Social Media as a Catalyst in the Advancement of Pharmacovigilance

Dr. J. Vijay Venkatraman*
Managing Director & CEO Oviya MedSafe

Introduction

The thalidomide tragedy of the early 1960s is widely regarded as the earliest and the most significant clarion call for standardized regulations to monitor the safety of marketed drugs across the globe. Interestingly, the possible link between thalidomide and phocomelia was first suggested by a published case report which led to the gradual accumulation of information that established and confirmed the causal relationship. One can imagine how challenging it could have been to exchange such critical data on drug safety, especially across countries, fifty years ago. But today, we have overcome these challenges thanks to the evolution of technology and globalization. Further, the growth of electronic media has contributed a lot to the science of Drug Safety by enabling much faster, easier and cheaper access to adverse event data. Social media, the newest offspring of the concepts of electronic communication and interactive technologies, is the most user-friendly tool to share any information and due to its complicated dynamics of authors being the audience and vice versa, is also the toughest to handle.

One of the key consequences of the thalidomide disaster was that pharmaceutical companies were mandated to identify and adopt all possible methods to monitor the safety of their marketed products (of course only in the regulated markets). Passive monitoring of drug safety was not acceptable anymore and pharmaceutical companies were forced to take a proactive approach which included periodic monitoring of published medical/scientific literature for mentions of suspected ADRs, development of risk management plans and risk minimization measures by performing ongoing risk-benefit analysis of their products. With enhanced understanding of pharmacovigilance principles and with drug safety regulations getting stricter across the globe, pharmaceutical companies had to choose to either invest in their pharmacovigilance systems or bear the heavy penalties levied by regulatory agencies. Of late, regulatory agencies have started looking beyond healthcare professionals for reporting adverse events and encourage consumer reporting. And, with changing times, screening of social networking sites and digital media for safety information is now emerging as part and parcel of the regular literature monitoring activities in any organization, as today's consumers are more likely to use social media to share their adverse drug experiences.

Monitoring adverse events linked to administration of medicinal products from all over the world is a huge challenge. Also, detecting potential signals in an appropriate manner from the reported adverse drug reactions is quite a complicated task. To address these concerns, many researchers have explored methods to detect adverse events in electronic health records. Collecting electronic health records from multiple sources is cumbersome. With the availability of Web 2.0 platforms and the popularity of social media, many consumers are now discussing and exchanging health-related information with their peers. Most of these online discussions involve references to the adverse drug reactions one experienced. Whether one likes or not, social media has become a widely used form of social discourse. Therefore, data mining of social media for information on suspected ADRs has not only been proven to be useful but has also been mandated by recently regulations for more realistic pharmacovigilance.

Global Regulations

The US FDA's draft Social Media Recommendations (June 2014) document highlights that pharmaceutical companies are responsible for product promotional communications on sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the company (eg Twitter, social networking sites such as Facebook) and the company's blogs. Under certain circumstances, companies are responsible for promotion on third-party sites too. A company is responsible for the content generated by an employee or agent who is acting on behalf of the firm to promote the company's product.

The EMA GVP module VI mandates that the Marketing Authorization Holders should regularly screen internet or digital media under their management or responsibility, for potential reports of suspected adverse drug reactions. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the marketing authorization holder. Unsolicited cases of suspected adverse drug reactions from the internet or digital media should be handled as spontaneous reports. The same reporting time frames as for spontaneous reports should be applied.

Also, the CIOMS Working group V indicates that a procedure should be in place to ensure daily screening by a designated person(s) of the website(s) in order to identify potential safety case reports. More regulation in this space is expected to evolve in the near future.

Notable Initiatives

There are many new e-applications which have been developed globally and accepted by regulatory bodies in order to simplify the ADR reporting and collecting methods. The US FDA has approved a mobile and web application called MedWatcher which allows users to learn about side effects of drugs, medical devices, and vaccines and to easily report adverse events to the FDA. Recently, the US FDA has signed a research collaboration with PatientsLikeMe, which is the largest and most active patient network online. Under the collaboration, PatientsLikeMe and the FDA will systematically explore the potential of patient-generated data to inform regulatory review activities related to risk assessment and risk management.

