

**DESIGNING USER INTERFACE REQUIREMENT PATTERNS FOR A
GENOMICALLY ENABLED CLINICAL DECISION SUPPORT SYSTEM
USING FRAILITY ASSESSMENT AS A PROTOTYPICAL EXAMPLE**

by

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Abstract

At present, the pervasive integration of genomics and other big data into routine clinical care has not been realized, particularly in primary care. One of the critical problems of personalized medicine is an effective and efficient presentation of large genomic data and evolving knowledge in a generalist clinical encounter setting.

To address this issue, this study aimed to design and evaluate a user interface for a genomic clinical decision support system intended for primary care physicians. This was a serial, multiple-methods study. This study focused on frailty and the clinically actionable aspects of the frailty lifecycle, such as risk assessment.

In phase one of this research, the Lead User method for the participatory design was used for the design of the user interface for genomically-enabled decision support. The concept ideation phase was followed by the design synthesis process in phase two. Phase two generated a set of system-agnostic and evidence-based requirement patterns and an integrated user interface design based on the patterns. In phase three, the integrated design was validated with Representative Users, and the patterns were refined.

The key novel contributions of this work were user interface requirement patterns for genomically-enabled clinical decision support and a requirement integration method that supported the pattern development.

The nineteen novel and validated requirement patterns are geared towards primary care providers as clinical users. The produced patterns addressed the presentation of CDSS notifications at the point-of-care and the display of detailed personalized risk information, including the risk factors and suggested interventions to address risk. These patterns are technology-agnostic and provide information to future implementers of clinical information systems. Producing theoretically-grounded and user-validated design patterns for presenting large evolving clinical data and knowledge, rather than a particular implementation, allows for this work to be relevant in various software-intensive clinical systems and contexts.

Methodologically, the study contributed by developing a requirement integration method that is practical, reproducible, and applicable to a wide variety of design problems where it is necessary to synthesize multiple design perspectives. The method ensures traceability of requirement origin and evolution. It supports theory-informed design and triangulation of evidence.

Lay Summary

This study aimed to design and evaluate a user interface prototype for presenting clinically actionable recommendations to a physician at the point of care when assessing a patient's frailty risk in the context of when there is wide-spread, integrated genome/phenome information.

The study addressed one of the key challenges of personalized medicine: how do clinicians feel that an EMR can help them to manage the enormous volume and complexity of the big data, such as the human genome, in a busy clinical setting, such as primary care.

The research leveraged participatory design methods by engaging family physicians as co-designers and usability evaluators through a series of expert interview sessions.

The outputs of the study were a set of system-agnostic and evidence-based requirement patterns for a genomic clinical decision support system and a novel requirement solicitation, integration, and validation method to support the pattern development.

Preface

This dissertation is an original intellectual product of the author, I. Davies. None of the text of the dissertation is taken directly from previously published articles.

The fieldwork reported in Chapters 4 and 6 was covered by UBC Ethics Certificate number H18-00637.

The design synthesis work was conducted by myself and my Ph.D. Supervisory Committee: Dr. Morgan Price, Dr. Jens Weber, and Dr. Sabrina Wong.

The design method used in the study is a refinement and extension of the Lead User method developed by Dr. Eric von Hippel.

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List of Abbreviations

CDSS – Clinical Decision Support System (singular or plural)

CFT – Cognitive Fit Theory

CLT – Cognitive Load Theory

DCog – Distributed Cognition

EMR – Electronic Medical Record

HCI – Human-Computer Interaction

IGM – Integrated Goal Model

SDM – Strategic Dependency Model

UI – User Interface

UTAUT - Unified Theory of Acceptance and Use of Technology

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Special thanks are owed to my family, who have supported me throughout my years of education in every possible way.

Dedication

To my family

INTRODUCTION

Chapter 1: Study Objectives, Approach, and Overview

1.1 Research Objectives

The study intended to explore the challenges for incorporating big data such as genomics into primary care through clinical decision support systems (CDSS). The study also aimed to document and test possible design solutions for this complex problem.

The specific objectives of the study were:

1. *Produce system-agnostic and evidence-based requirement patterns for a genomic CDSS using frailty risk assessment as a clinical use case by:*
 - a. *creating of a prototypical UI design for a novel genomic CDSS, through a participatory Lead User design and*
 - b. *validating the UI design with Representative Users.*
2. *Develop a systematic and reproducible method for requirement solicitation, integration, and validation to support pattern development.*

1.2 Overall Approach

To reach the study objectives, a qualitative, serial, three-phase, multiple-methods study was designed.

In Phase One of this research, the Lead User method was used for the participatory design of the UI for a genomically-enabled CDSS for point-of-care risk assessment. The Lead Users were defined as clinical experts with interest/expertise in decision support design, genomics, and geriatric frailty. Geriatric frailty was used as an illustrative clinical example for genome and phenome integration in primary care. The Lead Users provided their visions for the desired UI through a series of one-on-one semi-structured interviews with the researcher. This concept ideation stage of the study was followed by the design Synthesis process in Phase Two.

The Synthesis entailed the requirement analysis across the Lead Users. It resulted in an integrated set of UI design requirements documented as evidence-based requirement patterns, and an integrated UI prototype based on the requirement patterns.

In Phase Three, the requirement patterns were tested for external validity by testing the integrated prototype with Representative Users. The usability assessment employed task-based scenarios and a survey on the perceived acceptance and usefulness of the system.

This study resulted in a set of evidence-based validated UI requirement patterns for a genomic CDSS and the novel method for requirement engineering.

1.3 Dissertation Outline

The body of this dissertation contains five sections briefly described here:

Introduction – Describes the objectives of the study and summarizes the approach used to reach the objectives.

Background – Provides the context for this study and includes literature reviews on the foundations of this research: genomic medicine in primary care, CDSS and their potential for personalized medicine, and the informational components of preventive personalized risk assessment. This section also provides an overview of frailty as a clinical use case for this study. Further, the section focuses on the theoretical perspectives adopted for this research. The section also provides the background on the Lead User methodology adopted for this study. It also describes the goal-oriented modeling approach used to document and analyze Lead User requirements. Lastly, the section explains the requirement pattern as a means of encapsulating genomic CDSS requirements developed in this study.

Methods – Describes the methods for the three phases of the study: (1) Lead User Design, (2) Synthesis, and (3) Validation. Detailed data collection and analysis workflows and documentation templates are included. The method development and refinement were iterative, where the results of the study informed the method.

Results – There are three results chapters, one that describes the findings for each phase of the study and how the findings relate to the study objectives. The first phase results include the contextual analysis of frailty assessment, followed by the description of individual Lead User requirements and prototypes for a genomic risk assessment CDSS. The second phase results present a synthesis of the requirements in the form of patterns and an integrated UI prototype that supported the patterns. The third phase results present the validated requirement patterns based on Representative User usability testing.

Discussion – This section reflects on the key outputs of the study that supports the study objectives: the requirement patterns and the developed requirement integration method. The section highlights the key themes that have emerged from the findings. The contributions and the limitations of the deliverables are also discussed along with potential future work to address the limitations. This section also includes a brief summary of the research as a conclusion.

BACKGROUND

Chapter 2: Primary Care and Genomic Medicine

2.1 Primary Care as a Complex Socio-Technical System

This study focuses on the design of a CDSS for the primary care domain. For this reason, primary care is examined from the socio-technical perspective in an attempt to understand the CDSS setting. Research shows that if an artifact is examined and designed with little regard for the context in which it is intended to function, it may result in suboptimal implementation and adoption outcomes (Norman 2013). A techno-centric approach to system design may produce a system that meets its technical requirements but is still considered a failure if it does not deliver the support for real work that users expect and need (Baxter and Sommerville 2011). This problem has been exemplified by CDSS that, despite wide recognition of their importance in delivering quality, have not been adopted in routine care (Sittig et al. 2008).

A richer form of analysis and design is often necessary for technology to succeed, one that entails examining the ecosystem in which technology and its users interact. Socio-technical systems design is a form of such holistic approach to design that incorporates human, social, organizational, and technical factors as interdependent components that influence the functionality and usage of a computer-based system (Baxter and Sommerville 2011). One of the information technology domains where the socio-technical perspective has been specifically encouraged is health informatics (Whetton 2005; Eason 2007).

Primary care is a complex environment with multiple types of participants, tools, policies, and constraints. It satisfies the five key defining features of a socio-technical system defined by Badham et al. (Badham, Clegg, and Wall 2000): comprised of interdependent parts; adapts to and pursues goals in external environments; has an internal environment that contains separate but interdependent technical and social subsystems (people, work context, organizations); has equifinality (goals can be achieved in different ways); its performance depends on joint optimization of technical and social subsystems.

Various specific theories can be applied to a socio-technical system to analyze the social, technological, and behavioral issues involved in complex domains (Waterson et al. 2015). See Chapter 5 for the specific theoretical perspectives adopted for this study.

2.2 Genomic Medicine and Primary Care

Genomic medicine is the clinical pillar for this study. Therefore, the reader is briefly oriented to the concept of genomics and the current state of evidence for genomically-enabled CDSS UI design.

Genomics is the science that studies the full complement of genetic material encoded in an organism's DNA (Genome Canada 2017). In a broad sense, the term genomics also includes all related disciplines such as epigenomics, transcriptomics, proteomics, and more. Genomic medicine is a discipline that involves using genomic information about an individual as part of their clinical care (National Human Genome Research Institute 2016). This study embraced this definition.

The integration of genomics into clinical care is a prerequisite for the realization of personalized medicine (Flores et al. 2013). Indeed, some appreciable progress has already been made in this regard. Prediction of disease (onset and rate of progression) and prediction of treatment response (efficacy and toxicity) have been influenced by genomic information (Larson and Wilke 2015). The two domains that have spearheaded clinical utilization of genetic and genomic patient characteristics in care are pharmacology and oncology (Welch and Kawamoto 2013). While promising, this progress has been mostly restricted to specialist settings. For example, prescribing informed by gene-drug relationships is primarily implemented in cardiology and a few other specialties (Unertl et al. 2015). In the future, pharmacogenomics is likely to become a routine practice in primary care, but it has not been the case yet. Similarly, oncogenomics is mostly utilized by cancer care specialists, who have more significant clinical experience with molecular diagnostic techniques. It is the broader clinical community, not the specialists alone, that has to be involved in the genomic application of knowledge to patient care for translational genomics and personalized medicine to become widespread. This specifically applies to primary care physicians who typically are the first line of contact for patients. Moreover, it's been noted that clinically important gene variations often influence multiple clinical outcomes (Paaby and Rockman 2013). As the primary care providers play a significant role in maintaining continuity through longitudinal follow-up, they are uniquely positioned to help utilize genomic information through a patient's lifecycle (Larson and Wilke 2015).

Translational genomics has many challenges to overcome before it is routinely practiced at the point of care. Genomic data is enormously large, complex, and has far-reaching implications given its sensitive and informative nature. The essential issues related to genomic data utilization in health informatics systems include storage, analysis, clinical interpretation, privacy

and security safeguards. There have been considerable efforts to address these issues. However, the problem of how to present patient genomic data with the relevant phenotype variables and clinically actionable recommendations at the point of care has remained a mostly nascent research area. This is an important problem to address, given that UI design and workflow integration have been recognized as the biggest challenge for CDSS (Sittig et al. 2008).

In preparation for this research, a scoping review was conducted to assess the current state of genomically-enabled CDSS at the point of care in the ambulatory settings (the review has not been published as of this writing). Three publications were discovered where a point-of-care genomically-enabled CDSS designed for primary care were discussed (Alzubi, Zhou, and Watzlaf 2017; Pennington et al. 2017; Shyr et al. 2016). All were prototypical systems. Two addressed a very narrow aspect of the CDSS, such as presenting a specific genetic test result without further exploring how the result would be incorporated into patient care (Pennington et al. 2017; Shyr et al. 2016). One had a broader scope but described very high-level desired CDSS characteristics such as ‘easy-to-use’ without providing any further guidance or evidence (Alzubi, Zhou, and Watzlaf 2017). None of the three publications contained extensive or specific CDSS UI design guidelines, which would be needed to consistently incorporate genomically-enabled CDSS into EMRs.

There are several prominent initiatives such as the Electronic Medical Records and Genomics (eMERGE) Network¹, the Clinical Genome (ClinGen) Resource Project², and Implementing

¹ <https://www.genome.gov/Funded-Programs-Projects/Electronic-Medical-Records-and-Genomics-Network-eMERGE>

² <https://clinicalgenome.org/>

Genomics in Practice (IGNITE)³ consortium that are relevant to this study in a broader context. These initiatives are working on integrating genomic data into care, including primary care domain. Currently, however, the publications from these initiatives do not yet include specific lessons learned for the best CDSS UI approaches (Williams et al. 2019).

Overall, the literature on clinical genomic integration tends to focus on the ethical, social, economic, and other broad challenges of the integration. The bioinformatics challenges and how they could be addressed are often discussed on a high level. Few papers examine concrete technical aspects of integrating genomics into primary care (Masys et al. 2012; Welch et al. 2014), and even fewer address any aspects of the UI design (Pennington et al. 2017; Shyr et al. 2016). This sparse evidence for clinical implementation of genomics to address the needs of the primary care providers makes a compelling argument for this research work.

³ <https://www.genome.gov/Funded-Programs-Projects/Implementing-Genomics-in-Practice-IGNITE>

Chapter 3: CDSS

3.1 What is a CDSS?

A CDSS can be defined as an electronic system that assists health care providers, patients, and other stakeholders in the decision making process by providing pertinent knowledge, such as advice and guidance, and patient-specific information, intelligently filtered and presented at appropriate times, to improve health and healthcare (Osheroff et al. 2007). A CDSS can assist clinicians and patients with decisions around preventive and monitoring tasks, prescribing, and diagnosis and management of disease (Institute of Medicine (US) Committee on Quality of Health Care in America 2001). CDSS use information technology to help physicians avoid errors and improve efficiency in healthcare with the ultimate goal to benefit the patient and society overall (Patel et al. 2008).

CDSS can be classified based on their effect on clinical workflows: passive or active (Bell et al. 2014). Passive CDSS may include patient data reports, documentation templates, dashboards, and order sets. An active CDSS is typically based on predefined rules, such as clinical practice guidelines and protocols, which generate alerts, reminders, and suggestions. A CDSS may include a combination of passive and active features. A CDSS in an EMR may be an integral part of an EMR or an external system integrated into an EMR. Regardless of what type of CDSS is implemented, essential characteristics of an effective CDSS are that it enhances and eases clinical workflows; makes the workflows safer and more efficient; is not burdensome to its users (Richardson et al. 2010).

It has been widely recognized that appropriate use of CDSS is a requirement for achieving desirable levels of patient safety, care quality, patient-centeredness, and cost-effectiveness

through consistent, systematic, and comprehensive application of health-related knowledge (Osheroff et al. 2007; Chaudhry et al. 2006). There is empirical evidence demonstrating that CDSS can have a significant positive impact on patient care delivery (Kawamoto et al. 2005). However, a sub-optimally designed CDSS can also result in adverse outcomes for physician performance and patient care (Jaspers et al. 2011). There are many challenges for a successful CDSS with usability being one of the key potential shortfalls (Sittig et al. 2008). For example, one of the well-known factors that can hinder the CDSS effectiveness is alert fatigue that may result from redundant alerts (Ancker et al. 2017) or an overload of alerts with low specificity and low clinical relevance (Carli et al. 2018). Other recognized design-related barriers for successful CDSS usage are inadequate workflow integration (Liu et al. 2006) and cognitive overload associated with excessive amounts of extraneous information presented to the user (Faiola, Srinivas, and Duke 2015). These CDSS design challenges will likely increase with the integration of genomic and other big data into patient care.

3.2 Is a Genomically Informed CDSS Different?

The need for high-quality decision support for providers, patients, and other stakeholders is particularly highlighted in the context of personalized medicine, which includes complex and large genomic data (and other big data, such as passively-collected sensor data, for example) as one of the key components (West et al. 2006).

Next-generation sequencing technologies are now capable of generating enormous amounts of data in relatively short periods of time at an affordable price (Mardis 2013). Typical high-throughput whole-genome sequencing identifies over 3 million variants per person (Pelak et al. 2010), and whole-exome sequencing, on average, identifies 12,000 variants (Ng et al. 2008). Epigenomic analysis can already describe hundreds of thousands of regulatory elements per

patient's tissue type (Rivera and Ren 2013). The rate of growth for genomic data (for humans and other organisms) over the last decade has been rapid, with the total amount of produced data doubling every seven months (Stephens et al. 2015). This data acquisition rate is expected to grow as the cost of sequencing is going down, the technical sequencing abilities are improving, and the case for personalized medicine is gaining more appeal. Stephens et al. (Stephens et al. 2015) estimate that by the year 2025, up to 2 billion human genomes could be sequenced.

It is obvious that the enormous complexity and volume of genomic data far exceeds the boundaries of human cognition and requires effective CDSS at the point of care. For genomics to make its way into routine clinical practice, it is critical that the physicians, patients, and other stakeholders are presented with the right information at the right time in a way that does not impose an excessive additional cognitive burden (Sittig et al. 2008).

Traditional CDSS are usually based on a set of predefined rules aimed at supporting clinical workflows and processes (Richardson et al. 2010). A typical CDSS may take in several patient parameters; algorithmically analyze them based on clinical guidelines or other protocols; and produce a set of outputs such as alerts and care-plan templates. Even most advanced traditional CDSS operate on a relatively small set of inputs. However, this conventional approach is insufficient in the context of very large datasets, such as a patient's genome. A genomic CDSS must have the computational capacity to integrate big and complex genomic data with relevant genomic knowledge and pertinent phenome data. Privacy and security concerns of highly sensitive data such as a patient's genome also require specific considerations, although privacy and security must be respected for all types of patient data. Further, a genomic CDSS needs to distill the big data inputs into clear, clinically actionable, evidence-based information that

supports decision making at the point of care. The latter challenge must be addressed by the effective and efficient design of the CDSS UI. Currently, the evidence for how genomic and other big data can be best presented to a health care provider is limited (Dagliati et al. 2018). Therefore, more research is needed to determine if big data CDSS UI requirements are different from the traditional CDSS.

Chapter 4: Preventive Personalized Risk Assessment

4.1 What is Personalized Risk Assessment?

One of the emerging applications of genomic medicine is CDSS for preventive personalized health risk assessment. Personalized health risk information conveys the probability of future health outcomes, such as diseases or complications, for an individual patient. It is an increasingly common form of clinical evidence (Han et al. 2013).

With the advent of direct-to-consumer genetic testing, patients are becoming more familiar with the personalized risk assessment concept (Roberts and Ostergren 2013). This may cause more patients seeking genomically-based risk assessment from their health care providers.

Individualized risk information can be generated by a CDSS based on clinical prediction models that utilize patient data (for example, longitudinal data from an EMR and other big patient data such as genomics or passively collected sensor data) and clinical evidence to estimate individualized probabilities of a health outcome (Dagliati et al. 2018). Such statistical CDSS risk estimation algorithms would produce personalized risk as quantitative data.

4.2 Challenges for Presenting Personalized Risk Information at the Point of Care

There are a number of design challenges that need to be carefully addressed when considering a genomically-enabled CDSS for personalized risk assessment. The specific challenges that were relevant to this study were displaying risk notifications to a clinician as part of a clinical encounter as well as presenting detailed risk information, including specific patient risk factors and the suggested interventions to address risk.

4.2.1 Displaying Risk Notifications

The literature offers a number of evidence-based design principles for displaying CDSS notifications/alerts. Marcilly et al. (Marcilly et al. 2018) have collated such principles from various publications into six high-level guidelines: improve the signal-to-noise ratio (reduce unnecessary over-alerting); support collaborative work; fit the clinicians' workflow and their mental model; display relevant data within the alert; make the system transparent for the user; include actionable tools within the alert. Although these design principles were intended for a medication alerting system in a hospital or primary care context, they are informative for other kinds of alerting and notification systems such as risk assessment for a health outcome.

4.2.2 Presenting Probabilistic Information

Risk presentation can influence how an individual perceives risk (Timmermans, Ockhuysen-Vermeij, and Henneman 2008). Risk perception, in turn, can potentially affect medical decisions and behavior changes (Jones et al. 2005). Therefore, providing adequate health risk presentation, as part of a personalized risk assessment, is an important CDSS design problem.

Quantitative risk information can be challenging to accurately interpret for both the health professional and patient due to inherent human cognitive limitations (Tversky and Kahneman 1974). Moreover, understanding the probability of a health problem occurring may be particularly difficult in a care setting that involves stress, time pressure, and information overload posed on a provider and patient (Slovic et al. 2005) – all likely characteristics of a typical primary care encounter.

Individual differences, such as psychological biases, in information consumers also play a significant role in how risk is perceived (Gerrard, Gibbons, and Reis-Bergan 1999) as do varying degrees of numeracy fluency (Lipkus and Peters 2009; Wong et al. 2012). Further, there are significant differences in risk perception for different conditions (Shiloh et al. 2013).

The target information consumers for risk information presented by a CDSS in primary care are health care providers. However, a provider likely needs to communicate the risk information to a patient and often the patient's caregivers. Individualized calculation of risk in the communication between a provider and patient may have a more beneficial effect on key outcomes (screening, treatment choices, and modification of risk behaviours) than other forms of personal communication (Edwards et al. 2000). This requires considering optimal approaches to risk presentation for a range of audiences.

Risk presentation encompasses both an informational context and presentation format.

4.2.2.1 Informational Context

Regardless of the specific format of presenting outcome likelihood, a comprehensive understanding of risk requires a broad informational context in which to interpret the risk (Weinstein 1999).

Absolute vs. relative risk

The patient's risk can be presented in absolute or relative terms. However, individuals tend to over- or under-estimate relative risk information, and thus it is best to communicate risk in terms of both absolute risk and relative risk (Fischhoff, Brewer, and Downs 2014).

Uncertainty

A key element of risk information is uncertainty, where uncertainty is the range of risk estimates (Johnson and Slovic 1995). The variability of patient data quality, the strength of clinical evidence, and risk estimation algorithms necessitate presenting risk assessment in terms of a range of risk estimates rather than a point estimate. Some research suggests that people may not always adequately process high-level statistical concepts, such as confidence intervals, and not adjust their perception of numerical information for its overall quality (Peters et al. 2007).

Baseline Risk

One of the essential pieces of information that should be presented with the individualized risk score is baseline risk for a similar population with the similar characteristics and no other risk factors can be used as a base rate. The provision of baseline information results in more accurate risk estimates, irrespective of what format is used for risk communication (Natter and Berry 2005).

Risk Timeframes

The time span chosen for a risk score can influence risk perceptions (Fischhoff, Brewer, and Downs 2014). Therefore, risk timeframes are a necessary part of the informational context – a risk score is uninformative otherwise.

Interpretive thresholds

Interpretive thresholds, if any exist in relationship to a numeric risk score, can help understand risk magnitude (Lipkus 2007). For example, thresholds could specify ‘typical likelihood’ or ‘increased likelihood’ of an outcome.

Specific outcomes

Another key component to present along with probabilistic risk information is specific outcomes because risk can be viewed as a combined function of the probability of loss and consequence of loss (severity) (Lipkus 2007).

4.2.2.2 Risk Presentation Format

Three types of formats can be used to present quantitative health risk information: numeric, textual, and visual (Lipkus 2007). Each has its benefits and limitations.

Numeric Presentation

Numeric formats, such as percentages, probabilities, odds, and frequencies, offer precision. On the other side, some numeric formats may be difficult to interpret (Gigerenzer 2011; Sinayev et al. 2015) or may not be what information consumers, such as patients, need to aid in understanding risk (Zikmund-Fisher 2013).

Textual Presentation

Textual terms (often referred to as verbal terms in the literature) to express risk (e.g., high, medium, low) can be more intuitive, evoke emotion, and be easily understood, yet they lack

precision and can be perceived differently by the information consumers (Renooij and Witteman 1999).

Visual Presentation

Graphs can make numeric information easier to understand by reducing the amount of mental computation and replacing it with automatic visual perception (Wickens and Carswell 1995).

The most commonly suggested graphical formats for presenting individualized health risk are pictographs (Fischhoff, Brewer, and Downs 2014), risk scales or ladders (Ancker et al. 2006), and bar charts (Holmes-Rovner et al. 2005; Schapira, Nattinger, and McHorney 2001). Figure 1 presents sample visualizations of these four graphs for illustration purposes.

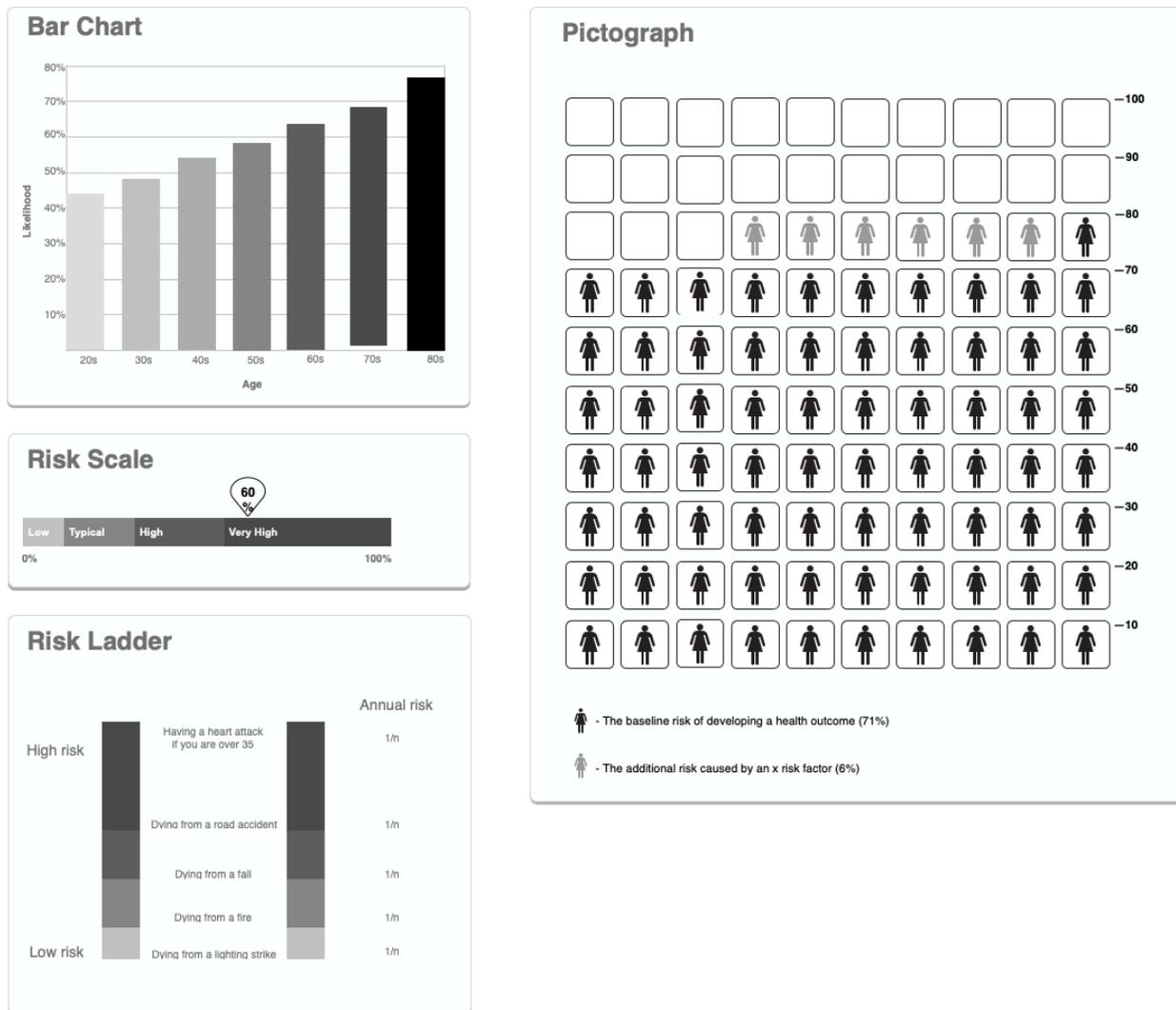


Figure 1 Common visual risk presentation formats

Pictographs

Pictographs are icon arrays that display a risk at the discrete level of measurement. Individual icons may be dots, faces, stick figures, or other graphics. Pictographs are better understood and provoke a more affective reaction, compared to percentages or proportions (Ancker et al. 2006). Pictographs are the optimal type of graph to communicate both gist and verbatim knowledge (Fischhoff,

Brewer, and Downs 2014). Pictographs with a random arrangement of icons may communicate randomness better than continuous arrays (Baty et al. 1997). However, continuous array pictographs allow people to use visual area judgment better to estimate proportions (Feldman-Stewart et al. 2000). It may also be more advantageous to use human figures for icons, as some users may find human icons more meaningful and easier to understand and identify with (Schapira, Nattinger, and McHorney 2001). To support sound quantitative judgements, the size of graphic elements in a pictograph should be proportional to the number it portrays; and the numerator and denominator should be visually salient (Ancker et al. 2006).

Risk scales and ladders

A risk scale or ladder is a continuous data scale. Some researchers postulate that because a patient's risk on a scale or ladder is evaluated as the distance from a baseline, such representation exploits the most efficient visual perception skill (Lipkus and Hollands 1999).

Bar charts

Bar charts are a suitable visualization approach to facilitate comparisons, particularly as a function of subgroups – comparing the magnitude of risk by different criteria such as age, sex, or race (Lipkus 2007). Bar charts are typically accurately interpreted because they exploit basic graphical perception abilities when judging positions or lengths against a scale (Cleveland and McGill 1984).

The evidence on the optimal universal risk presentation format for accurate risk interpretation/perception and promoting positive behavior change is inconclusive (Akl et al. 2011; Gigerenzer 2011; Timmermans, Ockhuysen-Vermeij, and Henneman 2008; Woloshin et al. 2000). This is likely because, as discussed above, the optimal presentation format is context-specific and may depend on many factors, including the care setting, the characteristics of the target information consumers, the nature of a condition, or outcome that the risk pertains to, the magnitude of risk. Therefore, when designing and implementing a UI that presents detailed individualized risk information, such factors should be considered. A potential strategy for presenting risk is using multiple formats for numerical risk by taking caution with qualitative modifiers (Lautenbach et al. 2013).

4.2.3 Presenting Risk Factors

Another key consideration for displaying personalized risk information is the optimal way to present the risk factors. Risk factors are individual characteristics, tests, historical information, etc. that predispose an individual to a health outcome (Kelly 1992). Antecedent factors for an outcome provide an important informational context for a risk score. They highlight how the constituent parts of the probability can or cannot be altered and thus help with risk assessment and interpretation (Rothman and Kiviniemi 1999). Providing risk factors can also help the CDSS users understand how a CDSS calculates the risk score. This knowledge may facilitate better trust in a CDSS (Bussone, Stumpf, and O'Sullivan 2015).

Patient risk factors for a health outcome have several dimensions that should be considered when presenting them to a provider. Risk factors can be classified as modifiable or non-modifiable (Bussone, Stumpf, & O'Sullivan, 2015), may have a wide range of evidence quality (Guyatt et

al. 2008) and described by the degree of contribution to the overall risk (Jostins and Barrett 2011). Many risk factors, and especially those from a typical EMR, are likely to have some data quality issues (Ray and Houston 2005) (data quality is discussed further in this chapter). Additionally, risk factors can be differentiated from protective factors – the characteristics that are associated with a lower likelihood of a negative outcome (Feng et al. 2017).

A health outcome can potentially have a large number of risk factors relevant to the patient. This will be particularly true with the pervasive availability of large datasets in routine clinical care and advanced risk estimation algorithms (Chen et al. 2012). Many conditions, such as common chronic diseases, have complex, multifactorial etiologies that involve the interplay of genomic risk factors, environmental risk factors, and other health conditions (Chatterjee, Shi, and García-Closas 2016). Polygenic risk prediction models already use tens of thousands of genomic loci to estimate the risk (Kong et al. 2015).

This study focused specifically on the presentation of genomic data at the point of care. However, other types of big patient data (e.g., patient-collected sensor data such as sleep and exercise) likely present similar issues (Cornet and Holden 2018).

Deterministic aspects of a patient's genomic information are generally not inherently different from other risk factors commonly used in health care prediction models (Evans and Burke 2008). However, effectively presenting patient risk factors that include big and complex data in the context of a primary care encounter has distinct challenges (Christensen et al. 2016).

4.2.4 Highlighting Data Quality

Individual patient data, longitudinal EMR data, and genomic data are key inputs for the genomically-enabled CDSS predictive models that generate personalized risk scores (Bates et al. 2014). However, such data are challenging for analysis, in part, due to data quality issues (Rose 2018).

Data quality in a clinical context can be defined as “the totality of features and characteristics of a data set, that bear on its ability to satisfy the needs that result from the intended use of the data” (Arts 2002). Many factors influence the quality of patient data. For genomic data, data quality issues may stem from biological, instrumental, environmental, or interpretation issues (Wu et al. 2017). For EMR data, quality problems may be caused by measurement and documentation errors (Chan, Fowles, and Weiner 2010). Moreover, data collection frequency plays a role in data quality. Collection frequency can vary for different data types: DNA data is generally invariant and typically requires one-time data acquisition; other genomic data may vary with environment, tissue types, and time and require multi-time-point acquisition; clinical variables in the EMR can change over time and typically have irregular sampling frequencies (Wu et al. 2017). The variability of collection frequency and varying length of available patient history may mean that some data that are important for generating a risk score are not available or outdated.

It is important to bring the data quality issues to the provider’s attention because erroneous, missing, and outdated patient data influence CDSS confidence (Hasan and Padman 2006). The provider may be able to take immediate data remediation steps such as update the patient’s

history or observations or order an investigation. Improving patient data quality may result in a more accurate risk score estimation.

4.2.5 Presenting Suggested Interventions to Ameliorate Risk

The suggested interventions to ameliorate risk help people develop a mental model that delineates the relevance of a given risk (Rothman and Kiviniemi 1999). When the risk for a health problem is being considered, information about what can be done to prevent the problem is integral in the clinical context for both the provider and the patient (Rothman and Kiviniemi 1999). Further, different presentation of an intervention's risks and benefits can impact clinical decisions (Carling et al. 2008).

The benefits of an intervention can be presented using absolute risk reduction (ARR), relative risk reduction (RRR), or number needed to treat (NNT). One of the most consistent findings in the literature is that, for communicating risk reductions of interventions, RRR, compared with ARR or NNT, may be perceived to be greater and is more likely to be persuasive for both health professionals and patients (Carling et al. 2008). However, presenting RRR alone can result in the overestimation of risk reduction and thus lead to misinterpretation (Akl et al. 2011). The drawback of the NNT may be that it is the most difficult format for patients to understand (Fischhoff, Brewer, and Downs 2014).

Risks and benefits of an intervention are typically presented as probabilities or frequencies. The literature appears equivocal on the best approach (Fischhoff, Brewer, and Downs 2014).

Engaging the information recipients in the process of risk evaluation may increase their understanding of risk and the likelihood of changing their behaviour to reduce risk (Emmons et al. 2004). One potential approach for CDSS user engagement is interactive risk calculators that allow the user to manipulate results of the risk score by selecting interventions and seeing how altering certain risk factors through interventions might change the risk score (Lautenbach et al. 2013). An example where interactive risk calculators are used for presenting individualized risk is 23andMe direct-to-consumer reports⁴. The 23andMe calculators utilize pictographs to visualize the risk information and how it changes with interventions.

4.3 Frailty as a Clinical Example for Risk Assessment

Integration of genomic medicine into clinical practice through effective CDSS will be relevant to most if not all aspects of patient care – from prediction to prevention to diagnosis and management. All aspects of human wellness and disease are influenced by genomics to some degree (Robinson 2016). However, centering on a specific clinical use case is helpful for defining the design scope, both for the designers and clinical users engaged in the design process. Therefore, this study focused on frailty and the clinically actionable aspects of the frailty lifecycle such as risk assessment.

Frailty can be described as “a state of increased vulnerability to poor resolution of homeostasis after a stressor event, which increases the risk of adverse outcomes, including falls, delirium, and disability” (Clegg et al. 2013). It is a common clinical condition in older adults associated with aging and the decline in reserve and function across multiple physiologic systems (Xue 2011).

⁴<https://www.23andme.com>

Frailty is not defined by a list of specific diseases but is a multisystemic and multifactorial condition, which encompasses the state of the entire organism on micro and macro levels (de Vries et al. 2011). It involves a complex interplay of physiological, environmental, and social factors (Walston et al. 2006). While the study of frailty in the context of genomics is relatively new, there are a growing number of studies on the association of frailty with genomic, epigenetic, proteomic and metabolomic biomarker signatures (Breitling et al. 2016; Collerton et al. 2014; Darvin et al. 2014; Fazelzadeh et al. 2016).

Frailty is a relevant topic in modern healthcare. It is a common condition associated with aging and a leading cause of death in seniors (Gill, Gahbauer, Han, & Allore, 2010). A systematic review on the prevalence of frailty in community-dwelling older persons showed that the overall frailty prevalence was around 10% and pre-frailty around 44% with higher frailty rates in women than in men (Collard, Boter, Schoevers, & Oude Voshaar, 2012). Another compelling statistic is that over a quarter of people older than 85 are estimated by some studies to be frail (Song, Mitnitski, & Rockwood, 2010). The population is aging globally, and the rate of aging is accelerating – with 461 million people over 65 in the year 2004 to an estimated 2 billion people by the year 2050 (Kinsella & Phillips, 2005). With the aging population trend, the prevalence of frailty is expected to increase. Frailty leads to poor health outcomes such as increased morbidity and mortality and has a significant burden on individual and societal levels (Clegg et al. 2013).

Early identification of at-risk individuals allows for early intervention when reversal or halting of frailty's progressive exacerbation may be possible and most effective (Puts et al. 2017). It has been shown that preclinical detection of frailty on molecular, cellular, and physiologic levels,

coupled with early interventions, is the most effective way to ameliorate health outcomes (Cameron et al. 2015).

Frailty risk assessment makes a compelling use case for enhanced decision support given the intricacy and dynamic nature of the associated genome, phenome, and environmental variables; frailty's prevalence and significant burden on personal and societal levels; and the importance of early risk identification and timely interventions.

Chapter 5: Theoretical Lenses for System Design

5.1 Role of Theory in System Design

A theory provides the means to outline the object of study and to highlight important issues for consideration (Barthelme and Anderson 2002). Halverson (Halverson 2002) defines a theory as a conceptual tool for making sense of a domain and providing additional leverage to the analysis of the problem. Halverson proposes that theories have four key powers: descriptive, rhetorical, inferential, and application. Halverson describes these attributes as follows. The descriptive power provides a conceptual framework that describes and makes sense of the world. The rhetorical power lies in the ability of the theory to name important aspects of the conceptual structure. The rhetorical power employs language and helps us talk about the system and describe it to others and ourselves. The inferential power represents the ability to make inferences or predictions about phenomena or consequences of interventions. The application power has to do with how theory applies to the real world for pragmatic reasons such as translating theory into concrete design guidelines. These four attributes can be helpful in theory selection and evaluation.

Many different high-level principles can be applied to HCI design depending on the nature of the system, as well as the goals set out by the designers. Typically, different theories relevant to HCI are not mutually exclusive but rather bring various aspects of HCI into focus. There are, but a few theories native to HCI as the majority of theories leveraged in HCI come from a variety of disciplines, for example, computer science, software engineering, economics. However, the root of theorizing about human thought and behavior processes such as learning and decision-making lies in psychology. As J.M. Carroll put it, HCI is a science of design that aims to understand and support humans interacting through technology (Carroll 1997). He called HCI an illustrative

example of psychology as a design science. The reader is referred to Crook & Sutherland (Crook and Sutherland 2017), who provide detailed examination of the progression of learning theories that pertain to technology and design.

5.2 Prominent HCI Theories

Each type of theoretical approach provides a different kind of explanation to the phenomenon under study and can be applied to HCI for various levels and scope of analysis. Table 1 gives examples of some of the most commonly mentioned theories in HCI literature from different theoretical traditions.

Table 1 Prominent HCI theories

Theoretical Tradition	Theory/Framework	Theory Originators	Key Principles
Behaviorism	Behaviorist Theory of Learning (Classical Conditioning, Operant Conditioning)	I. Pavlov, B.F. Skinner, J. Watson	Learning is based on stimulus-stimulus and stimulus-response-reinforcement
	Social Learning Theory	A. Bandura	People learn from each other, acceptance of mediating structures, role of emotions; bridge theory between behaviorism and cognitivism
Cognitivism and Information Processing	GOMS Model	S. K. Card, T. P. Moran, and A. Newell	A theory of the cognitive skills involved in HCI tasks. Cognitive structure consists of goals, operators, methods, and selection rules.
	Cognitive Load	J. Sweller	Examines total amount of mental effort being used in the working memory.
	Cognitive Fit	I. Vessey	Correspondence between task and information presentation format leads to superior task performance for individual users.
	Cognitive Dissonance	L. Festinger	Mental discomfort experienced by a person who simultaneously holds two or more contradictory beliefs, ideas, or values. People are motivated to reduce their cognition dissonance by changing their attitudes.
	Gestalt (laws of perceptual organization)	W. Kohler	The sum is greater than its parts. Laws of proximity, similarity, symmetry, figure-ground, closure
	Top Down Processing Theory	R. Gregory	Perception is a constructive process, which relies on top-down processing.
Socio-technical	Distributed Cognition	E. Hutchins	Extended mind; fundamental unit of analysis is a collection of individuals and artifacts and their relations to each other.
	Activity Theory	L. Vygotsky, A. Leont'ev	Human activities are systemic and socially situated phenomena; an activity is the unit of analysis.
	Situated Action	L. Suchman	Our actions are strongly influenced by the material and social circumstances; knowing is inseparable from doing; all knowledge is situated in activity bound to social, cultural and physical contexts; cognition cannot be separated from context.
	Soft Systems Methodology	P. Checkland, B. Wilson	A framework for analyzing 'soft problems' – complex problems where there are divergent views about the problem definition.

5.3 Selected Theories

This study adopted a socio-technical perspective on system design (Clegg 2000). The study of context, where primary care providers make clinical decisions, is important to understand what type of decision support is most appropriate. At the same time, the study focused on producing design solutions for optimal information presentation to primary care physicians for effective decision support. This approach examines interactions and information processing on the level of an individual. The work in this study also entailed a UI design validation phase to assess the usability and acceptance of the design. Therefore, this study employed the following theories: Distributed Cognition (Hutchins 1995) as a socio-technical theory, Cognitive Load (Sweller 1988) and Cognitive Fit (Vessey 1991) as the information processing theoretical base, and the Unified Theory of Acceptance and Use of Technology (Venkatesh et al. 2003) as part of validation methodology. These theories are described in more detail next.

5.3.1 Distributed Cognition

Distributed Cognition (DCog) (Hutchins 1995) originates from cognitive science. DCog framework in use today was first proposed by Edwin Hutchins, who based it on his studies of how airline cockpits and ship navigation systems operate (Hutchins 1995). Later Hutchins proposed his theory as a foundation for HCI (Hollan, Hutchins, and Kirsh 2000).

The value of DCog theory is that it examines the interactions between people and technology with a holistic consideration of the environment. DCog was used in this study to better understand how technology can contribute to and support the work of primary care providers.

DCog has three fundamental tenets stating that cognition is distributed, embodied and immersed in the culture. Hollan et al. (Hollan, Hutchins, and Kirsh 2000) described these principles as follows:

1. Socially Distributed Cognition

This idea follows a recognition in cognitive science that cognition occurs not only within an individual mind but has to be viewed as occurring in a distributed manner - across individuals, artifacts, and time.

2. Embodied Cognition

A key feature of DCog theory is that action is coordinated amongst embodied agents, where an agent could be a person or an artifact such as a device. In this sense, DCog puts human actors, artifacts, and organizational and social structures on equal footing.

3. Culture and Cognition

DCog theory sees culture as both emerging from the activity of human agents and, at the same time, shaping cognitive processes. It states that the study of cognition cannot be separated from the study of the cultural environment, context, and history.

In DCog a unit of analysis is a cognitive system composed of individuals and the artifacts they use and thus depends on the scope of what is being examined (Hutchins 1995). DCog examines cognitive processes by the functional relationships of elements that are part of the process, regardless of where these cognitive processes occur (Hollan, Hutchins, and Kirsh 2000).

DCOg principles were used to define the units of analysis for the design of the genomic CDSS UI. The data collection and analysis methods focused on elucidating key system goals, clinical workflows, information needs, and human and artifactual actors. This socio-technical approach for the analysis of the primary care system provided the means to both scope and contextualize the design.

5.3.2 Cognitive Load Theory

Cognitive Load Theory (CLT) was developed by John Sweller in the 1980s (Sweller 1988) based on the studies of problem-solving. CLT builds on the information processing research, which demonstrated the limited capacity and duration of working memory (Miller 1956).

CLT adopts the concept of schemas (complex combinations of elements in long-term memory which are acquired over a lifetime of learning) as cognitive structures that comprise an individual's domain-specific knowledge bases (Sweller 1988). Learning, therefore, is the processes of schema acquisition and change in the schematic structure of long-term memory over time (Sweller 1988). An expert is distinguished from a novice by having more sophisticated schemas for a particular domain, which is an essential element in problem-solving performance (Sweller 1988). For effective schema acquisition, information presentation (such as instructional material design or information visualization format) must be optimized to reduce working memory load.

CLT proposes three types of cognitive load: intrinsic, germane, and extraneous.

Intrinsic cognitive load is the inherent level of difficulty associated with a particular topic (Sweller, Van Merriënboer, and Paas 1998). This inherent difficulty is immutable – it cannot be improved or modified as it is intrinsic to the topic.

Germane cognitive load refers to the effort of creating a permanent store of knowledge - a schema in the long-term memory (Sweller, Van Merriënboer, and Paas 1998).

Extraneous cognitive load refers to the way information is presented to a learner and is determined by the design of the information presentation format (Sweller, Van Merriënboer, and Paas 1998). Unlike the intrinsic type of cognitive load, the extraneous level of difficulty is under the control of designers who develop information presentation formats. By reducing extraneous cognitive load, it is possible to free up more cognitive resources for processing intrinsic and germane loads – to facilitate better learning, problem-solving, and decision-making. The minimization of the extraneous cognitive load is especially relevant for difficult topics where the intrinsic and germane loads are high.

CLT provides guidelines for improving information presentation to improve intellectual performance (Sweller, Van Merriënboer, and Paas 1998). The initial focus of the theory was on decreasing the extraneous cognitive load through the improvement of instructional methods and visualization formats. However, the focus has evolved to address the expertise and skill level of learners and methods to promote germane cognitive load (Ayres and Gog 2009).

The concept of cognitive fit, described next, is important when addressing the reduction of extraneous cognitive load and enhancing germane load – the aspect that is dealt with by the Cognitive Fit Theory.

5.3.3 Cognitive Fit Theory

Cognitive Fit Theory (CFT) builds on the Information Processing Theory. Its original version was proposed by Iris Vessey (Vessey 1991) to explain how varying ways and forms of information presentation perform in different circumstances. The original CFT states that the task performance of an individual decision maker or problem solver is improved when there is a match between problem presentation format and problem-solving tools and the task (Vessey and Galletta 1991). When there is a mismatch, one of the two processes is likely to occur. The individual may reformulate a mental representation of the presented data to match the problem presentation (Vessey 1991). Alternatively, an individual may transform a mental representation of the given data based on the task in attempts to create a match (Vessey 1991). Both mismatch remediation approaches might require extra time or introduce errors and thus result in decreased decision-making and problem-solving performance (Vessey 1991).

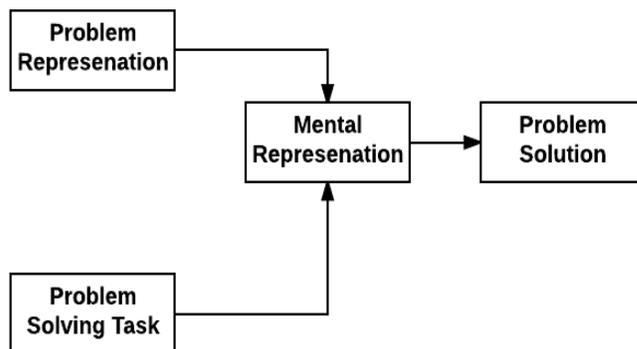


Figure 2 Original CFT

5.3.4 Information System Usage Behaviour

The Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh et al. 2003) has been empirically validated and extensively adopted for technology evaluation in various fields, including health informatics (Chao 2019). UTAUT examines three direct determinants of usage intention and behavior: performance expectancy, effort expectancy, and social influence. UTAUT also evaluates facilitating conditions as a direct determinant of user behavior. Gender, age, experience, and voluntariness are also considered as moderating variables that have an impact on the constructs of usage intention and behavior. These technology acceptance factors were factored into the UI evaluation criteria.

Chapter 6: Methodological Foundations

6.1 Lead User Method

The foundational co-design method for requirement gathering used in this study was the Lead User method. It was adapted and extended for this study, as described in the Methods chapter.

The principles of designing by users for users' and societal purposes, as opposed to focusing only on products and services themselves, are encapsulated by the participatory design approach. In this practice of co-design the user is seen as an expert in their experience who plays a significant active role in idea generation and concept development; the researcher is a facilitator and plays a role in supporting the user in providing them with tools for ideation and expression; the researcher is a key role for giving form to the ideas (Sanders and Stappers 2008).

Lead User method embodies the participatory design philosophy and the socio-technical view on system design (Clegg 2000). Lead User research is a qualitative method for understanding user needs for innovative products, processes, or services that are not presently available and represent the cutting edge of a given domain (Lüthje and Herstatt 2004). It is supported by empirical evidence as a generative method for novel concepts (Lüthje and Herstatt 2004). It was first proposed by E. von Hippel in 1986 as a method for novel concept generation for marketing research (von Hippel 1986). The premise of the method is based on empirical evidence showing that typical users are constrained by their experience and thus are unlikely to produce novel ideas or problem-solving strategies that conflict with what is familiar to them (von Hippel 1986). While engaging typical users is appropriate for various types of product research and evaluation, it may not be a fruitful approach for designing products that are not yet in the mainstream (von Hippel 1986). In contrast, the Lead User method intentionally seeks out

atypical users who are innovative and particularly progressive. This method describes Lead Users as those members of a user population that “are at the leading edge of important trends in a marketplace under study - and so are currently experiencing needs that will later be experienced by many users in that marketplace” and “anticipate obtaining relatively high benefits from obtaining a solution to their needs – and so may innovate” (von Hippel 1986). These two characteristics – experience the need early and expect a high benefit from a solution – are key to defining Lead Users. Lead User research is typically conducted in the initial phases of an innovation project to discover user needs and develop new ideas (Churchill, von Hippel, and Sonnack 2009). The focus of the method is on opportunity discovery and concept creation as opposed to concept evaluation or refinement.

6.2 Goal-Oriented Modeling

Goal-oriented analysis can facilitate early phases of the software design process, as it focuses on the understanding of the problem domain including elucidation of functional and non-functional requirements of the stakeholders, as well as how the requirements relate to the stakeholders’ overall objectives (Mylopoulos, Chung, and Yu 1999). Goals can be formulated at various levels of abstraction and this allows for a consideration of alternatives for how goals can be achieved by a specific solution (Franch et al. 2016). In other words, goal-oriented methods allow early domain exploration because they focus on the questions of who, how, why, instead of what. Goals are intentions expressed by stakeholders. Specific system requirements must be justified by linking the requirements to goals. Therefore, goals are less volatile than specific user requirements (van Lamsweerde 2000).

6.2.1 Goal-Oriented Analysis for Socio-Technical Systems

A goal-oriented approach also lends itself to the analysis of socio-technical systems through the lenses of the theories adopted for this study: Distributed Cognition, Cognitive Fit, and Cognitive Load. Goal-oriented modeling has been applied to represent requirements engineering as a distributed cognitive process, as requirements engineering process itself encompasses a complex socio-technical system (Hansen, Robinson, and Lyytinen 2012).

The goal-oriented analysis examines the actors involved in the socio-technical system (including human, technological, and organizational actors) and their goals with the aim of understanding the system in its entirety. It also allows the analyst to focus on the concept of resources, such as information, and how these resources can be represented and transformed within the system to fulfill the actors' goals. This view on a socio-technical system makes a goal-oriented analysis a practical approach for applying the DCog theory to system analysis.

6.2.2 Example Goal-Oriented Frameworks

There have been a number of goal-oriented frameworks proposed for eliciting system and user needs since the early nineties. For example, KAOS (knowledge acquisition in automated specification) framework (Dardenne, Fickas, and van Lamsweerde 1991) was the first widespread goal-oriented requirements engineering method. Key concepts in the KAOS model are agents and goals. Non-Functional Requirements (NFR) Framework (Chung and do Prado Leite 2009) is another widely adopted approach for early requirements gathering. NFR treats non-functional system requirements as system soft goals, however this framework, unlike KAOS, does not include the concept of an agent in its language.

6.2.3 iStar

iStar was partially based on the concepts proposed in KAOS and NFR, iStar framework was developed by Eric Yu as part of his doctoral studies at the University of Toronto (Yu 2009). iStar extended its predecessor frameworks to include not only agents and goals, but also roles (where agents playing roles become actors), tasks, and resources, as well as various types of dependencies and decomposition. Currently, iStar is one of the most widespread agent- and goal-oriented modeling and reasoning methods for early domain exploration and knowledge discovery (Franch et al. 2016). iStar supports models that represent intentional networks of actors and their dependencies within socio-technical systems (Franch et al. 2016). The simplicity and the range of constructs of iStar make it a suitable reasoning and modeling framework for this study where the Lead User design method is applied in a context of socio-technical system analysis.

iStar framework has been predominantly adopted in academia and has diverged into multiple variations since it was first proposed. In 2016, the iStar community standardized the iStar 2.0 core language that attempts to present a consistent set of concepts (Dalpiaz, Franch, and Horkoff 2016:0). iStar 2.0 is adopted for use in this study.

The key constructs of iStar 2.0 include actor and actor association links, intentional elements, and social dependencies. The reader is referred to the detailed iStar 2.0 Language Guide (Dalpiaz, Franch, and Horkoff 2016) for the comprehensive definition of iStar concepts. The use of iStar is also described in more detail in the Methods Chapter.

6.3 User Interface Requirement Patterns

One of the key outputs of this research is a set of UI requirement patterns for a primary care socio-technical system focused on risk assessment based on the large genome and phenome data sets. A pattern defines key requirements for a solution to a repeating problem (Alexander, Ishikawa, and Silverstein 1977). That is, it can describe the functionality and information needs of an actor while also abstracts away from the specific implementations details to allow for the solution to have greater applicability.

The idea of a requirement pattern devised for this study is based on the concept of a design pattern. A design pattern, in general terms, aims to discover, capture, and disseminate a design approach based on best design practices (Seffah 2015). A design pattern can encapsulate already available knowledge or introduce a novel approach to solving a design problem. Formulating design solutions as patterns allows them to be reusable and agnostic of the implementation medium. The goal of producing best practice patterns is to contribute to the inventory of effective design tools for a given domain (Seffah 2015).

The concept of a design pattern originated from the field of architecture when Christopher Alexander introduced the term in the 1970s in his book “A Pattern Language” (Alexander, Ishikawa, and Silverstein 1977). Alexander defined a pattern as having three key elements: a context, a problem, and a solution.” (Alexander, Ishikawa, and Silverstein 1977).

The software engineering field adopted the pattern concept in the late 1980s when pattern languages for object-oriented programming were introduced by K. Beck and W. Cunningham (Beck and Cunningham 1987). Since then, abundant literature has accumulated on the use of

patterns for software analysis, architecture, program design and implementation, and reengineering approaches. The concept of a pattern has been relatively recently adopted in the field of HCI as a proven design solution or the best human-computer interface design practice for a user problem that occurs in several contexts (Seffah 2015).

Chapter 7: Summary of the Background Section

The background section provided a review and descriptions of key foundational elements of the study. It discussed the genomic medicine and what role it may play in primary care in the near future. The section provided a definition of a CDSS and described, on a high level, what challenges genomic (or other big data) CDSS face in order to become useful clinical tools. Personalized frailty risk assessment was highlighted as the clinical example used for the study.

The background section described the theoretical perspectives adopted for the design work in this study: Distributed Cognition, Cognitive Load and Cognitive Fit. The Unified Theory of Acceptance and Use of Technology was also described as the theory for information system usage behavior.

The section also provided background information on the methodological foundations for this study: the Lead User method, Goal-oriented modeling including iStar, and the concept of requirement patterns was described as the patterns were the key output of the study.

Figure 3 illustrates the key four pillars that the study is based on and are described in this background section.

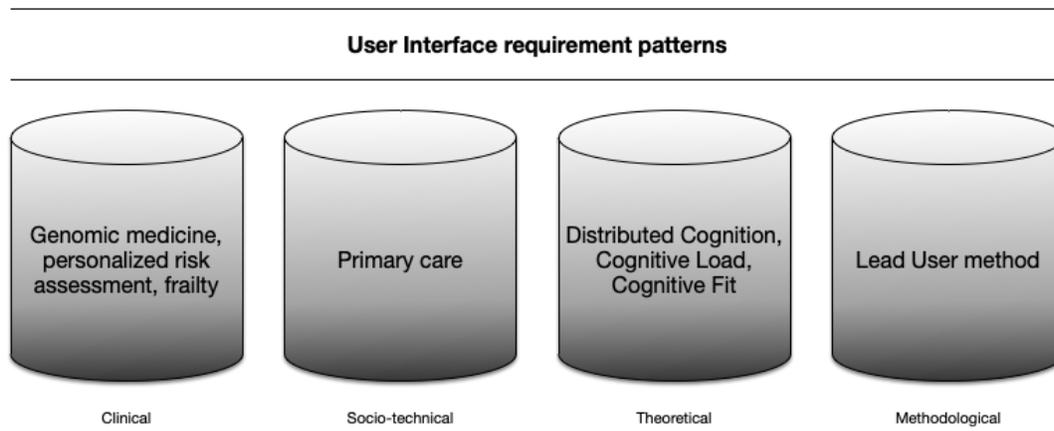


Figure 3 Foundational pillars of the study

METHODS

Chapter 8: Methods

8.1 Overall Study Design

The protocol for this study was approved by the UBC Behavioural Research Ethics Board (UBC Ethics Certificate number H18-00637).

This sequential, multiple-methods design study consisted of three phases: (1) Lead User Design, (2) Synthesis, and (3) Validation.

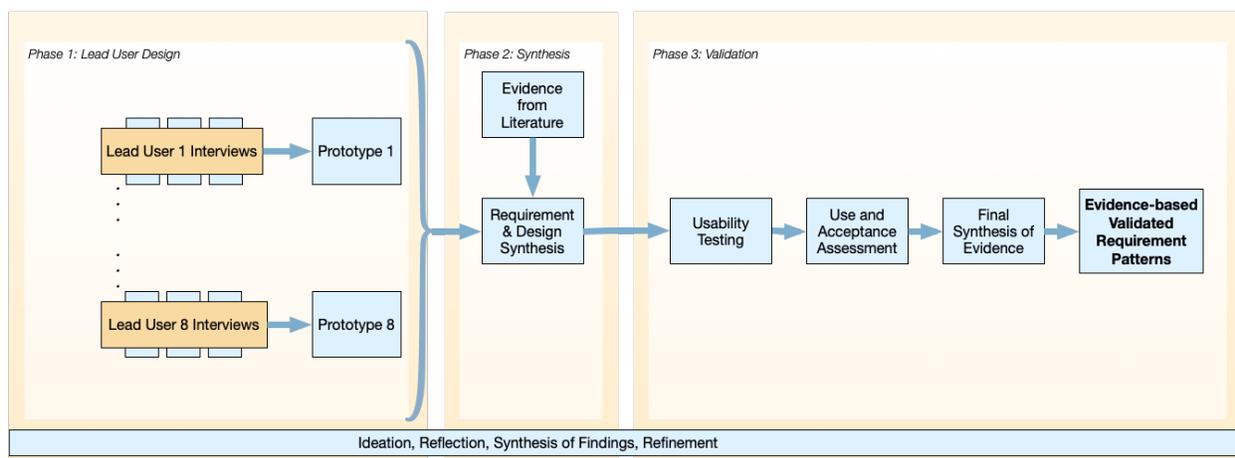


Figure 4 Study phases

8.2 Phase One: Lead User Design

Phase One leveraged the participatory design approach, the Lead User method, as adapted to information systems in the researcher's lab (Bellwood and Price 2015; Price et al. 2015). This method supports the socio-technical perspective on design and is specifically suited for novel

concept generation. The Lead User method employs co-design activities with innovative and creative Lead Users who are prominent experts in their domain. Each Lead User completed a series of one-on-one interviews with the researcher where the Lead User requirements for a CDSS were captured and validated through developing individual rapid UI prototypes.

8.2.1 Lead User Participants

The intention was to recruit approximately eight Lead Users for Phase One. The Lead Users were defined as primary care clinical experts with interest/expertise in decision support, genomics, and geriatric frailty.

8.2.1.1 Lead User Inclusion Criteria

- Primary care physician (would include family physician, general internal medicine, geriatrics)
- Experience in managing patients with geriatric frailty
- Strong knowledge and interest in genomics
- Have experience using at least one EMR at the point of care
- Have experience and a good understanding of CDSS

8.2.1.2 Lead User Exclusion Criteria

Exclusion criteria were not applicable. Inclusion criteria were sufficient to identify potential Lead Users for the study.

8.2.1.3 Lead User Recruitment

Initially, prospective Lead Users were searched through an extensive scan of public websites and publications. The focus was to identify individuals and research groups that focus on the integration of genomics and other big health-related data into patient care through information technology. However, this search yielded a fairly small number of potential Lead Users, and all appeared to be involved in active projects that could have intellectual property conflicts with participating in this research. These prospective Lead Users were not contacted as their recruitment was not deemed feasible.

