RCT	A computerized medication reconciliation tool for admission and discharge involving physicians, nurses, and pharmacists.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Harm and adverse events
Scotten 2015 [146] USA Patient N=NR Faculties N=8	HOS->PCP Discharge	Climate & patient outcome	Discharge safety/ interprofessional communication	To evaluate a project, including standardized communication, and techniques to continue care from inpatient, to discharge, across the post-discharge chasm, to hand-off with the primary care provider.	Children and their families discharged after hospital admission to their primary care provider	Intervention study: before-after design	The interprofessional quality improvement initiative included: (1) evidence-based teamwork system; (2) in situ simulation; (3) creation of an IP model of care; and (4) innovations in use of telehealth technology to continue care post-discharge.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Questionnaires: related concepts and non-validated questionnaires
Seidling 2010 [147] Germany Patient N=9978. Hospital wards N=95	PCP<->HOS Outpatient clinic and discharge	Initiatives, patient & HCP outcome	Medication safety	To evaluate a clinical decision support systems providing upper dose limits personalised to individual patient characteristics thus guaranteeing for specific warnings.	Outpatients and discharged patients	Intervention study: before-after design	A team of pharmacists, physicians and computer scientists built an algorithm for the definition of individual upper dose limits. We evaluated electronic prescriptions as included in discharge letters or printed onto prescription forms.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Sharma 2011 [148] USA N=36	HOS->PCP Discharge from ED	Patient outcome	Medication safety after discharge from ED	To compare the medication information that patients ultimately discharged from the ED provide to the ED staff vs. the medication information the patients provide at follow-up, and to classify and quantify the types of discrepancies between the two.	Adult patients discharged from the ED to home, reporting use of five or more medications	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Shastri 2014 [149] UK N=200	HOS->PCP Discharge	HCP outcome	Quality and timeliness of discharge letter	To audit the content and timing of discharge summaries from a psychiatric hospital as to whether it adheres to the local Trust guidelines.	Patients admitted and discharged from a psychiatric hospital	Intervention study: before-after design		HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Shen 2013 [150] USA Groups of pediatric hospitalist N=7	HOS->PCP Discharge	Initiatives & HCP outcome	Discharge safety/ timeliness of discharge letter	To achieve 90% documentation of hospitalist-PCP communication within 2 days of hospital discharge in <12 months.	All patients discharged from a paediatric hospital	Observational study: prospective design	A quality improvement project to improve the timeliness and reliability of discharge communication. After an initial face-to-face meeting, e-mail and regular conference calls were used to promote shared effort and learning.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Shu 2011 [151] Taiwan N=313	HOS->PCP Discharge	Patient outcome	Discharge safety	To investigate the impact of a quality improvement program, integrated post-discharge transitional care, in Taiwan's hospitalist system.	Adult patients admitted from the ED and later discharged home	Intervention study: non-randomized controlled trial	A post-discharge transitional care program, including a disease-specific care plan, telephone monitoring, hotline counselling and referral to a hospitalist-run clinic.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Sides 2012 [152] USA N=30	HOS->PCP Discharge	Initiatives & patient outcome	Medication safety at discharge	To assess the feasibility of medication coaching via telephone after discharge in patients with stroke.	Patients admitted with stroke or TIA with at least 2 medications changes between admission and discharge	Intervention study: non-randomized controlled trial	The medication coach contacted patients post-discharge via phone call to discuss risk factors, review medications and triage patients' questions to a stroke nurse and/or pharmacist.	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Cost; Physical and psychosocial outcomes; Patient knowledge; Feasibility intervention/ user friendliness; Care transition measure (CTM) (Coleman et al)

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Silva 2011 [153] USA N=94	PCP<->HOS Different outpatient transitions	Initiatives & patient outcome	Medication reconciliation	To explore a rule-based medication reconciliation algorithm to accomplish this task across different healthcare transitions.	Patients at the outpatient clinic	Observational study: prospective design	A medication reconciliation algorithm that creates a list of merged prescriptions.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Singh 2012 [154] USA N=104	PCP->HOS Referral	HCP outcome	Referral delays	We used a mixed quantitative-qualitative approach to analyse post referral colonoscopy delays in colorectal cancer patients and explored referring physician's perception of processes surrounding these delays.	Patients with newly diagnosed colorectal cancer	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Smith 2015 [155] USA N=90	PCP<->HOS admission and discharge	Patient outcome	Medication reconciliation	To assess if the pharmacy department should be more involved in the medication reconciliation process to assist in the reduction of medication errors that occur during transition of care points in the hospital setting.	Adult patients with at least 5 medications	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies
Soong 2014 [156] Canada N=214	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To examine the effect of a 72-hour post-discharge phone call on the patient's transition of care experience.	Adult general medical patients discharged home after hospitalization	Intervention study: RCT	A 72-hour post-discharge follow-up telephone call	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Patient knowledge; Care transition measure (CTM) (Coleman et al.)
Spalek 1999 [157] USA N=39	PCP<->HOS Overall continuity	Patient outcome	Continuity of care: anticoagulation (care chain)	To provide a continuum of patient care, decrease ED visits, decrease episodes of hospitalization, and increase patient satisfaction and quality of life.	Patients using anticoagulation	Intervention study: before-after design	An integrated anticoagulation health system in which a pharmacist is authorized to perform point-of-care testing for pro-trombin times, adjust doses of anticoagulants, order vitamin K, and schedule return visits per established guidelines.	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Physical and psychosocial outcomes; Patient knowledge; Care transition measure (CTM) (Coleman et al.)

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Spehar 2005 [158] USA N=1845	HOS->PCP Discharge	Patient outcome	Discharge safety	To identify ways to maximize improvement in post-discharge patient outcomes. This research targeted patients at risk for unscheduled readmissions, examined delivery system processes, and identified possible interventions for providing more seamless care.	Patients at risk for unscheduled readmissions	Observational study: retrospective + prospective design		HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Patient knowledge
Stafford 2011 [159] Australia N= 268	HOS->PCP Discharge	Patient outcome	Discharge safety: anticoagulation	To evaluate the clinical outcomes of a collaborative, home-based post-discharge warfarin management service adapted from the Australian Home Medicines Review (HMR) program.	Patients discharged from the hospital and newly initiated on or continuing warfarin therapy	Intervention study: non-randomized controlled trial	A post-discharge service of 2 or 3 home visits by a trained pharmacist in their first 8 to 10 days post-discharge. The post-discharge service involved point-of-care international normalized ratio (INR) monitoring, warfarin education, and an HMR, in collaboration with the patient's PCP and community pharmacist.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Staveski 2016 [160] India N=68	HOS->PCP Discharge	Patient outcome	Discharge preparedness	To compare parent and nurse perceptions of parent readiness for discharge after a structured nurse-led parent discharge teaching programme in India.	Parents of children who underwent cardiac surgery and nurses caring for children after cardiac surgery	Intervention study: before-after design	A parent education discharge instruction programme.	HCP & patient	Patient care experiences; Patient knowledge; Questionnaires: related concepts and non-validated questionnaires
Stein 2014 [161] Israel N=323	HOS->PCP Discharge	HCP outcome	Discharge safety/ discharge summaries	To evaluate a quality improvement model and training program for writing postoperative discharge summaries for three surgical procedures.	Patients who had been hospitalized for elective surgery	Intervention study: before-after design	A training session concerning the required content of the discharge summaries followed by random reviews and feedback on discharge summaries by the senior attending doctors.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Stella 2016 [162] USA N=131	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To determine whether treating hospitalists can identify and address early post-discharge problems through a structured telephone call.	Patients discharged from a general internal medicine service of a university-affiliated public safety net hospital	Observational study: prospective design	A post-discharge hospitalist call.	HCP & patient	ED visit; Productivity; Harm and adverse events
Steurbaut 2010 [163] Belgium N=197	PCP<->HOS Admission and discharge	HCP & patient outcome	Medication reconciliation	To assess the clinical pharmacist's performance in obtaining patients' medication histories and in reconciling these data with the medical records and medication orders and whether the patients' residential situation prior to hospitalization influences the number of drug discrepancies.	Elderly patients of a acute geriatric ward of a Belgian university hospital, who are prescribed at least 1 prescription drug	Observational study: prospective design	Medication reconciliation at admission by a clinical pharmacist.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Stone 2009 [164] USA N=23	PCP->HOS Admission	Patient outcome	Medication reconciliation at admission	To evaluate admission medication reconciliation in children with medically complex conditions by determining the availability and accuracy of five information sources and characterising admitting order errors.	Newly admitted children with medically complex conditions	Observational study: prospective design	Medication reconciliation at hospital admission using information from parents (and patient if appropriate), primary care provider, community-based pharmacy, current admission history and physical exam note, and admission electronic medical record.	HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Stuffken 2008 [165] the Netherlands N=17362	HOS->PCP Discharge	Patient outcome	Medication safety	To assess the association between hospitalization and medication therapy discontinuities.	Hospitalised patients	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Tamblyn 2012 [166] Canada Sample size calculation: N=3714	HOS->PCP Discharge	Patient outcome	Medication reconciliation at discharge	To determine if electronically enabled discharge reconciliation will reduce the risk of ADEs, emergency room visits and readmissions 30 days post-discharge compared with usual care.	Adult patients admitted to a general or intensive care medical or surgical unit, using prescription medication at admission, and discharged alive.	Intervention study: RCT	Electronic retrieval of the community drug list, combined with electronic discharge reconciliation.	HCP & patient	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs
Tan 2014 [167] Australia N=219	HOS->PCP Discharge	HCP outcome	Medication safety at discharge	To assess the accuracy of documentation of medication changes and expectations with regard to follow up from an acute assessment unit of a tertiary metropolitan hospital.	All patients admitted to an acute assessment unit	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Harm and adverse events
Tan 2015 [168] Australia N=722	HOS->PCP Discharge	HCP outcome	Quality of discharge summary	To assess the role of feedback and token incentives in improving discharge documentation.	Junior medical staff who compile discharge summaries	Intervention study: before-after design	Discharge summaries of junior medical staff was edited and fed back and positive incentives were given	HCP	Quality and timeliness of discharge summary; HCP satisfaction and opinions
Triller 2005 [169] USA N=4250	HOS->PCP Discharge	Patient outcome	Medication safety at discharge	The prevalence of risk factors for ADEs in patients discharged from the hospital	Patients 21 years and older, discharged from hospital, who were admitted to maternity or same day surgery units, or who had an actual or implied diagnosis of HIV infection or AIDS	Observational study: retrospective design		HCP	ADEs, medication errors and discrepancies; All-cause mortality; Readmission; Costs; Harm and adverse events
Tsilimingras 2015 [170] USA N=684	HOS->PCP Discharge	Patient outcome	Discharge safety	We aimed to determine the rate of post-discharge adverse events, classify the types of post-discharge adverse events, and identify risk factors for post-discharge adverse events in urban and rural patients.	Adult patients at risk for post-discharge adverse events	Observational study: prospective design		HCP & patient	Harm and adverse events

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Uijen 2013 [171] the Netherlands N=519	PCP<->HOS Overall continuity	HCP outcome	Continuity of care	To explore the level of experienced continuity of care of patients at risk for depression in primary care, and compare these to those of patients with heart failure.	Patients at risk for depression and chronic heart failure patients	Observational study: cross-sectional design		Patient	Interprofessional collaboration and communication; Patient care experiences; Questionnaires: related concepts and non-validated questionnaires
Uitvlugt 2015 [172] the Netherlands N=99	HOS->PCP Discharge	HCP & patient outcome	Medication safety at discharge	To assess the completeness of medication-related information in discharge letters and post-discharge PCP-overviews.	Patients discharged from the departments of neurology, cardiology, pulmonology and internal medicine	Observational study: prospective design		HCP	ADEs, medication errors and discrepancies; Quality and timeliness of discharge summary
van Melle 2016 [173] the Netherlands N=13	PCP<->HOS All transitions of care	Patient outcome	Transitional patient safety	To investigate whether transitional incidents can be identified from the medical records of the PCPs and the hospital and to assess the concordance of transitional incidents between medical records and patient interviews.	Patients that have experienced or have high risk for transitional incidents	Observational study: retrospective design		HCP & patient	Harm and adverse events
Varkey 2007 [174] USA N=102	PCP<->HOS Admission and discharge	Patient outcome	Medication reconciliation	To assess the effectiveness of a multidisciplinary medication reconciliation process was studied in an inpatient family medicine unit of an academic hospital centre.	All patients admitted a family medicine department	Intervention study: RCT	Medication reconciliation at admission and discharge by a pharmacist and physician. The reconciled admission and discharge medication lists was included in the hospital summary.	HCP	ADEs, medication errors and discrepancies; Length of hospital stay

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Villani 2014 [175] Italy N=80	HOS->PCP Discharge	Patient & organisational outcome	Discharge safety	To assess the clinical efficacy and cost of this system.	Patients with chronic heart failure leaving hospital after being treated for clinical instability.	Intervention study: RCT	A handheld PDA for the patient which kept in touch daily with the monitoring centre, communicating with the patient by asking simple questions about their symptoms and giving information and counselling through visual and audible reminders.	HCP & patient	Cause-specific mortality; Admission and inpatient care use; Specific disease-related outcomes; Costs; Patient adherence; Physical and psychosocial outcomes
Vira 2006 [176] Canada N=60	PCP<->HOS Admission and discharge	Patient outcome	Medication reconciliation	To describe the potential impact of a medication reconciliation process to identify and rectify medication errors at the time of hospital admission and discharge.	Patients admitted to an acute care unit	Observational study: prospective design	A study pharmacist conducted a medication reconciliation process at admission and discharge using information from patient, HCPs, and/or outpatient healthcare providers.	HCP	ADEs, medication errors and discrepancies
Vrijhoef 2001 [177] the Netherlands N=99	PCP<->HOS Overall continuity	Patient outcome	Substitution to a nurse practitioner	To assess the effects on quality of care, in terms of patient outcomes, when tasks in the care for outpatients with stable type 2 diabetes are transferred from internist to nurse specialist and from outpatient clinic to general practice.	Patients diagnosed with non-insulin dependent diabetes, without serious co-morbidity treated by a hospitalist	Intervention study: non-randomized controlled trial	Substitution of patient care from hospital internal medicine outpatient care to a nurse specialist in general practice.	HCP & patient	Visits to primary care; Admission and inpatient care use; Specific disease-related outcomes; Patient adherence; Patient satisfaction; Physical and psychosocial outcomes; Patient knowledge; Questionnaires: related concepts and non-validated questionnaires
Waring 2012 [178] USA Sample size calculation: N=2500	HOS->PCP Discharge	Patient outcome	Quality of discharge	To advance the science of acute coronary syndromes by examining the determinants and outcomes of the quality of transition from hospital to community and by quantifying the impact of potentially modifiable characteristics associated with decreased quality of life, rehospitalisation, and mortality.	Patients hospitalized with acute coronary syndromes	Observational study: prospective design		Patient	All-cause mortality; Readmission; Admission and inpatient care use; ED visits; Patient care experiences; Physical and psychosocial outcomes

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Warsame 2016 [179] USA N= not reported	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To develop a care model to decrease incidence of preventable errors in the complex multidisciplinary care of haematology inpatients at the time of discharge.	Discharged haematology Patients Receiving Chemotherapy	Intervention study: before-after design	A multidisciplinary discharge checklist.	HCP	Readmission; Quality and timeliness of discharge summary; Guideline use
Watkins 2012 [180] USA N=292	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To describe a social-worker navigator transitional care model for at-risk seniors being discharged from hospital to home.	Frail elderly patients at high risk of readmission	Observational study: prospective design	Post-discharge home visits to evaluate the home environment, assess medical management, and make referrals for other services.	Patient	Readmission; Costs; Patient satisfaction; Physical and psychosocial outcomes
Weiner 2010 [181] USA N=6785	PCP->HOS Referral	Organisational outcome	Referral quality and timeliness of appointment after referral	To determine the extent to which referral-based consultations were completed in a US medical institution. Factors associated with completion were identified.	Elderly patients receiving health care in an integrated, urban, tax-supported medical institution on an acADEsmic campus	Observational study: retrospective design		HCP	Referral: timeliness and inappropriateness
Were 2009 [182] USA N=668	HOS->PCP Discharge	HCP outcome	Discharge safety; pending tests	To determine the adequacy with which hospital discharge summaries document tests with pending results and the appropriate follow-up providers.	Patients with pending laboratory tests at discharge	Observational study: retrospective design		HCP	Diagnostic test follow up; Quality and timeliness of discharge summary
Williams 2015 [183] UK N=598	HOS->PCP Discharge	Patient outcome	Discharge safety	To describe the frequency and types of patient safety incidents associated with discharge from secondary to primary care, and commonly described contributory factors to identify recommendations for practice.	Patients that have experienced patient safety incidents associated with discharge from secondary to primary care reported to a reporting system	Observational study: cross-sectional design		HCP	Harm and adverse events

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Wilson 2001 [184] Australia N=569	HOS->PCP Discharge	HCP out-come	Discharge informa-tion time-liness and accuracy	To examine the reliability, effectiveness, accuracy and timeliness of hospital to PCP information transfer by discharge summa-ries produced in a general public hospital in New South Wales, Australia.	Patients discharged from medical, surgical, gynaecological, paediatric, and aged care	Observati-onal study: retrospective design		HCP	Quality and timeliness of discharge summary
Withering-ton 2008 [185] UK N=108	HOS->PCP Discharge	HCP & patient outcome	Commu-nication at discharge	To identify communication gaps at hospital discharge for older people who are readmit-ted within 28 days; to assess the contribu-tion of incomplete discharge information to readmission; to identify measures that might improve communication at hospital discharge.	Patients aged 75 and over who were readmitted as an emergency within 28 days of previous discharge	Observati-onal study: retrospective design		HCP & patient	Drug-related hospital (re) admission; Patient knowledge
Wong 2008 [186] Canada N=150	HOS->PCP Discharge	Patient outcome	Medica-tion recon-ciliation	To identify, characterize, and assess the clinical impact of unintentional medication discrepancies at hospital discharge.	All internal medicine patients admitted for at least 72 hours to a tertiary care teaching hospital	Observati-onal study: prospective design		HCP	ADEs, medication er-rors and discrepancies
Wortman 2008 [187] USA N=600	PCP<->HOS Admis-sion and discharge	Patient outcome	Medica-tion recon-ciliation	To examine a medication reconciliation program involving physicians, pharmacists, nursing staff, and other personnel at a com-munity hospital.	Patient admitted to hospital	Intervention study: before-after design	Medication reconciliation by a multidisciplinary team (physicians, pharmacists, nursing staff, and other personnel) at admission, transfer, and discharge.	HCP	ADEs, medication er-rors and discrepancies
Yi 2011 [188] Singapore N=24000	PCP->HOS Admission	Patient outcome	Medica-tion recon-ciliation	This article aims to describe the Tan Tock Seng Hospital medication reconciliation system and to highlight common medica-tion errors occurring following incomplete medication reconciliation.	All patients admit-ted to hospital	Observati-onal study: prospective design	Medication review by a pharmacist at admis-sion. Any discrepancies in medicines are brought to the doctors' attention. Patients are also counsel-led about changes to their medications.	HCP	ADEs, medication er-rors and discrepancies

Appendix table 3.5.1 continued

Author/ Year	Transition	Cult-behav-outcome continuum	Construct	Aim/ research question	Target population	Design	Intervention	Perspective/ Reported by	Used outcomes
Young 2013 [189] Australia N=775	HOS->PCP Discharge	HCP & patient outcome	Discharge safety	To investigate the effectiveness of a centralized, nurse-delivered telephone-based service to improve care coordination and patient-reported outcomes after surgery for colorectal cancer.	Adult patients with newly diagnosed colorectal cancer	Intervention study: RCT	Standardized calls from the centrally based nurse after discharge from hospital.	Patient	Readmission; ED visits; Patient care experiences; Patient satisfaction; Physical and psychosocial outcomes; Questionnaires: related concepts and non-validated questionnaires
Zhang 2013 [190] Australia Sample size calculation: N=456	PCP<->HOS Overall continuity	Patient outcome	Continuity of diabetes care (care chain)	To evaluate the health and clinical benefits of the new model of care, assesses the acceptability of the model to patients, PCPs and other health professionals, and examines the cost-effectiveness of the model.	Patients with complex and/ or uncontrolled T2DM	Intervention study: RCT	Diabetes care by a multidisciplinary team consisting of an Endocrinologist, advanced-skilled PCPs (known as Clinical Fellows), a credentialed diabetes educator and a podiatrist all located together in a community based complex diabetes service.	HCP & patient	Specific disease-related outcomes; Costs; Patient adherence; Patient satisfaction; Harm and adverse events; Physical and psychosocial outcomes; Patient knowledge
Zoni 2012 [191] Spain N=162	PCP->HOS Admission	Patient outcome	Medication reconciliation at admission	To assess the impact of an intervention aimed to decrease unintended discrepancies between patient's usual treatment and medications prescribed on admission to the department of internal medicine.	All patients hospitalized in a department of internal medicine, and whose prescriptions prior to admission included three or more drugs	Intervention study: before-after design	Medication reconciliation at admission by an electronic reconciliation tool that connected patients' usual medication with the electronic prescription program.	HCP	ADEs, medication errors and discrepancies

ADE=Adverse drug event; AE=Adverse event; DOC-questionnaire= Doctors' Opinions on Collaboration-questionnaire; ED=Emergency department; PCP=General practitioner; HCP=Healthcare professional; PCP=Primary care provider; RCT=Randomised controlled trial.

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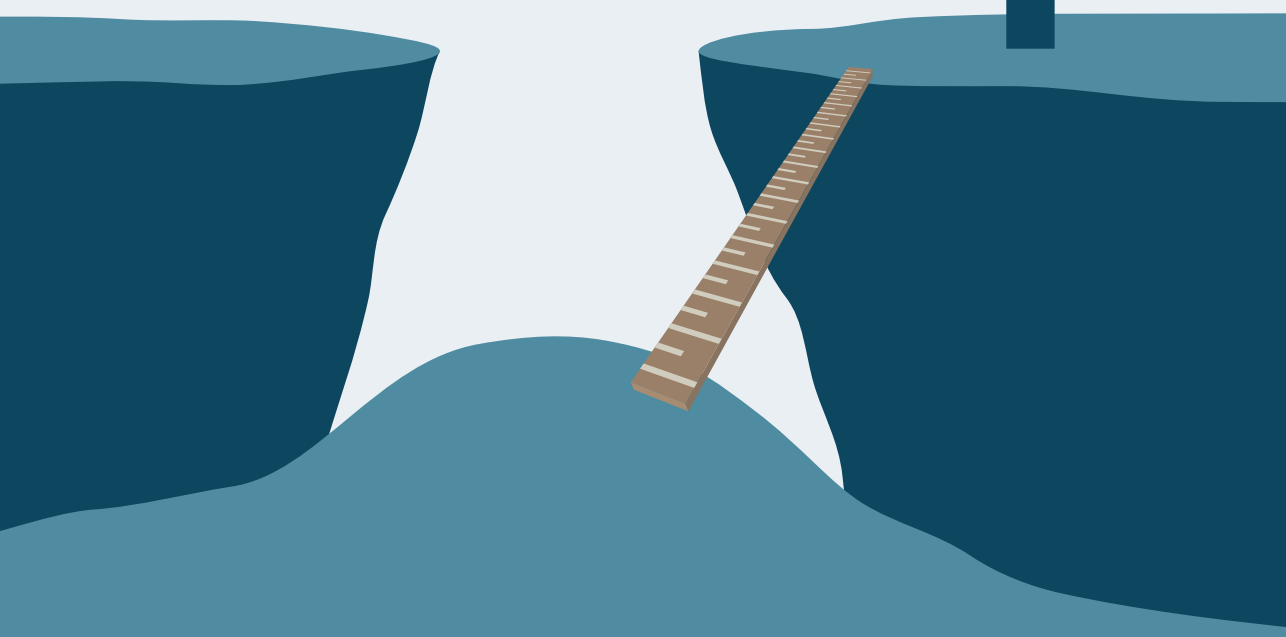

VALIDATION OF A QUESTIONNAIRE MEASURING TRANSITIONAL PATIENT SAFETY CLIMATE (TRACE) INDICATED DIFFERENCES IN TRANSITIONAL PATIENT SAFETY CLIMATE BETWEEN PRIMARY AND SECONDARY CARE

van Melle MA, van Stel HF, Poldervaart JM, de Wit NJ, Zwart DLM.

ABSTRACT

Background

This study describes the development and validation of the TRAnsitional patient safety Climate Evaluation (TRACE) questionnaire, measuring transitional patient safety climate from the perspective of general practitioners and hospital physicians. Patient safety climate reflects the professionals' perception of the organizational patient safety culture.

Study Design and settings

In the development of the TRACE we adjusted existing questionnaires on patient safety culture. Exploratory factor analysis (EFA) was performed. Internal consistency and correlations between factors and a global transitional patient safety rating were calculated.

Results

In total, 162 questionnaires were completed (response 23%; general practice: N=97, hospital physicians: N=65). Analysis of all respondents did not provide an interpretable factor solution. However, the EFA on the results of hospital physicians revealed 4 relevant factors: (1) Collaboration, (2) Speaking up, (3) Communication on transitional incidents and improvement measures, and (4) Transitional patient safety management. The internal consistency of these factors was good for hospital respondents (0.71 to 0.87) and fair to acceptable for general practices' respondents (0.63 to 0.72).

Conclusions

Although the TRACE questionnaire did not provide a solid factor structure in a combined sample of general practice and hospital respondents, the factors found reliable in hospital setting had acceptable reliability in general practice setting.

BACKGROUND

Patient safety encompasses the prevention of errors or reduction of adverse effects associated with healthcare.[1,2] As recently stated by Dixon-Woods, it has become increasingly clear that especially handover situations in which multiple actors and organisations transfer responsibility for a patient's care impose a risk on patients.[3] An important handover situation is the transition between primary and secondary care, for example when a patient is referred, discharged or receives concurrent care at both the general practitioner and hospital in the same time period. The growing number of chronic patients with multimorbidity and the urge of cost-effectiveness call for personalised, integrated care, with a shift towards primary care delivery, where medical specialists have a consulting role. This development results in more handovers. To prevent safety incidents in these handovers, communication and handover of information between these physicians is vital.[4] Therefore, the patient safety discussion needs to concentrate on integrated, multidisciplinary care provision.[5]

For multidisciplinary care provision, where multiple interactions between professionals create an extra risk for incidents, a constructive patient safety culture is needed to improve patient safety.[6] Patient safety culture is defined as the product of individual and group values, attitudes, competencies, and behavioural patterns.[7] In other words, culture is "the way we do things around here".[8]

The existence of a specific *transitional* patient culture can be debated, because a prerequisite for a working culture is that professionals are working in a shared environment and share attitudes and behaviour. In the current transitional pathway, there is neither a shared environment nor are there shared practices.[9] The transition takes place in a 'no man's land' where patients cross from one organisation to the other. Undoubtedly, however, there are "ways we do things around" patients who are referred, discharged or treated by several healthcare organisations simultaneously, which we would refer to as transitional patient safety culture.

We consider transitional patient safety culture as a meeting of the safety cultures that exist within two individual organisations (Figure 4.1). This culture thus comprises the values, attitudes, competencies, and behavioural patterns of the organisations and individuals involved in the transition, i.e, the way professionals working in these organisations think about and act towards each other. This makes transitional patient safety culture a unique domain, created from the organisations on either side, exporting their values outward towards the interface with the other organisation, aiming to form a hinge with the next location of care for their patients. These outward focused values reflect the way the organisations behave towards, interact with and therefore collaborate with each other.

Improvement asks for measurement.[10] When measuring patient safety culture a "snapshot" of this patient safety culture is captured which is called "the patient safety climate".[11] Patient safety climate reflects the professionals' perception of the organizational culture and can be measured through questionnaires.[12] Various

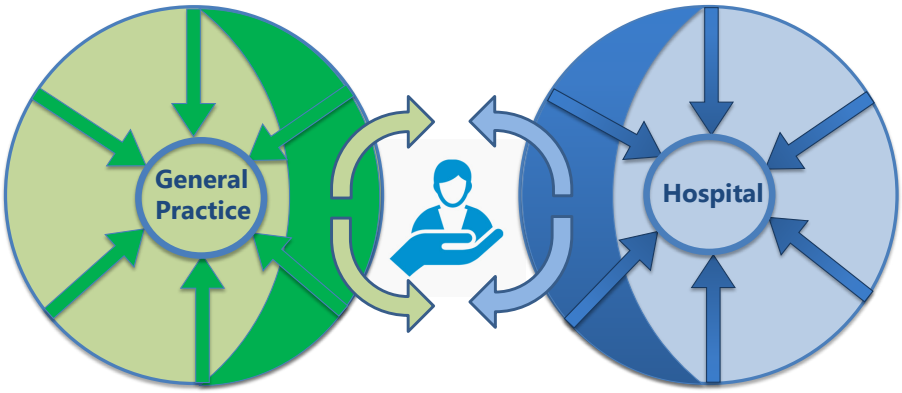

Figure 4.1 Schematic presentation of the position of transitional patient safety culture. *Transitional patient safety culture is part of safety culture within an organisation, but looking outward. Organisational patient safety culture looks inward.*

instruments have been developed to measure the patient safety climate within single organisations (e.g. Hospital Survey on Patient Safety Culture or HSOPSC for hospital, Systematic Culture inquiry On Patient safety in primary care or SCOPE for general practice).[13-15] A similar instrument is needed that assesses the transitional patient safety climates at the interface between different organisations that collaborate by caring for the same patients.

The aim of this study was to describe the construct of "transitional patient safety culture" and to validate the TRAnsitional patient safety Climate Evaluation (TRACE) questionnaire, developed for measuring transitional patient safety climate.

METHODS

Development and content validity

The development of the TRACE questionnaire was based on two existing patient safety culture questionnaires: The HSOPSC (acronym for: Hospital Survey on Patient Safety Culture) is a validated questionnaire measuring patient safety climate in hospitals, consisting of 42 items in eleven factors.[13] The SCOPE (Dutch acronym for Systematic Culture inquiry on Patient safety in Primary care) is a validated questionnaire to measure patient safety climate in general practice.[14] In developing the SCOPE, questions were derived from the Dutch HSOPSC and adjusted to fit general practice. The SCOPE questionnaire consists of 43 items in eight factors. Both questionnaires include sections on teamwork and handover (within general practice and within and between hospital units), incident reporting, adequacy of procedures and staffing, overall perceptions of patient safety, and expectations and actions of managers.

We used an iterative process to adjust these two questionnaires to form the TRACE questionnaire. First, all items of both questionnaires were reviewed and assessed on their fit for transitional patient safety culture. Items that did not fit transitional patient safety culture or could not be reformulated to fit transitional patient safety culture were deleted. Second, we reformulated questions to fit patient safety culture, which either meant changing a single word (e.g. "hospital unit" into "transitional care") or rewriting the whole question. Third, we added applicable items from questionnaires on mutual collaboration between general practitioners (GPs) and hospital physicians, as we consider collaboration as an expression of transitional patient safety culture.[16,17] We ended up with two reciprocal questionnaires for measuring patient safety at both sides of the transition. Several questions were mirrored: e.g. when a question asks about respect, we state both: "General practitioners treat me with respect" and "Hospital specialists treat me with respect". To establish content validity, patient safety experts and professionals from both general practice and hospital assessed the questionnaires. After consensus, the final TRACE questionnaire consisted of 20 items on transitional patient safety climate within three overarching themes: (1) transitional collaboration, (2) communication and (3) transitional patient safety. We also included a section with seven items on incident reporting and three questions on subjective assessment of patient safety in their own practice ("internal patient safety grade"), the other organisation ("external patient safety grade"), and transitional care (further referred to as "transitional patient safety grade"). The 20 items on transitional patient safety climate used a five-point Likert scale from "strongly disagree" to "strongly agree" or "never" to "always". The patient safety grades used a five-point Likert scale from "failing" to "excellent". Background questions assessed respondent characteristics and work-related information, e.g. the respondent's age, gender, function and working experience.

Validation

Data collection and participants

Data collection for validation of the questionnaire took place from September until November 2014 using the secure, online Net Questionnaire system (www.netqhealthcare.nl/en/). The TRACE questionnaire was digitally introduced in three regions in the Netherlands (Eindhoven, Hardenberg and Utrecht), within five different hospitals with their referring general practices. In total, the questionnaire was distributed digitally to 706 physicians; 309 in the 5 hospitals mainly among the departments of internal medicine, gastroenterology and cardiology and 397 GPs. The first invitation was dispersed by e-mail, followed by two reminders with an interval of two weeks. The data were automatically stored in the online system.

Statistical analysis

Exploratory factor analysis (EFA)
We performed an exploratory factor analysis (EFA) with Varimax rotation to investigate which factor structure would fit the data. Items not fitting into a larger factor were not excluded from the questionnaire. We performed Bartlett's test of sphericity; when significant ($p<0.001$) this would indicate that the data were appropriate for factor analysis. EFA models were computed using MPLUS 6.1, because this program allows analysing ordinal variables.[15] The decision on the most suitable model was based on the following fit indices: Chi-2, Root Mean Squared Error of Approximation (RMSEA), and Root Mean Square Residual (RMR). For the Chi-2, non-significant values (p above 0.05) are considered acceptable. An RMSEA $\leqslant$0.06 and RMR $\leqslant$0.08 indicate satisfactory model fit.[18] Based on Stevens et al., we decided to report only factor loadings above 0.40, which required at least 160 respondents.[19] The EFA was performed for the total population as well as for GPs and hospital physicians separately.

Reliability and construct validity
Mean factor scores were calculated by adding the values of each item response and dividing this total by the number of questions. Internal consistency of the factors was measured using Cronbach's alpha, both for the total population and separately for general practice and hospital. Intercorrelations between factors were calculated using Spearman's rho.

Construct validity is defined as the degree to which a test indeed measures what it claims to be measuring.[20] To assess construct validity, relations with other measures or values should be tested. Unfortunately, until now no measurement tool is created for the construct of transitional patient safety climate or anything closely related. As a surrogate for a related measurement tool we assessed the correlation with self-reported patient safety grades included at the end of the TRACE: internal ("*What is your opinion of patient safety in your own general practice/ hospital?"*), external ("*What is your opinion of patient safety in the hospital/ in general practice*"), and transitional patient safety grade ("*What is your opinion of patient safety in transitional care in your region?"*). We hypothesized that respondents who graded the transitional patient safety highly would also score higher on the items of the TRACE questionnaire than respondents with low transitional patient safety grades and that the correlation with the transitional patient safety grade would be higher than the correlation with both internal and external patient safety grade. This hypothesis was based on the relationship between patient safety culture and patient outcomes, found in multiple studies.[21-23] As transitional patient safety is part of the organizational patient safety culture, although looking outward, we expect transitional patient safety culture to be related to organizational (internal and external) patient safety, but especially with transitional patient safety.

The questionnaire contained positively as well as negatively worded items. Therefore, the negatively worded items were recoded to make a higher score always a more positive response. Descriptive statistics were used to summarize the characteristics of the respondents, namely age, gender, function and working experience. All statistical analyses were conducted using MPlus (for the EFA) (version 6.12) and SPSS (version 23).

Ethics

This validation study was part of a larger project on transitional patient safety, called the Transitional Incident Prevention Programme (TIPP).[24] According to Dutch law, this study was exempt of formal medical-ethical approval (medical-ethical review board UMC Utrecht, number 13/142). The development and validation of the TRACE questionnaire did not involve patients. The TRACE is an anonymous questionnaire, accessed by a general digital link.

RESULTS

In total, 162 individual questionnaires were returned from the three regions (97 from general practice and 65 from hospital; total response rate 23%). Table 4.1 describes the characteristics of the respondents, in total and separately for general practice and hospital.

The respondents in hospital and general practices significantly differed in gender and region, but not in age and working experience. In general practice, 61% of the respondents were female (N=59), while in hospital 75% was male (N=49, p<0.01). In the hospital respondents, the region of Hardenberg was under-represented compared to the GPs (p=0.04).

Exploratory factor analysis and item analysis

Table 4.2 shows item means, standard deviation (SD) and floor and ceiling effects. Item means ranged from 1.84 (B6. "*Hospital/ general practice informs us about improvements that have been made because of safety incidents*") to 4.01 (A5. "*Hospital specialists/ general practitioners treat me with respect*"). Both item B5 and B6 showed a floor effect of 35.8% and 40.7% respectively.

Bartlett's Test of sphericity was significant (p<0.001), so a factor analysis could be performed. EFA of the results of the total group of respondents did not lead to a significant and interpretable distribution of factors. The fit-indices reached an acceptable level in a 7-factor solution, which was difficult to interpret and left 3 items outside of a factor. We performed the EFA separately for general practice and hospital.

Table 4.1 Characteristics of respondents
Characteristics of respondents in total and separately for general practice and hospital physicians.

Characteristics		Total N=162	GP (n=97)	Hospital (n=65)
Gender *%(N)**	Male	53.7% (87)	39.2% (38)	75.4% (49)
	Female	46.4% (75)	60.8% (59)	24.6% (16)
Age *%(N)*	<39	31.5% (51)	29.9% (29)	33.8% (22)
	40-49	30.7% (50)	33.0% (32)	27.7% (18)
	50 and older	37.7% (61)	37.1% (36)	38.5% (25)
Work experience *%(N)*	0-10	42.0% (68)	36.1% (35)	50.8% (33)
	11-20	33.3% (54)	39.2% (38)	24.6 (16)
	21-30	20.4% (33)	20.6% (20)	20.0% (13)
	More than 30	4.3% (7)	4.1% (4)	4.6% (3)
Department *%(N)*	Internal medicine	-	-	13.8% (9)
	Gastro-enterology	-	-	27.6% (18)
	Cardiology	-	-	21.5% (14)
	Surgery			4.6% (3)
	Paediatrics			4.6% (3)
	Other	-	-	27.6% (18)
Region *%(N)*§	Hardenberg	17.3% (28)	22.7% (22)	9.2% (6)
	Utrecht	38.3% (62)	32.0% (31)	47.7% (31)
	Eindhoven	44.4% (72)	45.4% (44)	43.1% (28)
Practice organisation *%(N)*	Solo	-	22.7% (22)	-
	Multiple‡	-	40.2% (39)	-
	Healthcare centre	-	33.0% (32)	-
	With Pharmacy	-	4.1% (4)	-

GP=General practitioner
§ *Significant difference between GP and hospital, p<0.05*
‡ *multiple general practices in one building*

The EFA in hospital physicians showed the best fit in four factors: (1) collaboration (8 items), (2) speaking up (2 items), (3) communication on transitional incidents and improvement measures (6 items), and (4) transitional patient safety management (4 items). An overview of the four factors, the number of items within their factor loading is presented in Appendix 4.1. All but one item had a loading above the critical value of 0.40.[19] Item A6 "*We make agreements with the hospital/general practice about transitional care*" fitted best in factor 1 with a factor loading of 0.36. Model fit indices for this four-factor distribution were Chi-2 p=0.19, RMSEA of 0.04 and RMR of 0.05 Four items loaded on two factors, namely A5 "*Hospital specialists/ general practitioners treat me with respect*" (which loaded on factor 1 and 2), C1 "*General practitioners and hospital specialists discuss incidents in transitional care together*" (factor 1 and 3), C2 "*There are problems with patient safety in transitional care*" (factor 1 and 4), and C3 *"It is just by chance that more serious mistakes don't occur in transitional care"* (factor 1 and 4).

Table 4.2 Mean, standard deviation, missing, floor and ceiling effects per item.
n= recoded negative questions, SD=standard deviation

Item	Description	Total respondents			
		Mean	SD	Floor N (%)	Ceiling N (%)
A1	General practice and hospital collaborate well to provide patients the best of care.	3.51	0.81	1 (0.6%)	6 (3.7%)
A2	Exchange of information between general practitioner and hospital specialist goes well.	3.27	0.89	3 (1.9%)	5 (3.1%)
A3n	General practice and hospital are not well attuned to each other.	2.96	0.81	0 (0.0%)	1 (0.6%)
A4n	Problems often occur when information is exchanged between general practice and hospital.	2.55	0.87	7 (4.3%)	3 (1.9%)
A5	Hospital specialists/ general practitioners treat me with respect.	4.01	0.58	4 (2.5%)	24 (14.8%)
A6	We make agreements with the hospital/general practice about transitional care.	3.48	0.83	0 (0.0%)	9 (5.6%)
A7n	Things "fall through the cracks" when patients transition from general practice to hospital.	2.87	0.96	5 (3.1%)	2 (1.2%)
A8n	Things "fall through the cracks" when patients transition from hospital to general practice.	2.35	0.83	14 (8.6%)	2 (1.2%)
B1	I feel free to speak up if I see something that has a negative effect on transitional care.	3.81	0.72	1 (0.6%)	23 (14.2%)
B2	I feel free to question the decisions or actions of the hospital specialist/ general practitioner.	3.57	0.85	1 (0.6%)	22 (13.6%)
B3	We are informed by the hospital/ general practice about errors that occurred in our general practice.	2.18	0.84	30 (18.5%)	1 (0.6%)
B4	We inform the hospital/ general practice about errors that occur in their organisation.	2.86	0.89	7 (4.3%)	4 (2.5%)
B5	We inform the hospital/ general practice about improvements that have been made because of safety incidents.	2.00	1.00	58 (35.8%)	3 (1.9%)
B6	Hospital/ general practice informs us about improvements that have been made because of safety incidents.	1.84	0.87	66 (40.7%)	1 (0.6%)
C1	General practitioners and hospital specialists discuss incidents in transitional care together.	2.28	0.94	30 (18.5%)	1 (0.6%)
C2n	There are problems with patient safety in transitional care	2.66	0.84	6 (3.7%)	2 (1.2%)
C3n	It is just by chance that more serious mistakes don't occur in transitional care.	3.16	0.86	1 (0.6%)	6 (3.7%)
C4	In our general practice/ hospital, our procedures and systems are adequate to prevent mistakes in transitional care.	2.89	0.82	6 (3.7%)	1 (0.6%)
C5	In hospital/ general practice, the procedures and systems are adequate to prevent mistakes in transitional care.	2.69	0.82	8 (4.9%)	1 (0.6%)
C6	Incidents have led to positive changes in transitional care.	3.32	0.73	1 (0.6%)	5 (3.1%)

The EFA in general practice respondents resulted in 6 factors. (1) effect of collaboration (5 items), (2) speaking up (3 items), (3) improvement (3 items), (4) Procedures (2 items), (5) rest category (2 items), (6) item A7 "*things fall through the cracks when patients transition from general practice to hospital*." Items A4" Problems *often occur when information is exchanged between general practice and hospital"*, A6 "*We make agreements with the hospital/general practice about transitional care"*, B3 "*We are informed by the hospital/ general practice about errors that occurred in our general practice"*, and C1 "*General practitioners and hospital specialists discuss incidents in transitional care together"* did not load on any factor. Model fit indices for this six-factor distribution were: Chi-2 p=0.19, RMSEA of 0.04 and RMR of 0.05

We chose to use the hospital-based factor solution for our further analysis as this structure was best interpretable.

Table 4.3 Mean dimension scores in hospital and GP respondents, intercorrelations of the 4 factors and correlation with patient safety grades and number of incidents reported. N=162.
GP results are presented in italic.

Factors	Mean total (SD)	GP Mean (SD)	Hos Mean (SD)	Internal patient safety grade	Transi-tional patient safety grade	External patient safety grade	1	2	3	4
1 Collaboration	3.13 (0.51)	3.07 (0.42)	3.21 (0.62)	0.18 *0.31***	0.66*** *0.46***	0.53*** *0.33***	1			
2 Speaking up	3.69 (0.69)	3.71 (0.68)	3.67 (0.72)	0.14 *-0.01*	0.28* *0.13*	0.25* *0.04*	0.30* *0.15*	1		
3 Communi-cation on transitional incidents and improvement measures	2.41 (0.59)	2.33 (0.50)	2.54 (0.68)	-0.05 *0.03*	0.35*** *0.08*	0.08 *0.17*	0.39*** *0.11*	0.19 *0.08*	1	
4 Transitio-nal patient safety ma-nagement	2.85 (0.64)	2.76 (0.58)	2.98 (0.71)	0.41*** *0.33***	0.62*** *0.46***	0.46*** *0.40***	0.57*** *0.46***	0.25* *0.04*	0.24 *0.01*	1
Total TRACE	2.91 (0.42)	2.85 (0.33)	3.01 (0.51)	0.20* *0.31***	0.68*** *0.47***	0.47*** *0.39***	0.87*** *0.82***	0.46*** *0.30***	0.69*** *0.46***	0.68*** *0.64***
Number of reported TIs (median)	1-2 TIs repor-ted	1-2 TIs repor-ted	0	0.08 *0.05*	0.26* *0.10*	0.22 *0.11*	0.32*** *0.22*	0.05 *0.39***	0.26* *0.27***	0.10 *-0.04*

* *Correlation is significant at the 0.05 level (2-tailed).*
** *Correlation is significant at the 0.01 level (2-tailed)*
TI=Transitional incidents, GP=general practitioner. Correlations: Spearman's rho

Reliability and construct validity

The internal consistency for individual factors was acceptable when calculated for all respondents collectively (0.71 to 0.77) (Appendix 4.1). For general practice, the internal consistency was lower (0.63 to 0.72) compared to hospital (0.71 to 0.87). Table 4.3 shows the mean dimension scores, SD and correlations between the five factors and between the factors and the patient safety grades (internal, external and transitional). Mean dimension scores ranged from 2.41 (Communication on transitional incidents and improvement measures) to 3.69 (Speaking up) on a 1-5 scoring range. Correlation between factors was weak to moderate (Spearman's rho 0.19 to 0.57) for hospital and very weak to moderate (Spearman's rho 0.01 to 0.46) for GPs. The factors "Speaking up" (Spearman's rho 0.19 to 0.25 in hospital and 0.04 to 0.15 in GPs) and "Communication on transitional incidents and improvement measures" (Spearman's rho 0.19 to 0.39 in hospital and 0.01 to 0.11 in GPs) were poorly correlated to the other factors. Correlation between the total TRACE score and the transitional patient safety grade was 0.68 for hospital and 0.47 for GPs. The correlation with the internal and external patient safety grade was lower, as expected (Spearman's rho of 0.20 and 0.47 respectively for hospitals and 0.31 and 0.39 for GPs).

DISCUSSION

Main findings

In this study, we described the development of the TRACE questionnaire to measure transitional patient safety climate. We could not identify a structure that was valid for the whole group of respondents in both settings. However, analysis of hospital respondents revealed four relevant factors: (1) Collaboration, (2) Speaking up, (3) Communication on transitional incidents and improvement measures and (4) Transitional patient safety management. Differences in factors between hospital and general practice indicated that the concept of transitional patient safety culture differs between settings. Nonetheless, we believe that for improving transitional patient safety culture a single measurement instrument is needed that can be applied regionally, i.e. in actual collaborating hospitals and general practices. We therefore chose the hospital-derived factor solution for our further analysis, as this structure was best interpretable and relevant. Internal consistency for hospital respondents was good and for the GP respondents overall acceptable.

Interpretation of findings

The absence of a clear factor solution in the combined respondents group implies a different view on "transitional patient safety culture" in each setting. Indeed, formal transitional collaboration between hospital and general practice is still in its infancy with f.i. regional transitional agreements on chronic disease management or transitional incident reporting and learning[25,26] This can also explain the inability of items A6, B3, and C1 to load on any factor in the general practice population. It is not regular practice yet. However, development of a shared patient transitional safety culture is not unlikely, and might even be a goal in itself in order to achieve transitional safety. We therefore kept to our plan to develop one instrument. For this, we chose the best fit, being the factor distribution of the hospital.

Our hypothesis that the transitional patient safety grade would correlate more strongly with the total score and domain scores than the other patient safety grades was confirmed. Also, the transitional patient safety grade correlated moderately with the total score, which indicated that the construct of transitional patient safety climate and transitional patient safety are related but not the same as patient safety climate is only a precondition to patient safety.

Comparison to literature

The contrast we found between the factor loadings in general practice and hospital was not unexpected. For the development of the SCOPE questionnaire to measure patient safety in general practice, the HSOPSC was used as the basis. The EFA of the SCOPE also showed different factors, new items were introduced and other items excluded, for they did not fit any factor.[14] This is probably caused by a difference in concept of patient safety culture between general practice and hospital.[27] Hospitals and general practices are different worlds, where risks and nature of work vary. However, despite the differences between organisations, the need to collaborate in the care for the same patients is evident. [1,28] Hence, as debated above, patient safety culture needs a broader vision, overarching the interface between collaborating organisations, such as a hospital and their referring GP practices.[1] We tried to meet this broader scope and created a questionnaire measuring the transitional patient safety culture between connecting primary and secondary care organisations.

