Implementing Clinical Decision Support Tools in a Clinic Setting

Clinical and Research Processes and Steps

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1. **Develop initial project plan:**
    - ❖ Project title and aims/description of the project
    - ❖ Who is the study team?
    - ❖ Type of study – prospective/retrospective
    - ❖ Timeline
    - ❖ Resources – Recruitment, Data intake (Redcap), Data pull (ICS)
    - ❖ Funding sources – Did you request Informatics funding?
    - ❖ Recruitment Criteria – Inclusion/Exclusion
    - ❖ Data collection –
        - Legacy data need vs Epic or both
        - Discrete data vs open/free text
        - Where does the data live in Epic
        - Data Elements needed:
            - ✓ Demographic
            - ✓ Encounter
            - ✓ Diagnosis
            - ✓ Procedures
            - ✓ Labs/Vitals
            - ✓ Medication
            - ✓ Financial (billing)
            - ✓ Provider
            - ✓ Other

2. **Draft clinical and research processes** for feedback.
    - ❖ Determine how much integration needed.
        - For external applications integrated with EPIC - include the plan to create an entry in App Orchard to enable EPIC integration.
        - For minimal builds and/or primary research projects - traditional EPIC1 build team can assist with this, e.g. link to external site.
        - Fast Healthcare Interoperability Resource (FHIR) – allows one to use a tool across systems
3. **Budget and fees** – determine if fees will be set per hour, or tailored to the project.
    - ❖ **Please request an estimate before submitting a grant proposal**. Projects can be more than what PIs might initially think, and the worst-case scenario would occur if projects are funded and then unable to be completed as submitted with the budget allocated.
    - ❖ CCE, I^2 and EPIC do not have the same rates. Once guidance is given on which teams should be involved in the architecture of the build, contact the appropriate group for a budget estimate.
    - ❖ May need external consultants which are more expensive.

4. Contact the CCS if you need Research recruitment/coordinator resources or guidance. Submit Request Form through **Institute for Informatics (I^2) or Epic1 team –** depending on your research needs**.**
    - ✓ **ICS Data Services**: I2 Data Services
    - ✓ **I2 Website: About the Institute | Institute for Informatics (wustl.edu)**
    - ✓ **Epic1 Research**: Epic1 Research
    - ✓ **Epic1 Website:** Home (epic1.org)
    - ✓ **Epic TIPSheets: Epic Learning Home Dashboard** – Reporting and Research
    - ✓ **CCS Website**: Services | Center for Clinical Studies (wustl.edu)

5. **Additional Approvals/Reviews Needed:**
    - ❖ **Large Projects:** If your project is very large, requires multiple resources or involves a third party vendor, discuss the project with the **Clinical Research Steering Committee**. They meet monthly and can help advise on:
        - Is this research?
        - Is this clinical?
        - Is this feasible?
        - Is this a priority at the hospital level?
        - Will you need IRB approval?
        - Do we have the funding and resources?
    - ❖ **BPAs or Recruitment Reports**: Discuss the project with the **Special Project team.** They meet every 2 weeks. This committee can assist if you need a BPA (Best Practice Alert for Research) or report in Epic for recruitment. This group can also advise about the plan or you are ready to move to the process of implementation (for research or clinical purposes).
    - ❖ **Interfaces operations approval** is needed when CDS tool has data interface or data transfer, for example, when using FHIR. (Interface refers to the data interface, not the user interface). This does not include REDCap Smart on FHIR.
    - ❖ **MyChart team approval** is needed if sending bulk messaging to patients that are not consented (e.g. Recruitment). **If patients are consented**, and you are sending messages to a study patient on a treatment study, you do not need approval.
    - ❖ **Ambulatory operations approval is n**eeded when projects involve widespread implementation for patients or providers who might not have consented or know about the implementation.
        - This is not be needed, for example, when working with one clinic or group of providers whose leadership has given a Letter of Support.
        - This approval will be needed if implementing the tool widely after research study is completed. Currently, an EPIC 1 analyst will stop the CDS tool from working in EPIC after the study closes, for study-specific projects.
    - ❖ Present at **Clinical Champions Meeting** if widespread implementation in clinical care. For example, when a project ends, you would like all providers or all patients to have access to a CDS tool via a link on the Epic homepage or MyChart home page, or via direct integration into the EHR.

- ❖ **CCE approval** – approval required if using CDS tool as a Best Practice Alert (BPA). BPA appears for all patients meeting the criteria. (Usually not applicable during a research study, might be used for widespread implementation after a study.)
- ❖ **Security Review** is needed for any data transfer project with large vendors or implementation of a new platform/tool (research or clinical project). This is a long process and it is best to have a programming team representative submit on a PI's behalf given the details requested.
    - Depending on the project, approval may be required from both Washington University and BJC security review. In some instances WU security approval is suffice for BJC.
    - Security review timeframe is uncertain. Consider this when creating the project time line.
    - People involved can be HIPAA team, IRB team, BJC informatics, WU IT, attorneys.

Other considerations:

Data:

- Address **data governance issues** (for PHI) at this stage and understand how the requirements vary at different institutions, hospitals and clinics who might be involved.
- Consider how the risk model (if model is involved) will **stay up-to-date** as research emerges.
- Consider **transparency of data** – ensure clinicians and patients understand how any risk data (score) is calculated when using risk data to inform care decisions.

Timeline:

- Review the **timeline** and sequence of approval process with the programmers at I2 or CCE to implement the tool within the project timeline.
- If implementing this tool with an outside institution, consider additional steps required for approval, the sequence and time line which could be months long. For example, approval may be required from: IRB, stakeholders, chief medical information officer, and prioritization (EPIC) committee in a specific order for the project to advance.

Testing:

- **Usability testing** - Before launching the CDS tool, elicit feedback through usability testing. Then communicate to programmers and/or designers if problems occur with the code or changes to the tool are needed.
- **Soft launch** – After usability testing and once satisfied with the CDS tool, begin using the tool with a small number of clinicians and patients to address workflow concerns.

IRB:

- **IRB jurisdiction –** BJC sites that are not part of the main hospital campus may require an Institutional Agreement Form (IAA) or separate IRB for recruitment, ex. Christian North East.

Recruitment - CCS:

- **Volunteer for Health –** consider contacting for help with recruitment at WU. (Instead of staff screening charts, report or other algorithmic mechanism may be an option for recruiting.)

Research operations meeting:

- Monthly meeting during which new EPIC tools and upgrades are discussed. May be useful for coordinator staff to attend. Please contact the Epic1 Research team to be added to this meeting - hipresearchteam@wustl.edu

Audits:

- When screening through EPIC research staff should be saving MRNs of those screened.
- The ICS staff will retain all MRN's of participants that engage in studies that data extracts were performed in their audit log database.

❖ **Please see the Tip sheets, Websites and Decision Tree for further guidance on the services that ICS, CCS and Epic1 provide.**