

Legal and Ethical Issues in Evaluating Abortion Services

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ABSTRACT

When evaluation studies are conducted in a sensitive area, ethical and legal implications are bound to challenge evaluators. All too often, evaluators must deal with competing responsibilities in evaluating these programs or services. This article focuses on several ethical and legal issues that arose during an evaluation of abortion services. We discuss how we developed decision rules and considered trade-offs in dealing with these ethical and legal issues so that rational and objective decisions could be reached. We place this discussion within the context of balancing the utility and propriety evaluation standards with respect to obtaining true informed consent and protecting the privacy and confidentiality of data when evaluating abortion services. The article concludes with recommendations concerning the evaluation of abortion services.

INTRODUCTION

Conducting evaluation studies on induced abortion services is difficult, owing to people's difference of opinion about the ethics of the procedure and the controversy over whether research funds should be used to examine it. Although all evaluations require due attention to ethical and legal issues, evaluating abortion services is particularly challenging because of the sensitive nature of the topic. There is a real possibility that failure to adequately deal with ethical and legal issues will jeopardize the completion and usefulness of the evaluation.

This article discusses several ethical and legal issues in obtaining true informed consent and protecting the privacy and confidentiality of data when evaluating abortion services. The discussion is placed within the context of decision rules and trade-offs in balancing the utility and propriety evaluation standards (Joint Committee on Standards for Educational Evaluation, 1994). We conclude with recommendations for other evaluators who are involved with evaluation studies in this sensitive area.

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The ethical and legal issues discussed are based on the experience of the present author who was commissioned by the Ontario Ministry of Health (Canada) to conduct four evaluation studies on how abortion services were delivered in the province. (Some of the findings have been published—see Ferris & McMain–Klein, 1995; Ferris, McMain–Klein, Colodny, Fellows, & Lamont, 1996; Ferris, McMain–Klein, & Iron, 1997, 1998.) At the outset, we recognized the need to carefully consider the ethical and legal issues; however, some of these issues were unforeseen and ongoing. In this article I describe the complexity of our experiences and discuss what we considered in resolving the issues.

BACKGROUND

In January 1988, the Supreme Court of Canada (*Morgentaler, Smoling, Scott R, v. the Queen*, 1988) ruled that the abortion law within Section 251 of the Criminal Code was unconstitutional. The Court found that the Criminal Code limited access to a medical procedure, thereby infringing on a woman's right to life, liberty, and security as guaranteed under the Canada Charter of Rights and Freedoms. For the next three years, there was ongoing debate over the proposed replacement legislation, Bill C-43, which would have reinstated abortion as an indictable offense unless a medical practitioner deemed that the health or life of the woman was threatened by continued pregnancy. In 1991, Bill C-43 was defeated, leaving abortion to be regulated as any other medical procedure under the Canada Health Act. However, despite this change in legal status, ongoing debates continue in Canada about the ethics of induced abortion and whether it should be covered by universal health care plans.

Effects in Ontario

In 1987, the Ontario Ministry of Health (hereafter referred to as the Ministry) commissioned a study to examine provincial access to abortion services for the period of 1975 to 1985 (Powell, 1987). At that time, the Canadian Criminal Code allowed qualified medical practitioners to perform abortions with prior approval from a Therapeutic Abortion Committee (TAC) or an accredited hospital. The Powell Report examined numbers of abortions performed in the province and barriers to service, including the referral process. The report documented a number of systemic barriers that needed to be addressed to improve access to the procedure.

In 1990, after the defeat of Bill C-43, the Ministry initiated consultation with a Task Group of abortion providers to discuss the identified obstacles to equality and accessibility. The Task Group believed that despite the change in law, barriers perpetuated inequalities. Using the Powell Report (1975–1985 data) and their experiences as providers, they identified those barriers, such as too few hospitals and too few physicians performing abortions, which were perpetuating inequities in access to the procedure. The Task Group developed a framework for the implementation of strategies to ensure equitable access to abortions. There was general agreement between the Task Group and the Ministry that more information about access to abortion services was needed given that the last review was in 1985 before the defeat of Bill C-43.

