Your Data Your Choice

A Design Jam on Modernizing Health Care Consent Models to Unlock Health Innovation

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Also, a big thank you to the Privacy team at NLCHI for helping set up for the Design Jam event and to Dr. Charlene Simmonds and Mercy Dhlakama from the Health Research Unit, Memorial University and Perfect Day for their assistance in preparing this report.

Executive Summary

Health innovation and research can enhance healthcare and the services offered to patients across Canada. At the same time privacy protections are essential. We want to ensure that individuals maintain control of their information and that patients are willing to continue to participate in the health innovation and research ecosystem. Privacy must be supported as an enabler of innovation, not a barrier to it. This requires a shift in dialogue and an overall innovative approach to a dynamic consent process that ensures transparency and trust are at the heart of new technology and innovation.

Key Features Include:

Dynamic Consent Isn't a One Stop Deal

Accommodate Changing Contexts

Give Choice

Active Control for Patients

Check Back With Patients Over Time

Transparent

Account for Changing Preferences

Consent Literacy (Is Consent Simple?)

Clear Ownership to Drive Modern Consent

Introduction

> The models for consent and privacy ingrained in the health care system struggle to keep up with recent technological advances in health innovation.[1]

Background

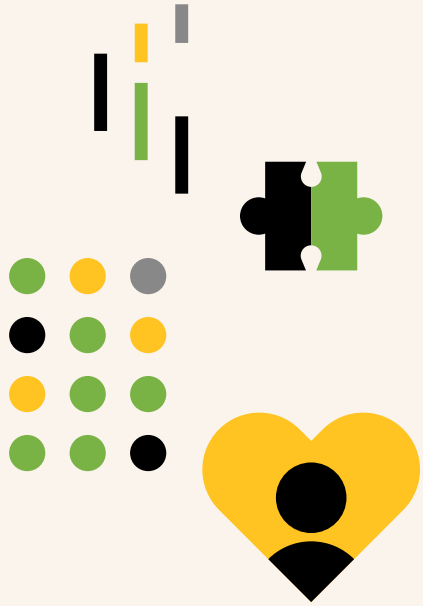
Health innovation is a major focus across Canada and the globe. Healthcare innovation includes those activities that generate value in terms of quality and safety of care, administrative efficiency, the patient experience, and patient outcomes.[1] Efforts are underway to transform health care by leveraging technology and data so that provinces and territories trail-blaze new ways to offer medical treatment and services. This shift has resulted in exciting innovations and the emergence of health-related commercial companies and startups across Canada. The results are increasing public-private partnerships, expansive interest in health data and more and more wearables, remote patient monitoring devices, 3D printing, Artificial Intelligence (AI) and many other innovation pursuits that have the potential to radically transform our health system.

Herein lies the challenge and increased tension. Privately run companies and startups must move at a fast pace to capitalize on their investments and provide evidence that the innovative technology, service or other offering provides value and benefit to the health care system. Companies require a nimble public health system to respond to requests for data to test, deploy or provide such proof. The health care system and regulatory environment are struggling to keep up with the pace of innovation and traditional models for consent and privacy can lag behind current technological capabilities. Hence, custodians of personal health information and privacy oversight bodies are often viewed as barriers to innovation and change.

Obtaining meaningful consent can be both bewildering and unpredictable for data custodians who bear responsibility for the data and for companies or health researchers seeking access to data. Patients and the public are similarly challenged in choices about the use of their health information. It is time to rethink how to manage privacy and consent to consider new models for real time, dynamic consent. The modern consent design jam was focused on putting patients at the heart of health innovation pursuits.

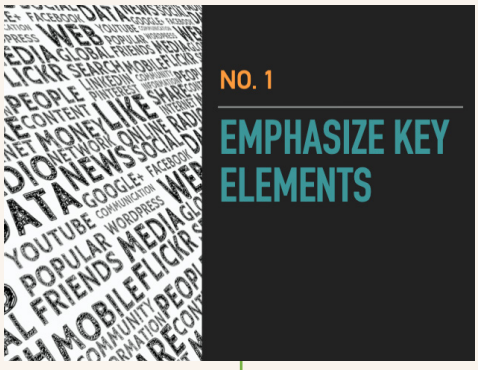
What is a Design Jam?

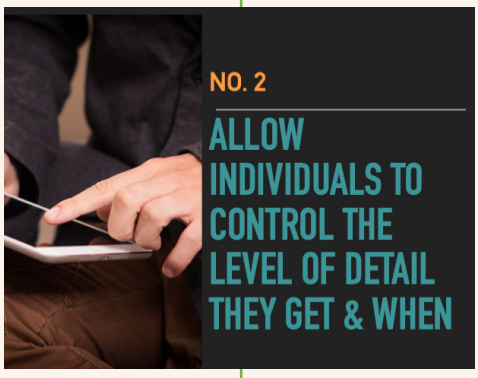
A design jam is an informal group brainstorming session, helping to identifying potential solutions to a given problem in a creative, collaborative way.

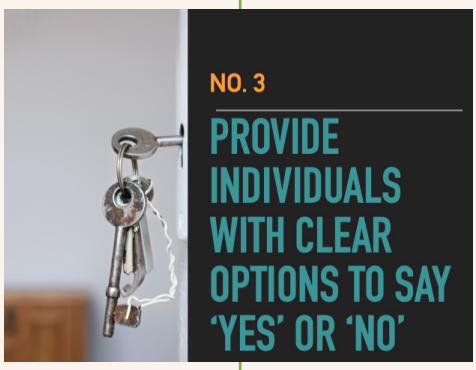


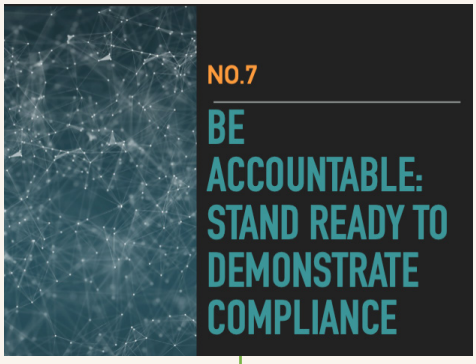
Our Approach

The Design Jam focused on the OPC's Guidelines for obtaining meaningful consent,[2] and aimed to identify modern consent solutions that view consent as a process and not just a one-time endeavor. The guidelines were displayed throughout the venue and participants were encouraged to reflect on and integrate these into their thinking throughout the Jam.









Project Goals

Generate new knowledge to ensure consent is upheld, while enabling health innovation across the health ecosystem.

Increase awareness and understanding on how data is shared with private innovation companies and how to put patients preferences at the forefront.

Identify potential modern real-time consent solutions.

Bridge the gap between public entities that hold personal health information and the private sector that seeks to access to health data.

Shift the dialogue and leverage privacy as an enabler for innovation and public-private partnerships.

> The planning team met monthly to determine the primary goals of the Design Jam

Project Planning Team

Multiple and diverse stakeholder perspectives were included during the Jam and on the project team. The planning committee included stakeholders from Memorial University, The Regional Eastern Health Authority, Government of Newfoundland and Labrador, Hacking Health, Bounce, the Newfoundland and Labrador Centre for Health Information and Canada Health Infoway. Patient perspectives were solicited throughout the planning stages through consultation with members of the patient advisory council of the CIHR-SPOR NL SUPPORT Unit.

What We Did

> The Design Jam assessed where and how consent could be embedded in the health system and beyond to ensure we maximize consent opportunities and patient choice.

The Event

The Design Jam was a sprint-like event, spanning one day, in which a broad range of participants (researchers, patients, clinicians, computer programmers, privacy professionals, decision makers, etc.) came together to collaboratively address how to enable meaningful consent.

Opening Panel Discussion

The Jam began with a panel discussion that set the stage for the day. Questions posed by the Facilitator to the panel included:

- What is happening today that is shifting the health landscape?
- Why is data important, who wants it and why?
- What are the biggest challenges with consent today? Research? Innovation?