Strengths and limitations

A strength of this study was that we started the development of the TRACE-questionnaire from the theoretical construct of transitional patient safety culture which is required in unobservable constructs.[29] We tested the psychometric properties of this questionnaire in a broad population in three different Dutch

regions, five hospitals and their referring general practices, which adds to robustness of our findings.

This study also has some limitations. First, not finding an interpretable factor solution in the whole dataset forced us to do our analyses separately on GPs and hospital physicians, leading to smaller numbers and therefore less reliability. However, even in small numbers, an EFA can provide a valid factor structure if the factor loadings are high enough. Considering the number of 65 respondents from hospital, a factor loading of 0.6 to 0.7 would be sufficient which would lead to exclusion of some items in our questionnaire. The exclusion of these items would affect content validity negatively. Because in factor analysis not only numbers but also interpretability is leading, we decided not to exclude these items.[30] Though, we recommend validating the TRACE questionnaire in a larger group of respondents.

Second, the response rate was rather low (23%) although not unusual for an open population study. Since recruitment was voluntary participants may not have been completely representative for an open population, f.i. fore runners in quality and safety management might be overrepresented. However, for a psychometric study this is of less importance since the focus is on clustering of items and not on the outcome score of the questionnaire.

Third, the hospital physician group we approached consisted of mainly internal medicine specialties. Yet, many adverse events occur in surgical settings.[31,32] Therefore, the validation of the questionnaire may be biased by selection. However, whether surgical patient safety culture actually differs from internal medicine specialties is debatable according to recent findings.[33] Nonetheless, both cross validation of factor solutions and confirmative factor analysis within different specialties is recommended to confirm the factor structure we found.

Implications of our findings

We argue that transitional patient safety culture will develop over the coming years. With the TRACE questionnaire, we provide an instrument for monitoring this expected development. However, for validity reasons the instrument itself needs monitoring too. Therefore, we recommend further scrutiny of its psychometric properties in larger and international populations by both exploratory and confirmatory factor analysis.

Conclusion

The TRACE questionnaire measures transitional safety climate, with a construct that fits the hospital setting, but should be critically appraised for the GP setting. Nonetheless, TRACE has acceptable psychometric characteristics for both hospital and GP settings. Future research should confirm the factor structure of the TRACE questionnaire.

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WHAT IS NEW?

Key findings
- 'TRACE', a survey aimed to measure transitional patient safety culture in both general practice and hospital was developed and validated.
- TRACE consists of four dimensions with fair to good reliability for both healthcare settings: collaboration, speaking up, communication about incidents and improvement and transitional patient safety management.
- The TRACE better fits the hospital than the GP setting

What this adds to what is known?
- The concept of 'transitional patient safety culture' is described. It concerns safety culture among healthcare providers involved in car transitions between primary and secondary care.
- Differences in factors between hospital and general practice indicated that the concept of transitional patient safety culture differs between general practice and hospital settings

What is the implication, what should change now?
- Transitional patient safety culture will develop over the coming years. With the TRACE questionnaire, we provide an instrument for monitoring this expected development. However, in the evolving of transitional patient safety culture, the psychometric properties of the TRACE should be reconfirmed over time.

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APPENDIX 4.1 FACTOR LOADINGS AND INTERNAL CONSISTENCY OF THE TRACE QUESTIONNAIRE

GP= general practitioner, Hos=hospital, α Cronbach's alpha

Item	Description	F1	F2	F3	F4	α	α GP	α Hos	GP F1	GP F2	GP F3	GP F4	GP F5	GP F6
1. Collaboration						0.77	0.63	0.87						
A1	General practice and hospital collaborate well to provide patients the best of care.	0.70							0.78					
A2	Exchange of information between general practitioner and hospital specialist goes well.	0.78							0.80					
A3n	General practice and hospital are not well attuned to each other.	0.80							0.63					
A4n	Problems often occur when information is exchanged between general practice and hospital.	0.73							*	*	*	*	*	*
A5	Hospital specialists/ general practitioners treat me with respect.	0.52								0.84				
A6	We make agreements with the hospital/general practice about transitional care.	0.36*							*	*	*	*	*	*
A7n	Things "fall through the cracks" when transferring patient from general practice to hospital/ when patients transition from general practice to hospital.	0.89									0.61			
A8n	Things "fall through the cracks" when transferring patient from hospital to general practice/ when patients transition from hospital to general practice.	0.73								0.60				
2. Speaking up						0.71	0.71	0.71						
B1	I feel free to speak up if I see something that has a negative effect on transitional care.		0.88									0.74		

APPENDIX 4.1 Continued

Item	Description	F1	F2	F3	F4	α	α GP	α Hos	GP F1	GP F2	GP F3	GP F4	GP F5	GP F6
B2	I feel free to question the decisions or actions of the hospital specialist/ general practitioner.		0.64									0.84		
3. Communication on transitional incidents and improvement measures						0.75	0.66	0.83						
B3	We are informed by the hospital/ general practice about errors that occurred in our general practice.			0.76					*	*	*	*	*	*
B4	We inform the hospital/ general practice about errors that occur in their organisation.			0.81								0.52		
B5	We inform the hospital/ general practice about improvements that have been made because of safety incidents.			0.75									0.76	
B6	Hospital/ general practice informs us about improvements that have been made because of safety incidents.			0.85									0.83	
C1	General practitioners and hospital specialists discuss incidents in transitional care together.			0.49					*	*	*	*	*	*
C6	Incidents have led to positive changes in transitional care.			0.53									0.62	
4. Transitional patient safety management						0.77	0.72	0.83						
C2n	There are problems with patient safety in transitional care				0.48				0.57					
C3n	It is just by chance that more serious mistakes don't occur in transitional care.				0.49				0.52					
C4	In our general practice/ hospital, our procedures and systems are adequate to prevent mistakes in transitional care.				0.95									0.84
C5	In hospital/ general practice, the procedures and systems are adequate to prevent mistakes in transitional care.				0.87									0.90

* *Not significantly related*

TRACE-huisartsenpraktijk

TRACE; TRAnsitional patient safety Climate Evaluation

In deze vragenlijst wordt uw mening gevraagd over onderwerpen op het gebied van transmurale patiëntveiligheid, onbedoelde gebeurtenissen, fouten en het melden van incidenten in uw huisartsenpraktijk, in het ziekenhuis en hiertussen. Het invullen zal circa 10 minuten in beslag nemen.

Transmurale zorg wordt gedefinieerd als: de zorg tussen huisartspraktijk en ziekenhuis en andersom.
Een **transmuraal incident** wordt gedefinieerd als: elke onbedoelde gebeurtenis die zich afspeelt in de zorg in de overgang van de eerste naar de tweede lijn of vice versa en geleid heeft, had kunnen leiden of nog zal leiden tot schade voor de patiënt.
Onder **onbedoelde gebeurtenis** wordt hier mede begrepen: (om het even welk soort) vergissing, fout, ongeval, ongeluk of afwijking.
Patiëntveiligheid wordt gedefinieerd als: het (nagenoeg) ontbreken van (de kans op) aan de patiënt toegebrachte schade (lichamelijk of psychisch), die is ontstaan door het niet volgens de professionele standaard handelen van hulpverleners en/of door tekortkoming van het zorgsysteem.

A: Samenwerking

	Zeer mee oneens	Mee oneens	Geen van beide	Mee eens	Zeer mee eens
A1. Huisartsenpraktijk en ziekenhuis werken goed samen om patiënten de beste zorg te verlenen.	①	②	③	④	⑤
A2. Er is een goede overdracht tussen huisarts en ziekenhuisspecialist.	①	②	③	④	⑤
A3. De huisartspraktijk en ziekenhuis stemmen niet goed af.	①	②	③	④	⑤
A4. Problemen ontstaan vaak bij de uitwisseling van informatie tussen huisartspraktijk en ziekenhuis.	①	②	③	④	⑤
A5. De specialisten uit het ziekenhuis behandelen mij met respect.	①	②	③	④	⑤
A6. Wij maken afspraken over de transmurale zorg met het ziekenhuis.	①	②	③	④	⑤
A7. Er vallen zaken “tussen wal en schip” als patiënten **van huisartspraktijk naar ziekenhuis** worden gestuurd.	①	②	③	④	⑤
A8. Er vallen zaken “tussen wal en schip” als patiënten v**an ziekenhuis naar huisartspraktijk** worden gestuurd.	①	②	③	④	⑤

B: Veiligheid voor feedback

	Nooit	Zelden	Soms	Meestal	Altijd
B1. Ik voel me vrij om te spreken als ik iets zie dat mogelijk een negatief effect heeft op de transmurale zorg.	①	②	③	④	⑤
B2. Ik voel me vrij om beslissingen of acties van de ziekenhuisspecialist ter discussie te stellen.	①	②	③	④	⑤

C: Communicatie over incidenten en verbetermaatregelen

	Nooit	Zelden	Soms	Meestal	Altijd
C1. Ik word geïnformeerd vanuit het ziekenhuis over vergissingen die bij ons in de huisartspraktijk voorkomen.	①	②	③	④	⑤
C2. Ik informeer het ziekenhuis over vergissingen die bij hen voorkomen.	①	②	③	④	⑤
C3. Ik informeer het ziekenhuis over verbetermaatregelen die genomen zijn naar aanleiding van incidenten in de zorg.	①	②	③	④	⑤
C4. Het ziekenhuis informeert mij over verbetermaatregelen die genomen zijn naar aanleiding van incidenten in de zorg.	①	②	③	④	⑤
C5. Huisartsen bespreken samen met ziekenhuisspecialisten voorgekomen fouten of incidenten in de transmurale zorg.	①	②	③	④	⑤
C6. Incidenten hebben tot positieve veranderingen geleid in de transmurale zorg.	①	②	③	④	⑤

4

D. Transmurale patiëntveiligheidsmanagement

	Zeer mee oneens	Mee oneens	Geen van beide	Mee eens	Zeer mee eens
D1. Er zijn problemen met de patiëntveiligheid in de transmurale zorg.	①	②	③	④	⑤
D2. Dat de ernstiger fouten in de transmurale zorg niet (vaker) gebeuren berust eigenlijk op toeval.	①	②	③	④	⑤
D3. De procedures en systemen in de huisartspraktijk zijn adequaat om vergissingen in de transmurale zorg te voorkomen.	①	②	③	④	⑤
D4. De procedures en systemen in het ziekenhuis zijn adequaat om vergissingen in de transmurale zorg te voorkomen.	①	②	③	④	⑤

E: Melden van incidenten

E1. Als u **in uw eigen praktijk** een incident meemaakt, meldt u dit dan?
- O JA, ik meld dit
- O NEE, ik meld dit niet

E2. Hoe vaak heeft u in de laatste 12 maanden een melding voor incidenten ingevuld en ingediend? Geef één antwoord.
- O geen meldingen
- O 1 tot 2 meldingen
- O 3 tot 5 meldingen
- O 6 tot 10 meldingen
- O 11 tot 20 meldingen
- O 21 meldingen of meer

E3. Als u **in de transmurale zorg** een incident meemaakt, meldt u dit dan op enigerlei wijze?
- O JA, ik meld dit-> ga verder met **vraag D4**
- O NEE, ik meld dit niet -> ga verder met **vraag D7**

E4. Indien u met JA antwoordde; hoe meldt u dit dan?
- O Bij mijn eigen praktijk
- O Bij een bestaand MIP-systeem van het ziekenhuis
- O Bij de betreffende afdeling
- O Bij de betreffende arts
- O Persoonlijk contact met het ziekenhuis

E5. Heeft u hierop iets terug gehoord van het ziekenhuis?
- O Ja
- O Nee

TRACE (Transitional patient safety Climate Evaluation)

E6. Hoe vaak heeft u in de laatste 12 maanden een incident in de transmurale zorg gemeld?

O geen meldingen
O 1 tot 2 meldingen
O 3 tot 5 meldingen
O 6 meldingen of meer

E7. Indien u bij vraag D3 met NEE antwoordde; waarom niet?

O Ik weet niet waar
O Ik voel me niet vrij dit te melden
O Ik meld geen incidenten
O Er gebeuren geen transmurale incidenten bij ons
O Het had geen gevolgen voor de patiënt
O Opgelost zonder melding
O Tijdgebrek
O Anders, nl….

F: Waardering voor patiëntveiligheid

F1. Geef **uw eigen praktijk** een beoordeling voor patiëntveiligheid. Geef één antwoord.
O Slecht O Matig O Acceptabel O Goed O Uitstekend

F2. Geef een beoordeling voor patiëntveiligheid **van de transmurale zorg.** Geef één antwoord.
O Slecht O Matig O Acceptabel O Goed O Uitstekend

F3. Geef een beoordeling voor patiëntveiligheid **in het ziekenhuis.** Geef één antwoord.
O Slecht O Matig O Acceptabel O Goed O Uitstekend

TRACE-ziekenhuis

TRACE; TRAnsitional patient safety Climate Evaluation

In deze vragenlijst wordt uw mening gevraagd over onderwerpen op het gebied van transmurale patiëntveiligheid, onbedoelde gebeurtenissen, fouten en het melden van incidenten in uw huisartsenpraktijk, in het ziekenhuis en hiertussen. Het invullen zal circa 10 minuten in beslag nemen.

Transmurale zorg wordt gedefinieerd als: de zorg tussen huisartspraktijk en ziekenhuis en andersom.
Een **transmuraal incident** wordt gedefinieerd als: elke onbedoelde gebeurtenis die zich afspeelt in de zorg in de overgang van de eerste naar de tweede lijn of vice versa en geleid heeft, had kunnen leiden of nog zal leiden tot schade voor de patiënt.
Onder **onbedoelde gebeurtenis** wordt hier mede begrepen: (om het even welk soort) vergissing, fout, ongeval, ongeluk of afwijking.
Patiëntveiligheid wordt gedefinieerd als: het (nagenoeg) ontbreken van (de kans op) aan de patiënt toegebrachte schade (lichamelijk of psychisch), die is ontstaan door het niet volgens de professionele standaard handelen van hulpverleners en/of door tekortkoming van het zorgsysteem.

A: Samenwerking

	Zeer mee oneens	Mee oneens	Geen van beide	Mee eens	Zeer mee eens
A1. Huisartsenpraktijk en ziekenhuis werken goed samen om patiënten de beste zorg te verlenen.	①	②	③	④	⑤
A2. Er is een goede overdracht tussen huisarts en ziekenhuisspecialist.	①	②	③	④	⑤
A3. De huisartspraktijk en ziekenhuis stemmen niet goed af.	①	②	③	④	⑤
A4. Problemen ontstaan vaak bij de uitwisseling van informatie tussen huisartspraktijk en ziekenhuis.	①	②	③	④	⑤
A5. Huisartsen behandelen mij met respect.	①	②	③	④	⑤
A6. Wij maken afspraken over de transmurale zorg met de huisartsen.	①	②	③	④	⑤
A7. Er vallen zaken “tussen wal en schip” als patiënten **van huisartspraktijk naar ziekenhuis** worden gestuurd.	①	②	③	④	⑤
A8. Er vallen zaken “tussen wal en schip” als patiënten v**an ziekenhuis naar huisartspraktijk** worden gestuurd.	①	②	③	④	⑤

B: Veiligheid voor feedback

	Nooit	Zelden	Soms	Meestal	Altijd
B1. Ik voel me vrij om te spreken als ik iets zie dat mogelijk een negatief effect heeft op de transmurale zorg.	①	②	③	④	⑤
B2. Ik voel me vrij om beslissingen of acties van een huisarts ter	①	②	③	④	⑤

C: Communicatie over incidenten en verbetermaatregelen

	Nooit	Zelden	Soms	Meestal	Altijd
C1. Ik word geïnformeerd vanuit de huisartsen over vergissingen die bij ons in het ziekenhuis voorkomen.	①	②	③	④	⑤
C2. Ik informeer huisartsen over vergissingen die bij hen voorkomen.	①	②	③	④	⑤
C3. Ik informeer huisartsen over verbetermaatregelen die genomen zijn naar aanleiding van incidenten in de zorg.	①	②	③	④	⑤
C4. Huisartsen informeren mij over verbetermaatregelen die genomen zijn naar aanleiding van incidenten in de zorg.	①	②	③	④	⑤
C5. Huisartsen bespreken samen met ziekenhuisspecialisten voorgekomen fouten of incidenten in de transmurale zorg.	①	②	③	④	⑤
C6. Incidenten hebben tot positieve veranderingen geleid in de transmurale zorg.	①	②	③	④	⑤

D: Transmurale patiëntveiligheids management

	Zeer mee oneens	Mee oneens	Geen van beide	Mee eens	Zeer mee eens
D1. Er zijn problemen met de patiëntveiligheid in de transmurale zorg.	①	②	③	④	⑤
D2. Dat de ernstiger fouten in de transmurale zorg niet (vaker) gebeuren berust eigenlijk op toeval.	①	②	③	④	⑤
D3. De procedures en systemen in de huisartspraktijk zijn adequaat om vergissingen in de transmurale zorg te voorkomen.	①	②	③	④	⑤
D4. De procedures en systemen in het ziekenhuis zijn adequaat om vergissingen in de transmurale zorg te voorkomen.	①	②	③	④	⑤

E: Melden van incidenten

E1. Als u **op uw afdeling** een incident meemaakt, meldt u dit dan?
- O JA, ik meld dit
- O NEE, ik meld dit niet

E2. Hoe vaak heeft u in de laatste 12 maanden een melding voor incidenten ingevuld en ingediend? Geef één antwoord.
- O geen meldingen
- O 1 tot 2 meldingen
- O 3 tot 5 meldingen
- O 6 tot 10 meldingen
- O 11 tot 20 meldingen
- O 21 meldingen of meer

E3. Als u **in de transmurale zorg** een incident meemaakt, meldt u dit dan op enigerlei wijze?
- O JA, ik meld dit-> ga verder met **vraag D4**
- O NEE, ik meld dit niet -> ga verder met **vraag D7**

E4. Indien u met JA antwoordde; hoe meldt u dit dan?
- O Bij mijn maatschap/ divisie/ afdeling
- O Bij een bestaand MIP-systeem van het ziekenhuis
- O Bij een andere afdeling
- O Bij de desbetreffende huisarts

E5. Heeft u hierop iets terug gehoord van de huisarts?
- O Ja
- O Nee

TIPP!, versie 1, 29 juli 2013

E6. Hoe vaak heeft u in de laatste 12 maanden een incident in de transmurale zorg gemeld?

O geen meldingen
O 1 tot 2 meldingen
O 3 tot 5 meldingen
O 6 meldingen of meer

E7. Indien u bij vraag D3 met NEE antwoordde; waarom niet?

O Ik weet niet waar
O Ik voel me niet vrij dit te melden
O Ik meld geen incidenten
O Er gebeuren geen transmurale incidenten bij ons
O Het had geen gevolgen voor de patiënt
O Opgelost zonder melding
O Tijdgebrek
O Anders, nl….

F: Waardering voor patiëntveiligheid

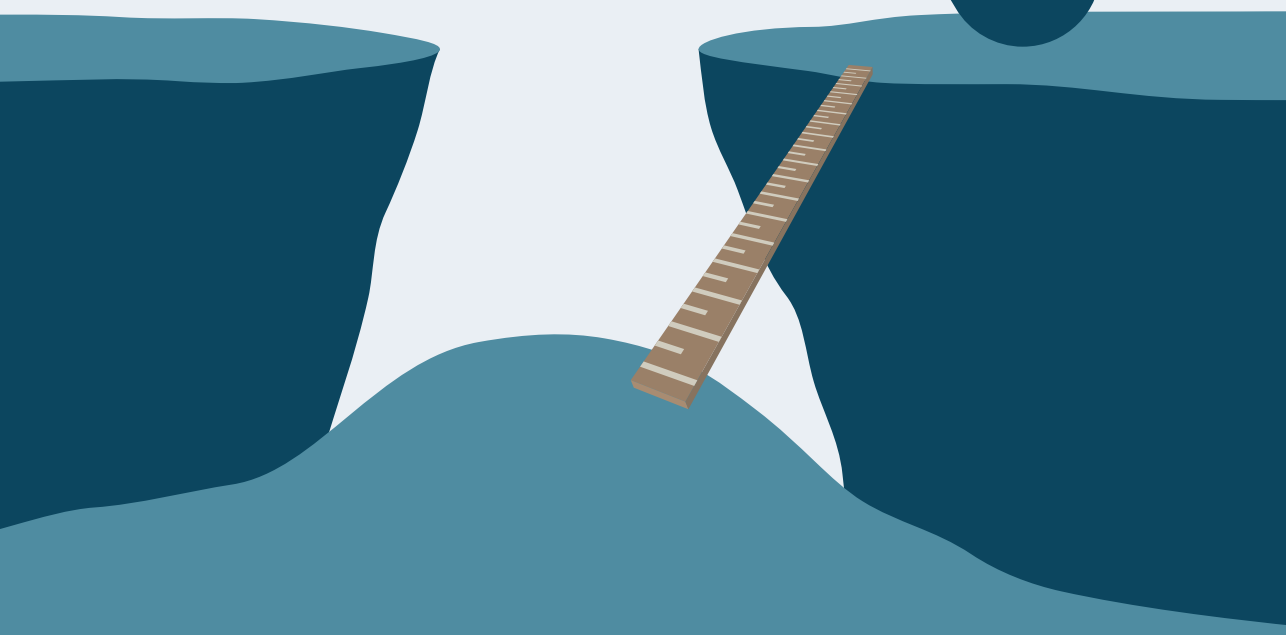
F1. Geef **uw eigen afdeling** een beoordeling voor patiëntveiligheid. Geef één antwoord.
O Slecht O Matig O Acceptabel O Goed O Uitstekend

F2. Geef een beoordeling voor patiëntveiligheid **van de transmurale zorg.** Geef één antwoord.
O Slecht O Matig O Acceptabel O Goed O Uitstekend

F3. Geef een beoordeling voor patiëntveiligheid **bij de huisartsen.** Geef één antwoord.
O Slecht O Matig O Acceptabel O Goed O Uitstekend

Under review

5



THE TRANSITIONAL RISK AND INCIDENT QUESTIONNAIRE (TRIQ) IS A VALID AND RELIABLE INSTRUMENT TO MEASURE TRANSITIONAL PATIENT SAFETY FROM THE PATIENTS' PERSPECTIVE

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ABSTRACT

Objectives

This study describes the development and validation of the Transitional Risk and Incident Questionnaire (TRIQ), which measures transitional patient safety from the patients' perspective.

Methods

The TRIQ questionnaire was developed based on literature review, tested in the target group using a think-aloud procedure, and validated by a cross-sectional study among patients receiving healthcare at the interface between general practice and hospital care in two regions in the Netherlands. Exploratory factor analysis (EFA) was performed and internal consistency was assessed. The relationship between the occurrence of transitional safety incidents (TSI) as measured by the TRIQ questionnaire and relational continuity, and between TSI occurrence and overall rating of transitions was assessed.

Results

In total, 451 questionnaires were used for analysis. The EFA provided a four-factor solution: 1) personal relation with general practitioner, 2) personal relation with hospital physician, 3) information exchange, and 4) treatment consistency. Internal consistency was good (composite reliability 0.75-0.95). An experienced TSI was related to a poorer relational continuity both with the general practitioner and hospital, and with a lower overall rating of all transitions.

Conclusions

The TRIQ questionnaire is a valid and reliable questionnaire to measure transitional patient safety from the patients' perspective.

INTRODUCTION

Patient safety incidents are common in healthcare at all levels, and safeguarding the patient from any unintended or unexpected incident is a major challenge for healthcare professionals. To prevent safety incidents in patients who are treated concurrently by multiple physicians or in multiple settings, communication and handover of information between the professionals is vital.[1] As the patient is the only constant factor, he or she is the only one that could assess the entire patient journey and give feedback on the quality and safety of received care. Therefore, the patients' perception is essential in looking at transitional patient safety.[2,3]

As patients report different safety issues than healthcare professionals, excluding patients will lead to a biased view on transitional patient safety.[4,5] Because most interventions to improve patient safety are initiated from a professionals' perspective, they may not be fully tailored to the patients' needs, and as a result they may only suboptimally affect patient outcomes.[6]

Therefore, we need a patient reported outcome measure (PROM) to accurately identify transitional patient safety issues and measure the effect of transitional safety interventions.[7-9] PROMs are available that measure related constructs to transitional safety such as continuity of care (a broader concept including continuity within a single organisation),[10-13] one way transitions like admission or discharge,[14,15] or safety in one specific patient group such as cancer patients.[16] Yet, a PROM measuring the generic concept of patient safety in healthcare transitions is not available.

The aim of this study was to describe the development and validation of the Transitional Risk and Incident Questionnaire (TRIQ), developed for measuring transitional patient safety from the patients' perspective.

METHODS

Setting

This study is conducted in the context of the Transitional Incident Prevention Programme (TIPP), a complex intervention study in the Netherlands aiming to improve transitional patient safety.[17]

Questionnaire development and content validity

We defined transitional safety incidents (TSIs) as any unintended or unexpected incident which could have or did lead to harm for one or more patients at transitions between care settings. As a first step in development of the TRIQ, we performed a literature study on frameworks related to transitional patient safety

and PROMs assessing related concepts, i.e. continuity of care, coordination of care, integrated care, self-care, patient satisfaction, discharge, and referral. We based our questionnaire on the conceptual framework for continuity of care by Reid *et al.* because its concepts are relevant for transitional safety as well.[18] Reid's framework identifies three different types of continuity of care: relational continuity, informational continuity and management continuity. Relational continuity encompasses the ongoing relationship between patient and healthcare provider over time, informational continuity means that information on earlier events is available for present care delivery, and management continuity ensures that care received from different providers is linked in a coherent way.[18] Yet, the framework consists of continuity both within and between healthcare settings. The aim of our questionnaire was to explicitly focus on continuity *between* distinct healthcare settings and its outcome in terms of patient safety: the prevention of harm and occurrence of incidents between healthcare settings (transitional patient safety). Therefore, we took Reid's framework as a basis for our questions. We considered informational and management continuity as vital for safe care transitions,[18] but in case of our questionnaire, only when directed at safety in care transitions between healthcare settings instead of within one healthcare setting. We did not consider Reid's domain of relational continuity an aspect of transitional patient safety in itself. Yet, we included it in our questionnaire as we consider lack of relational continuity as a risk factor for TSIs.[18] Aller et al. developed the CCAENA questionnaire based on Reid's framework, assessing care continuity across levels from the patients' perspective.[19] Although the concept of the CCAENA was closely related to our search for a questionnaire measuring transitional patient safety, we concluded that it did not fit our purpose. The CCAENA proved too extensive and was not suitable to the Dutch setting. Therefore, we developed a new questionnaire that among others includes parts of Aller's questionnaire which we adapted to the concept of transitional patient safety measuring harm and occurrence of incidents, and applied it to the Dutch healthcare system.

In the next step, we used an iterative method to construct items and presented them to patient safety experts, healthcare professionals and a patient panel. In the final development step, we performed a think-aloud process in which patients were interviewed and asked to think aloud when reading and answering the questions.[20] Interviews were audiotaped and the interviewer registered reactions indicating difficulties in instructions and item wording or meaning. Patients were asked to comment on the length and completeness of the questionnaire. The initial questionnaire was adjusted twice during this process.

Content of the TRIQ questionnaire

The final version consisted of 24 items. Eight items assessed relational continuity on a four-point scale from "always" to "never" or "very much" to "very little".

Sixteen items of the TRIQ measured informational or management discontinuity in healthcare transitions, as experienced by the patients. These sixteen items regarded all transitions between hospital and general practitioners, i.e. referral, hospital discharge, and joint care programs. All answers were reported on a four-point scale including "Yes", "Partially", "No" or "I don't know". If answers suggested discontinuity, patients were asked to explain their answer in a free-text field. The questionnaire is available online in appendix 5.1 (original Dutch version used for the validation) or in appendix 5.2 (English, translated version). We considered all patient reported problems as a possible TSI. We identified the definite TSIs by assessing all patient reported problems from the patient elaboration in the free text field. We considered the response category "I don't know" as no indication of a TSI. Finally, we included three items rating satisfaction with the experienced transition on a five-point scale ranging from "very bad" to "very good" with a "not applicable" option.

Validation process

Between November 2014 and January 2015, patients who were treated both in primary and secondary care were requested to fill in the TRIQ questionnaire, either online at home or on laptops at the hospital's outpatient clinic. Participants were selected from the departments of gastroenterology, cardiology and internal medicine of the St. Antonius Hospital (a specialised urban hospital with 848 beds in Nieuwegein), Diakonessenhuis (an urban hospital with 480 beds in Utrecht), University Medical Center Utrecht (a university hospital with 1042 beds in Utrecht) and Röpcke-Zweers Hospital (a rural hospital with 197 beds in Hardenberg). Patients were asked to participate at the moment they left the outpatient clinic after a visit. On request, patients could be assisted by medical students, who were trained to guide patients through the questionnaire without influencing their answers. Unfortunately, for organizational reasons we were not able to exactly determine the number of patients that were invited to participate. Therefore, we were not able to calculate an exact response rate. We analysed only those questionnaires in which patients had at least answered the first TSI identifying question C1 (appendix 5.1 and 5.2).

Statistical analysis

We assessed item completion and response percentages per item.

Exploratory factor analysis (EFA)

We performed an EFA with Geomin (oblique) rotation to investigate which factor structure would fit the data. Items not fitting into a larger factor were not excluded from the questionnaire because of the formative nature of the questionnaire.[21] We performed Bartlett's test of sphericity; when significant ($p<0.001$) this would indicate

that the data were appropriate for factor analysis. Exploratory factor analysis models were computed using MPLUS 6.1, as this program allows factor analysis of binary and ordered categorical variables.[22] The decision on the most suitable model was based on the following fit indices: Root Mean Squared Error of Approximation (RMSEA), Comparative Fit Index (CFI), Tucker Lewis Index (TLI), and Standardized Root Mean Square Residual (SRMR). An RMSEA≤0.06, CFI/TLI≥0.95 and SRMR ≤0.08 indicate satisfactory model fit.[22] Based on Stevens et al., we decided to report only factor loadings above 0.26, which required at least 400 respondents.[23]

Reliability and construct validity

Internal consistency of the factors was measured using Guttman's lower bound (GLB $\lambda 2$) and composite reliability because these measures are more suitable for dichotomous response data than Cronbach's alpha.[24,25] A GLB and composite reliability above 0.7 indicate acceptable internal consistency. Intercorrelations between factors were calculated. Construct validity is defined as the degree to which a test indeed measures what it claims to be measuring.[26] To assess construct validity, we computed the relationship between an experienced TSI as identified by the TRIQ with relational continuity and with a rating of satisfaction with the transition (discharge, referral or concurrent care). We hypothesized that respondents who experienced a TSI would rate both their relational continuity with either the general practitioner or hospital physician and their satisfaction with the transition lower than patients who did not experience a TSI. Also, we expected that patients with comorbidity or polypharmacy or a lower level of education would experience more incidents. Descriptive statistics were used to summarize the characteristics of the respondents, namely age, gender, level of education, ethnicity, comorbidity, polypharmacy, and the type of transitions that patients had experienced in the last six months. We used Mann-Whitney U, Chi^2 and Chi^2-for-trend to calculate the relationship between incidents and patient characteristics and between incidents and relational continuity and overall ratings of transitional patient safety. All statistical analyses were conducted using MPlus (for the EFA) (version 6.12) and SPSS (version 23).

Ethics

This study was exempted from ethical assessment by the medical ethic review committee of the University Medical Center Utrecht, Utrecht, the Netherlands (METC number 13/142).

RESULTS

Participants

In total, 458 questionnaires were returned, of which seven were excluded because all incident identifying questions were missing. This resulted in 451 questionnaires eligible for analysis. Response rate was 33.6% in the Utrecht and Nieuwegein area. Seven respondents stopped filling in the questionnaire halfway, leading to missing data halfway (from question D1 to baseline characteristics N=444, appendix 5.1 and 5.2).

The mean respondents' age was 64 years and gender was equally distributed (51% female) (Table 5.1). Seventy percent of patients had comorbidity and 44% of patients used at least 5 types of medication (polypharmacy). After reclassification, 533 transitional incidents were reported by 234 out of 451 patients (53%).

Most patients visited one to three different GPs and one to five different hospital physicians in the past year. The majority of patients had a high or very high level of confidence in their treating physicians in both general practice and hospital (Table 5.2).

Table 5.1 Baseline Characteristics of included patients N= 444

		Overall	No TSI N= 210	TSI N= 234
Female sex		226 (50.9%)	105 (50.0%)	121 (51.7%)
Age (median, range)		64 (19-99)	65 (20-89)	63 (19-99)
Polypharmacy (% yes)*		196% (44.1)	79 (36.4%)	117 (50.0%)
Co-morbidities*	0	132 (29.7%)	73 (33.6%)	59 (25.2%)
	1-2	264 (59.5%)	124 (57.1%)	140 (59.8%)
	3-5	51 (11.5%)	18 (8.3%)	33 (14.2%)
	≥6	3 (0.7%)	1 (0.5%)	2 (0.9%)
Education	Primary education	185 (41.7%)	91 (43.3%)	94 (40.2%)
	Secondary education	112 (25.2%)	52 (24.8%)	60 (25.6%)
	Higher education	147 (33.1%)	67 (31.9%)	80 (34.2%)
Ethnicity	Dutch	394 (88.7%)	189 (90.0%)	205 (87.6%)
	Not Dutch	50 (11.3%)	21 (10.0%)	29 (12.4%)
Transition past six months	Discharged from hospital*	85 (19.1%)	30 (13.8%)	55 (23.5%)
	Referred to hospital	178 (40.1%)	74 (34.1%)	104 (44.4%)
	Outpatient treatment	380 (85.6%)	181 (83.4%)	199 (85.0%)

* *Significant difference p<0.05*

Table 5.2 Distribution of answers in relational continuity, overall agreement and the relationship with transitional safety incidents, *%(N)*

		Overall	No TSI	TSI	P*
Do you see the same GP at every visit?	Always	221 (49.1%)	111 (50.9%)	110 (47.4%)	0.299
	Usually	195 (43.3%)	91 (41.7%)	104 (44.8%)	
	Sometimes	24 (5.3%)	11 (5.0%)	13 (5.6%)	
	Never	10 (2.2%)	5 (2.3%)	5 (2.2%)	
Do you see the same hospital physician at every visit?	Always	285 (63.3%)	154 (70.6%)	131 (56.5%)	0.001
	Usually	121 (26.9%)	50 (22.9%)	71 (30.6%)	
	Sometimes	25 (5.6%)	9 (4.1%)	16 (6.9%)	
	Never	19 (4.2%)	5 (2.3%)	14 (6.0%)	
How many different GPs have you seen in the past year?	1	237 (52.7%)	127 (58.3%)	110 (47.4%)	0.037
	2-3	198 (44.0%)	86 (39.4%)	112 (48.3%)	
	>3	15 (3.3%)	5 (2.3%)	10 (4.3%)	
How many different hospital physicians have you seen in the past year?	1	225 (50.0%)	126 (57.8%)	99 (42.7%)	0.002
	2-5	215 (47.8%)	90 (41.3%)	125 (53.9%)	
	5-10	9 (2.0%)	1 (0.5%)	8 (3.4%)	
	>10	1 (0.2%)	1 (0.5%)	0 (0.0%)	
Do you have confidence in your GP's professional ability?	Very high	30.2% (136)	31.7% (69)	28.9% (67)	0.070
	High	60.0% (270)	62.4% (136)	57.8% (134)	
	Low	8.0% (36)	4.6% (10)	18.6% (26)	
	Very low	1.8% (8)	1.4% (3)	2.2% (5)	
Do you have confidence in your hospital physician's professional ability?	Very high	170 (37.8%)	99 (45.4%)	71 (30.6%)	0.000
	High	268 (59.6%)	119 (54.6%)	149 (64.2%)	
	Low	12 (2.7%)	0 (0.0%)	12 (5.2%)	
	Very low	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Does your GP understand what you tell him/her?	Always	269 (59.8%)	145 (66.5%)	124 (53.4%)	0.002
	Usually	153 (34.0%)	66 (30.3%)	87 (37.5%)	
	Sometimes	26 (5.8%)	6 (2.8%)	20 (8.6%)	
	Never	2 (0.4%)	1 (0.4%)	1 (0.4%)	
Does your hospital physician understand what you tell him/her?	Always	284 (63.1%)	150 (68.8%)	134 (57.8%)	0.000
	Usually	152 (33.8%)	67 (30.7%)	85 (36.6%)	
	Sometimes	14 (3.1%)	1 (0.5%)	13 (5.6%)	
	Never	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Overall rating of your referral **N=314**	Very good	73 (23.2%)	39 (25.7%)	34 (21.0%)	0.701
	Good	210 (66.9%)	109 (71.7%)	101 (62.3%)	
	Moderate	21 (6.7%)	3 (2.0%)	18 (11.1%)	
	Poor	8 (2.5%)	1 (0.7%)	7 (4.3%)	
	Very poor	2 (0.6%)	0 (0.0%)	2 (1.2%)	
Overall rating of your discharge **N=187**	Very good	28 (15.0%)	13 (17.6%)	15 (13.3%)	0.001
	Good	123 (65.8%)	55 (74.3%)	68 (60.2%)	
	Moderate	24 (12.8%)	4 (5.4%)	20 (17.7%)	
	Poor	8 (4.3%)	2 (2.7%)	6 (5.3%)	
	Very poor	4 (2.1%)	0 (0.0%)	4 (3.5%)	

Table 5.2 Continued

		Overall	No TSI	TSI	P*
Overall rating of your concurrent care at the GP and hospital outpatient clinic **N=297**	Very good	41 (13.8%)	21 (15.9%)	20 (12.1%)	0.006
	Good	223 (75.1%)	110 (83.3%)	113 (68.5%)	
	Moderate	24 (8.1%)	1 (0.8%)	23 (13.3%)	
	Poor	7 (2.4%)	0 (0.0%)	7 (4.2%)	
	Very poor	2 (0.7%)	0 (0.0%)	2 (1.2%)	

* *Chi2-trend*
GP=general practitioner, TSI=transitional safety incident

TRIQ Item analysis

Table 5.3 shows the distribution of answers to the incident-identifying questions. More than 60% of the patients was not able to report on accurate communication between GP and specialist (D6). Likewise, over 40% of respondents could not judge the GP specialist collaboration (D5), the awareness of their GP of specialists' management (C6 and C8) or vice versa or the receipt of test results from the hospital (C9). Most TSIs were identified by the researchers from the free text fields of questions C9 (reporting of GP test results to the hospital physician), A7 (GP being informed about hospital discharge) and C4 (awareness of the GP of the specialist diagnosis). Unfortunately, not enough information was given in the free text field to assess the clinical impact of the TSIs.

Results from the Exploratory Factor Analysis

Bartlett's test of sphericity was significant (p<0,0001), so a factor analysis could be performed. The EFA reached acceptable fit-indices in a four-factor solution with an RMSEA of 0.047, a CFI/TLI of 0.959, and an SRMR of 0.090. The resulting four factors were: 1) personal relation with general practitioner (four items), 2) personal relation with hospital physician (four items), 3) information exchange (seven items), and 4) treatment consistency (eight items) (Table 5.4).

Five items loaded on two factors: B8 "Does your hospital physician understand what you tell him/her? ", C4 "Was your GP aware of the diagnosis newly established in hospital?", D5 "Do your GP and hospital physician work well together?", D6 "Do your GP and hospital physicians communicate with each other? ", and D7 "Do you have confidence in the collaboration between your GP and hospital physician?".

Table 5.3 Distributions of answers in incident identifying questions, *N (%)*

Question		N	N missing	Yes		Partially		No		I don't know		TSI (after reclassification)	
B9	Do you know who your primary responsible physician is for your current disease or health complaint?	451	0	400	(88.7%)			51	(11.3%)			44	(9.8%)
C1	Was your hospital physician aware of your previous medical history?	451	0	266	(59.0%)	47	(10.4%)	37	(8.2%)	101	(22.4%)	64	(14.2%)
C2	Was your GP aware of the decisions made and instructions given at the hospital?	451	0	236	(52.3%)	47	(10.4%)	44	(9.8%)	124	(27.5%)	73	(16.3%)
C4	Was your GP aware of your diagnosis newly established in hospital?	91	0	43	(47.3%)	10	(11.0%)	12	(13.2%)	26	(28.6%)	8	(1.8%)
C6	Was your GP aware of changes in your treatment plan made in hospital?	97	0	34	(35.1%)	8	(8.2%)	13	(13.4%)	42	(43.3%)	14	(3.1%)
C8	Did your GP receive the results of all hospital tests?	451	0	204	(45.2%)			40	(8.9%)	207	(45.9%)	31	(6.9%)
C9	Did your hospital physician receive the results of all test performed by your GP?	451	0	181	(40.1%)			62	(13.7%)	208	(46.1%)	18	(4.0%)
A7	Was your GP informed about your hospital discharge?	85	0	45	(52.9%)	25	(29.4%)	15	(17.6%)			12	(2.7%)
D1	Was a test done twice by both your GP and hospital physician in a short time?	444	7	264	(59.3%)			147	(33.0%)	34	(7.6%)	6	(1.4%)
D2	Did your GP and hospital physician give different information? *	444	7	415	(93.3%)	14	(3.1%)	16	(3.6%)			17	(3.8%)
D3	Do your GP and hospital physician give different advice? *	444	7	418	(93.9%)	14	(3.1%)	13	(2.9%)			15	(3.4%)
D4	Did your GP and hospital physician disagree on your treatment plan? *	444	7	290	(65.2%)	8	(1.8%)	18	(4.0%)	129	(29.0%)	17	(3.8%)
D5	Have your GP and hospital physician worked well together?	444	7	192	(43.1%)	27	(6.1%)	20	(4.5%)	206	(46.3%)	25	(5.6%)

Table 5.3 Continued

Question		N	N missing	Yes		Partially		No		I don't know		TSI (after reclassification)	
D6	Have your GP and hospital physicians communicated with each other?	444	7	114	(25.6%)	30	(6.7%)	24	(5.4%)	277	(62.2%)	28	(6.3%)
D7	Are you confident about the collaboration between your GP and hospital physician?	444	7	71	(16.0%)‡	302	(67.9%)‡	63	(14.2%)‡	9	(2.0%)‡		
D8	Do you know who to contact in case something is wrong?	444	7	399	(89.7%)			46	(10.3%)			46	(10.4%)

GP=General Practitioner, TSI=Transitional safety incident

* *negatively stated questions*

‡ *response options: Very high/ high/ low/ very low*

Table 5.4 Factor loadings and internal consistency of the TRIQ questionnaire

Item	Description	F1	F2	F3	F4	GLB λ2	CR
1. Personal relation with general practitioner						0.63	0.78
B1	Do you see the same GP at every visit?	0.56					
B2	How many different GPs have you seen in the past year?	0.62					
B3	Do you have confidence in your GP's professional ability?	0.76					
B4	Does your GP understand what you tell him/her?	0.74					
2. Personal relation with hospital physician						0.60	0.76
B5	Do you see the same hospital physician at every visit?		0.78				
B6	How many different hospital physicians have you seen in the past year?		0.47				
B7	Do you have confidence in your hospital physician's professional ability?		0.69				
B8	Does your hospital physician understand what you tell him/her?		0.48				
B9	Do you know who your directly responsible physician is for your current disease or health complaint?		0.69				
3. Information exchange						0.57	0.83
C1	Was your hospital physician aware of your previous medical history?			0.31			
C2	Was your GP aware of the decisions made and instructions given to you at the hospital (i.e. prescription changes, information on self-care management, future appointments in hospital)			0.88			
C4	Was your GP aware of your diagnosis newly established in hospital?			0.54			
C6	Was your GP aware of changes in your treatment plan made in hospital?			0.64			
C8	Did your GP receive the results of all hospital tests?			0.88			
C9	Did the hospital physician receive the results of all tests performed by your GP?			0.56			
A7	Was your GP informed about your hospital discharge?			0.55			
4. Treatment consistency						0.52	0.95
D1	Was a test done twice by both your GP and hospital physician in a short time period?				0.61		
D2n	Did your GP and hospital physician give different information?				0.94		
D3n	Did your GP and hospital physician give different advice?				0.98		
D4	Did your GP and hospital physician disagree on your treatment plan?				0.97		
D5	Have your GP and hospital physician worked well together?				0.86		
D6	Have your GP and hospital physician communicated with each other?				0.83		
D7	Are you confident about the collaboration between your GP and hospital physician?				0.66		
D8	Do you know who to contact in case something is wrong?				0.78		

GP= general practitioner, Hos=hospital, GLB=Guttman's lower bound, CR=composite reliability, n=negatively stated questions.

Reliability and construct validity

The internal consistency for individual factors was acceptable to good (composite reliability 0.75-0.95, glb λ2 0.52-0.63) (Table 5.4). Correlation between dimensions ranged from 0.19 to 0.31.

Patients with comorbidity and polypharmacy experienced more TSIs (Table 5.2). We did not find a relationship between other patient characteristics like educational level and TSIs.

As expected, experiencing at least one TSI identified by the TRIQ questionnaire was significantly related to a lower relational continuity in both general practice and hospital, except for item B1 "seeing the same GP at every visit". Additionally, an experienced TSI was related to a poorer overall rating of all transitions individually (Table 5.2).

DISCUSSION

Main findings

We developed and validated the TRIQ for measurement of patients' perspective on transitional patient safety. The TRIQ consisted of 4 domains: 1) personal relation with general practitioner, 2) personal relation with the hospital physician, 3) information exchange, and 4) treatment consistency. Our results demonstrated the TRIQ to be a valid and reliable instrument, with internal consistency scores of 0.75 or higher. Adequate content and face validity was achieved by building on the concept of continuity of care (Reid et al.), and by including both patients and professionals in the development.[18] The overall ratings of transitional care and the TRIQ domains were related, confirming the construct validity. Additionally, at higher comorbidity levels patients had an increased risk of experiencing TSIs according to the TRIQ. We conclude that the TRIQ is a valid and efficient diagnostic tool to adequately identify safety risks and transitional care incidents along the patient journey between the care levels of general practice and hospital.

Comparison to literature

Existing questionnaires either measure broader concepts such as continuity of care,[10-13] focus mainly on continuity within healthcare setting,[27,28] or limit themselves to one transition (mainly discharge) [14,15] or to one patient group.[16] The TRIQ was developed to measure patient safety from the patients' perspective when patients move between settings. Transitional patient safety specifically focusses on preventing medical errors during or after these healthcare transitions.

To our knowledge, the TRIQ is the first generic instrument to measure transitional patient safety and identify TSIs from a patients' perspective, providing essential information for directions of quality improvement initiatives. The questionnaire was developed together with patients and readability testing showed that the questionnaire was easily accessible to all patients.

Interpretation

Although in theory the patient should have the complete picture of the patient journey, it can be disputed whether patients are always able to adequately identify correct from incorrect healthcare. Especially unnecessary redundant testing (D1) needed reassessment of the responses, as patients reported tests as being redundant that, from a medical perspective, were correctly repeated within a short time period, such as blood tests for inflammation markers or electrocardiograms. Indeed, patients do not always have the specific medical knowledge to distinguish correct from incorrect repetition of tests. Additionally, TSIs may not always be directly recognised by patients for the incident may occur behind the scenes.[29] However, patients can identify the aftermath, such as lack of communication.[30] An example is that a patient notices that he receives the wrong medication or that the general practitioner is unaware of a hospital admission or new diagnosis, caused by a missing discharge letter. As a patient never actually sees a discharge letter or knows whether one has been sent or not, not all missing correspondence will be noticed. Therefore, we could only assess the experienced TSIs that have occurred by translating the patients' experiences in the free text fields of the TRIQ. Unfortunately, the patients did or could not describe the severity of these safety incidents, despite our attempts to measure harm with our questionnaire.

When assessing internal consistency, we used the Guttman's lower bound and composite reliability, which differed considerably. The composite reliability best reflected the dichotomous nature of our questionnaire items and the decent individual factor loadings found in our EFA, leading to our conclusion that internal consistency was acceptable to good. However, for optimal transparency we also chose to present the Guttman's lower bound.

