To Report? or Not to Report?

CASE COMMENTARY

To Report? Or Not to Report? That is the Dilemma

This is a complex study involving various stakeholders, some of whom do not directly participate in the research process. Firstly, there is a research agency which initiates the study, clearly driven by its concern for reproductive rights. The medical practitioners represent the other stakeholders. Access to them has been obtained through peers who are directly involved in the reproductive rights movement. Thus, in this case, it is clear that a subgroup of medical practitioners who are concerned with the advocacy of reproductive rights has been included in the study. In classical terms, they do not constitute a vulnerable population as they are fairly well organised, highly educated and socially respected. They can be expected to have a high level of autonomy and control over the research process.

There are other stakeholders in this study. This study has direct consequences for women, representing an opportunity to enter the debate on abortion. Such a study can help to bring to the public forum several uncomfortable facts that are probably well known, but which the state is unwilling to acknowledge. We find that a legislative decision to ban the use of misoprostol has been instituted in the face of all available evidence that indicates a high need for abortion services. As a response to this, women and medical practitioners have colluded to allow the unofficial use of misoprostol. Thus, although they are not the focus of the study, women are also implicated in an illegal act.

The state itself is a stakeholder in this study. As a reconciliatory measure, to address the serious problem of abortion-related morbidity and mortality without disturbing the anti-abortion policy, it has instituted a programme for post-abortion care. Undoubtedly this represents its attempt to bring about a compromise between the politically powerful anti-abortion lobby and women's

reproductive rights, or more aptly, women's reproductive needs. While it is not clear whether this study was commissioned by the state, it is definitely an interested recipient of the study findings. The stated purpose of this research is to inform and influence the programme for "Prevention and Management of Abortion and Its Complications". Thus, the logical objective of such a study would be advocacy with the state to evaluate the findings of this study and respond to it in the form of policy changes and programmatic provisions.

In this complex scenario, researchers must first consider their responsibility towards the participants, i.e., medical practitioners, and also their responsibility to other stakeholders in the study, especially women. The nature of their responsibilities is not simple to define. As stated earlier, the participants of the study are not vulnerable in classically defined terms, but at the same time, any lapse on the part of the researchers could seriously undermine their interests. The disclosure of the unofficial use of misoprostol may lead to pressure on researchers to violate confidentiality and identify individual practitioners who could face prosecution. More likely, it may lead to accentuated pressure to monitor the use of misoprostol, ending the "benign neglect" which has hitherto enabled the state to officially hold an anti-abortion position but allow women some access to post-abortion care. Eventually, such a move would affect the most vulnerable stakeholders in this study — women in need of abortion services, who would lose access to a useful and vital drug.

Within the boundaries of the formal ethical norms governing the research-participant relationship, there are many arguments for not reporting information related to the unofficial use of misoprostol. The design of the study would not have anticipated such information, and thus, it is quite likely that the information collected on it is not consistent and systematically documented. Secondly, it represents a "chance finding" which is significant, but may distract attention from less dramatic but equally important evidence on other aspects of post-abortion care, which were the original focus of the study. It is quite likely that the researchers had not *a priori* decided on the ethical norms to be applied to the reporting of such information and hence, have not specifically discussed this aspect with the participants. Thus, researchers are themselves responsible for weighing the risks and benefits of reporting such information without any knowledge about what their participants would have wanted. As a result, the balance of risks and benefits as explained to the participants would be unduly altered by reporting of a clearly illegal practice that could lead to prosecution of individuals or greater policing of the entire profession.

Researchers would be concerned about the long-term consequences of this study, both for their participants and the women in general, if reporting this finding leads to an investigation. They would also be concerned about their

own interests being jeopardised if they lose the faith of the participants or the state — which is the recipient of this research finding — and lose opportunities to conduct further research. Thus, researchers would be justified in deciding not to report evidence about the unofficial use of misoprostol.

There are equally compelling arguments for reporting the unofficial use of misoprostol, although this may be only a "chance finding". It would be interesting to consider why medical practitioners chose to disclose the fact they use misoprostol unofficially. It is unlikely that they were unaware that it is illegal. It is also unlikely that they felt too pressured by the researcher to reveal this uncomfortable fact. Thus, we can safely conclude that they had a reason for disclosing the truth. They probably saw this study as an opportunity to provoke more debate on the subject, hopefully leading to an acknowledgement of the need for drugs such as misoprostol. Hence, they may have informally weighed for themselves the risks and benefits of disclosing this information and decided in favour of doing so.

On their part, it is necessary for researchers to report this fact in order to present a credible picture of post-abortion care. If the use of misoprostol is an integral part of the care management, then glossing over this aspect would be a distortion of facts.

The state itself is not a monolith, but a dynamic entity, balancing various political interests. From the information provided in the case study, we find that there is a space for advocacy and dialogue, no matter how contested, within which reproductive rights groups are operating. Interestingly, in this situation, it is quite possible that the state itself may be well inclined to receive information about the use of misoprostol.

Thus, the decision to report such a finding would have to be based on a careful assessment of the following aspects. How reliable and consistent is the information? Can it be adequately validated? How significant is this finding within the overall picture of post-abortion care? What are the potential risks of reporting information to both the medical practitioners and women? Can these risks be justified when weighed against the potential benefits of reporting the finding? In the event that the potential risks are considerable and so are the potential benefits, are there strategies available for mitigating the potential risk to participants? There could be different mechanisms identified for mitigating the risk even while adhering to the earlier decision of communicating findings to the health agency and the professional association, i.e., the OB/GYN society.

Ethics committees are expected to play the difficult role of, firstly, protecting the interests of the participants and secondly, balancing the interests of the various stakeholders. Their advice that the findings of the study be shared with the government health agency is based on the concern for making research

relevant to practice, which is well within the mandate of the ethics committee. However, if a post-facto assessment reveals that the study findings' potential for causing harm to participants is considerably higher than was anticipated, a re-evaluation of the ethics committee's decision is justified. In this case, it would be desirable for the research agency to engage in dialogue with the ethics committee to reconsider its decision based on the new facts which have come to light. Technically speaking, the decision of an ethics committee would be binding on the researchers if the specific laws of that country mandate it and the norms of the institution conducting the research. Moreover, the mechanism of ethics committee review is based on the principle of self-regulation, which would be seriously undermined if the ethics committee's decisions are summarily dismissed, as they are thought to be impractical or erroneous. The decisions of the ethics committee are, ideally, based on a process of review of existing guidelines, assessment of the facts of each case and a process of consensus building through debate and discussion among individuals having different perspectives and backgrounds. Thus, it acts as a safeguard against the domination of the interests of any one stakeholder or perspective. A process of dialogue with the ethics committee may enable the researchers to arrive at a more considered decision which would be in the best interests of the stakeholders concerned.

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