Instead, the Lead Users that were recruited were identified through the second recruitment strategy: via academic/professional networks of the researcher's Ph.D. supervisor/P.I. of the research study. After the supervisor identified a potential Lead User, the supervisor made the initial contact. The supervisor approached the potential Lead User (via e-mail) and shared the invitation letter (Appendix A). No initial contact with the potential Lead User was made over the phone. The supervisor was transparent about their role in the project. The researcher was not included in the initial communication between the supervisor and a prospective Lead User. If the potential Lead User was interested in participating in the study, the Lead User got in contact with the researcher in a separate e-mail thread.

8.2.1.4 Informed Consent

Copies of the consent form (Appendix B) were e-mailed at least one week prior to the first interview for each recruited Lead User. Each Lead User had at least one week to review the consent form, ask the researcher questions, and reply with a signed consent form prior to the interviews. At the start of the first interview with each Lead User, the researcher ensured that the

participant understood the consent for the study, including the study's purpose, the type of involvement expected from the participant, and risks and benefits. In addition, it was made clear that participation was entirely voluntary: participants were free to withdraw from the study at any time without offering any reason for withdrawal and without fear of any consequences. The researcher ensured that all of the participants' questions regarding the study or their participation were answered, and the forms were signed before the interviews proceeded.

Participation as a Lead User was kept in confidence, and no identifiable information was shared or published.

8.2.1.5 Setting

Lead User interviews were conducted by the researcher with each Lead User one-on-one. The study protocol permitted conducting in-person interviews when feasible at the Lead User's private office. However, the protocol also allowed the sessions to take place remotely over video-conferencing when necessary.

8.2.1.6 Lead User Sessions

The Lead User needs and solutions for a genomic CDSS were explored through a series of one-on-one semi-structured interviews. A series of three interview sessions were planned per each Lead User. Each interview was intended to be approximately 60-90 minutes long. Each interview was conducted and analyzed separately for each Lead User (there were no group interview sessions with multiple Lead Users).

The researcher used an interview guide (Appendix C). The guide included questions that specifically focused on understanding the context of frailty risk assessment, including the actors and tools involved in frailty risk assessment and management, the information interchanged among the actors and tools, the Lead Users' goals, as well as optimization of users' cognitive fit and load for processing complex patient information and clinical evidence. This information was helpful in understanding what type of decision-support information and functionality was most appropriate in a generalist clinical setting at the point of care.

Geriatric frailty was used as a clinical example to provide a clinical context for genome and phenome integration at the point of care. A patient persona (simulated medical cases) was used to aid the Lead Users in their design ideation process. One fictitious patient persona was developed as part of this study. The persona was developed in consultation with the researcher's Supervisor, who is an expert in primary care. The persona incorporated some common risk factors for frailty, as well as some genomic, epigenetic, proteomic, and metabolomic biomarkers that the current literature associates with frailty (Breitling et al. 2016; Collerton et al. 2014; Darvin et al. 2014; Fazelzadeh et al. 2016). The Lead Users were encouraged, during the ideation sessions, to imagine how they would interact with the patient persona using their envisioned CDSS at the point of care. See Appendix D for the detailed persona used for this study.

All interviews were audio-recorded (interviews two and three were also screen recorded). The purpose of the audio- and screen-recording was to allow the researcher to do detailed analysis of the Lead User's requirements (design ideas). The interviews did not include any disclosure of patient-specific information for real patients. All Lead User data were de-identified.

The iterative data collection and analysis for the Lead User sessions can be summarized by the conceptual model in Figure 5.

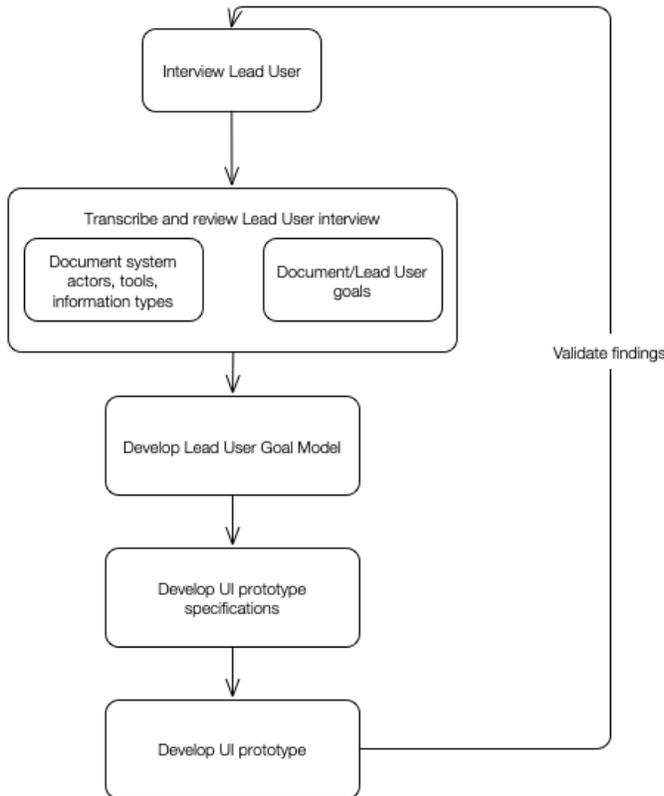


Figure 5 Conceptual model of the data collection and analysis process in Phase One

8.2.1.6.1 Interview 1

At the start of the first interview, basic characteristics of the Lead User were collected, such as their qualifications, age, gender, years in practice, experience level with electronic medical systems (see the background questions in Appendix C). The purpose of collecting basic Lead User characteristics was to better understand the diverse backgrounds of the Lead Users and their perspectives on design.

Next, the Lead Users were prompted to describe frailty risk assessment and management as a socio-technical system. The Lead Users were asked what actors and tools (electronic and other types) were involved, what type of information was exchanged among the actors and tools in order to facilitate clinical decision making.

In addition to describing the current state of frailty management, the Lead Users were asked to explore what actors, tools, information, and information flows would be important in the future when frailty risk assessment and management may encompass patients' genomic and other big data. Therefore, the contextual analysis focused on the future state. Although the CDSS design specifically focused on the primary care physician as the CDSS user, the understanding of the other involved system participants in the greater context was important to situate the CDSS design adequately.

Further, the Lead Users were asked to describe their goals and needs in the context of the envisioned CDSS. The first interview allowed the Lead User to express their vision for the genomic CDSS UI. Specifically, each Lead User described their functional (what a system should do) and non-functional (how a system should behave, look, and feel) requirements for the CDSS.

8.2.1.6.2 Interview 1 Analysis

The interview was transcribed and analyzed. The interview data were analyzed using qualitative analysis approach to:

- understand the context of frailty risk assessment using the Distributed Cognition theory for socio-technical systems and
- discover implicit and explicit Lead User goals and user interface design ideas using Cognitive Load and Cognitive Fit theories
- Frailty Management as a socio-technical system

The Distributed Cognition theory was used to analyze the context of frailty risk assessment and management in primary care from the perspective of a Lead User. The aim was to understand and document ‘who’ and ‘what’ play important roles in the socio-technical system that frailty management encompasses; what relevant information is involved; how this information is represented; how the information is propagated through the system actors and various tools (external representations) to facilitate clinical decision making.

Lead User Goals

Goal-oriented modeling was used to understand the goals of the Lead Users. Goal modeling is a useful technique for understanding the problem domain early in the concept ideation. Goals are objectives/requirements that a system should achieve through the cooperation of system actors and tools in a given context (see section 6.2 for more background on the goal-oriented modeling).

Rich Textual Documentation of Goals

As a first step of the Lead User requirements analysis, the interview was transcribed. Verbatim transcription was done for the relevant parts of the interview using a template that ensured the following details would be captured (see Appendix E):

- Lead User's goals – high-level functional requirements for the CDSS
- Goal qualities – high-level non-functional requirements that qualified the goals
- Lead User's rationale for their goals and qualities – this documentation included verbatim interview excerpts that expressed Lead User's thought processes
- Tasks required to achieve the goals – lower-level requirements
- Information resources required to achieve the goals, qualities, and tasks – the type and format of required information for optimal cognitive load and fit

It was this transcribing of the Lead User goals into the detailed textual format that allowed for immersion in the Lead User data during the analysis. The transcribing also provided necessary details about what the Lead User envisioned and for what reasons it was important. This detailed analysis of each interview helped formulate questions for the subsequent interview during the iterative co-design work with the Lead User.

Pictorial Goal Models

Goal model development was an iterative process. iStar modeling language (Yu 2009) was used to document the Lead User goal models (one goal model per each Lead User). The researcher translated a textual interview transcript, described above, into a goal model. A goal model captured the Lead User goals and goal qualities.

The reasons for the graphical and concise representation of the Lead User goals, in addition to the rich textual version, were as follows:

1. A goal model served as a quick reference to ensure that the Lead User prototype provided coverage for the Lead User goals that were determined to be in scope. A pictorial goal model had a much lower cognitive load than lengthy textual documentation although both types of documents were used for prototype development and were useful in different ways: the former providing both high-level and detailed requirements; the latter serving as a type of an overview and a check-list to ensure for high-level requirement fulfillment.
2. A goal model provided an overview of the breadth and depth of the requirements for a single Lead User. Analyzing a graphical goal model helped determine the boundaries of the design scope and also the areas of the requirements space that required additional ideation with a Lead User. For example, some Lead Users had goals that could not be realistically included in the scope of this study; some Lead Users heavily focused on one type of feature of a CDSS and provided less input on other features. A diagram provided a good cognitive fit to assess a large collection of requirements for scope coverage issues.
3. Goal models allowed for an easy comparison of the requirements across Lead Users, which was an important prerequisite work for synthesizing Lead User goals in Phase Two of the study.

Lead User UI Prototypes

The identified Lead User goals and design ideas served as inputs into the design of an initial visual HTML-based prototype for the Lead User (one for each Lead User). The purpose of the prototypes was to focus on clinically important functionality and information, including the

content and format. Google Material Design was used as a foundational UI framework. The prototype was designed and refined iteratively based on each of the three interviews.

The researcher developed the prototypes. Axure RP 8 was used as a prototyping tool. Axure facilitated the rapid design of interactive prototypes that allowed the researcher to create an interactive system that had a realistic feel and was based on the Lead User's goals and design ideas.

8.2.1.6.3 Interviews 2 & 3

The subsequent interviews with a Lead User focused primarily on validation of the Lead User's requirements through review and revision of the visual prototype. A Lead User had an opportunity to interact with the prototype, evaluate it, filling in gaps that were not clear, and provide ideas for prototype refinement. The researcher focused on confirming the Lead User's design ideas and gaining an understanding of the Lead User's rationale for their design ideas.

The researcher referred to the goal models developed as a result of the first interview. The goal models helped in bridging a Lead User's requirements and design: the system had to be designed to fulfill the specified goals.

The third interview was intended to specifically focus on finalizing the Lead User's design, clarifying any outstanding questions, and ensuring consistency between the prototype design and the goal models.

The Lead User prototype interactions were screen recorded for analysis.

8.2.1.6.4 Interview 2 & 3 Analysis

The second and third interviews were transcribed and analyzed.

The qualitative interview data were analyzed using the approach described in the Interview 1 Analysis section above. The screen recordings aided in analyzing the Lead User interactions with the prototype and provided context for the Lead User feedback.

The researcher refined the Lead User's specific goal model and their visual prototype after both the second and third interview sessions to incorporate the Lead User's feedback. The goal model and the visual prototype for each Lead User were finalized based on the outcomes of the last interview. The goal models or prototypes were not shared among the Lead Users. Each Lead User had their "own" documentation and prototype.

8.2.1.7 Compensation

A stipend of \$100Cdn was offered to each Lead User for each hour spent participating in Phase One (up to \$400Cdn total for all interviews).

8.3 Phase Two: Synthesis

Once all individual Lead User sessions were completed, the design artifacts generated for each Lead User (the description of actors, tools, and interchanged information types, goal models, and the visual prototypes) were analyzed and integrated in Phase Two. The outputs of Phase Two were an Integrated System Actors and Tools Model, an Integrated Goal Model, requirement patterns, and an integrated UI prototype based on the patterns.

8.3.1 The Synthesis Team Members

The synthesis was conducted by the Synthesis Team, consisting of the researcher and the Ph.D. Supervisory Committee. Throughout the synthesis process, the team was tasked with considering the following perspectives while developing all design artifacts:

Lead User

The researcher aimed to represent and advocate the design views and ideas from the Lead Users based on the insight gained from the individual Lead User interviews. This supported the participatory nature of this project where Lead Users are design originators and innovators.

Optimal Cognitive Load and Fit

This study specifically aimed to address the effective and efficient presentation of large, long, and complex patient data and medical knowledge to a provider, given time and resource constraints of a primary care encounter. The employed design principles for information presentation were based on the Cognitive Load and Cognitive Fit theories. The design throughout the study emphasized the minimization of the extraneous cognitive load imposed on the user by large and complex data, enhancement of the germane cognitive load for improved learning and decision making, and optimization of cognitive fit between the user goals and the CDSS.

Usability

Nielsen's well-established usability heuristics (Nielsen 1993) were used as usability criteria for identifying usability issues in the CDSS prototypes.

Quality Care

The CDSS had to strive to support quality patient care by delivering evidence-based, clinically actionable recommendations to the provider at the right time and in the right format. The clinical experts on the Synthesis Team evaluated these features.

Patient Privacy

Addressing patient privacy concerns through design is always important, especially in the context of genomic data that is persistent through a patient's life and can be highly informative about a patient's physical traits, risk factors, drug response predispositions, health conditions, and biological relationships to other individuals.

Patient Safety

A CDSS was intended to help providers avoid errors of both omission and commission. The CDSS interface features were evaluated to ensure they minimized the likelihood of erroneous clinical decisions. The CDSS had to provide quality information as well as let the provider know when the information was not available or was not of sufficient quality (e.g., lacked in correctness or completeness).

8.3.2 Setting

The study protocol permitted the group synthesis sessions to be held from the P.I. UBC assigned offices or via video-conferencing.

8.3.3 Synthesis Sessions

The intention was to have multiple synthesis sessions with each session lasting approximately three hours. The lengthy working sessions allowed for immersion into Lead User data. Between the sessions, the researcher prepared the materials and conducted additional research and analysis, such as reviewing relevant literature, for example.

The conceptual analysis workflow for the Synthesis can be illustrated in Figure 6.

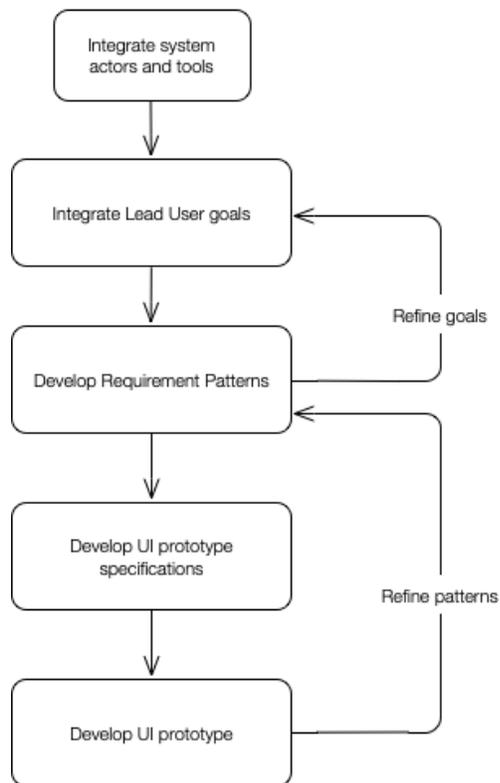


Figure 6 Conceptual model of the analysis process in Phase Two

8.3.3.1 First Synthesis Session

The first session allowed the researcher to orient the Synthesis Team to the synthesis process. A brief overview of the Lead User prototypes was presented to illustrate the scope of the designs from Phase One.

8.3.3.1.1 Integrated System Actors and Tools Model

The first task of the Synthesis Team was to review and finalize the draft model that presented the integrated view on the actors and tools that were documented in Phase One. The researcher collated the relevant data from each Lead User and drafted a System Dependency Model (SDM) using the iStar modeling language (Yu 2009). There were no conflicts among the actors and tools described by the Lead Users. The Lead User descriptions of the tools, actors, and their relationships were complimentary. The researcher combined the individual Lead User descriptions of actors and tools into one SDM to illustrate their interdependencies in one graphical view.

A note on terminology: in the Distributed Cognition theory, an actor is a human, and a tool is an artificial entity (e.g., a software component or a physical artifact such a paper chart); in iStar modeling language an actor is a human or an artificial entity.

8.3.3.1.2 Goal Models

Next, the Synthesis Team was expected to review the draft Integrated Goal Model. The first draft version of the model was prepared by the researcher based on the individual Lead User goal models.

The Synthesis Team was familiarized with the goal integration method that was specifically developed for this study (see Appendix F). The method specified a way to examine the goals of all Lead Users, unify them into one unified model, and ensure traceability of each Lead User's contributions into the unified model and how the contributions got adapted. The important features of the method are the origin, stakeholder, and integration assumption traceability.

The Team reviewed the common goals and resolved idiosyncrasies among the conflicting goals to produce the completed Integrated Goal Model using the goal integration method (see Appendix F for method details). The final model served as a foundation set of requirements for the development of the requirement patterns.

8.3.3.2 Subsequent Synthesis Sessions

The remainder of the synthesis sessions focused on the development of requirement patterns and the development of the UI prototype based on the patterns.

8.3.3.2.1 Requirement Patterns

The first draft of the patterns was created by the researcher and presented to the Synthesis Team for review. The patterns were based on:

- The Integrated Goal Model produced by the Synthesis Team – the model provided the overarching set of high-level requirements that the patterns supported.
- The Lead User goals and the prototypes from Phase One – the documented goals and prototypes were elaborated on during the synthesis process for determining the design requirements that supported the Integrated Goal Model.

- The literature for best practices on general UI design, CDSS design, and the presentation of health risk information with the considerations for cognitive load and fit.

The Team discussed elements of all patterns during the synthesis sessions. The Team ensured to consider the different perspectives on design: the Lead User, cognitive load and fit, usability, quality care, patient privacy, patient safety. Where consensus could not be reached, the Team went back to the literature for further guidance. Pattern development resulted in the refinement of the Integrated Goal Model.

The main criterion for defining a discrete pattern was that it had to encompass a reusable and a stand-alone set of requirements for a UI feature/component. The template for a requirement pattern was defined and is presented in Appendix G.

8.3.3.2.2 UI Prototype

Once the requirement patterns were produced by the Synthesis Team, the researcher developed a UI prototype to illustrate the patterns. The final synthesis sessions entailed the review of the integrated UI prototype by the Team. The prototype development and pattern refinement were iterative, where one informed the other.

8.4 Phase Three: Validation

The integrated UI prototype created in Phase Two was evaluated by Representative Users (clinical end-users) in Phase Three. The evaluation entailed an empirical approach, namely, participants were asked to complete a set of tasks using the prototype and follow the think-aloud protocol and complete a survey for assessing the likelihood of design acceptance by the users.

The purpose of Phase Three was to validate the Lead User findings in Phase One and the Synthesis decisions in Phase Two. Phase Three added to the evidence for the design patterns through testing the patterns with Representative Users for external validity.

8.4.1 Representative User Participants

The intention was to recruit approximately five to eight clinicians for the usability evaluation phase.

8.4.1.1 Inclusion Criteria

- Active primary care physician with license to practice in BC (would include family physician, general internal medicine, geriatrics)
- Experience in managing patients with geriatric frailty
- Have experience using at least one EMR system at the point of care

8.4.1.2 Exclusion Criteria

Exclusion criteria were not applicable. Inclusion criteria were sufficient to identify potential participants for Phase Three of the study.

8.4.2 Recruitment

Recruitment was through both the UBC Department of Family Practice newsletter and by direct email through the PhD supervisor's academic/professional network (invitation letter in Appendix I). The researcher was not included in the initial communication between the supervisor and a prospective participant. If the potential participant was interested in participating in the study, the participant got in contact with the researcher in a separate e-mail thread.

8.4.3 Informed Consent

Copies of the consent form (Appendix I) were provided to the participants electronically prior to the usability testing/validation sessions. Each participant had at least one week to review the consent form, ask the researcher questions, and reply with a signed consent form prior to the session. At the start of each usability evaluation session, the researcher ensured that each participant understood the consent for the study, reviewed the study, answered any questions, and the forms were signed before the sessions proceed.

Participation as a Representative User (usability tester) was kept in confidence, and no identifiable information was shared or published.

8.4.4 Setting

The usability evaluation sessions were conducted by the researcher with each participant one-on-one. The study protocol permitted conducting in-person interviews when feasible at the participant's private office (at the university or their preferred office). However, the protocol also allowed the sessions to take place remotely over video-conferencing.

8.4.5 Usability Testing Sessions

Each participant was invited to participate in a usability testing/evaluation session one-on-one with the researcher. Each evaluation session was planned to be approximately one-hour long. The interviews were audio- and screen-recorded for analysis.

The conceptual model of the data collection and analysis is presented in Figure 7. The description of how the usability testing sessions were structured is outlined below.

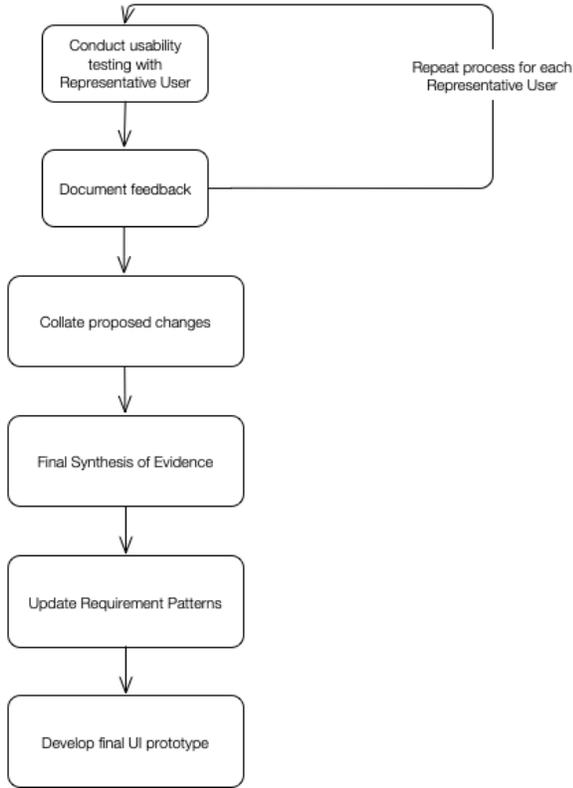


Figure 7 Conceptual model of the data collection and analysis process in Phase Three

8.4.5.1 Demographic Questions

The participants were asked to complete a brief demographic questionnaire (see Appendix J) to gain a better understanding of the participant’s background (clinical knowledge, experience with electronic systems).

8.4.5.2 Usability Evaluation Scenarios

This main part of the session entailed the use of task scenarios related to frailty risk assessment and the think-aloud-protocol to discover the users’ perception of the CDSS design.

The researcher demonstrated the prototype and prompted the participants to provide feedback on whether the CDSS provided necessary information and functionality to complete the tasks. The CDSS prototype interactivity was scripted; therefore, it was not feasible to allow the users to manipulate the CDSS directly.

The study's theoretical foundations of cognitive load and cognitive fit were leveraged for the validation process to assess whether the informational load was adequate to facilitate decision making and how each CDSS UI component fit with the frailty risk assessment/management tasks.

The scenarios used to engage the users and to solicit their feedback on the UI contained exploratory tasks and specific tasks. The tasks were related to the frailty risk assessment for the same persona used in Phase One of the study (Appendix D). The persona helped the participants imagine how they might perceive the CDSS frailty risk assessment recommendation and risk information during a typical primary care encounter in an office-based practice. Exploratory tasks were broad and aimed to learn how users discovered and explored information. Specific tasks were highly focused and were used to evaluate how well users could perform them and how satisfied they were with the system. Several tasks were predetermined, for example, the participant was asked to find CDSS notifications on an EMR patient summary page or determine the absolute risk reduction of a suggested intervention. However, the evaluation session with each participant was expected to evolve differently based on what aspect of the CDSS was most interesting and important to the participant.

The users were encouraged by the researcher to continuously verbalize their thoughts as they moved through the UI. This approach assessed users' information needs, reasoning, and feeling about the system. It also highlighted the sources of the usability issues with the system's interface.

8.4.5.3 Usability Questionnaire and Wrap-up

Each user was asked to fill out a brief usability questionnaire after the completion of the scenarios and the think-aloud protocol at the end of the usability evaluation session. The questionnaire was based on the Unified Theory of Acceptance and Use of Technology (UTAUT). See Appendix K for the questionnaire used in the study. The original UTAUT questions were slightly modified in terms of wording to accommodate the fact that the evaluated system was a UI prototype versus a fully developed system. Questions that were not relevant to the CDSS users or the nature of this study were removed. The original UTAUT survey was also expanded to reflect the use of cognitive theories for the design as adopted in this study.

The questionnaire assessed such constructs as performance and effort expectancy, social influence, and behavioral intentions.

8.4.6 Data Analysis

8.4.6.1 Scenarios and Think-aloud Protocol

The recordings and transcripts for the usability validation sessions were analyzed to determine usability issues with the prototype. The prototype served as a medium for the requirement pattern validation. For each interview, the participant feedback on the prototype was analyzed and documented in a structured format: participant opinions on the CDSS UI were transcribed

per each key UI component (each UI component was an implementation of one or more patterns).

Next, the proposed UI changes from the participants' feedback were extracted. The congruency of proposed changes across the participants was documented using a similar approach used for analyzing the congruency of goals across the Lead Users (Appendix F). All proposed changes from all the participants were first listed, then each proposed change was qualified and quantified with the number of participants that:

- *(P) Proposed* the same change - semantically the same, although it could have been worded differently
- *(PSIM) Proposed Similar Change*- semantically similar.
- *(NP) Not Proposed* - the change was not proposed at all
- *(C) Conflicting* – the participant had a conflicting suggestion

These proposed changes were brought to the Synthesis Team for discussion in order to conduct the final synthesis of evidence.

8.4.6.2 Final Synthesis of Evidence

The Team then collectively provided guidance on what revisions to the requirement patterns were needed based on this Validation phase of the study. This process was similar to the synthesis across the Lead Users conducted in Phase Two, where the input from the participants was analyzed, and the Team referred to the literature and used their expertise to make design decisions.

8.4.6.3 User Acceptance Questionnaire

All questionnaire results were tabulated and analyzed using descriptive statistics.

8.4.6.4 Prototype Refinement

The researcher made changes to the prototype produced in Phase Two to reflect the updates made to the requirement patterns finalized in Phase Three. The finalized prototype illustrated the key elements of the patterns. The screenshots from the prototype were included in the pattern documents as example visual representations of pattern implementation. Including the sample screenshots allow the pattern readers to envision how a pattern could be implemented.

8.4.7 Compensation

A stipend of \$100Cdn was offered to each clinician Representative User for the usability evaluation session in Phase Three.

8.5 Data Collection

All participant data were included in analyses. Data were anonymized before proceeding with analyses.

RESULTS

Chapter 9: Phase One Results

9.1 Lead User Participants

In Phase One, eight Lead Users were recruited and interviewed according to the study protocol. Seven of the eight Lead Users were from across Canada and one from Scotland. All participants had multiple relevant roles (for example, an academic, a leader in an open-source EMR community, a nursing home physician, and an office-based primary care physician).

All participants had extensive experience in managing frail patients in ambulatory and inpatient care settings. The participants were knowledgeable primary care physicians, with an average of nearly 26 years of primary care practice. Table 2 summarizes the characteristics of the participants and their collective experience. Although all Lead Users were very enthusiastic and interested in genomics and the role of big data in improving patient care, only one participant used genetic testing specifically for their frail patients in their practice. None of the participants ordered full or partial genome sequencing related to frailty or other aging-related conditions. This was expected, given the current limitations of clinical validity and utility of genomic data for frailty.

Table 2 Summary of Phase One research participants and their collective experience

Number of Lead Users Interviewed	8
Average Number of Interviews per Lead User	2.5
Average Age	55.5
Male Participants	7
Female Participants	1
Average Years of Experience in Primary Care Practice	25.8
Average Years Using EMR	15.9
Number of Lead Users Utilizing Genetic/Genomic Testing for Frailty	1

9.2 Lead User Interviews

All interviews with the Lead Users were conducted over six months. It took approximately four weeks to complete interviews and analysis for an individual Lead User. The total number of interviews for all Lead Users was 20 (average 2.5 / Lead User). Fifteen of the interviews took place over video conferencing, and five in-person. The original protocol included three interviews with each Lead User. However, four participants preferred to provide feedback on the last version of their prototype asynchronously, instead of participating in the third interview. In such cases, demo videos of their prototypes were created and shared. The Lead Users then provided feedback over e-mail.

9.3 Findings

9.3.1 Frailty Management as a Socio-technical System

Each Lead User described the actors and tools involved in frailty management (Table 3). There were no conflicts among the system participants, although some provided more details

(additional actors and tools) than others. The described system actors and tools were later synthesized into a Strategic Dependency Model in Phase Two of the study.

Overall, all Lead Users described frailty as a multifaceted chronic condition, where clinical decision making requires a complex set of information interchanges distributed among many system actors and tools with all components of the system evolving over time. The high-level categories of information that were involved in frailty assessment and management were: patient information such as phenome and genomic data, patient goals and preferences, provider characteristics and preferences, care setting characteristics, and clinical evidence. The information pieces were interchanged among the mental space of the actors and tools in complex configurations. The information needs of the actors were documented as part of goal modeling described in further in this chapter (see Lead User Goals).

Table 3 Actors and tools described by Lead Users

Lead User	Described Actors and Tools			
	Patient and patient's supports	Health care providers	Electronic health information systems	Other information systems
1	Patient	Family physician MOA Nurse Nurse practitioner	EMR CDSS Lab Hospital HIS	Internet resources DTC genotyping/sequencing services
2	Patient Patient's caregivers Patient's blood relatives	Family physician MOA Nurse Nurse practitioner Dietician Specialists Genetic counselor Pharmacist	EMR CDSS Lab Hospital HIS Imaging Patient Health Record Patient genomic data repositories	DTC genotyping/sequencing services Wearables and other passively-collected data sources
3	Patient Patient's caregivers	Family physician MOA Nurse Dietician Specialists Physio therapist Pharmacist	EMR CDSS Lab Hospital HIS	DTC genotyping/sequencing services Frailty assessment tools (e.g. CFS)
4	Patient Patient's caregivers	Family physician MOA Nurse Nurse practitioner	EMR CDSS Lab Hospital HIS Patient genomic data repositories	Internet resources DTC genotyping/sequencing services
5	Patient Patient's caregivers	Family physician MOA Nurse Nurse practitioner	EMR CDSS Lab Hospital HIS Imaging Patient Health Record	Research studies Comparative dashboards
6	Patient	Family physician MOA Medical student Occupation therapist	EMR CDSS Lab	DTC genotyping/sequencing services
7	Patient	Family physician MOA Specialists	EMR CDSS Lab Hospital HIS	Patient handouts Printed one-pagers on the wall
8	Patient Patient' caregivers	Family physician MOA Nurse Nurse practitioner	EMR CDSS Lab Patient genomic data repositories	DTC genotyping/sequencing services

Several noteworthy themes emerged from the analysis of frailty management context:

Importance of patient and patient's support system/family members

All Lead Users emphasized the patient as the key participant in their care. Moreover, most Lead Users stressed the importance of a patient's family, friends, and other caregivers, given that geriatric frailty typically involves both physical and cognitive frailty and often requires a system of support for a patient.

Consideration for patient's genetic relatives as important actors was also brought up by one Lead User. This group of actors needs to be carefully considered in the future when genomic data is available to the patient and provider. There may be significant implications and ethical issues around genomic data that may impact not only the patient but those related to the patient in the context of heritable conditions. An example brought up by Lead User 2 related to early-onset Alzheimer's, which would be a significant risk for cognitive frailty:

“Let's say, the patient has a gene for early-onset Alzheimer's, and it's heritable. This knowledge could impact his or her children, for example. What do we do with this information if the CDSS lets us know such sensitive patient details?” (Lead User 2)

Although addressing such issues was not in the scope of this research, these considerations are important to acknowledge for health system design overall.

Diversity of health care providers involved in frailty risk assessment and management

One theme that was consistent across all Lead Users was the description of frailty management as a team effort that should involve an interdisciplinary group of health care providers. For example, frailty care may be a collaborative system including a primary care physician, genetic councillor, specialists, nurses, MOAs, and allied health care professionals such as nutritionists, physio, and occupational therapists. The detailed support of team-based care workflows was out of scope for the CDSS design in this research, as it is a different complex design problem.

Distribution of patient information across a multitude of electronic health information systems

The Lead Users described how patient information is typically distributed across a multitude of systems actors such as the EMR in the physician's office, specialists' EMRs, lab, imaging, and hospital systems. Some genotyping data is already available to the patient through the Direct-To-Consumer genotyping services. However, only one Lead User utilized such genotyping data for their frail patients. Moreover, Lead User 2 was interested in wearable and other consumer health devices that could collect and analyze vast amounts of patient data pertinent to many health conditions and frailty in particular (for example, exercise, nutrition, sleep data). Lead User 2 also suggested that Patient Health Record systems should be considered as important tools that could be integrated with a CDSS in the context of frailty. Several Lead Users talked about the future where there will be multiple genomic data repositories that could provide data to the CDSS.

The scope of the design only included the integration of the currently available phenotypic data from an EMR and patient's genomic data that is expected to be available in the near future.

However, the results of this analysis brought to light other potential information processing entities that would require consideration in a broader context.

Clinical decisions are informed by many other digital and paper-based information systems

Based on the discussions with the Lead Users about how their decision-making processes are currently distributed among various information sources, it also became clear that the health care providers may use various resources and tools to help them address frailty with a patient. Such tools could include online references. The information representations that aid in decision making may also be paper ‘one-pages’ or similar tools commonly used in a clinic for quick references and patient handouts.

Importantly, all Lead Users stressed that the integration of genomics into primary care would expand the scope and the complexity of the tools and the available information. The Lead Users expressed concern about the potential for information overload, particularly in the context of an already busy primary care encounter.

The role of a laboratory service in masking/excluding sensitive data

All Lead Users agreed that a lab is a key system participant that, ideally, would address the masking and exclusion of sensitive patient data, such as parts of a patient’s genome, for example. This approach was adopted for the study as a working assumption that a CDSS design would not address the functionality for masking/unmasking of patient data.

Summary of the frailty management context

Generally, based on the Lead Users' description of frailty care context, it was evident that different Lead Users saw frailty management scope differently, based on the type of practice and clinical experience they had. For example, Lead Users with an interdisciplinary practice, as opposed to a single practitioner practice or smaller physician-only practice, tended to include a wider range of actors in the health care provider category of actors.

The Lead Users that were solely focused on and very experienced with geriatric frailty, as opposed to those with general practices with a proportion of frail patients, tended to also include a greater range of tools and information resources in frailty assessment and management. For example, such Lead Users described a higher number of specific frailty assessment tools.

The Lead Users with more experience in the EMR and CDSS design tended to perceive a CDSS as a tool with a broader degree of functionalities, above simply presenting a risk score and suggested interventions. Such Lead Users imagined the CDSS also to provide frailty education to the users, allow the users to enroll patients in relevant research trials, or compare the user's performance on managing frail patients with other providers or practices. While not all these features were in scope for the CDSS UI design of this study, the vision of the CDSS as a tool with potentially multiple diverse capabilities was insightful for potential future work directions.

Interestingly, the Lead Users had different levels of optimism about the clinical utility of genomic data for patient care – in frailty and primary care overall. While all participants were similarly knowledgeable about the potentials and limitations of genomic data, some Lead Users

were eager to incorporate such data into their practice, and others saw the genomic era too far in the future to realistically affect their daily practice.

Overall, this frailty care context analysis revealed that frailty management is a complex socio-technical system with a large number of interconnected actors and tools that interchange and transform many types of information. A CDSS, which is the focus of this research, constitutes but one entity in this complex socio-technical system. The understanding of how a CDSS fits into the complexity of frailty management is important to ensure that it meets not only the requirements of its direct users (family physicians) but also that it fits into the overall context. The evidence shows that designing for the socio-technical system can help avoid the perils of poor technology perception and adoption (Mumford 2006).

9.3.2 Lead User Goals for Frailty Risk Assessment

Part of Phase One was to understand not only the Lead User's specific design vision but also their goals and rationale that the design would support. Consistent with the goal-oriented modeling approach adopted for this study, the 'why' was more important to explore than the 'what.' For example, if a Lead User indicated that a recommendation should be in red, further exploration of such a statement could result in a goal to easily see (or to not miss) an important recommendation on a busy encounter page among all other patient data. The former is an example of a specific implementation (the 'what'), whereas the latter is a Lead User's goal ('why'). Goals can be thought of as high-level requirements that can be implemented in various specific ways.

The Lead User goals were documented in two formats: first in rich textual details and then translated into concise pictorial models.

To illustrate the rich textual documentation of goals that was done for each Lead User, a detailed example for Lead User 1 is included in Appendix L. This transcript is from the final version of the documentation for Lead User 1, based on their third and final interview. The transcripts for all Lead Users are not provided in this dissertation due to the length of the transcripts. The goals for all Lead Users are graphically represented in Appendix M.

A full iStar goal model was created for each lead user. Figure 8 illustrates the goals in a graphical format for Lead User 1. Appendix M is the full compendium of the goal models for all eight Lead Users. Note, these goal models only show the Lead User goals and qualities but not supporting tasks or information resources. Qualities are non-functional requirements that qualify the goals. The tasks and information resources are documented in detail in the textual documentation of goals for each Lead Users.

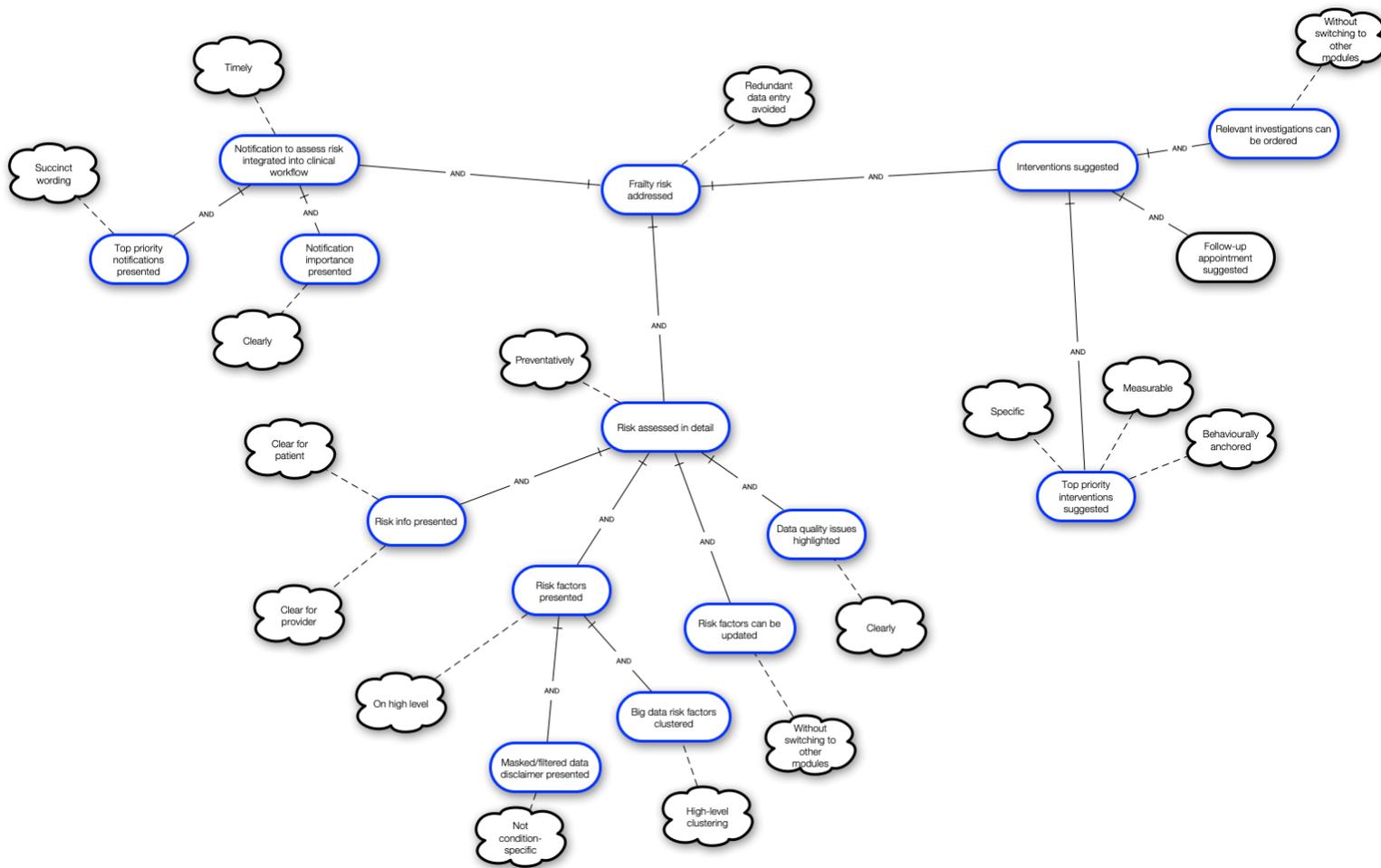


Figure 8 Lead User 1 goal model

Across all Lead Users, there were three consistent top-level goals:

1. Have CDSS risk notifications integrated into clinical workflows,
2. Have the ability to see detailed risk information, and
3. Have the suggested interventions to address risk.

The qualities for the top-level goals that were proposed by the Lead Users varied but were congruent (there were no conflicts among the proposed qualities). All the Lead Users emphasized the need for a CDSS to be timely, and to present the information in a concise manner that was clear for the provider and the patient. The proposed qualities very clearly reflected the need for an appropriate information load on a provider and a fit between a CDSS and a context of a busy clinical encounter.

While there was consistency on the highest-level goals, there was some dissimilarity in the sub-goals among the Lead User, as discussed below.

9.3.2.1 CDSS Notifications

9.3.2.1.1 Workflow Integration

The Lead Users consistently stressed that any CDSS tool used at the point of care must fit into their clinical workflows.

“This has to fit with what I’m already doing and how I’m doing it.” (Lead User 6)

“The CDSS would be another thing for me to look at. I need to see the notification, but it should not be too intrusive or distracting from what I need to do.” (Lead User 1)

The Lead Users explicitly stated that only the top few risk notifications should be presented during an encounter (this included the notification of frailty risk along with non-frailty risks). Most Lead Users felt comfortable with the top three being presented, with the rationale that the user can determine which one or two to address from the presented list. Lead User 4 suggested a single notification per encounter to reduce the extra cognitive load to the minimum:

“Realistically, I can deal with only one extra recommendation at most. Keep it very simple.” (Lead User 4)

The prioritization of CDSS notification was an important implied requirement for the Lead Users, although the Lead Users did not specify the comprehensive prioritization criteria. Across the Lead Users, the important high-level prioritization criteria that emerged were: the quality of clinical evidence, the strength of the recommendation for the particular patient, the patient goals and preferences of care, care/encounter context, provider characteristics and preferences.

9.3.2.1.2 Notification Details

There was variability for the level of proposed details that a notification needed to contain. Some Lead Users deferred to the CDSS to ensure adequate prioritization and thus did not need to see extensive rationale as part of the notification:

“I don’t really need to see all the information that triggered the notification, not on this level” (Lead User 7)

The majority of the Lead Users, however, wanted to explicitly see the key information that indicated the priority of the notification and the rationale for why it was triggered by the CDSS. They stated that they needed an easy way to identify the importance of the notification quickly. Some Lead Users suggested a visual cue (for example, using colour or icons), while others also wanted a rich informational context to be able to evaluate the notification. For these Lead Users, the user assessment of notification importance (and not relying solely on the CDSS to determine the importance) was critical in determining whether and how the notification should be actioned.

“I need to see, at a glance, why this is important to address today...I need the rationale to be clear to me here.” (Lead User 2)

Overall, across all Lead Users, there was a clear indication that the CDSS notifications must fit into the existing clinical workflows and be sufficiently informative for the user to determine the course of action.

9.3.2.2 Detailed Risk Assessment

The Lead Users uniformly required to access detailed frailty risk assessment information if they decided to act on a CDSS risk notification or wanted to go to a CDSS frailty risk assessment module proactively.

The key component of a CDSS risk assessment module for all Lead Users was the detailed patient risk and how it compares to the population risk. As Lead User 2 stated:

“Sometimes, that’s all I need to see. For example, if the patient’s risk is low or the same as the population risk, this may be the end of the discussion. I might not need anything else here.” (Lead User 2)

There was some variability, however, of what goals the Lead Users had around other components of a detailed risk assessment, as discussed below.

9.3.2.2.1 Presentation of Risk Factors

The presentation of risk factors was addressed in detail with each Lead User. The Lead Users proposed a number of dimensions that had to be considered when presenting risk factors to a provider at the point of care.

9.3.2.2.2 Default Display of Top Risk Factors

All Lead Users recognized that the risk factors are a part of an important informational context for a health outcome probability. However, the majority of the Lead Users proposed that the risk factors be available to the user on-demand due to the lower utility of reviewing the risk factor list and the concerns for screen space.

9.3.2.2.3 Clustering of Risk Factors

Modifiable vs. Non-modifiable Risk Factors

All Lead Users conceptually classified the risk factors as modifiable or non-modifiable, and all emphasized that the modifiable risk factors are of most interest.

“Really, I mostly care about what the patient and I can do, in partnership, to change the risk, to improve the outcome. I might be interested in the genomic factors sometimes, but I won’t likely have time to review that during the encounter.” (Lead User 1)

Lead Users 2 and 5 envisioned scenarios where it may be important to review the non-modifiable risk factors with a patient if certain non-modifiable risk factors (gene variations, for example) contributed a significant percentage to the risk. Lead User 5 phrased it as follows:

“If a patient has a really high risk due to something we can’t change, I want to explain that to the patient. I need to know how we could work around it and focus on what we can change.” (Lead User 5)

Lead User 4, in contrast, did not want the CDSS UI to provide non-modifiable risk factors to the user. This particular Lead User was only interested in the modifiable risk factors and specifically only the ‘pre-visit’ assessments such as BMI or grip strength documented by a nurse of an MOA prior to the visit with the physician (see Lead User 4 Prototype for illustration).

Overall, seven Lead Users proposed distinguishing and providing modifiable and non-modifiable risk factors. Their requirements on how this requirement could be implemented differed. For example, the Lead User 2 prototype achieves this through a filtering function (see

Lead User 2 Prototype). Several Lead Users proposed modifiable/non-modifiable risk categorization through displaying separate lists that could be expanded on-demand: modifiable and non-modifiable risk factors (see Lead User 3 Prototype as an example). Lead User 6 prototype distinguishes modifiable and non-modifiable risk factors in the overall list of risk factors but does not provide filtering or separation of the risk factors into separate lists Lead User 6 Prototype.

9.3.2.2.4 Clustering of Big Data

The question of how big data such as genomics can be integrated into point-of-care frailty risk assessment was at the centre of this study. Therefore, eliciting the Lead User goals, tasks, and information resource for the presentation of big data was particularly important in the context of risk factor display.

The surprising result was that not all Lead Users that supported grouping genomic data into clinically meaningful categories.

Five did propose clustering genomic data into high-level hierarchical categories, where a CDSS user could expand the categories in a progressively granular manner to get to specific individual risk factors. For example, a user could expand the ‘genomic risk factors’ group, which could be further expanded into ‘genetic biomarkers,’ ‘inflammation biomarkers,’ ‘muscle metabolites,’ and so on (see Lead User 1 Prototype for illustration). However, Lead Users 3 and 4 wanted to see individual genomic risk factors, such as gene alleles, presented in the list of non-modifiable risk factors if these risk factors contributed to the overall risk score significantly (see Lead User 3 Prototype, Lead User 4 Prototype for illustration). These Lead Users suggested that the big

data risk factors that had small contributions would not be shown to the user or would be shown as a single summary (e.g., genomics or other genomic factors). Their rationale for displaying such big data risk factors individually was that if they were contained in groups, they could be potentially missed and/or require the user to perform a number of clicks to get to them.

9.3.2.2.5 Highlighting Patient Data Quality Issues

The importance of patient data quality was a prominent theme that all the Lead User acknowledged. They emphasized that EMRs and other sources were likely to have outdated, erroneous, or missing patient data. Because the CDSS frailty risk score accuracy relied, in part, on the quality of patient data, all Lead Users agreed that data quality remediation is an important goal when considering the presentation of risk factors.

Seven out of eight Lead Users wanted the CDSS UI to highlight the issues with patient data and suggest how the data can be improved. All Lead Users were very knowledgeable about the issues of data quality in a typical EMR. Lead User 4 Prototype illustrates one example of how incomplete patient data could be brought to the attention of the user. In this design, the data quality issues are grouped into such categories as history, investigations, and observations, and the user can see at a glance the number of incomplete data items in each category. Another example where the data quality issues are prominently indicated to the user is in the Lead User 5 Prototype. Here the CDSS prompts the user to complete the data before generating a risk score. The designs of the other Lead Users that proposed the need to highlight the data quality issues are variations on these two design examples.

Unexpectedly, one Lead User with an extensive research background in EMR data quality specifically did not want the CDSS UI to include a data quality remediation functionality as part of the detailed risk assessment module. The Lead User stated their rationale as follows:

“Data quality is really important, but in reality, I do not have time to address it during a patient visit. There is just no time. There will be lots that’s missing, and I have other issues to address with the patient before I even get to frailty probably. Maybe if I had someone in my practice that could do data remediation... but no, I need the risk and what to do about it here. Nothing else.” (Lead User 6)

9.3.2.2.6 Displaying a Disclaimer about Masked or Filtered Data

Another goal that lacked agreement among the Lead Users was the display of a disclaimer about masked or filtered patient data. Although masking and filtering of patient data is not limited to genomic data, the Lead Users addressed it using genomics as a salient example. Four Lead Users felt it was necessary to have a banner-style disclaimer on the detailed risk assessment page where it would be stated, without being specific, that some patient data has been masked or filtered based on the patient’s preferences. Lead User 1 Prototype illustrates the implementation of this goal, where a disclaimer is shown for masked genomic data.

However, three Lead Users did not propose the requirement for this banner-style disclaimer about masked or filtered data. They addressed masked or filtered patient data as a type of data quality not dissimilar to other issues such as incomplete or outdated data. Moreover, Lead User 6 specifically proposed a goal not to display any disclaimers about masked or filtered data. This Lead User brought up this requirement based on their prior practical experience (and the

experience of other providers in the Lead User's country) with breakable masking for sensitive data in an EMR.

9.3.2.2.7 Updating Risk Factors

The majority of the Lead Users strongly emphasized that a CDSS user should be able to update the risk factors, where feasible, without switching to other EMR module. Lead User 8 echoed the sentiment expressed by most other Lead Users:

“So many EMRs require you to do a double entry for some things. I find it so frustrating and disrupting. I am doing one thing; then I have to go to some other screen to update something. This context switching is very distracting and can result in errors. Any good CDSS must ensure that there is no double data entry like that. The CDSS should automatically get all the relevant data from the EMR, and what I input in the CDSS should go to the patient record.” (Lead User 8)

9.3.2.3 Suggested Interventions

Prior to data collection, it was expected that the CDSS design scope would focus only on risk presentation and would not encompass intervention suggestions and care planning. However, early in the Lead User interviews, it became apparent that presenting risk information alone did not cognitively fit with the Lead Users' clinical workflows and decision making. Unanimously, the Lead Users expressed a variation of the following statement from Lead User 1:

“Unless you tell me what to do about this problem, I really don't care what the risk may be. I need actionable suggestions about how to help my patient.” (Lead User 1)

The design scope was expanded to include suggested interventions, as all the Lead Users expressed a number of relevant goals. However, due to the Lead User interview time limitations, the scope for suggested interventions was limited to the presentation of intervention for a single encounter. The evolution of a care plan over the episode of care was out of scope.

Similar to the goals for the CDSS notification, all the Lead Users stated that only the top few suggested interventions should be provided at a time. All the Lead Users proposed three suggested interventions.

Notably, the goals for if and how the risk/benefit information of interventions should be presented – was a contentious area across the Lead Users. Lead User 5 was the only proponent of displaying both the risks and benefits of a suggested intervention to the user. Lead Users 2 and 7 advocated only to show an intervention's benefit. Surprisingly, the other 5 Lead Users did not propose that risk or benefit be explicitly stated. It is important to note that the design of suggested interventions was addressed with the least rigor by the Lead Users for two reasons. First, the greater focus was on the presentation of risk information, as initially intended by this study. Second, the suggested interventions were typically discussed last during an interview. While all the Lead Users felt that a CDSS must provide suggested interventions along with risk information, time limitations likely did not allow the Lead Users to fledge out the intervention design details in sufficient depth.

9.3.3 Lead User UI Prototypes

Through the interview/analysis cycles for each Lead User, a UI prototype for each Lead User has been iteratively developed and validated. Two or three prototype versions were produced per Lead User, depending on the number of interviews. A final version of a Lead User prototype was completed based on the last interview with a Lead User.

Eight different final Lead User-validated prototypes resulted from this phase of the study.

Appendix O contains a detailed set of screenshots from all final Lead User prototypes. A Lead User prototype illustrated the Lead User goals as well as supporting tasks and required information resources.

As expected, the Lead User prototypes showed greater variability than the Lead User goal models. This was partly because a prototype implemented Lead User goals as well as supported tasks and information resources. Moreover, a prototype was but an instance of how a Lead User's goals could be met. Specifically, some goals shared among the Lead Users often were supported by different Lead User designs. This underscores the utility of the goal-oriented approach to requirements documentation, where the focus is to elucidate a 'why' vs. a 'what' to capture the information and functionality need of a Lead User rather than a specific example of a requirement implementation. For example, all Lead Users had a common goal to have the detailed patient risk information presented to them. The representation of such information took, however, different forms in the prototypes. For some Lead Users, such as Lead User 2, the risk information was represented in a textual and numerical format (see Figure 9). Some Lead Users, such as Lead User 5, envisioned a risk scale that visualized the patient and population risk (see Figure 10). Lead User 7 proposed both the textual and numerical format for risk representation,

as well as an interactive pictograph that visualized risk and allowed the user to visually see a potential risk reduction of one or more interventions (see Figure 11). Lastly, Lead User 8 had an entirely different approach to risk information presentation where the risk was visualized on a heat map (see Figure 12). All these different forms of presenting detailed patient risk in the prototypes aimed to meet the same user goal.

This design variability across the Lead Users was an important input into the Phase Two requirement synthesis process.

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment last assessment: [03-Jul-2017](#)
[more about frailty](#)

Patient's Risk: **25%** (15-35%) chance of becoming frail within next 5 years, patient is currently robust but has vulnerability to frailty.
 Population Average: **17%** for Caucasian women 65-74 years old.

Patient-Specific Risk Factors for Frailty

Currently showing: **Top 3** Filter by ▼

Patient Factor Category	Value (Range)	Modifiable	Absolute % of Contribution to Risk	Evidence Updated	Patient Info Updated
<input type="checkbox"/> Age ⓘ	70 years	no	8 to 12%	02-Oct-2008	06-Jan-1995
<input type="checkbox"/> Protein Intake ⓘ	Low	yes	2 to 6%	03-Jan-2009	21-Oct-2017
<input type="checkbox"/> Smoking Status ⓘ	Smoker	yes	2 to 4%	17-Jan-2006	20-Nov-2008

Showing 3 out of 17 categories

Incomplete Patient Information

Please update the following incomplete patient information for a more accurate Frailty Risk Score calculation:

[History](#) (3 items)
[Observations](#) (10 items)
[Investigations](#) (3 items)

Suggested Treatments to Reduce Frailty Risk

Currently showing: **Top 3** Filter by ▼

Increase Protein Intake Strength of evidence: **A** Severity for patient: **high** ☰

Current daily protein intake: 30 gr
 Recommended: 50-90 gr for female, 70 yrs, BMI 18.3 (165 cm, 50 kg), low activity level
 Increasing protein intake may reduce risk by 2 to 6% within next 5 years ⓘ
[update protein intake](#)

[patient handout](#)
[diet allowance form](#)
[DRI calculator](#)

Discussed with patient

Clinical notes:

Quit Smoking Strength of evidence: **A** Severity for patient: **high** ☰

Patient is a smoker: 1 ppd. 50 pack years
 Smoking cessation may reduce frailty risk by 2 to 4% within next 5 years ⓘ
[update smoking status](#)

[patient handout](#)
[smoking cessation clinic referral form](#)

Discussed with patient

Clinical notes:

Follow-up: Resistance Exercise Training Strength of evidence: **B** Severity for patient: **high** ☰

No resistance exercise training, poor muscle tone, slow gait
 Regular muscle building exercises may reduce risk of sarcopenia by 1 to 3% within next 5 years ⓘ
 Discussed with patient 03-Jul-2018 ([see notes](#))
[update exercise status](#)

[patient handout](#)
[seniors exercise groups - directory](#)

Discussed with patient

Clinical notes:

Showing 3 out of 10

Follow-up Reminder

 [appointment reminder](#)

Figure 9 Lead User 2 prototype – Default detailed frailty risk assessment page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Frailty Risk Score: **70%** (65-75%) chance of [Mobility Disability](#) within next 12 months, patient is currently high-functioning ⓘ
 Population Average: **35%** (30 to 40%) for Caucasian women 70-80 years old.

Patient's risk is high, **2x** compared to population average.

Patient Risk Factors for Frailty

The following risk factors were used in the Frailty Risk calculations.
[show modifiable risk factors](#)
[show non-modifiable risk factors](#)
Some genomic information has been filtered out upon patient's request

Patient Goals

Please complete [Patient Values and Goals for Frailty Risk and Management](#)
 This tool allows the patient, provider, and the clinical decision support system to better determine clinically actionable interventions to reduce frailty risk and manage frailty outcomes.

Suggested Interventions to Reduce Frailty Risk

Introduce Resistance Exercise Training Strength of evidence: A Severity for patient: high ⓘ
 Regular (3 times/week), mild intensity muscle building exercises may reduce risk of mobility disability and sarcopenia by 10% (5 to 15%) (absolute % of risk reduction) in next 12 months ⓘ
[absolute frailty risk/benefit calculator](#)

Risk Factor	Value	Normal Range (for age, gender)	Value Trend for Patient	Potential Harms/Benefits	Absolute % of Contribution to Risk	Patient Info Updated
Resistance Training	none ▼			Mobility disability, sarcopenia ⓘ	10% (5 to 15%) ⓘ	03-Jul-2018
Discussed with patient <input type="checkbox"/> Clinical notes: <input type="text"/> <div style="text-align: right;"> <input type="button" value="Clear"/> <input type="button" value="Save"/> </div>						

Quit Smoking Strength of evidence: A Severity for patient: high ⓘ
 Smoking cessation may reduce overall frailty risk by 5% (3 to 7%) (absolute % of risk reduction) in next 5 years ⓘ
[absolute frailty risk/benefit calculator](#)

Risk Factor	Value	Normal Range (for age, gender)	Value Trend for Patient	Potential Harms/Benefits	Absolute % of Contribution to Risk	Patient Info Updated
Smoking Status	1 ppd. 50 p yrs			COPD, Cancer ⓘ	5% (3 to 7%) ⓘ	31-Aug-2018
Discussed with patient <input type="checkbox"/> Clinical notes: <input type="text"/> <div style="text-align: right;"> <input type="button" value="Clear"/> <input type="button" value="Save"/> </div>						

Showing 2 out of 10 [more](#)

Figure 10 Lead User 5 prototype – Detailed frailty risk assessment page

Name: Annie Smith **Age:** 80 **DoB:** 21-Jan-1938 **Sex:** F **Health #:** 900 123 456

Integrated Geno/Pheno Geriatric Frailty Risk Assessment

Patient's 12-month absolute risk of recurrent falls: **80% (High)** ⓘ
Calculated based on patient data available in the EMR

Risk Calculator

The risk calculator shows patient risk factors used in the calculation. The calculator also presents suggested treatments and their relative benefits. You can update the patient-specific risk factors and/or select the treatments to see their impact on the risk score.

