CONFIDENTIALITY, FIDELITY, AND RESEARCH ETHICS

Bioethics: Course Notes | Brendan.Shea@rctc.edu

Learning Outcomes. In this lesson, you'll learn to:

1. Define confidentiality, and discuss the factors that might permit or require on to breach it.
2. Analyze the relationship between clinical and research ethics.
3. Explain the debate around "clinical equipoise" and the ethics of Randomized Control Trials (RCTs)

What is confidentiality? According to B-C, **confidentiality** is present "when one person discloses information to another, whether through words or other means, and the person to whom this information is disclosed pledges, implicitly or explicitly, not to divulge this information to a third party without the confider's permission."

Why does confidentiality matter? One reason for respecting confidentiality concerns the *consequences* of not doing so. For example, suppose that therapists began turning their patients over to the police every time they suspected they may harm themselves, or that physicians immediately informed every past sexual partner of patients with HIV. This may (eventually) lead to a situation in which patients with these conditions do not seek help at all. A second reason for respecting confidentiality concerns the principle of autonomy—one ought to respect the rights of competent adults to "live their own lives."

When can confidentiality be breached? B-C argued that this is a function of two things: (1) the *probability* that you could prevent harm by breaching confidentiality and (2) the *magnitude* of the harm that could be prevented. This leads to something like the following setup:

Prob. of Harm	Mag. of Harm	Examples?	Breach confidentiality?
High	Major	1.Highly infectious, deadly disease (pandemic influenza, drug-resistant TB, HIV patients with known risky behaviors) 2. Intent to murder someone	Usually yes (to authorities or third parties as allowed by law)
High	Minor	Infectious disease, treatable (gonorrhea, influenza)	Depends on policies
Low	Major	Predisposition toward violence (e.g., certain sorts of mental health disorders or drug use)	Depends on policies
Low	Minor	Behaviors that could possibly harm others (alcoholism, risky sexual behavior)	Usually not

WHAT IS THE NATURE AND PLACE OF FIDELITY AND FAITHFULNESS?

Medical professionals have obligations of **fidelity** (or "faithfulness") toward their patients. In some cases, these can come in conflict both with self-interest and other moral obligations[1]. Some example cases:

- **Divided loyalties.** Health care professionals are often employed by the military or by private corporations, and many researchers are employed by academic institutions. These employers often have aims distinct from patient welfare, and professionals must consider carefully how to respect the moral rights of the patient. This can sometimes lead to moral dilemmas (e.g., the case of a military physician who must consider whether to discharge a patient with a head wound).
- **Nurses, patients, and physicians.** Nurses are often in closer contact with patients than are physicians, and are thus more likely to realize if a treatment is not working. This can lead to situations in which the nurses must balance their obligations to the patient vs. their obligations to "carry out the treatment as directed by the physician." Studies have repeatedly shown that physicians *vastly* underestimate how frequent these sorts of ethical problems occur.
- **Conflicts of interest.** A **conflict of interest** exists when "an impartial observer would determine that a professional's judgments, decisions, or actions are at risk of being unduly influenced by his or her personal interests, such as financial interests or friendship." This can lead to cases of **overtreatment** (a physician orders a test or procedure because he stands to profit from it) or **undertreatment** (a physician declines to tell a patient about a costly treatment because she receives bonuses for "keeping clinic expenditures low"). Research has also shown that medical staff are often (probably unconsciously) influenced by things such as small gifts/meals from pharmaceutical and medical equipment companies.
- **Funding of research.** A significant portion of medical research is funded by companies that are interested in getting a certain outcome (e.g., getting a drug approved) and researchers sometimes have a financial stake in the outcome (e.g., they work for the company, or own stock). In general, researchers should NOT participate in studies involving human subjects if they have a financial stake in the outcome.
- **Actual, potential, apparent?** B-C argue that ALL appearances of partiality are to be avoided, and that there is little sense in trying to determine whether a *particular* researcher is capable of "being objective" in a certain situation. This is because (1) bias is often

[1] For a highly interest story about the potential conflicts of interest in pharma-funded clinical trials (and the very bad results they can lead to), see Carl Elliott, "The Deadly Corruption of Clinical Trials. One Patient's Tragic, and Telling, Story.," *Mother Jones* (blog), 2015, https://www.motherjones.com/environment/2010/09/dan-markingson-drug-trial-astrazeneca/. This case happened in Minnesota, and had has significant impacts on the University of Minnesota in the past decade (both on the medical and academic sides).

unconscious and unintentional, and (2) the only good way of preventing bias from occurring is through institutional policies, and not by considering the "character" of individual people.

