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The Use of Social Media in ADR Monitoring and Reporting

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Abstract

Background: The benefits of using social media for Adverse Drug Reaction (ADR) reporting are slowly becoming recognised, not just amongst regulatory authorities but also the pharmaceutical industry stakeholders and Healthcare Professionals (HCPs). If utilized correctly, ADR reporting and monitoring via social media could potentially prove to be an efficient and expeditious means of post-market safety surveillance and overcome limitations of traditional ADR reporting systems such as under-reporting.

Objectives: The purpose of the study was to determine the attitude and behaviour of the pharmaceutical industry, HCPs and the general public towards the concept of using social media as a tool for ADR reporting and monitoring.

Methods: A cross-sectional study was carried out on 17 pharmaceutical companies, 46 HCPs, and 100 members of the general public. Surveys were distributed, comprising of questions designed to elicit significant responses from the participants, in relation to the concept of using social media for Pharmacovigilance purposes.

Results: 83% of the general public participants agreed that patients would be more inclined to report suspected ADRs via social media, if the correct measures were in place. 63% of the HCPs believed that the concept of utilising social media for patient safety purposes would be feasible. 71% of the pharmaceutical companies stated they would consider this concept feasible from a legislative and industry perspective. Ethical and confidentiality issues were of the most common concerns amongst the various populations.

Conclusion: The results from the study indicate that a collaborative effort is required between the pharmaceutical industry, HCPs and the public before social media can reach its full beneficial potential as a tool in Pharmacovigilance. The study also shows that there is still a need to promote the importance of ADR reporting to the general public while additional regulatory guidelines may also be required to ensure the engagement of HCPs and pharmaceutical companies in reporting and monitoring ADRs on social media.

Keywords: Adverse drug reactions; Social media; Monitoring and reporting; Pharmacovigilance; Attitude and behaviour; Post-marketing safety surveillance

Introduction

Background

Post-marketing safety surveillance involves a framework of various stakeholders that work together to optimise patient safety. This includes regulatory authorities, pharmaceutical companies and HCPs. Regulatory authorities provide legislation and guidelines on the reporting requirements of ADRs for Marketing Authorisation Holders (MAHs). As a collaborative effort, HCPs are also required to report relevant ADRs to the necessary authorities [1]. This allows for a regulated framework of reporting and monitoring ADRs amongst the stakeholders.

The science of post-marketing drug safety surveillance in pharmacovigilance is however, an ever changing discipline. Current methods are focused on this collection and assessment of safety data through adverse event reporting and the monitoring of ADRs for marketed medicinal products. It is well established that post-marketing safety surveillance relies heavily on spontaneous adverse event reporting [2]. This method of reporting however has been associated with many limitations, primarily being a causative factor for the significant under-reporting of ADRs [3]. Regulatory authorities and the pharmaceutical industry have mainly relied on these traditional systems in pharmacovigilance, but in recent years, there has been development in implementing new techniques and safety tools for ADR monitoring and reporting. In particular, there has been growing interest in the potential use of social media as a safety tool for ADR reporting and signal detection.

The potential of digital media in pharmacovigilance

Social media and online health networking sites are continuously being promoted and adopted as a means of discussing health-related topics by patients. Many of these patients actively use these sites to share their experiences and possible adverse events related to medicinal products. This creates an opportunity for the exploitation of such information in ADR signal detection and public safety monitoring [4].

The use of social media in public safety monitoring has been well documented. Previous studies have shown how social media data can be utilised during occurrences of natural disasters to locate areas that have been most affected. The screening of social media data has also been shown to provide reporting trends during outbreaks of infections [5,6].

To date, the studies of the use of social media in pharmacovigilance have focused mainly on the data mining techniques required to screen these sites for safety information at a large scale. The results of these studies contextualise the potential of filtering adverse event-related information from social networking sites, as a means of ADR signal detection. While there are still many limitations associated with this

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technique, the rapid accessibility of social media sites could potentially allow for the real time detection of ADRs [7].

In addition to this, recent advances in mobile technology and data analytics have assisted in developing innovative initiatives that have looked at the possibility of using a social media application for the reporting of ADRs. Such a development could potentially be used as a safety-profile database that would allow for the reporting, monitoring and exchange of safety information [8].

While it is a legislative obligation for MAHs to have adequate pharmacovigilance systems in place, it is only the European Good Pharmacovigilance Practices (GVP) guideline requirements that MAHs "regularly" screen digital media for data on suspected adverse reactions [9]. Furthermore, inadequacies still exist in the reporting of ADRs by HCPs and such reporting is completely voluntary for the general public [10].

The use of social media by regulatory authorities and the pharmaceutical industry

For social media sites that are not under the direct responsibility of a pharmaceutical company, the relevant MAH is required to assess the suspect ADR-related information and determine if it qualifies for reporting to the competent authorities. This is only a requirement if the company becomes aware of this information. As it is not an obligatory requirement for MAHs to regularly screen external social media sites it is quite conceivable that essential ADR-related information goes undetected by the companies [9].

