NU IMPACT Study:
Recruiting and Consenting through the EDW in REDCap

CCCR-CTRIS, October 19th, 2021
Nikki Lancki, Senior Statistical Analyst
Michael Bass, Research Associate Professor
Outline

• NU IMPACT – background and study design
• Automation and System Integration used for Study Workflows

- Recruitment from EDW
- eConsent and survey-based longitudinal assessments in Redcap
- Study Tracker and Epic Integration
NU IMPACT Study Overview

• Northwestern University’s NU IMPACT builds upon an existing and EHR-integrated cancer symptom monitoring and management system (NMPRO)

• Test the effectiveness of a system-wide symptom management intervention when implemented across the Northwestern Memorial HealthCare Corporation (NMHC) outpatient oncology clinics using a clinic-level randomized roll-out implementation trial design, and embedded patient-level randomized controlled clinical trial (RCT)
  - The enhanced care (EC) approach aims to engage participants actively, and to increase self-efficacy in the monitoring and managing of their symptoms
  - The existing NMPRO constitutes usual care (UC)
NU IMPACT Study Design

Hybrid Type II Effectiveness-Implementation Trial

1. Clinic-level pragmatic randomized roll-out implementation trial (N=12,000; n=6,000 Pre-I & 6,000 Post-I)
   - Modified stepped-wedge (“staircase”)
   - System-level implementation evaluation
   - Draw comparisons within and between sites via evaluation of implementation of NMPRO usual care (UC), NU IMPACT intervention (EC)

2. Patient-level randomized controlled clinical trial (n = 6,000)
   - Embedded in the post-implementation phase
   - Group-based comparison of usual care (UC; n=3,000) vs. enhanced care (EC; n=3,000)
   - Primary outcomes are individual PROs over time
NU IMPACT – Workflow/Features to Consider

• Large volume of participants to recruit through EDW
• Electronic consent and survey-based patient-level data collection
• Randomization (gender, language, site, cancer continuum)
• Clinical units going live and pre to post implementation over time
NU IMPACT – Software system overview

Research Systems
- REDCap: Research Data Collection System
- Study Tracker: Trial Management System

Electronic Data Warehouse
- NU IMPACT website
- Enhance Care

Clinical Systems
- EPIC
- Hyperspace
- EPIC
- MyChart
NU IMPACT – Data Flow

Research Systems

- REDCap: Research Data Collection System
- Study Tracker: Trial Management System

NU IMPACT website
- Enhance Care

Electronic Data Warehouse

Clinical Systems

- EPIC
- Hyperspace
- EPIC
- MyChart

Reruitment
Consent
Compliance
<table>
<thead>
<tr>
<th>Project</th>
<th>Forms</th>
<th>Surveys</th>
<th>NU IMPACT</th>
<th>NU IMPACT Staging (Recruitment and Randomization)</th>
<th>NU IMPACT Spanish</th>
</tr>
</thead>
<tbody>
<tr>
<td>NU IMPACT</td>
<td>☐</td>
<td></td>
<td>2,178</td>
<td>22,891</td>
<td>9</td>
</tr>
<tr>
<td>NU IMPACT Staging (Recruitment and Randomization)</td>
<td>☐</td>
<td></td>
<td>1,795</td>
<td>3,200</td>
<td>1,832</td>
</tr>
<tr>
<td>NU IMPACT Spanish</td>
<td>☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
EDW Recruitment: Identifying eligible patients

- Northwestern Medicine Enterprise Data Warehouse (NMEDW) is the integrated repository of clinical and research data for NMHC and NU FSM
- Worked with EDW analyst (Quan Mai) to identify eligible patients:
  - Cancer diagnosis in medical record (ICD-9/ICD-10 code on problem list or encounter diagnosis) within past 10 years
  - Visit to clinic in past year
  - Age >=18 years
  - Additional eligibility:
    • Has valid email address
    • Provider agreed to patients being contacted
    • Seen by those providers at the departments (clinic sites) currently recruiting from
EDW Recruitment: Automation

• Goal was daily upload of identified eligible participants from EDW
• Added EDW data architect and nmedw_webbservice to REDCap project
• Requested API token on behalf of nmedw_webbservice

• Data architect created daily ETL (extract, transform, and load) process:
  - Run EDW analyst query that identifies eligible participants in EDW and fields for recruitment
  - Check REDCap database to compare if patient already in the current REDCap project (prevents overwriting)
  - Import eligible participant information and recruitment fields into REDCap
Automation of Recruitment Email

• REDCap project for upload of EDW recruitment data and consent/baseline data collection

• When new data is uploaded, use REDCap Automated Survey Invitation (ASI) logic to send email with link to Consent

• Use REDCap survey queue and auto-continue to continue into baseline assessment

• Enabled reminders if no response
Automation of Recruitment Email

Steps:

1. **Compose message**
   - **From:** [User Name]@northwestern.edu
   - **To:** All participants who meet the conditions defined
   - **Subject:** Research Opportunity: Using your voice to improve the quality of care for all Northwestern Medicine cancer patients

   **Text:**
   La versión en español está abajo.

   Dear [patient_firstname] [patient_lastname],

   I am writing to you about a research opportunity for patients currently receiving care in the Northwestern Medicine (NM) system. The NU IMPACT Study is working to improve the quality of the care you and other patients receive at NM Cancer Centers, and we are inviting you to participate!

