

Pharmacists' perception of educational material to improve patient safety

A cross-sectional study on practices and awareness in Germany

André Said, PhD, RPh^{a,*} , Leonard Freudewald, RPh^a, Natalie Parrau, MSc, RPh^a, Matthias Ganso, PhD, RPh^a, Martin Schulz, Prof, PhD, RPh^{a,b} 

Abstract

Educational material (EM) addresses particular safety information of medicinal products to healthcare professionals and patients. Since 2016, German national competent authorities label approved EM with a Blue Hand symbol. However, data is scarce regarding its usability as a safety communication tool in pharmacies to improve patient safety. The purpose of this study is to investigate for the first time pharmacists' awareness and perception of EM in the setting of community and hospital pharmacies in Germany.

The Drug Commission of German Pharmacists surveyed its nationwide network of 677 community and 51 hospital reference pharmacies, to investigate their awareness and perception of EM. The survey was conducted between January 16 and February 10, 2020 using SurveyMonkey. Data were analyzed using Microsoft Excel.

A total of 373 community and 32 hospital pharmacists participated; response rates were 55.1% and 62.8%, respectively. Overall, 320 (85.8%) community and all hospital pharmacists confirmed awareness of EM. Community and hospital pharmacists fully ($n=172$, 46.9% and $n=9$, 28.1%) or rather ($n=109$, 29.7% and $n=10$, 31.3%) agreed that EM for healthcare professionals is suitable to reduce risks of medicinal products. Moreover, 237 (64.7%) community and 17 (53.1%) hospital pharmacists confirmed to inform patients or care facilities about EM. Asking pharmacists on their personal perception of EM, the refinement of readability and accessibility was indicated.

Pharmacists confirm awareness of EM and its suitability as a safety communication tool. However, from a pharmacists' perspective, the applicability and readability of EM still needs further adjustment to improve patient safety.

Abbreviations: DHPC = direct healthcare professional communication, EM = educational material, MAH = marketing authorization holder.

Keywords: educational material, healthcare professional, pharmacy, safety, survey

1. Introduction

Risk minimization measures are interventions intended to prevent or reduce the occurrence of adverse reactions associated with the exposure to a medicinal product, or to reduce their severity on patients.^[1] The safety information included in the summary of product characteristics and the package leaflet, are part of the routine risk minimization measures, required for marketing authorization.^[2]

However, if risk minimization measures are assumed to be insufficient, the European Medicines Agency as a regulatory authority can request additional risk minimization measures.^[1,3] In the USA, the Food and Drug Administration can comparably request risk evaluation and mitigation strategies which may include medication guides, communication plans, and elements to ensure safe use.^[4,5] In fact, the field of additional risk minimization measures or risk evaluation and mitigating strategies is continuously developing.

Editor: Sreenath Nair.

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

All authors are employees of the ABDA – Federal Union of German Associations of Pharmacists e. V., Berlin, Germany.

M. Schulz has received speaker honoraria from Novartis and Sanofi, all outside the submitted work. His department has received research grants from the ABDA, Chambers of Pharmacists, Lesmueller Foundation, Foundation Pharmaceutical Care, and the Federal Ministry of Health, Germany, all outside the submitted work.

The authors have no conflicts of interest to disclose.

Supplemental Digital Content is available for this article.

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

^a Drug Commission of German Pharmacists (AMK), Heidestraße 7, ^b Institute of Pharmacy, Freie Universität Berlin, Berlin, Germany.

* Correspondence: André Said, Drug Commission of German Pharmacists (AMK), Heidestraße 7, 10557 Berlin, Germany (e-mail: A.Said@arzneimittelkommission.de).

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How to cite this article: Said A, Freudewald L, Parrau N, Ganso M, Schulz M. Pharmacists' perception of educational material to improve patient safety: a cross-sectional study on practices and awareness in Germany. *Medicine* 2021;100:11(e25144).

Received: 23 October 2020 / Received in final form: 16 February 2021 / Accepted: 19 February 2021

<http://dx.doi.org/10.1097/MD.00000000000025144>

In the European Union, additional risk minimization measures can range from Direct Healthcare Professional Communication (DHPC) over controlled access or distribution programs to interactive web-based tools and educational material (EM).^[6,7] This EM, as a part of the marketing authorization of a medicinal product, contains specific safety information and addresses relevant risk minimization measures to improve patient safety.^[8–10] The provision of EM can be necessary to maintain a positive benefit-risk ratio of the medicine and can be directed to healthcare professionals and patients (or care-givers).^[11–14]

For example, EM may help to remind patients about specific safety information they need to be aware of before and during treatment. EM in turn may outline what healthcare professionals need to consider when prescribing or administering a drug, or address required (regular) risk monitoring. Thus, EM exceeds mere awareness of the product information and needs to be aligned to the target group.^[15] To avoid patients to become confused or overwhelmed with the complexity of the content, readability and understandability of safety information is of highest importance.^[16] However, most research in the field of (the effectiveness of) risk minimization measures is performed in relation to a specific risk or medicine.^[17] Evaluation of problems and obstacles regarding the general usability of EM to improve patient safety is scarce. In fact, no comprehensive data exist from the perspective of German community and hospital pharmacists.

