

The Implications for Health Care: Learning from What Is and Shaping What Will Be

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What can we learn from past large scale health care projects?

- **From “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research**
- “On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.”
- “Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments.”
- “Questions of justice ... are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.”
- **All the way up to the Hwang Woo Suk affair...**

How do we know when it's appropriate to conduct clinical trials?

- **Not too early:**
- Not until we have in place procedures for the selection of subjects, including those that are demanded by autonomy, beneficence, and justice: “One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.” Belmont Report
- Not until our best scientists have a public consultation process where scientific fears are aired and debated (e.g. problems that have arisen with gene therapy trials)
- **But also, not too late:**
- Should by-pass animal trials where the animal disease model is not good
- Should fast track FDA and other approvals, subject to strict oversight and monitoring of clinical trials and justice concerns
- Should perhaps facilitate patient's ability to opt into clinical trials in cases of end of life altruism, but even sooner?

Can the ultimate cures and benefits be equitably distributed?

- **Special obligation** of “direct democracy” bond issues to have their burdens and benefits equitably distributed among all members of the community
- According to the third Belmont Report bioethical principle of justice, “whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research”, and suggests
- CIRM IP guidelines impressive start on royalty streams, licensing agreements, and pricing
- CIRM is intent on awarding grant monies equitably, emphasizing importance of training and giving grants to underrepresented minority and women students and scientists; could also explicitly target research institutions that employ and train disproportionate numbers of non-traditional students, if there was a way to incorporate this in grants criteria
- But major problems of equitable distribution remain for the future, many of which have to do with access and affordability (next slide)

What are the implications for affordability of and access to potential cures?

- Treatments likely to be extremely expensive, so keeping costs down relative notion for poor: offering treatments as “cheapest available” is far from “**available to all**” (c.f. generics in the worldwide fight against AIDS and other infectious diseases).
- For middle class, **insurance coverage**: Mandate to offer / cover? Experimental? Self-insured and small businesses?
- **Cost-benefit analysis** with competing non-stem cell therapies; by whom and how calculated and applied?
- Need to make sure that **access to clinical trials and to approved treatments** is no more or less easy for any one group of people than any other
- **Tissue match issues**: if primarily using stem cell lines from tissue banks, rather than genetically matched SCNT (as is likely in the short term), then need to be sure that the likelihood of a good tissue match is the same for all. Do demographic and socioeconomic factors correlate with the likelihood of a match, and if so, how to make sure that all groups are represented in stem cell banks? Necessary to recruit from minority populations for egg donation? Special problems with this.

Which diseases should be tackled first?

- Major approaches:
- 1. **Scientific prospects**: diseases most amenable to stem cell treatment
- 2. **Severity**: diseases with fastest ticking clock and worst symptoms
- 3. **Economic**: diseases where the expenditure / cure ratio is best
- 4. **Single path**: diseases lacking other treatments, regardless of severity
- 5. **Incidence**: diseases that afflict most Californians
- 6. **Public health**: diseases that disproportionately effect sectors of population that are least likely to be able to afford products of private sector R&D
- 7. **Organic**: building from existing interest in particular research questions and researcher expertise without regard to above criteria
- 8. **Activist driven**: diseases with the best organized activist community
- Without conversation, risk having no direction. Inter-campus and research institution competition in grants getting makes collaboration around optimal approach unlikely
- Object of this panel: to start these conversations with the public?