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Barriers and facilitators for systematically registering adverse drug reactions in electronic health records: a qualitative study with Dutch healthcare professionals

Isa P. A. C. Geeven[a], Naomi T. Jessurun [a,b], Arthur T. M. Wasylewicz[c], Marjolein Drent[d,e,f], Phyllis I. Spuls[g], Frank Hoentjen[h], Eugène P. van Puijenbroek [a,i], Harald E. Vonkeman [j,k], Koen P. Grootens[l], Martijn B. A. van Doorn [m], Bart J. F. van Den Bemt[n,o] and Charlotte L. Bekkers[o]

[a]Research Department, Pharmacovigilance Centre Lareb, 's-Hertogenbosch, The Netherlands; [b]Faculty of Science and Engineering, University of Groningen, Groningen, The Netherlands; [c]Pharmacology, Catharina Hospital, Eindhoven, The Netherlands; [d]Department of Pulmonology, St Antonius Hospital, Interstitial Lung Diseases (ILD) Center of Excellence, Nieuwegein, The Netherlands; [e]Department of Pharmacology and Toxicology, Faculty of Health and Life Sciences, Maastricht University, Maastricht, The Netherlands; [f]Ild Care Foundation Research Team, Ede, The Netherlands; [g]Department of Dermatology, Amsterdam University Medical Centers, Amsterdam Public Health and Infection and Immunity, University of Amsterdam, Amsterdam, The Netherlands; [h]Department of Gastroenterology, Radboud University Medical Center, Nijmegen, The Netherlands; [i]Reinier van Arkel Mental health Institution, Department of Geriatric and Hospital Psychiatry, 's-Hertogenbosch, The Netherlands; [j]Department of Rheumatology and Clinical Immunology, Medisch Spectrum Twente, Enschede, The Netherland; [k]Department of Psychology, Health and Technology, University of Twente, Enschede, The Netherlands; [l]Renier van Arkel Mental Health Insitutute 'S Hertogenbosch, The Netherlands; [m]Department Met Dermatology, ErasmusMC, Rotterdam, The Netherlands; [n]Department of Pharmacy, Sint Maartenskliniek, Ubbergen, The Netherlands; [o]Department of Pharmacy, Research Institute for Health Sciences, Radboud University Medical Centre, Nijmegen, The Netherlands

ABSTRACT

Background: Systematically registering ADRs in electronic health records (EHRs) likely contribute to patient safety as it enables the exchange of drug safety data. Currently, ADRs registrations by healthcare professionals (HCPs) is suboptimal. This study aimed to identify barriers and facilitators perceived by HCPs to register ADRs systematically in EHRs.

Research Design and Methods: A qualitative study with individual interviews was conducted among specialist physicians and hospital pharmacists from 10 different Dutch hospitals. A semi-structured interview guide was used to identify experienced barriers and facilitators for systematically registering ADRs. Data was analyzed following thematic analysis. Themes within barriers and facilitators were aligned with the Capability–Opportunity-Motivation–Behavior (COM-B) framework.

Results: In total, 16 HCPs were interviewed. Identified barriers were: lack of knowledge to recognize ADRs, time constraints, inadequate IT system, lack of support, stuck in routine, and not recognizing the importance of registering ADRs. Identified facilitators were: enhanced knowledge and awareness of ADRs, functional IT systems, expanding accountability for registration, and motivation toward registering.

Conclusions: Barriers and facilitators for registering spanned all aspects of the COM-B model and occurred in individual, social and environmental domains. Addressing these aspects could improve the registration of ADRs and may contribute to patient safety.

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1. Introduction

Patients who use medication frequently experience adverse drug reactions (ADRs), resulting in increased morbidity, mortality, and increased healthcare consumption [1]. It is estimated that ADRs account for 5% of all unplanned hospital admissions in the European Union and approximately 197,000 deaths annually [2–4]. Elderly are especially vulnerable where even around 9% of hospital admissions are caused by ADRs, of which some could be prevented [5].

Systematically registering ADRs can be described as using a standard template or separate field in electronic health records (EHRs). In this way registration of ADRs, may prevent hospital admission that are caused by ADRs or repeat ADRs. Previous studies showed that repeat ADR related hospital admission have increased in elderly and among patients with re-dispensed medication, around 10% experienced repeat ADRs [6,7]. According to van der Linden et al. around a quarter of the medications that are discontinued during hospitalization due to an ADR are prescribed again within six months after discharge [8]. Insufficient registration of ADRs and lack of communication to other relevant healthcare professionals may contribute to safety risks for patients and potential hospital admissions. Systematically registering ADRs in EHRs and communicating this information to other relevant healthcare professionals could facilitate in the prevention of ADR related hospital admissions [9,10].

