Context Sensitive Health Informatics: Human and Sociotechnical Approaches
M.-C. Beuscart-Zéphir et al. (Eds.)

doi:10.3233/978-1-61499-293-6-63

Using patient-reported experiences for pharmacovigilance?

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Abstract. Recent international guidelines encourage more prominent placement of patient-generated information about medications on the pharmacovigilance information landscape. Online platforms where patients share medication experiences with one another and with healthcare professionals are one possible avenue to accomplishing this goal. Public reports of medication-related events posted on the web, however, are under-utilized in the pharmacovigilance community. Moreover, little is known about who writes such reviews, what information is shared and how this information can be used by authorities. This paper reports the first results of a study of user and comment characteristics on a European-based platform.

Keywords. Patient experiences, web 2.0, pharmacovigilance

Introduction

The publication of patient experiences on the web is expected to increase in both scale and importance in the coming years [1]. As part of the 'web 2.0' generation of applications, a multitude of online platforms already encourage and enable patients to rate and review their care and to share their experiences with health services, professionals and products. By contributing to such platforms, patients potentially help not only one another in making decisions about their health and healthcare, but also healthcare providers in improving the quality of care and treatments [2-3].

Patient-reported information about experiences with medication use is of special interest to professionals and authorities working in the area of pharmacovigilance. Knowledge about medication effects is predominantly developed prior to release on the market through clinical trials and, once in use by patients, through post-marketing surveillance processes that, in many cases, are not patient centered [4]. Newly-published WHO guidelines [5] and a slightly older EU policy directive [6], however, encourage acknowledging the unique information that patients can provide and giving patient reports of experiences with medications (especially adverse events) a place on the pharmacovigilance information landscape.

This suggests the need for *new structures* that enable patients to report their experiences quickly and easily; for example, online platforms. However, although public reports of medication-related adverse events by patients have indeed increased in number with the growth of the Internet and early research has suggested the value of this information for understanding side effects [7], these are still under-utilized in the pharmacovigilance community [8]. Approaching such sites from a context-sensitive

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informatics perspective could provide useful insights about users and uses of such platforms, as well as about the necessary preconditions to ensuring use of the information created via these platforms within the pharmacovigilance community.

This article examines potential uses of information gathered via a European platform for reporting experiences with medicines for purposes of pharmacovigilance. After an explanation of the single case and methods used in the study, the characteristics of those using the platform to share experiences are briefly described. This is followed by a description of how information is structured and the categories of information this structure delivers. The discussion highlights three points about the current use of such sites that are potential barriers to optimal use of the information being gathered there.

1. Materials and Methods

The data for this article is taken from a single case (*mijnmedicijn.nl*), which is one of seven sites included in a larger study on crowdsourcing for health and the only site in the study that specifically addresses patient experiences with medications. The website is the first product developed by the Dutch company, Insight Pharma Services, which was established by a pharmacist and provides products and services to support the medical and pharmaceutical sector, including healthcare insurance companies, (groups of) pharmacies, corporations, governmental and non-governmental organizations. Insight Pharma Services also produces products such as plug-ins, widgets and data analysis packages.

Insight Pharma Services initiated a European platform for reviewing and sharing experiences with medications with the 2008 launch of the Dutch-language *Mijnmedicijn.nl.* This platform was expanded in 2010 to include German and French- language sites and later to include an Italian-language site (all under the name '*meamedica*'), whereby it serves (and receives input from) residents of the Netherlands, France, Germany, Italy, Belgium, Switzerland and Austria. There are plans to launch a Spanish language version of the platform in 2013. Since June 2010, the site has been working with Lareb (the Netherlands Pharmacovigilance Center), which collects information about medical side effects and reports possible safety issues to the National Board for the Evaluation of Medicines (College ter Beoordeling van Geneesmiddelen), the European Medicines Agency and the World Health Organization.

During this study, a content analysis (text, image and structure of home page and 'about us' page, press releases, disclaimer and privacy statement) was performed of the *Dutch* platform site, *mijnmedicijn.nl* and Insight Pharma Service's company homepage, *insightpharma.nl*. Comments submitted to *mijnmedicijn.nl* were reviewed (n=400), interviews were held with the site's developers (n=2) and authors of reviews (n=18) and basic demographic statistics about users (de-identified) were collected.