In Germany, the national competent authorities, the Federal Institute for Drugs and Medical Devices as well as the Paul-Ehrlich-Institute for vaccines and biomedicines, approve EM, which is labelled with a Blue Hand symbol since December 1, 2016.^[18,19] EM is provided by the marketing authorization holders (MAH) and can vary between booklets, checklists, alert cards, audio/video-guides, and others.^[20–22] As of June 18, 2020, almost 200 active substances are listed, for which EM is obliged in Germany.^[23]

As an independent national pharmacovigilance centre, the Drug Commission of German Pharmacists collects, assesses, and evaluates risks of medicinal products spontaneously reported by German pharmacists, as defined by § 63 of the German Medicinal Products Act.^[24,25] The Drug Commission of German Pharmacists is organized within the ABDA - Federal Union of German Associations of Pharmacists, the umbrella organization of all pharmacists in Germany.

To get access to comprehensive data on safety-related issues in pharmacy practice, the Drug Commission of German Pharmacists established a nationwide network of reference community and hospital pharmacies of various sizes, in terms of staff and turnover, and geographical locations.^[26,27]

We aimed to survey the reference pharmacies exploring pharmacists' perceptions of EM in everyday practice. In particular, barriers and obstacles regarding the usability of EM should be requested as well as suggestions to potentially overcome these issues.

2. Methods

2.1. The reference pharmacy network

At the time of the survey, the Drug Commission of German Pharmacists reference network included 677 community and 51 hospital pharmacies, respectively, and thus, comprised 3.5% of all community, and 13.7% of all hospital pharmacies in Germany.^[28] Reference pharmacies are appointed by the 17

State Chambers of Pharmacists and are distributed throughout the country. For nomination, several quality criteria apply: Verification of an established quality management system, high commitment in areas of education and advanced vocational training, and affinity for digital correspondence. Upon appointment, reference pharmacists were asked to accept the terms of agreement to participate in surveys. However, pharmacists have the option not to participate or not to respond to selected questions. Available characteristics of the reference pharmacies are provided in Supplementary material 1, <http://links.lww.com/MD/F895>.

Ethics Approval: Ethical approval was not required for the present study as no personal identifying information was collected.

2.2. Online Survey

A survey using the SurveyMonkey online tool (Dublin, Ireland) was developed. The authors compiled, evaluated and reviewed the questions until agreement (Supplementary material 2, <http://links.lww.com/MD/F896>). On December 19, 2019, reference pharmacies were notified via email about the upcoming online-survey and provided with the questionnaire on beforehand. The survey was launched on January 16, 2020. An email was sent to all reference pharmacies including a link to the ten-questions-survey. Reminders were sent on January 30, 2020 and February 6, 2020 to encourage participation. The survey concluded on February 11, 2020.

All reference pharmacists, who did not participate in the survey, were contacted via SurveyMonkey on February 24, 2020, to inquire the reason for non-attendance. This follow-up survey concluded on March 9, 2020.

2.3. Design and content of the questionnaire

The survey was structured in three parts, addressing EM in general, EM for health care professionals and for patients. The domains of interest comprised

- (1) the awareness and handling of EM in everyday practice,
- (2) pharmacists' perceptions of EM to improve patient safety, and
- (3) the identification of barriers and obstacles regarding the usage of EM in a community and hospital pharmacy setting.

Most questions were multiple choice. One question requested answers on a 5-point Likert-type scale of "fully agree" to "strongly disagree." For some questions, multiple answers and/or additional free-text comments were allowed. Available free-text answers were independently analyzed and summarized/categorized, by 2 authors. Disagreements were resolved by discussion.

2.4. Statistical Analyses

Descriptive statistics were compiled. The data were summarized in 2 datasets, for community and hospital reference pharmacists, respectively, and analyzed using Microsoft Office Excel 2016 (Microsoft, Redmond, WA, USA).

3. Results

In total, 373 community and 32 hospital pharmacists participated; response rates of 55.1% and 62.8%, respectively.

Table 1**A – C Educational material (EM) in pharmacy practice.****A) Awareness of educational material**

	Respondents [n (%)]	
	Community pharmacists (n=373)	Hospital pharmacists (n=32)
Yes	320 (85.8)	32 (100)
No	50 (13.4)	0
Not reported	3 (0.8)	0

B) Receipt of educational material

	Community pharmacists (n=370)	Hospital pharmacists (n=32)
Via postal shipping	316 (85.4)	32 (100)
Via fax	51 (13.8)	5 (15.6)
Via email	102 (27.6)	19 (59.4)
In-house distribution	20 (5.4)	2 (6.3)
Other	37 (10.0)	9 (28.1)
No receipt of educational material, thus far	34 (9.2)	0

C) To acquaint about educational material

	Community pharmacists (n=372)	Hospital pharmacists (n=32)
Homepage of the national competent authority	120 (32.3)	20 (62.5)
Homepage of the marketing authorization holder	148 (39.8)	16 (50.0)
Via pharmacy software	123 (33.1)	4 (12.5)
Others	22 (5.9)	8 (25.0)
No need to acquaint about educational material	82 (22.0)	3 (9.4)
Unknown how to acquaint about educational material	49 (13.2)	1 (3.1)

Statement of community and hospital pharmacists regarding (A) their awareness of EM, (B) the receipt of EM, and (C) the use of information platforms for EM. For (B) and (C), multiple answers were allowed. The narration of individual free text answer is not depicted.

3.1. Pharmacists' awareness of EM

Reference pharmacists largely confirmed their awareness of EM. In fact, nearly 86% of community and all hospital pharmacists responded to be familiar with EM in everyday practice (Table 1A). EM is received most often via postal shipping, followed by email and fax (Table 1B). Overall, 21 community pharmacists access EM via pharmacy software and six hospital pharmacists mentioned pharmacy sales representatives (free-text comments). When enquiring about existing EM, most reference pharmacists use the national competent authorities homepages and the concerned MAH's website (Table 1C).