Evaluation of Abortion Services Delivery

To address this information gap, four evaluation studies were commissioned. Experiences from these studies form the basis of the present discussion. We knew that we must be seen as credible and neutral, without advocacy for either side (Chelimsky, 1998; Datta, 2000). Our studies were designed as fact-finding projects with the goal of generating objective data to enable discussions. No particular opinion about the ethics of induced abortion was advocated.

We had two major foci: (1) to produce a comprehensive profile of hospitals that did and did not provide abortion services; and (2) to perform a comprehensive examination of all general hospitals to examine their practices and clinical issues. Our goals are summarized in Table 1. The evaluation studies were to examine access to abortion services in the province from a review of service providers. Service providers included hospitals, health units, free-standing clinics, and medical practitioners. Access was defined as the availability of services and the ability to acquire these services in a timely manner. These studies did not address the issue of quality of care except as it related to complications. Issues relating to geographical disparities in demand/procurability, availability of specialized services (e.g., for later trimester procedures, counseling services), referral routes, restrictions, and other potential barriers to service were examined.

To ensure that the evaluation served the information needs of intended users, we first identified our stakeholder group. The need to identify stakeholders is a feature of the utility standard (Joint Committee on Standards for Educational Evaluation, 1994). We identified two major stakeholders—the Ministry and participating hospitals and staff. The Ministry was viewed as the main information user since the evaluation results would contribute to health policy. Participating hospitals and staff would be affected by the evaluation since their information would inform us about these services.

We believed our evaluation studies could reflect all significant views and concerns of these two major stakeholder groups. We carefully considered whether the public should be treated as stakeholders and decided that to do so would make it immensely difficult to keep the focus on evaluating services rather than on discussing whether the procedure should be offered. Our mandate was not to debate whether abortion should be offered. However, our participating group of hospitals held diverse and conflicting views about whether abortion should be provided. Such diversity was important to capture in the hospital sector and we viewed it as being essential information for our evaluation.

LEGAL AND ETHICAL CONSIDERATIONS

Competing Evaluation Standards

Evaluations should have four basic attributes—utility, propriety, feasibility, and accuracy (Joint Committee on Standards for Educational Evaluation, 1994). The utility standard ensures that an evaluation will serve the information needs of the intended users. The propriety standard addresses the requirement that evaluations be conducted legally, ethically, and with due regard for the welfare of those involved in the evaluation as well as those affected by the evaluation. The feasibility standard ensures that an evaluation will be practical, prudent, and politically viable and cost-effective. The accuracy standard ensures

TABLE 1.
Summary of the Evaluation Foci

<i>Type of Information</i>	<i>Method</i>	<i>Comments</i>
Investigation into the provision of induced abortion services, including details on actual services provided, a profile of women who obtained the procedure, geographical variations in the use of these services, and clinical information such as complication rates, types of procedures, etc.	Information extracted from three secondary sources: the provincial universal health insurance coverage database, the National Health and Welfare Age/Sex Physician Claims Database, and the Therapeutic Abortion Services database (Abortion Registry). The latter database, provided to us by the Ministry, included information on residence of patients by county, along with age, marital status, gestation, complications, procedures, number of previous deliveries, number of previous abortions, and number of in-hospital days.	None of the three secondary databases identified individual patients, but hospitals were identifiable in the Abortion Registry by using a master-coding directory. Although the Registry database did not explicitly identify physicians, it is feasible that with some effort, individual physicians could have been identified.
An investigation of all general hospitals to examine the availability of hospital abortions, to compare the practices of those that provided abortions with those that did not, and to examine clinical issues in provider hospitals such as procedures used, staffing, medical follow-up, booking of operating room time, etc., during the previous two years.	Survey of all Ontario general hospitals (excluding those owned by or affiliated with religious denominations with confirmed nonprovider status). Chiefs of Staff, Chiefs of Obstetrics/Gynecology, and Directors of Nursing (or appropriate substitutes) answered the questionnaire for their hospital.	The protocol allowed for the identification of hospitals and individuals, but not for the public release of this information.

that an evaluation will provide technically valid and reliable information, and that it will produce accurate and impartial reporting about the features of a program that determine its merit. Close attention to these four evaluation standards should result in improved evaluations (Joint Committee on Standards for Educational Evaluation, 1994).

