Development of a CP Research Registry: A Centralized Multi-Site Service Approach
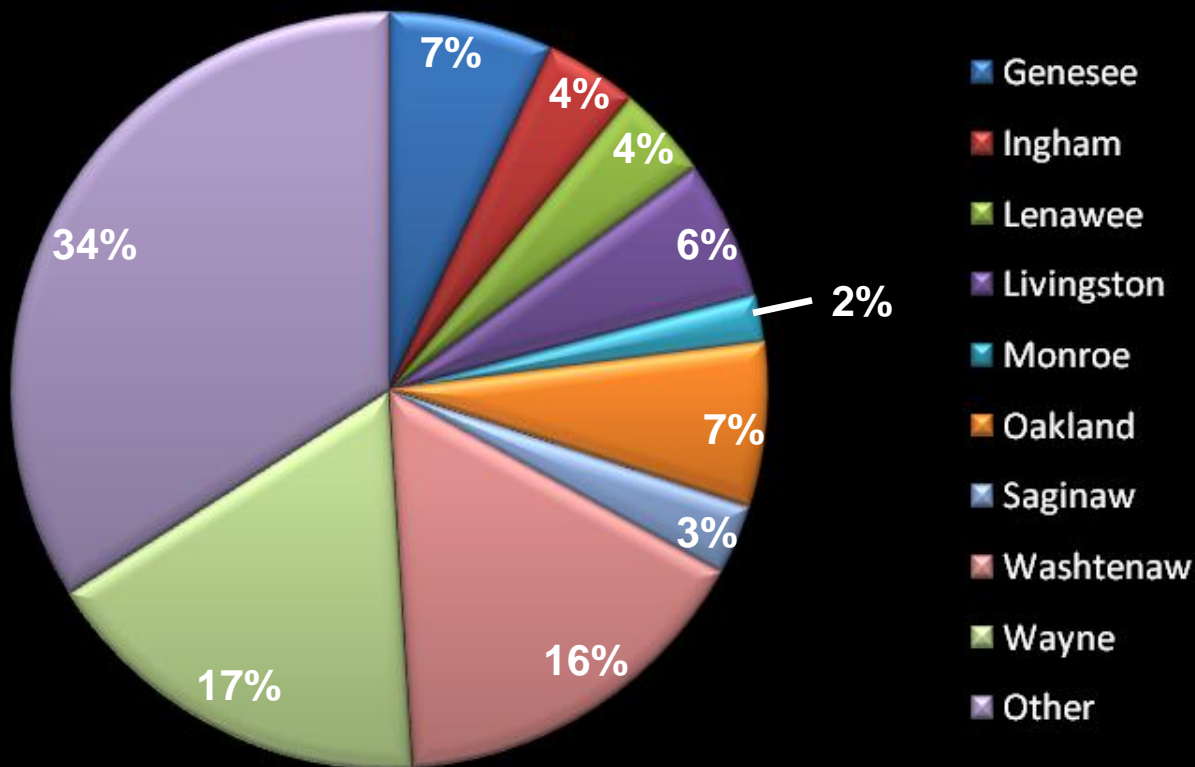
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Statement of the problem(s):

- University of Michigan is a large institution encompassing both campus and medical center locations.

- Researchers and clinicians who examine aspects of CP are dispersed around the full range of locations.

- Individuals in the area of U of M with CP diagnoses are not always seen clinically or academically by researchers studying CP.

- Individuals with CP diagnoses are not always aware of research opportunities.

- Researchers are struggling at times to recruit adequate numbers of participants w/CP diagnoses.

University of Michigan statistics Fiscal Year 2005-2006 clinical visits

Pie chart legend:
- Genesee
- Ingham
- Lenawee
- Livingston
- Monroe
- Oakland
- Saginaw
- Washtenaw
- Wayne
- Other

Pie chart values: 7%, 4%, 4%, 6%, 2%, 7%, 3%, 16%, 17%, 34%

Total of 945 individuals with diagnoses of CP seen for medical care at UMHS (includes 12 from out of state).

Development of a CP research registry

- Approach seen as a method to capture wider cross-section of Michigan residents with diagnoses of CP.

- A centralized registry decreases redundancies, maximizes cost efficiency, and decreases work load associated with management of multiple databases.

- Decrease the work needed for interested participants to find all of the relevant studies.

- Provide a "ready-made" recruitment option for researchers at the University to be linked with interested participants for research opportunities.

- Create a "meeting place" for researchers.

An opportunity to serve the regional CP research effort in Michigan

- **Phase 1**: Create a University of Michigan CP research registry with a goal of approaching the maximal number of qualified people to invite participation in the registry.

- **Phase 2**: Formalize collaborations with other large group facilities where large numbers of individuals with CP diagnoses are seen either clinically or for research participation.

- **Phase 3**: Statewide registry vs. National registry?

Phase 1: Develop a University of Michigan CP research Registry

- Coordinated effort with registry steering committee: Dr. Ed Hurvitz, Ms. Donna Omichinski, Ms. Jennifer Miner, Ms. Julie Stotler, Dr. Jacqueline Kaufman.

