Research Overview Presentation – December 18, 2018

Q&A

Analytic Tools

Access to tools:

What about research collaboration with our academic partners? Many of our clinician leaders are also researchers...and will they have access to these tools/data?

Yes. Provincial Research Administration (PRA) will continue to review ethics approved studies for access to health information under AHS custody and approve appropriate access for research purposes.

Can researchers use SlicerDicer to determine the number of de-identified potential research participants that meet inclusion/exclusion criteria to determine if a proposed research study (local or multi-site request) is feasible?

Yes - Using SlicerDicer as a preliminary method of determining the number of potential research participants would be a good use case for this tool.

Is REB approval necessary for the high-level feasibility and cohort exploration – for the purpose of hypothesis generation and subsequent grant writing?

REB approval is not required for the exploration of aggregate population data using SlicerDicer.

Example: Re: Flint Michigan water contamination – a physician using Epic started noticing some trends in patients, but did not have solid data. She used SlicerDicer to look across several local Epic sites for population level factors. This led to formalized study and intervention.

Can non-Epic data be uploaded to be analyzed in SlicerDicer?

Non-Epic data can be brought into Caboodle and then leveraged in SlicerDicer; however, this is not in scope for November.

Will we only be able to use Crystal reports for reporting?

You will have access to self-serve, in-system operational reports using a tool called Reporting Workbench. Crystal is but one third-party reporting tool that can be integrated with Connect Care; however, it is the only one for which Epic releases content. Existing Tableau dashboards can be setup to launch from Radar dashboards, and you can create custom tableau dashboards that pull data from Clarity or Caboodle if you have the appropriate training and access.

Functionality

Can patients choose not to be contacted about research opportunities?

Connect Care is configured such that all patients are eligible to be contacted about opportunities to participate in research studies, unless they choose otherwise. Patients can indicate at any point in their healthcare journey that they do not wish to be contacted about research opportunities and their wishes will be respected. The only exception occurs when a clinician providing care to a patient, in an AHS environment, determines that a research opportunity may be beneficial to that patient.
Can you add multiple studies?
Yes, if a patient is actively participating in more than one study in Connect Care, their record can be linked to each study.

Are Best Practice Advisories (BPAs) only for outpatients or also for the inpatient population?
The approach to BPAs is in the planning stages; however, they do function in both inpatient and outpatient settings.

Can the system detect adverse events based on pre-defined criteria (e.g., an abnormal lab test)?
There is no automated detection system. There is an automated notification if a patient is admitted or arrives in an emergency department.

Can you customize notifications - new medications or other treatments, test results, etc.?
Customization of notifications is part of the Clinical System Design process currently taking place. There is some flexibility to send messages to the Research Coordinator and/or the Principle Investigator but new types of notifications cannot be added.

Will the system distinguish between orders (Lab) that are part of the study and those associated with routine care? There can be a combination of both.
Yes, study coordinators will be able to link labs that are ordered for a research study - so that clinicians can understand where the lab result belongs (i.e. – research vs. standard of care) and to ensure that the result is routed back to the research team.

Will the system manage non-clinical research?
Coordinators queuing up orders or scheduling patients as part of a study will have access to participant management workflows. Non-clinical researchers, depending on their needs, may apply for access to the self-serve, in-system inquiry and reporting tools.

What resources are available to ensure we leverage the functions efficiently and effectively? (E.g. entering protocols, setting up BPAs, billing, closing studies, etc.).
The research services support model will be phased in to ensure that functionality is prioritized for launch. Then, followed by additional services to support new recruitment approaches and patient outreach.

Can task/orders be assigned to a study after completion?
No. Study record completion in the CIS closes all available workflows including tasks and orders.

Does the Connect Care system perform randomization for research studies using the Connect Care System?
No. The CIS is NOT a clinical research management system (CTMS/CRMS). It does not perform randomization. EPIC has some cool features that will help us in research, including patient management workflows, but it is not designed as a full CTMS.

Will qualitative research (patient interviews) be tracked using Epic tools at initial launch?
Our intention is to build patient questionnaires into the system from Day 1 and expose those via patient portal (MyChart). This is an iterative process – starting with core questionnaires (across all specialties), then at the specialty level, then eventually at the provider level (in the future).

**Research Administration**

Does the Connect Care Research component connect with NACTRC?
Yes, the Connect Care Project is working in Partnership with Provincial Research Administration and other partners, such as NACTRC. Data systems provisioning will be completed by the Provincial Research Administration (PRA) team, but systems cannot be provisioned until NACTRC issues Administrative Approval (in Edmonton Zone) or PRA (in all other zones). PRA and NACTRC work together to verify approval status of studies.

Recruitment methods must be submitted to HREBA. How would you include the Connect Care database as a recruitment tool?
This is determined during the intake process by PRA reviewing study needs. Researchers receive a questionnaire from PRA requesting the names of specific data repositories.

How is Research cost administration managed? E.g. cost for applying inclusion/exclusion, identifying patient cohorts, etc.?
For now, all study-centric costs will be tracked the same way they are today. Patient-centric costs will be reportable and tracked in the CIS.