It is evident, from the terminology used in these legislative requirements, that the reporting of ADR-related information from social media is somewhat open to interpretation. For the most part, pharmaceutical companies only effectively utilise social media for commercial purposes. Many companies employ social media accounts such as Twitter and LinkedIn. The main use for these media is for the dissemination of information in relation to the company's products [11].

The potential of using social media in post-marketing surveillance however is slowly gaining acceptance by the pharmaceutical industry. For example, some companies have utilised social networking sites to monitor health forums and conversations between patients and HCPs [11].

The previously mentioned data mining techniques, used to extract ADR-related information from social media sites, can be very time-consuming. There are still questions to be answered towards the feasibility of pharmaceutical companies in implementing social media screening systems. Furthermore, the resource that would be required for a company to actively screen for such data could be deemed inefficient and uneconomic [12].

The role of Healthcare Professionals (HCPs) in pharmacovigilance

An integral part of post-market safety surveillance is the role of HCPs and their duty to ensure patient safety. Arguably the largest responsibility within pharmacovigilance lies with the HCPs. While MAHs may face major criticism and legal actions when ADRs occur amongst a large population, it is ultimately the responsibility of the HCP for the prescribing or administration of the medicinal product. Doctors, nurses, dentists and pharmacists all play a part in either providing or administrating medicinal products and hence, have a duty to monitor and report any serious adverse events observed [1].

Different sources of ADR-related reports mean that some competent authorities will only be concerned with reports that have been reported directly from HCPs [13]. This stresses the importance of ADR reporting by these HCPs as well as the need for them to engage with their patients when they have experienced any drug-related adverse event.

Despite the moral duty and obligatory legal requirements for HCPs to report suspected ADRs, the under-reporting of these events amongst HCPs still remains to be a major concern in pharmacovigilance. Studies carried out on the attitude of HCPs towards ADR reporting have suggested several different reasons as to why this may still be occurring. Amongst these reasons was the lack of understanding of HCPs towards the established pharmacovigilance system within the respective country. This was complimented by their lack of awareness towards the systems in place for reporting suspected ADRs. Some of the cases suggested that ignorance towards their reporting requirements was a factor. Interestingly, incurred guilt was also suggested. This could be as a result of an occurrence of an ADR that could perhaps have been prevented by the HCP [10,14,15].

For HCPs, the value of utilising social media in ADR reporting and monitoring is still open to question. The heavy workload of HCPs was also suggested to be causative factors for ADR under-reporting [3]. Taking this into consideration, it would seem an enormous burden to require HCPs to actively screen social media sites for adverse event related information on medicinal products which they provide or prescribe. There is however, the potential to use social media in strengthening the relationships between HCPs and their patients. Health-related social networking sites provide reservoirs of information on marketed medicinal products. Patients and the general public often engage in discussions with HCPs on these sites and share their personal experiences with a specific medicinal product.

The importance of ADR reporting by the general public

As previously discussed, both patients and the general public are integral components to the post-marketing safety surveillance framework. Signal detection of ADRs relies heavily on the spontaneous reporting of adverse events. It is ironic to think that despite having pharmacovigilance build its foundations around patient safety, many patients would still choose not to report adverse events experienced from a medicinal product. Previous studies have suggested reasons as to why this could be happening at a high occurrence [3,8].

One reason suggests that there is a lack of awareness of patients towards the availability of reporting systems for ADRs and that there is difficulty in accessing such reports [8]. Evidently, if patients feel that reporting drug-related adverse events is too much of a burden, they would be reluctant to do so. Social media has unprecedented potential when it comes to promotional purposes. Could it perhaps be used by the pharmaceutical industry and HCPs to promote and facilitate the reporting of ADRs by the general public?

Another issue raised was that patients may perceive the reporting of a single drug-related adverse event as insignificant or inconsiderable [3]. This leaves us with the question as to whether social media could potentially be used to directly introduce the voice of the general public into post-marketing safety surveillance. As previously mentioned, online health forums and social networking sites provide a means for HCPs to engage with patients in discussions relating to medicinal products. If patients were to be convinced that they play an important role in pharmacovigilance, their adverse event experiences were being taken seriously and that there was a quick and convenient method of reporting such events, would they be more inclined to report ADRs?

Methodology

Study tool and design

The research methodology consisted primarily of a series of surveys, used to conduct a cross-sectional study involving three separate subsets of a population. The questionnaires were carefully designed to obtain both quantitative and qualitative results from the respondents. This in turn enabled the generation of results of potential statistical significance while still enabling the respondents to elaborate on their own opinions and views. Three separate questionnaires were designed for each population subset. Each one however was composed of ten different questions, separated into sections of varying objectives.

The first of these questionnaires was designed to be distributed to the general public. The aim was to determine the attitude and behaviour of patients and consumers of medicinal products, towards the potential use of social media in reporting personal adverse drug experiences. To obtain a realistic viewpoint of the general public, the survey was non-selectively distributed to a population from various backgrounds. All respondents were over the age of eighteen with no maximum-age limitations implemented. Demographic limitations were implemented however, that required the respondents to be from a European country. The first set of questions was designed to obtain quantitative data in relation to the number of users of social networking sites and health forums, and determine the reliability of information available on such sites. The second set was designed to evaluate the acceptance of the general public towards the use of social media as a platform for reporting adverse reactions from medicinal products. Lastly, the third set of questions aimed at providing qualitative feedback from the general public on the issues and challenges that still remain in utilising social media for patient safety purposes.