Systematically registering ADRs in EHRs could also be beneficial for other purposes, such as patient registries, research,

CONTACT Naomi T. Jessurun n.jessurun@lareb.nl Pharmacovigilance Centre Lareb, 's-Hertogenbosch, The Netherlands; Faculty of Science and Engineering, University of Groningen, Groningen, The Netherlands

and pharmacovigilance purposes, as it provides real world drug safety data. The teratogenicity of thalidomide during the sixties causing birth defects illuminated the importance of independent monitoring of medication after market approval. It changed the pharmacovigilance system, and spontaneous reporting of ADRs became organized and regulated [11]. National pharmacovigilance centers, such as the Netherlands' Pharmacovigilance Center Lareb, gathers and analyze ADR information from patients and healthcare professionals and provide up-to-date information on market-approved medication. However, underreporting of ADRs is still a continuing problem, and as a result, important information on ADRs comes together slowly, resulting in limited insights in medication safety profiles [1,12,13]. Systematically registered ADRs in EHRs contain real-time, real-world clinical data that could offer a possible, more proactive approach to pharmacovigilance [14,15].

To improve the registration of ADRs, one needs to understand why healthcare professionals do not register ADRs systematically. Information on reasons thereof or considerations to improve registration is currently lacking. Therefore, this study aimed to identify barriers and facilitators, perceived by hospital-based healthcare professionals in The Netherlands, to register ADRs systematically in EHRs.

2. Methods

2.1. Theoretical model

The healthcare professional's behavior to register ADRs systematically can be influenced by different determinants, including individual characteristics and those that involve the external environment. The COM-B model is a comprehensive model that covers both determinants and consists of three components: Capability, Opportunity, and Motivation [16]. Each component can be subdivided into two subcategories (Figure 1)

Capability is defined as individual knowledge and skills. A person should have the right psychological and physical capability to engage in the required specific behavior. *Opportunity* is defined as all factors that lie outside a person and can be physical or social. Physical opportunities can be provided by the environment, such as material resources or time, and social opportunities involve culture or social norms. *Motivation* can be automatic or reflective. Automatic motivation is described as the brain processes that direct behavior like impulses or habits. Reflective motivation can be affected by beliefs about consequences and planning [16,17]. According to this model, behavior results from the interaction between these components and behavior can also influences these individual components. The COM-B model is frequently used to identify barriers and facilitators to behavior change and was therefore selected for this study [16–20]. In this study, the COM-B model was used to develop the questionnaire and categorize the emerging barriers and facilitators perceived by healthcare professionals.

2.2. Study design and participants

A qualitative study with semi-structured interviews was conducted with healthcare professionals from 10 Dutch hospitals between January 2021 and March 2021. Specialist physicians