Despite the fact that 53% of our patients had experienced a minor TSI, the level of confidence in their healthcare providers remained high. Only in the hospital, the experience of a TSI was related to a lower confidence. Possibly the long standing personal doctor-patient relationship in general practice accounts for more sustainable appreciation and trust.[31]

Limitations

Our study has some limitations. First, the confirmation of a TSI was based on the subjective information provided by the patient in the free text. Unfortunately, the descriptions sometimes were not precise enough to assign a firm judgement. This may have led to an underestimation of the actual TSIs.

Second, due to a logistical error the number of eligible patients in the Hardenberg region was not registered, so for this area we could not calculate the response rate. However, as all eligible patients were approached for participation, we do not expect any influence on the results.

Third, the TRIQ was a digital questionnaire and therefore less accessible for elderly patients. We tried to solve this by the help of a medical student but this may have led to more socially acceptable answers in this patient group. However, we trained the students to assist without steering the answers. Additionally, not providing this assistance would probably have led to the underestimation and missing of specific types of TSIs associated with these high-risk patients.

Finally, the TRIQ is developed in the primary – secondary care interface in the Netherlands. For use in other countries, the TRIQ should ideally first be adapted and validated to fit a different context. Additionally, to be able to reliably assess effect of improvement plans, further testing of reliability (test-retest), measurement error and responsiveness is needed.

Conclusion

The TRIQ is a valid and reliable questionnaire for measuring transitional patient safety from the patients' perspective, and can be helpful in identifying safety incidents and monitoring the effect of safety improving interventions

DISCLAIMER AND SOURCES OF SUPPORT

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AUTHORS' CONTRIBUTIONS

MM and HS initiated the study. All authors contributed in the design of the study. MM and HS performed the study and developed the manuscript. DZ and JP closely supervised the manuscript development. MM, HS, JP, NW and DZ participated in reviewing and editing of various drafts of the manuscript and they all read and approved the final manuscript.

WHAT IS NEW?

Key findings

- The 'TRIQ' questionnaire is a valid and reliable questionnaire measuring transitional patient safety from the patients' perspective.
- The TRIQ consists of four dimensions: 1) personal relation with general practitioner, 2) personal relation with hospital physician, 3) information exchange, and 4) treatment consistency.

What this adds to what is known

- Patients with higher comorbidity levels had an increased risk of experiencing transitional safety incidents.
- In theory patients have the complete picture of the patient journey, but patients are not always able to adequately identify transitional safety incidents.

What is the implication, what should change now?

- Using the TRIQ incorporates the patients' perspective in identifying transitional safety incidents, providing input for quality improvement and monitoring the effect of safety improving interventions.

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APPENDIX 5.1 TRIQ QUESTIONNAIRE, ORIGINAL DUTCH VERSION

Uw ervaringen met de zorg tussen huisarts en ziekenhuis

Sommige patiënten komen zowel bij de huisarts als de specialist. Dat betekent dat zij de zorg van deze patiënt delen. Om deze zorg te kunnen verbeteren, willen wij graag úw ervaringen met de zorg tussen huisarts en ziekenhuis weten.

In deze vragenlijst staan vragen over de relatie met uw huisarts en specialist. Ook willen wij weten wat uw ervaringen zijn met het uitwisselen van informatie en de manier van samenwerken tussen de huisarts en specialist. Soms wordt u gevraagd uw antwoord toe te lichten. Wij willen graag weten wat er precies gebeurd is en wat de gevolgen voor u zijn geweest.

Het kan zijn dat u voor meerdere aandoeningen het ziekenhuis bezoekt. Deze vragenlijst gaat over de afdeling waar u deze vragenlijst nu invult.
Deze vragenlijst gaat over de **laatste keer** dat :

- u bent ontslagen uit het ziekenhuis of
- u door de huisarts naar het ziekenhuis bent verwezen of
- u op de polikliniek bent behandeld of gecontroleerd *(dit kunnen meerdere afspraken zijn geweest)*

Uw antwoorden worden onder codenummer verwerkt. Dit betekent dat alleen de onderzoekers weten welke antwoorden u heeft gegeven. Uw antwoorden worden niet doorgegeven aan derden (bijvoorbeeld uw huisarts en/of specialist). De behandelaars krijgen alleen te horen wat de ervaringen zijn van de hele groep patiënten. Dit onderzoek wordt uitgevoerd door onderzoekers van het UMC Utrecht en is goedgekeurd door de Medisch-Ethische Toetsings Commissie van het UMC Utrecht.

A. <u>Algemene informatie:</u>

A1. Voor welk gezondheidsprobleem of aandoening bent u op dit moment in het ziekenhuis? (*Graag kort in uw eigen woorden).* _____

A2. In welk **ziekenhuis** bent u op dit moment voor uw aandoening? _____

A3. Bij welke **afdeling/ poli** bent u nu voor uw aandoening? _____

A4. Welke aandoeningen heeft u nog meer, waarvoor u in het ziekenhuis of bij de huisarts behandeld wordt?

- ☐ Diabetes/ suikerziekte
- ☐ COPD/ longemfyseem
- ☐ CVA/ beroerte
- ☐ Kanker
- ☐ Reumatische aandoening
- ☐ Ernstige nierfunctiestoornissen
- ☐ Ernstige leverfunctiestoornissen
- ☐ Hartfalen
- ☐ Coronaire hartziekte
- ☐ Hartritmestoornissen
- ☐ Psychiatrische aandoening
- ☐ Dementie
- ☐ Verstandelijke beperking
- ☐ Epileptische aandoening
- ☐ Migraine
- ☐ Overig, nl……..

A5. Hoeveel verschillende medicijnen gebruikt u op dit moment*?(dit gaat om alle medicijnen die u voor al uw aandoeningen gebruikt)* ☐☐

A6. Bent u de laatste zes maanden voor deze aandoening:
(Hier zijn meerdere antwoorden mogelijk)

- ☐ Ontslagen uit het ziekenhuis -> ga naar **vraag A7**
- ☐ Door de huisarts naar het ziekenhuis verwezen? -> ga naar **vraag B1**
- ☐ Op de polikliniek behandeld of gecontroleerd -> ga naar **vraag B1**

A7. Was uw huisarts bij uw ontslag uit het ziekenhuis geïnformeerd?

- ☐ Ja
- ☐ Deels
- ☐ Nee

B. <u>De relatie met uw arts(en)</u>

B1. Heeft u een vaste huisarts die u ziet bij elke afspraak? *Deze vraag gaat over huisartsbezoek bij al uw gezondheidsproblemen*

- ☐ Altijd
- ☐ Meestal
- ☐ Soms
- ☐ Nooit

B2. Hoeveel verschillende huisartsen heeft u het afgelopen jaar gezien? *Deze vraag gaat over huisartsbezoek bij al uw gezondheidsproblemen*

- ☐ 1
- ☐ 2 of 3
- ☐ Meer dan 3

B3. Heeft u vertrouwen in de deskundigheid van de huisarts? *Deze vraag gaat over huisartsbezoek bij al uw gezondheidsproblemen*

- ☐ Zeer veel
- ☐ Veel
- ☐ Weinig
- ☐ Zeer weinig

B4. Begrijpt de huisarts wat u vertelt? *Deze vraag gaat over huisartsbezoek bij al uw gezondheidsproblemen*

- ☐ Altijd
- ☐ Meestal
- ☐ Soms
- ☐ Nooit

Deze vragen gaan over de aandoening en de afdeling waar u op dit moment bent in het ziekenhuis

B5. Heeft u een vaste specialist voor deze aandoening in het ziekenhuis?

- ☐ Altijd
- ☐ Meestal
- ☐ Soms
- ☐ Nooit

B6. Met hoeveel verschillende artsen heeft u het afgelopen jaar in het ziekenhuis gesproken voor deze aandoening?

- ☐ 1
- ☐ 2 tot 5
- ☐ 5 tot 10
- ☐ Meer dan 10

B7. Heeft u vertrouwen in de deskundigheid van de specialist?

- ☐ Zeer veel
- ☐ Veel
- ☐ Weinig
- ☐ Zeer weinig

B8. Begrijpt de specialist wat u vertelt?

- ☐ Altijd
- ☐ Meestal
- ☐ Soms
- ☐ Nooit

B9. Weet u wie uw hoofdbehandelaar is voor uw aandoening?
(Een hoofdbehandelaar is degene met wie u samen de beslissingen neemt over de behandeling van uw aandoening)

☐ Ja
☐ Nee

C. Het uitwisselen van informatie

Deze vragen gaan over de aandoening en de afdeling waar u op dit moment bent in het ziekenhuis

C1. Wist de specialist welke andere ziektes of gezondheids-problemen u heeft of in het verleden heeft meegemaakt? *Dit kan uit eerder ziekenhuisbezoek of door informatie van de huisarts.*

- ☐ Ja
- ☐ Deels
- ☐ Nee
- ☐ Weet ik niet

C2. Wist de huisarts wat in het ziekenhuis afgesproken is? Denk aan: verandering van geneesmiddelen, informatie over wat u thuis moet doen, terugkom afspraken.

- ☐ Ja
- ☐ Deels
- ☐ Nee
- ☐ Weet ik niet

C3. Is er onlangs bij u een **nieuwe aandoening vastgesteld** in het ziekenhuis?

- ☐ Ja-> Ga naar **vraag C4**
- ☐ Nee-> Ga naar **vraag C5**

C4. Wist de huisarts dat er een **nieuwe aandoening is vastgesteld** in het ziekenhuis?

- ☐ Ja
- ☐ Deels
- ☐ Nee
- ☐ Weet ik niet

C5. Is er onlangs bij u iets **veranderd aan uw behandeling** in het ziekenhuis?

- ☐ Ja-> Ga naar **vraag C6**
- ☐ Nee-> Ga naar **vraag C7**

C6. Wist de huisarts dat er onlangs iets **veranderd is aan uw behandeling** in het ziekenhuis?

- ☐ Ja
- ☐ Deels
- ☐ Nee
- ☐ Weet ik niet

C7. Hebben de huisartsenpraktijk en het ziekenhuis onderling contact gehad toen u in het ziekenhuis lag of tijdens uw behandeling op de polikliniek? *(bijvoorbeeld via mail, telefoon, brief of op een andere manier)*

- ☐ Ja
- ☐ Nee
- ☐ Weet ik niet

C8. Had de huisarts de uitslag van alle onderzoeken uit het ziekenhuis? *(Denk aan bijvoorbeeld een bloedonderzoek of röntgenfoto.)*

- ☐ Ja
- ☐ Nee
- ☐ Weet ik niet

C9. Had de specialist de uitslag van alle onderzoeken die de huisarts al gedaan had? *(Denk aan bijvoorbeeld een bloedonderzoek of röntgenfoto.)*

- ☐ Ja
- ☐ Nee
- ☐ Weet ik niet

D. <u>De samenwerking tussen huisarts en specialist</u>

Deze vragen gaan over de aandoening en de afdeling die u op de derde bladzijde heeft ingevuld.

D1. Is er een onderzoek voor hetzelfde meer dan één maal gedaan? *(Is er een onderzoek bij de huisarts én de specialist gedaan? Denk aan bijvoorbeeld een bloedonderzoek of röntgenfoto.)*

- ☐ Ja
- ☐ Nee
- ☐ Weet ik niet

D2. Gaven de huisarts en specialist u tegenstrijdige **informatie**?

- ☐ Ja
- ☐ Deels
- ☐ Nee

D3. Gaven de huisarts en specialist u tegenstrijdig **advies**?

- ☐ Ja
- ☐ Deels
- ☐ Nee

D4. Dachten de huisarts en specialist verschillend over uw behandeling?

- ☐ Ja
- ☐ Deels
- ☐ Nee
- ☐ Weet ik niet

D5. Werken de huisarts en specialist goed samen?

- ☐ Ja
- ☐ Deels
- ☐ Nee
- ☐ Weet ik niet

D6. Communiceren/ praten de huisarts en specialist met elkaar?

- ☐ Ja
- ☐ Deels
- ☐ Nee
- ☐ Weet ik niet

D7. Heeft u vertrouwen in de samenwerking tussen huisarts en specialist/ ziekenhuis?

- ☐ Zeer veel
- ☐ Veel
- ☐ Weinig
- ☐ Zeer weinig

D8. Weet u met wie u contact op kan nemen als er iets mis is. *(Bijvoorbeeld na ontslag, bij vragen over de behandeling enz?)*

- ☐ Ja
- ☐ Nee

D9. Weet de specialist/ het ziekenhuis hoe u thuis woont? (*Bijvoorbeeld: Woont u alleen of samen, woont u zelfstandig of heeft u veel hulp nodig?)*

- ☐ Ja
- ☐ Deels
- ☐ Nee

E. <u>Uw beoordeling van de zorg tussen huisarts en ziekenhuis</u>

E1. Beoordeel hoe **uw ontslag** is gegaan.
☐ Niet van Toepassing ☐ Zeer slecht ☐ Slecht ☐ Matig ☐ Goed ☐ Zeer goed

E2. Beoordeel hoe **uw verwijzing** is gegaan.
☐ Niet van Toepassing ☐ Zeer slecht ☐ Slecht ☐ Matig ☐ Goed ☐ Zeer goed

E1. Beoordeel hoe de gezamenlijke behandeling van huisarts en ziekenhuis is gegaan **tijdens uw controle(s) op de poli**.
☐ Niet van Toepassing ☐ Zeer slecht ☐ Slecht ☐ Matig ☐ Goed ☐ Zeer goed

F. <u>Informatie over u:</u>

F1. Wat is uw geboorte**jaar**?

1	9		

F2. Wat is uw geslacht?
☐ Man
☐ Vrouw

F3.Wat is uw hoogst afgeronde opleiding?
☐ (nog) geen
☐ Lagere school/ Basisschool
☐ Lager beroepsonderwijs
☐ MAVO, VMBO, 3 jaar HAVO
☐ HAVO/ VWO
☐ Middelbaar beroepsonderwijs
☐ Hoger beroepsonderwijs
☐ Universiteit

F4. Tot welke bevolkingsgroep behoort u?
☐ Nederlands
☐ Antilliaans/ Arubaans
☐ Kaapverdiaans
☐ Turks/ Koerdisch
☐ Surinaams– Creools
☐ Surinaams– Hindoestaans
☐ Surinaams– anders
☐ Marokkaans– Berbers
☐ Marokkaans– Arabisch
☐ Indonesisch
☐ Oost–Europees
☐ Aziatisch
☐ Anders

-Hartelijk dank voor het invullen van de vragenlijst-

APPENDIX 5.2 TRANSLATED ENGLISH VERSION

Experiences of care concurrently by both the general practitioner and hospital physician

The TRIQ questionnaire was developed in Dutch, and we used this original Dutch version in the validation study. This English version should first be validated before using it in practice.

Some patients visit both the general practitioner and hospital physician in the same time period. Therefore, these doctors both share responsibility for the patient's care. To improve this concurrent care by the general practitioner and hospital physician, we would like to learn from your experiences.

This questionnaire asks about your personal relationship with your general practitioner and your hospital physician. Furthermore, we ask your experiences with the information exchange and collaboration between your general practitioner and hospital physician. Sometimes, we will ask you to elaborate further on your answer. We are interested in what happened and what were the consequences for you.

Maybe you visit the hospital for more than one disease or health complaint. We would like you to answer this questionnaire for the disease or health complaint that caused you to visit the current department (the department you are visiting right now).

- This questionnaire concerns your last:
- discharge from hospital
- referral by the general practitioner to hospital
- treatment or consultation at the outpatient clinic (this may include multiple appointments)

A. General information

A1. For which disease or health complaint do you visit the hospital? _____

A2. What hospital are you with? _____

A3. Which department are you with? _____

A4. Which other diseases and health complaints do you have?

- ☐ Diabetes
- ☐ COPD
- ☐ CVA/ stroke
- ☐ Cancer
- ☐ Rheumatism
- ☐ Severe kidney disease/ failure
- ☐ Severe liver disease/ failure
- ☐ Heart failure
- ☐ Coronary heart disease
- ☐ Heart rhythm disorder
- ☐ Psychiatric disorder
- ☐ Dementia
- ☐ Intellectual disability
- ☐ Epilepsy
- ☐ Migraine
- ☐ Other, ...

A5. How many medicines do you use at the moment (for all your diseases and health complaints)? ☐☐

A6. In the last six months, have you been: (multiple answers possible)

- ☐ Discharged from hospital-> go to question **A7**
- ☐ Referred by your general practitioner to hospital? -> go to question **B1**
- ☐ Treated by both the general practitioner and hospital physician -> go to question **B1**

A7. Was your GP informed about your hospital discharge?

- ☐ Yes
- ☐ Partly*
- ☐ No*

B. Your personal relationship with your treating physicians

B1. Do you see the same GP at every visit? (This question concerns all visits to the GP, for all your diseases and health complaints

- ☐ Always
- ☐ Usually
- ☐ Sometimes
- ☐ Never

B2. How many different GPs have you seen in the past year? (This question concerns all visits to the GP, for all your diseases and health complaints

- ☐ 1
- ☐ 2 or 3
- ☐ More than 3

B3. Do you have confidence in your GP's professional ability? (This question concerns all visits to the GP, for all your diseases and health complaints

- ☐ Very high
- ☐ High
- ☐ Low
- ☐ Very low

B4. Does your GP understand what you tell him/her? (This question concerns all visits to the GP, for all your diseases and health complaints

- ☐ Always
- ☐ Usually
- ☐ Sometimes
- ☐ Never

The following questions only concern the department you are currently visiting

B5. Do you see the same hospital physician at every visit?

- ☐ Always
- ☐ Usually
- ☐ Sometimes
- ☐ Never

B6. How many different hospital physicians have you seen in the past year?

- ☐ 1
- ☐ 2 to 5
- ☐ 5 to 10
- ☐ More than 10

B7. Do you have confidence in your hospital physician's professional ability?

- ☐ Very high
- ☐ High
- ☐ Low
- ☐ Very low

B8. Does your hospital physician understand what you tell him/her?

- ☐ Always
- ☐ Usually
- ☐ Sometimes
- ☐ Never

B9. Do you know who your primary responsible physician is for your current disease or health complaint?

- ☐ Yes
- ☐ No*

C. Information exchange

C1. Was your hospital physician aware of your previous medical history?

- ☐ Yes
- ☐ Partly*
- ☐ No*
- ☐ I don't know

C2. Was your GP aware of the decisions made and instructions given at the hospital?

- ☐ Yes
- ☐ Partly*
- ☐ No*
- ☐ I don't know

C3. Has a new diagnosis been established in hospital recently?

- ☐ Yes-> Go to question **C4**
- ☐ No-> Go to question **C5**

C4. Was your GP aware of your diagnosis newly established in hospital?

- ☐ Yes
- ☐ Partly*
- ☐ No*
- ☐ I don't know

C5. Was your treatment plan changed in hospital recently?

- ☐ Yes-> Go to question **C6**
- ☐ No-> Go to question **C7**

C6. Was your GP aware of changes in your treatment plan made in hospital?

- ☐ Yes
- ☐ Partly*
- ☐ No*
- ☐ I don't know

C8. Did your GP receive the results of all hospital tests?

- ☐ Yes
- ☐ Partly*
- ☐ No*
- ☐ I don't know

C9. Did your hospital physician receive the results of all test performed by your GP?

- ☐ Yes
- ☐ No*
- ☐ I don't know

D. Collaboration between general practitioner and hospital physician

D1. Was a test done twice by both your GP and hospital physician in a short time?

- ☐ Yes*
- ☐ No
- ☐ I don't know

D2. Did your GP and hospital physician give different information?

- ☐ Yes*
- ☐ Partly*
- ☐ No

D3. Do your GP and hospital physician give different advice?

- ☐ Yes*
- ☐ Partly*
- ☐ No

D4. Did your GP and hospital physician disagree on your treatment plan?

- ☐ Yes*
- ☐ Partly*
- ☐ No
- ☐ I don't know

D5. Have your GP and hospital physician worked well together?

- ☐ Yes
- ☐ Partly*
- ☐ No*
- ☐ I don't know

D6. Have your GP and hospital physicians communicated with each other?

- ☐ Yes
- ☐ Partly*
- ☐ No*
- ☐ I don't know

D7. Are you confident about the collaboration between your GP and hospital physician?

- ☐ Very high
- ☐ High
- ☐ Low
- ☐ Very low

D8. Do you know whom to contact in case something is wrong?

- ☐ Yes
- ☐ No*

E. Overall rating of your care by both the general practitioner and hospital physician

E1. Give an overall rating of your discharge

☐ Not applicable ☐ Very poor* ☐ Poor* ☐ Moderate ☐ Good ☐ Very good

E2. Give an overall rating of your referral

☐ Not applicable ☐ Very poor* ☐ Poor* ☐ Moderate ☐ Good ☐ Very good

E3. Overall rating of your concurrent care at the GP and hospital outpatient care

☐ Not applicable ☐ Very poor* ☐ Poor* ☐ Moderate ☐ Good ☐ Very good

F. Information about you

F1. What is your birthyear?

1	9		

F2. What is your gender?

☐ Man
☐ Woman

F3. What is the highest education you completed?

☐ None
☐ Primary
☐ Secondary
☐ Higher

F4. What is your ethnicity?

_____

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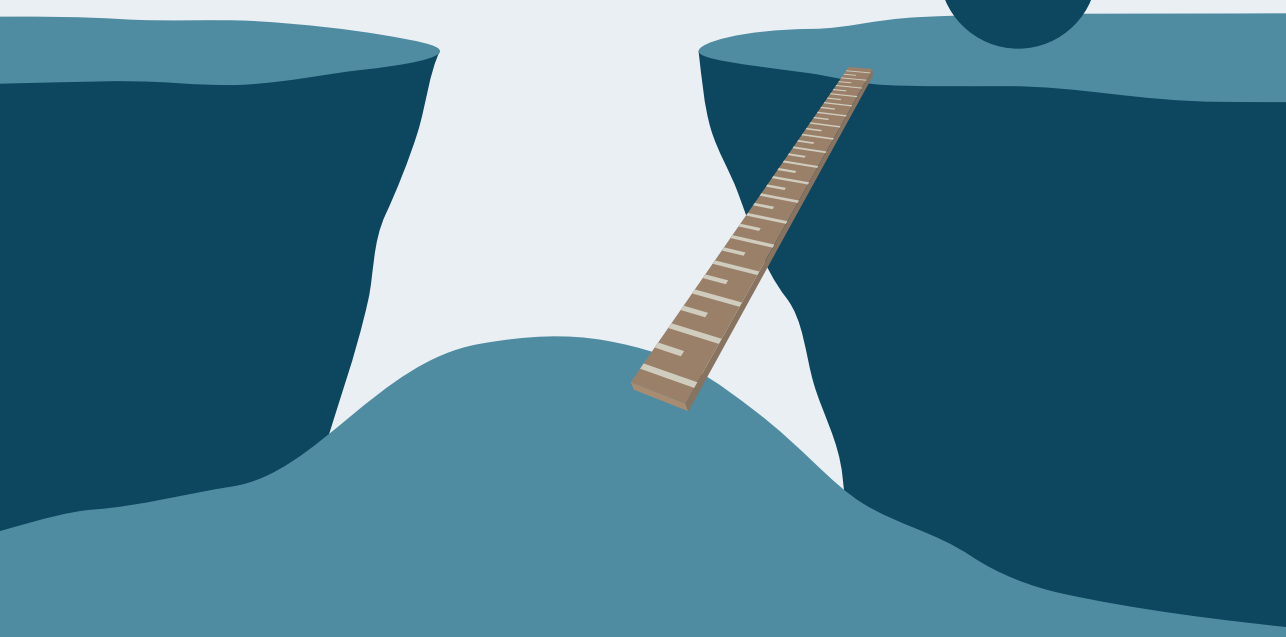

A PILOT STUDY ON IDENTIFICATION OF INCIDENTS IN HEALTHCARE TRANSITIONS AND CONCORDANCE BETWEEN MEDICAL RECORDS AND PATIENT INTERVIEW DATA

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ABSTRACT

Objectives

To investigate whether transitional incidents can be identified from the medical records of both the general practitioners and hospital and to assess the concordance of transitional incidents between medical records and patient interviews.

Design
A pilot study.

Setting

The study was conducted in two regions in the Netherlands: a rural and an urban region.

Participants
A purposeful sample of patients who experienced a transitional incident or are at high risk of experiencing transitional incidents.

Main outcome measures
Transitional incidents were identified from both the interviews with patients and medical records and concordance was assessed. We also classified the transitional incidents according to type, severity, estimated cause and preventability.

Results

We identified 28 transitional incidents within 78 transitions of which three could not be found in the medical records and another five could have been missed without the patient as information source. To summarize, eight (29%) incidents could be missed using solely medical records, and seven (25%) using the patients' information exclusively. Concordance in transitional incidents between patient interviews and medical records was 64% (18/28).

The majority of the transitional incidents were unsafe situations, however 43% (12/28) of the incidents reached the patient and 18% (5/28) caused temporary patient harm. Over half of the incidents were potentially preventable.

Conclusions

This pilot study suggests that the majority of transitional incidents can be identified from medical records of both the general practitioner and hospital. With this information, we aim to develop a measurement tool for transitional incidents in the medical record of both general practitioner and hospital.

INTRODUCTION

In the Netherlands, the general practitioner has a central role in the patients' journey. The general practitioner is the first point of contact, provides basic healthcare and is gatekeeper to the specialist healthcare services in hospitals. Transitions between the general practice (GP) and hospital include referral of patients from GP to hospital, discharge after hospital admission and concurrent care by both a general practitioner and specialist at the outpatient clinic. During these transitions, the primary interest is the establishment of a continuous, high quality, integrated care process in which patients' safety is guaranteed.[1,2]

During the patients' journey through the different levels of the healthcare system, patient safety incidents tend to accumulate.[3] It is important to identify these transitional incidents (TIs) and assess them adequately, to better understand the risks and improve patient safety during transitions in healthcare. A medical record review study is a tool for the assessment of patient safety and harm. Since the nineties, several large international medical record review studies have been conducted.[4-10] Initially, patient safety studies focused on hospitals, but recently record studies on incidents have also been performed in primary care settings.[11] However, medical record review of the patient journey between these levels of healthcare is yet to be explored.

For an adequate overview of the complete patient journey, the patient's story may render additional information. Studies on continuity of care hypothesize that patients are able to identify adverse events affecting their care.[12] Given the fact that the patient is the only continuous factor in all healthcare transitions, involving the patients' experience may even be an alternative route for adequate identification of TIs. With this pilot study, we aimed to investigate whether TIs can be identified from the medical records of both the general practitioners and the hospital and to assess the concordance between these medical records and the patient interviews. With this information, we intent to develop a measurement tool assessing transitional incidents in the medical record of both GP and hospital.

METHODS

Design and setting

We conducted a pilot study comparing the TIs identified from medical records of both the GP and hospital with those identified through patient interviews. Patients were recruited in two regions in the Netherlands: a rural region with one regional hospital and referring general practices and an urban region with one university hospital and one smaller city hospital, together with referring general practices. In both regions, we concentrated on patients treated in the internal, cardiovascular and gastroenterology departments. The study is part of a larger project on transitional patient safety, namely

the Transitional Incident Prevention Programme (TIPP).[13] According to Dutch law, this study was exempt of formal medical-ethical approval (METC number 13/142, medical ethical committee UMC Utrecht). The final goal of this pilot study is to develop a measurement tool for measuring TIs in the medical records of both the GP and hospital.

Patients

We used a convenience sampling strategy to recruit participants. Between October 2013 and July 2014, healthcare professionals of all participating hospital departments and affiliated GP practices were asked to recruit patients that experienced a TI or had a high risk of experiencing TIs. We considered comorbidity, polypharmacy, elderly patients and multiple transitions as risk factors for TIs. The healthcare professional gave eligible patients information on the TIPP study and asked whether the patient was willing to participate and whether our research office could contact them. If interested, patients received extra information on the nature of this pilot study by mail and by telephone. After giving consent, our researchers visited the patient at home for an interview. Prior to the interview, patients signed a written informed consent for the use of the interview data and the acquisition and use of their GP and hospital records.

Definitions

The absence of an international consensus about patient safety terms and definitions hinder comparison of studies.[14] Therefore, it is essential to emphasize the definitions we used in this article. The definitions are presented in table 6.1.

Table 6.1 Definitions of patient safety terms used in this manuscript.

Transition	Every shift/movement (e.g. referral, admission, discharge, consultation at outpatient clinic) patients make between healthcare professionals in primary and secondary care as their condition and care needs change during the course of illness. [2]
Transitional care	A set of services and environments designed to ensure the coordination and continuity of healthcare as patients transfer between different levels and locations of care. [2]
Transitional incident	Any unintended or unexpected event in patient care between different healthcare organizations which could have led or did lead to harm for one or more patients receiving care. In this report, we chose to focus on transitional incidents between general practice and hospital instead of all levels of care. If an unintentional event occurs in general practice and the results of the incident are noticed in the hospital or vice versa, this also counts as a transitional incident.
Adverse event	Any injury caused by medical care. [29]
Near miss	An act of commission or omission that could have harmed the patient but did not do so as a result of chance, prevention or mitigation. [30]
Unsafe situation	Circumstances or events occurred that had the capacity to cause error. [16]

Data collection

For our study, we used data from three sources: patient interviews, medical records of the GP and the medical records of the hospital. The patient interviews provided information about the incidents patients experienced during their transitions in healthcare. Subsequently, we retrieved their medical records through their GPs and the hospital departments and assessed whether any TIs were present. The data in the different data sources was collected independently and combined in the data collection and analysis.

We first constructed a chronological timeline of the journey of each individual patient, based on relevant information from the patient interviews. These timelines were used as guidance for the analysis of the medical record data. We also collected the following patient characteristics: age, gender, number of chronic diseases in history and number of currently used medications. Two researchers (MM, DE) jointly composed the timeline for the first patient. To establish a standard approach to identify and display relevant information from the interviews and the medical records, our researchers then constructed a second and third timeline independently. Disagreements were discussed until consensus was reached. One researcher (DE) constructed the timelines for the remainder of patients.

Data analysis

We counted the number of healthcare transitions per patient, calculated the period in which these transitions took place (in months) and the average number of transitions per patient. The transition period started with the first patient transition (usually from GP to hospital) and stopped at the end of the final transition back to the GP (usually when diagnostic process or treatment in hospital is completed) or the date of the medical record collection. A transition comprised of either a referral, a hospital discharge or visit to the outpatient clinic. The visit to the outpatient clinic was only included if an event occurred of which our researchers judged that the GP should be informed (e.g. in the case of a new diagnosis, the start of a new treatment, a treatment or policy change or discharge from the outpatient clinic). The source of the information was registered (medical record, patient interview or both). Subsequently, all TIs were identified and classified according to type, cause, severity and preventability. Because this study concerns a pilot study, the methods for identification of transitional incidents are still under development. An existing transitional incident assessment form was not available and jointly our researchers gained the experience of identifying TIs during the process. Again, to establish a standard approach, the first patient was assessed jointly and the second and third independently by our researchers MM and DE. For every transition made by the patient, the entire transition process was screened for possible transitional incidents, following the definition of transitional incidents in table 6.1. Our researchers used

a previously comprised list with the vulnerable steps in the transition process and risk factors for transitional incidents (e.g. accessibility, triage, diagnosis, diagnostic testing, medication/ prescription, communication/collaboration, referral and handoff information, in hospital referrals, the discharge process, self-care advice, after hours' care, multiple treating physicians, care coordinator) to guide the identification process. In this process, we were helped by the patient interview." The identified TIs were subdivided into three types of incidents: unsafe situations, near misses and adverse events (for definitions, see table 6.1). To classify the cause of the TI, we used the Eindhoven Classification Model, which distinguishes organization, technique, human acts and patients' actions as possible causal factors.[15] We did not request additional information from the involved GPs and specialists. Therefore, we could only estimate causal factors. Incidents can be the result of more than one cause so the total number of causes was higher than the number of incidents.

We classified severity of TIs according to the National Coordinating Council for Medication Error Reporting and Prevention Index (NCC MERP Index).[16] We added the items delay and mental harm to the NCC MERP index because we considered these items to better fit transitional care. This resulted in the following levels of harm:

A. 'Circumstances or events occurred that had the capacity to cause error',
B. 'Error occurred but did not reach the patient',
C. 'Error occurred that reached the patient but did not cause patient harm',
D. 'Error occurred that reached the patient and required monitoring to preclude harm of confirm that it caused no harm',
E. 'Error occurred that may have contributed to or resulted in temporary (mental or physical) harm or prolonged suffering from curable symptoms and required intervention',
F. 'Error occurred that may have contributed to or resulted in (mental or physical) harm and required an initial or prolonged hospital stay',
G. 'Error occurred that contributed to or resulted in permanent patient harm',
H. 'Error occurred that required intervention to sustain patient's life',
I. 'Error occurred that may have contributed to or resulted in patient death'.

Level A of the NCC MERP fits the definition of an 'unsafe situation', levels B through D pertain a ' near miss' and E through I an 'adverse event'.

We scored preventability on a 6-point scale from "(nearly) no evidence for preventability" to "(definitely) evidence for preventability" according to the current level of expected performance for healthcare professionals. A score of 4 to 6 indicated that the researcher regarded the incident as having more than 50% chance of being preventable. This subjective score is often used in medical record review studies.[10]

Finally, data sources of the TIs identified from the medical records and patient interviews were registered. Concordance between data sources of the TIs was determined.

RESULTS

Patients

The GPs and specialists of both regions identified 19 eligible patients: 11 by GPs and eight by specialists. Six from these 19 patients declined participation for the following reasons: language barrier (n=1), too much effort given their age (n=1), worsening of disease (n=2), nothing to report (n=1) and inability to reach the patient (n=1). In total, 13 patients were interviewed and of 12 patients all the medical records could be attained. In one patient, the patient journey included a general practitioner and two hospitals. Out of these two hospitals one record lacked. The median age of the participants was 59 years and 7/13 (54%) was female (table 6.2).

Table 6.2 Patient characteristics (n=13)

	n	IQR/%
Median age in years	59	28
Gender in % male	6	46%
Participating region in % urban	8	62%
Median number of transitions per patient	6	6,5
Median period of transitions in months	6	5,75
Number of chronic diseases[a] in history[b]		
≤1	6	46%
2-4	6	46%
≥5	1	8%
Number of medications used by the patient		
≤1	6	46%
2-4	2	15%
≥5	5	38%

a: Chronic diseases include: diabetes, Chronic Obstructive Pulmonary Disease, Cerebro Vascular Accident, cancer, rheumatoid disease, renal impairment, liver disease, heart failure, psychiatric disease and cognitive impairment;

b: Including the disease of the current episode that is used in this study

Transitional incidents

In total, the 13 patients made 78 transitions between GP and hospital with a median of 6 transitions per patient. The median period in which the patients transitioned was 6 months (range 1.5 weeks to 18 months). During these 78 transitions, the participating patients experienced 28 TIs. An illustration of the process of identifying and classifying incidents from our timelines is displayed in table 6.3. Table 6.4 shows a summary of our analysis of TIs for all patients.

Table 6.3 Example of a patient journey with corresponding narrative of timeline and analysis of transitional incidents

Time from first consultation	Narrative of timeline	Transitional incidents In this example four separate transitional incidents can be identified:
0 weeks	A 73-year old patient consulted the GP with epigastric pain and was treated with omeprazole according to the current guideline.	
2 weeks	The patient returned to the GPs office with persistent epigastric pain. The GP increased the dose and suggested to wait and see. Routine laboratory tests showed no abnormal results.	
4,5 months	The epigastric pain continued and new complaints surfaced: loss of appetite and weight loss. The patient was seen by a different GP. This GP suspected the presence of H. pylori and suggested a stool antigen assay or endoscopic testing. The patient chose the fecal assay.	
4 months and 3 weeks	The stool antigen assay was negative (possibly false negative, because the GP did not instruct the patient to stop the omeprazole temporarily)	
5 months and 1 week	Again the patient returned to the GPs office and was seen by the first GP who referred her to the hospital for an endoscopy.	
6 months	After a delay of four weeks the patient received a letter from the hospital about an appointment six weeks further on. The GP called the hospital and arranged an appointment at the outpatient quick diagnosis unit four days later.	1. Incorrect referral: the patient was referred to the regular outpatient clinic instead of the outpatient QDU (NM). The presence of a QDU was not known to the GP.
7 months	In the hospital, the patient is diagnosed with T_3NoMo gastric cardia carcinoma. The treatment consisted of perioperative chemotherapy followed by a total gastrectomy four months after the diagnosis.	
13 months	After an extended hospital admission because of several complications after surgery (such as anastomotic leakage and glucose fluctuations), the patient was discharged. One day after discharge the first GP visited the patient at home, prescribed medication and started glucose monitoring. At this moment, it was unclear to the patient how to use the diabetes medication. The discharge letter stated that the hospital requested the GP to monitor the glucose after discharge without further instructions.	2. Unclear discharge procedure for the patient: after discharge, it was unclear to the patient how to use the diabetes medication (US). 3. Inadequate and incomplete correspondence between hospital and GP: both the patient and the GP were not fully aware of the diabetes medication, monitoring, vitamin B12 injections and who the responsible physician was for further treatment (GP or hospital). (NM)

Table 6.3 Continued

Time from first consultation	Narrative of timeline	Transitional incidents In this example four separate transitional incidents can be identified:
14 months and 1 week	Coordination of the glucose monitoring and administration of the medication continued to be unclear to the patient. The patient and her family felt that the GP lacked control and requested further glucose monitoring by an internist. The patient was referred to the diabetes outpatient clinic in hospital for follow up.	
15 months	When the patient visited the outpatient clinic, the surgeon mentioned that vitamin B12 injections should have started immediately after discharge.	4. Absence of both an outpatient correspondence to the GP and a note in the hospital medical record about this specific consultation. This resulted in a 1-month delay of administration of vitamin B12 injections (NM).
16 months	At the next consultation, the surgeon asked the patient about vitamin B12 injections. The patient was unaware that she had to arrange this with her GP. She called the GPs office and asked for the vitamin B12 injections. The GP did not know about the injections because none of the letters mentioned this advice. The GP checked the advice by calling the outpatient clinic where it was found that the surgeon only mentioned it. The surgeon had laid the responsibility for the injections on the patient.	

Abbreviations: QDU: quick diagnosis Unit, AE = adverse event, NM = near miss, US = unsafe situation

Besides TIs between the GP and the hospital, we also encountered incidents between two different hospitals and between the GP and the community pharmacy. We did not include these incidents because they did not meet the focus of our study, namely transitional care between GP and hospital. However, it's likely that these incidents also enclose an opportunity for improving overall transitional patient safety.

Type and severity

The majority of the TIs was classified as an unsafe situation (16/28= 57%; NCC MERP category A). Of the other 12 TIs, seven were classified as near misses (7/28= 25%; four were classified as level C and three as level D. The remaining five TIs were classified as adverse events and resulted in harm to the patients (5/28= 18%; four were classified as level E and one as level F).

Cause

The most common causes of the TIs were human acts (n=18) and organization (n=17). Examples of TIs caused by human acts can be incorrect or delayed diagnosis, incomplete (referral or discharge) letters, and incorrect reassurance after only a part of the results of the diagnostics are known. An example of TIs caused by organization is a structural problem within a department that results in delayed (discharge) letters.

Preventability

Seventeen out of 28 incidents (61%) were considered as potentially preventable (8/16 of the unsafe situations, 4/7 of the near misses and 5/5 the adverse events).

Concordance between medical records and patient interviews

Table 6.5 shows the concordance between the medical records and patient interviews. Of the total of 28 identified TIs, 20 (71%) were clearly identifiable from the medical records. Three incidents (11%) were only reported by patients, and were not identifiable in the medical records. Of another five reported incidents (18%) clues were found in the medical records, but only after initial suggestion by the patient in the interview. Thus, these would have been missed without the initial alert by the patient. Six incidents were found only in the medical records and were not reported by patients. Thus the concordance in Tis identified through patient interviews and those identified using medical records was 64% (18/28). Incidents that would possibly have been missed if we used only medical records comprise of the following: delay of referral or diagnosis, ambiguity of discharge procedures or responsible physician to the patient and incomplete medical records (either because of inadequate registration by the physician or incompleteness of received medical records). Incidents missed when only using the patient interviews comprised of delayed information (e.g. discharge or outpatient letter) and a dissimulating patient in the interview.

Table 6.5 Concordance between medical records and patient interviews.
This table reports in which data source the transitional incidents was present.

Data sources		Patient interviews		
Medical records		present	absent	total
	present	18	7	25[b]
	absent	3	N/A[a]	3
	total	21	7	28

a: These incidents cannot be identified in both sources. This number is unknown.
b: In 5 of these 25 incidents, identification in the medical records proved challenging.

DISCUSSION

Main findings

In this pilot study of 78 transitions, 28 transitional safety incidents occurred. Twenty of these TIs could easily be identified from the records and five could be found in the medical record, but their identification was assisted by the information acquired from the patient interviews. Three transitional incidents mentioned in the patient interviews were untraceable.

Concerning the characteristics of these TIs, 23 were classified as unsafe situation or near misses. Five TIs caused the patient temporary harm (adverse events). None of the identified TIs caused permanent patient harm, interventions to sustain patient's life or patient death. More than half of all of the incidents appeared to be potentially preventable.

Strengths and limitations

This study has several strengths. To our knowledge this is the first study in which patient interviews were compared with medical records to investigate transitional patient safety and the incidence of TIs. Record analysis proved superior: in the majority of cases we found clues in the medical records that suggested the occurrence of a TI. The patient interviews did incidentally add TIs not found in the records. Furthermore, this study encompasses the entire transitional care process as it includes all patient transitions between GP and hospital. Other studies have investigated patient safety and incidents, but these studies were limited to either primary[11,17,18] or secondary care[10,19-21]. We could have described the incidents in more detail, however this was outside the scope and aim of this pilot study.

Our study also has potential limitations. Firstly, to identify TIs the researchers (MM, DE) depended mostly on information from the medical records, which was sometimes incomplete. For instance, the medical record did register an outpatient visit, but lacked a report on the content of the consultation. Also, referral or discharge letters were sometimes missing. The problem of incomplete medical records is inherent to medical record review studies and probably leads to an underassessment of incidents.[22] When only relying on the medical records (our main intent of this pilot study), an incomplete medical record (either because of inadequate registration by the physician or incompleteness of received medical records) can lead to underestimation of all types of TIs because of insufficient information. Other incidents that could also be missed are based on wrong, unclear or lacking information given to the patient, e.g. problems in the discharge procedure or assignment of a care coordinator. Information provided to the patient is often not registered in the medical record. Secondly, by starting analysis with the patient

interviews could have created hindsight bias as the researcher was not initially blinded when reading the medical records. Indeed, in five incidents we found clues in the medical records, but these could have been missed without the guidance of the patient interview. This may have led to overestimating the concordance between patient interviews and the medical records. However, this approach helped identifying subtle triggers in the transitional medical records which will potentially improve the development of our future medical record review tool.

Third, the classification models used for classification of the transitional incidents are not developed and validated for transitional care. For example, the NCC MERP Index for severity of harm has been developed for medication harm. However, as it was commonly used in medical record studies[10,11,23], and its categories were reasonably applicable, we chose to apply this in our study. The same applies to the Eindhoven Classification Model for causes of incidents and the 6-point scale for preventability.[24] In the classification of the causes of the identified TIs, it is plausible that there is an overestimation of the human causal component. This would be caused by the lack of background information that is usually collected in a formal incident analysis procedure. In the medical records, we are only able to judge the TI as a single independent incident. The organizational elements (e.g. the availability of a protocol, training of healthcare professionals, or patient safety culture) and technical causes (e.g. badly functioning or imprecise devices) underlying incidents are usually not registered in the medical record. Other contributory factors like information on time pressure and multitasking also lack in the medical record. As this is a pilot study, the methods of identifying TIs are still under development and transitional incidents were identified jointly by two researchers.

Finally, the small sample size of our study and the purposive recruitment method do not permit generalizing the results. Our study population consisted of patients with a higher risk of TIs because it served the purpose of our study, which was testing if TIs can be identified using the medical records of the GP and hospital. In the general population, possibly less TIs occur. We have also probably missed the most serious TIs causing permanent harm or death because of our sampling method starting with the patient interview.

Comparison to literature

Research has already shown that concordance exists between patient reported incidents and other methods of incident detection (e.g. medical record review studies, healthcare workers incident reporting, observation of consults). A systematic review by Ward et al. found that the highest concordance in hospitals lies between patient reporting and the medical record, ranging from 40% to 77%).[20,25-27] In primary care, less research on this topic is conducted. Starfield et al. showed a concordance ranging from 68% to 85% between medical records review and observation of consults between GP and patient.[28] However, all of these studies have been conducted within

one level of healthcare. This study showed a similar concordance between patient reported incidents and medical records from the GP and hospital in transitional care.

In healthcare transitions however, record review studies face several challenges. Transitional safety incidents are usually not reported in routine incident reporting systems, and for adequate identification and analyses medical records are required from both healthcare settings, namely GP and hospital. These records differ in both structure and design, which hampers their linkage. Subsequently, even if the patient records from both GP and hospital are collected, incidents related to the transition in care will often be difficult to identify, as they are simply not registered. Therefore, it is important to look for mismatches (e.g. medical histories, dates of hospital visits and correspondence) or redundant information (e.g. similar X-rays conducted by GP and hospital within a short period). Other clues include registered discontent of patient or healthcare provider (e.g. large numbers of consults, requests for a second opinion, emotional comments of a healthcare provider on communication with another healthcare provider). Also, possible consequences of TIs can provide a clue for its occurrence (e.g. death or readmission). For our main research study on transitional patient safety (TIPP)[13] we will further develop a method to link the electronic medical records of both the GP and hospital to identify and classify TIs within this data. Identification of these TIs will provide information to both GP and hospital for learning and improving patient safety in transitional care.

CONCLUSION

This pilot study suggests that the majority of transitional incidents can be identified in medical records, although numbers were small. Although patient interviews facilitate the identification process, they may not be necessary. With this information, we aim to further develop and test a method to identify transitional incidents in the medical records of both GP practice and hospital, without the guidance of patient interviews.

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AUTHORS' CONTRIBUTIONS

MM and DZ initiated the study. MM, DE, HS, NW and DZ designed the study. MM and DE performed the study and developed the manuscript. DZ closely supervised the manuscript development. MM, DE, HS, NW and DZ participated in reviewing and editing of various drafts of the manuscript and they all read and approved the final manuscript.

DATA SHARING STATEMENT

No additional data available.

Strengths and limitations

- To our knowledge this is the first study in which patient interviews were compared with medical records to investigate transitional patient safety and the incidence of Transitional Incidents.
- This pilot study encompasses the entire transitional care process as it includes all patient transitions between GP and hospital.
- As this study is a pilot study, the small sample size and the purposeful recruitment method do not permit generalizing the results.
- The models used for classification of the transitional incidents are not developed and validated for transitional care, for which no validated models yet exist.
- Starting analysis with the patient interviews could have created hindsight bias as the researcher was not initially blinded reading the medical records.

Table 6.4 Analysis of all identified transitional incidents. *This table presents a short narrative of the patient journey and all identified transitional incidents and their classifications presented per patient.*

a: National Coordinating Council for Medication Error Reporting and Prevention Index (NCC MERP Index)

- *A. 'Circumstances or events occurred that had the capacity to cause error',*
- *B. 'Error occurred but did not reach the patient',*
- *C. 'Error occurred that reached the patient but did not cause patient harm',*
- *D. 'Error occurred that reached the patient and required monitoring to preclude harm of confirm that it caused no harm',*
- *E. 'Error occurred that may have contributed to or resulted in temporary (mental or physical) harm or prolonged suffering from curable symptoms and required intervention',*
- *F. 'Error occurred that may have contributed to or resulted in (mental or physical) harm and required an initial or prolonged hospital stay',*
- *G. 'Error occurred that contributed to or resulted in permanent patient harm',*
- *H. 'Error occurred that required intervention to sustain patient's life',*
- *I. 'Error occurred that may have contributed to or resulted in patient death'.*

b: Preventability score:

- *1: (Nearly) no evidence for preventability*
- *2: Slight evidence for preventability*
- *3: Possibly preventable but not very likely, less than 50-50 but close call*
- *4: Probably preventable, more than 50-50 but close call*
- *5: Strong evidence for preventability*
- *6: (Definitely) evidence for preventability*

c: The assessment of causes was retrospectively done by two researchers (MM, CE) based solely on information from the patient interviews and medical records. No additional information was requested from the involved health care professionals to ensure privacy. Therefore, the results should be interpreted with caution and we decided to only identify the 'estimated' causes; d: 2 out of 4 incidents cannot entirely be objectified. Based on the information from the medical records the researchers cannot confirm whether the GP underestimated the patient's symptoms or if the situation fits the natural course of the disease.

