Sexual adverse drug reactions: patient impact and potential for pharmaceutical care

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Chapter 7

Views of primary healthcare providers on their role and challenges in counselling patients about sexual adverse drug reactions: a qualitative study

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Abstract

Background

Sexual adverse drug reactions (sADRs) can occur with many drugs and impact patients' drug adherence and quality of life. Nevertheless, sexuality is unfrequently discussed in healthcare practice. For sADRs, little is known about the challenges or frequency of discussion. In addition, primary care providers may have deviating views on the current care and responsibilities regarding sADRs.

Objective(s)

This study aimed to explore the views of general practitioners (GPs), GP nurses, pharmacists and pharmacy technicians on the distribution of responsibilities and current practice regarding informing about, detecting, treating and preventing sADRs and to identify challenges, facilitators and ideas for improvements in discussing sADRs in primary care.

Methods

Four focus groups, one for each profession, took place online between April and June 2021. A topic guide was followed with six questions on current practice and role division regarding sADRs and ideas to improve the discussion about sADRs. Video data of the focus groups were transcribed verbatim and analysed both deductively (role division, current practice, ideas) and inductively (barriers, facilitators).

Results

Efforts to counsel patients about sADRs were only taken when there was the time and privacy to do so. GPs considered themselves responsible for informing, detecting and treating sADRs, whereas the GP nurses considered themselves mainly responsible for detecting and the pharmacy team felt responsible for informing about sADRs. All also identified patient responsibilities, e.g. starting the conversation. Perceived challenges were both general (e.g. lack of knowledge and time) and specific (e.g. causality assessment difficult without before-treatment information about sexuality). Many ideas for improvement were identified, including intake consultations about information needs at pharmacies.

Conclusions

Dealing with sADRs was considered a shared responsibility between the prescriber, pharmacist and patient, which unfrequently took place in primary care. Their views provide a useful basis for those interested in improving the discussion of sensitive side effects in primary care.

Introduction

Medication can influence a person's sexuality. In fact, sexual adverse drug reactions (sADRs) are listed in the drug information of >300 drugs [1]. These medication-induced sexual problems can severely impact patients' therapy adherence, relationships and quality of life [2-4]. Unfortunately, healthcare providers seldom inform or ask their patients about sexual problems [5-7]. Many reasons for deterring from discussing sexuality have been identified, ranging from healthcare providers' attitudes (e.g. cultural norms), patient factors (e.g. not finding a suitable moment to start the conversation) to organizational factors (e.g. lack of time, training or knowledge) [5-9]. For sADRs specifically, little is known about the challenges or frequency of discussion. One study did identify that nurses feared informing about sADRs would scare patients or induce nocebo effects and thus preferred to withhold the information [10]. In addition, sADRs were the least discussed side effects in a small study about the practice of community pharmacists [11].

From studies with the Satisfaction with Information about Medication Scale (SIMS), it is known that for many drugs, patients have been particularly unsatisfied with the information received about the influence on their sex life [12-17]. The healthcare provider, however, is likely unaware of this low satisfaction. For example, physicians underestimated the prevalence and bothersome of side effects, especially of sADRs, during SSRI treatment [17].

Information about sADRs can be provided by different healthcare professionals, who may have different role perceptions concerning sADRs. For cardiac in-patients, for example, most doctors, nurses and pharmacists believed that their own profession should counsel the patient about whether the medication will affect the patient's sex life [12]. In primary care, the general practitioner (GP) and pharmacist are the main healthcare professionals to provide drug information and thus information about sADRs. Their role division has become more complex and unclear because of role redefinitions and role delegation, e.g. to GP nurses and pharmacy technicians. As a consequence, it is possible that GPs, community pharmacists and their teams have deviating views on the current care and responsibilities of one another regarding sADRs.

To decrease the burden of sADRs on patients, adequate information about sADRs and the possibility to discuss sADRs in healthcare consultations are pivotal. A fundamental step in reaching this goal is understanding the perceptions of GPs, pharmacists and their teams about their own role and the role of the others regarding sADRs. For this reason, this study aimed to explore the views of these primary healthcare professionals on the distribution of responsibilities and current practice regarding dealing with sADRs and to identify challenges, facilitators and ideas for improvements in discussing this sensitive side effect in primary care.

Method

Design

This study aimed to explore the current practice, role division, barriers and facilitators and ideas for improvements regarding dealing with sADRs in primary care (i.e. informing about, detecting, treating and preventing sADRs). Focus groups as qualitative method were chosen to deepen our understanding of the perspectives and to profit from the interaction among participants within the groups of healthcare providers. In primary care, side effects fall mainly under the responsibility of the GPs, GP nurses, community pharmacists and pharmacy technicians. Therefore, a total of four focus groups, one for each healthcare profession, was organized.

Setting

This study took place in the Netherlands, where the law states that prescribers and pharmacists have a treatment agreement with patients and therefore the duty to inform the patient about their drug treatment (Medical Treatment Agreement Act (Dutch: WGBO)). To reduce the workload of GPs, GP nurses have taken over tasks in the majority of the Dutch GP practices [6]. By law, the tasks of the GP nurse are part of the responsibilities of the GP, who must ensure that the GP nurse is clearly instructed and sufficiently competent to perform the delegated tasks. Likewise, in the Dutch community pharmacies, the community pharmacists are supported by a team of pharmacy technicians, while remaining responsible for their work [18]. Notably, under strict regulation, GP nurses with certain specialisations (e.g. diabetes) can prescribe medication that is predefined in a protocol.

