LHS Case Study

University of Minnesota Efforts to Optimize Anticoagulant use in COVID-19 Patients

Soon after the COVID-19 Pandemic began in early 2020, the University of Minnesota (MHealth Fairview)Team recognized the importance of hypercoagulability in COVID-19 and wanted to provide evidence-based support for decisions about using anticoagulation for patients in their healthcare system hospitalized with COVID-19. They sought to do this in a 'learning health system' context that would optimize the cycle from evidence to guidance to action to data and back to evidence. They worked closely with the ACTS initiative and others to support these efforts. Their activities and collaborations can be a springboard for broadly enhancing knowledge ecosystem function in a target-focused manner across many targets and settings, as outlined in the ACTS LHS Proposal.

Below is a DRAFT/UNVETTED overview of UMN's LHS efforts for anticoagulation in COVID-19 patients. The purposes for sharing this information here are to illustrate how 1) initiatives such as the ACTS COVID-19 Evidence to Guidance to Action Collaborative can support target-focused LHS enhancement efforts within and across stakeholder organizations and 2) this work can provide a model that can be adapted to build on work and collaborations producing the ACTS LHS Concept Demonstration to advance the ACTS LHS Proposal.

- Launching Clinical Decision Support to Address a Priority Need (*Integrate tools into systems and workflows - current state*)
    - Early in the pandemic UMN implemented a home-grown, non-standard-based CDS intervention to reflect their experts' assessment of the best evidence-based approach to anticoagulation in this new patient cohort.
    - This work highlighted the need to track evolving evidence and guidelines on the topic to keep their CDS intervention current.
    - It also highlighted the difficulties of sharing CDS interventions on the target across collaborating organizations.
- Managing Evolving Guidance (*Produce Living, Local Guidance*)
    - As the pandemic unfolded, a UMN hematologist on the project team manually created a table listing the anticoagulation recommendations for COVID patients from major guidelines, sorted by population (e.g., hospitalized patients in ICU vs. non-ICU settings).
    - Maintaining the currency of this table was a challenge. It was hard to know who was producing guidelines, when the guidelines were updated, and what the changes were when a guideline was updated.
    - The ACTS Computable Evidence and Guidance Tools Requirements Project was developing a set of non-contextualized requirements (features, capabilities, functional and technical requirements) for tools to create, store, manage, and disseminate computable evidence and guidance. The group refocused these efforts in mid-2021 to create 'contextualized requirements,' with this need to track evolving COVID anticoagulation evidence and guidance as an example use case. An 'experiential requirements development approach' was applied to create an actual demonstration of a Recommendations Summary Browser focused on COVID anticoagulation.
        - The Recommendations Summary Browser (Table) was developed by taking each relevant recommendation from selected guidelines and creating a computable form of the recommendation, then creating a summary table that selects computable recommendations meeting the specific criteria (target population and intervention) and displays selected details (name of organization, population, recommended action, strength of recommendation, date of recommendation). This was seen by many stakeholders at UMN and other organizations as a promising approach to getting a quick summary of all the relevant guidance, but this revealed two additional challenges to overcome.
            - The tool itself did not signal what is new or changed since the last time it was viewed, or have a feature for notification when recommendations change. (Such notifications are a planned enhancement to this demo tool.)
            - The other challenge is that there can be a significant delay between when important new evidence is published and when guideline panels adjust their recommendations. Links to sources to search for current evidence were added to the demo tool, but there was no way to see the collective evidence on the topic and how this evidence base has changed since the recommendations were generated.
    - *Broader Implications - advancing standards*
        - FHIR Resources for Recommendation can make the effort above reproducible, interoperable and reusable; Recommendation Resources are under active discussions now with the HL7 CDS Work Group to propose these as new FHIR Resources, **an action stimulated by these ACTS activities**
- Managing Evolving Evidence (*Aggregate/Synthesize Living Evidence*)
    - Finding and Sharing Evidence
        - A UMN CDS project lead was challenged by the need to communicate the new and complex evidence regarding anticoagulation dosing for patients hospitalized with COVID-19 to inform groups making decisions about CDS implementation.
        - He found the detailed summaries of the Evidence on the FEvIR Platform (the computable evidence - e.g., as surfaced in the Recommendations Summary Browser) highly useful.
        - He recognized the value of the overall summary function of the Recommendations Summary Browser and needed an analogous tool to support browsing pertinent evidence as it evolves. That is, to inform possible updates to the UMN CDS intervention before guideline panels update their recommendations in response to new, potentially practice changing evidence.
        - On August 31, 2021, he asked Computable Publishing LLC through the COVID-19 Knowledge Accelerator if an "Evidence Summary Browser" could be created; these organizations immediately prioritized the development of the Computable Publishing: Evidence Report Viewer.
        - By September 15, Computable Publishing LLC created the Evidence Report Viewer and summarized this new COVID anticoagulation evidence across 4 Evidence Reports (FHIR structure for presenting information related to scientific knowledge [as opposed to patient data]). the following Evidence Reports provide standards-based, computable expressions of:

