# Healthcare Difficulties in the Post-GDPR Era

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## Abstract

The medical profession centres on the philosophy and principles of providing patients with the best evidence-based care. In doing so, medical clinicians must remain up-to-date with local and international best practice, engage in auditing practice to review and refine practices and engage in an open-relationship with the patient at the forefront of their practice. Protecting the patient encompasses best practice, moral and ethical principle while balancing risk and beneficence and ensuring non-maleficence, justice and patient autonomy. Alongside these aspects, comes the reality of advancing societal requirements which impact on medical practice and governance. The changing dynamic of patient consent that is required with the new General Data Protection Regulation (GDPR) requirements has changed the face of research in Ireland and Europe, with significant implications for research beyond as well. This piece will explore how healthcare data should be available for use for health research without the necessity to seek patient consent.

## Introduction

An integral and strongly ingrained feature of being a truly conscientious and excellent doctor centres on protecting the patient (Irish Medical Council, 2016). One could say that this becomes part of our physician's DNA. As we journey through medical school, internship and then climb the ranks, we come to see the patient as a holistic entity rather than simply as a presenting complaint (Beauchamp and Childress, 2008). With that, comes the brave responsibility of upholding confidentiality, empowering the patient and doing no harm. We raise our hands on taking the Hippocratic oath and pledge to always do good in the name of our patients. To do good includes the fundamentals of beneficence, non-maleficence, justice and autonomy (Beauchamp and Childress, 2008). Alongside these ethical and moral pillars, comes the reality of advancing 21st century medical practice and governance. With the current implementation of greater patient security in the form of the General Data Protection Regulation (GDPR) (Health Research Board, 2018), healthcare data and research has been shook-up and demanded to pull its scrubs-up. In the interest of fulfilling these essential criterias, healthcare data should be available for us for health research, without necessarily requiring patient consent. Patient safety will still be maintained with governing bodies such as the Irish Medical Council and Ethics Committees. Necessitating consent will simply hinder evidence based medicine and the much needed advancing care and training, which comes with healthcare data and research.

## The Risks

In the past how many times have you quickly glimpsed, scrolled down and clicked on a website or mobile app "Terms & Conditions", simply to move on to the next step? In honesty, we've all done it a million times. Google and Facebook hoard copious amounts of detail about our message threads, websites and links we've visited, all in an effort to study and gain insight to facilitate their products and process (Thielman, 2017). Many don't mind when convenient pops-ups for nearby fertility clinics appear on our screen, how considerate of them to notice that the user is a geriatric want-to-be mother at 38 years with intently ticking ovaries. The irony is that the same openness is far from accepted when it comes to healthcare data and research (Cassell and Young, 2002). The field is almost seen as a looming monster coming to strip patients of their autonomy and rights (Beauchamp and Childress, 2008). Is healthcare-data research truly riskier than other research that analyses our information? Simply because the data is not health or medically related, does not make it less risky (Thielman, 2017). Risk can be defined as the potential to cause harm (Beauchamp and Childress, 2008), a feature which medicine attempts to avoid at every level. Initially consent can appear as a protective means of avoiding risk, especially regarding vulnerable persons (Beauchamp and Childress, 2008). On the other hand, avoiding a risk can itself create an unexpected

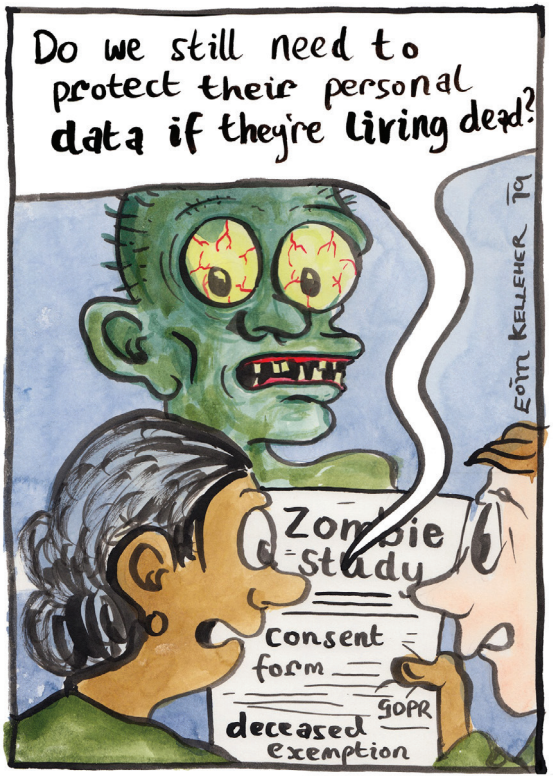
domino effect of further risks. Take the Australian government's approach to schooling and vaccinations; the right to education, safety and autonomy are all upheld by the government, however all citizens are treated equally and required to vaccinate their children prior to schooling. In doing this, there is a more global outlook on preventing risk (Salmon et al., 2006; Kirby, 2017). This is highly relevant in the Irish context with the current outbreak of measles (Lynch, 2018; Ireland, 2019). Accessing existing healthcare data to remedy this current risky wave, with greater vaccine uptake in this case, will greatly benefit the management and prevention of such an outbreak (Lynch, 2018). Having access to healthcare data to improve health research is in essence a means of improving the quality of the overall health system for patients and the practicing clinicians.

