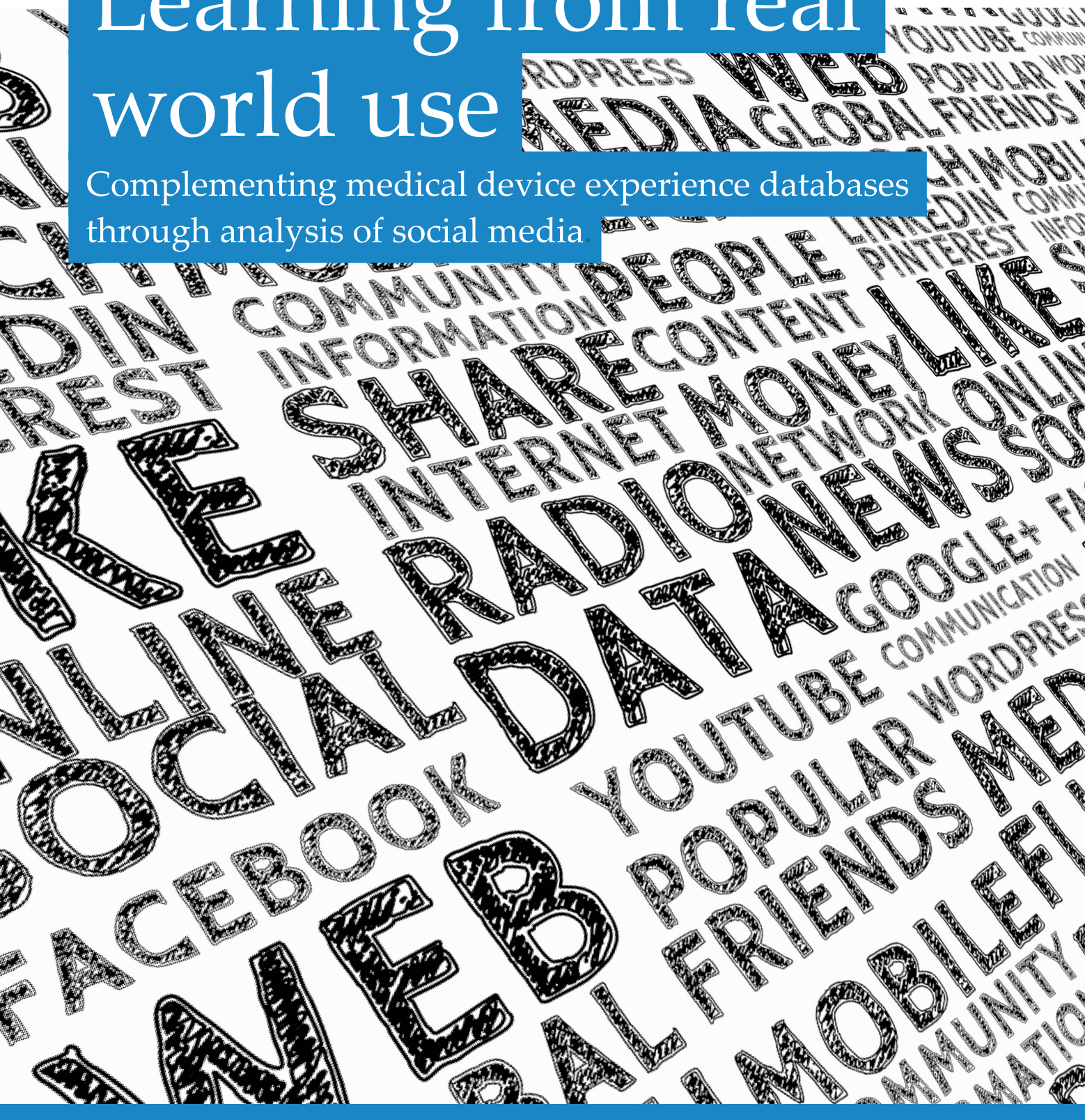
Learning from real world use

Complementing medical device experience databases through analysis of social media.



Medical & Healthcare

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Learning from real world use – complementing medical device experience databases through analysis of social media.

The problem: medical device usability

Medical device manufacturers are required to demonstrate compliance with agreed criteria relating to the safety, quality and performance of medical equipment. As part of these requirements recent focus has shifted towards minimising use related risk – for example errors that arise as a result of "confusing or unclear on-screen user instructions" (AAMI, 2010) or number entry errors (Figure 1). For medical devices there are standards and guidance that can be applied; either in terms of design requirements that are proven to mitigate error; testing that shows there aren't use related concerns (usability engineering); or post market vigilance which allows monitoring of performance in terms of safety and usability.

