



Editorial

Hello, medical device fans! Social media is increasingly integrated into all aspects of our daily lives, even for many of you non-digital natives (myself included). In this issue, we look at how the medical device industry is beginning to utilise social media as a tool to

monitor the safety of devices as part of post-market surveillance activities. Karelia Tecante, a post-market surveillance specialist, shares her insights into the use of these new tools and how social media listening could eventually become a standard source of adverse event reporting. I expect that some

of you may soon be integrating the outcomes of social media listening into your clinical evaluation reports and post-market clinical follow-up plans and reports. Happy reading!

Kelly

Social media in the medical device industry as a tool for post-market surveillance

With the European Union Medical Device Regulation publication (EU MDR 2017/745), it became clear that post-market surveillance (PMS) would require significant changes. The need to implement PMS activities different from traditional ones became apparent in white papers and conferences. As a result, the term *social media* first appeared under proactive PMS. In the medical device industry, social media has been used primarily for digital marketing and human resources recruiting, so several questions have emerged: what is meant by social media as a PMS activity, how can social media be used to gather information on the safety and performance of medical devices, how does this process work, and how many resources are required for this task?

Social media and social media listening

Concerning PMS, social media is directly related to social media listening (SML), which is the monitoring of public digital conversations on the internet to retrieve and understand customers' opinions about a brand, a product, or both. A common misconception is that social media only refers to platforms like Facebook or Instagram. However, it also includes forums, blogs, portals, community and microblogging sites (e.g., Twitter and Instagram), digital magazines and newspapers, online TV, and virtually every website on the internet (Figure 1).

SML as a tool for health monitoring and surveillance

SML is not a recent concept; it is directly tied to increasingly rapid uptake of social media in the

last 12 years, as people began using it more frequently to discuss their personal lives, health, and illness. Consequently, social media has gained increasing recognition as an essential information source in the health sector. For example, Boston Children's Hospital HealthMap was founded in 2006 as a platform that utilises informal online sources for disease outbreak monitoring and real-time surveillance of emerging public health threats (www.healthmap.org). The pharmaceutical industry has already recognised SML as a pharmacovigilance tool to detect adverse events (AEs) and adverse drug reactions (ADRs) and is notably ahead of the device industry. Many publications can be found on this topic, including articles on data mining solutions to analyse social media information for pharmacovigilance. Projects have been developed to explore the value of social media to identify AEs (e.g., WEB-RADAR and Vigi4Med); the FDA is even sponsoring projects with specific patient forums to detect AEs; and innovations in data mining solutions have been used to detect ADRs from Google and Yahoo search logs.¹⁻³ Hence, it is not surprising that regulatory authorities are now expecting SML as a proactive PMS activity in the medical device industry.

Nevertheless, to the author's knowledge, there are few to no publications on this topic applied to the device industry, and considering

this, one can only wonder if this procedure can be effectively applied to medical devices. Box 1 summarises the benefits and difficulties described by experts on pharmacovigilance that apply to the device industry.¹⁻⁶

SML tools

Significant progress has been made in some technical aspects of SML that have overcome some of the challenges outlined in Box 1. Specifically, the automated search and retrieval of data based on initially given input has resulted in several software packages to support device manufacturers in making SML a less-time consuming task. Just to name a few, Talkwaker, BrandWatch, SocialBakers, Awario, Hootsuite,

Digimind, Sprout Social, Awario, Insights, Buzzsumo, Brand 24, and Synthesio offer different packages and support levels. Some of these programs are even used for pharmacovigilance and have capabilities to report AEs to competent authorities. These online platforms work on the same principle: a query for a determined topic with keywords like a brand and product name is created by pulling posts and comments, referred to as mentions, from the internet. Data can be gathered for a specific period or in real-time. Mentions

can be limited to different countries and languages; alerts can be created; and frequent posters or influencers can be identified. Data can

Overall, scholars agree that social media data could be a tool to augment PMS capabilities, but much work must still be done to overcome the associated challenges.



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shinedentaloh Let's talk FAILURE.

This is a X-ray of my implant 4 months after it was placed... right before it was unscrewed right back out of my head. My bone failed to grow around the implant and lock it into place. Instead my body walled it off from the surrounding bone and basically 'rejected' it. So what to do? Remove the implant, place more bone, and wait to try again in the spring.

Although implants have a very high success rate, sometimes they don't always go as planned. I honestly believe they're still the next best thing to a natural tooth and that's why we're trying again.

