Developing a Clinical Research Registry in Autism Spectrum Disorders

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https://centerforstartservices.org/mhidd-national-research-consortium
Outline

• Review KKI-CARD clinical research registry

• Review clinic informatics infrastructure

• Review study of caregiver consent to the registry
Center for Autism and Related Disorders

- Large, multidisciplinary ASD clinic located in Baltimore, MD
- >2000 Patients per year
- Diagnostic and Treatment
- Research, Education, Outreach
Creating Advances in Autism Research (IRB Approved Registry)

Use of Medical Records for Research

Contact for Future Research
The Quantified Visit

Pre-Appointment
- Baseline Survey
  - Demographics
    - Age
    - Gender
    - Race
    - Ethnicity
    - Address
    - Email
    - Insurance
  - Encounter
    - Date
    - Appoint. Type
    - Provider Type
    - Department
    - ICD-10
  - Flowsheets
    - 450+ Clinician-administered Assessments (e.g., IQ)
  - Smart forms
    - Custom Diagnoses via Best Practice Alerts
- Reason for Visit
  - Standardized Patient-reported outcomes
    - CAARE

Appointment

Post-Appointment
- Qualtrics®XM
  - Outcome Survey
    - Patient-reported outcomes and satisfaction measures

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Examples of registry research


• The goal of this study was to: 1) examine caregiver agreement to hear about research opportunities by joining a local clinical research registry; 2) factors related to consent.

• CARD (N=5228) and Neuropsychology (N=5040) clinics were included
Consent for Contact

- Overall, 80% of caregivers consented
- Significant increase in CARD between 2014-2017
Factors related to consent

- Factors associated with providing consent:
  - Race: Black/AA < All other*
  - > Parent-reported Mental Health Symptoms/Sleep Problems in both clinics
  - Fewer days until appointment
  - Non-Significant: Informant-Type, IQ or ASD Severity, Distance to clinic, Parental Education level
Factors related to consent II

- Significant insurance x clinic interaction
Summary

• Pre-appointment online consent can be obtained at fairly high levels (80%+).
  – 98% of those who agree to be contacted agree to allow for consent to the EMR for research (data not shown)

• Consent is not equivalent across populations

• Recruitment registry is useful in its own right, however the clinical data will be useless unless the EMR system has been designed
Thank You!

Contact: kalb@kennedykrieger.org
Research Clinic Partnership
Nicole Takahashi, MS
December 22, 2021
Overview

- Building research infrastructure
- Database evolution
- Research core description, advantages
- Research clinic partnership
- Key elements for success
Building research infrastructure

• 2008 – The Thompson Center (TC) became a clinical site for two large national autism networks

• Most early research at the center was conducted by small fragmented research teams

• A center database was established from a legacy research registry

• The TC database formed the foundation of our research core
Database evolution

• Initially the TC database was only used by research staff

• The database evolved to incorporate clinic workflows and electronic clinical data collection

• The TC database is now a high impact resource used across the center that helps to inform clinical practice
The Thompson Center research core

1) provides a central resource for storage and access to phenotypic data
2) facilitates subject recruitment for research studies
3) provides research-grade psychometric testing
Research core services

- Research consultation
- IRB
- Recruitment
- Research-reliable assessment
- Project management
- Data collection
- Biospecimen collection & processing
- Data entry
- Data management
- REDCap project creation
- Assist with abstract and manuscript preparation
Research core advantages

- Can sustain core group of experienced research staff
- Reduced reliance on single source of soft money
- Research core has established relationships with clinicians, knowledge of clinic workflows
- Access to shared database of phenotypic information
- Centralized targeted research recruitment
- Decreased assessment redundancy
- Streamlined pipeline from clinic to research
Research clinic partnership

Research collaboration with clinic is mutually beneficial

- Research recruitment in clinic
- Database used to create triage algorithm
- Collaboration with clinic to reduce waitlist and create expedited path to evaluation
- Focus on early screening by integrating into pediatric practice
- Research may identify at risk children and facilitate appropriate referrals
Key elements for success

• Leadership support, value added to center
• Nurture relationship between clinic and research
• Critical mass of funded research studies
• Establish career path to retain talented research staff
• Cross-training of research staff on diverse projects
• Clinician on each study research team
• Database
CADB REDCap Implementation: Integrating Research & Clinic

Deanna Swain, Ph.D.
REDCap
Research Electronic Data Capture

Build Online Databases

Send Surveys to Participants

Save Data in a Secure and HIPAA Compliant Environment

Please complete the survey below.
Thank you!

Would you like to participate in our survey?

Yes
No

1) Name

2) Would you like to participate in our survey?

