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User preferences for a mobile application to report adverse events following vaccination

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The passive surveillance system is an important tool in pharmacovigilance of vaccines. However, reporting of adverse events following immunization (AEFI) post-marketing has limitations regarding under-reporting, biased reports and lack of exposure data resulting in imprecise estimates. New mobile application technology may provide an opportunity for an enhanced surveillance. A pre-requisite for the use of new app-based technology is to identify practical challenges and end users' preferences for design of app-features. The objectives were (i) to investigate the recruitment and feasibility of an app-based study in Germany, (ii) to assess individuals' motivation to participate in such a study and (iii) to identify app-features for reporting AEFI. We conducted a cross-sectional study among employees of a financial institution who attended the occupational health office during the seasonal influenza vaccination in November 2017. Participants tested feasibility and assessed an app prototype for AEFI reporting by using a case vignette and a questionnaire. Of the 153 attending employees, 65 (42%) agreed to participate and returned the questionnaire. Twenty-three (63%) rated the experience of reporting AEFI with the app prototype to be positive. Among three features offered for gamification, collecting points was most frequently chosen (n=22, 34%). The main reason for declining participation was the apprehension about data protection (n=28, 43%). Results suggest that the app-based technology was well accepted and is a suitable supplement for AEFI reporting and in our study. A convincing data protection concept is likely to enhance acceptability of such a system.

1. Introduction

The vigilance of medicinal products post-marketing is essential for the detection of rare adverse reactions. For decades, the passive surveillance system has been an efficient and cost-effective method to capture new safety signals in the vaccinated population (Heergewegh et al. 2007; European Medicines Agency 2015; Tubert et al. 1992). Although it has greatly contributed to drug safety, there are considerable limitations such as imprecise information on the denominator, under-reporting and delay in reporting (Hasford et al. 2002; Hazell and Shakir 2006; Waller 1992). In addition to post-marketing passive surveillance, an enhanced safety surveillance to capture adverse events following immunization (AEFI) is particularly important for the annually modified influenza vaccines (European Medicines Agency 2014).

Mobile tools like smartphones can supplement the established reporting system for AEFI if designed in an efficient, user-friendly manner. In Germany, 78% of adults own a smartphone (Pew Research Center 2019). Their wide accessibility and portability may enhance the likelihood for individuals to directly report AEFI simply and in real-time. Active and individual-centered reporting of AEFI through SMS or app was implemented, e.g. in Australia and in Canada (Westphal et al. 2016; Wilson et al. 2016). In Europe, apps also have been developed for individuals, but only for passive reporting and without individual-centered technology (Montastruc et al. 2018; Oosterhuis et al. 2018). In fact, despite the growing number of health research related studies utilizing mobile apps, fundamental practical difficulties concerning studies based on apps are hardly addressed (Zhang et al. 2017). Other than health apps that provide direct benefit for the user, (e.g. allergy apps advising on adequate measures (Techniker Krankenkasse 2019)) the individual's motivation can be limited in absence of direct health or other benefits. This is the case for voluntary reporting of AEFI. Therefore, not only a high technological level of mobile health apps is crucial, but also the involvement of the end user in the development process (McCurdie et al. 2012). Thereby, preferences from cultural or social contexts that influence app usage should be considered (Bol et al. 2018; Kayan et al. 2006; Matthew-Maich et al. 2016; Peltonen et al. 2018; Taylor and Silver 2019). Our aim was to integrate end users from the first stage of app development to address the individuals' needs, and thus improve users' adherence to the app. We approached this by investigating the recruitment and the feasibility of an app-based study in Germany to report adverse events after influenza vaccination by using a prototype of an app. We assessed individuals' motivation to participate in an app-related study and identified suitable app-features for an app to report AEFI.

2. Investigations and results

2.1. Study design and setting

We conducted a cross-sectional study in November 2017 in a financial institution in Berlin (Germany) during the occupational influenza vaccination. Prior to recruitment, we circulated study information *via* electronic and printed advertisements. On two consecutive vaccination days, four trained study personnel recruited participants. To be eligible, employees had to own a smartphone, be vaccinated by the occupational health physician, be fluent in German and be at least 18 years old. Employees who

met these criteria and voluntary agreed to participate received a participant information sheet, a link to our self-developed app prototype for AEFI reporting and a QR code of the app prototype, a randomly generated personal identifier (ID), a case vignette and a pen and paper questionnaire. For the voluntary participation in the study, the participants received a power bank as a gift.