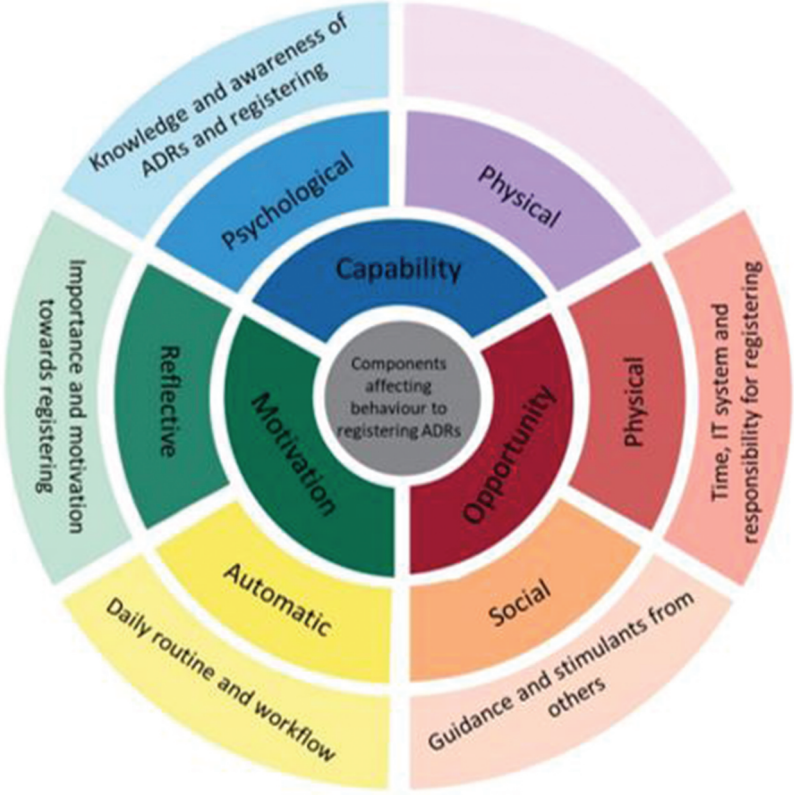

Figure 1. The COM-B model [16].

regularly prescribing medication for chronic diseases and hospital pharmacists were eligible for inclusion. Purposive sampling was used to select eligible participants from the network of the Dutch pharmacovigilance center Lareb. Participants were invited by e-mail and asked to recommend other healthcare professionals for participation. Eligible participants came from three academic hospitals (Amsterdam UMC, Erasmus MC, Radboud UMC) and seven general hospitals (St.Antonius Hospital, Bernhoven Hospital, Catharina Hospital, Haga Hospital, Jeroen Bosch Hospital, Maxima Medical Center, and Medical Spectrum Twente). Verbal consent was obtained from all participants before the start of the interview and included in the transcripts which were sent back for consent.

2.3. Data collection

Individual, face-to-face interviews were conducted by video calls by a researcher (IG) using a semi-structured interview guide. The research team (IG, NJ, CB) developed the interview guide during several discussion rounds. Questions were categorized into the COM-B model (Appendix 1) to cover all three components.

Two pilot interviews with a specialist physicians and hospital pharmacist were held to test the interview guide on comprehensibility and clarity. Participants provided feedback on the interview guide, and after some minor adjustments, regarding the question about the purpose of registering, a final version was made.

During the interview, participants were questioned about their current behavior to register an ADR systematically in the EHR, including perceived advantages and disadvantages. This was followed by questions about experienced barriers and what could help to overcome these barriers. Data was collected until saturation (i.e. when no new themes, findings, or concepts emerge) was reached. Interviews were audio-recorded and transcribed verbatim by IG and send back for their consent.

2.4. Data analysis

Data were analyzed using inductive thematic analysis to identify themes emerging from the data using the software program NVivo (release 1.3) [21,22]. First, three researchers (IG, NJ, CB) independently coded the first transcript. Open codes were compared and discussed until all consensus was reached. After that, two researchers (IG and NJ) open coded a second transcript which was reviewed by CB and discussed until all agreed. The following transcripts were coded by IG and reviewed by NJ. Then, open codes were placed into categories following axial coding by IG and reviewed by NJ and CB. Lastly, axial codes were placed into overarching themes by the researchers individually and discussed with all authors until agreement on the final themes was reached. The final themes were subsequently placed into the COM-B model.

3. Results

In total, 39 healthcare professionals were approached for participation, of whom 16 agreed to participate. After interviewing eight specialists and eight hospital pharmacists, information saturation was reached. Interviews lasted between 20 and 42 minutes. The demographic characteristics of the participant are listed in Table 1.

Participants had different behavior regarding systematically registering ADRs in EHRs. Some of them registered ADRs systematically, addressed the added value and did not perceive any barriers. Conversely, other participants never registered ADRs systematically and were not familiar with it. According to one pharmacist, inadequate registration is a common problem that leads to substantial loss of information which can have consequences for patient safety. It was acknowledged that the registration of ADRs should be improved:

> For instance, when an ADR occurs during hospitalization. Only 50% of these ADRs were captured in a medical letter were sent to the general practitioner. About 20% of the information in the letter is transferred to the system of the general practitioner. 50% of the information about ADRs is already lost because of not registering it systematically in the electronic health record. So there is a massive loss of information and this could have disastrous consequences for the patient. (Hospital pharmacist)

Themes reflecting barriers and facilitators perceived by participants were placed under the corresponding component of the COM-B model (Table 2). These themes will be discussed accordingly and illustrated with quotes. Figure 1 shows which domains influence the behavior of registering.

The two inner layers represent the three components of the COM-B model, including the subcategories. The different domains, that emerged from the interviews, are placed at the corresponding component and subcategory of the COM-B model in the outside layer.

