Document Purpose

The purpose of this report is to document recommendations for the ORCATECH life lab related to The Hofer-Price Pilot Project’s Specific Aim 1.

Document Versions

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>0.01</td>
<td>Initial Draft</td>
</tr>
<tr>
<td>0.02</td>
<td>Feedback from Scott Hofer and Vincenza Gruppuso</td>
</tr>
<tr>
<td>1.0</td>
<td>First version shared with ORCATECH</td>
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Project Rationale

This work is part of the current project between ORCATECH and IALH at University of Victoria: “Incorporating Conventional Clinical Data into Remote Home-based Assessment”. Part of the project is to connect five homes in Victoria to the ORCATECH infrastructure at OHSU. That work is ongoing through the UVic Institute on Aging and Lifelong Health. Part of the project is to explore options for connecting practices with ORCATECH in meaningful ways. This report relates to the later, and it relates to Specific Aim 1.

Specific Aim 1

To identify and classify the key EMR-based data-types that may be most amenable to actionable and meaningful use at two levels: 1) determining added value or utility of these conventional clinical data types in conjunction with remotely sensed continuous data as well as home-based self-report in building prediction algorithms for clinical outcomes, and 2) based on this knowledge, providing a framework for how to best present this integrated data to clinicians. Embodied in this aim will be understanding the cognitive challenges and the logistic challenges of health system based information including issues of data ownership, consent and potential security and privacy concerns.
Study Approach

ORCATECH Data
Data being collected by ORCATECH was reviewed with consideration to elements that would be of value to a primary care clinician. Specifically, each data source in ORCATECH was reviewed for data types that would have immediate value with little or no additional training.

EMR Data
EMR data was considered, reviewing several existing interoperability standards. The upcoming HL7 FHIR standard was considered and the data elements summarized with consideration for use in ORCATECH.

Architectural Options
Finally, a review of existing interoperability approaches was undertaken. Leveraging our research group’s Canadian and international experience with interoperability, we propose an architecture that would allow for ORCATECH data to be shared with clinicians through electronic means. The report focuses on conceptual architecture as the specific architecture will vary between healthcare systems, for example the actual implementations will vary between EMRs in BC and between HMOs in the US. Architectural patterns and common approaches were considered and a review and mapping of datatypes was completed as part of this work.

This architecture was reviewed at the UVic in an iterative manner to improve its description.

Findings
First, we review the various ORCATECH data collection methods, highlighting content that would be meaningful to a primary care clinician and some of the values and challenges to interoperability. Next, we attempt to categorize the data. Finally, we describe a range of conceptual architectural options for interoperability between ORCATECH and clinical information systems (CISs).

ORCATECH Data Collection
Data collection in the ORCATECH project occurs in multiple ways through a number of assessments, some of these are through an interview and / or physical exam and some are through patient reported outcomes, others are collected through electronically connected devices in the home.

Initial Assessment
As part of agreeing to be part of the ORCATECH project, a battery of baseline assessments are completed with the participant. These include both clinical and neuropsychological testing. The assessment includes a wide range of domains and takes some time to complete. There are different sets of assessments that are completed, depending on certain criteria. For example, the following assessments are completed for “UDS3, odd year”:

- A5: Subject Health History
- M-CIRS (Modified Cumulative Illness Rating Scale)
- NCSE (Neurobehavioral Cognitive Status Examination)
• B4: Global Staging – CDR (Clinical Dementia Rating)
• Neurological Exam
• B1: Physical Exam
• Modified UPDRS (Unified Parkinson Disease Rating Scale)
• Tinetti Gait (OBAS)
• Tinetti Balance (OBAS)
• B8: Physical/Neurological Exam Findings
• B9: Clinician Judgment of Symptoms
• D1: Clinician Diagnosis
• D2: Clinician-Assessed Medical Conditions

The subject health history includes a range of topics from common diagnoses, substance use, to mental health. Several of the tests included in the initial assessment are standardized tests with details that can be summarized into a reportable scale (e.g., the Global Staging - Clinical Dementia Rating, Tinetti Gait Scale).

