The Differences Between Clinical and Research Visits at a Batten Center of Excellence

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BACKGROUND

Children and their families may choose to be seen at the University of Rochester Batten Center (URBC) for either a clinical visit, a research visit, or both. There are differences between the two types of visits which may be confusing to parents.

When the URBC medical team sees children at the annual BDSRA meetings, those visits are research only visits. Other members of the research team, including research colleagues from the Cognitive Neurophysiology Lab at the University of Rochester Medical Center, may also attend the BDSRA meeting.

TAKE HOME MESSAGES

- Research will gather information about many individuals, and will combine that information to obtain generalizable knowledge.
- Clinical care focuses on the individual story and needs of one person (and their family) at a time.

RESEARCH VISITS

Goal of Research Studies
- Research studies look to answer to a question

Key Elements of a Research Study
- **Research protocol**: describes how the research team will gather information to answer their question
- **Institutional Review Board (IRB):** An IRB committee must grant approval, before the research study can begin. The IRB ensures that the study is ethical, not too risky for subjects, and will be properly run.
- **Consent:** A parent or legal guardian must provide written consent for their child to participate in research. The consent must list the possible risks of the research, as well as possible benefits. For some research, there may not be a benefit to the child.
- **Confidentiality:** Each participant is given a unique number to be used on all study documents except for the consent, to protect the confidentiality of the participant. Research information is not shared with the participant's medical provider.
- **Database:** Information (data) is gathered and entered into a database.
- **Analysis:** Once the data are gathered, researchers use statistics to look for emerging patterns. For example, this is how we determined the average age of vision loss in CLN3 disease.
- **Data Storage:** There must be a plan for how long data are stored by the research team, or if the data will be destroyed after the study is completed. Data cannot be shared with other researchers unless the IRB approves it.
- **Costs:** Participants in research studies may or may not have their costs covered for taking part. The consent form will disclose any costs that will be paid by the study team or study sponsor, or that the participant/family may incur.
- **New Information:** Any time there is new information that could affect the decision to continue participating, such as a change in the risks and benefits of being in the study, a new consent form must be signed by the parent or legal guardian.
- Reports are not typically generated for clinical use from the data gathered in research studies

URBC RESEARCH AND CLINICAL EVALUATIONS JUNE 2017- MAY 2018

NEW SUBJECTS: 19, RETURN SUBJECTS: 19

THE TEAM SAW SUBJECTS WITH CLN 1, 2, 3, 5 AND 6

SEVEN SUBJECTS HAD A CLINICAL + RESEARCH VISIT

ONE SUBJECT HAD THEIR 14TH RESEARCH EVALUATION BY THE TEAM

CLINICAL VISITS

Goal of Clinical Visits:
- Are a second opinion neurology visit to The University of Rochester Batten Center of Excellence

Key Elements of Clinical Visit
- **Review of Medical Background**: Previous medical records and genetic testing results are obtained, as they help the team understand each child's story
- **Medical Exam:** The visit is completed in a clinic exam room and a medical history, list of medications, family history and neurologic examination are completed
- **Documentation:** A clinic note is completed in the electronic medical record, signed by the team members who completed the visit and sent to the referring health care provider.
- **Costs:** The visit is charged to the child's health insurance and generates a report for the child's primary doctor
- **Recommendations:** Suggestions for medication changes or other approaches can be made to the referring health care provider
- **Information Sharing:** If a release of information is signed, the URBC team members can discuss medical and educational information with the child's current medical providers, therapists and school.

CONCLUSIONS/IMPLICATIONS

Research visits differ from clinical visits. Generating individual reports from research findings can be difficult for researchers, since individual data are not as meaningful in research as group data. Clinical visits look at each person individually and can generate reports with suggestions for medications and other treatments.