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Drug administration errors in an institution for individuals with intellectual disability: an observational study

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Abstract

Background Medication errors can result in harm, unless barriers to prevent them are present. Drug administration errors are less likely to be prevented, because they occur in the last stage of the drug distribution process. This is especially the case in non-alert patients, as patients often form the final barrier to prevention of errors. Therefore, a study was set up aimed at identifying the frequency of drug administration errors and determinants for these errors in an institution for individuals with intellectual disability (ID).

Methods This observational study ('disguised observation') was conducted within an institution in the Netherlands caring for 2500 individuals with ID and lasted from October to December 2004 with a case control design for identifying determinants for errors. The institution consists of both day care units and living units (providing full-time care), located in different towns. For the study, five units from different towns were selected. Within each study unit, the administration of drugs to patients was observed for 2 weeks. In total, 953 drug administrations to 46 patients (25 male, mean age 25.8 years, range 2–73 years) were observed.

Results With inclusion of wrong time errors, 242 administrations with at least one error were observed [frequency = 242/953 (25.4%)] and with exclusion 213 administrations with at least one error were observed [frequency = 213/953 (22.4%)]. Determinants associated with errors were routes of administration 'oral by feeding tube' (OR 189.66; 95% CI 46.16–779.24) and 'inhalation' (OR 9.98; 95% CI 4.78–20.80), the units 'adult full-time care' (OR 2.12; 95% CI 1.05–4.35) and 'children daytime care' (OR 10.80; 95% CI 4.43–26.29) and the absence of a distribution robot (OR 4.0; 95% CI 2.67–5.95). None of the identified errors were reported to the voluntary reporting system.

Conclusion This study shows that administration errors in an institution for individuals with ID are common and that they are not formally reported to the voluntary reporting system. Furthermore, it identified some determinants that may be the focus for future improvements aimed to reduce error frequency.

Keywords drug administration errors, intellectual disability introduction, medication safety

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Introduction

Besides beneficial effects, drugs can cause harm to patients. This harm consists of adverse drug reactions, also referred to as intrinsic harm (caused by the pharmacological properties of the drug), and medication errors. Medication errors may or may not lead to patient harm, but when it does it can be referred to as extrinsic harm [harm caused by (erroneous) handling of the drug, not by the drug itself] (Van den Bemt *et al.* 2000). Both adverse drug reactions and medication errors can be summarized as drug-related problems.

In recent years, the interest in drug-related problems has increased, which was greatly stimulated by the report 'To err is human' of the Institute of Medicine (Kohn *et al.* 1999). This report focuses on medical errors, with special attention to medication errors. Medication errors may occur throughout the entire drug distribution system, from prescribing to administration of drugs (Van den Bemt *et al.* 2000). The administration of drugs is a very critical step because the possibilities of correcting errors at this stage are limited (Wright & Katz 2005). Therefore, administration errors may result in direct harm to the patient. Patients who are alert often form the last barrier to administration errors, which puts non-alert patients (e.g. mentally disabled or sedated patients) at increased risk.

In hospitalized patients, several studies on administration errors have been performed, for example, in specific wards like the intensive care unit (Tissot *et al.* 1999; Van den Bemt *et al.* 2002; Rothschild *et al.* 2005) or in paediatrics (Wilson *et al.* 1998; Ross *et al.* 2000) and in hospitals in general (Greengold *et al.* 2003). However, studies on administration errors in institutions for individuals with intellectual disability (ID) have rarely been published. The only study performed (Stupalski & Russell 1999) does not use the disguised observation technique, which is the recommended method for studying administration errors (Allan & Barker 1990; Dean & Barber 2001). Furthermore, no studies have been published on the determinants of administration errors in institutions for individuals with ID. Therefore, we conducted a disguised observation study to identify the frequency of administration errors as well as the determinants for these errors in such an institution.