Discussion with panelists and the audience was lively and engaged.

In keeping with the interdisciplinary nature of the planning team and the design of the day, the panel included a range of consent perspectives.

Cris Carter
Patient Representative

Carole Piovesan
Innovation Representative
Federal Digital Charter

Sean Murray
Regulator Representative
Office of the Information & Privacy Commissioner NL

Brenda Wilson
Health Research Representative
Associate Dean, Community Health & Humanities, Faculty of Medicine, Memorial University

Meshari Alwashmi
Innovation Representative
Chief Scientific Officer, BreatheSuite

Angela Power
Facilitator

Design Jam Solutions

In order to look for new opportunities to enable patient choices, we first looked at how and when patients interact with the health system. We distributed the opportunities across six domains or potential opportunities to enact informed consent. These opportunities—or potential consent solutions—included: online MCP renewal, hospital kiosks, patient portals, research portals, point of clinical care, and mobile apps. Overall, consent choices for how personal (health) information cannot be an afterthought.

A novel part of the Jam was the composition of working tables. Each consent table included a mix of stakeholders including patients, clinicians, privacy regulators, provincial government decision makers, commercial innovators and researchers. This unique set up ensured a wide mix of perspectives was applied to the consent focus of each table.

> Patient choices and desires need to be considered throughout patients' entire journey through the health system and must be built into the design and fabric of our health technology and processes.

Working Tables

MCP Renewal

These participants explored how consent for the use of personal health information might be possible through the process of provincial health card renewal. Provincially, NL is moving towards an electronic portal for common public services (such as MCP renewal, vehicle registration, etc.) and this group explored whether and how obtaining consent might be possible through this venue.

Hospital Kiosks

These participants focused on how patient kiosks used for appointment/procedure check in at hospitals and healthcare clinics could be used as a mechanism for consent.

Patient Portals

Participants in this group explored how the province could introduce electronic patient portals that would be another potential solution for obtaining consent. They explored what kinds of consent could be obtained through such portals (e.g., for research, proxy clinical care decisions, etc.) and how the interface might look.

Researcher Portals

This group was tasked with thinking about how a research portal could be created to support patient choice and consent about ethics-approved research projects.

Point of Care

Participants in this group brainstormed how patient consent is currently handled at the point of clinical care and whether this consent stop in the patient's journey could be an avenue for other consent opportunities (e.g., research, data sharing).

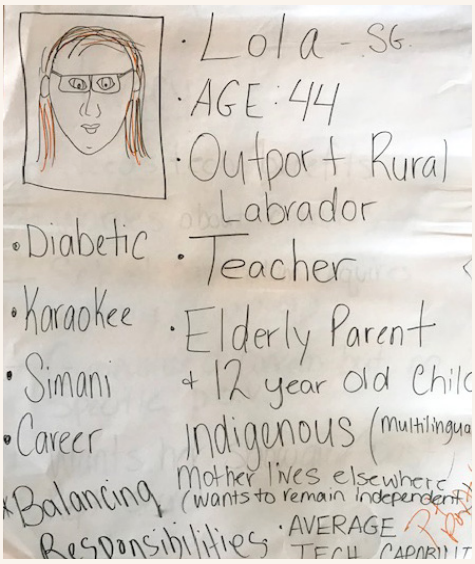
Mobile apps

This group brainstormed consent opportunities and challenges in mobile applications and considered how current consent mechanisms on mobile apps might be modified to support a modern consent solution.

> Including patient perspectives and opening dialogue amongst privacy folk and innovators was paramount.

> The goal was to live a day in a patient's shoes so that meaningful ideas were generated.

What was in the Jam?



The Jam followed a format similar to a Hacking Health event and was comprised of several stages: **Define/Empathize**; **Ideate**; **Prototype**; and **Pitch and Pick**. These are briefly explained below.

Define/Empathize

In the first phase each group was charged with creating a hypothetical patient profile and encouraged to empathize with this patient as he or she moved through their potential consent solution. There were no limits set on who these hypothetical patients could be—e.g., youth, seniors, living in rural or urban areas of the province, working or retired, member of a minority group, any education or income level, and so on. In this way, multiple patients and their hypothetical lives and beliefs about consent could be conceptualized, providing some context for consent considerations.

Ideate

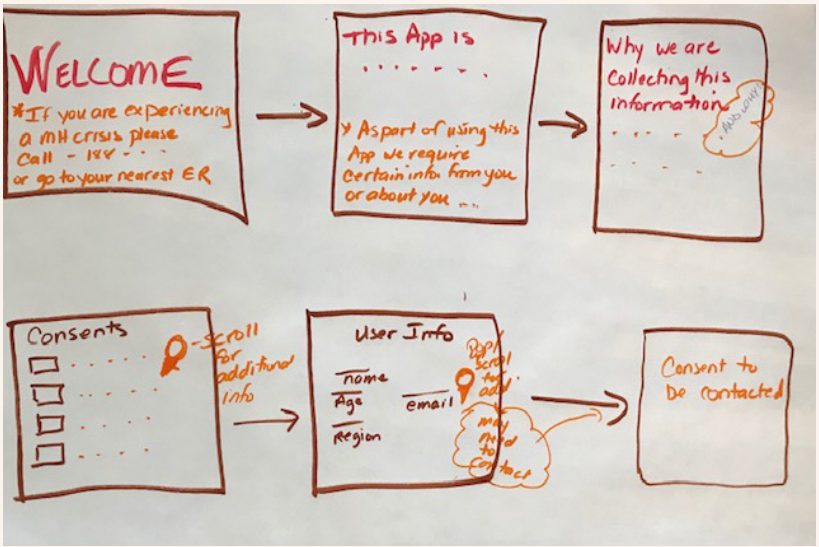
In the second phase groups were asked to brainstorm how obtaining consent might look in the context of their table scenario. They were encouraged to think broadly, outline best case scenarios, identify challenges to what they were proposing and to write down any and all ideas using flip charts, sticky notes, and drawings. The goal in this phase was to generate as many ideas as possible.

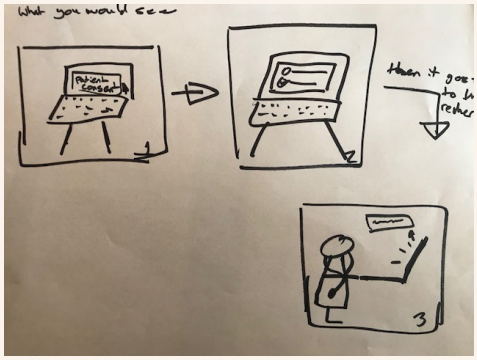
Prototype

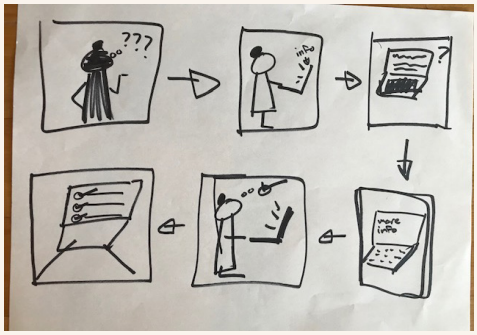
In the third phase groups were tasked with narrowing down their ideas for obtaining consent in their scenario and to begin to graphically depict how a consent prototype could actually look (e.g., internet pages, app interfaces, specific language that might be used to present consent opportunities, etc.).

Pitch and Pick

In the final phase all groups reported back to the larger group. A goal here was to identify similarities and differences among the consent solutions and to identify the most promising consent prototypes. The top two prototypes were chosen by the morning panel and received a prize for their efforts.







What We Found

> "Everything we touch collects our data, from phones to fitbits."

Panel Discussion & Audience Feedback

Panel members posed challenges and opportunities related to consent for the use of health information. The following key themes were raised by panelists and in the lively audience discussion that followed:

Consent literacy

A key challenge is a lack of awareness of how personal data is collected and used in this digital age. Participants noted how cell phones are feeding information back to companies continuously; even children's games downloaded to a cell phone are producing personal data that is tracked.