The second questionnaire was to be distributed to HCPs. Similarly to the general public survey, the questions asked were designed to ascertain the views of various HCPs towards the use of social media in reporting and monitoring suspected ADRs. The sample population comprised various HCPs including medical doctors, pharmacists, nurses, dentists and healthcare workers. These professionals were sourced from different working environments including hospitals, clinics, clinical trial sites and pharmacies. As with the general public sample population, a European demographic limitation was implemented to ensure consistency in results. The first set of questions in the survey was designed to obtain details on the behaviour of HCPs towards the use off and reliability of health-related information available online. The second set of questions aimed at contextualising the importance of the patient-HCP relationship, by obtaining the personal opinions of HCPs towards the ethical issues surrounding the use of patient health information online. The last set of questions looked at the willingness of HCPs towards implementing the idea of ADR reporting/monitoring via social media. Additionally, the questions were aimed at ascertaining the collaborative effort between relevant stakeholders that must be implemented for such a concept to come in to effect.

The final questionnaire was to be distributed to individuals within pharmaceutical companies to determine the attitude and behaviour of the pharmaceutical industry towards the potential implementation of social media as a platform for post-marketing surveillance. The sample population for this survey was very specific and limited. Individuals from various pharmaceutical companies were selected to complete the survey. Each of these companies was an MAH that held a license to market pharmaceutical products within the EU. The individuals selected were qualified professionals working within the pharmacovigilance sectors of their respective companies and had strong knowledge of the pharmacovigilance systems in place. Due to these limitations, the survey questions aimed at providing more qualitative than quantitative responses from the various pharmaceutical companies. The first set of questions asked about the company's pharmacovigilance systems in place and the behaviour of the company towards the monitoring of digital media sources. The second set of questions aimed at determining the familiarity of the individuals towards the legislative requirements in place for social media screening by MAHs. The final set of questions asked were designed to convey the opinions of the individuals towards the limitations and potential benefits of introducing social media screening as a key component of post-marketing safety surveillance.

Data collection and analysis

All three questionnaires were prepared using the online survey tool, SurveyMonkey®. Separate links to each survey were generated and subsequently distributed to the relevant sample populations. The survey links were distributed to the participants via email and various forms social media including Facebook and LinkedIn. The surveys were open for responses for approximately four weeks to allow adequate time for a higher and more meaningful response rate. The online tool allowed for a maximum of 100 responses for each survey.

Data analysis of the survey's closed-ended responses was performed to provide basic descriptive statistics and potentially significant quantitative information. Analysis of the data obtained from the open-ended questions was performed to provide more expressive, qualitative information.

Results

Responses from the general public

The survey for the general public received a maximum response rate of 100 participants. All closed-ended questions were successfully completed while some participants chose not to share their full opinion within the two open-ended questions. A significant number of participants indicated that they are current active users of health networking sites or online health forums (n=42, 42%), but a relatively higher number said they are not active users (n=58, 58%).

When asked about their attitude towards the information available on such sites, more than half of the participants (n=58, 58%) admitted to have had used these forms of digital media to acquire information on a medicinal product which they have been prescribed. Relative to this, exactly half of the respondents (n=50, 50%) said that they would take into consideration suspected ADR related information posted on Facebook or Twitter before the use of a medicinal product.

An essential aspect to determining the attitude of the general public, was to ascertain which key patient-safety stakeholders would they feel comfortable utilising health information which they have posted online. 72 (72%) of the total respondents stated that they would be comfortable giving consent to HCPs, 51 (51%) said they would give consent to health authorities, while only 34 (34%) said they would be comfortable with pharmaceutical companies using their posted information. 16 (16%) however expressed that they would not feel comfortable giving consent to any of these individuals or organisations to utilise their health-related information (Figure 1).

The monitoring of social media for ADR-related information by these stakeholders is a concept that majority of the respondents believed should be obligatory (n=73, 73%). Furthermore, a significantly high number of respondents (n=83, 83%) agreed that if the voice of