Methods

Setting and study population

The study was conducted within a large institution in the western part of the Netherlands caring for a total of almost 2500 individuals with ID. The group consists of both day care units and living units (providing full-time care), located in different towns and villages. For the study, five units from five different towns/villages were selected. The selection process was carried out with the purpose of obtaining a representative subset of units, looking at the factors type of unit (daytime or living, adults or children) and type of medication distribution system (use of distribution robot or not, documentation of administration on cardex or not, distribution by pharmacist, by parents or by general practitioner). Furthermore, to be included in the study, a sufficient amount of medication had to be used by the clients of the unit. In this way, five units were selected, of which the characteristics are depicted in Table 1. In all units, medication is sometimes administered by qualified nurses, but the majority of medications are administered by caretakers, who have in general less specific training in handling of drugs than nurses do.

Finally, in all units, a voluntary reporting system for medication errors exists.

For each unit, a 2-week study period was used, in which a week was defined as Monday through Friday from 06.30 u to 19.00 u. The study was performed from October to December 2004.

Study design

The study was a prospective, observational study of administration errors. An administration error was defined as any error in the preparation and administration of drugs by caretakers, i.e. a deviation from written, printed or verbal medication orders (used by the caretakers to administer drugs), a deviation from the drug information sheets provided by the manufacturer and/or a deviation from general medication procedures used in the units. Administration errors were detected by using the disguised observation technique (Allan & Barker 1990). Caretakers were unaware of the goal of the study (they were told that the observer came to study the drug distribution system). One observer followed the caretakers preparing and administering drugs. This observer had a bache-

Table 1 Characteristics of the five studied units

1	2	3	4	5
Children	Adults	Adults	Adults	Children
Daytime care	Full-time care	Daytime care	Full-time care	Full-time care for specific periods*
Caretakers pick medication	Distribution robot†	Distribution robot†	Caretakers pick medication and put medication in week-boxes‡	Caretakers pick medication
Medication from parents (home)	Medication from pharmacy	Medication from pharmacy (via unit where patients stay the night)	Medication from general practitioner	Medication from parents (home)
No documentation of administration on cardex	Documentation of administration on cardex	No documentation of administration on cardex	Documentation of administration on cardex	Documentation of administration on cardex
Clients have severe ID (IQ 20–34)	Clients have severe ID (IQ 20–34)	Clients have severe ID (IQ 20–34)	Clients have moderate ID (IQ 35–49)	Clients with moderate to severe ID (IQ 20–49)

* Children spend a specific amount of time (e.g. a weekend) in this unit on a full-time basis and then return home.

† In these units, the same distribution robot is used.

‡ Week-boxes are boxes which divide the medication into days of the week and time of day, thus facilitating the correct administration.

ID, intellectual disability.

lor degree in pharmacy. In order to become familiar with the technique of disguised observation, there was a 1-week training period in a unit not participating in the study. For ethical reasons, when the observer expected an administration error to have serious consequences for the patient, he would intervene before the error reached the patient.

All observations (client and drug name, dose, time, etc.) were noted on a data collection form designed especially for the study. Afterwards, the observations were compared with the written or printed medication orders. Observations were also compared with the drug information sheet in order to detect errors in the relationship of administration with meals and in the preparation of drugs. Finally, for errors concerning the administration of drugs through enteral feeding tubes, a reference guide used in the Tilburg hospitals was used to determine whether an error had occurred (consisting of general rules with respect to the administration of drugs through an enteral feeding tube and of a list of drugs that should not be crushed), because general medication protocols on this subject were either lacking in the units or contained insufficient information. Furthermore, the Tilburg reference guide is in accordance with other nationally used guidelines on the administration of medication through enteral feeding tubes.

Errors were classified into eight categories (Table 2) (Allan & Barker 1990). A wrong time error was defined as the administration of a drug at least 60 min earlier or later than prescribed.