Recruitment of participants

The focus groups took place online because of contact restrictions during the COVID-19 pandemic. For online focus groups, it is recommended to use small groups, to remain the essential elements of participant engagement and interaction among the participants [19]. Therefore, the intended group size was three to seven participants. The participants were purposively sampled from connections of the study team, followed by snowball sampling. Those with interest in participating were sent information and after a few days, a link from Castor EDC (Ciwit B.V., The Netherlands) to sign their informed consent. An online gift card (15 euros) was given as a financial incentive in exchange for participation.

Data collection

One focus group for each profession took place between the 30th of April and 10th of June, 2021, on Microsoft Teams. Because of busy schedules of the GP nurses, their focus group was divided in one meeting with two participants and another with one participant. The focus groups were led by R.G. and E.B., who alternated the role of moderator and technical assistant, and were video-recorded on Microsoft Teams.

Topic guide

The topic guide for the focus group first introduced the topic with information (types of sADRs, high-risk drugs; research aim) and a quiz that included patient cases, to probe participants into thinking about sADRs in their own practice. After that, the discussion was guided by six questions: (1) In which manner sADRs are discussed in each practice (2–5) Who is responsible for informing, detecting, preventing and treating sADRs and (6) What should change in the current practice to improve the discussion of sADRs. The term 'responsible' was chosen purposefully, to probe the participants in thinking about their role in terms of accountability.

Data analysis

The video data of the focus groups were transcribed verbatim, anonymised and entered in Atlas.ti (ATLAS.ti Scientific Software Development GmbH, Germany; version 22) for analysis. Deductive analysis was applied to extract the role division and current practice of the GP practice and community pharmacy in informing, detecting, preventing and treating sADRs (codes: role division and current practice in each of the four processes). In addition, to explore challenges and facilitators in discussing sADRs, the focus groups were also analysed inductively. Two researchers (R.G., M.T.) analysed the data separately, after which agreement was sought during a consent meeting.

Ethical consideration

All participants filled in an informed consent to use the anonymized transcriptions of the focus groups for this study. The content and scientific validity was evaluated by the scientific committee of the department of Clinical Pharmacy and Toxicology at the Leiden University Medical Center (LUMC). In addition, the Medical Ethical Assessment Committee (METC) of the LUMC declared this study as not subjected to the Medical Research Involving Human Subjects Act (WMO) (METC number: N21.045).

Results

Three to four participants participated in each group of healthcare professionals (GPs, GP nurses, community pharmacists, pharmacy technicians). The focus groups lasted between 53 and 60 minutes, the individual meeting with the GP nurse 33 minutes. Most participants were female and worked in cities, see Table 7.1. One physician in the GP group worked in a neighbourhood team for mental health and one pharmacist in the community pharmacy group worked in a team for patients with Parkinson's disease.

Table 7.1: Demographics

Healthcare professionals	Participant	Female / Male	Work experience (years)	Location of work	Specialisms
General practitioners	GP1	Male	4	City	
	GP2	Male	5	City	
	GP3	Female	4	City	Neighbourhood team for mental health
GP nurses	GPn1	Female	15	City	Somatic diseases
	GPn2	Female	14	City	Mental health
	GPn3	Female	12	City	Somatic diseases and elderly care
Community pharmacists	CP1	Female	1	City	
	CP2	Female	27	City	Team for patients with Parkinson's disease
	CP3	Female	10	City	
Pharmacy technicians	Phtech1	Female	16	City	
	Phtech2	Female	45	Village	
	Phtech3	Female	22	Village	
	Phtech4	Female	2	City	

GP=general practitioner; GPn=GP nurse; CP=community pharmacist; Phtech=Pharmacy technician.

Role division

How the participants of the focus groups talked about responsibility and role division regarding sADRs differed greatly, from 'should', 'could play a role' to 'task' and 'lawful obligation'. The content of a role or task also differed. In Table 7.2, the views on role division by each healthcare professional are summarized with detailed wording.

> *'I find responsibility a strong word. I would say that we can play an important role* [in detecting sADRs], *I can see that.'* – CP3 (Pharmacist)

> *'I feel more responsibility for recognizing than for detecting* [sADRs]. *So we get a lot of complaints during consultation hours, also about sexual complaints or about libido.*

Then I do consider it our responsibility to think 'hey, that is drug-related' and very often it is or at least it plays a role.' – GP1 (General practitioner)

Shared and individual responsibilities

The healthcare professionals agreed that sADRs are a shared responsibility between the prescriber, the pharmacist and the patient. Although the pharmacist was considered to have the most expertise regarding the topic, this did not influence the perceived responsibility of the pharmacist. From a more individual perspective, the GPs considered themselves responsible for the whole treatment and thus all processes regarding sADRs, the GP nurses considered themselves mainly responsible for detecting sADRs and the pharmacy team mostly felt responsible for informing about sADRs and evaluating the drug treatment.

'Look, I think that we mainly have to name that there can be some side effects and if they have doubts that they [patients] *can call the GP about that. I do think we have tasks in that, to facilitate that, but not…I am not like, well, that* [informing about sADRs] *is my responsibility. If I receive signals or something, in that case I should do something with it. That I do consider my responsibility.'* – GPn2 (GP nurse)

In addition, if another healthcare professional was considered not responsible, playing a role in the task could often still be visualized. However, in the focus groups of GPs and GP nurses, doubts were expressed about potential responsibility of the pharmacy team, because of the patients' privacy.