For usability engineering, one approach revolves around simulated use testing – testing a device out of context but with real world users. The reason for the use of simulation is that testing a prototype in a real world context (for example a hospital) may be unacceptable when technology has yet to be proven. The limitation of simulated use testing is that an artificial environment may not represent the subtleties of real world use (for example workarounds and adaptations) – these are important factors to take into account when seeking improvement opportunities. Although there is a benefit in simulated use testing, there is also benefit in understanding how users really work with equipment. Current practice recognises this need and recommends that those involved in the manufacture of medical devices consult incident reporting systems. For example the FDA MAUDE (Manufacturer and User Facility Device Experience) database contains records relating to the safety and performance of medical devices submitted to the FDA by manufacturers, health care professionals, health care facilities and members of the public. There were over 2 million submissions in 2016. There is a potential to use this information to identify known use related problems and factor them into the design of medical equipment. By understanding issues with existing technology the design of new technology can be improved.

Figure 1: Infusion pumps can be prone to number entry errors.

How does it work at the moment?

In terms of currently recognised practice 62366-1 and 62366-2 identify a series of external resources that can be used to identify known problems with a user interface. 62366-1 and 62366-2 are commonly recognised usability engineering standards that apply across the product lifecycle. As part of this process the manufacturer of a medical device is expected to review use related issues during and after the design process. For example if a manufacturer is producing an infusion pump that contains a number entry feature and a database such as MAUDE contains examples of issues relating to this feature, they would be expected to identify and analyse this incident, use it as input into the risk management file and validate the design accordingly. Similarly, FDA final guidance: "Applying human factors and usability engineering to medical devices" (FDA, 2016) states that identification of known use related problems can come from a variety of sources including:

- **Customer complaints**
- **Sales teams**
- **Previous human factors and usability engineering studies**
- **Journal articles, conference proceedings**
- **Relevant internet sites such as MAUDE**

In principle reviewing these sources can provide input for the design process, in practice there are concerns that such information can be hard to analyse. 62366-2 provides reference to this issue:

"In some cases, use-related problem reports do not explicitly cite or describe USER INTERFACE problems. Rather, they describe an event without providing substantial details that would suggest there is a USER INTERFACE design issue. Moreover, searching databases using terms such as human factors or USABILITY ENGINEERING cannot result in findings. Consequently, analysts can need to conduct a broader search for problems and analyse each case to determine if they suggest a pertinent problem to be avoided."

Learning from incident data is not straight forward. For example mapping between the free-text narratives describing an incident, the root causes of the incident and the potential for improvement can be challenging. Sometimes the necessary information is not contained in the output. Take Figure 2 for example – there is no way of knowing what occurred and how the design of the equipment could have prevented it. It follows that those tasked with reviewing this data are often challenged when it comes to finding the right information; they may not be able review all records and may have trouble interpreting content. Incident reports may be focused on the network surrounding the device, but not the device itself. They may allude to a Root Cause Analysis but not describe it in full detail. Different interpretations of a report may occur and information may be unclear, ambiguous or conflicting.

Figure 2: Example MAUDE records relating to an infusion pump.

Taking the analogy of a spotlight illuminating real world practice: the focus of the beam impacts on the potential to "see" design improvements. If the spotlight is weak, unfocused or pointing in the wrong direction we might miss opportunities for improvement. This paper proposes ways that the spotlight can be strengthened – how the analysis of systems like MAUDE can be supplemented by review of other public domain sources such as blogs, discussion forums and social media.

The approach

The use of social media has gained recognition in other industries where there is a need to understand the safety implications of unconstrained / uncontrolled use i.e. the real world behaviours that occur when a product is released onto market. Analysis for the pharmaceutical industry has shown healthcare related discussions posted on Yahoo! or Google groups contain descriptions that meet the criteria for an adverse event for approximately 1 in every 500 posts (Davies, 2008). The analysis of social media offers advantages over existing techniques as there are many more records produced at greater frequency across a diversity of population.
This data can be used to inform positive as well as negative claims about a product. For example, in an article exploring the use of social media to collect safety and efficacy information in the pharmaceutical industry, Martin Goldman outlines the potential to leverage the 38 million social media users in the UK to understand more about how people really use a product (Goldman, 2016). In terms of using this type of data to inform the design of new products, there are various approaches including:

- **Analysis of on-line content (e.g. use of resources such as blogs).**
- **Online surveys utilising social media; feedback via apps.**
- **Analysis of content that can be used to track user behaviour in real time.**

These techniques integrate in different ways across various parts of the usability engineering process. For example designers may check a discussion forum to understand variations in workflow associated with the product; they may sensitise themselves to issues that users experience; they may review online content to inform risk analysis. The following are examples of the different types of technique and how they may be applied to support usability engineering.

Figure 3: Example of YouTube content outlining medical device workflow.