As other evaluators will attest, there are often conflicting responsibilities with respect to these standards when making decisions in the evaluation process. For our work, two evaluation standards tended to compete for priority—the utility and propriety standards. We tried to balance these two standards when making decisions but, given the complexity of our task, we sometimes had to decide that propriety issues should take precedence over the utility of the evaluation or vice versa. The competing areas, where we most had to balance our priorities, involved conducting and reporting evaluation results in ways that encouraged

follow-through by stakeholders (utility standard) and rights of participants and disclosure of findings (propriety standard). For the purposes of our analysis, the discussion is organized around these areas.

Ensuring “True” Informed Consent to Participate

Informed consent was defined as an understanding that an individual health practitioner or a spokesperson for a hospital, communicating either directly or through an appropriate agent, agreed to participate in our study after the potential risks and benefits of doing so were disclosed. Obtaining informed consent is one of the requirements of the propriety standard concerning the rights of human subjects.

Our data were obtained from two sources: databases maintained by the Ministry or another governmental institution, and a hospital questionnaire that we developed for use in the evaluation (see Table 1). Concerning the former, health evaluators often use secondary databases designed for ongoing epidemiologic surveillance of medical care or for administrative purposes because they provide data on large populations (Huston & Naylor, 1996). In such cases, the databases have not been established to address a specific hypothesis but are being used posthoc to answer a research or evaluation question. Accredited hospitals (before 1988) and accredited clinics (between 1988 and 1990) were legally required to provide the Ministry with monthly reports concerning abortions in their institutions, because the procedure was legal only in these facilities. After 1988 and 1990, neither hospitals nor clinics, respectively, were required to submit confidential monthly abortion statistics. However, almost all did so. These statistics included types of procedures performed, the number performed, the gestational ages, and any complications. The Abortion Registry in which this information was stored included the identity of the hospitals (although not of individual patients), so that one could examine the data by hospital and by geographic region. The Abortion Registry database is unavailable to the public under the current provincial Freedom of Information Act because the small size of some hospitals makes it possible, with some effort, to identify individual physicians. Protocols are in place regarding who can have access to the data, their level of access, and how the data can be used. For our study, we were provided with five years of the Abortion Registry data on tape so that we could manipulate and manage the data in-house.

Did those contributing data to the Abortion Registry give informed consent for its use by us? In our jurisdiction, physicians who have admitting privileges to a hospital have legislative requirements concerning the record that must be compiled for each patient. The hospital is the custodian of such medical records. The question became this: Had the hospital as health information custodians consented to participate in our research? The perception of and actual occurrence of escalating threats to abortion providers and violence by abortion protesters over the previous several years had led to increased alarm. These threats resulted in government officials, physicians, and hospitals keeping information about who was performing the procedure more closely guarded than ever, except for referral purposes. (Our study showed, however, that hospitals continued to contribute to the Registry database.) We sought legal opinions about informed consent. The Ministry was satisfied that because they had commissioned our work and we were using the data for the same purposes for which it was originally intended, hospital consent was extended to include participation in our evaluation.

Our other source of data were a questionnaire that we sent to individuals in the

province's general hospitals. Our protocol involved first informing the Chief Executive Officers (CEOs) of the hospitals of the study, and notifying them that some of their staff would be asked to answer questions about the provision or nonprovision of abortion services in their hospital. We saw this as an important professional courtesy, especially given that staff receiving the package might contact their CEOs about it, either for clarification or to seek consent to answer for their hospitals, or for other reasons.

