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Decision-makers perspective on how to optimize the eventual implementation of a genetic risk stratification approach for breast cancer detection and prevention in Quebec

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Background

- Developments in genomics have opened possibilities for early detection and prevention of breast cancer based on each individual's risk level.
- Genetic stratification approaches in personalized medicine may considerably improve our ability to identify women at higher risk of developing breast cancer.
- This personalized approach could include younger women at higher risk of breast cancer who are not targeted by current age-based programs
- Such women at higher risk could then benefit from risk-adapted mammography screening.
- To deliver on these promises, such approaches need to be implemented in practice.



Current breast cancer screening programs

- Age-based mammography screening offered within the context of a systematic program.
- Benefits women 50-69 years old (74 years old cut-off under consideration)
- Have been criticized for:
 - Low participation rates
 - High number of false positive results and follow-up exams
 - Uncomfortable procedures
- Fail to screen younger women at high risk of developing breast cancer (35-49 y. old)
- Breast cancer tends to be much more aggressive in this younger age group.
- Although 35-49 years old have a lower risk of breast cancer, they contribute to 23% of the total burden of the disease.

The PERSPECTIVE Project

PERSPECTIVE aims to develop a risk-stratification approach for BC screening. This approach would identify individuals at higher risk through an algorithm based on genetic tests as well as personal risk factors.

Then, **risk adapted** screening and prevention measures can be proposed to women (e.g. more frequent mammography, earlier mammography, preventive surgery)

This project includes multidisciplinary teams (e.g. algorithm development, genomic research, public engagement, economic valuation)

Role of the McGill University Centre of Genomics and Policy

Evaluate normative and organizational barriers to the implementation of a risk-stratification approach

Risk-stratification and primary health care

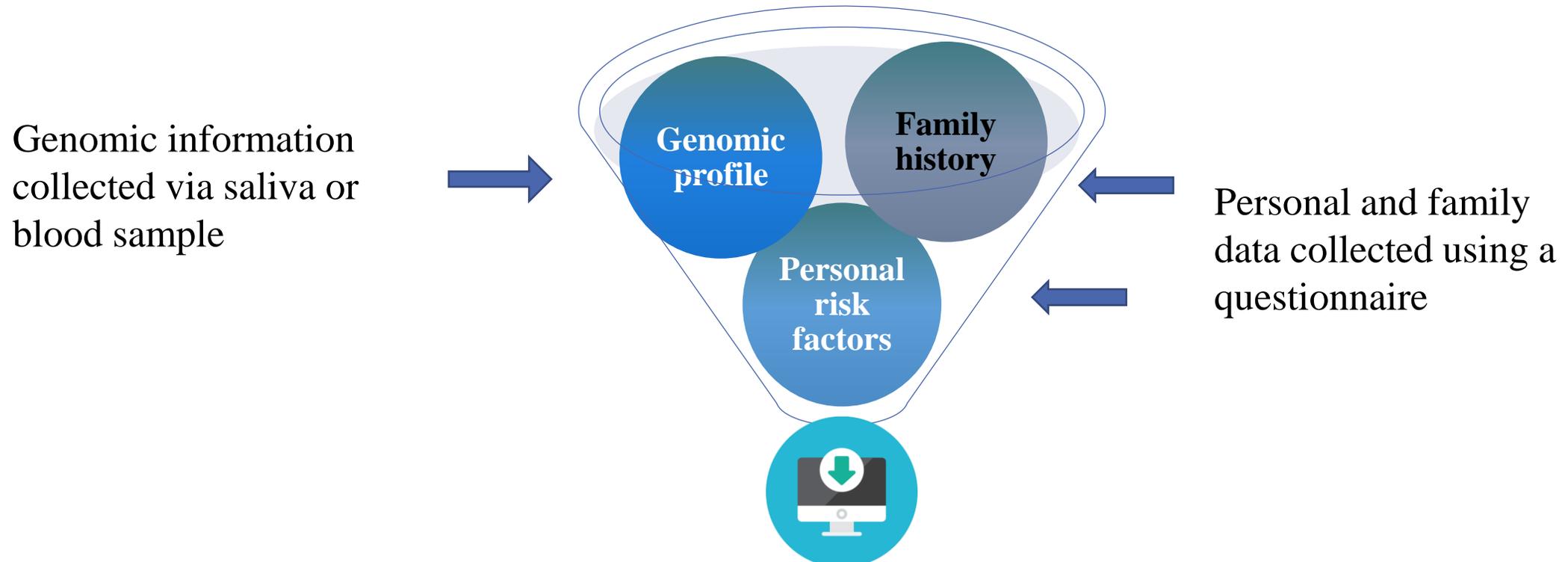
The implementation of a risk-stratification approach to breast cancer prevention raises social, ethical and organizational challenges.