Risk Factors <i>Some genomic data are masked and thus excluded from the calculation</i>	Absolute Risk Risk Time Period: 12 months	Relative Benefit of Suggested Interventions: 0%
<p>Age ⓘ 80 yrs</p> <p>History of Falls ⓘ 1 in last 12 months; right humerus fracture</p> <p>Osteoporosis ⓘ yes</p> <p>Smoking Status ⓘ 1ppd. 50 pack years</p> <p>Antihypertensive Medications ⓘ Ramipril – tablet – DOSE 2.5 mg – oral – once a day</p> <p>Body Mass Index ⓘ 18.3 Height: 165 cm Weight: 50 kg (underweight)</p> <p>Inflammatory Biomarkers ⓘ Increase</p> <p>CpG Islands Methylation ⓘ Increase</p> <p>MMSE Score ⓘ Missing</p> <p>Gait Speed ⓘ Missing</p> <p>Daily Protein Intake ⓘ Outdated</p>	<p>20% No event</p> <p>80% Total with an event</p> <p>0% Number who benefit from treatment</p> <p>NNT - Number needed to treat</p> <p>50% Baseline events using age alone</p> <p>30% Additional events "caused" by risk factors</p>	<p><input type="checkbox"/> Mobility Aids</p> <p>Relative Benefit: 25%</p> <p>Benefits of Treatment Reduced risk of falls Greater independence</p> <p>Harm of Treatment Dependence on mobility aids</p> <p>Patient Handout Mobility/assistive aids guide</p> <p><input type="radio"/> not relevant <input type="radio"/> patient declined <input type="checkbox"/> discussed with patient</p> <p>Clinical notes: <input type="text"/></p> <p><input type="button" value="Clear"/> <input type="button" value="Save"/></p> <hr/> <p><input type="checkbox"/> Strength Building Exercise</p> <p>Relative Benefit: 15%</p> <p>Benefits of Treatment Reduced risk of falls Improved muscle strength Decrease in depression Improved sleep quality Improved physical and mental functions</p> <p>Harm of Treatment Potential for activity-related injury</p> <p>Patient Handout Exercise guide to reduce falls for frail seniors</p> <p><input type="radio"/> not relevant <input type="radio"/> patient declined <input type="checkbox"/> discussed with patient</p> <p>Clinical notes: <input type="text"/></p> <p><input type="button" value="Clear"/> <input type="button" value="Save"/></p>

Figure 11 Lead User 7 prototype – Default detailed frailty risk assessment page

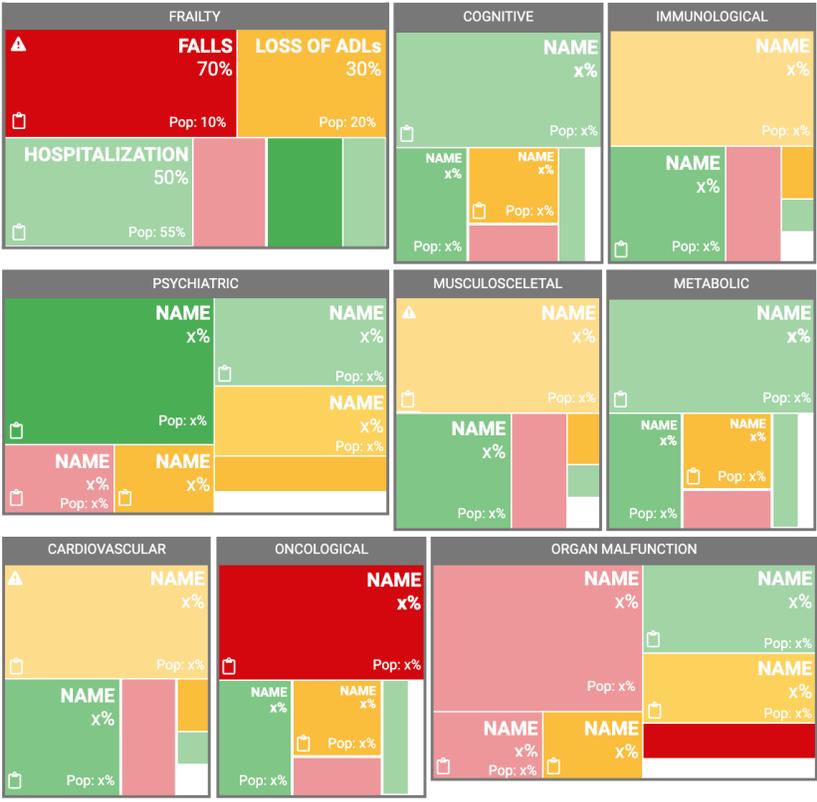
Name: Annie Smith **Age:** 80 **DoB:** 21-Mar-1938 **Sex:** F **Health #:** 900 123 456

Risk Assessment

- Views**
- Health Domain**
- [Absolute Risk Range](#)
 - [Work Status](#)
 - [Relative Risk Level](#)
 - [Strength of Evidence](#)
 - [Patient Priority](#)
 - [Data Quality](#)
 - [Provider Priority](#)

Life-time risk for 48 conditions evaluated and grouped by Health Domains. Size of rectangles within each Health Domain represents absolute risk. Colour represents risk level relative to population average. Population average is based on patient's age, gender, and ethnicity.

- Search**
- Start typing ...
- [Age-related Macular Degeneration](#)
 - [Alzheimer's](#)
 - [Arrhythmia](#)
 - [Basal Cell Carcinoma](#)
 - [Breast Cancer](#)
 - [Colorectal Cancer](#)
 - [Congestive Heart Failure](#)
 - [COPD](#)
 - [Depression](#)
 - [Falls](#)
 - [Loss of ADLs](#)
 - [Loss of Hearing](#)
 - [Lung Cancer](#)
 - [Melanoma](#)
 - [Myocardial Infarction](#)
 - [Non-Hodgkin Lymphoma](#)
 - [Obesity](#)
 - [Osteoporosis](#)
 - [Ovarian Cancer](#)
 - [Pancreatic Cancer](#)
 - [Parkinson's](#)
 - [Renal Impairment](#)
 - [Rheumatoid Arthritis](#)
 - [Sarcopenia](#)
 - [Stomach Cancer](#)
 - [Type 2 Diabetes](#)
- [> more](#)



Use mouse wheel to zoom in and out.
 Hover mouse cursor over a condition to see more details on the risk score.
 Double-click to go to the condition management module.

Reduced risk Increased risk

Figure 12 Lead User 8 prototype –Risk assessment page showing a holistic view for patient’s risks

9.4 Summary of Findings

Eight Lead Users were engaged for this phase of the study as co-designers. The key outputs of Phase One were: a description of socio-technical actors, tools, and information resources involved in frailty risk assessment and management; Lead User requirements documented as Lead User goals; and visual UI prototypes that illustrated their requirements. The prototypes provided a platform for CDSS design ideation, and a means to validate the Lead user requirements. The findings from Phase One were synthesized in Phase Two and evaluated with representative users for external validity in Phase Three of the study.

Chapter 10: Phase Two Results

10.1 Synthesis Team Members

The synthesis process was carried out by the Synthesis Team that had four members. The Team consisted of the Ph.D. Supervisory Committee and the researcher. No study subjects or external experts were recruited for this phase. Each member of the interdisciplinary Team brought a different set of complementary skills and expertise into the Synthesis process, as very broadly summarized in Table 4.

Table 4 Summary of Phase 2 Synthesis Team members' expertise

Team Member 1	Primary care, family medicine, health information system analysis and design, genetics
Team Member 2	Patient, software engineering, system safety
Team Member 3	Primary care nursing, patient-reported quality of care
Team Member 4	Health information system analysis and design, quality assurance, Lead User perspectives

10.2 Synthesis Sessions

The Synthesis Team reviewed draft requirement patterns, linking back to Phase One materials and evidence when discussing proposed patterns. Data used for this phase of the study were the findings of Phase One: the system context described by the Lead Users, the Lead User goals, and the Lead User UI Prototypes. The Synthesis Team met regularly over six months for a total of 20 meeting hours. The majority of meetings took place over video conferencing.

10.3 Findings

10.3.1 Integrated System Actors and Tools

Part of Phase One entailed a detailed analysis of frailty assessment and management as a socio-technical system. The analysis showed frailty to involve various types of clinical information interchanged among many actors and tools as part of distributed clinical decision making. Phase Two focused specifically on examining and integrating the system actors and tools, described by the Lead Users in Phase One, into one cohesive model. Before integrating the goals proposed by the Lead Users in Phase One, it was important to understand how frailty care decision-making is distributed among human and technological entities and what role a CDSS plays in this socio-technical context.

The system actors and tools were documented into one integrated Strategic Dependency Model (SDM), as illustrated in Figure 13.

There were no conflicts among the actors and tools described by different Lead Users. The Synthesis Team reviewed and approved the SDM. The goal outlined in blue is ‘Frailty risk assessed,’ and is the goal posed by this research. As the SDM depicts, a primary care provider relies on the CDSS to fulfill this goal. This core goal is further specified in the Integrated Goal Model described in the next section (Integrated Lead User Goals).

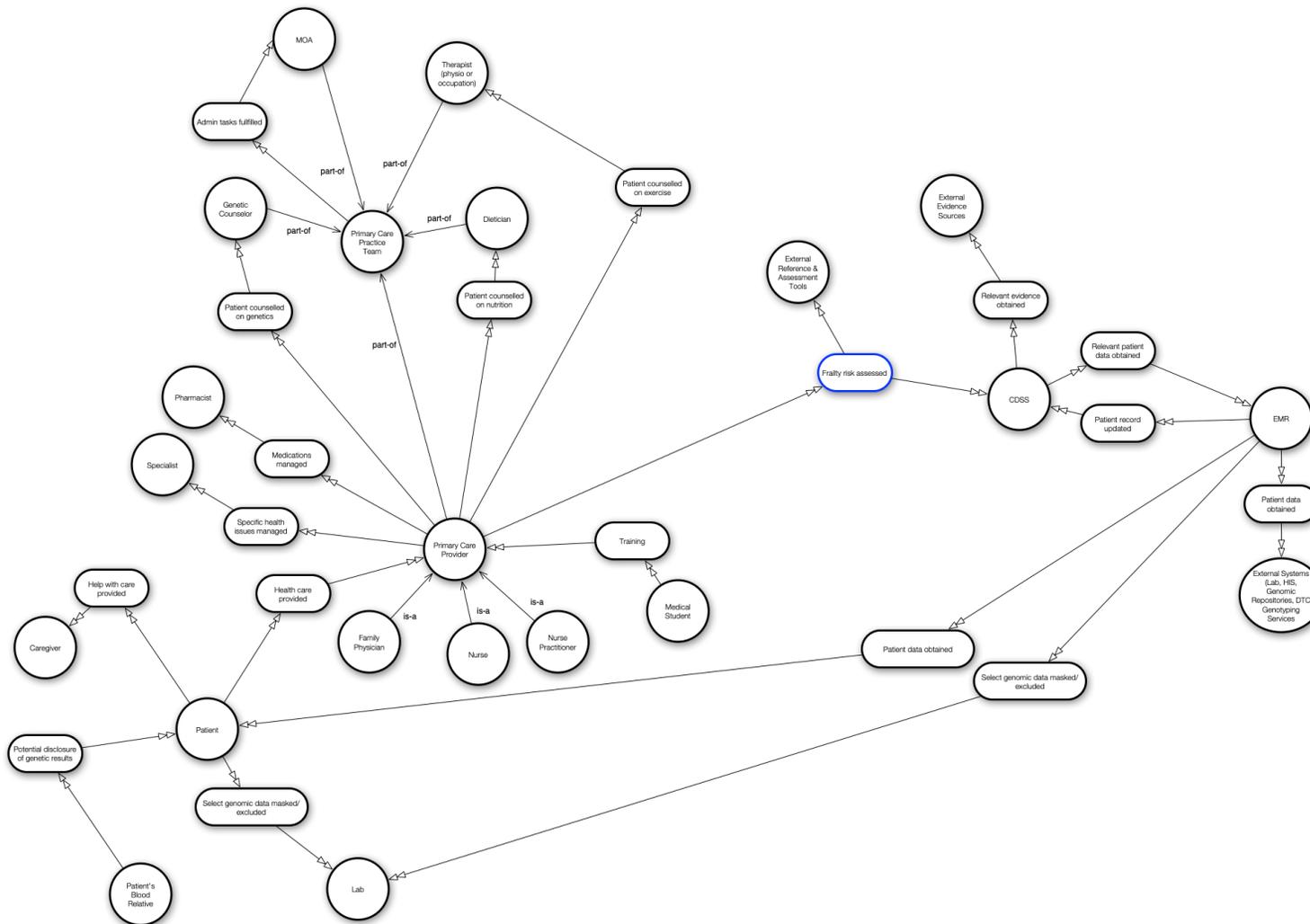


Figure 13 Strategic Dependency Model depicting the actors and tools that may be involved in frailty risk assessment

The Team recognized that the SDM was not exhaustive intentionally, but instead attempted to illustrate that frailty involves a complex set of interconnected actors and tools. The Team acknowledged that, in reality, frailty management for each patient would involve a different configuration of actors and tools that change over time. For example, a patient's set of comorbid conditions may require the engagement of different specialists. Various stages of frailty may also entail different assessment tools. Patient data may come from a variety of sources, particularly as the care model moves towards big data where genomic repositories, and passively collected sensor data may become increasingly added to the patient data set. External evidence sources for the CDSS are likely to advance also. Moreover, health care providers may rely on a multitude of electronic and other information resources mentioned by the Lead Users (for example, various web sites and print-outs used in the clinic). Such tools would not be feasible to enumerate in an SDM comprehensively.

Consistent with the Lead Users, the Team emphasized the importance of addressing frailty with the patient and the patient's supports at the center of the care model. This was later addressed in goal modeling/integration and the requirement pattern development, where patient goals of care were factored in many aspects of CDSS design.

The Synthesis Team confirmed the assumption expressed by the Lead Users that masking or exclusion of patient data (for example, parts of a patient's genome excluded per patient's request) would be handled at the laboratory level and not addressed as part of CDSS UI design. It is feasible to include such functionality in the CDSS; however, the unmasking or inclusion of such data was confirmed to be out of scope for this research by the Synthesis Team. This assumption is illustrated in the SDM with the goal titled "Select genomic data

masked/excluded,” where the Patient actor and the EMR actor rely on the Lab to exclude or mask select data.

10.3.2 Integrated Lead User Goals

The second output of the Synthesis was an Integrated Goal Model that systematically unified the high-level Lead User goals documented in Phase One. There were two iterations for the unification of the goals and goal qualities with version changes documented in Appendix O. The tables provide originator, origin, and integration rationale traceability.

Figure 14 shows the resulting Integrated Goal Model with goals only. Figure 15 shows the goals with the associated qualities. This integrated set of goals and qualities became the foundation for the detailed UI requirement patterns for a genomic CDSS: the patterns supported the goals.

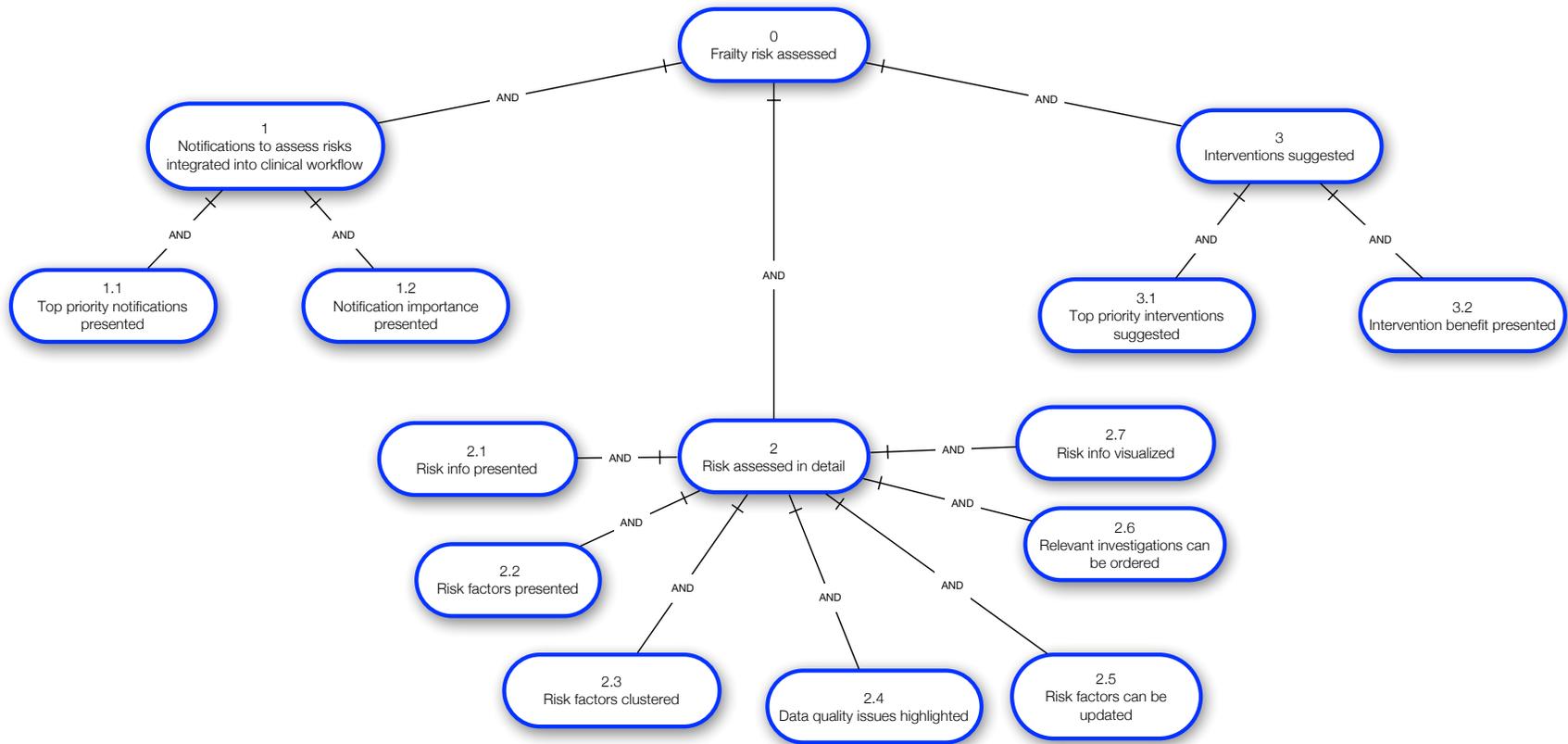


Figure 14 Integrated Goal Model illustrating the goals

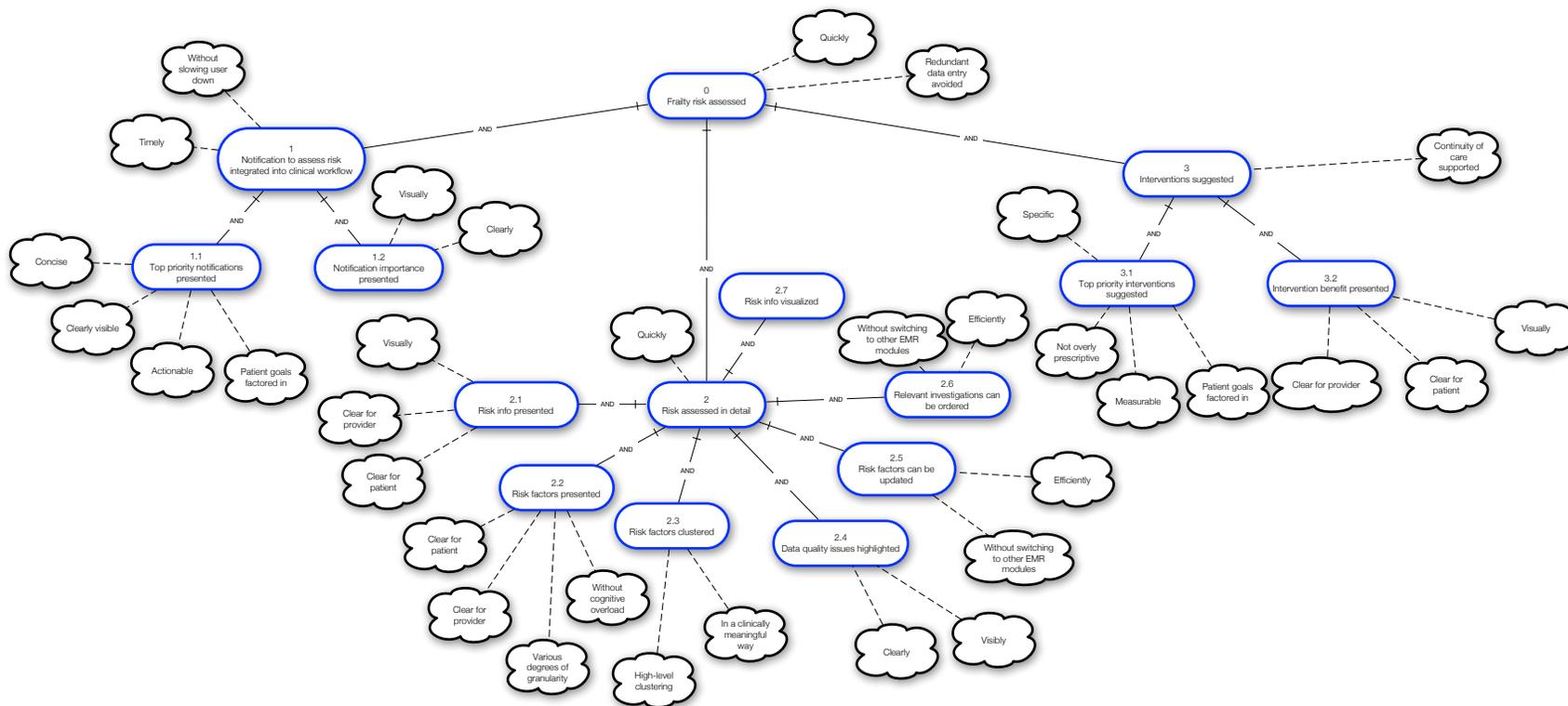


Figure 15 Integrated Goal Model illustrating the goals and the qualities

The Synthesis Team agreed by consensus on the three, synthesized top-level goals. These were unanimously proposed by the Lead Users in Phase One:

1. Have CDSS risk notifications integrated into clinical workflows,
2. Have the ability to see detailed risk information, and
3. Have the suggested interventions to address risk.

The qualities proposed by the Lead Users for these top-level goals were also confirmed. The qualities embodied the requirements for the CDSS to be aligned with the users' existing mental models and decision-making process. It was important for the Lead Users to have the ability to assess risk quickly within the context of a typical encounter. Redundant data entry had to be avoided, and the continuity of care had to be supported over time.

The majority of goal analysis and integration were spent on the sub-goals of the top-level goals listed above. Most sub-goals were also largely consistent: same, semantically similar across the Lead Users, or proposed by the majority of the Lead Users without conflicts. The goals that had more significant inconsistencies or conflicts were elaborated in more detail by the Synthesis Team. These sub-goals are organized under the three top-level goals below. Only the incongruent sub-goals and their harmonization by the Synthesis Team are described in detail.

10.3.2.1 CDSS Notifications

10.3.2.1.1 Workflow Integration

The goals for the presentation of CDSS notification during a clinical workflow were largely consistent among the Lead Users. It was important for the Lead Users to see a small number of

the most important notifications during an encounter. The notifications had to be available in a timely manner during a decision-making process. The Lead Users wanted to have sufficient informational context to quickly and easily assess the relevance and significance of the notification in order to make a decision for how/if the notification should be actioned. As there were no incongruencies or conflicts, the goals for presenting the CDSS notifications were reviewed and approved by the Synthesis Team. These requirements are reflected in the Display Health Outcome Risk Assessment Notifications pattern and its sub-patterns.

10.3.2.1.2 Notification Details

There were significant differences in the level of details that the Lead Users suggested for a notification. While some took a minimalist approach, most suggested a rich informational context. The Synthesis Team reviewed all the different types of information that the Lead Users proposed for the inclusion in a notification. The literature did not provide specific guidance for preventive CDSS notifications or how big data can be summarized/integrated into a notification. General CDSS UI guidelines (Sittig et al. 2008; Miller et al. 2018) that related to the notification/alert design were reviewed, as well as several publications that did comprehensive reviews of specialized CDSS such as medication alerting systems (Horsky et al. 2012; Marcilly et al. 2018).

Guided by the Lead User data and the limited available input from the literature, the Synthesis Team determined that CDSS notifications should be clear, concise, yet have a wide range of clinical information for the user to make an informed decision on how the notification could be actioned. These requirements are reflected in the Display Health Outcome Risk Assessment Notifications pattern and its sub-patterns.

10.3.2.2 Detailed Risk Assessment

Detailed risk assessment was an area that necessitated the majority of synthesis work. Here the Synthesis Team deliberated the inconsistencies among the Lead User goals for visualization of risk info, presentation of risk factors, and the display of an explicit stand-alone disclaimer for masked or excluded patient data.

10.3.2.2.1 Visualization of Risk

The visualization of a risk score did not initially come out of the Lead User data as a prominent requirement. The visualization requirement was documented as a quality for some Lead Users indicating that patient risk information could be presented ‘Visually.’ For some Lead Users, the visualization requirement was documented as a task (lower-level requirement) that would be fulfilled by a CDSS as part of the risk presentation goal. Some Lead Users did not propose any visualization, stating that would be unnecessary or potentially distracting (none of the Lead Users were explicitly against visualization). The Lead Users who did propose the visualization tended to rate the utility of risk visualization as fairly low, as a ‘nice-to-have’ but not a key goal.

However, during the synthesis process, it became apparent that risk score visualization should be considered as one of the key goals in the Integrated Goal Model for the following reasons.

Firstly, the Synthesis Team members who were tasked to represent the patient perspective in the synthesis process felt that accessible and clear risk score visualization would be a valuable tool for risk communication to the patient, particularly in the context of frailty where a patient may have compromised cognitive resources. Secondly, the evidence from the literature for the display of risk information was reviewed, and studies widely showed that when the numeric risk information is accompanied by a graphical presentation, patients tend to perceive risk more

accurately (Waldron et al. 2011). Moreover, the evidence indicated that presenting risk information in different formats may aid in better cognitive fit for different types of information consumers (Lautenbach et al. 2013) – both patients and providers.

Based on the patient perspective and the evidence from the literature, the Synthesis Team decided to include risk information visualization as one of the goals in the Integrated Goal Model. This goal became a foundation for the development of a requirement pattern for risk visualization (see Visualize Health Outcome Risk pattern). A pictograph-based approach was selected as pictographs have been shown to be the most effective way to communicate complex risk information to patients (Wong et al. 2012; Fischhoff, Brewer, and Downs 2014).

10.3.2.2.2 Presentation of Risk Factors

Focusing on the presentation of risk factors was one of the main tasks of the Synthesis Team.

The Synthesis Team had to determine the goals for presenting the risk factors in a way that fits with the provider's workflows and facilitated decision making. The Team focused on analyzing several dimensions important for the risk presentation.

10.3.2.2.3 Default Display of Top Risk Factors

The majority of the Lead Users specified that the list of the risk factors should be available on-demand only. From the Lead User data, it also became apparent that the risk factors had to be explicitly differentiated as modifiable and non-modifiable. The modifiable (actionable) risk factors with the greatest contribution to the risk score were of most interest to the Lead User, as

the physicians are action-oriented and need to know what modifiable risk factors can be targeted with interventions.

The literature reviewed by the Synthesis Team supported the rationale for making the risk factors clearly available to a user. Antecedent factors for an outcome provide an important informational context for a risk score (Rothman and Kiviniemi 1999). The risk factors highlight how the constituent parts of the probability can or cannot be altered and thus help with risk assessment and interpretation (Rothman and Kiviniemi 1999). Providing risk factors can also help the CDSS users understand how a CDSS calculates the risk score. This knowledge may facilitate better trust in a CDSS (Bussone, Stumpf, and O’Sullivan 2015).

The Synthesis Team decided that the top small number of the top modifiable risk factors should be available by default with the option for the provider to view more risk factors. This decision was made based on two arguments. First, the literature that underscored the importance of the risk factors as part of the risk evaluation context. Second, displaying the risk factors explicitly can highlight data quality issues that the risk factors may have, allowing the user to remediate the data quality issues.

The detailed requirements for risk factor presentation were captured in the Display Risk Factors pattern and its sub-patterns.

10.3.2.2.4 Clustering of Risk Factors

As described in Phase One results, the majority of the Lead Users strongly advocated the clustering of the genomic risk factors into high-level groups. Only two Lead Users did not

support the clustering of genomic data into clinical categories, and their prototypes displayed individual risk factors such as gene alleles on the overall list of risk factors (see Lead User 3 Prototype, Lead User 4 Prototype for illustration).

The Lead User data suggested variation for the level of clustering granularity that was desirable. For example, some Lead Users wanted a very high level of grouping of the risk factors such as Proteomic Biomarkers, while others preferred the risk factors to be clustered into more granular groups such as Inflammation Biomarkers or Renal Biomarkers, for example. Therefore, flexibility in presentation format had to be considered to support the providers' information needs adequately.

The literature did not appear to provide concrete guidance on presenting the big data risk factors (genomic or other types of big data) to the provider in a manner consonant with the provider's mental model to ensure cognitive fit. Nor did the literature suggest specific categories for organizing big patient data.

The Synthesis Team expanded the discussion on the clustering of risk factors from big data to clustering of all types of risk factors into clinically meaningful hierarchical categories. The Team suggested that clustering can be potentially utilized for all types of patient risk factors, not only big data. For example, the traditional risk factors can be grouped into such categories as Lifestyle or Blood Work.

The Team made a decision to include the goal for the clustering of risk factors and proposed that an existing nomenclature such as what a particular EMR may be using or a standard

nomenclature such as LOINC could be utilized to determine the grouping. Moreover, the Team indicated that the user should ideally have the ability to define custom groupings for the risk factors. The user customization of risk factor grouping would facilitate an appropriate cognitive fit for different types of users and risk assessment/management contexts.

The detailed requirements and considerations for big data clustering were documented in the requirement patterns for risk factor presentation (see Display Risk Factors pattern).

10.3.2.2.5 Highlighting Patient Data Quality Issues

All Lead Users stressed the importance of addressing the quality of patient data used by a CDSS based on their experience with suboptimal data quality in most EMRs. The majority of the Lead Users stated that data quality issues should be brought to the attention of the user during a risk assessment/management task to facilitate data remediation. One Lead User, in contrast, did not feel that a provider can feasibly correct data quality during a clinical encounter due to time and cognitive limitations. This Lead User felt that highlighting data quality at the point of care would thus be unnecessary and even distracting to the user. This Lead User saw data quality remediation as an important task, but one that should be done outside of the encounter.

There is an abundance of evidence from the literature on the data quality problems with longitudinal EMR data (Ray and Houston 2005; Price et al. 2017). EMR data may vary in regards to how it was collected, detail levels, precision, and subjectivity (Cruz-Correia et al. 2018), documentation and measurement correctness (Chan, Fowles, and Weiner 2010). Moreover, a genomic CDSS would incorporate biomarker data as another input into its

predictive models for risk assessment. For genomic data, quality issues may stem from biological, instrumental, environmental, or interpretation issues (Wu et al. 2017).

Moreover, data collection frequency plays a role in data quality and precision of risk assessment. Collection frequency can vary for different data types: genome data is invariant and typically requires one-time data acquisition; other genomic data may vary with environment, tissue types, and time and require multi-time-point acquisition; clinical variables in the EMR have irregular sampling frequencies (Wu et al. 2017). The variability of collection frequency and varying length of available patient history may mean that some data that are important for generating a risk score are not available or outdated.

The literature also supports the value of explicitly bringing the data quality issues to the provider's attention because erroneous, missing, and outdated patient data influence CDSS risk confidence and, thus, risk interpretation of a provider (Hasan and Padman 2006). Data quality, in other words, is an integral part of the risk interpretation context.

In agreement with the majority of the Lead User and supported by the literature, the Synthesis Team made a decision that highlighting data quality as part of risk assessment/management at the point of care is an important goal. This would potentially allow the provider to interpret the risk score accuracy better. Further, the provider can then take immediate data remediation steps with the patient, such as updating the patient's history or observations or ordering an investigation.

The requirements for highlighting data quality issues in the risk factors were elaborated in the Display Risk Factors pattern.

10.3.2.2.6 Displaying an Explicit Disclaimer about Masked or Filtered Data

Half of the Lead Users proposed the display of a stand-alone prominent banner-style disclaimer for masked or filtered patient data on the detailed risk assessment page. One Lead User, in contrast, was explicitly against displaying such a banner. Three other Lead Users felt that it was sufficient to indicate the masking or exclusion of data in the list of risk factors, essentially treating such patient data as having a type of quality issue (masking or exclusion indicate incompleteness in the patient's record). The first (preliminary) version of the Integrated Goal Model did capture the goal of having the explicit banner-style disclaimer for masked or filtered data. It was important to include this goal for the Synthesis Team review, given that half of the Lead Users felt strongly in favour of it.

The literature overview indicated that there is much debate about disclosure considerations for patient data used for clinical decision making at the point of care (Harman, Flite, and Bond 2012). Moreover, the topic of 'genetic exceptionalism' is especially contentious. One viewpoint is that genetic/genomic data access should be treated similarly to other sensitive information in an EMR/EHR (Glaser et al. 2008). The literature did not, unfortunately, appear to provide guidance for a specific evidence-based approach to addressing sensitive risk factors in a UI for a health care system such a CDSS.

After some debate, the Synthesis Team decided to treat masked or filtered data, whether it pertains to genomics or other types of data, as a variation of data quality. For example, if a risk

factor had a masked value, the CDSS could indicate that the value was masked similarly to indicating that the value was outdated, not documented, or potentially erroneous. This requirement is captured in the Display Risk Factors pattern.

Consequently, the goal to display an explicit disclaimer about masked filtered patient data was deemed unnecessary as it would be addressed by highlighting patient data quality issues. The final version of the Integrated Goal Model, therefore, does not include a goal to display a separate disclaimer for masked or filtered data.

10.3.2.3 Suggested Interventions

The Synthesis Team confirmed that the scope of the CDSS design must include suggested interventions. The literature also stated that when the risk for a health problem is being considered, information about what can be done to prevent the problem is integral in the clinical context for both the provider and the patient (Rothman and Kiviniemi 1999). The Synthesis Team decided that the study scope would not include the care plan design for an entire episode of care but would focus on how suggested interventions could be presented during a single encounter. The CDSS care plans that span an episode of care (their complexity for comorbid conditions and evolution over time, particularly) are complex design problems beyond the capacities of this study.

The synthesis debate around the suggested interventions focused mainly on the presentation of risks and benefits of suggested interventions.

10.3.2.3.1 Presenting Risks and Benefits

While all the Lead Users agreed that suggested interventions should be presented as part of detailed risk assessment, there were differences in what key intervention details should be displayed. The elements that required most deliberation by the Synthesis Team were intervention risks and benefits. Only one Lead User proposed that both the risk and benefit of an intervention should be presented. Two Lead Users proposed displaying a benefit, and the rest did not propose any risk or benefit information to be shown.

The topic of risk and benefits presentation is one that is extensively discussed in the literature (Fischhoff, Brewer, and Downs 2014). The literature suggests that different presentation of an intervention's risks and benefits can impact clinical decisions (Carling et al. 2008).

The Synthesis Team determined that absolute risk reduction (ARR) should be provided for a suggested intervention. This decision is congruent with one of the most consistent findings from the literature: ARR, as opposed to relative risk reduction (RRR), results in a more accurate interpretation of intervention benefit (Akl et al. 2011). The Team also concluded that intervention risk should not be included as it is often difficult to accurately estimate the risk of a frailty-related intervention (as opposed to a medication, for example) for a patient and such information provides an additional cognitive load to the user with a limited benefit for decision making. Moreover, the Synthesis Team proposed that the suggested interventions be integrated with risk visualization, allowing the user to select one or multiple suggested interventions and visually see their potential impact on the overall risk score.

The requirements for presenting intervention benefits are captured in the Display Suggested Intervention pattern.

10.4 Requirement Patterns

The third and main output of the Synthesis was a set of requirement patterns for a genomic CDSS UI.

A requirement pattern, as defined for this study, is a set of high-level requirements that describe the system functionality and information needs of a user. A pattern attempts to define key requirements for a solution to a repeating problem (Alexander, Ishikawa, and Silverstein 1977). An example of a repeating problem may be ‘how to present numerical risk information to a provider with minimal cognitive load and maximum cognitive load to support clinical decision making?’ The requirement patterns abstract away from the specific implementation details, making them reusable across different systems (such as different EMR implementations).

The patterns in this study are based on the Lead User data from Phase One and the synthesis materials, including the evidence from the literature (these details are in the patterns and are not repeated in this section).

The produced patterns were grouped into four categories: Notifications, Risk Presentation, Risk Factors, and Suggested Interventions. The reader is referred to the finalized version (based on the results of the overall study) of the pattern map and the description of the individual patterns in Figure 16 and Table 7 respectively.

Appendix V includes detailed requirement patterns. Appendix H provides the definition of pattern structure and how a pattern should be read/interpreted.

The patterns were used to create the final integrated UI prototype that was used in the validation phase of the study (Phase Three), as described in the next chapter.

10.4.1.1 Requirement Pattern Synthesis Example

This section illustrates how the Synthesis Team reviewed one requirement pattern, Visualize Health Outcome Risk. This is used to briefly illustrate the synthesis process.

First, the Synthesis Team went back to the original Lead User prototypes from Phase One to review specific proposed approaches to risk visualization. The Team discussed and acknowledged the variability in the Lead User prototypes for visualization: risk scales, a pictograph, a heat map.

Next, the Synthesis Team turned to the literature for best practice for risk visualization. The conclusion from the literature review was that a pictograph was likely the optimal approach for visualizing risk for a provider and a patient. Studies show that 10x10 continuous arrays with human figures for icons pictographs are the best type of graph for communicating both the gist and verbatim knowledge (Fischhoff, Brewer, and Downs 2014; Feldman-Stewart et al. 2000; Schapira, Nattinger, and McHorney 2001).

Moreover, the literature also indicated that engaging the information recipients in the process of risk evaluation may increase their understanding of risk and the likelihood of changing their

behaviours to reduce risk (Emmons et al. 2004). One suggested approach for such engagement is the use of interactive visual calculators that allow the user to manipulate results of the risk score by selecting interventions and seeing how altering certain risk factors through interventions might change the risk score (Lautenbach et al. 2013). Lead User 7 Prototype illustrated these best risk visualization and patient engagement principles through an interactive pictograph-based risk calculator.

After some discussion on options, fit of those options to the decision making and workflow, supported by the evidence and using the Lead User 7 Prototype example, the Synthesis Team came to consensus on the approach. Then the Team specified detailed requirements for risk visualization and the integration of visualization with suggested interventions in the Visualize Health Outcome Risk pattern.

10.4.2 Integrated UI Prototype

The final output of Synthesis was the design of a UI prototype that met the requirements described in the requirement patterns. Appendix P provides screenshots to illustrate the integrated UI prototype. The integrated prototype was implemented by the researcher and was based on Material Design UI guidelines and components. The prototype represented one example of requirements implementation, as the patterns could be implemented in a variety of ways depending on the underlying UI framework and pattern interpretation by the CDSS developers.

The prototype served several purposes: to test the patterns through implementation, to illustrate the patterns, and to be used as a medium to validate the CDSS UI requirements with representative users in Phase Three of the study (see the next chapter).

10.5 Summary of Findings

Four types of design artifacts were produced during the synthesis portion of the study: a Strategic Dependency Model (SDM) that illustrated the actors and information tools that may be involved in frailty assessment and management; an Integrated Goal Model that served as a foundational set of high-level requirements for the requirement patterns; a set of eighteen detailed CDSS UI requirement patterns; an integrated UI prototype based on the patterns.

The requirement patterns and the integrated UI prototype were used in Phase Three of the study.

Chapter 11: Phase Three Results

11.1 Representative User Participants

Six Representative Users were recruited and interviewed according to the study protocol. Each participant was interviewed once for approximately one hour.

All participants were from Canada. Just like the Lead Users in Phase One, all participants were experienced primary care physicians with multiple relevant roles (for example, an academic, a nursing home physician, and an office-based primary care physician).

Table 5 summarizes the characteristics of the participants and their collective experience in primary care, using EMRs, and current utilization of genetic testing in their practice.

The Representative Users differed from the Lead Users from Phase One in three aspects. First, the Representative Users were not generally involved in EMR or CDSS design projects as extensively as the Lead Users. The Lead Users, in contrast, all had health system design experience, which was an important Lead User characteristic for CDSS UI ideation in Phase One. Second, Phase Three participants did not tend to have a significant background in genetics/genomics. In contrast, the Lead Users had either an educational, research, or some practical experience with different aspects of integrating genomic data into patient care (although only one Lead User employed genetic testing specifically for their frail population). Third, the Representative Users were tasked to play a different role in the study, compared to the Lead Users. While the Lead Users wore designer hats and were engaged in several hours of detailed ideation sessions, the Representative Users were specifically asked during a single one-hour usability testing session to envision the use of the CDSS in a realistic care setting. The

Representative Users then provided feedback from the perspective of a physician who was seeing a complex elderly patient within the time and resource constraints of a typical primary care encounter.

Table 5: Summary of Phase Three research participants and their collective experience

Number of Representative Users Interviewed	6
Average Age	49
Male Representative Users	4
Female Representative Users	2
Average Years of Experience in Primary Care Practice	18
Average Years Using EMR	10
Number of Representative Users Utilizing Genetic/Genomic Testing for Frailty	0

11.1 Usability Testing Sessions

All usability testing sessions with the participants were conducted over three weeks. Four participants were interviewed in-person and two over video conferencing.

11.2 Findings

11.2.1 UI Prototype Feedback and Resulting Pattern Changes

During the usability testing, the Representative Users reviewed all screens in the prototype and provided feedback on each component of the UI prototype. The detailed transcribed feedback from all participants is included in Appendix Q.

Overall, the participants had a positive impression of the prototype. All participants felt that the CDSS would be a helpful tool in assessing frailty in their current practice, even in the current state without the genomic data.

Representative User 1 stated:

“I would really like to see this tool when I do periodic health exams with my elderly patients now.” (Representative User 1)

The participants also stated that a CDSS like this would be an indispensable tool when big data are integrated into primary care, as the big data would be above the human cognitive capacities for effective interpretation.

The Synthesis Team reviewed the detailed feedback in the context of the top three goals that the prototype supported (the goals were proposed by the Lead Users in Phase One, confirmed by the Synthesis Team in Phase Two, used for the development of the requirement patterns and, consequently, the UI prototype). The goals were:

1. Have CDSS risk notifications integrated into clinical workflows,
2. Have the ability to see detailed risk information, and
3. Have the suggested interventions to address risk.

The participant feedback affirmed the majority of the requirements. However, there were several proposed changes to the UI prototype that prompted further deliberation by the Synthesis Team

to determine the necessary updates to the requirement patterns. The Synthesis Team reflected on the evidence from the literature during the deliberation, where appropriate. Appendix S shows the list of proposed changes and what decisions were made by the Synthesis Team. Appendix S itemises the changes that were made to the requirement patterns. Appendix U contains the complete set of the finalized requirement patterns.

The participant feedback and the requirement pattern changes are summarized below. Note that not every feedback element is discussed here as the focus is on describing and rationalizing the more prominent themes for each of the top three goals.

11.2.1.1 CDSS Notifications

11.2.1.1.1 Workflow Integration

The Representative Users all agreed that the CDSS notifications should support a user's clinical workflow. They concurred with the design principle of having only a small number of the most important and relevant notifications to be displayed during an encounter.

“The notifications have to be accessible to me on whatever page I am working on during the encounter. It could be the face sheet, or it could be the encounter notes. It's important they are integrated into my EMR and my way of working.” (Representative User 5)

11.2.1.1.2 Notification Details

The changes that the Representative Users suggested for the CDSS notifications all related to the cognitive load imposed by the amount of information a CDSS notification contained. The

Representative Users very clearly stated that some details in the UI prototype were unnecessary and were likely overwhelming for a user.

An interesting finding was that the Representative Users tended to rely on the system for appropriate and implicit prioritization of the notifications. Therefore, they placed low importance on having an explicit indication of a notification's importance/relevance/priority using visuals (e.g., by the use of colour or icons). Some suggested not displaying key patient risk factors. Some even suggested that showing evidence quality or recommendation strength would not be needed. Overall, the Representative Users did not feel that extensive rationale was needed to be shown explicitly for why the notification was triggered. They did propose having relevant rationale details available on-demand, for example, in a 'view more info' link for each notification.

"I'll trust the system. I don't need to see the rationale why this was triggered unless I dig deeper. Just tell me the risk is high and I'll decide if I should address it. I'll let the system do the thinking and prioritization, and I'll rely on that if the system is good."
(Representative User 4)

The Representative Users were also mindful that preventive notifications, such as a recommendation to assess for frailty, would have to be displayed in a manner that would not deter the user's attention from acute and more urgent patient issues.

"The patient doesn't come in for prevention. I have the presenting complaint to deal with, and potentially many other issues come up." (Representative User 5)

The Representative Users emphasized the need to have a very concise CDSS notification with minimal information necessary for deciding whether a notification should be addressed with the patient at the point of care. The rationale was that a typical EMR page where the notifications would be relevant would usually contain a large amount of salient information about the patient. All this information already competes for the attention of the user and imposes a significant cognitive load.

In particular, the majority of the Representative User did not consider the risk score confidence and the population risk to be among those minimal necessary information pieces in a CDSS risk *notification*. Note that a notification in the UI prototype contained an absolute risk percentage and a relative risk (e.g., high/medium/low or increase/typical/decreased); therefore, there already was an implicit comparison to the population in the relative risk.

“There is always going to be some uncertainty about a risk estimate. If I trust the system and the system only shows a risk score that is sufficiently reliable, I don’t need to see the confidence interval.” (Representative User 6)

“Population risk is not helpful for decision making here. If the system says the risk is High, it’s High. I’ll trust that.” (Representative User 4)

Moreover, as Representative User 1 explicitly pointed out, the population risk could cause confusion if the nature of the population is not clearly stated:

“Take out pop risk as it’s not clear what population is used. Is it patients of that age and gender or patients with similar genetics or what? Regardless, I don’t need this much detail here. In the detailed risk assessment module – yes, but not here. Too much detail to include pop risk.” (Representative User 1)

Overall, the participants tended to favour very minimal detail on the notification level with the option to see more: in a linked informational page (the details for how the CDSS derives and prioritizes the notifications) and in the detailed risk assessment module.

Based on the participant feedback, the Synthesis Team made the following changes to the requirement pattern titled Display Health Outcome Risk Assessment Notification:

Remove the requirement to display confidence interval

The confidence interval may impose unnecessary cognitive load on the user and is not likely to influence the provider’s decision making. The assumption is that a CDSS would only provide risk estimates, as part of a CDSS notification, where the risk score has an acceptable confidence interval.

Remove the requirement to display the population risk

As the notification already contains a relative risk, the population risk may be unnecessary. Moreover, without explicitly qualifying the population, a population risk score may be unclear to the user.

The Synthesis Team felt that, despite the opposite sentiments from some Representative Users, the evidence quality, the recommendation strength, and the top risk factors were part of an essential informational context for a CDSS notification.

11.2.1.2 Detailed Risk Assessment

The Representative Users confirmed the need for a separate risk assessment module that would present the detailed risk information such as patient's risk, population risk, risk trending, and risk factors. Overall, the Representative Users felt that the level of detail, the presentation format, and functionality in the UI prototype were suitable for detailed risk presentation. The two most prominent themes in the feedback were the visualization of risk information and the presentation of the risk factors.

11.2.1.2.1 Visualization of Risk

The Representative Users unanimously confirmed the need for patient risk visualization. The pictograph approach for displaying risk received positive feedback. The Representative Users saw the presentation of risk in an accessible manner as a valuable tool for communicating complex risk information to a patient.

“Showing the risk to the patient in a simple way is very useful. I can just turn my screen and show them the pictograph. It is very easy to understand at a glance. I can show them how we could change the risk. That is very powerful.” (Representative User 3)

Moreover, the integration of risk visualization with the suggested interventions also had positive reception from the Representative Users, as described in the Suggested Interventions section further in this chapter.

11.2.1.2.2 Default Display of Top Risk Factors

The participant feedback included suggestions for improving the information ordering on the detailed risk assessment to improve the cognitive fit between the CDSS and how physicians typically assess and manage risk with a patient. The feedback focused on how/where the list of risk factors should be presented. The integrated prototype that the participants were testing displayed patient's risk, followed by a small number of risk factors with the option to view more, and then suggested interventions. This order of key information components did not fit with the mental model of half of the Representative Users. These three participants strongly indicated that the presentation of the risk factors, even when only a small number of the risk factors is shown by default, on the detailed risk assessment page should not have primary prominence. They suggested not displaying any risk factors by default and making them available on-demand. The three Representative Users stated that the risk factors, as displayed on the tested UI prototype, took up too much screen space. Placing the risk factors between the risk information and the suggested interventions appeared to break the natural order of how the physicians expected to see risk information. This feedback was encapsulated in the following statements:

"I need the risk and what to do about it - this is how I think." (Representative User 2)

"Risk factors take up too much space and prominence on the screen. Need to see risk and then suggested interventions right away. Make risk factors available as a link. It's

not that we, physicians, are not intellectually curious about what goes into the risk calculation (that's important), but we don't have time to review that list. Besides, the suggested interventions target the top risk factors and tell us what they are."

(Representative User 6)

Several Lead Users in Phase One also tended to prefer the risk factors to be shown as a linked resource. However, the Synthesis Team in Phase Two made a decision that the top small number of risk factors should be shown by default (after the patient risk score and before the suggested interventions) to provide a rich informational context for risk evaluation. The feedback from the Representative Users prompted a reconsideration of this requirement. The final decision, based on the reflections on the cognitive fit between the physician's mental model and the UI, was to display the risk factors on-demand only. Having the risk factors displayed on-demand (e.g. through a link) would not interrupt the user's natural workflow from reviewing the patient's risk details to the suggested interventions. The user would have an option to see the risk factors if needed. This change was reflected in the Display Health Outcome Risk Detail pattern.

11.2.1.2.3 Clustering

The Representative User unanimously supported the differentiation of modifiable vs. non-modifiable risk factors. In terms of determine appropriate clustering for big data risk factors, the feedback was mixed. The majority supported clustering. Several indicated they would like to see individual big data risk factors such as an allele displayed outside of the cluster if that risk factor had significant contribution to the risk score. These Representative Users commented that clustering such risk factors would 'hide' them and would require extra clicks for the user to discover them. At the same time, they acknowledged that such approach may be confusing if the

risk factors is displayed outside of the cluster and in the cluster again. Overall, the Representative Users stated that imagining how to best present big complex data at the point of care was difficult, given that they have had no practical experience with such data. No changes were made to the patterns in regard to clustering based on the Representative User feedback.

11.2.1.2.4 Highlighting Patient Data Quality Issues

The decision to display the risk factors on-demand prompted the Synthesis Team to reconsider how patient data quality issues should be highlighted to the user. One of the key goals in the Integrated Goal Model was to highlight the risk factors where the values were incomplete. This was addressed in the UI prototype that was used for the usability testing in Phase Three: the participants were presented with the top patient risk factors by default, the data quality issues were highlighted within the risk factor list, and the users had specific filter options to find the incomplete risk factors. However, the Synthesis Team acknowledged that if the risk factors were to be available on-demand only, the data quality issues would become much less obvious to the user, and this would diminish the user's opportunity to remediate the data quality problems. The Team decided that there should be a separate UI component on the detailed risk assessment page that would explicitly highlight the data quality issues. The Team acknowledged that displaying a UI component adds to the user's cognitive load and disrupts the natural workflow from reviewing the patient's risk details to the suggested interventions. However, the Synthesis Team felt that highlighting data quality and thus allowing the user to take corrective actions (and potentially to obtain a more accurate risk score) was justified because the EMR data quality is known to be a major challenge for predictive risk modeling.

The requirements for highlighting data quality issues in a separate stand-alone component were documented in the Display Incomplete Patient Data pattern.

11.2.1.3 Suggested Interventions

The requirement to display suggested interventions as part of a risk assessment was strongly supported by all Representative Users. They agreed with the Lead Users and the Synthesis Team decision to display a top number of the most important and relevant suggestions. The majority of comments from the Representative Users centered around the pictograph-based interactive risk calculator for demonstrating the potential benefit of suggested interventions.

11.2.1.3.1 Presenting benefits of suggested interventions

All Representative Users stated that an interactive risk calculator that was integrated with the visual risk presentation was one of the top valuable features of the CDSS.

“I think showing how the interventions could impact the risk is very powerful. It is very difficult to do right, given how complex risk is. This tool is a step in the right direction.”
(Representative User 6)

At the same time, several Representative Users highlighted the potential limitations of the risk calculator. One issue that repeatedly came up was the combination of recommendations for a patient with co-morbidities. Representative User 2 noted that interventions often target multiple conditions:

“Suggested interventions are tricky. Some may target multiple conditions. Think smoking cessation or exercise. It’s good for nearly everything. How do you show that? Also, one intervention can be good for one thing but bad for another. We often treat the heart at the expense of kidneys when we reduce salt, for example. How do you show risk and risk reduction (or increase) across all these conditions in a holistic way?”

(Representative User 2)

Further, visualizing risk for a very broad phenotype such as frailty may be a challenge, given that a complex condition has many constituent components. Representative User 3 suggested that it may be of value to allow the user also to see more granular risk estimates and how they could be influenced by the suggested interventions. For frailty, it could be a risk of falls and a risk of hospitalization, for instance.

Addressing these challenges was beyond the scope of this research work but warranted noting. Such requirements were captured in ‘Other considerations’ in the Visualize Health Outcome Risk and Display Suggested Intervention patterns.

11.2.2 UTAUT Survey Results

At the end of the usability session, each Representative User was asked to fill out the UTAUT survey based on their testing experience with the CDSS. Table 6 summarizes the frequencies and corresponding percentages for the participants’ perceptions regarding the CDSS.

The intention to use the CDSS was high due to the influences of all six constructs.

For Performance Expectancy, there was a general agreement that the CDSS provided adequate information in an appropriate manner and that the CDSS would fit into their workflows as a useful tool. The Effort Expectancy ratings showed that the participants saw the CDSS as clear, understandable, and easy to learn. Attitude Towards Using Technology indicated that the participants would welcome having the CDSS in their existing practices. The responses for Social Influences showed that the participants anticipated the support for the CDSS use in their organizations but had slightly lower expectations for the social influences of the important people around them. Most participants anticipated that they would have the resources and knowledge to use the CDSS.

The UTAUT results were incorporated into the final synthesis of the requirements patterns.

Table 6 Descriptive statistics for UTAUT results (n=6)

Construct	Item		Strongly Disagree	Disagree	Slightly Disagree	Neutral	Slightly Agree	Agree	Strongly Agree
Performance Expectancy	PE1	I easily found the information I needed to help me make decisions.						5 (83.3%)	1 (16.7%)
	PE2	The CDSS presented complex information in a clear, easy-to-understand, and well-organized manner.						2 (33.3%)	4 (66.7%)
	PE3	The CDSS did not impose unnecessary mental burden (e.g., unclear or confusing recommendations, etc.)					1 (16.7%)	3 (50.0%)	2 (33.3%)
	PE4	The CDSS would fit well with my clinical workflows and inference processes.					1 (16.7%)	2 (33.3%)	3 (50.0%)
	PE5	I would find the CDSS useful for my job.						1 (16.7%)	5 (83.3%)
Effort Expectancy	EE1	My interaction with the CDSS would be clear and understandable.						2 (33.3%)	4 (66.7%)
	EE2	Learning to operate the CDSS would be easy for me.						4 (66.7%)	2 (33.3%)
Attitude Toward Using Technology	ATT1	Using the CDSS in my practice would be a good idea.						1 (16.7%)	5 (83.3%)
	ATT2	The CDSS would make work more interesting.					1 (16.7%)	3 (50.0%)	2 (33.3%)
Social Influence	SI1	People who are important to me would likely think I should use the CDSS.					3 (50.0%)	1 (16.7%)	2 (33.3%)
	SI2	I think the organization I work at would be supportive of the use of the CDSS.					1 (16.7%)	2 (33.3%)	3 (50.0%)
Facilitating Conditions	FC1	I would have the resources necessary to use the CDSS.				1 (16.7%)		4 (66.7%)	1 (16.7%)
	FC2	I have the knowledge necessary to use the CDSS.						3 (50.0%)	3 (50.0%)
Behavioural Intentions to Use the System	BI1	I would use the CDSS in my practice.						1 (16.7%)	5 (83.3%)

11.2.3 Finalized Requirement Patterns

The patterns were updated and finalized based on the results of Phase 3: the UI feedback from the Representative Users and the UTAUT results. The Synthesis Team consulted the literature and used its expertise in the final synthesis of the patterns.

Figure 16 shows the map of the finalized requirement patterns, and Table 7 provides brief descriptions of all the individual patterns. The map of the patterns shows their interdependencies and the scope that is covered. The patterns are independent entities where each pattern represents a set of reusable requirements. The pattern interdependencies depicted in Figure 19 represent the configuration of the patterns used specifically for the genomic CDSS in this study.

Appendix V includes detailed requirement patterns. Appendix G provides the definition of pattern structure and how a pattern should be read/interpreted.

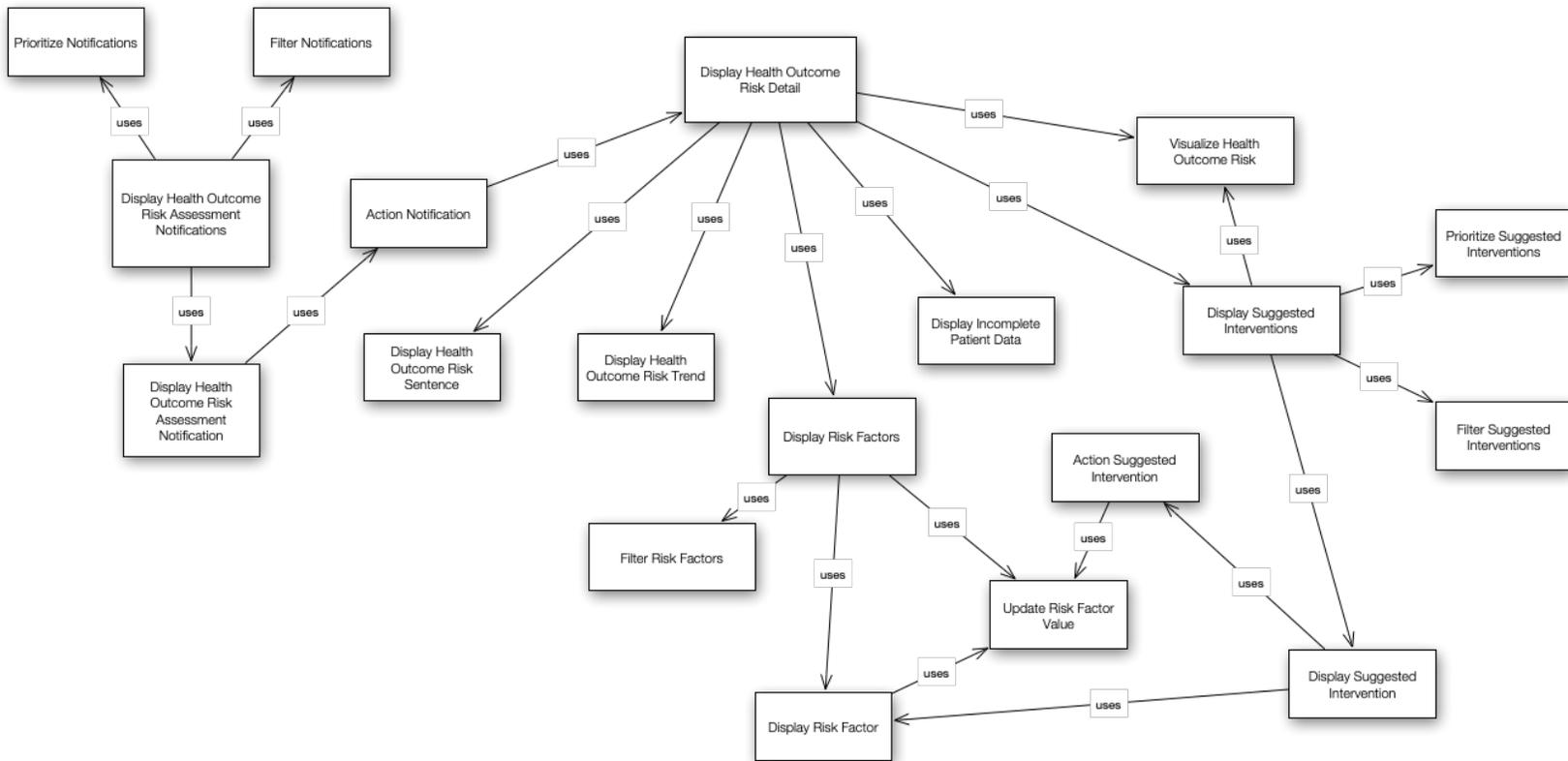


Figure 16: Requirement patterns map

Table 7 Requirement patterns descriptions

Pattern category	Pattern	Description
Notifications	Display Health Outcome Risk Assessment Notifications	Display multiple CDSS notifications for health outcome risk assessments.
	Prioritize Notifications	Provide a set of heuristics for prioritizing all relevant risk assessment notifications.
	Filter Notifications	Provide guidance for filtering health outcome risk notifications.
	Display Health Outcome Risk Assessment Notification	Display a single CDSS notification to assess a patient for a health risk.
	Action Notification	Specify the options that a user should have for explicitly actioning a risk assessment notification presented by the CDSS.
Risk Presentation	Display Health Outcome Risk Detail	Display detailed personalized risk information with a broad information context required for comprehensive risk assessment.
	Display Health Outcome Risk Sentence	Display patient-specific quantitative risk information for a health outcome in a numeric and text format as a sentence.
	Display Health Outcome Risk Trend	Provide guidance for how a patient's historical health outcome risk should be trended.
	Visualize Health Outcome Risk	Display patient-specific quantitative risk information for a health outcome in a graphical format.
Risk Factors	Display Risk Factors	Display patient's risk factors for a health condition, as part of detailed risk assessment.
	Filter Risk Factors	Provide guidance for filtering patient risk factors that are available in the comprehensive list of patient's risk factors, as part of detailed risk assessment.
	Display Risk Factor	Display the details for an individual risk factor when viewing patient risk factors for a health condition.
	Update Risk Factor Value	Provide guidance for updating an individual risk factor for a health outcome in two contexts: when viewing patient risk factors for a health condition and when actioning a suggested intervention.
	Display Incomplete Patient Data	Display incomplete patient data for the risk factors, as part of detailed risk assessment.
Suggested Interventions	Display Suggested Interventions	Display suggested interventions to manage the personalized health risk for a condition.
	Prioritize Suggested Interventions	Provide a set of heuristics for prioritizing suggested interventions in the context of a detailed risk assessment.
	Filter Suggested Interventions	Provide guidance for filtering the suggested interventions that are presented as part of detailed risk assessment.
	Display Suggested Intervention	Display a suggested intervention to reduce the negative outcomes related to a personalized health risk for a condition.
	Action Suggested Intervention	Specify the options that a user should have for explicitly actioning and documenting the actions for a suggested intervention presented by the CDSS.