3.1. Capability (psychological)

3.1.1. Barrier

3.1.1.1. Lack of knowledge to recognize ADRs. Multiple participants indicated that they, or others, lacked sufficient knowledge to recognize and thus register ADRs. It was discussed that identifying ADRs is challenging as its clear association with medication use is not always seen. As a result, ADRs were not registered when participants were not entirely sure

Table 1. Participants characteristics (n = 16).

Characteristic	Number (n = 16)
Gender	
Male	*7*
Female	*9*
Profession	
• Specialist physician	*4*
Dermatologist	*1*
Gastroenterologist	*1*
Psychiatrist	*1*
Pulmonologist	*1*
Rheumatologist	*8*
• Hospital pharmacist	
Years of work experience in hospital	
• *0–9*	*4*
• *10-19*	*6*
• *20–30*	*4*
• *> 30*	*1*

Table 2. Barriers and facilitators perceived by participants categorized into the corresponding COM-B model component.

COM-B component	Barrier	Facilitator
Capability (physical)*	-	-
Capability (psychological)	Lack of knowledge to recognize ADRs	Enhanced knowledge and awareness of ADRs
Opportunity (physical)	Time constraints Inadequate IT system	Expanding accountability for registering Functional IT system
Opportunity (social)**	Lack of support	-
Motivation (reflective)	Importance is not recognized	Motivate registering
Motivation (automatic)**	Stuck in routine	-

*No barriers and facilitators related to capability (physical) were discussed during the interviews.
**No facilitators related to opportunity (social) and motivation (automatic) were discussed during the interview

about their causality. Especially previous unknown ADRs were often not recognized by healthcare professionals:

> It would be easy if a patient would take medication and an hour later, there is a reaction. However, it is often not that easy and there are many possible causes for that reaction. Most of the time, there is a lack of doing the right checks to confirm that your prescribed medication causes it. That makes registering sometimes difficult. (Hospital pharmacist)

> The decision is often based on knowledge about ADRs. So if something happens, and I know it is a well-known ADR associated with the current medication, the chance of identifying it as an ADR is more likely. When it is something unexpected and I do not associate with the medication at all, the chance that I will recognize it as an ADR and register it is very small. (Specialist physician)

3.1.2. Facilitator

3.1.2.1. Enhanced knowledge and awareness of ADRs.

To enhance knowledge of registering ADRs systematically, some participants discussed that education for healthcare professionals could serve as a facilitator to provide information about how ADRs are developed over time and how to identify their relationship with medication. It was also suggested that stimulants by other specialists or colleagues could facilitate in increasing the awareness toward registering ADRs systematically in the EHR:

> There is far too little attention for ADRs. Not only for registering them but also for ADRs in general. Far too little attention is paid to this in the education of hospital pharmacist … actually, there is no attention for this aspect. It is not an integral part of the education. (Hospital pharmacist)

> We try to educate and stimulate students or specialists in training by explaining to them which questions to ask patients about ADRs. (Specialist physician)

3.2. Opportunity (physical)

3.2.1. Barriers

3.2.1.1. Time constraints.

Healthcare professionals experienced lack of time as main barrier for registering ADRs. This was related to the effort needed to obtain detailed information from the patient about the ADR and the subsequent registration of all information in the EHR:

> In my opinion, registering the ADR systematically during a consult is time consuming. (Specialist physician)

> You want to do it in a structured way, so you want to know whether the patient experienced ADRs. If that is the case, then you want to know when it started, how serious it was, how long the symptoms did last, what action had the patient undertaken, and did it help? All of these questions should be asked, which is time consuming and is often not achievable in our busy schedule in clinical practice. (Specialist physician)

3.2.1.2. Inadequate IT system.

Participants addressed that the current IT system was not adequately facilitated for easy registration. The ADR field has limited accessibility during consultations and was not easy to fill in, becoming a barrier for registering. Many participants valued information exchange with other healthcare providers in other settings for adequate guidance on patient's medication use. However, they acknowledged that the current IT system is not interchangeable with other systems, which also hindered the motivation for registration in the used system:

> The way the ADR field is put together can help but sometimes also hinder registering an ADR. It takes time to find the right place to register it and then you must fill in several questions before it is registered. In that way, your system does not facilitate it appropriately. (Specialist physician)