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pain and greater trochanter avulsion fracture.

Patient was taken back to the OR the next day for revision surgery on traction table. Fracture reduced well with traction, but she had a massive thigh hematoma drained before incision was made. During surgery, she had a bent screw and a fracture that extended along the lateral wall to the level of the bent screw.

Intraoperative cultures were taken to r/o infection. The two-hole plate was removed and three-hole plate exchanged with trochanteric stabilization plate placed. Multiple locking screws placed into greater trochanter and head segment to increase stability and making it a fixed

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dr.cherylpark_dds_facp Patient referred for jammed abutment removal on Straumann BI implant. Crossfit connection. Removed and replaced with healing abutment.

#implantdentistry #dentalimplants #implantcomplications #prosthodontist #implantscrewremoval #implantabutments

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op.dr.semml_koyuncu Dış merkezde femur kırığı nedeniyle opere edilmiş hastanın çivisinde hareket nedeniyle kırıkta kayma ve diz bölgesinde kemikte aşınma yaparak yeni kırık riski oluşturduğu için dizden #retrogradenail ile #basarilitedavi sonucu #allahinizniyle ameliyat sonrası ilk gün yürütüldü ve merdiven inip çıkma çalışıldı.

#travma #femur #femurfracture #implantfailure #intramedullarynail #femorálnail #şifaallahtan #erkenhareket #harekethayattır #lifeismotion #beyşehirdevlethastanesi

78w

03 likes
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Figure 1. Examples of Instagram public posts related to the device industry

Box 1. Advantages and challenges of using social media to detect AEs

Advantages

- Large amounts of real-time, real-world usage information
- Geographic and population diversity
- Direct access to patient perspectives
- Opportunity for niche studies
- Identification of institutions through HCP posts for potential PMCF studies
- Potential to cover the known under-reporting of AEs

Challenges

- Conceptual – Value of data
 - Level, quality, and credibility of information
 - Risk of misinformation
- Environmental
 - Compliance
 - Regulatory framework
- Technical
 - Data mining/analysis
 - Large amounts of data; a significant amount of noise expected
 - Duplicate reports (parallel posting)
 - Text classification (e.g., colloquial language, misspellings)

Abbreviations:

HCP, health care professional; PMCF, post-market clinical follow-up; AE, adverse events.

be classified based on sentiment analysis, and many other analytical tools are available. Sentiment analysis algorithms may help identify AEs, but many mentions are still classified as neutral.

SML in PMS

Some primary considerations could be recommended to establish SML as a PMS activity:

- A. A clear purpose should be established when SML is used.^{1,4}
- B. Queries should be clearly defined and fine-tuned, including the number of queries and keywords for each query.
- C. A systematic process should be established including, for example, social media, data crawling, mentions analysis, alerts, automated reports, and team roles.
- D. Elements required for a valid AE should be defined, including (1) identifiable reporter (user name, handle, email), (2) identifiable patient (could be the reporter or a reporter with knowledge of someone else experiencing an event), (3) identifiable brand, and (4) identifiable AE.^{1,4,7}
- E. Reportability requirements must be established, specifically regarding how to proceed in case of incomplete information.^{1,4,7}
- F. Rules for follow-up with posters should be defined.⁴ Follow-up should not be a requirement when SM is used as a complimentary PMS activity.
- G. Adequate documentation to outline the

process to record and archive primary source data from SM should be created.

- H. Data protection laws, ethical standards, and regulatory compliance should be considered.¹

Considerations and future work

The use of SML in PMS has been abundantly discussed with different views. Some minimum criteria are needed to import social media mentions into PMS databases confidently.¹⁻⁶ Overall, scholars agree that social media data could be a tool to augment PMS capabilities, but much work must still be done to overcome the associated challenges. SML as a PMS activity may not be suitable for all medical devices as its utility

The introduction of implant cards in the coming years could facilitate this task because more accurate information on patients' knowledge and awareness will be gathered.

depends on the device's nature and market share. Reluctance to explore SML in the device industry seems to come from the overwhelming number of AEs; however, the many potential benefits make it worth exploring. The introduction of implant cards in the coming years could facilitate this task because more accurate information on patients' knowledge and awareness will be gathered. Finally, device manufacturers and regulatory authorities should expect to work more closely to reach agreements

and educate the sector on the value of SML in PMS.

Conflicts of interest

The author declares no conflicts of interest.

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