Despite the need to increase consent literacy, workshop participants also noted consent fatigue, recognizing that no one wants to read small print terms and conditions, nor spend copious amounts of time reading consent forms.

Ultimately, we need to create a society of critical thinkers who have the ability to navigate the digital world and changing landscape of consent. We must enhance digital literacy, begin a concerted public discussion about consent in an effort to build awareness of the current uses of our health information, and put in place mechanisms that allow innovation without quashing our democratic right to privacy.

Social licence for the use of personal health information

Closely related to the notion of consent literacy is the need for a social licence. Google, Amazon, and other tech companies are essentially data mining companies and are collecting personal data on the assumption that they have social licence from the public to do so. Design Jam attendees questioned whether such a social licence truly existed. Do consumers really know what they are providing consent for? Attendees recognized we all love the ability to "Google anything" for free (so we think), but as one attendee noted, "we pay with our privacy."

A critical need is to advance the conversation about this social licence with the public, and this is clearly linked to the public's current knowledge and awareness of how their information is being used and shared, as well as how we can put patients' wishes and desires at the heart of our consent models. A wider public discussion and consideration on patients and public desires is needed around the use and sharing of data, as well as consent. What do we want as a Canadian society? Ultimately, as one decision-maker noted, "It's very important that we have the social licence to proceed."

Privacy in a digital world

It was recognized that the healthcare system is still very paper-based and slow, with practitioners often working in silos. Today, however, there are alternatives that make it easier, convenient and faster to access healthcare. An example was shared of an app that allows patients to consult with a doctor and have a prescription in hand within minutes. Attendees noted that this trend can undercut the healthcare system: There is no sharing of information with patients' providers, but the app company now has access to at least some of patients' health information. As one participant noted, "Google knows everything, but my doctor doesn't."

Some attendees suggested we need to change how we think about the public and private sectors as these are merging in some ways. For example, Alexa is using the NHS database to give medical advice; private companies are a part of virtual healthcare delivery. The traditional way of providing healthcare is lagging behind. The need to protect patient privacy in this virtual healthcare landscape was noted as a serious challenge. There are also limitations to what we can accomplish with consent in the context of certain private enterprises (e.g., 23&me and Ancestry.com). "There is nothing more identifying than your genome sequence; but my DNA is my daughter's DNA." Thus, we may need to consider different models for consent when there is the potential for impact on others.

The need for diversity

It was recognized that Canada's diverse population makes it challenging to ensure everyone is adequately informed about potential uses of their health information. Differences in language and/or culture need to be explicitly considered in consent materials and mechanisms. Thus, a key question is how do we ensure that we provide diverse and culturally-appropriate information to patients in a way they understand (in a healthcare delivery, research or commercialization context)?

> Consent cannot occur in a vacuum. We need to provide multiple opportunities to check back in with patients and find out whether their wishes have changed over time.

There is a need to consider how to uphold privacy in this digital healthcare landscape.

In the context of consent for health research and decisions about healthcare treatment, it was recognized that many segments of society have not traditionally been represented, raising questions about the applicability of treatments to which patients consent, but may not be applicable. For example, the health research data upon which many treatment models are founded are comprised of a very select group of people (e.g., white, male, wealthy). A clinician noted, "The entire practice of medicine is based on a 70kg Caucasian male." Thus, better diversity across health research and innovation initiatives is sorely needed. How do we ensure marginalized individuals get the same opportunities (e.g., those who do not have access to technology) to provide meaningful consent?

Can access to data and innovation be achieved while respecting consent and privacy?
Attendees generally agreed this was possible, though highly challenging. It was suggested that a central "group" is needed to guide innovation and research and oversee new technology. This group must have a standards team who reviews all technology and provides the seal of approval; initiatives must meet all security and privacy provisions. Further, this group must have the power to hold parties accountable in the event of breaches.

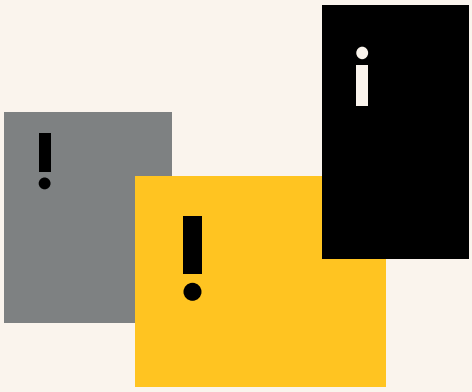
Attendees also suggested a need to find the line between personal responsibility (what are we sharing/when) and a societal responsibility (ways that government can give people back control of information). This will require us to improve our consent models to allow patients to make decisions on the use of their personal health information.

Potential Consent Solutions

Research Portal

This group focused on how to alert potential participants about research projects.

Reaching patients is an important first step in an iterative process. A broader consent may be required in order to first make contact with patients about health innovation opportunities. The current system for initial contact about research or health innovations is problematic in that only a person in patients' direct circle of care can make contact. It also means that inappropriate mining of health records may be the only manner to obtain a list of patients who are a match for a potential health research or innovation opportunity. For example, if there is a new diabetes app it can be quite difficult to obtain a list of patients to trial the new technology unless a clinician identifies the patient. Opportunities are lost. This means many patients are simply not aware of research and innovation opportunities, which itself can be unethical. Any endeavor for a consent for contact should be province-wide, administered first through all provincial hospitals, clinics, etc. where patients must register for an appointment or procedure, and ultimately funded and governed by the provincial government (administered and managed daily by the province's health authorities).



A research alerts service would be accompanied by early and ongoing public information campaigns to raise awareness of the service.

General Overview

All patients registering at any provincially-funded healthcare service facility would be asked by the reception staff if they would be interested in joining a 'research alerts' service. A one-page information sheet would be available to patients explaining the purpose of the service is to allow patients to consent to giving their contact information to be informed about ethics-approved research projects and/or health innovation opportunities. They would

be advised that adding their contact information to the service did not mean they were agreeing to research, only that they agree to being contacted about potential projects. If patients consented at the point of registration to be contacted, the reception staff would add their name and contact information to the service database. At the time of consenting to be contacted, patients may be given the option to choose what type of research projects they want to be notified about (e.g., all research, cancer research, etc.). If patients wanted to think about the request to provide contact information for the alerts service, appropriate contact information would be included on the one pager and patients would be encouraged to use it if they wanted to consent at a later date.

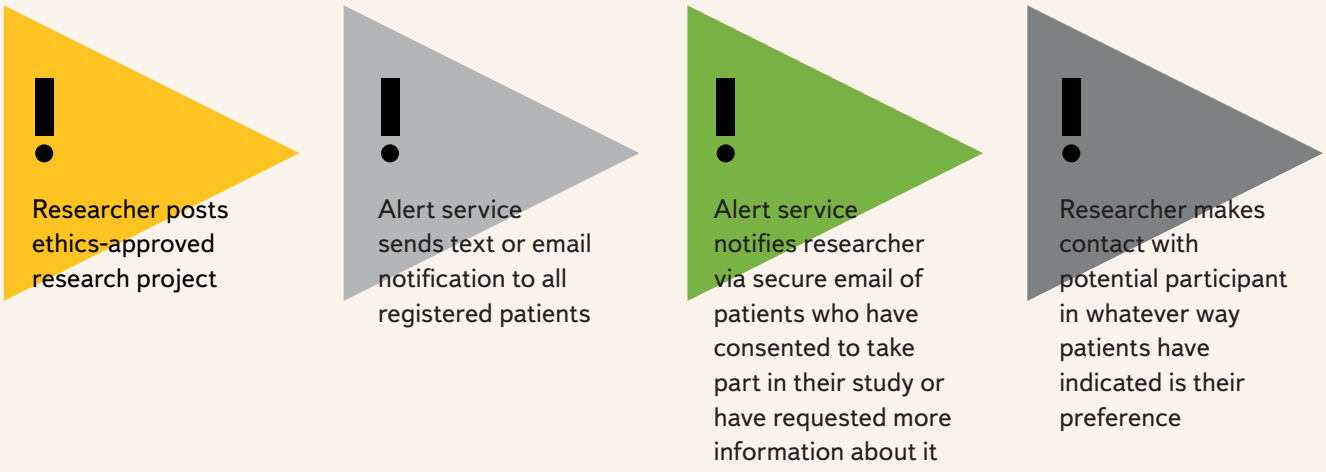
We envision giving patients choice at the time of initial request to receive alerts via text message or email notification. Depending on resources (e.g., funding, staff), we envision eventually being able to allow notification by phone call or mailout.