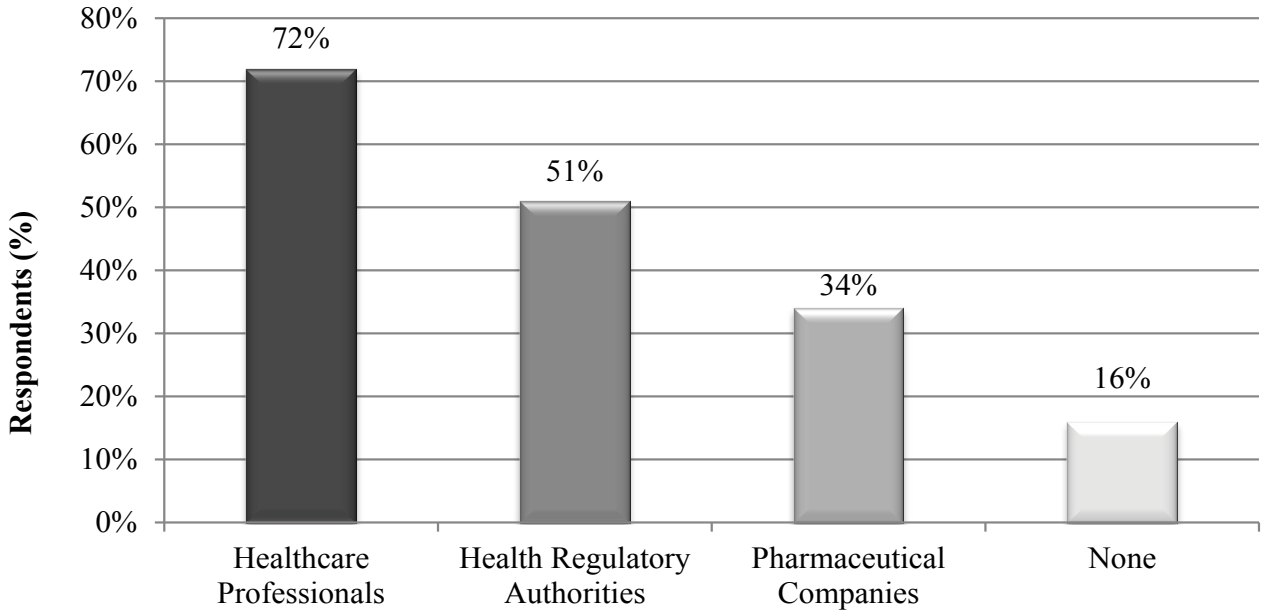

Figure 1: Number of respondents who feel comfortable with HCPs, health authorities and pharmaceutical companies in using their personal health information posted online.

the public was introduced directly into the conversation and they were reassured of the important role they play in ADR reporting, patients would be more inclined to report suspected ADRs via digital and social media.

Regarding the general public's reluctance to post adverse experiences online, the participants were asked to describe what factors would make them hesitant to do so. To no surprise, privacy and confidentiality issues were the predominant reason (n=30, 30%). The other reasons for hesitancy in reporting are outlined in Table 1.

The participants were also given the opportunity to express their views towards the possible challenges and limitations that would need to be overcome to achieve acceptance of social media ADR reporting within the general public. The responses were divided into separate categories of challenges and limitations. These are outlined in Table 2.

Finally, there was positive feedback from the general public towards the idea of introducing a mobile application that allows reporting of ADRs directly to health authorities, pharmaceutical companies or HCPs. 90% (n=90) agreed that if such a concept did materialise, the general public would be more inclined to report suspected ADRs via this platform.

Responses from the healthcare professionals

The survey for the HCPs received a response rate of 46 participants. As with the general public survey, all closed-ended questions were successfully completed while some participants chose not to share their full opinion within the open-ended questions. The respondents comprised of 34 medical doctors (74%), 3 nurses (7%), 2 dentists (4%). 7 participants (15%) indicated that they were either medical interns or healthcare workers while 0 responses were received from pharmacists. From these 46 respondents, a notable 72% (n=33) indicated that they are current active users of social networking sites or online health forums.

To achieve a better understanding of the behaviour of HCPs towards monitoring social media, the participants were asked to convey the frequency at which they would screen sources of social media for medical and ADR-related information. Over 43% (n=20) said they would only rarely do so while almost 35% (n=16) stated that they would never carry out such practice (Figure 2)

Subsequently, the HCPs were asked if they would take into consideration, relevant ADR-related information on social media sites, when prescribing or providing medicinal products. 59% (n=27) of the participants indicated that they would take such information into consideration while 41% (n=19) stated that this would not be within their general practice.

From a feasibility perspective, there was a predominantly positive feedback from the HCPs towards the concept of utilising social media in reporting and monitoring suspected ADRs. 63% (n=29) of the respondents believed that the concept is feasible amongst HCPs. In addition to this, 72% (n=33) of the HCPs expressed that ADR reporting and monitoring via social media is a concept that they would be willing to adopt in the future.

Majority of the HCPs were in agreement over the need for a collaborative effort between relevant stakeholders, in order for the concept of social media ADR monitoring and reporting to come into full effect. 52% (n=24) of the respondents agreed that this was necessary while 37% (n=17) said that they strongly agreed with this proposition.

When asked about the proposed benefits of utilising social media as post-marketing safety surveillance tool, 74% (n=34) of the respondents agreed and 9% (n=4) strongly agreed, that the concept could potentially be used to alleviate the high occurrences of under-reporting (Figure 3).

The ethical aspects of utilising patient health information from social media were also questioned and the HCPs were asked to provide their own opinions or concerns on this issue. The total amount of responses were analysed resulting in the identification of 3 common concerns amongst the HCPs (Table 3).