'That it [sADRs] *is discussed at the counter in the pharmacy, no, that does not seem right'* – GPn1 (GP nurse)

Delegated responsibilities

Notably, pharmacists and GPs considered pharmacy technicians and GP nurses only responsible for carrying out the protocols they were assigned to, as the pharmacists and physicians had delegated tasks to their teams, but remained the ones responsible for their work.

'If we instruct them [GP nurses] *to do that* [detect sADRs], *I think they should do it. Look, GP nurses should indeed tick boxes of lists, that they can do really well, that is why it is good care. So if we put it in the list then they should do it. Often, they also do it. And the way how, we can discuss, but the responsibility is with the GP, I think.'* – GP1 (General practitioner)

Table 7.2: Role and responsibility perceptions concerning sADRs of pharmacists, pharmacy technicians, GPs and GP nurses

	Pharmacist	Pharmacy technician	GP	GP nurse
Informing	Own profession + Definitely responsible, otherwise it happens nowhere ± Not the only ones responsible Prescriber ± Also responsible, especially for high-risk drugs	Own profession + Lawful obligation to inform about ADRs + Patient should not leave without information + More a task for the pharmacy than GP + Pharmacy more responsible than GPs + Should provide the AIS information ± Not the only ones responsible ± Task: scan already given information prescriber ± Should give more explanation than GP ± Intention to inform about sADRs during first dispense – Should not be at pharmacy counter GP/prescriber + More responsible: at basis of treatment + Should tell the main points (>10% ADRs) ± Shared responsibility	Own profession + Responsibility for what GP prescribes + Definitely a responsibility, but little time + Bigger role than the pharmacist ± Responsibility for prescriber and dispenser ± Shared responsibility with the pharmacist Prescriber ± Should at least advice for common sADRs GP nurse ± Responsible if prescribing a new drug Pharmacist / pharmacy technician + Ph tech follow protocol, thus responsible + Role Ph tech to give explanation about ADRs ± Most important role: to complement GP ± Shared responsibility, because educating about drugs is part of pharmacists' job ± Responsibility for prescriber and dispenser	Own profession + Pointing out ADRs is an important part of the work of GP nurse 'mental health' ± Can play role in ADR informing because of connection with patient ± More of a directing function, a co-responsibility, to guide patient to the most relevant information GP / pharmacist + ADRs is the pharmacist's profession and also the GP's responsibility + Important task of the prescriber ± Pharmacy is more responsible than GP nurse to inform important ADRs ± Discussing drugs is a collaboration between GP, GP nurse, pharmacist ± Knowledge about ADRs is expected from pharmacists
Detecting	Own profession + Should evaluate ADRs + Responsible, but how has not been shaped ± Should facilitate that patients know where to go by asking about ADRs ± sADRs should be evaluated together with drug effect – Not responsible, could play an important role Prescriber + Should do or delegate the follow-up Patient ± Cannot take responsibility with low understanding of the medical circuit ± Cannot have all responsibility	Own profession + Responsible for detecting ADRs + Should evaluate the treatment with the patient ± Should regularly ask about ADRs ± Should do something when sADR is detected ± Should pay attention to patient's body language during evaluation, ask different ways	Own profession + Responsible for associating complaint to drug, more than for questioning ADRs + Responsible for what is instructed to GP nurse + Responsible because cannot build upon knowledge of GP nurse ± Less responsibility than for informing ± Some responsibility to ask about sADRs for high-risk drugs ± Bigger role than the pharmacist Specialist nurses + Should do what is instructed by physicians ± Can evaluate ADRs ± More knowledge = more responsibility Pharmacist / pharmacy technician + Should ask about ADRs during dispense ± Responsible if there is a protocol Patient ± Shared responsibility to start topic when asked about ADRs	Own profession + Responsible to give opportunity to discuss sADRs + Responsible to do something with signal + Responsibility to detect sADRs and then direct to GP, the prescriber + Job to call GP about sexual urges ± Should discuss sADRs when the topic is vaguely introduced by the patient ± Should talk about sADRs if patient asks ± Should regularly ask about sexual function, also when patient is better ± Not responsible, but facilitating role to inform about ADRs and direct to GP – Should not ask about sexual function where there is not (yet) a connection Other healthcare providers ± GP more responsible, because prescribes ± Others should also take time for sADRs – Situation pharmacy is not suitable for discussing sADRs Patient ± Should start the topic themselves (if it well explained by healthcare provider)