After loading the app prototype *via* the given link or QR code and entering the ID, participants were instructed to test the app prototype by entering all provided information of the case vignette. It comprised of fictive information of a 26-year-old woman, including information about the vaccine she received, her medical data and her occurring AEFI, e.g. fever, dizziness (available from the authors on request). To attain a comparable basis for evaluating the data entry, all participants received the same case vignette.

In the app, each predefined AEFI had to be chosen from a list. We created two app prototype versions by using two different lists: List 1 was based on the System Organ Class (SOC) of the Medical Dictionary for Regulatory Activities (MedDRA) (MedDRA 2019), list 2 consisted of layman's terms. Whether the participants tested the app prototype version 1 or version 2 was determined by the ID. To achieve an even distribution, the IDs were block-randomized.

After the participants had tested the app, they assessed the app prototype in both, the app and by a paper questionnaire. The questionnaire which was specifically developed and pre-tested (Porst 2014) for this study, covered five categories: (i) sociodemographic characteristics, (ii) experiences with the established reporting system, (iii) experiences with the app prototype and preferences and (iv) attitudes towards study participation (available from the authors on request). The questionnaire contained closed, semi-opened and open questions. Besides categorical and continuous variables, we also included questions with a 5-point Likert scale to measure individuals' attitudes towards statements concerning the reasons to participate in a study with an app-based reporting system and to measure their experience with the app. We aggregated the 5- to a 3-point Likert scale ("rather disagree/negative" and "disagree/negative" as "disagree/negative", "rather agree/positive" and "agree/positive" as "agree/positive"). E.g., both, individuals who indicated "rather agree" and individuals who indicated "agree" for the statement "I would participate in an app-based AEFI reporting study because I am interested in vaccine safety", were grouped as "agree" for this question.

To further assess app-prototype and the feasibility of the app, the study personnel conducted informal and unstructured interviews as part of a participatory observation. The study personnel paralleled the study process passively by observations. These results were evaluated by the end of each study day and were qualitatively documented.

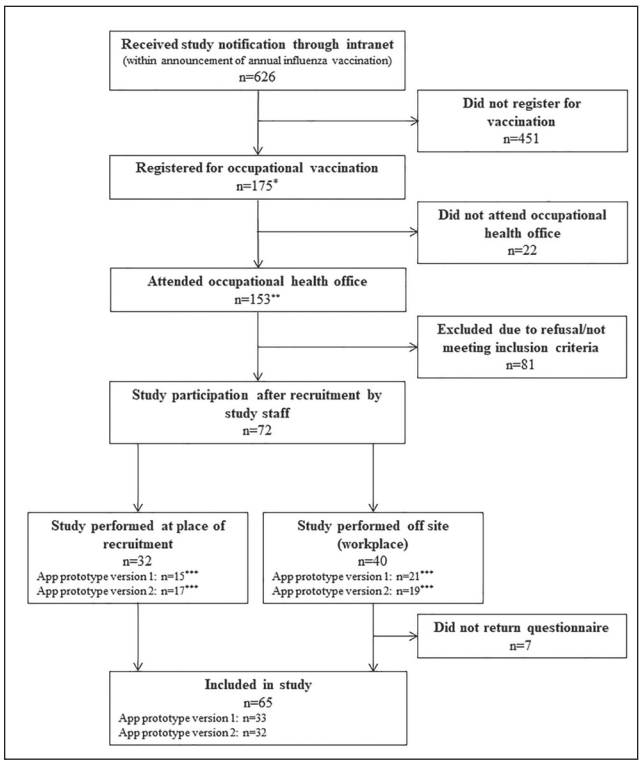

Fig. 1: Recruitment of study participants *Of these, 163 registered for influenza vaccination **One person showed up without registration ***Randomly assigned (block-wise)

2.2. Data management and analysis

For data validation, the paper questionnaire data was entered manually and independently in a Microsoft Excel® spreadsheet by two investigators (MN and MC). Responses were defined as missing if participants selected more than one answer option in single choice questions and if participants provided answers for conditional questions that were supposed to be skipped. In situations where participants skipped yes/no-conditional questions but answered the subsequent ones, the conditional questions were assumed as being answered in the affirmative. For data visualization and analysis, the two questions about app difficulties were merged as one.

All free text responses were analyzed by two researchers (MC and MN) independently, using an inductive approach (Mayring 2019). This implies that categories were directly derived from the open-ended responses. Final subcategories and categories were discussed and agreed upon the two researchers. Inconsistent data entry information were agreed upon the two investigators and persisting disagreements arbitrated by a third reviewer (JJO). The paper questionnaire data were merged with the app data by ID. We applied Mann-Whitney-U test and chi square test using Stata version 14. Data were visualized using Microsoft© Excel 2010.