   Please visit our website at [URL] for more information.

   **OPTIONAL: Enable reminders**
   - Re-send invitation as a reminder if participant has not responded by a specified time.

2. **Specify conditions for sending invitations**
   - When the following survey is completed:
   - When the following logic becomes true:
   - Ensure logic is still true before sending invitations.

   **Text:**
   [In English]

   **Text:**
   [Spanish]

   [Image]

   **Research Opportunity:**
   Using your voice to improve the quality of care for all Northwestern Medicine cancer patients.

   **Text:**
   Dear [Name],

   I am writing to you about a research opportunity for patients currently receiving care in the Northwestern Medicine (NM) system. The NU IMPACT Study is working to improve the quality of the care you receive at the Northwestern Medicine Cancer Center, and we are inviting you to participate.

   You are being contacted because you are a patient at a NM Cancer Center, and you have consented to participate in this study.

   Participation in this study will involve the completion of online study questionnaires (from a computer, smartphone, or other mobile device) over the next year.

   - Study questionnaires are conducted during a one-year period.
   - Study questionnaires are emailed directly to you, and you will be contacted using your computer or mobile device.
   - For every study questionnaire you complete, you will be entered into a raffle for a chance to win a $100 gift card. A raffle will occur every quarter (every 3 months) and there will be 5 winners every quarter.

   **Note:** This means that if you complete two study questionnaires within a quarter (3 months), your name will be placed in the raffle drawing.

   If you would like to participate, simply click the NU IMPACT Study link provided below. It will take you to a protected website where you will be asked to review and sign a consent form and then complete the first questionnaire. The consent form will provide detailed information about the study and how we plan to protect your privacy and the information you provide.

   Please visit our website at [URL] for more information.

   If you have any questions, please contact us at [email] or [phone].

   [Image]
EDW Recruitment Lessons Learned

- Communication is important (weekly meetings with EDW analyst)
- Use a unique ID (EDW ir_id) for REDCap Record ID to avoid issues with overwriting
- Be specific /detailed in query request
- Defining eligibility: list of ICD codes versus Grouper ID
- Recognize limitations of electronic health record for eligibility and be prepared to address any issues
- Test out on smaller scale and scale up
- EHR recruitment response rate can be low (10-11%)
- Importance of RA/project manager
- Expect the unexpected, and be ready to respond
Randomization Considerations

• Pre-Implementation: Randomization to survey version for “counterbalance”

• Post-Implementation: Randomization to survey version and intervention arm (Enhanced or Usual Care) stratified by:
  - Site (7 clinical units)
  - Gender (Male, Female)
  - Cancer Continuum (Curative, Non-curative, Survivorship)
  - Language Preference for study (English or Spanish)

• Sites transition from Pre to Post Implementation at different times

• Needed to communicate treatment assignment to Epic to control display of MyChart
Randomization Allocation Tables

- Created allocation tables for each strata using statistical software
- Separate lists Pre-I and Post-I

<table>
<thead>
<tr>
<th>Name</th>
<th>Date modified</th>
<th>Type</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>E_F_C_1_L.csv</td>
<td>9/21/2020 9:33 AM</td>
<td>Microsoft Excel CSV</td>
<td>19 KB</td>
</tr>
<tr>
<td>E_F_C_1_P.csv</td>
<td>9/21/2020 9:30 AM</td>
<td>Microsoft Excel CSV</td>
<td>18 KB</td>
</tr>
<tr>
<td>E_F_C_2_L.csv</td>
<td>9/21/2020 9:33 AM</td>
<td>Microsoft Excel CSV</td>
<td>19 KB</td>
</tr>
<tr>
<td>E_F_C_2_P.csv</td>
<td>9/21/2020 9:30 AM</td>
<td>Microsoft Excel CSV</td>
<td>18 KB</td>
</tr>
<tr>
<td>E_F_C_3_L.csv</td>
<td>9/21/2020 9:33 AM</td>
<td>Microsoft Excel CSV</td>
<td>19 KB</td>
</tr>
<tr>
<td>E_F_C_3_P.csv</td>
<td>9/21/2020 9:30 AM</td>
<td>Microsoft Excel CSV</td>
<td>18 KB</td>
</tr>
<tr>
<td>E_F_C_4_L.csv</td>
<td>9/21/2020 9:33 AM</td>
<td>Microsoft Excel CSV</td>
<td>19 KB</td>
</tr>
<tr>
<td>E_F_C_4_P.csv</td>
<td>9/21/2020 9:30 AM</td>
<td>Microsoft Excel CSV</td>
<td>18 KB</td>
</tr>
<tr>
<td>E_F_C_5_L.csv</td>
<td>9/21/2020 9:33 AM</td>
<td>Microsoft Excel CSV</td>
<td>19 KB</td>
</tr>
<tr>
<td>E_F_C_5_P.csv</td>
<td>9/21/2020 9:30 AM</td>
<td>Microsoft Excel CSV</td>
<td>18 KB</td>
</tr>
<tr>
<td>E_F_C_6_L.csv</td>
<td>9/21/2020 9:33 AM</td>
<td>Microsoft Excel CSV</td>
<td>19 KB</td>
</tr>
<tr>
<td>E_F_C_6_P.csv</td>
<td>9/21/2020 9:30 AM</td>
<td>Microsoft Excel CSV</td>
<td>18 KB</td>
</tr>
<tr>
<td>E_F_C_7_L.csv</td>
<td>9/21/2020 9:33 AM</td>
<td>Microsoft Excel CSV</td>
<td>19 KB</td>
</tr>
<tr>
<td>E_F_C_7_P.csv</td>
<td>9/21/2020 9:30 AM</td>
<td>Microsoft Excel CSV</td>
<td>18 KB</td>
</tr>
</tbody>
</table>