In addition, administration errors were classified into nine classes of seriousness derived from the National Coordinating Council for Medication Error Reporting and Prevention taxonomy of medication errors: A – an error has been made but the medication does not reach the client; B – an error has been made and the medication reaches the client, but no harm is done (B1 – medication not administered; B2 – medication administered but no harm); C – an error has been made which results in an increased frequency of monitoring, but no harm is done; D – an error has been made and harm is done [D1 – temporary damage necessitating treatment; D2 – temporary damage resulting in an increased length of hospital stay (or, for this study, in hospitalization of the client); D3 – permanent damage; D4 – client

Table 2 Categories of errors

Category	Definition
Omission error	Drug prescribed, but not administered
Unordered drug error	Drug administered, but not prescribed
Wrong dose preparation error	Drug prepared in wrong way
Wrong dose form error	Drug given in wrong dosage form
Wrong route error	Drug given by wrong route of administration
Wrong administration technique error	Drug administered using a wrong technique (all enteral feeding tube errors are classified this way)
Wrong dose error	Dosage too high or low
Wrong time error	Drug given at least 60 min early or late

nearly dies]; E – an error has been made which results in the death of the client (Van den Bemt *et al.* 2002).

The error severity was classified independently by two hospital pharmacists (PvdB and EvR). For those errors that were classified in different classes of severity, the two pharmacists came together to reach consensus.

All drugs were classified according to the Anatomical Therapeutic Chemical (ATC) code (Anonymous 2003).

During the study period, all reports of drug administration errors were also collected.

The study is in accordance with the principles in the Declaration of Helsinki. Because the study was entirely observational (noninterventional) and all data were collected anonymously, informed consent and ethical approval were not necessary.

Data analysis

The observation period of 2 weeks per unit (i.e. in total 10 weeks) was primarily chosen in order to have the possibility to study enough opportunities for medication administration. Assuming an average error frequency of 5%, $\alpha = 0.05$ and power of 80%, a sample size of 263 medication administrations was calculated (about 60 per unit). Therefore, to be on the safe side, an observation period of 2 weeks was chosen.

The following variables were registered and entered into a database (MS Access 2000): patient age and gender, unit, drug (name and dosage form) and ATC code, day and time of administration, route of administration, number of drugs and number of dosages administered to a client that day, whether an error has been made or not, error category and error seriousness category, number of years of experience of caretaker and medication supplied by distribution robot or not (even in units with a distribution system using a robot, not all drugs can be supplied by the robot, e.g. liquid dosage forms).

These data were analysed using the Statistical Package for Social Sciences (SPSS) version 10.0.

The frequency of errors (fE) was calculated by dividing the number of administrations with one or more errors (nE) by the sum of the number of observed drug administrations (whether ordered or not) (nA) and the number of drugs observed to be omitted (nO). Thus:

$$fE = nE/(nA + nO)$$

The error frequency was reported as a percentage ($fE \times 100\%$). As wrong time errors are generally considered less serious than other errors (Allan & Barker 1990), the overall results are reported both including and excluding these errors.

The association between potential determinants (patient age and gender, drug class, administration route, number of drugs and number of dosages per client, day and time of administration, unit, distribution robot or not and experience of caretaker) and the occurrence of errors (both including and excluding wrong time errors) was studied using univariate logistic regression analysis. In this way, for each determinant an odds ratio was calculated together with a 95% CI.

Results

In total, 953 drug administrations to 46 clients (25 male, mean age 25.8 years, range 2–73 years) were observed. When wrong time errors were included, 242 administrations with at least one error were observed [frequency = 242/953 (25.4%)] and when they were excluded, 213 administrations with at least one error were observed [frequency = 213/953 (22.4%)].

During the study period, no drug administration errors were reported in the units.

The error frequencies per unit and the demographic variables of the patient per unit can be found in Table 3.

As each administration could involve multiple errors, 263 errors were observed when wrong time errors were included and 234 when they were excluded. Table 4 shows the errors for the five units, divided into categories and into classes of seriousness, with examples for each category and class. In total, administration technique errors were the most frequently occurring category, followed by omission errors and wrong dose errors. The errors were in general of intermediate seriousness.

The association between the occurrence of administration errors and several determinants is shown in Table 5, both for all errors and for all errors excluding wrong time errors.