2.3. Sociodemographic characteristics

Out of 153 employees receiving the occupational vaccination, 65 (42%) participants returned the questionnaires and were included in our analysis (Fig. 1). The majority had a General Education Certificate [Abitur] (n=51, 78%) and were male (n=35, 54%). Thirty participants (46%) were aged between 45 to 54 years, fourteen participants (21%) ≥55 years, seven (11%) between 25 to 34 years, six (9%) between 18 to 24 years and 35 to 44 years respectively. Two participants (3%) did not provide any information about age, sex and education.

2.4. Experiences with the established reporting system

About half of the participants (n=29, 45%) indicated having ever experienced an AEFI. A similar number (43%, n=27) stated to have never experienced any and seven (11%) did not remember. Two (3%) participants did not provide any information about their experiences with AEFI. Out of those who experienced an AEFI (n=29),

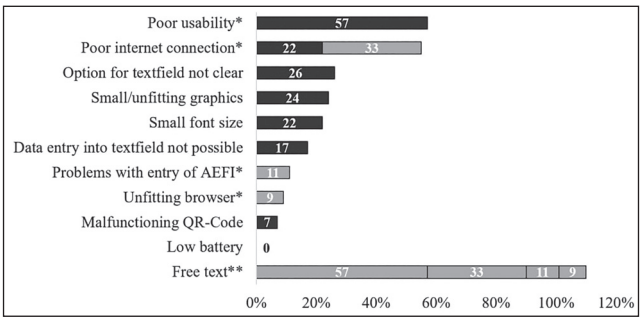

Fig. 2: Difficulties during app prototype usage Multiple-choice question, n=46 *Inlcudes free text answer, which were grouped according to their content into poor internet connection, poor usability, unfitting browser, problems with entry of AEFI. Added free text answers are highlighted in grey. **Free text answers were grouped by two investigators into four categories: poor internet connection, poor usability, unfitting browser and problems with entry of AEFI. The order of categories correspond to the order of the shown bars.

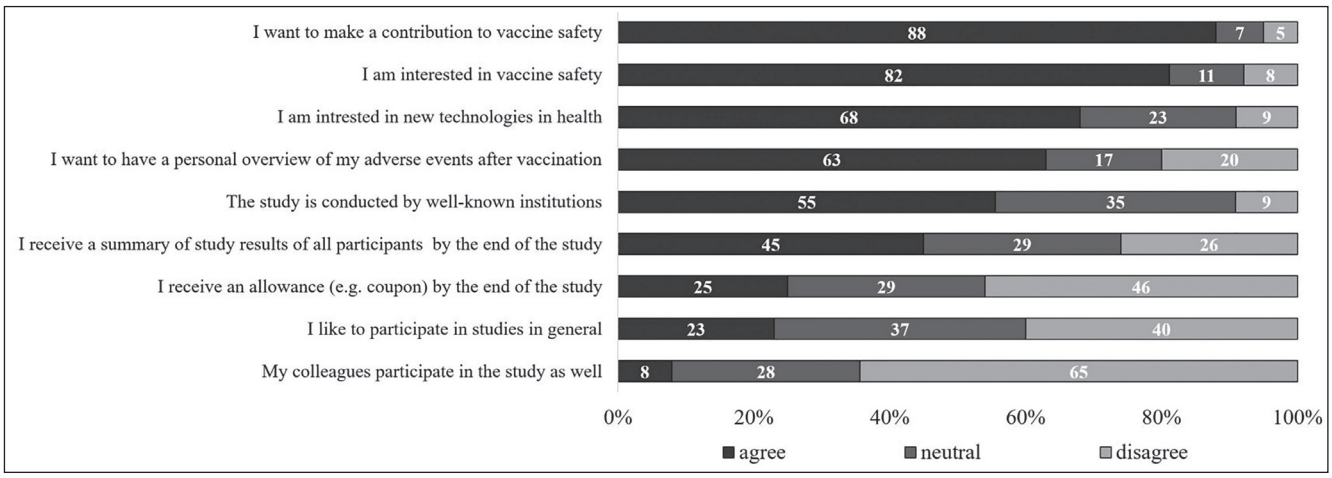

Fig. 3: Reasons to participate in a study of an app-based AEFI reporting, AEFI: adverse event following immunization