In the EU, the WEB-RADR project is developing a mobile application for patients and healthcare professionals to report suspected ADRs to national EU regulators, and investigating the potential of publicly available social media data for identifying drug safety issues. The WEB-RADR project is funded by the IMI, a large-scale public-private partnership between the EU and the pharmaceutical industry association EFPIA.

Meanwhile, the Indian Pharmacopoeia Commission (IPC) - the National Coordination Centre for the Pharmacovigilance Programme of India (PvPI) under the Ministry of Health & Family Welfare, Government of India, recently developed in collaboration with NSCB Medical College, Jabalpur a revolutionary mobile application which simplifies the process of ADR reporting by healthcare professionals to the national programme. This mobile application was specifically designed to facilitate the needs of the IPC to ensure hassle-free ADR reporting.

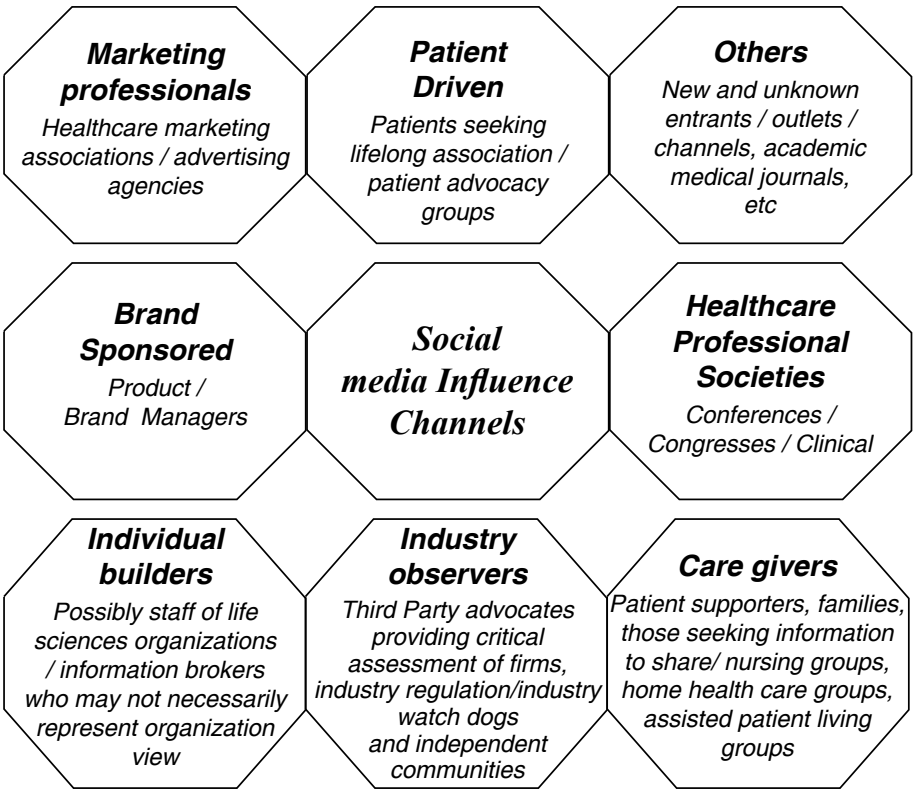
*E-mail: vijay.j@oviyamedsafe.com

Similarly, a few other emerging countries, especially in Africa, have developed and deployed customized electronic applications for reporting ADRs to their national programmes.

Recently, the Uppsala Monitoring Centre (UMC, the WHO Collaborating Centre for International Drug Monitoring) has launched VigiAccess, a web application which could be used by anybody to access information on reported cases of adverse events associated with over 150000 medicines and vaccines. VigiAccess gives users access to statistical data from the more than 10 million cases reported from over 120 countries contained in VigiBase, the WHO database of suspected ADRs maintained by the UMC in Sweden. The agency has also come up with novel initiatives like 'Take & Tell' to promote consumers to report adverse events to their doctors, which is now trending on social media.

Social Media Screening

There are many types of social media including Blogs, Wiki, Twitter and Social media platforms (Facebook, LinkedIn etc). Usually social media includes unstructured data & processes, contain unregulated information and are generally not quality driven; while drug safety activities involve structured data & processes, are highly regulated and are generally quality driven. The success lies in connecting these two different worlds and capturing the relevant adverse event data without compromise.



