The Potential Role of Social Media in Pharmacovigilance in Nepal: Glimpse from a Resource-limited Setting

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ABSTRACT

Introduction: An ever-increasing trend in the use of social media offers a potential forum for exchanging information in developing countries. Easy access, quick dissemination and widespread use necessitate the incorporation of social media in adverse drug reactions reporting and pharmacovigilance activities.

Aim: To highlight the potential role of the use of social media in pharmacovigilance activities in a developing country like Nepal.

Materials and Methods: A review of all relevant literature was conducted from scholargoogle and PubMed databases using the search terms 'Social media', 'Pharmacovigilance', 'Nepal', 'drug safety', 'social network' and 'adverse drug reaction'. In addition, a general search was conducted in Google search engine using similar terminologies. The identified literature was reviewed by the authors and the most relevant ones within the scope of the topic were included.

Results: Social media use is common; the number of social media users is on increasing trend even in developing countries like Nepal. There are some unique scopes of social media in pharmacovigilance, including improving awareness, reporting and signal detection. In resource-limited settings, social media can play a crucial role in disseminating drug safety and related information. Incorporating social media in pharmacovigilance has challenges, particularly the problem associated with the authenticity and validity of information available in social media platform.

Conclusion: Social media may have an opportunity in the pharmacovigilance system. However, there is limited evidence about its feasibility and validity. Systematic research should be conducted to investigate the feasibility of using social media for the pharmacovigilance system.

INTRODUCTION

Social Media are vibrant and collaborative computer-mediated communication tools. An existence of social networking has developed a symbol of effervescent and translucent communications and has rapidly turned into the ideal system of communication and information sharing [1,2]. Social media and networking may have a vital role and information dissemination capacity in today's digitalised world. Consumers sharing encounters about Adverse Drug Reactions (ADRs) and knowledge of drug on social media could be intriguing for the use of information [3-5]. Additionally, a clear exchange of information about the advantage and danger of medications is a key requirement for ensuring safety. A little information at times benefits the correspondence (warnings or admonitions) to enhance drug use [6]. For the surveillance of drug safety, Social media are presently measured as a probable corresponding foundation of knowledge [7].

Safe and quality use of medicines is a great concern for every stakeholder in the healthcare system such as a physician, pharmacist and nurse, among others. Edwards IR and Aronson JK, defined an ADR as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product" [8]. ADRs are connected with increased mortality and hospitalisations and have a huge economic impact [3,9-11]. In many cases, they lead to treatment failure. Some ADRs can be fatal as well. Pharmacovigilance is the set of activities which is associated with the recognition, assessment, understanding and prevention of adverse effects caused by or to be caused by medicines [12]. Therefore, Post-Marketing Surveillance (PMS) of marketed drugs has become vital to pharmaceutical manufacturers,

countrywide organisations and another country or region-specific drug regulatory authorities and regulatory affair bodies [13].

Clinical trials are imperious for the evaluation and safety of the new medical products and devices. There are rare Adverse Events (AEs) generally discovered before they reach the market or are generally reported during PMS (pharmacovigilance) period, i.e., during the phase IV clinical trial. On the other hand, it is imperative to take note, that not all studies of Phase IV are PMS studies, nonetheless, every PMS study is a study of Phase IV. Phase IV is likewise an imperative period of development of drug [14]. Studies of Phase IV are further different in the design than the earlier clinical preliminaries which are the principal thing to note about studies of Phase IV [15]. A shared objective of studies of phase IV gives proof that the health intervention can be effectively and securely coordinated into public health or clinical practice yet additionally that the interventions stay viable and its execution is not related with any serious adverse effects [16]. The post-marketing AE reporting systems are still under-utilised by the clinicians and the patients in developing countries. Consequently, maximum AEs goes unreported to regulators [17]. For the information and evidence which is related to the Pharmacovigilance, social networking websites are useful as they are the possibly significant ocean of the information. However, their actual value stays to be completely understood. Social networking website has the volume and prompt nature which provide probable openings for constant observing of ADRs, the more noteworthy catch of ADR reports and expedited signal detection if used effectively [18].