> You should look at a way to share this information. You register it in your own system, but you can't share this information easily with Lareb or other healthcare professionals. (Hospital pharmacist)

Some healthcare professionals worried about the number of alerts that would be automatically generated when all ADRs would be registered, because the ADR field is linked to medication monitoring in the drug prescription system:

> Sometimes it is really annoying to find out that there is an irrelevant alert that pop-ups in your system. If you look at how often you deal with an allergy or ADR that results in switching of the medication. It hardly happens. (Hospital pharmacist)

3.2.2. Facilitator

3.2.2.1. Expanding accountability for registration.

A facilitator that emerged from the time constraint barrier was to have a specific ADR specialist who identifies ADRs and registers them in the ADR fields, outside the current patients-specialist consultation. Some participants suggested that the patient could have responsibility for ADR registration by filling in questions about occurred ADRs, in a form or a mobile phone app, whereafter it is sent to the EHR and checked by the attending specialist:

> To facilitate proper registering of ADRs, you may need to choose a specific person for this. So if you want to register ADRs, you have to remove that part out of the consultation moment and have it done and registered by another person in a different place. (Specialist physician)

> You are not going to ask all these ADR related questions to the patient during the consultation, but you are going the use the information that is already there because the patient has filled in a questionnaire. In that way your time during the consultation is

much more efficient, because you do not have to use the time to ask about ADRs. (Specialist physician)

3.2.2.2. Functional IT system.

Predominantly, all healthcare professionals emphasized the need for an adequate IT system that facilitates ADR registering. For instance, having functional fields that are easy and quick to access during a consultation and assisting in registering ADRs. Participants valued a single national system that facilitates information exchange with other relevant healthcare professionals in primary or secondary care:

> Very specifically, I think you should be able to register it with just a few clicks. So when I'm informed about an ADR, I open the ADR field and I should be able to go through it in 5 to 10 seconds with just 3 to 4 clicks. (Specialist physician)

> I do not understand that in the Netherlands, with all its advanced systems, this kind of simple information cannot be exchanged between healthcare professionals. It should be registered in a way that everyone, who is involved in the healthcare of a patient, has access to it. (Specialist physician)

3.3. Opportunity (social)

3.3.1. Barrier

3.3.1.1. Lack of support.

Participants experienced a lack of support from colleagues, as well as professional organizations, as a barrier for registering. According to some participants, the lack of protocols or guidelines emphasizing the need for ADR registering facilitated by hospitals or on nation-level likely hampered registration for many healthcare professionals:

> It would help a lot to understand why you should register an ADR. If you understand how an ADR occurs and what you may prevent by registering it, that would really help. So I think there is far too little attention from the Royal Dutch Pharmacists Association and Dutch Hospital Pharmacist Association for that. Far too little attention. (Hospital pharmacist)

> Almost everything is written down in guidelines and protocols. An important integral part is how we, as healthcare professionals, deal with the registering of ADRs … There are no protocols or guidelines in hospitals. That is my experience, and I have worked in a lot hospitals. (Hospital pharmacist)

3.4. Motivation (reflective)

3.4.1. Barrier

3.4.1.1. Importance is not recognized.

Not recognizing the added value of registering ADRs systematically was a barrier toward registering. Often, benefits for patients, optimization of future treatments, and research purposes were not seen. Some participants acknowledged that common, mild or moderate ADRs are part of the treatment, and they perceived no need to register these, which resulted in insufficient registration:

> You also need to see the importance of completing the separate ADR field. I really wonder if everyone sees the importance. If a specialist decides to discontinue a specific medicine, he may think: 'why should I register this in a separate field?' I understand that question, but the next person also wants to know because otherwise, he might prescribe the medication again. (Hospital pharmacist)

> Patients who take NSAIDs have stomach issues 20-30% of the time, so there is limited added value of registering that. You can register those ADRs, but it takes much time. It will not change the percentage that is affected by this ADR. So it does not add value to keep track of those kinds of ADRs. (Specialist physician)

3.4.2. Facilitator

3.4.2.1. Motivate registering.

To overcome this barrier, participants believed that to improve registration, motivation thereof should be increased. This could be done by emphasizing the added value, such as drug safety monitoring, decision support for the following specialist, or to conduct research for larger patient groups:

> It can be beneficial for the patients' treatment if you properly register that he developed diarrhoea caused by metformin, although it is a very well-known ADR. If someone new is going to change the medication for diabetes, he is aware of the fact that metformin is not the right choice for that patient. (Hospital pharmacist)

