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Social Media and Networks in Pharmacovigilance
Boon or Bane?

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Whether one likes them or not, social media such as Twitter and blogs in general, and networks such as Facebook and LinkedIn have become a very widely used form of social discourse. They allow anyone who has access to the Internet, or who is a (self-selected) member of a particular network, to contact each other. Despite some attempts at political controls, they are as close to universal free expression as one can get.

1. Background

In pharmacovigilance, many are wary about public involvement in knowledge gathering and sharing relating to adverse drug effects. A Letter to the Editor in this issue of *Drug Safety* by Knezevic et al.[1] is a well balanced account, giving evidence of the potential usefulness of a Facebook group for reporting individual case harm reports, and at the same time showing that there are some disadvantages. We will take this opportunity to consider not only the specific issue of using social networks for reporting, but also to contemplate some aspects of the broader social media's potential impact on drug safety.

Some years ago, during CIOMS discussions on the pharmaceutical industry's role in collecting and reporting adverse drug reactions, the assembled experts considered whether the pharmacovigilance responsible people should be required to trawl the Internet for safety information on their products; there was a unanimous view that to do this was an impossible task, unenforceable and not cost effective. The EU's Volume 9A of the Rules Governing Medicinal Products in the European Union[2] has the following to say about adverse reactions seen on the web:

*"**4.3.3 Information on Adverse Reactions from the Internet:** The Marketing Authorisation Holder should regularly screen websites under their management or responsibility, for potential reports on adverse reactions. The Marketing Authorisation Holder is not expected to screen external websites for information on adverse reactions. However, if a Marketing Authorisation Holder becomes aware of an adverse reaction on any other website the Marketing Authorisation Holder should review the case and determine whether it should be reported in expedited manner in accordance with Chapter I.4, Sections 3.1 and 3.5.*

The Marketing Authorisation Holder should consider utilising their websites to facilitate adverse reaction collection, e.g. by providing adverse reaction forms for reporting or by providing appropriate contact details for direct communication. In relation to such reported adverse reactions, identifiability of the reporter and Patient refers to the existence of actual people."[2]

Whilst this seems to uphold the general principles of the CIOMS experts, there are a couple of ambiguities in the first paragraph. Websites under the Marketing Authorisation Holder's (MAH) 'responsibility', and if the MAH 'becomes aware of' are phrases that seem to edge the door open to broader web-searching activity by the MAH.

As far as EU Member States are concerned, the new Directive 2010/84/EU[3] of the European

Parliament and of the Council says that they should:

Article 102 (b): "facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats";

Article 106 (e): (provide) "information on the different ways of reporting suspected adverse reactions to medicinal products to national competent authorities by healthcare professionals and patients, including the web-based structured forms referred to in Article 25 of Regulation (EC) No 726/2004."[3]

All this seems to further broaden the need to consider new possibilities of reporting adverse effects. The main point is that none of us can really ignore the world wide web, the information it carries and the impact of that information.

2. The Thesis

An increasing number of pharmacovigilance professionals, but by no means all, believe in the desirability of direct reporting by patients, and perhaps other consumers and the public (which are not the same groups of people, although they merge into each other). Giving access to the public to voice their concerns on therapeutic outcomes is generally regarded as healthy, particularly if there is a climate of distrust, as there seems to be, of those who make decisions about medicines and their safety.

The use of health professionals as an intermediary in reporting may result in reports being censored in various ways and, at worst, no report being made. Several publications attest to the richness of information to be found in patient free-text descriptions of their problems, and also that the volume of useful reports is enhanced, thus aiding earlier hypothesis formation and signals, for example.[4] Underreporting of adverse reactions is frequently mentioned as a serious problem, and to try to improve reporting seems to be the motivation around the latest EU legislative acts.

Therefore, part of the thesis for use of social media is partly to further enable patient and public reporting, and the argument for patient interaction and support through the social networks is succinctly made by Knezevic et al.[1] It might well be that the combination of such mutual support and the ability to report adverse experiences will be an attraction, and interaction between reporters may produce an increased richness of information, particularly relating to severity and seriousness of the described effects and their impact on patients' lives.

