Emerging Technologies (Social Media, Smartphones, And Tablets, Etc.) And Need To Update Safety Reporting Methodologies In India

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Abstract: Keeping in mind India's safety reporting system, this article explores potential areas of Indian pharmacovigilance, requiring changes for building a robust safety reporting system with the use of emerging technologies including social media, smartphones and tablets. As of now, we (INDIA) do not have guidance on how and where to report the drug safety related information through emerging technologies like social media, or even mobile phones in Schedule Y and Central Drugs Standard Control Organization (CDSCO) approval letter. Some of the agencies like Medicines and Healthcare products Regulatory Agency (MHRA), United States (US) Food and Drug Administration (FDA) are taking steps to develop technology based safety reporting which will allow society a user friendly reporting. Indian health authorities only uses paper based traditional reporting, don't even have e-reporting ways for safety, which is 21st century's need.

Keywords: Adverse event, Apps, Media, MHRA, Pharmacovigilance, PvPI, Schedule Y, Smartphones, Tablets, US FDA

I. INTRODUCTION

Social Media, Smart Phones (Androids, iPhones, or iPads), and Tablets are 21st century technologies which have shown tremendous potential to improve human life including healthcare; clearly, social media sites have reached the mainstream. As per recent news, to emphasize on advances toward a world centered on mobile devices and Internet services, Microsoft skips version 9 of operating system and the next version will be called Windows 10.

According to a survey conducted in 2012, nearly 85% of US adults own a cell phone and half (53%) of those are smartphone owners. About 31% of cell phone owners said they use their phone to look for health or medical information online. In India, total mobile phone users were reported as 904.51 million at the end of March, 2014, registering a monthly growth of 0.13%. In smartphone usage, India is now at third position among the top countries with an estimated 117 million subscribers.

The popularity of mobile health is rising continuously among smartphone owners. These days, smartphones are gradually being used for monitoring health, diet and exercise. The recent growth of such emerging technologies (smart phones and tablets apps and social medias such as Facebook, Twitter, blogs, etc.) has given a platform to people to share their medical experiences publicly on the internet. Such data sharing, if properly harnessed, could provide valuable information for monitoring the safety of licensed medicines available in the market. These emerging technologies are now a day used by pharmaceutical companies and patient advocacy

groups to reach out and provide support to patients and their families affected by rare or orphan diseases.

Now, the mobile based apps are available for a range of public health issues and these apps has been recognized by competent authorities such as the Centers for Disease Control and Prevention, the United Nations, MHRA and the US FDA. Some of the popular apps included Medscape and Epocrates. Medscape from WebMD is one of the most downloaded medical apps which offer free Continued Medical Education to physicians. The Epocrates app is currently being used by nearly 50% of the doctors, as per survey. The regulatory agencies viz. MHRA and US FDA have taken some steps on how to use or harness these means to get and to transmit information vital to the public health.

Currently, if we experience side effect after intake of a medication, we check the package leaflet that comes with the used medicine for information on the ways to report it. There might be several ways such as filling in an online form (link), reporting over the telephone and filling in a form from the prescribing doctor or local pharmacy. The need of developing such technologies in addition to current procedures is to increase the drug safety reporting. Higher patient exposure and continuous monitoring of AEs can only reveals a fuller pattern of AEs for marketed drugs. In some cases, rare AEs may be serious enough to warrant additional precautions or even withdrawal of a medicine from the market. Importantly regulatory agencies and health sources have now realized the usefulness of social media tools.

Hence the growing use of emerging technologies by patients and healthcare professionals (HCPs) creates a need for reporting forms to be provided on these platforms so that patients can easily report side effects at real-time and to ensure regulators receive adverse drug reaction (ADR) reports that are easy to access and complete.

II. CURRENT PRACTICE IN INDIA

CDSCO Guidelines and Schedule Y' are the key guiding sources on drug related AE reporting. The Pharmacovigilance Program of India (PvPI) was introduced in India to promote patient safety. It is slowly getting familiarized with the Indian population including HCPs. India used Pharmacovigilance network via Vigiflow software most extensively with 62,000 report submissions. Of the total 8.5 million ADR case reports submissions, India ranked fifth in Asia accounting for 0.7 per cent of the global data base.

However, lack of commitment from Indian Pharmaceutical companies and HCPs, the PvPI has not reached to the desired goal. Physicians are under no mandatory obligation to report instances of ADR to the competent authorities. The country needs to sustain the pace of patient safety and improve the drug reaction reporting culture in India among doctors.

III. THE MHRA AND US FDA'S INITIATIVES

The Medicines and Healthcare Products Regulatory Agency (MHRA) of United Kingdom have taken an initiative to develop an app for ADR reporting- 'the WEB-RADR project', as announced in a press release. The project is three-year collaboration with MHRA, European regulators, the pharmaceutical industry, and academics. This app will allow consumers and HCPs to report ADRs via smartphones. The social media discussions will also be looked into by the consortium to gather additional information about medicines.

The US FDA delivered a notice of solicitation called for a "contractor capable of providing it with social media monitoring services capable of analyzing consumer sentiment and social media 'buzz'". The US FDA also rolled out new consumer-friendly forms and web-based learning tools for the ease of consumers to report adverse events related to drugs and medical devices. The US FDA is also supporting a consumer mobile app called MedWatcher which is a free tool complimentary to the 'Form FDA 3500B'. This app allows patients and physicians to submit AE reports to the US FDA via smartphone or tablet. The app provides users with a brief 4-step form that is submitted electronically to the US FDA, thereby considerably simplifies and expedites the reporting process.

