Chapter 65
Ethical Implications of Incidental Findings in Pediatric Research

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ABSTRACT

This chapter reviews the literature and ethics of disclosure of incidental findings in pediatric research. A clear example of an incidental finding is an unexpected abnormal finding, such as a brain tumor, on a research neuroimaging scan of a volunteer. When the research participant is a child, the issue of what to disclose and who to disclose to becomes more complicated. Parents play an important decision-making role in the lives of their children, and in conjunction with researchers, decide the benefits and risks children are exposed to in research settings. The potential ethical concern is parents making decisions that counter the interests of the child and how to handle information obtained that is outside the anticipated research findings.

DECISION MAKING ROLE IN PEDIATRIC RESEARCH

To evaluate pediatric treatments for safety and effectiveness, sound research that involves pediatric subjects is important. The literature has raised questions about the appropriate role of parental and family interests in clinical decision making for children. The American Academy of Pediatrics, which maintains the position that children and adolescents should not be excluded from medical decision making without persuasive reasons, advocates participation of children in these decisions to the extent that their ability allows. The United Nations, in its Convention on the Rights of the Child, acknowledges the right of every child to self-determination, dignity, respect, noninterference, and the right to make informed decisions. These rights serve to recognize that physician's primary obligation is to the child, whose preferences and views are helpful to guide decisions (Harrison, Kenny, Sidarous, & Rowell, 1997). The rights also remind the medical profession to shape medical decisions towards the needs of the child. Involving

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children neither means excluding parents, but rather involving children at a level matching with their development, experience, and desire to participate, while upholding parents' responsibility.

When it comes to pediatric research, informed consent is essential to protect the rights of the patient. Regulations guiding research with children are outlined in Subpart D (Additional Protections for Children Involved as Subjects in Research) of the Common Rule (Protection of Human Subjects, 45 CFR 46). The majority of pediatric centered research requires permission from one parent and conditions for obtaining child assent. These requirements are of greatest significance when the research may involve (a) greater than minimal risk but presenting the prospect of direct benefit to individual subjects, or (b) a minor increase over minimal risk and no prospect of direct benefit than other considerations take place.

Pediatric assent is defined at an affirmative agreement to participate, not merely the child's failure to dissent. Federal guidelines do not specify age limits, but it is generally agreed that efforts to involve children in health-related decision making should begin around age seven (Ross, 2006); assent or dissent should be given more serious consideration as the child enters adolescence. Ethically, health care professionals are obligated to involve mature minors in decision making in so far as they are able.

A mature minor is a person under 18 who has the capacity to make informed health care decisions – based on a clinical assessment of the person's emotional maturity, age, experience, intelligence, and the decision to be made. Generally in the law there is a concept known as the "Rule of 7's" that interprets the general maturity of children. Under the age of 7 it is assumed that children are not mature. For ages 7-14 it is assumed that children are not mature, but depending on the circumstances, they can demonstrate maturity to make a decision regarding their health. Over the age of 14 it is assumed that children are mature, but they can also demonstrate to lack maturity depending on the circumstances. Overall, pediatric researchers cannot judge an adolescent strictly on age – a clinical assessment of other factors is always necessary.

What is the justification for also requiring parental permission when the child reaches the age of assent or consent? The ethical justification for requiring parental permission for children's research participation is fixed on the idea of respect for parental decision-making authority. In the ideal situation, guardians know their children best and care for their welfare so parental decisions can be assumed to promote children's best interests. The boundaries of the patient-physician relationship are hard to define in pediatric research because of the sometimes necessary involvement of the child's surrogate decision maker usually, the parent. The triadic relationship (Wilfond & Carpenter, 2008), patient-parent-physician, adds a layer of complexity because it often means considering both the child's interests and possibly what the parents see as the family's or their best interests.

In a hypothetical example, a 13 year old asthma patient may agree to take part in a study that requires him to fill out a survey related to his symptoms weekly for a year. The research incentive is 60 dollars at the completion of the study. The 13 year old patient is excited about the possibility of 60 dollars and may assent to participate in the research study, but the parents may disagree on the grounds that they perceive involvement in the study it will take away time from other extracurricular activities and not benefit the patients direct health.

ETHICAL ISSUES IN PEDIATRIC RESEARCH

The Hippocratic Oath is an oath traditionally taken by graduating physicians and other healthcare professionals swearing to practice medicine honestly. In its original form, practitioners are asked to vow they