IS THERE A DISTINCTION BETWEEN CLINICAL AND RESEARCH ETHICS?

Historically, many writers have argued that there is distinction between **clinical ethics** (the professional ethics relevant to medical staff concerned with the care of patients) and **research ethics**[2] (the professional ethics relevant to biological and medical research staff). B-C argue that there is no reason to make this distinction, as clinical staff increasingly face many of the same problems as research staff:

- **When is research on human subjects justified?** B-C argue that any research on human subjects must have (1) a goal of valuable knowledge, (2) a reasonable chance of actually leading to this knowledge, (3) a need to use human subjects, (4) a proportional benefit (to the future patients who will someday benefit from the research) to risks (to the subjects participating in the study), (5) fair selection of subjects, and (6) good protection of subjects' privacy and confidentiality. Only AFTER these requirements are met should researchers (7) ask subjects for their informed consent.
- **How can medical professionals minimize the "therapeutic misconception"?** The **therapeutic misconception** occurs when patients believe that participating in a research trial is likely to benefit *them,* when it is much more likely to benefit patients in the *future*. This false belief can sometimes lead patients to take unwarranted risks.
- **How can randomized control trials respect patients' best interests?** Most medical research involves **randomized control trials (RCTs)** in which subjects are randomly assigned to (1) an **experimental** group that receives the treatment being tested or (2) a **control** group that does NOT receive this treatment (but instead receive a **placebo**, an **active control** using an alternate treatment, or no treatment).
- **When should patients be withdrawn from RCTs?** During the course of an RCT, evidence may start to accumulate that (1) the new treatment is much more effective than the control or (2) the new treatment is much less effective than the control. This means that researchers are no longer in a state of clinical equipoise, and must seriously consider moving *all* the subjects to the more effective treatment (though this must be balanced against the benefits of finishing the RCT).

DOES CLINICAL EQUIPOISE MAKE SENSE?

Some medical ethicists hold that RCTs are appropriate only when researchers are in a state of **clinical equipoise,** which occurs when there is no reason to think that patients will be "better off" in either the control group or the experimental group. Other ethicists think this is a bad principle For example, suppose drug A is known to cure about 40% of patients with disease D. Drug B has been tested in rats, and it cured around 50% of rats. While there is no guarantee it would have similar effects on humans, there is no particular reason to think that it wouldn't.

- Proponents of clinical equipoise would approve of testing drug D, *so long as the control group received drug A and NOT a placebo.* Why? Proponents of this view hold that giving patients a placebo would be immoral, when we know that there is an effective treatment. Placebos should be used only when there is genuine ignorance about how to treat the disease at all.
- Critics of clinical equipoise would also approve of the trial, although they would probably favor a placebo-controlled trial, since these are often more effective than are active control trials—that is, they make it much easier to tell whether the drug is working and thus, whether it would be worthwhile to start using it for treatment. Active controls may lead to a *good* drug being rejected.
- B-C adopt a moderate position: Placebo-control trials should be used only when necessary, and subjects must be informed of why and how the placebos are being used (even though they won't know if they themselves will receive placebos). For example, they hold it would be wrong to give cancer patients "placebo" anti-nausea drugs, as has happened in the past.

Proponents and critics of clinical equipoise also disagree about what to do if a new drug seems to be *working* (for example, suppose that 18 out of the first 20 patients treated with drug B survive). Proponents of clinical equipoise would generally support making the drug more widely available (and perhaps ending the trial early, in order to put *everyone* on the drug). Again, the critics would emphasize that this would make it much more difficult to figure out how well the drug actually worked[3].

REVIEW QUESTIONS

1. Explain B-C's analysis of confidentiality, and when to respect/break it. Do you agree with this analysis? Why or why not?
2. What is the duty of fidelity as it relates to medical professionals and their patients? Give two examples of ways that might be violated.
3. What is a randomized control trial? Give an example of a situation in which an RCT ought to be stopped, or patients ought to be withdrawn.
4. In your own words, explain the idea of clinical equipoise. Now, give an example of an experiment which would violate it.

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[2] See the SEP article on clinical research ethics: David Wendler, "The Ethics of Clinical Research," in *The Stanford Encyclopedia of Philosophy*, ed. Edward N. Zalta, Winter 2017, 2017, https://plato.stanford.edu/archives/win2017/entries/clinical-research/.

[3] For a recent (and influential) critique of clinical equipoise, see Franklin G. Miller and Steven Joffe, "Equipoise and the Dilemma of Randomized Clinical Trials," *New England Journal of Medicine* 364, no. 5 (February 3, 2011): 476–80, https://doi.org/10.1056/NEJMsb1011301.