Therefore, the present authors aimed to explore the current status of pharmacovigilance and feasibility of usage and scope of social networking in uplifting drug safety status in Nepalese context, which can ultimately be useful for others in similar nations.

Use of Social Media In Nepal

Nepal is a developing nation located adjacent to China in the North and India on the other sides. Social media in the recent past had played a crucial role in Nepal during the time of a major earthquake disaster in 2015, where in a tweet for Nepal with hashtags like "#EarthquakeNepal #RebuildNepal #NepalEarthquakeRelief #ICanYouCanWeCan #HelpNepal" helped to reach stakeholders and the general public [19]. Considering that underreporting of ADRs is a major challenge associated with pharmacovigilance programs, strategies must be sought to overcome the same [20]. Social media appears to be a viable solution to overcome under-reporting of ADRs. Facebook, Twitter, Google Plus, Pinterest, etc are widely used in Nepal for health communications. In addition, social media is also widely used for communicating health information, career development of health professionals and students, public health surveillance and health policy [21-24].

Is the Social Media Use a Future of Pharmacovigilance?

Social media has developed to be a fundamental information foundation for pharmacovigilance studies where a growing number of people post adverse reactions to medical drugs that are previously unreported [21]. Enhanced reachability and computing power have opened the avenue for using social media for pharmacovigilance [17]. Social Media is the developing philosophy for pharmaceutical organisations to move from the out-dated pharmacovigilance systems and safety reporting methods in the direction of additional patient-focused models for examining, monitoring and reporting safety information and evidence. These social media can provide a platform for easy and open communication between the patients/consumers and healthcare providers regard to the utilisation of medicinal products, subsequently building open trust. For example, a private or public group can be created including all parties to share the communication [22]. However, it is necessary for a responsible healthcare professional to monitor these platforms to authenticate the information.

The potential scope of social networks in pharmacovigilance has attracted attention, it can be potentially used to identify ADRs. The social networking platforms which can be used for pharmacovigilance can range from routine social networking websites like Facebook, Twitter to websites specially tailored to healthcare, wellness programs and support linkages such as "Patients Like Me, Daily Strength, and Med Help" [18]. There have been some previous appraisals in these issues, which have emphasised about the methods of pharmacovigilance through the social networks and have also analysed numerous textual sources on pharmacovigilance, as well as biomedical literature, clinical narratives in addition to the social networks [18]. Most of those articles has been limited to developed countries. However, much has not been discussed about its potential in developing countries, where health literacy, social media access and health information knowledge is very different than those of developed countries. Therefore, with this background, we aimed to evaluate the potential role of social networks on pharmacovigilance in developing countries like Nepal.

Social media are imparting their effects during the transition from the out-of-date pharmacovigilance systems and safety reporting methods for the pharmaceutical companies towards the more patient-centric replicas of investigating, monitoring and reporting safety data but the effects are in the starting stage in Nepal. These social platforms have the capability for straight forward and open communications among patients/consumers and health care providers regarding the use of medicinal products, thereby serving mutual trust and transparency [22]. Speculating from the outburst of the social media, it can be predicted that monitoring of social networking sites will turn into a regular utility in the future of pharmacovigilance in a long run. Vigilant calculation, as well as an assessment of the practice of social media, are the prerequisites

for their application in pharmacovigilance programs and these can be achieved by means of a prevalidated pharmacovigilance tool that may assess and evaluate the social media in terms of their significance and impression on patients' outcomes. For the effective use of social media, their overall cost-benefit exploration and assessment of the regulations and acts are mandatory [23].