Patient reports have been notoriously hard to track on tools such as Facebook and Twitter, leading to regulatory concerns with regards to pharmacovigilance practices; thereby a need to identify shortcomings and enhance reporting standards. Pharma companies are also getting support from health authorities towards compliance with the pharmacovigilance rules amid the rise of online technologies. This includes the publication draft FDA guidance on 'interactive promotional media', covering Twitter, Facebook and blogs.

IV. THE WAY FORWARD: NEED FOR REFORM OF SAFETY REPORTING IN INDIA

Unlike International Conference on Harmonization, MHRA and US FDA, India has limited information available in Schedule Y focused to drug safety and CDSCO essential to design a detailed pharmacovigilance guideline. Such guideline shall incorporate all relevant areas of pre and post marketing safety, addresses to current loopholes and brings in more clarity and transparency. Most importantly, the guidelines shall be in tune with the current international norms by keeping a goal of advantage India for participating in multinational clinical trials. Also being a high and growing number of social media and smartphone users, India has a good opportunity to enhance drug safety reporting through these means if properly channelized with public interest.

In light of this, we suggest to have a clear guidance in respect to drug safety reporting via emerging technologies (such as social media tools and smartphone apps) and to develop a mobile based app which is compatible with the emerging technologies such Androids, iPhones, or iPads and also available on platforms like social media, blogs, etc. The app should have following features-
✓ It should be driven by science, comprehensive, easy to download
✓ Provide a mechanism for monitoring and tracking an ADR

- Be clear on nature of questions to collect data
- Ensure ease of functionality and navigation
- Simple and easily understandable questionnaire- use of layman language

✓ Provide information and updates about diseases and reported ADRs, Side effects, etc. related to them
✓ Provide remote diagnostics
✓ Communication with medical support team

Most importantly, educating the contributors including the users will be the key factor for success of this project.

V. DISCUSSION AND CONCLUSION

The use of the emerging technologies such as internet sites, smartphones, tablets and other non-classic means of data collection and communication will open up the way for real-time, rapid analysis of drug use. We will be able to track the effectiveness of drug along with its adverse events, and safety issues, as well as a lot of other useful information on the drug. This data will be picked up in a fraction of the time and, perhaps, at a fraction of the cost of more classic epidemiologic techniques; if only we could figure out how to do this and get the public interested in supplying data.

REFERENCES

[1] Bailey B. Microsoft says new operating system will be called Windows 10, skips 9 to emphasize advances. Cox Media; Science and Technology news article; 2014 [Accessed on 2014 Oct 1]. Available from: http://www.cox.com/myconnection/today/news/science-andtech/article.cox?moduleType=apNews&articleId=55701dc71bcc477f9c25083a1f5ec80b.

[2] Fox S, Duggan M. Mobile Health 2012; Pew Research Internet Project; 2012 [Accessed on 2014 October 1]. Available from: http://www.pewinternet.org/2012/11/08/mobile-health-2012/.

[3] Telecom Regulatory Authority of India. Highlights on Telecom Subscription Data as on Mar. 31, 2014. Press Release No. 25/2014; 2014 [Accessed on 2014 Oct 1]. Available from: http://www.trai.gov.in/WriteReadData/WhatsNew/Documents/Press%2520Release-TSD-Mar,14.pdf.

[4] European Medicines Agency. WEBAE - Leveraging Emerging Technology for Pharmacovigilance. 2013 [Accessed on 2014 Oct 1]. Available from: http://www.imi.europa.eu/webfm_send/912.

[5] Orphan Druganaut Blog. Social Media and Patients: Smart Phone Apps 2014 [Accessed on 2014 October 1]. Available from: http://orphandruganaut.wordpress.com/2014/04/14/social-media-and-patients-smartphone-apps/

[6] Husain I. Will Epocrates slowly become irrelevant in the iPad era? 2012 [Accessed on 2014 October 1]. Available from: http://www.kevinmd.com/blog/2012/10/epocrates-slowly-irrelevant-ipad-era.html.

[7] European Medicines Agency. Guideline on good pharmacovigilance practices (GVP). EMA; London; 2012:1-84.

[8] European Medicines Agency. Guidance on ADR reporting 2014 [Accessed on 2014 Oct 1]. Available from: www.ema.europa.eu/docs/en_GB/document_library/Other/2014/02/WC500161114.pdf.

[9] Medicines and Healthcare products Regulatory Agency. Pharmacovigilance learning module: Importance of monitoring adverse effects. 2013 [Accessed on 2014 Oct 1]. Available from: http://www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/Medicineslearningmodules/Pharmacovigilancelearningmodule/pharmacovigilancelearningmodule/Pharmacovigilance/Importanceofmonitoringadverseeffects/index.htm.

[10] Pharmacovigilance Programme of India (PvPI). PvPI Newsletter Apr., 2014 [Accessed on 2014 Oct 1]. Available from: http://www.ipc.gov.in/PvPI/Newsletter_April_issue.pdf.

[11] Medicines and Healthcare products Regulatory Agency. UK regulator leads innovative EU project on the use of smartphones and social media for drug safety information. Sep., 2014 [Accessed on 2014 October 1]. Available from: http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON454333.

[12] Policy and Medicine. FDA Releases MedWatcher Reporting for Healthcare Providers, Patients and Caregivers. 2014 [Accessed on 2014 Oct 1]. Available from: http://www.policymed.com/2014/01/fda-releases-medwatcher-reporting-for-healthcare-providers-patients-and-caregivers.html.

[13] Food and Drug Administration. Guidance for Industry Fulfilling Regulatory Requirements for Post-marketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics. 2014 [Accessed on 2014 Oct 1]. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf.

[14] Brahmachari B, Fernandes M, Bhatt A. Pharmacovigilance for clinical trials in India: Current practice and areas for reform. Perspect Clin Res.; 2011; Apr-Jun; 2(2): 49–53.