Table 6.4 Continued

Patient	Age *(years)*	Gender M/F	Narrative of patient journey	Number of transitions (timespan in months)	Number of transitional incidents	Description transitional incidents	Severity *(type: NCC MERP[a])*	Preventability *(6-point scale)[b]*	Estimated cause of incident[c]
1	82	M	A patient was admitted with heart failure After discharge, the patient consults his GP, but the GP had not received a discharge letter. The delayed letter itself, once received, was unclear about further monitoring of blood values. Short hereafter, the patient was readmitted. On another occasion, the Peripheral IV catheter was not removed at discharge from A&E so the GP assistant removed it.	6 (in 3,5 months)	4[d]	Incomplete and unclear discharge procedure	Near miss: cat C	4	Human acts
						Omission of removal of peripheral IV catheter at discharge	Near miss: cat D	6	Human acts
						Discharge letter: lacked when patient consulted GP (received 2 weeks after discharge: not delayed)	Unsafe situation: cat A	2	Organisation and patient related
						Delayed discharge letter: lacked when patient consulted GP (received 4 weeks after discharge)	Unsafe situation: cat A	4	Organisation
2	42	F	A young patient was referred to the outpatient QDU. She was reassured several times by the GP and in hospital during and after rectal examination and colonoscopy, but diagnosis turned out to be anal carcinoma. Patient saw several doctors at the QDU, resulting in faulty and incomplete information about the upcoming treatment. The patient requested the GP for a second opinion in another hospital.	3 (in 6 months)	3	Unprepared resident at third appointment (unaware of treatment), resulting in temporary mental harm	Adverse event: cat E	6	Human acts
						Inaccurate reassurance by GP and after colonoscopy	Unsafe situation: cat A	4	Human acts
						Delayed outpatient letter (delay: 4 weeks)	Unsafe situation: cat A	3	Organisation

Table 6.4 Continued

Patient	Age *(years)*	Gender M/F	Narrative of patient journey	Number of transitions (timespan in months)	Number of transitional incidents	Description transitional incidents	Severity *(type: NCC MERP[a])*	Preventability *(6-point scale)[b]*	Estimated cause of incident[c]
3	73	F	A patient was referred to the hospital for a colonoscopy. When the patient did not get an appointment for 5 weeks the GP contacted hospital, ehich informed the GO about the existence of a QDU. The patient was immediately referred. And diagnosed with gastric cancer. Patient was operated and developed diabetes mellitus. After discharge diabetes medication and monitoring were unclear to the patient and GP. Prescription of vitamin B12 injection was omitted and not communicated to the GP.	6 (in 8 months)	3	Incorrect referral	Near miss: cat D	4	Organisation
						Unclear discharge procedure regarding diabetes medication and glucose monitoring (unclear to patient)	Unsafe situation: cat A	4	Human acts
						Unclear and incomplete correspondence between GP and hospital	Near miss: cat C	3	Organisation
						Absence of outpatient letter and note in hospital medical record about consultation	Near miss: cat C	6	Human acts and organisation
4	46	F	A patient with dyspnea was discharged after a laparoscopic hysterectomy and shortly after readmitted with pneumonia. Also, an unacknowledged vesicovaginal fistula resulted in persistent urinary incontinence, for wghich the patient had multiple reoperations in another hospital. This patient journey contains transitions between GP and physicians in two different divisions of two different hospitals (four stakeholders in the hospitals).	13 (in 10 months)	3	Patient was discharged with breathing discomfort (dyspnea), 2 days later readmission for pneumonia	Adverse event: cat E	4	Human acts
						Delayed diagnosis of fistula	Adverse event: cat E	4	Human acts
						Incomplete discharge letter: no mention of postoperative bleeding and urinary incontinence	Unsafe situation: cat A	6	Human acts

Table 6.4 Continued

Patient	Age *(years)*	Gender M/F	Narrative of patient journey	Number of transitions (timespan in months)	Number of transitional incidents	Description transitional incidents	Severity *(type: NCC MERP[a])*	Preventability *(6-point scale)[b]*	Estimated cause of incident[c]
5	79	M	A patient underwent an emergency operation because of rupture of an AAA. Insufficient guidance and information from both the hospital and the GP leads to dissatisfaction in the patient.	3 (in 3,5 months)	2	Delayed discharge letter: lacked when patient consulted GP (delay: 4 weeks)	Unsafe situation: cat A	6	
						Unclear discharge procedure	Unsafe situation: cat A	2	Organisation human acts and patient related
6	70	F	A patient was referred to the outpatient QDU for a colonoscopy. An incidental gynecological finding resulted in an urgent referral to the gynecologist.	2 (in 3 weeks)	0	None	NA	NA	NA
7	67	M	A patient was referred to hospital for a colonoscopy but was eligible for referral to the QDU because of his previous history of polyps. The GP was not aware of the presence of a QDU. In hospital he was diagnosed and treated for a polyp.	2 (in 1,5 week)	1	GP was unaware of possibility to refer to QDU, did not result in delay of diagnosis	Unsafe situation: cat A	2	Organisation and human acts
8	47	F	A patient was referred to the ophthalmologist with complaints of vision loss and swelling of the right eye and was seen by un optometrist who diagnosed tear film insufficiency. When the patient returned after several weeks to the GP with persistent complaints, the GP referred the patient to an OP in a different hospital. Here, the OP diagnosed an orbital meningioma for which the patient had neurosurgical treatment. This patient journey contains transitions between GP and ophthalmologists in 2 different hospitals	6 (in 6 months)	2	Incorrect triage: GP referred to ophthalmologist but instead patient was seen by optometrist	Unsafe situation: cat A	5	Organisation
						Incorrect diagnosis by the optometrist, resulting in delay of actual diagnosis	Adverse event: cat E	4	Human acts

Table 6.4 Continued

Patient	Age *(years)*	Gender M/F	Narrative of patient journey	Number of transitions (timespan in months)	Number of transitional incidents	Description transitional incidents	Severity *(type: NCC MERP[a])*	Preventability *(6-point scale)[b]*	Estimated cause of incident[c]
9	6	F	A GP requested X-rays in two directions for a child with chronic femoral pain. To limit radiation exposure the radiology department only made one X-ray, which showed no abnormalities. Because of persistent complaints the patient was referred to a pediatrician, who diagnosed Ewing sarcoma. This patient journey contains transitions between GP, radiology department and pediatricians in 2 different hospitals.	16 (in 18 months)	2	Non-compliance with GP order for X-rays in two directions, resulting in delay of diagnosis	Adverse event: cat F	5	Human acts and organisation
						Delayed discharge letters after chemotherapy (delay range: 1-2 months)	Unsafe situation: cat A	3	Organisation
10	63	M	A patient consulted the GP with rectal bleeding. GP and patient decided to wait and see. After 6 months the patient returned with similar symptoms and was referred to the outpatient QDU, where he was diagnosed with and treated for polyps.	2 (in 6,5 months)	0	None	NA	NA	NA
11	59	M	A patient contacted the GP OHSC for sudden severe headache and focal paresthesia of the left arm. The GP OHSC suggested to wait and see. After persistent complaints, the patient consulted his own GP and was referred to neurologist who diagnosed a minor stroke. After discharge, the patient was not satisfied because of insufficient guidance and information from the neurologist, resulting in patient consulting the GP.	2 (in 2 months)	2	Delayed diagnosis of minor stroke	Near miss: cat D	2	Human acts
						Insufficient guidance and lack of information from neurologist	Unsafe situation: cat A	4	Human acts and organisation

Table 6.4 Continued

Patient	Age *(years)*	Gender M/F	Narrative of patient journey	Number of transitions (timespan in months)	Number of transitional incidents	Description transitional incidents	Severity *(type: NCC MERP[a])*	Preventability *(6-point scale)[b]*	Estimated cause of incident[c]
12	50	M	A patient was referred to the rheumatologist and internally referred to a rehabilitation specialist because of osteoarthritis. Lyme was diagnosed (tested at patients request) and treated with antibiotics. The patient was not satisfied because of vagueness surrounding Lyme diagnosis and lack of coordination of treatment, resulting in a second opinion. The RS discovered an abnormal skin lesion and notified the GP. Excision of the skin lesion by the GP showed malignancy *(excision and diagnosis is patient information only)*.	6 (in 7 months)	2	Incomplete GP medical record: no mention of excised skin lesion	Unsafe situation: cat A	5	Human acts and organisation
						Unclear course regarding Lyme disease, resulting in second opinion	Unsafe situation: cat A	2	Organisation, human acts and patient related
13	36	F	A patient was discharged and readmitted because of persistent abdominal symptoms with rectal bleeding. An endoscopy showed diverticulitis. Patient was later admitted to hospital for treatment of de novo diabetes mellitus and treated by a diabetes specialist nurse at the outpatient clinic. After transferal of treatment to GP, the patient was unaware of transferal and contacted her general practice. This patient journey consisted of two separate episodes within one department.	11 (in 12 months)	3	Unclear to patient who diabetes care coordinator is	Near miss: cat C	3	Patient related and human acts
						Communication from diabetes specialist nurse about outpatient treatment is lacking	Unsafe situation: cat A	2	Organisation

Abbreviations: AAA = abdominal aortic aneurysm, A&E = accident and emergency, GP = general practitioner, IV = intravenous, NA = not applicable, OP = ophthalmologist, OHSC = out-of-hours service center, QDU = quick diagnosis unit, RS = rehabilitation specialist.

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Under review

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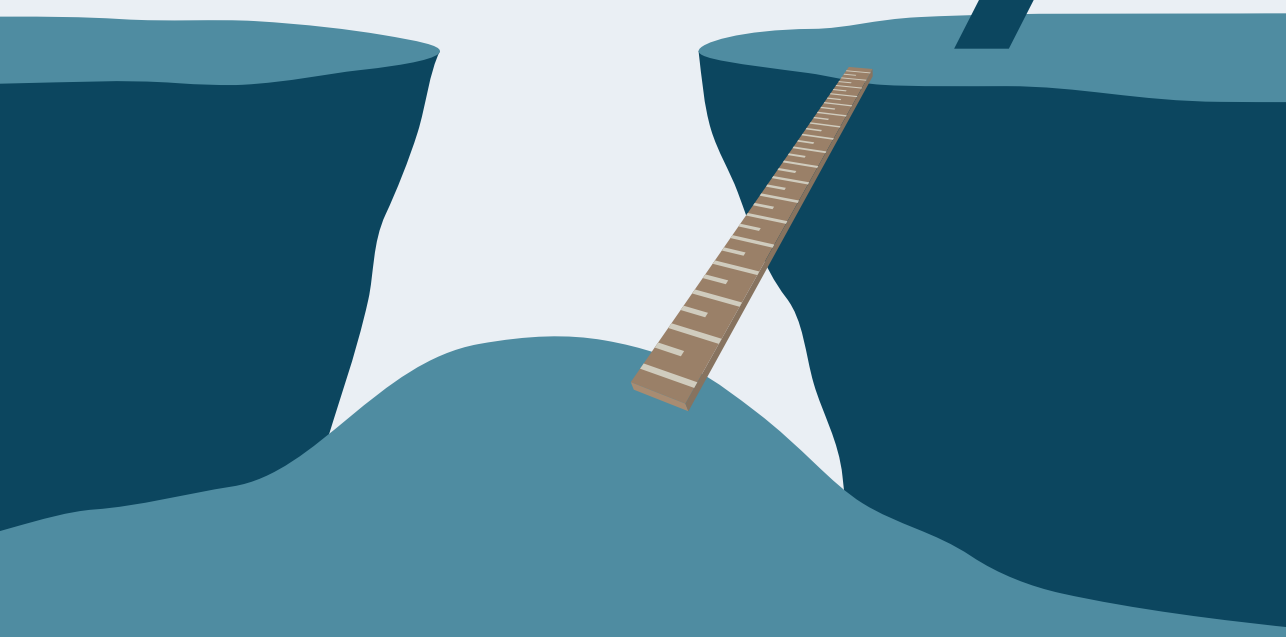

VALIDITY AND RELIABILITY OF CLINICIAN-BASED MEDICAL RECORD REVIEW IDENTIFYING TRANSITIONAL PATIENT SAFETY RISKS IN MERGED PRIMARY AND SECONDARY CARE PATIENTS' RECORDS

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ABSTRACT

Objectives

Inadequate information transfer during transitions in healthcare is a major patient safety issue. Aim of this study was to assess the reliability and validity of clinician-based review of medical records to identify transitional safety incidents (TSIs).

Study design and settings

Combined primary and secondary care medical records of 301 patients who had visited their general practitioner and the University Medical Center Utrecht, the Netherlands in 2013 were randomly selected. Six trained reviewers assessed these medical records on presence of TSIs. To assess inter-rater reliability, 10% of medical records were independently reviewed twice. To assess validity, the identified TSIs were compared with a reference standard of three objectively identifiable TSIs.

Results

The reviewers identified TSIs in 52 (17.3%) of all transitional medical records. Variation between reviewers was high (range: 3 to 28 per 50 medical records). Positive agreement for finding a TSI between reviewers was 0%, negative agreement 80%, and the Cohen's kappa -0.15. The reviewers identified 43 (22%) of 194 objectively identifiable TSIs.

Conclusion

Reliability of clinician-based assessment of transitional medical records was low. Although the TSIs that were identified by clinicians were valid, they missed almost 80% of them. Restructuring the clinician-based record review procedure is necessary.

INTRODUCTION

Multidisciplinary care provided by professionals from different settings (e.g. between general practice and hospital) is prone to patient safety incidents.[1,2] Transitions between healthcare settings as well as concurrent care by medical specialists and general practitioners (GPs) can lead to "transitional safety incidents" (TSIs). TSIs may range from unsafe situations like discrepancies between the patients' medical record in hospital or general practices to adverse events causing harm to the patient, such as unplanned readmissions or even death.[2,3]

TSIs are common: after hospital discharge almost 50% of patients are confronted with a potential health-threatening situation, such as inadequate handover or medication errors.[3] It is estimated that more than 25% of all readmissions may be prevented by improving the communication to the GP and the patient and by improving the discharge process.[4,5] Furthermore, concerning the referral process, specialists deem 10% of referrals as possibly inappropriate and only 16% of all referral letters are perceived as "good".[6,7] As both referral and discharge letters contain information that is key to the patient's care, its 'loss in transition' by inadequate communication or inadequate information exchange processes leads to potential unsafe care.[8,9]

To contribute to the improvement of transitional patient safety, we designed the Transitional Incident Prevention Programme (TIPP). In short, in a controlled before-after study we aimed to assess the effectiveness of a multifaceted TIPP intervention, targeting transitional patient safety between general practice and hospital, executed in both an urban and rural setting.[4] The current paper evaluates the assessment method of the primary outcome in this intervention program.

Patient safety is most often assessed through identification of safety incidents in a medical record review study.[10-12] As other patient safety measurement methods, like incident reporting by healthcare professionals or questionnaires assessing patient experiences, are inadequate to count the actual number of incidents[13], we chose medical record review as the primary instrument to assess the effect of the TIPP intervention. In this study, we assessed the reliability and validity of clinician-based identification of transitional safety incidents in a patient record database with both primary and secondary care patient's data.

METHODS

Patient selection

For the transitional medical record database, we included patients from the departments of cardiology and gastroenterology at the University Medical Center Utrecht, the Netherlands. Inclusion criteria were: 1) patients who were hospitalized

or visited the outpatient clinics of these departments between the first of April 2013 and the first of October 2013 (n=2069), 2) patients registered with a referring GP affiliated with the primary care research database of the Julius Primary Care Network (an academic routine care registration network , with 300.000 patients from 200 GPs) in the city of Utrecht with at least one note in the GP's medical record in the aforementioned period. Of the eligible medical records (n=1399), we selected a random sample of 301 patients with a complete transitional medical record. (Figure 7.1).

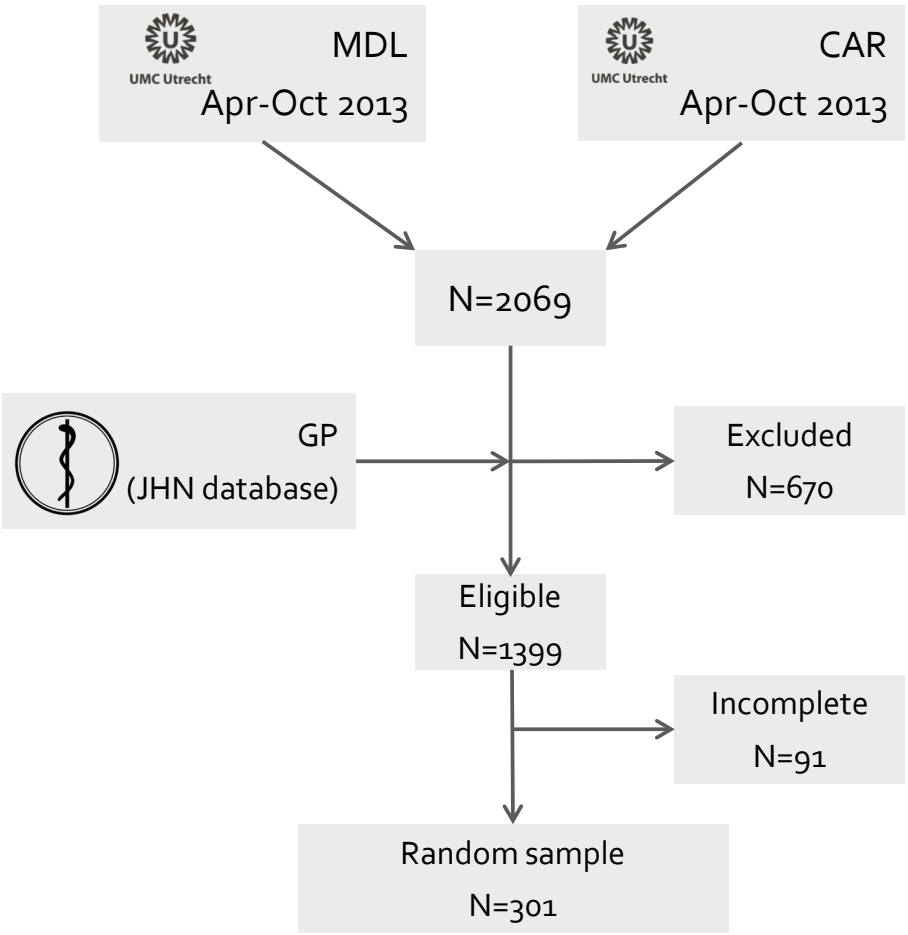

Figure 7.1 Flowchart of patient selection *for the clinician based medical record review study of the TIPP study*

Linking medical records from primary and hospital care

Currently, in The Netherlands hospitals and GPs work in separate electronic medical record systems. For this study, we constructed a digital transitional medical record database consisting of data from both general practice and hospital. According to current privacy regulations, a Trusted Third Party (TTP) linked the patients' records from both sources after pseudonymising the data. The anonymous transitional medical records contained: patients' age and gender, admissions to the cardiology and/or gastroenterology departments, nursing documentation, and the following information from both the GP and the hospital: medical history, current medication, documented consultations, diagnostic examinations, and correspondence. A digital timeline based on the collected medical records was created for each patient to summarize the patient journey.

Reviewers

We chose a multidisciplinary group of six reviewers who reviewed the medical records individually. To cover all possible views on TSIs, we chose reviewers from all professions involved: three GPs, two cardiologists, and one gastroenterologist. The reviewers had the possibility to consult each other. The reviewers received a half-day training on the medical record review process, the definition of TSIs, and the context of the TIPP study. During the training, the reviewers practiced with case histories and the transitional medical record database. During the data collection period, the reviewers attended one additional meeting on the record review process in order to discuss and solve problems they encountered during data collection.

Review process

The review process was based on methodology from previous medical record review studies[14,15] which shaped the development of a systematic identification form for TSIs, and the process of testing and refining, as well as the reviewers' training. The definition of a TSI was "any unintended or unexpected event in patient care between different healthcare organizations which could have led or did lead to harm for one or more patients receiving care".[16] Fifty transitional medical records were randomly assigned to each of our reviewers and instructions were given to identify TSIs during the study period. When a TSI was identified, the reviewers summarised and classified the TSI according to type, cause, severity and preventability. We used the Eindhoven Classification Model to characterise the cause[17] and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) to classify the severity of the TSI.[18] Preventability was classified using a 6-point scale from "(nearly) no evidence of preventability" to "(definitely) evidence of

preventability".[14] The reviewers also assessed the quality of the medical records. For details of the review steps and classifications see appendix 7.1 and 7.2.

Reliability

To determine inter-rater reliability, a random sample of 10% of the medical records was reviewed by two reviewers independently. All reviewers re-reviewed five medical records that were already reviewed. To assess inter-rater variation, we collected reviewer characteristics: age, gender, medical specialty, working experience, scientific experience, experience in incident analysis, and their opinion on three statements regarding incidents and transitional safety using a 5-point Likert scale from strongly disagree to strongly agree (Table 7.1).

Table 7.1 Patients' and reviewers' characteristics. *Characteristics of reviewed patients (1a) and reviewers (1b).*

1a Patient characteristics (N=301)		
Age, *mean (range)*		60 (19 -93)
Male sex, *N(%)*		167 (56%)
Medical specialty, *N(%)*	General practice	301 (100%)
	Cardiology	211 (70%)
	Gastroenterology	90 (30%)
1b Reviewer characteristic (N=6)		
Age, *mean (range)*		55 (32 - 72)
Male sex, *N*		3
Medical specialty, *N*	General practitice	3
	Cardiology	2
	Gastroenterology	1
Years of working experience as a medical specialist or GP, *range*		0.5 – 32
Carried out a scientific research before, *N yes*		5
Carried out a medical record research before, *N yes*		6
Experience with analysing medical incidents, *N yes*		1
Worked as a teaching physician, *N yes*		3
Statements results reviewers (N=6)		
1: How useful is medical research focused on incidents, rated on a scale from 1 to 10, with 10 being the most positive, *range*		7 – 9
2: As healthcare is complex care transitions are not ever flawless. Yet, not all of these flaws represent safety incidents, *range*		Neutral – Strongly agree
3: Incidents always harm the patient, *range*		Strongly disagree – Disagree

GP=General practitioner

Validity

For validating our record review method, we focused on construct, content and concurrent validity. Construct validity is defined as "*The degree to which the scores of an instrument are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups)"*. In a previous pilot study, we assessed the construct validity by comparing our medical record review method with patient interviews and found a concordance of 64%.[16,19]

Content validity is defined as*: "the extents to which items appear 'on the face of it' to be measuring what the instrument is intended to measure".*[20] We first searched the literature and existing medical record review studies within organisations.[14,15,21] Then, we used these existing intra-organisational record reviews to develop our clinician-based review method identifying TSIs. Hospital specialists, GPs and an expert in medical record review studies (ML) were consulted to assess our clinician-based record review method and we tested the usability. Subsequently, we asked the reviewers to judge our TSI identification method on completeness and clarity.

Concurrent validity is defined as *"the extent to which scores on a new measure are related to scores from a criterion measure administered at the same time".*[19] As no criterion measure exists within transitional patient safety[12], we used a standardised assessment of three objectively identifiable TSIs as a reference standard, namely 1) presence and timeliness of correspondence from hospital to GP, 2) redundant diagnostic testing (i.e. a diagnostic test unnecessarily performed by both GP and hospital in a short time period), and 3) communication of in-hospital prescription changes to the GP. These objectively identifiable TIs were systematically assessed by our research team using a strictly protocolled step-by-step guide, as described in more detail in appendix 7.1. Additionally, to assess whether all reviewer-identified TSIs met the definition of a TSI, the research team assessed all reviewer-identified TSIs.

Statistical analysis

We calculated differences between the patients of which the medical records were reviewed (N=301) and the patients of which all eligible medical records (N=1399), using Kruskal-Wallis test for continuous variables and the Pearson Chi-Square test for categorical variables. With descriptive statistics, we presented the total of TSIs and the number per reviewer, type, cause, severity and preventability. To assess the inter-rater reliability, we tested positive and negative agreements of identified TSIs and calculated Cohen's kappa and intraclass correlation (ICC) model 2 in which Cohen's kappa disregards our varying reviewer pairs (observer nested within subjects) and the ICC disregards the binomial nature of our outcome.[20] Difference between reviewer and relations between reviewer characteristics and the identification of TSIs were analysed with Pearson Chi-Square test. IBM SPSS Statistics 21.0 was used for all statistical analyses.

Ethical approval

The TIPP study was exempt from formal medical-ethical approval according to Dutch law (METC numbers 13/142) and the TIPP medical record review method was approved as an addendum (METC addendum 13-142/C) by the medical ethical committee UMC Utrecht, the Netherlands. All reviewers signed a confidentiality agreement.

RESULTS

Patient and reviewer characteristics

The 301 randomly selected patients were not significantly different from the total group of 1399 patients in the database. Their median age was 60 years (19-93), 56% was male and 70% visited the cardiology department (Table 7.1). Patient characteristics were evenly distributed between the reviewers, except for age. The age of the patients reviewed by reviewer III was significantly higher (median of 67 years). The age of the reviewers ranged between 32 and 72 and they had 0.5 to 32 years of working experience as a GP or specialist (Table 7.1).

Characteristics of identified transitional incidents

In total, the 301 reviewed patient records revealed 422 transitions between general practice and hospital or vice versa (1.4 transitions per patient in 6 months). In 52 of 301 (17.3%) records in total 60 TSIs were identified, which means one TSI in every seven care transitions.

The main types of identified TSIs concerned "Information from hospital to general practice" (n=35; 60% of total TSI), "Medication and other prescriptions" (n=19; 32%) and "Registration in the medical record" (n=16; 27%). The majority of TSIs were assigned to organisational (n=44; 73%) or human causes (n=20; 33%). No TSIs were judged to be patient-related. As multiple types or causes could be attributed to a single TSI, these numbers add up to more than 100%. Our reviewers assessed 48 (89%) TSIs as an unsafe situation (NCC MERP category A), 3 (5%) TSIs as a near miss that did not reach the patient (NCC MERP category B) and 2 (3%) TSIs as reaching the patient, of which one led to temporary harm (NCC MERP category C and F). Severity of seven TSIs could not be assessed because of insufficient information. Thirty (55%) of TIs were assessed as probably or definitely preventable. Preventability of five TSIs could not be assessed because of insufficient information. The overall quality of the medical records was rated as "sufficient". Box 7.1 shows some examples of identified TSIs.

Box 7.1 Examples of identified TSIs in the medical record review

- The hospital specialist stops two prescriptions, however, two months later the general practitioner repeats the old medication prescriptions
- Medication in hospital's record and general practitioner's record differs; (acenocoumarol vs fenprocoumon)
- In a discharge letter, two different cholesterol inhibitors are prescribed. The patient finds out and contacts his general practitioner
- No note of atrial fibrillation with moderate heart function and complaints of dyspnea diagnosed in hospital in the medical record of the general practitioner
- The cardiologists medical record does not mention diabetes diagnosed by the general practitioner (other risk factors are registered)
- No note or letter of a hospital admission in the general practitioner's medical record
- The general practitioner calls the hospital for the results of a colonoscopy in hospital because of persistent complaints. The general practitioner did not receive correspondence of the results or treatment and the patient does not know.
- After discharge, the discharge letter asks the general practitioner to check the patient's potassium level, however the blood test is not performed
- A patient has 3 types of potential potassium-elevating medication separately prescribed by the general practitioner or the hospital physician, but the potassium blood level is never checked
- The general practitioner's medical record notes indicate doubt about the first responsible physician for treating the patient's high blood pressure (cardiologist or general practitioner) in a patient with poor medication adherence. Because the patient prefers the GP, he takes up the treatment. Patient is discharged from the outpatient visits to the cardiologist.

The frequency of TSIs identified per reviewer ranged from 3 - 28 in 75 transitions. Five of the six reviewers identified three to ten incidents, and one identified a total of 28 TSIs (reviewer VI). Patients' age or gender did not differ between those patients who did and those who did not experience a TSI. The patients who experienced a TSI were more frequently treated by the cardiologist (82.7%) compared to patients who did not experience a TSI (67.5%).

Reliability

In the 30 transitional medical records reviewed by two reviewers independently, ten TSIs (33%) were found in total (Table 7.2). The positive agreement was 0%, the negative agreement was 80%, Cohen's kappa was -0.15 and ICC was -0.18.

Table 7.2 Inter-rater reliability in 30 transitional medical records reviewed by two reviewers independently.

		Second reviewer		
		TSI identified	**No TSI identified**	**Total**
First reviewer	**TSI identified**	0	7	7
	No TSI identified	3	20	23
	Total	3	27	30

TSI=Transitional safety incident

Validity

Content validation: Reviewers reported neither missing items nor obscurity in the TSI identification method used. Yet, reviewers showed having a problem applying the definition of TSI to frequently occurring, 'small' transitional failings. Despite of the instructions to apply the definition of TSI strictly and conservatively, they inclined to subscribe the small failings as minor imperfections instead of TSIs or as consequences of the incomplete research database. The fact that all but one reviewer agreed with the statement "As healthcare is complex care, transitions are not ever flawless. Yet, not all of these flaws represent safety incidents" also indicated that reviewers had doubts about the content validity (Table 7.1). The only reviewer who did not agree with the statement identified most TSIs.

Concurrent validation: Ninety-two percent of the reviewer-identified TSIs met the researchers' definition of a TSI. Using the reference standard for TSIs our research team identified 194 objectively identifiable TSIs in 179 (62%) medical records: of these, 153 regarded correspondence, 5 regarded redundant diagnostic testing, and 36 reflected communication of prescription changes. Only 43 (22%) of these TSIs were identified by the reviewers and hence 151 (78%) TSIs were missed. Within reviewers, the percentage of objectively identifiable TSIs found ranged from 3 to 47%.

DISCUSSION

Main findings

In the current form, clinician-based transitional medical record review proved not to be a reliable method for TSI identification. Although TSIs were identified in one in seven care transitions and 92% of these proved correctly labelled as TSI, reviewers missed 78% of objectively identifiable TSIs. The inter-rater reliability was low and reviewers significantly differed in frequency and characteristics of the identified TSIs. Hence, the identification and categorization of TSIs was undoubtedly subjective. The limited agreement with our reference standard and the high variability between reviewers points at a lack of a shared understanding of the definition of a TSI, despite of the format of the review procedure or the training.

Comparison to literature

The reliability of our review method was much poorer than in other medical record review studies. While the inter-rater reliability in medical record reviews by clinicians, aimed at identifying incidents inside hospitals, ranged between fair to substantial agreement (Cohen's kappa 0.24 – 0.71)[12,22-24], we found a poor Cohen's kappa of -0.15.

Variation in patient selection, types of patient records and/or reviewers' characteristics may explain these differences. For instance, in a comparable study on identification of TSIs after discharge, Forster et al. found a suboptimal inter-rater reliability (Cohen's kappa 0.26) in 319 case reports of patients with poor outcomes following discharge. Because these patients are known to have a high risk for TSIs, incidents would have been be easier to identify and therefore the agreement probably was better than in our study in which we did not select on high risk, but included all patients visiting hospital and general practice.[24] Second, in contrast to Forster et al. in which hospital-based reviewers assessed hospital medical records, our reviewers assessed medical records that originated from different organisations. Additionally, others may have worked with reviewers from the same discipline while we consciously chose to work with a heterogeneous group of reviewers in terms of medical disciplines, and hoped this would add to the sensitivity of the record review. However, because of these different backgrounds, they had different, often contrasting views on TSIs and the healthcare system which may have resulted in the identification of different TSIs. For, as much as we would like *one* healthcare system, the current healthcare system is fragmented in which hospitals and general practices have their own language and view on patient safety.[25] Together, it is likely that the variation in reviewer characteristics has hampered the reliability of our TSI identification process. [23]

Our reviewers may have had problems identifying TSIs because they viewed incidents from a clinician's perspective instead of a patient safety perspective. Such general underestimation of incidents and harm by clinicians is described previously.[26] Clinicians deal with risks on a daily basis. They learn to be resilient and deal with unsafe situations instantly at their occurrence, thus making risk management part of routine practice.[13] However, such attitude could lead to a loss of awareness about the state of the systems and processes that impact patient care, thus hampering identification of safety incidents, and adding to the subjectivity of the identification process.

Strengths and limitations

Our study has several strengths. First, the transitional medical records database included *all* transitions from general practice to hospital and vice versa. This adds to the content validity as we were able to follow the patient's journey and measure patient safety crossing healthcare levels.[27] Second, many studies that measure patient safety and incidents only include adverse events; we typically included *all* potentially harmful incidents that indicate weaknesses in the system.[28]

Concerning limitations all double medical records were randomly distributed among the other reviewers, leading to 15 different pairs of reviewers (instead of specific reviewer-pairs), which might have decreased inter-rater reliability. Together with the limited number of reflective consensus meetings, this might have decreased inter-rater reliability. Also, the assessment by an expert team on transitional patient safety as the reference standard, as is often done in diagnostic studies, may be first choice.[29] However, this was not feasible in practice and the total of missed TSIs would increase because this expert team would have assessed all TSIs instead of only three items. Finally, correspondence of discharge and visits to the outpatient clinic was regularly missing. It was often unclear whether this was caused by failure in the data extraction, or the result of omission or faulty registration of correspondence in the hospital.

Implications

In order to be a reliable measurement tool for TSIs the clinician-based medical record review method needs to be improved. Possibilities for improvement of medical record reviews suggested in the literature are making the transitional medical record database more complete, developing a more robust and standardised identification process, improving training and manual, and selecting a more homogeneous group of reviewers.[12,22-24,30]

Conclusion

Designing a valid clinician-based assessment of transitional incidents in merged primary and secondary care medical records is challenging. In such assessment, clinicians indeed can identify TSIs that are clinically relevant and indicate room for improvement. Yet, the current clinician based identification method needs considerable adjustments to improve reliability and validity. This study serves as a starting point to optimise the identification process of TSIs.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors participated in the design of the study. MM, JP, and OV acquired the data. MM, JP, HS and OV analysed and interpreted the data. MM, DZ, JP, OV and NW drafted the manuscript, HS and ML critically revised the manuscript. All authors read and approved the final manuscript.

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Data sharing statement

No additional data is available.

Strengths and limitations

- In this study, we assessed validity and reliability of a transitional medical record review method in a transitional medical record, containing both the medical record of the general practitioner and hospital
- The transitional medical records database included *all* transitions from general practice to hospital and vice versa, allowing us to follow the patient's journey and measure patient safety crossing healthcare levels

- We aimed to identify *all* potentially harmful incidents that indicate weaknesses in the system, not only adverse events
- As no accomplished reference standard is available in transitional patient safety, we chose a suboptimal reference standard.
- Validity and reliability was possibly affected by our heterogeneous reviewer group from both general practice and hospital, the limited number of the use of random pairs for the interrater reliability.

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APPENDIX 7.1a CLINICIAN BASED MEDICAL RECORD REVIEW

Six medical specialists (three general practitioners (GPs), two cardiologists, one gastroenterologist, some of whom were retired) reviewed the transitional medical records. The reviewers received a half-day training. This training included: the definition of transitional safety incidents (TSIs), casuistry and practicing with the transitional medical record. One transitional medical record was reviewed jointly. The training was given by two researchers (MM, JP) of the Transitional Incident Prevention Programme (TIPP) study and an expert on medical records reviews (ML). The review process took three weeks, in which the reviewers attended one reflective meeting to discuss uncertainties and improve consensus.

The reviewers were instructed to identify TSIs in the medical record between the first of April 2013 and the first of October 2013. When a patient had visited both the gastroenterologist and cardiologist, the reviewers were instructed to only assess the journey between GP and cardiology. First, reviewers summarized the patient's journey. When a TSI was identified, the reviewer gave a summary of the TSI and classified the TSI according to type, cause, severity and preventability. Multiple TSIs could be identified in a single transitional medical record.

The classification of the type of TSIs was based on a previously composed list of susceptible steps in the transitional care process and risk factors for TSIs (appendix Table 7.1.1).

Appendix Table 7.1.1 Classifications of type

	Type
1	Referral information from GP to hospital
2	Information from hospital to GP (e.g. not available, delayed, incomplete, incorrect, ignored in hospital)
3	Diagnostic examination (e.g. not performed, twice performed, incorrect test)
4	Medication/prescription (not registered, double or incorrect medication)
5	Most responsible physician
6	Communication/co-operation
7	Triage
8	Diagnosis
9	Self-care advise
10	Accessibility
11	Out-of-hours service
12	Discharge from the outpatient clinic (other than correspondence)
13	Discharge after hospitalization (other than correspondence)
14	Referral to outpatient clinic (other than correspondence)
15	Referral to hospital for emergency department or hospitalization (other than correspondence)
16	Record-keeping in the medical record

GP=general practitioner.

The classification of the cause of TSIs was based on the Eindhoven Classification Model, which differentiates "techniques", "organization", "human acts" and "patient related" as causal factors. Both the categorization of type and cause were multiple response questions.

The classification of the severity of TSIs was based on the National Coordinating Council for Medication Error Reporting and Prevention Index (NCC MERP Index), which is frequently used to classify the severity of errors. The items "mental harm" and "delay" were added to the NCC MERP Index to fit the subject of transitional care better. The levels of the NCC MERP were divided into three groups: 1) "unsafe situations", which corresponds with level A of the NCC MERP Index, 2) "near misses", which corresponds with level B through D and 3) "adverse events", which corresponds with level E through I (Appendix Table 7.1.2).

Appendix Table 7.1.2 Classification of severity

A	"Circumstances or events occurred that had the capacity to cause error"
B	"Error occurred but did not reach the patient"
C	"Error occurred that reached the patient but did not cause patient harm"
D	"Error occurred that reached the patient and required monitoring to preclude harm or confirm that it caused no harm"
E	"Error occurred that may have contributed to or resulted in temporary (mental or physical) harm or prolonged suffering from curable symptoms and required intervention"
F	"Error occurred that may have contributed to or resulted in (mental or physical) harm and required an initial or prolonged hospital stay"
G	"Error occurred that contributed to or resulted in permanent patient harm"
H	"Error occurred that required intervention to sustain patient's life"
I	"Error occurred that may have contributed to or resulted in patient death"

The classification of the preventability of TSIs was divided into a six-point scale, ranging from "(nearly) no evidence of preventability" to "(definitely) evidence of preventability". Beforehand, additional questions were asked to trigger the reviewer's train of thoughts. Furthermore, the reviewers were asked during which transition of the healthcare process the TSI had happened (at referral, at hospitalization, at/after discharge, during/after visit to the outpatient clinic, at a visit to the GP or unclear). If needed, consultation with other medical specialties (cardiologist, gastroenterologist, GP) was available. When a reviewer indicated uncertainty about a (possible) TSI, an expert reviewed the transitional medical record as well. Next, the reviewers evaluated the quality of the medical records of both the GP and the hospital separately and the correspondence between the two, categorized in "good", "adequate", "moderate", "poor" and "not possible to review due to missing data". The case report form is can be found in Appendix 7.1b.

APPENDIX 7.1b STANDARDISED ASSESSMENT OF OBJECTIVELY IDENTIFIABLE TIS

Two researchers assessed three objectively identifiable TSIs as a reference standard. These three TSIs consisted of (1) presence and timeliness of correspondence from hospital to GP; (2) redundant diagnostic testing performed twice both by the GP and hospital; and (3) communication of prescription changes made in the hospital. First, the researchers assessed the number of visits to the outpatient clinic, number of hospital admissions and number of visits to the GP. Second, they assessed the number of transitions, in which a referral by the GP, discharge by the outpatient clinic or after hospital stay, and important policy changes in hospital that demanded communication with the GP were counted as a transition. Third, they assessed if correspondence was present in the medical record, and if correspondence was timely (within 14 days after the transition). When the correspondence was not present or delayed, we considered this a transitional incident. Fourth, the researchers assessed the performed diagnostic tests. When the test was performed both by the GP and the hospital within three months and met the inclusion criteria, we considered this a TSI. Inclusion criteria were: 1) any laboratory test that is not routine (e.g. hormones, virus serology or other blood levels that are not susceptible to acute change), 2) blood- or urine cultures, 3) radiology (echo, x-rays or spectroscopy), 4) event recording (heart rhythm registration), 5) pathology tests (smear tests, skin biopsy), and 6) spirometry. Exclusion criteria: 1) any diagnostic test that requires repetition (e.g. urine analysis, electrocardiography), 2) blood tests susceptible to acute changes (e.g. troponin, CRP, BSE, leucocytes, blood gas analysis), 3) diagnostic testing usually not performed or requested by the GP (CT-scans, MRIs, colonoscopies, liquor testing), 4) diagnostic tests performed twice because of deterioration of the patient 5) diagnostic tests that are performed twice within one organisation (within the general practice or hospital). Last, researchers identified prescription changes in the hospital medical record (both in the written consultation text and the medication prescription), and checked the GP medical records for confirmation or clues of the communicated prescription change. When no sign of communication or prescription change was found in the GP medical record, we considered this a TSI.

APPENDIX 7.2 CASE REPORT FORM USED BY REVIEWERS FOR MEDICAL RECORD REVIEW

Date medical record review (dd-mm-yyyy)

		-			-				

Name reviewer

1. SUMMARY OF PATIENT

Give a short summary of the patient in this medical record .
Example: A 75-year old male with an extensive medical history and polypharmacy is admitted to hospital with a myocardial infarction. After discharge, he is checked at the outpatient clinic.
Example 2: A 69-year old female is referred to the gastroenterologist with rectal bleeding. She is diagnosed with haemorrhoids and treated accordingly.

2. TRANSITIONAL MEDICAL RECORD REVIEW

Definition of a transitional safety incident: Any unintended or unexpected event in patient care between different healthcare organisations which could have led or did lead to harm for one or more patients receiving care. In the TIPP study, we chose to focus on transitional incidents between primary care and hospital instead of all levels of care. If an unintentional event occurs in primary care and the results of the incident are noticed in the hospital or vice versa, this also counts as a transitional safety incident.

In this medical record, we use a broad definition of "incident". The following incidents are included:

- **Adverse event:** Any injury caused by medical care.
- **Near miss**: An act of commission or omission that could have harmed the patient but did not do so as a result of chance, prevention or mitigation.[1]
- **Unsafe situation**: Circumstances or events occurred that had the capacity to cause error.[2]

([1]) Aspden P, Corrigan JM, Wolcott J, Erickson SM, editors for the Committee for Data Standards for Patient Safety, Institute of Medicine. Washington, D.C.: The National Academic Press; 2004.
([2]) *National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Medication Errors Council revises and expands index for categorizing errors. Definitions of medication errors broadened [Internet]. June 12, 2001. Available from:* http://www.nccmerp.org/press/press2001-06-12.html.

2a) IDENTIFICATION OF THE TRANSITIONAL SAFETY INCIDENT

Check the following transitions and risks for TSIs. Did something go wrong in one of the following processes?

- ☐ **Information from GP to hospital (referral information).** This information can be delayed, incomplete or incorrect. Even if this information is present in hospital, it can be ignored or missing. Pay attention, in this pilot the referral letters cannot be found in the medical record.
- ☐ **Information from hospital to GP (discharge letters, letters from the outpatient clinic).** This information can be delayed, incomplete or incorrect. Even if this information is present at the GP, it can be ignored or missing.
- ☐ **Diagnostic research.** Diagnostic research can be performed twice (by GP and hospital) within a short period, or cannot be performed. Also, the incorrect diagnostic research can be performed.
- ☐ **Medication or other prescription (e.g. wound care, stoma care, material for incontinence)**
- ☐ **Most responsible physician.** The most responsible physician should be appointed to every patient; sometimes this is not done, or there is obscurity in who is the most responsible physician.
- ☐ **Communication and collaboration.** This comprises of all communication or collaboration, except communication by mail (discharge letters, referral letters and letters from the outpatient clinic).
- ☐ **Triage**
- ☐ **Diagnosis**
- ☐ **Self-care advise**
- ☐ **Accessibility**
- ☐ **Care in out-of-office hours**
- ☐ **Discharge from the outpatient clinic.**
- ☐ **Discharge after hospital admission.** Concerning the discharge process, excluding the discharge letter.
- ☐ **Referral to outpatient clinic.** Concerning the referral process itself, excluding the referral letter.
- ☐ **Referral to the emergency department.**
- ☐ **Record keeping in medical record**
- ☐ **Other, namely……**

Have you identified a transitional safety incident?

- ☐ Yes
- ☐ Possibly
- ☐ No

You need to fill in part 3 and 4 for every individual transitional safety incident you have identified.

3 THE TRANSITIONAL SAFETY INCIDENT

Summarize the TSI
Example 1: A week after discharge a patient visits his GP, who has not received a discharge letter yet.
Example 2: A patient is known with heart failure and uses diuretic medication (Bumetanide) prescribed by the cardiologist. Because of swollen ankles, the GP prescribes Furosemide (another diuretic medicine) because he is ignorant of the use of Bumetanide. Three months later the nurse at the heart failure outpatient clinic discovers the double medication.

3a) TIMING OF THE TRANSITIONAL SAFETY INCIDENT

Timing of TSI:
- ☐ At referral
- ☐ During hospital admission
- ☐ At or after discharge
- ☐ At/ after visit to the outpatient clinic
- ☐ At/ after visit to the GP

In which part of the healthcare process the TSI occurred?

☐ Information from GP to hospital (referral information)
- ☐ No referral information received
- ☐ Delayed
- ☐ Incomplete
- ☐ Incorrect
- ☐ Present, but ignored at the hospital

☐ Information from hospital to GP (discharge letters, letters from the outpatient clinic)
- ☐ No information received
- ☐ Delayed
- ☐ Incomplete
- ☐ Incorrect
- ☐ Present, but ignored at the GP

☐ Diagnostic research
- ☐ Not performed

- ☐ Doubly performed at GP and hospital
- ☐ Wrong diagnostic test

☐ Medication or other prescription (e.g. wound care, stoma care, material for incontinence)

- ☐ Absent
- ☐ Double medication
- ☐ Incorrect

☐ Most responsible physician

- ☐ Obscurity
- ☐ None appointed

☐ Communication and collaboration
☐ Triage
☐ Diagnosis
☐ Self-care advice
☐ Accessibility
☐ Out-of-office hours
☐ Discharge from the outpatient clinic
☐ Discharge after hospital admission
☐ Referral to the outpatient clinic
☐ Referral to hospital (either admittance or emergency department)
☐ Record keeping in medical record
☐ Other, namely…..

During which shift did the TSI occur?

☐ Day shift (8:00 – 17:00 mon-fri)
☐ Evening sift (17:00 – 23:00 mon-fri)
☐ Night shift (23:00 – 8:00 mon-fri)
☐ Weekend day shift (8:00 – 17:00 sat-sun)
☐ Weekend evening shift (17:00 – 23:00 sat-sun)
☐ Weekend night shift (23:00 – 8:00 sat-sun)

3b PREVENTABILITY OF THE TRANSITIONAL INCIDENT

What factors contributed to the TSI?

☐ Out-of-office service
☐ Time constraints
☐ Complex patient
☐ Language barrier
☐ Emergency
☐ Known complication
☐ Referral within hospital
☐ Multiple departments involved within the hospital
☐ Multiple hospitals involved
☐ Multiple GPs involved

☐ Other, namely…..

Was the TSI (potentially) preventable?

- ☐ (Nearly) no evidence for preventability
- ☐ Slight evidence for preventability
- ☐ Possibly preventable but not very likely, less than 50-50 but close call
- ☐ Probably preventable, more than 50-50 but close call
- ☐ Strong evidence for preventability
- ☐ (Definitely) evidence for preventability

Did you answer "Probably preventable, more than 50-50 but close call", "Strong evidence for preventability" or "(definitely) evidence for preventability", please answer the following question:

Describe how the TSI could have been prevented:

3c SEVERITY OF THE TRANSITIONAL INCIDENT

What was the severity if the TSI?

Did the TSI cause hospital admission or lengthening of hospital stay?

- ☐ No
- ☐ Yes: hospital admission
- ☐ Yes: readmission
- ☐ Yes, lengthening of hospital stay of ….. days
- ☐ Not possible to assess

What harm did the TSI cause the patient?