Several of the measures used have overlapping content. For example, Alcohol Use is screened in multiple tools. In the NACC UDS, alcohol use asks about frequency of use (at least one drink in a day) over a three-month period. Later, it asks about clinically significant impairment impacting an aspect of life over the last 12 months. In the OBAS-PAFH Baseline alcohol amount per day is quantified and screening related negative consequences are included.

Many of these tests have standardized reporting, which is important for reproducibility and consistency. While the results are standardized for the instrument, these results do not appear to be linked to standardized terminologies / ontologies. This has an impact on how easy it would be to provide integration of the data into a CIS. For example, many of the diagnoses are recorded by tick box, but these would need to be mapped to a more standard nomenclature such as ICD or SNOMED to be used in a CIS. In looking at the breadth of content in the initial assessment, this work would be manageable, but would require a specific project to do that work and a clinical informatics working group to review and validate the mappings. Some of this work may have been done within ORCATECH already or with other research groups, but that is not clear.

Passive Monitoring
Key to the ORCATECH living lab is a collection of passive monitoring tools that are connected to the university and pass data electronically, in real time, to the ORCATECH. Passive monitoring includes real-time movement data as well as several connected devices for weight, etc. Some of these data could be easily consumed by a CIS, such as weight. Some of the data, such as motion tracking, have no clear place to be recorded in an EMR; however, summary statistics could be generated that would be meaningful. The best example of this would be gait. LOINC has a concept “Physical findings of Gait” (32433-5). SNOMED has many gait concepts, including gaits like: cautious gait, lurching gait, foot-drop gait, shuffling gait, and several others. It has concepts for findings like walk and walk on the flat. It also has concepts for the Tinetti balance and gait scales.

Weekly Survey
Participants are encouraged to complete an online weekly survey that gets information on:
• Activities related to home activities (being away from home, having visitors, changes to the home furniture) that would impact the reading of the motion sensors
• Changes in care (e.g. medications, hospitalizations)
  • Hospitalizations - dates, planned vs unplanned, ED vs admission, reasons
• Health events such as reporting falls
  • Falls: when, injury (yes/no), nature of falls
  • Injuries: persona, car, property, someone else
• PROMs, such as screening for low mood, loneliness, and pain.
  • Health limitations due to illness, infection, surgery, ADR
• Feedback on the weekly survey

From the weekly summary, there are several components that could be shared with an EMR, but work with providers would be needed to see how they want to receive this information as there could be a significant issue of content overload, especially if a provider has a large number of patients who are in ORCATECH (see the discussion). Rarer events such as hospitalizations, falls, and injuries might be events that providers want to be notified of, if they are not notified through other means.

Annual Review
The annual review is a more comprehensive assessment, similar to the initial assessment. See Initial Assessment for a description of the data collected.

ORCATECH Data Categories
The following table categorized the ORCATECH data into types that are relevant to the discussion of interoperability and clinical use.

<table>
<thead>
<tr>
<th>Data Category</th>
<th>Description</th>
<th>Volume / Freq</th>
<th>Provider Consumable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validated Assessment Instruments</td>
<td>There are a range of instruments used.</td>
<td>Annually</td>
<td>Many are consumable by the provider, however, volume would be a challenge for most providers.</td>
</tr>
<tr>
<td>Patient Updates on Status / Events</td>
<td>Recorded patient’s recent history</td>
<td>Weekly</td>
<td>Many would be, such as hospitalizations and some of these events are clearly clinically relevant.</td>
</tr>
<tr>
<td>PROMs</td>
<td>Recorded patient’s current function</td>
<td>Weekly</td>
<td>Some would be, especially if there are significant changes.</td>
</tr>
<tr>
<td>Biometric Data</td>
<td>recorded through instrumentation</td>
<td>weekly —&gt; continuously, depending on the device.</td>
<td>Some would be, particularly in the context of health conditions (e.g. CHF and rapid weight increase). Others (e.g. patterns of activity) are not yet ready for clinical interpretation.</td>
</tr>
</tbody>
</table>
EMR Data - FHIR and HL7

HL7 has been developing the FHIR clinical data standard (see https://www.hl7.org/fhir/) to support implementable interoperability that allows for sharing of data in a computable manner. It builds on previous HL7 work in this area and v1.0.2 and DSTU 2 is the current officially released versions as of 2017-Feb. It is free to implement with several implementation tools and appears to have support from industry. FHIR has additional elements described in their documentation and further review should be considered as part of an implementation project. FHIR can be extended with additional information and specific FHIR Profiles can be developed for specific needs. The development of a FHIR profile is a considerable amount of work, requiring HL7 and informatics expertise.