Finally, the HCP participants were given the opportunity to describe what they considered to be the current limitations in implementing the

Reasons for hesitancy	Participants (n)	Participants (%)
Privacy, trust and confidentiality issues	30	30%
Unsure about the validity of the adverse event	10	10%
Concerns on the negative impact of the report towards the product or company responsible	9	9%
Fear of retaliation or exposure	5	5%
Embarrassment	3	3%

Table 1: Reasons for hesitancy by the participants to report personal drug adverse experiences on social media.

Challenge or limitation	Participants (n)	% of total participants
Overcoming privacy, trust, consensual and confidentiality issues	17	17%
Ensuring the efficiency and reliability of the process	15	15%
Increasing the awareness of the general public towards the concept	11	11%
Creating a digital media system or platform to accommodate reporting	7	7%
Overcoming the age barrier that suggest elderly would not comply	7	7%
Overcoming ignorance or lack of interest towards reporting ADRs	2	2%

Table 2: Challenges and limitations that need to be addressed or overcome to achieve acceptance of social media ADR reporting by the general public.

Common concerns	Respondents (n)	% of total participants
Patients should be informed prior to use of their health information and consent must be obtained	6	13%
Medical ethics for HCPs could be breached	6	13%
Anonymity and privacy of the patient needs to be ensured when using their information for ADR reporting purposes	15	33%

Table 3: Common ethically-related concerns expressed amongst HCPs towards the use of patient information for ADR monitoring and reporting.

use of social media in post-marketing safety surveillance. The most common limitations mentioned were those related to the validity and bias of adverse events reported on social media (28%, n=13). This was followed, unsurprisingly, by concerns towards maintaining patient confidentiality (22%, n=10) (Table 4).

Responses from the pharmaceutical companies

From the 17 pharmaceutical company respondents, more than half of the companies (n=9, 53%) were confirmed to be responsible for some form of digital media, in which safety information relative to their pharmaceutical products could be reported. The active screening of external social media sites for ADRs however was less common with only 5 (29%) of the companies indicating that they are actively involved in monitoring external social media sites for potential ADR-related information.

Positive feedback was also received towards the idea of introducing a mobile application for reporting and monitoring ADRs. 71% (n=12) agreed that this could potentially act as a platform for the expedited reporting and monitoring of suspected ADRs. Furthermore, all respondents agreed that a collaborative effort must be achieved amongst the pharmaceutical industry, HCPs and consumers if social media is to be used as a tool in ADR monitoring and reporting. While 53% (n=9) of the respondents agreed to this suggestion, 47% (n=8) of the respondents stated that they strongly agree.

The participants were also asked to voice their opinions towards the potential ethical and data privacy issues surrounding the use of patient health information available on social media. The responses are outlined in Table 5.

The feasibility in the concept of using social media in ADR reporting and monitoring did not seem to be a concern for the majority. 71% (n=12) of the respondents stated they would consider this concept feasible from a legislative and industry perspective. All respondents did however indicate that limitations do exist in this from a regulatory and industrial commercialisation perspective (Figure 4).

Finally, it was important to obtain the opinions of the pharmaceutical companies towards the potential beneficial outcomes that could arise from the use of social media in post-marketing safety surveillance. The responses are outlined in Table 6.

Discussion

Accepting the use of social media for pharmacovigilance purposes

A major component of the study involved ascertaining the acceptance of ADR reporting and monitoring via social media amongst all the stakeholders involved. For such a concept to be even considered for implementation, a mutual attitude of acceptance between the pharmaceutical industry, HCPs and the general public was considered essential. From the results of the surveys in this study, this attitude of acceptance was conveyed throughout the responses from each target population. While many of the respondents expressed their concerns towards the challenges and limitations surrounding the idea, both the quantitative and qualitative results indicated a positive attitude amongst all target populations.

While this mutual attitude of acceptance is necessary amongst all stakeholders involved, achieving the approval of patients and the general public is a priority. The first thing to consider from the results was the significant number of respondents who stated that they are

Challenge or limitation	Participants (n)	% of total participants
Validity and bias of reporting on social media	13	28%
Maintaining patient privacy and confidentiality	10	22%
The need for a reporting platform that is credible and unbiased	3	6.5%
Increasing awareness amongst HCPs	6	13%

Table 4: Common challenges and limitations expressed by HCPs towards implementing the use of social media as a post-marketing safety surveillance tool.

Concerns	General opinions
It is difficult. In principle the data cannot be used without permission	Once the person posts something in the digital media it means he/she consents to the use of his/her data
It is unethical to monitor social media postings without making the company's presence known	If the terms and conditions are clearly available for users there shouldn't exist any issues
Concerns on a data protection stand point. Public should not have a name identifier but rather a unique patient ID	-
Important to keep patient data confidential	-
Concerns on the potential use of the patient data by unauthorised individuals, exploiting them etc.	-

Table 5: Concerns and general opinions of the pharmaceutical companies towards the potential ethical and data privacy issues surrounding the use of patient health information available on social media.

