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COMMENTARY

To dispense or not to dispense? Ethical case decision-making in pharmacy practice

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Abstract In daily practice, pharmacists are regularly confronted with moral problems in which deciding what to do is not always a straightforward decision. In this contribution we show how the use of a specific method for moral deliberation can (in retrospect or prospective) aid moral judgements. We use the case of dispensing isotretinoin to demonstrate one ethical reflection method, namely the Utrecht Method.

Keywords Ethical case deliberation · Isotretinoin · Method · Pharmacy ethics

Impacts on practice

- Methods for ethical case deliberation support health care providers in decision-making by offering a systematic and structured approach.
- The Utrecht method facilitates a transparent argumentation and ethically justified decision-making.
- A methodological approach is a valuable aid to seek common ground in complex moral problems occurring in pharmacy practice.

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Introduction

Pharmacists frequently face moral problems in daily practice [1]. The Dutch Charter Professionalism of the Pharmacist explicitly mentions the ethical aspects of professional practice and the core values of pharmacists [2]. Yet, professional codes and guidelines do not offer tools for moral deliberation in daily practice; methods for moral deliberation aim to fill this gap. Professional ethics education makes use of a variety of methods in order to facilitate moral case deliberation [1, 3]. In this article we focus on one method that was developed by the Dutch Centre for Bioethics and Health Law[1] and is frequently used in education, namely the so-called Utrecht Method [4, 5]. We use a case to illustrate how to interpret and apply each of the steps of this method in order to assist moral deliberation in pharmaceutical practice.

Background of the method

The Utrecht method is a reflective tool that focuses on daily life dilemmas of professionals such as health care providers. Action-guiding questions like 'what should I do?' are starting point for moral deliberation, which ends with a concrete advice. Moreover, the method seeks reasons *to*

[1] The Centre for Bioethics and Health Law is currently the Ethics Institute.

justify what decision can be accounted for to patients and colleagues, as ethical issues require transparency. The method is open to various normative perspectives people hold in practice; one's religious inspired ethics or ethical theoretical viewpoint can be part of the deliberation process. According to Rutgers and Heeger the Utrecht Method is, compared to other methods, attractive for its 'fit' with professional practice: it resembles the clinical eye most professionals are trained for [4]. Even more, the method consists of a limited amount of questions (8) in order to be a feasible tool in practice. We present these questions accompanied with reflection on a case.

The case: Isotretinoin

A 21-year-old woman presents a dermatologist's prescription for isotretinoin indicated for systemic treatment of severe cystic acne in patients resistant to standard therapy. Other treatments have been ineffective for this patient. An important characteristic of isotretinoin is its teratogenic potential: it has been shown to cause adverse effects and birth defects if taken during pregnancy or before conception. The EU therefore implemented a compulsory Pregnancy Prevention Programme (PPP) [6]. Isotretinoin is contraindicated in pregnant women and can only be prescribed to patients of childbearing potential if they use contraceptives from 4 weeks before starting with isotretinoin until 4 weeks after treatment discontinuation. Furthermore, pregnancy tests should be taken before, during and after discontinuation of treatment. Isotretinoin should only be prescribed by or under supervision of physicians who have experience with prescribing systemic retinoids. In our case the pharmacy dispensing records suggest that the patient is not using contraceptives. On inquiry, the patient is well informed and her request is based on an autonomous choice. She confirms she is not using contraceptives, as she is not sexually active.

What is the moral question?

A case generally leads to multiple (moral) questions. One might, for example, question whether current policy regarding prescription and dispensing of isotretinoin is overly strict. Should all women use contraception, even if they do not intend to be sexually active during the treatment period?

We suggest formulating the moral question in our case as: Should the pharmacist provide the patient with isotretinoin? This question is neutral and concrete, does not contain moral arguments yet and explicates who needs to decide (the pharmacist).

Which actions are possible?

At this stage we identify possible actions without deciding on them. The pharmacist can decide to:

1. Dispense isotretinoin without further discussion;
2. Dispense after verifying the patient is well-informed and understands the risks of not using contraceptives in case of sexual activity;
3. Dispense when, based on consulting both the patient and the dermatologist, the risk is negligible;
4. Decide not to dispense when the patient does not use contraceptives.

Each alternative shows a difference in priority and it is not immediately clear which alternative should be chosen, based on what considerations. Further questions in the Utrecht Method will give more insight in relevant considerations.

Is there a lack of relevant information?

Ethical decisions need to be substantiated with relevant facts. Therefore, a thorough understanding of relevant information is necessary. First, the requirement to prescribe only to women in their childbearing years under strict pregnancy prevention measures supported by a Pregnancy Prevention Programme is related to the ethical consideration that harm to the unborn child should be prevented. Possible harms are increased risk of congenital anomalies that is, craniofacial, cardiac, thymic and central nervous system defects [7]. The rate for elective abortions out of fear of the drug's risks is high; studies report 60 % to almost 80 % elective terminations [8, 9]. Reports on the risk of major birth defects rang from nearly 6 % to almost 30 % [7–9]. As Schaefer states, statistical calculations should be interpreted carefully since the number of electives terminations is high and the proportion of informative pregnancies low [9]. The risk of major birth defects increases with the period of prenatal exposure [8, 9]. There is an increased risk of spontaneous abortion as well; however, an accurate estimation is not available [9]. Finally, studies show that compliance to the PPP is limited and isotretinoin pregnancies still occur [10, 11]. Recently a Dutch study estimated that 2 per 10,000 pregnancies were exposed to isotretinoin during pregnancy [7].