3.2. Pharmacists providing EM for health care professionals

EM for health care professionals can address physicians, pharmacists and representatives of other health professions.

Thus, asking if and to whom respective EM is forwarded, community pharmacists most often named pharmaceutical staff (also in subsidiaries), followed by resident physicians in private medical practice and (long-term) care facilities (Table 2). Hospital pharmacists provide EM most often to physicians or the respective hospital ward and to members of the hospital's drug commission.

3.3. Pharmacists' perceptions of EM for health care professionals

Using a 5-point Likert-type scale ranging from "fully agree" to "strongly disagree," reference pharmacists were asked to state their personal level of agreement to seven statements concerning several attributes of EM for health care professionals. As shown in Fig. 1A-B, the consent of community and hospital pharmacists was generally high. More precisely, pharmacists fully or rather

Table 2**Pharmacists distribute educational material (EM) to other healthcare professionals.****Forwarding educational material to other healthcare professionals**

	Respondents [n (%)]	
	Community pharmacists (n=366)	Hospital pharmacists (n=32)
Pharmaceutical staff (also in subsidiaries)	269 (73.5)	15 (46.9)
Physicians or hospital wards	23 (6.3)	28 (87.5)
Members of the hospital's drug commission/committee	6 (1.6)	19 (59.4)
Resident physicians in private practice	95 (26.0)	1 (3.1)
(Long-term) care facilities	68 (18.6)	3 (9.4)
Others	14 (3.8)	3 (9.4)
Educational material is generally not forwarded	53 (14.5)	2 (6.3)

Community and hospital pharmacists report their EM distribution practice. Multiple answers were allowed. The narration of individual free text answer is not depicted.

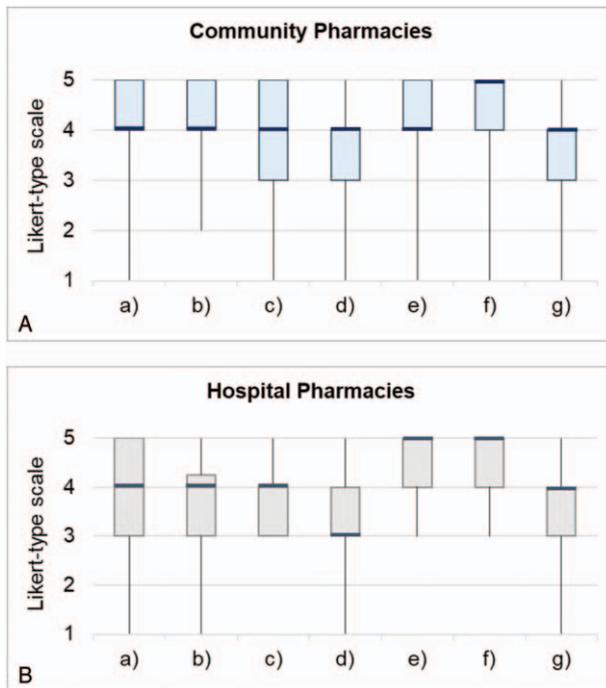


Figure 1. A-B Perceptions of educational material (EM) for healthcare professionals. Consent of (A) community and (B) hospital pharmacists was rated [on a 5-point Likert-type scale from 1 “strongly disagree” to 5 “fully agree”] to the following statements: a) “EM is suitable to reduce risks of medicinal products.”; b) “EM focusses on concrete safety concerns.”; c) “EM contains clear information as well as precise measures for risk minimization.”; d) “EM is understandable and measures are doable within an appropriate time.”; e) “EM is identifiable.”; f) “EM is not combined with advertising.” and g) “EM is easy to find.”. Pharmacists selecting “prefer not to say” are not depicted. Box plots represent the median (horizontal line) and interquartile range (box) and whiskers extend to the minimum and maximum values. Number of respondents vary for community (n=357–367) and hospital pharmacists (n=31–32).

agreed that EM: “. . . is suitable to reduce risks of medicinal products.”, “. . . focusses on concrete safety concerns.” and “. . . contains clear information as well as precise measures for risk minimization.” (Supplementary material 3, <http://links.lww.com/MD/F897>). Moreover, the majority of community and hospital pharmacists fully agreed or rather agreed, that EM is easy to identify and that it is not combined with advertising. Finally, most pharmacists rather or partly agreed that EM is easy to find, and that EM is regarded understandable and the respective measures are doable within an appropriate time.

3.4. Pharmacists’ experiences with EM for patients

The majority of reference pharmacists confirmed to actively inform patients or supplied (long-term) care facilities about existing EM for patients (Table 3A). However, the question whether patients, for example during a consultation, actively present EM, such as a patient alert card, was denied by most community and hospital pharmacists, respectively (Table 3B). Likewise, when asking about the frequency of requests for EM within the last three months prior to the survey, the majority of community and almost all hospital pharmacists stated, that patients did not ask for or demand EM at all (Table 3C). At least, 12.5% and 18.8% of community pharmacists estimated a request once or 2 to 5 times within the last three months.

3.5. Barriers and obstacles in the use of EM

Reference pharmacists were asked for their individual perspective on current barriers and obstacles regarding the usage of EM and additionally were requested to give suggestions for improvement. The survey differentiated between EM for healthcare professionals and patients.