In Canada, no legislation requires public hospitals to participate in Ministry-sponsored research; therefore, public hospitals do not require staff participation in such studies. However, if the hospital believes it is important to participate they could communicate this to their employees. It is possible that paid staff members who were asked to answer for their institution could feel pressured to or not to respond. Given the sensitivity of the topic to hospitals and employees, we wanted to be responsive to the hospital environment. To ensure that individuals could feel free not to answer, we included in the survey package a postcard that recipients could return to us, without their hospital's knowledge, stating that they would neither be returning the questionnaire nor transferring it to someone else, and requesting no further contact from us. Furthermore, we let recipients know that their hospitals would not be notified as to who on their staff had answered the questionnaire, even if they requested this information.

Ensuring "True" Informed Consent to Have Results Published

Our legal agreement with the Ministry included a clause that allowed us to publish our results independently. Although we determined that those contributing data to the Abortion Registry had given informed consent to allow us to analyze the information, the next question was whether they had consented to its public release. While the information was submitted confidentially from hospitals to the Ministry, it was unclear whether the government's publishing of the data in some form would violate any agreements between themselves and the hospitals. The legal interpretation was that while we were holders of personal information (hospital-specific data and physician-specific data), we would be prohibited from disclosing information relating to specific individuals or patients. However, the release of aggregate data would be permissible. We decided to make our findings public through the usual vehicles (e.g., peer-review publications, technical reports, presentations) using aggregate data. We imposed stringent safeguards on how we would release the information. These precautions are described in the next section.

With respect to our survey data, we knew that our participants had agreed to the public release of the aggregate data. To our surprise, the response rate to our survey was 97%. Although in our reports we limited what we said about the 3% of hospitals that did not participate, the publication of our findings would provide some information about their sizes; consequently, readers so motivated might be able to deduce which hospitals had not participated. We had told potential participants that their decision concerning participation would not be known by their hospital. It is possible that we did not resolve this particular issue completely. A separate issue was whether the 3% of hospitals could be at risk if they could be identified. These hospitals were not abortion providers and we surmised that they were at a low risk for harassment, as provider hospitals reported being significantly more at risk for harassment than nonprovider hospitals (Ferris et al., 1998). Those wanting to access abortion services or who advocate access to abortion services would want to know about these 3% of nonproviding hospitals. This point is discussed later.

Protecting the Privacy and Confidentiality of Data

Privacy refers to the freedom of research participants to decide for themselves the time, circumstances, and extent under which their attitudes, beliefs, behaviors, and opinions are to be shared with or withheld from others (Kelman, 1977). *Confidentiality* refers to how private information is managed and shared. Researchers should refrain from sharing confidential information without permission from the participants, unless required or permitted to do so by law. Sometimes the law with respect to a particular case under consideration is unclear or does not address the issues before the researcher. In this case, ethical principles will guide the researcher in balancing their various responsibilities.

In reporting both the Registry data and the survey data, we considered how best to protect participants by respecting the confidentiality and privacy of the data. We had to address two major concerns. First, during the time that we were collecting and analyzing our data, several abortion protesters were charged and ultimately tried for allegedly picketing too close to independent health facilities that performed abortions. Because this court case was current and our data were pertinent to the issue, there was a concern that we could be subpoenaed to present the court with identifying information about the facilities that performed abortions, or that we could be asked to supply the data under the Freedom of Information Act. There have been cases in which the records of epidemiologists have been subpoenaed (Holder, 1985). Second, with regard to the survey data, we owned the information, and its legal status was less clear than in the situation of the Registry data. (We were prohibited by law from releasing the Registry data and subsequent analyses in any way not specified in the agreement with the Ministry.) We also knew that several antiabortion advocacy groups requested access under the Freedom of Information Act to nonaggregate data about hospitals and physicians performing the procedure and that we could receive such a request ourselves. (Their request was denied and in the appeal proceedings the Privacy Commissioner upheld the government position denying access to nonaggregate abortion data.)