Treating	Own profession + Responsible to do something + Important signaling role ± Limited responsibility, act as sounding board and hand over to GP ± Can think of suitable solution Patient, prescriber, pharmacy technician ± Patient, prescriber and pharmacy: equal responsibility for treatment – Pharmacy technicians are less responsible for any treatment	Own profession + Responsible for timely informing patient to go to GP in case of sADRs ± Task to advise discussing ADR with prescriber ± Can only direct patient to prescriber – Should not inform about other drug options Prescriber + Is responsible ± Most suited to help the patient Pharmacist ± Can be asked questions by prescriber	Own profession + Responsible for the treatment of sADRs, because GP treats the whole patient GP nurse – No specific role in treatment of sADRs Pharmacist ± Role to propose solution (medication reviews) ± Can be contacted by GP for advice – No specific role in treatment of sADRs	Own profession ± Partly the task of the GP nurse ± Principle of the 'extended arm' that GP nurse can do a few things according to protocol, but that you go back to the GP when you cannot figure it out GP + The final responsible person is always the GP, is principle of the 'extended arm' + Task of GP to treat sADRs
Preventing	Own profession ± Role to contact prescriber about alternative solution when information made patient not want treatment – Not responsible, but could have role	Own profession ± Can only contact prescriber when information made patient not want treatment – Not responsible because the responsibility suits prescriber more Prescriber + Responsible for preventing sADRs, because of more suitable timing and location ± More responsible than the pharmacy ± Has the task 'prevention' more than pharmacy	Own profession + Important to inform patients and then consciously make a decision about that Pharmacist ± Should contact prescriber when patient does not want drug because of sADRs ± Can only help with secondary prevention (duration and severeness complaint)	Own profession – Responsibility is limited to giving explanations and education, thus not prevention – Cannot prevent ADRs, only detect them

Each column shows the view of the healthcare provider of the title of the column, firstly about their own role and then about the other healthcare providers. The statements are evaluated to one of the three underlying meanings: 'there is a role' (+), 'there may be a role' (±) or 'there is no role' (-); sADRs=sexual adverse drug reactions; GP=general practitioner.

The pharmacy technicians and GP nurses, on the other hand, did see a role for themselves outside these protocols; GP nurses felt that they should discuss sADRs when the topic is vaguely introduced by patients and pharmacy technicians remarked that they should evaluate the treatment with the patient, pay attention to the patient's body language during this evaluation and afterwards also regularly ask about ADRs.

> *'I believe that pharmacy technicians should regularly ask about side effects that patients experience.'* – Phtech4 (Pharmacy technician)

Responsibility for prevention

Concerning the prevention of sADRs, it was considered important that the prescriber included sADRs into the decision-making for the drug treatment. Afterwards, the pharmacy team should contact the prescriber when the information provided in the pharmacy made the patient not want the treatment.

> *'Indeed, I think that it is good to inform people and then take a conscious decision about it* [sADR risk]*.'* – GP2 (General practitioner)

Responsibility of the patient

The patient's responsibility was also highlighted in each focus group. One GP considered the patient responsible to start the conversation about sADRs when they would ask about side effects of the drug treatment. Similarly, the GP nurses concluded that, under the condition that the healthcare professionals had sufficiently explained the risk for sADRs, the patient is responsible to start the conversation. Pharmacy technicians mentioned that patients are responsible for reading the drug information leaflet and for arranging a translator if needed. Community pharmacists did consider a shared responsibility with the patient, but questioned the extent to which the patient could take its responsibility.

> *'…So only that, not finding your way with basic things…yeah then how will you know where to go if you experience problems during the treatment. So I hope the patient is man enough to raise the topic when something is going on, no matter where, but I can imagine that not knowing where to go can create a barrier to take your responsibility as a patient.'* – CP1 (Pharmacist)

> *'I think that the responsibility to do something, that means that they* [patients] *have to tell at least something and I think that that perhaps is an even bigger barrier than the knowledge about the state of affairs in healthcare.'* – CP2 (Pharmacist specialized in Parkinson's disease)

Current practice in the GP practice

Informing about sADRs

In the GP practices, patients who were prescribed a drug with high risk for sADRs were informed about sADRs when the GP knew about the high risk and there was time left in the consultation.

> *'Look, things like a SSRI, yes, with those I do discuss it* [sADRs]. *But things like a betablocker, well, then I ask sporadically once I think about it at that moment, but it is not something that I, as a standard, check when someone comes back from the cardiologist with a betablocker or if I started it myself. So I think the answer is variable. I think there is a lot to win, but I also think that the really common ones* [drugs with high risk for sADRs] *that we do ask about sADRs with those.'* – GP2 (General practitioner)

In comparison, the physician in the mental health team shared that sADRs were always part of their consultations. She argued that otherwise prescribing cascades could occur. If the patient would mind the (potential) sADR, she would suggest a different antidepressant or antipsychotic drug. One GP would also start patients with a history of experiencing many ADRs on lower doses than suggested in the guidelines.

> *'I notice that I sometimes with a risk patient or when you think 'that one may get that side effect' that I start with a lower doses. So starting lower with a betablocker or for example the citalopram drops and then starting with only like 2 drops. The vulnerable people of whom you think they may be bothered by it, I notice, I start lower than the guidelines say.'* – GP1 (General practitioner)

The GP nurses did not specify any ADRs at the start of a drug treatment, to decrease patients' worries and the risk for nocebo effects. Instead, they explained the patient that ADRs may occur, often for a short period and that patients should call the GP practice if they had questions about symptoms. This approach differed for other very common ADRs, that only occur at the start of the treatment:

> *'There are medication that very often show the same side effect at the start, for example metformin, there you see very often the first days that they experience some bother of diarrhea or flatulence. That I do always name when I start patients on that like 'well, that is a day of ten, fourteen, but then it should be done.'* – GPn3 (GP nurse)

The GP nurse specialized in mental health also assessed sexual activity during the first consultation and if the patient's depressive symptoms had disappeared, asked about changes

in the patient's relationship. In addition, another GP nurse commented that she would take away patients' fear to start diabetes medication by informing that without the medication, there is a risk for diabetes-induced sexual dysfunction.