Analysis of on-line content

A simple example relates to searching sites such as YouTube. A search on a type of device will reveal a selection of content and can form a basic input into the design process. Videos often contain information relating to clinical practice, workflow and relevant behaviours. In the absence of other information, this approach provides a basic grounding in how the technology is used. For example the following content (Figure 3) shows a nurse setting up a syringe driver in a hospital.

https://www.youtube.com/watch?v=kcifvE5pZYc

It gives us an idea how this type of medical equipment is used in situ (e.g. the nurse would be likely to follow this procedure). It also provides some tips for design – for example the nurse uses the battery compartment lid to lever out the battery. A design team could use this information to learn about how users interact with equipment, the type of customisation that occurs and explore the opportunities for error – for example incorrectly fitting the battery.

A development on this idea includes the analysis of similar content using a formal approach – for example specifying which sources will be searched (such as specific discussion groups / websites); specifying limits (e.g. language of content); defining combinations of search terms / exclusion criteria. Tools such as Google Advanced Search can help define such an approach. This input can be reviewed and used as input for a use specification or risk analysis.

Online surveys

Another approach is to use the internet to actively collect data – for example using digital media as a tool for administering and collecting surveys. Online surveys are quick to administer; they can reach a large number of people and data is collated automatically. They can also reveal safety related concerns. For example in a study of TuDiabetes.org network members were polled and of 549 participants, 75 reported device-related adverse events. Of these 3 had been reported to the FDA (Mandl et al., 2014).

This approach may be leveraged through use of existing networks. For example, sites such as PatientsLikeMe provide the means for patients to enter a combination of structured and unstructured data. This is compiled into a health history charting (for example) use of medication, side effects and experiences of using medicinal products. This information (which also includes positive and negative experiences of device use) can be searched, analysed systematically and used to target surveys. The data relates to 500,000+ people with 2,700+ conditions and at the time of writing there were 14,046 examples of forum discussions relating to "device malfunctions". Such sites can either be used to target surveys or be used as a data source for analysis in their own right (e.g. how many people are reporting concerns with a given type of equipment and what are those concerns?).

Analysis of content that can track user behaviour

Another approach is to analyse the side products of user interactions or look at overarching trends. For example, if a large number of individuals are conducting searches associating a given product to concerns or negative sentiment analysis can reveal this trend. A simple example can be found relating to the recall of a well known infusion pump in 2010. A spike coincides with the recall date however there are also multiple blips that occurred earlier in this timeline, potentially indicative of an emerging problem (Figure 4).