At the time of rollout, researchers would also be advised about the alert service and encouraged to use the service as a place to post their research projects. Memorial University and the health authorities would have to coordinate efforts to advertise and encourage use of the research alerts service. A run-in phase of aggressive advertising and public information campaigns would be needed in order to build awareness.

When a researcher posts a research opportunity, all registered patients receive a text or email notification about the project (according to their preference). Contact information will be available for each project, and ideally, a live chat box option is available for each, so patients and researchers can interact in real time. At least to start, we envision a way for patients to post thoughts and questions for each project that researchers will have to monitor and respond to as they see them.

As projects are posted, and depending on where they are in the recruitment process, patients can consent to taking part immediately or to agree to be contacted by the research team for more information. In either case, the alerts service would contact the research point of contact by secure email with patient names and contact information and with direction (e.g., consented to take part or requesting more information).

Draft Prototype



A **Research Alerts Service**, funded and managed by the provincial government, likely through health authorities. Reception staff province-wide ask patients at point of check-in if they consent to being part of the alert service. Supported by an early and ongoing public information campaigns to raise awareness of the service.

Mobile Applications

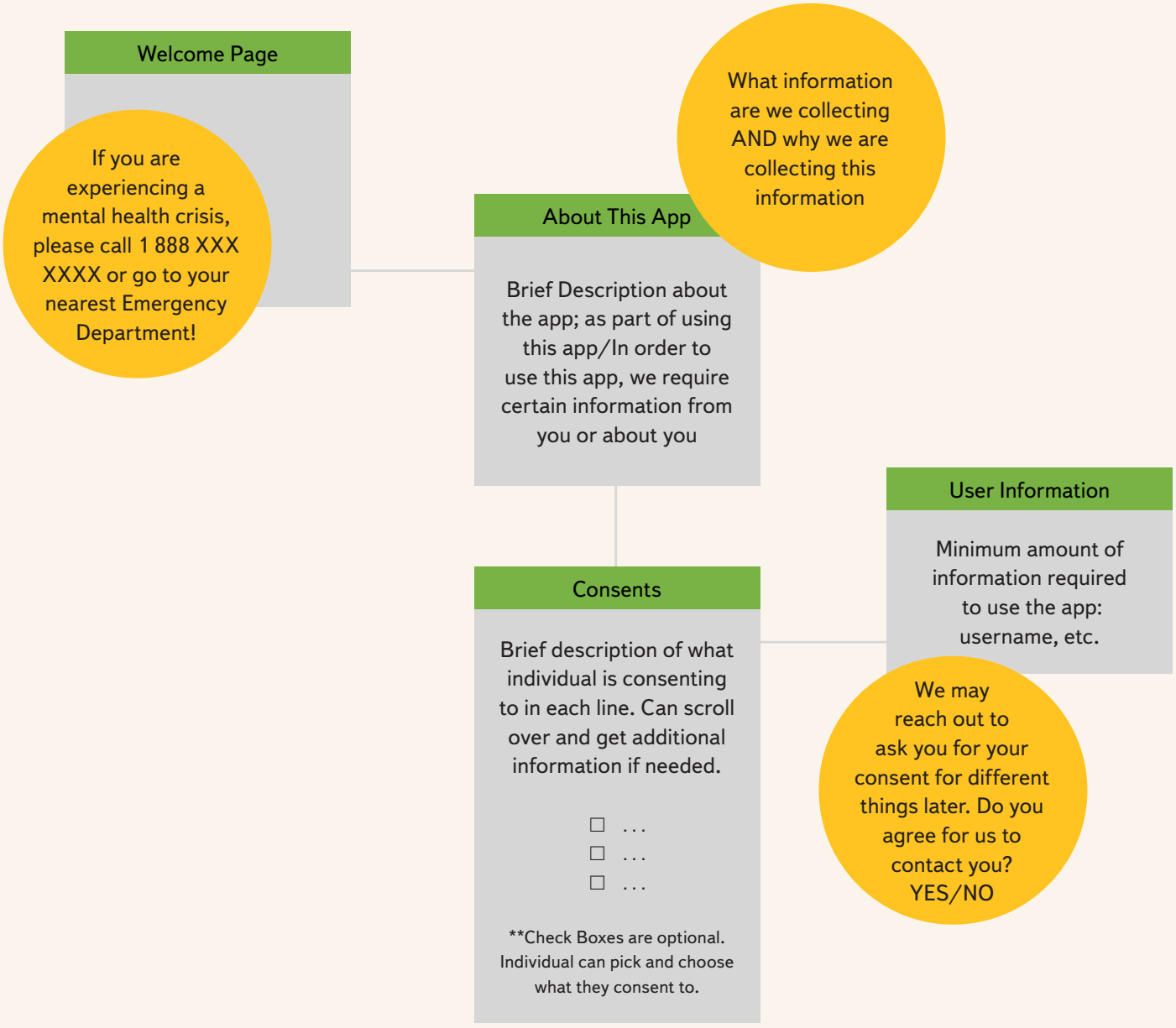
This group created a user persona, Gary, a 25 year old rural resident of NL who works out of province and experiences isolation and loneliness. The app considered was a mental health app.

Summary of Key Points

- Consent is contextual—acknowledge Gary's situation and reason for consulting the app.
- When signing up for the app, a brief overview of the app would be given, along with a notice that in order to use the app, some personal information would be collected.
- Explicitly point out that there are privacy implications to using this app via a pop up notice.
- The amount of personal information requested should be the minimum amount required for app operations and nothing else.
- A list of information being asked for is presented that users can scroll over to see the rationale for collecting that information and what is done with it—this should be a best practice for all apps.
- Terms and conditions should be a checklist.
- If the app developers wish to add on additional uses/ disclosures of information in the future, the user must be contacted and re-consented. All of this should be in plain language, with itemized checklists that the person has to respond to actively.
- Consent should also be revocable with clear instructions on how to do that.

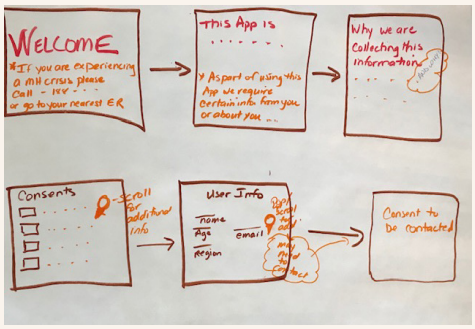
- It is important to check in at a later point to ensure that Gary understands what he consented to, and whether he still consents.
    - POP UP CHECK IN: This is what you previously consented to. Do you still agree?
- Right care; Right Person; Right time
    - Different consent for different situations/ different purposes (e.g. when in mental health crisis vs. when not in a crisis).

Prototype: Mobile App



MCP renewal

This group's user persona was a 40 year old working professional Mom living in urban NL. She is generally knowledgeable about privacy, and has high expectations about privacy, technology, convenience, and ease of use. She requires detailed information to feel comfortable making decisions and is concerned about transparency and compliance.



Summary of Key Points

- Improvements in current renewal process could include the use of visuals, audio, clicks to consent page, the option of a family profile, as well as a feedback option (e.g., opportunity for users to provide feedback about the process they are interacting with).
- There should also be evidence for compliance (thus building trust).
- MCP registration would need to be a separate process from any kind of consent (for research, innovation, etc.). Users cannot provide consent at this interface, but could agree to be contacted for more information. This information would only be presented after MCP renewal and it would be clear that this is a separate and distinct process.