When looking at all errors, the determinants male gender (OR 1.64; 95% CI 1.23–2.19), ATC drug classes hormones (OR 13.82; 95% CI 5.63–33.93) and respiratory drugs (OR 6.43; 95% CI 3.33–12.41), routes of administration 'oral by feeding tube' (OR 189.66; 95% CI 46.16–779.24) and 'inhalation' (OR 9.98; 95% CI 4.78–20.80), the units 2 (OR 2.12; 95% CI 1.05–4.35) and 1 (OR 10.80; 95% CI 4.43–26.29) and the absence of a distribution robot (OR 4.0; 95% CI 2.67–5.95) are associated with a higher risk of administration errors. On the other hand, the use of drug class 'central nervous system' (OR 0.47; 95% CI 0.34–0.67) and the time class '2 PM to 6 PM' (OR 0.48; 95% CI 0.34–0.68) are associated with a lower risk of administration errors. For all errors excluding time errors, these results remained essentially the same (see Table 5).

Discussion

This is a study within an institution for individuals with ID that uses the disguised observation technique for the assessment of drug administration errors and that also looks into determinants for administration errors. To our knowledge, only one previous study is published that looks into administration errors within an institution for individuals with ID. This study by Stupalski and Russell uses information from medication error reports and then finds an error rate of 0.1% of medication doses administered (Stupalski & Russell 1999). We find much higher error rates (25% when including wrong time errors and 22% when excluding these errors). This is known from another study that compares different methods for detecting medication errors and that also concludes that the observation method yields the most reliable results (Flynn *et al.* 2002). The seriousness class of the errors was intermediate, which means that they were judged

Table 3 Demographic variables and error frequency per unit

	1	2	3	4	5
Mean age (years) (median; range)	7.0 (5; 2–15)	48.9 (49; 35–73)	33.2 (28; 24–51)	52.3 (57; 32–70)	9.7 (9.5; 4–14)
Gender (% male)	84.9	35.4	49.2	61.2	51.8
Number of medication administrations observed	53	390	61	242	228
Error frequency including wrong time errors (%)	63.8	27.8	16.4	21.5	20.5
Error frequency excluding wrong time errors (%)	63.8	24.5	16.4	17.8	16.5

Table 4 Administration errors for the five units, divided into categories and into classes of seriousness

	1 *n* (%)	2 *n* (%)	3 *n* (%)	4 *n* (%)	5 *n* (%)	Total *n* (%)
Categories						
Omission	–	29 (25.2)	–	2 (3.8)	9 (18.0)	40 (15.2)*
Unordered drug	–	4 (3.5)	–	13 (25.0)	1 (2.0)	18 (6.8)†
Wrong dose preparation	–	–	–	–	6 (12.0)	6 (2.3)‡
Wrong dose form	–	–	–	–	–	–
Wrong route	–	–	–	–	–	–
Wrong administration technique	32 (88.9)	52 (45.2)	10 (100)	25 (48.1)	14 (28.0)	133 (50.6)§
Wrong dose	4 (11.1)	19 (16.5)	–	3 (5.8)	11 (22.0)	37 (14.1)¶
Wrong time	–	11 (9.6)	–	9 (17.3)	9 (18.0)	29 (11.0)**
Total	36 (100)	115 (100)	10 (100)	52 (100)	50 (100)	263 (100)
Seriousness						
B2	4 (11.1)	51 (44.3)	– (0.0)	33 (63.5)	30 (60.0)	118 (44.9)††
C	32 (88.9)	64 (55.7)	10 (100.0)	19 (36.5)	20 (40.0)	145 (55.1)‡‡

* For example, lactulose omitted.

† For example, fusidinic acid eyegel administered which was terminated already 2 days before.

‡ For example, two drugs for inhalation mixed together the day before administration.

§ For example, budesonide tablets given with meal in stead of before meal; 82 of the errors in this category consisted of enteral feeding tube errors (For example, drug administered through enteral feeding tube without stopping the enteral feeding).

¶ For example, 15 mL of lactulose in stead of 30 mL.