BIOETHICS AND THE LAW: TARASOFF V. CALIFORNIA BOARD OF REGENTS[4]

On October 27, 1969, Prosenjit Poddar killed Tatiana Tarasoff. Plaintiffs, Tatiana's parents, allege that two months earlier Poddar confided his intention to kill Tatiana to Dr. Lawrence Moore, a psychologist employed by the Cowell Memorial Hospital at the University of California at Berkeley. They allege that on Moore's request, the campus police briefly detained Poddar, but released him when he appeared rational. They further claim that Dr. Harvey Powelson, Moore's superior, then directed that no further action be taken to detain Poddar. No one warned plaintiffs of Tatiana's peril...

We shall explain that defendant therapists cannot escape liability merely because Tatiana herself was not their patient. (1) When a therapist determines, or pursuant to the standards of his profession should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to protect the intended victim against such danger. The discharge of this duty may require the therapist to take one or more of various steps, depending upon the nature of the case. Thus it may call for him to warn the intended victim or others likely to apprise the victim of the danger, to notify the police, or to take whatever other steps are reasonably necessary under the circumstances.

In the case at bar, plaintiffs admit that defendant therapists notified the police, but argue on appeal that the therapists failed to exercise reasonable care to protect Tatiana in that they did not confine Poddar and did not warn Tatiana or others likely to apprise her of the danger. Defendant therapists, however, are public employees. Consequently, to the extent that plaintiffs seek to predicate liability upon the therapists' failure to bring about Poddar's confinement, the therapists can claim immunity under Government Code section 856. No specific statutory provision, however, shields them from liability based upon failure to warn Tatiana or others likely to apprise her of the danger, and Government Code section 820.2 does not protect such failure as an exercise of discretion.

Plaintiffs, however, plead no relationship between Poddar and the police defendants which would impose upon them any duty to Tatiana, and plaintiffs suggest no other basis for such a duty. Plaintiffs have,therefore, failed to show that the trial court erred in sustaining the demurrer of the police defendants without leave to amend.

Plaintiffs therefore can amend their complaints to allege that, regardless of the therapists' unsuccessful attempt to confine Poddar, since they knew that Poddar was at large and dangerous, their failure to warn Tatiana or others likely to apprise her of the danger constituted a breach of the therapists' duty to exercise reasonable care to protect Tatiana.

In this case, Tatiana Tarasoff was murdered by Prosenit Poddar. Prosenit had previously told his therapist about his plan, and the therapist had told the police (who arrested and released him). The court ruled that the therapists and police could NOT be sued for releasing Poddar. However, they could BE held accountable for failing to warn Tatiana. Do you agree? Why or not?

BIOETHICS IN HISTORY: TUSKEGEE SYPHILIS STUDY[5]

"In 1932, the Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for blacks. It was called the "Tuskegee Study of Untreated Syphilis in the Negro Male."…The study initially involved 600 black men – 399 with syphilis, 201 who did not have the disease. The study was conducted without the benefit of patients' informed consent. Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. In exchange for taking part in the study, the men received free medical exams, free meals, and burial insurance. Although originally projected to last 6 months, the study actually went on for 40 years.

In July 1972, an Associated Press story about the Tuskegee Study caused a public outcry that led the Assistant Secretary for Health and Scientific Affairs to appoint an Ad Hoc Advisory Panel to review the study…The panel found that the men had agreed freely to be examined and treated. However, there was no evidence that researchers had informed them of the study or its real purpose. In fact, the men had been misled and had not been given all the facts required to provide informed consent…The men were never given adequate treatment for their disease. Even when penicillin became the drug of choice for syphilis in 1947, researchers did not offer it to the subjects. The advisory panel found nothing to show that subjects were ever given the choice of quitting the study, even when this new, highly effective treatment became widely used…The advisory panel concluded that the Tuskegee Study was "ethically unjustified"--the knowledge gained was sparse when compared with the risks the study posed for its subjects."

The response to this study marked the beginning of modern "research ethics," which emphasizes the importance of **voluntary informed consent** and regular oversight of research by **institutional review boards.**

Suppose contemporary researchers wanted to do a long-term study of drug-resistant syphilis in a similar community (generally poor, and with little knowledge about the relevant condition or its treatment). If you were on the institutional review board, what safeguards might you require before you let the study go ahead?

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[4] Tarasoff v. Regents of University of California, 551 P. 2d 334 (Supreme Court No. S.F. 23042).

[5] "Tuskegee Study and Health Benefit Program - CDC - NCHHSTP," October 3, 2018, https://www.cdc.gov/tuskegee/index.html.