Another option is HL7 v3 CDA, which has been around longer. Typically, these interoperability documents are more verbose that FHIR, but there may be more local expertise and experience with these with the CIS and EMR vendor community. That is the case in BC and Canada.

If ORCATECH is considering consuming EMR data it would likely be through one of these standards. The build out of ORCATECH’s data platform to consume and manage a richer clinical information system’s data could be considerable and would require a deeper analysis.

**TABLE: EXAMPLE FHIR CLINICAL RESOURCE CONCEPTS (FROM HTTPS://WWW.HL7.ORG/FHIR/CLINICAL.HTML) WITH DESCRIPTION OF POTENTIAL APPLICABILITY.**

<table>
<thead>
<tr>
<th>Concept</th>
<th>Description (from HL7)</th>
<th>Applicability to ORCATECH</th>
</tr>
</thead>
<tbody>
<tr>
<td>AllergyIntolerance</td>
<td>Risk of harmful or undesirable, physiological response which is unique to an individual and associated with exposure to a substance</td>
<td>Known allergies may be relevant to ORCATECH</td>
</tr>
<tr>
<td>ClinicalImpression</td>
<td>A record of a clinical assessment performed to determine what problem(s) may affect the patient and before planning the treatments or management strategies that are best to manage a patient's condition. Assessments are often 1:1 with a clinical consultation / encounter, but this varies greatly depending on the clinical workflow.</td>
<td>This field captures diagnoses / impressions made at clinical encounters and thus may have temporal correlation with changes in patient status that can be seen in ORCATECH data.</td>
</tr>
<tr>
<td>Concept</td>
<td>Description (from HL7)</td>
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</tr>
<tr>
<td>----------------------</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Condition</td>
<td>Use to record detailed information about conditions, problems or diagnoses recognized by a clinician. There are many uses including: recording a diagnosis during an encounter; populating a problem list or a summary statement, such as a discharge summary.</td>
<td>Knowing long-term conditions from the provider’s perspective will reduce data collection burden and could be updated routinely.</td>
</tr>
<tr>
<td>Procedure</td>
<td>An action that is or was performed on a patient. This can be a physical intervention like an operation, or less invasive like counseling or hypnotherapy.</td>
<td>Procedure history like condition has value and receiving it through FHIR reduces collection burden.</td>
</tr>
<tr>
<td>FamilyMemberHistory</td>
<td>Significant health events and conditions for a person related to the patient relevant in the context of care for the patient.</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>This resource is primarily used for the identification and definition of a medication. It covers the ingredients and the packaging for a medication.</td>
<td>Medications, including instructions and the changes over time are important interventions that can impact data observed.</td>
</tr>
<tr>
<td>Immunization</td>
<td>Describes the event of a patient being administered a vaccination or a record of a vaccination as reported by a patient, a clinician or another party and may include vaccine reaction information and what vaccination protocol was followed.</td>
<td>May or may not be useful to know.</td>
</tr>
<tr>
<td>Observation</td>
<td>Measurements and simple assertions made about a patient, device or other subject.</td>
<td>This is a large set of potential elements from lab results to vital signs. These could be very valuable in correlating ORCATECH data with clinical status over time. Many of these are already coded (e.g. in LOINC) and this would aid in the automatic interpretation.</td>
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Interoperability Options

Through this review and analysis of interoperability, there are three broad options that could be considered for integration with care. They are highlighted (in red) in the figure below. Each option should not be considered in isolation, they can be used in conjunction.