## Historical Governance

Two years after the second World War, the Nuremberg Code was established to protect patients and vulnerable people from harmful involvement in medical experiments and procedures(The British Medical Journal, 1996). Almost 15 years later, a modified version of the Nuremberg Code was acquired by the World Medical Association, and became the Declaration of Helsinki (The British Medical Journal, 1996). These documents provided the primary fundamentals of consent, ethics in medicine and a stringent focus on ensuring non-maleficence and patient autonomy (Beauchamp and Childress, 2008). The Helsinki Declaration divides research into two forms: therapeutic and non-therapeutic. As per the declaration, "subjects must be volunteers and informed participants in the research project... and each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations, anticipated benefits and potential risks of the study... The subject should be informed of the right to abstain from participation in the study.." (The British Medical Journal, 1996). The model implies that medical research in relation to patient participation is cushioned by safety parameters designed and monitored by protective bodies to enable safe research. Further developing the Helsinki model, interventions used in medical research can be agreed or declined by patients, similar to any other service, regardless of their benefit or impact.

Let's consider a maternity-care case study in Ireland, specifically a series of listeriosis cases amongst a pregnant cohort at the Rotunda hospital. A retrospective review of laboratory investigations confirmed listeriosis in 9 pregnancy-associated cases and concluded that the immigrant population was most at risk (The Irish Times, 2008). The findings highlighted the lack of targeted education in women's mother tongue as well as the lack of written education, leaflets, in multiple languages. Improvements were implemented on a local level in an effort to provide better care to women and babies, especially any at high risk. Such a simple yet incredibly transformative act in medical care could not have been achieved if we followed the Helsinki declaration fully and sought retrospective consent for the analysis of all those women. The declaration, which promotes opting in or out of research, is poorly adapted to guiding this form of healthcare data and research. If women opted out of the retrospective analysis, the possibility of establishing the above findings may have been greatly reduced. Vital aspects such as safe care, beneficence and autonomy would all have been compromised (Beauchamp and Childress, 2008). Autonomy generally refers to one achieving self-governance, determining their own path, as well as taking responsibility for oneself (Beauchamp & Childress, 2008). It may appear challenging to achieve responsibility if women declined being part of the retrospective analysis. The lack of women taking responsibility would greatly reduce the study analysis and compromise the progress which was made, producing the appropriate leaflets. More plainly, would one woman's right to opt-out outweigh the rights of all the other current and future women and babies who could benefit from the knowledge gained? This voice of reason says no. The deeper philosophical principles of such an example can be traced back to John Rawl's theory of utilitarianism (Rawls, 1971). Utilitarianism centres on the principle of doing good for the greater good of the population, unlike Kant's deontological framework which values the individual above all else more (Misselbrook, 2013), the latter of which is much more in line with both the Helsinki declaration and GDPR. Within respecting the patient's rights, one also cannot deny the responsibility that a medical institution has to reviewing their practices, ensuring service quality and improvement, and delivering evidence based medicine. Inhibiting the research and auditing process, which is regarded as a vital step in refining and ensuring best care, by strictly necessitating consent in all uses of healthcare data at such a basic level of medical care,

would only cause overall maleficence and injustice to the public at large (Cassell and Young, 2002).