Sooner rather than later, social media monitoring will, in the long-run, turn into standard practice in Pharmacovigilance (PV). Nonetheless, before that, cautious assessment and appraisal of the utilisation of social media as a pharmacovigilance device should be viewed as; both regarding importance and effect on outcomes.

Pharmacovigilance Activities in Nepal

Department of Drug Administration (DDA) is Nepal's National Drug Authority established in 1979 as per the requirement of the Drug Act, 1978 [24]. Production, import/export, sales, distribution, and storage of drugs are regulated in Nepal by DDA. DDA established the National Centre for Pharmacovigilance in 2004 [25] and Nepal became a member of the WHO program for International Drug Monitoring in 2007 [26]. At present, there are 12 regional pharmacovigilance centres in Nepal, established to report ADRs to the national pharmacovigilance centre, and ultimately to the Uppsala Monitoring Centre (UMC) in Sweden [27,28]. Knowledge scores among consumers regarding pharmacovigilance are low and require advocacy and improvement. Consumers can be an important pillar in the prevailing pharmacovigilance system in Nepal. The awareness about the pharmacovigilance and ADR reporting systems for consumers through the establishment of consumer pharmacovigilance centre at the hospitals could be an important step towards it [29]. In Nepal, there are huge numbers of community pharmacies which can play an active role in collecting the ADR reports from consumers and forwarding them to the National Centre for Pharmacovigilance.

Pros and Cons of Social Media use in Pharmacovigilance

Keeping in mind the end goal to understand the advantages, internet-based media embrace, variously specialised, administrative and moral difficulties remain to be addressed [18]. There are various advantages and disadvantages of using social media for automatic ADR monitoring.

Unique Advantages of Social Media

For the entire advantages of social media, it involves the watchful amalgamation of each of the data foundations or information to produce substantial signals. When the internet and social media are used in an appropriate manner, it can turn out to be a critical impetus in the change of the Pharmacovigilance practice not long from now. Established techniques for pharmacovigilance approaches will certainly win through, yet social media can possibly turn into an additional new-age device to screen information progressively, making it an early pointer of potential security issues to facilitating examination. Further, this would empower pharmaceutical organisations to create more robust product safety profiles by utilising the additional gathered social media information.

The unique advantages of social media are as follows:

From social media, there are higher chances of capturing ADRs by mining the information that patients would not really complain about going to their specialist or medical attendant. The doctor could all the more likely analyse issues and disease, yet patients can more readily identify with adverse occasions and reactions. For example- some simple statement about health conditions following administration by a patient can be mapped into important ADR signals.

Significant sampling: There are also a special category or group of patients. They can be pregnant women, children or elderly patients. There are often restricted on or after in clinical trials, because of

the risk of teratogenicity or due to moral concerns. However, these group of people can address to dynamic consumers of social media. So, the pattern of ADRs can without a doubt be perceived by utilising social media as the medium.

Business promoters and sponsors are using social networking websites progressively, for their business purposes, where they plan to fit different diseases and their management, medications, expenses of medicine, their therapy like resistance, ADRs, AEs, their illness or medical condition. This can be an open door for future researches and can be distinguished from the neglected requirements like management and notoriety of a specific company and competitors which can be a type of focused vision and insights.

Healthcare experts and patients are embracing the social networking sites in a progressive manner, where they exchange the experiences of their ADRs with the approved medicinal item.

Social networking sites display different pathways and strategies which can empower organisations to travel future, starting conventional methods of pharmacovigilance as well as security information reporting techniques towards more patient-driven models for detailing, exploring and observing of safety database. These pathways have the capacity in the direction of permitting quick and open correspondence amongst organisations and the customers/patients and social insurance suppliers utilising the restorative items, in this way helping foster straightforwardness and construct open trust [18,30].

Disadvantages of Social Media

- Unlike other sectors, information obtained/provided for health care decision makings should be reliable, valid and authentic. The drawbacks and complications found while using the client created content of social media may incorporate issues with the validity, decency, uniqueness, recurrence and notability of the information [30]. Because of the constrained measure of patients taking an interest in such preliminaries and the moderately brief timeframe these preliminaries cover, uncommon ADRs may not be accounted [31].