As outlined in Tables 4 and 5, many pharmacists explicitly answered, that no barriers or obstacles were currently seen and that no suggestions could be made either, from their point of view. However, the majority addressed current issues and suggested respective measures for improvement.

Table 3

A – C Pharmacists’ view on educational material for patients.

A) Counselling patients about educational material

	Respondents [n (%)]	
	Community pharmacists (n=366)	Hospital pharmacists (n=32)
Yes	237 (64.7)	17 (53.1)
No	87 (23.8)	12 (37.5)
Not reported	42 (11.5)	3 (9.4)

B) Patients actively showing educational material to pharmacists

	Community pharmacists (n=366)	Hospital pharmacists (n=32)
Yes	83 (22.7)	3 (9.4)
No	275 (75.1)	17 (53.1)
Not reported	8 (2.2)	12 (37.5)

C) Patients requesting educational material (within the last three months)

	Respondents [n (%)]				
	Never	Once	2–5 times	6–10 times	> 10 times
Community pharmacists (n=367)	242 (65.9)	46 (12.5)	69 (18.8)	8 (2.2)	2 (0.5)
Hospital pharmacists (n=31)	29 (93.6)	1 (3.2)	1 (3.2)	0	0

Statement of community and hospital pharmacists whether (A) they counsel patients about EM and (B) patients present EM during consultation. (C) Frequency of patients actively requesting EM from pharmacists. Data is shown in relation to given rates within the past three months (never, once, 2–5 times, 6–10 times, > 10 times).

Table 4
Difficulties in handling educational material (EM).

Problems/Obstacles in the use of educational material in everyday pharmacy practice		Response; Respondents (n)
Educational material for healthcare professionals		
Community pharmacists (n=251)	<ul style="list-style-type: none"> No current problems/obstacles (87) Generally high effort regarding time, personnel and bureaucracy (44) Inconvenient/complicated access to and/or availability of EM (35) Difficult handling of EM (especially in hard copy) (21) Stressful to adequately consider EM in (daily) information flood (15) 	
Hospital pharmacists (n=24)	<ul style="list-style-type: none"> No current problems/obstacles (8) Inconvenient/complicated access to and/or availability of EM (6) Stressful to adequately consider EM in (daily) information flood (4) Generally high effort regarding time, personnel and bureaucracy (3) Readability: Information too long and/or hard to understand (3) 	
Educational material for patients		
Community pharmacists (n=249)	<ul style="list-style-type: none"> No current problems/obstacles (78) Readability: Information too long and/or difficult to understand (35) Difficult handling of EM, especially in print/hard copy (27) Generally high effort regarding time, personnel and bureaucracy (23) Patients are still unfamiliar with EM (21) 	
Hospital pharmacists (n=24)	<ul style="list-style-type: none"> No current problems/obstacles (7) No/too little contact between hospital pharmacy staff and patients (5) Inconvenient/complicated access to and/or availability of EM (5) Readability: Information too long and/or difficult to understand (1) 	

Community and hospital pharmacists comment on respective problems/obstacles in the use of EM for healthcare professionals and for patients, respectively. The four to five most common answers are outlined.

Regarding EM for healthcare professionals, community and hospital pharmacists criticized the inconvenient or complicated access to and availability of EM. In addition, community and hospital pharmacists stated, that the adequate consideration of EM in daily practice is burdensome, because of the general information overload. Likewise, community pharmacists refer to the difficult handling of EM for healthcare professionals and for patients, especially hard copy material, in terms of quantity and storage. Concerning EM for patients, community and hospital pharmacists refer to aspects of readability: the (written)

information is too long and/or difficult to understand. Moreover, community pharmacists assume that patients are still unfamiliar with (the context of) EM.

3.6. Pharmacists' suggestions for improvement

Both, community and hospital pharmacists refer to the availability of EM and propose a single central online-database for EM for healthcare professionals and further suggest to limit the amount of information and to depict the respective content more concisely. Moreover, community pharmacists suggest to implement EM in pharmacy software, triggering an automatic notification, if a respective medicinal product contains EM. Concerning EM for patients, community pharmacists suggest to further simplify the content by using lay language and by increasing the number of pictures or pictograms. Both, community and hospital pharmacists additionally propose to provide a reference to existing EM by printing the Blue Hand symbol or a QR-code (with a link to the EM) on the packages of respective medicinal products, to increase the awareness and facilitate accessibility.

4. Discussion

For the first time, the use of EM by German pharmacists was comprehensively assessed, including their experiences during consultation with patients. EM comprise additional risk minimization measures to promote the safe and effective use of medicinal products. EM should provide detailed information and describe concisely the actions that are required to prevent and minimize risks to patients.^[29–31] For the first time, this study shows that pharmacists consider EM as suitable to reduce risks of medicines and address specific safety concerns to improve patient safety.

A recent study proposed, that amongst other specific risk communication tools (e.g. DHPC) health care professionals in

Table 5
Improving the handling of educational material (EM).