11.2.4 Finalized UI Prototype

Based on the finalized patterns, the UI Prototype was updated to reflect the changes described above and in the requirements. Although the prototype did not illustrate the patterns exhaustively, it did implement the majority of the requirements, as shown in Appendix T.

11.3 Summary of Findings

Phase Three was a smaller part of the study in terms of data collection and analysis volume. However, it was an important component of the study, where the UI prototype was validated with Representative Users. Several important changes were made to the patterns based on the Representative User feedback. This verification to help evaluate the external validity enhanced the strength of the requirements patterns for a genomic CDSS produced by this research.

DISCUSSION

Chapter 12: Key Themes in Design Findings

12.1 Requirement Patterns

One of the main outputs of the study was a set of practical UI design requirement patterns for a potential, future-state CDSS for personalized health risk assessment at the point of care. Figure 16 shows the map of the finalized requirement patterns, and Table 7 provides brief descriptions of all the individual patterns. Appendix U includes detailed requirement patterns. Appendix G provides the definition of pattern structure and how a pattern should be read/interpreted.

To summarize the process of pattern development, the requirement patterns produced in this study have emerged from the Lead User data discovered in Phase One, integrating and validating findings through the subsequent phases. This multi-step iterative development of the patterns allowed for the use of multiple methods, investigators (the Synthesis Team included health informatics and clinical experts), cognitive theories, and evidence sources to create the evidence base for the patterns. This triangulation in design research can enhance the validity of the results by considering a broader range of perspectives, reducing subjectivity inherent in qualitative research, and confirming the findings through the convergence of information from different sources (Heale and Forbes 2013; Carter et al. 2014). The patterns generated in this study specifically address the issue of integrating big data, such as genomics, into decision making. The patterns were developed using frailty as a clinical example. However, they can potentially be applied to preventive risk assessment for other chronic conditions. The patterns are system-agnostic and evidence-based.

12.2 Key Themes from this Research

Several prominent themes emerged in the process of CDSS design and pattern development.

The evolution of several patterns is described to illustrate the themes and show where the triangulation of methods, investigators, theories, and evidence sources was particularly valuable in pattern development.

12.2.1 Tension Between Cognitive Load and Cognitive Fit in CDSS Design

According to the Cognitive Fit theory, CDSS functionality and information representation have to be aligned with a problem (clinical task) to match the user's mental model to reduce cognitive effort and to ensure adequate cognitive load (Chang et al. 2016).

Throughout the study, it became apparent that there were different perspectives from different participants concerning managing cognitive load while ensuring cognitive fit. Some advocated for a richer informational context in the CDSS UI, while others emphasized the need to present information in a maximally concise manner with minimal cognitive load. These differences in defining appropriate cognitive load to ensure cognitive fit (i.e., the type, amount, and presentation format of clinical information for optimal decision making) stemmed from the fact that the user characteristics and the context of care largely define what cognitive load is needed to ensure the cognitive fit between the CDSS and the clinical tasks. In other words, the definition of an appropriate cognitive load and fit varies across different types of CDSS users. For Representative Users, for example, the cognitive load of a particular visualization may be greater than for expert Lead Users who are more intimately familiar with the evidence and interpreting the evidence and thus are able to more quickly process the displayed data (Paas, Renkl, and Sweller 2004).

To address the differences, the Synthesis Team turned to the literature and considered the importance of ensuring sufficient information to make informed clinical decisions, as that would ultimately impact patient safety. To a degree, the patterns also attempted to accommodate the variability of required cognitive load and fit by providing some flexibility that allowed the user to configure what information is displayed (beyond the minimal information set). This flexibility could help ensure that the UI meets the goals of a wide range of users. Moreover, the patterns are not prescriptive and are intended to be evidence-based design guidelines that could be adapted by the CDSS implementers as needed.

Ensuring the balance between cognitive load and fit is a design challenge that this research attempted to investigate. However, more studies are necessary to further the evidence for the robust design guidelines. While there are studies investigating the relationship between cognitive load and fit in other domains (Kopp, Riekert, and Utz 2018; van der Land et al. 2013), the literature for health systems design is limited (Chang et al. 2016).

The following pattern is used as an example where there were tensions between the cognitive load and fit in the Lead User and the Representative User findings. The description of the pattern evolution shows how the tensions were addressed through Synthesis.

Example Pattern: Display Health Outcome Risk Assessment Notification

The Display Health Outcome Risk Assessment Notification pattern describes how to display a specific risk assessment notification during a clinical encounter. A risk assessment notification would typically be generated by a CDSS in the context of a clinical activity such as a visit regarding another primary reason. See Appendix U.2 for the detailed pattern description.

There were differences in opinion among the study participants on the amount of information that should be shown as part of a notification even before one decided to intentionally assess frailty risk. The level of suggested details in a notification varied substantially not only between the Lead Users and the Representative Users but across the Lead Users as well. The rationale for detailed notifications was that the provider should have enough information to determine the priority of the notification and if/how it should be addressed during the encounter. The Synthesis Team reviewed the evidence on high-level CDSS UI guidelines (Sittig et al. 2008; Miller et al. 2017) and CPOE CDSS (Horsky et al. 2012; Marcilly et al. 2018). While the evidence from the literature was informative, it did not provide concrete informational content guidelines. The Synthesis Team's initial consensus was for a more detailed notification. Finding an appropriate cognitive fit of the notification was key for safety reasons and to allow the provider to determine if/how the recommendation should be actioned, despite the increase in cognitive load. However, the feedback from the Representative Users *specifically* emphasized the need for a minimal amount of information that would be included in a CDSS notification. Rationale included: trust in the CDSS to prioritize the notifications appropriately, context of other competing demands in an encounter, and alert fatigue.

In the final deliberations, the Synthesis Team decided to strive for conciseness (minimizing additional cognitive load) while showing enough to action the notification (cognitive fit). This was an example where the benefits of cognitive fit outweighed expected increase in cognitive load (Kopp, Riekert, and Utz 2018). The informational context of a notification still remained rich, as reflected in the Display Health Outcome Risk Assessment Notification pattern (and see Figure 17).

Preventive Recommendations	
<input checked="" type="radio"/> All <input type="radio"/> Active <input type="radio"/> Completed <input type="radio"/> Not Addressed <input type="radio"/> Dismissed	
<input type="radio"/> Delegated <input type="radio"/> Deferred	
Address Frailty ↗ Status: Not Addressed Patient's risk: High, 80% for Frailty in next 3 yrs. Key patient risk factors: age, low BMI, low protein intake.	Recommendation: strong Evidence Quality: high
DISMISS DELEGATE DEFER	<i>i</i>
Screen for Diabetes Type 2 ↗ Status: Not Addressed Patient's risk: High, 40% for Diabetes Type 2 in next 5 yrs. Key patient risk factors: obesity, hypertension, genetics.	Recommendation: strong Evidence Quality: moderate
DISMISS DELEGATE DEFER	<i>i</i>
Address Caffeine Consumption ↗ Status: Patient Declined Patient's risk: Moderate, 15% for CHD in next 10 yrs. Key patient risk factors: Slow caffeine metabolizer, heavy coffee drinker (8 per day).	Recommendation: conditional Evidence Quality: moderate
DISMISS DELEGATE DEFER	<i>i</i>
Rows per page: 3 1-3 of 10 < >	

Figure 17 CDSS risk assessment notification on a Patient Summary page, “Address Frailty”

12.2.2 Cognitive Fit for the Patient as Information Consumer in an Encounter

While the focus of this study was on the primary care physician as the direct user of the CDSS, the patient is also a key information consumer of CDSS. The physicians needed the CDSS not only to provide a risk estimate and suggested actions, but they also wanted the CDSS to help them communicate that information to their patients. CDSS has an important role in patient-physician relationship (Aziz, Bearden, and Elmi 2015). In the context of risk assessment, communicating individualized risk to the patient may have a more beneficial effect on key outcomes (screening, treatment choices, and modification of risk behaviours) than other forms of personal patient-provider communication (Edwards et al. 2000).

Thus, the design needs to consider fit for the patient as an indirect user. In this study, several patterns include patient-facing requirements: Visualize Health Outcome Risk, Display Health

Outcome Risk Trend, Display Suggested Interventions. The Visualize Health Outcome Risk pattern is used next to illustrate the importance of considering cognitive fit between the CDSS and the patient's needs for information. For this pattern, the literature supported the notion that a graphical representation can be an effective tool for risk communication to patients (Wickens and Carswell 1995; Fischhoff, Brewer, and Downs 2014; Ancker et al. 2006; Holmes-Rovner et al. 2005; Schapira, Nattinger, and McHorney 2001). While the study did not involve patients as co-designers, the study findings did emphasize the importance of patient's perspectives and were considered in all phases of the study. Engaging patients would be a logical next step in the design process of the patterns.

Example Pattern: Visualize Health Outcome Risk

This pattern was intended to display patient-specific quantitative risk information for a health outcome in a graphical format. In this pattern, risk visualization is presented in addition to the risk in a numeric and text format. See Appendix U.13 for the detailed pattern description.

Risk visualization did not surface as a prominent requirement from the Lead User data initially. Most Lead Users felt that presenting patient risk in a numeric and textual format was sufficient for their needs.

The Synthesis Team deliberated the risk visualization, strongly considering published research, and decided that visualizing the risk score was an important feature. Engaging the information recipients in the process of risk evaluation may increase their understanding of risk and the likelihood of changing their behaviours to reduce risk (Emmons et al. 2004). Pictographs have been shown to be the most effective way to communicate individualized risk information to

patients (Wong et al. 2012; Fischhoff, Brewer, and Downs 2014). They are more quickly and better comprehended and may prevent patients from being biased by other data presented in the risk discussion (Fagerlin, Zikmund-Fisher, and Ubel 2011). Interactive risk calculators further improve user engagement (Lautenbach et al. 2013). Therefore, risk visualization also became an interactive risk calculator as a result of the Phase Two requirement definition. The Representative Users unanimously approved this approach in testing. In fact, it was the CDSS UI component that received the most enthusiastic feedback. All Representative Users said they would utilize the visualization as part of their risk discussion with the patient.

Risk visualization was an example where triangulating the evidence sources, and particularly cognitive theories for the patterns, had a clear benefit. The Lead User data did not surface this requirement sufficiently, while the literature, the Synthesis Team experts, and especially the Representative Users, emphasized visualization as a necessary goal that CDSS must support. This goal was driven by the need to ensure an appropriate cognitive fit for the patient in order to communicate complex information such as risk and intervention benefits. Figure 18 illustrates the implementation of the Visualize Health Outcome Risk pattern in the finalized UI prototype.

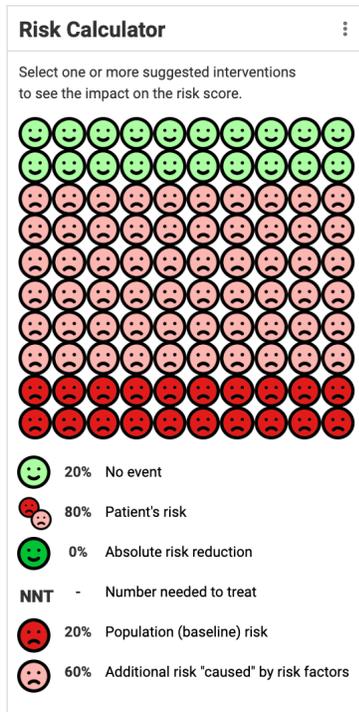


Figure 18 Risk visualization as part of detailed risk assessment

12.2.3 Presentation of Big Data in a Point of Care CDSS is Similar to Traditional CDSS

In the context of risk assessment, it was the presentation of risk factors where the design problem of big data display arose. A health outcome can potentially have a large number of risk factors relevant to the patient. This will be particularly true with the increasing availability of large datasets in routine clinical care (genomics, sensors, patient reported outcomes, etc.) and advanced risk estimation algorithms (Chen et al. 2012). Many conditions, such as common chronic diseases, have complex, multifactorial aetiologies that involve the interplay of genomic risk factors, environmental risk factors, and other health conditions (Chatterjee, Shi, and García-Closas 2016). Polygenic risk prediction models already use tens of thousands of genomic loci to estimate the risk (Kong et al. 2015). Addressing the display of risk factors is important because the risk factors are considered an important constituent part of the probability and may help with

a more accurate interpretation of the risk (Kelly 1992; Rothman and Kiviniemi 1999). Some evidence suggests that explicitly making the risk factors available to the user may help the users better understand how the CDSS calculates the risk and thus facilitate trust in a CDSS (Bussone, Stumpf, and O'Sullivan 2015).

One clear message from the study participants was that all risk factors should be classified as modifiable or non-modifiable and that the UI should clearly differentiate these categories. Most participants stated that they would only likely review the top modifiable risk factors during an encounter.

Notably, the literature did not provide guidance on how to summarize and cluster big clinical data (see *Is a Genomically Informed CDSS Different?* In the Background section). The studies based on the practical use of big data in primary care are also limited (Dagliati et al. 2018). The study participants, even Lead Users, stated that it was hard to imagine the optimal way of presenting big data such as genomics, given that typical primary care physicians do not use it routinely in their practice.

This study highlighted many aspects that need to be considered when presenting risk factors in a way that is informative for the provider, yet not overwhelming. A key finding of this study was that users require high-level summaries of the data. For the most part, the participants considered big data risk factors to be not different from the traditional EMR patient data in terms of presentation at the front end. The focus of all participants was on understanding patient's risk and obtaining suggested interventions to ameliorate risk (see more in *Need to Include Interventions as Part of Risk Assessment* section further in this chapter), and less so on the list of

the details of the risk factors that contribute to the risk score. Many participants expressed concern about the limited time and cognitive resource availability to review the risk factors during a busy clinical encounter. Overall, there were two key goals for the display of risk factors supported by the patterns: to have the risk factors available on-demand only and to have them hierarchically clustered and summarized on a very high level. The evolution of the Display Risk Factors pattern is described to illustrate how these goals were addressed in the patterns.

Example Pattern: Display Risk Factors

Display Risk Factors pattern addressed the presentation of a patient's risk factors for a health condition as part of a detailed risk assessment. The detailed pattern is presented in Appendix U.6.

All Lead Users recognized the importance of including patient risk factors in the detailed risk assessment and most suggested not showing the list of risk factors by default but instead having the risk factors accessible on-demand. Further, the majority of the Lead Users proposed clustering the risk factors into high-level categories, although the Lead Users did not propose definitive categories other than modifiable vs. non-modifiable risk factors.

The Synthesis Team initially decided that a small top number of risk factors should be available by default to provide a richer informational context for the risk score and to highlight potential data quality issues. The Team felt that some cognitive load imposed by the default display of the risk factors would facilitate a better cognitive fit for data quality remediation. The Synthesis Team supported the modifiable/non-modifiable categorization for displaying and clustering risk factors.

Representative Users all supported the modifiable/non-modifiable distinction, but they tended to be more action oriented, wanting to get to the suggested interventions after assessing overall risk. They did not want a default display of risk factors. The Representative Users highlighted that the interventions targeted modifiable risks. So, in fact, the interventions, embedding the key modifiable risks, actually better fit their mental model.

The final pattern has the risk factor list as an on-demand resource to accommodate the user's cognitive load and fit. Moreover, this design decision resulted in a new pattern that would address the highlighting of data quality issues for the risk factors (see 12.2.4 section further in this chapter).

Figure 19 illustrates the implementation of the Display Risk Factors pattern. The screenshot shows the risk factors when the user chooses to view the risk factors, sets the filter to 'All', and expands the Biomarker cluster.

Risk Factors						
<input checked="" type="checkbox"/> All <input type="checkbox"/> Modifiable <input type="checkbox"/> Incomplete <input type="checkbox"/> History <input type="checkbox"/> Observations <input type="checkbox"/> Conditions <input type="checkbox"/> Investigations <input type="checkbox"/> Medications						
<input type="checkbox"/> Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated	
<input type="checkbox"/> Age	70 yrs		12 – 17%	<input checked="" type="checkbox"/>	06-Jan-1995	
<input type="checkbox"/> BMI	18.3 (L)	18.5 – 24.9	10 – 12%	<input checked="" type="checkbox"/>	03-May-2016	
<input type="checkbox"/> Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%	<input checked="" type="checkbox"/>	04-Jun-2019	
<input type="checkbox"/> Smoking Status	Current. 1ppd. 50 pack yrs	Cessation	6 – 10%	<input checked="" type="checkbox"/>	23-Feb-2018	
<input type="checkbox"/> Grip Strength			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Gait			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Walking ½ mile			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Climbing 10 steps			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Dementia			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Physical exercise	No exercise		6 – 10%	<input checked="" type="checkbox"/>	12-Jul-2019	
<input type="checkbox"/> Benzodiazepin Medicat...	1 mg – oral - three times...		4 – 6%	<input checked="" type="checkbox"/>	12-Jul-2019	
<input type="checkbox"/> Hydrocodone-Acetamin...	5mg/300 mg - oral - twice...		4 – 6%	<input checked="" type="checkbox"/>	12-Jul-2019	
<input type="checkbox"/> Inflammation Biomark..	1 of 3		4 – 6%	<input checked="" type="checkbox"/>		
<input type="checkbox"/> PRT-1	Increase		4 – 6%	<input checked="" type="checkbox"/>	04-May-2018	
<input type="checkbox"/> PRT-2			0.5 – 1.5%	<input type="checkbox"/>		
<input type="checkbox"/> PRT-3			0.5 – 1.5%	<input type="checkbox"/>		
<input type="checkbox"/> Genetic Biomarkers	1 of 3		4 – 6%	<input checked="" type="checkbox"/>		
<input type="checkbox"/> Muscle Metabolites	10 of 15		4 – 6%	<input checked="" type="checkbox"/>		
<input type="checkbox"/> Gender	Female		3 – 5%	<input checked="" type="checkbox"/>	06-Jan-1995	
<input type="checkbox"/> Ethnicity	Caucasian		0.5 – 1.5%	<input checked="" type="checkbox"/>	06-Jan-1995	
<input type="checkbox"/> Education Level			0.5 – 1.5%	<input type="checkbox"/>		

Rows per page: 18 1-18 of 18

Figure 19 Risk factors displayed on demand – filter option is set to ‘All’, Inflammation Biomarkers cluster expanded

12.2.4 Need to Embed Data Quality Remediation as Part of a Clinical Workflow

Facilitating data quality remediation as part of CDSS use was a key requirement. EMR data quality is often suboptimal (Singer et al. 2017), indeed the magnitude of data quality problems as shown by accuracy rates of medical data repositories ranged from 67%-100%, and completeness ranged from 31%-100% (Stein et al. 2000). While these numbers cannot be directly applied to

each EMR and all data types, they suggest that data quality is a significant problem in medical records. EMR data quality becomes a major limitation for effective CDSS application and evaluation (Ray and Houston 2005; Cruz-Correia et al. 2018; Chan, Fowles, and Weiner 2010; Price et al. 2017).

There are two compelling evidence-based reasons to bring data quality issues to the provider's attention. First, explicitly bringing the data quality issues to the provider's attention, as part of risk context, can influence the provider's perception of risk confidence and thus can facilitate a more accurate interpretation of risk (Hasan and Padman 2006). This is an important consideration for a risk assessment CDSS for ensuring cognitive fit and informed decision making. Second, a CDSS can play an active role in supporting data quality remediation if it includes the tools for the provider to address the issues. For example, Galanter et al. showed that integrating data quality improvement mechanisms into a CPOE CDSS substantially improved the accuracy of a problem list in an EMR (Galanter et al. 2010).

The development of the Display Incomplete Patient Data pattern illustrates how the requirements for addressing data quality took shape.

Example Pattern: Display Incomplete Patient Data

This pattern was intended to display incomplete patient data for the risk factors in the risk assessment module. The incomplete data is presented as a separate visual component in addition to the comprehensive list of the risk factors. See U.10 for more details on this pattern.

The Lead Users were knowledgeable about EMR data quality based on their practice experience and health informatics research projects. This was reflected in their goals. The majority expected a CDSS to play an important role in data quality improvement at the point of care by identifying pertinent data quality issues and providing quick and easy ways to correct the data problems.

The Representative User preferred to focus on the suggested interventions without having their workflow interrupted by data quality remediation tasks.

The Synthesis Team decided that it was important for data quality issues to be made obvious to the user by highlighting them in the list of risk factors and by providing a separate UI component for incomplete patient data. This was a compromise between assuring a cognitive fit for the provider and facilitating data quality remediation (a goal). Given the magnitude of data quality problems in most EMRs (Chan, Fowles, and Weiner 2010; Ray and Houston 2005) and the significant limitations the data quality issues present for personalized risk assessment, the Synthesis Team felt that explicitly highlighting data quality issues to the users was required.

The highlighting and remediating data quality was addressed in the patterns in two ways. First, the list of risk factors indicated data quality issues and allowed the user to take action to improve the data. The requirements included visibly differentiating risk factors with data quality issues through colour, icons, and an explicit textual indication of the issue. The filter options for the risk factor list also allowed multiple ways to surface data quality issues for different types of patient data (e.g., incomplete observations, orders, history). This was illustrated in the Display Risk Factors pattern shown in Figure 19. Second, a separate UI component was proposed to

include only data quality issues related to the risk assessment. These requirements became encapsulated in the Display Incomplete Patient Data pattern.

The requirements also included the ability for the user to update risk factors with data quality issues from within the risk assessment module without going to other EMR modules. This in situ data quality remediation intended to minimize the cognitive effort for the user by eliminating context switching from the CDSS to other parts of the patient's chart. Context switching increases cognitive load (Gopher, Armony, and Greenspan 2000).

The implementation of the pattern in the finalized prototype is illustrated in Figure 20.

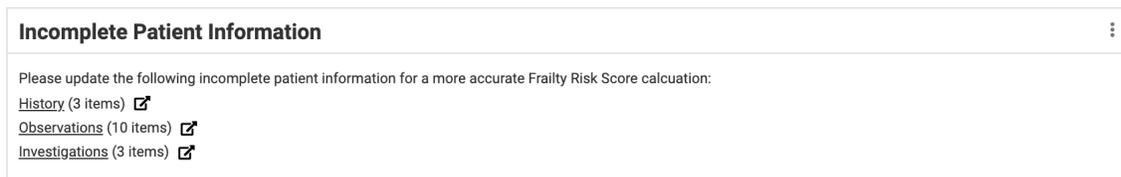


Figure 20 Highlighting patient data quality issues as part of detailed risk assessment

12.2.5 Need to Include Interventions as Part of Risk Assessment

The initial intention of the study was to explore only the presentation of patient risk at the point of care in the context of big data such as genomics. The expectation was to focus on what information and functionality were required for the risk assessment notifications and risk details while leaving care planning to address risk out of scope. However, at the start of Phase One, it was immediately clear that suggested interventions are an integral part of the risk context for the physician and patient. The physicians needed to know what issues were most important, urgent, and relevant and what could be done to address them. Preventive risk notifications and

recommendations were an especially poignant example of CDSS where patient issues may be important but not urgent. Such issues may be of lower priority to the physicians, and if they do choose to address them, they need a clear suggestion for action and a clear rationale for the action's benefits to the patient.

The literature supports this: presenting probabilistic information about a health problem is insufficient in the context of care; it is also necessary to present the information on what causes the problem (the risk factors) and what can be done to ameliorate risk (Rothman and Kiviniemi 1999; Kelly 1992).

The requirements for presenting suggested interventions within an encounter were captured in the Display Suggested Interventions pattern and its related patterns. The description of how this pattern evolved demonstrates how the evidence for presenting suggested interventions was built.

Example Pattern: Display Suggested Interventions

The pattern was intended to display suggested interventions to manage the personalized health risk for a condition. All Lead Users stressed that presenting risk without the recommendations on how the risk could be addressed with the patient has little to no clinical utility.

The Synthesis Team in Phase Two supported the inclusion of suggested interventions into the requirement patterns. The Representative Users unanimously concurred with the requirements to include suggested interventions as part of the detailed risk assessment. Just like the Lead Users, they emphasized that the physicians are action-oriented and are pressed for time during a typical encounter, which may require addressing multiple patient issues with different, sometimes

competing, priorities. To support the flow of care as described by the users, the Display Suggested Intervention pattern also included additional information about the intervention, its strength of evidence, strength of recommendation, and embedded the risk factors in the description. In this way, more information both enhanced cognitive fit and reduced cognitive load, as the interventions (and tools such as patient handouts) were readily available to support the decisions and actions within the encounter.

Figure 21 illustrates the implementation of Display Suggested Interventions pattern and the related Visualize Health Outcome Risk pattern in the finalized UI prototype.

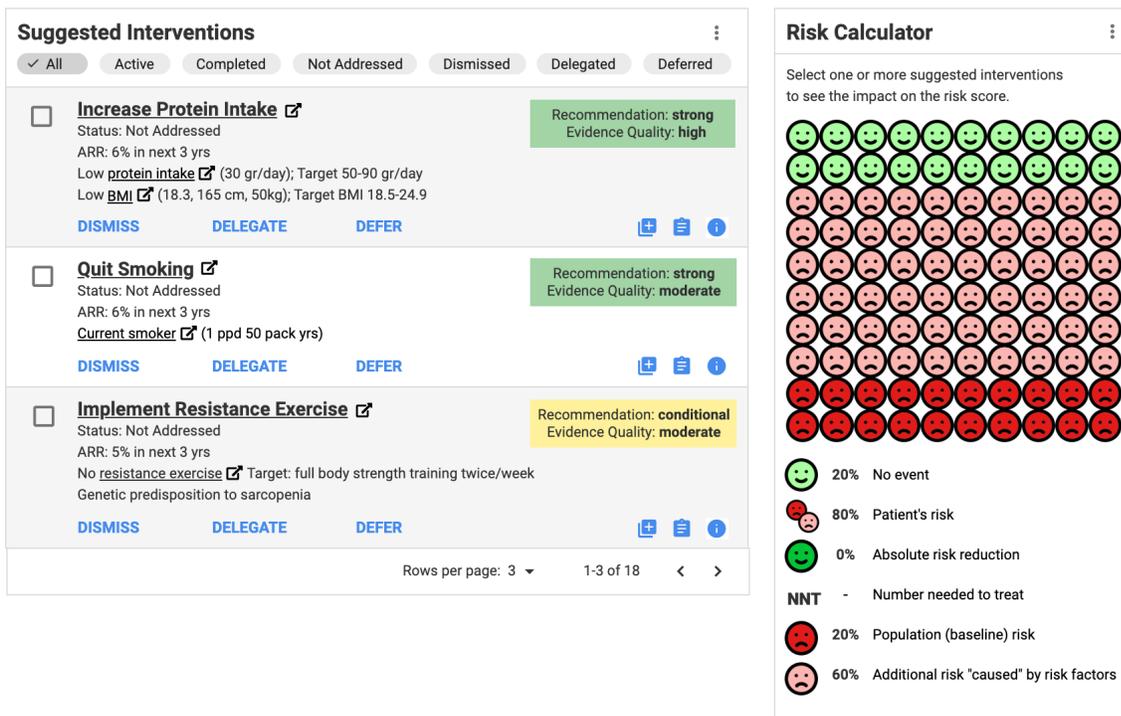


Figure 21 Suggested interventions and the visual, interactive risk calculator, as part of detailed risk assessment

Chapter 13: Contributions and Limitations

13.1 Contributions

This study provided two key novel contributions:

1. The requirement patterns were a novel contribution in several aspects. The patterns narrowed the gap between the research on big-data enabled generalist point-of-care CDSS, which is predominantly conceptual, and the practical guidelines for designing such systems.
2. Methodologically, this study contributed to our understanding of requirements solicitation, integration, and validation through a novel method.

13.1.1 Contributions of Requirements Patterns

13.1.1.1 The patterns provide practical system-agnostic design guidelines

First, the health informatics literature overview did not discover comparable requirement patterns for a CDSS. Microsoft Health Common User Interface (CUI)⁵ was a somewhat conceptually related endeavor, however it was prescriptive for one platform and did not include CDSS UI design. The patterns developed in this study, in contrast, focused on requirements for clinical information and functionality of a CDSS while abstracting away implementation details. The high-level system-agnostic patterns produced in this study, thus, can be developed in any EMR and can utilize different foundational UI frameworks.

⁵ The project is no longer supported and, thus, cannot be referenced.

The patterns contribute to the body of research for CDSS overall. The literature offers several general CDSS design best practices (Sittig et al. 2008; Miller et al. 2017; Miller et al. 2018) but often lacks in concrete guidance for specific design problems and a review found a lack in guidelines for functional and design requirements (Miller et al. 2018). Thus, the patterns produced in this study attempt to fill this gap between conceptual best practices and specific UI component specifications.

13.1.1.2 The patterns explored the integration of big data into primary care CDSS

Second, the patterns addressed the integration of big data such as patient's genomics into primary care. The current literature is plentiful with a discussion about the potential of big data once it becomes pervasive in routine patient care (Vassy et al. 2015; Flores et al. 2013; Hood and Rowen 2013; Raghavan and Vassy 2014). However, we found minimal specific evidence (see section 2.2 in Background) for the health system design for integrating such data into the tools that primary care physicians can use. The value and the novelty of the patterns are that they provide specific system design guidelines for how a CDSS could integrate genomics into primary care practice. The patterns accounted for the specificities of point-of-care use, including the complexity of genomic data interpretation by generalists, as well as cognitive and other resource constraints of a typical primary care encounter. Moreover, the patterns addressed the issue of practical data quality remediation as part of risk assessment. Data quality is a significant limitation for the materialization of personalized medicine (Wei and Denny 2015).

13.1.1.3 The patterns advanced a design framework for frailty risk assessment using genomic data

The patterns were developed and validated using frailty as a clinical example. While there are many clinical tools for frailty risk assessment used in primary care, none currently utilize genomic biomarkers or other big data in routine patient care to predict risk in the form of a CDSS (Williams et al. 2017; Lippi et al. 2015). The requirement patterns are one step towards practically contextualizing frailty in the big data context in primary care. The patterns were generalized to address risk presentation for any chronic condition, although it is important to highlight that the patterns were not tested in this study outside of the frailty context.

13.1.2 Methodological Contributions

The method developed in this study addressed requirement solicitation, integration, and validation. The method was system-agnostic and thus could be applied to a wide variety of design problems. The methodology and documentation templates are open source (templates and example documentation included in this dissertation). The method includes rigorous analysis and documentation processes to reduce bias, as well as ensures traceability of design decisions. The development of the method added to our knowledge in several ways:

13.1.2.1 Advancing the evidence for the Lead User method in health system design

The application of the Lead User method to health system design has been limited mostly to the lab of the researchers involved in this dissertation (Price et al. 2015; Bellwood and Price 2015), although the method has been fairly widely adopted in a number of other domains (Churchill, von Hippel, and Sonnack 2009). The application of the Lead User method to the CDSS design, therefore, expands the knowledge on how the method can be adapted for the specifics of health

informatics. This is an important contribution because innovation is needed in health informatics in Canada (MacNeil et al. 2019), especially for designing in anticipation of near-future trends.

13.1.2.2 Extension of the Lead User method to include requirement integration

This study extended the original Lead User design method beyond the elicitation of the Lead User requirements. The original Lead User method provides guidance on soliciting requirements from the leading domain experts but does not encompass a process for unifying the requirements into a cohesive set of finalized requirements using a reproducible and transparent method.

The problem of systematic requirements unification belongs in the domain of software engineering, where a number of requirement integration approaches exist (Baslyman 2018; Sabetzadeh and Easterbrook 2006). Generally, these methods could not be applied directly in this work because they were not easily scalable across multiple Lead User requirement sets (8 in this study) as they focused on integrating two requirement sets. Therefore, this study developed a systematic, reusable, scalable, and practical method that would allow the integration of multiple requirement sets through the use of goal models and a synthesis team. The key strength of the method was that it facilitated the evolution of the Goal Model and the patterns while ensuring traceability of origin and integration rationale. Unlike other methods, the approach developed in this study should be more accessible for qualitative researchers without extensive software engineering and view modeling backgrounds. The method devised in this work could be applied to the Lead User studies or other early product development methodologies focused on eliciting goals and design ideas from multiple stakeholders.

13.1.2.3 Patterns as part of the method

An application of a particular method often results in a specific design and the specific requirements documentation for that particular design. Such documentation is often not reusable for other products or contexts (Toval et al. 2008). This study's method produces system-agnostic and reusable requirement patterns. A requirement pattern template was developed and is included in the Appendix H. The patterns are mapped to the Integrated Goal Model (the patterns support the goals) and are a means to document the evidence collected, analyzed, and synthesized for the patterns. Including a medium for system-agnostic requirement documentation into the method facilitates the reuse potential of the findings produced by the method (Wieggers and Beatty 2013).

13.1.2.4 Extension of the Lead User method to include validation through rapid prototyping

Interactive prototypes were used extensively in each of the three phases of this study for requirement validation. While requirement validation through rapid prototyping in itself is not novel, an explicit process for the validation of the findings from Lead User research is rarely included as part of the Lead User method (Helminen 2016). Visual prototyping proved to avoid unnecessary extraneous cognitive load on the Lead Users and the synthesis team. Prototyping ensured a good cognitive fit between the format of the requirements and the ideation and validation tasks that were asked of the Lead Users by the study and by the Representative Users in testing. Prototype designs better align with users' mental models than other methods for ideation and validation, thereby reducing cognitive load and improving usability (Earnshaw and Schmidt 2017).

13.1.2.5 Including triangulation of evidence from multiple sources

The method incorporated systematic triangulation of multiple sources of evidence, which strengthens qualitative research (Carter et al. 2014; Jonsen and Jehn 2009). The foundational data for the patterns came from the Lead Users in Phase One. The Lead User results were then interpreted and synthesized in Phase Two with evidence from the literature and expert opinions of the Synthesis Team. The Representative Users tested and provided additional perspective, enhancing the evidence base for the patterns.

13.1.2.6 Incorporating theoretical foundations

System design methods tend to be applied without explicitly defining a theoretical framework to support the method (Peschl and Stary 1998) even though theory-informed design has the potential to improve design outcomes (Durrani and Durrani 2009). Thus, this study incorporated theoretical lenses on the design context and the cognition of an individual user. The theories selected were used to help structure the analysis and to reason about competing goals and requirements. Theoretical constructs were highlighted throughout all phases of the study and helped to draw out several key requirements that might not have become obvious without applying these theoretical lenses.

13.2 Limitations of the Patterns and the Method and Future Work to Address Limitations

The study was rigorously designed. However, there were several methodological and practical aspects that presented potential threats to the internal and external validity of the requirement patterns that resulted from the study. The limitations are discussed with suggestions for potential mitigation options and future work.

Lead User sample size

The patterns were largely based on the data from Phase One. The sample size for the Lead User design in Phase One was relatively small.

Recruitment was challenging. By definition, Lead Users come from a small pool of experts. Some potential Lead Users could not commit to the time requirement, some had concerns about intellectual property rights. This is a known challenge of the Lead User method (Lüthje and Herstatt 2004), as lead experts in a field may anticipate benefits from their ideas and seek patents and might be already involved in other related projects that do not allow collaboration elsewhere. Several potential Lead Users were unable to participate due to such concerns.

The original Lead User method developers suggest engaging around twelve to fifteen Lead Users for an ideation project (Churchill, von Hippel, and Sonnack 2009). They cite several successful innovations, including commercial projects, that grew from groups that engaged a dozen Lead Users (Churchill, von Hippel, and Sonnack 2009). Moreover, the findings from other Lead User studies (Lüthje and Herstatt 2004) suggest that the number of experts needed is small if the knowledge is distributed rather homogeneously across the field, which is the case for primary care frailty risk assessment. Therefore, it is reasonable to state that the sample size was sufficient to collect meaningful evidence.

Lack of diversity for Lead User roles and types

All Lead Users were primary care physicians, as intended in the study. The Lead Users were also all academics. Some of the Lead User practices were team-based, but not all. The lack of representation from other roles (nurses, for example) and the academic focus of the Lead Users

may impede the generalization of the study results to other users and care settings. For example, nurses in interdisciplinary care practices may have different perspectives and approaches to risk assessment, disease prevention, and collaborative patient management, which means different workflows. Academic and non-academic primary care providers may have different views on patient care (Christmas et al. 2010). To partially overcome this limitation, the evidence from the Representative User testing was used to compare and contrast the Lead User data. Other approaches could include recruiting different provider roles for the Lead User. Patient Lead Users could also be considered as patients are important risk information consumers.

The Lead Users were also predominantly male. There is evidence suggesting that there may be important differences in information processing among sexes (Chung and Monroe 1998). While this consideration was not addressed in this study, future work should attempt to consider the gender dimension in the design. Further, future design studies could benefit from engaging Lead Users with a greater range of ages and years of experience as such characteristics could also result in different user perspectives.

Frailty as a single clinical use case

Geriatric frailty was used as a clinical example throughout the study. Frailty is a broad phenotype which lends itself well as an example where big data, and particularly genomics, may play a significant role in personalized risk assessment. However, using a single condition to develop and test the patterns is a recognized limitation. For example, frailty is relevant to a specific subset of patients (the complex elderly patients) and has many defined typically slow progressing stages. This may influence the acuity/priority of risk notifications for assessment. Frailty has many potential outcomes which is relevant to the granularity of how risk is presented.

These threats to construct validity could be mitigated by using several different dissimilar conditions as clinical use cases. For example, risk assessment CDSS designs for geriatric and pediatric conditions could be contrasted. Future studies could include: repeating this study to develop a set of patterns for another condition or applying the patterns from this study to design a CDSS for a different condition directly.

Focus on suggested interventions in the scope of a single encounter

The study scope did not include the care plan design for an entire episode of care. The design research addressed the presentation of suggested interventions during a single encounter. The evolving CDSS care plans that encompass an episode of care can be complex, particularly for comorbid conditions. Future work could address complex care plans involving big data such as genomics.

Genomics as a single type of big data

The study examined the integration of genomics (defined broadly to include other “omics”) into point-of-care risk assessment. Comparing the results of this study to the studies that would address the presentation of other types of big data, such as passively collected patient sensor data, for example, would be insightful. Specifically, addressing patient activity data, exercise data or sleep data in the context of risk assessment would be an interesting next step, as such data are important for nearly every clinical condition. Such studies have the potential to verify and add evidence to the requirement patterns produced in this work.

Scenario-based methodology for Lead User design

The Lead User design portion of the method was scenario-based, using a single, fictitious persona. As such, this approach could not include an exhaustive list of all CDSS use cases. The participants were encouraged to express their design ideas beyond the predefined scenarios. However, the interview time limitations did not allow for the coverage of all potential breadth and depth of CDSS design. Intentionally, the focus of the study was on assessing risk for a single condition, as risk assessment for co-morbid conditions is inherently very complex clinically. In reality, an elderly patient who may be at risk of frailty is likely to have a complex set of interdependent health issues that may require a holistic risk assessment and suggested treatments. Focusing on risk assessment for one condition-at-a-time without concurrently considering other patient health issues may be a considerable oversimplification of how patients present in the real world.

Indirect pattern validation through UI prototype testing

The patterns were validated indirectly as part of Phase Three work. The Representative Users tested the UI prototype and provided feedback. The Synthesis Team reviewed the feedback and determined what changes were appropriate for the patterns. This form of validation was feasible for this study. However, the limitation of such an approach is that the patterns were tested indirectly. The integrated prototype was but one possible implementation of the patterns. The Representative Users may have inadvertently been biased towards a certain perception of the prototype based on the selected UI design framework. One future avenue for directly validating the patterns would be the engagement of EMR developers. Ideally, a variety of different EMR vendors would validate the patterns by implementing them fully in their EMRs. Such validation feedback would be a valuable input into the patterns' external validity.

Testing limited to the lab

It is also important to acknowledge that the requirement patterns were developed and validated in a lab. Robust validation of the patterns would include the use of the patterns for production health systems with an infrastructure to collect feedback on the patterns' real-world use and to integrate the feedback into the evolving patterns. The hope is that this will be the future direction of this work.

Single Researcher bias

A threat to internal validity was the bias introduced by the researchers. Much of the work was done by a single researcher: the majority of the literature review, raw data collection, and raw data analysis. This was partly mitigated in the following ways: First, Lead User validation was integrated into Phase One. Second, the Synthesis Team reviewed the process and outputs, comparing to evidence and lead user prototypes. Third, saturation into several aspects of the research question promoted internal validity.

Methodological limitations

Further, like any design approach, the developed method had its limitations. The key methodological limitations for internal validity included:

- *Subjectivity inherent to goal definition*

Categorization of requirements as goals, supporting sub-goals, or tasks was subjective. Based on the experiences of this study, this was found to be a drawback for comparing and integrating goal models across multiple stakeholders.

- *Subjectivity inherent to the Synthesis process*

The Synthesis required expert opinion for goal integration and detailed requirement definition. Data collection and analysis documentation were rigorous; however, decision making was subjective and prone to bias. As this study showed, bias can be partially mitigated by Representative User testing to enhance external validity.

Chapter 14: Research Summary

The study intended to explore the challenges of incorporating big data into primary care through CDSS. The study aimed to answer the question of *how to manage the enormous volume and complexity of big data, such as the human genome, in a busy clinical setting, such as primary care.*

The study answered this question by building the evidence for a CDSS using genomics as a prototypical example. The study found that *a big data-enabled CDSS must present high-level information summaries to the primary care provider while highlighting significant actionable data with specific suggested interventions.*

The study has achieved its main objectives: to develop CDSS UI requirement patterns for personalized genomically-enabled risk assessment; and to develop a supporting requirement solicitation, integration, and validation method. The patterns and the developed method are novel in several aspects, adding to knowledge for CDSS and health system design overall.

The patterns provide practical system-agnostic design guidelines that specifically address big data in primary care. The patterns fill a gap of conceptual CDSS best practices and specific UI component specifications. Moreover, the patterns advance the design framework for frailty risk assessment using big data at the point of care.

The method developed is systematic and practical to apply. This study advances the evidence for applying the Lead User method to health systems. The method includes rigorous and systematic

requirement integration and documentation process that ensures traceability of design decisions. The method builds upon theoretical foundations for analyzing systems as socio-technical entities, and for examining optimal approaches for the individual user's cognitive load and cognitive fit. The study highlighted the benefits of underpinning work like this with appropriate theoretical foundations. There were many times in each phase where the Team considered the foundations and considered options based on each theory.

Both the requirement patterns and the supporting method developed in this work have many potential avenues for evolution in future studies.

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Appendices

Appendix A Phase One – Invitation Letter

User Interface Design for a Genomic Clinical Decision Support System Lead User Invitation Letter <Date>

We are inviting primary care physicians with interest/expertise in clinical decision support, genomics, and geriatric frailty, to participate in a user interface design study. We are exploring how experts envision the future of electronic records that have embedded genomic data and how they work to support primary care. This study is part of a Ph.D. project carried out at the University of British Columbia (Island Medical Program) under the supervision of Dr. Morgan Price. This research explores one of the critical challenges for personalized medicine: how to manage the enormous volume and complexity of the human genome in a busy clinical setting, such as primary care.

We are seeking participants that fulfill the following study eligibility criteria:

- Primary care physician
- Experience in managing patients with geriatric frailty
- Strong knowledge and interest in genomics/epigenetics/proteomics
- Have experience using at least one electronic medical record system at the point of care
- Have experience or a good understanding of clinical decision support systems

Your participation in the study will consist of three sessions that will each take approximately 60 minutes of your time. These sessions will help us understand your vision for how complex ‘omic and other data (phenome, genomics, proteomics, environmental variables), medical knowledge can be best presented to a primary care provider to support care during a typical encounter. We are using frailty as a case study.

Through these sessions, the researcher will translate your ideas into visual prototypes for you to see and revise. The interviews will be audio- and screen – recorded. Your participation will occur at a mutually convenient site and time (or remotely). We are able to compensate you for your time (\$100Cdn per hour, up to \$400Cdn for three interviews).

Your participation in this study is completely voluntary. If you consent to participate in this study, your identity will be kept confidential.

If you have any questions or if you are interested in participating in this study, please reply to the researcher, Iryna Davies ([REDACTED]) or the Ph.D. supervisor, Dr. Morgan Price ([REDACTED]).

Thank you for your consideration to help us with this study.

Iryna Davies
Ph.D. Student, Experimental Medicine Program, UBC

Morgan Price, MD, PhD, CCFP, FCFP
Associate Professor, UBC Family Medicine, Island Medical Program

Appendix B Phase One – Consent Form

Consent Form Lead User Design – Phase One User Interface Design for a Genomic Clinical Decision Support System

Principal Investigator: Dr. Morgan Price, Department Family Practice, University of British Columbia, [REDACTED].

Ph.D. Student: Iryna Davies, Experimental Medicine Program, University of British Columbia, [REDACTED].

You are invited to participate in a study entitled: “**User Interface Design for a Genomic Clinical Decision Support System**”. This study is part of a Ph.D. project carried out at the University of British Columbia, Island Medical Program. You are being asked to participate in this study as you have the unique characteristics of lead users within your field – you are an expert in primary care and geriatric frailty, have strong knowledge in genomics, and have interest in designing clinical information systems.

Purpose and Objectives

The purpose of this project is to create and validate a set of user interface prototypes for a genomic Clinical Decision Support System. The design will focus on how large and complex genomic data can be incorporated and shown to a primary care physician during a clinical encounter.

The question to be addressed is:

How would you, as a lead user, design a genomically enabled clinical decision support system intended for the point-of-care in a family practice setting?

Importance of this Research

The recent decades have seen an increasing capability of science to decode the complexity of disease from molecular to population scales. This trend has been accompanied by a transformation in technological abilities to generate, store, analyze and interpret genomic data. However, the pervasive integration of genomics into routine clinical care has not been realized, particularly in primary care. One of the critical challenges for personalized medicine is how to manage the enormous volume and complexity of the human genome in a busy clinical setting, such as primary care. Effective and efficient presentation of such large clinical data and evolving knowledge in a generalist clinical encounter setting remains to be a mostly nascent research area.

This study will result in user interface prototypes for a genomically-enabled clinical decision support system for primary care. The prototypes will illustrate design options

for presenting integrated genome/phenome patient information, along with clinically actionable recommendations, to a primary care physician at the point of care and decision-making. The resulting prototypical design will be based on lead users' ideas and will be validated by typical clinical users such as family physicians who may not have extensive genomic knowledge.

The prototypical interface designs could be implemented in various clinical systems in the future. This study could contribute positively to the integration of personalized medicine into routine clinical practice and thus improvement in patient care.

What is involved?

The research will be conducted remotely via audio/video conferencing software such as Skype or Zoom (or in person if possible, at a mutually convenient location).

If you agree to voluntarily participate in this research, there will be three semi-structured information interviews with the researcher. During these interviews, you will be asked to discuss your thoughts and ideas about the presentation of patient's genomic information at the point of care. The sessions will transition such that the researcher will share back to you (in sessions two and three) visual designs for a genomic clinical decision support system based on your earlier recommendations. The visual designs will be shown to you by the researcher either in person on her laptop or via audio/video conferencing software during sessions two and three. Those designs will be refined based on your feedback. The results from individual sessions will be compared to the results from other participating lead users (prototypes will not be shared among lead users).

Other than reviewing and signing this consent form, you will not be asked to review any documentation prior or after the interview sessions.

The interviews will be audio- and screen –recorded (screen recordings will be taken during sessions two and three to capture your interaction with the designed prototype). The purpose of the audio- and screen- recordings is to capture your goals and design ideas. The researcher will transcribe the audio and use it for the analysis of your design requirements.

Participation in this study will require you to spend approximately 60 minutes of your time per session (three sessions will be planned for you). You will receive compensation for your time in the interviews up to \$400Cdn.

Risks

There are no known or anticipated risks to you by participating in this research.

Benefits

As a participant, you will have an opportunity to share your expertise and express your design ideas for a novel genomic clinical decision support system. This research will contribute positively to the integration of personalized medicine into routine clinical practice. The effective and efficient presentation of complex genomic data at the point of care has a potential to improve clinical care and patient outcomes.

Voluntary Participation

Your participation in this research must be completely voluntary. If you do decide to participate, you may withdraw at any time without any consequences or any explanation. If you do withdraw from the study, your data will not be used in the analysis and will be destroyed.

Confidentiality

All your unique and identifying data will be stripped from the audio recordings (screen recordings by their nature will not contain any identifying information) during the transcription process. Your personal information, such as your name or any other demographic information, will NOT be published anywhere.

Your confidentiality and the confidentiality of the data will be protected by storing all audio and screen recordings on an encrypted and password-protected computer. All data will be archived electronically on UBC's secure Workspace 2.0.

Compensation

You will be offered \$100Cdn for each hour spent participating in the interviews with the researchers.

Dissemination of Results

It is anticipated that the results of this study will be shared with others in the following ways:

- (1) Presentations at scholarly meetings
- (2) In journal papers
- (3) At the Ph.D. defense of the researcher

Disposal of Data

Data from this study will be disposed of after 5 years by securely erasing any computer files. Any paper materials will be shredded.

Contacts

If you have any questions about the study, please contact Iryna Davies at [REDACTED]; [REDACTED] or Dr Morgan Price at [REDACTED]; [REDACTED].

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at [REDACTED] or if long distance e-mail RSIL@ors.ubc.ca or call toll free [REDACTED].

Your agreement below indicates that you understand the above conditions of participation in this study and that you have had the opportunity to have your questions answered by the researchers. If you agree to participate, please sign below.

Name of the Participant

Signature of the Participant

Date

Appendix C Phase One – Interview Guide Example

User Interface Design for a Genomic Clinical Decision Support System Lead User Method

Semi-structured interview guide (Example)

Session 1

Session 1 is intended to elicit the initial set of requirements as well as get background data on the participant.

Throughout this interview, confirm the reasons behind feature requests or design ideas. The ideas are important, but the underlying reasons and goals are also very important in our overall process. Specific focus should be on the design strategies for minimizing extrinsic cognitive load and optimizing cognitive fit in the context of complex and large patient data (genome, phenome, environmental variables) and clinical evidence.

Opening Remarks

“Hello, I am Iryna Davies, thank you for agreeing to participate! I am researching how patient’s genomic (including genomics, proteomics, metabolomics, and other ‘omics) information can be effectively integrated into clinical decision making at the point of care in a family practice setting. I would like to learn about what would make your ideal genomically enabled clinical decision support system (CDSS). I would like to find out how a genomic CDSS can and should work to help you in your office-based practice.

You were recommended as a good person to talk to about this subject.

For this study, I would like to meet with you 3 times to get and validate your ideas on what makes a good genomic CDSS. I will use your ideas to build a mock-up (a user interface prototype) and, in sessions 2 and 3, show it to you to confirm what you have said. I am doing this with about eight users and will then synthesize a final design based on findings from all the lead user designs.

Right now, let’s focus on your ideas. This first session will take about 60-90 minutes. During this session, I will ask you some background questions about your practice and then we’ll get into how you do and do not want a genomic CDSS to work to help you in practice. Do not necessarily limit yourself to your current system you use in the office and how it could be improved. Right now we want to discuss your design ideas.

Before we begin, I wanted to answer any outstanding questions you might have about how these sessions will work.”

Answer questions.

“Anything further? If not and if you are agreeable, we can begin.

Let me just confirm that I have your written consent.

I will start by turning on the audio recording.”

Turn on the audio-recording.

Background Questions on the Interviewee

These questions are designed to provide the interviewer with a sense of the person’s level of knowledge and expertise.

1. Age: _____ Gender: _____
2. How long have you been in practice?
3. Please describe your experience managing patients with geriatric frailty.
4. Please describe your background/knowledge/interest in genomics.
5. Do you use any aspect of genomics in your practice (e.g. have you ever ordered a whole genome/exome sequencing for a patient?)

How long have you been using an electronic medical record system?

Persona Overview

Review one patient persona with the lead user (persona descriptions were provided to the lead user in advance of the interview). Go over the next two sections (Current Frailty Risk Assessment Workflows and Envisioned/Ideal Risk Assessment Workflows) using one persona at a time. Repeat with the second persona: review the second persona description and go over the two sections again.

Current Frailty Risk Assessment Workflows

Using a persona, ask the lead user to describe how they currently address frailty risk assessment.

Focus on: scenarios for which risk assessment is done; key goals; who is involved besides the patient and family doctor; what type of patient data is used; what patient data is typically lacking; what tools are used (electronic, paper, other); what works well and what does not.

Envisioned/Ideal Risk Assessment Workflows (with Genomic Data)

Using a persona, ask the lead user to describe how an ideal decision support system would help them make frailty risk assessment. Ask the user to imagine that an ideal decision support system incorporates genomic (as well as epigenomics, proteomic, and other ‘omics) patient data and clinical evidence. Specifically, focus on the integration of large and long patient genome and phenome with clinically-actionable recommendations.

For each design feature described by the lead user, prompt the lead user to describe the reasons for their design choice. Specifically, prompt the user to describe how a given design feature matches his/her decision-making model and helps the user make decisions; what information the lead user needs and in what format; what information is not needed; who and what helps the lead user make decisions and how.

Focus on understanding how the design features proposed by the lead user will help him/her maximize cognitive fit (between how the data is presented by a CDSS and how the user makes decisions) and minimize the extrinsic (unnecessary) cognitive load (to allow for more cognitive resources dedicated to learning and decision making), given the constraints of a typical primary care encounter.

Prompting Questions:

- What CDSS features would help you enhance your decision-making workflows and inference processes?
- How would you like to see complex and large information (patient’s detailed phenome, ‘omics data, clinical knowledge, and recommendations) presented to you in a clear and easy-to-process way during a typical encounter?
 - What information is important and what information is not necessary?
 - What are appropriate ways to classify, group, and summarize such information?
- How should the CDSS address multiple recommendations for a patient (e.g. if patient has co-morbidities or if there are various guidelines for the same condition)? How should multiple recommendations be prioritized, filtered, and reconciled? What context, provider, and patient characteristics/preferences should be considered?
- What information should be automatically processed (e.g. extracted from your medical record system, calculated, etc.) by the CDSS to reduce your cognitive load?
- What types of data presentation formats are appropriate for different tasks?
- What range of flexibility would you like the CDSS to have for allowing different inference processes (e.g. should the CDSS allow you to specify preferences, defaults, etc. for input and output data)?
- What CDSS help and guidance features are important for you to have as part of the system? For example, do you want to know what algorithms are used for generating the recommendations, what input data is evaluated, what knowledge sources are used, what capabilities and limitations the system has?

Wrap up

“Thank you, this has been very interesting. Before we wrap up, let me reflect back what I have heard. What I have heard is:”

Reflect back what has been said in terms of design

“Have I heard you correctly?”

Do you have anything else to add?

Thank you. Now I am going to review the recording and my notes and capture your words into a visual mock-up. I hope I can show that to you at a follow up session.

Would you be available for a follow up to see the visual mock-up, the next session would likely take about an hour?"

Arrange follow up session.

Session 2 and 3

Session 2 and 3 designed to reflect back what has been learned in a visual format. These sessions will (a) confirm requirements / design and (b) use the visual components to draw out new design ideas. As these sessions are based very much on the design from the user in the earlier sessions, the information below is illustrative.

Session Introduction

"Thank you for agreeing to have this follow-up session. I appreciated your insight in the previous session. I will review with you a mock-up or wireframe of the design features based on the information you gave me last time. You will tell me where I got it right and where I need to revise. We will also go through a few sections that I need to better understand your ideas.

Do you have any questions?"

Answer questions.

Design Walkthrough

"I am going to share screen now / show you the wireframes and turn on the recording. Let me know if you see the screen."

Using one persona at a time and relevant decision-making tasks, walk through the design with the lead user (the researcher will control the computer using a preplanned workflow with the prototype system). Allow for the lead user to ask questions and provide feedback.

Prompting Questions

- Does this capture your ideas for a genomic clinical decision support system?
- We did not talk about this section in detail – can you describe to me what you meant would go here?
- Is this information presented the way you envisioned? What is needed? Why? What is not needed?
- Does this make sense?
- How could this be done differently? Better?
- Would you use this over what you currently use? Why?
- Does this fit into your workflow as you expected when we first talked about it?

- Wrap-up

“Thank you. Before we wrap up, let me make sure I have captured your thoughts. What I have heard is:”

Reflect back what has been said

“Have I heard you correctly?”

“Do you have anything else to add?”

If this is session 2: *“I will make the changes to your design and then I would like to show them to you again for confirmation. Would you be available for a follow up to 30-60 minutes to review the changes?”* Arrange follow up session.

If this is session 3: *“I will make the changes to your design based on what I have learned today. Your design will be considered finalized. You will have an opportunity to review the outcome of the study when I finish this project. The final results will be published in my dissertation and possibly several publications. Thank you very much for your participation.”*

Appendix D Patient Persona

The persona used for this study represents a typical patient who may present for geriatric frailty in a primary care setting. The persona incorporates various levels of complexity of phenome, genome, and environmental characteristics relevant to frailty risk assessment. The persona was developed to prompt the users about different issues relevant to the genomic CDSS design. A high-level summary of the proposed persona is presented below.

Annie Smith

Annie is a seventy-year-old retired psychology professor. She is physically active and socially engaged in her community through various types of volunteering. Annie feels well and full of energy and enthusiasm for life. She loves to learn and takes an active role in her health.

Annie has never smoked, pays close attention to her nutrition and enjoys a glass of red wine at dinner.

She had breast cancer in her early 60's but is in full remission. Annie does have mild hypertension, but it is under control through daily exercise and medication (she takes ramipril daily). Annie has an anaphylactic allergy to peanuts and thus carries an EpiPen with her. She also takes daily acetaminophen for the mild osteoarthritis pain she has in her wrists. Annie takes multivitamins and fish oil for general health.

Annie's mother and older sister had breast cancer at around age 60. Annie's father had Alzheimer's in his 70's, as did Annie's paternal aunt. Annie's older brother suffers from hypertension and her older sister has osteoarthritis in her knees.

Annie recently paid out of her pocket and obtained her whole genome sequence as well as epigenomics, proteomic and metabolomic profiles. She is very interested in knowing her risks for various diseases, and frailty in particular. She has seen several of her older close friends end up in care homes due to physical and mental frailty. Annie is determined to educate herself about frailty risks and what she can do to maintain her independence in the future.

Annie comes to her family physician, Dr. Smith, with her genomic information and asks him what her frailty risk score is based on all this data in combination with her medical record. Annie also wants to know how Dr. Smith is going to calculate the frailty risks score (what information he is going to evaluate). Annie is eager to identify her risk factors so she can research the latest literature on frailty interventions. She also wants to focus on modifiable factors to improve her future outcomes. Annie wants to track her progress and see how her risk score changes each time she visits Dr. Smith based on her latest health status and evolving evidence.

Highlighted Design Challenges

- Presenting and interpreting the frailty risk score, its components, evidence, and changes over time:
 - Presenting detailed risk score information
 - Presenting and interpreting risk assessment score and its quality, given the missing inputs for the score calculation
 - Presenting different types of risk factors, including large genome data
 - Differentiating modifiable and non-modifiable risk factors
 - Estimating risk score changes based on interventions for modifiable risk factors (e.g., exercise and diet improvements).
 - Tracking risk score changes based on patient's health status, interventions and evolving evidence.
 - Presenting suggested interventions
- Actioning incomplete patient data:
 - Indicating to the provider what type of important patient information is missing
 - Accommodating patient's preferences for not disclosing parts of their genome (or other sensitive info) to the patient and the primary care provider
 - Predicting changes in risk score and quality, given the availability of missing information.

Appendix E Rich Textual Documentation of Goals – Template

Table 8 Textual documentation of goals - template

Goals, Qualities, Tasks	Provider’s Rationale	Information Resources
Document goals, qualities, and tasks in a hierarchical way (qualities describe the goals, sub-goals support the goals, tasks support the goals.)	Document detailed rationale for the proposed goals, qualities and tasks. Focus on the ‘why’ behind the ‘what’ to understand how the requirements optimize cognitive load and fit.	Describe specific information resource that the user needs to support the proposed goals, qualities, and tasks.

Appendix F Goal Integration Method

The challenge of integrating multiple requirement sets was that the literature on requirements engineering tends to provide various methods that typically concern the harmonization of two sets of requirements (Sabetzadeh and Easterbrook 2006; Baslyman 2018). The requirements integration methods examined in the literature were informative but did not appear to scale up for this study. Moreover, there was a need for a goal integration method that was accessible to qualitative researcher from various disciplines without a software engineering background or complex tools. Therefore, a custom method for unifying multiple-goal sets into a harmonized model was developed in this study. The focus of the method was to ensure originator (Lead User), origin (hierarchical place in a specific Lead User goal model), and unification rationale/assumption traceability. The traceability had to be maintained throughout the evolution of the Integrated Goal Model as it went through multiple iterations during the Synthesis phase of the study.

The process steps are described next.

Goal Integration Steps:

1. **Identify top-level goals for each Lead User goal model.** A Lead User goal model can include both top-level and supporting sub-goals. The sub-goals typically provide more details on how the top-level goals could be achieved. Each goal model needs to be reviewed in detail to ensure correct goal hierarchies.
2. **List all the top-level goals from all the Lead Users in one list.** All the top-level goals are examined across all the Lead Users to ensure no requirements are lost in the unification process.
3. **Analyze each goal's congruency across all Lead Users.** A matrix is created for the list of all top-level goals to indicate whether each Lead User:
 - *(P) Proposed* the same goal - semantically the same, although it could be worded differently
 - *(PSIM) Proposed Similar Goal* - semantically similar. For similar goals, document a similar goal in the matrix.
 - *(NP) Not Proposed* - the goal was not proposed at all.
 - *(C) Conflicting* – Lead User had a conflicting goal. For conflicting goals, document the conflicting goal in the matrix.
4. **Derive the unified goals and document rationale.** The Synthesis Team needs to confirm the proposed goals and harmonize/resolve similar and conflicting goals into the Unified Model. The goals are documented with the goal numbering indicating the hierarchical relationship among goals. Note that the expertise and opinions of the Synthesis Team have the most weight on the goal integration decisions. For example, even if a certain goal is proposed by the majority of Lead Users, the Synthesis Team can

deem it as not includable in the finalized Integrated Goal Model if the Synthesis Team has compelling evidence-based reasons (for example, based on the literature).