- Hypersensitivity reactions or other patient-specific reactions can be yet obscure when a medicinal product is marketed. From the pre-marketing testing stage, the groups like children, women, old-aged patients and high-risk patients are in general avoided [32]. Conventionally, post-marketing surveillance or pharmacovigilance exercises depend exceptionally on spontaneous reporting systems for ADRs detailed by health care professionals to the regulatory authorities. Nonetheless, data acquired from breaking down spontaneous reporting systems is additionally restricted because of a few reasons, for example, under-reporting by healthcare experts, the absence of adequate clinical information, reporting predisposition and long-lasting dormancy [33].

Key hindrances in the application of social media in pharmacovigilance [18,34,35].

Some of the main challenges related to the usage of social networks for pharmacovigilance are:

- Drugs may be labelled differently with their brands, active ingredients, or terms of generic drugs (for example, "antibiotic"). In this case, it may be difficult to gather complete and exact information and subsequently complicate the identification of the ADRs.

- ADRs can be discussed by means of self-inventive informal words or empathies that may not be available in the current medicinal dictionaries, textbooks or journal articles. This can be a challenge when one wants to interpret such words.

- The random use of terminologies with bad grammars, spelling mistakes, abbreviations may be problematic.

- Discussion and more argument of a drug may result in undue anxieties of adverse events among the social media users and subsequently to the non-users as well through their contacts.

- Although social media are influential, the sole dependent groups or users may require extensive training in statistics which is time-consuming and expensive.

- Other challenges above all may be the maintenance of the confidentiality of the patients and reports from ethical perspectives.

- Although social media can be used to map signals of ADRs for new therapies, they cannot be relied on to identify the quantitative details about the ADRs. For example- one ADR reports may be shared by many people. All that shared information should be counted as a single incidence only.

- Social media can be used in numerous languages. Therefore, collecting information about ADRs from social media depends upon how that information is collected and from where they are collected (diverse languages have different terminologies for a single ADR). The machine learning (artificial intelligence) would help to solve this problem, however, there must be adequate use of such words to make them identifiable automatically by machine.

- Data privacy and individual information assurance concerns surrounding encompassing such mining and revelation additionally require extraordinary consideration.

- Curating and cleaning of the data would likewise be mandatory to moderate the danger of spreading bits of gossip/fabricated wellbeing concerns. Over this, is the overall not too bad assortment that is addressed by social networking sites and frameworks organisation. Associated difficulties at this juncture are perplexing and not just kept to semantic issues and understanding, but instead relate to social arrangements, usage, and intangibles.

The Authenticity of Social Media

Web-based social networking sites have incited perspective changes in manners of an individual's [36], and have additionally changed the world on equally at the micro and macro level by empowering long-lasting and uninterrupted communication [37]. Social media has established itself as a significant spatial extension of any nations [36]. At the same time, there are issues of authenticity (like authors credibility, quality of knowledge shared and discontinuity of media content) is emerging as one of the issues, which can be accounted as pestered when sharing data in social media [37].

At the point when the trust is in question, the consequences may consist of deactivating of the accounts and making of multiple profiles, which may prompt the flood of the 'ghost' matters. From an overview of issues and difficulties among Malaysian web-based social networking clients, validity showed-up as one of the critical issues of reliance on social media in the pharmacovigilance framework. Alternate issues that surfaced were the credibility of the report, content and its source. The other issues that have surfaced were the issue of quality of the knowledge learned or information obtained through social networking channels [36].

