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The Moral and Legal Need to Disclose Despite a Certificate of Confidentiality

Erin Talati Paquette and

Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern University

Lainie Friedman Ross

MacLean Center for Clinical Medical Ethics, University of Chicago

This case raises four central questions: (1) Is there a duty to disclose? (2) What protection does the Certificate of Confidentiality (COC) provide? (3) What, if anything, could have been done to avoid this situation? and (4) What are the next steps? In answering these questions, we must consider the ethical and legal obligations of researchers and institutional review boards (IRBs) with research involving children.

IS THERE A DUTY TO DISCLOSE?

Is there a legal duty to report this case of statutory rape? Generally, state laws regarding mandated reporters encompass four types of reporters: (1) broad mandates to general citizens aware of any child abuse or neglect; (2) mandates to narrower groups of individuals who in the course of their professional activities suspect child abuse or neglect; (3) mandates to those who come into contact with children through their employment; and (4) mandates to specifically identified types of reporters, which may or may not include psychosocial researchers (Liss 1994). The first three types of laws require that researchers who learn of potential child abuse report it to the proper authorities. Even for states with a narrower list of mandated reporters, it is likely that at least one member of a research team would be included. If any member of the research team is a mandated reporter, arguably the entire team should be held to this standard.

Irrespective of legal obligations to report, researchers have ethical obligations to preserve the well-being of children they enroll, even if it adversely affects their research. Known as either the “jeopardy principle” (Society for Research in Child Development 2013 and Scott-Jones 1994) or “scientist-citizen dilemma” (Veatch 1987 and Fisher 1994), there is broad ethical consensus to prioritize the well-being of children over the production of generalizable knowledge. Some researchers object to this requirement, arguing that (1) generalizable knowledge is important; (2) reporting of uncertain abuse may disproportionately place scrutiny on low-income families who may be overrepresented in studies of risky behaviors; and (3) some team members lack adequate training to detect abuse, although their reports will be taken quite seriously (Scott-Jones 1994 and Fisher et al. 1996). Like all mandatory reporters, researchers should be thoughtful regarding decisions to

report. When *uncertain*, state laws mandating reports of abuse and neglect encourage good faith reports. In this case, the team learned that a child enrolled in their study had experienced *certain* statutorily defined sexual abuse based on the age difference between the adolescent mother and the father, such that they are legally obligated to report (Fisher 1994). Even if the adolescent denied abuse, the ethical obligation to report still exists because the obligation to protect a child does not depend on the child's ability to recognize the harm. Therefore, the researchers are obligated both ethically and legally to disclose the abuse they discovered.

WHAT PROTECTION DOES THE CERTIFICATE OF CONFIDENTIALITY PROVIDE?

An unanswered question is whether procuring a COC abdicates the legal responsibility of researchers to report. The Public Health Service Act protects the privacy of research subjects by "withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals" (42 USC §241 (d)). COCs, issued under the Act, restrict "compelled disclosure of identifying information about subjects enrolled in sensitive...research" (Office for Human Research Protections). COCs are obtained for a broad array of research (Lutz et al. 2000; Coffey and Ross 2004; Earley and Strong 1995) where researchers show that the risk of loss of confidentiality would be damaging to individual subjects (Carney et al. 2000). Some have argued that COCs exempt researchers from compelled disclosure of all confidential information learned in the course of research (Liss 1994).

There is ongoing confusion over whether COCs afford absolute protection against certain disclosures, including child abuse and neglect. Study investigators, research subjects, IRBs, and legal counsel differ in their knowledge level and familiarity with COCs (Coffey and Ross 2004; Catania et al. 2007; Beskow 2012; Wolf et al. 2012). In part, differences arise because only one court has spoken directly to the issue of the Certificate's validity, upholding the COC, and promoting a widespread belief of absolute protection of confidentiality under COCs (Beskow, Dame, and Costello 2008).

Guidance documents issued by the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP) indicate limits on the Certificate's scope. The NIH advises that "personally identifiable information protected by a Certificate may be disclosed under the following circumstances, [including] voluntary disclosure...on such things as child abuse..." The NIH asserts only that COCs issued for communicable diseases *must* provide assurance "that reporting requirements for communicable diseases will be met," remaining silent about child abuse (U.S. Department of Health and Human Services; NIH Office of Extramural Research). Some have interpreted this silence to mean that the investigator is released from other reporting requirements (Earley and Strong 1995). OHRP, on the other hand, clarifies that "Certificates of Confidentiality protect subjects from compelled disclosure of identifying information, but do not prevent...voluntarily disclosing certain information about research subjects, such as evidence of child abuse" (Office for Human Research Protections 2003).

WHAT, IF ANYTHING, COULD HAVE BEEN DONE TO AVOID THIS SITUATION?

In planning studies where investigators can anticipate a possible need for these types of disclosures, federal regulations and NIH guidance on COCs insist that informed consent documents outline limits to confidentiality (U.S. Department of Health and Human Services; NIH Office of Extramural Research). Prior to requesting a COC, researchers must obtain IRB approval (Carney et al. 2000). IRBs can require revisions if appropriate risks and disclosure limits are not enumerated, including the risk of abuse and neglect. Then, when the Certificate is obtained, limits on confidentiality have already been identified.

Data show that adolescent girls are more likely to get pregnant when they have older sexual partners (Lindberg et al. 1997). Five to 10 percent of all sexually active and pregnant adolescent girls have partners who are more than 5 years older (Lindberg et al. 1997; Darroch, Landry, and Oslak 1999). As such, (1) the consent forms should have incorporated the risk of identifying statutory rape; and (2) the study protocol should have included how to address such findings. This would have allowed the adolescent to decline participation. Investigators may object that placing such limits on confidentiality may bias and reduce enrollment. As discussed above, this scientist-citizen dilemma should always be resolved in the direction of protecting a child at risk (Fisher 1994).

Given that the risks were not anticipated, the researchers were correct to seek institutional legal advice and then to ask their IRB how to proceed. As mandated reporters, the COC does not legally prevent them from voluntary compliance with mandated reporter statutes. Morally, the investigators have an obligation to seek assistance for a minor who may be at ongoing risk for abuse. Investigators who discover possible abuse or neglect that is not as clear-cut as in this case, however, may turn to their IRB or legal counsel to provide guidance prior to making a voluntary disclosure.

NEXT STEPS

The IRB should work with the investigator to amend the protocol and consent documents in case future situations necessitate disclosures. Those involved in consenting subjects must be trained to discuss the protections of confidentiality and the limits of confidentiality including the reporting of child abuse and neglect. Investigators will also need to work with an NIH Certificate Coordinator to amend their Certificate, as a change in the limits of confidentiality to consent forms likely would constitute a “significant” change, requiring an amended application for a Certificate (U.S. Department of Health and Human Services; NIH Office of Extramural Research).

Moving forward, the most useful intervention to provide the broadest safety net for children would be for the NIH to publish definitive guidance on the expectation of researchers to meet mandatory reporting laws about child abuse and neglect—even when a COC is procured—to eliminate concerns about liability for voluntary disclosure of identifying information in these circumstances (Earley and Strong 1995). Still, most would agree that the Certificate, which is meant to prevent *compelled* disclosures from investigators, does not

prevent *voluntary* disclosures from researchers regarding abuse and neglect (Coffey and Ross 2004).

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