Using Medical Records in Epidemiological Research

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Alison Venn is an epidemiologist at the Menzies Centre for Population Health Research, University of Tasmania, and Director of the Tasmanian Cancer Registry. Her main research interests are in women's reproductive health, cancer and cardiovascular disease. Medical records and disease registries have been important sources of data in her research.

Issues relating to the ownership, privacy, security and access to health records are central to epidemiological practice. Research ethics guidelines and privacy legislation make provision for researchers to access identified health data in recognition of the important public health benefits that can be gained. In practice, however, different stakeholders' expectations about access to medical records can threaten the feasibility of some types of research. Two case studies are presented that describe research into the long-term effects of controversial hormone treatments. These illustrate how high public expectations of the safety and effectiveness of medical interventions can compete with interests in the confidentiality of individual medical records. This paper was originally delivered at the Australian Society of Archivists Conference in Sydney in August 2002 and published on a CD-ROM of the conference proceedings.

Introduction

Epidemiologists study the distribution and determinants of disease and other health-related states in populations. They are found in academic, government and commercial sectors and are involved in diverse activities such as collecting routine health statistics, conducting disease

surveillance, evaluating the effectiveness of clinical therapies and public health interventions and trying to establish the causes of disease. Epidemiologists collect information about groups of individuals by direct measurement, the use of questionnaires or interviews, and from medical records and other routinely collected health information.

Issues relating to the ownership, privacy, security and access to medical records affect many epidemiologists on a daily basis. Research that uses medical records must be approved by an appropriate institutional ethics committee and must meet the standards set by the National Health and Medical Research Council (NHMRC) in its Statement on Ethical Conduct in Research Involving Humans.[1]

The issues most commonly considered by Human Research Ethics Committees (HRECs) when reviewing epidemiological research include: whether data about individuals is identified, potentially identifiable or de-identified; whether the consent of individuals is being sought for the use of identified or identifiable data; how data are being collected and stored in the short and long term; how the data will be used; who has access to the data; and how confidentiality will be preserved in the analysis and presentation of study results. The NHMRC guidelines also state that, where identified or potentially identifiable data are used in research, a HREC must be satisfied that the information will be collected, dealt with and stored in accordance with the *Privacy Act 1988* (Cth). This Act has recently been amended and ten National Privacy Principles form the core of its private sector provisions.

Two studies that I have been working on over the last ten years illustrate some of the challenges encountered when doing research that requires the use of medical records. Each of these studies has addressed important research questions of public interest, has required extensive use of medical records, and has encountered difficulties in relation to the access, privacy and accuracy of those records.

The first of these studies aimed to determine whether the use of fertility drugs with in vitro fertilisation (IVF) and related treatments increased the risk of cancer in women. The second study is investigating the long-term health and psychosocial effects of hormone treatment to reduce the adult height of tall girls.

The possibility of adverse effects of medical intervention on women's reproductive health or cancer incidence is a sensitive matter for patients

and clinicians and an issue with potential medico-legal implications. These concerns have highlighted some of the competing interests in the use of medical records for research purposes and the vulnerability of certain kinds of study.

Case study 1: Cancer in women treated with fertility drugs

Research question and public health importance

Fertility drugs have been used since the 1960s for the purpose of stimulating women's ovaries to produce eggs. Initially these drugs were used to treat infertility arising from hormonal problems and a failure to ovulate. In the last two decades their use has expanded greatly with the development of IVF and related reproductive technologies. With these treatments, fertility drugs are used in relatively high doses and in new combinations to stimulate the production of many eggs (on average about eight or nine) and to thereby increase the chance of fertilisation in any given treatment cycle. The majority of women treated in IVF programs do not have an underlying problem with ovulation – they usually have other causes of infertility. In Australia in 1999, 1.7% of all Australian births were the result of assisted reproductive technologies. For the 4,319 births that were conceived in that year, over 17,000 treatment cycles commenced using fertility drugs to stimulate superovulation.

While IVF has been of benefit to many, there have been concerns amongst patients, scientists and clinicians about the possibility of serious long-term health risks associated with this type of use of fertility drugs, particularly the possibility of an increased risk of breast and gynaecological cancers. In 1996, an Australian study was initiated with the aim of establishing whether the risk of breast and gynaecological cancers was increased in women who had had treatment with fertility drugs for IVF.