CONCLUSION

Obviously, social media might be valuable for screening what is going on in the network, however, this sort of information and the nature of the information should likewise be considered while considering any further administrative decision. Since underreporting of ADRs is a common problem in Nepal, it would be appropriate to explore more and more options and prospects for tapping the power of social media in pharmacovigilance activities. However, there could be potential challenges and combined efforts of all key stakeholders that overcome the difficulties. Thus, in the near future social media can be a great tool for ADR reporting and a great platform for consumers and pharma-companies to discuss their opinions and experiences regarding the use of the medicinal product and devices.

REFERENCES

[1] Grajales III FJ, Sheps S, Ho K, Novak-Lauscher H, Eysenbach G. Social media: a review and tutorial of applications in medicine and health care. J Med Internet Res. 2014;16(2):e13.

[2] Pillow MT, Hopson L, Bond M, Cabrera D, Patterson L, Pearson D, et al. Social media guidelines and best practices: recommendations from the Council of Residency Directors Social Media Task Force. West J Emerg Med. 2014;15(1):26.

[3] Butt TF, Cox AR, Lewis H, Ferner RE. Patient experiences of serious adverse drug reactions and their attitudes to medicines. Drug Saf. 2011;34(4):319-28.

[4] Hughes S, Cohen D. Can online consumers contribute to drug knowledge? A mixed-methods comparison of consumer-generated and professionally controlled psychotropic medication information on the internet. J Med Internet Res. 2011;13(3):e53.

[5] Herxheimer A, McPherson A, Miller R, Shepperd S, Yaphe J, Ziebland S. Database of patients' experiences (DIPEx): a multi-media approach to sharing experiences and information. The Lancet. 2000;355(9214):1540-43.

[6] Dusetzina SB, Higashi AS, Dorsey ER, Conti R, Huskamp HA, Zhu S, et al. Impact of FDA drug risk communications on health care utilization and health behaviors: a systematic review. Medical Care. 2012;50(6):466.

[7] Lardon J, Bellet F, Aboukhamis R, Asfari H, Souvignet J, Jaulent MC, et al. Evaluating Twitter as a complementary data source for pharmacovigilance. Expert Opin Drug Saf. 2018;17(8):763-74.

[8] Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. The Lancet. 2000;356(9237):1255-59.

[9] Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA. 1998;279(15):1200-05.

[10] Ahmad SR. Adverse drug event monitoring at the Food and Drug Administration: your report can make a difference. J Gen Intern Med. 2003;18(1):57-60.

[11] Xu R, Wang Q. Large-scale combining signals from both biomedical literature and the FDA Adverse Event Reporting System (FAERS) to improve post-marketing drug safety signal detection. BMC Bioinformatics. 2014;15(1):17.

[12] WHO. The Importance of Pharmacovigilance - Safety Monitoring of Medicinal Products. 2002 [cited 2018 August 29]; Available from: http://apps.who.int/medicinedocs/en/d/Js4893e/1.html.

[13] Gurulingappa H, Mateen-Rajpu A, Toldo L. Extraction of potential adverse drug events from medical case reports. J Biomed Semantics. 2012;3(1):15.

[14] Suvarna V. Phase IV of drug development. PerspectClin Res. 2010;1(2):57.

[15] Wells KB. Treatment research at the crossroads: the scientific interface of clinical trials and effectiveness research. Am J Psychiatry. 1999;156(1):5-10.

[16] Smith PG, Morrow RH, Ross DA, editors. Field Trials of Health Interventions: A Toolbox. 3rd edition. Oxford (UK): OUP Oxford; 2015 Jun 1. Chapter 22, Phase IV studies. Available from: https://www.ncbi.nlm.nih.gov/books/NBK305508/

[17] Pierce CE, Bouri K, Pamer C, Proestel S, Rodriguez HW, Van Le H, et al. Evaluation of Facebook and Twitter monitoring to detect safety signals for medical products: an analysis of recent FDA safety alerts. Drug Saf. 2017;40(4):317-31.