Suggestions how to improve current use or handling of educational material		Response; Respondents (n)
Educational material for healthcare professionals		
Community pharmacists (n=185)	<ul style="list-style-type: none"> Implement EM in pharmacy software / notifications via software (39) <ul style="list-style-type: none"> No suggestions can be made (35) Limit the amount of information and depict content concisely (24) Reduction of bureaucratic burden in everyday practice and/or remuneration for (additional) effort (22) <ul style="list-style-type: none"> Establish <u>one</u> central online database for EM (18) 	
Hospital pharmacists (n=18)	<ul style="list-style-type: none"> Direct notification for (new) EM, e.g. via email (5) <ul style="list-style-type: none"> Establish <u>one</u> central online database for EM (4) Limit the amount of information and depict content concisely (3) No suggestions can be made (3) 	
Educational material for patients		
Community pharmacists (n=184)	<ul style="list-style-type: none"> Implement EM in pharmacy software / notifications via software (36) <ul style="list-style-type: none"> No suggestions can be made (34) Use of understandable (layman) and multilingual texts; pictures (25) Reduction of bureaucratic burden in everyday practice and/or remuneration for (additional) effort (20) Provide symbol (Blue Hand) or QR-code (link) on packages (18) 	
Hospital pharmacists (n=18)	<ul style="list-style-type: none"> Establish ward-based pharmacists (3) <ul style="list-style-type: none"> Provide symbol (Blue Hand) or QR-code (link) on packages (3) Direct notification for (new) EM, e.g. via email (3) No suggestions can be made (3) 	

Community and hospital pharmacists propose potential options to improve the usage of EM for healthcare professionals and for patients, respectively. The four to five most common answers are outlined.

several European countries are least aware of EM. This may refer to the fact, that EM has not been available for long enough, or is still not issued for a large enough number of medicinal products.^[32] Thus, the positive effect on patient health and safety is still limited.^[33,34]

4.1. Differences in the community and hospital pharmacy setting

This survey reveals that participating pharmacists confirmed a high awareness of EM and thus, take responsibility to forward and distribute the respective information to the addressees, which are distinct in the community and the hospital pharmacy settings. For example, German hospital law and the Ordinance on the Operation of Pharmacies intend a hospital's drug commission, consisting of physicians and pharmacists. Its primary task is to prepare and update a list of medicinal products, intended for ongoing safe use in the hospital. Thus, the information of its members about EM and other safety information (e.g. DHPC) primarily by hospital pharmacists is reasonable.

Though pharmacists frequently confirmed to actively inform patients about EM, hospital pharmacists also criticized to have no or too little contact to inpatients. It was therefore suggested in this survey, to regularly implement ward-based pharmacists, to improve the multidisciplinary care of patients,^[35,36] also regarding the use of EM. However, until yet, the nationwide mandatory inclusion of ward pharmacists in German hospitals is not statutory.

4.2. Pharmacists preferably access EM in electronic form

The concerned pharmaceutical company compiles and distributes EM, still mainly via postal shipping; a cost-intensive and most notably time-delaying process. As this survey reveals, pharmacists prefer the direct information via email (or other electronic implementations), to reduce the high amount of hard copy material in their shelves. Consistent with previous studies, pharmacists point out the constantly high level of stress in everyday practice.^[37] This can at least in part be attributable to continuously incoming printed news, sales promotion and other (drug safety) information. This results in lack of time and reduced capacity to adequately consider the risk minimization measures provided as EM, with possibly negative impacts on patient safety.^[38,39]

Suggestions to potentially overcome these limitations from the perspective of pharmacists, focus on electronically implemented EM, for example, in one central web-based database or in the pharmacy software to allow its access on demand.^[40,41] In Germany, EM is currently available on the homepages of the respective national competent authorities (Federal Institute for Drugs and Medical Devices and Paul-Ehrlich-Institute) and of the concerned pharmaceutical company. However, one single comprehensive database providing all existing EM, as proposed, is still missing. Since July 2017, a growing number of EM is also implemented in the pharmacy software, complementary to the summary of product characteristics and the package leaflet.^[42] This service is probably still unknown for some community and hospital pharmacists, as the results indicate. Assuming that the technical interface can be established, the implementation in pharmacy software would be a prerequisite to constantly (re-) notify pharmacists about available EM, e.g. via pop-up windows, directly when counselling and dispensing medicines to patients.

4.3. The Blue Hand symbol is considered useful to enhance awareness

Officially approved EM can be identified by a symbol of a Blue Hand since December 2016.^[10] This Blue Hand refers to the Red Hand symbol, introduced in 1969 by the German Pharmaceutical Industry Association, to indicate the importance of DHPC as an intervention to deliver important safety information directly to healthcare professionals. Since then, the Red Hand is the common way to communicate new and emerging risks of medicinal products in Germany.^[43] In conjunction to this, the unique Blue Hand should signal that the respective material does not contain advertising and needs to be considered thoroughly.

For the first time, pharmacists largely confirmed that EM is easily identifiable and not combined with advertising. Pharmacists appreciate the unique label of a Blue Hand and suggest to print this symbol on all packages of concerned medicinal products. This could enhance the awareness of EM specifically amongst patients, who are still (largely) unfamiliar with EM, as participating pharmacists assumed. Similar attributions are anticipated for boxed warnings or the black triangle symbol (▼) for newly approved drugs, to promote pharmacovigilance.^[44,45]

4.4. Pharmacists assume to improve patient awareness of EM

Pharmacists barely received direct patients' requests for EM within the last three months prior to the survey. These results may indicate, that patients are largely uninformed or unaware about EM or less prepared to show a therapy pass or patient alert cards to pharmacists (or other health care professionals) during consultation. However, caution is advised when interpreting this finding. It remains speculative, whether for example, the prescriber were not instructing patients about EM, or if patients even feel overprotected, due to the repetitious reminding of EM at each consultation, and thus avoid to actively show or request EM. The latter aspect might especially pertain for medicines of high turnover and risks of high prevalence or relevance. For example, patient alert cards addressing the teratogenic effect of valproate or certain retinoids are considered an integral part of each patient consultation in the framework of a pregnancy prevention program.^[46,47] Physicians and pharmacists, likewise, need to confirm, that women understand the need for effective contraception and accept to undergo regular follow-up and pregnancy testing. Here, a patient-specific (electronic) documentation, e.g. in the pharmacy software, seems reasonable.

