Interview with Associate Professor Angela Ballantyne about electronic health records

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Rex has recently completed his 5th year of medicine at the University of Otago, and is undertaking a BMedSc(Hons) with the Public Health department in Wellington. He is concerned about the overlooked health disparities that affect Asian New Zealanders, and is working on developing the skillset he needs to effectively engage with these issues.

Logan is a final year medical student at The University of Auckland. He is passionate about academia and is currently pursuing a career as a clinician-scientist in neonatology and neurodevelopment. Most recently, he has developed an interest in open science, and how new technological advances will impact the future of medicine.

Gisela is a 4th year medical student in Wellington who has had the privilege of doing her intercalated PhD with the Wellington Cardiovascular Research Group. She tries to maintain some of her hobbies outside of medicine and research, such as card making.

Angela Ballantyne is an Associate Professor of bioethics at the University of Otago, Wellington. She has an interest in the ethics of big data, such as that contained within electronic health records (EHRs) and has published several papers on this topic.

Electronic health records are digital files containing patient information that are used by medical practitioners to guide management. In some circumstances they are also used for research.

This interview has been edited for clarity and conciseness with Associate Professor Ballantyne's approval.

Are there particular benefits of conducting research from EHR data over other study methods?

EHRs usually give you a much broader picture. They do not replace something like a randomised control trial (RCT), but in combination they can be really helpful. Populations that are typically excluded from traditional research can be represented by EHRs. RCTs give you high-quality evidence by reducing the variables and therefore are often not representative of real-world populations. Historically, women, particularly if they were of child-bearing years or pregnant, were excluded from trials. This still has an impact today, for example, on the accuracy of our cardiovascular clinical guidelines, which were based on populations with systemically under-represented women.

However, all of these patients will typically receive clinical care, so often the only place you can find a picture of how interventions are working for these populations is in the clinical data.

What are some ethical considerations of using this data for research?

Research with clinical records is a type of secondary use of the data. You collect the data for clinical care, and subsequently use it to answer research questions. There is so much data-sharing, linking, and secondary use going on – it is a very complex ecosystem. The first ethical challenge is that it is very difficult to get patients' consent for each use of their data, but we could take a more transparent approach. If we are not getting explicit consent from patients to use their data for research, we must increase transparency so patients can easily find out what is happening with their data, the justification for its use, and who is responsible for managing data security. After transparency comes public engagement. There are concerns of backlash if the public are not engaged. For example, with EHRs in Australia, where 2,500,00 people opted out of the new EHR system.[1]

There are concerns around bias in the data as well. If the input data are biased, the result will also be biased, and 'knowledge' based on the data can risk embedding and perpetuating bias. If the data coming in is not representative, then the results will naturally not be representative. There was the case in Aotearoa where the passport photo of an Asian applicant was rejected by the automated photo checker when it concluded his eyes were shut.[2] Most of the faces used to train facial recognition programs are European, so it is much less accurate with non-European faces. While clinical data is much more representative than traditional research data, it still reflects the bias that results from different ethnic, gender and geographic access to care. We know that doctors systematically undertreated African Americans for pain, and if we do not effectively correct for this bias when using the clinical data, there is a risk the resulting algorithm could suggest African Americans need less pain relief than European patients.[3]

Governance is another important ethical consideration. Te Mana Raraunga, the Māori Data Sovereignty Network, are a group of Māori academics who advocate for formal co-governance and power-sharing models for the use of datasets containing Māori data.[4]

Are there circumstances where ethics review may not be needed?

The regulatory system is incredibly fragmented, so health data can fall under many different pieces of regulation. This makes it very complex for researchers to know how they can use it. Under the Health Information Privacy Code, health agencies can release data if it is not identifiable, or if it is within the parameters of the purpose for which the information was disclosed. So if a patient is in hospital, and discloses their health information to the clinician, the clinician can share that with the rest of the clinical team or call other departments for advice. The patient would expect that to happen in a hospital, so you do not have to ask for consent each time.

However, research is outside the original purpose for which the data was collected from the patient. So if clinicians or researchers want to use it for research (in an identifiable form), they either need to go back and re-consent each patient or ask a research ethics committee for approval to use the data without explicit consent. One argument I have made in a recent paper is that I think we need some sort of data-specific research ethics committee in Aotearoa.[5] Research ethics committees have expertise in clinical and observational research, but do not really have expertise in data security, computer science, or statistics. A data-specific research ethics committee would include experts in data science, data ethics, lawyers, Māori data governance, and health.