> *'Especially with diabetes I notice a fear to start medication. Then I do point out that if we do nothing about it, then there is also the danger of sexual dysfunction.'* – GPn3 (GP nurse)

Detecting sADRs

After the initial consultation, the GPs and GP nurses would only ask patients about ADRs in general. This strategy was considered to reduce the risk for nocebo effects but still provide patients with the opportunity to start the conversation about potential ADRs. One GP nurse noted that in her experience, many patients were very open about experienced sADRs. When patients would indeed report or mention potential sADRs, the GP nurse would discuss the symptoms and evaluate if the patient would like to change the drug treatment. At the focus group of GPs, the importance of first evaluating the patient's care question was highlighted, since patients commonly only wanted to know the cause for their symptoms, not a change in the drug treatment or an additional drug. The latter was not preferred by any of the physicians, although the mental health physician noted that for certain patients additional drugs are needed because the cause of sexual complaints cannot be changed.

> *'I have experienced that I start a sort of monologue about everything I know about erectile problems and start thinking of pills and then they say: but I do not want that, I just wanted to know if it is from that or that it will at some point work again, so I can tell my wife.'* – GP1 (General practitioner)

> *'Of course you have other enhancers that you could add if nothing else is possible. That is done often in psychiatry, I have to say…with the chronic patients, who live under supervision and are for example chronically schizophrenic, who really cannot get away from using that medication.'* – GP3 (Physician in mental health care team)

Current practice in the community pharmacy

Informing about sADRs

In the pharmacy, sADRs are part of the first dispense consultation points of high-risk drugs. If considered possible, pharmacy technicians complied with this, mostly by pointing out the sADR on the personal information leaflet or by taking the patient to the private consultation room. Several pharmacists and pharmacy technicians noted that they or their

colleagues did not go into detail or retained from informing about sADRs completely, because it is not something they would think about, because it is unknown if the patient will experience the side effect or because of religious reasons. Moreover, the pharmacy technicians assumed that sADRs were already included in the shared decision-making for a drug treatment.

> *'I think that many of the pharmacy technicians that work with us just do not go into this* [sADRs] *and not even think about that these side effects might occur. So I fear that in many of the first dispenses this is not discussed and then side effects like nausea and diarrhoea, those are simply named in the same breath with all other potential side effects. There are no problems there.'* – CP1 (Pharmacist)

> *'In principle, it is discussed at the first dispense, but then we do not go into much detail, it is discussed that the complaints may occur…but we do not go into much detail because you do not know if those people get the complaints.'* – Phtech2 (Pharmacy technician)

The first dispense information provision about a high risk for sADRs differed in some cases. For example, one pharmacy technician worked in a small pharmacy with no consultation room. They had agreed with the local prescribers that patients would be informed about sensitive ADRs by the prescriber. In addition, in some pharmacies, the patients received a link for an online drug information video, which included the common ADRs for that drug. Moreover, the pharmacists reflected that they mainly informed male patients about sADRs, not females.

> *'When we talked about it a couple of minutes ago, at that time I also thought 'do I do that with everyone in the same manner? But it is really that I mainly with men think 'Oh, yes! Sexual side effects!' And with women, while I myself am a women, those I ignore a bit.'* – CP1 (Pharmacist)

Detecting sADRs

When patients returned for a second dispense, the pharmacy team asked a general question if ADRs were experienced. During follow-up dispenses, questions about ADRs were no longer asked. Nevertheless, pharmacy technicians did consider themselves able to recognize when a patient would like a private conversation, e.g. about sADRs. Community pharmacists also sometimes discussed sADRs during medication reviews, for example with the patients with Parkinson's disease.

'The second dispense is more extensive with some than with others. Of course, there are always more possibilities for conversations. I do think that we are all capable of recognizing that a conversation with the patient is desired.' – Phtech1 (Pharmacy technician)

'So I start with 'what are your biggest problems at this moment' when I go into a new consultation. For example a maximum of three, because otherwise it becomes unmanageable. And if within those there is something in the direction of sexuality, then that becomes one of the most important points. So it depends on what they indicate.' – CP2 (Pharmacist specialized in Parkinson's disease)

In the case that a sADR would be detected, the pharmacy technicians would provide information about how common the sADR are for the specific drug and would address that the physician could prescribe a substitution drug. The interviewed pharmacists acknowledged that although they would refer to themselves or the prescriber, they would not know how to help patients in case of a sADR.

'And that may be difficult, because I say very general now, assuming that this occurs, get in contact with us or talk about it with your doctor, but actually I would not know how to solve such a problem when it occurs, yeah trying another drug, but you cannot just do that. So I find that difficult.' – CP1 (Pharmacist)

Facilitators and challenges in discussing sADRs

Although most participants considered sADRs as just another side effect, they did recognize that sometimes they experienced more challenges to inform about, detect or simply discuss them. Table 7.3 summarizes these challenges. On the other hand, best practices that facilitated the discussion of sADRs, were also noted during the focus groups. For instance, a pharmacist named sADRs in a list with other side effects to put less emphasis on the sADR. Detecting of sADRs was facilitated in the setting of the community pharmacy by questionnaires about side effects and by several listening skills, such as reading the patient's body language and reading between the lines. The physician in the mental health team highlighted that information about potential positive effects of drugs on sexual function was also beneficial.