Who are the stakeholders and what are their perspectives?

The interest of stakeholders helps to identify relevant considerations and it requires to 'step into the shoes of the other'. Notice that not all interests of stakeholders can simply be assumed; it often requires communication to learn their perspectives. In our case the patient, the

dermatologist and the pharmacist are immediate stakeholders. Although a future child does not yet exist, it may also be a relevant perspective for the deliberation process. Such a child has an interest in its own well-being, not being harmed and an opportunity to live a life of one's own. We come back to this point in dealing with question 5 and 6.

Notice that the interest of the patient can be multiple. Primarily she may want to get rid of her severe acne that may strongly impact her quality of life. We can expect her to want to be fully informed on the beneficial and adverse effects of isotretinoin, including information about the PPP. For the dermatologist and the pharmacist the patient's well-being is of importance, that the acne can be controlled by treatment and risks and benefits of the treatment are proportionate, as well as that the patient is well informed, and has given informed consent. Furthermore, from the pharmacist's and dermatologist's perspective to avoid any negative consequences of the treatment for a future child may be important as well.

What are the arguments for and against the question at stake?

Stakeholders' perspectives can lead to different relevant arguments. The patient's perspective leads to the following arguments. First, the patients need for isotretinoin will likely benefit her for a condition that can have great impact on her quality of life. This is one argument in favour of dispensing the drug. Another argument is based on respecting autonomy: if the patient fully understands the information, her given informed consent would be in favour of delivering the drug. Counter-arguments are possible harms for the patient (like psychological effects in case the patient gets pregnant and faces the question of an elective abortion out of fear for the drug's risk, or—in case she continues the pregnancy—the risk of an infant with malformations), and possible harms for a future child (that is the potential risk of congenital anomalies). We will now directly focus on the argument to respect the autonomous request of the patient and the well-being of a future child and see how to balance and weigh them.

How strong are the arguments in this case?

We now focus on two arguments by looking at their validity: respect for autonomy and harm to the future child. The pharmacist is confronted with what seems an autonomous choice of the patient and a responsibility not to harm a future child. Even though adults are assumed to be competent it is still important to check this. Is she able to understand and weigh the information and to make a decision based on this information? Respect for autonomy obligates health care providers to disclose adequate information, including the risks in case of pregnancy and how to prevent them, and ensure understanding and foster decision-making. However, it is not self-evident that autonomous choices from patients always need to be followed. When other people can be harmed, autonomy is limited. But does 'other people' include a foetus or future child? Some philosophers will indeed argue that a potential child cannot be harmed [12]. A child cannot complain later about the harm done to him, because otherwise it would not have come to existence at all. This viewpoint would imply that a physician or pharmacist is only allowed to refuse requests if such actions result in the birth of a child whose existence is worse than not existing. However, this may be a very minimal standard: only when the consequences are abominable a physician can override a patient's wishes.

Interestingly, the Dutch Association for Obstetrics and Gynaecology currently accepts a higher standard in case of in vitro fertilisation (IVF) [13]: IVF is not carried out if there is *substantial risk* of serious harm to the future child.[2] In analogy we can argue that the pharmacist has to avoid 'substantial risk of serious damage for the future child'. To apply this criterion we need to know more about this specific group of users' chances of pregnancy as well as we need to include case-specific aspects.

Which action is preferred based on the considered arguments?

At this stage, we return to initial options and seek the best action. The first option (to dispense isotretinoin immediately) is clearly not in line with the moral consideration of the well-being of a future child. Option 4 (no isotretinoin when the patient doesn't use contraceptives) is in line with the moral consideration to prevent serious harm to the future child but is against the wish of the patient. Option 2 (safeguard adequate informed consent) acknowledges respect for autonomy. We also saw that an autonomous request may not suffice to dispense medication; "respect for autonomy does not support a claim right" [15]. Other considerations, in this case harm to a potential child, could outweigh the autonomous request. We therefore prefer option 3 (dispense when based on consulting both the patient and the dermatologist the risk is negligible). Although this option implies deviation of the PPP, exceptions to non-adherence to the PPP can be accepted when risks of pregnancy are negligible (e.g. homosexuality of the patient). In order to verify whether contraception is indeed

[2] For a justification of this standard, see Den Hartogh who argues that a physician is involved in a specific project, and it is contrary to the project to facilitate the birth of a life marred by serious defects. These considerations relate to the quality of life of any future child whomever that may be [14].

not necessary or disproportionate, consultation of the pharmacist with both patient and dermatologist is needed.

How to implement the preferred action?

This last step demands clarity on what is to be done by whom. In our view it is up to the pharmacist herself to communicate with the patient and to consult the dermatologist. In the present case this may be fairly clear, but in the context of team effort and team consultation coordination of the preferred action requires careful attention.

Conclusion

The Utrecht method aims to provide a structure for moral deliberation and decision-making. Its focus on transparency and openness to a variety of perspectives helps to seek common ground among deliberators. The advantage of this model is that the number of questions is feasible and that it leads to a fairly simple structure for ethical deliberation. The method is less useful to discuss more abstract issues, such as if and what medication should be refunded by health insurances. Notice that no method of ethical reflection itself guarantees a good outcome. Rather, the quality of the outcome hinges on the quality of the moral deliberation itself, namely the analysis of data, concepts and arguments. Deliberating with others is often helpful to improve the quality of the deliberation process, a conclusion that is also arrived at in other methods of case deliberation [1, 2, 16].

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