2. Results

2.1. User characteristics

Since the site was launched in 2008, the number of visitors to the site has increased annually. Between January 2011 and January 2012, there were 1,950,701 visits to the site, and 8261 new medication experiences/evaluations were added (for a total at that

time of 21,941 reviews). Of the site visitors, 85% find the site via a search engine, when searching for the name of a medication and 70% are unique visits (one time only from a given IP address). Generally +/- 1 % of site visitors leave a review, meaning that 99% of visitors merely read the information that is there or use other aspects of the sites (e.g. surveys).

The largest group of authors (posting a medication review) consists of women between ages 20-50. Young users (under 20 years old) and elderly (older than 70 years old) are the least represented in this user group, forming respectively 5.82% and 5.17% of the writing population. On the site, visitors posting a review can indicate how many medications they are currently using. The largest group of users posting a review to the site indicates using only 1 medication (31%). However, because this information field originally was not a required field on the site, for 46%, the number of medications is unknown.

Most authors write a review about medications they are currently taking and have been taking for less than one month. They also usually only write one review, meaning most reviews posted on the site are 'unique'. Clearly related to these user characteristics, the top three categories of medications that are reviewed on the site are anti-depressive, anti-conception and cholesterol medications.

2.2. Format of reviews/experiences

A medication review consists of two parts, an *obligatory* quantitative rating (5-point scale, symbolized by stars) of five aspects of the medication and an *optional* free text field where users can share personal experiences and 'review' their medication. The five characteristics being rated are: 1) effectiveness of the medication, 2) number of side effects, 3) degree/seriousness of side effects, 4) ease of use and 5) general satisfaction. Insight Pharmaceutical Services chose to include the first four themes because these are often heard by pharmacists when discussing medication with patients. Furthermore, they support the general assessment given with characteristic number five (general satisfaction), which, according to the site developers is important, but insufficient as a stand-alone quality indicator.

Insight Pharma Services chose a five-star rating system because it is a recognizable evaluation scheme (e.g. comparable ratings for hotels and restaurants) that gives more granularity than a three-star rating (e.g. a traffic light system). Moreover, because Dutch law forbids grading medications for the reason that this might imply a recommendation of one above another, the developers felt that a five-point scale would be more appropriate than e.g. a ten-point scale, which – while recognizable – too closely resembles Dutch grading schemes.

2.3. Types of information posted

There were four categories of information found in the user experiences/reviews: 1) Effects and Side effects, 2) Variables related to medication use, 3) Asking a question, 4) Giving advice. Comments fitting the first category are the most prominent across all types of medication. Approximately 70% of the reviews fall into the first information category: effects of the medication (i.e.: is it working?) and the side effects. Because the side effects are a recurrent theme in many reviews, this gives users the impression that the reviews are negative. However, only approximately 25% of the reviews appear to be 'negative'. Negative reviews on the five-point scale are generally explained in the

comments: the user is of the opinion that the medication is not working or that the negative side effects seem to outweigh the positive effects.

The category, 'Variables related to medication use,' refers to length of and reason for use, dosage and additional medications. Those sharing experiences feel this information is important to other users of the same medication because it helps them assess the degree of similarity between the two situations and thereby the applicability of someone else's experience to their own situation. As part of this description, some individuals choose to indicate when they have felt it necessary to adjust dosage, stop using a certain medication, etc. The site intervenes in the interest of patient safety to remind site visitors not to stop or adjust medication use without consulting the prescribing physician.

Questions that are posed vary, but generally reflect that the author wants to check what will happen during medication use and whether his/her experiences up until that point are normal. This category is closely related to the fourth category, sharing advice, where medication users share tips with one another about, for example, how to deal with side effects. At the time of analysis, the option to comment on reviews was new, whereby there was little visible interaction between users about the content of the comments posted. A point for future study is whether users who post reports early in their medication trajectory return to post follow-up information on their experiences and how this develops into a long-term overview of user experiences with medications or into an online conversation with other users about their experiences.

3. Discussion

This paper reports the first results of a study of the Dutch website of a European-based pharmacovigilance platform. The idea behind this platform is that patients can share their experiences, which may help to bridge an information gap by using terminology that is closer to an individual patient's understanding than that found in professional or industry language. Bridging this information gap is not just a unidirectional process. The site developers consider the site as potentially relevant to a number of actors in healthcare, including the pharmaceutical industry, professionals, health insurance companies and patient representative organizations, not only in the Netherlands, but also in the European countries where a local version of the site is available. In their opinion, the knowledge about positive and negative experiences with using medications that is created through collating the information reported on an online platform is complementary to knowledge developed through information gathered elsewhere (e.g. through clinical trials and post-marketing surveillance). Therefore, they argue, it can potentially lead to more patient-centered quality improvement within the pharmaceutical sector and more patient-centered pharmacovigilance. This is also the argument put forth by Wu et al [7] based on their categorization of side effect information produced during online discussions.