- How to invite participation internally
  - Automatic invitation
  - Advertise within high yield clinics

- Work with other groups known to conduct research in the area of CP and related conditions (neurosurgery, orthopedics, pediatrics, etc.).

- Work with clerical staff to develop logistics necessary for invitation extension to ALL qualified candidates.

Phase 1: Getting the ball rolling: nomenclature and IRB.

- **What to call this: registry, database, etc.?**
  - Discussed pros and cons of use of term "registry" internally and with people outside of steering committee.
  - What kind of information would be held?

- **Get approval for maintaining private health information (PHI) in a registry for ultimate use affiliated with research recruitment.**
  - Labor intensive procedure (IRB applications, wording)
  - Data vs. purely contact info?
  - How can we best protect the interests of registrants and researchers?

Consent form content

- **Purpose:** "The purpose of the Cerebral Palsy Research Registry is to provide interested members in the community a central location to register interest in being contacted by researchers of the Cerebral Palsy Research Consortium of Michigan (CPRCoM) for research opportunities. The registry helps CPRCoM researchers identify and invite voluntary registrants who are eligible for future and current research studies involving cerebral palsy (CP)."

- **Definition:** "A research registry is a secured database that stores limited contact and demographic information about voluntary participants, and is accessible only to authorized personnel, and only with approval of the Institutional Review Board which oversees research activities."

- <u>**Aim:**</u> "Members of the CPRCoM aim, through research, to increase their knowledge about the health and quality of life of individuals with CP and it is anticipated that you/your child's participation in this registry will aid researchers in more readily connecting them with interested and qualified participants."

- <u>**Limits of consent:**</u> "By signing this consent, you/your child agree to participate in this registry and indicate your willingness to be contacted by a representative from the consortium to participate in future research specific to CP. <u>**By agreeing to participate in this registry, you are *NOT* agreeing to participate in all research, rather you are agreeing to be contacted by CPRCoM with opportunities to participate in research about CP.**</u>"

Demographics questionnaire with consent form

- Who completed form?

- Gender

- DOB

- Race/ethnicity

- Does person w/CP communicate by:
  - Speak
  - Gesture
  - Communication board
  - Other asst tech
  - Other

- Visual and/or Hearing impairment?

- Gross Motor Function Classification System questions (GMFCS)

- Manual Ability Classification System questions (MACS)

- Expressive production questions (ExPRS)

- Questions regarding comprehension of spoken commands

- "I want more info about…"

What's new here?

- **Recruitment strategy**:
  - All in PM&R w/CP diagnosis provided info w/check-in paperwork.
  - Goal to create similar system within other departments with higher rates of patient visits with diagnoses of CP.

- **Not waiting for people to find us:** we alert all w/CP diagnosis when coming for clinic visits.

- **Multi-site service approach**: A localized registry such as this:
  - Maximizes fiscal resources
  - Serves researchers and community members
  - Allows researcher-researcher alliances/collaborations
  - dissemination of CP specific information to interested parties.

Phase 2: Collaborate in Michigan

- Already underway – contacting other centers in Michigan to extend invitations to join the centralized database.

- Institutional collaborative members will be able to request names/contact info for registrants who meet the requirements for an approved study:

  – Must provide approved IRB from home institution

  – Only essential information to contact potential participants would be provided

  – Fee for service? Will ask researchers to budget for cost of using the registry resource to maintain infrastructure of service.

  – Database as a repository in current conceptualization rather than an epidemiological database for intensive study.

Phase 3: State vs. National Registry?

- Given increased clinical and research efforts surrounding CP and advanced state of development of registry site this may provide an excellent platform for a regional node or state-based registry for Michigan.

- Like other medical conditions, national registries and regional registries should be helpful in advancing research and awareness about CP. Much value in partnering with more established registries (e.g. Chicago land area collaborative; www.cpregistry.org) to model smaller state-based "feeder" registries locally and potentially pooling information nationally.

- State and National registries as ways to team up researchers with interested participants, researchers with researchers, and participants with information.

Where do we go from here?

- Open registry for business locally (U of M and greater Ann Arbor region)

- Finalize relationships with institutes within Michigan to create a true collaborative dedicated to matching researchers, individuals with CP, and resource-disseminating entities together.

- Management and upkeep of database (e.g. updates, re-contact for participants who turn 18, etc.).

- Nothing is for free…long-term money management strategies.

- We must return to the issue of a national registry (without recreating the wheel!). This is both to the benefit of researchers who study CP and individuals with CP diagnoses who are seeking advancements in science.

THANK YOU!
Questions?

- **University of Michigan Cerebral Palsy Research Registry Steering Committee:**
  - Donna Riccio Omichinski, BA, CCRP
  - Jennifer Miner, BS, MBA, CCRP
  - Julie Stotler, BA
  - Jacqueline Kaufman, PhD
  - Edward Hurvitz, MD

  - Tremendous thanks to Danielle Sandella, BS for comprehensive website and registry design.