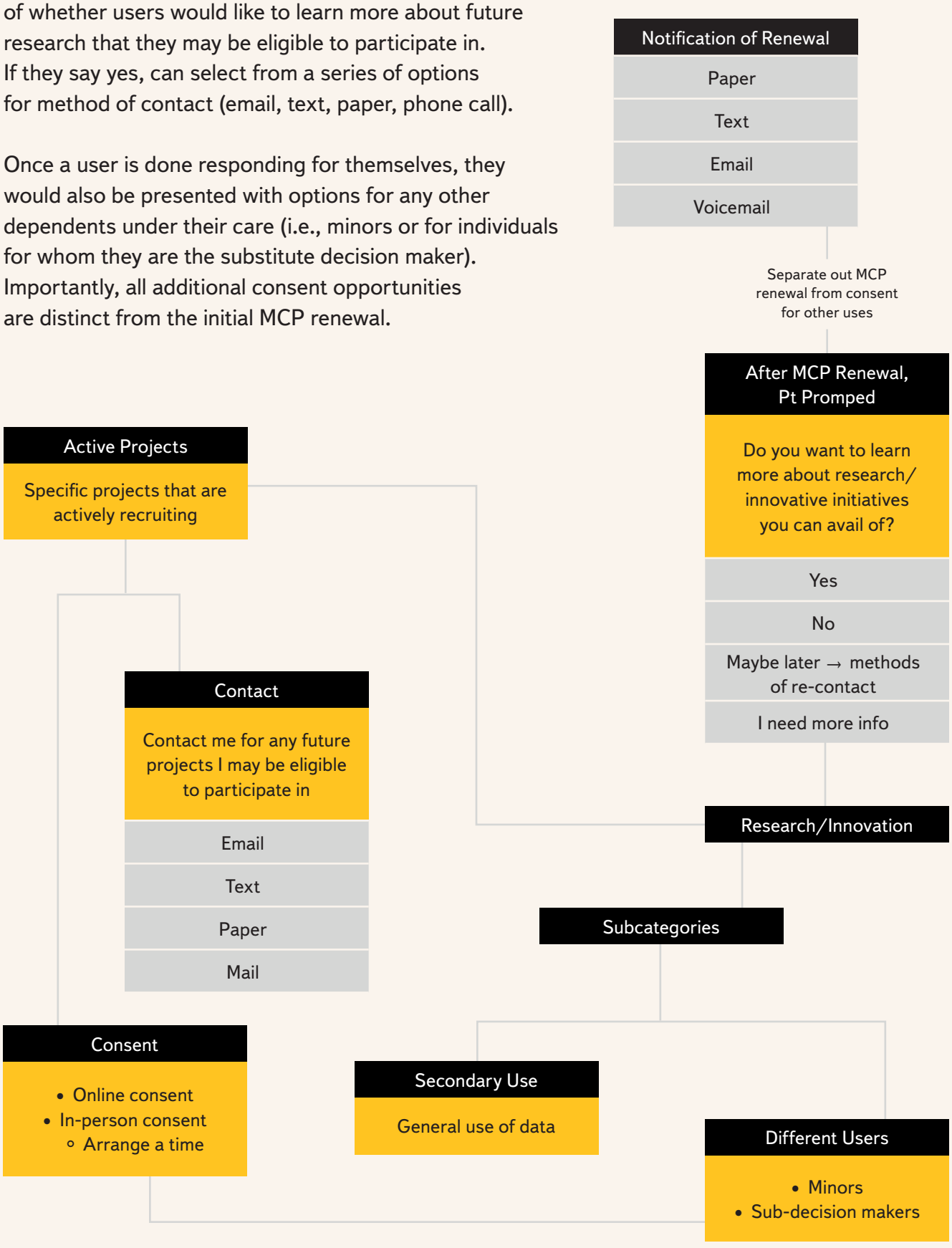
Three options available: yes, no, and I would like more information. Have constant feedback loops to have more information provided. There should be the ability to ask questions in real time—when online, use a robot; provide availability to call or discuss something in person.

If a patient selects yes, for research or innovation opportunities for example, the system could then drill down into subcategories (e.g., different areas of focus for research). An online system would be populated with all ongoing projects that are recruiting participants in that subcategory. If a user selects a project, they will be presented with a variety of consent options (e.g., online consent, or if they prefer an in-person consent model, they can request this and will be taken to a calendar with specific dates to choose from to meet with the project PI).

There would also be another category of possibility of whether users would like to learn more about future research that they may be eligible to participate in. If they say yes, can select from a series of options for method of contact (email, text, paper, phone call).

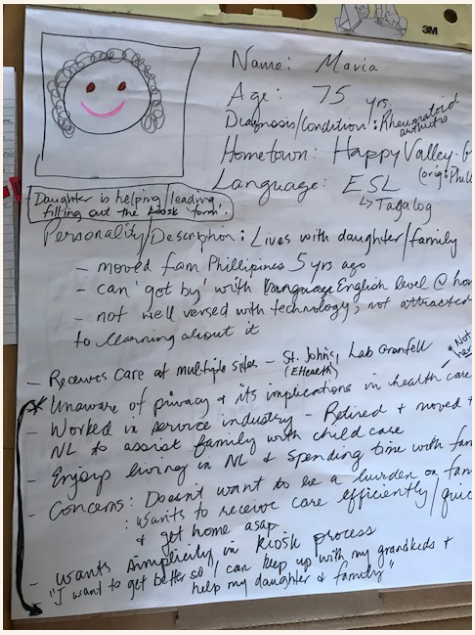
Once a user is done responding for themselves, they would also be presented with options for any other dependents under their care (i.e., minors or for individuals for whom they are the substitute decision maker). Importantly, all additional consent opportunities are distinct from the initial MCP renewal.

Prototype: MCP Renewal



Patient Kiosks

This group discussed how consent for the use of personal health information could be enabled at patient kiosks in healthcare settings (e.g., hospitals, clinics, pharmacies). The table's user persona was Maria, a 75 year old patient with Rheumatoid arthritis living in Labrador. Maria is originally from the Philippines, lives with her daughter and has limited English. She is not technology proficient and has little interest in learning about it. The privacy of her health information is not on her radar.