Also, in a lot of health research, people want access to identifiable data too. The EHRs are not accurate enough that researchers are prepared to use them in their current state. Typically, they need to go back and recheck things, and to do this they need the identifiable datasets. As soon as you want access to identifiable data you need to go through research ethics approval, which can be burdensome and discouraging for researchers.

If the data has been made non-identifiable, are there any issues with using the data for research without going through an exhaustive process?

The glaring problem with this is that existing regulation assumes there is a clear difference between identifiable data and de-identified data. However, this is not really true, and our regulations have not caught up with that.

There have been cases where data scientists have proved they can re-identify individuals from supposedly de-identified datasets. Although there is probably not a huge incentive for someone to do that, it is very misleading to the public to say that de-identified datasets are unable to be re-identified. Take for example the Integrated Data Infrastructure (IDI). A lot of the rhetoric around it is that it is all anonymous, but Aotearoa is a population of around 4,700,000 people, and there are data about many aspects of our lives in there. I think we need to have a much more nuanced conversation with the public about this. I trust the IDI because I trust their process of vetting and training researchers, and I trust the professionalism of the researchers; just like I trust clinicians and medical students not to share my clinical data inappropriately when I see them at the hospital or at the general practitioner's (GP) clinic.

I am also bothered by agencies who claim their datasets are secure, but then act surprised when there is a data breach. There will be data breaches, just as there will be medical errors in the medical system. The question is how often we think it is going to happen, what plans we have to mitigate that harm, and how these risks are weighed against the benefit we think we can achieve from sharing and using the data.

Should the primary function of EHRs be for patient care or for research?

This relates to the concept of a learning health-care system. Clinical care operates under a best interest model – the goal is to help this patient get better. In research, you are trying to generate knowledge to inform medicine and so you are weighing the goals of society against the interests of the research subjects. In the past, we separated clinical care and research in response to high-profile research ethics scandals. These were cases of doctors exploiting their patients by conducting research on them at the expense of the patients' best interests. Some examples include the Tuskegee study in the United States and the "unethical experiment" in Aotearoa (addressed in the Cartwright Inquiry).[6,7] In response to the public outrage – which was justified – many governments had public inquiries, and the results of which effectively split research off from clinical care.

Proponents of a learning health-care system challenge this separation, and argue that it would be better to have a constant feedback cycle where you are providing clinical care, evaluating that care, then feeding this new knowledge back into clinical care.[8] They are arguing for much more integration of research into clinical practice, and this could take a whole range of different forms: from the use of EHRs for research, to pragmatic trials. For example, you could take two GP clinics; one might roll out a new policy on how to treat back pain while the other continues their existing care, and then we compare results. Some have argued that for these sorts of minimal-risk trials you could add a simplified informed consent process into the clinical consultation, rather than having the full research informed consent process.

I recently published papers that argued, in certain contexts, patients have an ethical obligation to share their data.[9,10] In Aotearoa the health care we receive is evidence-based and the reason we have this evidence is because prior patients (from around the world) have contributed to the research enterprise. So as part of paying that forward, we should, under certain circumstances, be willing to share our clinical data for research. This enables future patients to benefit from the knowledge gained from our data just as we have benefitted from previous patients. Ethically, I think this is much clearer in a public health system, in the sense that there is solidarity with all of us generating knowledge and benefitting from each other. I think this would be different in a private health system. Regardless, there have to be parameters of some kind to ensure the data is being used in a trustworthy way, and governed appropriately.

Overall, I think the primary function of EHRs should still be patient care, but I think a very important secondary function is research.

Can there be a conflict between these two goals?

One way there could be conflict is if groups who have high levels of distrust of the medical community choose not to seek the needed health care because they are worried about lack of data confidentiality. One place we saw this was the controversy involving the Ministry of Social Development (MSD) data-for-funding contracts. The MSD argued that it had a right to individual client level data (rather than aggregated data) because it needed the client level data to properly evaluate non-governmental organisation (NGO) services, particularly where clients were using multiple services. Some NGOs, such as Rape Crisis, pushed back on that.[11] They serve a vulnerable community and they warned that people would stop seeking their services (or lie about their personal information) in fear of the NGO passing that information to the MSD. So we need to avoid a situation where public distrust of data sharing and/or secondary research leads to patients failing to seek care, or being reluctant to disclose sensitive information to their providers.

Are there times where public health research involving these datasets outweighs the individual interests of patients in control over their data?

Again, I think it is a spectrum. We already have accepted public health principles for when we can take data, whether a patient consents to it or not. For example, with notifiable diseases the potential threat to the public outweighs the interests of the individual. We must still minimise the autonomy and liberty restrictions, and maximise data security and de-identification as much as possible.