** For example, diazepam tablet more than 1 h late.

†† For example, wrong time error for metoclopramide.

‡‡ For example, administration of levothyroxine after meal in stead of before.

by the raters as unlikely to have caused damage to the patients. However, we did not look into adverse events in the patients, which is a limitation of this study. On the other hand, even non-serious errors may be indicators of failures in the drug distribution system that potentially lead to more serious errors. They thus deserve the same attention as serious errors, because the lessons that can be learned from them seem the same as for serious errors.

None of the observed administration errors were formally reported to the voluntary reporting system. This reflects the substantial amount of underreporting characteristic for such systems. Reasons for this underreporting may be the failure to see the benefits of reporting and the lack of knowledge on good practices for drug administration (so the caretakers do not even know they are making mistakes). A better feedback on reports and education may improve the reporting rates.

Within institutions for individuals with ID, no previous studies looking into determinants of administration errors have been published. In fact, in general, very few studies look into this aspect of errors. One of the few studies that assessed determinants for administration errors was carried out in the intensive care unit (Van den Bemt *et al.* 2002). As in this study, our present study shows that administration of drugs through enteral feeding tubes is a determinant for administration errors. As many clients in unit 1 received tube feeding, this may account for the high percentage of administration errors within unit 1.

Clear protocols, teaching sessions and advice given by the pharmacist may help prevent this type of errors. The same may be true for respiratory drugs. These drugs are often administered using inhalers that require special techniques, which may explain why they are associated with a high risk of administration errors in our study. As these errors may have skewed the data, repeating the analysis with exclusion of these errors would give the results for the less obvious errors. However, we were interested in identifying all errors (both occurring frequent and less frequent) and therefore we limited the data analysis to the entire data set.

Table 5 Association of administration errors (both with and without wrong time errors) with determinants (statistically significant associations in bold)

	With wrong time errors OR (95% CI)	**Without wrong time errors OR (95% CI)**
Patient characteristics		
Age category (years)		
1–15	Ref.	Ref.
16–70	0.77 (0.57–1.05)	0.76 (0.55–1.05)
>70	0.85 (0.45–1.62)	0.82 (0.42–1.62)
Gender		
Female	Ref.	Ref.
Male	**1.64 (1.23–2.19)**	**1.62 (1.20–2.18)**
Drug characteristics		
ATC drug class*		
Gastro-intestinal	Ref.	Ref.
Cardiovascular	0.79 (0.33–1.92)	0.91 (0.37–2.22)
Gynaecological	0.43 (0.14–1.28)	0.37 (0.11–1.28)
Hormones	**13.82 (5.63–33.93)**	**15.94 (6.46–39.28)**
Musculo-skeletal	1.02 (0.38–2.72)	1.17 (0.44–3.15)
Central nervous system	**0.47 (0.34–0.67)**	**0.52 (0.36–0.74)**
Respiratory	**6.43 (3.33–12.41)**	**5.27 (2.63–10.54)**
Route of administration*		
Oral	Ref.	Ref.
Oral by feeding tube	**189.66 (46.16–779.24)**	**221.43 (53.81–911.18)**
Inhalation	**9.98 (4.78–20.80)**	**8.74 (4.03–18.93)**
Nasal	2.29 (0.21–25.38)	–*
Number of drugs/day/client		
0–4	Ref.	Ref.
5–10	0.89 (0.67–1.19)	0.91 (0.68–1.23)
Number of dosages/day/client		
0–4	Ref.	Ref.
5–10	1.22 (0.82–1.82)	1.07 (0.72–1.61)
>10	0.66 (0.43–1.01)	**0.61 (0.39–0.94)**
Drug distribution system characteristics		
Unit		
3	Ref.	Ref.
2	**2.13 (1.05–4.35)**	1.93 (0.94–3.94)
1	**10.80 (4.43–26.29)**	**10.80 (4.43–26.29)**
4	1.40 (0.66–2.94)	1.15 (0.54–2.45)
5	1.43 (0.68–3.02)	1.18 (0.55–2.52)
Distribution robot†		
Yes	Ref.	Ref.
No	**4.0 (2.67–5.95)**	**3.63 (2.41–5.45)**
Time characteristics		
Time class		
7 AM to 10 AM	Ref.	Ref.
10 AM to 2 PM	1.33 (0.86–2.07)	1.46 (0.94–2.27)
2 PM to 6 PM	**0.48 (0.34–0.68)**	**0.39 (0.27–0.58)**
6 PM to 7 PM	0.31 (0.09–1.04)	**0.22 (0.05–0.96)**