Study design

The study design we used is known as a cohort or follow-up study. We identified 29,700 women who had registered with one of ten IVF clinics in Australia prior to 1993, using the electronic medical records of the collaborating IVF clinics. Women in the cohort were followed through time to determine how many developed cancer. Cases of cancer were

ascertained by linking the names of IVF patients with data collected by the State cancer registries. The number of cancers that arose was compared with the number expected given the incidence of cancer in women of the same age in the general population.

The need to use medical records and disease registry data

Medical records were essential for this study in that they enabled us to identify a large representative cohort of women who were treated with fertility drugs for IVF. Because cancers are relatively rare in women of this age group (most were under fifty years of age), it was essential that a large number of women were included in the study. Cancer is a notifiable disease in each State and Territory in Australia and access to cancer registry data therefore provided the most reliable method of ascertaining the number of cancers that had occurred in the cohort.

Ethical issues

The data used in this study were identified in that they included the names, dates of birth and addresses of IVF patients and record-linkage with data collected by the cancer registries was conducted without the consent of individuals in the study. The NHMRC ethical guidelines state that a HREC may approve access to data without individual consent when the HREC is satisfied that:

- it is impossible in practice, due to the quantity, age or accessibility of the records to be studied, to obtain consent, *and*
- the public interest in the research outweighs to a substantial degree the public interest in privacy.

Our study involved very large numbers of medical records and had aims that we believed were in the public interest. It was on this basis, and on the basis of important precedents in Australia and internationally, that we believed our study was feasible and ethics approval justified.

Challenges

This study required us to submit applications to twenty-four HRECs that served the IVF clinics, cancer registries and universities involved. It took more than twelve months to get the necessary ethics approvals: a relatively frequent experience in multi-centre studies and a significant

disincentive for researchers to undertake this kind of work. Of note was the variability in the responses of IVF clinics and their HRECs regarding the release of identified data. Two clinics decided not to participate in the study because of concerns about a breach of confidentiality. Two HRECs refused to approve the study because they believed they would be in breach of their duty of confidentiality and exposed to the threat of litigation.[2] Fortunately, the study was approved by enough HRECs to allow us to assemble a large cohort of IVF patients and to complete the study.

Once the study was underway, a range of other problems occurred. The medical records were mostly in the private sector and not always subject to stringent recordkeeping practices. Problems were encountered when records were fragmented between referring specialists and the clinics providing treatment, some clinicians had disposed of records, there were missing and inaccurate data for some study variables and difficulties accessing records because of the locations used for storage. All of these problems were overcome to the best of our ability and with considerable effort.

The final outcome of this study was the finding that cancers of the breast, ovary and uterus were no more common in women treated with fertility drugs with IVF than in the general population. The findings were published in *The Lancet* and used widely in patient information brochures in Australia and elsewhere.[3]

Case study 2: Long-term effects of hormone treatment to reduce the adult height of tall girls

Research question and public health importance

Synthetic oestrogens have been used in the treatment of tall stature in girls since the 1950s. The treatment works by accelerating puberty and stopping the growth of the long bones. Treatment has been available for psychosocial indications for girls with a predicted adult height exceeding 177cm or more.[4]

Although this treatment is relatively uncommon in Australia now, a recent survey of paediatric endocrinologists in the US showed that 22% of 411 respondents had provided hormone treatment to reduce the adult height of tall girls in the preceding five years.[5]

Previous studies have described occasional short-term side effects of treatment but little is known about the long-term outcomes for women. The possibility of adverse effects of treatment received media and political attention in Australia in 1997, which, in conjunction with the establishment of a consumer group, Tall Girls Inc., increased the recognition of the need for research to address these issues.

Funding for a study was eventually secured from the Commonwealth Department of Health and Human Services during 2000 and the study is now in its third and final year.

The study aims to examine a broad range of health and psychosocial outcomes in women who were treated with oestrogens during adolescence and to compare them with women who were assessed for tall stature as girls.

In addition to examining potential benefits and harms associated with treatment, the study will contribute to our broader understanding of how high levels of oestrogens in adolescence might influence subsequent reproductive health.