'Especially with these sexual side effects that you really have to listen very carefully between the lines because they are for sure not going to tell us 'I have a premature ejaculation' or 'I cannot get an erection anymore.' – Phtech2 (Pharmacy technician)

Table 7.3: Challenges to discuss sexual adverse drug reactions in primary care

Actor or situation	Challenge	Example quote
Healthcare practice	Unknown intentions of other healthcare professionals	*Maybe because the physician was like 'we will evaluate* [sADRs] *later' and that you then, well, can scare someone by naming right away a whole list of side effects. So that actually more consciously has been decided to do that at a later time* – CP3
	DIL is difficult to understand, not in native language	*Patients are not likely to read the drug information leaflet, that is clear for me. It has too much information and also sometimes in wording that they do not understand* – GPn3
	Restricted consultation time in GP practice and pharmacy	*Ow, yes and then I also have to start about that sex and then we are already at the end of the consultation for which you are already looking at the clock like 'ow I have to go to the next' or it is coffee break or something like that* – GP1
	Lack of privacy at counter or when a translator or family member is present	*It is really unpleasant when the neighbour is behind like 'oh he cannot do it anymore' so yeah, you do look a bit and yes, if someone else is next to the patient then it is also a different story of course, because if the wife comes to pick it up then I think yeah it is a different story to tell that he...* (widens eyes) – Phtech2
Healthcare provider	Personal barrier: finding it difficult to discuss sexuality	*I find it quite difficult to make those side effects* [sADR] *discussable while when you think about it then it is a side effect and it is normal to discuss, but perhaps that is more something of myself, simply that I find it a bit odd to discuss it* – Phtech3
	Religious restrictions to discuss sexuality	*I have a few colleagues who do not want to do this conversation with men so they also do not dispense Viagra and such drugs because of their religious beliefs and in that case they always call someone else to do that conversation* – Phtech1
	Assumption that elderly are not sexually active	*Well, yes, it is a bit your own assumptions of course and your personal interpretation, but* [sADRs] *can be just as well a big problem for that person, who can be still sexually active and get complaints. That is really an eye-opener* – Phtech2
	Lack of knowledge about sADRs	*It is also a lack of knowledge. We do not have fully alert which* [drugs cause sADRs] *… the SSRIs and betablockers are known, but for the rest my knowledge stops there* – GP2
	Not finding an angle to start the conversation	*I think that sex in some instances is simply not discussable. So that is very complicated, then you would need really good conversation skills to find an entrance for it, I think* – CP2
Patient	Unknown baseline sexual function of patient	*I always say, what is the chicken and what is the egg? Sexual side effects or at least sexual complaints also occur in the context of psychiatry…So then it is the disease itself that causes someone to have too much or too little libido* – GP3
	Unknown information need of patient	*I think that we sometimes think we know what people need, but we have not asked that at all* – CP3

Table 7.3 continues on next page.

Table 7.3: *Continued*

Actor or situation	Challenge	Example quote
Patient	Unknown if patient finds sexuality important	*What for the one person is a problem, does not have to be for the other...the one person says 'well, I find it acceptable, because other than that I have a lot of effect of* [the drug] *so for me we do not have to do something with that' and the other says 'well, for me it is so bothersome, I really want another'* – CP3
	Females report their problems less	*I have actually never heard of women that they have complaints but of men, those often come with erectile dysfunction* – GPn1
	Preference of patients for a GP of own gender	*The men mostly come to me and those want to discuss the sexual side effects with me and not so much the women, those go to my female colleague and talk about that. So then I also notice automatically sort of a barrier of 'Oh yeah that they will bring up for discussion next time with my female colleague'* – GP1
	Patient does not speak a language in common and there is no translator present	*I do notice that with people who have a language barrier and when there are also cultural differences, then I think I will not likely do that* [discuss sADRs]*...I have to say that I do not have many consultations with a translator, but I would likely also not do it in that case* – GP2
	(Belief that) in patient's culture sexual problems are not discussable	*Because in certain cultures it is not allowed that you start a conversation about that* [sexual problems] – GPn3
	Patient unable to take central position in health	*It often is about the patient central. If you speak in those terms, it is of course the question to what extent the patient itself can play a central role* – CP1
	Patients not associating treatment with sexual function	*'You may experience sexual side effects', then patients know that it can be from the drug, 'Doctor, I want another drug', while if it goes worse and one does not know why, then they will not come, I think* – GP2
Informing about sADRs	COVID-19 restrictions: hampered patient communication	*Especially now that we can use the consultation room less, what we did do before the corona period, then we just did a first dispense about SSRIs and such in the consultation room and then you just have a bit more privacy to discuss it* – CP3
	Fear of inducing nocebo effects or low therapy adherence	*I can also not expect the pharmacy or doctor to discuss every small letter from the drug information leaflet, because then of course no one will take their medication* – GP3
Detecting sADRs	Detecting of sADR is followed by unknown action	*What do I do with it when the patient comes with* [sADRs]*, what are the interventions you can do, that you at least know that if you switch or that certain antidepressants do not have those side effects* – GP3
	No connection with the patient	*You should not ask about that as long as there is not a connection, when you have someone for the first time in front of you. Yeah, that is not one of the first questions you ask!* – GPn3

DIL=drug information leaflet; sADR=sexual adverse drug reaction.

> *'Sometimes it is not the medication but the disease and in that case the SSRI can help. So someone who in the context of the depression is bothered by sexual side effects then the clearing up of that depression because of a SSRI is also helping.'* – GP3 (Physician in mental health team)

From the question what could be changed to improve the discussion about sADRs, the following eight organisational and/or material suggestions emerged: 1) gender-specific drug information leaflet in simple words, 2) sADRs more integrated in protocols, 3) more sADR information in GP practice, 4) different content and organisation of information consultations in pharmacy, 5) more time available for second dispenses, 6) improved reachability pharmacist, 7) different patient evaluation pharmacy, 8) collaboration between GP practice and pharmacy.