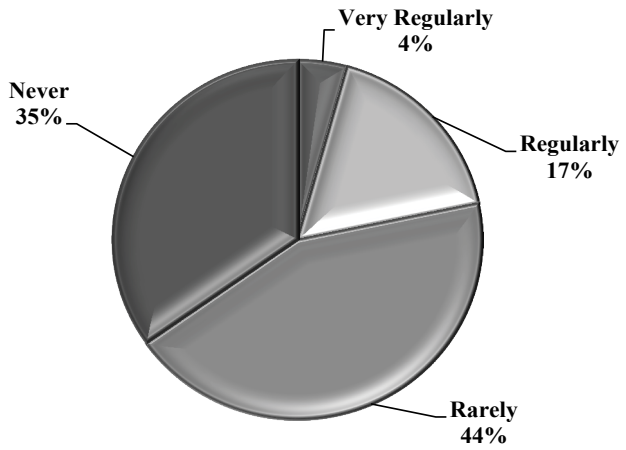

Figure 2: Frequency at which HCPs would monitor sources of social media for medical or ADR-related information.

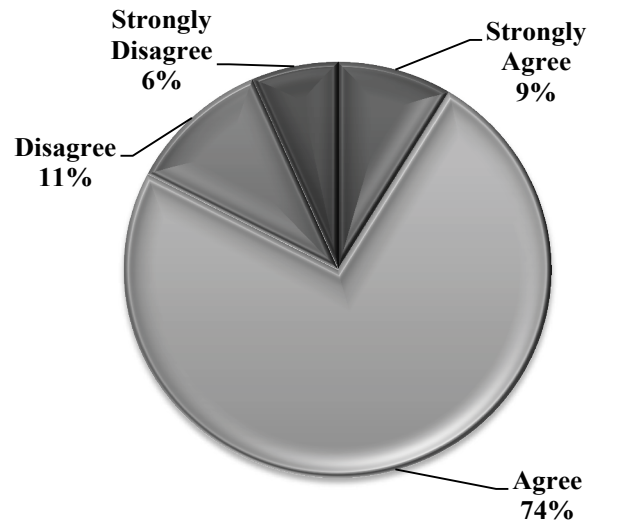

Figure 3: Percentage of HCP participants who either agree or disagree with the possibility of using social media to alleviate the high occurrences of under-reporting and to provide a more expeditious means of reporting adverse events.

current active users of health networking sites or online health forums. Obtaining medicinal product-related information from such sites was shown to be a popular practice amongst the general public with more than half of the respondents claiming to do so. Additionally, half of the respondents sought to obtain information on other social networking sites such as Twitter and Facebook.

The use of social media by the public to report or share drug adverse events is a growing phenomenon. In one particular study, a scoping review of relevant literature was carried out which put into perspective, the vast quantity of ADR-related information that can be extracted from social media [16]. Furthermore, the sheer number of users of health networking sites, such as Patients like Me, exemplifies the attitude of patients towards utilising social media in sharing personal experiences with medicinal products [17].

Determining the acceptance of the HCPs towards social media ADR reporting and monitoring was essential due to key role that they play in ensuring patient safety. As previously mentioned, the patient-HCP relationship is a critical component to the ADR-reporting process. As patients generally turn to their doctors first following a suspected ADR, there is a moral and ethical obligation on such HCPs to relay this information back the responsible MAH.

Health networking sites, online health forums and blogs can all be used by HCPs as tools for self-education, promotion of healthcare ideas, sharing of information and to engage with patients and consumers. Studies have shown that a significant number of HCPs do use social media sites for professional reasons [18]. This attitude and behaviour is reflected in our own survey results too, with over 70% of the HCP participants indicating that they are current active users of social networking sites or online health forums.

When it comes to screening social media sites, specifically for ADR-related information, the attitude of the HCPs was not as positive. Only 21% indicated that they would either regularly or very regularly screen social media sites for ADR-related information. This was an interesting response, taking into consideration that almost 60% of the HCPs stated that they would take into consideration, relevant ADR-related information on social media sites, when prescribing or providing medicinal products. Additionally, over 70% of the HCPs expressed that ADR reporting and monitoring via social media is a concept that they would be willing to adopt in the future.

If the attitude towards the concept of using social media for patient safety purposes was so positive, why is it that the majority of HCPs indicated that they would either rarely or never screen social media sites for ADR-related information? Ethical and confidentiality issues are evidently the most prominent concerns for HCPs. However, the lack of any legislation stating that HCPs are obliged to include ADR-related social media screening within their medical practice, could also be a significant contributory factor.

It can be argued that the acceptance of the pharmaceutical industry of implementing social media screening techniques is highly dependent on the legislation that surrounds this practice. As previously mentioned, MAHs are required to assess any relevant suspected ADR-related information which they come across, on a social media site that is not under their responsibility. As reflected in our results, many companies will have responsibility for their own social media sites by

S. No.	Potential benefits
1.	There could be a value for products used directly by patients. Potentially signals can be picked up earlier
2.	Valuable information will circulate more rapidly
3.	I consider it is just an evolution on the way we will retrieve ADRs. It is more in line with nowadays daily behaviours. It will increase the speed of reporting and hopefully new signals will arise
4.	Obtaining direct and unfiltered patient or user experiences
5.	We will benefit from a larger worldwide database to screen for potential ADRs and have a better knowledge of the medicine profile
6.	More ADR reports will be captured as it would be a more convenient way for most people to report - With more reports rarer ADR's may be revealed - More people will become aware of any updates/ongoing findings related to the use of a particular drug which may have not previously surfaced
7.	Quick response to patients where the drug is not working and stopping side effects as they arise.
8.	More awareness for patients and companies
9.	Accurate ADR reporting, the capturing of safety data at real time can offer healthcare analysts to see a pattern and allow regulatory bodies to make decisions accordingly and to take action promptly

Table 6: Beneficial outcomes, proposed by the pharmaceutical companies, which could potentially arise following the implementation of social media as a safety tool in post-marketing safety surveillance.