- ☐ A Unsafe situation: "Circumstances or events occurred that had the capacity to cause error"
- ☐ B Near miss: "Error occurred but did not reach the patient"
- ☐ C Near miss: "Error occurred that reached the patient but did not cause patient harm"
- ☐ D Near miss: "Error occurred that reached the patient and required monitoring to preclude harm or confirm that it caused no harm", namely……..
- ☐ E Adverse event: "Error occurred that may have contributed to or resulted in temporary (mental or physical) harm or prolonged suffering from curable symptoms and required intervention", namely…….
- ☐ F Adverse event: "Error occurred that may have contributed to or resulted in (mental or physical) harm and required an initial or prolonged hospital stay", namely…….
- ☐ G Adverse event: "Error occurred that contributed to or resulted in permanent patient harm", namely……..

- ☐ H Adverse event: "Error occurred that required intervention to sustain patient's life", namely…….
- ☐ I Adverse event: "Error occurred that may have contributed to or resulted in patient death"

Can the health status of the patient return to his/her health status before the TSI?

Daily activities
- ☐ Yes
- ☐ No
- ☐ Patient is deceased
- ☐ Not applicable

Independence
- ☐ Yes
- ☐ No
- ☐ Patient is deceased
- ☐ Not applicable

3d) CAUSE OF THE TRANSITIONAL INCIDENT

Can you identify a possible cause for the TSI?
- ☐ No
- ☐ Yes, namely…..
- ☐ Technical factors—equipment, software, forms
- ☐ Organizational factors—policies, procedures, and protocols
- ☐ Human factors—knowledge-based (familiar procedures applied to frequent decision-making situations), rule-based (routine tasks requiring little conscious effort), and skill-based (problem solving activities often in new situations)
- ☐ Patient related: Failures related to patient characteristics or conditions, which are beyond the control of staff and influence treatment.
- ☐ Other, not possible to classify further in the categories mentioned above, namely
- ☐ Not possible to identify a probable cause because of missing data

4 CONSULTATION OF AN EXPERT/ SPECIALIST

Do you wish an expert opinion in this case?
- ☐ Yes
- ☐ No

What medical specialty:
- ☐ Gastroenterology
- ☐ Cardiology
- ☐ General practitioner

Question to the expert

Answer specialist:

Has the reviewer's opinion changed?

- ☐ Yes, namely…..
- ☐ No

Are there any other doubts in answering CRF? These doubts will be addressed in the reviewers' group meetings

- ☐ Yes, about question……
- ☐ No

If you answered yes, what is the obscurity or doubt?

Are there any other TSIs you have not addressed yet in the CRF?

- ☐ Yes -> a new TSI CRF (part 3 and 4) opens
- ☐ No -> go to part 5

5 MEDICAL RECORD QUALITY

Medical record of the GP

	Poor	Moderate	Adequate	Good	Not applicable
Medical history	○	○	○	○	○
Medication	○	○	○	○	○
Resuscitation code	○	○	○	○	○
Allergies	○	○	○	○	○
Consult registration	○	○	○	○	○
Diagnostics	○	○	○	○	○
Correspondence/ handoff from hospital	○	○	○	○	○
Other, namely…	○	○	○	○	○

What is the overall quality of the GP's medical record?

- ☐ Poor
- ☐ Moderate
- ☐ Adequate
- ☐ Good

Did you answer "poor" or "moderate"? Was the medical record:

- ☐ Incomplete, namely …….(What part; please describe in short)
- ☐ Inadequate, namely …….(What part; please describe in short)
- ☐ Poor, namely …….(What part; please describe in short)
- ☐ Other, namely …….(What part; please describe in short)

Did you have enough information to assess the TSI?

- ☐ Yes
- ☐ Partly, namely …… (What part of the medical record did you miss end for which review question?)
- ☐ No, namely….. (What part of the medical record did you miss end for which review question?)

Hospital medical record

	Poor	Moderate	Adequate	Good	Not applicable
Medical history	○	○	○	○	
Medication	○	○	○	○	
Resuscitation code	○	○	○	○	
Allergies	○	○	○	○	○
Consult registration	○	○	○	○	○
Diagnostics	○	○	○	○	○
Admission registration	○	○	○	○	○
Nurses report	○	○	○	○	○
Inter-collegial consultations within the hospital	○	○	○	○	○
Correspondence to GP (e.g. discharge letter or letter from out-patient clinic)	○	○	○	○	○
Other, namely….	○	○	○	○	○

What was the overall quality of the hospital medical record?

- ☐ Poor
- ☐ Moderate
- ☐ Adequate
- ☐ Good

Did you answer "poor" or "moderate"? Was the medical record:

- ☐ Incomplete, namely …….(What part; please describe in short)
- ☐ Inadequate, namely …….(What part; please describe in short)
- ☐ Poor, namely …….(What part; please describe in short)
- ☐ Other, namely …….(What part; please describe in short)

Is the correspondence between hospital and GP in any way inadequate? E.g. Is important information missing in the referral letter, such as relevant history of medical treatment? Or is important information missing in hospital correspondence to the GP, like further planned medical policy?

- ☐ Yes
- ☐ No
- ☐ Too little information in medical record, correspondence was missing

Did you answer yes: What correspondence was inadequate? (type, location in the medical record and date)

Direction of the correspondence:

- ☐ GP to hospital
- ☐ Hospital to GP
- ☐ Other, namely…

What information was missing?

Did you have enough information to assess the TSI?

- ☐ Yes
- ☐ Partly, namely……(what did you miss and what part of the review did it affect?)
- ☐ No, namely……(what did you miss and what part of the review did it affect?)

Do you have other observations regarding the medical record (of either the GP or the hospital)?

- ☐ Yes, namely…….
- ☐ No

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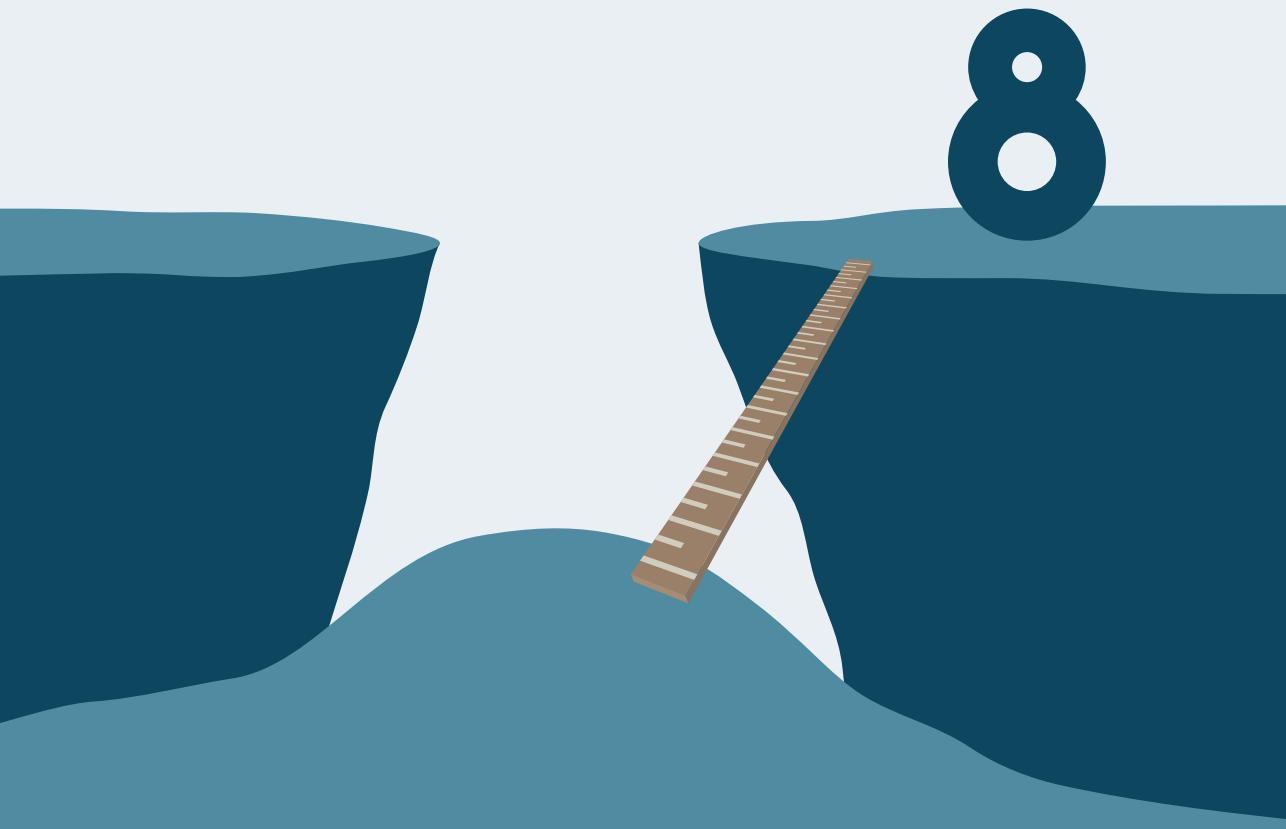

IN-HOSPITAL PRESCRIPTION CHANGES AND DOCUMENTATION IN THE MEDICAL RECORDS OF THE PRIMARY CARE PROVIDER: RESULTS FROM A MEDICAL RECORD REVIEW STUDY

Poldervaart JM, van Melle MA, Willemse S, de Wit NJ, Zwart DLM

ABSTRACT

Background

An increasing number of transitions due to substitution of care of more complex patients urges insight in and improvement of transitional medication safety. While lack of documentation of prescription changes and/or lack of information exchange between settings likely cause adverse drug events, frequency of occurrence of these causes is not clear. Therefore, we aimed at determining the frequency of in-hospital patients' prescription changes that are not or incorrectly documented in their General practitioner's (GP) medical record.

Methods

A medical record review study was performed in a database linking patients' medical records of hospital and GP. A random sample (n=600) was drawn from all 1399 patients who were registered at a participating general practice as well as the gastroenterology or cardiology department in 2013 of the University Medical Center Utrecht, the Netherlands. Outcomes were the number of in-hospital prescription changes that was not or incorrectly documented in the medical record of the GP, and timeliness of documentation.

Results

Records of 390 patients included one or more primary-secondary care transitions; in total, we identified 1511 transitions. During these transitions, 408 in-hospital prescription changes were made, of which 31% was not or incorrectly documented in the medical record of the GP within the next 3 months. In case changes were documented, the median number of days between hospital visit and documentation was 3 (IQR 0-18).

Conclusions

One third of in-hospital prescription changes was not or incorrectly documented in the GP's record, which likely puts patients at risk of adverse drug events after hospital visits. Such flawed reliability of a routine care process is unacceptable and warrants improvement and close monitoring.

INTRODUCTION

Transitions between different healthcare settings put patients' safety at risk. Transitions between primary and secondary care include referral, discharge after a hospital admission and outpatient clinic visits. The number of such patient transitions is likely to increase worldwide, caused by an aging patient population with increasing prevalence of multimorbidity receiving care at home, with an increasing number of professionals involved in transitional care pathways.[1,2,3] Indeed, there is a shift from secondary to primary care, triggered by a need to minimize healthcare costs without having to compromise on quality of care.[4,5]

Every care transition is a potential threat to continuity and safety, with potential risks, near misses and adverse events.[6,7] Haggerty et al. divided the concept of continuity of care into three domains, namely managerial continuity, relational continuity and informational continuity.[7] Several studies found inadequate documentation and lack of communication between different care providers (thus informational (dis)continuity) to be common during care transitions, whilst timely transfer of the medical information after discharge is considered an essential condition for maintaining patient safety during health care transfers.[8,9]

Given the increase in polypharmacy in the last decade, one of the most challenging parts of exchanging patient information is to safeguard an accurate record of medication use of the patient at referral or discharge.[10,11] Healthcare providers are often not fully updated with their patient's actual medication use.[12,13] For example, 27% of drugs that were stopped in the hospital because of adverse drug events were found to be re-prescribed after discharge by the general practitioner (GP).[14] Burnett et al. found a reliability of 81-87% for the several clinical systems studied (such as available outpatient information), of which 20% of reliability failures were associated with a potential risk of harm.[15] A gap in information is likely to cause medication errors, with the potential to cause patient harm and to result in additional healthcare costs.[16] Yet, knowledge on the frequency of breaches in the continuity of information on changes in patients' medication prescriptions between primary and secondary care is scarce.[17] One reason for this is that until now in The Netherlands the electronic medical records (EMRs) of both settings mostly are not linked.

In the Netherlands, every citizen is listed with a GP who serves as gatekeeper to the next levels of healthcare. The GP, a trained family physician working a private general practice in the community, refers patients who need diagnostics or therapy that can solely be provided by medical specialists, to hospitals. Medical specialists see these patients in outpatient specialty care settings or after (acute) hospital admission. When a patient is discharged, or after visiting the outpatient specialty care, changes in treatment plans need to be adequately synchronized with the next care provider, -in the Netherlands always the GP, who provides concurrent care or follow-up and is generally the coordinator of care.[18] The in- and outpatient settings of the hospital work in same EMR, however, GPs work independently from

the hospital, cannot access this record and use different EMR systems. Transitional communication occurs mostly digitally, but also through paper mail and telephone.

So, although in-hospital changes (during outpatient clinic visit, hospital admission or visit to the emergency department) should be communicated, letters are not always written or sent timely by the medical specialist, nor correctly received and processed by the GP. Furthermore, patients may collect their new or changed prescriptions as prescribed by the medical specialist at the community pharmacist, but also at the hospital pharmacist. Only the community pharmacist is connected to the GP's record, and therefore medication prescriptions handled by the hospital pharmacist will not be transferred to the GP record. These suboptimally connected local processes impede tracking the full medication journey from the in-hospital prescription change to actual registration and continuation in the primary care setting and thus impede assessing current performance of settings, as well as the possibility to measure effects of interventions.

Therefore, we aimed for determining the frequency of no or incorrect documentation of in-hospital patients' prescription changes in their GP's medical record, by reviewing individual patient data in a research database with linked primary and secondary care EMRs.

METHODS

Study design

A retrospective observational study was performed, using linked EMRs from one academic hospital and 40 of their affiliated general practices. This was a sub study of the Transitional Incident Prevention Program (TIPP) study. The TIPP study was designed to develop and test a program for enhancing patient safety during healthcare transitions between hospital and primary care.[19]

Setting and patient selection

For this study, we created a research database in which we linked patients' primary and secondary care EMRs.

We conducted the current medical record study using data from 2013 at the cardiology and gastroenterology department of the University Medical Center Utrecht, a 1042-bed academic hospital, situated in Utrecht, a city in the Netherlands, and referring general practices affiliated with the Julius Huisartsen Network (Dutch network of GPs participating in research). This linked record included the content of the EMR of both the GPs (Promedico, Medicom) and hospital (Chipsoft); we used the contacts with the healthcare provider (i.e. free text fields), correspondence of

the medical specialist to the GP (e.g. discharge letters or outpatient clinic follow-up letters), and the prescription overviews. Inclusion criteria were adult patients who had transitioned from the hospital to their GP or vice versa in 2013, e.g. who had been discharged from the two hospital departments (cardiology or gastroenterology) or had had contact with the hospital outpatient clinic or emergency room; and they were registered as a patient at one of our affiliated GPs. Records were excluded when patients did not experience a care transition, or the medical record was empty. We randomly sampled 600 (43%) of the 1399 eligible patients for analyses. To secure data transfer in terms of privacy, selection, linking and pseudononymizing of the medical record data was all conducted by a trusted third party (ZorgTTP Houten, the Netherlands; a company specialized in secure linkage and pseudonimisation of data).

Data collection

Transitions

Data was collected regarding age, sex and department that patients visited and the number of transitions. Transitions were categorized into a 'hospital admissions' group (at least 1 night in the hospital) and a 'short hospital contacts' group. The 'short hospital contacts' group consisted of three categories: (1) (telephone) contacts with the medical specialist of the outpatient clinic, (2) emergency room visits, or (3) short-stay hospital admissions (<1 day) in which medication was self-managed during the stay. Intercollegiate consultations were excluded as these did not involve patient transitions. If an outpatient clinic visit or emergency room visit was followed by a hospital admission, this visit was not counted separately, as then prescription changes would only be handed over to the GP after discharge.

Prescription changes

Subsequently, every transition was separately assessed for changes in prescriptions. We defined changes as any alteration in medication during hospital admission or outpatient clinic visit, and divided these changes into the following 4 types also used by Uitvlugt et al.: prescription of new medication ('Start'), termination of medication ('Stop'), change in dose or frequency of a medication was changed ('Change in frequency/dose') or a change from one medication to another medication in the same medication group ('Switch').[17] Changes in dermatological preparations, drugs prescribed for a short period (e.g. antibiotics) and over-the-counter medication were excluded, because these changes typically are more likely not to be communicated to the GP, noted in the prescription overview of the GP; knowing this makes interpretation difficult when these prescriptions are not noted. The type of changes, generic name, dosage and corresponding medication group was labelled according to the most commonly used medication database in the Netherlands.[20]

Documentation of prescription change in record of GP
Subsequently, we evaluated whether the in-hospital prescription changes were documented in the medical record of the GP, either in the prescription overview or in the free text fields of the medical record. We had data available of every patient for the whole of 2013. Prescription changes should ideally be documented in the record of the GP the next day after discharge, however, we checked up to three months after the change made in the record of the medical specialist. For each prescription change we calculated the number of days between discharge or outpatient clinic visit and entry in the medical record of the GP. If no (correct) documentation of the prescription change was found, possible explanations (such as a temporarily change) were explored by further studying the linked medical records.

Outcomes

The primary outcome was the percentage of in-hospital prescription changes that was not or incorrectly documented in the medical record of the GP. We distinguished three different types of documentation regarding prescription changes. First, when a prescription change (in terms of name, dosage and frequency) was present and correctly noted in the prescription overview of the GP and also correctly noted in the free text fields, this was classified as "Correct documentation". Second, an absent or incorrect notation in the prescription overview, but with a correct notation in the free text field was classified as "Inadequate documentation", as well as correct notation in the prescription overview but incorrect notation in the free text fields: it is better than no documentation at all, but still concerns a discontinuity in information or even incorrect information. Since in daily practice the prescription overview and free text fields both are used by the practice nurse or primary care provider, this presents a potential risk for patient safety. Last, an absent or incorrect notation in both the prescription overview and free text fields was classified as "No documentation"; the latter type corresponded to our primary outcome. An example of this primary outcome was when a prescription was stopped by a cardiologist, but still prescribed later on by the GP.

Secondary outcome was the time lag between prescription change and documentation in the medical record of the GP, which for safety reasons ideally would be implemented in the prescription overview of the GP within one day. We calculated the median number of days and benchmarked the time lag against the cut-off point of one day, two weeks (the duration for which new medications normally are prescribed at the pharmacy in The Netherlands) and three months (the maximum duration for which medications are prescribed). Subsequently, the number and characteristics of transitions, prescription changes and medication groups involved in prescription changes were assessed, as well as the age and sex of patients.

Statistical analysis

Continuous variables are presented as means (± standard deviation, SD) or medians (interquartile ranges, IQR) when data was not normally distributed, while categorical variables are presented as numbers (percentage). All data were analyzed using IBM SPSS Statistics version 21.

RESULTS

Patient characteristics, transitions and prescription changes

In total, 2,069 patients were hospitalized or had visited the outpatient clinics of the

Table 8.1 Patient and transition characteristics

Patients		390
Mean age, years (SD)		59 (±17)
Age ≤45		68 (16.7%)
Age 46-64		144 (35.3%)
Age ≥65		196 (48.0%)
Male		212 (54.4%)
Department		
Cardiology		200 (51.3%)
Gastroenterology		150 (38.5%)
Patients treated at both the cardiology and gastroenterology department		40 (10.2%)
Hospital admissions	**Number of transitions**	**68**
	With prescription changes	45 (66.2%)
	Department	
	Cardiology	42 (61.8%)
	Gastroenterology	26 (38.2%)
	Mean duration of stay in days (SD)	4.4 (±4.6)
Short hospital contacts*	**Number of transitions**	**1443**
	With prescription changes	237 (16.4%)
	Department	
	Cardiology	750 (52.0%)
	Gastroenterology	693 (48.0%)
Total	**Number of transitions**	**1511**
	With prescription changes	282 (18.7%)
	Department	
	Cardiology	792 (52.4%)
	Gastroenterology	719 (47.6%)

* *Outpatient clinic contacts, emergency room visits and short-stay hospital admissions*
SD: standard deviation

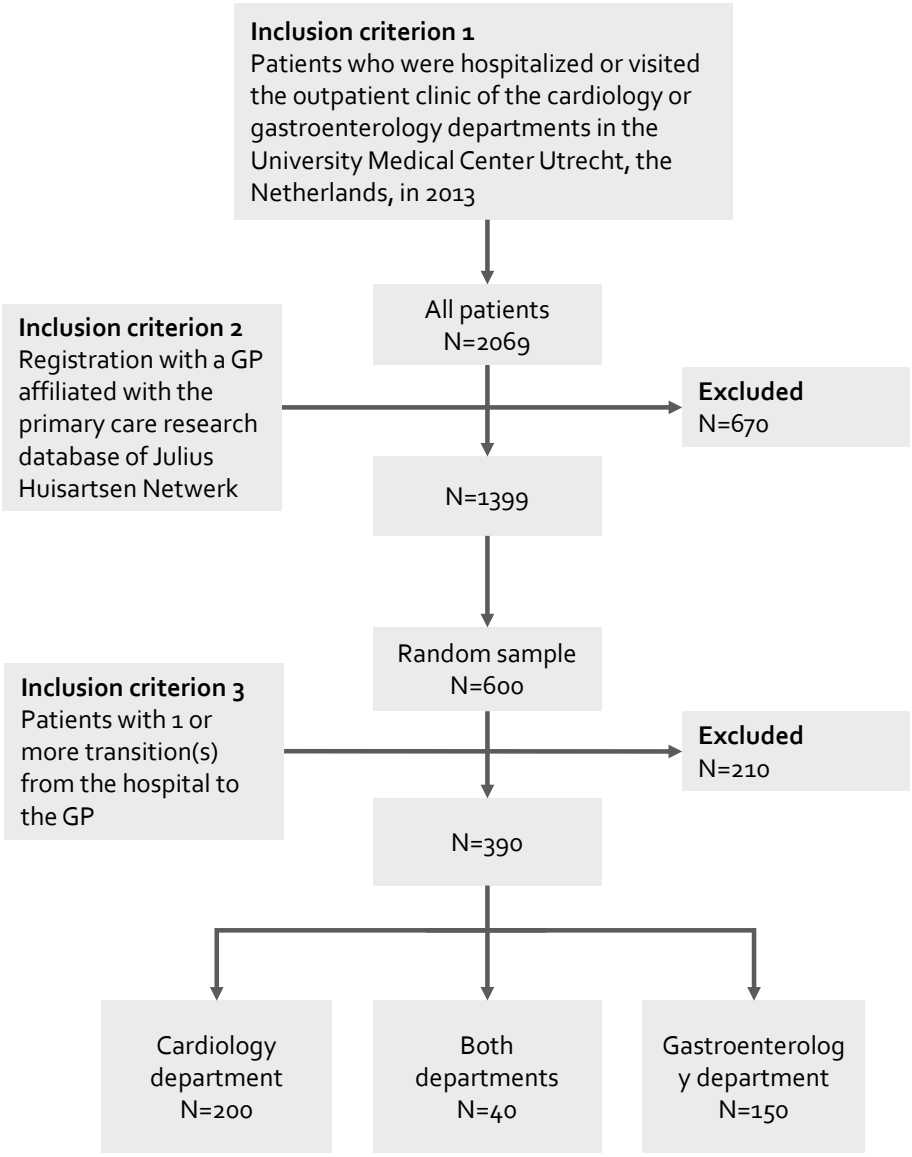

Figure 8.1 Flowchart of selected patients for assessment of reliability of the clinical system of in-hospital prescription changes and the documentation in the medical record of the GP
GP: general practitioner; Julius Huisartsen Netwerk: Dutch network of GPs participating in research

cardiology and gastroenterology department in 2013 (Table 8.1, Figure 8.1). Of those, 670 patients were not registered as a patient at one of our affiliated GPs, thus 1,399 patients remained in our linked database, of which a random sample of 600 was extracted. Of those, 210 patients did not have a care transition upon second look, or the medical record was empty, and were excluded. Thus, 390 patients remained eligible for final analysis, of which 54% was male and the mean age was 59 years (SD 17). Of all patients, 200 (51%) visited the cardiology department, 150 patients (39%) the gastroenterology department and 40 patients (10%) visited both departments. In the records of these 390 patients we identified a total number of 1,511 transitions from the hospital to the GP; 68 (5%) of these were hospital admissions and 1,443 (95%) were short hospital visits. We identified 408 prescription changes in 282 (19%) of these transitions, more often after admissions than after short hospital visits (Table 8.1).

Documentation of prescription changes

In 126 (31%) of the 408 prescription changes, the change was not or incorrectly documented in the GP's medical record ("No documentation") (Table 8.2a). For 27 (21%) of the 126 prescription changes, a possible explanation could be found in the medical record. A description of these explanations are displayed in Appendix 8.1.

In 86 (21%) of the 408 prescription changes, this was noted correctly in the prescription overview of the medical record ("Correct documentation"). In 196 (48%) changes, the change was not or incorrectly noted in the prescription overview of the GP but was mentioned in free text fields ("Inadequate documentation"). Of those 408 changes, the type of change concerned the start of medication in 220 (54%), in 77 (19%) the stopping of medication, in 87 (21%) the change of dose or frequency of prescription, and in 24 (6%) it concerned switch of medication.

In the incorrectly documented prescription changes, the type of change mostly concerned the start of prescription (n=60, 48%) or the change of dose or frequency of prescription (n=46, 37%).

Documentation specified for different patient groups

Documentation of prescription changes differed between age groups: among patients younger than 45 the prescription change was not documented in 40%, and for patients of 65 or older in 24% (Table 8.2b). Documentation also differed between departments: no documentation occurred for 45% of the patients visiting the gastroenterologist, against 25% visiting the cardiologist.

Table 8.2a Type of documentation of prescription changes, divided by the type of prescription change (start, stop, dose/frequency change and switch)

	Correct documentation Correct notation in prescription overview of GP Correct notation in free text fields	Inadequate documentation Incorrect/no notation in prescription overview of GP; Correct notation in free text fields OR Correct notation in prescription overview of GP; Incorrect notation in free text fields	No documentation Incorrect/no notation in prescription overview of GP Incorrect/no notation in free text fields
Total number of changes: n= 408 (100%)	**86 (21.1%)**	**196 (48.0%)**	**126 (30.9%)**
Type of change within the types of documentation			
Start[1] n= 220 (53.9%)	43/86 (50.0%)[#]	117/196 (59.7%)	60/126 (47.6%)
Stop[2] n= 77 (18.9%)	21/86 (24.4%)	43/196 (22.0%)	13/126 (10.3%)
Dose/freq change[3] n= 87 (21.3%)	17/86 (19.8%)	24/196 (12.2%)	46/126 (36.5%)
Switch[4] n= 24 (5.9%)	5/86 (5.8%)	12/196 (6.1%)	7/126 (5.6%)

1. *A new medication was added*
2. *A medication was stopped*
3. *The dose or frequency of a medication was changed*
4. *There was a switch from one medication to another in the same medication group*

\# *Percentages shown are the type of change (e.g. "Start") divided by the total number of changes in this particular type of documentation (e.g. "Correct documentation").*

GP: general practitioner

Table 8.2b Documentation of prescription changes in the record of the general practitioner, for different patient groups

	Total number of prescription changes	Correct documentation	Inadequate documentation	No documentation
Sex				
Women	n=187	38 (20.3%)	93 (49.7%)	56 (30.0%)
Men	n=221	48 (21.7%)	103 (46.6%)	70 (31.7%)
Age				
≤45	n=68	5 (7.4%)	36 (52.9%)	27 (39.7%)
46-64	n=144	30 (20.8%)	62 (43.1%)	52 (36.1%)
≥65	n=196	51 (26.0%)	98 (50.0%)	47 (24.0%)
Department				
Cardiology	n=289	69 (23.9%)	148(51.2%)	72 (24.9%)
Gastroenterology	n=119	17 (14.3%)	48 (40.3%)	54 (45.4%)

Timeliness of documentation

If changes were adequately documented in the record of the GP, this happened within a median number of 3 days (IQR 0-18) after hospital visit or discharge (Table 8.3). For 26% of the patients, the change was documented within a day, for 41% within two weeks and for 55% within three months.

We observed small differences between the type of change and median number of days of documentation, namely 2 for start and switch versus 5 for dose or frequency change. We observed the same trend for the timeliness of 1 day, 2 weeks and 3 months, with the dose and frequency change being less often documented within those cut-offs. For example, when a prescription change was started or switched, 59% and 67% was registered in the prescription overview of the GP within 3 months, compared to 43% for dose or frequency change (Table 8.3).

Table 8.3 Timeliness of documentation of prescription changes in the record of the general practitioner

Documentation		Start[1] n= 220	Stop[2] n= 77	Dose/freq change[3] n= 87	Switch[4] n= 24	Total n= 408/331**
Prescription overview	Number of days, median (IQR)*	2 (0-16)	n/a≠	5 (0-33)	2 (1-14)	**3 (0-18)**
	≤ 1 day	64 (29.1%)	n/a	15 (17.2%)	6 (25.0%)	**85 (25.7%)**
	≤ 2 weeks	99 (45.0%)	n/a	24 (27.6%)	12 (50.0%)	**135 (40.8%)**
	≤ 3 months	129 (58.6%)	n/a	37 (42.5%)	16 (66.7%)	**183 (55.3%)**
Free text fields	Number of days, median (IQR)*	7 (4-14)	3.0 (1-9)	4 (1-24)	2 (1-8)	**5 (2-14)**

1. *A new medication was added*
2. *A medication was stopped*
3. *The dose or frequency of a medication was changed*
4. *There was a switch from one medication to another in the same medication group*

* *Median number of days before documentation of the prescription change. Undocumented prescription changes are not included in this analysis.*

** *This number is the total number of prescription changes. Second number is the number of prescription changes that should have been documented (minus 'stop'). Only the prescription changes that should have been documented are used for calculating percentages.*

≠ *in this category, timeliness could not be assessed, since when a prescription is stopped, this can only be assessed in the GP's record after 3 months, when we could see in the prescription overview of the GP that the patient did not receive the stopped prescription as a recurrent prescription (since the GP had stopped the prescription).*

Medication groups

For the cardiology department, 23 different groups of medication were involved in changes, of which three groups of medication were responsible for half of all prescription changes (Figure 8.2a). These consisted of beta-blockers (21%),

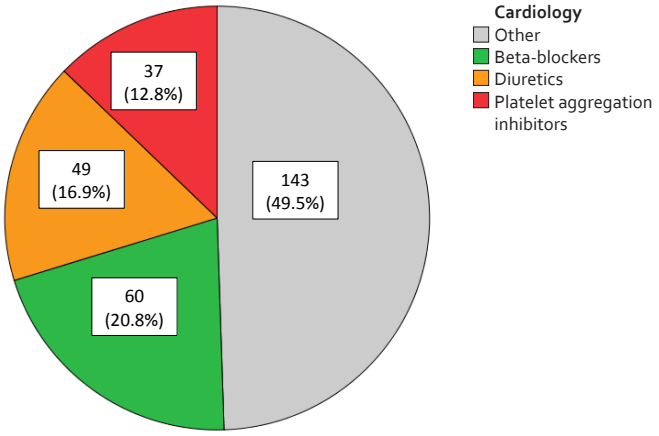

Figure 8.2a Distribution of total prescription changes per medication group for patients treated at the cardiology department (N=289)

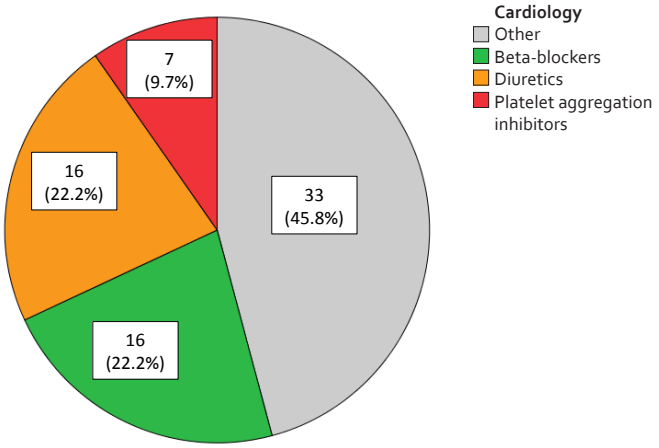

Figure 8.2b Distribution not or incorrectly documented prescription changes per medication group for patients treated at the cardiology department (N=72)

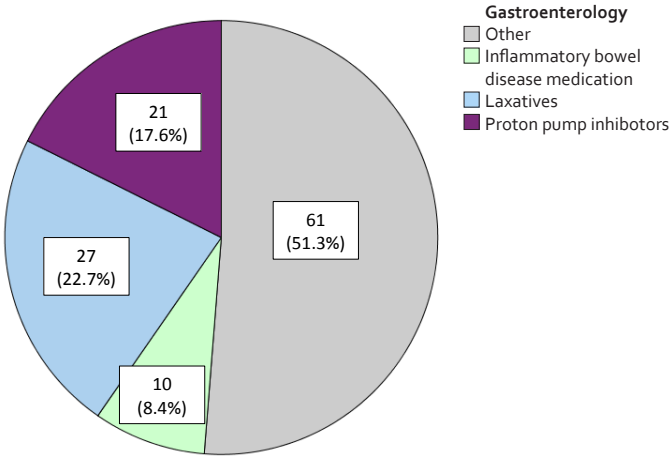

Figure 8.3a Distribution of total prescription changes per medication group for patients treated at the gastroenterology department (N=119)

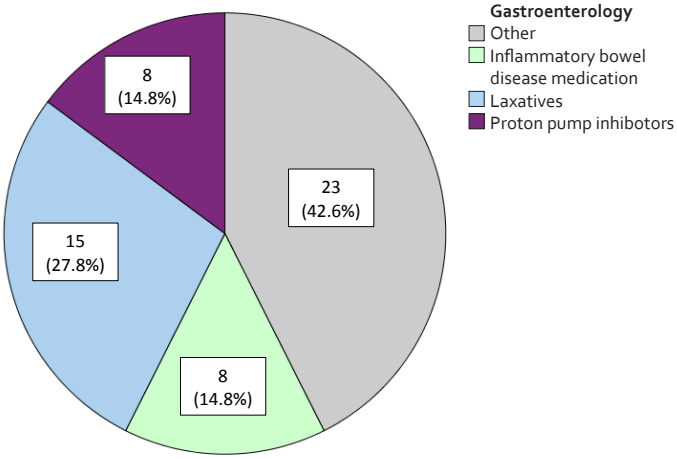

Figure 8.3b. Distribution of not or incorrectly documented prescription changes per medication group for patients treated at the gastroenterology department (N=54)

diuretics (17%) and platelet aggregation inhibitors (13%). For the gastroenterology department, 19 different groups of medication in total were involved, of which laxatives (23%), proton pump inhibitors (18%) and medication for the treatment of inflammatory bowel disease (8%) were the three medications mostly changed (Figure 8.3a).

Comparing the medication groups involved in total changes versus the medication groups involved in changes that were not documented, medication relatively more often not documented were beta-blockers and diuretics (44% of not documented prescription changes by the cardiologist, Figure 8.2b) and laxatives (28% of not documented prescription changes by the gastroenterologist (Figure 8.3b).

DISCUSSION

We reviewed the transitional documentation of prescription changes in patients' medical records, and found that one third of all in-hospital prescription changes were not documented in patient's medical record of the GP. Of these, in 80% of cases we could not trace a satisfying underlying reason (e.g. temporarily given medication) in the medical record of the medical specialist. Changes mostly concerned the start of a prescription in 53.9% (total changes) and 47.6% (not documented changes). When prescription changes were documented correctly, they were found after a median of three days (IQR 0-18.3) in the GP's patient records. The types start and switch were more often documented timely than the type dose or frequency change.

Our current findings are grossly in line with other studies. Another Dutch study showed a breakdown in information in each step of the discharge communication process, with only 50% of all prescription changes correctly documented in GPs' overviews two weeks after discharge.[17] This higher rate of incorrect documentation might reflect the shorter follow-up of two weeks, the use of medication reconciliation with the patient (including over-the-counter medication), and the fact that only discharge was assessed (and not also the outpatient clinic transition).

Despite Dutch multidisciplinary guidelines on information transfer from hospital to GP and on transfer of medication, the criterion of informing the next healthcare provider within 24 hours was not fulfilled.[21,22] Two small surveys showed that 25% of the GPs did not receive any communication from the hospital within 4 weeks after visit to the outpatient clinic.[23,24] Bell et al. found that for 58% of all discharge summaries the goal of sending the letters within two weeks was not reached.[25] Kripalani et al. reported that 51-77% of the discharge summaries is not received by the GP after four weeks, affecting the quality of care in 25% of follow-up visits.[26] However, this research concerns the deliverance of information from the hospital, and not the subsequent registration of this information in the GP's medical record, as assessed by us.

Problems with (timely) deliverance of sufficient information on the part of the hospital are partially responsible for the found high level of undocumented

prescription changes. Undoubtedly it is not the only weak link in the process. The ability of the GP to correctly process prescription changes to the records may be influenced by the amount of time available for administrative tasks, the information processing system and the level of collaboration with the community pharmacist.[27,28] We found a relatively high number of documentation of prescription changes within one day. This is most likely due to automated documentation by the pharmacist's system that currently in the Netherlands often is connected with the GP's. A comprehensive and reliable system implementing all prescription changes directly into the medical record of the GP and/or pharmacist would be a definite solution.

Notably, we found unexpected differences between prescription changes made by the gastroenterologist and the cardiologist, as well as the fact that younger patients seem to be more at risk for absent documentation. A possible explanation may be that many older patients have automated dispensing systems (Baxter), providing the patient with the correct medications on each moment of drug intake during the day, and which are closely monitored by 'own' pharmacists. In contrast, younger patients could pick up their medication anywhere without communication to the GP or their regular pharmacist. However, this finding should be interpreted cautiously, as statistically testing and correcting for interactions was not feasible in our sample.

Our study has several strengths. In contrast to other record studies, we studied the documentation of prescription changes in linked primary-secondary care medical records. Combining patients' primary and secondary care EMRs provided us with a more complete picture of the implementation of prescription changes on the receiving side. Furthermore, we looked at all care transitions; not only hospital discharge but also outpatient clinic visits, emergency room visits and short stay hospital admissions. Third, we looked at the prescription overview in the medical record as well as free text fields of the medical record of the GP, providing us optimal information of the medication. Finally, when documentation was absent or incorrect, we tried to find an explanation in the medical record, improving clinical accuracy of interpretation of our results.

Yet, our study also has certain limitations. First, since this concerns a retrospective study, we could often not establish the intention of a prescription change by the medical specialist in the hospital's medical record. However, this does still not diminish the found results of undocumented prescription changes. Second, adverse drug events such as allergies and serious side effects were not included in our outcome, since data was not available to assess this. This would have made our outcome even more clinically relevant. Third, certain patient characteristics (e.g. educational level or presence of comorbidity) were unavailable, which limited our options to explore which patients were more vulnerable for insufficient transfer of information. Last, this concerned a single center study, decreasing generalizability.

When classifying documentation as in this study, it is important to keep in mind that insufficient quality of documentation is not necessarily insufficient quality of care. An individual case in which a prescription change was made due to an important clinical reason (e.g. a drug allergy) is handled equally as a prescription change that

has a lower level of clinical importance (e.g. start of a laxative). Also, the pharmacist or the GP often intercepts deficits in documentation before and corrects the missing information 'outside the registration' before any harm can be done to the patient. Results should therefore not be interpreted as a direct reflection of medical errors or poor quality of care, but as a reflection of documentation quality.

Various literature reviews demonstrate that discharge information is often insufficient or incomplete. A recent review including 19 studies (2007-2014) showed that 21% of the discharge summaries did not include post-discharge medication.[29] This might partly explain why these changes do not end up in the GP's medical record. Moreover, doctors learn to deal with poor documentation on a daily basis and are well capable of preventing patient harm caused by those documentation flaws in most cases. This level of resilience probably is the main explanation as to why outcomes on documentation differ from outcomes on medical errors and adverse events.[30] However, we do hypothesize that this informational discontinuity will have its effect on patient safety. The more flaws in the healthcare process occur, the higher the risk for fatal slips.[31] Undocumented prescription changes unnecessarily increase the risk in the patient journey. Unique in this study is the use of a linked EMR, providing a more complete view on this patient journey between different healthcare settings, which was used to measure the extent of the problem, as well as trying to find reasons for undocumented prescription changes. We did provide insight in the extent of the problem, even though causes for omission were mostly not found. Both outcomes are a start for improvement strategies, in order to decrease the risk for harm for patients. The ultimate solution, which would be a single shared EMR through all levels of care, is up until now not within sight in the Netherlands.

CONCLUSIONS AND IMPLICATIONS

To conclude, one third of the prescription changes after hospital visits was not found in the medical record of the GP. Additionally, when changes were correctly documented it was often not within the debatable timeframe of two weeks. It is likely that failures in adequate transfer of prescription changes do unnecessarily put the patients' health at risk. Understanding the background for incorrect or absent documentation of prescription changes can guide us towards designing interventions that sufficiently address these patient safety issues.

Ethics approval

According to Dutch law, this study was exempt of formal medical-ethical approval (METC number 13/142, medical ethical committee University Medical Center Utrecht), and the medical record study was deemed as not requiring full assessment

because data was anonymized and this was executed by a trusted third party; the privacy of the patients was assured (METC-letter -13-142/C).

Consent to publish

Not applicable.

Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

DZ, MM and JP designed the study. JP, MM, SE acquired the data. JP and SE analyzed the data. JMP, SE, MM, NW and DZ drafted the manuscript. All authors read and approved the final manuscript.

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APPENDIX 8.1 EXPLANATIONS FOR INCORRECT OR NO DOCUMENTATION IN THE MEDICAL RECORD OF THE GENERAL PRACTITIONER

No documentation Incorrect/no notation in prescription overview of general practitioner Incorrect/no notation in free text fields	**126 (100%)**
Possible explanation	27 (21.4%)
Change was temporarily made (e.g. antibiotics)	10
Change made within two weeks before end 2013 (data not available for 2014)	4
Acetylsalicylic acid prescribed instead of carbasalate calcium	3
Patient went to a different care provider shortly after discharge	3
Change was reversed by patient	3
Change regarded the number of days a fentanyl patch could be worn	3
Dosage was changed but was already prescribed in 'new' dosage (so practitioner already had new dosage in medical record)	1
No explanation	**99 (78.6%)**

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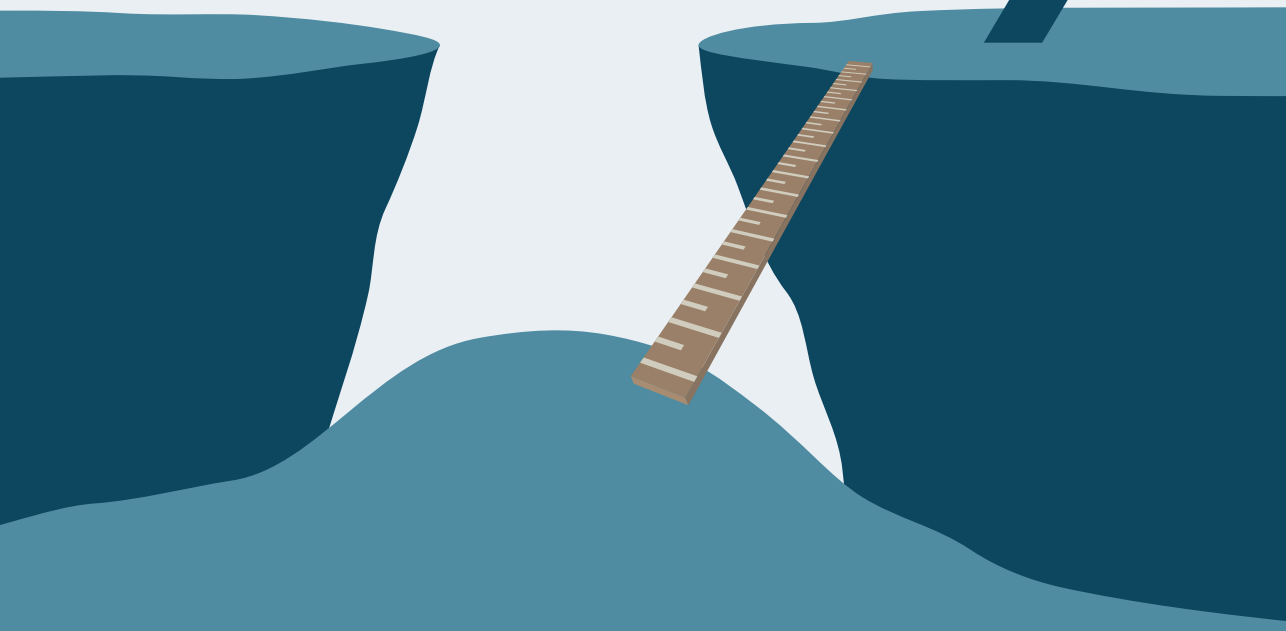

IMPROVING TRANSITIONAL PATIENT SAFETY: RESEARCH PROTOCOL OF THE TRANSITIONAL INCIDENT PREVENTION PROGRAMME (TIPP)

van Melle MA, Zwart DLM, de Bont AA, Mol IWM, van Stel HF, de Wit NJ

ABSTRACT

Introduction

Patient transitions between primary and hospital care include referral, discharge, and simultaneous care by the outpatient clinic and the general practitioner (GP). Research on referrals and discharge shows that safety incidents in these transitions are common. We developed the multifaceted Transitional Incident Prevention Programme (TIPP), which aims to improve transitional patient safety preventing future incidents. With this study, we aim to evaluate the effectiveness of the TIPP programme on transitional patient safety, and to evaluate its implementation and the acceptance in GP-practices and hospitals.

Methods

The TIPP intervention study is a controlled before and after study combined with qualitative methods. The study will be conducted in both rural and urban settings including three hospitals, together with referring general practices.
The TIPP intervention is aimed at three aspects of transitional safety:
1) Healthcare process, 2) Transitional patient safety culture, and 3) Patient participation. Together with the participating hospital departments, GPs and patients, we will develop a tailored improvement programme, taking into account the different context of each setting.

Discussion

The purpose of this protocol paper is to present and discuss the research design and methodology of the TIPP intervention.

Trial registration: Dutch Trial Register NTR4810

INTRODUCTION

Internationally, there is an increasing shift from secondary to primary care in order to reduce healthcare costs simultaneously with sustained quality and safety of care.[1,2] This restructures care by creating healthcare chains that connect current organisations along similar patient groups, in which the general practitioner (GP) has a coordinating role.[3,4]

In these healthcare chains patients transfer from general practice to hospital care for diagnostics, treatment, and monitoring to receive adequate care at the right healthcare level. The increase of both collaborative care between different care levels as well as the number of patient transitioning enlarges the challenge of securing safe continuity of care, which in this study is summarised in the concept of 'transitional patient safety'.

Patient risks do not present homogeneously within the different care levels, for primary and hospital care differ in patient presentation, epidemiology of diseases and obviously also in organisation of healthcare.[5] Nor do these organisations share a common view on the concept of patient safety. These differences result in errors when patients pass the boundaries.[4]

Indeed, research on patient transitions between primary and hospital care, e.g. discharge, referral, and simultaneous care at both levels, revealed many patient safety incidents. Numbers on incidents vary between 20%[6] and 50%[7] of discharged patients, depending on design of the study, definition and patient group. The incidents' consequences ranged from minor harm to disability and death and half were supposedly preventable. At referral, GPs often fail to communicate relevant patient information or the reasons for the referral to the specialist or patients are referred inappropriately according to the specialist.[8] Martinussen et al showed that specialists considered only 15.6% of the referral letters to be "usually good".[9]

To improve transitional patient safety, it is vital that healthcare professionals in primary and secondary care understand each other's working methods, and practice good communication and openness.[10] Many emphasize the need for a system-based approach in healthcare in which the patient has a central role.[11,12] A system-based approach is defined as: the demonstration of "an awareness of and responsiveness to the larger context and system of healthcare and the ability to effectively call on system resources to provide care that is of optimal value."[13]

This system-based approach would facilitate physicians to move competently within the larger systems of care providing interdisciplinary, coordinated, and safe care [11], the main focus in this approach being the patient.[3,14] The healthcare professional should learn to read the medical case stories from a patient point of view. This awareness may reduce adverse events, and help doctors to recognise the complete patient journey through the healthcare chain.[15] In such system, patients themselves also should be aware of their health status and their journey through the healthcare chain.[16] Indeed, they are the only constant in the whole process of the transition from general practice to hospital and vice versa.