There are websites such as TheBody.com[5] which deal with one disease, in this case HIV/AIDS. It has a feature called HealthTracker where patients can record, for their own use, their laboratory results, medications and a diary on what is happening in their lives, and they can create graphs and reports to send out. The blogs on the site record much information on the patients' experiences of treatment; there is also a wealth of information about adverse effects. This example of a website and talk forum for a single disease entity is not quite the same thing as a social network group, but shares some of the attributes of information mutuality and immediacy.

The same goes for a website such as Healthtalkonline.org[6] (originally, and still, available as www.dipex.org.uk); it, too, contains many detailed descriptions of people's experiences with diseases and their treatments, good and bad, although this site has a discussion forum covering a wide variety of illnesses.

These sites are different from Facebook and other social networks in that they are both more broadly public and with a specific focus on illness and/or health. However, the margins are blurred since Facebook can be organized in focus groups, as illustrated by Knezevic et al.,[1] which provide education and guidance specifically for the subset of members included in the group, and there is apparently an enforcement of some rules of engagement as there is for Healthtalkonline. Within broader social media there can also be provision for more focused discourse.

Another important point remains. The Facebook group set up by Knezevic et al.[1] was specifically designed to get adverse reaction reports to the authors' institution. As a project it was very successful in attracting nearly 1000 personal profiles and 21 adverse reaction reports, a 2% yield in 7 months of operation; none of the 21

adverse reaction reports were regarded as implausible. For much of the social media there is no intent to obtain or channel pharmacovigilance information to pharmacovigilance professionals – the information is simply there, floating in the ether!

3. The Antithesis

Good though the yield was for Knezevic et al.,[1] the authors acknowledge that the personal profiles of the participants show that they were a very selective sample of the population, in particular they were very well educated and 12% stated that they were employed (for others the data on employment was missing). In a sense, these represent surprisingly strong biases for a widely used social networking medium, but it seems inevitable that the use of such networks will carry biases such as the health professional input in this case. In theory, there may be groups who will use networks to express strong, or even false, commentary in reports for or against medicines. One can add that the information direct from patients and the public is unchecked by health professionals before submission, which can have its bad side as well as the argued good, above. Unscrupulous people may send in false reports and information, something that is already known to occasionally happen for reports through our current pharmacovigilance systems, but easier to perpetrate through less monitored social media.

The EU's Volume 9A[2] states *''In relation to such reported adverse reactions, identifiability of the reporter and Patient refers to the existence of actual people.''* This may be difficult to ensure, since individuals may not submit their full identity for a variety of reasons and, in any case, individuals' sites can be tampered with, or used by persons other than the registered owner. The identity of the reporter/patient is also problematic from another angle. It is not at all clear whether any information on the Knezevic et al.[1] Facebook site is regarded as confidential, but it states on their 'wall' that all information is public and group names do seem to be accessible by anyone. Facebook has a set of ten principles[7] that are admirable, but the second of them reminds us of some difficulties over privacy:

''Ownership and Control of Information: People should own their information. They should have the freedom to share it with anyone they want and take it with them anywhere they want, including removing it from the Facebook Service. People should have the freedom to decide with whom they will share their information, and to set privacy controls to protect those choices. Those controls, however, are not capable of limiting how those who have received information may use it, particularly outside the Facebook Service.''

It is quite clear that once information has left the origin there can be no guarantee on what users do with it, and the larger the group the larger that problem may be. Once information is shared control is lost.

The aim for openness by the social media has perhaps caused some reason for concern because of highly publicized incidents, which have caused some notoriety for Facebook, and could therefore be regarded as a negative. On the other hand, we have no reason to believe that this view is other than a bias based on media reporting of occasional bad consequences attributed to the use of Facebook, which is used by millions without apparent problem. Some people respond to published adverse drug reaction signals in the same way – the rare possible harm is used to overshadow the more frequently seen benefits from drugs!