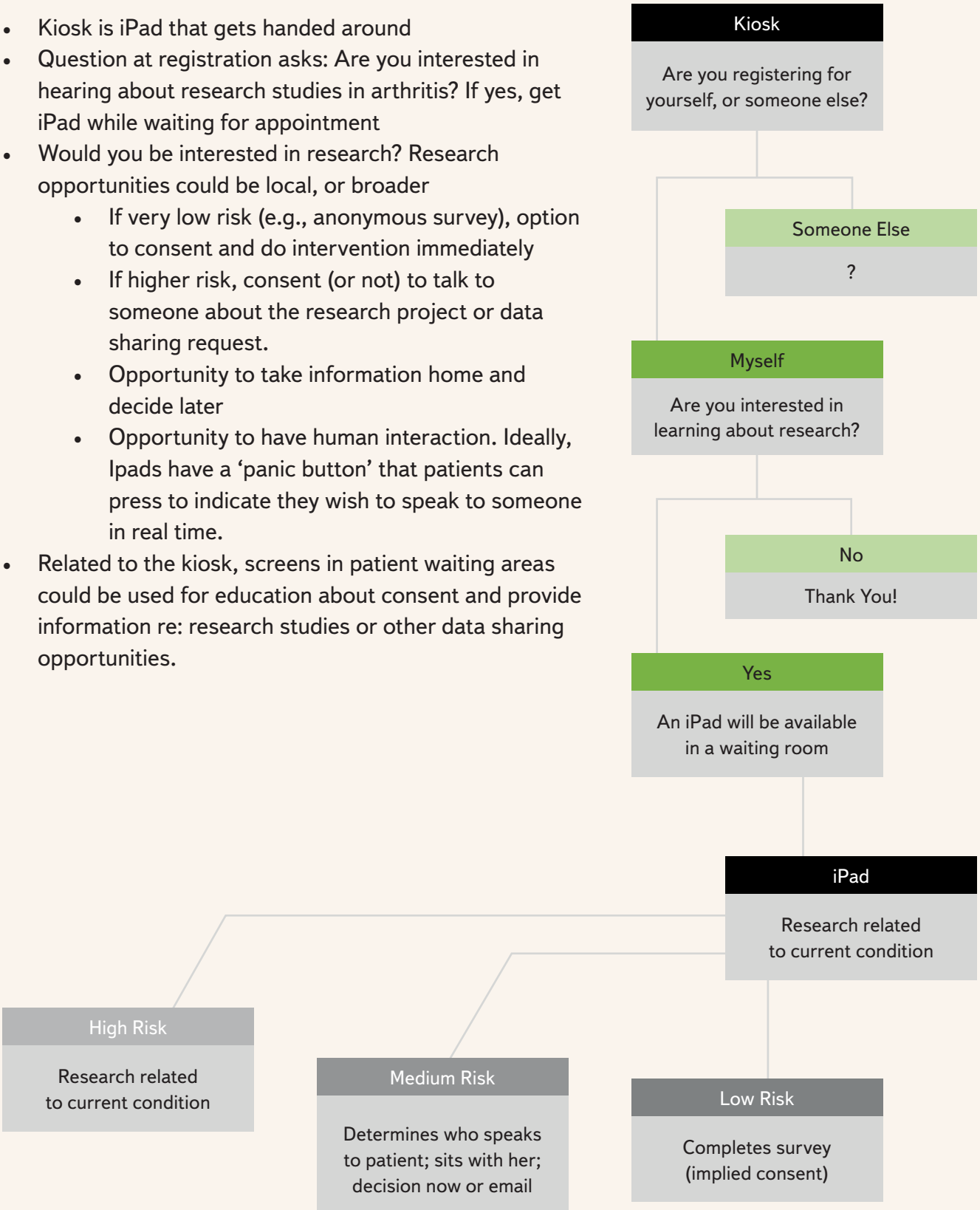
Summary of Key Points

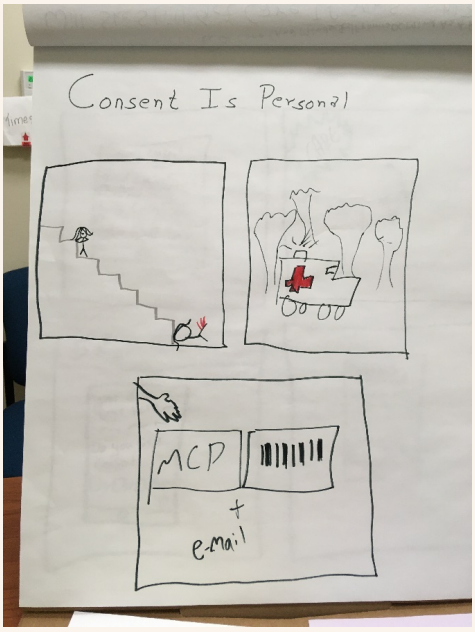
- The kiosk process must be simple and quick given patients are on the way to appointments. The ability to register from home is useful if technology is available.
- Acknowledge that family members may be helping patients register at the kiosk for appointments or other healthcare services.
- The kiosk speaks and is interactive; could consider games to make it interesting.
- The kiosk uses a patient's name once he or she registers
- The kiosk is on wheels so it can be moved to patients in the case of limited mobility
- Once initial registration is complete, a Pop-up window could present a research or commercial request for data—what the goal is, how patients might personally benefit. Patients are asked if they would like more information while waiting for their appointment. If yes, an iPad kiosk will be available at the waiting area.
- A Pop-up window could also ask—e.g., Can we send you more information about data sharing? Would you like your name to go into a database for contact about future research?
- The kiosk has a FAQ section. Ideally, a "Floater" is available at kiosk—a staff person to answer questions; in the ideal setting, there are multiple floaters speaking multiple languages available.
- iPad Kiosk would also be available while waiting for appointments (more below).

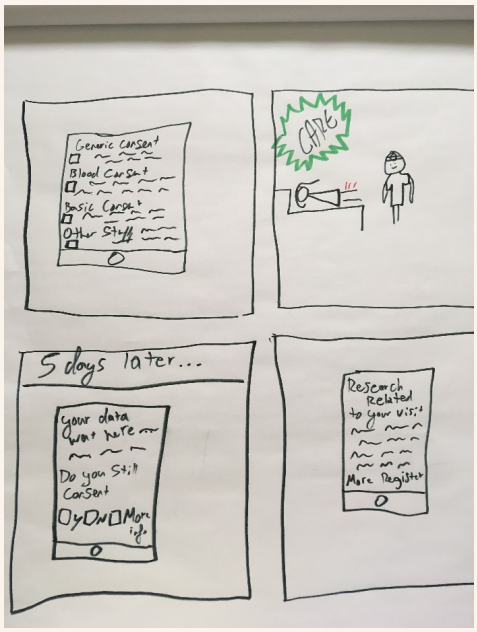
Kiosks at waiting areas for appointments/procedures in health settings:

- Kiosk is iPad that gets handed around
- Question at registration asks: Are you interested in hearing about research studies in arthritis? If yes, get iPad while waiting for appointment
- Would you be interested in research? Research opportunities could be local, or broader
    - If very low risk (e.g., anonymous survey), option to consent and do intervention immediately
    - If higher risk, consent (or not) to talk to someone about the research project or data sharing request.
    - Opportunity to take information home and decide later
    - Opportunity to have human interaction. Ideally, Ipads have a 'panic button' that patients can press to indicate they wish to speak to someone in real time.
- Related to the kiosk, screens in patient waiting areas could be used for education about consent and provide information re: research studies or other data sharing opportunities.

Prototype: Self-Registration Kiosk







Point of Care (face-to-face)

This group's user persona was Darlene, a 53 year old, divorced Mom with a Grade 10 education. She lives in rural NL and worries about providing for her family. She doesn't trust the government and doesn't really understand what is meant by the privacy of her health information.

Summary of Key Points

- Patient's electronic medical record, pharmacy data, etc. are linked to patient's MCP#
- At point of care, patient's MCP links to all patient data:
    - If patient is accessing care in an emergency situation, consent is presumed but data links provide care providers with current list of meds, health status (chronic conditions e.g., diabetes, allergies, etc.) deemed relevant to immediate care needs
    - Advance directives to particular interventions could be linked as well (e.g., no blood products for patients who are of the Jehovah's Witness faith)
    - Patient could restrict access to parts of medical record deemed 'sensitive' that would be accessible only with explicit consent
- When patient is stabilized and capable, explicit consent can be obtained for ongoing care
    - Advance directives can be revisited
    - Permission to access restricted aspects of record can be revisited

Patient profile could generate list of research studies, data sharing requests or innovation opportunities for which the patient might be eligible.