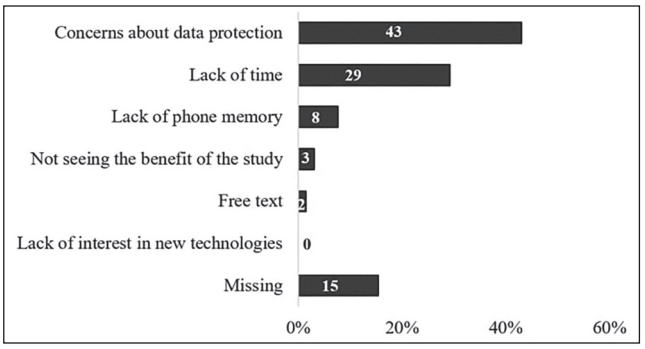

Fig. 4: Reasons not to participate in a study of an app-based AEFI reporting AEFI: adverse event following immunization

one (3%) reported it through the established reporting system. The reasons for not reporting were a) AEFI considered to be non-severe (n=24, 85%), including one participant who stated in the free text option "It was just a slight reddening", b) lacking awareness of the possibility to report (n=12, 43%) and c) missing information about where to report AEFI (n=9, 32%). Other reasons were lack of time (n=5, 18%), the uncertainty of a causal relationship between the AEFI and the vaccine (n=2, 7%). No participant indicated fear as a reason for not reporting in the multiple-choice question.

2.5. Experiences with the app prototype and preferences

More than half of the participants (n=41, 63%) rated a mobile reporting system for adverse events as positive, fourteen (22%) as neutral and six (9%) as negative. Four participants (6%) did not provide any answers for this question.

Regarding technical issues, around two third (n=46, 71%) experienced difficulties using the app prototype; most commonly related to usability (n=26, 57%) and internet connection (n=25, 54%) (Fig. 2). The rating of the mobile reporting system was higher among participants without reported difficulties compared to those with reporting difficulties (p=0.02).

The maximum tolerable number of additional push-notifications on the mobile phone as a reminder to report AEFI was indicated as follows: twenty-eight (43%) participants would tolerate one, 25 (38%) two and six (9%) three notifications. Two participants (3%) would not use an app with push-notifications and three participants (5%) had no preferences. One (2%) participant did not indicate any preferences on the number of push-notifications. Having a General Education Certificate was positively associated with the number of push-notifications tolerated (p=0.04).

Of the three options offered as a game element for adherence reporting, collecting points within the app was most frequently chosen (n=22, 34%), followed by a ranking system (n=12, 18%) and receiving medals (n=10, 15%). Twenty-one (32%) participants did not provide any information about their preferences.

Most participants (n=41, 63%) indicated willingness to use an app for reporting AEFI within a study for one month. A duration of seven months or more would be acceptable to ten (15%). Eight (12%) would use it for two and four (6%) for three months. Two participants (3%) did not indicate any information about this question.

Differences between the two app prototype versions were neither found in the overall rating of the app prototype (p=0.66) nor in the rating of finding the AEFI by the two provided lists (p=0.41).

2.6. Attitudes towards study participation

For the majority of participants (n=57, 88%) the main motivational aspect for study participitation is the perceived contribution to vaccine safety. Sixteen participants (25%) indicated receiving an allowance as a motivation for the study participation of an app-based AEFI reporting. The study-participation of peers was less relevant (n=5, 8%) (Fig. 3); however, it was more relevant for females than males (p=0.04). The main concern for not participating in such a study was data protection (n=28, 43%). One participant (2%) indicated via free text "a disreputable provider" as a reason for non-participation (Fig. 4).

2.7. Participatory observation

During recruitment of participants for our study, we observed the following: first, during the recruitment process the majority of employees were standing in line waiting to be called for their occupational vaccination. Second, not all employees carried their smartphone to the occupational health office. Thus, we recruited employees also before they received their vaccination in addition to our initial recruitment procedure. For those who were not willing to return to get their smartphones, we offered to perform the study off site, e.g. working place. In line with the questionnaire results, the most frequently notable complain during study recruitment was the insufficient internet connection recognized with the use of several mobile providers and the local Wi-Fi access point. To address these difficulties, we provided a dedicated smartphone with reliable internet connectivity to a small number of participants. The study personnel were on site to support participants using this new, unknown smartphone.

Another technical shortcoming was the drop-down list for selecting the recognized AEFI, which did not automatically adjusted to the used smartphone, depending on the operating system and browser.

3. Discussion

The main result our study implicates is the feasibility of an app-based study of AEFI reporting. Almost half of the employees at the occupational vaccination were initially interested in our

study of an app-based AEFI reporting. Despite technical issues encountered during the course of app prototype usage, more than half of the study participants were in favor of reporting AEFI using the app prototype.

Regarding app-features, almost all study participants would tolerate push-notifications in our study. Push-notifications, displaying as pop-up messages, badges or in the form of lists on the mobile phone, are a powerful and valuable tool to keep individuals engaged with the app (Pham et al. 2016). A lack of such a feature can even lead to individuals abandoning health-related apps (Murnane et al. 2015). If implementing push-notifications for apps, one can either set the times for push notifications automatically or allow the user to decide their preferred times.