[18] Sloane R, Osanlou O, Lewis D, Bollegala D, Maskell S, Pirmohamed M. Social media and pharmacovigilance: a review of the opportunities and challenges. Br J ClinPharmacol. 2015;80(4):910-20.

[19] Thakur DN. Social media: opportunity or threat to public health in context of Nepal. Health Prospect. 2016;16(1):07-09.

[20] Shrestha S, Shrestha S, Palaian S. Can clinical pharmacists bridge a gap between medical oncologists and patients in resource-limited oncology settings? An experience in Nepal. J Oncol Pharm Pract. 2018;2018:1078155218784734.

[21] Chowdhury S, Zhang C, Yu PS. Multi-Task Pharmacovigilance Mining from Social Media Posts. arXiv preprint arXiv:1801.06294. 2018 Jan 19.

[22] O'Connor S, Hanlon P, O'Donnell CA, Garcia S, Glanville J, Mair FS. Understanding factors affecting patient and public engagement and recruitment to digital health interventions: a systematic review of qualitative studies. BMC Med Inform Decis. 2016;16(1):120.

[23] The Impact and Use of Social Media in Pharmacovigilance. Available from: https://www.sciformix.com/wp-content/uploads/Social_Media_in_PV_Whitepaper.pdf.

[24] Department of Drug Administration. About Us. Available from: http://www.dda.gov.np/content/about-us.

[25] Department of Drug Administration. Drugs Act, 2035, (1978) 1978 [cited 2018 August 29]; Available from: http://apps.who.int/medicinedocs/documents/s18829en/s18829en.pdf.

[26] Palaian S, Ibrahim MI, Mishra P. Pattern of adverse drug reactions reported by the community pharmacists in Nepal. Pharm Pract. 2010;8(3):201.

[27] Department of Drug Administration. Pharmacovigilance. 2018 [cited 2018 August 29]; Available from: http://www.dda.gov.np/content/pharmacovigilance.

[28] Shrestha S, Khanal S. Establishment of the first cancer hospital-based pharmacovigilance center in Nepal. Research in social & administrative pharmacy: RSAP. 2018;14(11):1088-89.

[29] Jha N, Rathore DS, Shankar PR, Thapa BB, Bhuju G, Alshakka M. Need for involving consumers in Nepal's pharmacovigilance system. Australas Med J. 2014;7(4):191.

[30] Sarker A, Ginn R, Nikfarjam A, O'Connor K, Smith K, Jayaraman S, Upadhaya T, Gonzalez G. Utilizing social media data for pharmacovigilance: a review. J Biomed Inform. 2015;54:202-12.

[31] Corrigan OP. A risky business: the detection of adverse drug reactions in clinical trials and post-marketing exercises. Soc Sci Med. 2002;55(3):497-507.

[32] Carnovale C, Gentili M, Fortino I, Merlino L, Clementi E, Radice S, on behalf the ViGer Group. The importance of monitoring adverse drug reactions in elderly patients: the results of a long-term pharmacovigilance programme. Expert Opin Drug Saf. 2016;15(2):131-39.

[33] Matsuda S, Aoki K, Kawamata T, Kimotsuki T, Kobayashi T, Kuriki H, et al. Bias in spontaneous reporting of adverse drug reactions in Japan. PLoS One. 2015;10(5):e0126413.

[34] Larkin M. Social media for pharma – an expert's view. 2014 [cited 2018 August 21]; Available from: https://www.elsevier.com/connect/social-media-for-pharma-an-experts-view.

[35] Edwards IR, Lindquist M. Social media and networks in pharmacovigilance.:boon or bane? Drug Saf, 2011;34(4):267-71.

[36] Ismail S, Latif RA. Authenticity issues of social media: credibility, quality and reality. World Academy of Science, Engineering and Technology International Journal of Humanities and Social Sciences. 2013;7(2):355-62.

[37] Paslawsky A. The growth of social media norms and government's attempts at regulation. Fordham Int'l LJ. 2011;35:1485.

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