The sheer size and success of social media and networks is a cause for concern simply because of the extra workload and resources data retrieval and analysis would entail if we had to manage drug safety data from throughout the web. There is a vast amount of information on drug safety matters that social media and networks collectively contain, some of it useful and some not, depending on the perspective and needs of the user/reviewer. There is a format, agreed between regulators and industry in the International Conference on Harmonisation (ICH) regions, for transmission of case-report information (ICH E2B). The absence of oversight of the social media means that such consistency is likely to be less well achieved if these media are used for reporting adverse reactions. The lack of use of standardized terminologies and dictionaries for describing

adverse effects and drug products will also cause problems, and that is assuming that there is a method for trawling information from the web, which could capture all the relevant information 'out there' systematically and without biases.

That there is so much unstructured information available in fragments gives potential for biases and confusions. Health professionals already have the fascinating, but unenviable, task of discussing the implications of such heterogeneous information with patients. Some of the information may directly impugn medical practices, causing concerns of very variable realism!

On top of all this is the global diversity that is represented by social media and networking. The challenges here are manifold and not just confined to linguistic issues and translation, but relate to social structures, practices and intangibles.

4. A Resolution and Way Forward?

The paradox of the use of social media in pharmacovigilance reflects a general paradox in society and in science. We look for more evidence on which to base our decisions, which largely comes from well controlled science and the carefully considered generalizations experts can make from it, as well as from expertly considered case material. On the other hand, members of the public are both demanding, and now have resources, to make their individual cases using the media; they have a right to do so and their different perspective will inevitably add both value and confusion. Openness and collective decision making is also more to the fore, and this includes the concerns of all minorities.

We have to therefore embrace both perspectives: we need to make generalizations to do the most good to most people, and we also need to know about the exceptions and why they occur, particularly when harm is the issue. Personal descriptions of adverse effects of drugs should be as informative and from as close to the source as possible if we are to understand why outliers behave differently from the norm, as well as the extent of the overall harm caused them. To know how *many* are 'different' from or represent the norm is a separate issue.

Since social media and networks are already used widely to exchange and debate safety issues related to drugs, in reality the negative commentary above perhaps reflects denial or a dismissive attitude to a major challenge coupled with a lack of imagination about how the information might be useful and how to deal with it technically. Knezevic et al.[1] have usefully suggested how to use one social medium to enhance reporting in a very similar way to standard patient reporting, but this is just the starting point.

Data is not the same as knowledge; wherever there is data, there is a need to tame it – find it, collate it, analyse it and communicate the results for useful purposes. Apart from data retrieval based on exact lexical matches, concept-based searches allow us to find related information fit for purpose; data mining and other techniques allow us to identify unexpected patterns in data around any lexical, linguistic or conceptual focus; using algorithms and human historical and contextual knowledge allows us to determine what and how to investigate further before hypothesizing. Using such methods on accessible data on the Internet is the way we should move, carefully testing them as we go.

Google Insights for Search[8] has provided us with a tool that allows us to look at any public concerns, as measured by web traffic, which can also include drugs and disease (adverse effect) terms. Using this tool is fascinating, but it has a long way to go before it can be used for the purpose of pharmacovigilance; at the moment it is just a way of browsing possible associations, without much precision. As an example, it is easy to find that montelukast linked to 'side effects' is a recent web phenomenon; 'avandia side effects' shows several peaks in recent years, whereas a search on 'avandia adverse reactions' does not yield a result since there is ''not enough search volume to show graphs''. It is absorbing to consider how and why there are regional differences in web traffic (this is automatically displayed); for instance, there is growing traffic on 'pharmacovigilance' in India – is this linked to an increase in adverse reaction reporting or drug safety concerns, or to the launch of a nationwide pharmacovigilance programme … yes, this is wonderful

to speculate over, but we really do need to think very hard about how to utilize all that ether pharmacovigilance information!

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