# Ethical and human factors in large-scale medical record analysis

The large-scale analytics project intended to use practice-level session data to rank medical providers has the potential for many ethical issues. This report outlines factors of consent, an ethical briefing to staff involved in the project, details of issues with the external storage of data, and considers possible misused of the project’s results.

## Informed consent

To meet the standard of informed consent, those consenting must:

1. Be able to consent (or have a designated proxy) (Kim 2010).
2. Understand the possible negative consequences of their consent (De Leon Siantz 1988).
3. Understand the possible positive consequences of their consent (De Leon Siantz 1988).
4. Not be the subject of any coercion to consent (such as being threatened or bribed) (Kim 2010).

The first requirement is not incumbent on the design of the system; it only needs to be appropriately evaluated. The second and third requirement relate to the information provided to the patients. To meet these standards, those whose data will be used must have the risks and benefits of the system explained, including how their data will be used, stored, and transformed. This is not being met by the current system implementation plans.

The fourth requirement relates to the way in which participants are given information and asked to consent. The system as proposed does not offer any inducement to consent, but there are possible consequences to lack of consent. Those practices which do not offer data will receive rankings of 0 under the new system. If this is made known to the patients, it may affect the patient’s choice to consent. For this reason, practices not providing data should not be included in the rankings rather than assigned a 0.

To ensure the system meets informed consent requirements, patients should be provided with information on the system and how their data will be used. There should not be any strong inducement for patients to participate, or any risk negative repercussions if their consent is withheld. Participating practices could be asked to distribute information on the study and options for the patients to provide consent. This may have to take place over many months.

### Absence of consent

If there is a lack of consenting patients it will be impossible to achieve a robust result. A determination of the number of patients needed to produce meaningful data should be made ahead of time, and those practices without data should not have rankings calculated. This may mean that there is not enough patient data to create the rankings system.

One approach would be to re-examine the definition of efficiency. The system assumes that the number of patients seen per hour is the greatest measure of efficiency, but there are other measures that do not require direct use of patient data, including financial and funding information or collecting information directly from physicians.

Another option would be to use an opt-out system instead. Many reasons for a lack of consent could be logistical – patients not actively opposing the use of their data but not willing to take proactive effort to register consent. Other large scale data projects have used an opt-in approach (Vandenbroucke & Olsen 2014). This has a serious ethical implication however, as lack of an opt-out rejection should not be treated as equivalent to informed consent (Mittelstadt & Floridi 2016). Therefore, this is not the preferred option.

## Ethical briefing statement to staff

In carrying out this work, it is important that you all adhere to the highest ethical standards. Private medical records are one of the most sensitive forms of data and using it to rank practices has many potential pitfalls.

The system proposed would use human data to gain insight into a research problem (efficiency of medical practices) and distribute the findings for implementation. This is the same process research projects take, meaning that the most relevant code of conduct for this project is the National Health and Medical Research Council’s *Australian Code for the Responsible Conduct of Research* (ACRCR).

This code is intended to guide the ethical conduct of research in Australia and covers the values that the research community is expected to uphold. The other key guidance for this project comes from the Australian Privacy Principals (APP), which are part of the Privacy Act 1988 and govern the use and storage of personal data (*The Australian Privacy Principles* 2014).

Every member project team must therefore familiarise themselves with both documents mentioned above and adhere to three specific guidelines that have been developed with reference to these codes and principals:

1. **All personal data should be treated with the highest respect and security**. Australian Privacy Principal 11 requires data to be protected from ‘misuse, interference and loss’ as well as ‘unauthorised use, modification or disclosure’ (*The Australian Privacy Principles* 2014 pp. 14). Additionally, the ACRCR requires that research participants be treated with respect, which here extends to patient data (National Health and Medical Research Council 2018, pp.2).
2. **Analyses should be robust and rigorous, particularly those that will be used to make recommendations or guide decisions. This includes actively seeking out bias in the data or analytical techniques.** ACRCR principle 2 requires that all biases be avoided or, if unavoidable, be acknowledged (National Health and Medical Research Council 2018, pp.2). If biases are discovered, steps should be taken to resolved them within the project, and in the case where this is not possible, the relevant bias should be clearly identified in published material alongside data.
3. **All consequences should be considered prior to releasing this work, including possible misuse.** Research work does not take place in a vacuum, and we have an ethical responsibility to think carefully about both the use and possible misuse of all data and results before distribution (National Health and Medical Research Council 2018, pp.2).

## Standards for medical records

The Australian code of conduct for doctors outlines rules around the keeping of medical records; that they should be ‘held securely’ and not ‘subject to unauthorised access’ (Medical Board of Australia 2014). Anyone handling these records should uphold this same ethical standard, meaning all necessary steps are taken to safeguard these records.

Principle 8 of the APP specifically addresses the offshoring of data and requires that those who store data outside the country ensure any outside entity complies with the principles. More generally, this establishes an ethical precedent in which the keeping of records outside a company, including in offshore locations, should not take place without establishing that the receiving entity will comply with the same guidelines as the company itself.

Storing data internationally should be given special consideration in an ethical context, as issues that can arise from differing cultural ethical perspectives (Kohls & Buller 1994). There are also legal issues present, with different statutes applying in different countries. International organisations should be provided with clear guidelines for the treatment of records, preferably in the form of a direct contract.

## Unintended use of analysis

Human factors (and ergonomics) is the study of human interaction with objects and systems (Karwowski 2012). There is no way to prescribe the way humans will use a system, even if guidance is offered. Therefore, it’s important to consider the misuses that are possible from any analysis or system that is produced. Distributing a ranking of essential service providers has already taken place, and this presents a good opportunity to learn what human factors have become an issue.

In 2010, the Australian Government introduced a website designed to provide comprehensive information to help parents make decisions about their child’s schooling (Australian Curriculum, Assessment and Reporting Authority 2020). The primary measure on this website is a school’s performance in the National Assessment Program – Literacy and Numeracy (NAPLAN). Schools are not directly ranked, but the information present on MySchool makes this possible, and media outlets have created and distributed rankings (Mockler 2013).

Many submissions to a review of MySchool and NAPLAN reported that the rankings lead to schools and teachers focusing on teaching material on the NAPLAN tests rather than the curriculum itself, manipulating student data to attempt to get better results, and even the falsification of results (Ragusa & Bousfield 2017). This stems from a concern that results displayed on MySchool are the main factor parents will use in choosing an institution for their children.

This situation can easily be applied to the ranking of medical practices. In this case it may lead to a practice pressuring doctors to rush patients through appointments, manipulating data by recording session start and end times differently, or in the extreme reporting false data. This would be because the ranking could become the major factor by which patients choose clinics to attend.

## References

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