5. **Document rationale for each revision of the unified goals.** To ensure traceability throughout the entire unification process, the rationale and the nature of the changes to the unified goals are documented with each iteration of the Integrated Goal Model.
6. **For the finalized Unified Goal Model, synthesize qualities for each goal across all Lead Users.** All the qualities proposed by the Lead User for each goal in the Integrated Model are listed. The Synthesis Team discusses the proposed qualities, harmonizes/resolves similar and conflicting qualities, and integrates the qualities in the Integrated Goal Model.

Appendix G Requirement Pattern Template

Pattern Title

Updated: <date>

Version:

Authors:

Status

A description of the robustness of the design ideas expressed in the pattern.

- **Conceptual:** a sketched pattern idea from one author, generated as an idea to explore.
- **Draft:** a pattern based on evidence, from the Lead User study and/or literature.
- **Validated:** a pattern tested and refined with Representative Users.

Intended To

A problem and context description in which the pattern can be used.

Not Intended To

Explicit statements about not intended uses and goals of the pattern.

Clinical Context

Situations in which the pattern may be usable/applicable. The reasons why the pattern provides value to the user.

Users

Intended end-users for the functionality and information described in the pattern.

Visualization Examples

Solution Description

- **Strive To**
Specific requirements for the desirable design features where such features are feasible.
- **Avoid**
Specific requirements for what should be avoided in the design.
- **Other Considerations**
Other requirements that were discovered in the study but were not sufficiently analyzed due to scope or evidence limitations. These requirements were captured for consideration in future research.

Related Patterns

- **Used By**
Parent patterns

- **Uses**
Child patterns

Appendix H Phase Three – Invitation

User Interface Design for a Genomic Clinical Decision Support System Recruitment Letter

<Date>

We are inviting primary care physicians, with experience in managing patients with geriatric frailty, to participate in a user interface design study. We are exploring how experts envision the future of electronic records that have embedded genomic data and how they work to support primary care. This study is part of a Ph.D. project carried out at the University of British Columbia (Island Medical Program) under the supervision of Dr. Morgan Price. This research explores one of the critical challenges for personalized medicine: how to manage the enormous volume and complexity of the human genome in a busy clinical setting, such as primary care.

We are seeking participants that fulfill the following study eligibility criteria:

- Primary care physician
- Experience in managing patients with geriatric frailty
- Have experience using at least one electronic medical record system at the point of care

Your participation in the study will consist of one interview session that will take approximately 60 minutes of your time. In the session, we will ask you to review a novel design for an electronic medical record system that includes genomic information. You will complete usability testing on the prototype and provide us feedback on how to improve the design.

We will be able to compensate you at \$100Cdn/hr for your time.

Your participation in this study is completely voluntary. If you consent to participate in this study, your identity will be kept confidential.

If you have any questions or if you are interested in participating in this study, please reply to the researcher, Iryna Davies ([REDACTED]) or the Ph.D. supervisor, Dr. Morgan Price ([REDACTED]).

Thank you for your consideration to help us with this study.

Iryna Davies
Ph.D. Student, Experimental Medicine Program, UBC

Morgan Price, MD, PhD, CCFP, FCFP
Associate Professor, UBC Family Medicine, Island Medical Program

Appendix I Phase Three – Consent Form

Consent Form Usability Validation – Phase Three User Interface Design for a Genomic Clinical Decision Support System

Principal Investigator: Dr. Morgan Price, Department Family Practice, University of British Columbia, [REDACTED].

Ph.D. Student: Iryna Davies, Experimental Medicine Program, University of British Columbia, [REDACTED].

You are invited to participate in a study entitled: “**User Interface Design for a Genomic Clinical Decision Support System**”. This study is part of a Ph.D. project carried out at the University of British Columbia, Island Medical Program. You are being asked to participate in this study as a primary care clinician with expertise in managing geriatric frailty patients to help evaluate the usability of a genomic clinical decision support system.

Purpose and Objectives

The purpose of this project is to create and validate a set of user interface prototypes for a genomic Clinical Decision Support System. The design will focus on presenting large and complex genomic data to a primary care physician during a clinical encounter.

The question to be addressed is:

How do you, as a clinical expert, perceive the usability aspects of the proposed genomically enabled clinical decision support system intended for the point-of-care?

Importance of this Research

This study will result in user interface prototypes for a genomically-enabled clinical decision support system for primary care. The prototypes will illustrate design options for presenting integrated genome/phenome patient information, along with clinically actionable recommendations, to a primary care physician at the point of care and decision-making.

The prototypical interface designs could be implemented in various clinical systems in the future. This study could contribute positively to the integration of personalized medicine into routine clinical practice and thus improvement in patient care.

What is involved?

The research will be conducted at a mutually convenient time and place, including remotely via audio/video conferencing software such as Skype or Zoom.

If you agree to voluntarily participate in this research, there will be one usability evaluation session with the researcher. During the session, you will be asked to perform a set of predefined

scenario-based tasks while interacting with the prototype system. The evaluation process will entail the use of the think-aloud-protocol where you will be encouraged to verbalize your thoughts, feelings and perceptions about the system usability. At the end of the session, you will also be asked to fill out a short usability survey.

Other than reviewing and signing this consent form, you will not be asked to review any documentation prior or after the usability evaluation session.

The usability session will be audio- and screen –recorded (screen recordings will be taken during the session to capture your interaction with the prototype). The purpose of the audio- and screen- recordings is to capture your feedback. The researcher will transcribe the audio and use it for the analysis of your design improvement ideas.

Participation in this study will require you to spend approximately 60-90 minutes of your time for the usability evaluation session. You will also receive \$100Cdn compensation for your participation in the usability session.

Risks

There are no known or anticipated risks to you by participating in this research.

Benefits

As a participant, you will have an opportunity to share your expertise and express your ideas for how the novel genomic clinical decision support system prototype can be improved. This research will contribute positively to the integration of personalized medicine into routine clinical practice. The effective and efficient presentation of complex genomic data at the point of care has a potential to improve patient outcomes.

Voluntary Participation

Your participation in this research must be completely voluntary. If you do decide to participate, you may withdraw at any time without any consequences or any explanation. If you do withdraw from the study, your data will not be used in the analysis and will be destroyed.

Confidentiality

All your unique and identifying data will be stripped from the audio recordings (screen recordings by their nature will not contain any identifying information) during the transcription process. Your personal information, such as your name or any other demographic information, will NOT be published anywhere.

Your confidentiality and the confidentiality of the data will be protected. All materials will be stored only on encrypted and password-protected computers. Dr. Price will digitally archive all materials on UBC's secure servers (Workspace 2.0) for at least 5 years as per UBC policy.

Compensation

You will be offered \$100CAD for participating in the usability test.

Dissemination of Results

It is anticipated that the results of this study will be shared with others in the following ways:

- (1) Presentations at scholarly meetings
- (2) In journal papers
- (3) At the Ph.D. defense of the researcher

Disposal of Data

Any paper materials will be scanned and digitally stored, the paper will then be shredded. Electronic data from this study will be disposed of after 5 years by securely erasing any computer files.

Contacts

If you have any questions about the study, please contact Iryna Davies at [REDACTED] or Dr Morgan Price at [REDACTED].

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at [REDACTED] or if long distance e-mail RSIL@ors.ubc.ca or call toll free [REDACTED].

Your agreement below indicates that you understand the above conditions of participation in this study and that you have had the opportunity to have your questions answered by the researchers. If you agree to participate, please sign below.

Name of the Participant	Signature of the Participant	Date
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Appendix J Phase Three – Demographics Questionnaire

1. Age: _____ Gender: _____
2. How long have you been in practice?
3. Please describe your experience managing patients with geriatric frailty.
4. Please describe your background/knowledge/interest in genomics.
5. Do you use any aspect of genomics in your practice (e.g. have you ever ordered a whole genome/exome sequencing for a patient?)

Appendix K Phase Three – Usability Questionnaire

Table 9 Usability questionnaire

		Strongly Disagree	Disagree	Slightly Disagree	Neutral	Slightly Agree	Agree	Strongly Agree
Performance Expectancy	I easily found the information I needed to help me make decisions.							
	The CDSS presented complex information in a clear, easy-to-understand, and well-organized manner.							
	The CDSS did not impose unnecessary mental burden (e.g., unclear or confusing recommendations, etc.)							
	The CDSS would fit well with my clinical workflows and inference processes.							
	I would find the CDSS useful for my job.							
Effort Expectancy	My interaction with the CDSS would be clear and understandable.							
	Learning to operate the CDSS would be easy for me.							
Attitude Toward Using Technology	Using the CDSS in my practice would be a good idea.							
	The CDSS would make work more interesting.							
Social Influence	People who are important to me would likely think I should use the CDSS.							
	I think the organization I work at would be supportive of the use of the CDSS.							
Facilitating Conditions	I would have the resources necessary to use the CDSS.							
	I have the knowledge necessary to use the CDSS.							
Behavioural Intentions to Use the System	I would use the CDSS in my practice.							

Appendix L Rich Textual Documentation of Goals

Table 10 Example textual documentation of goals

Goals, Qualities, Tasks	Provider's Rationale	Information Resources
<p>0. Frailty risk addressed</p> <p><i>(Redundant data entry avoided)</i></p>	<p>“It’s important to me that I don’t enter data twice anywhere if it’s in the EMR already, especially.”</p>	<ul style="list-style-type: none"> • CDSS integrated into EMR
<p>1. Notification to assess risk integrated into clinical workflow</p> <p><i>(Timely)</i></p>	<p>“CDSS should show an alert based on patient EMR record indicating that a certain issue needs to be addressed deeper. An alert should be based on ‘case findings’ principles. It must be integrated with my workflow, with whatever I am doing during a regular encounter... It’s important that I get the alert at the right time.”</p>	<ul style="list-style-type: none"> • Recommendations to assess risk on patient summary or encounter screen
<p>1.1 Top priority notifications presented</p>	<p>“Everything should be worded succinctly.”</p>	
<p>1.1.1 View a small number of recommendations per encounter</p>	<p>“I need to see 3 or 5 recommendations max with an option to see more”</p>	<ul style="list-style-type: none"> • ‘Patient Recommendations’ panel on an EMR screen with 3-5 recommendations • An option to see more recommendations, if applicable
<p>1.1.2 View recommended tasks</p>	<p>“Patient summary or encounter screen are suitable places for the alerts. I need to see what I should be doing.”</p>	<ul style="list-style-type: none"> • Recommended tasks in the Patient Recommendations panel on a patient summary or encounter screen
<p>1.1.3 Notification importance presented</p> <p><i>(Clearly)</i></p>		
<p>1.1.3.1 View patient-specific rationale</p>	<p>“List of key patient factors (data from EMR) that triggered an alert should be shown here. For example, patient is diabetic, has no HbA1C.”</p>	<ul style="list-style-type: none"> • List of key patient factors (data from EMR) that triggered an alert should be shown

Goals, Qualities, Tasks	Provider's Rationale	Information Resources
1.1.3.2 View evidence summary	"A very succinct reason for why this is shown, in terms of evidence."	<ul style="list-style-type: none"> One-liner of evidence
1.1.3.3 View more evidence	"Include an option to see more evidence for the alert - a link with a summary of evidence (what is the evidence based on such as, for example, A evidence based on double-blind control studies that are summarized here, etc.)"	<ul style="list-style-type: none"> 'view evidence summary' link
1.1.3.4 View strength of evidence	"An alert should have level of evidence shown (e.g. use Canadian Task Force grades of recommendations (e.g. A -Good level of evidence for the recommendation to consider a condition))"	<ul style="list-style-type: none"> Strength of evidence
1.2 Go to separate risk assessment module	"Risk assessment must be only triggered if it is relevant to the patient. The user would go into a separate module to work on frailty assessment"	<ul style="list-style-type: none"> Separate frailty risk assessment module
2. Risk assessed in detail <i>(Preventatively)</i>		
2.1 Risk info presented <i>(Clear for patient, Clear for provider)</i>	"See 23andMe how they define risk very clearly for patients. Need to also define it clearly for a provider."	
2.1.1 View frailty definition	"Need to explain to the physician and patient why becoming frail is a bad thing. Frailty should be defined as it means different things for different people. Can use Fried's phenotype or a Frailty Index (or other definitions). Otherwise 'frailty' is just a word. Need a link to the definition of frailty that must include a section of Negative Outcomes."	<ul style="list-style-type: none"> Frailty definition as patient-specific outcomes
2.1.2 Print frailty definition for patient	"This should be printable for the patient."	
2.1.3 View patient risk score	<p>"Provider needs to easily see the patient's risk score."</p> <p>"Use 5 years as a timeframe."</p> <p>"CDSS wording must be very clear that predisposition to a condition is not the same</p>	<ul style="list-style-type: none"> Patient's risk score as a % Patient risk score time frame: 5 years Disclaimer that risk represents probability and not certainty

Goals, Qualities, Tasks	Provider’s Rationale	Information Resources
	‘you will get it’. Wording must be careful. Risk should be expressed as probability. See 23&Me wording.”	<ul style="list-style-type: none"> • Patient risk score quality (high/med/low qualifiers and their definition in terms of % of patient data missing)
2.1.4 View population risk score	<p>“Provider needs to see how patient’s risk compares to the population risk level. The comparison (to the population risk) should be as specific as possible (e.g. for a certain age, gender, ethnicity, etc.).</p> <p>Risk should be explained: ‘compared to this specific population, your risk of becoming frail in the next timeframe is X’.”</p>	<ul style="list-style-type: none"> • Population risk score as % for comparable gender, ethnicity and age category
2.1.5 View risk score trend	<p>“It is useful to see how the risk score changes over time.”</p> <p>“Trending should include quality of risk scores.”</p>	<ul style="list-style-type: none"> • A link to the definition of frailty that must include a section of Negative Outcomes • Quality for each score (low/med/high)
2.2 Risk factors presented <i>(On high level)</i>		
2.2.1 View a brief summary of top risk factors	<p>“Provider needs to see a summarized list of what patient-specific risk factors make up the risk score.”</p> <p>“Need to see as much at a glance as is required to explain it to the patient – 2 or 3 sentences to begin a conversation with a patient. I need to see anything that triggers me to worry about you, patient, as a healthcare provider”.</p> <p>“The risk factors have to be appropriately summarized for the physician and the patient.”</p>	<ul style="list-style-type: none"> • Brief summary of top risk factors (1-2 lines)
2.2.2 View all modifiable risk factors (Shown on demand)	<p>“Modifiable risk factors are most important to see. Provider’s goal is intervening in a way that decreases morbidity and mortality, so the provider needs to see modifiable risk factors as the most important category. The physician needs information that he/she can use to influence care.</p>	<ul style="list-style-type: none"> • List of risk factors (patient factor, value and range, relative and absolute % of contribution, brief evidence summary, link to more evidence, strength of evidence)

Goals, Qualities, Tasks	Provider's Rationale	Information Resources
	<p>For modifiable factors especially, must differentiate between absolute and relative numbers. This is important.”</p> <p>“In the list of individual risk factors (if the user chooses to see them), need to include a link for more evidence. The link must go to a relevant and up-to-date summary article that summarizes the evidence (summary is key, don't need to see all the separate studies and study protocols, etc.). A summary can say: “These 5 studies were done that put together in a meta-analysis show x related to y”).”</p>	
<p>2.2.3 View all non-modifiable risk factors (Shown on demand)</p>	<p>“Can include a link to non-modifiable risk factors but it would be a separate list just for information.”</p>	<ul style="list-style-type: none"> List of risk factors (patient factor, value and range, relative and absolute % of contribution, brief evidence summary, link to more evidence, strength of evidence)
<p>2.2.4 Big data risk factors clustered (<i>High-level clustering</i>)</p>		<ul style="list-style-type: none"> Omic factors grouped on a high level and groupings are included in the list of non-modifiable risk factors
<p>2.2.4.1 View clusters on the list of risk factors</p>	<p>“No need to explain/break-down genomics factors on the main page of risk factors.</p> <p>If a user wants to see, say, specific genes that contribute to risk, they could click on “Genetic Biomarkers” and see the genes but even here things should be on a very high level (this gene is linked to this phenotype). Summarizing and grouping such factors is key.”</p>	<ul style="list-style-type: none"> A cluster on the list of risk factors and its contribution to overall risk
<p>2.2.4.2 View individual risk factors within clusters</p>	<p>“User can click the groupings and see individual components (e.g. genes for Genomic Biomarkers). Individual components have: Biomarker (e.g. gene/variant or a protein), Patient Info Updated date, Phenotype Associated with Biomarker. Evidence summary with a link to see more, Evidence Updated date”</p>	<ul style="list-style-type: none"> List of risk factors within a cluster (patient factor, value and range, or variant, associated phenotype, brief evidence summary, link to more evidence, evidence updated date)
<p>2.2.5 Masked/filtered data disclaimer</p>	<p>“Provider should know that something is missing (e.g. some genomic data was filtered out based on patient's preferences) but this shouldn't be too specific.</p>	<ul style="list-style-type: none"> A statement on the summary of risk factors (seen at a glance) that some patient data are missing (if appropriate)

Goals, Qualities, Tasks	Provider's Rationale	Information Resources
presented (<i>Not condition-specific</i>)	<p>Patient should have a right to decide to filter any type of data but must make this decision with “eyes wide open”. Lack of data influences decision making on the provider’s part. Patient should decide if the provider should know that something was filtered out (or if the provider shouldn’t know).</p> <p>The notification to the provider should be very generic, not on the condition level but rather on a general level such as: “Certain genetic data has been filtered out at the patient’s request”</p>	<p>due to filtering based on patient’s preferences</p>
2.3 Risk factors can be updated (<i>Without switching to other modules</i>)	<p>“I should be able to update a risk factor and not have to go somewhere else in the EMR.”</p>	
2.4 Data quality issues highlighted (<i>Clearly</i>)	<p>“Data points that are important for the risk score calculation but are missing or of poor quality (e.g. old data) should be shown. It should be easy to see.”</p>	<ul style="list-style-type: none"> List of missing /low quality data points important for calculation.
3. Interventions suggested	<p>“Provider needs to see a plan to mitigate the risk factors.</p>	
3.1 Top priority interventions suggested (<i>Specific, Measurable, Behaviourally Anchored</i>)	<p>“The interventions must be behaviourally anchored and measurable. The wording should be very specific.”</p>	
3.1.1 View suggested patient actions	<p>“Interventions should be identified on different levels. Patient actions:</p> <ul style="list-style-type: none"> Make sure you do this as a patient. For example, exercise prescription in very specific term “walk 2 blocks per day for a week and then increase to 3 blocks per day. Interventions should be measurable, behaviorally anchored.” <p>“Wording for plan items should be straightforward, easy to understand and specific. Tell me exactly how much the</p>	<ul style="list-style-type: none"> Interventions patient should be doing

Goals, Qualities, Tasks	Provider's Rationale	Information Resources
	patient should exercise, for example (e.g. walk around the block two time three times per week and then increase to four times per week.”	
3.1.2 View suggested provider actions	<p>“Provider actions: Make sure you do this as a provider together with the patient (e.g. physical exam)”</p> <p>“I need links to the appropriate history in the EMR (e.g. lab history, med history) to have more context.”</p>	<ul style="list-style-type: none"> • Actions provider should be doing • Links to other EMR modules per each intervention
3.1.3 Intervention can be actioned	“Allow the provider to acknowledge that the recommendation was discussed, will be addressed another time or should be dismissed (without judgement on the provider, without requiring a specific reason for dismissal).”	<ul style="list-style-type: none"> • Checkboxes: <ul style="list-style-type: none"> ○ Address another time ○ Dismiss recommendation (don't require reason why)
3.1.3.1 Mark intervention as discussed		<ul style="list-style-type: none"> • ‘discussed with patient’ checkbox
3.1.3.2 Defer intervention		<ul style="list-style-type: none"> • ‘address another time’ checkbox
3.1.3.3 Dismiss intervention		<ul style="list-style-type: none"> • ‘dismiss’ checkbox
3.2 Follow-up appointment suggested		
3.2.1 View suggested appointment date	“There should be something like: Will re-see patient in 6 months. This would be useful.”	<ul style="list-style-type: none"> • Recommended next appointment
3.2.2 Book appointment	“I should be able to book from here.”	<ul style="list-style-type: none"> • Ability to book next appointment
3.3 Relevant investigations can be ordered (<i>Without switching to other EMR modules</i>)	“Labs and things like that should be easy to order from here. They can be seen as a type of intervention. This is something for the provider to do to fill in the DQ gaps.”	<ul style="list-style-type: none"> • Ability to order investigations

Appendix M Lead User Goal Models

M.1 Lead User 1 Goal Model

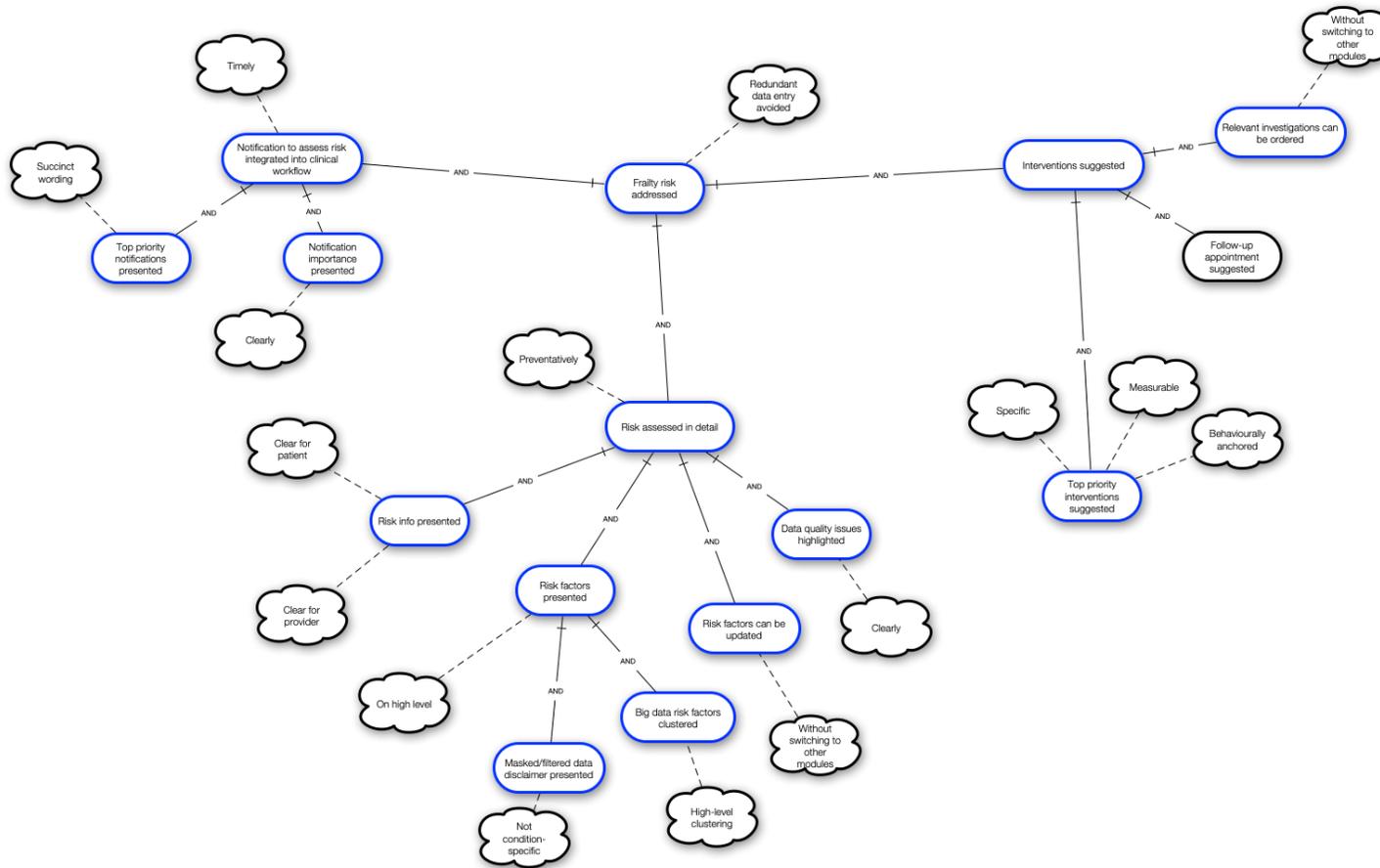


Figure 22 Lead User 1 goal model

M.2 Lead User 2 Goal Model

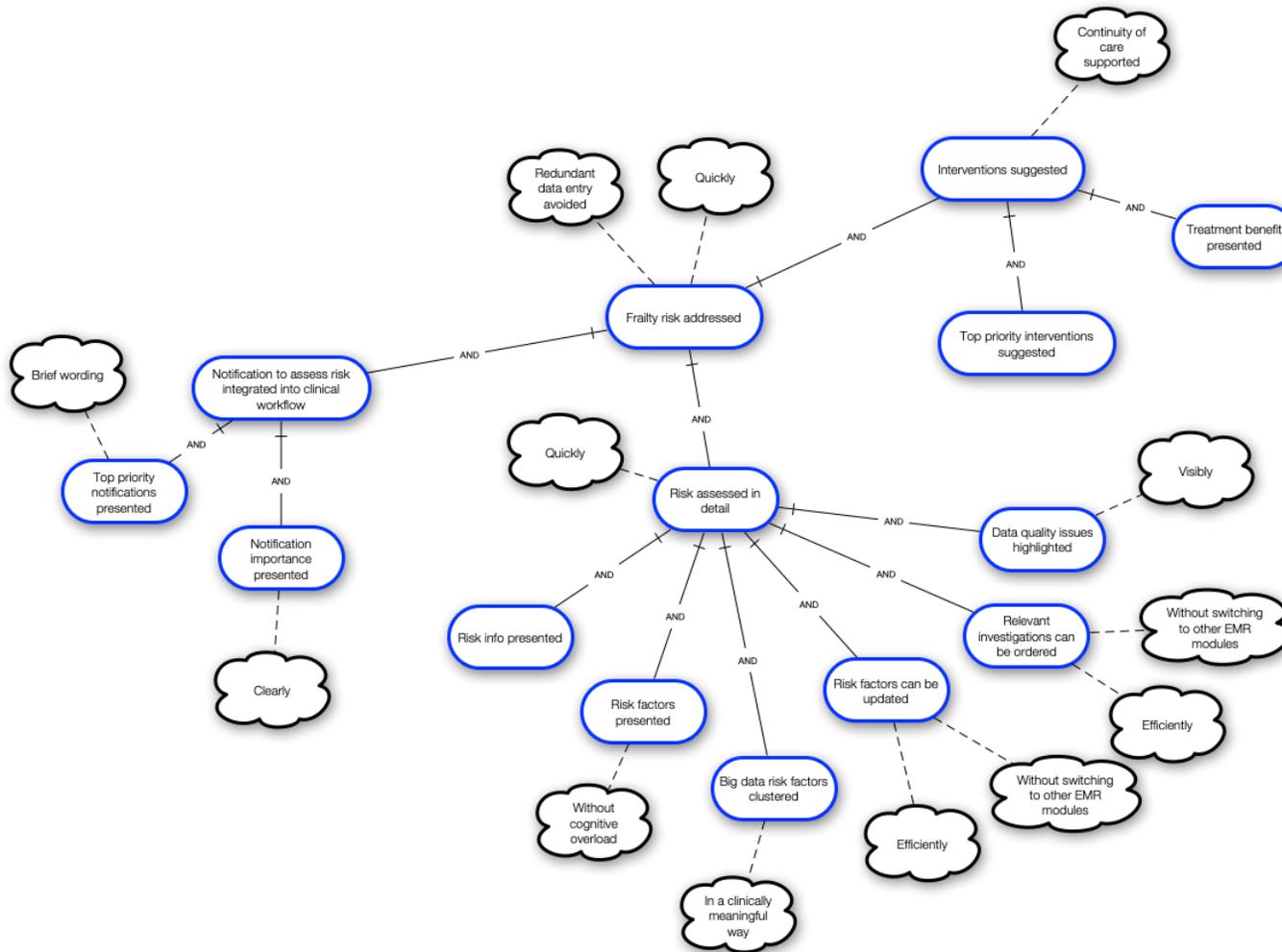


Figure 23 Lead User 2 goal model

M.3 Lead User 3 Goal Model

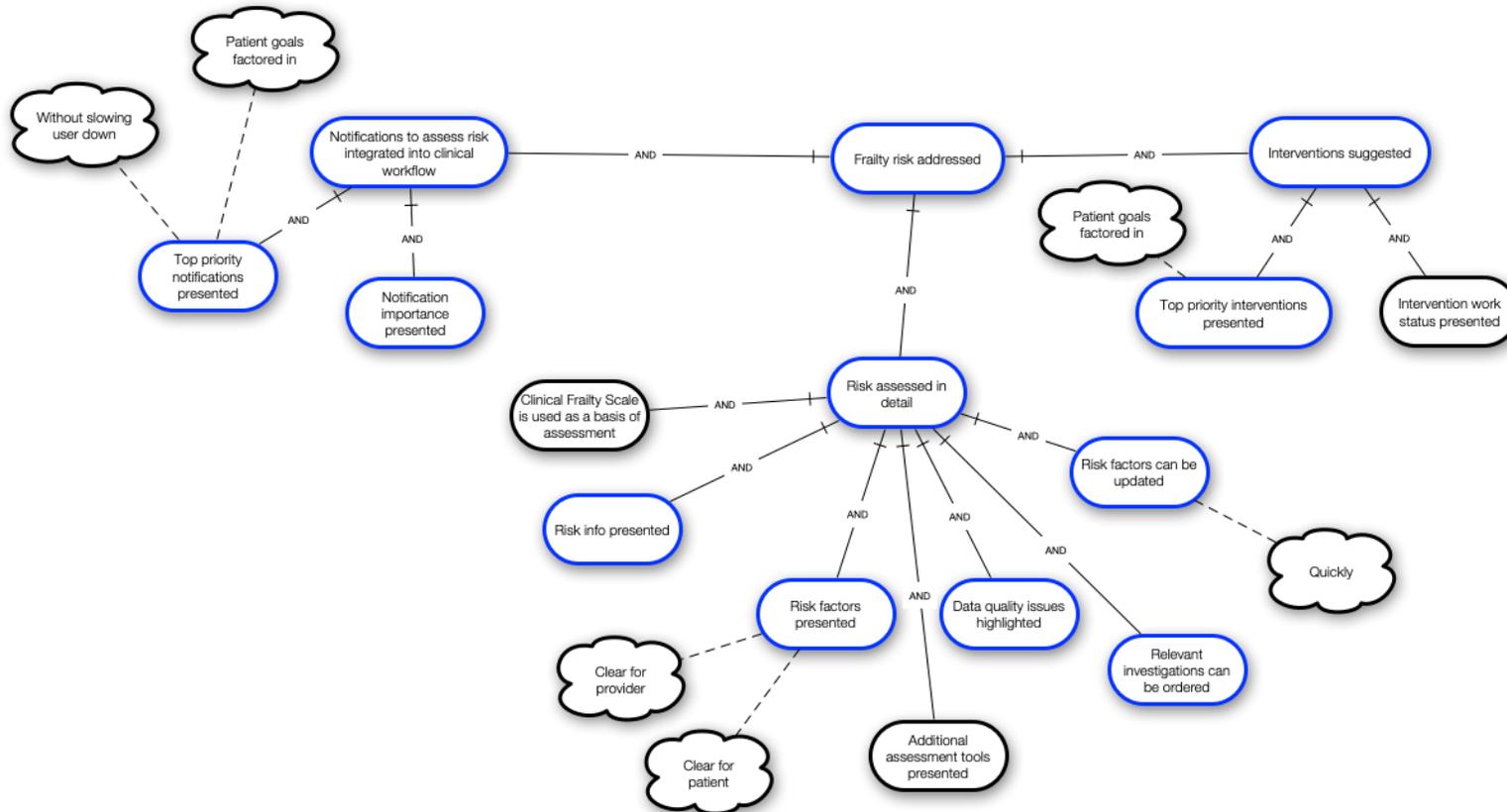


Figure 24 Lead User 3 goal model

M.5 Lead User 5 Goal Model

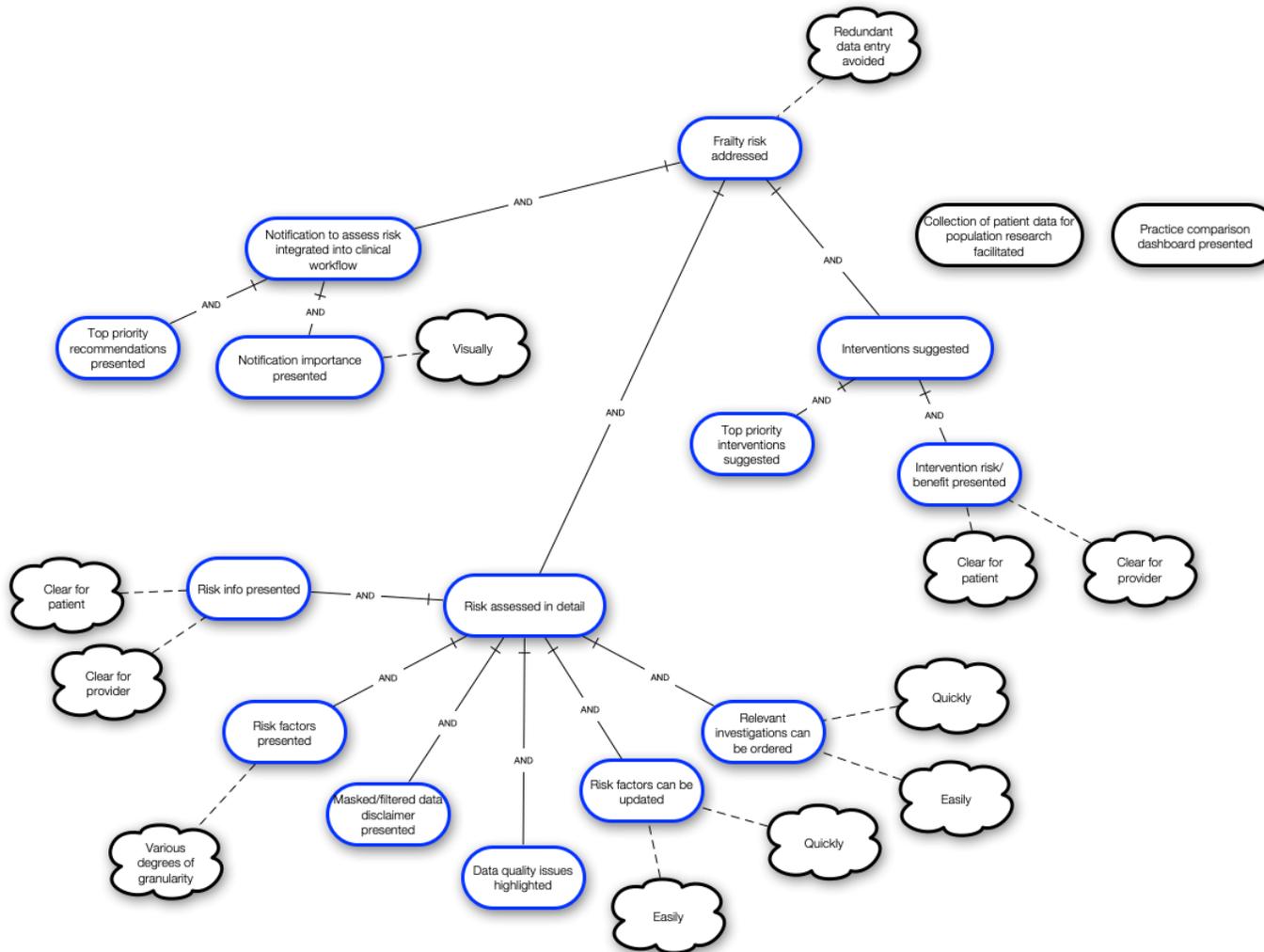


Figure 26 Lead User 5 goal model

M.6 Lead User 6 Goal Model

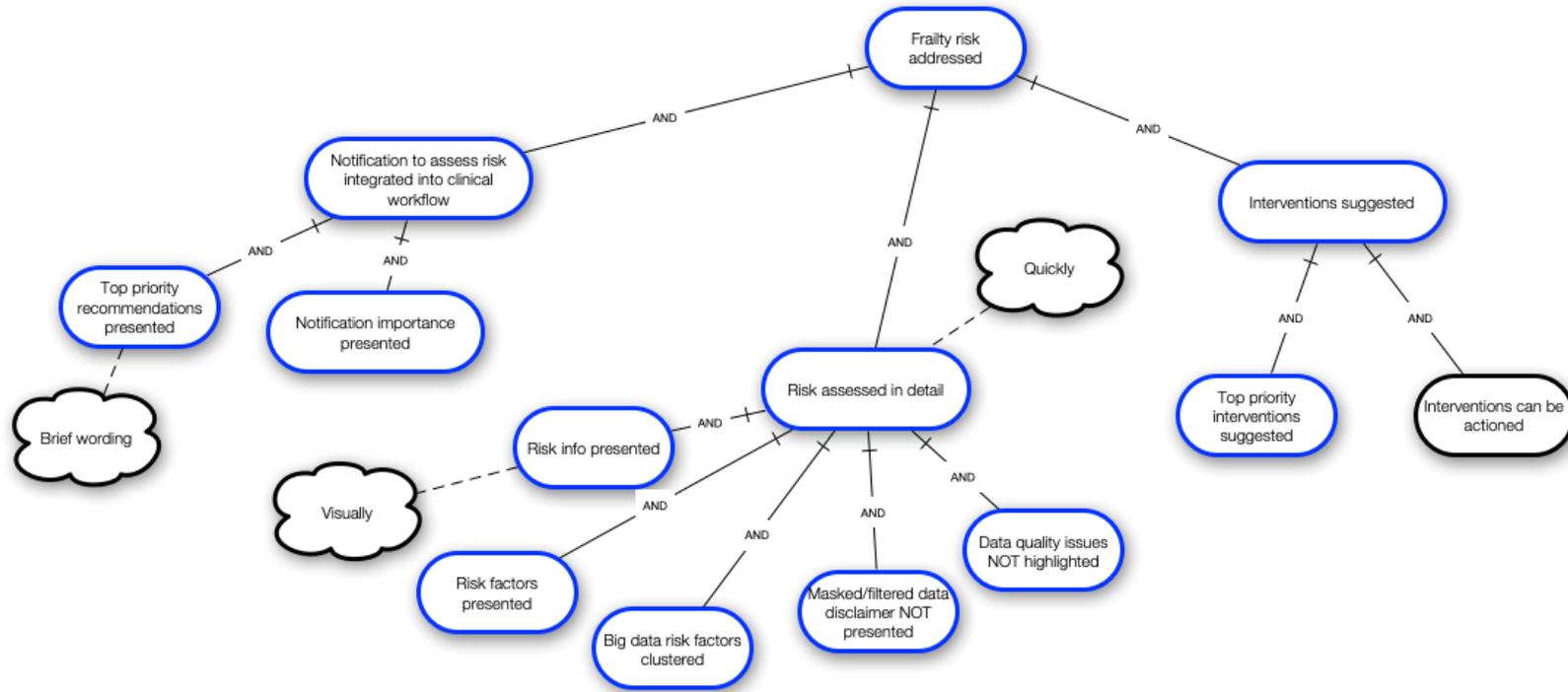


Figure 27 Lead User 6 goal model

M.7 Lead User 7 Goal Model

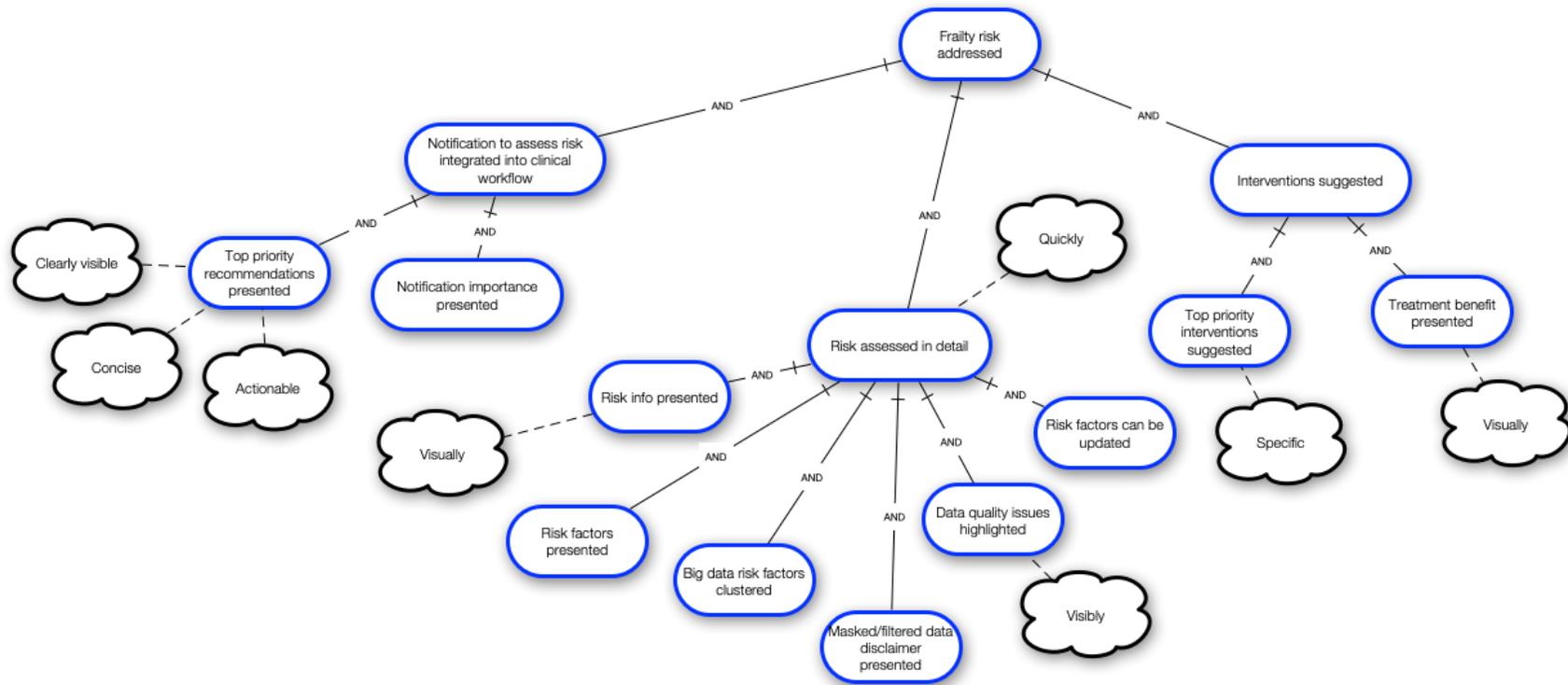


Figure 28 Lead User 7 goal model

M.8 Lead User 8 Goal Model

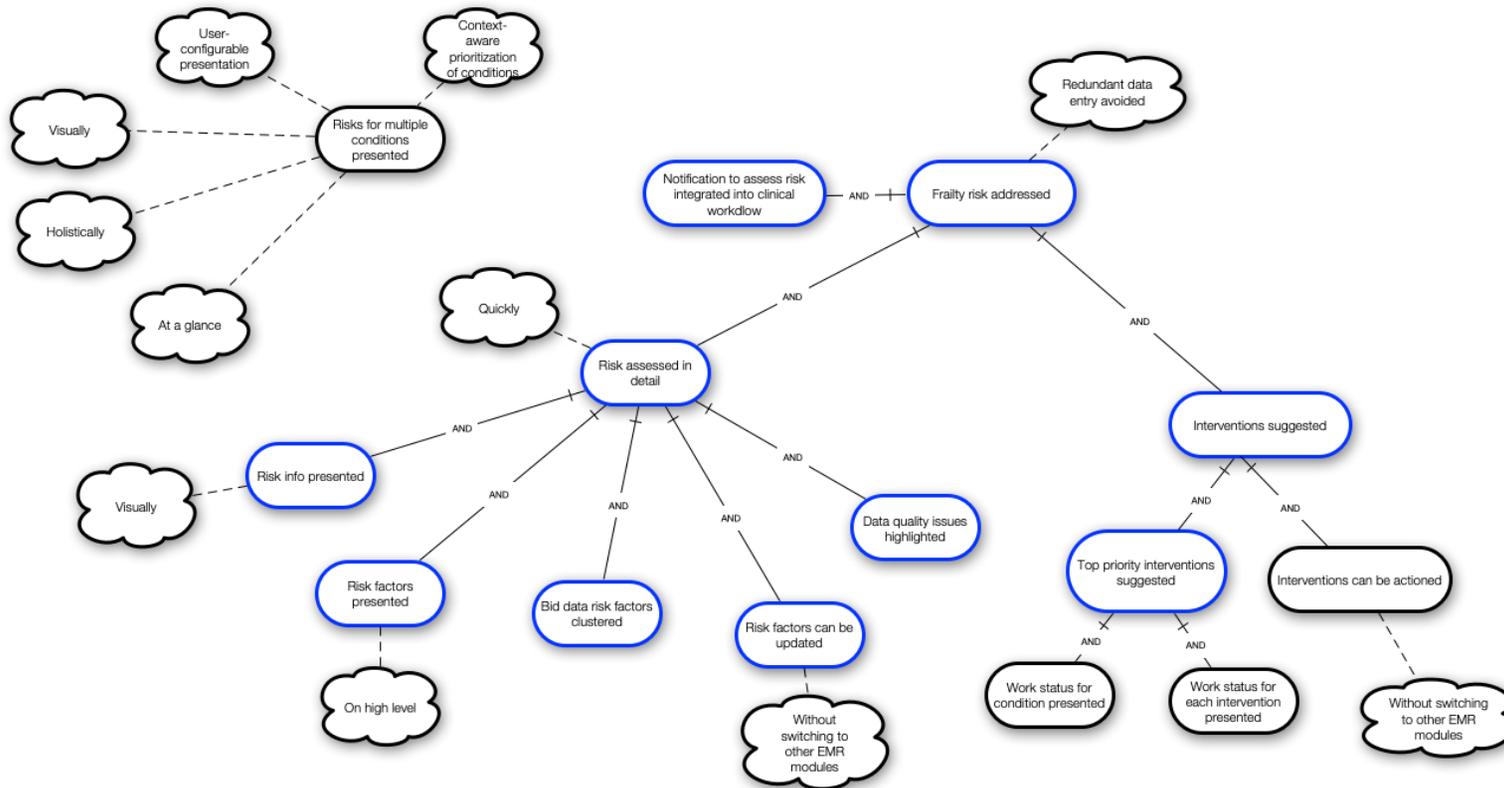


Figure 29 Lead User 8 goal model

Appendix N Lead User Prototypes

This appendix includes the screenshots from the Lead User prototypes. Note that the age of the fictitious persona varies on some prototypes (visible on the patient header) as some Lead Users suggested using a different age for their clinical examples. The screenshots do not illustrate full functionality of the prototypes, but rather capture the key main pages.

N.1 Lead User 1 Prototype

Name: Annie Smith	Age: 70	DoB: 21-Jan-1948	Sex: F	Health #: 900 123 456
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Encounter History

18-Jan-2018: Headaches – G. Jones
24-Sep-2017: Fatigue – G. Jones
02-Feb-2016: Med review – G. Jones

[more](#)

Allergies

Peanuts - anaphylaxis - 1950
Penicillin - rash, suspected - 1955

Problem List

Hypertension - 2010
Osteoarthritis - Wrists - 2010
COPD - 2008
Diabetes - 2000

Immunization History

Fluviral - intramuscular - 23-Nov-2017
Fluviral - intramuscular - 07-Nov-2015

Genomic Profiles

Whole Genome Sequencing - 05-Jan-2018
Proteomic Profiling - 04-May-2018

Patient Recommendations

[Order HbA1c](#)
Patient has Diabetes type 2. No HbA1c on record in last 6 months.
HbA1c is recommended as a routine method to monitor control of diabetes.
Strength of evidence: **A** [view evidence summary](#)

[Address Frailty Risk](#)
Patient is a smoker, has sedentary lifestyle, and has low protein intake in diet.
Frailty risk assessment is recommended for people 70 and over with multiple risks.
Strength of evidence: **B** [view evidence summary](#)

[Record Blood Pressure](#)
Patient has Hypertension. No BP on record in last 3 years.
Regular BP assessment is recommended.
Strength of evidence: **B** [view evidence summary](#)

Showing 3 out of 10 [more recommendations](#)

Current Medications

Ramipril - tablet - DOSE 5 mg - oral - once daily
Acetaminophen - tablet - DOSE 500-1,000 mg - oral - three times a day
Salbutamol - 100 mcg/puff - DOSE 200 mcg - inhaled - two puffs four times a day
Metformin - tablet - DOSE 500 mg - oral - two times a day

Family History

Father: Alzheimer's
Mother: Breast Cancer
Sister: Breast Cancer, Osteoarthritis in Knees
Brother: Hypertension
Paternal Aunt: Alzheimer's

Social History

Smoker: 1 ppd. 50 pack years
Alcohol: 1 glass of wine per day
Other: denies use
Exercise: minimal, sedentary lifestyle
Nutrition: vegetarian

[more](#)

Figure 30 Lead User 1 prototype - CDSS risk assessment notifications on a Patient Summary page

Name: Annie Smith	Age: 70	DoB: 21-Jan-1948	Sex: F	Health #: 900 123 456
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Geriatric Frailty Risk Assessment		see previous assessments
more about geriatric frailty		
<div style="background-color: #0070C0; color: white; padding: 10px; text-align: center;"> <h1 style="margin: 0;">20%</h1> <p style="margin: 0; font-size: small;">Patient's risk of becoming frail within next 5 years score is calculated using Integrated Geno/Pheno Index</p> </div>		
<div style="text-align: center;"> <h1 style="margin: 0;">5%</h1> <p style="margin: 0; font-size: small;">Population average for caucasian women who are 65-74 years old</p> </div>		

Patient Risk Factors for Frailty
<p>Patient record indicates that patient has multiple risk factors for developing frailty, including age, gender, family history, smoking status, low-protein diet, sedentary lifestyle, inflammation markers, and other genomic factors. Risk factors predispose patient to becoming frail, but they do not guarantee frailty development.</p> <p><i>Certain types of genomic information has been filtered out upon patient's request</i></p> <p>see modifiable patient risk factors used for frailty risk calculation</p> <p>see non-modifiable patient risk factors used for frailty risk calculation</p>

<p>Risk Score Confidence: Medium</p> <p style="font-size: x-small;">high: 90-100% of patient data available; medium: 70-89% of patient data available; low: less than 70% of data available</p> <p>see missing patient information</p>
--

Figure 31 Lead User 1 prototype – Default detailed frailty risk assessment page (Part 1)

Frailty Risk Mitigation Action Plan	
<p>Patient Actions to Reduce Frailty Risk</p> <p>1 Quit Smoking Patient record indicates that patient is a smoker Smoking cessation may prevent or delay frailty development Strength of evidence: A Attend smoking cessation clinic weekly</p> <p> <input type="checkbox"/> discussed with patient <input type="checkbox"/> address another time <input type="checkbox"/> dismiss recommendation see more info </p> <p>Notes: <input style="width: 100%;" type="text"/></p> <p>2 Introduce Regular Exercise Patient record indicates that patient is a sedentary. Moderate exercise may prevent or delay frailty development Strength of evidence: B Start with short walks around the block twice a day</p> <p> <input type="checkbox"/> discussed with patient <input type="checkbox"/> address another time <input type="checkbox"/> dismiss recommendation see more info </p> <p>Notes: <input style="width: 100%;" type="text"/></p> <p>3 Increase Protein Intake - Review progress Intervention was discussed with patient on 03-Jul-2018 (see note) Patient record indicates low daily protein intake Increasing protein intake may reduce risk of sarcopenia Strength of evidence: A Add 1-2 eggs for breakfast</p> <p> <input type="checkbox"/> discussed with patient <input type="checkbox"/> address another time <input type="checkbox"/> dismiss recommendation see more info </p> <p>Notes: <input style="width: 100%;" type="text"/></p> <p style="text-align: right;">Showing 3 out of 10 more</p>	<p>Provider Action Items</p> <p>1 Order Serum Albumin Patient record indicates no recent Serum Albumin results. lab history Lower albumin levels are correlated with frailty. Strength of evidence: B</p> <p> <input type="checkbox"/> order Serum Albumin <input type="checkbox"/> address another time <input type="checkbox"/> dismiss recommendation see more info </p> <p>2 Order TSH Patient record indicates no thyroid-stimulating hormone (TSH) results Early examination of the TSH serum level recommended for evaluating metabolism and muscle function of the elderly. Strength of evidence: B</p> <p> <input type="checkbox"/> order TSH <input type="checkbox"/> address another time <input type="checkbox"/> dismiss recommendation see more info </p> <p>3 Review Medications Patient record indicates multiple current medications. med history Polypharmacy can contribute to frailty development. Strength of evidence: B</p> <p> <input type="checkbox"/> med review completed <input type="checkbox"/> address another time <input type="checkbox"/> dismiss recommendation see more info </p>
Next Appointment	
<p>Next recommended appointment: within 6 months book appointment</p>	

Figure 32 Lead User 1 prototype – Default detailed frailty risk assessment page (Part 2)

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Geriatric Frailty Risk Assessment [see previous assessments](#)
[more about geriatric frailty](#)

20%
 Patient's risk of becoming frail within next 5 years
 score is calculated using [Integrated Geno/Pheno Index](#)

5%
 Population average for caucasian women who are 65-74 years old

Patient Risk Factors for Frailty

Patient record indicates that patient has multiple risk factors for developing frailty, including age, gender, family history, smoking status, low-protein diet, sedentary lifestyle, inflammation markers, and other genomic factors. Risk factors predispose patient to becoming frail, but they do not guarantee frailty development.
Certain types of genomic information has been filtered out upon patient's request

[hide modifiable patient risk factors used for frailty risk calculation](#)
[see non-modifiable patient risk factors used for frailty risk calculation](#)

Modifiable Patient Risk Factors for Frailty

#	Patient Factor	Value (Range)	Impact on Probability of Developing Frailty in Next 5 Years relative % (absolute %)	Evidence	Evidence Grade
1	Smoking Status	Smoker, 1 ppd, 50 pack years	10% (2%)	Smoking for over 10 years increase frailty risk by 60% in people 60 and over see more	A
2	Exercise Level	Low, sedentary lifestyle	10% (2%)	Exercise is the interventional modality that has consistently shown benefit in preventing and treating frailty and its key components see more	A
3	Daily Protein Intake	Low, 0.4 grams/per kg (0.8-10 grams/per kg)	5% (1%)	Low protein intake contributes to sarcopenia. Elderly women benefit from consuming more protein than current nutritional guidelines. see more	B

Displaying 3 of 16 factors

1 2 3 4 5 NEXT

Risk Score Confidence: Medium
 high: 90-100% of patient data available; medium: 70-89% of patient data available; low: less than 70% of data available
[see missing patient information](#)

Figure 33 Lead User 1 prototype – Detailed frailty risk assessment page with top modifiable risk factors shown

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Geriatric Frailty Risk Assessment [see previous assessments](#)

[more about geriatric frailty](#)

20%

Patient's risk of becoming frail within next 5 years
score is calculated using [Integrated Geno/Pheno Index](#)

5%

Population average for caucasian women who are 65-74 years old

Patient Risk Factors for Frailty

Patient record indicates that patient has multiple risk factors for developing frailty, including age, gender, family history, smoking status, low-protein diet, sedentary lifestyle, inflammation markers, and other genomic factors. Risk factors predispose patient to becoming frail, but they do not guarantee frailty development.
Certain types of genomic information has been filtered out upon patient's request

[see modifiable patient risk factors used for frailty risk calculation](#)
[hide non-modifiable patient risk factors used for frailty risk calculation](#)

Non-Modifiable Patient Risk Factors for Frailty

#	Patient Factor	Value (Range)	Impact on Probability of Developing Frailty in Next 5 Years relative % (absolute %)	Evidence
1	Age	70	25% (5%)	Age is the main risk factor for frailty. see more
2	Genetic Biomarkers	Risk-conferring variants	1% (0.2%)	Certain genetic variants influence frailty age of onset, progression rate, and outcomes see more
3	Inflammation Biomarkers	Increase	1% (0.2%)	Chronic and systemic inflammation is a strong predictor of frailty see more

Displaying 3 of 16 factors

1 2 3 4 5 NEXT

Risk Score Confidence: **Medium**

high: 90-100% of patient data available; medium: 70-89% of patient data available; low: less than 70% of data available
[see missing patient information](#)

Frailty Risk Mitigation Action Plan

Patient Actions to Reduce Frailty Risk

Provider Action Items

Figure 34 Lead User 1 prototype – Detailed frailty risk assessment page with top non-modifiable risk factors shown

N.2 Lead User 2 Prototype

Name: Annie Smith	Age: 70	DoB: 21-Jan-1948	Sex: F	Health #: 900 123 456
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Encounter History

18-Jan-2018: Headaches – G. Jones	▼
24-Sep-2017: Fatigue – G. Jones	▼
02-Feb-2016: Med review – G. Jones	▼
more	

Allergies

Peanuts - anaphylaxis - 1950
Penicillin - rash, suspected - 1955

Problem List

Hypertension - 2010
Osteoarthritis - Wrists - 2010
COPD - 2008
Diabetes - 2000

Immunization History

Fluviral - intramuscular - 23-Nov-2017
Fluviral - intramuscular - 07-Nov-2015

Genomic Profiles

Whole Genome Sequencing - 05-Jan-2018
Proteomic Profiling - 04-May-2018

Patient Recommendations

Currently showing: **Top 5** Filter by ▼

[Order HbA1c](#) ⓘ Strength of evidence: **A** Severity: **high** ☰
Diabetes type II. No HbA1c in last 6 months. Last HbA1c was 8%.

[Discontinue Vicodin](#) ⓘ Strength of evidence: **E** Severity: **high** ☰
History of falls in last 2 years.

[Assess Frailty Risk](#) ⓘ Strength of evidence: **B** Severity: **high** ☰
Multiple risk factors, 25% chance of becoming frail within next 5 years.

[Discuss Smoking Cessation](#) ⓘ Strength of evidence: **A** Severity: **medium** ☰
Heavy smoker: 1 ppd. 50 pack years.

[Declined: Address High Caffeine Consumption](#) ⓘ Strength of evidence: **B** Severity: **medium** ☰
Slow caffeine metabolizer, poor sleep, heavy coffee drinker (8 cups/day).

Showing 5 out of 10

Current Medications

Ramipril - tablet - DOSE 5 mg - oral - once daily
Vicodin - tablet - DOSE 5mg/300 mg - oral - twice a day
Salbutamol - 100 mcg/puff - DOSE 200 mcg - inhaled - two puffs four times a day
Metformin - tablet - DOSE 500 mg - oral - two times a day

Family History

Father: Alzheimer's
Mother: Breast Cancer
Sister: Breast Cancer, Osteoarthritis in Knees
Brother: Hypertension
Paternal Aunt: Alzheimer's

Social History

Smoker: 1 ppd. 50 pack years
Alcohol: 1 glass of wine per day
Other: denies use
Exercise: daily walks
Nutrition: vegetarian

Figure 35 Lead User 2 prototype - CDSS risk assessment notifications on a Patient Summary page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment last assessment: [03-Jul-2017](#)
[more about frailty](#)

Patient's Risk: **25%** (15-35%) chance of becoming frail within next 5 years, patient is currently robust but has vulnerability to frailty.
 Population Average: **17%** for Caucasian women 65-74 years old.

Patient-Specific Risk Factors for Frailty

Currently showing: **Top 3** Filter by ▼

Patient Factor Category	Value (Range)	Modifiable	Absolute % of Contribution to Risk	Evidence Updated	Patient Info Updated
<input type="checkbox"/> Age ⓘ	70 years	no	8 to 12%	02-Oct-2008	06-Jan-1995
<input type="checkbox"/> Protein Intake ⓘ	Low	yes	2 to 6%	03-Jan-2009	21-Oct-2017
<input type="checkbox"/> Smoking Status ⓘ	Smoker	yes	2 to 4%	17-Jan-2006	20-Nov-2008

Showing 3 out of 17 categories

Incomplete Patient Information

Please update the following incomplete patient information for a more accurate Frailty Risk Score calculation:

[History](#) (3 items)
[Observations](#) (10 items)
[Investigations](#) (3 items)

Suggested Treatments to Reduce Frailty Risk

Currently showing: **Top 3** Filter by ▼

Increase Protein Intake Strength of evidence: **A** Severity for patient: **high** ☰

Current daily protein intake: 30 gr
 Recommended: 50-90 gr for female, 70 yrs, BMI 18.3 (165 cm, 50 kg), low activity level
 Increasing protein intake may reduce risk by 2 to 6% within next 5 years ⓘ
[update protein intake](#)

[patient handout](#)
[diet allowance form](#)
[DRI calculator](#)

Discussed with patient

Clinical notes:

Quit Smoking Strength of evidence: **A** Severity for patient: **high** ☰

Patient is a smoker: 1 ppd. 50 pack years
 Smoking cessation may reduce frailty risk by 2 to 4% within next 5 years ⓘ
[update smoking status](#)

[patient handout](#)
[smoking cessation clinic referral form](#)

Discussed with patient

Clinical notes:

Follow-up: Resistance Exercise Training Strength of evidence: **B** Severity for patient: **high** ☰

No resistance exercise training, poor muscle tone, slow gait
 Regular muscle building exercises may reduce risk of sarcopenia by 1 to 3% within next 5 years ⓘ
 Discussed with patient 03-Jul-2018 ([see notes](#))
[update exercise status](#)

[patient handout](#)
[seniors exercise groups - directory](#)

Discussed with patient

Clinical notes:

Showing 3 out of 10

Follow-up Reminder

[appointment reminder](#)

Figure 36 Lead User 2 prototype – Default detailed frailty risk assessment page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment last assessment: [03-Jul-2017](#)
[more about frailty](#)

Patient's Risk: **25%** (15-35%) chance of becoming frail within next 5 years, patient is currently robust but has vulnerability to frailty.
 Population Average: **17%** for Caucasian women 65-74 years old.

