Research – The Connect Care Clinical Information System: System Overview

Introduction

The Connect Care Clinical Information System is an electronic tool that provides healthcare providers one central access point to patient information, common clinical standards and best healthcare practices. A single CIS will be implemented across Alberta *wherever AHS holds the legal record of care*. As part of Connect Care, a single Clinical Information System (CIS) will be implemented across Alberta. The vendor that has been selected to provide the software for this CIS is Epic.

Implementation

Connect Care will be in place everywhere Alberta Health Services (AHS) provides healthcare services and where we partner to provide healthcare services using the AHS record of care. This includes: Hospitals, Clinics, Continuing Care, Cancer centres, mental health facilities, AHS-run community health sites, Carewest, CapitalCare, Covenant Health, Calgary Laboratory Services and DynaLIFE locations. Connect Care will also allow patients to access their information electronically from wherever they have Internet access. Connect Care implementation is happening in multiple waves to minimize disruptions for patients and healthcare providers. There will be nine implementation waves in total, happening between late 2019 and late 2022.

The Connect Care CIS implementation is helping to address the fact that as of 2019, AHS has more than 1,300 independent health information systems, many which help manage patient information. One such system is eCLINICIAN which will be replaced on November 3rd 2019 by Epic Ambulatory (version MAY 2019) which is one part of Connect Care. eClinician currently operates on Epic Ambulatory 2014. Other systems will be replaced in alignment with the Connect Care implementation timeline.

Connect Care Data

Through the system design, AHS is working to ensure we incorporate international data standards into the Connect Care. This will enable us to share our health system and patient outcome data with other health authorities or jurisdictions. AHS will store information in a provincial data centre, which has ample capacity for the recommended computing and storage equipment that Connect Care will need. All patient information will be controlled by AHS and stored in Alberta.

Four enterprise-level data centres – two in Edmonton and two in Calgary – will share the data processing load for Connect Care. These distributed data centres ensure data safety and continued performance in the event of a data centre outage. All Connect Care data will be stored on AHS-owned servers located in Alberta. The system architecture is designed so that even a complete loss of a single data centre would result only in a brief, temporary outage before switching to an alternative data centre. If the network connection to a data centre were completely lost or a major power outage occurred, each facility would be

able to access business continuity functionality to maintain access to patient data. Clinical data will be stored in at least three different data centres so that even if two data centres were completely lost, the Connect Care data would be restorable. In summary, as information within the CIS is mirrored, it is essentially backed up in real time, continuously.

Compliance and Certification

Many research users ask whether the Connect Care CIS is 21 CFR Part II compliant? In brief, current Food and Drug Administration (FDA) guidance states that Electronic Health Records (EHRs) are not subject to 21 CFR Part 11 and that The Office of National Coordinator for Health Information Technology (ONC) Certification is the standard required. For current certification information, see Epic's ONC Health IT Certification Details document. A white paper providing more details on this can be found here.

Additional System Information

System Description: A privacy impact assessment (PIA) has been submitted to the Office of the Information and Privacy Commissioner of Alberta (OIPC) which provides a CIS system description available outlining the descriptions of the system functionality and architecture. This document provides diagrams of data flow and all legal authorities. We expect excerpts of this document to become available after review and approval by OIPC.

Vulnerability Assessments: AHS is committed to conducting regular vulnerability assessments on Connect Care. These will include physical and technical assessments. Risks will be documented and prioritized based on severity. If vulnerabilities are uncovered that impact Connect Care, Epic has an established process for notification and remediation. AHS has designed and built Connect Care to allow for a faster update process when system updates are released. AHS conducted a vulnerability assessment during the design and build stages of Connect Care and is in the process of addressing the findings.

Monitoring: Study monitors can view patient records to perform monitoring. The process for how external study monitors will be provisioned for access to the system to review patient charts is in an interim state of implementation and will be communicated to the research teams upon implementation. *As part of interim state, until external study monitors can be provisioned access to the view portal, monitors can continue their existing approaches with study teams.* Interim state process is as below:

For studies that are being run in previous eClinician sites (now launched as part of Connect Care, Wave 1)
- Interim state will be the same as before CC – Monitors will have access to the chart via "over the shoulder" view. The "over the shoulder" view can be done with both eClinician (for retrospective data) and Connect Care for current data.

For studies that are being run in previous paper chart sites (now launched as part of Connect Care, Wave 1)
- Interim state **(Until Epic Care link is available)**:
  - For data/chart information after November 3rd, 2019: Users will have to allow monitor access through "over the shoulder" view.

The Connect Care Provider Portal (CCPP) is a web-based application that allows external study monitors to view AHS patient information in Connect Care. CCPP Users can audit study protocol compliance and data capture by cross-referencing the information submitted by the local study team with source documentation. Users will be using the CCPP to review health information released to them by study staff for this purpose. The CCPP enables AHS to limit user access to information about patients approved for the research study they are monitoring and provides an audit trail that was not possible with paper charts. Users must complete the privacy training (via video) and the "Introduction to Connect Care Provider Portal" prior to gaining access to the CCPP. Completion is monitored by AHS IT based on their active directory accounts.

Retention: As with all of AHS records, the CIS and the patient records included within are retained in alignment to the AHS Records Management Policy (#1133), and the AHS Records Retention Schedule (#1133-01). Of specific note, for records related to Clinical Trials including information related to adults and minors participating in clinical trials - which includes assessment, diagnosis, screening and treatment of a client in an acute care, ambulatory care, community care, continuing care, mental health, and rehabilitation setting, and further includes identity of the client, diagnosis, reason for health services encounter, justification for treatment and documented results, research completed or date of discharge / last contact/ deceased - there is a 25 years records retention requirement. This is in alignment to the Health Canada Guidance for Records Related to Clinical Trials - Section 6.

The Connect Care research support team can be emailed with any further questions or concerns at cc.research@ahs.ca and more can be found out about the Health System Access team and System Innovations & Programs at http://ahs.ca/research.

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Connect Care