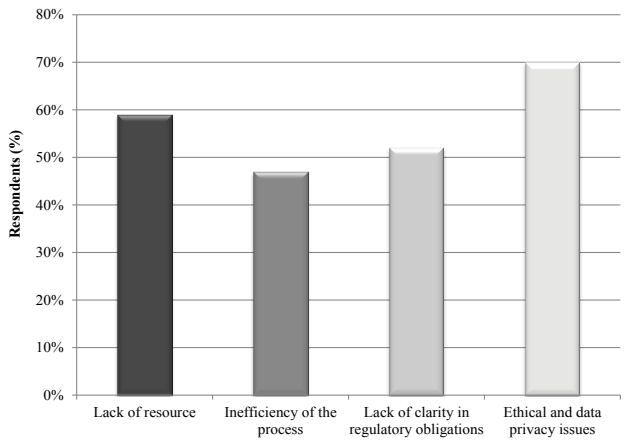

Figure 4: Limitations which pharmaceutical companies believe exist within the concept of using social media in ADR monitoring and reporting.

which users of their medicinal products can report suspected ADRs. However, only 29% of the companies indicated that they are actively involved in monitoring external social media sites for potential ADR-related information.

If over 70% of the respondents stated they would consider this concept feasible from a legislative and industrial perspective, it is interesting that majority of the companies still choose not to engage in the monitoring of external social media sites. Again, the possible reasons for this, are reflected in the challenges and limitations conveyed by the participants. Ultimately, the likeliness of these stakeholders to adopt the concept of social media ADR monitoring and reporting comes down to the risk-benefit profile of such a concept.

Common challenges, concerns and limitations

To understand the risks involved in utilising digital media for Pharmacovigilance purposes, it is necessary to reflect on the challenges, concerns and limitations that were voiced by the target populations. The most pronounced concerns amongst the respondents were of ethicality and confidentiality. This stresses the need for a transparent system of trust between the various populations, particularly between patients and HCPs.

Only 34% of the general public respondents said they would be comfortable with pharmaceutical companies using health-related information from their personal posts online. A significantly higher percentage of respondents would give consent to HCPs to utilise such information (72%). While there may be a high degree of trust from the general public towards HCPs, almost 90% of the respondents agreed on the need for prior consent.

From the HCP responses, it is evident that their challenge is to obtain the consent of the patient or consumer, while ensuring that anonymity and privacy will be maintained. HCPs would need to be careful not to breach their own medical ethics and code of conduct. Furthermore, if the concept social media ADR monitoring and reporting did become a common practice amongst the various stakeholders, it could create possible challenging levels of patient influence. In the event of a patient reporting an ADR online, there could be a concern that it could lead to negative feedback and possible litigation against the HCP responsible for prescribing and supplying the medicinal product.

From a pharmaceutical industry perspective, the responses from the general public indicate that it would be more difficult for MAHs to obtain the consent of patients and consumers for the use of their health-related information. Some of the general public respondents alluded to the "fear of retaliation" from pharmaceutical companies. As reflected in the results, patients would be more inclined to report to HCPs or directly to health regulatory authorities.

Despite the major ethical challenges that are present, the need for requiring consent prior to the use of an individual's publically-posted information is still a topic of debate. As stated by one of the pharmaceutical company respondents, "once the person posts something within the digital media, it means he/she consents to the use of his/her data". Studies have estimated that the quantity of fully-public Facebook accounts is approximately 25% while for Twitter, around 90% of the feeds are believed to be fully public [19,20]. With a few of the companies indicating that they are already screening external social media sites for ADR-related information, it is clear that the data privacy regulations of certain social media sites do not hinder individuals or organisations from screening and mining for health-related information.

Another common concern amongst the general public and HCPs was in relation to the validity of reported adverse events and ensuring their reliability. While many of the respondents stated that there could be bias within reported events, all suspected ADRs reported to MAHs must go through regulatory assessment by the MAH regardless, to determine if an adverse event meets criteria for reporting to the regulatory authority. Using social media to monitor for suspected ADRs may be time-consuming for MAHs, but ultimately it should not affect the validity of ADRs being reported to competent regulatory authorities.

Recent studies and future considerations

While both HCPs and the general public contribute heavily to the post-marketing safety surveillance process, it is ultimately the responsibility of the MAH of the medicinal product to report ADRs back to the competent authorities. The limitations outlined by the respondents within pharmaceutical companies, illustrate why many MAHs may still be hesitant to adopt the idea of social media screening within their pharmacovigilance systems. The "lack of resource" and "inefficiency of the process" may seem like valid reasons for MAHs to not incorporate social media screening within their pharmacovigilance systems. Many recent studies however, have provided results that could perhaps reduce the legitimacy of such reasons.