- Patient could agree to be contacted about particular research projects or could defer deciding to be contacted to a later time

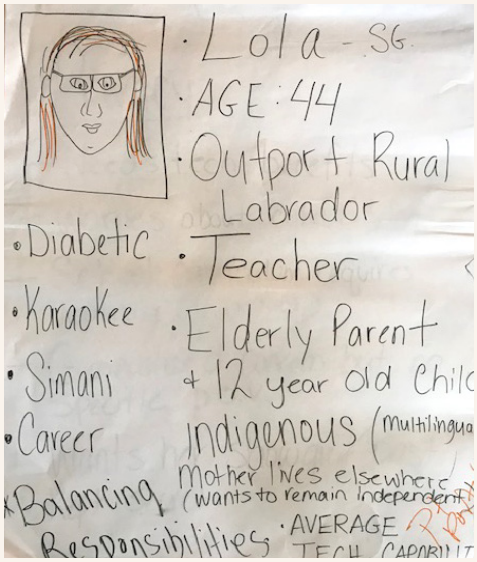
- Could have a list of options for research contact (e.g., Never, ask me again in 3/6/12 months) etc.
- Similar list of options could be available with regard to controlling access to PHI for research purposes

Guiding principles

- Dynamic consent: a patient's state of mind at the time of care may be altered if they are in an emergency and require care immediately.
- Patient compromised by point of care context. Efforts must enable consent, but not introduce influence by person asking for their consent
- Needs to be able to "recall" data if consent changes (e.g., opportunities for consent withdrawal must be available)
- Simplify the language, consider visual approach to consent (watch a video), use pictures
- Consent navigator to answer questions
- Guide or cheat sheet for the physician to use when consenting. In an appointment with a physician, using EMR, perhaps a notification pops up identifying the patient meets requirement for an ongoing study. The physician can ask the patient if they would like more information or get consent to be contacted later
- Alternatively, patients can be given a website or a QR code to scan get more information about the project and how data is used.

Prototype

- Consent is personal and process of consent needs to be dynamic
- MCP card is scanned
- Via a cell phone or tablet a person completes a "consent" questionnaire (dynamic consent)
- Individual can revisit their consent at any point in the future



Patient Portal

The user persona created at this group was Lola, a 44 year old teacher living in rural Labrador. She is responsible for both a 12 year old child and a senior parent who still lives in their own home (and wants to remain independent). She has diabetes, is Indigenous and speaks several languages. She has average tech capabilities and understands a little about privacy with general concerns, but no specific view.

Key Summary of Points

In order to embed consent, the capability of the patient portal or a Personal Health Record (PHR) needs to be known and a plan for patient education about the portal would need to be in place. Given that a patient portal provides patients with direct access to their personal information, it is the ideal location to control who has access to that information, particularly as it relates to third parties for innovation projects or initiatives.

Consent Management services could be enacted in three areas:

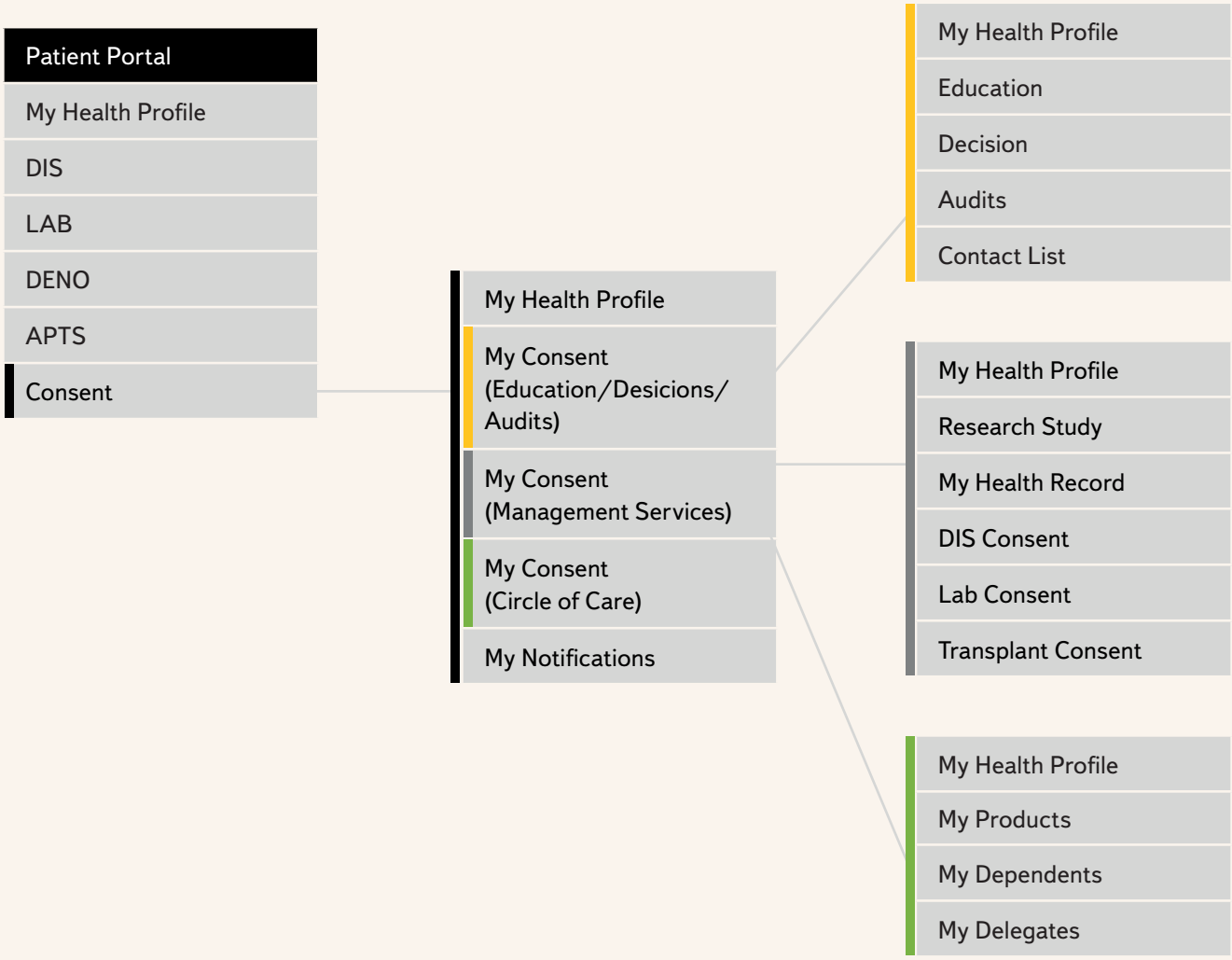
1. Medical—e.g., DNR or other care preferences
2. Research—selecting what to be involved in
3. Data Privacy—controlling access to different domains such as pharmacy, medical imaging or other record level information.

Patient portal ideas

- Manage one's own consent—patients must have an option where they can review what they consented to and have the ability to withdraw without submitting a formal request
- The portal should allow patients to dedicate responsibility to someone—such as a caregiver or someone with power of attorney and the opportunity to revoke these decisions or dedicate another should be present
- All users should have the ability to view their own profile, but also any for whom they are responsible

- All users should be able to use the portal to participate in their own care (e.g., ability to turn on or off notifications such as upcoming appointment messages)
- All patients need to understand the Patient Profile capabilities; an 'ask a question/leave a comment' box would be useful. A contact list of individuals for further information should also be available on the portal.
- The portal would ideally support more than one language and have a simple interface.
- The portal could support a research section that allowed patients and researchers to communicate or at least allow patients to express interest/ask questions about research studies.

Prototype: Patient Portal



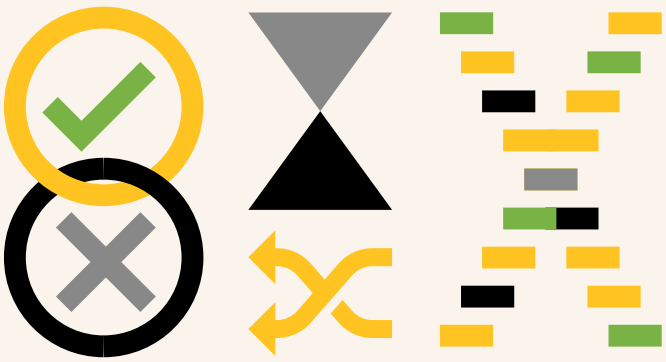
Key Features of Modern Consent

Most group discussion focused on consent for health research or innovation opportunities (whether in clinical contexts or not).