A proper understanding of the risks addressed by EM is key to verify that patients implement and maintain the actions that are required to ensure the safe use of their medicine. As pharmacists indicate in this survey, the refinement of readability of EM by using lay language and the (additional) use of pictures or pictograms could be helpful to counsel patients adequately, and to promote a necessary self-education. The use of validated readability scores could be helpful to estimate reading difficulties of EM by word and sentence complexity.^[48] Limiting the length of EM and use of visual aids could further enhance understandability, as pharmacists proposed. Thus, validation of tools for evaluating subjects' satisfaction with EM, similar as for package leaflets, is recommended.^[49] Moreover, the (additional) provision of audio/video-guides could overcome difficulties in understanding paper-based EM.^[50] However, further studies

are required to evaluate which measures can enhance the effectiveness of EM to improve patient safety.

4.5. Final remark

Pharmacists confirmed awareness of EM and highly appreciate the Blue Hand symbol as a unique EM identifier, to further enhance patients' awareness of EM. However, to support EM usability in everyday practice, pharmacists demand an easy electronic access alongside adequate technical support for notification of existing EM. Simplification of EM is also highly recommended to further improve patient safety.

4.6. Limitations

The reference pharmacists are probably not representative of the larger cohort of German community and hospital pharmacists. It is unknown whether the data provided are based on pharmacy records or from recall, leading to more subjective answers. In addition, the risk of misclassification and imprecision is increased when one participant answered on behalf of the pharmaceutical staff, who likewise use and distribute EM in pharmacy practice. Therefore, the questionnaire was provided on beforehand and the survey was conducted a month long, allowing a comprehensive internal discussion of the requested information.

The response rates of 55.1% and 62.8%, respectively, increase the potential risk of bias, overestimating pharmacists' awareness of EM.^[51] However, the follow-up survey confirmed that non-participation was mainly not attributed to the lack of knowledge about EM, but to the lack of time (Supplementary material 4, <http://links.lww.com/MD/F898>). Compared to other surveys, the response rate and number of participating pharmacists were high.^[52–54]

5. Conclusion

Successful implementation of EM requires contributions from all stakeholders, including MAH, regulators, healthcare professionals and patients. This survey is the first to comparatively explore German community and hospital pharmacists' perceptions of EM. Pharmacists confirm the substantial use and awareness of EM, which is considered suitable to improve patient safety. However, obstacles and barriers were identified; for example, readability and understandability of EM needs improvement. These new insights may stimulate decision making and specify best practices regarding the requirements for EM in future, to adequately and sustainably prevent harm to patients and ensure their safety.

Acknowledgments

We thank all pharmacists who participated in this survey.

Author contributions

Conceptualization: André Said, Leonard Freudewald, Natalie Parrau, Matthias Ganso, Martin Schulz.

Data curation: André Said, Leonard Freudewald, Matthias Ganso, Martin Schulz.

Formal analysis: André Said, Leonard Freudewald, Natalie Parrau, Matthias Ganso.

Investigation: André Said, Leonard Freudewald, Natalie Parrau, Matthias Ganso, Martin Schulz.

Methodology: André Said, Leonard Freudewald, Natalie Parrau, Matthias Ganso, Martin Schulz.

Project administration: André Said, Martin Schulz.

Supervision: André Said, Martin Schulz.

Validation: André Said, Martin Schulz.

Visualization: André Said, Leonard Freudewald, Natalie Parrau, Matthias Ganso.

Writing – original draft: André Said, Martin Schulz.

Writing – review & editing: André Said, Leonard Freudewald, Natalie Parrau, Matthias Ganso, Martin Schulz.