> Once you properly register it, you can do some retrospective research with it. Today 'Big Data' is very popular. If you register ADRs in a structured way, you can also do something with that information and prepare guidelines to avoid them in the future. (Specialist physician)

3.5. Motivation (automatic)

3.5.1. Barrier

3.5.1.1. Stuck in routine.

According to some participants, many healthcare professionals are used to record everything about a patient and their treatment in the clinical note. Registering an ADR in a separate field in the EHR is not part of this daily routine, which resulted in a barrier for registering:

> I think that the biggest barrier is that it is not part of the workflow, part of the normal work process. (Hospital pharmacist)

> Typing in the clinical note is just easier. Otherwise, you have to find the right place to register something and sometimes it is not in a logical place in the system. (Specialist physician)

4. Discussion

The results of this qualitative study provide insight into the perspectives of healthcare professionals on barriers and facilitators of systematically registering ADRs in hospital EHRs. The emerged barriers and facilitators occurred at all three components of the COM-B model, but they did not span all subcategories. Barriers for registering emerged at the opportunity level such as time constraints, an inadequate IT system and lack of support. There were also barriers at motivational and capability level including being stuck in daily routines and not having the right knowledge of recognizing ADRs. To facilitate in registering of ADRs, different solutions were suggested on different components of the COM-B model, such as improvement of the IT system and expanding the accountability for registration of ADRs.

The COM-B model indicates that the behavior of healthcare professionals regarding registering ADRs consists of an interaction of capability, opportunity, and motivation. Interventions need to change one or more of these components for behavior to change. This study suggests that it can start with increasing the general awareness of ADRs and the importance of registering them to

stimulate the willingness and motivation to enhance registering. Having a facilitated IT system, that is easy to access during daily consultations, including information about the impact of the ADR on the patient, could improve the registering of ADRs.

Overall, the findings of this qualitative study indicate that systematically registering ADRs should primarily add value to the process of medication prescribing and patient safety. Improvements of the IT system in the EHR could facilitate the exchange of registered ADR information with other relevant healthcare professionals which may prevent resuming medication that caused ADRs. For secondary use, registered ADR data in EHR could facilitate drug safety research and pharmacovigilance activities. This is in accordance with previous studies that showed the relevance to these purposes of registering ADRs in EHRs [14,23,24]. Trifirò G et al. indicates that registering ADRs in EHRs can result in the availability of large amount of data and gives the opportunity to study drug safety on a wider scale. However, it is important that this data on ADRs is of high quality (i.e. recognize the causality of the occurred ADR) which is in accordance with a barrier (lack of knowledge to recognize ADRs) that emerged from this study [25].

Differences in perspectives and behavior regarding registering ADRs in ADR fields were attributable to variation in EHR systems. Most participants mentioned that registering ADRs in a separate field was not incorporated in their daily routine, so ADRs were often registered in a way that is simple and convenient to the healthcare professional. This was in line with previous research [26]. Van der Linden et al. showed that systems can differ in the way ADRs are documented as well as how they alert to drug represcription [9]. Just as in our study, it stresses the need for an optimized system to document ADRs and sharing this registered information with all relevant healthcare professionals.

To the best of our knowledge, no studies have been conducted to identify barriers and facilitators for registering ADRs systematically by hospital pharmacists and specialist physicians in hospital EHRs. However, some other studies have described barriers and facilitators to spontaneous reporting of ADRs by healthcare professionals to pharmacovigilance centers [4,27,28]. These studies showed various reasons for the inadequately spontaneous reporting of ADRs, such as time restraints, the ADR not being directly linked to the used prescribed medication, difficulty in accessing reporting forms, lack of motivation, and some had problems with defining an ADR. Suggested methods to improve the spontaneous reporting of ADRs included more straightforward guidelines on what to report, education and training in recognizing ADRs, and developing a better understanding of the purpose to improve the quantity and quality of reports [4,27,29]. The conclusions of these studies are for some key points similar to our findings.

4.1. Strengths and limitation

The strength of this study is that it uses a semi-structured interview to provide in-depth insights into the perceived barriers and facilitators. Barriers and facilitators emerged at different components of the COMB-B model and could be effective in designing suitable improvements to optimize the quality and frequency of systematically registering ADRs in EHRs [9]. Systematically registering ADRs could enhance the exchange of safety data, preventing hospital admissions due to ADRs or undesirable represcriptions. It could also be an essential step in making the data accessible for patient registries, research or pharmacovigilance activities.

