The role of an ethics advisory board in self-regulation

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Recent allegations of misconduct involving a California assisted reproduction clinic transferring embryos from unconsenting donors into recipients oblivious of the source, resulting in the birth of several babies, have initiated a growing national concern that there is insufficient ethical supervision in reproductive medicine. The nation was appalled, practitioners felt betrayed and patients expressed concern. A basic trust was violated. That this could happen became an unsettling worry leading several organizations and vocal individuals to call for more regulation at the state or federal level similar to the British Human Fertilisation and Embryology Authority (HFEA).

While ethical guidance is imperative for assisted reproductive technology, it is my belief that cumbersome state and federal bureaucracies are an inappropriate means to accomplish the desired objectives. What allegedly happened at the California clinic was wrong. If proven, it may well be judged a legal violation rather than an ethical oversight (Robertson, 1996).

At the Faulkner Centre for Reproductive Medicine (FCRM), a freestanding clinic on the hospital campus, we have taken a different approach for considering ethical concerns that has proven highly successful at a local level. When FCRM was established, I asked the hospital administration to create an ethics committee with our team whose mission it was to address the complex and ongoing issues faced in reproductive medicine (Mahowald, 1996). The intent was to emulate hospital ethics committees already in place and proven successful at a majority of institutions for patients who require chronic, acute or terminal care. The outcome was the creation of an interdisciplinary reproductive medicine ethics advisory board that includes the medical director, a geneticist, staff nurses, embryologists, psychiatrists, clergy, attorneys, a pediatrician, ethicists and a member of the hospital's general ethics committee to serve as a liaison with the hospital. The open communication prevents non-disclosure or even poor communication. Guests with specific areas of expertise are invited when needed. We specifically chose the forum of an ethics advisory board rather than a reproductive medicine institutional review board (IRB) to allow inclusion of all clergy. In contrast to an IRB which sanctions treatments or technology development with their benefits, risks and alternatives, an ethics advisory board provides case review, education and policy development. This distinction allows the clergy to provide their perspective without appearing to approve of in-vitro fertilization (IVF) and other techniques that are unacceptable to some religions.

The advisory board meets quarterly and discusses several cases or circumstances each meeting. Examples include donor selection criteria (i.e. family history, past medical/genetic history, motivation, etc.), age cut-offs for recipients, and selection criteria for gestational carriers. Other examples include policy and procedures to protect confidentiality, concerns surrounding informed consent and information for future disclosure. An IRB could not and would not serve this type of function. Notwithstanding, few would argue that an immense and important role exists for the IRB (Ellis, 1995).

Likewise, no amount of state or federal regulation of assisted reproduction can prevent the type of occurrence that allegedly happened in the California clinic any more than existing state or federal laws prevent them from being broken (Robertson, 1996). Stated another way, individuals cannot be regulated to be ethical any more than they can be regulated to be honest.

IRBs serve an exemplary role as a universal vehicle to develop technology. Furthermore, an immense amount of external regulation currently exists in the USA. IVF centres already respond to a federal mandate (Wydenc Act) to report their data (under the Centers for Disease Control) and IVF laboratories are coming under CLIA regulations. Physicians are board certified by the American Board of Obstetrics and Gynecology and an independent National Advisory Board on Ethics in Reproduction (NABER) is in place. The Federal Trade Commission oversees IVF advertising practices and the American Society for Reproductive Medicine (ASRM) has written ethical guidelines. Resolve monitors IVF centres for consumers and state and federal laws are in existence that regulate many aspects of reproductive medicine. A number of Federal laws pertain to reproduction including the US constitution which protects reproductive decisions under the right to privacy. In the case of Eisendstadt versus Baird, the court wrote 'if the right of privacy means anything it is the right of the individual, married or single, to be free of unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget.
a child'. The Federal Organ Transplant Act of 1986 defines 'human organ' in terms that allow ovum and sperm donation [U.S.C.A. #274(e)]. Additionally, numerous laws specifically address assisted reproduction.

A total of 34 states and the District of Columbia have statutes regarding therapeutic donor insemination (TDI), 10 states have laws mandating infertility insurance coverage. Informed consent, quality assurance and record keeping are required for all ART procedures. At least 25 states have laws specifically directed toward regulating fetal research, 15 states prohibit a woman from selling an embryo for experimentation and nine states prohibit women from donating an embryo or fetus for research purposes (Jaeger, 1996). Many more statutes currently exist. The disparity observed among these statutes reflects the heterogeneity of attitudes observed between different regions of the country and speaks to the complexities that federal regulations would create.

While most ethical principles are universal, their implementation is not. For instance, IVF is generally unacceptable in Ireland and surrogacy was only recently approved in Israel. Preimplantation genetic diagnosis is not considered ethical in Germany and all experimentation on embryos is forbidden in France (Lansac, 1996).

Because ethics are not inherent to individuals and technology is not static, in my opinion, what is needed is a viable educational instrument to review cases and to teach ethics locally, not a static list of state or federal regulations. To accomplish this, an ethics advisory board should be an integral part of every assisted reproduction programme. To paraphrase former United States Speaker of the House of Representatives Tip O’Neal, ethics, like politics, is local.

References

Received on April 11, 1996, accepted on May 30, 1996