**ORCATECH Scheduled Report (Push)**

In this option, ORCATECH pushes reports to an appropriate provider (or providers) at regular intervals of time to update the provider on the status of the patient, as assessed by ORCATECH. Timing would should be discussed with engaged clinicians, but a quarterly, biannual, or annual frequency may be most appropriate. Ideally, it would be linked to, for example, the timing of the annual assessment so that that information is current for the provider.

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<tr>
<th>Concept</th>
<th>Description (from HL7)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>DiagnosticReport</td>
<td>The findings and interpretation of diagnostic tests performed on patients, groups of patients, devices, and locations, and/or specimens derived from these. The report includes clinical context such as requesting and provider information, and some mix of atomic results, images, textual and coded interpretations, and formatted representation of diagnostic reports.</td>
<td>While these may be harder to interpret automatically, it could be very valuable to correlate diagnostic findings with ORCATECH status.</td>
</tr>
</tbody>
</table>
**ORCATECH Triggered Report (Push)**

In this option, ORCATECH pushes reports to an appropriate provider (or providers) based on defined trigger events. This would require a routine operation to occur in ORCATECH to query for triggering events. There are several trigger event categories that could be considered, including:

- **A specific event trigger** — in this trigger a single activity triggers a report generation and sending. For example, completion of the annual assessment.

- **A lack of an event trigger** — in this trigger it is the absence of an activity (likely over a specified time) that triggers a report. For example, a patient cannot be contacted within a period of time, no home-data for a period of time.

- **A result value trigger** — in this trigger it is the specific value of a result that triggers a report to the provider as compared to whether or not a data element exists. For example, a positive answer to the fall question or a positive answer to the hospitalization question could trigger the report.

- **A combination of results trigger** — in this trigger it is specific combinations of results that would trigger the report. For example, a patient that has CHF and a weight increase of 5 pounds would trigger an alert, but for a patient without CHF, this would not trigger an alert. Within this group, there are several triggers to consider, including:
  - **Change over time** — repeat measures of a single variable with a marked change over a short period of time, even if it falls within normal limits. Changing gait speed could be an example.
  - **Cumulative deficit** — repeat measure of a single variable over time that, individually, do not trigger an alert but with repeat scores become more clinically relevant. For example, a single low mood score that is not sufficient to trigger an alert but having that consistently low for months.
  - **Combinations of Data** - disparate data types that together can trigger specific alerts. The CHF example above is an example.

The triggering rules could become complex over time and the rational for reporting should be clear and highlighted to the provider.

**Provider Requested Report (Pull)**

In this model, a provider would be able to actively request a report from ORCATECH in real-time or near real-time on their patient. This could be through messaging between clinical information systems (e.g. EMR) and ORCATECH or could be through a web portal. The advantage to this model is the providers pull the information and thus are likely already engaged in the care at that point in time with the patient and there are reduced issues related to overburdening providers who are not engaged. However, in this model, there will be challenges in maintaining a current list of providers who may request access on a patient level, ensuring that the providers are who they say they are, etc.

**NOTE:** An additional option, making all ORCATECH data available to providers on demand was considered, but not explored extensively, due to the expected cognitive burden for providers to learn the meaning of the data. We would expect that this would reduce the number of providers willing to receive or ask for data.
Recommendations and Discussion

The specific interoperability options are very dependent on the local ecosystem where ORCATECH resides. As BC researchers, we are not familiar with the various overlapping healthcare systems that the patients in the life lab interact with or how Health Information Exchanges (HIE) are set up in Oregon. Thus, we have drawn on our national and international experience and principles on data exchange for the following recommendations. Further, we have kept our focus on conceptual design.

Interoperability Model

The two push models presented (scheduled and triggered) are likely the easiest to implement and can provide considerable flexibility for ORCATECH to get clinically meaningful information to care providers. Both the scheduled and triggered reports can be developed out incrementally and updated within ORCATECH as new evidence develops over time, requiring less work from the EMR vendors. A request model would be tricky to manage as ORCATECH would have to be in a position to manage electronic requests for information. This would require managing lists of providers (including credentials, passwords, etc.), which would be challenging to maintain over time.

If an HIE is available, it would make sense to align with the local / regional HIE. In BC, for example, it would be possible to leverage the Excelleris electronic results and report distribution system.