Patient-Specific Risk Factors for Frailty

Currently showing: All Filter by ▼

Patient Factor Category	Value (Range)	Modifiable	Absolute % of Contribution to Risk	Evidence Updated	Patient Info Updated
<input type="checkbox"/> Age ⓘ	70 years	no	8 to 12%	02-Oct-2008	06-Jan-1995
<input type="checkbox"/> Protein Intake ⓘ	Low	yes	2 to 6%	03-Jan-2009	21-Oct-2017
<input type="checkbox"/> Smoking Status ⓘ	Smoker	yes	2 to 4%	17-Jan-2006	20-Nov-2008
<input type="checkbox"/> Movement ⓘ	Daily walks - 3km	yes	-4 to -2%	23-May-2015	01-Feb-2017
<input type="checkbox"/> Strength Training ⓘ	No muscle building exercises	yes	1 to 3%	23-May-2015	01-Feb-2017
<input type="checkbox"/> Gender ⓘ	Female	no	1 to 3%	02-Oct-2008	06-Jan-1995
<input type="checkbox"/> BMI ⓘ	Outdated info	yes	not included -10 to 15%	04-May-2012	03-May-2016
<input type="checkbox"/> Serum Albumin ⓘ	Outdated info	yes	not included -5 to 10%	13-Dec-2017	08-Oct-2015
<input type="checkbox"/> TSH ⓘ	Missing info	yes	not included -4 to 6%	23-Aug-2015	
<input type="checkbox"/> Education Level ⓘ	Missing info	yes	not included -4 to 6%	20-May-2017	
<input type="checkbox"/> Benzodiazepine Medication ⓘ	1 mg three times a day over last 2 years	yes	1 to 3%	05-Mar-2002	17-Jun-2018
<input type="checkbox"/> Frailty Promoting Inflammation Biomarkers ⓘ	group (1 out of 3)		0.5 to 1.5%		
<input type="checkbox"/> Frailty Promoting Genetic Biomarkers ⓘ	group (1 out of 3)		0.5 to 1.5%		
<input type="checkbox"/> Frailty Protective Genetic Biomarkers ⓘ	group (3 out of 3)		-0.5 to -1.5%		
<input type="checkbox"/> Ethnicity ⓘ	Caucasian	no	0.5 to 1.5%	09-Feb-2009	06-Jan-1995
<input type="checkbox"/> Frailty Promoting Muscle Metabolites ⓘ	group (0 out of 15)		0.5 to 1.4%		
<input type="checkbox"/> Additional Minor Factors ⓘ	group (10 out of 10)		<0.5%		

Showing 17 out of 17 categories (46 factors total)

Follow-up: Resistance Exercise Training Strength of evidence: B Severity for patient: high ⓘ
No resistance exercise training, poor muscle tone, slow gait

Figure 37 Lead User 2 prototype – Detailed frailty risk assessment page with risk factors filter set to ‘All’

N.3 Lead User 3 Prototype

Name: Annie Smith	Age: 70	DoB: 21-Jan-1948	Sex: F	Health #: 900 123 456
--------------------------	----------------	-------------------------	---------------	------------------------------



Encounter History

- 18-Jan-2018: Headaches – G. Jones
- 24-Sep-2017: Fatigue – G. Jones
- 02-Feb-2016: Med review – G. Jones

[more](#)

Allergies

- Peanuts - anaphylaxis - 1950
- Penicillin - rash, suspected - 1955

Current Medications

- Chlorothiazide - tablet - DOSE 25 mg - oral - twice daily
- Warfarin - tablet - DOSE 2 mg - oral - once a day
- Salbutamol - 100 mcg/puff - DOSE 200 mcg - inhaled - two puffs four times a day
- Metformin - tablet - DOSE 500 mg - oral - two times a day
- Citalopram - tablet - DOSE 40mg - oral - once a day

Patient Recommendations

[Order Creatinine and Electrolyte Panel](#)

Patient has hypertension, on chlorothiazide. No creatinine and electrolytes in last 6 months. ⓘ

Strength of evidence: **A** Impact to patient: **high** Patient's priority ▼

[Order Hemoglobin](#)

Patient is on warfarin, no hemoglobin in last 3 months. ⓘ

Strength of evidence: **A** Impact to patient: **high** Patient's priority ▼

[Assess for Frailty Risk](#)

Patient is a smoker, has depression, underweight, 2 falls in last 12 months, has other risk factors. ⓘ

Strength of evidence: **B** Impact to patient: **high** Patient's priority ▼

Showing 3 out of 10

Problem List

- Falls - 2018
- Deep vein thrombosis - 2018
- Depression - 2018
- Diabetes - 2000
- Hypertension - 2010
- COPD - 2000

Family History

- Father: Alzheimer's
- Mother: Breast Cancer
- Sister: Breast Cancer, Osteoarthritis in Knees
- Brother: Hypertension
- Paternal Aunt: Alzheimer's

Social History

- Smoker: 1 ppd. 50 pack years
- Alcohol: 1 glass of wine per day
- Other: denies use
- Exercise: daily walks
- Nutrition: vegetarian

[more](#)

Immunization History

- Fluviral - intramuscular - 23-Nov-2017
- Fluviral - intramuscular - 07-Nov-2015

Genomic Profiles

- Whole Genome Sequencing - 05-Jan-2018
- Proteomic Profiling - 04-May-2018

Figure 38 Lead User 3 prototype - CDSS risk assessment notifications on a Patient Summary page

Name: Annie Smith		Age: 70		DoB: 21-Jan-1948		Sex: F		Health #: 900 123 456	
Clinical Frailty Scale (CFS) *									
Please re-assess patient on the CFS. Last assessment done 02-Jul-2016 (with result: CFS 1)									
<input type="radio"/>	1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age		<input type="radio"/>	2 Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally , e.g. seasonally					
<input type="radio"/>	3 Managing Well – People whose medical problems are well controlled , but are not regularly active beyond routine walking.		<input type="radio"/>	4 Vulnerable – While not dependent on others for daily help, often symptoms limit activities . A common complaint is being "slowed up", and/or being tired during the day					
<input type="radio"/>	5 Mildly Frail – These people often have more evident slowing , and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.		<input type="radio"/>	6 Moderately Frail – People need help with all outside activities and with keeping house . Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.					
<input type="radio"/>	7 Severely Frail – Completely dependent for personal care , from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).		<input type="radio"/>	8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.					
<input type="radio"/>	9 Terminally Ill - Approaching the end of life. This category applies to people with a life expectancy <6 months , who are not otherwise evidently frail .								
<input type="button" value="Cancel"/>					<input type="button" value="Save"/>				
<p>Scoring frailty in people with dementia</p> <p>The degree of frailty corresponds to the degree of dementia. Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.</p> <p>In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.</p> <p>In severe dementia, they cannot do personal care without help.</p> <p><small>* 1. Canadian Study on Health & Aging, Revised 2008. 2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.</small></p> <p><small>© 2007-2009. Version 1.2. All rights reserved. Geriatric Medicine Research, Dalhousie University, Halifax, Canada. Permission granted to copy for research and educational purposes only.</small></p>									



Figure 39 Lead User 3 prototype – Detailed frailty risk assessment page where user is prompted to assess the patient using the Canadian Frailty Scale

Integrated Geno/Pheno Geriatric Frailty Risk Assessment

Patient's Risk of becoming [Mildly Frail \(CSF 5\)](#) within next 6-12 months: **HIGH (30%)**
 Patient is currently [Vulnerable \(CF4\)](#) ⓘ

Population Average for progressing from Vulnerable (CSF 4) to Mildly Fail (CSF 5) within 6-12 months: **10%** for Caucasian women 70-74 years old ⓘ

Patient's Key Risk Factors

The following risk factors have been used to calculate patient's risk score.
[modifiable risk factors](#)
[non-modifiable risk factors](#)

Additional Frailty Assessment Tools

The following assessments are recommended to further evaluate patient's frailty risk and adverse outcomes:

[Grip strength](#)

[Gait speed](#)

[MoCA](#)

[EQ-5D-5L](#)

[Recalculate Risk Score](#)

Additional Patient Data

Please consider completing 6 additional patient data points to generate a more accurate patient Frailty Risk score.
[incomplete patient information](#)

Interventions to Mitigate Frailty Risk

[Goals of Care](#)
[Implemented Interventions](#)

Address High Blood Pressure ⓘ Strength of evidence: **A** Impact to patient: **high**

Hypertension: BP 150/95 (high)
 Increased risk of cardiovascular, cerebrovascular, peripheral artery, and kidney diseases; cognitive impairment

Addressed with patient
 Defer
 Patient declined
 Dismiss

[update BP](#)
[review medications](#)

[patient handout](#) [Clinical notes:](#)

[Clear](#) [Save](#)

Lower SSRI Dose ⓘ Strength of evidence: **A** Impact to patient: **high**

Poor CYP2C19 metabolizer, on Citalopram 40 mg/day
 Do not exceed 20 mg/day. Increased risk of QT prolongation

Addressed with patient
 Defer
 Patient declined
 Dismiss

[review medications](#)

[patient handout](#) [Clinical notes:](#)

[Clear](#) [Save](#)

Quit Smoking ⓘ Strength of evidence: **A** Impact to patient: **high**

Heavy smoker: 1 ppd. 50 pack years
 Increased risk of severe frailty (complete dependency for personal care and mortality)

Addressed with patient
 Defer
 Patient declined
 Dismiss

[update smoking status](#)

[patient handout](#)
[smoking cessation clinic referral form](#) [Clinical notes:](#)

[Clear](#) [Save](#)

Showing 3 out of 10 [more](#)

Trending

overall frailty
 grip strength
 gait speed
 self-reported health

[Clear All](#) [Graph](#)

Figure 40 Lead User 3 prototype – Default detailed frailty risk assessment page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Geno/Pheno Geriatric Frailty Risk Assessment

Patient's Risk of becoming [Mildly Frail \(CSF 5\)](#) within next 6-12 months: **HIGH (30%)**

Patient is currently [Vulnerable \(CF4\)](#) ⓘ

Population Average for progressing from Vulnerable (CSF 4) to Mildly Fail (CSF 5) within 6-12 months: **10%** for Caucasian women 70-74 years old ⓘ

Patient's Key Risk Factors

The following risk factors have been used to calculate patient's risk score.

[hide modifiable risk factors](#)

[non-modifiable risk factors](#)

Modifiable Patient-Specific Risk Factors for Frailty

Risk Factor	Value	Normal Range (for age, gender)	Contribution to Risk (absolute %)	Patient Info Updated
Blood pressure	155/95 (high)	90/60 - 120/80 ⓘ	4% ⓘ	03-Jun-2018
Smoking status	heavy smoker 1 ppd. 50 pack years		4% ⓘ	01-Oct-2017
History of falls	2 in last year		3% ⓘ	04-May-2018
BMI	18.3 Height: 165 cm Weight: 50 kg (underweight)	18.5-24.9	3% ⓘ	16-Feb-2018
Daily protein intake	30 gr (low)	50 – 90 gr for patient's BMI (18.3), ⓘ exercise level (lightly active)	2% ⓘ	09-Feb-2018
Depression	persistent depressive disorder		2% ⓘ	05-Jan-2018
Movement	short walk 1-3 times/week (lightly active)		-2% ⓘ	09-Feb-2018
Strength training	none		2% ⓘ	17-Jan-2018
Sleep	5-6 hrs/night (low)	7-8 hrs/night	1% ⓘ	23-Nov-2017
Arthritis	Acute, wrists		1% ⓘ	20-Jul-2018

Showing 10 out of 15

[more](#)

Additional Frailty Assessment Tools

The following assessments are recommended to further evaluate patient's frailty risk and adverse outcomes:

[Grip strength](#)

Figure 41 Lead User 3 prototype - Detailed frailty risk assessment page with top modifiable risk factors shown

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Geno/Pheno Geriatric Frailty Risk Assessment

Patient's Risk of becoming [Mildly Frail \(CSF 5\)](#) within next 6-12 months: **HIGH (30%)**
 Patient is currently [Vulnerable \(CF4\)](#) ⓘ
 Population Average for progressing from Vulnerable (CSF 4) to Mildly Fail (CSF 5) within 6-12 months: **10%** for Caucasian women 70-74 years old ⓘ

Patient's Key Risk Factors

The following risk factors have been used to calculate patient's risk score.
[modifiable risk factors](#)
[hide non-modifiable risk factors](#)

Non-Modifiable Patient-Specific Risk Factors for Frailty

Risk Factor	Value	Contribution to Risk (absolute %)	Patient Info Updated
Age	70 years	2% ⓘ	14-Jun-2000
Gender	Female	1% ⓘ	14-Jun-2000
APOE allele	APOE4 (homozygous)	1% ⓘ	03-May-2018
Interleukin 6 (IL-6)	Increase	0.5% ⓘ	03-May-2018
CpG islands methylation	Increase	0.5% ⓘ	03-May-2018

Showing 5 out of 10 [more](#)

Additional Frailty Assessment Tools

The following assessments are recommended to further evaluate patient's frailty risk and adverse outcomes:

[Grip strength](#)

[Gait speed](#)

[MoCA](#)

[EQ-5D-5L](#)

Additional Patient Data

Please consider completing 6 additional patient data points to generate a more accurate patient Frailty Risk score.
[incomplete patient information](#)

Figure 42 Lead User 3 prototype - Detailed frailty risk assessment page with top non-modifiable risk factors shown

N.4 Lead User 4 Prototype

Name: Annie Smith	Age: 80	DoB: 21-Jan-1938	Sex: F	Health #: 900 123 456
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Encounter History
18-Jan-2018: Headaches – G. Jones
24-Sep-2017: Fatigue – G. Jones
02-Feb-2016: Med review – G. Jones
more

Allergies
Peanuts - anaphylaxis - 1950
Penicillin - rash, suspected - 1955

Problem List
Hypertension - 2010
Deep vein thrombosis - 2018
Depression - 2018
Diabetes - 2000

Immunization History
Fluviral - intramuscular - 23-Nov-2017
Fluviral - intramuscular - 07-Nov-2015

Provider Recommendations
Assess for Frailty (high risk)
<input type="checkbox"/> not relevant <input type="checkbox"/> patient declined <input type="checkbox"/> remind later <input type="checkbox"/> dismiss <input type="checkbox"/> delegate ▼

Current Medications
Chlorothiazide - tablet - DOSE 25 mg - oral - twice daily
Warfarin - tablet - DOSE 2 mg - oral - once a day
Salbutamol - 100 mcg/puff - DOSE 200 mcg - inhaled - two puffs four times a day
Metformin - tablet - DOSE 500 mg - oral - two times a day

Family History
Father: Alzheimer's
Mother: Breast Cancer
Sister: Breast Cancer, Osteoarthritis in Knees
Brother: Hypertension
Paternal Aunt: Alzheimer's

Social History
Smoker: 1 ppd. 50 pack years
Alcohol: 1 glass of wine per day
Other: denies use
Exercise: daily walks
Nutrition: vegetarian
more

Genomic Profiles
Whole Genome Sequencing - 05-Jan-2018
Proteomic Profiling - 04-May-2018

Figure 43 Lead User 4 prototype - CDSS risk assessment notifications on a Patient Summary page

Name: Annie Smith	Age: 80	DoB: 21-Jan-1938	Sex: F	Health #: 900 123 456
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Integrated Geno/Pheno Geriatric Frailty Risk Assessment		risk score trend
<p>Patient's Frailty Risk in next 6 months to a year: HIGH (40%) ⓘ</p> <p>High probability of falls, mild dementia, higher order IADLs dependency</p> <p><i>some genomic data have been masked as per patient's preferences and are not included in risk score calculations</i></p>		
Incomplete Patient Information		
<p>The following patient information is missing or outdated for Frailty Risk calculation:</p> <p>History (3 items)</p> <p>Observations (10 items)</p> <p>Investigations (3 items)</p>		
Pre-Visit Frailty Assessment Results		
<p>view assessment results</p> <p>documented: 08-Aug-2018</p>		
Interventions to Reduce Frailty Risk		
<p>Protein Intake Increase</p> <p>Low daily protein intake (30 gr), 50-90 gr recommended for patient's BMI (18.3) and light activity levels.</p> <p>Strength of evidence: A</p> <p><input type="checkbox"/> discussed <input type="checkbox"/> not relevant <input type="checkbox"/> patient declined <input type="checkbox"/> remind later <input type="checkbox"/> dismiss <input type="checkbox"/> delegate ▼</p>		
<p>SSRI Dose Reduction</p> <p>Poor CYP2C19 metabolizer, on Citalopram 40 mg/day. Dose over 20 mg/day can increase risk of QT prolongation.</p> <p>Strength of evidence: A</p> <p><input type="checkbox"/> discussed <input type="checkbox"/> not relevant <input type="checkbox"/> patient declined <input type="checkbox"/> remind later <input type="checkbox"/> dismiss <input type="checkbox"/> delegate ▼</p>		
<p>Caffeine Intake Reduction</p> <p>Ultra-slow caffeine metabolizer, high caffeine intake (8 cups/day), poor sleep.</p> <p>Strength of evidence: B</p> <p><input type="checkbox"/> discussed <input type="checkbox"/> not relevant <input type="checkbox"/> patient declined <input type="checkbox"/> remind later <input type="checkbox"/> dismiss <input type="checkbox"/> delegate ▼</p>		
Showing 3 out of 10		more

Figure 44 Lead User 4 prototype – Default detailed frailty risk assessment page

Name: Annie Smith **Age:** 80 **DoB:** 21-Jan-1938 **Sex:** F **Health #:** 900 123 456

Integrated Geno/Pheno Geriatric Frailty Risk Assessment [risk score trend](#)

Patient's Frailty Risk in next 6 months to a year: **HIGH (40%)** ⓘ
 High probability of falls, mild dementia, higher order IADLs dependency
some genomic data have been masked as per patient's preferences and are not included in risk score calculations

Incomplete Patient Information

The following patient information is missing or outdated for Frailty Risk calculation:

[History](#) (3 items)
[Observations](#) (10 items)
[Investigations](#) (3 items)

Pre-Visit Frailty Assessment Results

[hide assessment results](#)
 documented: 08-Aug-2018

Measurement	Results	Normal Range (for age, gender)	Patient Info Updated
MoCA	22.1 mild cognitive impairment	>26 no dementia 18-26 mild cognitive impairment 11-17 mild dementia 6-10 moderate dementia <6 severe dementia	08-Aug-2018
BP	155/95 high	90/60 - 120/80	08-Aug-2018
BMI	18.3 (height: 165 cm weight: 50 kg) underweight	18.5 - 24.9	08-Aug-2018
Gait Speed	0.58 m/s at risk of falls	0.90 - 1.3 m/s	08-Aug-2018
Grip Strength	13 kg weak	14.7 - 24.5 kg	08-Aug-2018

Showing 5 out of 5 measurements

Interventions to Reduce Frailty Risk

Protein Intake Increase
 Low daily protein intake (30 gr), 50-90 gr recommended for patient's BMI (18.3) and light activity levels.
 Strength of evidence: **A**

discussed not relevant patient declined remind later dismiss delegate ▼

SSRI Dose Reduction
 Poor CYP2C19 metabolizer, on Citalopram 40 mg/day. Dose over 20 mg/day can increase risk of QT prolongation.
 Strength of evidence: **A**

Figure 45 Lead User 4 prototype - Detailed frailty risk assessment page with 'pre-visit' risk assessment results shown

N.5 Lead User 5 Prototype

Day Sheet				21-Aug-2018
Provider: Dr. John Smith				
Appt Time	Patient's Name	Age	Reason for Visit	Recommendations
8:00	Annie Smith	70	Headaches, fatigue	Order HbA1c ▲ Assess frailty risk - missing patient data
9:00	Jane Brown	80	Echo and stress test results	Assess frailty risk ▲
9:30	Lucy Grey	72	Hypertension	Assess frailty risk ▲
10:00	Jeremy Peterson	50	COPD	Discuss smoking cessation ▲
10:30	Lilly Rae	18	Ear infection	
11:00	Sam Jones	78	Insomnia	

Figure 46 Lead User 5 prototype – Day Sheet page

Name: Annie Smith	Age: 70	DoB: 21-Jan-1948	Sex: F	Health #: 900 123 456
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Patient Recommendations

[Order HbA1c ▲](#) ≡

Diabetes type II. No HbA1c in last 6 months. Last HbA1c was 8% (high for this patient)

[Assess Frailty Risk - missing patient data](#) ≡

Patient is 70 yrs old, some patient data are missing for risk assessment.

Showing 2 out of 5 [more](#)

Current Medications

Ramipril - tablet - DOSE 5 mg - oral - once daily

Vicodin - tablet - DOSE 5mg/300 mg - oral - twice a day

Salbutamol - 100 mcg/puff - DOSE 200 mcg - inhaled - two puffs four times a day

Metformin - tablet - DOSE 500 mg - oral - two times a day

Family History

Father: Alzheimer's

Mother: Breast Cancer

Sister: Breast Cancer, Osteoarthritis in Knees

Brother: Hypertension

Paternal Aunt: Alzheimer's

Social History

Alcohol: 1 glass of wine per day

Other: denies use

Exercise: daily walks

Nutrition: vegetarian

Encounter History

18-Jan-2018: Headaches – G. Jones ▼

24-Sep-2017: Fatigue – G. Jones ▼

02-Feb-2016: Med review – G. Jones ▼

[more](#)

Allergies

Peanuts - anaphylaxis - 1950

Penicillin - rash, suspected - 1955

Problem List

Hypertension - 2010

Osteoarthritis - Wrists - 2010

COPD - 2008

Diabetes - 2000

Immunization History

Fluviral - intramuscular - 23-Nov-2017

Fluviral - intramuscular - 07-Nov-2015

Genomic Profiles

Whole Genome Sequencing - 05-Jan-2018

Proteomic Profiling - 04-May-2018

Figure 47 Lead User 5 prototype - CDSS risk assessment notifications on a Patient Summary page

Name: Annie Smith	Age: 70	DoB: 21-Jan-1948	Sex: F	Health #: 900 123 456
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Integrated Pheno/Geno Geriatric Frailty Risk Assessment			
Incomplete Patient Information			
Patient record does not contain sufficient patient information to generate a Frailty Risk Score. Please update the following patient information on key frailty risk factors to generate a Frailty Risk Score.			Calculate Risk
Risk Factor	Value	Patient Info Updated	Absolute % of Contribution to Risk
Walking & Climbing Steps	Missing Info		-10 to 25%
BMI	Outdated Info	03-May-2016	-10 to 10%
Smoking Status	Missing Info		-5 to 5%
Showing 3 out of 3			

Figure 48 Lead User 5 prototype - Detailed frailty risk assessment page illustrating the data quality issues

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Frailty Risk Score: **70%** (65-75%) chance of [Mobility Disability](#) within next 12 months, patient is currently high-functioning ⓘ
 Population Average: **35%** (30 to 40%) for Caucasian women 70-80 years old.
 Patient's risk is high, **2x** compared to population average.

Patient Risk Factors for Frailty

The following risk factors were used in the Frailty Risk calculations.
[show modifiable risk factors](#)
[show non-modifiable risk factors](#)
Some genomic information has been filtered out upon patient's request

Patient Goals

Please complete [Patient Values and Goals for Frailty Risk and Management](#)
 This tool allows the patient, provider, and the clinical decision support system to better determine clinically actionable interventions to reduce frailty risk and manage frailty outcomes.

Suggested Interventions to Reduce Frailty Risk

Introduce Resistance Exercise Training Strength of evidence: A Severity for patient: high ⓘ
 Regular (3 times/week), mild intensity muscle building exercises may reduce risk of mobility disability and sarcopenia by 10% (5 to 15%) (absolute % of risk reduction) in next 12 months ⓘ
[absolute frailty risk/benefit calculator](#)

Risk Factor	Value	Normal Range (for age, gender)	Value Trend for Patient	Potential Harms/Benefits	Absolute % of Contribution to Risk	Patient Info Updated
Resistance Training	none ▾			Mobility disability, sarcopenia ⓘ	10% (5 to 15%) ⓘ	03-Jul-2018

Discussed with patient Clinical notes:

Clear Save

Quit Smoking Strength of evidence: A Severity for patient: high ⓘ
 Smoking cessation may reduce overall frailty risk by 5% (3 to 7%) (absolute % of risk reduction) in next 5 years ⓘ
[absolute frailty risk/benefit calculator](#)

Risk Factor	Value	Normal Range (for age, gender)	Value Trend for Patient	Potential Harms/Benefits	Absolute % of Contribution to Risk	Patient Info Updated
Smoking Status	1 ppd. 50 p yrs			COPD, Cancer ⓘ	5% (3 to 7%) ⓘ	31-Aug-2018

Discussed with patient Clinical notes:

Clear Save

Showing 2 out of 10 [more](#)

Figure 49 Lead User 5 prototype – Detailed frailty risk assessment page (Part 1 of the screenshot)

Suggested Frailty Studies for Patient Enrollment			
Study	Patient Eligibility	Investigators	
Preclinical and Genomic Factors of Frailty	High-functioning, multiple risk factors for mobility disability, homozygous for APOE2	John Hopkins Center on Aging and Health	enrolment details
Showing 1 out of 1			

Practice Comparison Dashboard			
See how your frailty management compares to other primary care teams.			
<input type="text" value="select criteria"/>	<input type="text" value="select teams"/>	<input type="button" value="View Dashboard"/>	

Figure 50 Lead User 5 prototype – Detailed frailty risk assessment page (Part 2 of the screenshot)

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Frailty Risk Score: **70%** (65-75%) chance of [Mobility Disability](#), within next 12 months, patient is currently high-functioning ⓘ
 Population Average: **35%** (30 to 40%) for Caucasian women 70-80 years old.
 Patient's risk is high, **2x** compared to population average.

Patient Risk Factors for Frailty

The following risk factors were used in the Frailty Risk calculations.
[hide modifiable risk factors](#)
[show non-modifiable risk factors](#)
Some genomic information has been filtered out upon patient's request

Modifiable Risk Factors

Risk Factor	Value	Normal Range (for age, gender)	Value Trend for Patient	Potential Harms/Benefits	Absolute % of Contribution to Risk	Patient Info Updated	Strength of Evidence	Severity for Patient
Walking & Climbing Steps	Difficulty and behaviour adaptation		n/a	Mobility disability ⓘ	20% (18 to 24%)	27-Aug-2018	A	high
BMI	18.3	18.5-24.9	▼ Decrease	Sarcopenia ⓘ	8% (5 to 10%)	27-Aug-2018	A	high
Daily Protein Intake	30g	50-90 gr	▲ Increase	Sarcopenia, fatigue, weakness ⓘ	5% (3 to 8%)	05-Mar-2018	A	medium

Showing 3 out of 15 [more](#)

Patient Goals

Please complete [Patient Values and Goals for Frailty Risk and Management](#)
 This tool allows the patient, provider, and the clinical decision support system to better determine clinically actionable interventions to reduce frailty risk and manage frailty outcomes.

Suggested Interventions to Reduce Frailty Risk

Introduce Resistance Exercise Training Strength of evidence: **A** Severity for patient: **high** ⓘ
 Regular (3 times/week), mild intensity muscle building exercises may reduce risk of mobility disability and sarcopenia by 10% (5 to 15%) (absolute % of risk reduction) in next 12 months ⓘ
[absolute frailty risk/benefit calculator](#)

Normal Range	Value Trend for	Potential	Absolute % of
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Figure 51 Lead User 5 prototype - Detailed frailty risk assessment page with top modifiable risk factors shown

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Frailty Risk Score: **70%** (65-75%) chance of [Mobility Disability](#), within next 12 months, patient is currently high-functioning ⓘ
 Population Average: **35%** (30 to 40%) for Caucasian women 70-80 years old.

Patient's risk is high, **2x** compared to population average.

Patient Risk Factors for Frailty

The following risk factors were used in the Frailty Risk calculations.
[show modifiable risk factors](#)
[hide non-modifiable risk factors](#)
Some genomic information has been filtered out upon patient's request

Non-Modifiable Risk Factors

Risk Factor	Value	Normal Range (for age, gender)	Value Trend for Patient	Potential Harms/Benefits	Absolute % of Contribution to Risk	Patient Info Updated	Strength of Evidence	Severity for Patient
Age	70 yrs			Increase in frailty risk ⓘ	10% (5 to 15%)	03-Feb-1995	A	high
IL-6	6 pg/ml	< 5 pg/ml	▲ Increase	Inflammation and increase in frailty risk ⓘ	3% (1 to 5%)	17-Apr-2018	B	medium
APOE	APOE2 homozygous			Protective from Late Onset Alzheimers ⓘ	-5% (-8 to -3%) protective	15-Mar-2018	B	medium

Showing 3 out of 15 [more](#)

Patient Goals

Please complete [Patient Values and Goals for Frailty Risk and Management](#)
 This tool allows the patient, provider, and the clinical decision support system to better determine clinically actionable interventions to reduce frailty risk and manage frailty outcomes.

Suggested Interventions to Reduce Frailty Risk

Introduce Resistance Exercise Training Strength of evidence: A Severity for patient: **high** ⓘ
 Regular (3 times/week), mild intensity muscle building exercises may reduce risk of mobility disability and sarcopenia by 10% (5 to 15%) (absolute % of risk reduction) in next 12 months ⓘ
[absolute frailty risk/benefit calculator](#)

Figure 52 Lead User 5 prototype - Detailed frailty risk assessment page with top non-modifiable risk factors shown

N.6 Lead User 6 Prototype

Day Sheet							27-Aug-2018
Provider: Dr. John Smith							
Appt Time	Patient's Name	Age	DoB	Sex	Health #	Reason for Visit	Recommendations
8:00	Annie Smith	70	21-Jan-1948	F	900 123 456	Annual health checkup	Assess frailty risk
9:00	Jane Brown	80	03-Mar-1938	F	900 789 789	Echo and stress test results	
9:30	Lucy Grey	72	19-Apr-1950	F	900 123 123	Hypertension	
10:00	Jeremy Peterson	50	05-Feb-1968	M	900 122 122	COPD	Discuss smoking cessation
10:30	Lilly Rae	18	10-Oct-1999	F	900 111 111	Ear infection	
11:00	Sam Jones	78	13-Mar-1940	M	900 222 222	Insomnia	

Figure 53 Lead User 6 prototype – Day Sheet page

Name: Annie Smith	Age: 70	DoB: 21-Jan-1948	Sex: F	Health #: 900 123 456
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<p>Current Encounter</p> <p>27-Aug-2018: Annual Health Checkup</p> <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div> <p style="text-align: right;"><input type="button" value="Clear"/> <input type="button" value="Save"/></p>	<p>Allergies</p> <p>Peanuts - anaphylaxis - 1950 Penicillin - rash, suspected - 1955</p>
<p>Encounter History</p> <p>18-Jan-2018: Headaches – G. Jones</p> <p>24-Sep-2017: Fatigue – G. Jones</p> <p>02-Feb-2016: Med review – G. Jones</p> <p style="text-align: right;">more</p>	<p>Patient Recommendations</p> <p>Order HbA1c Strength of evidence: A Impact to patient: high</p> <p>Assess Frailty Risk Strength of evidence: B Impact to patient: high</p> <p style="text-align: center;">Showing 2 out of 2</p>
<p>Problem List</p> <p>Hypertension - 2010 Osteoarthritis - Wrists - 2010 COPD - 2008 Diabetes - 2000</p>	<p>Current Medications</p> <p>Ramipril - tablet - DOSE 5 mg - oral - once daily Vicodin - tablet - DOSE 5mg/300 mg - oral - twice a day Salbutamol - 100 mcg/puff - DOSE 200 mcg - inhaled - two puffs four times a day Metformin - tablet - DOSE 500 mg - oral - two times a day</p>
<p>Immunization History</p> <p>Fluviral - intramuscular - 23-Nov-2017 Fluviral - intramuscular - 07-Nov-2015</p>	<p>Family History</p> <p>Father: Alzheimer's Mother: Breast Cancer Sister: Breast Cancer, Osteoarthritis in Knees Brother: Hypertension Paternal Aunt: Alzheimer's</p>
<p>Genomic Profiles</p> <p>Whole Genome Sequencing - 05-Jan-2018 Proteomic Profiling - 04-May-2018</p>	<p>Social History</p> <p>Alcohol: 1 glass of wine per day Other: denies use Exercise: daily walks Nutrition: vegetarian</p>

Figure 54 Lead User 6 prototype – CDSS risk assessment notifications on an Encounter page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Frailty Risk Score: **65%** (55-75%) chance of falls, loss of independence in iADL in next 6-12 months, patient is currently high-functioning but vulnerable to frailty

65%

Frailty Risk Score Quality: **high** ⓘ

Patient Risk Factors for Frailty

[Show patient risk factors used for Frailty Risk calculations](#)

Suggested Interventions to Reduce Frailty Risk

SSRI Dose Reduction Strength of evidence: **A** Severity for patient: **high** ⓘ

Poor CYP2C19 metabolizer, on Citalopram 40 mg/day.
Dose over 20 mg/day can increase risk of QT prolongation.

[update medications](#)

Discussed with patient

Clinical notes:

Increase Protein Intake Strength of evidence: **A** Severity for patient: **high** ⓘ

Low daily protein intake (30 gr), 50-90 gr recommended for patient's BMI (18.3) and sedentary activity levels.
Increasing protein intake may improve muscle mass and function, reduce risk of sarcopenia and falls.

[update protein intake](#)

Discussed with patient

Clinical notes:

Figure 55 Lead User 6 prototype – Detailed frailty risk assessment page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Frailty Risk Score: **65%** (55-75%) chance of falls, loss of independence in iADL in next 6-12 months, patient is currently high-functioning but vulnerable to frailty



Frailty Risk Score Quality: **high** ⓘ

Patient Risk Factors for Frailty

[Hide patient risk factors used for Frailty Risk calculations](#)

Risk Factor Category	Value (Range)	Normal Range (for age, gender)	Modifiable	Absolute % of Contribution to Risk	Patient Info Updated
Age ⓘ	70 years		no	14 to 18%	06-Jan-1995
Daily Protein Intake ⓘ	30 gr	50-90 gr	yes	10 to 14%	21-Oct-2017
Smoking Status ⓘ	Heavy smoker: 1 ppd. 50 pack years		yes	10 to 14%	20-Nov-2008
Pharmacogenomic Factors			yes	5 to 7%	04-Jul-2018
Gender ⓘ	Female		no	3 to 7%	05-Feb-1995
BMI ⓘ	18.3	18.5-24.9	yes	2 to 4%	03-May-2016
BP ⓘ	150/90	90/60 - 120/80	yes	2 to 4%	03-May-2016
Activity Level ⓘ	Sedentary	18.5-24.9	yes	1 to 3%	01-Feb-2017
Ethnicity ⓘ	Caucasian		no	0.5 to 1.5%	06-Jan-1995
Inflammation Biomarkers			no	0.5 to 1.5%	17-Jun-2018
Genome Variants			no	0.5 to 1.5%	22-May-2018
Muscle Metabolome Biomarkers			no	0.5 to 1.5%	09-Feb-2018

Showing 12 out of 12

Suggested Interventions to Reduce Frailty Risk

SSRI Dose Reduction Strength of evidence: **A** Severity for patient: **high** ☰
 Poor CYP2C19 metabolizer, on Citalopram 40 mg/day. Discussed with patient

Figure 56 Lead User 6 prototype – Detailed frailty risk assessment page with top risk factors shown

N.7 Lead User 7 Prototype

Name: Annie Smith	Age: 80	DoB: 21-Jan-1938	Sex: F	Health #: 900 123 456
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Patient Recommendations

Patient at High Risk of Recurrent Falls

[Consider mobility aids and exercise](#)

not relevant patient declined

Current Medications

Citalopram – tablet – DOSE 40 mg – oral – once a day

Ramipril – tablet – DOSE 2.5 mg – oral – once a day

Family History

Father: Alzheimer's

Mother: Breast Cancer

Sister: Breast Cancer, Osteoarthritis in Knees

Brother: Hypertension

Paternal Aunt: Alzheimer's

Social History

Smoker: 1 ppd. 50 pack years

Alcohol: 1 glass of wine per day

Other: denies use

Exercise: none

Nutrition: vegetarian

[more](#)

Genomic Profiles

Whole Genome Sequencing - 05-Jan-2018

Proteomic Profiling - 04-May-2018

Encounter History

18-Jan-2018: Headaches – G. Jones

24-Sep-2017: Fatigue – G. Jones

02-Feb-2016: Med review – G. Jones

[more](#)

Allergies

Peanuts - anaphylaxis - 1950

Penicillin - rash, suspected - 1955

Problem List

Fall - right humerus fracture – 2018

Osteoporosis – 2016

Depression – 2015

Hypertension – 2015

Immunization History

Fluviral - intramuscular - 23-Nov-2017

Fluviral - intramuscular - 07-Nov-2015

Figure 57 Lead User 7 prototype - CDSS risk assessment notifications on a Patient Summary page

Name: Annie Smith	Age: 80	DoB: 21-Jan-1938	Sex: F	Health #: 900 123 456
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Integrated Geno/Pheno Geriatric Frailty Risk Assessment

Patient's 12-month absolute risk of recurrent falls: **80% (High)** ⓘ

Calculated based on patient data available in the EMR

Risk Calculator

The risk calculator shows patient risk factors used in the calculation. The calculator also presents suggested treatments and their relative benefits. You can update the patient-specific risk factors and/or select the treatments to see their impact on the risk score.

Risk Factors	Absolute Risk	Relative Benefit of Suggested Interventions: 0%
Some genomic data are masked and thus excluded from the calculation	Risk Time Period: 12 months	

Age ⓘ 80 yrs
History of Falls ⓘ 1 in last 12 months; right humerus fracture
Osteoporosis ⓘ yes
Smoking Status ⓘ 1ppd. 50 pack years
Antihypertensive Medications ⓘ Ramipril – tablet – DOSE 2.5 mg – oral – once a day
Body Mass Index ⓘ 18.3 Height: 165 cm Weight: 50 kg (underweight)
Inflammatory Biomarkers ⓘ Increase
CpG Islands Methylation ⓘ Increase
MMSE Score ⓘ Missing
Gait Speed ⓘ Missing
Daily Protein Intake ⓘ Outdated

20% No event

80% Total with an event

0% Number who benefit from treatment

NNT - Number needed to treat

50% Baseline events using age alone

30% Additional events "caused" by risk factors

Mobility Aids
Relative Benefit: 25%
Benefits of Treatment
 Reduced risk of falls
 Greater independence
Harm of Treatment
 Dependence on mobility aids
Patient Handout
[Mobility/assistive aids guide](#)
 not relevant patient declined discussed with patient
 Clinical notes:

Strength Building Exercise
Relative Benefit: 15%
Benefits of Treatment
 Reduced risk of falls
 Improved muscle strength
 Decrease in depression
 Improved sleep quality
 Improved physical and mental functions
Harm of Treatment
 Potential for activity-related injury
Patient Handout
[Exercise guide to reduce falls for frail seniors](#)
 not relevant patient declined discussed with patient
 Clinical notes:

Figure 58 Lead User 7 prototype - Detailed frailty risk assessment page

FRAILITY

FALLS

[Frailty Management Module](#)

Absolute Lifetime Risk: **70%** (High – 7-fold increase compared to population risk)

Strength of Evidence: **A**

Population Risk: **10%**

Patient Priority: **high**

Last Addressed: **Feb 12, 2019**

Provider Priority: **low**

Work Status: Ongoing

Patient Data Quality: **low**

Modifiable Risk Factors and Suggested Interventions to Reduce Risk of Falls

Risk Factor	Value	Last Documented	Suggested Interventions	Last Addressed	Work Status
Polypharmacy	6 current meds	Nov 15, 2018	Medication Review		
Osteoporosis	yes	Feb 3, 2015	Calcium and Vitamin D Supplements Mobility Aids		
Body Mass Index	18.3 Height: 165 cm Weight: 50 kg (underweight)	Jan 24, 2019	Daily Protein Intake Increase		
Smoking Status	Current smoker 1 ppd. 50 pack years	Dec 5, 2018	Smoking Cessation	Feb 12, 2019	Ongoing
MMSE score	Missing	Nov 15, 2018			
Gait Speed	Outdated	Aug 4, 2014			

Non-Modifiable Risk Factors for Falls

Risk Factor	Value	Last Documented
Age	80	Jul 17, 2000
History of Falls	1 in last 12 months: right humerus fracture	Dec 23, 2018
Inflammatory Biomarkers	Increase	Feb 12, 2019
CpG islands Methylation	Increase	Feb 12, 2019
Select Genomic Biomarkers	Masked	Mar 3, 2018

Figure 60 Lead User 8 prototype – Risk assessment page with frailty selected

Appendix O Goal Integration Tables

Table 11 Goal integration table

LU Goals	LU1	LU2	LU3	LU4	LU5	LU6	LU7	LU8	Summary Across LUs	Integration Decision for IGM V1	Integration Rationale for IGM V 1	IGM V1 Goal #	IGM V1 Goal	Integration Decision for IGM V2	Integration Rationale for IGM V 2	IGM V2 Goal #	IGM V2 Goal
Frailty risk addressed												0	Frailty risk addressed			0	Frailty risk addressed
Notification to assess risk integrated into clinical workflow	P	P	P	P	P	P	P	P	P:8; PSIM:0; NP:0; C:0	Accept	Proposed by all Lead Users, no conflicting goals.	1	Notification to assess risk integrated into clinical workflow			1	Notification to assess risk integrated into clinical workflow
Top priority notifications presented	P	P	P	P	P	P	P	NP	P:7; PSIM:0; NP:1; C:0	Accept	Proposed by the majority of Lead Users, no conflicting goals.	1.1	Top priority notifications presented			1.1	Top priority notifications presented
Notification importance presented	P	P	P	NP	P	P	P	NP	P:6; PSIM:0; NP:2; C:0	Accept	Proposed by the majority of Lead Users, no conflicting goals.	1.2	Notification importance presented			1.2	Notification importance presented
Risk assessed in detail	P	P	P	P	P	P	P	P	P:8; PSIM:0; NP:0; C:0	Accept	Proposed by all Lead Users, no conflicting goals	2	Risk assessed in detail			2	Risk assessed in detail
Risk info presented	P	P	P	P	P	P	P	P	P:8; PSIM:0; NP:0; C:0	Accept	Proposed by all Lead Users, no conflicting goals	2.1	Risk info presented			2.1	Risk info presented
															Added an explicit goal to visualize the risk info as it became an important requirement based on the evidence from the literature and the LU prototypes.	2.7	Risk info visualized

LU Goals	LU1	LU2	LU3	LU4	LU5	LU6	LU7	LU8	Summary Across LUs	Integration Decision for IGM V1	Integration Rationale for IGM V 1	IGM V1 Goal #	IGM V1 Goal	Integration Decision for IGM V2	Integration Rationale for IGM V 2	IGM V2 Goal #	IGM V2 Goal
Risk factors presented	P	P	P	PSIM (Pre-visit assessment results presented)	P	P	P	P	P:7; PSIM:1; NP:0; C:0	Accept	Proposed by all Lead Users, Lead User # proposed a similar goal: "Pre-visit assessment results presented". Pre-visit results are a subset of risk factors)	2.2	Risk factors presented			2.2	Risk factors presented
Masked/filtered data disclaimer presented	P	NP	NP	P	P	C (Masked/filtered data disclaimer NOT presented)	P	NP	P:4; PSIM:0; NP:3; C:1	Accept	Proposed by half of Lead Users. One Lead User did not want masked data disclaimer based on their experience in their practice indicating that it created confusion and privacy issues. The Synthesis Team accepted the goal with the intention to discuss it further.	2.3	Masked/filtered data disclaimer presented	Delete Goal	The Synthesis Team decided that masking or any other exclusion of patient data is a type of a data quality issue and the data quality can be indicated per each individual risk factor.	N/A	N/A
Big data risk factors clustered	P	P	NP	NP	NP	P	P	P	P:5; PSIM:0; NP:3; C:0	Accept	Proposed by the majority of Lead Users, no conflicting goals. This is a key goal for displaying big data without imposing excessive cognitive load on the user.	2.4	Big data risk factors clustered		Renamed to 'Risk Factors clustered'. Clustering can pertain to any types of risk factors (e.g. modifiable vs. non-modifiable, etc.)	2.3	Risk factors clustered

LU Goals	LU1	LU2	LU3	LU4	LU5	LU6	LU7	LU8	Summary Across LUs	Integration Decision for IGM V1	Integration Rationale for IGM V 1	IGM V1 Goal #	IGM V1 Goal	Integration Decision for IGM V2	Integration Rationale for IGM V 2	IGM V2 Goal #	IGM V2 Goal
Data quality issues highlighted	P	P	P	P	P	C (Data quality issues NOT highlighted)	P	P	P:7; PSIM:0; NP:0; C:1	Accept	Proposed by the majority of Lead Users. One Lead User indicated they would not have time to address data quality issues and therefore they didn't want the issues presented. The Synthesis Team indicated this goal to be important for data quality remediation and potential improvement of the risk score accuracy.	2.5	Data quality issues highlighted			2.4	Data quality issues highlighted
Risk factors can be updated	P	P	P	P	P	NP	P	P	P:7; PSIM:0; NP:1; C:0	Accept	Proposed by the majority of Lead Users, no conflicting goals.	2.6	Risk factors can be updated			2.5	Risk factors can be updated
Interventions suggested	P	P	P	P	P	P	P	P	P:8; PSIM:0; NP:0; C:0	Accept	Proposed by all Lead Users, no conflicting goals	3	Interventions suggested			3	Interventions suggested
Top priority interventions suggested	P	P	P	P	P	P	P	P	P:8; PSIM:0; NP:0; C:0	Accept	Proposed by all Lead Users, no conflicting goals	3.1	Top priority interventions suggested			3.1	Top priority interventions suggested
Relevant investigations can be ordered	P	P	P	P	NP	NP	NP	NP	P:4; PSIM:0; NP:4; C:0	Accept	Proposed by half of Lead Users, no conflicting goals.	3.2	Relevant investigations can be ordered	Change Goal Hierarchy	Moved from a sub goal of "Interventions suggested" to a sub goal of "Risk assessed in detail". Investigations (e.g. labs) are risk factors, although they can also be considered a type of intervention.	2.6	Relevant investigations can be ordered

LU Goals	LU1	LU2	LU3	LU4	LU5	LU6	LU7	LU8	Summary Across LUs	Integration Decision for IGM V1	Integration Rationale for IGM V 1	IGM V1 Goal #	IGM V1 Goal	Integration Decision for IGM V2	Integration Rationale for IGM V 2	IGM V2 Goal #	IGM V2 Goal
Intervention risk/benefit presented	NP	PSIM (Treatment benefit presented)	NP	NP	P	NP	PSIM (Treatment benefit presented)	NP	P:1; PSIM:1; NP:5; C:0	Accept	The Synthesis Team determined this to be an important goal that allow treatment comparison.	3.3	Intervention risk/benefit presented	Update Goal Title	The title of the goal was changed to reflect the focus on presenting risk benefit. Presenting risk, in addition to the benefit, can be done in supporting resources for each intervention.	3.2	Intervention benefit presented

Table 12 Qualities integration table

IGM Goal #	IGM Goal	Qualities Proposed by Lead Users								IGM Goal Qualities	Integration Rationale for IGM V 2
		LU1	LU2	LU3	LU4	LU5	LU6	LU7	LU8		
0	Frailty risk addressed	Redundant data entry avoided	Redundant data entry avoided, Quickly			Redundant data entry avoided			Redundant data entry avoided	Redundant data entry avoided, Quickly	
1	Notification to assess risk integrated into clinical workflow	Timely		Without slowing user down	Timely					Timely, Without slowing user down	
1.1	Top priority notifications presented	Succinct wording	Brief wording	Patient goals factored in	Minimal wording		Brief wording	Clearly visible, Concise, Actionable		Concise, Clearly visible, Actionable, Patient goals factored in	Succinct wording', 'Minimal wording', 'Brief wording' qualities are similar to 'Concise' quality
1.2	Notification importance presented	Clearly	Clearly			Visually				Clearly, Visually	
2	Risk assessed in detail	Preventatively	Quickly		Quickly		Quickly	Quickly	Quickly	Preventatively, Quickly	

		Qualities Proposed by Lead Users								IGM Goal Qualities	Integration Rationale for IGM V 2
IGM Goal #	IGM Goal	LU1	LU2	LU3	LU4	LU5	LU6	LU7	LU8		
2.1	Risk info presented	Clear for patient, Clear for provider				Clear for patient, Clear for provider, Visually	Visually	Visually	Visually	Clear for patient, Clear for provider, Visually	
2.2	Risk factors presented	On high level	Without cognitive overload	Clear for provider, Clear for patient		Various degrees of granularity			On high level	Without cognitive overload, Clear for provider, Clear for patient, Various degrees of granularity	Various degrees of granularity' implies on high- and low-levels.
2.3	Big data risk factors clustered	High-level clustering	In a clinically meaningful way							High-level clustering, In a clinically meaningful way	
2.4	Data quality issues highlighted	Clearly	Visibly					Visibly		Clearly, Visibly	
2.5	Risk factors can be updated	Without switching to other EMR modules	Without switching to other EMR modules, Efficiently	Quickly		Quickly, Easily			Without switching to other modules	Efficiently, Without switching to other EMR modules	Efficiently' quality implies 'Quickly' and 'Easily'
2.6	Relevant investigations can be ordered	Without switching to other EMR modules	Efficiently, Without switching other EMR modules			Quickly, Easily				Efficiently, Without switching to other EMR modules	Efficiently' quality implies 'Quickly' and 'Easily'
2.7	Risk info visualized										
3	Interventions suggested		Continuity of care supported							Continuity of care supported	
3.1	Top priority interventions suggested	Specific, Measurable, Behaviorally Anchored		Patient goals factored in	Not overly prescriptive, Patient goals factored in			Specific		Patient goals factored in, Specific, Not overly prescriptive, Measurable	Some interventions may not be behaviorally anchored (e.g. a surgical intervention).
3.2	Intervention benefit presented					Clear for provider, Clear for patient		Visually		Clear for provider, Clear for patient, Visually	

Appendix P Integrated UI Prototype Screenshots

The screenshots show the key features of the integrated prototype. Figure 61 illustrates how CDSS notifications for risk assessment can be presented on an EMR page during a clinical encounter. Here a patient summary is depicted; however, CDSS notifications could be shown on any other landing or working EMR page that a user would have open when working with the patient (for example, an encounter note page). Figure 62 is a screenshot of the detailed risk assessment module where the majority of the risk information would be presented to the user at a glance. Such information includes risk details, risk factors, and suggested intervention. Figure 63 shows the risk factors when the risk factor filter is set to 'All.' Figure 64 illustrates the interactive pictograph-based risk calculator where a user can select one or more suggested interventions to see their potential impact on the risk score.

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456



Encounter History

18-Jan-2018	Headaches - G. Jones
24-Sep-2017	Fatigue - G. Jones
02-Feb-2016	Med review - G. Jones

Rows per page: 3+ 1-3 of 3

Problem List

Hypertension	2010
Osteoarthritis - Wrists	2010
COPD	2008
Neuritis	2017

Immunization History

Fluoral - intramuscular	23-Nov-2017
Fluoral - intramuscular	07-Nov-2015

Genomic Profiles

Whole Genome Sequencing	05-Jan-2018
Proteomic Profiling	04-May-2018

Social History

Smoker: 1 pack, 50 pack years
 Alcohol: 1 glass of wine per day
 Other: denies use
 Exercise: none
 Nutrition: vegetarian

Preventive Recommendations

All
 Dismissed
 Delegated
 Deferred

Assess for Frailty [↗](#) Recommendation: **strong**
 Evidence Quality: **high**

Patient's risk: **High, 80%** (75-85%) for Frailty in next 3 yrs. Pop risk: 20%.
 Key patient risk factors: age, low BMI, low protein intake.

DISMISS DELEGATE DEFER ⓘ

Screen for Diabetes Type 2 [↗](#) Recommendation: **strong**
 Evidence Quality: **moderate**

Patient's risk: **High, 40%** (35-45%) for Diabetes Type 2 in next 5 yrs. Pop risk: 22%.
 Key patient risk factors: obesity, hypertension, genetics.

DISMISS DELEGATE DEFER ⓘ

Address Caffeine Consumption [↗](#) Recommendation: **conditional**
 Evidence Quality: **moderate**

Declined
 Patient's risk: **Moderate, 15%** (13-18%) for CHD in next 10 yrs. Pop risk: 10%.
 Key patient risk factors: Slow caffeine metabolizer, heavy coffee drinker (8 per day).

DISMISS DELEGATE DEFER ⓘ

Rows per page: 3 1-3 of 10 < >

Current Medications

Ramipril - tablet	DOSE 5 mg - oral - once daily
Hydrocortisone Acetaminophen - tablet	DOSE 5mg/500 mg - oral - twice a day
Salbutamol - 100 mcg/puff	DOSE 200 mcg - inhaled - two puffs four times a day
Benzydiazepine - tablet	DOSE 1mg - oral - three time a day

Family History

Father:	Alzheimer's
Mother:	Breast Cancer
Sister:	Breast Cancer, Osteoarthritis in Knees
Brother:	Hypertension
Paternal Aunt:	Alzheimer's

Figure 61: Integrated prototype - CDSS risk assessment notifications on a Patient Summary page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Risk: **High 80%** (75-85%) for becoming [Frail](#) in next 3 years.
 Population Risk: **20%** for Caucasian women 65-74 years old.
 Patient's current status: [Pre-Frail](#)

Risk Factors

All
 Modifiable
 Incomplete
 History
 Observations
 Conditions
 Investigations
 Medications

<input type="checkbox"/> Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/> BMI	18.3 (L)	18.5 – 24.9	10 – 12%	<input checked="" type="checkbox"/>	03-May-2016
<input type="checkbox"/> Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%	<input checked="" type="checkbox"/>	04-Jun-2019
<input type="checkbox"/> Smoking Status	Current. 1ppd. 50 pack yrs	Cessation	6 – 10%	<input checked="" type="checkbox"/>	23-Feb-2018

Rows per page: 3 1-3 of 11

Suggested Interventions

- All
 Dismissed
 Delegated
 Deferred
 Active
 Completed
- Increase Protein Intake**
 ARR: 6% in next 3 yrs
 Low [protein intake](#) (30 gr/day)
 Target: 50-90 gr for female, 70 yrs, [BMI](#) 18.3 (165 cm, 50 kg), low activity level
 Recommendation: **strong** Evidence Quality: **high**
 DISMISS DELEGATE DEFER
 - Quit Smoking**
 ARR: 6% in next 3 yrs
[Smoking status](#) 1 ppd. 50 pack years
 Recommendation: **strong** Evidence Quality: **moderate**
 DISMISS DELEGATE DEFER
 - Implement Resistance Exercise**
 ARR: 5% in next 3 yrs
 No [exercise](#) genetic predisposition to sarcopenia.
 Recommendation: **conditional** Evidence Quality: **moderate**
 DISMISS DELEGATE DEFER
- Rows per page: 3 1-3 of 18

Risk Calculator

Select one or more suggested interventions to see the impact on the risk score.

20% No event
 80% Patient's risk
 0% Absolute risk reduction
NNT - Number needed to treat
 20% Population (baseline) risk
 60% Additional risk "caused" by risk factors

Figure 62: Integrated prototype – Default detailed frailty risk assessment page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Risk: **High 80%** (75-85%) for becoming [Frail](#) in next 3 years.
 Population Risk: **20%** for Caucasian women 65-74 years old.
 Patient's current status: [Pre-Frail](#)

Risk Factors

All
 Modifiable
 Incomplete
 History
 Observations
 Conditions
 Investigations
 Medications

<input type="checkbox"/>	Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	Age	70 yrs		12 – 17%	✓	06-Jan-1995
<input type="checkbox"/>	BMI ii	18.3 (L)	18.5 – 24.9	10 – 12%	✓	03-May-2016 !
<input type="checkbox"/>	Protein Intake ii	30 gr/day (L)	50 – 90g/day	6 – 10%	✓	04-Jun-2019
<input type="checkbox"/>	Smoking Status	Current. 1ppd. 50 pack yrs	Cessation	6 – 10%	✓	23-Feb-2018
<input type="checkbox"/>	Grip Strength			6 – 10%	–	
<input type="checkbox"/>	Gait			6 – 10%	–	
<input type="checkbox"/>	Walking ½ mile			6 – 10%	–	
<input type="checkbox"/>	Climbing 10 steps			6 – 10%	–	
<input type="checkbox"/>	Dementia			6 – 10%	–	
<input type="checkbox"/>	Physical exercise	No exercise		6 – 10%	✓	12-Jul-2019
<input type="checkbox"/>	Benzodiazepin Medicat...	1 mg – oral - three times...		4 – 6%	✓	12-Jul-2019
<input type="checkbox"/>	Hydrocodone-Acetamin...	5mg/300 mg - oral - twice...		4 – 6%	✓	12-Jul-2019
<input type="checkbox"/>	Inflammation Biomark... ▼	1 of 3		4 – 6%	✓	
<input type="checkbox"/>	Genetic Biomarkers ▼	1 of 3		4 – 6%	✓	
<input type="checkbox"/>	Muscle Metabolites ▼	10 of 15		4 – 6%	✓	
<input type="checkbox"/>	Gender	Female		3 – 5%	✓	06-Jan-1995
<input type="checkbox"/>	Ethnicity	Caucasian		0.5 – 1.5%	✓	06-Jan-1995
<input type="checkbox"/>	Education Level			0.5 – 1.5%	–	

Rows per page: 18 1-18 of 18 < >

Figure 63: Integrated prototype – Detailed frailty risk assessment page with risk factors filter set to ‘All’

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Risk: **High 80%** (75-85%) for becoming **Frail** in next 3 years.
 Population Risk: **20%** for Caucasian women 65-74 years old.
 Patient's current status: **Pre-Frail**

Incomplete Patient Information

Please update the following incomplete patient information for a more accurate Frailty Risk Score calculation:

[History](#) (3 items) [Observations](#) (10 items) [Investigations](#) (3 items)

Suggested Interventions

All
 Active
 Completed
 Not Addressed
 Dismissed
 Delegated
 Deferred

Increase Protein Intake Recommendation: **strong**
Evidence Quality: **high**

Status: Not Addressed
ARR: 6% in next 3 yrs
Low **protein intake** (30 gr/day); Target 50-90 gr/day
Low **BMI** (18.3, 165 cm, 50kg); Target BMI 18.5-24.9

[DISMISS](#) [DELEGATE](#) [DEFER](#)

Quit Smoking Recommendation: **strong**
Evidence Quality: **moderate**

Status: Not Addressed
ARR: 6% in next 3 yrs
Current smoker (1 ppd 50 pack yrs)

[DISMISS](#) [DELEGATE](#) [DEFER](#)

Implement Resistance Exercise Recommendation: **conditional**
Evidence Quality: **moderate**

Status: Not Addressed
ARR: 5% in next 3 yrs
No **resistance exercise** Target: full body strength training twice/week
Genetic predisposition to sarcopenia

[DISMISS](#) [DELEGATE](#) [DEFER](#)

[ADD TO PLAN](#) Rows per page: 3 1-3 of 18

Risk Calculator

Select one or more suggested interventions to see the impact on the risk score.

