A tension in healthcare research

Exploring the debate at the heart of regulation changes for clinical trials in the United States

Introduction

In January 2017, the US Department of Health and Human Services (HHS) issued a final rule on long awaited updates to the regulations governing clinical trials in the United States. The purpose of these regulation changes is to increase protections for people who participate in clinical research, in a changing research landscape where data privacy and permanent anonymity for patients is increasingly difficult to guarantee.

In this article, we examine the growing tension between two needs:

- The need to protect patient data and ensure the patients at the heart of clinical research can benefit from the studies they enable.

- The need to maintain the pace of research and take advantage of new technologies that can aid clinical research and healthcare more broadly.

Regulations in the United States are being updated to increase protections for patients

Why have the regulations been updated?

When the current regulations were first put in place in 1991, clinical trials looked very different. Most trials took place at a single site, typically a university or medical institution. In the decades since, clinical trials have grown in scale and trials often take place across multiple sites. The data collected in trials is now digitised and can be shared in ways not accounted for by the existing regulations[1].

Given how clinical trials are now conducted compared to the early 1990s, existing requirements around key areas such as informed consent were found to no longer be sufficient. Some of the key changes brought about by the new regulations include better provisions for gaining informed consent. In particular, ensuring the focus is on helping participants understand what they are consenting to – rather than avoiding lawsuits for the institutions carrying out the research[2].

There have been some key historical cases where patient data has been used in multiple studies without the participants' understanding or knowledge. For example, the cases of Henrietta Lacks and members of the Havasupai tribe in Arizona. In both cases, concerns were raised over whether the participants would have consented to all the uses of their data had they known how their samples might be used; as well as whether the participants were adequately compensated for their contributions, considering the profits that were made from medicines developed using their samples[2]. While these are older cases, the ethical concerns they raised remain central when thinking about informed consent, why it matters and what it is for.

How does the final rule differ from the NPRM?

Based on detailed feedback from the industry, the final rule differs in some significant ways from the Notice of Proposed Rule Making (NPRM) original published in September 2015. The complete final rule and a summary of the key changes from the proposal can be found on the Office of the Federal Register website[3].

One of the major updates originally proposed would have redefined the term 'human subject' to include all biospecimens collected in a trial, even those which have been anonymised[4]. The proposed redefinition of 'human subject' came about as new technology and research methods are making it increasingly possible to retroactively identify research participants by combining data sources, and as new applications for data collected during trials are being developed.

This proposed change to the regulations would have required that researchers gain new informed consent for all future use of biospecimens. The reason this change was not included in the final rule was due to large scale concerns around slowing research, impacting on researchers' ability to make new medicines available to meet the needs of the population.

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Although it was not included in the final rule, this proposed change to the definition of 'human subject' gets to the heart of a wider tension within healthcare research. How do researchers continue to offer adequate protections for research volunteers while ensuring the pace of research is maintained, and that regulatory burdens do not limit the scope of the research undertaken?

While the proposed change to the definition of 'human subject' did not go through in this instance, there is no doubt this debate will continue. Some areas of technology and scientific research that make this such a key concern for modern researchers include:

The ability to combine multiple patient data sources

Multiple sources of patient information are increasingly being merged through the use of electronic health records (EHR). These digital copies of a patient's full medical history can provide healthcare professionals with a complete picture of a patient's health[5]. There are many potential benefits to this. For example, being able to access patient healthcare data from all sources (which may include clinical trial data) alongside traditional medical history may allow a physician to more quickly identify potential health problems with a patient. However, it is also conceivable that security breaches could lead to data being accessed in ways that put patients at risk or compromise their privacy[6]. Procedures to ensure patients are protected from such risks must be part of how we develop these systems of data sharing, and how access to this data is controlled.

DNA sequencing

Researchers working in DNA sequencing have shown that despite the expectation that people who participate in genomic research will remain anonymous, in some cases it is possible to identify individuals relatively easily. Researchers at the Whitehead Institute for Biomedical Research in the US "...identified nearly 50 people who participated in a large genomic study based on some of the participants' genomes and other publicly accessible information."[7] It is becoming increasingly common for people to volunteer their genomes for research, as well as using paid services to understand their genetic history. With researchers requiring volunteers for their studies, and companies profiting by providing DNA services, it is important that people understand the ways their genetic data might or could be used; and that there are regulations to ensure all data is handled securely.

Increased use of point of care testing and wearable technology

New technologies including point of care testing devices, and wearable technology such as continuous glucose monitoring systems, means it's possible to generate more data about patients than ever before. The potential uses of this data are still being discovered and developed, and as we start to access more data and identify new applications for its use, new risks to patient privacy may also emerge – which must be accounted for with new or updated regulations[8].

In one instance, researchers were able to identify genomic study participants based on their genomes and other publicly available information

What does this mean for clinical research?

The ability to collect more data, to drive increasingly significant scientific breakthroughs, and to conduct large scale clinical research using data in both primary and secondary research settings is exciting for the clinical research industry. However, the need to protect patient privacy and ensure that study volunteers are not exploited remains central to ensuring the integrity of the research carried out.

The new regulations from the HHS improve conditions for patients by refining processes around informed consent, and they benefit researchers by reducing administrative burdens and ensuring important secondary research can continue without interruption. However, the debate over supporting fast paced, innovative research while protecting patient data will remain active. Clinical researchers should be prepared for future regulation changes as we come to better understand how the modern clinical research landscape may affect study participants in the future.

As the ability to collect more data drives new scientific breakthroughs, patient privacy must be protected

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