References

- [1] European Medicines Agency. Guideline on good pharmacovigilance practices (GVP): Module XVI - Risk minimisation measures: selection of tools and effectiveness indicators (Rev 2) [EMA/204715/2012 Rev 2*]. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-xvi-risk-minimisation-measures-selection-tools_en-3.pdf. Accessed September 9, 2020.
- [2] European Medicines Agency. Guideline on good pharmacovigilance practices (GVP): Module V - Risk management systems (Rev 2) [EMA/838713/2011 Rev 2*]. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2_en.pdf. Accessed September 9, 2020.
- [3] Rubino A, Artime E. A descriptive review of additional risk minimisation measures applied to EU centrally authorised medicines 2006-2015. *Expert Opin Drug Saf* 2017;16:877–84.
- [4] Gassman AL, Nguyen CP, Joffe HV. FDA Regulation of prescription drugs. *N Engl J Med* 2017;376:674–82.
- [5] Hung A, Sieluk J, Doshi P. The untapped potential of pharmacy leaflets for informing patients about drug benefits and risks. *JAMA Intern Med* 2016;176:11–2.
- [6] European Medicines Agency. Guideline on good pharmacovigilance practices (GVP): Module XVI Addendum I - Educational materials [EMA/61341/2015]. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/12/WC500198761.pdf. Accessed September 9, 2020.
- [7] European Medicines Agency. Guideline on good pharmacovigilance practices (GVP): Module XV - Safety communication (Rev 1) [EMA/118465/2012 Rev 1*]. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-xv-safety-communication-rev-1_en.pdf. Accessed September 9, 2020.
- [8] Lem J, Younus M, Aram JA, et al. Evaluation of the effectiveness of additional risk minimization measures for voriconazole in the EU: findings and lessons learned from a healthcare professional survey. *Pharmaceut Med* 2019;33:121–33.
- [9] Zomerdijs IM, Sayed-Tabatabaei FA, Trifirò G, et al. Risk minimization activities of centrally authorized products in the EU: a descriptive study. *Drug Saf* 2012;35:299–314.
- [10] Heymans L, Huber M, Paeschke N, et al. Schulungsmaterial zur Minimierung von Arzneimittelrisiken. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2018;61:1088–92.
- [11] Smith MY, Morrato E. Advancing the field of pharmaceutical risk minimization through application of implementation science best practices. *Drug Saf* 2014;37:569–80.
- [12] Banerjee AK, Zomerdijs IM, Woode S, et al. Post-approval evaluation of effectiveness of risk minimisation: methods, challenges and interpretation. *Drug Saf* 2014;37:33–42.
- [13] Giguère A, Légaré F, Grimshaw J, et al. Printed educational materials: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev* 2012;10:CD004398.
- [14] Zografos LJ, Andrews E, Wolin DL, et al. Physician and patient knowledge of safety and safe use information for aflibercept in Europe: evaluation of risk-minimization measures. *Pharmaceut Med* 2019;33:219–33.
- [15] Hohmann NS, Garza KB, Surry D, et al. Communicating benefits and risks of generic drugs to consumers: Patient and caregiver opinions of two