Several limitations of our study should be acknowledged. First, healthcare professionals were selected by purposive sampling, out of the network of pharmacovigilance Lareb, which could have resulted in selection bias. Because some of the participants were closely involved with other ADR related research of Lareb, their knowledge and awareness of the added value of registering ADRs could have been influenced. However, healthcare professionals who were not involved in ADR related research were also included and we made sure to receive sufficient opinions by including healthcare professionals from a variety of academic and general hospitals. On further notice, this study was conducted in Dutch settings with their used EHR systems. Some barriers are related to Dutch used EHR systems and could therefore differ between other countries and settings. So there could be a lack of global insights into the problem of registering ADRs in EHRs. Finally, the sample size across some of the specialist physicians is small. The goal was to collect a broad and diverse view of a heterogeneous population, who had in common that they all prescribed medication for chronic use. Data collection was ceased when saturation, i.e. when no new themes emerged from the data, was achieved. We did not aim to achieve saturation within medical specialties and involving more participants within medical specialties would not have altered in additional perspectives or information.

5. Future research

The present study identifies several barriers and proposes different facilitators to overcome them, which is a first step. The outcomes of this study could encourage further research should evaluate the effectiveness of different improvements or strategies proposed to improve registering ADRs. Future qualitative research may comprise focus groups with healthcare professionals, hospital departments, and software manufactures to discuss facilitators for improving ADR registering in EHRs and how to implement these facilitators in practice. Also including primary care healthcare professionals, such as general practitioners or pharmacists, could provide more insights into perceived barriers and facilitators regarding the exchange of ADR data from hospital EHRs. Finally, an international study to identify barriers and facilitators of registering of ADRs systematically could enhance more global insights.

6. Conclusion

This qualitative study highlights individual and system related barriers that influenced behavior of healthcare professionals toward systematically registering ADRs in EHRs. Classification of both barriers and facilitators based on the different components of the COM-B model could be effective in designing suitable interventions or improvements regarding the behavior of healthcare professionals toward the registering of ADRs in ADR fields in EHRs which may contribute to research purposes and enhancing patient safety.

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Data availability statement

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

ORCID

Naomi T. Jessurun http://orcid.org/0000-0002-8267-1259
Eugène P. van Puijenbroek http://orcid.org/0000-0002-2236-1398
Harald E. Vonkeman http://orcid.org/0000-0003-3792-7718
Martijn B. A. van Doorn http://orcid.org/0000-0003-1672-7899

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Appendix 1

Interview guide categorized in COM-B model

General questions

In what way are you informed when an adverse drug reaction occurs? (in other words, how do you know that a patient has an adverse drug reaction?)

Do you have any other comments/recommendations you would like to make on this topic?

Capability

What do you know about the possibility to register an adverse drug reaction in a structured way in the electronic health record? (In the corresponding adverse drug reaction field)

How do you register an adverse drug reaction in an structured way?

When you are informed about an adverse drug reaction, what is the main reason, for you, to register it in the electronic health record?

- What would be a reason for you, not to register an adverse drug reaction?
- What could help to register an adverse drug reaction in a structured way?

With what purpose do you register an adverse drug reaction?

Opportunity

What is a barrier that prevent you from registering an adverse drug reaction in a structured way?

- Can you elaborate these barriers?
- Are there any technical issues (IT/system related) problems that you encounter when registering an adverse drug reaction in a structured way? Can you elaborate them?
- Are there any time related issues when you want to register an adverse drug reaction in a structured way? Can you explain this?
- What could help you to overcome these problems/barriers?

To what extent is, registering an adverse drug reaction in a structured way, supported by your colleagues/unit/department?

How does this effect whether you will register an adverse drug reaction in a structured way?

- What could help to improve this?

Are there any guidelines that facilitate registering an adverse drug reaction in a structured way?

- Can you tell me more about these guidelines?

What are your experiences to what extent registering in a structured way is supported by the professional group (doctors, pharmacists) ?

- Would this help you to register in a structured way?

Motivation

According to you, what advantages are there for registering adverse drug reactions in a structured way?

- Can you elaborate these advantages?
- Are there any disadvantages?

In general, what could help you to register an adverse drug reaction in a structured way?

- Which things needs to be changed?