Many tools aiming to improve the transition in referral or discharge have been developed and implemented [6,16-20], such as regular meetings between GPs and specialists, case managers, the patient record (either patients carrying their own patient health record or accessible digital medical records for patients provided by the hospital), discharge guidelines, and guidelines for referral and discharge letters. However, only few tools have been systematically studied on their effect.[21] Also, these tools have been studied separately whilst a comprehensive intervention targeting the healthcare process, culture and patient aspects simultaneously seems more appropriate for improving transitional patient safety.

We developed a multi-faceted programme (the Transitional Incident Prevention Programme; TIPP) to improve transitional patient safety and prevent future incidents. With this study, we aim to evaluate the effectiveness of the TIPP programme on transitional patient safety, and to evaluate its implementation and the acceptance in GP-practices and hospitals.

METHODS

Study design and hypotheses

The TIPP intervention study is a controlled before-after study which will be conducted in two settings. We will use a mixed method approach to measure and explain the effectiveness of TIPP, combining quantitative and qualitative research methods. The effectiveness of TIPP will primarily be evaluated overall, but also within the two settings separately. Figure 9.1 shows a flow diagram of the study design.

The TIPP study is a controlled before-after study. This figure shows the outcome measures of the between and within group comparison in time. The time period between T=0 and T=1 is approximately 18 months.

We include a convenience sample of two voluntary participating health regions in our study. Both regions include at least one hospital and multiple general practices. The two regions contrast in setting, i.e. rural vs. urban, which will provide sufficient heterogeneity to assess the influence of contextual factors on the effect of TIPP.

We hypothesize that: (i) Implementing TIPP will reduce unplanned emergency room (ER) visits, rehospitalisation and inappropriate referrals (ii) Implementing TIPP improves the transitional patient safety culture, (iii) Implementing TIPP reduces healthcare costs due to preventing ER visits, rehospitalisation and inappropriate referrals. In addition, we will conduct a process evaluation, assessing acceptability, appropriateness, and feasibility of the intervention in each setting, related to the differences in contextual factors that influence adoption, fidelity, and penetration of TIPP.[22]

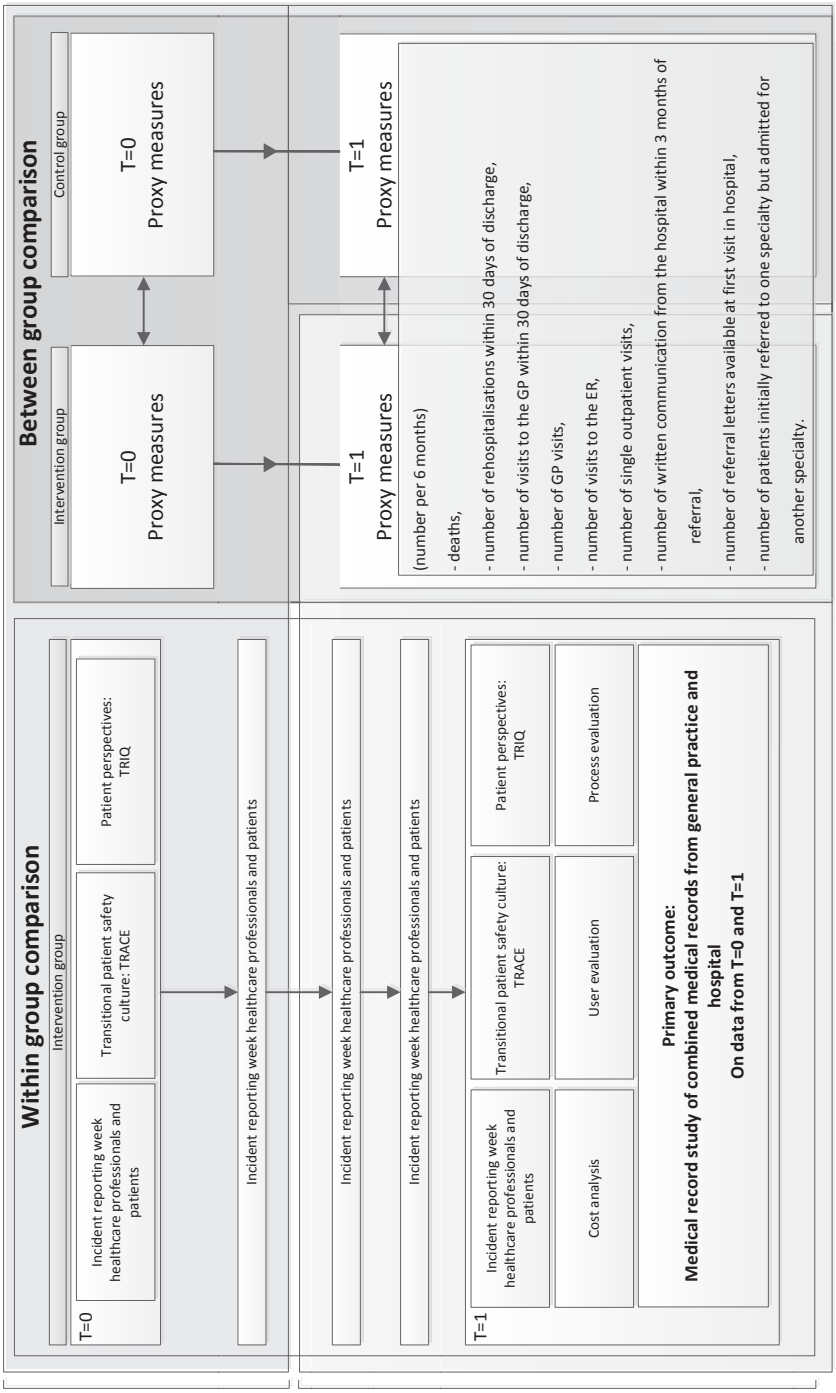

Figure 9.1 Flow diagram of the design of the TIPP intervention study.

Study settings

Rural setting
The first rural region consists of a regional hospital (Röpcke-Zweers, 197 beds), together with 18 referring general practices in the same region. Together these healthcare professionals treat the majority of patients in this area. The estimated number of patients in this area is 68000. We will focus on healthcare paths with high turnovers, in which many transitions are expected. In this rural area, we will limit our intervention to medical disciplines internal medicine (including gastroenterology) and cardiology.

Urban setting
The second setting consists of two hospitals, a University Hospital (UMC Utrecht, 1042 beds), which provides both nation-wide and regional care and a smaller city hospital (Diakonessenhuis, 480 beds). Together they provide hospital healthcare for the patients in the Utrecht area. In addition, we have selected 44 referring general practices, working in two collaboration groups in the Utrecht area. The estimated number of patients in this area is 194000. In this urban area, we will limit our intervention to the cluster of 'medical disciplines' gastroenterology and cardiology.

Control group
The control group consists of the non-participating departments in the hospitals in the Utrecht region, and the non-participating general practices in the larger Utrecht area. These departments and practices continue to work as usual.

Patient selection

We will include patients in usual care who are at risk for a transitional incident. These patients have experienced a transition from GP to hospital or vice versa: they have either been referred to or discharged from hospital, or have visited the outpatient clinic at the time of the study. It is a dynamic population.

Intervention

TIPP is a multi-faceted intervention containing several components aimed at different aspects of transitional safety, developed in an earlier phase of the project using the Intervention Mapping approach.[23] With extensive literature search and qualitative methods we assessed both general transitional safety problems, as well as the major setting-specific transitional problems.

We identified three important aspects of transitional safety:
1) The healthcare process
2) Transitional patient safety culture
3) Active patient participation

In the TIPP programme, each aspect will be targeted by either general or setting specific intervention components. The components can be tailored to the specific wishes of each setting because implementation of a complex intervention largely depends on context.[24,25]

Healthcare process

The intervention component aiming at the healthcare process consists of a renowned risk assessment tool such as a prospective risk analysis of a major problem in their setting or the systematic report and analysis of transitional incidents. These tools will identify the most common processes that fail during transition of care for each participating hospital department together with the referring GPs.[26,27] In addition, we will provide existing tools to improve these processes. The participants themselves are responsible for designing and executing their own improvement plans. We will include and facilitate both (i) already existing plans that touch on and influence transitional care (e.g. an initiative to improve medication reconciliation) and (ii) initiatives of healthcare organisations which originated from the TIPP diagnosis of transitional care.

Transitional patient safety culture

We will organise a transitional safety workshop for professionals. In this workshop, we will provide information about transitional safety, but especially focus on creating a shared vision of communication, collaboration and responsibility in transitional care. Also, introducing the GPs and specialists to each other is an intervention in itself.[28,29] Preliminary results of a qualitative study suggest this will lower the threshold for spontaneous feedback between professionals, in order to facilitate approaching the colleague to whom the patient is transferred for discussing medical policy or problems. Furthermore, mutually reporting and analysing transitional incidents together are culture interventions themselves.[27]

Patient participation

From the start, patients are involved in the TIPP project (i) through participation of the Dutch Federation of Patients and Consumer Organisations in the Netherlands (NPCF) in the advisory board of the project, (ii) participation of trained patients in the local project groups that determine the intervention components, together with representatives of the participating hospital departments and GPs, and (iii) through patient interviews with patients that have experienced a transitional incident preceding the trial.

We used the information gathered from these patients to create a tool for patient empowerment: a patient info card. The patient info card provides information to address major safety items in transitional care using cartoons and short easy

Table 9.1 Examples of intervention components for each of the three important aspect of transitional safety voiced by the TIPP participants. GP= general practitioner

Health care process	Transitional patient safety culture	Patient empowerment
Transitional incident reporting committee: Providing a neutral place for feedback of incidents, will provide insight in system errors in transitional patient safety and fosters improvement of the healthcare process. Also, it improves transitional patient safety culture by stimulating feedback between GP and hospital and exchanging news.		**Patient info card:** providing information to patients to address major safety items in transitional care using cartoons and short easy understandable language
Safe email communication: providing a place to communicate short messages about specific patients. This does not replace the extensive communication (e.g. discharge letters), but offers a place to communicate important (but not urgent) messages about medical policy requests (e.g. control lab tests a week after discharge) or changes (e.g. medication changes after outpatient visit)	**Transitional patient safety culture workshop:** Introducing GP's and hospital professionals and providing information about transitional risks and safety, to create a shared vision on communication, collaboration and responsibility in transitional care. Introducing the professionals to each other will lower the threshold to communicate and provide feedback on specific patients.	**Medication passports:** providing patients with (empty) medication passports before the first outpatient appointment. A patient will be requested to fill in the passport according to the medication they use at that moment. There is also room for their medical background and allergies.
A prospective risk analysis (PRA) or Healthcare Failure Mode and Effect Analysis (HFMEA) of a regional problem in transitional care. E.g. an HFMEA on discharge of patients from the outpatient clinic to the GPs or hospital diagnostics requested by the GP (like gastroscopy or cardiac stress test) [26, 27].	**Regular (half-yearly) informal gatherings between professionals from GP and hospital:** personal acquaintance between professionals from GP and hospital will lower the threshold to communicate and provide feedback on specific patients.	**A patient health app:** providing a patient with a digital medication passport on their smartphone or tab to register their medication, medical background, and allergies and update the medication regularly (after every adjustment).

understandable language.[30] During the intervention period, the hospitals and GPs will be requested to supply this card to their patients.

Many other patient tools have already been created to minimize transitional risks (e.g. a patient record: either patients carrying their own patient health record or accessible digital medical records for patients provided by the hospital, medication lists, patient access to medical files).[31,32] The local project groups, consisting of patients involved in regional and national patient unions, staff from our participating hospital departments and affiliated GPs, will decide whether they will use one or more of these tools, and if so, which one. The patients in our local project groups are "professional" patients recruited by patient platforms for helping with quality improvement. Table 9.1 shows examples of improvement plans for each of the three important aspect of transitional safety.

Outcomes and measurements

Primary outcomes of between group comparisons
We will use the following proxy measures to assess the effectiveness of the intervention: death, number of rehospitalisations within 30 days of discharge, number of visits to the GP within 30 days of discharge, number of GP visits, number of visits to the ER, number of single outpatient visits, number of written communication from the hospital within 3 months of referral, number of referral letters available at first visit in hospital, and number of patients initially referred to one specialty but admitted for another specialty. All proxy measures are measured in a six months' time period.

Within group comparison
Within the intervention group we aim to assess the effect of TIPP in more detail. Because we measure in more detail, we use more sources of data. Also, we use qualitative measurements to better understand the links between theory and empirical findings.
Study parameters for this within intervention group comparison are:

1) The proxy measures from the between group comparison; A composite endpoint of: serious adverse events (death, possibility of death or major permanent loss of function), unplanned visits to the ER, re-admission within 30 days, and non-appropriate referrals, all within a six months' time period. This composite endpoint will be extracted from a different data source from the proxy measures.
2) Number, nature and harm of incidents collected through a combination of methods: professional- and patient-reported incidents and incidents found in a medical record review.
3) Transitional patient safety culture according to the healthcare workers, as measured by the TRAnsitional patient safety Culture Evaluation (TRACE) (see § Data collection; Transitional patient safety culture).
4) The costs of (avoided) visits to the ER, readmissions, non-appropriate referrals and incidents in a six months' time period compared to the direct costs of TIPP.
5) Patient perception of transitional patient safety, as measured by the Transitional Risk and Incident Questionnaire (TRIQ) *(*see § Data collection; Patient perceptions on transitional patient safety and incidents).

For the process evaluation, we will qualitatively assess the following aspects:

1) Components of TIPP that were actually implemented and used in the healthcare chain (process evaluation)
2) Experiences of participants (user evaluation)

Measurements and instruments

Between group comparison
General Practitioners and hospital database; proxy measures for transitional care will be collected from the routine care data registries of the participating general practices and from the hospital database for each participating hospital departments.

Within group comparison
Patient and professional characteristics: The patient characteristics collected are: gender, age, education level, co-morbidity and the number of types of medication used at this moment. The professional characteristics collected are: gender, age, function, and working experience (years).

Medical record review study: At both T=0 and T=1, a trusted third party (TTP; an independent organisation) will select a random sample of patients equally spread over all participating hospital departments who were at risk of transitional incidents in the last 6 months. These patients will then be cross-referenced with the database of the GPs in our study group, and a random selection of patients will be pulled from these. Then, the TTP will link the GP and hospital files and anonymise them. Trained employees will screen the records by using triggers indicating potential transitional risks or incidents. Because no trigger tool exists for transitional safety problems, we are developing a transitional trigger tool. Medical records positive for at least one trigger will further be reviewed by a physician. They will be trained in recognising and evaluating transitional incidents. Patient characteristics (age, gender, comorbidity and total number of medicine used at this moment) and characteristics of incidents (type, harm, location) will be scored. According to the Eindhoven Classification Model, the type of incidents will be scored as incidents in organisation, technology, human behaviour, or as patient related.[33] Harm and potential harm will be classified according to The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) harm index[34], which is a 9-point scale from "none" to "death".

For our composite endpoint, data on serious adverse events, acute visits to the ER, re-admission within 30 days and non-appropriate referrals will be registered. To assess the inter-observer reliability of the doctors' review, a second doctor will review a random sample of records and the absolute agreement and intraclass correlation coefficient (ICC) for inter-observer agreement (absolute agreement, single measurement) will be calculated.[35]

Incident reporting: Approximately every 4 months, the professionals (the entire staff of the participating hospital departments and GP practices) and patients will be requested to report all transitional incidents for a week. Hospital personnel will report through the hospital incident reporting system, which will be slightly adjusted to fit transitional incidents. GPs will use a confidential digital reporting system that can be traced back to the reporting professional and patients can use either an anonymous paper or digital incident reporting form.

A team consisting of at least one independent specialist, one independent GP, and a researcher experienced in analysing incidents will judge incidents based on the characteristics of the incidents (type, harm, location) as mentioned in the medical record review study.

Patient perceptions on transitional patient safety and incidents: Because no questionnaires existed for this purpose, we developed the Transitional Risk and Incidence Questionnaire (TRIQ) which was based on literature and qualitative research. The TRIQ is a questionnaire asking patients whether they have experienced risky situations and transitional incidents. In the development of the TRIQ, we used Reid et al's framework for continuity of care (a related term, but broader than transitional care, for it also contains the continuity within one organisation).[36] The framework consists of three dimensions: relational continuity, informal continuity and communicational continuity. The development of the TRIQ will be described elsewhere. During the TIPP trial, patients will be requested at T=0 and T=1 to fill in the TRIQ. Patients at risk for transitional incidents will be selected at the outpatient clinics. The patient can either fill in the questionnaire by him/herself or be assisted by a medical student.

Transitional patient safety culture: Because no questionnaires existed for this purpose, we developed the TRAnsitional patient safety Culture Evaluation (TRACE) which was adjusted from two current patient safety culture questionnaires used in the hospital setting (Dutch version of the AHRQ Hospital Survey on Patient Safety Culture; HSOPS)[37] and in a general practice (SCOPE questionnaire, which is derived from the Dutch version of the HSOPS, SCOPE is a Dutch acronym for systematic culture inquiry on patient safety)[38]. The development of the TRACE will be described elsewhere. During the TIPP trial, professionals (all personnel with experience in transitional care from the participating hospital departments and general practices) will complete a patient safety culture questionnaire at T=0 and T=1.

Cost-analyses: The costs of (avoided) visits to the ER, readmissions, non-appropriate referrals, and incidents, all within a 6 months' time period, will be compared to the direct costs of TIPP. The evaluation of the costs of (avoided) visits to ER, readmissions, referrals, contacts at the GP practice and incidents will be based on the most recent unit prices according to the reference prices for the Netherlands.[39] To estimate the costs of the TIPP intervention, all direct costs will be calculated. We will include all personnel costs in organising, executing and participating in the components of the intervention. We will exclude the developing costs of the intervention and all research-related costs to the TIPP research programme itself.

Qualitative data collection

Process evaluation: We will assess the actual implementation of the TIPP intervention by measuring implementation outcomes: the adoption, fidelity, and penetration of TIPP.[40] These implementation outcomes will be collected from the participating hospital departments and GPs on a regular basis, using interviews, self-reporting and (participative) observations.

User evaluation: We will collect information from the participating hospital departments and GPs on their experience with TIPP. We will use participant (including patients) observations, interviews and group interviews to assess acceptability, adoption, penetration and appropriateness of TIPP.[41]

Context/ Characteristics of healthcare facilities: At the start of the study, the departments and GPs will be characterised by their context. In the participating GP practices, we will observe and collect the following data: form of cooperation, yearly number of patients, patients' gender, ethnicity and mean age, full-time equivalent positions of GPs and other personnel, mean regional social economic status, number of competitive hospitals in the region. In the participating departments, we will observe and collect the following data: regional or university hospital; yearly number of patients; patients' gender, ethnicity and mean age; full-time equivalent positions of physicians and other personnel; mean regional social economic status, number of regional competitive hospitals, and number of referring general physicians. Also, key process indicators for implementation of patient safety interventions will be described using a framework based on the Model for Understanding Success in Quality (MUSIQ tool).[41]

Statistical analysis

Statistical power: The power calculation for the effect of TIPP is based on the primary outcome, as collected in the medical record study. The following assumptions are used: a reduction of frequency of transitional incidents from 17 % to 13% (25% reduction) with a power of 80% and an alpha of 0.05. We expect an average of 2 transitions in each patient within half a year. The percentage of 17% transitional incidents was based on literature study; we averaged the mean of re-hospitalizations and non-appropriate referrals in systematic reviews on discharge and referrals, which probably is a conservative estimation of the total of transitional incidents. We adjusted the sample size to the expected cluster effects.[42] This resulted in a sample size of 800 patients before and 800 patients after the intervention.

Patient- and setting characteristics will be analysed using descriptive statistics. They will also be used as possible determinants in the primary and secondary effects. The difference in change in the primary outcome between intervention and control regions will be calculated using Poisson regression analysis, taking into account the clustering into departments and hospitals. Effects of implementation on transitional patient safety culture and patient perception will be calculated with multiple regression analysis, again taking into account the clustering into departments and hospitals.[35] Cost-analysis will be analysed through subtraction of all direct costs of the intervention from the yield of the intervention (e.g. costs of ER visits, avoided readmissions, costs of inappropriate referrals. All statistical analyses will be performed using SPSS 21 or SAS 9.2 for Windows.

Ethics and trial status

Our project is sponsored by the Ministry of Health, Welfare and Sport and ACHMEA. According to Dutch law, this study was exempt of formal medical-ethical approval (METC number 13/142, medical ethical committee UMC Utrecht). For the medical record study, we requested an extra assessment by the medical ethical commission. The medical ethical committee Utrecht deemed the record study to be according to Good Clinical Practice; the privacy of the patients is assured (METC-letter - 13-142/C) The TIPP study is on-going. Active data collection started on November 1st 2014 and will run until June 2016

DISCUSSION

The purpose of this protocol paper is to present the research design and methodology of the TIPP intervention. This trial assesses the effectiveness of a multifactorial complex intervention on transitional patient safety. In addition, it will give more insight into the major risks of transitional care, as well as determinants of successful implementation of a complex intervention. This will result in a matrix to diagnose and improve transitional patient safety that can be broadly implemented.

We faced several methodological challenges during the design of the TIPP trial.

Definitions

The first challenge was to define the concept under study. Terms like continuity of care, integrated care, and transitional care are not well defined in literature and are used interchangeably. Recent initiatives have tried to reach consensus on the definitions and concepts, but results are inconclusive.[43] Table 9.2 shows the definitions we used in our research. 'Continuity of care' is a very broad multidimensional concept containing personal continuity (within one care-provider), team continuity (within an organisation) and cross-boundary continuity (transitional care).[14] Integrated care is a strategy to improve patient care which also focuses on processes within and between organisations[44], in which TIPP focuses only on the integration between general practice and hospital (vertical integration). Transitional care applies to actions of healthcare providers between organisations with the patient as the centre which suits the purpose of TIPP to improve care between organisations. In this action, the patient transitions from one organisation to the other. Therefore, we chose to use the term 'transitional care'. With 'transitional patient safety' we refer to patient safety in transitional care.

Table 9.2 Definitions of expressions used in the protocol

Patient safety	The prevention of errors and adverse effects to patients associated with healthcare.[53]
Patient safety incident	A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients.[54]
Patient safety culture	The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management. Organisations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.[55]
Continuity of care	Either (i) the provision of services that are coordinated across levels of care - primary care and referral facilities, across settings and providers; (ii) the provision of care throughout the life cycle; (iii) care that continues uninterrupted until the resolution of an episode of disease or risk; or (iv) the degree to which a series of discrete healthcare events are experienced by people as coherent and interconnected over time, and are consistent with their health needs and preferences.[37]
Integrated care	A concept bringing together inputs, delivery, management and organisation of services related to diagnosis, treatment, care, rehabilitation, and health promotion. Integration is a means to improve services in relation to access, quality, user satisfaction and efficiency.[45]
Transitional care	A set of actions designed to ensure the coordination and continuity of healthcare as patients transfer between different locations or different levels of care within the same location.[56]
Transitional patient safety	Patient safety at transitions of care.
Transitional incident	Any unintended or unexpected incident at transitions of care which could have or did lead to harm for one or more patients.
Risky situation	Circumstances or events that had the capacity to cause error.[57]

Design

Of course, the strongest design to evaluate the effect of an intervention is the randomized controlled trial. However, (clustered) randomisation in transitional healthcare creates insolvable problems because involvement of three different stakeholders (hospital, GP and patient). Randomising at each different level of the healthcare chain creates contamination in the other. Also, there is an important risk of contamination when assigning the GPs to a group because of the organisational structure in practices and the collaboration GP groups in the region (so-called 'HAGROs'). Because of this assignment problem, interventions in transitional care are usually studied in a non-randomised observational design. Major observational studies on patient safety and transitional care have been criticized on the lack of a control group.[45,46] Additionally, both settings (hospitals and GP structure) are crucially different in organisation, region and patient care. The participating departments within the three hospitals are different in patient category and risk of transitional

incidents. Cluster randomising the hospitals or hospital departments is not possible because they are not comparable. In all, we chose a controlled before-after study design to evaluate the effect of TIPP. For the 'between group' comparisons, we only use surrogate outcomes to improve efficiency. Doing all measurements in the control group would mean that a major part of the intervention was also done in the control situation which would invalidate the control group comparison. In TIPP, we consciously chose to combine quantitative and qualitative data. Using triangulation of these data helps to clarify the theoretical propositions and the basis of our results. This offers a better understanding of the links between theory and empirical findings.[47]

Design of the intervention

TIPP is a multi-faceted intervention containing several components aimed at different areas of transitional safety. Research has shown that an intervention is more effective when aimed at different levels of a process.[48-50] We chose to intervene with the three different stakeholders (hospital, GP and patient), but also within the different facets of transitional patient safety; patient safety culture, the healthcare process and patient participation. The components can also be tailored to the specific wishes of each setting because it is known that implementation of a complex intervention largely depends on context.

Outcome

To capture incidents there are two commonly used methods which both have limitations. The first one is reviewing medical records. The main risk is not recognising the incidents, which can lead to underestimation. The second method is incident reporting. The critical factor is the motivation and time of the healthcare worker (and patient in our study) to actually report events. In our study, we decided to apply both methods. Also, the number of incidents reported is ambiguous as both an increase and decrease could indicate an improvement in transitional patient safety. Although one would expect a reduction in incidents, a raised awareness in healthcare will result in an increase in incident reporting. This effect especially shows in healthcare areas where patient safety initiatives are relatively new[51], like transitional care. Because of our relatively short study period, we do not expect to find a reduction during our research.

Recruitment

Selecting the proper setting for our study was challenging. We needed both the hospital and GPs in a region to voluntarily participate in our research. Therefore, we chose a convenience sample. This may lead to a selection because it is likely that the most motivated hospital and practices will decide to participate. Of course, this selection may lead to overestimation of the effect, because forerunners may execute the intervention precisely. Underestimation of the effect is also possible because the room of improvement in forerunners op patient safety is smaller. To improve generalizability, we chose to include two very different settings (one rural and one urban, including a university hospital). By developing a context-related intervention, we aim to facilitate broader interest and implementation.

Follow up

TIPP is a complex intervention and may have a diffuse effect which could blur quantitative measurement. The effect usually only manifests after a longer time period.[52] Therefore, we use mixed methods to understand the potential effect.

Strengths and limitations

Summarizing the above-mentioned subparagraphs, our study has limitations caused by the methodological challenges. The TIPP intervention study is an observational study in which we recruited a voluntary convenience sample of regions and hospital departments, which differ in organisation, risks and patient care. This can lead to a selection of participants and either an under- or overestimation of the effect of the intervention. Another limitation is the measurement of the effect of the TIPP intervention. Improvement of transitional safety is difficult to capture in a measurement. Therefore, we chose different measurements for all the three aspects of transitional patient safety: healthcare process, transitional patient safety and patient empowerment. Still, the possibility remains that incidents will be missed.

The TIPP intervention's strength is that it is unique because it involves all patient transitions between hospital and GP and vice versa (referral, discharge and simultaneous GP and outpatient treatment) and is the first to include all direct stakeholders in the transitional process (hospital, GP and patient and their families). It engages in different levels of the transitional process, from patient safety culture through the healthcare process to the patient him/herself. Research has shown that intervening at different levels of a system is more effective than a singular intervention. We implement TIPP in two very different settings, a rural and an urban/academic setting. This will result in additional information on the importance of the context when implementing the intervention.

Additionally, we use both qualitative and quantitative methods to provide insight into how the interventions are implemented. By conducting semi-structural qualitative interviews with frontline staff, we will gain a deeper understanding of how the intervention works.

CONCLUSION

Although the design faced various challenges, TIPP offers a valid scientific evaluation of a structured and integrated approach to improve transitional safety and prevent transitional incidents. Once proven effective, it can be broadly implemented in daily clinical practice.

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

DZ and IM initiated the study. MM, HS, AB, NW and DZ designed the study. MM developed the protocol. HS and DZ closely supervised the protocol development. All authors participated in reviewing and editing of various drafts of the manuscript and they all read and approved the final manuscript.

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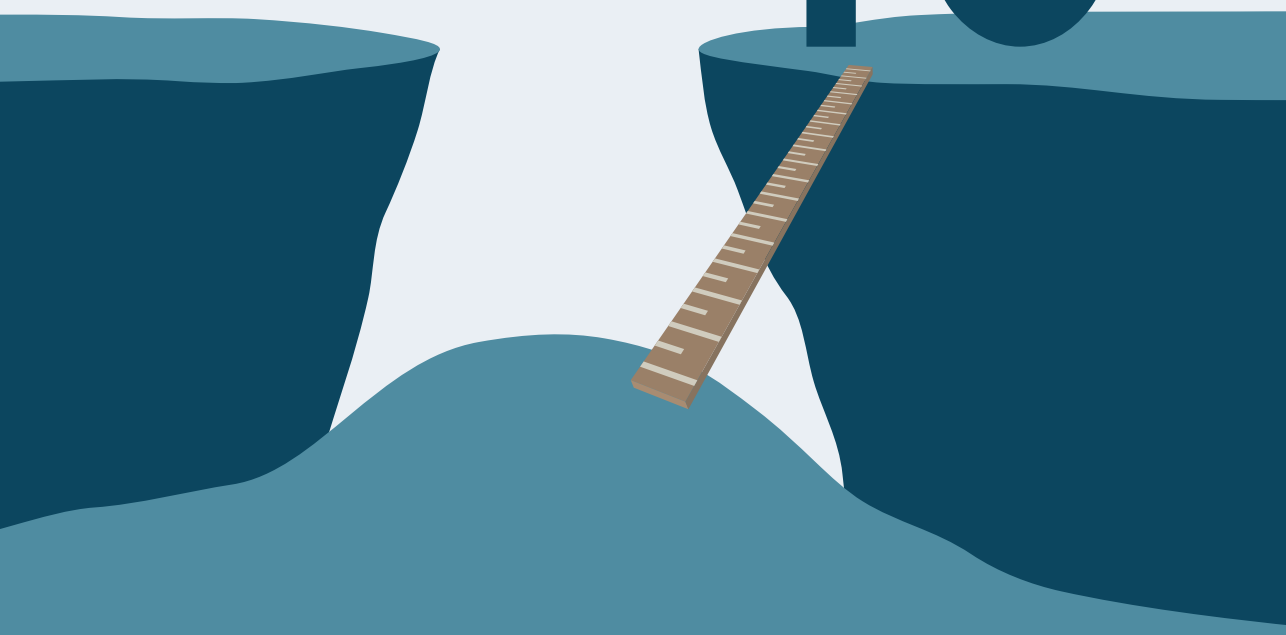

THE EFFECTIVENESS OF THE TIPP MULTIFACETED INTERVENTION PROGRAMME TO IMPROVE TRANSITIONAL PATIENT SAFETY

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ABSTRACT

Objectives

Our aim was to develop and evaluate the effect of a multi-faceted intervention aimed at preventing transitional safety incidents (TSIs) and improving transitional patient safety.

Design

A controlled before-after trial.

Setting

Cardiology and gastroenterology departments from 3 hospitals together with their affiliated general practices in two regions in the Netherlands received the intervention between April 2015 and August 2016. Internal medicine and neurology departments and non-participating general practitioners served as controls.

Intervention

We assessed the effect of the complex Transitional Incident Prevention Programme (TIPP) targeting three domains of transitional safety, namely the healthcare process, the professionals' culture around care transitions and the patient's participation.

Main outcome measures

Primary outcomes between groups were death and 30-day readmissions rate (health outcomes). Secondary outcomes were: 1) healthcare utilisation; 2) incidence of TSIs; 3) direct medical costs; 4) healthcare professionals' perception of transitional patient safety climate; and 5) a process- and user evaluation. TSIs were assessed three ways: 1) objectively using a transitional medical record review study conducted in linked medical records of both hospital and GP; 2) subjectively as experienced by patients; and 3) during five incident reporting weeks;

Results

We found no statistically significant effect of the TIPP intervention on the primary outcomes nor on healthcare utilisation. Medical record review identifying TSIs in the time period before and after the TIPP intervention also did not show any improvement (N=600 versus N=618; 83.4% versus 82% respectively, p=0.81). Transitional patient safety as experienced by patients improved significantly after the intervention, with a decrease from 38% to 31% of patients that experienced at least one TSI (RR 0.86, p=0.002). The transitional patient safety climate as perceived by the healthcare professionals showed a statistically significant decrease after the intervention in three out of four dimensions (N= 286; collaboration, difference -0.21, p<0.001; communication on incidents and improvements, difference -0.22, p=0.003; and transitional patient safety management, difference -0.17, p=0.009). The cost consequence analysis indicated that the intervention was cost-effective.

Conclusion

The TIPP programme had no relevant effect on health outcomes, nor on healthcare utilisation or on TSIs identified in the medical records. However, improved patient perception of transitional patient safety and decreased ratings for transitional patient safety climate among professionals indicated an increase in awareness.

Trial registration: Dutch trial register NTR4810

INTRODUCTION

The number of transitions between different domains of healthcare is increasing, due to expanding medical knowledge, the ageing of the population with subsequent increasing morbidity, and substitution between hospital and primary care.[1] As a result, patients are being referred, admitted and discharged more frequently and often receive care in different healthcare levels at the same time. In countries with a gatekeeper system, these transitions are monitored by the general practitioner (GP), who acts as care coordinator and gatekeeper to hospital care. In the non-gatekeeping systems, where primary and specialty care often work independent and in parallel, care coordination is lacking.[2,3] In both healthcare systems, GPs and specialists have to collaborate to avoid ineffective care and patients' harm, even though they are not part of the same organisation and often unfamiliar with each other's working environment and needs.[4]

Studies have shown that transitions in healthcare are at risk for incidents, so-called transitional safety incidents (TSI).[5,6] TSIs are defined as "any unintended or unexpected event in patient care between different healthcare organisations which could have led or did lead to harm for one or more patients receiving care". They can be subdivided, according to impact and severity, in unsafe situations (circumstances that have the potential to cause error), near misses (an act of commission or omission that could have harmed the patient but did not do so as a result of chance, prevention or mitigation) and adverse events (any injury caused by medical care).[7] Forster et al. showed that 20% of the discharged patients experience an adverse event, of which over half could have been prevented, with severity ranging from no harm till death.[5] The main types of discharge related errors are: errors in communication and medication handover, incomplete handover of care, and inadequate patient instruction.[5,6] In case of referral, handover of information often fails; only 16% of referral letters is considered as of good quality by the hospital specialist.[8]

Patient safety is gaining increased attention, and there is growing societal and professional urgency to limit potential harm for patients.[9-11] However, until recently, most of the efforts for improvement had been confined to a single professional domain, i.e. primary or hospital care, not addressing the interface.[10,12] Currently, the focus is broadening to bridge the borders of healthcare settings[13] and several interventions have been developed to improve the referral and discharge process.[14-17] Nevertheless, most interventions were studied in isolation, while it is known that the effectiveness increases when aiming at different levels of the care process, and interventions are designed as multifaceted programs.[16,18-21]

We developed the multifaceted Transitional Incident Prevention Programme (TIPP) to improve transitional safety in the interface between general practice and hospital. In this study, we report the impact of implementation of the TIPP programme on patient harm and TSIs.

METHODS

Study design

We used a mixed method approach within a pragmatic, non-randomised, experimental design with before-after control group comparison to assess the effectiveness of TIPP. Details of the study protocol are reported elsewhere.[22] The intervention period lasted from April 2015 until August 2016. The period between October 2014 and April 2015 was used as a baseline comparison.

Setting

The TIPP study was carried out in two settings in the Netherlands. The urban setting consisted of the affiliation of two hospitals with collaborating general practices in Utrecht, the Netherlands: the University Medical Center Utrecht (1,042 beds) providing (supra) regional academic care and the Diakonessenhuis, an urban general hospital (480 beds).[23,24] In total 44 general practices participated, with approximately 194,000 patients, referring to these two hospitals. The rural setting consisted of a single general hospital, the Röpcke-Zweers in Hardenberg (197 beds) with 18 referring general practices (approximately 68,000 patients). In all three hospitals, the departments of cardiology and gastroenterology participated in the intervention, while the departments of internal medicine and neurology acted as secondary care controls. Non-participating general practices in the larger Utrecht area were selected as general practice controls. In total, 451 professionals participated in the intervention, 258 from hospital and 193 from general practice.

Intervention

The TIPP intervention is a multifaceted programme, and targeted at three important conditions to improve transitional safety: optimising the process of care, improving the transitional patient safety climate and stimulating patient participation.[22] In close collaboration with professionals and patients we developed generic interventions to tailor the interventions to their specific needs. Also, in order to facilitate implementation of the context-specific interventions, we offered expert support from the research team. We intended that all departments would choose and implement at least one context-specific intervention. In addition, we ensured leadership commitment of all participating organisations with formal agreements and regular meetings. The responsibility for actual implementation of the intervention components was assigned to the local leadership on the work floor.

The following generic elements of the TIPP intervention were implemented in the two intervention areas: 1) instalment of a regional transitional incident report committee; 2) the organization of five TSI reporting weeks, during which healthcare professionals and patients in both hospital and general practice were requested to report all TSI's; 3) organisation of a workshop on transitional patient safety culture, in which GPs and specialists mutually discussed their working processes guided by recently reported TSIs; 4) interprofessional education for GPs and hospital specialists in training in transitional patient safety; and 5) implementation of a transitional patient information leaflet specifically designed in collaboration with the Dutch patient federation ("Patiënten Federatie Nederland") (appendix 10.1). Two context-specific programs were implemented as part of the intervention: 1) introduction of a transitional group consultation with cardiologist and GP for stable cardiac patients that could be handed over from the outpatient clinic to the GP, and 2) the implementation of a digital referral platform (Zorgdomein) to facilitate information exchange between primary and specialist care, which was actually implemented hospital-wide.[25]

Participants

We used a dynamic cohort of patients in the two regions who had been referred to, discharged from, or visited the outpatient clinic of one of the three hospitals during the study period. In the qualitative part of the evaluation, both specialists and GPs as well as patients from the two areas participated.

Outcomes

Given the fact that the first objective of the TIPP intervention was to avoid patient harm we used potential serious adverse events as primary outcome: (1) the number of deaths and (2) the number of readmissions within 30 days among all patients admitted or seen at the outpatient clinic during the intervention period. As secondary outcomes, we used the total number of TSIs, a set of safety related indicators of healthcare utilisation, and direct healthcare costs.

We compared the primary outcomes and secondary healthcare utilisation outcomes (as from now together referred to as "health and utilisation outcomes") in the intervention and control group (between-group comparison). For all other outcomes, we compared results before and during the TIPP intervention solely in the intervention group (within-group comparison).[22]

In addition to the TSI-related outcomes, we studied process outcomes to explain the potential (in-) effectiveness of TIPP: healthcare professionals' and patients' perceptions of transitional patient safety, evaluation of the TIPP intervention's implementation and user satisfaction.

Measurements

Data were collected over two six months' time periods, before (May - November 2014) and during the TIPP intervention period (February – August 2016).

TSI-data collection

All data for the primary and secondary outcomes were collected from the hospital registration database, except the total number of GP visits, which was collected from the Julius Primary Care Database, the academic routine care registration cohort in which all GPs in the Utrecht region participate.[26] Transitional safety incidents were assessed in three ways: 1) through a medical record review study, 2) by surveying patient experienced TSIs and 3) during the five incident reporting weeks. In order to be able to objectively calculate the number of TSIs in the medical record review study, we created a transitional patients' database, by linking general practice and hospital care registrations. Therefore, we used a so-called Trusted Third Party pseudonymised data linkage procedure (TTP Houten).[27] Patients were included in this database if they were registered with a participating GP, and had been hospitalized or had visited the outpatient clinics of the participating hospital departments in the period before (May - November 2014) or at the end of the intervention (February - August 2016). Unfortunately, this data linkage could not be implemented in the region of Hardenberg, so the rural region could not participate in the transitional medical record study. Six trained final-year medical students identified TSIs in the medical record in two six month-periods: before (May - November 2014) and during the TIPP intervention (February – August 2016), for which they used an extensive manual. The following TSIs were collected: discrepancy in medical history between hospital and GP, discrepancy in chronic medication use, incorrect referral to the outpatient clinic, unclear discharge procedure, delayed or missing correspondence to GP, in-hospital change of medication not reaching the GP, in-hospital change of treatment plan not reaching the GP, new diagnosis failed to reach GP, unnecessary diagnostic tests[10,28].

For the assessment of the number of TSIs as experienced by patients, we used the Transitional Risk and Incident Questionnaire (TRIQ). This is a 24-item validated instrument consisting of four dimensions: 1) personal relation with GP, 2) personal relation with hospital specialist, 3) information exchange, and 4) treatment consistency.[29] Besides collecting data on TSIs experienced by patients (dimension 3 and 4), it measures the process outcome of patients' perceptions on transitional patient safety (dimension 1 and 2). Between November 2014 and January 2015 and September and December 2016, patients at the outpatient clinics of participating hospital departments were asked to fill in the digital questionnaire on laptops. On request, patients were assisted by a medical student, trained to guide patients through the questionnaire without influencing their answers.

During five periodic incident reporting weeks between November 2014 and August 2016, both patients and healthcare professionals were asked to report

(on paper or digitally) any TSIs they encountered. Patients at the outpatient clinic and general practices were notified by posters and leaflets and could hand the TSI written on a standard reporting form to the receptionist or deposit it in a suggestion box. Healthcare professionals were asked by email, newsletter and during a staff meeting to report any TSI to their respective incident reporting system.

As indicators of healthcare utilisation we included (1) the total number of GP visits; (2) the number of GP visits within 30 days of discharge; (3) (potentially redundant) hospital care consumption, defined as the combined number of visits to the emergency department, single outpatient visits, number of referrals to the emergency department for one specialism, but admission for another, divided by the total number of patients at risk; and (4) the number of patients with missing outpatient correspondence to the GP within 3 months of referral to the outpatient clinic, plus the missing percentage of patients with a referral letter present at first outpatient clinic visit combined, divided by the number of patients at risk.

Cost consequence analysis

We compared the direct medical costs in the intervention group before and during the intervention, including the number of visits to the emergency department, readmissions, non-appropriate referrals and visits to the GP in the measurement periods, and the costs of the TIPP intervention itself. The direct medical costs were calculated by multiplying the difference in healthcare consumption before and during the TIPP intervention with their respective unit costs following Dutch guidelines for health economic research.[30] For the intervention-related costs, we calculated costs for the academic and general hospital departments separately. Methodology of the cost consequence analysis is presented in detail in online appendix 10.2.

Process related data

Patients' perceptions on transitional patient safety were measured using two dimensions of the TRIQ questionnaire (see above), namely: 1) personal relation with GP and 2) personal relation with hospital physician.

For the assessment of the professionals' perception of the transitional patient climate, we used the TRAnsitional patient safety Climate Evaluation (TRACE). This is a validated instrument consisting of 20 questions covering four dimensions: 1) collaboration; 2) speaking up; 3) communication on incidents and improvements; and 4) transitional patient safety management.[31] A digital invitation was sent to all healthcare professionals of our participating general practices and hospital departments before (November 2014) and after (September 2016) the intervention period, including reminders after two and four weeks. Mean scores were computed for the four dimensions of the TRACE. Scores ranged from 1 (negative) to 5 (positive).

For the evaluation and users' satisfaction of the intervention we conducted 17 in-depth semi-structured interviews (duration approximately 20 minutes) and two focus groups with GPs, specialists and quality managers during May and June 2016 [7,22,32].

Sample size

The health and utilisation outcomes were measured in the census population. For the secondary outcome of TSIs measured in the medical record study, the power calculation was based on the number of TSIs as identified in medical records. The following assumptions were used: a prevalence of TSIs of 60%[28] and an average of two transitions in each patient within six months. To determine a clinical relevant drop in number of TSIs of 25% (from 60 to 45%) with a power of 80% and an alpha of 0.05, and adjusted for the expected cluster effect (a cluster size of 50 with a correlation of 1.05)[33], the required sample size in the intervention and control group each was 600 patients.

Statistical analysis

Patient- and setting characteristics were analysed using descriptive statistics. All statistical analyses were performed using SPSS 24 and SAS 9.3. Poisson regression was performed to assess the health and utilisation outcomes, correcting for baseline measurement and overdispersion. For the GP visits within 30 days of discharge, we used Poisson regression, correcting for potential confounders age, gender, social economic status, hospital specialty, and polypharmacy. For the medical record review study, TSIs were analysed using a generalized linear model for counts, correcting for clustering and potential confounders age, gender and number of transitions. For the TSIs identified with the TRIQ questionnaire, we assessed the number of patients that had experienced at least one TSI and the number of incidents per patient using Poisson regression, corrected for clustering and potential confounders age, gender, comorbidity, ethnicity, and education. Additionally, we corrected for type of transition, for these differed significantly between the periods before and during the TIPP intervention. The number and characteristics of incidents collected through five incident reporting weeks were assessed using descriptive statistics. Costs were analysed using descriptive statistics in Excel. The process-outcomes of the TRIQ questionnaire were assessed using Chi-square for trend. The mean dimension scores of the TRACE were analysed using a linear mixed model, correcting for clustering and potential confounders age, gender, working experience, and profession. The health and utilisation outcomes were analysed on cluster level. All other outcomes were analysed on an individual level. For the process evaluation, data collected with the questionnaire was analysed using descriptive statistics. For the user evaluation, interviews and focus groups were assessed and discussed within the research team. Table 10.1 shows the available sources of data per outcome measure.

Table 10.1 Setting and data sources per measurement
Presenting available data per measurement

		Between group comparison	Within group comparison				
Region	**Source/ participants**	Health and utilization outcomes	Medical record review study	Incident reporting	TRACE	TRIQ	Process and user evaluation
Urban	General practice	X	X	X	X	X	X
	General hospital	X	X	X	X	X	X
	Academic hospital	X	X	X	X	X	X
Rural	General practice	-	-	X	-	X	X
	General hospital	X	-	X	-	X	X

TRACE=Transitional patient safety climate evaluation (healthcare professionals' perception), TRIQ=Transitional risk and incident questionnaire (patients' perception)

Ethical approval

According to Dutch law, this study was exempted of formal medical-ethical approval (medical ethical committee UMC Utrecht number 13/142). The medical ethical committee Utrecht deemed the medical record study to be according to Good Clinical Practice.

RESULTS

Baseline patient data

The total number of patients visiting the participating hospital departments during the intervention period was 51,004 (intervention group) and 50,281 (control group). The total number of patients in participating general practices was 335,352 (intervention group) and 168,806 (control group) (see appendix 10.3). The GP patients were younger than the hospital patients (mean 45 years versus 62). In the intervention, the mean age was higher (62 versus 59 years) and there were less female patients (46% versus 53%) as compared to the control group, mainly because of the older and predominant male patient population visiting the cardiology departments. In both general practice and hospital patients, approximately 50% was female. (Table 10.2; for more details appendix 10.3 table 10.1)

Table 10.2 Total number and characteristics of patients participating in the intervention and control group, before and during the intervention (hospital and general practice)

		Intervention group		Control group	
		Hospital	General practice	Hospital	General practice
Number of patients (N)	Before TIPP intervention	23,775	166,416	24,085	83,657
	During TIPP intervention	27,229	168,936	26,196	85,149
Age (mean, SD)	Before TIPP intervention	62.8 (16.51)	45 (17.87)	58.8 (19,06)	47 (17.82)
	During TIPP intervention	61.9 (16.20)	45 (17.96)	58.6 (19.03)	48 (18.02)
Gender (N, % female)	Before TIPP intervention	11,096 (46.7%)	88,483 (53.2%)	12,861 (53.4%)	42,598 (50.9%)
	During TIPP intervention	12,459 (46.8%)	89,283 (52.8%)	13,883 (53.0%)	43,543 (50.8%)

Outcomes

Primary outcomes

In the intervention group, the death rate during the intervention was 1.7% (N=460), compared to 1.9% before (N=450), and in the control group 2.8% (N=726) and 2.5% (N=595) respectively. The relative risk between intervention and control group after correction for baseline and overdispersion was 0.82, 95%CI 0.64-1.06. The readmission rate in the intervention group was 17.4% (N=1,659 of 9,518 admissions) during the TIPP intervention compared to 17.0% (N=1,554 of 9,155 admissions) before, in the control group 14.8% (N=957 of 6,461 admissions) and 18.5% (N=1,245 of 6,749 admissions) respectively. After correction, the relative risk between intervention and control group was 1.37, 95%CI 1.01-1.84). This result was due to an increase in readmissions within one intervention department (N=837 before and N=1,009 during TIPP). For detailed results, see table 10.3.