Submit
CADB Clinic & REDCap Flow

1. Intake
2. Packet 1
3. Admin & Screening Visit
4. Packet 2
5. Psychology Evaluation
6. Data Entry
**New Patient Intake**

**Intake Process**

Old → New

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**NEW PATIENT INTAKE FORM**

**Event Name:** Intake

<table>
<thead>
<tr>
<th>Record ID</th>
<th>2021739</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of call</strong></td>
<td>12-16-2021</td>
</tr>
<tr>
<td><strong>CADB employee initials</strong></td>
<td>DMS</td>
</tr>
<tr>
<td><strong>Is an interpreter needed for services?</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>What language did the caller speak?</strong></td>
<td>Spanish</td>
</tr>
</tbody>
</table>

**REMINDER:** Please inform family that all visits will be in-person.

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**Patient Information**

**Patient first name**

**Patient preferred name**

**Patient middle name**

**Patient last name**

**Patient date of birth**

**Patient age at time of intake (MONTHS)**
Dear new CADD family,

Thank you for completing the required CADD forms. We will be in touch if anything is missing or if we need additional documents. Our team will process your packet in the order it was received. In the meantime, we wanted to provide you with some additional information regarding what to expect next.

Insurance Clearance: You may receive a call from one of our patient finance representatives to review your plan benefits for our specialty services. If you have any out of pocket expenses, this will be explained during this phone call.

Screening Appointment: You will then receive a call to schedule your screening appointment with our Social Worker. This screening appointment will help us gather additional information regarding how CADD can best help PIPED DATA.

Please note, all of the information you provided in the packet may not be reviewed for several months. CADD does not provide ongoing mental health therapy or crisis intervention services. If you or PIPED DATA has mental health concerns, please contact a licensed mental health care provider in your area for advice or treatment options.

If PIPED DATA is experiencing a psychiatric emergency, please contact 911 or go to the nearest emergency room.

Please do not reply to this email, rather direct any questions or concerns to us by telephone at 916-987-5848 option #1.

We look forward to seeing you!

Thank you.
Administration Team

- Add patient to EPIC
- Create referral for screening visit
- Verify benefits with family
- Schedule screening visit
Screening Appointment

- Completed by Social Worker
- Review and consent family
- Complete M-CHAT follow-up questions if needed
Dear CADB family,

Thank you for scheduling your assessment for Test with our Psychology team for 12-29-2021. In order for us to best serve you, we will need additional information which can be completed at the link below.

*Please complete these forms as soon as possible but no later than 12-15-2021. If we do not receive your completed questionnaires by this date, we may need to reschedule your appointment.*

You may open the survey in your web browser by clicking the link below:

*Autism Impact Measure (AIM)*

If the link above does not work, try copying the link below into your web browser:

https://redcap.ctc.well.cornell.edu/redcap_protocols/surveys/?e=!Peoq51Ib57f6m7

This link is unique to you and should not be forwarded to others.
Best Case Scenario

- AIM
- Past Evaluations
- CBCL ★
- ABAS ★
- RBS-R
- DASCA

Data Collection Instruments

- Add new instrument:
  - Create
  - Import
  - Upload

Survey options:
- Survey Queue
- Survey Login
- Survey Notifications

Past Evaluations

- Does Test have a current Individualized Family Service Plan (IFSP) or Individualized Education Program (IEP)?
  - Yes
  - No

- Does Test have a current 504 Plan?
  - Yes
  - No

Copies of report cards
- Upload file

You indicated that Test has a previous diagnosis of ASD. Please upload a copy of the report (medical professional or psychologist).
- Upload file

- Has Test previously completed a psychological evaluation?
  - Yes
  - No

- Psychiatric hospitalization discharge paperwork
- Upload file

Genetics Testing and Reports
- Upload file

Neurology evaluations
- Upload file

Additional file:
- Upload file
Worst Case Scenarios

1. Family gets reminder email 5 days after 1st email received
2. Scheduler receives 2-week warning email
3. Psychology technicians receive 1-week warning email
4. Family fills out forms on iPad during in-person visit
Ways REDCap can be helpful for...

Clinicians
- Access patient survey data from anywhere
- Treatment outcome monitoring

Researchers
- Item level data collected for all surveys
- Auto-scoring reduces time on back-end
- Multi-site studies can easily share data

Administrators
- Track clinician throughput
- Track clinic flow and efficiency
- Make workflow explicit
Next Steps

- **Customize**: Customize for adult patients and non-English speaking families
- **Combine**: Complete merger of legacy data
- **Guidelines**: Create guidelines for future project creation
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