There are signs that social media websites can be used to discover hitherto unreported possible adverse reactions, but we are still in the early days in realizing it as a proven method. In this digital era, online discussion is the easiest thing to do and hence adverse events identified from social media must be considered at par with the consumer-reported adverse events received through conventional channels. Pharmaceutical companies would benefit by evolving a customized code of conduct for their organizations on how their employees should engage themselves in social networking. For any user to join a company-sponsored site, appropriate permissions and restrictions should be provided in advance in the form of terms and conditions. Companies should also have mechanisms to screen and capture adverse events from these websites. If a third party vendor has been involved, they must be clearly advised about this pharmacovigilance obligation of the marketing authorization holder.

Advantage of Social Media Mining

To stay competitive, it is essential for organizations today to interact online with their customers, which would position them as a company that listens to public opinion. This implies increased probability of capturing adverse events which may have otherwise gone unnoticed. Pharmaceutical companies will be able to detect trends/patterns of reported ADRs by analyzing social media data. They can gather the most updated information about the drug and their company, including sentiment analysis and use it to make amends for their identified weaknesses. Also, collecting real world evidence will help shape the development of their existing and new drugs. Further, this will help in building trusted relationships between the company and the patients.

Challenges in Data Mining

The guidance documents mentioned above are not clear about the scope and scale of monitoring of non-company sponsored digital media. Also, establishing and confirming the identities of the Patient and the Reporter, both of which are amongst the following four required elements for a valid ADR report as referenced in the FDA draft guidance for adverse event reporting and in GVP Module VI, is expected to pose quite a lot of practical challenges:

- Identifiable Patient
- Identifiable Reporter
- Suspect Drug
- Adverse Event/reaction

There are a number of additional technical challenges to be overcome including:

- Identification of duplicate safety information with respect to data originating from digital media i.e. the same ADR may be reported by the same or a different user on multiple digital media platforms, requiring robust methods for the evaluation of data reliability;
- There is a challenge of multiple languages used on social media and how data collected from posts in different languages would map to standard ADR terms;
- Additionally data privacy and personal data protection issues need special attention; and
- Data curation and cleaning would be required on a regular basis to mitigate the risk of rumours or false information being reported as ADRs with malicious intentions.

Possible Solutions

Social media data mining can be simplified and regulated if we can adopt the following ways in order to find emerging, self-reported medical insights such as adverse events associated with medicines and medical devices:

a) Social media data mining policy

By developing practical guidelines for MAHs to enlighten them about how such social media surveillance can be used to supplement traditional methods of reporting: At the initial stages we can limit the scope of data mining to only the popular social media sites. The companies should use social media experts for data mining purposes. To avoid language issues, the search can be limited to English to start with, as it is the most commonly used language on the Internet.

b) Use of Technology

A common single platform needs to be developed in order to collect information from different web sources. These platforms have to be coupled with series of algorithms which will enable the extraction of data to result in integrated insights on ADRs reported from various social media.

c) Mobile Applications

Affordable and easy to use mobile applications can be developed and circulated among the consumers to make them report the ADRs directly.

Conclusion

The sudden exponential increase in social media usage over the past few years raises new challenges for drug safety and adverse event reporting across the globe but also hints at huge prospect for pharmaceutical companies to access up-to-date feedback about their drugs enabling them to act faster and more efficiently than with previous reporting methods. The use of the Internet, smartphones, tablets and other non-conventional means of data collection and communication is paving the way for real-time, rapid analysis of drug use. Thus, social media has started to play an undeniably significant role in pharmacovigilance. Collecting data from social media websites gives us a greater chance of capturing ADRs about which a patient may not have informed their doctor or caregiver. Physicians are great at diagnosing illnesses and noting objective signs, but patients are great at reporting subjective reactions and feelings. Today, social media has leveled the field for all stakeholders of Patient Safety to share their thoughts and with a little of cautious supervision, can be a great catalyst for all of us to understand pharmacovigilance more quickly and more completely than we ever did in the past.

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