Report Format

A standard should be selected that would allow for a range of ORCATECH reports to be designed over time. HL7 has been doing this kind of work for years. A FHIR document may be able to contain much of the ORCATECH data, with some extensions. An HL7 v3 CDA document is likely readily consumable in the US by the most number of clinical information systems and could be transported to various HIEs. An ORCATECH specific CDA or FHIR document could be designed to include human readable information and coded information that would be computer interpretable. Much of the information captured by ORCATECH can be mapped to standard terminologies, such as ICD, LOINC, and SNOMED. Several of the assessment questions have idiosyncratic values (e.g. 9 for unknown) that would likely need mapping to a better data model.

Alternately an HL7 v2 message could be considered, depending on the local context, but we recommend exploring FHIR first.

Decision Support Triggered Reporting

To meet the needs above, there should be some clear triggers that are set for ORCATECH reporting. These should be simple, such as triggered by the completion of an annual review so that care providers understand why they are getting the reports. These triggers can also be more complex, based on the individual’s scoring (or lack of scoring). The specifics of the triggers will depend on ongoing development of ORCATECH’s knowledge base. It is challenging now to propose specific triggers as the evidence is developing. Over time the clinical oversight committee could be tasked with the review of proposed trigger sets, expanding over time. The triggers should start out simply and be stated in the reports.
Summarized and Clinically Meaningful Reporting
One of the challenges with providing ORCATECH data to busy care providers is volume. ORCATECH collects a lot of data — both from the passively collected biometric data and the data collected in the annual assessments. There is potential value in the data, but the value would likely be lost to the clinician in the volume of data. Thus, careful summarization is required to maximize the value of the ORCATECH data reaching clinicians.

ORCATECH reports should be provided to clinicians in a manner that meets the following criteria:
1. Volume is not overwhelming so it can be reviewed by a busy clinician.
2. Frequency is not too high so that regular reports become noise.
3. Response time (e.g. time from trigger to report) is short enough to allow for clinical response.
4. Reason for the report is clear, so the clinician is prompted to focus attention appropriately.
5. The data is focused on the reason for the report.
6. The data is contextualized so that it can be interpreted by the clinician. This could be completed in much the same way as some imaging and pathology reports or some laboratory testing. Providing additional reasoning for alerts (e.g. weight increase of 7 pounds in the context of CHF).
7. The data is actionable by the clinician, either directly or indirectly (e.g. through discussion with other members of the patient’s circle of care).

ORCATECH Receiving EMR Data
As part of the considerations of interoperability, we considered ORCATECH receiving information from EMRs and other clinical information systems. While there is a clear benefit to ORCATECH to receive or have access to the data held in various EMRs, there are also many hurdles to consider, including: willingness to participate (both EMR vendor and providers), consent, privacy, security, interoperability, developing data models in ORCATECH, and assessing data quality. These are considerable hurdles, and, thus, we suggest that this be considered at a later stage, once push interoperability is successful. Providers and patients will be more likely willing to work with ORCATECH as they receive benefits rather than just being a data source.

Future Work
As a proposed conceptual architecture, this design would need to be considered and tested in a real world implementation. Much more work is needed from this initial conceptual design document. For example:

- Evidence-based recommendations from ORCATECH data still need to be developed and this is ongoing work of the research.
- The specifics of the ORCATECH reports would need to be prototyped and clinically vetted before testing. Prototyping could be done with a small group of clinicians and tested in the real world without electronic interoperability.
- Interoperability capability in ORCATECH would have to be established. This would need to be mapped and connected to clinical information systems.
- CDSS rules would need to be developed to trigger the specific reports.
Summary

This report describes a review of the current ORCATECH data and presents considerations for interoperability of ORCATECH with clinical information systems, such as EMRs. Several options are presented as conceptual architectures and workflows for incorporating the “big data” of ORCATECH into care. An iterative approach is preferred, looking at pushing focused, clinically actionable reports to providers through HIEs to their EMRs first. Over time and based on experience and feedback, this work could expand to include more reporting. Future steps could include a bidirectional connection where ORCATECH can leverage EMR data in the ongoing longitudinal analysis.