## Modern Governance

In modern 21st century medicine, protecting patients has come in the form of GDPR, the EU's new data protection regulation which came into effect as of May 2018 (The European Commission, no date). It replaces the EU's previous data protection directive and governs the collection, use and storage of all personal data of living individuals. GDPR is highly relevant to medical information as medical data is collected, stored and used manually, handwritten and now digitally in some healthcare units in Ireland. GDPR claims to strengthen a patient's right in relation to their personal health data and forces those who collect, use and disclose such data to be more accountable for their actions (Health Research Board, 2018). GDPR does not differentiate procedural or clinical consent from the use of existing outcomes for ensuring best practice, and this point in particular means that when carrying out research or audits with the intention of publishing the findings publically without specific individual consent from each patient it would be in breach of GDPR (Department of Health Ireland, 2018). This difficulty has already been seen, with the Department of Health having to issue multiple clarifications, and in numerous healthcare services that must audit their services with the intention of publishing data in order to maintain safe standards in medical practice. A health service that has been vocal on the issue is that of the Oncogenetic services in Ireland (Holland, 2018). Standard oncology practice requires verification on the conditions reported in relatives to aid in better diagnosis and treatment. Normally this is achieved through the cancer registry and or death certificates. As per GDPR rules, relatives who have reported having cancer are now required to engage in a data request, alongside proof of identity and official documentation showing proof of address. Dr. Gallagher, a consultant oncologist and specialist in cancer genetics, fears that this process will be viewed by members of the public as "cumbersome"and lead to poor engagement, resulting in a limited ability to verify diagnosis, carrying a detrimental impact to patients and management (Holland, 2018). Placing such a barrier in the face of vital healthcare data, will only hinder much needed advancements, needed to care for such high risk patients.

## GDPR

Similar to the Helsinki declaration, the focus of GDPR holds strongly to an individual's right over the collective good. The collective good encompasses other patients and future care which is created on the basis of learning from the present. Furthermore, there is a legal obligation which all practicing clinicians and medical units must uphold, auditing and refining their practice to keep up with local and international best practice (Irish Medical Council, 2016; Royal College of Physicians Ireland, 2018). This is a requirement of the colleges that a physician, surgeon or GP is a member of. Following the introduction of GDPR, it is unclear if GDPR places all these fundamentals of ensuring evidence based care at risk. The reality of GDPR in Irish practice will present itself for physicians and surgeons, at all levels, which are required by both The Royal College of Physicians and The Royal College of Surgeons, respectively, to complete "a minimum of one audit annually" (Royal College of Physicians Ireland, 2018; Royal College of Surgeons Ireland, 2018). While this is part of the professional competence schemes and continuous professional

development, the burden of every doctor across the country seeking retrospective consent for their annual audit means that audits will be compromised, small cohorts will be selected to minimise workload and publication opportunities will be compromised. This will also remove independent and self-directed continuous learning (free of the basic requirements sought by the Colleges), which is a vital stepping stone to becoming a more competent self-starting practitioner. Overall fully engaging with GDPR will potentially change the face of medical training, requiring a more bubble-wrapped or over cautious approach to what should be a two-way process, centred on the pillars of beneficence, non-maleficence, justice and autonomy. These pillars apply not only to the patient, but the pillars also apply to the service provider, the medical clinician. The rights to protection, to best care and working within safe parameters are mutual and finding the balance between the individual's right to consent and the public's right to the best possible health service, which should be based on evidence based medicine, which requires access to healthcare data.

## Evidenced-Based Medicine

Evidence based medicine centres on the partnership between hard scientific evidence, clinical expertise, and the individual patient's needs and choices (Grol and Wensing, 2004). Within achieving this, there is a gap between best practice and the reality of providing clinical care. A Lancet study highlighted that up to 20% or more of health care provided is not needed or potentially harmful to patients (Grol and Grimshaw, 2003). The challenge and discrepancy appears to already exist prior to GDPR, despite the best efforts of healthcare research and clinicians. Nevertheless, with the new stringent GDPR legislation in action, the ability to improve the partnership between evidence based medicine and clinical practice may only prove more challenging. If GDPR was to be followed, the reality of only consented patient cohorts in selections will dominant the scene. If health data was reduced to only ever analysing consented patients, results will automatically introduce selection bias. Such data will distort results and ultimately not be representative of the true evidence of the healthcare service. Instead, healthcare data and practice will become based on convenient sampling, rather than truly empirical evidence based medicine, for ultimately safe practice (Cassell and Young, 2002).

## Conclusion

Our advancements in modern day medicine have been greatly attributed to evidence-based medicine and healthcare data which is paving the way forward for medical clinicians to provide the utmost best care to all patients. The main means of ensuring this, is maintaining the availability of healthcare data for healthcare research. The importance of this has been seen with the effects of the current Irish meningitis outbreak, the reforms in oncogenic care to follow GDPR rules and the very real negative effects on medical training. Patient safety will always remain at the forefront of the clinician's ethos and practice, with regulatory bodies and best practice ensuring the same (Irish Medical Council, 2016). A more balanced approach could even suggest the possibility of research exemptions, however that may also prove problematic as to then classifying what and how the exemption will be followed through. Going forward, it is integral to ensure that reducing risk and ensuring safety does not in fact lead us into a downward spiral of risk obsession and away from the heart of providing the best evidence-based care. Healthcare data is a necessity for healthcare research, and negatively controlling it with necessitating consent will only comprise what we have trained and worked hard for, safe, up-to-date and effective clinical care.

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