Table 5 *Continued*

	With wrong time errors OR (95% CI)	Without wrong time errors OR (95% CI)
Day		
Monday	Ref.	Ref.
Tuesday	1.11 (0.69–1.78)	1.19 (0.73–1.94)
Wednesday	1.18 (0.75–1.88)	1.14 (0.70–1.86)
Thursday	0.85 (0.53–1.37)	0.89 (0.54–1.46)
Friday	1.07 (0.67–1.71)	1.05 (0.64–1.71)
Caretaker characteristics		
Experience (years)		
0–2	Ref.	Ref.
3–5	0.92 (0.62–1.37)	0.99 (0.66–1.49)
>5	0.96 (0.67–1.36)	0.95 (0.65–1.37)

* Classes with one or more empty cells are not shown (e.g. drug class ocular: only three administrations that all contained one or more errors).
† Medication supplied by distribution robot or not.
Ref., reference category; ATC, Anatomical Therapeutic Chemical.

Using a distribution robot appears to result in a lower incidence of administration errors, which gives another opportunity of reducing errors in institutions for individuals with ID. Both unit 3 and unit 2 used a distribution robot, but nevertheless the rate of errors was higher in unit 2 (at least when including wrong time errors). This may be caused by the fact that in this unit a relative large proportion of the medication was in liquid dosage forms and thus not distributed by the robot. As caretakers become used to the robot system, they may also make more mistakes with drugs not dispensed by that system. Therefore, a further recommendation is to give proper attention to drugs that can not be dispensed by the robot. Finally, dispensing drugs with a distribution robot has no influence on wrong time errors and these seem to explain at least part of the higher error frequency in unit 2, compared with unit 3.

The number of drugs/day/client and the number of dosages/day/client showed no statistically significant association with medication errors. One could expect the workload (and thus the error rate) to increase when these numbers rise. Yet, there seems to be a trend for a lower risk of errors when the number of drugs or dosages increases. One article describes that errors are also more likely to occur when workload is too low, which may explain this trend (Leape 1994). Another explanation is that these determinants are not good measures of workload.

Another surprising finding is the lack of association between experience of caretaker and the risk of errors. As caretakers in these units lack formal education on drugs and their administration, they mainly learn by doing (except for one general course that is offered to inexperienced caretakers). Learning by doing would mean that adding more years of experience would create a higher degree of training. Thus, it was hypothesized that more years of experience would lead to a decreasing risk of errors.

The other determinants that we studied give no clear clues to prevention of errors. For example, the high risk of errors within the drug class hormones is largely due to administration of thyroid hormone together with food. Whether this is due to lack of knowledge of the caretakers or due to other factors is unknown and merits further investigation.

A limitation of our study is the fact that we used univariate in stead of multivariate regression analysis. This was performed because we were interested in identifying all possible determinants for administration errors. The results of our study can then be used in, for example, intervention studies that focus on one of the determinants we identified.

Another limitation of our study is the short study period and the fact that the observations were carried out during daytime on weekdays only.

Notwithstanding the above-mentioned limitations, this study shows that administration errors in an institution for individuals with ID are common. Furthermore, it identified some determinants that may be the focus for future improvements in order to reduce the error frequency.

Conclusion

Drug administration to individuals with ID is prone to serious errors, because the individuals themselves are not alert and therefore cannot intervene when an error occurs. This study shows that indeed many errors occur at the administration stage of the drug distribution process. Fortunately, also some determinants are identified that can be used to improve the quality of the administration process.

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