Maestro Care (Epic) and Clinical Research Updates
Denise Snyder
Terry Ainsworth
Cory Ennis
Duke Office of Clinical Research
May 08, 2013

Duke’s Complex but Productive Research Environment

- Duke’s 10 schools, 8 university institutes, and the Duke University Health System collectively received over $355MM from the NIH in 2011
- Duke led the nation in industry funding for research with $215MM, an amount almost double that of the next highest academic institution [NSF 2012]

21,760 participants enrolled in 425 NIH protocols from 2006 - 2011

Current Research Billing Process/Systems
Drivers in Maestro Care Future State Research Workflow

- Explored and found considerable functionality for managing clinical studies in Epic 2012
- No interfaces possible with Velos eResearch or eIRB – Can happen in Optimization
- Paramount to create a robust mechanism for routing research and standard of care charges
- Need a comprehensive study and subject registry

Decision to use Epic 2012 Research Functionality

- Order Sets and Billing Calendars
- New in Epic 2012

Result - Simplified Systems Integration.
Challenges Overcome

- One Study: One Fund Code
  - Epic only allows one code per study.
- Central Grant Scheduling volume
  - Redirecting unusual schedule requests to peripheral schedulers
- Group signing of order sets
  - PI can sign an order set for the entire protocol – once
- Research "Flag" in the Maestro header
- The use of Billing Calendars vs single orders
  - Epic single orders cannot designate Payer
- Use of Beacon – Oncology therapeutic treatment plans
  - Used for oncology clinical trials
- Naming convention for research orders

Decision to use Billing Calendars and Order Sets

- Epic 2012 enables the creation of a Billing calendar for clinical trials
  - Maps to a visit schedule
  - Chargeable events and items identified, appropriately coded (eg V70.7 modifier) and mapped to Payer (sponsor, insurance)
- Linked at build time to an order set for the study
  - Maps orders to chargeable events and items in billing calendar
- As Charges drop, cross-checked against calendar, coded and routed appropriately
- Review process cleans up

Which Studies need Order Sets and Billing Calendars by Go-live?

- 4047 Active studies in eIRB
  - Excluding:
    - Exempt studies
    - CRU oversight (i.e. DORI)
    - No CRU oversight
    - CRU oversight
    - Retrospective Studies
    - Completed but data analysis ongoing
    - Completed but subject followup

- 815 CRU feedback:
  - External sponsors
  - Recent enrollment?
  - Total Enrollment?
  - Active after June 2013?

- 357 PRMO feedback:
  - High charges AND IDEs
  - Blue grids (other payers)
  - Striped grids
  - Charges > $40,000
  - Yellow/green/pink grids
  - Two color grids
  - One color grids

- 552 High Priority Non-oncology
- 195 High Priority Oncology (Beacon)
Research Workflow Validation – February 6th
• Stop Light Evaluations
• 90+ Subject Matter Experts and Stakeholders from across the Research Enterprise – A success based on Feedback.

Epic and Research - Timeline

Building Order Sets and Study Calendars
• 552 high priority studies have become 564 as new studies added, some closed.
• "war room" team assembled in Hock Plaza, jointly funded by DUHS and SOM.
  – 6 FTE from PRMO + 3 temp staff
  – 6.5 FTE from DOCR
  – 3 FTE from ORI, Project management from Maestro
  – Managers from PRMO, DOCR, ORI
  – Certified contractors – 3 Orderset build, 3 oncology build, 2 Willow pharmacy build.
Research Build Progress

- All study administrative records are built in Maestro (so it knows studies, PI's, Fund codes, etc.)

- A mass upload of patients enrolled in studies that are active and generating bills was performed on May 1st.

- Periodic updates to both will be performed as new studies activate.

Training

EPIC Clinical Research Training

- Understand the training requirements for EPIC Wave 4 research integration
  - Curriculum by role
  - Other materials required

- Quantify the number of individuals requiring research training

- Next steps – Develop curriculum, secure resources, train, go-live and maintain
Training Numbers by Role – 947 in Total

- Clinical Research Coordinators
  - 153 coordinators will need to have Wave 4 CRC Go Live training.
  - 257 coordinators have already or will be trained to use Maestro Care in Wave 2 and 3. They will need a cut over information to function in Wave 4 Go Live inpatient and clinics.
  - 15+ nurse coordinators will need additional Wave 4.

- View Only Researcher Training
  - 438 individuals will require View Only information. Depending on Maestro Care requirements, this can be an online module much like eBrowser instruction is today. If not using eBrowser today, you will not need Maestro training. Now is not the time to be added!

- Dual Role
  - 64 individuals have DLHS roles in addition to research responsibilities (MDs, IPs, NPs, CRNA, etc.) and will be trained by Maestro Care for that clinical role. They will need the similar cut over information that the Wave 2 and 3 trained coordinators will need.

- Research Billing Training
  - 35 will require training in the functions of research billing as part of the EPIC research build.

Maestro Care Research Navigator

Research Flag
Subject Participation Status

Protocol Calendar

Research Order Set
Registration Process

- DOCR Central registration process
- Participant will receive email with date and time of their scheduled session
- Email DOCR help with questions about assigned course schedule
- At the end of all trainings, participants must pass a quiz in order to secure Maestro Care access
- Maestro Care accounts will be set up centrally by DOCR for participants who have successfully completed the Maestro Care training and quiz

Testing, Reporting, Security and Cutover

Maestro - Reporting for Research Administration

- Eleven model Epic reports
  - Subject enrollment by study (eResearch)
  - Upcoming appts by study (CTOV)
- The Maestro Care reporting team is creating custom research billing reports for the PRMO and research staff to utilize.
- Investigating other potential custom reports needed by the research enterprise.
Security Templates

• Templates define role and the available functionality each user is able to utilize within the system.

• Multiple templates can be applied to a single user “RN + CRC” role or “billing + compliance role”.

• Security role/templates are being assigned and will be uploaded prior to Go-Live.

Cutover

• “Cutover” encompasses the activities required to successfully migrate data, functionality and support from the old systems to Maestro Care.

– Reporting
– Scheduling
– Appointments/Orders**
– Command Center Support

**Scheduled research encounters in IDX past June 22nd will need to be re-inputted into Maestro

What to know for post Go Live

• All patients recruited from a Duke patient pool will be registered in Epic (no more bill risk determination)
• Duke Regional and Duke Raleigh remain on their current health record systems until Feb 2014.
• eResearch will remain available for non-Duke patients and expanded subject demographic information.
• Updates from eResearch to the Subject Billing Registry will cease and the Registry will be available as a data archive only.