When managing the survey data, we used unique codes to identify each respondent and hospital. Once our analyses were complete, we removed the identifiers from the questionnaires—removing individual identifiers as soon as possible is an appropriate method of dealing with sensitive data (U.S. Department of Health and Human Services, 1999). However, given the different sizes of the hospitals and the nature of their responses to some questions, it might have been possible, even without the identifiers, for a determined reader to establish the identity of some hospitals and individual respondents. Accordingly, we designed the questionnaire so that the first sheet with this second-level data could be removed. This protected our identifying data should the evaluator be compelled to bring the data with her to court (subpoena duces tecum). However, it would not protect the release of the confidential data if she were subpoenaed to attend as a court witness. Because the courts require that they hear all testimony that may affect a case under litigation, it is possible that researchers whose findings could have bearing on a case, may be compelled to disclose the information in a deposition or in court. There has been concern from the research community about scientists being compelled to disclose information about their unpublished findings in a deposition or in court. The release of findings in court could affect the viability of the research if it is in progress or could result in findings being released before being peer-reviewed (and there may be errors in the collection, analysis, or interpretation of data, and hence legal decisions could be made based on flawed science). In an editorial in *The New England Journal of Medicine*, the chair of the American Bar Association's section on Science and Technology said that

scientists should not expect absolute exemption from subpoena, but that rules concerning compelled disclosure need to be in place so that it does not have adverse effects on research (Black, 1997). In Canada, rules have not been developed for the courts and it would be up to each court to balance the best interests of the public in this regard. In this case, the courts would need to decide if partial disclosure that allowed for the protection of individual health practitioners and hospitals would best serve the public's interest and, if so, what conditions would be made on the partial production of the report to mitigate the harm caused by full disclosure.

In addition to privacy considerations, we needed to carefully consider how to report the data without compromising the confidentiality primacy while still providing sufficient information to be useful. In one publication on regional differences in the utilization of abortion services, in which we analyzed data by county, we decided to use a unique number for each county rather than its name (Ferris & McMain–Klein, 1995). This allowed us to present small area variations on such issues as gestational limits and procedural differences, while concealing the county locations of the hospitals. In a later publication in which we organized the data by health planning regions, which have large geographic boundaries, we named the regions but continued to identify the county-specific data by number rather than by name. While providing the county names would not be naming hospitals, the size of some counties could lead to the identification of individual hospitals, even if we merged several counties for reporting purposes. Given the limited number of physicians in some hospitals that could perform the procedure, it may be possible for someone to identify the physicians(s) who performed the procedure at the hospital. At the time of our publication, the province was allowing the release of hospital and county information on medical procedures so that consumers and hospitals could be more informed. The agreements between the Ministry and us contained provisions restricting the access and disclosure of personal information about specific individuals or patients. However, it was arguable whether the hospital identification numbers, which do not relate to a specific individual, were so protected. Although abortion is treated under the Canada Health Act like other medical procedures, we believed that it was different because of the environment in which it was offered. Consequently, we did not release hospital- or county-specific data when pressured by the media to do so.

Balancing the Utility and Propriety Standards

Our decision not to release the hospital-based information in our publications meant that we put a priority on the propriety standard above the utility standard. Clearly, the use and impact of the evaluation would have been greater for the Ministry and possibly for the participants in the evaluation if identifiable information had been released. We could not see how we could release identifiable information to the participants in such a way that the public did not obtain access to it. Nearly half of the hospitals that provided abortions reported being harassed for doing so. Hence, we decided that releasing any information that could lead to their identification could result in unnecessary harm. In addition, regardless of whether or not they provided abortion services, hospitals and their staff needed to have their privacy protected.

Although it was viable to withhold this information from the participants and the public, the Ministry required certain information for policy decisions. Our original intention was to release the hospital and county identifiers to the Ministry, along with our interpretation of the situation in each county. However, as our studies progressed, there were more requests under

the Freedom of Information Act for public access to detailed information from the Ministry about abortion services, and it appeared possible that our reports could one day be included in a request under this Act. Therefore, providing the Ministry with the level of analysis it required meant that ultimately the identification of individual physicians and hospitals might become public. Several legal opinions concluded that our reports might not be currently obtainable under the Act; however, there was no guarantee that this decision would hold in the future. After much consultation, it was decided with the Ministry that we would provide the government only with the same reports that we were making available to the public.