- 20% No event
- 65% Patient's risk
- 15% Absolute risk reduction
- NNT** 7 Number needed to treat
- 20% Population (baseline) risk
- 45% Additional risk "caused" by risk factors

Figure 64: Integrated prototype - interactive risk calculator

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Appendix Q UI Prototype User Feedback

Table 13 UI prototype user feedback

Representative User #	Risk Notifications	Detailed Risk Panel	Risk Factors	Suggested Interventions	Risk Calculator
1	<p>"Take out pop risk as it's not clear what population is used. Is it patients of that age and gender or patients with similar genetics or what? Regardless, I don't need this much detail here. In the detailed risk assessment module – yes, but not here. Too much detail to include pop risk."</p> <p>"Allow user to mark recommendation as lower priority (as a dismissal reason perhaps)."</p> <p>"Allow delegating to multiple roles (e.g. to a nutritionist and nurse)."</p>	<p>"Allow the risk trend to be sharable with the patient (e.g. print or e-mail) as it's a useful educational piece for the patient."</p>	<p>"This is useful but maybe show measurements in metric and imperial systems."</p>	<p>"I really like this. Good level of info."</p>	<p>"Allow the pictograph to be sharable with the patient."</p>

Representative User #	Risk Notifications	Detailed Risk Panel	Risk Factors	Suggested Interventions	Risk Calculator
2	<p>"Too much detail on this level. Leave suggested action (Assess Frailty), relative risk (e.g. High) and key risk factors. Take out %, confidence interval, pop risk. Think how you can work the model of change into the states of the recommendation (e.g. 'patient is contemplating change' vs. 'patient declined')."</p>	<p>"Allow the Frailty definition to be sharable with patient."</p> <p>"Allow the risk trend to be sharable with patient - smoking would be a very good example to show how risk is reduced over years."</p>	<p>"Risk factors take up too much space on the screen. I need the risk and what to do about it - this is how I think. Need to see risk and then suggested interventions right away. Move risk factors to the bottom of the page, consider making them a linked resource (user can see the risk factors if they choose to). Focus on presenting risk and suggested interventions."</p>	<p>"Move suggested interventions up on the page above the risk factors. Showing 3 interventions is perfect. I need to give the patient one piece of homework only. "Show top 3 because I may determine some interventions are not relevant given the patient's situation, for example."</p> <p>"Suggested interventions are tricky. Some may target multiple conditions. Think smoking cessation or exercise. It's good for nearly everything. How do you show that? Also, one intervention can be good for one thing but bad for another. We often treat the heart at the expense of kidneys when we reduce salt, for example. How do you show risk and risk reduction (or increase) across all these conditions in a holistic way?"</p>	

Representative User #	Risk Notifications	Detailed Risk Panel	Risk Factors	Suggested Interventions	Risk Calculator
3	<p>"I would like a separate button to tell the MOA to book an appointment to address the issue (e.g. an appointment for frailty assessment)."</p> <p>"The details here are useful. Deferral should probably be a timeframe based as not known how often the patient comes in. Would like a filter to see completed/addressed recommendations. I would like to see what I have done already".</p> <p>"Risk factors should have values and trends."</p>	<p>"Current patient state is not very helpful."</p> <p>"Risk trend is not very helpful unless I can see the interventions on the graph so I can see how the interventions changed the risk trajectory."</p> <p>"Seeing the slope change due to intervention vs. a typical slope would be very powerful."</p>	<p>"Show risk factors on demand only. They take up too much screen otherwise and break up the flow of information: risk and interventions should follow."</p> <p>"Show specific big data risk factors (e.g. Huntington's) separately on the list as they can get buried in the grouping otherwise."</p>	<p>"Add a link to patient handouts. I may not have time to talk about an intervention but may give the patient a print-out and say we'll talk about it next time."</p> <p>"Same as on the Pt Summary, have a button to let the MOA know an appointment should be booked for a specific intervention."</p>	<p>"Allow the pictograph to be sharable with the patient."</p> <p>"A pictograph may be challenging for a very broad phenotype such as frailty."</p> <p>"Showing the risk to the patient in a simple way is very useful. I can just turn my screen and show them the pictograph. It is very easy to understand at a glance. I can show them how we could change the risk. That is very powerful."</p>

Representative User #	Risk Notifications	Detailed Risk Panel	Risk Factors	Suggested Interventions	Risk Calculator
4	<p>"3 Recommendations max. The recommendations are action-oriented which is very good (Tell me what should be done)."</p> <p>"Population risk is not helpful for decision making here. If the system says the risk is High, it's High. I'll trust that."</p> <p>"Take out confidence interval, population risk. Pop risk is not clear re what population is used."</p> <p>"Avoid duplicating outcome if it's mentioned in the action statement ("Assess for Frailty", risk for Frailty is X). Remove recommendation strength and evidence quality. If recommendations are personalized (precision medicine) then these guideline attributes (guidelines are generic and not-patient specific) should not be here. In the current UI it's not clear if recommendation and evidence are specific for this patient or are general guideline attributes. The system should prioritize based on multiple criteria and only present top recommendations, so this info is not needed as it is also confusing."</p> <p>"I'll trust the system. I don't need to see rationale why this was triggered unless I dig deeper. Just tell me the risk is high and I'll decide if I should address it. I'll let the system do the thinking and prioritization and I'll rely on that if the system is good."</p> <p>"Change how the Dismiss dialog works (here and on the Interventions) to reduce clicks, have a drop-down for dismiss reasons (although this won't allow notes)."</p>	<p>"Patient's current state is useful only if it's specific. For example, it would be very useful to see patient's current CFS state currently and their risk of progression to the next CFS stage. If the current state is always the same for the condition (e.g. pre-diabetic) then it's not informative or useful. Current state is only useful if there is a continuum for the condition states (e.g. CFS)."</p>	<p>"Big data risk factors should be grouped even if one item in the group (e.g. a specific allele) is a big contributor. "We will get used to seeing grouped big data items."</p>	<p>"Change how the Dismiss dialog works (here and on the Interventions) to reduce clicks, have a drop-down for dismiss reasons (although this won't allow notes). I won't dismiss interventions most likely. I would defer if patient declined as I want to see what the system recommends."</p>	<p>"Think about how to show change in risk in a less confusing way although the current way is good, how can it be made better."</p>

Representative User #	Risk Notifications	Detailed Risk Panel	Risk Factors	Suggested Interventions	Risk Calculator
5	<p>"The notifications have to be accessible to me on whatever page I am working on during the encounter. It could be the face sheet, or it could be the encounter notes. It's important they are integrated into my EMR and my way of working."</p> <p>"If risk is High, it should be in red. There is a lot of information in an EMR page that competes for my attention. The patient doesn't come in for prevention. I have the presenting complaint to deal with, and potentially many other issues come up."</p> <p>"Take out confidence interval - not useful on this level and it's too much info."</p> <p>"Pop risk is helpful."</p> <p>"Key risk factors shouldn't be here as it's too much info. Take out strength of recommendation and evidence quality - too much info on this level."</p> <p>"Suggested format (max 2 lines): High, 80% (pop risk: 20) for Frailty in next 3 yrs."</p> <p>"Think about combining the dismissal and deferral - some declined or not relevant recommendations should be revisited at a certain time-frame."</p>	<p>"Current patient state is useful for some conditions."</p> <p>"Risk graph would be useful for annual reviews to show to the patient (no need to show specific intervention points - need to show the big picture only, i.e. how the slope changes)."</p>	<p>"Absolute % of contribution is too much info. If the risk factors are ordered appropriately the % are not that important and introduce a lot of clutter. "ARR is shown in the Risk Calculator as is so I don't need % here."</p> <p>"Clustering of big data risk factors is very important. No need to take out big contributors out of the clusters."</p>	<p>"Don't show ARR as it takes space and is confusing to the patient. The Risk Calculator pictograph shows the risk reduction already so no need to duplicate."</p> <p>"Recommendation strength and evidence quality are helpful here (but not on the Pt Summary 'Preventive Recommendations')."</p> <p>"Consider how dismissed and deferred functionality may be combined."</p>	<p>"Think how to show patient risk if it's below the pop risk on the pictograph."</p>

Representative User #	Risk Notifications	Detailed Risk Panel	Risk Factors	Suggested Interventions	Risk Calculator
6	<p>"Consider having the recommendations on the working page (e.g. encounter page). They should always be there. Having them on the landing page only may result in me not seeing them sometimes. A patient presents for other reasons often and if I have time, I might look at the preventive recommendations and address them."</p> <p>"Make the recommendations much more concise (e.g. high risk for frailty)." "There is always going to be some uncertainty about a risk estimate. If I trust the system and the system only shows a risk score that is sufficiently reliable, I don't need to see the confidence interval."</p> <p>"Make the important recommendations in the prominent colour that the EMR uses (e.g. red in OSCAR). "Physicians are compelled to clear the red. Different EMRs have different colours to indicate something hasn't been completed." "I want something that says I am important, look at me."</p>	<p>"Relative risk magnitude is very helpful."</p> <p>"Frailty definition is helpful as this is also an educational tool."</p> <p>"Current status is good."</p> <p>"Confidence interval not helpful in decision making."</p> <p>"Risk graph is not very useful. How am I actually going to use this? If you have any graphs, projection of the risk into the future is more useful, saying this is how your risk will increase unless you do something."</p>	<p>"Risk factors take up too much space and prominence on the screen. Need to see risk and then suggested interventions right away. Make risk factors available as a link. It's not that we, physicians, are not intellectually curious what goes into the risk calculation (that's important) but we don't have time to review that list. Besides, the suggested interventions target the top risk factors and tell us what they are."</p> <p>"Cluster all non-modifiable into one category."</p> <p>"Risk factor trending is useful (unlike the trending of the overall score historically)."</p> <p>"Not clear if some risk factors are 'what you should be doing.'"</p>	<p>"I need to know the risk and what to do about it. What is the biggest bang for the buck?"</p> <p>"Showing several suggested interventions is great as I can ask the patient what they'd like to tackle."</p> <p>"Make it clear that selecting an intervention doesn't add it to plan, but only lets you see the impact on the risk."</p> <p>"Add a button to action/add to plan (i.e. Do this) and make it the first action button before Dismiss, Delegate, Defer. Currently, the 'add to plan' button has lower visibility and feels like it's of less importance."</p> <p>"Add more info for each intervention (e.g. summary of increasing protein intake or summary of suggested exercises or a referral letter to an OT). Allow the user to attach their custom 'one-pagers' for different intervention types (e.g. We have tons of one-pagers plastered on our walls for different interventions)."</p>	<p>"Explain synergy of different interventions for ARR."</p>

Appendix R Changes Proposed by Representative Users

Table 14 Changes proposed by Representative Users

UI Component	Proposed Changes	RU 1	RU2	RU3	RU4	RU5	RU6	Summary Across RUs	Synthesis Team Decision	Decision Rationale
Risk Notifications	Remove confidence interval	NP	P	NP	P	P	P	(P:4; NP:2)	Accept	Confidence interval imposes additional cognitive load on the users and is not likely to influence the provider's decision making, assume the CDSS only provides notifications where the risk score has an acceptable confidence interval.
	Remove population risk	P	P	C	P	C	P	(P:4; C:2)	Accept	Population risk information imposes additional cognitive load on the users and is not likely to influence the provider's decision making. The notification already includes a relative risk (e.g. high) which is relative to the population. Population risk without describing the nature of the comparative population can be confusing.
	Remove recommendation strength and quality of evidence	NP	NP	NP	P	P	P	(P:3; NP:3)	Reject	Recommendation strength and quality of evidence can have an impact on the user's decision making whether to address the notification.
	Remove patient's absolute risk	NP	P	NP	NP	NP	P	(P:2; NP:4)	Reject	The evidence supports the design decision to display patient's risk in absolute percentages.
	Remove key risk factors	NP	C	C	NP	P	P	(P:2; C:2; NP:2)	Reject	Key risk factors provide important informational context for the notification.
	Add ability to see risk factor values and trends	NP	NP	NP	NP	NP	NP	(P:1; NP:5)	Reject	Insufficient evidence to make the change.
	Highlight high risk scores in a prominent colour	NP	NP	NP	NP	NP	NP	(P:1; NP:5)	Reject	The requirement patterns contain a requirement to differentiate the entire notification based on priority using colour. No sufficient evidence to highlight the risk score itself.
	Build in the model of change into the notification/recommendation state	NP	P	NP	NP	NP	NP	(P:1; NP:5)	Accept	This was added as a consideration into the patterns. Not in scope to provide detailed requirements.
	Allow delegation to multiple roles	P	NP	NP	NP	NP	NP	(P:1; NP:5)	Accept	This was added as a consideration into the patterns. Not in scope to provide detailed requirements.
Provide 'book appointment' button for the issue	NP	NP	P	NP	NP	NP	(P:1; NP:5)	Reject	Addressed already through the delegation functionality. No sufficient evidence to change the UI requirements.	

UI Component	Proposed Changes	RU 1	RU2	RU3	RU4	RU5	RU6	Summary Across RUs	Synthesis Team Decision	Decision Rationale
	Add a filter to see all active, addressed, and not addressed notifications	NP	NP	P	NP	NP	NP	(P:1; NP:5)	Accept	Integrated into the requirement patterns.
Detailed Risk Panel	Remove current patient state	NP	NP	P	C	C	C	(P:1; C:3; NP:2)	Reject	Proposed change conflicts the majority of the Representative Users.
	Remove confidence interval	NP	NP	NP	NP	NP	P	(P:1; NP:5)	Reject	No sufficient evidence to change the UI requirements.
	Allow user to see interventions or significant new risk factors on the risk graph	NP	NP	P	NP	C	NP	(P:1; C:1; NP:4)	Accept	Added into other considerations. Not in scope to provide detailed requirements.
Risk Factors	Display risk factors on-demand only	NP	P	P	NP	NP	P	(P:3; NP:3)	Accept	To accommodate cognitive fit, the risk factors should be available on-demand only as a linked resource.
	Separate individual big data risk factors out of the big data clusters if they are big contributors.	C	C	P	C	C	C	(P:1; C:3)	Reject	Not supported by the majority of the participants. Cognitive load considerations suggest clustering of all big data risk factors into clinically meaningful categories.
	Remove absolute percentage of contributions column.	NP	NP	NP	NP	P	NP	(P:1; NP:5)	Reject	No sufficient evidence to make the change to the patterns.
Suggested Interventions	Build in the model of change into the notification/recommendation state	NP	P	NP	NP	NP	NP	(P:1; NP:5)	Accept	This was added as a consideration into the patterns. Not in scope to provide detailed requirements.
	Allow delegation to multiple roles	P	NP	NP	NP	NP	NP	(P:1; NP:5)	Accept	This was added as a consideration into the patterns. Not in scope to provide detailed requirements.
	Provide 'book appointment' button for the issue	NP	NP	P	NP	NP	NP	(P:1; NP:5)	Reject	Addressed already through the delegation functionality. No sufficient evidence to change the UI requirements.
	Add a filter to see all active and not addressed notifications	NP	NP	P	NP	NP	NP	(P:1; NP:5)	Accept	Integrated into the requirement patterns.
	Remove ARR %	NP	NP	NP	NP	P	NP	(P:1; NP:5)	Accept	In conflict with evidence. ARR is an important piece of information for deciding on whether to implement an intervention.

Appendix S Pattern Changes Based on UI Prototype Feedback

Table 15 Pattern changes

Pattern category	Pattern	Pattern changes
Notifications	Display Health Outcome Risk Assessment Notifications	
	Prioritize Notifications	
	Filter Notifications	Expansion of the filter range to allow the user to see which notifications are being addressed by the provider and the patient and which have been dealt with and completed.
	Display Health Outcome Risk Assessment Notification	Removal of the reference to the Display Health Outcome Risk Sentence pattern and integrated the key elements from the Display Health Outcome Risk Sentence pattern into this pattern (confidence interval and population risk were excluded). Clarification of the recommendation strength definition. Recommendation strength should pertain to the strength of the personalized recommendation generated by the CDSS for the given patient (as opposed to population-based guideline strength rating). Addition of a requirement to display the work status of the notification: Active, Completed, Not Addressed, Dismissed, Delegated, Deferred.
	Action Notification	
Risk Presentation	Display Health Outcome Risk Detail	Specification that risk factors should be available on-demand only.
	Display Health Outcome Risk Sentence	
	Display Health Outcome Risk Trend	Addition to 'Other Considerations': to allow the user to configure what data is displayed on the graph, in addition to the patient and population risk trends (for example, allow the user to see points in time for the implemented interventions and/or new significant risk factors).
	Visualize Health Outcome Risk	
Risk Factors	Display Risk Factors	
	Filter Risk Factors	
	Display Risk Factor	
	Update Risk Factor Value	
	Display Incomplete Patient Data	Addition of a new pattern to address how the incomplete data should be explicitly highlighted.
Suggested Interventions	Display Suggested Interventions	Added a 'Strive To' to allow the user to select one or more suggested interventions and add them to the care plan.
	Prioritize Suggested Interventions	
	Filter Suggested Interventions	Expansion of the filter range to allow the user to see which notifications are being addressed.
	Display Suggested Intervention	Added a requirement to allow the user to add custom content for interventions as part of CDSS settings. Added a requirement to display the work status of the notification: Active, Completed, Not Addressed, Dismissed, Delegated, Deferred
	Action Suggested Intervention	

Appendix T Finalized UI Prototype

Name: Annie Smith
Age: 70
DoB: 21-Jan-1948
Sex: F
Health #: 900 123 456



Encounter History

- 18-Jan-2018: Headaches - G. Jones
- 24-Sep-2017: Fatigue - G. Jones
- 02-Feb-2016: Med review - G. Jones

Rows per page: 3+ 1-3 of 3

Problem List

- Hypertension - 2010
- Osteoarthritis - Wrist - 2010
- COPD - 2008
- Insomnia - 2017

Immunization History

- Fluoral - intramuscular - 23 Nov 2017
- Fluoral - intramuscular - 07 Nov 2015

Genomic Profiles

- Whole Genome Sequencing - 05 Jan 2018
- Proteomic Profiling - 04 May 2018

Social History

- Smoker: 1 pack, 30 pack years
- Alcohol: 1 glass of wine per day
- Other: denies use
- Exercise: none
- Nutrition: vegetarian

Preventive Recommendations

✓ All
Active
Completed
Not Addressed
Dismissed

Delegated
Deferred

Address Frailty [↗](#)

Recommendation: **strong**
 Evidence Quality: **high**

Status: Not Addressed

Patient's risk: **High, 80%** for Frailty in next 3 yrs.

Key patient risk factors: age, low BMI, low protein intake.

DISMISS
DELEGATE
DEFER
ⓘ

Screen for Diabetes Type 2 [↗](#)

Recommendation: **strong**
 Evidence Quality: **moderate**

Status: Not Addressed

Patient's risk: **High, 40%** for Diabetes Type 2 in next 5 yrs.

Key patient risk factors: obesity, hypertension, genetics.

DISMISS
DELEGATE
DEFER
ⓘ

Address Caffeine Consumption [↗](#)

Recommendation: **conditional**
 Evidence Quality: **moderate**

Status: Patient Declined

Patient's risk: **Moderate, 15%** for CHD in next 10 yrs.

Key patient risk factors: Slow caffeine metabolizer, heavy coffee drinker (8 per day).

DISMISS
DELEGATE
DEFER
ⓘ

Rows per page: 3 1-3 of 10

Current Medications

- Ramipril - tablet - DOSE 5 mg - oral - once daily
- Hydrocodone/Acetaminophen - tablet - DOSE 5mg/300 mg - oral - twice a day
- Salbutamol - 100 mcg/puff - DOSE 200 mcg - inhaled - two puffs four times a day
- Benzodiazepine - tablet - DOSE 1mg - oral - three time a day

Family History

- Father: Alzheimer's
- Mother: Breast Cancer
- Sister: Breast Cancer, Osteoarthritis in Knees
- Brother: Hypertension
- Paternal Aunt: Alzheimer's

Figure 65: Finalized prototype - CDSS risk assessment notifications on a Patient Summary page

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Preventive Recommendations

All
 Active
 Completed
 Not Addressed
 Dismissed

Delegated
 Deferred

Address Frailty [↗](#) Recommendation: **strong** Evidence Quality: **high**

Status: Not Addressed

Patient's risk: **High, 80%** for Frailty in next 3 yrs.

Key patient risk factors: age, low BMI, low protein intake.

DISMISS **DELEGATE** **DEFER** ⓘ

Screen for Diabetes Type 2 [↗](#) Recommendation: **strong** Evidence Quality: **moderate**

Status: Not Addressed

Patient's risk: **High, 40%** for Diabetes Type 2 in next 5 yrs.

...ity, hypertension, genetics.

DEFER ⓘ

sumption [↗](#) Recommendation: **conditional** Evidence Quality: **moderate**

for CHD in next 10 yrs.

caffeine metabolizer, heavy coffee drinker (8 per day).

DEFER ⓘ

Rows per page: 3 1-3 of 10 < >

Dismiss recommendation?

- Not relevant
- Patient declined
- Addressed elsewhere
- Other reason

Notes

CANCEL **CONFIRM**

Encounter History

- 18-Jan-2018: Headaches - G. Jones
- 24-Sep-2017: Fatigue - G. Jones
- 02-Feb-2016: Med review - G. Jones

Rows per page: 3+

Problem List

- Hypertension - 2010
- Osteoarthritis - Wrist - 2010
- COPD - 2008
- Incontinence - 2017

Immunization History

- Fluoral - intramuscular - 23-Nov-2017
- Fluoral - intramuscular - 07-Nov-2015

Genomic Profiles

- Whole Genome Sequencing - 05-Jan-2018
- Proteomic Profiling - 04-May-2018

Social History

- Smoker: 1 pack, 50 pack years
- Alcohol: 1 glass of wine per day
- Other: denies use
- Exercise: none
- Nutrition: vegetarian

Family History

- Father: Alzheimer's
- Mother: Breast Cancer
- Sister: Breast Cancer, Osteoarthritis in Knees
- Brother: Hypertension
- Paternal Aunt: Alzheimer's

Figure 66: Finalized prototype - CDSS risk assessment notifications on a Patient Summary page. Notification dismissal options are illustrated

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Risk: **High 80%** (75-85%) for becoming **Frail** in next 3 years.
 Population Risk: **20%** for Caucasian women 65-74 years old.
 Patient's current status: **Pre-Frail**

Incomplete Patient Information

Please update the following incomplete patient information for a more accurate Frailty Risk Score calculation:

- [History](#) (3 items)
- [Observations](#) (10 items)
- [Investigations](#) (3 items)

Suggested Interventions

All
 Active
 Completed
 Not Addressed
 Dismissed
 Delegated
 Deferred

<input type="checkbox"/> Increase Protein Intake Status: Not Addressed ARR: 6% in next 3 yrs Low protein intake (30 gr/day); Target 50-90 gr/day Low BMI (18.3, 165 cm, 50kg); Target BMI 18.5-24.9 DISMISS DELEGATE DEFER	Recommendation: strong Evidence Quality: high
<input type="checkbox"/> Quit Smoking Status: Not Addressed ARR: 6% in next 3 yrs Current smoker (1 ppd 50 pack yrs) DISMISS DELEGATE DEFER	Recommendation: strong Evidence Quality: moderate
<input type="checkbox"/> Implement Resistance Exercise Status: Not Addressed ARR: 5% in next 3 yrs No resistance exercise Target: full body strength training twice/week Genetic predisposition to sarcopenia DISMISS DELEGATE DEFER	Recommendation: conditional Evidence Quality: moderate

Rows per page: 3 1-3 of 18

Risk Calculator

Select one or more suggested interventions to see the impact on the risk score.

- 20% No event
- 80% Patient's risk
- 0% Absolute risk reduction
- NNT** - Number needed to treat
- 20% Population (baseline) risk
- 60% Additional risk "caused" by risk factors

Figure 67: Finalized prototype – Default detailed frailty risk assessment page

Name: Annie Smith Age: 70 DoB: 21-Jan-1948 Sex: F Health #: 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Geriatric Frailty

What is it

Geriatric frailty is a clinically recognizable state of older adults with increased vulnerability, resulting from age-associated declines in physiologic reserve and function across multiple organ systems, such that the ability to cope with everyday or acute stressors is compromised. Frailty leads to functional impairment and adverse health outcomes and is reversible or attenuated by interventions.

Negative outcomes

Frailty can lead to increased vulnerability for adverse health outcomes such as falls, disability, dependency in activities of daily living, hospitalization, and mortality.

What causes the condition

Chronic inflammation is likely a key underlying mechanism that contributes to frailty directly and indirectly through other intermediate pathophysiologic processes. Etiology of frailty is not fully understood yet. Potential etiologic factors include genetic/epigenetic and metabolic factors, environmental and lifestyle stressors, and acute and chronic diseases.

Typical signs and symptoms

- Weakness. Grip strength: lowest 20% (by sex, body mass index)
- Slowness. Walking time/15 feet: slowest 20% (by sex, height)
- Low level of physical activity. Kcal/week: lowest 20%
- Exhaustion; poor endurance. Exhaustion (self-report)
- Weight loss. >10lb lost unintentionally in prior year

When it develops

Geriatric frailty develops in older age, typically after 65 years of age. Age is the main risk factor for frailty.

How common is the condition

The overall prevalence of frailty in community-dwelling older adults aged 65 years and over in Canada and the US ranges from 7% to 12%. It increases with age from 3.9% in the age-group 65–74 years to 25% in the age group older than 85 years. The prevalence of frailty is higher in women than in men and higher in African Americans than in Caucasians.

How is it treated

Interventions for the frailty syndrome should aim to 1) prevent, delay, reverse, or reduce the severity of frailty, and 2) prevent or reduce adverse health outcomes in those whose frailty is not reversible.

Exercise and comprehensive geriatric interdisciplinary assessment and treatment are the key interventions for the frailty syndrome at the present time. Given the complex nature of this geriatric syndrome, any single agent or approach targeted to one single organ system may not achieve optimal results. Multimodality strategies intervening in potential biological, sociobehavioral, and environmental stressors should be considered for the frail elderly.

This CDSS module uses the Integrated Geno/Pheno Index. For other frailty risk assessment tools, see [Geriatric Frailty Risk Assessment Calculators](#). Read more at: [John Hopkins Frailty Assessment](#), [National Institute on Aging](#), [Gene reviews](#), [Genetics Home Reference](#)

60% Additional risk "caused" by risk factors

Figure 68: Finalized prototype – Detailed frailty risk assessment page. An example frailty definition is illustrated (the content is intended for demonstration purposes only)

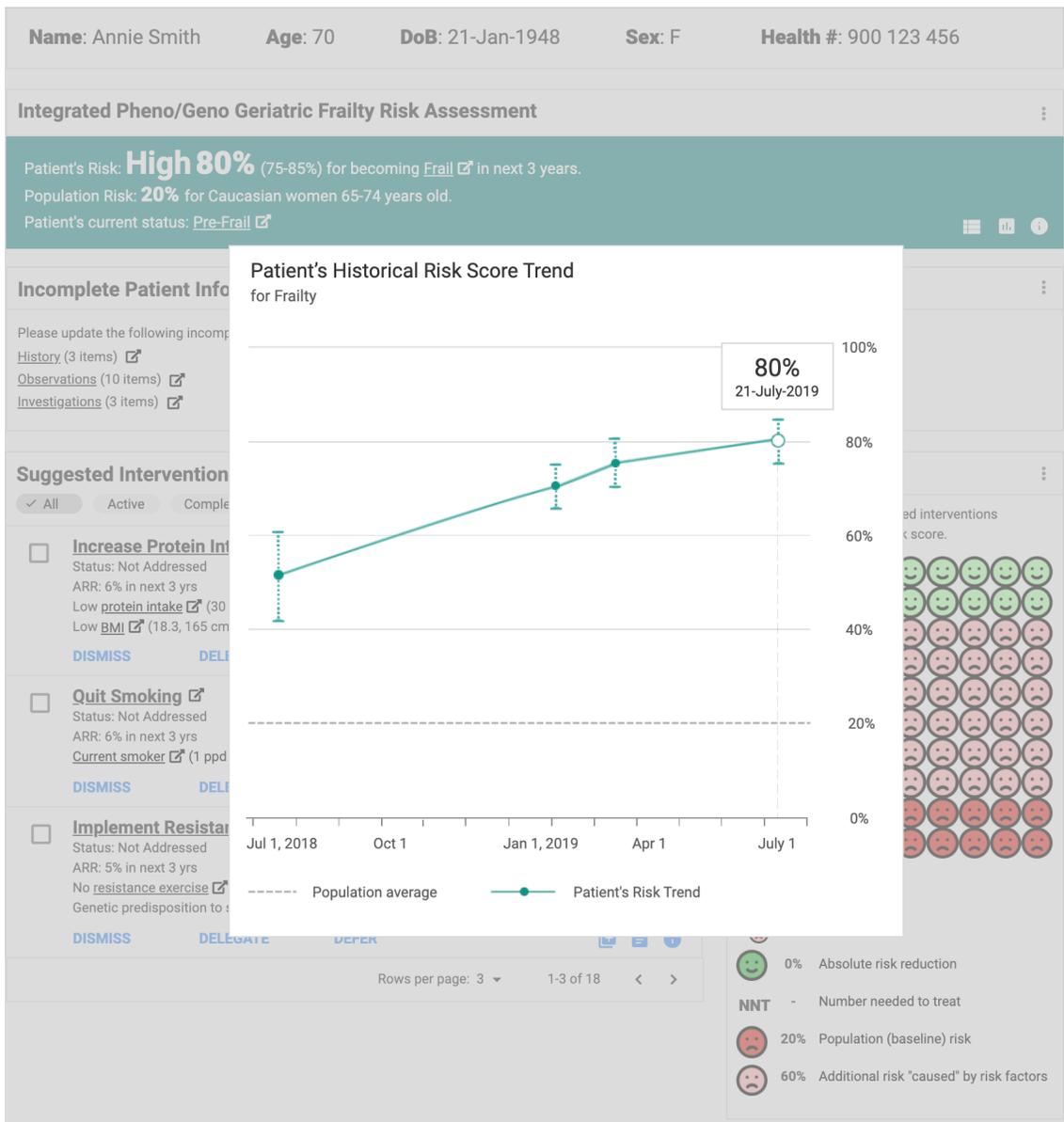


Figure 69: Finalized prototype – Detailed frailty risk assessment page. Risk score trending is illustrated

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Risk: **High 80%** (75-85%) for becoming [Frail](#) in next 3 years.
 Population Risk: **20%** for Caucasian women 65-74 years old.
 Patient's current status: [Pre-Frail](#)

Risk Factors

All
 Modifiable
 Incomplete
 History
 Observations
 Conditions
 Investigations
 Medications

<input type="checkbox"/>	Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	BMI	18.3 (L)	18.5 – 24.9	10 – 12%	<input checked="" type="checkbox"/>	03-May-2016
<input type="checkbox"/>	Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%	<input checked="" type="checkbox"/>	04-Jun-2019
<input type="checkbox"/>	Smoking Status	Current. 1ppd. 50 pack yrs	Cessation	6 – 10%	<input checked="" type="checkbox"/>	23-Feb-2018

Rows per page: 3 1-3 of 11

Incomplete Patient Information

Please update the following incomplete patient information for a more accurate Frailty Risk Score calculation:

- [History](#) (3 items)
- [Observations](#) (10 items)
- [Investigations](#) (3 items)

Suggested Interventions

All
 Active
 Completed
 Not Addressed
 Dismissed
 Delegated
 Deferred

- Increase Protein Intake**
 Status: Not Addressed
 ARR: 6% in next 3 yrs
 Low [protein intake](#) (30 gr/day); Target 50-90 gr/day
 Low [BMI](#) (18.3, 165 cm, 50kg); Target BMI 18.5-24.9
 DISMISS DELEGATE DEFER
- Quit Smoking**
 Status: Not Addressed
 ARR: 6% in next 3 yrs
[Current smoker](#) (1 ppd 50 pack yrs)
 DISMISS DELEGATE DEFER
- Implement Resistance Exercise**

Risk Calculator

Select one or more suggested interventions to see the impact on the risk score.

Figure 70: Finalized prototype – Detailed frailty risk assessment page. Risk factors displayed on-demand with the default filter set to ‘Modifiable’

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Risk: **High 80%** (75-85%) for becoming **Frail** in next 3 years.
 Population Risk: **20%** for Caucasian women 65-74 years old.
 Patient's current status: **Pre-Frail**

Risk Factors

All Modifiable **Incomplete** History **Observations** Conditions Investigations Medications

<input type="checkbox"/>	Risk Factor	Value	Target	Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	BMI	18.3 (L)	18.5 – 24.9	10 – 12%	<input checked="" type="checkbox"/>	03-May-2016
<input type="checkbox"/>	Grip Strength			6 – 10%	<input type="checkbox"/>	
<input type="checkbox"/>	Gait			6 – 10%	<input type="checkbox"/>	

Rows per page: 18 1-3 of 3

Incomplete Patient Information

Please update the following incomplete patient information for a more accurate Frailty Risk Score calculation:

- [History](#) (3 items)
- [Observations](#) (10 items)
- [Investigations](#) (3 items)

Suggested Interventions

All Active Completed Not Addressed Dismissed Delegated Deferred

- Increase Protein Intake**
 Status: Not Addressed Recommendation: **strong** Evidence Quality: **high**
 ARR: 6% in next 3 yrs
 Low protein intake (30 gr/day); Target 50-90 gr/day
 Low BMI (18.3, 165 cm, 50kg); Target BMI 18.5-24.9
 DISMISS DELEGATE DEFER
- Quit Smoking**
 Status: Not Addressed Recommendation: **strong** Evidence Quality: **moderate**
 ARR: 6% in next 3 yrs
 Current smoker (1 ppd 50 pack yrs)
 DISMISS DELEGATE DEFER

Risk Calculator

Select one or more suggested interventions to see the impact on the risk score.

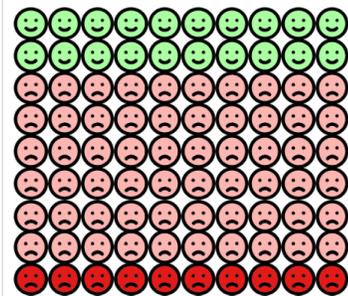


Figure 71: Finalized prototype – Detailed frailty risk assessment page

Risk Factors						
<input checked="" type="checkbox"/> All <input type="checkbox"/> Modifiable <input type="checkbox"/> Incomplete <input type="checkbox"/> History <input type="checkbox"/> Observations <input type="checkbox"/> Conditions <input type="checkbox"/> Investigations <input type="checkbox"/> Medications						
<input type="checkbox"/> Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated	
<input type="checkbox"/> Age	70 yrs		12 – 17%	<input checked="" type="checkbox"/>	06-Jan-1995	
<input type="checkbox"/> BMI	18.3 (L)	18.5 – 24.9	10 – 12%	<input checked="" type="checkbox"/>	03-May-2016	
<input type="checkbox"/> Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%	<input checked="" type="checkbox"/>	04-Jun-2019	
<input type="checkbox"/> Smoking Status	Current. 1ppd. 50 pack yrs	Cessation	6 – 10%	<input checked="" type="checkbox"/>	23-Feb-2018	
<input type="checkbox"/> Grip Strength			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Gait			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Walking ½ mile			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Climbing 10 steps			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Dementia			6 – 10%	<input type="checkbox"/>		
<input type="checkbox"/> Physical exercise	No exercise		6 – 10%	<input checked="" type="checkbox"/>	12-Jul-2019	
<input type="checkbox"/> Benzodiazepin Medicat...	1 mg – oral - three times...		4 – 6%	<input checked="" type="checkbox"/>	12-Jul-2019	
<input type="checkbox"/> Hydrocodone-Acetamin...	5mg/300 mg - oral - twice...		4 – 6%	<input checked="" type="checkbox"/>	12-Jul-2019	
<input type="checkbox"/> Inflammation Biomark..	1 of 3		4 – 6%	<input checked="" type="checkbox"/>		
<input type="checkbox"/> PRT-1	Increase		4 – 6%	<input checked="" type="checkbox"/>	04-May-2018	
<input type="checkbox"/> PRT-2			0.5 – 1.5%	<input type="checkbox"/>		
<input type="checkbox"/> PRT-3			0.5 – 1.5%	<input type="checkbox"/>		
<input type="checkbox"/> Genetic Biomarkers	1 of 3		4 – 6%	<input checked="" type="checkbox"/>		
<input type="checkbox"/> Muscle Metabolites	10 of 15		4 – 6%	<input checked="" type="checkbox"/>		
<input type="checkbox"/> Gender	Female		3 – 5%	<input checked="" type="checkbox"/>	06-Jan-1995	
<input type="checkbox"/> Ethnicity	Caucasian		0.5 – 1.5%	<input checked="" type="checkbox"/>	06-Jan-1995	
<input type="checkbox"/> Education Level			0.5 – 1.5%	<input type="checkbox"/>		

Rows per page: 18 1-18 of 18

Figure 72: Finalized prototype – Detailed frailty risk assessment page. Risk factors – filter option is set to ‘All’, Inflammation Biomarkers cluster is expanded

Name: Annie Smith **Age:** 70 **DoB:** 21-Jan-1948 **Sex:** F **Health #:** 900 123 456

Integrated Pheno/Geno Geriatric Frailty Risk Assessment

Patient's Risk: **High 80%** (75-85%) for becoming **Frail** in next 3 years.
 Population Risk: **20%** for Caucasian women 65-74 years old.
 Patient's current status: **Pre-Frail**

Incomplete Patient Information

Please update the following incomplete patient information for a more accurate Frailty Risk Score calculation:

- [History](#) (3 items)
- [Observations](#) (10 items)
- [Investigations](#) (3 items)

Suggested Interventions

Increase Protein Intake
 Status: Not Addressed
 ARR: 6% in next 3 yrs
 Low [protein intake](#) (30 gr/day); Target 50-90 g
 Low [BMI](#) (18.3, 165 cm, 50kg); Target BMI 18.5-24.9
 DISMISS DELEGATE DEFER

Quit Smoking
 Status: Not Addressed
 ARR: 6% in next 3 yrs
[Current smoker](#) (1 ppd 50 pack yrs)
 DISMISS DELEGATE DEFER

Implement Resistance Exercise
 Status: Not Addressed
 ARR: 5% in next 3 yrs
 No [resistance exercise](#) Target: full body strength training twice/week
 Genetic predisposition to sarcopenia
 DISMISS DELEGATE DEFER

Rows per page: 3 1-3 of 18

Dismiss recommendation?

- Not relevant
- Patient declined
- Addressed elsewhere
- Not feasible to action
- Other reason

Notes

Frailty Risk Calculator
 Select one or more suggested interventions to see the impact on the risk score.

- 20% No event
- 80% Patient's risk
- 0% Absolute risk reduction
- NNT** - Number needed to treat
- 20% Population (baseline) risk
- 60% Additional risk "caused" by risk factors

Figure 73: Finalized prototype – Detailed frailty risk assessment page. Suggested intervention dismissal options are illustrated

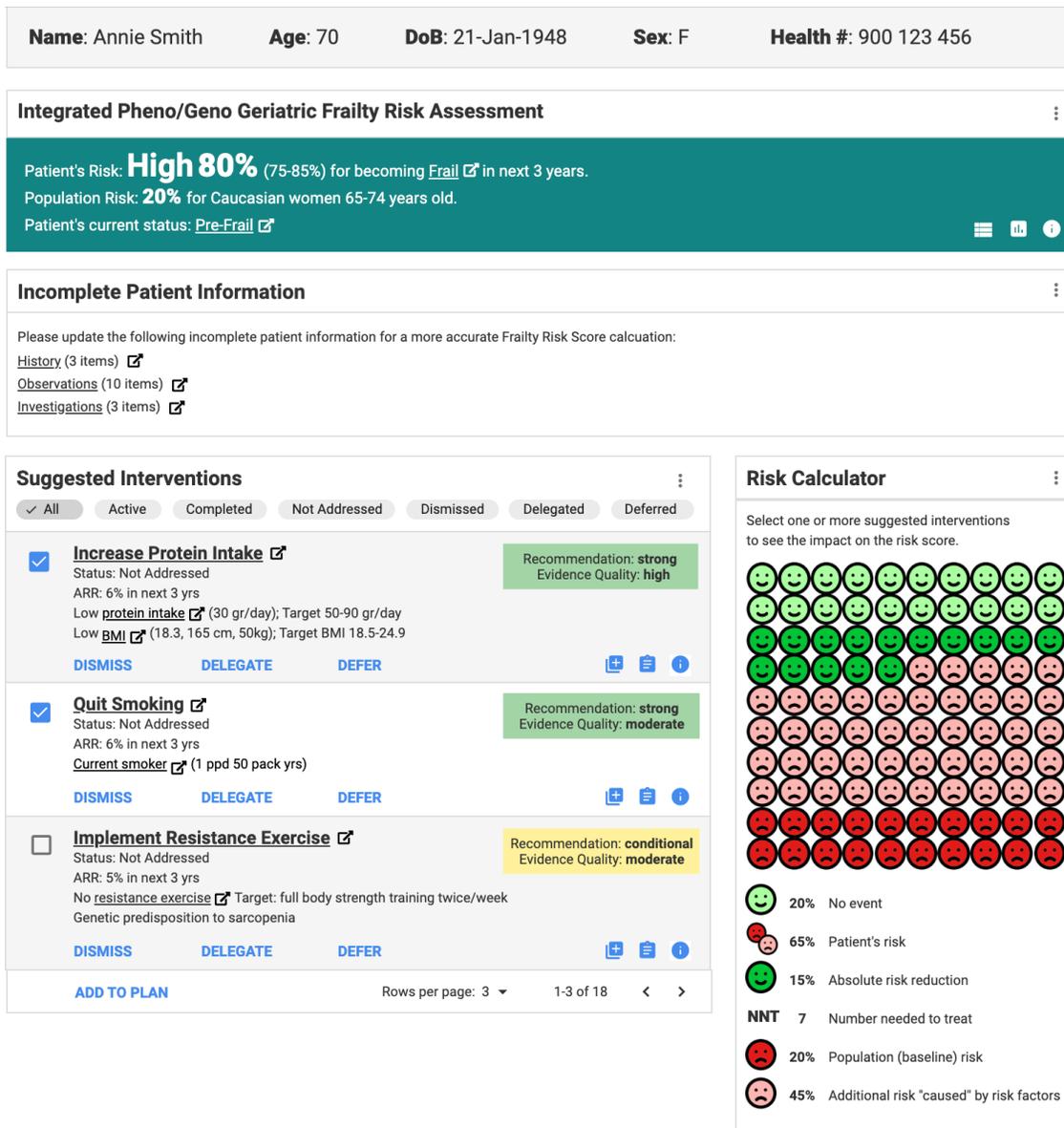


Figure 74: Finalized prototype – Detailed frailty risk assessment page

The illustration shows how the user can select multiple suggested interventions and to view their potential impact on the frailty risk score (see the Risk Calculator pictograph widget on the screenshot). The user can also add the selected interventions to plan which would initiate the necessary clinical workflows that are outside of the scope for this study

Appendix U Requirement Patterns

U.1 Display Health Outcome Risk Assessment Notifications

Updated: July 16, 2019

Version: 0.04

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to provide guidance for displaying multiple CDSS notifications for health outcome risk assessments. The notifications addressed in the pattern only pertain to risk assessments for chronic health conditions.

The focus of the pattern is on how multiple risk assessment notifications should be presented at the point of care to the primary care provider.

Not Intended To

- Address the presentation of notifications for other types of risks. Only notifications for risk assessments for chronic health conditions are in scope. The notifications of other types, such as recommendations for acute conditions or medication alerts, for example, are not in scope as they may require different content, presentation logic, format, and functionality.
- Address reflective practice CDSS notifications.
- Specify the details of how individual notifications should be displayed (see Display Health Outcome Risk Assessment Notification).

Clinical Context

An EMR may be integrated with multiple CDSS that generate real-time notifications based on patient data and clinical context. Incorporation of large patient data sets (including genomic data, passively collected data, etc.) into routine clinical practice is likely to exacerbate the problem of a large number of notifications with varying degrees of clinical utility (Van Ness 2016; Larson and Wilke 2015).

Given the limitations of a typical primary care encounter, it is critical that the provider is presented only with the most relevant CDSS notifications of highest priority (Sittig et al. 2008). The notifications must also be appropriately integrated into the clinical workflows to support informed decision making (Horsky et al. 2012).

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses and allied health professionals. NOTE: The focus was on primary care physicians, the scope may change based on the scope of practice.

Visualization Example

The screenshot displays a 'Preventive Recommendations' interface. At the top, there are filter buttons: 'All' (selected), 'Active', 'Completed', 'Not Addressed', 'Dismissed', 'Delegated', and 'Deferred'. Below the filters, three recommendation cards are listed:

- Address Frailty** (link icon): Status: Not Addressed. Recommendation: **strong**, Evidence Quality: **high**. Patient's risk: **High, 80%** for Frailty in next 3 yrs. Key patient risk factors: age, low BMI, low protein intake. Action buttons: DISMISS, DELEGATE, DEFER. Info icon.
- Screen for Diabetes Type 2** (link icon): Status: Not Addressed. Recommendation: **strong**, Evidence Quality: **moderate**. Patient's risk: **High, 40%** for Diabetes Type 2 in next 5 yrs. Key patient risk factors: obesity, hypertension, genetics. Action buttons: DISMISS, DELEGATE, DEFER. Info icon.
- Address Caffeine Consumption** (link icon): Status: Patient Declined. Recommendation: **conditional**, Evidence Quality: **moderate**. Patient's risk: **Moderate, 15%** for CHD in next 10 yrs. Key patient risk factors: Slow caffeine metabolizer, heavy coffee drinker (8 per day). Action buttons: DISMISS, DELEGATE, DEFER. Info icon.

At the bottom, there is a pagination control: 'Rows per page: 3', '1-3 of 10', and navigation arrows.

Figure 75: CDSS risk notifications

Solution Description

Strive To

- Integrate notifications into clinical workflows at the right time in the decision-making process. For the notifications to assess patient health outcome risk, the notifications should be presented at the initial page that the user opens during a clinical encounter. In some EMRs it may be a patient summary, in others an encounter page, or a combination of both where the user has a patient summary and can enter clinical notes. Ensure the notifications are also accessible from the working page that the user is using during the encounter while conducting relevant clinical tasks.
- Provide notifications in near-real time. The CDSS should be responsive to the data entered in the patient's chart during the encounter. The CDSS should update, reprioritize, and display relevant notifications within the encounter.
- Ensure the notifications are visible to the user but are not unnecessarily obtrusive.
- Combine notifications if there are multiple CDSS recommendations that are conflicting or similar. Patients with co-morbidities are most likely to have multiple recommendations from multiple sources (Sittig et al. 2008). CDSS should reconcile the recommendations, using clinical evidence, to present one cohesive notification to the user.
- Display a limited number of top priority notifications with the option to view more (see Display Health Outcome Risk Assessment Notification)
 - Prioritize notifications (see Prioritize Notifications)

- Allow filtering of notifications (see Filter Notifications)
- Clearly indicate to the user the number of displayed notifications and the number of not displayed notifications.
- Allow the user to adapt the intrusiveness of notifications (Marcilly et al. 2018). This would include allowing the user to define the threshold for what notifications are displayed at the point of care.
- Allow the user to access information on how the CDSS content is generated and how it is displayed (Marcilly et al. 2018). The user should have the necessary information to understand what notifications/recommendations the CDSS can and cannot generate (what patient data are checked, sources of evidence; the algorithms used, types of conditions/outcomes/events covered; duration of notification activation); how the notifications are prioritized.
- Convey the state of the CDSS to the user. If the notifications are not available due to a system outage, it should be made clear to the user. The visibility of system status (Nielsen 1994) is a key requirement for patient safety.

Avoid

- Inducing notification fatigue by displaying notifications that are not timely or relevant.
- Interrupting user's workflow. Interruptions provide more opportunities for error and place a higher cognitive load on the user (Patel et al. 2008).

Other Considerations

A CDSS can use risk assessment notifications to optimize patient management within a care team and optimize individual provider's scheduling. For example, a CDSS can suggest scheduling an appointment of adequate length with an appropriate member of patient's care team.

Related Patterns

Used By

- None

Uses

- Display Health Outcome Risk Assessment Notification
- Prioritize Notifications
- Filter Notifications

U.2 Display Health Outcome Risk Assessment Notification

Updated: October 8, 2019

Version: 0.04

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to provide guidance for displaying a single, specific CDSS notification to assess a patient for a health risk. The notification type addressed in the pattern only pertains to risk assessment for developing a chronic health condition, such as frailty risk assessment.

Not Intended To

- Address the presentation of notifications for other types of risks. Only a notification for risk assessment for a chronic health condition is in scope. Other types of notifications (e.g., medication alerts) may have a different presentation format, functionality, and informational context.

Clinical Context

A risk assessment notification would typically be generated by a CDSS in the context of a clinical activity such as a visit regarding another primary reason (e.g., review a chronic disease, refill medications, review bloodwork, address pain). Particularly in these contexts, the provider already has a significant cognitive load. Therefore, only the essential and actionable information should be provided in the notification (de Jong 2010), to allow the provider to assess the relevance and importance of the notification. The notification must be displayed in a concise and clear format.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope the of practice.

Visualization Example

Address Frailty [↗](#)

Status: Not Addressed

Recommendation: **strong**
Evidence Quality: **high**

Patient's risk: **High, 80%** for Frailty in next 3 yrs.

Key patient risk factors: age, low BMI, low protein intake.

DISMISS **DELEGATE** **DEFER** [i](#)

Figure 76 A CDSS notification

Solution Description

Strive To

- Structure the notification consistently to ensure users can easily find the relevant data (Horsky et al. 2012):
 - Display a notification title
 - Each notification should have a unique title
 - The title should clearly describe the notification's clinical intent
 - The title should be concise
 - The title should be the most visible element of the intervention
 - Display the work status of the notification: Active, Completed, Not Addressed, Dismissed, Delegated, Deferred
 - The status should be consistent with the notification filter options (see Filter Notifications)
 - Display patient's estimated health outcome risk score:
 - Patient's absolute risk in percentages
 - Round the numbers, if appropriate, to avoid decimals.
 - The magnitude of patient's risk compared to population risk.
 - Provide information about what population is used for comparison. Provide this information on-demand in a linked resource.
 - Indicate which range patient's risk falls into.
 - Use decreased/typical/increased or low/normal/high ranges. Such interpretive thresholds can help understand risk magnitude (Lipkus 2007).
 - Consider confidence intervals for the ranges when calculating what range patient falls into.
 - Concrete health outcomes/consequences. Risk can be viewed as a combined function of the probability of loss and consequence of loss (Lipkus 2007).
 - A risk timeframe. The risk score is not informative without a timeframe. Time span chosen for a risk score can influence risk perceptions (Fischhoff, Brewer, and Downs 2014). Short timeframes may be best for achieving risk reduction through behaviour change (Waldron et al. 2011). For example, for frailty, the following timeframe is suggested:
 - 1 to 3 years
 - Display a summary of key patient risk factors that the notification relates to
 - Summarize the risk factors on a high level (e.g., '85 yrs old, recurrent falls, multiple risk factors')
 - Display recommendation strength
 - Recommendation strength should pertain to the strength of the personalized recommendation generated by the CDSS for the given patient (as opposed to population-based guideline strength rating).
 - If possible, use an established and recognizable rating system for recommendation strength grading.

- Indicate the recommendation strength using a word. In addition, use colour or shape, if appropriate (Phansalkar et al. 2010).
 - Clearly differentiate notifications with different levels of recommendation strength (Marcilly et al. 2018).
 - Display evidence quality
 - For the grading of evidence quality, use an established and recognizable rating system, such as the Canadian Task Force on Preventive Health Care's GRADE (Bell et al. 2013).
 - Indicate the evidence quality using a word. In addition, use colour or shape, if appropriate (Phansalkar et al. 2010).
 - Clearly differentiate notifications with different levels of evidence quality (Marcilly et al. 2018).
- Provide access to evidence supporting the suggested intervention on-demand with clear signposts to information.
- Include actionable tools within the notification (see Action Notification).

Avoid

- Mandating that the user address the notification. The CDSS should recommend an action but not require the user to address it unless the notification is critical.

Other Considerations

- None

Related Patterns

Used By

- Display Health Outcome Risk Assessment Notifications

Uses

- Action Notification

U.3 Prioritize Notification

Updated: October 9, 2019

Version: 0.04

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to provide a set of heuristics for prioritizing all relevant risk assessment notifications.

The focus is on the preventive care for chronic conditions, including health promotion and mitigation of negative health outcomes. The notifications are displayed by CDSS at the point of care (e.g. during a visit) for a primary care provider.

Not Intended To

- Specify prioritization criteria for the notifications of other types, such as those related to acute health issues (e.g., medication or allergy alerts). Prioritization rules may be different for the notifications presented in another part of a clinical workflow and for other types of health conditions and outcomes.
- Describe how to prioritize the notifications that have a change of state such as notifications that are deferred, declined, dismissed, delegated, or are due for a follow-up. Such notifications may have complex prioritization rules and workflows associated with them and are out of scope for this study. See also Filter Notifications for different states of notifications.
- Define a precise prioritization algorithm.

Clinical Context

With increasing evidence, patient data sources, and computing power, CDSS can generate a multitude of patient-specific notifications related to health outcome risks. The integration of genomic data and other large data into routine clinical practice and the advancement of predictive modeling may greatly increase the number of notifications delivered to the provider (Glaser et al. 2008). The notifications may vary in their urgency, evidence, and application in a given context. They may not always be important, feasible, or possible to address during an encounter.

Prioritization is important in determining the optimal sensitivity and specificity of notifications displayed to the provider (Coleman et al. 2013). Reducing notification/alert fatigue is a key challenge for CDSS usability (Sittig et al. 2008).

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

N/A

Solution Description

Strive To

- Use a patient-specific prioritization model based on an individual patient's current status (Downs and Uner 2002).
- Update the notification priority, if possible, based on new data / information available during a patient encounter.
- Prioritize notifications based on:
 - recommendation strength
 - patient's health outcome risk magnitude
 - absolute risk score
 - risk score confidence interval
 - risk timeframe
 - severity of outcomes
 - patient-specific criteria
 - importance to the patient
 - urgency due to patient circumstances
 - actionability of the recommended clinical action
 - feasibility of the recommended clinical action
 - provider characteristics
 - provider role
 - provider preferences for notification intrusiveness
 - context of care
 - care setting
 - Certain clinical tasks may not be feasible or relevant in some primary care clinics with a limited scope.
 - encounter type
 - The primary reason for the encounter may determine what other clinical tasks a CDSs should and should not suggest. Duration of an encounter plays a role in determining what clinical tasks are feasible.
- Allow the user to customize the prioritization criteria.

Avoid

- None

Other Considerations

- None

Related Patterns

Used By

- Display Health Outcome Risk Assessment Notifications

Uses

- None

U.4 Action Notification

Updated: July 16, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to specify the options that a user should have for explicitly actioning a risk assessment notification presented by the CDSS. The notification type that is in scope is a health outcome risk notification for a chronic condition.

Not Intended To

- Describe the specific workflows for actioning the notification. The pattern focuses on describing what options the provider should have, but not how each action should be implemented in detail.
-
- Address actioning of the notifications of other types (e.g., medication or allergy alerts). The required actions may be different for the notifications presented in another part of a clinical workflow and for other types of health conditions and outcomes.

Clinical Context

A provider's decision about a CDSS recommendation should be easily translated into action (Marcilly et al. 2018). A provider may simply ignore the notification or act on it in some way and not document the actions. However, to facilitate the provider's workflow and sound documentation practices, the CDSS design should strive for an optimal cognitive fit between the UI and provider's intentions - the fit of technology to task (Vessey and Galletta 1991).

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Examples

Address Frailty [↗](#)

Status: Not Addressed

Recommendation: **strong**
Evidence Quality: **high**

Patient's risk: **High, 80%** for Frailty in next 3 yrs.

Key patient risk factors: age, low BMI, low protein intake.

DISMISS **DELEGATE** **DEFER** [i](#)

Figure 77: A CDSS notification - a user can action the notification in various ways

Dismiss recommendation?

Not relevant

Patient declined

Addressed elsewhere

Other reason

Notes

[CANCEL](#) [CONFIRM](#)

Figure 78: Dismissal options for a CDSS notification

Solution Description

Strive To

- Allow the user to access the detailed risk assessment module from the notification.
 - Part of the notification such as the title should link to the risk assessment module (see Display Health Outcome Risk Detail).
- Allow the user to manage a notification state over time. Provide options for at least the following states / tasks:
 - Dismiss the notification.
 - Require a reason for dismissal. The user must specify one of the following reasons:
 - ‘not relevant’
 - ‘patient declined’
 - ‘addressed elsewhere’
 - ‘other reason’
 - Allow additional notes for the dismissal reason.
 - Defer the notification. For example, for X time or N number of visits.
 - Delegate the notification to another provider.
- Clearly indicate how the notification was actioned by the user or other providers. Over time, a notification may be viewed by multiple providers or the same provider multiple

times. Previous actions and decisions should be clearly visible with data on who last actioned the notification, how, and when.

- Record user actions and history of changes in the patient's medical record.
- Ensure feedback on user actions to the CDSS to improve the generation and prioritization of notifications.

Avoid

- None

Other Considerations

- If there is a recommended single clinical action for the recommendation (e.g. order lab test, take blood pressure, update body weight), consider allowing this to be actioned from the notification directly.
- Consider integrating the model of change into the options for actioning a notification.

Related Patterns

Used By

- Display Health Outcome Risk Assessment Notification

Uses

- Display Health Outcome Risk Detail

U.5 Filter Notifications

Updated: October 9, 2019

Version: 0.04

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to provide guidance for filtering health outcome risk notifications.

Not Intended To

- Specify filtering for notifications for other types of risks. Only notifications for risk assessments for chronic health conditions are in scope.

Clinical Context

CDSS may generate a multitude of patient-specific notifications. Each notification has various characteristics that are important for the provider to decide on how to action the notification.

CDSS should present the most clinically relevant notifications to the user. However, the user may need to review the notifications based on different criteria of interest. An ability to filter notifications allows the provider to narrow down high volumes of notifications and to surface the most relevant results quickly.

Another benefit of filters is that they are informative about the content that is being displayed, which is advantageous for users not familiar with the content.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

The screenshot shows a 'Preventive Recommendations' interface. At the top, there are filter buttons: 'All' (checked), 'Active', 'Completed', 'Not Addressed', 'Dismissed', 'Delegated', and 'Deferred'. Below the filters, three recommendation cards are displayed:

- Address Frailty**: Status: Not Addressed. Recommendation: strong, Evidence Quality: high. Patient's risk: High, 80% for Frailty in next 3 yrs. Key patient risk factors: age, low BMI, low protein intake. Action buttons: DISMISS, DELEGATE, DEFER.
- Screen for Diabetes Type 2**: Status: Not Addressed. Recommendation: strong, Evidence Quality: moderate. Patient's risk: High, 40% for Diabetes Type 2 in next 5 yrs. Key patient risk factors: obesity, hypertension, genetics. Action buttons: DISMISS, DELEGATE, DEFER.
- Address Caffeine Consumption**: Status: Patient Declined. Recommendation: conditional, Evidence Quality: moderate. Patient's risk: Moderate, 15% for CHD in next 10 yrs. Key patient risk factors: Slow caffeine metabolizer, heavy coffee drinker (8 per day). Action buttons: DISMISS, DELEGATE, DEFER.

At the bottom, there is a pagination control showing 'Rows per page: 3' and '1-3 of 10'.

Figure 79 Filter options for CDSS risk notifications

Solution Description

Strive To

- Apply a default filter that displays a small number of top priority notifications, for example display top 5.
- Provide the following filters:
 - 'All' - all the notifications for the patient.
 - 'Active' - notifications for the conditions that are in the process of being addressed by the patient and provider (i.e., work in progress)
 - 'Completed' - notifications for the conditions that have been addressed and are considered completed.
 - 'Not Addressed' - notifications that have not been addressed yet.
 - 'Dismissed' - dismissed notifications.
 - 'Deferred' - deferred notifications.
 - 'Delegated' - notifications that are delegated to other providers.
- If compatible with the UI design for filtering, provide a count of items per each filter parameters in the filter selector. For example, All (10), Dismissed (3).
- Display applied filters. Showing the 'applied filters' separately in a single combined overview list (e.g., 'Currently showing: deferred') allows the user to quickly and easily see what filter parameters were selected.
- When filters are applied, hide irrelevant content and only show filtered items.

- Be explicit about the number of items shown and NOT shown in a view for the applied filters.
 - To ensure items are not overlooked, use a count of the total number of items.

Avoid

- Displaying an excessively long list of notifications in one view regardless of the filter setting. This can occlude important information on the screen. Consider pagination or scrolling if appropriate.

Other Considerations

- None

Related Patterns

Used By

- Display Health Outcome Risk Assessment Notifications

Uses

- None

U.6 Display Risk Factors

Updated: October 8, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern addresses the display of patient's risk factors for a health condition, as part of detailed risk assessment.

Not Intended To

- Display risk factors in other parts of physician workflow (e.g., the risk factors displayed in CDSS notifications outside of the risk assessment module, or suggested treatments in the risk assessment module).