Across all potential consent solutions, a need for some kind of 'system' or 'database' was noted, usually to function as a clearing house of consent opportunities and/or a catalogue of patient contact information and contact preferences. Most groups suggested the implementation and ongoing management of such a system would require dedicated provincial government or federal resources, including personnel and infrastructure, as well as third party oversight to implement privacy and technical safeguards.

While very similar concepts arose across groups, slight differences emerged that suggested a one-size-fits-all consent solution was not endorsed for all consent contexts. Genetics research and innovation contexts were specifically noted as needing a distinct process given the familial nature of this health information. Emergency clinical care was another area noted as requiring a delayed approach to consent for anything other than the emergent care.

However, key overarching principles emerged across all consent solution scenarios that correspond well with the OPC's guidelines for obtaining meaningful consent. The Design Jam suggested the following be part of a modern consent solution for the use of personal health information.



Dynamic

Use more than just text in all consent contexts; incorporate visuals, audio, and interactive online features (e.g., bots and pop-up features)

Accommodate changing contexts

There must be a separate and distinct process for consent in various situations patients find themselves (e.g., clinical care, registering for an appointment, renewing MCP card). However, all solutions could present the option to consent for future contact. In this way, a bank of patient contact information is maintained that becomes an initial contact list where research or innovation opportunities are later presented. For in-person, non-emergent clinical encounters, patients can be prompted at the time of check in whether they wish to hear about research or innovation opportunities while waiting for appointments.

Give Choice

Choice in how patients want to be contacted with future consent opportunities should be presented whenever feasible (e.g., mail, text, phone, email).

Active Control for Patients

Active choices should be the norm in all consent contexts—e.g., patients have to actively respond to consent opportunities (whether clicking online or scrolling over information before proceeding, or verbally for in-person situations).

Check Back and In With Patients

In keeping with a dynamic and active consent model, patients should have the ability to review their consent preferences at any time in online situations or at least at regular intervals during in person encounters (what research or innovation/data requests have they consented, or consent for ongoing clinical care, advance directives, etc.).

Transparent

Essential information (e.g., why is data being collected and who will access it) must be provided in real time for all consent solutions, with the ability to read/attend to more in-depth information at a later time or immediately according to preference.

Account for Changing Preferences

Consent must be revocable and patients must be actively prompted at regular intervals—e.g., in online situations, this can easily be offered via pop-up boxes that specify what the patient initially consented to with a follow up question about whether they still consent.

Consent Literacy

Resources must be dedicated to increasing consent literacy more broadly, recognizing that not everyone has the same level of understanding about the potential uses of their personal health information. Some working groups recommended using current resources better—e.g., use of video screens in patient waiting rooms to increase consent literacy or current patient registration kiosks. This seems a logical place to initiate efforts to increase consent literacy. Gone are the days of terms and conditions and 20 pages consent forms that mean very little or are hard to understand.

Ownership to Drive Modern Consent

Provincial governments, potentially through the health authorities, must dedicate ongoing resources to implementing, managing and evaluating consent solutions.

Implications and Future Work

> Canadians must be assured that privacy is an enabler of innovation, not a barrier to it.

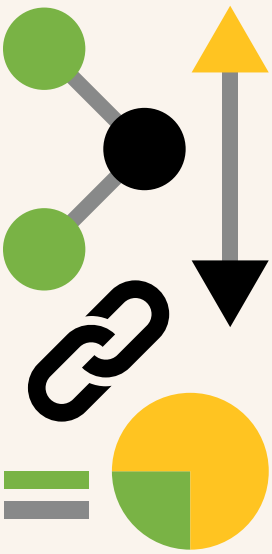
Going Forward

Health innovation and research can enhance the provision of healthcare and the services offered to patients across Canada. However, privacy protections are essential if we are to ensure that individuals maintain control of how information about them is collected, used and disclosed, and are willing to continue to participate in the health innovation and research space. This requires a shift in dialogue and an overall innovative approach to a dynamic consent process that ensures transparency and trust are at the heart of new technology and innovation.

The Design Jam explored where and how consent could be embedded in the health system to ensure we maximize transparency about uses of personal health information and patient choice. At least six different consent solutions were explored and most fit well within a dynamic consent model—generally referring to personalized, online consent and communication platforms.[3] While such platforms are designed to facilitate a flexible, ongoing consent process, patients must be able to set up their preferences regarding interest in projects, access to their data by third parties, read through consent information at their leisure, and specify how often and by what means they would like to be contacted about uses of their personal health information.

Dynamic consent models have been used in several recent clinical and population health research projects and are welcomed by patients and researchers.[4,5] The solution

enables patients to control access to their information, while allowing data users to know exactly which level of privacy risks patients are willing to take and what data can or cannot be used for which purposes. Consent preferences can be updated or changed at any time and the platform would allow the secure storage of consent records, providing a reliable and fully tracked audit trail. The technology for a Dynamic Consent platform could be developed to meet security standards with expectations similar to requirements for electronic health records;[3,6] the platform could also be linked to other health information systems such as patient electronic records or laboratory management systems.



The Design Jam demonstrated that a significant lack of understanding of the potential uses of health information exists, even among informed stakeholders. Data demands are increasing and most new health technologies need access to data and patients in order to go from concept to implementation. Public education and awareness campaigns are needed to ensure we create a society of consent and data literate individuals. In this way, we might best promote patient autonomy and truly informed consent. Education and awareness building would also be needed specifically for a Dynamic Consent platform; the experience of others suggests that once introduced to a dynamic consent interface, patients recognized its benefits and endorsed its usefulness.[7]

The Design Jam further demonstrated that adequate resources—in staff, funding and infrastructure—will be needed to develop and maintain modern consent solutions. Governments and private sector companies seeking access to data will have to seriously think about how we provide dedicated resources if we are to uphold privacy as a fundamental citizen right, but still enable health innovation and research.

> A modern consent model includes transparent information exchange and ongoing consent, shifting the individual's role from a passive 'subject' to an active participant.

Future research would be valuable to test consent comprehension, which can be instituted in the consent process to ensure that privacy considerations are understood, including who, what, where, when and how information will be collected, used and disclosed. Dynamic consent platforms allow the testing of comprehension before consent is provided.[5] Research on the social license for the collection and use of personal health information is also needed to help design dynamic consent platforms in ways that accord with the public's values and preferences.

Conclusion

The Design Jam provided a rare opportunity to bring together key stakeholder groups to brainstorm potential informed consent models for the use of personal health information. Dynamic consent interfaces are a viable solution, and can be supplemented with face-to-face alternatives for those participants who indicate such a preference.[3]

Community, Sectorial & Industry Involvement

Bounce is a "Mission-driven catalyst accelerating the Growth of Newfoundland and Labrador's (NL's) Emerging Health Innovation Sector" Bounce runs numerous events, including hacking health cafes, hackathons, ideation workshops, pitch events, and more, and participate in related health innovation events in NL. With broad ranging influence and connections across Canada, Bounce and the Hacking Health NL Chapter are the go-to resource for all health innovation companies and serve as a crucial link to the commercial sector. As such they are best positioned to partner with this Design Jam to ensure appropriate dissemination and uptake of results across the spectrum.

The Newfoundland and Labrador Centre for Health Information (the Centre) is responsible for developing and implementing the province's confidential and secure electronic health record (EHR). The Centre also works to improve the health of all Newfoundlanders and Labradorians by providing quality health information to health professionals, the public, researchers and health system decision-makers. The Centre is a crown corporation of the Government of Newfoundland and Labrador. It also receives funding from Canada Health Infoway, which funds EHRs across Canada. The Centre is best positioned to partner with this Design Jam as they are the primary entity where health innovators go to access personal health information. In addition, they are in the process of exploring a data lab for health innovation and a patient portal. Together, these e-health initiatives offer incredible opportunities to bring the Design Jam consent model to life.

Provincial / Territorial Support

Finally, the Department of Health and Community Services (DHCS), Government of Newfoundland and Labrador is driving a "Provincial Health Innovation Action Plan" with the aim to enhance the delivery of health services through the provinces Regional Health Authorities.

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