Many of these challenges concern the principles of primary health care:

- Health promotion through screening and prophylactic measures
- Accessibility regardless of geographic location
- Participation in decision-making regarding own health
- Respect for diversity of cultural and psychosocial backgrounds



Breast cancer risk stratification process



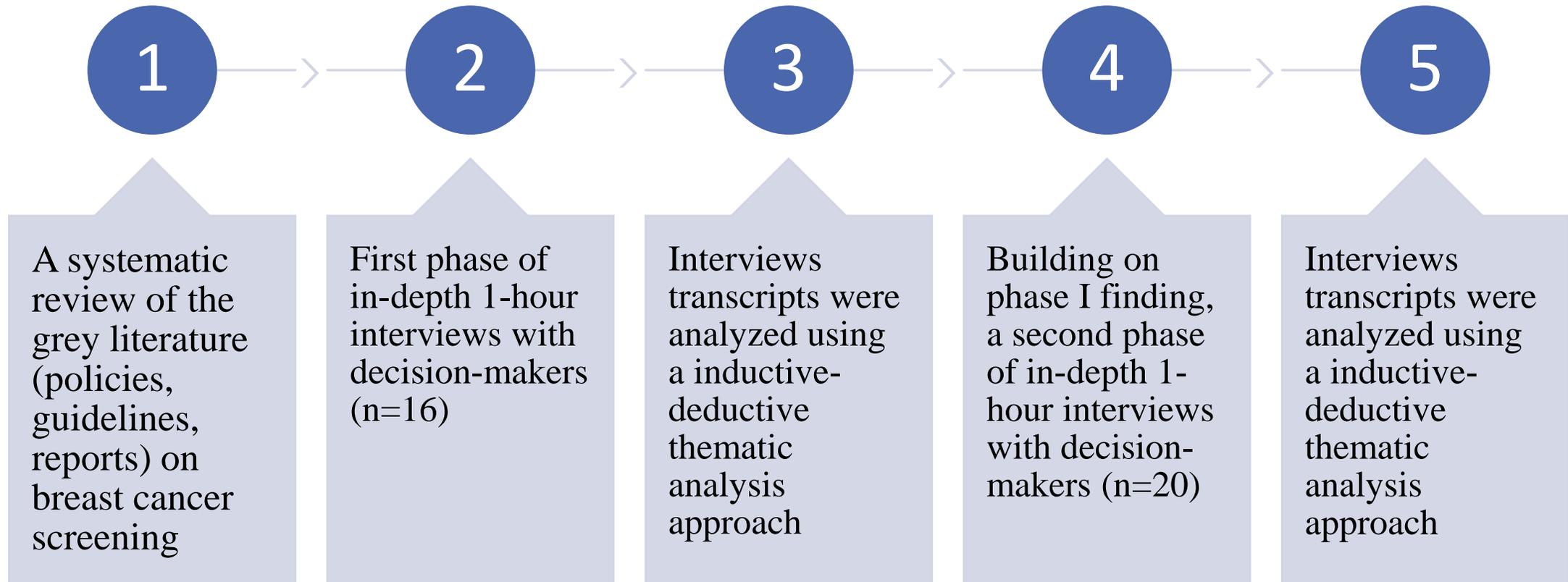
Individual breast cancer lifetime risk (%)

< 17%	17% to 30%	> 30%
Screening adapted for risk near to the general population	Screening adapted for Intermediate risk	Screening adapted for High risk

Research objectives

- **Phase I:** Identify social, ethical and organizational challenges associated with the implementation of a risk-stratification approach in the context of primary healthcare in the province of Québec.
- **Phase II:** Explore possible application scenarios with decision-makers, identify optimization strategies facilitating the implementation of a risk-stratification approach in Québec and anticipate mitigation strategies to addressing barriers identified in Phase I.