Ethics committees do grant consent waivers to allow researchers to use health data without consent when the public interest in the research outweighs the personal interest in privacy. I think this is broadly reasonable (though I would argue for slightly different criteria). For example, maybe we want to look at the relationship between influenza immunisation during pregnancy and fetal and neonatal health outcomes; we would need to link the mother and child's health records, and might also want to link to Births, Deaths and Marriages Registration to include data on still births. I think this sort of study, prima facie, has high public interest and could potentially justify proceeding without consent. Transparency, community engagement, and governance would be important issues to consider here.

It has been suggested that alongside basic demographic and clinical information, EHRs should also include a more comprehensive evaluation of societal and behavioural determinants of health. What do you think about that?

A lot of that information is probably getting discussed in an informal manner but not comprehensively collected. I can see the benefit of collecting social data, though GPs do not have a huge amount of time anyway, so you are weighing up how valuable it is going to be with how long it will take to collect. You also need to try to ensure consistency in how the information is recorded and coded, and the more information you collect the more variability you are going to have to manage. Another concern is how quickly that information changes and keeping the information updated. For example, living situations might change reasonably often. However, if you can also use those records for research purposes, you are maximising the benefit relative to the investment in data collection.

I also think you are going to run into trust issues with patients. When questions arise organically and are relevant to the clinical consultation, I think patients find that quite natural and understand its purpose. However, they might be wary if they suddenly feel like they are getting this interrogation from their doctor, the sort they might expect from Work and Income. For any data you are collecting, you have got to make sure that you are still operating within the spectrum of trust and that patients understand why these questions are being asked and feel that it is safe to tell you. One thing we know in relation to data collection is that patients make up stuff if they do not trust you. Trust is core to the clinical relationship, and we can not lose that.

Theoretically, if collection of this information was normalised, could this information be used in a way that affects health inequities?

It is a question of what you do with the data. You have to ask what is the purpose of collecting the data, what is the context, have you communicated appropriately with the target group, and is everybody on the same page? It could decrease health inequities if that data ensures more vulnerable patients get the care they need. For example, we can map populations to show where the health need is greatest. One way you could see an increase in health inequities is if there is backlash among certain populations who suddenly feel like they are being surveilled in a way they do not trust. They might start to disengage from the health system.

It is also important how you present the output of the research. Do you frame the results according to a deficit narrative (why certain populations are failing to achieve good health) or do you have a resilience narrative (why, despite systemic racism, are some populations doing well and how can we learn from that). These narratives can be really powerful.

Part of what is tricky about EHRs is that on one hand, they give you the most comprehensive picture of health needs in Aotearoa. They are often better than research that systemically excludes a lot of populations from the research pool. So, they are especially useful for planning health service delivery and trying to address complex multi-dimensional problems such as the relationship between poverty and health, and to target high needs groups. On the other hand, vulnerable marginalised groups tend to have more distrust of centralised systems. They are the ones who may be more reticent about volunteering their data to the government, and often for very good reason. When you look at the history of research and public health, we see that governments have collected data about populations in order to implement policies around segregation, forced re-education of children, dispossession of land, and so on. This is why it is so important to proceed at the pace of trust and involve communities in setting a research agenda that meets their needs.

Are there any unique perspectives that we should keep in mind as future doctors of Aotearoa that international research will not necessarily cover?

First, it is important to consider the extent to which research based on overseas data will be relevant and applicable to our population – both in terms of biological samples and health data. Māori and Pasifika populations are not well represented in the international genomic resource base. There is a risk of increasing health inequity if this under-representation is not addressed, because the research results will not deliver genomic technologies with clinical utility for these ethnic groups.

A second challenge is how to honour Te Tiriti o Waitangi and the need to develop appropriate co-governance models for big data (derived from EHRs or biological samples). There is lots of debate about social license. Social license is the degree to which a community accepts a practice, in this case data sharing, linking, and re-use. Often you do not know you have breached the social license until you have stepped too far and you get public backlash. So, the idea is that you have accepted data use within the social license. Te Mana Raraunga has argued that we also need a cultural license, which means the extent to which iwi and Treaty partners think data use is culturally appropriate.

Finally, if people wanted more information about this topic what do you recommend?

I would suggest people look at the United Kingdom (UK) Nuffield Council Reports.[12] They do high-quality and accessible work on all sorts of medical ethics topics, with recent reports on artificial intelligence and big data. Also, the UK health system is similar enough to what we have in Aotearoa that a lot of the information is still very relevant to us.

One thing it does not cover is the Aotearoa-specific focus on the Te Tiriti o Waitangi. Te Mana Raraunga and their website has links to great resources on data sovereignty.

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Conflicts of Interest

Rex Liao is a NZMSJ student reviewer.

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