This is Part II of a three part series on ethics and HD research.

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Part II- Respect, Beneficence and Justice

Ethics and Research on Huntington’s Disease

Respect for individuals involved in research may also mean that new information gathered in the course of research should be distributed to the participants. This requirement is not written into the regulations, but may be required by thoughtful reflection on what respect for persons means to subjects. For example, should a new procedure be found to be far superior to the old procedure the benefit of the new procedure should be disclosed to everyone affected. This attention to the perspective of the participant may be required by the ethical principle of either respect for persons or beneficence. Treating participants as an end in themselves and not only as a means to the research goal requires ongoing communication with subjects of research.

What about Beneficence?

Beneficence, which means to do good, requires ongoing attention to the experience of subjects. While informed consent is the most commonly known ethical requirement of research, it is not sufficient as a base for a full ethical analysis of research. The principle of beneficence first requires the research have a favorable risk to benefit ratio. In other words, if the potential for harm is large but the potential knowledge to be gained from the research is small, it would be unethical to conduct the research. Second, if research may be carried out under some conditions which would minimize the risk to subjects without impairing the scientific value of the research, the less risky alternative should be used. Finally, the principle of beneficence requires the potential benefits to individual subjects are maximized.

Clinical research seeks to answer questions about which we need new knowledge. Sometimes we find out that there are important but unanticipated risks involved in research. The principle of beneficence requires researchers as well as participants to be alert to unanticipated adverse events. There is no settled way of deciding how one set of benefits weighs against a distinct set of risks. This is especially true where the benefits may accrue to society in general or future sufferers of the disease rather than the current participants in research. Until we can identify the harms experienced by participants in current research we cannot assess the possible risks these individuals face.

What Does Justice Have to do with Huntington’s Disease?

Justice, the third principle outlined in the Belmont Report, requires fair selection of subjects. In the past some groups have been selected for inclusion in research because they were vulnerable or convenient. In 1997 President Clinton apologized to the survivors and families of subjects in the Tuskegee Syphilis Study for the acts done by the United States government to black men in Macon County, Alabama from the 1930’s through 1972. These men, living in rural Alabama, were chosen because of their race, their remote location and their lack of independent financial sources. They were denied treatment for syphilis even after effective treatment became available. It is in remembering such tragedies that we are reminded that we violate our own humanity when we allow such acts to be done to anyone among us. Only when we remember such events can we move forward with renewed attention to the selection only of those persons who fit with the social needs of convenience. Justice requires not only that researchers recruit subjects fairly across all social spectra, but that geographically we allow a wide range of individuals to participate. An analysis of justice requires that we consider both the risks to potential subjects and the benefits of participation in research. In some instances we categorically disallow certain risks from being born by vulnerable persons such as children or mentally incompetent persons. In other instances our attention needs to be focused on the potential for inclusion among a community of

(Con’t page 2)
individuals involved in research. Such participation may allow for greater educational opportunities or for access to the newest treatments. The issues to be examined include demographic factors (are we excluding women for no good reason), racial, economic, and other social issues as well as the allocation of burdens and benefits. As with the other principles, justice requires us to be reflective and thoughtful, and always consider the perspective of participants.

Next issue
Part III- Concluding thoughts

The Many Hats of Jane Paulsen

Many in the HD community know Dr. Jane Paulsen as the Co-Director of the HDSA Center of Excellence at the University of Iowa. But Jane Paulsen wears many hats and has projects that influence people and policy at the local, state, national and international level.

Within the University community, Dr. Paulsen directs the Division of Psychology in the Department of Psychiatry and chairs neuropsychology training in the Department of Psychiatry. She lectures to psychiatry residents and neuroscience graduate students. Jane supervises psychology graduates students on thesis and dissertation projects.

On the local state level, she is an active member of the Iowa Elder Affairs committee.

Nationally, Dr. Paulsen is known as an engaging speaker to HDSA state conferences. She is an editorial board member on five national journals and a reviewer on 17 other journals that cross disciplines from psychology to neurology to neuroscience. Jane sits on numerous committees often holding officer status.

Dr. Paulsen’s publication list includes over 70 articles and 75 abstracts. She is the author of 6 books and 10 book chapters.

Jane’s current research projects are generously funded by the National Institute of Neurologic Disorders and Strokes and the National Institute of Human Genome Research. This includes the PREDICT study that looks at neurobiologic predictors of HD and is being carried out at 21 sites in the US and 3 sites in Canada and Australia. The ELSI study of ethical, legal and social issues in genetic disease will look at the testing process in pre-symptomatic Huntington’s patients. Dr. Paulsen is also interested in using brain imaging techniques (like MRI) to identify early predictors of HD.

The University of Iowa is very fortunate to have such a talented person in their midst and the HD community benefits from her knowledge and creative thinking.