- FDA-developed educational materials. *Res Social Adm Pharm* 2019; 15:1489–93.
- [16] Wilson EAH, Wolf MS. Working memory and the design of health materials: a cognitive factors perspective. *Patient Educ Couns* 2009;74:318–22.
- [17] Artime E, Qizilbash N, Garrido-Esteva M, et al. Are risk minimization measures for approved drugs in Europe effective? A systematic review. *Expert Opin Drug Saf* 2019;18:443–54.
- [18] Paul-Ehrlich-Institut. Educational Material. Available at: <https://www.pei.de/EN/medicine-safety/educational-material/educational-material-node.html>. Accessed September 9, 2020.
- [19] Bundesinstitut für Arzneimittel und Medizinprodukte. Educational material. Available at: https://www.bfarm.de/EN/Drugs/vigilance/InformationRisks/EducationalMaterial/_node.html. Accessed September 9, 2020.
- [20] Radadiya D, Gonzalez-Estrada A, Lira-Vera JE, et al. Colonoscopy videos on YouTube: are they a good source of patient education? *Endosc Int Open* 2020;8:E598–606.
- [21] Warner ET, Kennedy M, Maschke A, et al. Evaluation of existing patient educational materials and development of a brochure for women with dense breasts. *Breast* 2020;50:81–4.
- [22] Artime E, Kahlon R, Méndez I, et al. Linking process indicators and clinical/safety outcomes to assess the effectiveness of abatacept (Orencia) patient alert cards in patients with rheumatoid arthritis. *Pharmacoepidemiol Drug Saf* 2020;29:664–74.
- [23] Bundesinstitut für Arzneimittel und Medizinprodukte. Wirkstoffe und Arzneimittel, für die die Erstellung von Schulungsmaterialien beauftragt worden ist. Available at: <https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/Tabelle-educatmaterial.html>. Accessed September 9, 2020.
- [24] Ganso M, Goebel R, Melhorn S, et al. Lipidpneumonie durch Lipid-haltige Nasensprays und -tropfen. *Laryngorhinootologie* 2016; 95:534–9.
- [25] Said A, Ganso M, Parrau N, et al. Medikationsfehler in der Praxis: Die Bedeutung von Look- und Soundalikes als Mitursache von Medikationsfehlern. *Bulletin zur Arzneimittelsicherheit* 2019;24–36.
- [26] Said A, Ganso M, Freudewald L, et al. Trends in dispensing oral emergency contraceptives and safety issues: a survey of German community pharmacists. *Int J Clin Pharm* 2019;41:1499–506.
- [27] Said A, Goebel R, Ganso M, et al. Drug shortages may compromise patient safety: results of a survey of the reference pharmacies of the Drug Commission of German Pharmacists. *Health Policy* 2018;122:1302–9.
- [28] ABDA - Federal Union of German Associations of Pharmacists. German Pharmacies: Figures Data Facts 2020. Berlin. Available at: <https://www.abda.de/aktuelles-und-presse/publikationen/detail/german-pharmacies-figures-data-facts-2019/>. Accessed September 9, 2020.
- [29] Nkeng L, Cloutier A-M, Craig C, et al. Impact of regulatory guidances and drug regulation on risk minimization interventions in drug safety: a systematic review. *Drug Saf* 2012;35:535–46.
- [30] Kludas L, Kriston L, Metzner F, et al. Steigerung von elterlichem Gesundheitswissen durch schriftliches Informationsmaterial unter Berücksichtigung des familiären sozioökonomischen Status: Eine randomisiert-kontrollierte Studie. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2018;61:385–93.
- [31] Hoeve CE, Francisca RDC, Zomerdijs I, et al. Description of the risk management of medication errors for centrally authorised products in the European Union. *Drug Saf* 2020;43:45–55.
- [32] Vries ST de, van der Sar, Maartje JM, et al. Safety communication tools and healthcare professionals' awareness of specific drug safety issues in Europe: a survey study. *Drug Saf* 2018;41:713–24.
- [33] Grudniewicz A, Bhattacharyya O, McKibbin KA, et al. Redesigning printed educational materials for primary care physicians: design improvements increase usability. *Implement Sci* 2015;10:156.
- [34] Grudniewicz A, Kealy R, Rodseth RN, et al. What is the effectiveness of printed educational materials on primary care physician knowledge, behaviour, and patient outcomes: a systematic review and meta-analysis. *Implement Sci* 2015;10:164.
- [35] Langebrake C, Hilgarth H. Clinical pharmacists' interventions in a German university hospital. *Pharm World Sci* 2010;32:194–9.
- [36] Gerdemann A, Griese N, Schulz M. Pharmacy interns on the ward—a pilot study. *Pharm World Sci* 2007;29:34–8.
- [37] Piening S, Haaijer-Ruskamp FM, Graeff PA, et al. Healthcare professionals' self-reported experiences and preferences related to direct healthcare professional communications: a survey conducted in the Netherlands. *Drug Saf* 2012;35:1061–72.
- [38] Weatherby LB, Nordstrom BL, Fife D, et al. The impact of wording in “Dear doctor” letters and in black box labels. *Clin Pharmacol Ther* 2002;72:735–42.
- [39] Schächtele S, Tümen T, Gafmann K-G, et al. Implementation of warnings from Dear Doctor Letters (Rote-Hand-Briefe): an analysis of medication data from a large cohort of elderly patients. *Dtsch Arztebl Int* 2014;111:255–63.
- [40] Brody RS, Liss CL, Wray H, et al. Effectiveness of a risk-minimization activity involving physician education on metabolic monitoring of patients receiving quetiapine: results from two postauthorization safety studies. *Int Clin Psychopharmacol* 2016;31:34–41.
- [41] Vries ST de, van der Sar, Maartje JM, et al. Communication on safety of medicines in Europe: current practices and general practitioners' awareness and preferences. *Drug Saf* 2017;40:729–42.
- [42] ABDA Pharma-Daten-Service. Plus X. Available at: https://abdata.de/datenangebot/abda-datenbank/plus_x/. Accessed September 9, 2020.
- [43] Kaeding M, Klika C, Schmälter J. Pharmacovigilance in the European Union: Practical implementation across member states. s.l.: Springer, 2017.
- [44] Li R, Curtis K, Zaidi STR, et al. Effect of the black triangle scheme and its online educational campaign on the quantity and quality of adverse drug event reporting in Australia: a time series analysis. *Expert Opin Drug Saf* 2020;1–7.
- [45] Horton DB, Gerhard T, Davidow A, et al. Impact of the black triangle label on prescribing of new drugs in the United Kingdom: lessons for the United States at a time of deregulation. *Pharmacoepidemiol Drug Saf* 2017;26:1307–13.
- [46] European Medicines Agency. New measures to avoid valproate exposure in pregnancy endorsed. [EMA/375438/2018]. Available at: https://www.ema.europa.eu/en/documents/referral/valproate-article-31-referral-new-measures-avoid-valproate-exposure-pregnancy-endorsed_en-0.pdf. Accessed September 9, 2020.
- [47] European Medicines Agency. Updated measures for pregnancy prevention during retinoid use.: Warning on possible risk of neuropsychiatric disorders also to be included for oral retinoids [EMA/261767/2018]. Available at: https://www.ema.europa.eu/en/documents/referral/retinoid-article-31-referral-updated-measures-pregnancy-prevention-during-retinoid-use_en.pdf. Accessed September 9, 2020.
- [48] Chan HW, Russell AM, Smith MY. What is the quality of drug safety information for patients: an analysis of REMS educational materials. *Pharmacoepidemiol Drug Saf* 2018;27:969–78.
- [49] Pires C, Rosa PJ, Vigário M, et al. Validation of a new tool for evaluating subjects' satisfaction with medicine package leaflets: a cross-sectional descriptive study. *Sao Paulo Med J* 2019;137:454–62.
- [50] Kim JJ, Mohammad RA, Coley KC, et al. Use of an iPad to provide warfarin video education to hospitalized patients. *J Patient Saf* 2015;11:160–5.
- [51] Agyemang E, Bailey L, Talbot J. Additional risk minimisation measures for medicinal products in the European Union: a review of the implementation and effectiveness of measures in the United Kingdom by one marketing authorisation holder. *Pharmaceut Med* 2017;31:101–12.
- [52] Crijns I, Mantel-Teeuwisse A, Bloemberg R, et al. Healthcare professional surveys to investigate the implementation of the isotretinoin Pregnancy Prevention Programme: a descriptive study. *Expert Opin Drug Saf* 2013;12:29–38.
- [53] Aro Jorge Tavares P de, Baraviera T, Hamamoto Filho PT, et al. Evaluating educational material from the perspective of informal caregivers of children with hydrocephaly: a qualitative study. *World Neurosurg* 2020.
- [54] Théophile H, Miremont-Salamé G, Robinson P, et al. Relevance of a “Dear doctor letter” to alert healthcare providers to new recommendations for vitamin D administration. *Eur J Clin Pharmacol* 2011;67:681–6.