        - Anticoagulation for Non-critically ill COVID-19 Multiplatform RCT EvidenceReport (https://fevir.net/18816): a critically appraised summary (risk of bias assessment) of the primary outcome (organ support free days) in this trial published in NEJM
        - Anticoagulation for Non-critically ill COVID-19 RAPID trial RCT EvidenceReport (https://fevir.net/18824): a critically appraised summary (risk of bias assessment) of selected outcomes in the trial published in medRxiv preprint
        - Anticoagulation for Non-critically ill COVID-19 Individual RCTs Table EvidenceReport (https://fevir.net/18831): a table showing side by side the 2 RCT summaries above
        - Anticoagulation for Non-critically ill COVID-19 Summary of Findings from RCTs Table EvidenceReport (https://fevir.net/18881): a table showing results for selected outcomes (from meta-analyses where available or from individual trials when no meta-analysis was available). These meta-analyses were reported in the medRxiv preprint.
    - Computable summary information as outlined above offers promise for making it easier to understand precisely what the results of studies show and to precisely understand how confident (or uncertain) we are in these results, so that their potential implications for changing practice can be fully assessed.
- Evaluating Evidence
    - Computable Publishing LLC recently developed ClinicalTrials.gov-to-FHIR Converter, and is tracking ClinicalTrials.gov entries related to COVID-19
    - In this process, they discovered pertinent studies (e.g., the RAPID trial - see here for computable summary) available as preprints (and they were not being considered for guideline updates while still in preprint form)
    - This team also noted that the multiplatform RCT on COVID anticoagulation published in NEJM on 8/4/21 was lacking in many critical appraisal dimensions
    - COKA/CP LLC built into the FEvIR Platform the Comment/Rating Builder to enable many to contribute to Post-publication Review, and used this tool to create a multi-party critical appraisal of NEJM COVID anticoagulation report (see here for this appraisal in a FHIR format)
- *Broader Implications - advancing standards*
    - FHIR Resources for Evidence and ArtifactComment make the effort under "Evaluating Evidence" noted above reproducible, interoperable and reusable
        - ArtifactComment is under active discussions now with the HL7 CDS Work Group to propose these as new FHIR Resources, **an action stimulated by these ACTS activities**
    - FHIR Resources for EvidenceReport make the effort under "Managing Evidence" noted above reproducible, interoperable and reusable
        - EvidenceReport is maturity level 0 (a draft resource) – in discussions by HL7 community about how it best fits in FHIR, but HL7 has agreed to support an EvidenceReport Profile of Composition Resource
    - FHIR Resources for Evidence and EvidenceVariable are maturity level 1 – accepted by HL7 community and led by the EBMonFHIR/COKA project

Making CDS Interventions Standards-based, Interoperable (*Create Tools*)

- The UMN Team is working with the COVID-19 Digital Guideline Working Group (C19 DGWG) and a health IT vendor (Apervita) to create a SMART on FHIR app version of the COVID anticoagulation CDS UMN has had in place since early 2020.
- **This ACTS LHS concept demonstration is fostering deeper explorations between UMN and their EHR vendor** (Epic) around opportunities for Epic to more robustly support UMN's efforts on this, and for UMN to help Epic understand how they can more broadly help their client base with these needs.
    - *Broader Implications:* rather than having conversations like this playing out *only* in pairwise fashion between CDOs and their EHR vendors and others, it would be more efficient and effective if these were complemented by conversations across many CDOs and EHR/HIT vendors to ensure progress toward the interoperable, robust knowledge ecosystem outlined in the ACTS LHS Concept Demonstration. For example, the governance and coordination mechanisms outlined the ACTS LHS Proposal can be used for such cross-CDO/cross-health IT supplier synergy cultivation.

Sharing / Disseminating Tools and Guidance

- UMN plans to freely/publicly share their COVID anticoagulation SMART on FHIR CDS app - e.g., via the CDS Connect artifact repository and Epic's App Orchard. See the Marketplace portion of the ACTS LHS Concept Demo for more information about the challenges and opportunities related to CDS app marketplaces. See the ACTS LHS Concept Demonstration for examples of next steps that can be taken to realize such marketplaces that meet stakeholder needs much better than current options.

Integrating CDS Into Systems and Workflows

- UMN has a proven track record for developing and scaling clinician-acceptable CDS from both within and outside their institution, with over 20 implementations annually. Their approach is called "SCALED" (SCaling AcceptabLE cDs), and an article describing this approach is under review at a peer-reviewed journal [update as appropriate]. As with many CDS implementations though, UMN has faced challenges with optimal clinician leverage of their COVID anticoagulation CDS. There is an opportunity for UMN to further enhance the efficiency of effectiveness of their CDS deployments by leveraging insights synthesized in other playbooks and tools, e.g., as outlined in the Guidance Implementation portion of the ACTS LHS Concept Demo.

Gathering, Analyzing and Applying Data about Care Processes and Results

- UMN has a robust process for gathering and analyzing data about COVID anticoagulation-related care processes and results [details]. They use this information to drive quality improvement efforts for this COVID anticoagulation target [details] and have also prepared a manuscript for submission to a peer reviewed journal [update as appropriate] describing their results so this information can expand the evidence base for this target.
- The lack of standardized data models for patient data impedes this work. To address these gaps, UMN [need some additional details about the following items and to explain the implications for readers and ACTS Concept Demo and proposal]:
    - Is implementing Clinetic pipeline for EPIC data pre-processing and standardization
    - Hired a PhD Terminologist to develop terminology server and map entire EHR to OMOP (completed 6/2021) standard.
    - Hired 3x ETL/Data Analysts to develop automated pipeline to process EHR data into a real-time database
    - Is developing external collaborations with other health systems with preprocessed EHR real-time databases
    - Is participating in N3C
- To address lack of standardized plumbing [define what this means] UMN implemented FHIR APIs across the M Health Fairview system and hired FHIR Development team.
    - UMN and their EHR vendor (Epic) participating together in the ACTS COVID Collaborative and LHS Concept Demo effort provid ed opportunity to align Epic's Development priorities (e.g., related to FHIR resource support) with UMN so their needs can be addressed efficiently and effectively. **Recommendation for others:** include EHR vendor in integration and API discussions so they can provide information and connections to resources to address those needs.