The first four points were mentioned with the goal to improve the information provision about sADRs. For the different information provision in the pharmacy, a pharmacy technician believed that they should listen more to the patients' needs and the pharmacists imagined to do an intake with their frequent visitors about what they expect concerning information from the pharmacy. They also questioned whether the second instead of the first dispense would be better suited for the provision of ADR information, as it would lower the potential to scare the patients.

> *'200 patients that visit your pharmacy often or should visit often, with those you should really have a periodic…or in any case an intake of what they expect from you. And I think that with that, you can chart what they expect about how and especially about what you will inform them…And I think we arrive to this conclusion because it* [potential sADR] *is very private information, so you will not find it out in the two minutes they are at the counter.'* – CP2 (Pharmacist specialized in Parkinson's disease)

Topics five to seven were mentioned to improve sADR detection. One pharmacy technician suggested to give patients who started with a new drug treatment a second period of try-out, because patients also develop side effects after the first try-out period (a standard of two weeks in the Netherlands). Similarly, the pharmacists suggested to do the drug evaluation after 2–4 weeks, independent of the drug dispenses. Another improvement in the drug evaluation could be to call patients later when the pharmacy technician had the feeling that there was something the patient did not want to say at the counter. Moreover, the evaluation could also be improved if patients could reach out to community pharmacists more easily and consequently experienced less barriers to discuss sADRs with an easily accessible healthcare professional. To improve the pharmacists' accessibility, GP nurses suggested to disclose the possibility for appointments with a pharmacist on the personal drug information leaflet.

'To afterwards ask 'I had the feeling that you did have some questions, is that true?' …Perhaps they start that conversation [about sADRs] *easier on the telephone…but we should have the time to do that.'* – Phtech3 (Pharmacy technician)

'I think it can simply be emphasized by the pharmacy like 'may you have questions about the medication, would you like to discuss that in private, it is always possible to make an appointment' That could be disclosed and you always get such a note with it, right? Then it could be emphasized again. You do not have to discuss this at the counter with the pharmacy technician. I think that will already take away a barrier.' – GPn2 (GP nurse)

Lastly, collaboration was mentioned by a GP nurse, who appreciated having polypharmacy consultations with the local community pharmacist, to discuss patient cases. Community pharmacists also considered it beneficial and feasible to agree with the local prescribers on that the pharmacy team actively asked about sADRs at the second dispense and to agree on which actions would follow a sADR detection in the pharmacy. In addition, one pharmacist mentioned that if the patient's medical-pharmaceutical file would be shared among the different healthcare providers, this would make it possible to divide and control tasks such as informing or asking about sADRs.

'If you could agree that we would actively ask this at a follow up dispense, or apart from that, and in that case these are the action we can do. So when do we refer, when do we not refer to the prescriber with certain complaints. I think you could agree on that quite well.' – CP3 (Pharmacist)

'And how you then do that task division, yeah, that is only possible if you can work in a sort of common file. Because otherwise you are sending faxes back and forth or something similarly dramatic.' – CP2 (Pharmacist specialized in Parkinson's disease)

Discussion

This qualitative study is the first to explore the roles, current practice, challenges and potential improvements regarding sADRs in primary care. The discussion about sADRs was considered a shared responsibility between the prescriber, pharmacist and patient and mainly took place when the circumstances (e.g. availability privacy and time) allowed this. On an individual level, the GPs considered themselves responsible for informing, detecting and treating sADRs, but acknowledged that this was not always reflected in their practice. The GP nurses considered themselves mainly responsible for detecting sADRs, for which the patient should start the topic when the GP nurse created a possibility for discussing

side effects. The pharmacy team mostly felt responsible for informing about sADRs. While they also felt responsible for evaluating the drug treatment, they reflected that this was barely shaped in the community pharmacy. In addition, several challenges and ideas to improve the discussion about sADRs were identified.

Some of the challenges to discuss sADRs are known to impede healthcare practice in general, especially a lack of knowledge about the side effect, a lack of time and cultural and religious barriers. Other challenges were most likely caused by the sensitivity of the topic. For example, healthcare providers having personal barriers to discuss sexuality, the difficulty of finding a way to start the conversation, the need for privacy and the preference of patients to discuss sexuality with a healthcare professional of their own gender have all been identified before in research about sexuality in healthcare [5-9]. Religious restrictions on the side of the healthcare provider have also been previously reported, although this mostly concerned emergency contraceptives and abortifacients [20]. Besides these well-known barriers, four new challenges were identified in this study: (1) unknown intentions of other healthcare professionals concerning drug information, (2) difficult causality assessments because the pre-treatment sexual function is generally unknown, (3) patients who cannot take a leading position in their health and thus cannot bring up health problems themselves and (4) the potential for nocebo effects or low therapy adherence as a consequence of sADRs information. Only for the first challenge a suggestion was provided to overcome the barrier: pharmacists proposed to agree with GPs that patients would be informed about sADRs during the second drug dispense.

