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A duty to participate in research

Electronic health records

Patients' health records have been recently digitized. It entails that a researcher has an easy access to large health database that contains valuable information. In a health care system with universal health coverage what should be the right policy: 1. Should patients have an moral obligation to give access to their anonymized healthcare records? Should the system incentivize opt-in or disincentive (or even punish) opt-out?

It does not hurt

"Jimmy, a bright, energetic, and confident 8-year-old, suffered from a serious inborn immune deficiency characterized by a disorder in white cell function. Jimmy spent a significant percentage of his life in the hospital, fighting off obscure infections. Given the rarity of his disease, Jimmy also spent a good deal of time enrolled in clinical research aimed at understanding his condition and immune function in general. In the spring of 1999, investigators developed a protocol to obtain white cells from individuals with Jimmy's disease. The investigators believed that studying the cells in the laboratory might provide information about the specific white cell deficiency that characterizes the disease and, perhaps, might yield important insights into immune function in general. Several factors made Jimmy an especially good candidate for the procedure. He had undergone similar procedures in the past and had never experienced any ill effects. In addition, Jimmy had a rare genetic variant of the disease that was little understood." The study is thought to be within the limits of minimal risk. Should this kind of study be obligatory? If this study is obligatory, what it would mean for Jimmy's parents and Jimmy himself?

(source: D. Wendler, The Assent Requirement in Pediatric Research, (in:) The Oxford Textbook of Clinical Research Ethics, E. J. Emanuel, C. Grady, R A. Crouch, R. K. Lie, F. G. Miller, D. Wendler (eds.), Oxford 2008, p. 661-669.)

Provider's consent

Embedded research in learning healthcare systems (LHS) requires from an individual or institutional providers releasing sensitive information concerning patients and provider itself. An individual healthcare provider might be forced to release sensitive information pertaining to quality of his/her professional judgement (accuracy of diagnosis), drugs prescribing patterns, ethical choices (end-of-life decisions, rationing of healthcare, invoking conscience clause). An institutional and an individual provider might be forced to reveal business information, concerning actual costs of treatment, a chain of supply, contractors, employment patterns. Moreover because data analysis is a complex undertaking there is also reputational risk for both individual and institutional providers. An individual or an institution can be unjustly labeled as ineffective or bad. As long as participation in LHS is voluntary for institutions all these risks could justify abstaining from participation in LHS or at least abstaining from certain aspects of learning activities. But is individual and institutional reservation justified?

Prescribed vs. invited clinical trials

Emily A. Largent et al. proposes a system of ethically integrated care and research. She suggests that a patient within a learning healthcare system can be obliged to take part in some kind of research, although not all research projects would be obligatory. She distinguishes between "prescribed trials" and "invited trials". "Trials qualify for prescribed status if they are judged to be compatible with optimal medical care in light of current knowledge and if associated research procedures pose no more than minor net risks, compared with usual care. Minor net risks are analogous to the U.S. regulatory category of "minimal risk […]. Prescribed trials include randomized, controlled trials designed to answer clinically important questions regarding the relative merits of two or more medically indicated treatments, such as antibiotic drugs to treat meningitis or packages of treatment interventions to treat low back pain. […] Patients can refuse trial participation, just as they can refuse conventional medical treatment; however, if a prescribed trial is enrolling patients and a given patient meets eligibility criteria but refuses enrollment, treatment outside the trial is reimbursed but with a substantially higher copayment."

"A second kind of trial is the "invited" trial. Invited trials include those for which there is greater uncertainty about risks and benefits of treatments under investigation, as well as those that involve more than minor net risks to participants from research interventions that are uncompensated by a prospect of direct benefit. Trials comparing two medically indicated treatments that differ substantially in invasiveness, burden, or type of side effects and many randomized, controlled trials of investigational or off-label agents or procedures are also included in the invited category. New treatments may be offered provisionally through invited trials while the Research Integrated Health System (RIHS) collects additional information on safety and efficacy to determine if the treatment will eventually be incorporated into the member benefits package. Conventional, research-specific informed consent is obtained for invited trials, and patients are free to decline participation without penalty and to receive standard, validated treatment (if available) as a reimbursed alternative. RIHS physicians, however, must discuss the availability of invited clinical trials with eligible patients and encourage them to participate."

Examples:

Prescribed trials

"Mrs. Jonsen visits her primary care provider, Dr. Chen, because she has a chronic cough. A chest x-ray confirms that she has pneumonia and requires antibiotics. Dr. Chen tells Mrs. Jonsen that the RIHS is currently conducting a clinical trial comparing two Food and Drug Administration-approved antibiotics to see which is more effective in treating pneumonia. The trial is not blinded, but it is randomized. Therefore, Dr. Chen calls the pharmacy, and the research pharmacist tells Dr. Chen which of the two antibiotics to prescribe for Mrs. Jonsen. Mrs. Jonsen is informed about the benefits and risks of the selected treatment in the informal manner of routine drug prescription."

"Billy and his mother go to Dr. Balch, Billy's pediatrician, to have Billy vaccinated for seasonal flu. Dr. Balch informs Billy and his mother that RIHS is conducting a trial to compare the effectiveness of an inhaled form of the flu vaccine to a traditional injection in children. Dr. Balch tells Billy's mother that randomization has occurred at the physician level and that all of the patients in his practice are receiving the flu shot. Billy receives the shot. All materials are prepared and edited by course leaders. All sources of the cases are listed, where there is not quotation, the leaders are the authors. The materials can be use freely for educational purposes. In case of any other commercial or public use a permission of author must be sought."

Invited trials

"Dr. Tate, a retired rheumatologist, has been suffering from osteoarthritis for several years. He has now made an appointment with Dr. Smith to determine if he would benefit from knee surgery. Dr. Smith invites Dr. Tate to participate in a trial comparing outcomes from a widely used but never validated knee surgery to a sham surgery intervention. Dr. Tate, appreciating the need for rigorous evaluation of the surgical procedure and the modest risk of the sham surgical intervention, agrees after careful consideration to enroll in the trial."

"Mrs. Williams is pregnant with her first child. The baby has been diagnosed via sonogram with a heart defect requiring surgical correction. Dr. Reynolds, the obstetrician, invites Mrs. Williams to participate in an RIHS study examining health outcomes after in utero heart surgery. Dr. Williams assures Mrs. Williams that her child can have reimbursed open-heart surgery after birth regardless of whether she participates in the trial. Mrs. Williams asks for more time to discuss the trial with her husband."

(Source: Largent EA, Joffe S, Miller FG. Can research and care be ethically integrated?. Hastings Center Report. 2011 Jul 8;41(4):37-46.)