E = English, F = Female, C = Curative, 5 = Site 1, I = Post-Implementation

treat
1 = EC version 1
2 = UC version 1
3 = EC version 2
4 = UC version 2
Stage 1: Nightly recruitment/enrollment process (EDW -> REDCap)

**NU IMPACT Staging (Recruitment and Randomization)**

**Criteria Field(s)**
- Consent::Consent Date

**Stratified Field(s)**
- EDW Data::Site
- EDW Data::Gender
- EDW Data::Cancer Continuum
- Consent::Language

**Assignment Field(s)**
- Randomization:: UUID
- Randomization:: assignment
- Randomization:: date

**Legend**
- Input data
- Output data
- Processing code/program

**C# program runs daily via Windows scheduled task**

**Allocation tables hosted on NU File server**

**NU IMPACT**
- Registration:: Cancer Continuum
- Registration:: Gender
- Registration:: Site
- Registration:: Language Preference
- Registration:: UUID
- Registration:: Treatment Arm

**NU IMPACT Spanish**
- Registration:: Cancer Continuum
- Registration:: Gender
- Registration:: Site
- Registration:: Language Preference
- Registration:: UUID
- Registration:: Treatment Arm
Follow-up Assessments (REDCap)

- Separate REDCap projects for follow-up of consented participants (English & Spanish)
- Follow-up consented/active participants (anyone who withdraws from study will not be contacted)
- Monthly survey-based assessments sent using REDCap ASI logic based on days from consent and if actively enrolled

<table>
<thead>
<tr>
<th>Redcap Measures</th>
<th>BL</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly Screener*</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Comprehensive Assessment**</td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*PROMIS CATs (Pain, Fatigue, Physical Function, Anxiety, Depression), PRO CTCAE, Physical Health
**Includes measures on Healthcare Utilization, Health Literacy, Financial Distress, Isolation, Communication, Self-efficacy, Support
Roll out of clinics in steps/over time

- Clinic unit roll out order randomized
- Pre-Implementation data collection for 6 months, then switch to Post-Implementation
- Added form in REDCap (Configuration file) to track which sites go live when
  - Includes fields for dates started Pre and Post
  - Current status for each site (referenced by C# program)
REDCap → Study Tracker Interface

** Study Tracker Interface with REDCap:

⚠️ I am interested in learning more about using REDCap for eConsent. How can I learn more?

A webinar recently took place on this topic and includes many details that are beneficial when considering the use of REDCap for eConsent. Learn the benefits of the eConsent Framework and Study Tracker push while obtaining some important tips and steps for setup. The webinar session is only available after logging in with your NU NetID and while on the VPN. The video is ~40 minutes in length.

You may access the video here 🜿.
Study Tracker Interface and Epic Integration

- All clinical studies overseen by the NU IRB involving FSM faculty are required to record participants in Study Tracker.
- Study tracker pushes information to Epic (hourly) for billing purposes (study billed for medical services for research not patient or their insurance).
- Utilized this infrastructure to integrate NU IMPACT randomization assignment into patient record to control an individual patients’ MyChart Display for EC vs UC.

MyChart Display of NMPRO scores over time (EC only)
Stage 2: Nightly registration process (REDCap -> StudyTracker)

NU IMPACT/Spanish

Criteria Field(s)
Consent::Consent Date

Stratified Field(s)
Registration::UUID
Registration::First Name
Registration::Last Name
Registration::DOB
Registration::Gender
Registration::MRN
Registration::Ethnicity
Registration::Race
Registration::Budget Arm

C# program runs daily via Windows scheduled task

Study Tracker API

Study Tracker
Randomization/Epic integration Lessons Learned

• Consider other competing project work/resources when determining a timeframe

• We were able to test in a development environment, but more difficult to test when live in Epic

• Rely on communication with study RA/staff/etc
Questions?

Email:
nicola.lancki1@northwestern.edu
michael-bass@northwestern.edu