Healthcare utilisation

The mean hospital healthcare use decreased in both intervention and control group (from 15.6% to 14.4% and from 22.3% to 21.3% respectively), significantly more in the intervention group (relative risk 0.9, 95%CI 0.84-0.98) (table 10.3). In the intervention and control group the percentage of missing correspondence did not differ; 36% (N=6,105 of 16,952 patients at risk) during and before TIPP (N=4,516 of 12,556 patients at risk) in the intervention group versus 35% (N= 11,888 of 33,834 patients at risk) during and 36% (N=9,978 of 28,080 patients at risk) before TIPP respectively in the control group.

The mean number of GP visits per patient decreased from 2.98 to 2.61 visits within the intervention group, and from 2.92 to 2.54 visits in the control group. Poisson regression shows a significant difference in favour of the control group

Table 10.3 TSI-related outcomes (health and utilization outcomes of TIPP intervention in intervention and control group

		Mean				
		Before TIPP intervention	During TIPP intervention	During TIPP, corrected*	RR (95% CI)	p
Primary health outcome						
Death rate[a]	Intervention	0.019	0.017	0.015	0.82 (0.64-1.06)	0.13
	Control	0.025	0.028	0.018		
Readmission rate[b]	Intervention	0.170	0.174	0.024	1.37 (1.02-1.84)	**0.040**
	Control	0.185	0.148	0.018		
Utilisation outcomes						
Mean hospital healthcare use per patient[c]	Intervention	0.156	0.144	0.144	0.90 (0.84-0.98)	**0.009**
	Control	0.223	0.213	0.159		
Missing correspondence rate[d]	Intervention	0.360	0.361	0.373	1.11 (0.94-1.31)	0.23
	Control	0.355	0.351	0.337		
GP visits, *mean number per patient*	Intervention	2.98	2.61	**		
	Control	2.92	2.54	**	**	**
GP visits within 30 days of discharge, *mean number per patient* ***	Intervention	2.19	1.62	NA	0.72 (0.62-0.83)	<0.001

CI=confidence interval, NA=not applicable, RR=relative risk

* *corrected for baseline and overdispersion*

** *Because of the limited data, no correction for overdispersion and baseline could be performed*

*** *Data could only be collected in the intervention group*

A: Death rate = total deceased patients/ total patients that have visited the outpatient specialty clinic or have been admitted

B: Readmissions = Total readmitted patients / total admissions

C: Hospital healthcare use = (number of visits to the emergency department + number of referrals to the emergency department for one specialism, but admission for another+ the number of patients with a single outpatient visit) / total patients at risk

D: Missing correspondence = (the number of written communication from the hospital to the GP within 3 months of referral to the outpatient clinic, + the number of referral letters available at first outpatient clinic visit) / total patients at risk

(relative risk = 1.03, 95% CI 1.02-1.03; p<0.001), but no correction for baseline and overdispersion could be performed, so this analysis should be viewed with caution. The mean number of GP visits within 30 days of discharge decreased from 2.19 to 1.62 during the intervention (relative risk 0.72, 95% CI 0.62-0.83; p<0.001), corrected for clustering and confounding.

Number of TSIs

Medical record review: In total 1,218 patients were included: 600 before and 618 during the intervention. The median age was 63 years, 46.3% was female, and 46.1% had polypharmacy. These 1,218 patients experienced 2,210 transitions, with

a median of 1 transition per patient. During the review, the absolute agreement between reviewers was 76.9%, the positive agreement was 86.1%, and the negative agreement 31.8%. When patients visited multiple departments, we regarded them as separate patient journeys. In total, the 1,218 patients experienced 1,282 patient journeys. We identified a TSI in 82.6% of the patient journeys, with a median of 2 TSIs for all patients (see table 10.3).

We found TSIs in 83.4% before and 82% of the medical records during the TIPP intervention (B -0.01, p=0.81). The mean number of TSIs per patient was 1.55 before and 1.60 during the TIPP intervention (B=0.05, p= 0.17) (table 10.4). These results were similar for all intervention departments.

Patient experienced TSIs: In total, 685 patients filled in the TRIQ questionnaire, 372 before and 313 during the TIPP intervention (table 10.4). Three patients stopped filling in the questionnaire halfway (missing <1%). The median age was 64 and 53.2% was female, 70.1% of patients had at least 1 co-morbid condition and 44.7% used 5 drugs or more. As to the experienced transitions, the percentage of recently referred patients differed significantly within the time periods from 42.2% before to 28.4% during the TIPP intervention (appendix 10.4). The percentage of patients who experienced a TSI decreased from 38% (N=141) before to 31% (N=97) (relative risk 0.86, 95% CI 0.78-0.95; p=0.002) during the TIPP intervention. This decrease was found for all departments and for all types of incidents. The total number of experienced TSIs experienced by all patients did not differ before and during the intervention (relative risk 0.72, 95%CI 0.59-1.03; p=0.077) (Table 10.4).

Incident reporting weeks: In total, 20 TSIs were reported in the incident reporting weeks before and 19 during the TIPP intervention. Most incidents were reported directly after the start of the TIPP study (N=12), after which reporting slowed down. A similar effect was observed after the interprofessional education workshop. Most incidents were reported in general practice (12 before and 15 during the intervention).

Cost consequence analysis

The medical record review data showed an increase of visits to the emergency department (plus 7 per 1000 patients) and of non-appropriate referrals (plus 15 per 1000 patients) and a decrease in readmissions (minus 16 per 1000 patients) and visits to the GP (minus 180 per 1000 patients) during the TIPP intervention. Per 1000 patients, the costs during TIPP were €37,571 lower than before TIPP for a general hospital, and €51,962 lower for a university hospital. As to the costs of the TIPP intervention; first year costs (including start-up costs) would range between €100,764 and €157,988 for a university department and between €105,283 and 166,365 for a general hospital department. See appendix 10.2 for the specification of start-up and running costs and costs per component of the TIPP intervention.

Process outcomes

Patient perception of transitional patient safety: In the first two process-related dimensions of the TRIQ, personal relation with the GP and hospital specialist and

Table 10.4 Effect of TIPP on transitional patient safety incidents
Measured using a medical record review, a patient-experience questionnaire and incident reporting weeks

Medical record review study							
				Estimated Marginal Means after correction			
	Total	Before TIPP intervention	During TIPP intervention	Before TIPP intervention	During TIPP intervention	B (95% CI)	p
Number of patient journeys assessed (N)	1282	632	650				
Patients with at least one TSI, *N (%)*	1060 (82.6%)	527 (83.4%)	533 (82%)	83.4%	82.9%	-0.01 (-0.06-0.04)	0.81
Total number of TSIs	2018	978	1040				
Number of TSIs per person	1.57	1.55	1.6	1.524	1.608	0.05 (-0.02-0.13)	0.17
Patient experienced TSIs							
	Total	Mean		Estimated mean after correction		RR (95%CI)	p
		Before TIPP intervention	During TIPP intervention	Before TIPP intervention	During TIPP intervention		
Number of patients (N)	685	372	313				
% patients that have experienced a TSI, *N (%)*	238	141 (38%)	97 (31%)	0.46	0.40	0.86 (0.78 - 0.95)	0.002
Total number of TSIs per patient	0.69	0.79	0.58	0.91	0.71	0.72 (0.59 - 1.03)	0.08
Incident reporting weeks							
	Total	Before TIPP intervention	During TIPP intervention				
Total reported TSIs, *N*	47	25	22				
Patient reported TSIs, *N*	8	5	3				
Healthcare professional reported TSIs, *N*	39	20	19				

TSI=Transitional patient safety incident, RR=relative risk

Table 10.5 Effect of TIPP on healthcare professionals' perspectives on transitional patient safety climate, using the TRACE questionnaire.

	Before TIPP intervention Mean	During TIPP intervention Mean	Difference (CI)	p
Collaboration	3.23	3.01	-0.21 (-0.30 to -0.11)	<0.001
Speaking up	3.65	3.78	0.08 (-0.11 to 0.26)	0.42
Communication on incidents and improvements	2.34	2.14	-0.22 (-0.36 to -0.08)	0.003
Transitional patient safety management	3.01	2.83	-0.17 (-0.29 to -0.04)	0.009

CI=Confidence interval

the overall rating of transitions were rated highly by the patients. Both did not differ significantly before and during the TIPP intervention (data not shown).

Healthcare professionals' perception of transitional patient safety climate: In total, 286 healthcare professionals filled in the TRACE questionnaire (133 before and 153 during the intervention; response rate 44% and 38% respectively). Hundred-and-five (36.7%) were GPs and 181 (63.3%) hospital professionals. During TIPP, more GPs participated (42.5% versus 30%, p=0.020), especially those working in health centers (69.4% versus 44.7% of GPs, p=0.032). During TIPP, a larger part of the participating professionals came from the cardiology department (77.3% versus 44.6%, p=0.001) (appendix 10.4). Respondents from general practice and hospital differed in gender age and years of work experience (appendix 4). The mean scores of the dimensions "Collaboration", "Communication on transitional incidents and improvement measures" and "Transitional patient safety management" were negatively affected by the TIPP intervention (3.23 to 3.01, 2.34 to 2.14 and 3.01 to 2.83, respectively) (Table 10.5). Only the dimension "Speaking up" increased non-significantly from 3.65 to 3.78.

Process- and user evaluation: We gathered information from 91 healthcare professionals. Agreement on the relevance of improving transitional patient safety was a facilitator, but the integration of the intervention at department level and the degree to which the intervention was implemented as intended were low (data not shown). There were organizational and cultural barriers to the reporting of TSIs. Overall, active participation in the TIPP programme on the work floor was limited, particularly because healthcare professionals believed they lacked time and prioritized more urgent matters.

DISCUSSION

Main findings

In this study, we could not demonstrate a consistent effect of the TIPP intervention programme on reduction of patient harm. The number of deaths did not change. Moreover, the readmission rate increased during the TIPP intervention. This was explained by the increase of readmissions in the gastroenterology departments, related to stricter admission criteria for invasive endoscopies. We found no relevant effect of the TIPP intervention on the utilisation outcomes. The effect of the TIPP programme on the incidence of TSIs was heterogeneous: we found no change in the number of TSIs in the medical record review but we did demonstrate a drop in the number of patient-experienced TSIs. The cost consequence analysis indicated that the avoided healthcare expenses largely compensated the costs of the TIPP intervention. However, because changes in healthcare use was not significant, these results should be viewed with care. Furthermore, as only two context-specific intervention were implemented, costs for context-specific interventions may not be reliably estimated. However, the only department-specific intervention (transitional group consultation) was a relatively expensive intervention, and therefore it can provide a fair indication. Finally, we found a negative effect of the TIPP intervention on the professionals' perception of transitional patient safety climate. We hypothesize that this indicates an increase of awareness, which was also supported by the process and user evaluation.

Comparison to literature and interpretation

Although we designed TIPP as a context-tailored, comprehensive multi-faceted intervention targeting all main aspects of transitional patient safety, the absence of effect was not unexpected, and can be explained by several factors. First, the study period of 15 months was too short for a complex patient safety intervention to reach full impact.

Furthermore, the implementation of TIPP was suboptimal when evaluating within the five domains of the Consolidated Framework for Implementation Research (CFIR).[34] As to the *intervention domain*, we took into account the context of our participants, by first diagnosing their main transitional safety problems and then facilitating the implementation of a context-tailored intervention using a bottom-up approach.[35] The intention was that the participating departments together with the GPs would use our problem assessment, and would generate and implement their own context-dependent improvement plans. Unfortunately, as part of CFIR's *inner settings domain*, the implementation climate was not adequate, as quality improvement capacity proved to be insufficient and other priorities directly related

to patient care and urgent hospital-wide patient safety issues were prioritised. Furthermore, in the *implementation process* and *characteristics of individuals* domains, many of the first-hand individuals involved with TIPP changed jobs, leading to a loss of transitional safety champions and with that loss of engagement on department level leading to incomplete execution of intervention components. However, the lack of effect may also be caused by the generic aspect of the intervention, which might have been too distant from the outcome measurements.

We did find a negative effect of TIPP on the transitional patient safety climate. The dip in the professionals' rating of patient safety climate score likely indicates response shift, which is often seen in self-reported health surveys.[36] The culture intervention (the joint workshop for primary and secondary care professionals) and problem-analysis, aimed to change the healthcare professionals' awareness and understanding of transitional patient safety and transitional patient safety climate. Evaluating themselves on that dimension may have altered the healthcare professionals' perspective, inducing a different frame of reference between baseline and post intervention measurement. Evidence shows that interventions may take five years to actually increase patient safety climate, after first showing a decrease in score.[37]

We also found an effect of the TIPP intervention on patient perception of transitional patient safety. We hypothesize that the increase of awareness in healthcare professionals influenced communication between professional and patient and as a result improved patient perception of their safety. However, the communication between healthcare professionals from different settings as measured with the TRACE and the secondary outcome on missing correspondence did not improve.

Limitations

Besides the methodological design issues described in the research protocol[22], our study has several limitations. First, for the primary and secondary outcomes we extracted the data from several hospital and general practice databases, resulting in a dataset of mixed type and quality. Second, the patient population within the primary outcome concerned a large quantity of patients that had not actively received the intervention in person. This led to dilution of the potential effect. Third, patients of different departments within the same hospitals may be difficult to compare because of difference in case-mix, instead of comparing the same patient groups within different regions. To compensate for these differences, we corrected for baseline measurement and overdispersion, leading to a conservative estimation of the effect. Fourth, the rate and severity of the identified TSIs was probably underestimated as both in the TRIQ questionnaire and medical record review study the deceased patients were excluded for they do not visit the outpatient clinic in case of the TRIQ, and are omitted from the GP's medical record database so are

excluded from the medical record review study. Lastly, the respondent populations for both the TRACE and TRIQ questionnaire were dynamic, so an unknown part of the respondents overlapped between the two measurement periods. However, to ensure anonymity we could not link these patients, which led to loss of information and possible underestimation of the effect of the intervention.

Overall, the TIPP intervention was developed to improve transitional safety in the Dutch healthcare system and might not be generalizable. Notwithstanding, we included both rural and urban hospitals providing secondary and tertiary care to maximise generalisability. Moreover, as many countries have a similar healthcare organisation, and communication and collaboration between healthcare settings are a safety risk worldwide, TIPP can provide important lessons, tools, and improvement ideas for healthcare organisations outside of the Netherlands.

Implications

The first step in behaviour change lays in awareness. As transitional patient safety climate contrives of "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management" when handling patient transitions, awareness is a precursor for change in patient outcomes.[38,39] The TIPP intervention programme provides us with the tools and ammunition to create a sense of urgency and activate the healthcare professionals into action. This caused our participants to use our initiative to put the topic on the agenda. Since TIPP, several initiatives and collaborations have sprouted; the transitional incident reporting committee is functional in all participating organisations and has included other healthcare organisations, such as community pharmacists, anticoagulation service, and a home care organisation; joint resident seminars have started; safe email-communication has been initiated; one of the participating hospitals started a vast improvement project on ensuring timely correspondence to GPs and an already existing medication verification initiative has been extended to the outpatient clinic. However, to sustain the effect and facilitate further changes and interventions, permanent reminding is needed of the problems in transitional patient safety, e.g. by trend analysis of and feedback on reported incidents. We recommend a reassessment of the transitional patient safety and transitional patient safety climate on a yearly basis to provide input on progress and to provide information on further improvement opportunities. Nationwide, we recommend healthcare insurance companies to stimulate transitional patient safety by introducing a patient-centred bundle of payments that connects the healthcare settings and to provide financial incentives, such as introducing a quality indicator on transitional collaboration or interprofessional learning in the region.

CONCLUSION

Although we could not identify relevant changes in health outcomes and incidents of TSIs, TIPP has increased awareness for the improvement of transitional patient safety in the study regions. Additionally, we provided measurement tools to map transitional patient safety and transitional patient safety climate, and suggested improvement plans. Significant investments will be needed to use these tools, to successfully improve transitional patient safety and ultimately patient outcomes.

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AUTHORS' CONTRIBUTIONS

All authors designed the study. JP and MM acquired the data. MM, JP and HS analyzed the data. MM, DZ, JP and NW drafted the manuscript. All authors read and approved the final manuscript.

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APPENDIX 10.1 TRANSITIONAL PATIENT INFORMATION LEAFLET

Samen met uw huisarts en ziekenhuis werken aan veilige zorg

UMC Utrecht Julius center

TIPP!

Patiëntenfederatie Nederland
samen de zorg beter maken

Samen met uw huisarts en ziekenhuis werken aan veilige zorg

Let op: uw behandelaar heeft misschien niet alle informatie

Geef uw behandelaar alle informatie over uw gezondheidstoestand. Uw behandelaar heeft misschien niet alle informatie paraat. Vertel alles wat van belang kan zijn. Vertel uw behandelaar ook over contacten met andere zorgverleners.

Geef alle medicijnen die u gebruikt door aan uw huisarts en ziekenhuis

Uw behandelaars moeten altijd weten welke medicatie u gebruikt. Alleen dan kan de behandelaar de juiste keuzes maken voor uw behandeling. Bezoekt u voor het eerst de behandelaar? Geef een actueel medicatieoverzicht af. Of neem de medicijnen die u gebruikt mee. Laat het uw behandelaars altijd weten als er iets gewijzigd is in uw medicijnen.

Neem iemand mee naar de afspraak

Het is nuttig om iemand mee te vragen naar de afspraak. Bijvoorbeeld uw partner of mantelzorger. Iemand die met u meedenkt en met wie u het bezoek later nog eens kan bespreken. Twee horen meer dan één.

Weet bij wie u terecht kunt bij vragen en problemen

Vraag wie uw vaste aanspreekpunt is voor elk van uw gezondheidsproblemen en bij wie u moet zijn voor vragen en problemen.

Maak duidelijk als u iets niet begrijpt of als iets niet loopt zoals u verwacht

Stel vragen als u iets niet begrijpt. Als u merkt dat iets niet goed gaat, meld het dan meteen bij uw behandelaar. Bijvoorbeeld als gemaakte afspraken niet worden nagekomen. Of als uw zorgverlener u niet op tijd terugbelt met een uitslag. Geef ook aan wat uw wensen zijn.

Weet welke vervolgafspraken er zijn

Zorg dat u weet wanneer u voor controle terug moet komen. Weet wat u wel of niet mag doen. Wanneer en bij wie komt u terug? Dit kan zowel bij uw huisarts of in het ziekenhuis zijn. Moet u voor uw volgende afspraak iets doen? Bijvoorbeeld bloedprikken of een klachtendagboek bijhouden.

Ontwikkeling in het kader van de TIPP-studie, afd HAG Julius Centrum, UMC Utrecht in samenwerking met de Nederlandse Patiënten Consumenten Federatie (NPCF).

Deze kaart is tot stand gekomen in samenwerking met Achmea en Patiëntenfederatie NPCF
Deze kaart is gemaakt op www.mijnzorgveilig.nl, een initiatief van Patiëntenfederatie NPCF.

APPENDIX 10.2 COST CONSEQUENT ANALYSIS

Although no causality could be ascertained between the TIPP intervention and the increase and decrease in healthcare use, we did perform an exploratory cost consequence analysis to assess the costs of the TIPP intervention versus the potentially avoided healthcare costs.

METHODS

(Avoided) Healthcare use

Information for healthcare use was collected from the medical record review database that contained both the general practice and hospital medical record, linked per patient. Sixth year medical students assessed the information from the general practitioners and hospital database. They collected research department related emergency department visits, readmissions to the research department within 30 days of discharge, visits to the GP related to the health complaint associated to the research department related health complaint, and non-appropriate referrals to the research department in a six months' period before (May - November 2014) and during (February - August 2016) the TIPP intervention. To rate a referral as non-appropriate, the students identified single outpatient visits and assessed from the free text if the hospital specialist judged the referral as not appropriate. Subsequently, we subtracted the counts before the TIPP intervention from the counts during the TIPP intervention to calculate the extra or avoided costs. Then, we multiplied the counts with their respective unit costs conform Dutch guidelines for health economic.[1] To calculate readmission costs, we used the mean length of hospitalisation (5 days), multiplied with the cost for one hospital admission day. All costs were calculated for a university and general hospital separately, both per 1000 patients and for an average number of patients for a university hospital department (15000 patients) and a general hospital department (6000 patients) per year. These average patient numbers were derived from the total number of patients yearly visiting our research departments in both our university and general hospitals respectively.

Costs of the TIPP intervention

Direct costs were used applying the healthcare perspective. For each healthcare worker's function, hourly wages were calculated using their respective mean salary scale and number of production hours, according to the Dutch guidelines for health economic research.[1] Relevant salary scales were acquired from the human recourses departments of our participating hospitals and general practices. For hospital

specialists, an hourly wage for patient care and outside of patient care derived from the Dutch guidelines for health economic research was applied when relevant. For the cost analysis, the TIPP intervention was divided in two phases: the diagnostic phase in which the local transitional patient safety is assessed and main problems are identified, and an intervention phase in which interventions (both generic and specific interventions tailored to context) are implemented. In the diagnostic phase, we considered to be compulsory components: healthcare professionals' perception of transitional patient safety (TRACE questionnaire), patients' perception of transitional patient safety (TRIQ questionnaire), and focus groups for healthcare professionals and patients respectively. Optional components of the diagnostic process were a medical record review and health and utilization outcomes. In the intervention phase, we considered compulsory components: the construction of a (regional) transitional incident reporting committee, a joint workshop for both general practice and hospital healthcare professionals, and the implementation of a patient information card (all generic interventions). Optional components of the intervention were: joint education for general practice and hospital specialists in training (generic intervention) and a group consultation to provide information for stable patients discharged from the outpatient clinic to the general practitioner for further follow-up (specific intervention). For each component, the healthcare professionals and researchers involved were requested to estimate the different tasks involved and total hours spent in detail. These were multiplied with their hourly wages. Initial start-up costs and yearly running costs were calculated separately. All costs were calculated for both university and general hospitals.

RESULTS

The medical record review data showed non-significant increases in visits to the emergency department (+7 per 1000 patients) and non-appropriate referrals (+15 per 1000 patients) and non-significant decreases in readmissions (–16 per 1000 patients) and visits to the GP (–180 per 1000 patients). Per 1000 patients, the avoided costs were €37,571 for a general hospital, and €51,962 for a university hospital. The avoided costs would be approximately €225,446 for an average general hospital department with 6,000 patients a year, and €799,424 for an average university department with 15,000 patients a year. As to the costs of the TIPP intervention; for a general hospital department, the initial start-up costs for the compulsory components of the TIPP intervention were approximately €12,444, and the yearly running costs ranged between €43,203 and €100,674 of which the highest proportion was for the transitional incident reporting committee and the reporting and analysis of transitional incidents (range €13,440 - €58,330 when successful). The start-up costs for the optional components were €27,080, and the yearly running costs ranged from €22,555 to €26,165 of which the medical record review study was the main part. For university hospitals, the start-up costs of the

compulsory components of the TIPP intervention were approximately €11,602, and the yearly running costs ranged between €40,632 and €96,654. The start-up costs of the optional components were €26,613, and yearly operating costs ranged between €21,916 and €23,118 (Appendix 10.2 Table 10.2.1).

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Appendix 10.2 Table 10.2.1 **Summary costs per component of the TIPP intervention**

Assembly of the costs in detail can be requested with the author.

(Avoided) healthcare use									
	per 1000 patients Before TIPP	per 1000 patients During TIPP	Difference per 1000	Unit costs general hospital	Total costs general hospital per 1000 patients	Total costs average department in general hospital of 6000 patients	Unit costs university hospital	Total costs university hospital per 1000 patients	Total costs average department in university hospital of 15000 patients
Visits to the emergency department	135	142,40	+7,4	€ 259	€ 1.916,60	€ 11.499,60	€ 259	€ 1.916,60	€ 28.749,00
Readmissions	36,67	21	-15,67	€443x5 days	€ 34.709,05	€ 208.254,30	€642x5 days	€ 50.300,70	€ 754.510,50
Visits to the GP	1628,3	1448,2	-180,08	€ 33	€ 5.942,64	€ 35.655,84	€ 33	€ 5.942,64	€ 89.139,60
Non-appropriate referrals	1.67	16,18	+14,51	€ 80	€ 1.160,80	€ 6.964,80	€ 163	€ 2.365,13	€ 15.476,95
Total avoided costs					€ 37.571,29	€ 225.445,74		€ 51.961,61	€ 799.424,15

Appendix 10.2 Table 10.2.1 Continued

Costs intervention; compulsory components						
Organisation and coordination (basic employment)						
		University hospital			General hospital	
	Initial costs	Minimum running costs	Maximum running costs	Initial costs	Minimum running costs	Maximum running costs
Quality assurance officer 0,2 fte	0	12115,01	12115,01	0	13878,66	13878,66
Diagnosis transitional patient safety*						
		University hospital			General hospital	
	Initial costs	Minimum running costs	Maximum running costs	Initial costs	Minimum running costs	Maximum running costs
TRACE; healthcare professionals' perception	€ 79,82	€ 1.164,67	€ 1.164,67	€ 72,00	€ 1.234,14	€ 1.234,14
TRIQ; patients' perception	€ 159,64	€ 663,02	€ 663,02	€ 144,00	€ 740,10	€ 740,10
Focusgroup employees	€ 0,00	€ 500,94	€ 500,94	€ 0,00	€ 526,00	€ 526,00
Focusgroup patients	€ 0,00	€ 1.406,28	€ 1.406,28	€ 0,00	€ 1.516,99	€ 1.516,99
Generic interventions*						
		University hospital			General hospital	
	Initial costs	Minimum running costs	Maximum running costs	Initial costs	Minimum running costs	Maximum running costs
Transitional incident reporting committee	€ 11.362,44	€ 12.711,14	€ 56.239,56	€ 12.228,36	€ 13.440,46	€ 58.329,70
Joint workshop general practice and hospital	€ 0,00	€ 10.712,08	€ 23.205,82	€ 0,00	€ 11.086,14	€ 23.667,52
Patient information card	€ 0,00	€ 1.359,19	€ 1.359,19	€ 0,00	€ 780,81	€ 780,81
Total costs compulsory components TIPP intervention						
		University hospital			General hospital	
	Initial costs	Minimum running costs	Maximum running costs	Initial costs	Minimum running costs	Maximum running costs
Total costs compulsory components	€ 11.601,90	€ 40.632,33	€ 96.654,49	€ 12.444,36	€ 43.203,30	€ 100.673,92

Appendix 10.2 Table 10.2.1 Continued

Costs optional components						
Diagnosis transitional patient safety						
		University hospital			General hospital	
	Initial costs	Minimum running costs	Maximum running costs	Initial costs	Minimum running costs	Maximum running costs
Medical record review study	€ 18.870,00	€ 11.583,54	€ 14.382,90	€ 18.574,00	€ 11.814,76	€ 15.021,64
Health and utilization outcomes	€ 1.256,52	€ 2.006,57	€ 2.006,57	€ 1.324,80	€ 2.075,12	€ 2.075,12
Generic improvement strategies						
		University hospital			General hospital	
	Initial costs	Minimum running costs	Maximum running costs	Initial costs	Minimum running costs	Maximum running costs
Joint education for general practice and hospital specialists in training	€ 1.073,84	€ 2.358,82	€ 2.761,62	€ 1.091,76	€ 2.371,98	€ 2.774,78
Specific improvement strategies						
		University hospital			General hospital	
	Initial costs	Minimum running costs	Maximum running costs	Initial costs	Minimum running costs	Maximum running costs
Group consultation	€ 5.412,72	€ 5.967,36	€ 5.967,36	€ 6.089,48	€ 6.293,12	€ 6.293,12
Total costs optional components TIPP intervention						
	University hospital	General hospital				
	Initial costs	Minimum running costs	Maximum running costs	Initial costs	Minimum running costs	Maximum running costs
Total costs optional components	€ 26.613,08	€ 21.916,29	€ 23.118,45	€ 27.080,04	€ 22.554,98	€ 26.164,66

APPENDIX 10.3 TABLE 10.3.1 TOTAL NUMBER AND CHARACTERISTICS OF PATIENTS PARTICIPATING IN THE INTERVENTION AND CONTROL GROUP, BEFORE AND DURING THE INTERVENTION, PER DEPARTMENT AND ORGANISATION (HOSPITAL AND GENERAL PRACTICE)

Intervention group									
		Academic hospital Utrecht		General hospital Utrecht,		General hospital Hardenberg,		**Hospital overall**	**General practice**
		Gastro-enterology	Cardiology	Gastro-enterology	Cardiology	Gastro-enterology	Cardiology		
Number of patients (N)	Before TIPP intervention	4774	7818	2987	3021	1166	4009	**23775**	**166416**
	During TIPP intervention	5216	9227	3259	3276	1637	4614	**27229**	**168936**
Age (mean, SD)	Before TIPP intervention	57 (16.98)	64 (17.03)	60 (18.92)	70 (14.62)	58 (17)	67 (14)	**62.76 (16.51)**	**45 (17.87)**
	During TIPP intervention	55 (16.77)	62 (17.05)	59 (17.57)	70 (14.26)	57 (16)	67 (14)	**61.89 (16.20)**	**45 (17.96)**
Gender (N,% female)	Before TIPP intervention	2339 (49.0%)	3049 (39.0%)	1741 (58.3%)	1498 (49.6%)	665 (57.0%)	1804 (45.0%)	**11096 (46.7%)**	**88483 (53.2%)**
	During TIPP intervention	2556 (49.0%)	3598 (39.0%)	1773 (54.4%)	1559 (47.6%)	851 (52.0%)	2122 (46.0%)	**12459 (46.8%)**	**89283 (52.8%)**
Control group									
		Academic hospital Utrecht,		General hospital Utrecht,		General hospital Hardenberg,		**Hospital overall**	**General practice**
		Neurology	Internal medicine	Neurology	Internal medicine	Neurology	Internal medicine		
Number of patients (N)	Before TIPP intervention	6357	1405	5312	4742	1996	4273	**24085**	**83657**
	During TIPP intervention	7335	1616	5783	4912	2306	4244	**26196**	**85149**
Age (mean, SD)	Before TIPP intervention	52 (22.25)	54 (18.04)	59 (19.44)	64 (17.13)	58 (18)	64 (16)	**58.84 (19,06)**	**47 (17.82)**
	During TIPP intervention	51 (21,93)	54 (17.73)	61 (19.25)	64 (17.81)	59 (17)	64 (16)	**58.56 (19.03)**	**48 (18.02)**
Gender (N,% female)	Before TIPP intervention	2988 (47%)	717 (51.0%)	3007 (56.6%)	2784 (58.7%)	1058 (53.0%)	2307 (54.0%)	**12861 (53.4%)**	**42598 (50.9%)**
	During TIPP intervention	3521 (48%)	808 (50.0%)	3100 (53.6%)	2878 (58.6%)	1199 (52.0%)	2377 (56.0%)	**13883 (53.0%)**	**43543 (50.8%)**

APPENDIX 10.4 TABLE 10.4.1 CHARACTERISTICS OF PATIENT RESPONDENTS OF THE TRIQ QUESTIONNAIRE MEASURING TRANSITIONAL PATIENT SAFETY FROM THE PATIENTS' PERSPECTIVE.

		Total	Before TIPP intervention	During TIPP intervention	P-value[a]
		N=685	N=372	N=313	
Sex, female N(%)	362 (53.2%)	194 (52.6%)	168 (53.8%)	0.740	
Age median (IQR)	64 (22)	63 (22)	66 (21)	0.060	
Comorbidity N(%)	None	109 (29.3%)	109 (29.3%)	96 (30.7%)	0.416
	1	136 (36.6%)	136 (36.6%)	119 (38.0%)	
	2	80 (21.5%)	80 (21.5%)	52 (16.6%)	
	≥3	47 (12.6%)	47 (12.6%)	46 (14.7%)	
Polypharmacy, yes. N(%)		306 (44.7%)	161 (43.3%)	145 (46.3%)	0.424
Ethnicity N(%)	Dutch	321 (86.3%)	321 (86.3%)	281 (89.8%)	0.324
	Non-Dutch	33 (22)	33 (22)	22 (15)	
Education N(%)	Primary	171 (46.3%)	171 (46.3%)	124 (39.7%)	0.168
	Secondary	95 (25.7%)	95 (25.7%)	83 (26.6%)	
	Tertiary	208 (30.5%)	103 (27.9%)	105 (33.7%)	
Hospital N(%)	General hospital Utrecht	226 (33.0%)	111 (29.8%)	115 (36.7%)	0.056
	Academic hospital Utrecht	149 (21.8%)	92 (24.7%)	57 (18.2%)	
	General hospital Hardenberg	310 (45.3%)	169 (45.4%)	141 (45.0%)	
Medical department N(%)	Cardio	336 (49.1%)	182 (48.9%)	154 (49.2%)	0.943
	Gastroenterology	241 (35.2%)	190 (51.1%)	159 (50.8%)	
Transition N(%)	Discharge	126 (18.4%)	69 (18.5%)	57 (18.1%)	0.910
	Referral	246 (35.9%)	157 (42.2%)	89 (28.4%)	0.000
	Concurrent care outpatient clinic and GP	580 (84.8%)	310 (83.3%)	270 (86.3%)	0.001

APPENDIX 10.4 TABLE 10.4.2 RESPONDENT CHARACTERISTICS OF HEALTHCARE PROFESSIONAL RESPONDENTS OF THE TRACE QUESTIONNAIRE MEASURING HEALTHCARE PROFESSIONAL PERCEPTION ON TRANSITIONAL PATIENT SAFETY CLIMATE

			Total			Before TIPP intervention			During TIPP intervention			P-value
Characteristics	N		Total (N=286)	GP (N=105)*	HOS (N=181)*	Total (N=133)	GP (N=40)*	HOS (N=93)*	Total (N=153)	GP (N=65)*	HOS (N=88)*	
Gender N(%)	248	Female	176 (71.0%)	77 (77.0%)	99 (66.9%)	77 (68.8%)	30 (78.9%)	47 (63.5%)	99 (73.8%)	47 (75.8%)	52 (70.3%)	0.485
Age in years med (IQR)	244		40 (20)	44 (19)	36.5 (21)	40 (17)	41.5 (15)	39(22)	39.5 (21)	50.5 (20)	35,5 (16)	0.697
Work experience in years med (IQR)	244		9 (14)	12.5 (17)	7 (11)	9 (11)	11 (10)	7 (11)	9.5 (15)	16 (22)	6 (11)	0.682
Hospital	162	General hospital Utrecht	x	x	110 (67.9%)	x	x	63 (71.6%)	x	x	47 (63.5%)	0.353
		Academic hospital Utrecht	x	x	52 (32.1%)	x	x	25 (28.4%)	x	x	27 (36.5%)	
Department N(%)		Gastro-enterology	x	x	63 (42.9%)	x	x	41 (55.4%)	x	x	22 (29.7%)	0.001
		Cardiology	x	x	85 (57.4%)	x	x	33 (44.6%)	x	x	52 (70.3%)	
Practice organisation N(%)	100	Solo	x	4 (4.0%)	x	x	3 (7.9%)	x	x	1 (1.6%)	x	0.032
		Multiple‡	x	36 (36.0%)	x	x	18 (47.4%)	x	x	18 (29.0%)	x	
		Healthcare centre	x	60 (60%)	x	x	17 (44.7%)	x	x	43 (69.4%)	x	
Function N(%)	248	Physician	141 (56.9%)	72 (72.0%)	69 (46.6%)	62 (55,4%)	31 (81.6%)	31 (41.9%)	79 (58.1%)	41 (66.1%)	38 (51.4%)	0.666
		Non-physician	107 (43.1%)	28 (28.0%)	79 (53.4%)	50 (44.6%)	7 (18.4%)	43 (58.1%)	57 (41.8%)	21 (33.9%)	36 (48.6%)	
Respondents with missings N(%)	286	% cases with missings	29 (10.1%)	3 (2.9%)	26 (14.4%)	17 (12.8%)	2 (5.0%)	15 (16.1%)	12 (7.8%)	1 (1.5%)	11 (12.5%)	0.168

GP=general practice, HOS=hospital

**Distribution of respondents between GP and hospital was significantly different in the baseline vs the intervention period*

‡ Multiple independent general practices under one roof =

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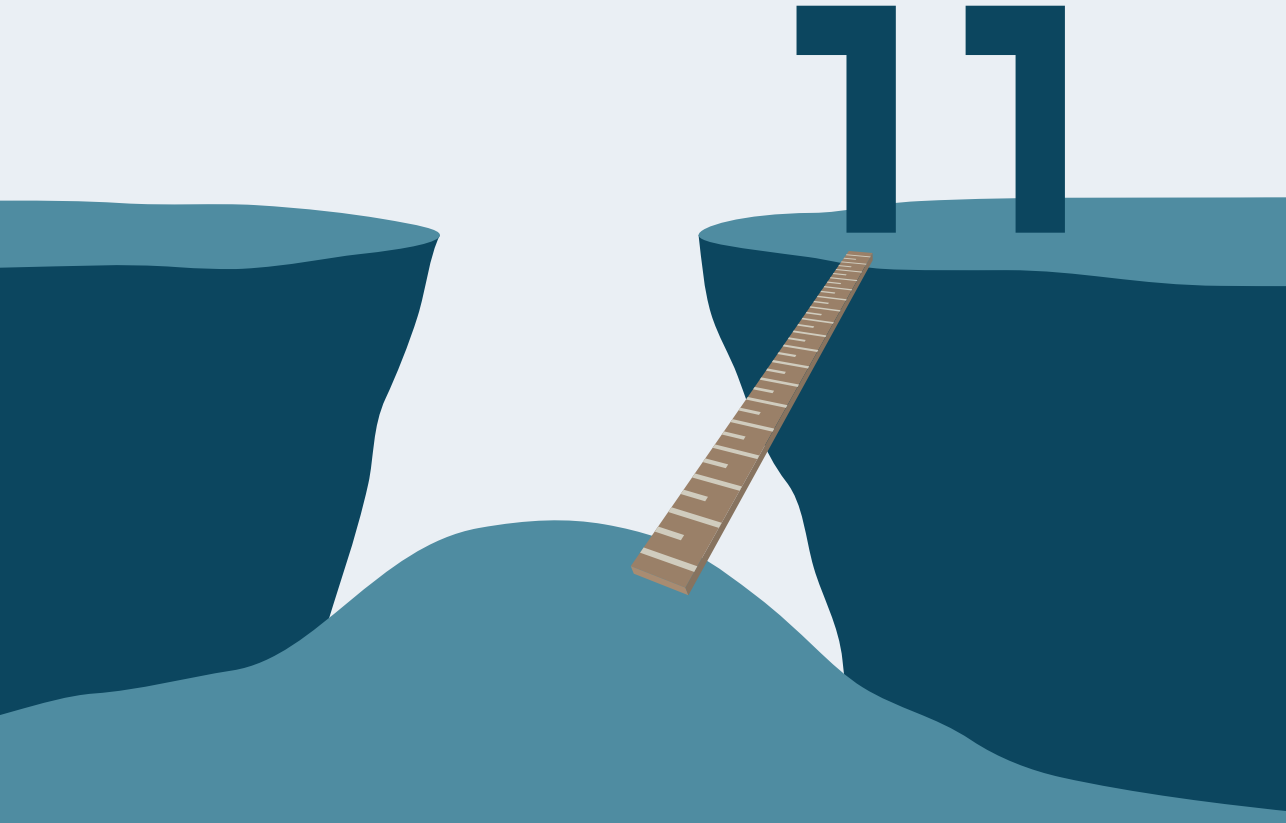

GENERAL DISCUSSION

GENERAL DISCUSSION

The aim of this thesis was to explore the frequency and background of transitional patient safety incidents, to develop instruments that measure different aspects of transitional patient safety, and to design and evaluate TIPP, an intervention programme to improve transitional patient safety. In this final chapter, we discuss the main study results and give reflections on the process of exploring, measuring, and improving transitional patient safety.

Main results

Transitional incidents occur frequently in daily clinical practice. We identified transitional safety incidents (TSIs) in over 80% of medical records ranging from unsafe situations to adverse events. Half of all patients reported to have experienced a TSI based on the TRIQ questionnaire. The majority of TSIs were related to the discharge or referral process between hospital and general practice, and regarded inadequate information exchange. One third of in-hospital prescription changes were not or incorrectly documented in the general practitioner's record, which likely puts patients at risk of adverse drug events after hospital visits.

TSIs occur at the interface of primary and secondary care, in the grey zone which is not organised, and where nothing is registered. Therefore, it is important to identify precursors and risk factors of TSIs, such as mismatches in GP's or specialist's registration and information gaps. To do so, we created a transitional medical record, linking patients' data from general practice and hospital. Despite the full information available, the reliability of clinician-based assessment of transitional medical records proved low, three out of four TSIs were missed. This may have been caused by a different perception between professionals from primary and secondary care about what a TSI entails. Review by a homogeneous group of final-year medical students strongly improved reliability of the transitional medical record review.

We found no instruments that measure the full range of transitional patient safety, but only instruments that focused on specific aspects of health care transitions, such as the discharge process or collaboration between the settings. The validity of these instruments, however, is suboptimal, and they are infrequently used in intervention studies. Many different outcomes are used in transitional patient safety research, using different data collection methods and involving a spectrum of stakeholders which makes current research difficult to compare.

In addition to the transitional medical record review method, we successfully developed two new measurement tools.

The TRAnsitional patient safety Climate Evaluation (TRACE), measures transitional patient safety climate in four dimensions: (1) collaboration, (2) speaking up, (3) communication on transitional incidents and improvement measures, and (4) transitional patient safety management. Validation of the TRACE questionnaire

in a combined sample of general practice and hospital respondents indicated that the transitional patient safety culture in primary and secondary care differs substantially.

The Transitional Risk and Incident Questionnaire (TRIQ) proved a valid and reliable questionnaire to measure transitional patient safety from the patients' perspective in four domains: 1) personal relation with general practitioner, 2) personal relation with the hospital physician, 3) information exchange, and 4) treatment consistency. Results of the TRIQ indicated that although in theory patients have the best overview of their health care journey, they are not always able to adequately identify TSIs, especially when related to organisational continuity (all that goes on behind the curtains, in organisation and information transferral).

We could not demonstrate an effect of the multifaceted TIPP intervention programme on serious health events, such as death and readmissions. The TIPP programme had a positive effect on the frequency of patient experienced TSIs, but a negative impact on professionals' perspective of the transitional patient safety climate.

Results in context; challenges in transitional patient safety research

The theory behind transitional patient safety: defining new constructs

When we started the TIPP programme, patient safety had been on the agenda for two decades. It started off from "to err is human"[1], but nowadays most hospitals have a safety and quality department with quality officers. Likewise, in general practice patient safety monitoring has been organized with incident reporting procedures like "Veilig Incident Melden" (VIM, a Dutch acronym for Safe Incident Reporting),[2] and in practice accreditation procedures like the "NHG praktijk accreditering" (NPA®).[3] However, patient safety at the interface had not yet been established as a construct.

Transitional patient safety is closely related to the concept 'continuity of care', which reflects if patients experience care over time as coherent and linked. Continuity of care occurs when separate and discrete steps in healthcare provision are connected and when those elements of care that endure over time are maintained and supported. This may regard one healthcare provider, one department or healthcare organisation, or cross the borders of the healthcare organisation, which is the space in which transitional patient safety exists. Furthermore, continuity of care covers quality aspects like efficiency, effectiveness, equity, and timeliness, while transitional patient safety focuses on the prevention or reduction of harm associated with patient transitions.[4] Thus, compared to continuity of care, transitional patient safety particularly focuses on safety outcomes instead on organisational aspects. As described by Reid et al., three different dimensions of continuity of care are identified: 1) relational continuity, which encompasses the ongoing relationship

between patient and healthcare provider over time, 2) informational continuity, which means that information on earlier events is available for present care delivery, and 3) management continuity, which ensures that care received from different providers is linked in a coherent way.[5] As we deemed these dimensions transferable to transitional patient safety, we adopted them as a theoretical basis for our measurement tools. However, we did not consider relational continuity as part of transitional patient safety, but as conditional for safe transitions. In that sense, relational (dis)continuity can be seen as a risk factor.

Another construct to be developed was the transitional patient safety culture which is 'the way we do things around care transitions'.[6] There was no explicitly defined and jointly agreed set of rules and regulations at the interface between primary and secondary care. The reason is probably that there is no shared environment nor shared practice between professionals, as they each work in their own domain. However, there are "ways we do things around" patients who are referred, discharged or treated, and therefore an implicit transitional patient safety culture does exist *within* every primary or secondary care organisation that collaborates in patient care. It is embedded in each organisation and consists of the core values that direct the way these organisations behave, interact and collaborate with each other. Indeed, to improve patient safety at the interface the cultures of collaborating organisations around transitions need to be made explicit, and aligned. Making them explicit will create the awareness necessary to change the present safety climate; alignment will make transitional safety sustainable.

Explanation of the results; disappointing outcomes?

When we developed the TIPP programme, we hoped to be able to demonstrate effectiveness of the multifactorial intervention programme. However, upfront we did realize it was an ambitious goal, and we think a number of factors may explain the absence of a clear intervention effect.

First of all, time may have been too short for such a complex and ambitious process. As described earlier, the TIPP programme comprised of three phases: a diagnostic phase in which we conducted a problem analysis of the current transitional patient safety and explored the available measurement tools, a developmental phase in which we developed measurement tools and improvement plans, and an intervention phase in which we implemented the intervention programme and measured is effect.

Safety interventions require more time to change clinical practice, and we knew from the start that it would be difficult to demonstrate improvement. Earlier, patient safety initiatives demonstrated that it can take up to five years to demonstrate an affect.[7] Time is even more of importance in transitional patient safety, as multiple organisations are involved, and all stakeholders need to agree. For example, the establishments of transitional incident reporting platforms proved time-consuming, as they needed to be approved by all quality departments and boards of participating hospitals and GPs' organisations.

Although no effect was measured on primary outcomes, we did find a positive change in patient-experienced incidents and a negative effect on healthcare professionals' perception of transitional patient safety culture. We regard the latter resulting from an increased awareness among professionals which may have triggered better communication to their patients who were about to be transferred. Moreover, we observe that the transitional safety discussion now has started in the participating regions. For instance, the transitional incident reporting platform matured, and was even connected to other healthcare organisations, such as the regional laboratory service (SALTRO), community pharmacists and home nursing care.

The development of complex interventions is challenging and requires choices on study design, implementation and outcomes. As recommended by the Medical Research Council and Datta et al.[8,9], we chose a multidimensional approach to develop the generic components of the TIPP programme, aiming at the healthcare process, transitional patient safety culture and the patient's role. Still, the intervention programme may have been too generic, not matching with the local situation. We did intend context-specific interventions to be developed from the work floor itself. Only two such interventions were implemented, namely 1) the introduction of a transitional group consultation with cardiologist and GP for stable cardiac patients that could be handed over from cardiologist to the GP, and 2) the implementation of a digital referral platform (Zorgdomein) to facilitate information exchange between primary and specialist care, of which the latter was actually hospital-wide.[10] Furthermore, an important generic intervention, the transitional incident reporting committee, was available for both the intervention and control departments. This may have further diluted the effect.