**Research – other**

Has it been decided whether research study consents will be part of the consent navigator?
Study consents are approved as part of the patient’s record of care. The process for researchers to upload consent letters to Connect Care is yet to be determined. For the initial launch, consents will be scanned; during optimization enabling consents for the navigator will be considered.

Is there a risk for unmasking for double blind studies?
Double blind studies have been discussed as a scenario for particular consideration. We recommend double blind study orders be performed on paper requisitions outside of the system or that an unblended study coordinator be assigned access to the CIS.

Will we need to re-consent participants in long term studies to have access to the data in Connect Care?
Recommendations for consent are provided by our Research Ethics Boards and are dependent on the nature of the study.

Could we suggest that a real study coordinator walk through entire system with real patient?
Yes, this is planned.

**Connect Care Initiative**

How is the existing clinical data being populated into Connect Care for Day 1 go live?
How do you identify your cohort if you need data from legacy systems? Also what do you see as the role of the person accessing this specific data?

When data is required for a study from an AHS data repository, including the new CIS, the Principal Investigator requests access and you may be able to use new self-serve, in-system inquiry and reporting tools.

Will the existing database in use in our clinic be converted and stored?

This depends on the specific database in question, whether it is remaining, and the governance body that is approving. [List of applications for conversion](https://extranet.ahsnet.ca/teams/Architecture/SitePages/Connect%20Care%20Architecture%20-%20Conversion.aspx).

With eClinician (EPIC) BPAs had to go through CISU, and this was a failure. Will this be self-serve?

The research services support model will be phased-in to ensure prioritized functionality for launch is available first followed by additional services to support novel recruitment approaches and patient outreach. Most clinical tools will not become self-serve. We will still have a central review/approval/build process, though it will likely be different from the pre-existing process.

**Analytics Administration**

Will DIMR continue to exist and pool with existing AHS data using PHN linkage?

Analytics (DIMR) will continue to exist as will the EDW (AHSDRR). The EDW contains data from AHS, Alberta Health and other external data sources linking on PHN and other key fields, as required.

Does all study data get uploaded to the Caboodle Data Warehouse? What about non-study patients?

Caboodle will not be available for the November 2019 launch; it should arrive as part of an upgrade during future rollouts. These enhancements allow users to use SlicerDicer starting from the data set of research studies, or the population of patient-study associations. All patient information is uploaded in Caboodle, including study and non-study patients. DIMR will still be the main repository and Caboodle will be a database within DIMR. As a result, access will still be through DIMR and add-on products will be potentially be available within that framework.

Will we be able to add on another reporting product to the new/update data warehouse?

We do not plan, at this time, to integrate any REDCap databases with Connect Care or the data warehouse for launch. This will be an optimization project. As previously mentioned, data from outside of AHS can be accessed via Caboodle; however this will not be available for the November launch. Incorporating REDCap data would require data standards and use of shared patient identifiers across the various systems.

What is the process for requesting historical paper charts?

If the data is not in Connect Care, current processes would continue to apply.
Information Privacy

Does the study team have access to full patient’s chart?
Yes, AHS and University-based research team members including coordinators will have access to the CIS according to their approved study role and access.

Is the data stored in Canada?
Yes, the data is stored on Canadian servers.

Who are the study monitors? How are they selected and assigned? Trained?
For industry studies with external monitors, there is a release to study monitor workflow that is available to research study teams. The monitors will have access to the full chart of the patients that have been released to them. The Universities/AHS would give them View Only access, so they can perform monitoring duties. For internal study monitoring there will be a specific role and access to support study oversight.

Can you provide detail regarding access for external monitors/auditors?
If study monitors are accessing via provider portal (EpicCare Link) – the interface is very straightforward and requires little structured training.

If Study monitors are going to have full access - what is the expected timeline to get them access and what steps are required for completion by them/steps involved.
Plans for providing this access are still in development.

Has direct contact of patients for recruitment been approved? HIA does not allow direct contact.
In AHS facilities, if there has not been access to health information for a patient, a Research Coordinator may directly approach the patient. If health information has been accessed for this patient before approaching the patient, an AHS intermediary (i.e. – a trusted member of the Patient’s care team). Must confirm the patient is comfortable with being approached. When the patient is approached outside of AHS facilities, the PRA team may assist with identifying the appropriate route for contacting the patient, including assisting with mail outs.

What checks and balances exist for using the new data access tools (SlicerDicer, Reporting Workbench, Radar Dashboards) to ensure people are authorized to access retrospective data? Will they need to enter an REB number?
This depends on the type of study. The requirement for ethics approval and the individual access assigned to the person requesting the data. Patient confidentiality: HIA still takes precedence when accessing patient information

Data Quality/Governance

What is definition of data quality? Completeness, correctness, applicability of context to care? What are the tools checking for?
DIMR is developing a data quality position paper and will participate in data quality discussions sharing the framework and processes currently in place as requested and required. DIMR is working with Critical
Care to capture their practice for monitoring and remediating data quality at source (i.e., ensuring required fields are entered with accurate data).

What are plans for data quality assurance?
All reporting content will be tested during implementation to ensure that the reports/dashboards are configured correctly and that the appropriate data is included/excluded from each report. There is also the potential for an existing QA process at AHS, to be incorporated into the testing of reporting content to ensure that the data quality meets AHS standards. DIMR is developing this process.