Had the public been a major stakeholder, we might have balanced our priorities differently. The public would want to know which hospitals did and did not provide abortion services, as well as our information involving the demographics of women obtaining abortions. Advocates on both sides of the issue would want to know about the hospitals that could provide abortion services (e.g., had a gynecological department) but chose not to. However, because the public was not a major stakeholder, we did not weigh their needs heavily in our evaluation design. We did believe that it was our responsibility to provide objective information about abortion services to all groups and, therefore, did publish our findings and report the work to the public through publications and through the media.

RECOMMENDATIONS

Table 2 presents our recommendations for other evaluators conducting studies in this sensitive area. While these recommendations are applicable for all evaluation studies, the sensitivity of this particular topic makes their resolution particularly pertinent.

CONCLUSION

The pervasive issue was to balance the priorities of our responsibilities to the Ministry as policy makers with our responsibilities to our participants. We could not argue against public access to information, as we believed this to be important. In fact, we maintained the legal right to publish our aggregate findings at the outset, because we believed that practitioners and the public must be given an opportunity to review the evaluation results. However, we also believed that, given the current environment of escalated violence and broadened rights regarding access information, protection of our participants was a paramount issue. On balance, we felt that the public's right to know needed to be tempered with our need to protect the privacy and confidentiality of those involved in the research. Other evaluators may have identified different stakeholders and balanced their responsibilities differently.

Policy makers need evaluation information about abortion services. To be most useful, these data need to be reported in disaggregated form so that informed decisions can be made about abortion services by geographic area. Unfortunately, the level of disclosure required to fully meet the needs of policy makers could put the research participants at risk because of the possible legal difficulties in keeping this information confidential. Hence, even among our stakeholders, we had to prioritize our responsibilities. In the end, because no other published Canadian studies used registry data and survey methods about abortion services, the infor-

TABLE 2.
Recommendations Concerning Evaluating Programs in Sensitive Areas

Registry Data

If working with data obtained from a government registry database, do the following:

1. Review the conditions under which the data were submitted to the registry. It is important for contributors to have agreed to have their data released or that custodians of the data ensure that the information is accessed or used in a way that is consistent with the policies under which it was submitted to the registry.
2. Inquire about the legal status of the information in the database and whether your analysis of it could put you in a position of releasing your findings during legal proceedings. If it could, consider whether this has any implications for your evaluation study.
3. Seek clarification as to whether your analysis would be obtainable under legislative Acts that allow public access to governmental information. If it would, consider whether this has any implications for your evaluation study.

Survey Data

If using a survey method, before sending out a questionnaire, do the following:

1. Consider carefully the conditions of participation, and ensure that unusually high or low response rates will not affect your ability to meet these conditions. Develop a contingency plan to ensure that you meet your ethical obligations with varying response rates.
2. Seek legal consultation on the status of your data. Do not make statements to elicit participation that are incongruent with this consultation. For example, if there is a possibility that one day you could be forced to release your data in a court of law, do not promise potential participants that no one will ever know how they answered a question. Consider the various options available to you should your data identify participants or possibly lead to their identification. Be clear with participants how you will protect the confidentiality of the data and the circumstances under which you may be required by law to release it.

Final Reports

1. Before you begin, seek consultation as to the legal status of any of your submitted reports with regard to legislative Acts that allow public access to confidential information. Be prepared to discuss whether your report should be exempt from such access laws, and understand that the public's right to know is a fundamental right of living in a democratic society.
 2. Before you begin, consider the possibility of various future events and if these occur, how this might influence the legal or ethical status of any of your submitted reports. Seek advice from colleagues regarding whether these events are likely to occur, and if so, consider them when negotiating with the eventual holder of your submitted report.
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mation was valuable. From the perspective of the government, the public, and practitioners, the evaluation provided information needed to better understand these services. From the Ministry's perspective, it could improve access to the procedure throughout the province.

Issues concerning the level of disclosure of data and the balance between the protection of human subjects and providing useful information for policy formation and implementation will continue to be a concern for other evaluation studies, especially those in sensitive areas. Although others may have weighed judgments differently, we hope the complexity of our experience, the open discussions about the ethical and legal implications of the various options, and our recommendations are useful to other evaluators.

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