However, results from previous studies suggest that individuals may not be able to predict the right time to receive push-notifications; therefore personalized settings regarding the time of reception appear to be less important than the content (Fischer et al. 2010). Moreover, neither the timing nor the frequency seem to have a decreased effect on app-usage in the context of health behavior change interventions (Dennison et al. 2013; Morrison et al. 2017). Nevertheless, since an app for reporting AEFI can only offer limited variability in content, and the usage of the app primarily relies on the intrinsic and altruistic motivation of the individual, the frequency of push-notifications could still have an impact on app adherence.

Gamification is the utilization of game design elements in a non-gaming context and is another strategy to increase users' engagement with the app (Deterding et al. 2011; Hamari et al. 2014). In our study, a large proportion of participants did not answer the question about their preferences of game features. The reasons for this are not clear. However, the majority of participants stated that the perceived contribution to vaccine safety would be the main reason to participate in the study, rather than receiving an extrinsic motivator, e.g. a financial compensation. This indicates, in line with the results of a study conducted by Bongartz et al. 2017, that altruistic and intrinsic motivation may outweigh extrinsic motivation and complex gamification might not be required to ensure adherence to a AEFI reporting app.

Regarding non-participation in the study, the main concern was related to data protection. In fact, these results are in line with other studies (Prasad et al. 2014; Whittaker 2012). Moreover, our study was conducted at a time where the European General Data Protection Regulation was updated; therefore, the awareness for data protection might have been high. Nevertheless, individuals' privacy attitudes do not necessarily predict their privacy behavior. Despite concerns, individuals' decisions on using private-information sensitive apps are not influenced (Pentina et al. 2016). The phenomenon of individuals not acting upon their concerns is also well-known as the "privacy paradox" (Acquisti and Grossklags 2004; Barth and de Jong 2017). However, this might not apply to app usage in context with sensitive health data. In fact, the fear of data abuse appears to be particularly prevalent in Germany: a survey by Morey et al. shows that concerning protection of health data, Germans are even willing to pay more than three times as much for protection of health data compared to individuals from UK (Harvard Business Review 2015). Therefore, transparency about data usage in Germany might still have an impact on the participation of an app-based AEFI reporting study.

Lack of time was another frequently mentioned reason for not participating in a study of an app-based AEFI reporting. Since usability has a direct influence on app-usage, the usability has to be ensured to minimize the users' effort and time (Iqbal et al. 2017; Krebs and Duncan, 2015; Lieffers et al. 2014). This also implies that the time needed for app entries needs to be balanced against the amount of information desired for the research.

The main insights our study provides are relevant information for a real application of an app-based study for AEFI reporting during the seasonal occupational influenza vaccination. We were able to evaluate a comprehensive picture of the study process by using a questionnaire and participatory observation. However, the study was exploratory and based on a convenience sample of working adults in an occupational setting. Generalizability of findings, e.g. app-preferences and motivation to participate, are therefore limited.

During our study, we had to deal with some technical difficulties. The main difficulty was related to internet connectivity. However, the quality of the internet connectivity has to be considered in such approaches. In fact, insufficient internet connection may negatively affect participation and participants' satisfaction. Thus, before implementation, the internet connectivity has to be tested and ensured. In addition, questions about the app-features were based on an app prototype, thus limiting the ability to portray a realistic picture of an actual native app. Compared to native apps, web-apps require a constant internet connection to function properly. This can limit the usability of the app, as observed in our study. Further, since the drop-down list of AEFI adjusted to the type of smartphones used, the AEFI lists were not completely shown to all participants. Therefore, the comparability of the two app versions by finding the AEFI in the drop-down list was limited. Besides the technical issues, having used a fictive case-vignette to test data entry may also have led to participants not fully identifying themselves with the situation and may therefore have affected the experience with the app.

For study participations, the altruistic perceived contribution to vaccine safety outweighs the egoistic motivator, e.g. financial compensation. Therefore, complex game elements in an app-based AEFI reporting may not be needed. To enhance app-adherence, the implementation of customized push-notifications could be beneficial. To promote participation, an easily understandable and convincing data protection concept is needed.

4. Experimental

The study protocol was reviewed by the ethical committee of the Medical Association of Lower Saxony in Germany and by the Federal Commissioner for Data Protection and Freedom of Information. With the voluntary submission of the questionnaire, participants consented to the study participation. All procedures performed in this study involving human participants were according to the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No individual personal data were collected.

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