A recent study carried out by GlaxoSmithKline, described a method by which publically available Facebook and Twitter data could be screened for safety information and Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs). These PTs are the certified medical terminology that the pharmaceutical industry utilises for regulatory purposes. The study displays the resource capabilities of large pharmaceutical company to carry out screening of social media at a massive scale [2].

Other similar studies however have illustrated how a large scale of Twitter posts can be examined for adverse events over a relatively short period of time. In one study, the authors display how they were able to extract over 4000 potential adverse events from over 6 million Twitter posts following a data collection period of approximately 7 months [12]. Additionally, a study carried out by the analytic tools company Brandwatch, displayed how they were able to use their own screening tool to identify 17 adverse events from posts related to 24 of the most common drugs used in diabetes [21].

These studies are just of few examples which demonstrate the methods and technologies available for the pharmaceutical industry for online surveillance and data mining. Taking this into consideration, it is clear that the general attitude of the pharmaceutical industry needs to be refined towards utilising social media in Pharmacovigilance. Additionally, the lack of clarity in regulatory obligations, expressed by the respondents, needs to be considered by the regulatory agencies responsible for producing relevant legislation and regulatory guidelines.

Despite the capabilities of the screening methods conveyed in the studies mentioned above, many ADRs which have been obtained through social media screening may have occurred a very long time before they become discovered. Hence, a platform that would allow for expedited reporting and monitoring of suspected ADRs would perhaps be a major step towards utilising the true potential of social media in pharmacovigilance.

The concept of introducing a digital media platform for reporting and monitoring ADRs is currently being considered at a European level. Web-Recognising Adverse Drug Reaction (Web-RADR) is a European Union-based initiative that is focused on the development of methods, frameworks and tools for social media-based drug safety. The initiative is looking to develop a mobile application that would serve as platform to allow expedited reporting and monitoring of adverse events in several major European languages. The application also aims to create a framework of transparency between MAHs, HCPs and patients. This platform will allow for the sharing of health-related information while respecting the data privacy rights of its users [8]. There was a good response in favour of such an application from all target populations in this study. The potential benefits described by the pharmaceutical industry respondents illustrate the potential beneficial outcomes that could arise from such a concept. Introducing such an innovative platform could help overcome the challenges, concerns and limitations expressed by survey respondents. It could also potentially help increase awareness in the importance of reporting and monitoring ADRs on social media to patients and HCPs.

Limitations of the study

As the surveys were distributed to individuals who live or work within Europe, the demographic limitations of the study are important to take into consideration. These limitations would perhaps impact the responses from the pharmaceutical companies the most due to the differences in legislative requirements and regulatory guidelines outside of Europe. The attitude of HCPs and patients towards using social media for ADR reporting may also differ in developing countries, for example. In addition to this, there limitations could exist in the survey distribution method. These were distributed to individuals via email and sources of social media thus excluding potential participants who perhaps have limited or no access to such resources. It is interesting to speculate that such individuals are amongst those who remain unaware of the current resources available to report suspected ADRs.

Furthermore, the attitude and behaviour of using social media in pharmacovigilance may also vary depending on the age of the individual. Some of the general public respondents alluded to the challenge of getting the elderly to comply with using modern technology to report ADRs.

From a survey participant perspective, the lack of response from pharmacists within the HCP cohort could perhaps also be considered as a limitation. However, similarly to doctors and nurses, pharmacists also have the same moral duty and legal requirements to report any suspected ADRs which they have been informed off. For this reason, it would seem very unlikely that their attitude towards reporting and monitoring ADRs on social media would differ significantly from the other HCP participants. Nevertheless, it would be interesting to determine the opinions and views of pharmacists towards using social media as a tool for augmenting patient safety.

Conclusion

The attitude of the pharmaceutical companies, HCPs and general public towards the use of social media in ADR monitoring and reporting, was generally positive. It is clear from the results of our surveys and the results from previous studies, that implementing such a novel concept will be dependent on both a strong technological approach and a mutual collaboration between the relevant stakeholders involved.

Recent advances in data analytics and the introduction of the Web-RADR initiative will facilitate the tracking of trends from data captured in digital and social media. While the concept of screening social media sites by MAHs has been shown to be feasible, the use of a mobile digital application will allow for a much more rapid exchange of information while overcoming many of the challenges that still exist.

While many potential beneficial outcomes were determined from the study, evaluating the true beneficial potential of social media as tool in pharmacovigilance will require further investigation once the concept becomes a more regular practice amongst the relevant stakeholders. That being said, there is still a need to promote the importance of ADR reporting to the general public and inform them of the various options for reporting that are available. Amendments to legislation or additional guidelines may also be required to ensure the engagement of HCPs and pharmaceutical companies in reporting and monitoring ADRs on social media. Finally, a risk-benefit assessment of the concept will need to be carried out and a regulated framework, involving all relevant stakeholders, will need to be built around this risk-benefit profile.

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