Study design

This study is following-up approximately 1,300 women who were assessed or treated for tall stature from the late 1950s through to the mid-1980s. The majority of these women were the patients of one Australian paediatrician and about a third of them received hormone treatment. The untreated women provide an important comparison group of tall women.

The follow-up has entailed identifying eligible participants from medical records, tracing them to a current address and inviting them to complete a postal questionnaire and telephone interview. Key outcomes of interest include reproductive health, mental health and satisfaction with treatment. Small groups of women are being asked to participate in focus groups and individual in-depth interviews to explore more fully their experiences of being medically assessed or treated for tall stature.

The need to use medical records

Medical records were needed to identify a large and representative group of eligible study participants and we were fortunate that such

records had been maintained. Reliance on volunteers recruited through the media or the Tall Girls consumer group would have resulted in a study sample that was too small and prone to selection factors that might lead to biased results.

Ethical issues

This study was approved by the ethics committees of La Trobe University and the Royal Children's Hospital. Important ethical considerations in this study related to the need to access patients' names from medical records held in private practice and to trace women to a current address without breaching confidentiality about the nature of the assessment and treatment they had received. Although, by necessity, we accessed the names and original contact details of eligible patients from the medical records, we will not be abstracting all the relevant clinical details needed for the study until we have the women's permission.

At the time the research commenced, it was planned that the elderly paediatrician who had seen most of these women would write to his former patients with an invitation to participate. Some months after the study started, the paediatrician died and, according to his wishes, we continued with the research.

Challenges

The majority of women and parents with whom we have had direct contact have been accepting of our approach and many have been pleased that the study is being conducted. Others have expressed strong concern that the research team's access to their name represents a breach of confidentiality and they have demanded an explanation as to how this could be allowed.

The new amendments to the Privacy Act, which cover medical records in private practice, make provision for the disclosure of health information for research relevant to public health. Although this provision exists in the Act and the study has ethics approval from the relevant HRECs, the use of medical records for this study is at odds with the expectations of some members of the public. The research assistants working on the study are very professional in responding to concerns about confidentiality but this is certainly a stressful aspect of the project and complaints of any kind tend to make ethics committees anxious about approving such studies in future.

The study has presented other challenges. Several women who were assessed or treated for tall stature have contacted their doctors to seek access to their medical records without success. The knowledge that we are able to access the records for research purposes has prompted some women to ask us to provide them with the information. This places us in an unusual and difficult position: we have obligations to the medical practitioners who are assisting us with our research, and to our study participants. The solution to this problem has yet to be found but it is a factor that might discourage clinicians from making available their private practice records in future.

Finally, on a matter of archiving practice, some clinicians have been willing to assist in the study but have been prevented from doing so because they have no way of readily identifying which of their hundreds or thousands of former patients were seen for tall stature or its treatment. Others have destroyed their records or have declined to assist for other reasons.

This study will be completed in a year's time and only then will we be able to assess the final balance of the public benefit and private harm resulting from our use of medical records for this epidemiological research.

Conclusions

Considerable public health benefits can be achieved with epidemiological research using medical records. The studies described here seek to address concerns about the long-term effects of controversial hormone treatments and would not have been possible without the use of medical records. Although the public has high expectations that medical interventions should be effective and safe in the long term, people also expect that their medical records will be confidential and there is little recognition of the circumstances under which medical records might be accessed for research purposes.

The National Statement on Ethical Conduct in Research Involving Humans and the Privacy Act make provision for research using records without individual consent but do not provide guidance on all the issues facing epidemiologists conducting this kind of work. Public concern about privacy and differing interpretations of the ethical and legal frameworks affecting the use of medical records mean that researchers,

ethics committees and funding bodies can be reluctant to embark on, or support, studies that are seen to be sensitive or likely to receive complaints. The challenge ahead is to have an informed public debate about these issues and to create an environment where researchers can be confident that their practice is of a high ethical standard and of value to the community.

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Endnotes

[1] *National Statement on Ethical Conduct in Research Involving Humans*, Commonwealth of Australia, 1999.

[2] F Bruinsma, A Venn & L Skene, 'Accessing Patients' Records Without Individual Consent for Epidemiological Research', *Journal of Law and Medicine*, 2000, vol. 8, pp. 76–80.

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