Notably, although the inclusion of four different professions made the perspectives presented in this study broad, the perspectives are not exhaustive. This is a limitation inherent to qualitative study designs, but should also be noted here because of the use of a convenience sample and the small number of participants. The convenience sample likely had more interest in the topic and therefore possibly distinct views from the general population of healthcare providers. In addition, only 3–4 healthcare providers participated in each focus group, whereas focus groups in presence generally exist of 6–8 participants. For this study with an online format, the number was regarded as adequate, considering that more would have developed a different group feeling, with less participation of each individual as a result. Lastly, it remains unknown to what extent perspectives might be missing, because the design of one focus group per healthcare professional made it impossible to test data saturation within each healthcare profession. The study's findings should thus be interpreted as first insights in potential perspectives on the topic, with the general population likely showing less experience and more barriers in counselling patients about sADRs. The strength of this study lies in the inclusion of primary healthcare professionals

for who ADRs are daily practice but who are, for the topic of ADRs, little investigated regarding their responsibilities and current practice.

The patient's responsibility in informing, detecting and discussing sADRs was an important topic, started by the participants themselves. The term 'patient responsibility' has no single definition. In this study, pharmacy technicians used the term to point out patients' tasks in informing about sADRs, whereas the GPs and GP nurses used the term to describe the detection of sADRs as a process in which both the healthcare provider and the patient have their own tasks for which they are responsible. Some of the tasks they assigned to patients have been identified before, especially for patients to address sexual problems themselves [5-7]. These tasks are understandable in the context of patient centredness, yet are rather disputable. Firstly, in the Netherlands, the lawful duties of the patient are limited to informing the healthcare provider and cooperating during examination and treatment. One can debate whether the patient's duties to inform and cooperate include, for example, reporting an ADR when it causes low drug adherence. Secondly, the patient can only report a sADR if he or she is aware of the potential association between sexual problems and medication. Healthcare providers fulfilling their tasks in educating patients is thus a prerequisite for patients to 'take up their responsibility'. In addition, some patients (e.g. with low literacy or severe depression) cannot take their responsibility because they are unable to report sADRs or do not know what to report and where to report it. This problem concerns many people. Inadequate or problematic health literacy, for instance, was found in a quarter of the Dutch population, and in almost half of the European population [21]. Another problematic view is that pharmacy technicians regarded patients responsible for reading the drug information leaflet, even though about 10% of the population have low literacy skills [22]. Lastly, patients likely disagree with the proposed tasks, as many expressed a preference for the healthcare provider to start the conversation about sexual problems [23-25]. This study thus emphasizes both the importance of 'patient responsibility' for primary healthcare providers as well as the ambiguity of the term.

The study participants also expressed doubts about providing patients with information about sADRs. They feared that this information would deter patients from using the drug, induce nocebo effects or lower drug adherence. Drug adherence has indeed been associated with the amount of drug information provided [26]. For this reason, personalized information has been suggested, based on the individual's needs and preferences for drug information. Unfortunately, also providing the preferred drug information does not guarantee satisfied patients. In a small study, Kusch *et al.* found that drug users generally did not understand the consequences of receiving as much information as possible [26]. Many or their participants changed their initial preference to less information. Importantly,

drug adherence and nocebo effects are, besides the received information, also influenced by the individual's perceived sensitivity to drugs and adherence also by the actual experience of sADRs [4, 27]. Concerning nocebo effects, men who were informed about the risk for sADRs at the start of finasteride or a betablocker indeed reported sADRs more often than not-informed men [28, 29]. However, to our understanding, potential nocebo effects in the shape of sADRs have not been researched for other drugs nor for female patients. Therefore, future research should determine if and how the risk for nocebo effects can be lowered in healthcare practice. Some potential mechanisms have already been reported, such as working with the patient's belief about medication and providing a choice between equivalent drugs [30, 31]. For now, the appropriateness of providing sADR information cannot be assumed without questioning the patient's beliefs about medication and preferences regarding drug information.

As suggested by the study participants, periodic and open conversations with patients are needed. For this purpose, the participants proposed changes to the current pharmacy processes, with an information needs consult for the frequent visitors of the pharmacy and different content and timing for the treatment evaluation. They also suggested a new format for the drug information leaflet, which should be easy to understand, with a standard section about drug's influences on sex life, and a gender-specific ADR section. Studies on the use of plain language, pictograms and translations to patient's native language for drug labels or information leaflets have shown that these methods can significantly increase patient's understanding of drug information, although complete understanding was never reached [32, 33]. Regarding gender-specific information, Dickinson *et al.* found that the concept was welcomed by the readers [34]. However, some were concerned that it could lower the quality of information, feasibility of delivery and increase the risk of providing incorrect information. Interestingly, their gender-specific adjustments did not include side effects. The proposals to improve the reachability of the pharmacist and to have GP practices and pharmacies collaborate regarding sensitive topics were other novel ideas that were brought forward in this study. Hopefully, these ideas from practitioners in practice can be adopted by academics and policy makers to test and possibly improve the current practice regarding sensitive side effects.

Conclusion

GPs, GP nurses, pharmacists and pharmacy technicians all considered counselling about sADRs a shared responsibility between the prescriber, pharmacist and patient. Their perspective about responsibilities for sADRs were not reflected in their practice, because

of challenges that are common in healthcare practice (e.g. lack of time) or that occurred because of the sensitivity of sADRs. On top of this, talking about sADRs also faced unique challenges (e.g. not knowing patients' baseline sexual function). Their perspectives, experiences and ideas to improve care for sADRs provide a useful basis for those interested in improving the discussion of sensitive side effects in primary care.

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