But, how effective are such websites in meeting this last goal in practice? The subsequent sub-sections discuss three issues that reflect potential barriers to effective use of this information within the pharmacovigilance community: 1) reaching a critical mass, 2) representation of the user group and 3) difficulty in capturing experiences. These potential barriers need to be addressed before the promises associated with effecting change through sharing patient experiences on the web can be realized.

3.1. Reaching a critical mass

Because the site actively monitors and vets the information that is submitted to the site, the developers are the first to notice a pattern in the information or to signal a safety issue, which places a moral responsibility on the site to act on such patterns or signals when necessary [3]. *Mijnmedicijn.nl* has taken this up in two ways. First, the site developers work together with Lareb (see case description above) and second, the site analyzes trends in the data on its own and discusses these trends with various actors in healthcare.

At the moment, the burden of reporting to Lareb lies with the site visitors. When a contributor to the site identifies the side effects of the medication as serious, s/he receives an email from Insight Pharma with the request also to submit this information to Lareb via a special form that is integrated within the *mijnmedicijn.nl* website. Currently, approximately 750 submissions to *mijnmedicijn.nl* were also resubmitted to Lareb. Although this number may seem low, especially when broken down by medication category, it is important to realize that the site currently makes the largest contribution to Lareb from a *patient-oriented* view.

The site acknowledges that not everyone who receives a request makes the additional submission to Lareb and that it is yet unclear what the precise benefits of its own analyses are. But the site is still in development. Efforts to increase the number of submissions to Lareb are ongoing and the amount of site data that can be analyzed and discussed with actors in healthcare continues to grow. This suggests that it might just be a matter of time until the amount of data gathered through the site reaches a *critical mass*, which is a prerequisite for further use by pharmaceutical authorities. Coupling data from the Dutch site with data from the rest of the European platform – which increases not only the amount, but also the scope, of the data – will help.

3.2. Representation

A second issue that may affect use in practice is whether the typical contributions adequately represent the highest-risk areas for pharmacovigilance. Contributing to the site requires a certain degree of computer skill, health literacy and the ability to formulate experiences such that they can be used by others. Although the site helps with this (through requiring quantification and by collating experiences into general overviews), it still requires work on the part of visitors to the site and may be a reason that more visitors do not contribute their experiences.

Moreover, significant risks lie, for example, in the potential interactions between multiple medications. Poly-pharmacy is more prominent in specific demographic groups, such as the elderly, or individuals with a lower SES, as well as for patients with certain chronic conditions etc. The user characteristics indicate that these may not typically be the groups sharing their experiences on the site. Furthermore, medications are rated individually, rather than in combination, so being able to understand medication interaction is largely dependent on the degree of information that an individual author chooses to reveal. That there are multiple medications may be known because of the required fields, but which medications these are may not always be evident. The comments may therefore not be representative for exactly the areas and groups where pharmacovigilance is most important.

3.3. Difficulty in capturing experiences

A final issue for consideration is the potential misalignment between how the site is currently set up and used and how patients experience their medication use. Medication use is a process, rather than an event, and visitors share experiences at various phases of this longer process. During interviews, patients revealed that they often had difficulty in giving a one-off assessment. That is, some aspects of their experiences changed during use, whereby they had difficulty in summarizing their valuation of the five aspects of use in one measurement. The website could be improved by finding a way to capture experiences with medication use over time.

4. Conclusions

Publication of patient experiences with various aspects of their care via online platforms is becoming increasingly important. The expectations for how such information can effect positive changes in healthcare, especially in creating more patient-centered pharmacovigilance, are great. However, as this case shows, use of the information generated on such sites can be increased, which will be better realized once the structure of such platforms is improved. The intricacies of the pharmaceutical case reiterate the importance of studying not only the functionality of an application, but also the context in which applications, users and use are situated.

Acknowledgements

The author is grateful to Wendela Wessels from Insight Pharma Services for facilitating this research, Robbert–Paul Zeillemaker for help with data collection and Jos Aarts and Jolanda Dwarswaard for providing critical comments on a Dutch version of this text.

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