Mark your calendar for the HDSA National Conference June 11-13, 2004
The Adams Mark Hotel
St Louis, Missouri

Iowa HDSA conference
July 17, 2004
9am-3pm
Airport Holiday Inn
Des Moines, IA

HDSA Support Groups:
Des Moines
Iowa Lutheran Hospital
University Ave at Pennsylvania
4th Friday at 7:30 pm

Stuart
St John’s Catholic Church
4th Monday at 7 pm
For info, call Diana (712) 523-2885

Support Group Schedule
Iowa City
University of Iowa Hospitals and Clinics
Note New location
Della Ruppert Conference Room
6th floor Colloton Pavilion elevator H
6612 JCP
Time
1:00-3:00 pm
snacks provided

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 25</td>
<td>Wellness Strategies, Small group discussions</td>
</tr>
<tr>
<td>May 23</td>
<td>Video, Small group discussions</td>
</tr>
<tr>
<td>June 27</td>
<td>Update on National Convention</td>
</tr>
</tbody>
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Current Research Projects and Trials at the University of Iowa

In the fight to understand Huntington’s Disease (HD), scientists use many different types of research. The first phase is basic research which explores the ways that cells and chemicals interact in order to see how things work. The second phase is clinical research which takes basic research data and determines how it can be applied to treat or cure a medical problem in humans. Observational trials can be an important precursor to therapy trials. These studies attempt to document the symptoms and progression of a disease or condition to later judge the effectiveness of a particular drug or treatment. By volunteering to be a part of clinical research, you play a vital role in advancing scientific understanding.

**PREDICT-HD**

This trial will help to define the earliest changes in HD. Individuals who have been genetically tested, are pre-symptomatic and 26 years of age or older are encouraged to enroll.

**fMRI**

Functional Magnetic Resonance Imaging (fMRI) scanning is used to produce pictures of brain activity. Individuals who have been genetically tested, are pre-symptomatic and 18 years of age or older are continually being recruited for this 3-4 hour study, taking place in Milwaukee, Wisconsin.

**PET**

A type of brain scan, Positron Emission Topography, is being used to examine the activity of the brain in persons at risk for HD. Individuals who have been genetically tested, are pre-symptomatic for HD and 18 years of age or older are eligible.

**MRI**

Participants receive a magnetic resonance imaging (MRI) scan, which produces a picture of brain structure in HD. This will provide useful information about the disease process in HD. Individuals who are gene positive for HD are eligible to participate.

**PHEND-HD**

Stay tuned for more information on the Phenylbutyrate Development for Huntington’s Disease study. A clinical trial testing the safety, tolerability and clinical impact of the drug phenylbutyrate in people with HD will begin in late Summer 2004.

**Startle in Pre-symptomatic HD**

The purpose of this trial is to characterize the startle reflex, the unlearned response to a startling stimulus, in HD prior to the onset of motor symptoms. Individuals who have been genetically tested, are pre-symptomatic and 18 years of age or older are invited to participate in this study.

**Genetic Discrimination Study (ELSI)**

The purpose of this research study is to better understand the experiences and practices of persons who have received genetic testing. The research involves a one-time telephone interview about individual experiences and perceptions regarding discrimination. We hope that this may identify topics of concern to others who are at risk for HD. Adult individuals who have been genetically tested and who are pre-symptomatic are eligible to enroll.

**Optimism**

This study looks at optimism, distress and coping styles. Information gained will help researchers understand how certain belief systems influence mental health and the ways in which people with Huntington’s disease deal with situations.

**Patient and Companion Ratings of Symptoms of Huntington’s Disease**

The purpose of this research study is to better understand differences in the way that people who have HD and their companions rate the presence of motor, cognitive and emotional experiences in themselves and each other.

**Caregiving in HD**

This study was developed to investigate how caregiver’s functioning is impacted by various characteristics.

**call or email us for more information about current studies**

(800) 777-8442 ext 34307 or (319) 353-4307 or hdinfo@uiowa.edu

Karen Brown, HDSA Chapter President with Tiffany Helmrichs, NE Hoop Coordinator hoop it up in Arlington, IA on March 13, 2004. Join your local hoop-a-thon in the next month at:

- April 3- Audubon 12-5 pm
  Audubon High School

- April 17- Des Moines 1-3 pm
  AIB College Activities Center

- April 18- Marion 1-5 pm
  Wilkins Elementary School
Ten Ways to Simplify your Life

1. Extend your boundaries- it is okay to say no

2. drop your to-do’s- get rid of the tasks that you keep telling yourself will get done but you always find something more interesting to do

3. remove clutter- relieve stress by removing clutter

4. develop your values- make clear what is important to you. develop your values and live to those values.

5. examine your beliefs- what are your core beliefs? Your beliefs may be limiting your ability to let go of tasks that don’t add value.

6. create priorities- determine 1-2 things you want to accomplish in the next year including career, home, relationships and self.

7. give yourself permission to relax- relaxing is not being lazy. give yourself some time to think.

8. if you are struggling, let it go- give yourself a mental break.

9. take care of yourself- take care of your body and mind. eat well, get some exercise.

10. have fun- find things that bring you joy.

thanks to www.care-givers.com and Jennifer Ottolino