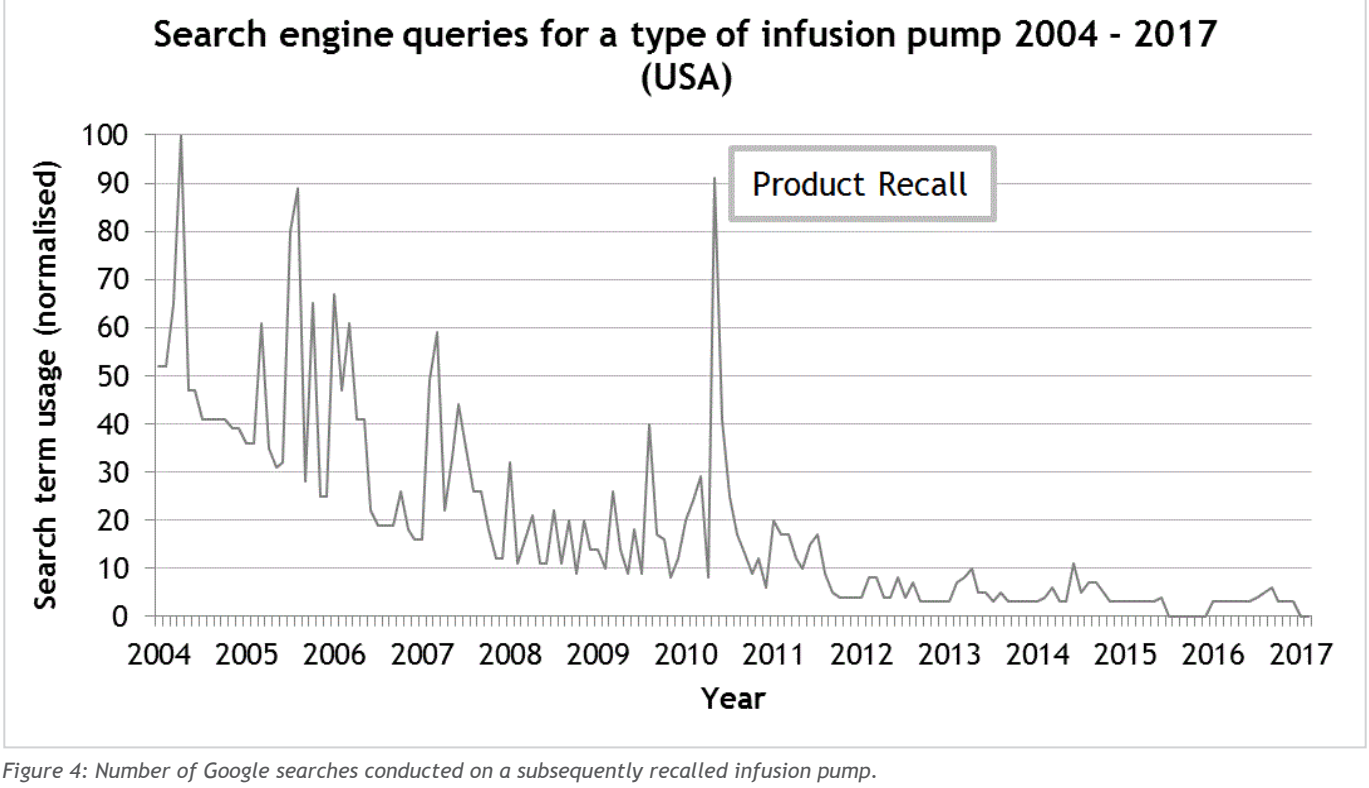

Figure 4: Number of Google searches conducted on a subsequently recalled infusion pump.

This type of data may not be restricted to analysis of public domain content - for example, Lee et al. (2012) analysed infusion pump log files and found an occurrence of “door open” alarms, which could have only resulted from workarounds or violations in practice. This information was used to improve the management of equipment in a hospital and could be used as an input for future versions of equipment – for example how can the design accommodate the temptation for the user to stop the infusion by opening the door of the pump?

Similar principles may apply to a broad range of digital health technologies (i.e. those that aren’t classified as medical devices). Wearable technologies, health apps and personal informatics tools allow users to collect large amounts of data that can be used to monitor behaviours and improve the design of technology.

What are the regulatory issues?

An important consideration for social media research is how does it fit into existing ethical and regulatory frameworks? For example when data is collected in a market research facility, participants can be informed about the purpose that it will be used for. Protection can occur in terms of anonymity and consent to use data. The exercise can be structured to minimise risks to the participant, for example avoiding sensitive topics. On digital platforms things are different as there is minimal control over what gets posted and how it becomes amalgamated. It is also difficult to inform someone who has posted information about how that information will be used retrospectively. This is a very complicated area, but increasing amounts of guidance is becoming available. For example the BHBIA (British Healthcare Business Intelligence Association) stating the following which applies to listening to and scraping of social media (scraping is an automated process of data mining which can be applied to on-line resources in order to extract data at scale):

"You must observe the terms of use of online sites and services. These may prohibit you from copying content (listening and scraping) without permission. You can however still read and précis it."

"If copying content is allowed you must only report anonymised data unless participants have given informed consent for their personal data to be used for the purpose(s) that you intend to use it."

"Consent is sometimes obtained as part of the terms of use (but you must consider whether in these circumstances they extend to your purported use and you are acting in compliance with data protection law), sometimes directly."

"You mustn’t identify participants without their consent."

https://www.bhbia.org.uk/guidelines/legalandethicalguidelines.aspx

This means that if data is separated from personal information then it can be collected from a site, as long as the terms of service permit this. If they do not then there would be a need to involve the site administrator. It also means that personal data may be used however consent may be required which could go beyond any initial agreement that was signed during initial use. If anonymised data is passed on then there is also a requirement to make sure that it cannot be de-anonymised. See the ESOMAR (European Society for Opinion and Marketing Research) guidelines on social media research for more information.

https://www.esomar.org/knowledge-and-standards/codes-and-guidelines.php

Summary

The growing use of digital platforms changes the way we practice usability engineering and it is worth exploring the use of digital media to understand real world use (and misuse). These techniques offer many benefits and can be applied both pre and post market. Benefits include:

- **Digital media provides a source of data from millions of users and is being constantly generated.**
- **Digital media can supplement simulated testing, which may be limited by simulation artefacts.**
- **Digital media can provide both positive and negative examples of device use.**

Digital media can supplement analysis of incident reporting as the reports submitted to an incident reporting system may be constrained through failure to provide the right type of information; incident reports are often submitted from “within the system” and therefore may avoid focus on the type of information that would inform design.

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Prior to joining PDD, Chris worked on the CHI+MED project at University College London, understanding the relationship between human factors, human error and interactive device design. (http://www.chi-med.ac.uk/). Chris provides tools and techniques that optimise the safety and usability of equipment and has published research relating to procurement, the representation of complex systems and safety and usability.

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