During the intervention phase, the intervention fidelity was suboptimal, especially concerning the implementation of the generic TIPP components. Fidelity is the degree to which an intervention is implemented as it was intended.[11,12] As mentioned earlier, the transitional incident reporting system was implemented, but probably in full process too late to reach a measurable effect. The workshop on transitional patient safety culture was partly successful, but only a fraction of the target group (40 of approximately 200 professionals) attended the workshop. The implementation of the patient information leaflet differed between departments as well. Collaboration in complex interventions is challenging and requires time and commitment. [13] Leadership's commitment, local champions, capacity and room for thoughts and creative ideas are needed for a true change of climate.[14,15] In our study, we observed that investments we made as a research team to achieve these preconditions did hardly sustain. Leadership changes, financial challenges and external inspection or participating organisations by the Dutch Health Inspection negatively impacted the execution of the TIPP intervention. Such influence of the 'outer world' seems inevitable in larger real-life studies, but complex, inter-organisational studies probably are even more vulnerable.[16]

Methodological considerations

Three issues concerning validation of our measurement tools need additional discussion. The first concerns the type of concepts that are measured in transitional patient safety. Both transitional patient safety and transitional patient safety culture are formative concepts instead of reflective concepts. A formative concept is composed of independent, albeit correlated variables, in which the components are defined by the theorised construct. Examples are the Apgar score in perinatal care, socioeconomic status, health-related quality of life scale, and the human development index. In a reflective construct, the indicators of a construct are considered to be caused by that construct; the indicators reflect the underlying, not directly observable construct. Examples are an intelligence scale, anxiety, and reading ability. These two measurement models are conceptually and psychometrically different, and need different ways of validation.[17] Yet, validation techniques for reflective constructs are the standard in medical research. Without exception, these reflective techniques were applied to the systematically identified available measurement tools described in the review (Chapter 3). In reflective constructs, items are interchangeable and excluding items that do not statistically belong to the construct does not alter the content validity of the construct. However, validation of formative constructs with reflective techniques often resulted in exclusion of many relevant items or even whole dimensions in these measurement tools. Omitting anything that does not statistically fit, which is usual in reflective techniques, is not suited for formatively defined constructs. If one does so, consequently only part of the concept will be covered by the measurement tools validated by reflective techniques such as factor analysis. We believe, this has led to hampered content validity of many current transitional safety measurement tools. In general, this bias is not discussed in current publications, nor addressed when measuring the construct. Nonetheless, as no consensus has been reached on how to validate formative constructs, we also chose the prevailing validation technique of factor analysis, but only to check whether the data supported our construct and to refine the construct. Accounting for transitional patient safety being formative, we consciously chose not to exclude any items in the process to not abandon the intended construct.

Another challenge in validating our measurement instruments was the fact that there are no reference standards available, which limits the possibility to establish whether the measurement tool indeed measures the construct. This was especially a problem in the validation of the medical record review method, in which we intended to first develop a trigger tool. Trigger tools are often used in medical record reviews to preselect TSI's at risk through identification of red flags for potential incidents. Trigger tools limit the number of medical records that have to be searched. However, we couldn't adequately validate the trigger tool as a diagnostic tool for transitional patient safety incidents because we missed a reference standard. Therefore, the trigger tool could not be used and all transitional patient records needed to be fully

reviewed. Consequently, as a measurement tool for TSIs the record review method remains quite time-consuming.

Lastly, as there were no adequate instruments for measuring transitional safety, we needed to develop them before the baseline measurement. Although we managed to validate both questionnaires, the TRIQ and TRACE, on the dimensions content validity, internal consistency and construct validity we did not assess minimal important change, test-retest reliability and responsiveness because of time constraints. Therefore, both measurement tools are not sufficiently validated to measure change over time or the effect of a transitional patient safety intervention.[18] Hence, the results of our TIPP trial should be interpreted with caution.

Observations; what did we learn?

The patient travels through different worlds

General practice and hospital are two separate worlds, with barely any interaction.[19] Especially in urban settings, healthcare providers from each setting hardly know each other, which is a barrier for warm handovers through direct communication. Furthermore, there is a difference in the way healthcare professionals in each setting approach risks and safety issues. Although all doctors have had the same medical training, the world in which they subsequently start working shapes them, and modulates the way they perceive risks and safety. Yet, a different role of primary and secondary care is functional; actually, it is the fundament of our health care system. As one of our participants stated: "in general practice most patients are healthy, unless proven otherwise, and in hospital patients are ill, unless proven otherwise". Different patient populations result in a different approach of patients with comparable complaints, which easily leads to misunderstanding in the expectations professionals have of what the other setting needs to do to continue the patient's journey. We observed this during the validation of a clinician-based medical record review (chapter7). For this study, we purposefully chose to include expert reviewers of both settings, assuming that we would cover the whole range of TSIs. Yet, the TSIs identified by the GPs had hardly any overlap with those found by hospital specialists. Discussion revealed that they had different views on safety issues. This experience led us to use trained final-year student reviewers in the intervention study, for they still had the same shared education, and some experience in both settings. The drawback of this approach is that we may have missed the more complicated TSIs, such as potential interactions between prescribed medication in both general practice and hospital. Also during the validation of the TRACE questionnaire, it was difficult to find a common factor structure for the respondents from both settings. All together, we believe that for sustained improvement of transitional patient safety continuous attention to connecting these two different worlds will be needed.

Information Technology as a barrier to effective transitional patient safety
Next to organisational, personal and professional barriers, the fragmentation of information technology (IT)-systems also threatens transitional safety. Primary care practices and hospitals each have their own electronic medical record, and communication between the systems is difficult. Additional tools are developed, but f.i. the referral ICT tool (Zorgdomein) is separated from that for discharge information exchange. This is even more complicated in medication reconciliation, in which a third system, that of the community pharmacists is involved. This leads to life threatening medication discrepancies in the medical records in general practice and hospital. IT handover support has been installed in hospitals, but these are rarely used, largely due to a lack of interoperability between systems from different vendors.[20]

The clinical versus safety perspective
As one of the nestors of safety research, Charles Vincent, stated: in healthcare, three types of care exist: 1) standard care, consisting of identical and repetitive care, such as the provision of medication, radiotherapy, and preparation of surgery; 2) routine care, consisting of similar, but not identical repetition, such as chronic care; and 3) non-routine care, consisting of non-repetitive care in which uncertainty is high, such as trauma care or the initial complaints that may point at a threatening disease of an individual in primary care.[21,22] These types of care all ask for a different risk and patient safety strategy. In standard and routine care, procedures and guidelines lead to safe care. In non-routine care, clinical intuition and experience are of vital importance. In healthcare, physicians constantly move between these types of care.

These distinct types of healthcare match with the current safety I versus safety II discussion. In safety I, safety is defined as "a state where as few things go wrong because of identifiable failures or malfunctions of specific components: technology, procedures, the human workers and the organisations in which they are embedded".[23] The aim of Safety I is to eliminate risk and prevent the causes by high reliable systems and procedures, which would be a suitable safety management approach for standard and routine care. However, in healthcare things usually go right, also in non-routine care. Safety II ensures that 'as many things as possible go right' and relates to the system's ability to succeed under varying conditions.[23] Taking or embracing risks is daily practice and physicians learn to be resilient, and to handle these risks on the spot. When we understand how things usually go right, we can also understand what factors can derail the healthcare process.

During discussion with clinicians about the TIPP results, we often met scepticism about TSIs. In the medical record review, the majority of TSIs concerned unsafe situations, i.e. incidents without any consequence for the patient yet. Professionals questioned whether these incidents were actually clinically relevant, as they were considered as part of daily practice, and they perceived it to be the physicians' role to prevent risky situations developing into harm. So, unsafe situations were viewed from a Safety II, non-routine care stance. Such a clinical view contrasts with the

safety scientists' view, who stresses that every (even small) unsafe situation may lead to patient harm. They advocate for reliable procedures that will safeguard patients from harm. From this safety I perspective, the majority of transitional care, such as writing timely and adequate correspondence, is standard, or at most routine care which needs to be contained by systems' and procedures' improvements. However, clinicians seem to ascribe the majority of smaller transitional safety issues as inevitable flaws, with which they have to deal in daily practice, whether these flaws could be prevented by structuring the process or not. Maybe, such an almost passive stance towards daily incidents is even reinforced by the reality that solving many of these information exchange flaws would require major system's change, such as compatible or even integrated IT systems, or a proactive organisational safety. Both changes are not in individual clinicians' power to accomplish, neither in hospitals nor in single GP practices. Still, we believe a discussion among all stakeholders about which parts of care transition processes should be attributed to routine care and which to non-routine care, and who should target what, would be fruitful next steps in improving transitional safety.

The patient's role in care transitions

As we discussed in the introduction, the patient is the central and only constant factor in care transitions. In the TIPP study, we found that patients have different visions on transitional patient safety and their potential role in it. The younger and more 'experienced' patients seemed very capable of steering their own healthcare journey and participating in risk reduction. Other patients seemed willing to help safeguard their transitional safety, but did not know how to play this role. And a third group seemed not willing to participate, either because they thought it was the professionals' responsibility, or because they did not feel capable doing so. As one of our participating professionals stated when he discussed differences in patients' roles with a patient-representative: "It is really striking, that the patient knows everything about his car: the name of the paintwork, the number of cylinders. But he doesn't know anything about the drugs he takes for his health problems". These observations based on a small set of interviews and informal patient contacts collide with research on patient activation.[24] Our observations confirm that differences in patients' perceived needs and abilities determine their involvement in transitional safety. Improvement strategies should focus on supporting healthcare providers in engaging the individual patient to participate in transitional safety, tailored to their needs, capacity and willingness. For instance, which patients would be willing to carry their own information in a personal-held record? Or, will patient portals in which they can access their health records support the prevention of TSIs? We conclude that care transitions should be made transparent and explicitly explained to the patient as the key participant in the healthcare journey!

Recommendations

Research

The results of our study suggest that improving transitional patient safety is feasible, although effects on the primary outcomes and on the frequency of objectively measured transitional patient safety incidents were not found. As this may be caused by the short time period for the intervention, we recommend the effect measurements to be repeated in 3 years. At that time, we believe the construct of transitional patient safety will have established itself. In addition, we recommend the further validation of the TRACE and TRIQ questionnaire. We recommend further scrutiny of its psychometric properties in larger and international populations by confirmatory factor analysis and analysing their ability to reliably measure relevant change.

Additionally, in the TIPP programme, we focused on the transitions between general practice and hospital only. We did not cover other healthcare organisations involved in care transitions, such as nursing homes, home care services, anticoagulation services, pharmacies, etcetera, nor the transitions within the same settings such as two hospitals, or the GP out-of-hours services and regular day care general practices. Despite this potentially overwhelming number of interfaces, research on transitional safety should be expanded to include these settings. For these purposes, the TIPP programme and its measurement tools can be used as a basis.

Clinical practice

Although the difference between primary and secondary care serves as a fundament of our healthcare system, for safety reasons we need to better bridge the gap between them. We believe that this space should be consciously defined as the domain between collaborating healthcare organisations that take care of the same patient population. For improving organisation of the transitional space, we think we need to invest in three steps.

First, we need to create awareness, both of the healthcare professionals involved as well as of patients. Using the outcomes and measurement tools developed in the TIPP programme can provide insight in the current status of transitional patient safety of the local setting. Even though clinicians question the clinical relevancy of the TSIs identified, most do acknowledge the magnitude of the problem, and also recognize the system's flaws. This first step will create problem ownership.

Second, we need to bring the stakeholders together. We need professionals to understand the entire patient journey, including the healthcare processes and risk situations on the other side of the gap. They need to learn about each other's domains and update regularly as settings and organisations are rapidly changing. Understanding what is needed for the next responsible healthcare professional to take over care of the patient is crucial for ensuring seamless and safe patient care. Primary and secondary care will continue to reason from different stances,

and inherently speak different languages. Therefore, persistent attention and investments will be needed to maintain a generative transitional patient safety culture. Formal and informal meetings with interprofessional learning and discussion will be essential for such maintenance, as well as reciprocal practice visits to understand each other's operational processes. To start building transitional patient safety culture even earlier, interprofessional learning should be an obligatory part of specialty training in both general practice and hospital specialties.

Third, healthcare organisations need to invest in a healthy internal structure, that is capable of connecting with the 'next door' healthcare organisations caring for the same patients. It should not be allowed to implement an IT system that is not compatible with regionally partnering healthcare organisations. A shared electronic medical record could solve most of the problems with medication discrepancies and inadequate correspondence at short notice. Of course, a shared medical record will not prevent all TSIs, just because it will not ensure adequate collaboration or mutual understanding. Unfortunately, the road towards a shared medical record is probably long, given the commercials interests and the current debate around privacy issues. In the meantime, making tools like Zorgdomein reciprocal, ensuring safe email or app groups between the professionals of different care settings for short questions and notifications, such as ensuring follow-up of blood values or prescriptions, will be fruitful and feasible next steps.

Policy

The Dutch government aims for quality and affordability in healthcare, providing the best care for acceptable costs. Transitional safety is an essential part of that goal. We believe that improving and ensuring transitional safety is a shared responsibility that requires joint effort of professionals and their healthcare organisations. However, we need the leading bodies, such as the government, healthcare insurers and all occupational organisations, to get involved, set priorities create facilities between primary and secondary care organisations.

Efforts for a sustainable transitional safety should come from both sides, from general practice and hospital care. However, the current payment model is not very compatible with transitional safety demands. Indeed, it is easy to wait for the partnering organisation to take the initiative. Moreover, there are always pressing internal issues that need funding, and transitional efforts are not often prioritized. So, to be able to facilitate inter-organisational, multidisciplinary improvement plans, such as joint workshops, transitional incident reporting platforms or group consultation supporting substitution (and thus transition!) of care, we need a joint vision of policy makers on how to facilitate implementation of transitional safety initiatives, and on how to get them funded. For instance, insurance companies could set a combined payment bundle, or incentivize regions to build a positive transitional patient safety culture in a collaborative (infra)structure fit for providing safe care transitions.

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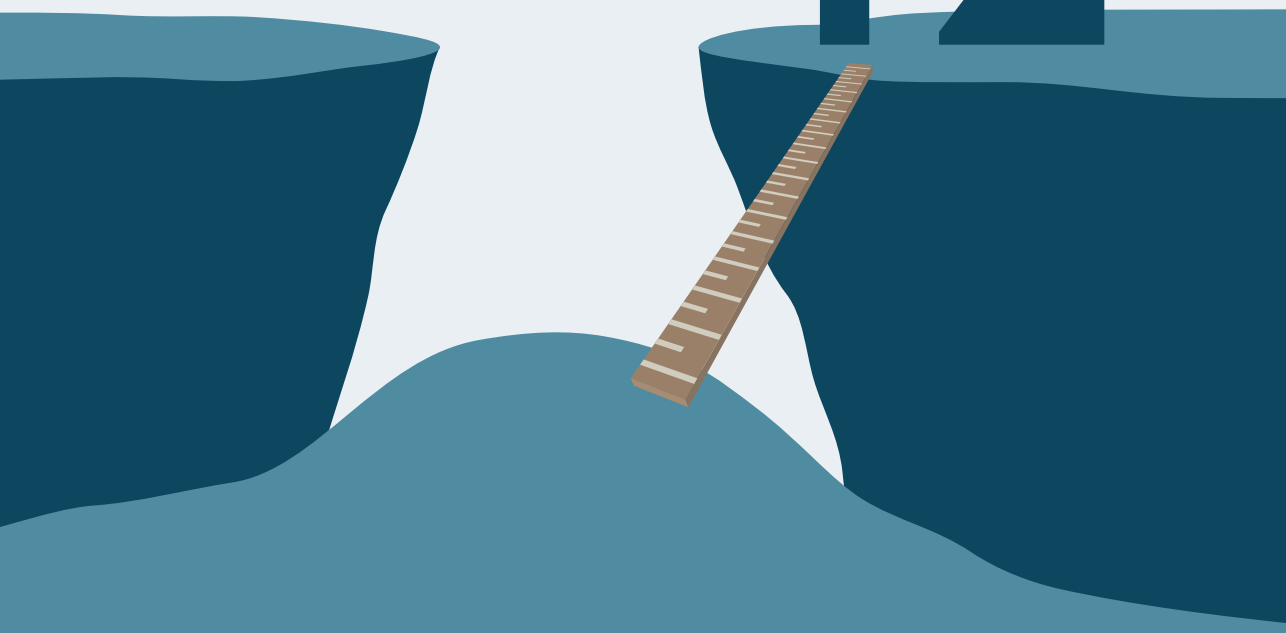

APPENDIX

12.1 SUMMARY

Patients often are treated by multiple healthcare professionals, both in general practice and hospital. Therefore, patients experience transitions between different healthcare settings, for instance at referral, discharge, and visits to the Emergency Department, or outpatient department. All these care transitions require adequate handover of vital information. When handover processes are not well executed, transitional safety incidents (TSIs) occur. A TSI is defined as "any unintended or unexpected event in patient care between different healthcare settings which did or could have led to harm for the patient." TSIs can be classified according to severity as unsafe situations (circumstances or events that enhance the risk for error), near misses (an act of commission or omission that could have harmed the patient but did not do so as a result of chance, prevention or mitigation) and adverse events (any injury to a patient caused by medical care).

Although there is a fair amount of evidence for the unsafety of patient transitions and the background processes causing them, evidence for success of improvement strategies is scarce. Interventions that proved to work in one setting appear to be difficult to scale up, and evidence on their potential to actually improve safety during patient transitions is contradictory. Most interventions to improve transitional patient safety are aimed at the actual care transition process, or at the professional actions when patients are handed over. However, for optimal effect, we also need a constructive safety culture. Transitional patient safety culture consists of the values, attitudes, competencies, and behavioural patterns of the organisations and/or professionals involved in care transitions. In addition to the healthcare provider, the patient, as central actor in transitions, could also actively participate. Getting the patient involved might boost transitional patient safety as patients may be in the position to monitor and mitigate transitions during their journey in health care.

To improve transitional patient safety, valid measurement instruments are required to map the safety culture, the patients' and professionals' perceptions of transitional patient safety, and to evaluate the effect of interventions.

This thesis was part of the Transitional Incident Prevention Programme (TIPP). The overall aim of TIPP was to develop an improvement strategy and toolbox for improving transitional safety between hospitals and their regional partnering general practices. To achieve this, we needed further understanding of the current practice of care transitions in the Netherlands, and we needed to develop measurement tools assessing background and outcomes of transitional safety.

The first chapter of this thesis gives an overview of the nature of TSIs (Chapter 2). In the next chapter, we performed a literature search to identify available validated measurement tools and outcomes used to measure transitional patient safety (Chapter 3). Subsequently, we developed and tested instruments to measure improvement of transitional patient safety (Chapter 4, 5, 6, and 7). In chapter 8 we measured medication prescription discrepancies during healthcare transitions.

Finally, we report the results of a controlled before-after trial measuring the effect of the TIPP intervention (Chapter 9 and 10).

In **Chapter 2** we provide an overview of the nature of TSIs collected from both patients and healthcare providers during the diagnostic phase of TIPP. We collected the TSIs through incident reporting systems, surveys, interviews and focus group discussions and classified them according to type, cause, and severity. In total, we collected 548 TSIs, 411 reported by patients and 137 by healthcare providers. Most TSIs concerned handover correspondence from hospital to general practitioner (26%), referral (14%) and communication and collaboration other than written correspondence (14%). One-hundred-and-ninety-one TSIs provided sufficient information to be classified according to cause. Of these, 48 % could be attributed to organisational and 43% to human factors. Concerning severity, 149 TSIs could be assessed. Twenty-four percent of TSIs concerned unsafe situations, 45% concerned near misses, and one third of TSIs caused harm to the patient. Three lethal TSIs were reported. Patients more often reported TSIs related to inadequate referral, repeated diagnostic testing and uncertainty about the first responsible physician than healthcare professionals. Healthcare professionals typically reported medication-related TSIs. This disparity between professionals and patients reflects a different perspective on transitional patient safety. Interventions to improve transitional patient safety should focus on information exchange to bridge the gap between hospital and general practice.

In **Chapter 3,** we systematically reviewed all validated measurement tools and explored the outcomes that have been used in transitional patient safety. We searched PubMed, Cinahl, Embase and Psychinfo and used a combination of search strategies on three topics: 1) transitional care, including various terms and keywords synonymous and related to transitional care, 2) measurement, and 3) patient safety. Given the aim of this systematic review, we included all quantitative studies that: 1) assessed the quality of validated measurement tools on aspects of transitional patient safety (validity assessment), and 2) used an outcome measure to report the effect of improvement interventions or cross-sectional evaluations of aspects of transitional patient safety (outcome inventory). We identified 17 studies for the validity assessment and 191 studies for the outcome inventory, respectively. The overall quality of the validated measurement tools was acceptable; however, validation was mostly incomplete, especially regarding the measurement of change over time. The outcome inventory showed that the identified validated measurement tools were hardly used. Furthermore, the outcome measures used and the means of data collection of these outcomes were heterogeneous. Especially, measurement tools for transitional patient safety culture and for the referral process are lacking.

Chapter 4 describes the development and validation of a questionnaire to measure perception of healthcare professionals on transitional patient safety culture: the TRAnsitional patient safety Climate Evaluation (TRACE). Transitional patient safety

culture comprises the values, attitudes, competencies, and behavioural patterns of the organisations and individuals involved in the care transition, i.e, the way professionals working in these organisations think about and act towards each other. A constructive transitional patient safety culture is a precondition for safe transitional care. As safety culture is continuously developing, when measuring patient safety culture, we actually take a snapshot. This is called the "safety climate". We distributed the questionnaire among GPs and hospital physicians, but exploratory factor analysis did not provide factors that were shared between both groups. In hospital respondents, we identified four factors that were related to transitional patient safety management: collaboration, speaking up, communication on transitional incidents and improvement measures, and transitional patient safety management. The reliability of these four factors was good among hospital physicians' and acceptable among general practitioners. Therefore, we concluded that the clinimetric properties of the TRACE are appropriate for measuring transitional patient safety culture. Yet, the difference in factor loadings between the general practice and hospital setting indicated a different transitional patient safety culture in both settings.

Chapter 5 describes the development and validation of a questionnaire measuring the patients' experiences of transitional patient safety, the Transitional Risk and Incident Questionnaire (TRIQ). The TRIQ consisted of questions regarding risk factors (relational continuity with both the general practitioner and hospital physician), and of patient-experienced TSIs. To test the readability of the TRIQ, we first performed a think aloud procedure with patients receiving care from both general practitioner and hospital physician, and adjusted the questionnaire according to the results. A subsequent exploratory factor analysis of the answers of 451 respondents provided four factors relevant for TSIs from a patient perspective: 1) personal relation with general practitioner, 2) personal relation with hospital physician, 3) information exchange, and 4) treatment consistency. The internal consistency of the questionnaire was good (composite reliability 0.75-0.95). As expected, a TSI experience was related to poorer relational continuity both with the general practitioner and hospital, and with lower overall rating of all transitions. We concluded that the TRIQ is a valid and reliable questionnaire to measure transitional patient safety from the patients' perspective.

In **Chapter 6**, we investigated whether TSIs could actually be identified in the transitional medical record. For this, we interviewed thirteen patients who either had experienced a TSI or were at high risk for TSIs and requested consent to collect their individual medical records from general practice and hospital. We used the patient interview as a guideline to reconstruct the patient journey through the medical records and identified the TSIs in both the interviews and the medical records separately. In total, we identified 28 TSIs. The majority of the TSIs concerned unsafe situations, but almost one in five TSIs caused temporary harm. Three TSIs mentioned

by the patient could not be found in the medical record. Another five were difficult to find in the files and were probably identified because of the information from the patient interview. Seven TSIs were identified from the medical record, but not from the patient interview. Concordance between patient interview and medical record was 64%. These results led us to believe that TSIs can be adequately identified from patients' medical records, from both general practice and hospital. In these records, we need to look for mismatches, redundant information, written free text clues, and possible consequences such as harm.

Subsequently, we developed a medical record review method identifying TSIs in a purposely developed transitional medical record linking the medical records from general practice and hospital. In **Chapter 7**, we assessed the reliability and validity of the medical record review method. Six trained reviewers, all medical specialists in general practice, gastroenterology or cardiology, assessed 301 patient medical records from patients who visited cardiology and/or gastroenterology and their GPs. In 52 medical records TSIs were identified. Ten percent of the medical records were assessed by two reviewers. Variation between reviewers was high in number and type of TSI. Agreement between the reviewers was poor (0% positive agreement, 80% negative agreement, kappa -0.15). Compared to three types of objectively identifiable TSIs as assessed by research assistants, the reviewers missed almost 80%. We concluded that reliability of the clinician based transitional medical record review was low. The method needed adjustments, such as improving the transitional medical record database itself, developing a more robust and standardised TSI identification process, improving reviewers' training and manual, and selecting a more homogeneous group of reviewers.

In **Chapter 8** we aimed to determine the frequency of in-hospital patients' medication prescription changes that are not or incorrectly documented in the general practitioner's medical record, as this puts a patient at risk for adverse drug events. Therefore, we performed a medical record review study in the transitional medical record linking general practice and hospital data. In a random sample of 600 patients, we identified 408 in-hospital prescription changes in 390 patients. In one of three of these prescription changes, we could not find the prescription change documented in the GP's medical record within 3 months after the prescription change. Medications relatively more often not documented were beta-blockers, diuretics and laxatives. If changes were documented, the median number of days between hospital visit and documentation was 3 (IQR 0-18).

Chapter 9 is a detailed description of the study protocol of a controlled before-after study designed to measure the effect of the Transitional Incident Prevention Programme (TIPP). TIPP was designed as a multifaceted complex intervention aiming to improve transitional patient safety by preventing TSIs. The study was conducted in a rural and an urban region in the Netherlands, with three hospitals

and 62 general practices. The gastroenterology and cardiology departments of all three hospitals participated. The control group consisted of the non-participating departments (neurology and internal medicine) of all three hospitals, and the non-participating general practices in the urban region. The multifaceted intervention contained generic and context-specific components, aiming at three major aspects of transitional patient safety: 1) optimising the process of transitional care, 2) improving the transitional patient safety culture and 3) stimulating patient participation. The primary outcome of the comparison between the intervention and the control group, consisted of proxy endpoints for possible serious adverse events (death and readmission) and healthcare use. Secondary outcomes, that we assessed in the before- and after- comparison in the intervention group, were the number and nature of TSIs collected through a combination of methods (the medical record review, the TRIQ questionnaire and professional and patient reported incidents through incident reporting weeks), transitional patient safety culture using the TRACE, and costs. Furthermore, we qualitatively assessed the effect using a process and user evaluation.

In Chapter 10 we present the results of the TIPP intervention trial. All outcomes were measured before (October 2014 to April 2015) and after (February – August 2016) implementation of TIPP. Statistical analysis showed no improvement on the primary outcomes (death, readmission and healthcare use). In addition, TIPP did not affect the number of TSIs as measured by medical record review and incident reporting weeks. The fact that over 80% of medical records revealed at least one TSI does indicate problems in transitional patient safety.

We did find a positive effect of TIPP on patient experienced TSIs (a decrease from 38% to 31%) and a negative effect on the transitional patient safety culture, as measured by the TRACE questionnaire. Three TRACE dimensions, namely collaboration, communication on incidents and improvements, and transitional patient safety management, decreased significantly, probably indicating a response shift induced by a raised awareness. The process and user evaluation also suggested increased awareness. As awareness is the first step in behavioural change and subsequent improvement of transitional patient safety, we believe TIPP has the potential to spur improvement in transitional patient safety.

In Chapter 11 we discuss the main study results and give an overall reflection on the process of exploring, measuring, and improving transitional patient safety. As the results of the TIPP trial suggests, transitional patient safety can be improved, but it will take time.

TIPP did provide useful measurement tools to identify TSIs in the medical record, map patients' perceptions of transitional patient safety and to assess the transitional patient safety climate among professionals. All are needed to create a sense of urgency around transitional safety and to monitor improvement. During the development of these measurement tools, we met challenges such as

the definition of the constructs, methodological issues regarding validation, and time constraints limiting completeness of the validation process. Additionally, the implementation in our intervention study was suboptimal because of suboptimal leadership commitment, a high turnover of local champions, and a lack of quality improvement capacity.

In our studies, we learned that, from a safety perspective, primary and secondary care are two separate worlds. Each has its own goal and view on risk and patient safety, which often leads to misunderstanding. This is further aggravated by the fact that the medical record keeping is strictly separated. To improve transitional patient safety, the gap between the settings needs to be bridged. First, we need to create awareness, bring the stakeholders together to get to know each other and the other's working processes. Healthcare organisations need to connect IT systems. Improving and ensuring transitional patient safety is a shared responsibility, of both settings but also of the leading bodies, such as the government, healthcare insurers, and occupational organisations.

Finally, the patient is the central and only constant factor in care transitions. Patients could be engaged to participate in their own transitional patient safety, although the capacity and willingness to participate varies. The healthcare professional should identify the patients that are willing and able to, and involve them in ensuring their safety in healthcare.

12.2 SAMENVATTING

Veel patiënten worden behandeld door meerdere zorgverleners, zowel in de huisartspraktijk als in het ziekenhuis. Het bewegen van patiënten tussen deze settingen (oftewel 'transities'), zoals verwijzing, ontslag of bezoeken aan de Spoedeisende hulp of polikliniek, vereist een adequate informatieoverdracht. Wanneer deze overdracht niet goed worden uitgevoerd, is er kans op een transmuraal incident (TI). Een TI wordt gedefinieerd als "een onbedoelde gebeurtenis tijdens het transmurale zorgproces die tot schade aan de patiënt heeft geleid, had kunnen leiden of (nog) zou kunnen leiden" en kunnen geclassificeerd worden naar ernst in respectievelijk 'onveilige situaties' (omstandigheden of gebeurtenissen die het risico op fouten vergroten), 'near-misses' (een onbedoelde gebeurtenis die voor de patiënt geen nadelen oplevert omdat de gevolgen ervan op tijd zijn onderkend en gecorrigeerd) en 'adverse events' (een onbedoelde gebeurtenis resulterend in zorggerelateerde schade). Hoewel er veel bewijs is over de onveiligheid bij transities van patiënten en de oorzaken hiervan, is er weinig bewijs over het succes van verbeteringsstrategieën. Successen van interventies in de ene situatie lijken moeilijk te herhalen in andere settings en het gemeten effect op transmurale patiëntveiligheid in de verschillende onderzoeken is tegenstrijdig.

De meeste interventies voor de verbetering van transmurale patiëntveiligheid zijn gericht op het zorgproces rondom de transitie, oftewel het handelen van zorgprofessionals wanneer patiënten worden overgedragen. Voor een optimaal effect is echter ook een constructieve veiligheidscultuur nodig. Transmurale patiëntveiligheidscultuur wordt gedefinieerd als 'het geheel aan normen, waarden, opvattingen en omgangsvormen ten aanzien van transmurale patiëntveiligheid'. En naast de zorgverlener kan de patiënt, als centrale actor in transities, ook actief deelnemen aan de transmurale patiëntveiligheid door het zorgproces te monitoren.

Deze thesis is onderdeel van het Transmuraal Incident Preventie Programma (TIPP). Het doel van TIPP was om een strategie en een toolbox te ontwikkelen voor de verbetering van de transmurale patiëntveiligheid. Hiervoor hadden we eerst meer inzicht nodig in de huidige stand van zake in Nederland, en moesten we valide en betrouwbare meetinstrumenten ontwikkelen om de transmurale patiëntveiligheidscultuur en de percepties en ervaringen van patiënten en zorgverleners over de heersende transmurale patiëntveiligheid in kaart te brengen en het effect van interventies te meten.

Het eerste hoofdstuk van dit proefschrift geeft een overzicht van de aard van TI's (Hoofdstuk 2). In het volgende hoofdstuk beschrijven we een literatuuronderzoek om bestaande gevalideerde meetinstrumenten en uitkomsten die worden gebruikt om transmurale patiëntveiligheid te meten te identificeren en evalueren we waar meetinstrumenten misten (hoofdstuk 3). Vervolgens hebben we noodzakelijke meetinstrumenten ontwikkeld en gevalideerd. (hoofdstuk 4, 5, 6 en 7). In hoofdstuk 8 onderzoeken we inadequate communicatie over medicatievoorschriften tussen

de settings. Ten slotte rapporteren we de resultaten van de gecontroleerde TIPP-interventie studie waarin we het effect van de TIPP interventie meten (hoofdstuk 9 en 10).

Hoofdstuk 2 geeft een overzicht van de aard van TI's die zijn verzameld bij zowel patiënten als zorgverleners. Hiervoor gebruikten we incidentenrapportage, enquêtes, interviews en focusgroep discussies. De TI's werden geclassificeerd naar type, oorzaak en ernst. In totaal verzamelden we 548 TI's, 411 gerapporteerd door patiënten en 137 door zorgverleners. De meeste TI's betroffen de correspondentie van ziekenhuis naar de huisarts (26%), verwijzing (14%) en communicatie en samenwerking buiten de schriftelijke correspondentie (14%). Honderd-een-en-negentig TI's bevatten voldoende informatie om deze in te delen naar oorzaak. Hiervan had 48% een organisatorische en 43% een menselijke oorzaak. Qua ernst konden 149 TI's worden beoordeeld: 24% van de TI's betrof onveilige situaties, 45% near-misses en een derde adverse events. Er werden drie fatale TI's gemeld. Patiënten rapporteerden vaker TI's over inadequate verwijzing, dubbeling in diagnostische testen of onzekerheid over de hoofdbehandelaar. Zorgverleners rapporteerden vaker over medicatie-gerelateerde TI's. Dit verschil tussen meldingen van zorgverleners en van patiënten reflecteert hun verschil in perspectief op transmurale patiëntveiligheid. Het verbeteren van de informatieoverdracht is een mogelijke verbeterstrategie om de kloof tussen ziekenhuis en huisartspraktijk te overbruggen.

In **hoofdstuk 3** hebben we systematisch alle gevalideerde meetinstrumenten geïdentificeerd en beoordeeld, en alle uitkomsten die in de wetenschappelijke literatuur gebruikt worden voor het meten van transmurale patiëntveiligheid geïnventariseerd. We hebben PubMed, Cinahl, Embase en Psychinfo doorzocht, gebruik makend van een zoekstrategie gebaseerd op drie componenten: 1) transmurale zorg (inclusief synoniemen en gerelateerde termen), 2) meten en 3) patiëntveiligheid. Inclusiecriteria waren: alle kwantitatieve studies die 1) meetinstrumenten valideren op het gebied van transmurale patiëntveiligheid (validiteitsbeoordeling), en 2) uitkomsten gebruiken om transmurale patiëntveiligheid te meten, zowel cross-sectioneel als om het effect van een interventie te meten (uitkomst-inventarisatie). We identificeerden 17 studies voor de validiteitsbeoordeling en 191 studies voor de uitkomst-inventarisatie. De algehele kwaliteit van de gevalideerde meetinstrumenten was acceptabel; de validatie was echter meestal onvolledig, vooral wat betreft het meten van veranderingen in de tijd. Uit de uitkomst-inventarisatie bleek dat de geïdentificeerde gevalideerde meetinstrumenten nauwelijks werden gebruikt. Bovendien waren de gebruikte uitkomstmaten en de wijze van gegevensverzameling van deze uitkomsten heterogeen. Met name ontbraken meetinstrumenten voor de transmurale patiëntveiligheidscultuur en voor het verwijzingsproces.

Hoofdstuk 4 beschrijft de ontwikkeling en validatie van een vragenlijst voor het meten van de perceptie van zorgprofessionals op de transmurale patiëntveiligheidscultuur: de TRAnsitional patiënt safety Climate Evaluation (TRACE). Transmurale patiëntveiligheidscultuur wordt gedefinieerd als 'het geheel aan normen, waarden, opvattingen en omgangsvormen ten aanzien van transmurale patiëntveiligheid' d.w.z. de manier waarop zorgverleners omgaan met de patiëntveiligheid als patiënten naar de andere setting toe gaan. Een constructieve patiëntveiligheidscultuur is een voorwaarde voor veilige transmurale zorg. Omdat de veiligheidscultuur voortdurend in ontwikkeling is, maken we bij het meten van de veiligheidscultuur een momentopname. Dit wordt het "patiëntveiligheidsklimaat" genoemd. Voor de validatie hebben we de vragenlijst verspreid onder huisartsen en ziekenhuisartsen. Verkennende factoranalyse leverde geen duidelijke factoren op voor deze gecombineerde groep. Factoranalyse bij de ziekenhuisartsen identificeerde vier factoren die verband hielden met transmurale patiëntveiligheid: samenwerking, veiligheid voor feedback, communicatie over transmurale incidenten en verbetermaatregelen en transmurale patiëntveiligheidsmanagement. De betrouwbaarheid van deze vier factoren was goed onder de ziekenhuisartsen en acceptabel onder de huisartsen. Hieruit concludeerden we dat de klinimetrische eigenschappen van de TRACE geschikt zijn voor het meten van transmurale patiëntveiligheidscultuur, alhoewel het verschil in de factor-verdeling tussen de huisartsenpraktijk en het ziekenhuis duidt op een verschillen in transmurale patiëntveiligheidscultuur tussen beide settings.

Hoofdstuk 5 beschrijft de ontwikkeling en validatie van een vragenlijst voor het meten van patiënten ervaringen met transmurale patiëntveiligheid, de Transitional Risk and Incident Questionnaire (TRIQ). De TRIQ bestond uit vragen naar relationele continuïteit met zowel de huisarts als ziekenhuisarts, en naar patiënt-ervaren TI's. Om de leesbaarheid van de TRIQ te testen, hebben we eerst een 'think aloud' procedure uitgevoerd met patiënten die zowel bij de huisarts als in het ziekenhuis werden behandeld en de vragenlijst aangepast aan de hand van hun opmerkingen. Een verkennende factoranalyse met 451 ingevulde patiënten vragenlijsten leverde vervolgens vier factoren van transmurale patiëntveiligheid op: 1) persoonlijke relatie met de huisarts, 2) persoonlijke relatie met ziekenhuisarts, 3) informatie-uitwisseling en 4) consistentie van de behandeling. De interne consistentie van de vragenlijst was goed (composite reliability 0,75-0,95). Zoals verwacht, was het meegemaakt hebben van een TI gerelateerd aan een slechtere relationele continuïteit, zowel met de huisarts als in het ziekenhuis, en met een lagere algehele beoordeling van alle soorten transities. We concludeerden dat de TRIQ een valide en betrouwbare vragenlijst is om het patiëntperspectief op transmurale patiëntveiligheid te meten.

In **hoofdstuk 6** onderzochten we of TI's geïdentificeerd kunnen worden in het medische dossier. Hiervoor interviewden we dertien patiënten die ofwel een TI hadden meegemaakt of een hoog risico liepen op een TI. Ook vroegen we hun

toestemming om hun medisch dossier op te vragen uit zowel de huisartsenpraktijk als het ziekenhuis. We gebruikten het patiënten interview als richtlijn om het zorgpad van de patiënt te reconstrueren en legden de medisch dossiers hiernaast. We identificeerden alle TI's in zowel de interviews als de medisch dossiers. In totaal identificeerden we 28 TI's waarvan de meerderheid onveilige situaties betroffen. Bijna een op de vijf TI's veroorzaakte (tijdelijke) schade. Drie TI's die door de patiënt genoemd werden konden niet worden gevonden in het medisch dossier. Nog eens vijf TI's waren moeilijk te vinden in het dossier en werden waarschijnlijk geïdentificeerd vanwege de informatie uit het patiënten interview. Zeven TI's werden geïdentificeerd uit het medisch dossier, maar niet genoemd in het patiënten interview. De overeenstemming tussen de patiënten interviews en medisch dossiers was 64%. Hieruit concludeerden we dat TI's voldoende adequaat geïdentificeerd kunnen worden in het medisch dossier van de huisartsenpraktijk en het ziekenhuis gezamenlijk. Voor de identificatie moet in de dossiers gezocht worden naar mismatches, dubbele informatie, aanwijzingen in de vrije tekst en mogelijke gevolgen zoals schade.

Vervolgens hebben we een systematische methode ontwikkeld voor het identificeren van TIs in medisch dossiers in een speciaal voor dit onderzoek ontwikkeld transmuraal dossier dat de medisch dossiers van de huisarts en het ziekenhuis met elkaar verbindt.

In **Hoofdstuk 7** beoordelen we de betrouwbaarheid en de validiteit van deze beoordelingsmethode. Zes getrainde beoordelaars, allen geneeskundig specialisten – huisartsen, maag-darm-lever(MDL)-artsen en cardiologen- beoordeelden 301 medisch patiëntendossiers van patiënten die hun huisartsen en de cardiologie en/of MDL bezochten. In 52 medische dossiers werden TI's geïdentificeerd. De variatie tussen beoordelaars was hoog in aantal en type. Tien procent van de medische dossiers werd beoordeeld door twee beoordelaars. De overeenstemming tussen de beoordelaars was slecht (0% positieve overeenstemming, 80% negatieve overeenstemming, kappa -0,15). Vergeleken met drie objectief identificeerbare TI's, misten de beoordelaars bijna 80%. We concludeerden dat de betrouwbaarheid van deze beoordelingsmethode door artsen laag was en dat de methode moest worden aangepast, onder andere door het completer maken van de transmurale database, het ontwikkelen van een robuuster en meer gestandaardiseerd TI-identificatieproces, het verbeteren van de training en de handleiding en het selecteren van een meer homogene groep beoordelaars.

In **Hoofdstuk 8** hebben we de frequentie bepaald van afwezige of onjuiste documentatie in het medisch dossier van de huisarts van in het ziekenhuis veranderde medicatie voorschriften. Door onjuiste of afwezige communicatie en documentatie loopt de patiënt risico op een adverse drug event oftewel een medicatie-gerelateerd adverse event. Dit onderzoek werd uitgevoerd in het speciaal voor TIPP ontwikkelde transmuraal dossier welke de medisch dossiers van de huisarts en het ziekenhuis

met elkaar verbindt. In een aselecte steekproef van 600 patiënten identificeerden we 408 medicatie veranderingen gedaan in het ziekenhuis in 390 patiënten. Bij een van de drie van deze medicatiewijzigingen konden we deze wijziging niet binnen drie maanden terugvinden in het medisch dossier van de huisarts. Medicijnen die relatief vaak niet werden gedocumenteerd waren bètablokkers, diuretica en laxeermiddelen. Wanneer de medicatiewijzigingen wel werden gedocumenteerd in het huisartsendossier, gebeurde dit binnen 3 dagen van het ziekenhuisbezoek.

Hoofdstuk 9 is een gedetailleerde beschrijving van het onderzoeksprotocol van een gecontroleerde voor-na-studie naar het effect van het Transmuraal Incident Preventie Programma (TIPP). TIPP is ontworpen als een multi-component, complexe interventie gericht op het verbeteren van de transmurale patiëntveiligheid door het voorkomen van TIs. Het onderzoek werd uitgevoerd in een landelijke en een stedelijke regio in Nederland, met drie ziekenhuizen en 62 huisartspraktijken. De afdelingen maag-darm-leverziekten en cardiologie van de drie ziekenhuizen namen deel. De controlegroep bestond uit niet-deelnemende afdelingen (neurologie en interne geneeskunde) van alle drie de ziekenhuizen en de niet-deelnemende huisartspraktijken in de stedelijke regio. De TIPP-interventie bevatte generieke en context-specifieke componenten gericht op drie belangrijke onderdelen van transmurale patiëntveiligheid: 1) optimalisatie van de transmurale zorgoverdracht 2) verbetering van de transmurale patiëntveiligheidscultuur en 3) stimulering van patiëntenparticipatie. De primaire uitkomsten van de vergelijking tussen de interventie en de controlegroep bestond uit mogelijke ernstige schade (overlijden en heropname) en hoeveelheid zorgconsumptie. Secundaire uitkomsten, die we in de voor-na-vergelijking in de interventiegroep hebben beoordeeld, waren: het aantal en de aard van TI's verzameld via een combinatie van methoden (de medische dossierbeoordeling, de TRIQ-vragenlijst en in incidentmeldweken gerapporteerde incidenten door patiënten en zorgverleners), de transmurale patiëntveiligheidscultuur gemeten met de TRACE-vragenlijst en kosten. Daarnaast voerden we een proces- en gebruikersevaluatie uit met kwalitatieve methoden.

In **hoofdstuk 10** presenteren we de resultaten van de TIPP-interventiestudie. Alle uitkomsten werden gemeten vóór (oktober 2014 tot april 2015) en na (februari - augustus 2016) implementatie van TIPP. Statistische analyse liet geen verbetering zien van de primaire uitkomsten (overlijden, heropname en zorgconsumptie). Bovendien had TIPP geen invloed op het aantal TI's gemeten in de medisch dossiers en gerapporteerd in incidentmeldweken. Het feit dat meer dan 80% van de medische dossiers ten minste één TI bevatte, wijst op problemen in de transmurale patiëntveiligheid. We vonden wel een positief effect van TIPP op door de patiënt ervaren TI's (een afname van 38% naar 31%) en een negatief effect op de perceptie van zorgverleners op de transmurale patiëntveiligheidscultuur, gemeten met TRACE-vragenlijst. Drie TRACE-dimensies, namelijk samenwerking, communicatie over transmurale incidenten en verbetermaatregelen en transmurale patiëntveiligheidsmanagement,

namen significant af, wat waarschijnlijk wijst op een response-shift veroorzaakt door een toegenomen bewustzijn. Deze toename van het bewustzijn in zorgverleners werd ook gevonden in de proces- en gebruikersevaluatie. Aangezien bewustzijn de eerste stap is in gedragsverandering en de daaropvolgende verbetering van de transmurale patiëntveiligheid denken we dat TIPP verbeteringen in de transmurale patiëntveiligheid teweeg kan brengen.

In **Hoofdstuk 11** bespreken we de belangrijkste studieresultaten en geven we een algemene reflectie op het proces van evalueren, meten en verbeteren van de transmurale patiëntveiligheid. Zoals de resultaten van de TIPP-studie suggereren, kan de transmurale patiëntveiligheid worden verbeterd, hoewel dit tijd zal vergen.

TIPP levert meetinstrumenten om TI's in het medisch dosier te identificeren, de ervaringen van patiënten in de transmurale patiëntveiligheid en de perceptie van zorgverleners op de transmurale patiëntveiligheidscultuur in kaart te brengen. Deze meetinstrumenten zijn nodig om een 'sense of urgency' rond transmurale patiëntveiligheid te creëren en om verbetering te meten. Tijdens de ontwikkeling van deze meetinstrumenten kwamen we meerdere uitdagingen tegen, zoals het definiëren van de nieuwe constructen, methodologische problemen en een krap tijdspad, die de volledigheid van het validatieproces beperkten. Bovendien was de implementatie in onze interventiestudie suboptimaal vanwege onvoldoende consistente betrokkenheid van leiderschap, teveel (natuurlijk) verloop van onze 'champions', en gebrek aan capaciteit voor kwaliteitsverbetering.

Tijdens deze studie hebben we geleerd en ondervonden hoezeer de eerste en tweede lijn, vanuit het oogpunt van transmurale patiëntveiligheid, twee gescheiden werelden zijn. Elke lijn heeft zijn eigen functie en visie op risico en patiëntveiligheid, wat tot misverstanden kan leiden. Dit wordt nog verergerd door het feit dat het medisch dossier strikt gescheiden is. Om de transmurale patiëntveiligheid te verbeteren, moet de kloof tussen de instellingen worden overbrugd. Ten eerste moeten we bewustzijn creëren en de zorgverleners bij elkaar brengen om elkaar en elkaars werkprocessen te leren kennen. Zorginstellingen moeten IT-systemen met elkaar verbinden. Het verbeteren en waarborgen van transmurale patiëntveiligheid is een gedeelde verantwoordelijkheid, zowel van instellingen, als ook van bestuurlijke instanties, zoals de overheid, zorgverzekeraars en beroepsorganisaties. Ten slotte is de patiënt de centrale en enige constante factor in zorgtransities. Patiënten kunnen betrokken worden bij hun eigen transmurale patiëntveiligheid, hoewel bij hen de capaciteit en de bereidheid om deel te nemen varieert. Daarom moet de zorgverlener patiënten identificeren die bereid en in staat zijn om een actieve rol te spelen en hen betrekken bij het waarborgen van hun transmurale patiëntveiligheid.

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12.4 LIST OF PUBLICATIONS

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12.5 ABOUT THE AUTHOR

Marije van Melle was born on the 24th of September 1976 in Amersfoort. After senior school at the Erasmus College in Zoetermeer, she studied Medicine at the University of Utrecht. After graduating in 2006, she worked as a resident doctor, mainly in Cardiology. In 2010 she started a master "Evidence based practice" at the University of Amsterdam (Amsterdam Medical Center), in which she obtained her degree and title of Clinical Epidemiologist in 2013. In 2012 she started working as a research physician at the Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht University. In 2013, she seized the opportunity to start a PhD project on transitional patient safety at the same center, under supervision of Prof. N.J. de Wit, Dr. D.L.M Zwart, and Dr. H.F. van Stel, which has resulted in the studies presented in this thesis. Currently, she works as a research associate at the University of Cambridge, Department of Public Health and Primary Care, where she conducts research on early diagnostics of cancer in primary care at the CanTest collaborative.