Clinical Context

There are several reasons a provider may need to review patient risk factors related to a health outcome:

- To determine the risk factors and the magnitude of their contribution to the overall health risk score.
 - This information can be used to inform the provider and patient about the risk factors. This can be a starting point for discussing potential interventions for modifiable risk factors or informing the patient about the role of non-modifiable factors.
 - Displaying the risk factors can help the provider understand how a CDSS calculates the risk score.
- To review the risk factor data quality. Highlighting data quality issues in the list of risk factors (e.g., missing or outdated data) allows the provider to take data quality remediation actions and potentially improve the accuracy of the risk score (e.g., order a lab test or record a patient observation such as BMI). This facilitates a cognitive fit with the user workflow: reviewing and updating patient data.
- To follow up on the evidence for a risk factor of interest as an education opportunity.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

Risk Factors						
<input type="radio"/> All <input checked="" type="radio"/> Modifiable <input type="radio"/> Incomplete <input type="radio"/> History <input type="radio"/> Observations <input type="radio"/> Conditions <input type="radio"/> Investigations <input type="radio"/> Medications						
<input type="checkbox"/>	Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	BMI	18.3 (L)	18.5 – 24.9	10 – 12%		03-May-2016
<input type="checkbox"/>	Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%		04-Jun-2019
<input type="checkbox"/>	Smoking Status	Current. 1ppd. 50 pack yrs	Cessation	6 – 10%		23-Feb-2018

Rows per page: 3 1-3 of 11 < >

Figure 80: Risk factors – filter option is set to ‘Modifiable’ and top three modifiable risk factors are displayed

Risk Factors						
<input checked="" type="radio"/> All <input type="radio"/> Modifiable <input type="radio"/> Incomplete <input type="radio"/> History <input type="radio"/> Observations <input type="radio"/> Conditions <input type="radio"/> Investigations <input type="radio"/> Medications						
<input type="checkbox"/>	Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	Age	70 yrs		12 – 17%		06-Jan-1995
<input type="checkbox"/>	BMI	18.3 (L)	18.5 – 24.9	10 – 12%		03-May-2016
<input type="checkbox"/>	Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%		04-Jun-2019
<input type="checkbox"/>	Smoking Status	Current. 1ppd. 50 pack yrs	Cessation	6 – 10%		23-Feb-2018
<input type="checkbox"/>	Grip Strength			6 – 10%		
<input type="checkbox"/>	Gait			6 – 10%		
<input type="checkbox"/>	Walking ½ mile			6 – 10%		
<input type="checkbox"/>	Climbing 10 steps			6 – 10%		
<input type="checkbox"/>	Dementia			6 – 10%		
<input type="checkbox"/>	Physical exercise	No exercise		6 – 10%		12-Jul-2019
<input type="checkbox"/>	Benzodiazepin Medicat...	1 mg – oral - three times...		4 – 6%		12-Jul-2019
<input type="checkbox"/>	Hydrocodone-Acetamin...	5mg/300 mg - oral - twice...		4 – 6%		12-Jul-2019
<input type="checkbox"/>	Inflammation Biomark...	1 of 3		4 – 6%		
<input type="checkbox"/>	Genetic Biomarkers	1 of 3		4 – 6%		
<input type="checkbox"/>	Muscle Metabolites	10 of 15		4 – 6%		
<input type="checkbox"/>	Gender	Female		3 – 5%		06-Jan-1995
<input type="checkbox"/>	Ethnicity	Caucasian		0.5 – 1.5%		06-Jan-1995
<input type="checkbox"/>	Education Level			0.5 – 1.5%		

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Figure 81: Risk factors – filter option is set to ‘All’

Risk Factors						
<input checked="" type="checkbox"/> All <input type="checkbox"/> Modifiable <input type="checkbox"/> Incomplete <input type="checkbox"/> History <input type="checkbox"/> Observations <input type="checkbox"/> Conditions <input type="checkbox"/> Investigations <input type="checkbox"/> Medications						
<input type="checkbox"/>	Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	Age	70 yrs		12 – 17%	✓	06-Jan-1995
<input type="checkbox"/>	BMI	18.3 (L)	18.5 – 24.9	10 – 12%	✓	03-May-2016
<input type="checkbox"/>	Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%	✓	04-Jun-2019
<input type="checkbox"/>	Smoking Status	Current. 1ppd. 50 pack yrs	Cessation	6 – 10%	✓	23-Feb-2018
<input type="checkbox"/>	Grip Strength			6 – 10%	✗	
<input type="checkbox"/>	Gait			6 – 10%	✗	
<input type="checkbox"/>	Walking ½ mile			6 – 10%	✗	
<input type="checkbox"/>	Climbing 10 steps			6 – 10%	✗	
<input type="checkbox"/>	Dementia			6 – 10%	✗	
<input type="checkbox"/>	Physical exercise	No exercise		6 – 10%	✓	12-Jul-2019
<input type="checkbox"/>	Benzodiazepin Medicat...	1 mg – oral - three times...		4 – 6%	✓	12-Jul-2019
<input type="checkbox"/>	Hydrocodone-Acetamin...	5mg/300 mg - oral - twice...		4 – 6%	✓	12-Jul-2019
<input type="checkbox"/>	Inflammation Biomark..	1 of 3		4 – 6%	⚠	
<input type="checkbox"/>	PRT-1	Increase		4 – 6%	✓	04-May-2018
<input type="checkbox"/>	PRT-2			0.5 – 1.5%	✗	
<input type="checkbox"/>	PRT-3			0.5 – 1.5%	✗	
<input type="checkbox"/>	Genetic Biomarkers	1 of 3		4 – 6%	⚠	
<input type="checkbox"/>	Muscle Metabolites	10 of 15		4 – 6%	⚠	
<input type="checkbox"/>	Gender	Female		3 – 5%	✓	06-Jan-1995
<input type="checkbox"/>	Ethnicity	Caucasian		0.5 – 1.5%	✓	06-Jan-1995
<input type="checkbox"/>	Education Level			0.5 – 1.5%	✗	

Rows per page: 18 1-18 of 18

Figure 82: Risk factors – filter option is set to ‘All’, Inflammation Biomarkers cluster is expanded

Solution Description

Strive To

- Display a limited number of top risk factors with the option to view more.
- Prioritize the risk factors by the contribution to the overall risk score.
 - For the risk factors with incomplete data, prioritize based on potential contribution. For the important risk factors, this allows the user to action incomplete data and improve the accuracy of the risk score.
 - In all views, display the risk factors in descending order by the contribution.
- Visually differentiate modifiable and non-modifiable risk factors.
- Allow the user to filter the risk factors (see Filter Risk Factors).
- Group risk factors into clinically relevant categories
 - Base grouping on an established nomenclature (e.g., LOINC, SNOMED)

- Ensure congruency between the filter options and groupings.
- Display details for the individual risk factors in the current view (see Display Risk Factor).
- Allow the user to update the risk factors (see Update Risk Factor Value).

Avoid

- None

Other Considerations

- The ability to search for a specific risk factor may be of use to some users.
- Allow users to configure the risk factor grouping granularity (e.g., ‘All blood work’ vs. ‘Chemistries’; ‘Lifestyle’ vs. ‘Nutrition’ and ‘Exercise’).

Related Patterns

Used By

- Display Health Outcome Risk Detail

Uses

- Filter Risk Factors
- Display Risk Factor
- Update Risk Factor Value

U.7 Display Risk Factor

Updated: July 11, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to provide guidance for displaying the details for an individual risk factor when viewing patient risk factors for a health condition (see Display Risk Factors).

Not Intended To

- Display a risk factor in other parts of physician workflow (e.g., the risk factors displayed in CDSS notifications outside of the risk assessment module, or suggested treatments in the risk assessment module).

Clinical Context

A provider needs to see essential information about a risk factor to determine its importance and if/how the risk factor should be actioned.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Examples

Risk Factors

All
 Modifiable
 Incomplete
 History
 Observations
 Conditions
 Investigations
 Medications

<input type="checkbox"/> Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/> Age	70 yrs		12 - 17%	<input checked="" type="checkbox"/>	06-Jan-1995
<input type="checkbox"/> BMI <input checked="" type="checkbox"/>	18.3 (L)	18.5 - 24.9	10 - 12%	<input checked="" type="checkbox"/>	03-May-2016 <input checked="" type="checkbox"/>
<input type="checkbox"/> Protein Intake <input checked="" type="checkbox"/>	30 gr/day (L)	50 - 90g/day	6 - 10%	<input checked="" type="checkbox"/>	04-Jun-2019
<input type="checkbox"/> Smoking Status	Current, 1ppd, 50 pack yrs	Cessation	6 - 10%	<input checked="" type="checkbox"/>	23-Feb-2018
<input type="checkbox"/> Grip Strength			6 - 10%	<input type="checkbox"/>	
<input type="checkbox"/> Gait			6 - 10%	<input type="checkbox"/>	
<input type="checkbox"/> Walking 1/2 mile			6 - 10%	<input type="checkbox"/>	
<input type="checkbox"/> Climbing 10 steps			6 - 10%	<input type="checkbox"/>	
<input type="checkbox"/> Dementia			6 - 10%	<input type="checkbox"/>	
<input type="checkbox"/> Physical exercise	No exercise		6 - 10%	<input checked="" type="checkbox"/>	12-Jul-2019
<input type="checkbox"/> Benzodiazepin Medicat...	1 mg - oral - three times...		4 - 6%	<input checked="" type="checkbox"/>	12-Jul-2019
<input type="checkbox"/> Hydrocodone-Acetamin...	5mg/300 mg - oral - twice...		4 - 6%	<input checked="" type="checkbox"/>	12-Jul-2019
<input type="checkbox"/> Inflammation Biomark...	1 of 3		4 - 6%	<input type="checkbox"/>	
<input type="checkbox"/> Genetic Biomarkers	1 of 3		4 - 6%	<input type="checkbox"/>	
<input type="checkbox"/> Muscle Metabolites	10 of 15		4 - 6%	<input type="checkbox"/>	
<input type="checkbox"/> Gender	Female		3 - 5%	<input checked="" type="checkbox"/>	06-Jan-1995
<input type="checkbox"/> Ethnicity	Caucasian		0.5 - 1.5%	<input checked="" type="checkbox"/>	06-Jan-1995
<input type="checkbox"/> Education Level			0.5 - 1.5%	<input type="checkbox"/>	

Rows per page: 18 1-18 of 18 < >

Figure 83: Risk factors

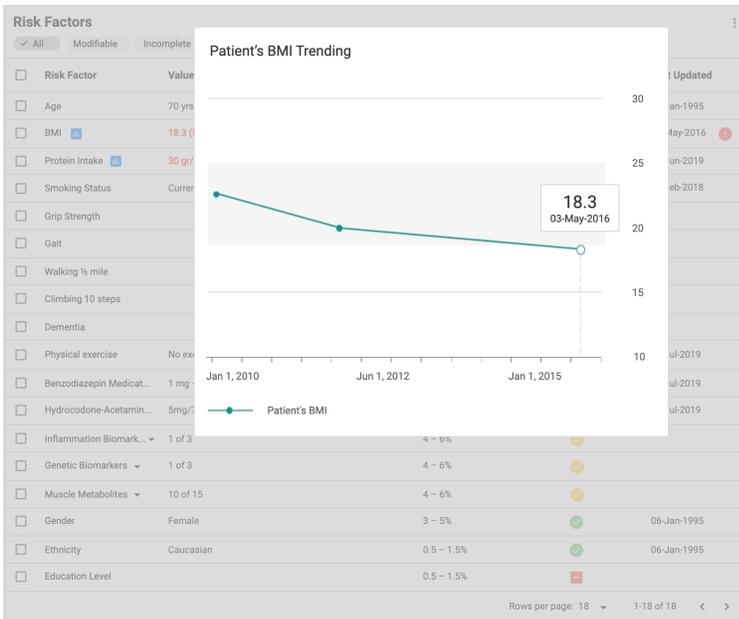


Figure 84: Risk factor value trend

Solution Description

Strive To

- Display the following information for an individual risk factor:
 - risk factor title
 - For a group of risk factors, display the title for the group (e.g., Proteomic Biomarkers).
 - patient's recorded risk factor value
 - For a group of risk factors, leave blank.
 - target range for patient (the desired value range for the patient):
 - Display target range for patient (alternately, if needed, use normal range for similar patient group e.g., grouping by age and gender as proxy).
 - Clearly display the patient's risk factor's relative value if out of bounds of the target range (e.g. low or high or critical high) (e.g., Hemoglobin is 85, which would be LOW)
 - Provide access to information on how the target range was determined.
 - For a group of risk factors, leave blank
 - percentage of contribution to the overall risk score in absolute percentages or a percentage range (e.g., 5-10%)
 - whether a risk factor is modifiable or not
 - For a group of risk factors, indicate modifiable/non-modifiable unless the risk factors in the group are a mix of modifiable and non-modifiable ones
 - patient data last updated date
 - For a group of risk factors, leave blank
- Allow user to see value trending information for a risk factor without switching to other EMR modules.
- Provide access to evidence summary as a linked resource on-demand with clear signposts to information. Include the following in the evidence summary:
 - short description
 - evidence last updated date
 - evidence quality
 - For the grading of evidence quality, use an established and recognizable rating system, such as the Canadian Task Force on Preventive Health Care's GRADE (Bell et al. 2013).
- If a risk factor or a group of risk factors has data quality issues:
 - Specify the data quality issues (e.g., outdated, missing, incomplete, masked, excluded, or potentially erroneous values).
 - Explicitly indicate when a risk factor or a group of risk factors was not included in the calculation of the overall risk score.
- Allow the user to update risk factor values (see Update Risk Factor Value).

Avoid

- Relying on colour alone to highlight important information (e.g., to indicate data quality issues). Use other signifiers in addition to colour.

Other Considerations

- Consider integrating suggested interventions with the modifiable risk factors if this is consistent with the clinical information system's usual workflow.
- If displaying protective factors (e.g., a particular allele or value provide reduction in risk):
 - Indicate that the risk factor reduces risk by prefixing percentage of contribution with a minus (e.g., -4 to -2 %).
 - Use colour to highlight that the factor is protective.

Related Patterns**Used By**

- Display Risk Factors

Uses

- Update Risk Factor Value

U.8 Update Risk Factor Value

Updated: July 12, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to provide guidance for updating an individual risk factor for a health outcome in two contexts: when viewing patient risk factors for a health condition (see Display Risk Factors) and when actioning a suggested intervention (Action Suggested Intervention).

Not Intended To

- Update risk factors in other parts of physician workflow (e.g., the risk factors displayed in CDSS notifications outside of the risk assessment module).
- Address any aspects of unmasking for masked data.

Clinical Context

A provider needs an easy way to update a patient risk factor during a detailed risk assessment workflow. Updating entails documenting patient values such as history, observations, and conditions. It also includes ordering investigations to obtain patient data (e.g., ordering a lab test).

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

Risk Factors						
<input checked="" type="checkbox"/> All <input type="checkbox"/> Modifiable <input type="checkbox"/> Incomplete <input type="checkbox"/> History <input type="checkbox"/> Observations <input type="checkbox"/> Conditions <input type="checkbox"/> Investigations <input type="checkbox"/> Medications						
<input type="checkbox"/>	Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	Age	70 yrs		12 – 17%	✓	06-Jan-1995
<input checked="" type="checkbox"/>	BMI	18.3 (L)	18.5 – 24.9	10 – 12%	✓	03-May-2016
<input type="checkbox"/>	Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%	✓	04-Jun-2019
<input type="checkbox"/>	Smoking Status	Current, 1ppd, 50 pack yrs	Cessation	6 – 10%	✓	23-Feb-2018
<input type="checkbox"/>	Grip Strength			6 – 10%	✗	
<input type="checkbox"/>	Gait			6 – 10%	✗	
<input checked="" type="checkbox"/>	Walking ½ mile			6 – 10%	✗	
<input checked="" type="checkbox"/>	Climbing 10 steps			6 – 10%	✗	
<input type="checkbox"/>	Dementia			6 – 10%	✗	
<input type="checkbox"/>	Physical exercise	No exercise		6 – 10%	✓	12-Jul-2019
<input type="checkbox"/>	Benzodiazepin Medicat...	1 mg – oral - three times...		4 – 6%	✓	12-Jul-2019
<input type="checkbox"/>	Hydrocodone-Acetamin...	5mg/300 mg - oral - twice...		4 – 6%	✓	12-Jul-2019
<input type="checkbox"/>	Inflammation Biomark...	1 of 3		4 – 6%	⚠	
<input type="checkbox"/>	Genetic Biomarkers	1 of 3		4 – 6%	⚠	
<input type="checkbox"/>	Muscle Metabolites	10 of 15		4 – 6%	⚠	
<input type="checkbox"/>	Gender	Female		3 – 5%	✓	06-Jan-1995
<input type="checkbox"/>	Ethnicity	Caucasian		0.5 – 1.5%	✓	06-Jan-1995
<input type="checkbox"/>	Education Level			0.5 – 1.5%	✗	

3 selected

Figure 85: Risk factors – multiple risk factors selected

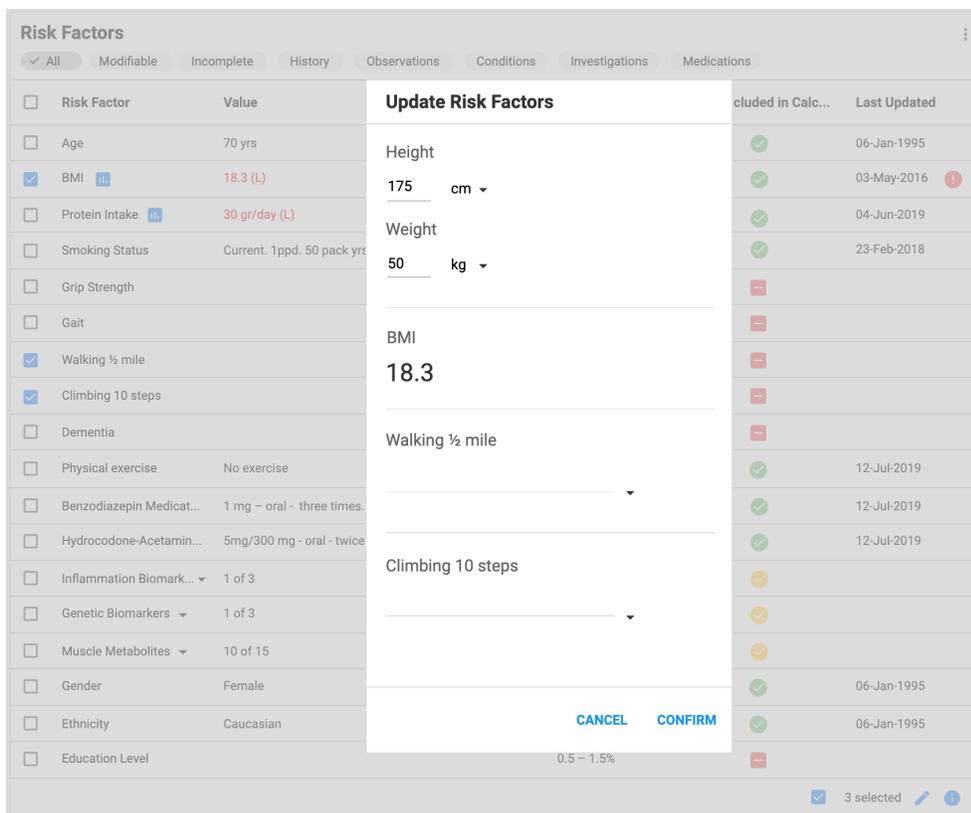


Figure 86: Risk factors – multiple risk factors can be updated

Solution Description

Strive To

- Allow the user to update patient values in the same view where the current state of patient data is displayed.
 - The user should not have to switch to other EMR modules to update patient data.
- Support the management of missing information by allowing the user to document null data values with reasons for the omission (e.g., data item was not possible to capture, omitted at the patient's request, etc.).
- Allow the user to select one or multiple risk factors to update.
- Make it clear to the user when the risk score is updated or not updated based on risk factor value updates. It must be obvious to the user how the system handles data updates.

Avoid

- None

Other Considerations

- Some updating of patient data may require linking to other modules in the EMR (e.g., a MOCA form, lab ordering module)

Related Patterns

Used By

- Display Risk Factors
- Action Suggested Intervention

Uses

- None

U.9 Filter Risk Factors

Updated: July 12, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern provides guidance for filtering patient risk factors that are available in the comprehensive list of patient's risk factors, as part of detailed risk assessment.

Not Intended To

- Address filtering in other parts of physician workflow.

Clinical Context

A CDSS should make the most important risk factors available to the provider by default. However, the provider may need to review the risk factors based on various criteria, depending on the provider's interest. An ability to filter the risk factors allows the provider to narrow down high volumes of information and to surface the most relevant results quickly.

An additional benefit of filters is that they are informative about the content that is being displayed, which is advantageous for users not familiar with the content.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

<input type="checkbox"/>	Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	BMI	18.3 (L)	18.5 – 24.9	10 – 12%		03-May-2016
<input type="checkbox"/>	Protein Intake	30 gr/day (L)	50 – 90g/day	6 – 10%		04-Jun-2019
<input type="checkbox"/>	Smoking Status	Current, 1ppd, 50 pack yrs	Cessation	6 – 10%		23-Feb-2018

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Figure 87: Risk factors – filter option is set to ‘Modifiable’ and top three modifiable risk factors are displayed

<input type="checkbox"/>	Risk Factor	Value	Target	↓ Absolute % Contrib...	Included in Calc...	Last Updated
<input type="checkbox"/>	BMI	18.3 (L)	18.5 – 24.9	10 – 12%		03-May-2016
<input type="checkbox"/>	Grip Strength			6 – 10%		
<input type="checkbox"/>	Gait			6 – 10%		

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Figure 88: Risk factors – filter options are set to ‘Incomplete’ and ‘Observations’

Solution Description

Strive To

- Apply a default filter that displays a small number of top risk factors.
- Provide filter options to surface the risk factors based on various criteria. Note that the filter options have to be congruent with the way the risk factors are grouped into clinical categories. The following filter options are suggested:
 - ‘All’ - all the risk factors for the patient.
 - ‘Top X’ - a small number of top risk factors (a default filter).
 - ‘Modifiable’ - modifiable risk factors only.
 - ‘Incomplete’ - the risk factors with data quality issues (missing, outdated, or masked data).
 - ‘History’ - the risk factors that are classified as subjective data or patient history data (e.g., patient-reported smoking status, diet, sleep, mood).
 - ‘Observations’ - the risk factors that are classified as patient observations data (e.g., weight, height, MOCA, MMSE).
 - ‘Conditions’ - the risk factors that are classified as health conditions and diagnoses (e.g., diabetes, chronic renal failure).
 - ‘Investigations’ - the risk factors that are classified as patient investigations data (e.g., lab tests, imaging).
 - ‘Medications’
- Apply filters to the list of risk factors that is in context.

- A grouped risk factor (e.g., Inflammation Biomarkers) should be treated as a single risk factor on the parent list of the risk factors for the purposes of filtering.
- Individual risk factors within a group should have filters consistent with the filter functionality described in this design pattern.
- Allow multi-select of filter options. This allows the user to find items quickly.
 - Allow the user to multi-select options that can be combined correctly logically.
- If compatible with the UI design for filtering, provide a count of items per each filter option in the filter selector (e.g., All (100), Top 3 (3), Contributing (95)).
- Display applied filters. Showing the ‘applied filters’ separately in a single combined overview list (e.g., ‘Currently showing: Incomplete, Investigations’) allows the user to easily see what filter parameters were selected.
- When filters are applied, hide irrelevant content and only show filtered items.
- Be explicit about the number of items shown and NOT shown in a view for the applied filters.
 - To ensure items are not overlooked, use a count of the total number of items.

Avoid

- Displaying an excessively long list of risk factors in one view regardless of the filter settings. This can occlude important information on the screen. Consider pagination or scrolling if appropriate.

Other Considerations

- None

Related Patterns

Used By

- Display Risk Factors

Uses

- None

U.10 Display Incomplete Patient Data

Updated: July 12, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

This pattern is intended to display incomplete patient data for the risk factors in the risk assessment module. The incomplete data is presented as a separate visual component in addition to the comprehensive list of the risk factors (Display Risk Factors).

Not Intended To

- Display incomplete data for the risk factors in other parts of the physician workflow (e.g., outside of the risk assessment module).

Clinical Context

Calculation of a personalized health risk score requires patient data for the risk factors. The degree of risk score confidence is largely determined by the quality of such data. It is expected that some patient data may be incomplete in an EMR: outdated, erroneous, or not documented. As the list of risk factors for an outcome may be large, highlighting data quality issues in the risk factor list alone is not sufficient. The provider may not review the risk factors during an encounter or review only select risk factors (e.g., the top few).

Explicitly bringing incomplete patient data to the provider's attention in a separate visual component as part of risk assessment is important for the following reasons:

- Knowledge of what is missing may improve the accuracy of the risk score interpretation and clinical decision making.
- Data quality remediation. The provider may be able to update incomplete patient data to improve the risk score confidence (e.g., update a value, order a test). For the intentionally excluded data, such as masked data, the provider may be able to start a relevant conversation with the patient.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

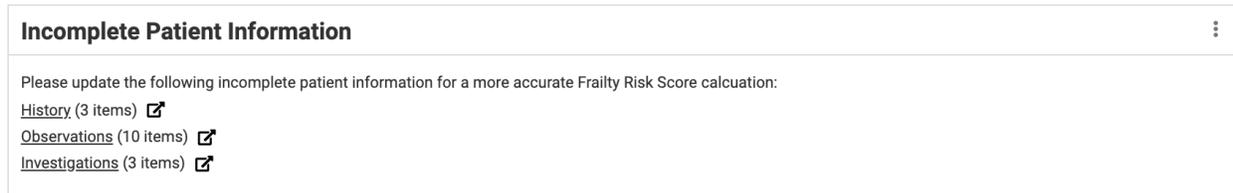


Figure 89: Incomplete patient information panel

Solution Description

Strive To

- Group incomplete data into the following categories: History, Observations, Investigations, Conditions.
 - Display the groups and indicate a number of incomplete data items for each category. For example, History (2), Observations (10), Investigations (3), Conditions (1).
 - Allow the user to view the incomplete data items within each group on-demand.
- Prioritize incomplete data items within each category by the contribution (or potential contribution) to the overall risk score.
- Display details for each data item (see Display Risk Factor).
- Allow the user to update patient data (see Update Risk Factor Value).

Avoid

- Displaying an excessively long list of incomplete patient data items in one view. This can occlude important information on the screen. Consider pagination or scrolling if appropriate.

Other Considerations

- A useful CDSS functionality may be the generation of data quality notifications for the provider and the other health care team members. For example, a CDSS may notify an MOA or a nurse that the patient's BMI or BP are outdated and the MOA may be able to document those measurement prior to the patient's visit with the physician.

Related Patterns

Used By

- Display Health Outcome Risk Detail

Uses

- Display Risk Factor
- Update Risk Factor Value

U.11 Display Health Outcome Risk Detail

Updated: October 9, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to display detailed personalized risk information.

The pattern presents risk information with a broad informational context required for comprehensive risk assessment at the point of care.

NOTE: this pattern includes several other patterns for specific components. Please see the Uses section.

Not Intended To

- Address other types of risk, such as acute condition risks or intervention risks.

Clinical Context

The detailed health risk information can be presented to a provider in an electronic medical record (EMR) by a CDSS in several scenarios:

- Patient or patient's caregivers proactively request health risk information for a specific outcome.
- A CDSS notifies a provider of a potential health risk for a patient and provider decides to assess the risk in detail.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

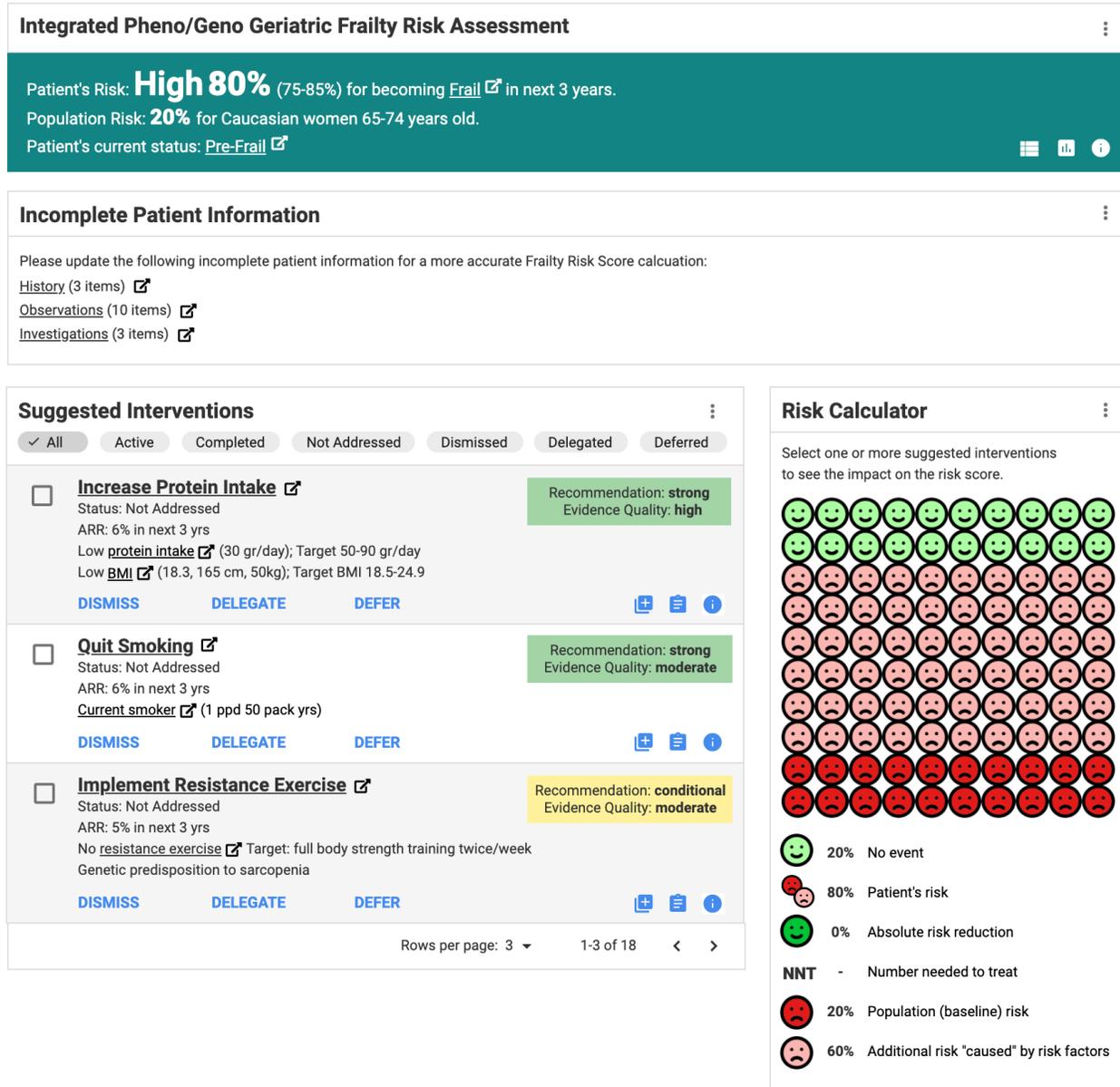


Figure 90: Health outcome risk details – a risk assessment module

Solution Description

Strive To

- Provide a separate CDSS module for detailed risk assessment.
 - The module should be accessible through a notification to assess risk (see Display Health Outcome Risk Assessment Notification) or directly by the user from the EMR.

- Provide sufficient informational context in which to interpret the risk and make clinical decisions (Rothman and Kiviniemi 1999; Weinstein 1999):
 - Display health outcome risk information in a numeric and text format (see Display Health Outcome Risk Sentence).
 - Provide a visualization of the health outcome risk information on-demand (see Visualize Health Outcome Risk).
 - Provide a patient risk trend on-demand (see Display Health Outcome Risk Trend).
 - Provide access to previous risk assessments on-demand.
 - Display patient’s risk factors (see Display Risk Factors) on-demand.
 - Risk factors should be available to the user if the user selects to view them. Providing risk factors on-demand only allows more prominence and screen space for patient’s risk and suggested interventions.
 - Highlight incomplete patient data (Display Incomplete Patient Data).
 - Display suggested interventions to mitigate negative health outcomes (see Display Suggested Interventions).
- Provide access to patient education resources on-demand.
- If patient data do not reach a sufficient quality threshold (i.e., if the risk score confidence interval is too wide):
 - Provide the score.
 - Make it clear to the user that the score has a wide confidence interval.
 - Allow the user to update incomplete patient data to improve the score quality (see Display Incomplete Patient Data).
- Allow the user to access the information about how the CDSS content is generated and how it is displayed (Marcilly et al. 2018). The user should have the necessary information to understand the CDSS capabilities (the algorithms used; types of outcomes/events covered; what patient data are checked; what evidence supports the algorithms, including evidence sources, currency and quality of the evidence).
- Achieve a high-density information presentation.
 - The most important information should be displayed to the user compactly and at a glance.
 - Additional information, of lower priority, can be provided on demand as linked resources.
- Convey the state of the CDSS to the user. If the notifications are not available due to a system outage, it should be made clear to the user. The visibility of system status (Nielsen 1994) is a key requirement for patient safety.

Other Considerations

- None

Related Patterns

Used By

- None

Uses

- Display Health Outcome Risk Sentence
- Visualize Health Outcome Risk
- Display Health Outcome Risk Trend
- Display Risk Factors
- Display Incomplete Patient Data
- Display Suggested Interventions

U.12 Display Health Outcome Risk Sentence

Updated: October 8, 2019

Version: 0.04

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

This pattern is intended to display patient-specific quantitative risk information for a health outcome in a numeric and text format as a sentence. The pattern defines the information components and the structure for the risk sentence. The display of risk information includes sufficient contextual data elements for risk interpretation as needed in the context of the clinical activity.

Not Intended To

- Display risk in a graphical format (see Visualize Health Outcome Risk)
- Display a risk trend (see Display Health Outcome Risk Trend)

Clinical Context

Quantitative risk information in a numeric and text format can be presented to a provider in an EMR by a CDSS in the following scenario:

The provider accesses a CDSS risk assessment module; the module displays a health risk estimate for the patient.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

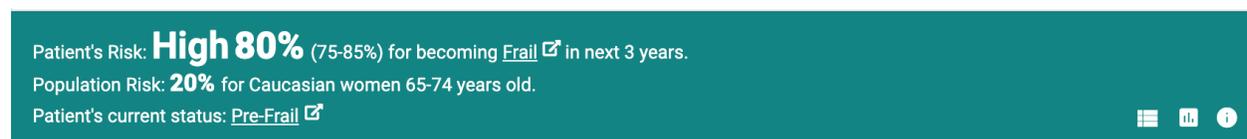


Figure 91: Health outcome risk sentence in a risk assessment module

Solution Description

Strive To

- Display risk in a sentence structure with the following components:
 - Patient's absolute risk in percentages
 - Round the numbers, if appropriate, to avoid decimals.
 - Patient's absolute risk score confidence as a confidence interval in percentages. A key element of risk information is uncertainty (Johnson and Slovic 1995). Risk score confidence expresses the quality of the numerical risk (Peters et al. 2007).
 - Population absolute risk in percentages. The risk for the population with the same characteristics (e.g., age, gender, ethnicity) may be used as a base rate. Provision of baseline information results in more accurate risk estimates (Natter and Berry 2005).
 - The magnitude of patient's risk compared to population risk.
 - Provide information about what population is used for comparison.
 - Indicate which range patient's risk falls into.
 - Use decreased/typical/increased ranges. Such interpretive thresholds can help understand risk magnitude (Lipkus 2007).
 - Consider confidence intervals for the ranges when calculating what range patient falls into.
 - Concrete health outcomes/consequences. Risk can be viewed as a combined function of the probability of loss and consequence of loss (Lipkus 2007).
 - For frailty specifically, consider specifying functional status decline as limitations of specific Activities of Daily Living (ADLs) (Vermeulen et al. 2011).
 - A risk timeframe. The risk score is not informative without a timeframe. Time span chosen for a risk score can influence risk perceptions (Fischhoff, Brewer, and Downs 2014). Short timeframes may be best for achieving risk reduction through behaviour change (Waldron et al. 2011). For example, for frailty, the following timeframe is suggested:
 - 1 to 3 years
 - Patient's current health status, relevant to the risk, if applicable. Current health status provides a patient-specific baseline. For example, for frailty, a current status may be 'robust' or 'pre-frail' or a Canadian Frailty Scale stage (Rockwood et al. 2005).
- Provide access to further details such as definitions, clinical evidence on demand in context, with clear signposts to further information.
- Ensure that the patient's absolute risk and patient's risk magnitude compared to population (risk range) are the most visible information elements on the risk sentence. In some cases, this information is all a provider may need (e.g., if the risk is typical).

Avoid

None

Other Considerations

- Consider allowing the user to configure the criteria for what population is used for comparison.

Related Patterns

Used By

- Display Health Outcome Risk Detail

Uses

- None

U.13 Visualize Health Outcome Risk

Updated: July 15, 2019

Version: 0.04

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to display patient-specific quantitative risk information for a health outcome in a graphical format.

Not Intended To

- Display a risk trend (see Display Health Outcome Risk Trend).

Clinical Context

Quantitative risk information in a graphical format can be presented to a provider in an EMR as part of a CDSS risk assessment module where risk information is elaborated in detail. Risk visualization should be presented in addition to the risk in a numeric and text format (see Display Health Outcome Risk Sentence). Presenting risk information in different formats may facilitate better cognitive fit for different types of information consumers (Lautenbach et al. 2013).

Graphs can make numeric information easier to understand by reducing the amount of mental computation and replacing it with automatic visual perception (Wickens and Carswell 1995).

Visualizations can also help a provider in translating the data to patients. Studies show that when the numeric risk information is accompanied by a graphical presentation, patients tend to perceive risk more accurately (Waldron et al. 2011).

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

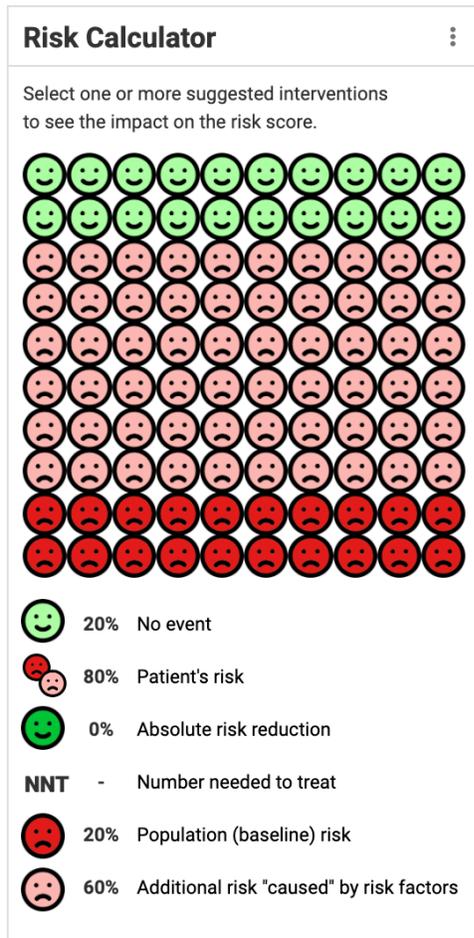


Figure 92: Risk pictograph

Solution Description

Strive To

- Provide a graphical representation of risk.
- Use a pictograph to visualize patient's risk for a specified timeframe.
- Display the following risk information:
 - Patient's absolute risk
 - Population risk
- Use continuous icon arrays, rather random icon arrays, to facilitate visual area judgement (Feldman-Stewart et al. 2000).
- Use icons with human figures (faces or stick figures), rather than abstract images such as asterisks (Schapira, Nattinger, and McHorney 2001). Anthropomorphic icons are preferred by patients and are associated with better risk recall (Zikmund-Fisher 2013).

- Use a square 10x10 icon pictograph (use a denominator of 100) for patient's risk over 1%. For very small risks (<1%), use a sufficiently large denominator (Fischhoff, Brewer, and Downs 2014).
- Accompany the pictograph with a legend and brief text explanations of the visualized data and conclusions to be drawn.
- Integrate the pictograph with the suggested interventions to provide an interactive risk/benefit calculator (see Display Suggested Interventions).

Avoid

- Relying on colour alone to communicate or emphasize information. Use other signifiers, such as captions and text explanations, to clarify what information is displayed.

Other Considerations

- Consider allowing the user to change the granularity of the risk estimates. For broad phenotypes such as frailty this could entail showing the risk for various frailty outcomes (falls, hospitalization, etc.).

Related Patterns

Used By

- Display Health Outcome Risk Detail
- Display Suggested Interventions

Uses

- None

U.14 Display Health Outcome Risk Trend

Updated: October 3, 2019

Version: 0.04

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to provide guidance for how a patient's historical health outcome risk should be trended.

Not Intended To

- Address predictive trending. Only a historical risk trend is in scope.

Clinical Context

A patient's historical health risk trend shows how a quantitative risk score changed over time.

A provider may use trending information when doing a detailed risk assessment. Trending can be a useful tool for both the provider and patient for the following tasks:

Evaluate the patient's trajectory: is the patient's risk increasing or decreasing and at what rate. Assess the impact of implemented interventions (e.g., the patient stopped smoking) or new risk factors (e.g., the patient acquired an infection) on the risk trend.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

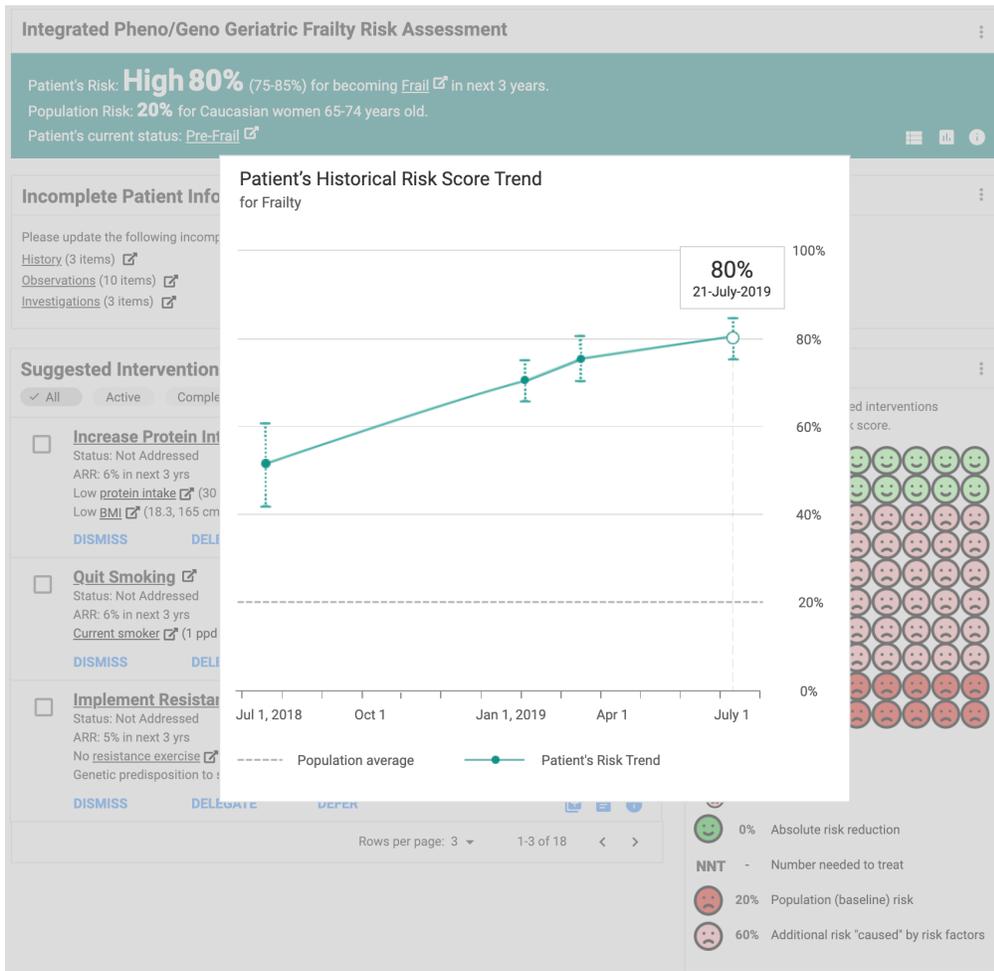


Figure 93: Risk trend

Solution Description

Strive To

- Visualize trending using a time series graph, where each point on the graph corresponds to both a time and a quantitative risk score.
- Display a patient risk trend and a population risk trend in one view.
- For each patient risk score point represented on the graph provide the following information:
 - Patient's absolute risk in percentages
 - The confidence interval for each patient risk score as percentage ranges
- Provide clear labels to explain what information is displayed.

Avoid

- Relying on colour alone to communicate or emphasize information. Use other signifiers in addition to colour.

Other Considerations

- Consider establishing a threshold for patient risk score confidence and only trend risk scores above the threshold. The confidence of an estimated risk is fundamentally dependent on patient data quality which is expected to vary greatly in an EMR (Cruz-Correia et al. 2018). This makes it difficult to compare risk scores with confidence intervals that have significant variability in width. Ensure the user can access information about what data is graphed and how as a linked resource.
- Consider allowing the user to configure what additional data is displayed on the graph, in addition to the patient and population risk trends. For example, allow the user to see points in time for:
 - implemented interventions
 - new significant risk factors

Related Patterns

Used By

- Display Health Outcome Risk Detail

Uses

- None

U.15 Display Suggested Interventions

Updated: October 3, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to display suggested interventions to manage the personalized health risk for a condition. The focus is on the preventive care, including health promotion and mitigation of negative health outcomes. The recommended interventions are patient-specific and are presented as part of a detailed risk assessment.

The pattern focuses on displaying suggested interventions within a singular encounter.

Not Intended To

- Specify how an individual intervention should be displayed (see Display Suggested Intervention).
- Address comprehensive care planning that spans an entire episode of care. Only the suggested interventions within an encounter are in scope.

Clinical Context

Presenting a personalized health risk score without suggested interventions to manage the risk is of little clinical value. Recommended interventions have to be an integral part of a detailed risk assessment.

The suggested interventions would be presented in a detailed risk assessment module as one group of recommendations related to a clinical task (e.g., a task to assess frailty risk). The provider may access the suggested interventions in two ways:

- During a clinical workflow, the provider gets a CDSS notification to assess the patient's risk for a condition. The provider follows up on the notification and accesses the detailed risk assessment module.
- The provider accesses the detailed risk assessment module without a specific CDSS notification. The provider may proactively seek detailed risk information for a given condition, or the patient may request the risk information from the provider during an encounter.

A provider may review the suggested interventions in order to:

- Interpret the risk score and its applicability to the patient. Risk reduction interventions partially determine the significance of the risk score to a patient. For example, if the interventions are not feasible or relevant, the risk score itself may be of limited value.
- Determining a treatment plan. Making informed decisions requires providers and patients to understand the harms and benefits of intervention options.

- Reviewing treatment progress (the extensive details of how a care plan would evolve for an episode of care were not in scope, however, treatment progress would be an important part of ongoing risk assessment).

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

Suggested Interventions		
<input checked="" type="checkbox"/> All <input type="checkbox"/> Active <input type="checkbox"/> Completed <input type="checkbox"/> Not Addressed <input type="checkbox"/> Dismissed <input type="checkbox"/> Delegated <input type="checkbox"/> Deferred		
<input type="checkbox"/>	Increase Protein Intake ↗ Status: Not Addressed ARR: 6% in next 3 yrs Low protein intake (30 gr/day); Target 50-90 gr/day Low BMI (18.3, 165 cm, 50kg); Target BMI 18.5-24.9 DISMISS DELEGATE DEFER	Recommendation: strong Evidence Quality: high
<input type="checkbox"/>	Quit Smoking ↗ Status: Not Addressed ARR: 6% in next 3 yrs Current smoker (1 ppd 50 pack yrs) DISMISS DELEGATE DEFER	Recommendation: strong Evidence Quality: moderate
<input type="checkbox"/>	Implement Resistance Exercise ↗ Status: Not Addressed ARR: 5% in next 3 yrs No resistance exercise Target: full body strength training twice/week Genetic predisposition to sarcopenia DISMISS DELEGATE DEFER	Recommendation: conditional Evidence Quality: moderate
Rows per page: 3 1-3 of 18		

Figure 94: Suggested interventions

Solution Description

Strive To

- Provide suggested interventions in real time. The CDSS should be responsive to the changes in patient data. The CDSS should update, reprioritize, and display relevant interventions dynamically.
- Combine suggested interventions if there are multiple recommendations that are conflicting or similar. Patients with co-morbidities are most likely to have multiple recommendations from multiple sources (Sittig et al. 2008). CDSS should reconcile the recommendations, using clinical evidence, to present one cohesive suggested intervention to the user. NOTE: the combination of conflicting and similar recommendations is not in scope of this study.
- Display a limited number of top priority interventions with the option to view more
 - Prioritize interventions (see Prioritize Suggested Interventions).
 - Allow the user to filter the interventions (see Filter Suggested Interventions).

- Allow the user to access information on how the CDSS content is generated and how it is displayed (Marcilly et al. 2018). The user should have the necessary information to understand what recommendations the CDSS can and cannot generate (what patient data are checked, sources of evidence; the algorithms used, types of conditions/outcomes/events covered; duration of recommendation activation); how the recommendations are prioritized.
- Allow the user to select one or more suggested interventions and add them to plan. Adding interventions to plan would initiate appropriate workflows for the interventions (the details of such workflows are not in scope of this requirement pattern).
- Provide an interactive risk/benefit calculator for the suggested interventions.
 - Integrate the calculator with the risk pictograph (see Visualize Health Outcome Risk).
 - Allow the user to manipulate the results of the risk score by selecting suggested interventions and seeing how altering certain risk factors through interventions might change the risk score on the pictograph.
 - Allow the user to select multiple interventions, including an option to select all suggested interventions, to see the combined impact of the interventions on the risk score. If not possible (e.g., due to the limitations in available evidence), allow the user to select one intervention at a time.

Avoid

- None

Other Considerations

- None

Related Patterns

Used By

- Display Health Outcome Risk Detail

Uses

- Display Suggested Intervention
- Prioritize Suggested Interventions
- Filter Suggested Interventions
- Visualize Health Outcome Risk

U.16 Display Suggested Intervention

Updated: July 16, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to display a suggested intervention to reduce the negative outcomes related to a personalized health risk for a condition. The intervention is presented as part of a group of suggested interventions (see Display Suggested Interventions) in the context of a detailed risk assessment.

Not Intended To

- None

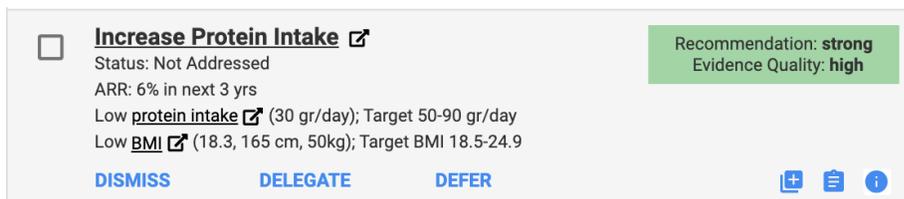
Clinical Context

A provider typically experiences a high cognitive load during a primary care encounter. The cognitive demands would be exacerbated by a detailed risk assessment task which could require making decisions about potentially multiple treatment/intervention options. Therefore, a suggested intervention should provide sufficient and only necessary information and tools for the provider to evaluate the intervention importance and relevance, and whether/how it should be addressed with the patient.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example



The screenshot shows a card for a suggested intervention. On the left, there is a checkbox and the title "Increase Protein Intake" with a link icon. Below the title, the status is "Not Addressed", the ARR is "6% in next 3 yrs", and there are two lines of target information: "Low protein intake (30 gr/day); Target 50-90 gr/day" and "Low BMI (18.3, 165 cm, 50kg); Target BMI 18.5-24.9". On the right, a green box contains the text "Recommendation: strong" and "Evidence Quality: high". At the bottom, there are three buttons: "DISMISS", "DELEGATE", and "DEFER", followed by three small icons: a plus sign, a list icon, and an information icon.

Figure 95: A suggested intervention

Solution Description

Strive To

- Structure the suggested intervention consistently to ensure users can easily find the relevant data (Horsky et al. 2012):
 - Display an intervention title
 - Each intervention should have a unique title

- The title should clearly describe the intervention’s clinical intent
 - The title should be concise
 - The title should be the most visible element of the intervention
 - Display the work status of the intervention: Active, Completed, Not Addressed, Dismissed, Delegated, Deferred
 - The status should be consistent with the notification filter options (see Filter Suggested Interventions).
 - Display a summary of key patient risk factors that the intervention targets. An intervention may pertain to a large number of risk factors (e.g., thousands of genome variants that relate to one phenotype). The risk factors should be summarized adequately (e.g., ‘genomic risk factors’ instead of specific variants presented to the user) and only a small number of the key risk factors should be presented.
 - For each key risk factor provide:
 - risk factor title
 - patient’s recorded risk factor value (e.g., smoking pack years, increased/decrease in inflammation biomarkers)
 - what reference range the value falls into (low/normal/high)
 - target range for patient (alternately, if needed use normal range for similar patient group e.g., grouping by age and gender as proxy)
 - Display the absolute risk reduction (ARR) of intervention as specific to the patient as possible
 - present ARR consistent with the overall risk timeframe
 - present ARR consistent other suggested interventions’ ARR timeframes to facilitate comparison among suggested interventions (Fischhoff, Brewer, and Downs 2014).
 - Display recommendation strength
 - For the grading of recommendation strength, use an established and recognizable rating system, such as the Canadian Task Force on Preventive Health Care’s GRADE (Bell et al. 2013).
 - Indicate the recommendation strength using a word. Consider using a colour or shape, if appropriate (Phansalkar et al. 2010).
 - Clearly differentiate interventions with different recommendation strengths (Marcilly et al. 2018).
- Use clear labels to explain what information is displayed to the user.
- Provide access to evidence supporting the suggested intervention on-demand with clear signposts to information.
 - Ensure the evidence describes the benefits and harms of the intervention.
- Allow the user to add custom content for suggested interventions as part of CDSS settings. Custom content should be added for an intervention type and not a specific intervention instance. Example custom content may include frequently used references or handouts for a certain type of intervention.
- Include actionable tools within the suggested intervention (see Action Suggested Intervention).
- Allow alternative ways to address the suggested intervention. The suggested intervention should be specific but not overly restrictive in how it is implemented (e.g., a suggested intervention may be ‘increase protein intake’; the system should allow the provider to

implement it in the ways most appropriate to the patient such as different changes in diet or supplementation, based on patient's circumstance).

Avoid

- Mandating that the user address the suggested intervention. The CDSS should recommend an action but not require the user to address it unless the recommendation is critical (e.g., a recommendation related to a severe drug-drug interaction).
- Avoid displaying a suggested intervention's Relative Risk Reduction (RRR) alone. If displaying RRR, ARR must also be presented (Fischhoff, Brewer, and Downs 2014).

Other Considerations

- Consider grouping related recommended actions and integrating them into a suggested intervention as sub-actions. One intervention may be composed of multiple clinical sub-actions. For example, a recommendation to 'increase muscle mass' may be composed of multiple recommended sub-actions such as 'increase protein intake', 'introduce resistance strength training'. NOTE: the details of grouping sub-actions was not in the scope of the study.
- Consider how an intervention can have impact on multiple conditions (e.g., smoking cessation or exercise). An intervention may also have a positive impact on one condition but a negative impact on another. Displaying such information was out of scope for the study but presents interesting and important design challenges.

Related Patterns

Used By

- Display Suggested Interventions

Uses

- Action Suggested Intervention

U.17 Prioritize Suggested Interventions

Updated: July 15, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to provide a set of heuristics for prioritizing suggested interventions in the context of a detailed risk assessment.

The suggested interventions are displayed by the CDSS in a detailed risk assessment module (see Display Health Outcome Risk Detail).

Not Intended To

- Specify prioritization criteria for suggested interventions outside of the detailed risk assessments for chronic health conditions. Prioritization rules may be different for recommendations presented in another part of clinical workflow and for other types of health conditions and outcomes.
- Describe how to prioritize the suggested interventions that have a change of state such as suggested interventions that are deferred, declined, dismissed, delegated, or are due for a follow-up. Such suggested interventions may have complex prioritization rules and workflows associated with them and are out of scope for this pattern. See also Filter Suggested Interventions for different states of suggested interventions.
- Define a precise prioritization algorithm.

Clinical Context

As part of a detailed risk assessment, the provider will be presented with suggested interventions to reduce the adverse health outcomes related to the risk. A CDSS may generate a large number of recommended actions with varying degree of relevance to the patient. The relevance is based on the evidence for the recommendation and patient-specific context.

Given the constraints of a typical primary care encounter, only the top priority recommendations should be presented to the provider by default.

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

N/A

Solution Description

Strive To

- Use a patient-specific prioritization model based on an individual patient's status at a given point in time (Downs and Uner 2002).
- Prioritize suggested interventions based on:
 - Absolute Risk Reduction (AAR) of the intervention
 - severity of outcomes
 - evidence quality
 - recommendation strength
 - For the grading of evidence quality and recommendation strength, use an established and recognizable rating system, such as the Canadian Task Force on Preventive Health Care's GRADE (Bell et al. 2013).
 - healthcare system factors:
 - availability of intervention
 - coverage
 - patient-specific factors:
 - intervention feasibility
A recommendation strength takes into account an intervention's feasibility and costs (to the patient and society) on a population level. However, it is important to consider the feasibility to a specific patient. Different patient with the same risk factors may have different circumstances and access to healthcare. The interventions that are easier and more realistic to implement successfully for a given individual should be prioritized.
 - patient-specific cost of intervention
 - patient's documented care goals
Patients may have different values and preferences for the care process and outcomes.
- Allow the user to customize the prioritization criteria.

Avoid

- None

Other Considerations

- Consider showing/hiding a suggested intervention based on the provider's role. For example, some interventions may have privacy implications.

Related Patterns

Used By

- Display Suggested Interventions

Uses

- None

U.18 Filter Suggested Interventions

Updated: October 9, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The design pattern is intended to provide guidance for filtering the suggested interventions that are presented as part of a detailed risk assessment for a chronic health condition (see Display Suggested Interventions).

Not Intended To

- None

Clinical Context

A CDSS may generate a multitude of recommended interventions to reduce adverse health outcomes related to the risk.

CDSS should present the most clinically relevant interventions to the user. However, the user may need to review the list of suggested interventions based on different criteria of interest. An ability to filter interventions allows the provider to narrow down high volumes of information and to surface the most relevant results quickly.

Another benefit of filters is that they are informative about the content that is being displayed, which is advantageous for users not familiar with the content.

Users

This design pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

The screenshot shows a 'Suggested Interventions' interface. At the top, there are filter buttons: 'All' (selected), 'Active', 'Completed', 'Not Addressed', 'Dismissed', 'Delegated', and 'Deferred'. Below the filters, there are three intervention items, each with a checkbox, a title, status, ARR, and details. Each item has a recommendation and evidence quality box, and action buttons (DISMISS, DELEGATE, DEFER) and a menu icon.

Intervention	Status	ARR	Recommendation	Evidence Quality
Increase Protein Intake	Not Addressed	6% in next 3 yrs	strong	high
Quit Smoking	Not Addressed	6% in next 3 yrs	strong	moderate
Implement Resistance Exercise	Not Addressed	5% in next 3 yrs	conditional	moderate

Figure 96: Filter options for suggested interventions

Solution Description

Strive To

- Apply a default filter that displays a small number of top priority suggested interventions, for example display top 5.
- Provide the following filters:
 - 'All' - all the suggested interventions for the patient.
 - 'Active' - interventions that are in the process of being addressed by the patient and provider (i.e., work in progress).
 - 'Completed' - interventions that have been addressed and are considered completed.
 - 'Not Addressed' - interventions that have not been addressed yet.
 - 'Dismissed' - dismissed suggested interventions.
 - 'Delegated' - suggested interventions that are delegated to other providers.
 - 'Deferred' - deferred suggested interventions.
- If compatible with the UI design for filtering, provide a count of items per each filter parameters in the filter selector. For example, All (10), Dismissed (3).
- Display applied filters. Showing the 'applied filters' separately in a single combined overview list (e.g., 'Currently showing: deferred') allows the user to quickly and easily see what filter parameters were selected.
- When filters are applied, hide irrelevant content and only show filtered items.
- Be explicit about the number of items shown and NOT shown in a view for the applied filters.

- To ensure items are not overlooked, use a count of the total number of items.

Avoid

- None

Other Considerations

- None

Related Patterns**Used By**

- Display Suggested Interventions

Uses

- None

U.19 Action Suggested Intervention

Updated: July 15, 2019

Version: 0.03

Authors: Dr. Morgan Price, Iryna Davies

Status

Validated

Intended To

The pattern is intended to specify the options that a user should have for explicitly actioning and documenting the actions for a suggested intervention presented by the CDSS (see Display Suggested Intervention).

Not Intended To

- Describe the specific workflows for actioning the intervention. The pattern focuses on describing what options the provider should have, but not how each action should be implemented in detail. Each type of intervention may have various workflows that are not in scope of this pattern.

Clinical Context

A provider's decision about a CDSS recommendation should be easily translated into action (Marcilly et al. 2018). A provider may simply ignore the suggested intervention or act on it in some way and not document the actions. However, to facilitate the provider's workflow and sound documentation practices, the CDSS design should strive for an optimal cognitive fit between the UI and provider's intentions - the fit of technology to task (Vessey and Galletta 1991).

Users

This pattern is aimed at all primary care providers, such as physicians, nurse practitioners, nurses, and allied health professionals. NOTE: The focus was on primary care physicians; the scope may change based on the scope of practice.

Visualization Example

The screenshot shows a card for a suggested intervention. On the left, there is a checkbox and the text 'Increase Protein Intake' with an external link icon. Below this, it says 'Status: Not Addressed', 'ARR: 6% in next 3 yrs', and two lines of clinical data: 'Low protein intake (30 gr/day); Target 50-90 gr/day' and 'Low BMI (18.3, 165 cm, 50kg); Target BMI 18.5-24.9'. At the bottom left are three buttons: 'DISMISS', 'DELEGATE', and 'DEFER'. At the bottom right are three icons: a plus sign, a list icon, and an information icon. On the right side of the card, there is a green box containing the text 'Recommendation: strong' and 'Evidence Quality: high'.

Figure 97: A suggested intervention

The dialog box is titled 'Dismiss recommendation?'. It contains five radio button options: 'Not relevant' (which is selected), 'Patient declined', 'Addressed elsewhere', 'Not feasible to action', and 'Other reason'. Below these options is a text input field labeled 'Notes'. At the bottom of the dialog are two buttons: 'CANCEL' and 'CONFIRM'.

Figure 98: Dismissal options for a suggested intervention

Solution Description

Strive To

- Provide functionality for documenting the intervention action plan.
 - The documentation options should align with the intervention workflow. A workflow can include clinical documentation templates (e.g., forms, SOAP notes), handouts, and other tools.
 - The documentation should be structured and computer-interpretable to support the CDSS.
- Allow the user to update patient data for the relevant risk factors (see Update Risk Factor Value).
- Provide quick access to other parts of the patient's medical record that allow the user to see relevant detailed patient information (e.g., a link to the prescription module or lab results).
- Allow the user to manage an intervention over time. Provide options for the following tasks:
 - Dismiss the intervention.
 - Require a reason for dismissal. The user must specify one of the following reasons:

- ‘not relevant’
- ‘patient declined’
- ‘addressed elsewhere’
- ‘not feasible to action’
 - Allow additional notes for the dismissal reason.
 - Defer the intervention. For example, for X time or N number of visits.
 - Delegate the intervention to another provider.
- Clearly indicate how the suggested intervention was actioned by the user or other providers. Over time, a suggested intervention may be viewed by multiple providers or the same provider multiple times. Previous actions and decisions should be clearly visible with data on who last actioned the suggested intervention, how, and when.
- Record user actions and history of changes in the patient’s medical record.
- Ensure feedback on user actions to the CDSS to improve the generation and prioritization of suggested interventions.

Avoid

- None

Other Considerations

- Consider integrating the model of change into the options for actioning a suggested intervention.

Related Patterns

Used By

- Display Suggested Intervention

Uses

- None