Methodological considerations



Repartition and characteristics of interviewees

Phase I (n=16)

Expertise	Level of decision		
Implementation	4	National	9
Evaluation	6	Regional	7
Management	6		

Phase II (n=20)

- 8 Regional decision-makers
- 9 National decision-makers (e.g. Cancerology, Public Health, Ministry of Health)
- 3 Professional associations representatives (e.g. nurses, physicians)

Opportunities and barriers

Phase I Results

Pratiques et organisation des soins

Recherche originale

Influence des facteurs organisationnels sur l'implantation d'une approche personnalisée de dépistage du cancer du sein

Influence of organizational factors on implementation of a personalized approach to breast cancer screening

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↳ **Résumé**

Objectif : La stratification en catégories de risque, selon des facteurs génétiques et cliniques, permettra bientôt d'améliorer les programmes de dépistage du cancer du sein. Nous avons voulu comprendre l'influence des dimensions organisationnelles sur l'éventuelle implantation de cette approche au Québec.

Méthodes : Des entretiens semi-dirigés ont été effectués auprès de 16 décideurs et gestionnaires du programme québécois de dépistage du cancer du sein (PQDCS). Un cadre d'analyse insti-

↳ **Summary**

Objective: Stratification of individuals into risk categories according to genetic and clinical factors will soon improve breast cancer screening programs. This study assessed the influence of organizational factors on the possible implementation of this approach in Quebec.

Methods: Semi-structured interviews were conducted with 16 managers and decision-makers involved in the Quebec breast cancer screening program (PQDCS).

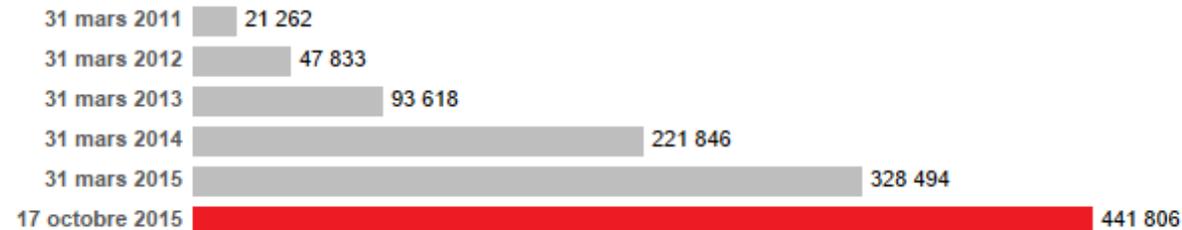
Québec healthcare system

- Based on public insurance and universal access principles
- Vast territory with very remote areas (1 667 441 km²)
- Limited access to family physicians
- Very limited number of genetic counsellors
- 14 clinics providing genetic counselling in Quebec



PATIENTS EN ATTENTE D'UN MÉDECIN DE FAMILLE

Dans l'ensemble du Québec





Complexity and inequalities

- Interviewees estimated that the complexity of an approach using notions of genetics and statistics could be a factor in social inequities
- Can be more difficult for women to make an informed decision to take part (or not) in the screening program.
- These concerns were decoupled with regards to:
 - Women from migrant backgrounds
 - Linguistic minorities
 - Lower literacy and numeracy levels
 - Limited understanding of risk and statistics

Equity, access and resources allocation

Some interviewees were concerned with the increase of anxiety versus the availability of resources to address women's psychosocial needs.

Who will answer women's questions and concerns?

- For women without a family physician
- When resources under the current breast cancer screening program are overburdened

Equity was addressed from the point of view of inter-regional access to scarce genetic counseling services.

- Only 3 of the 14 genetic clinics are outside Montreal
- Only 1 is outside a major city (CIUSSS Saguenay-Lac-St-Jean)



Preliminary results Phase II

Solutions proposed to
address these challenges

Fostering accessibility despite limited resources

- General agreement regarding the important role that clinical nurses could play in such an approach (e.g. pre-test counseling, sample collection, and post-test communication for lower risk categories).
- However, women at higher risk should be referred to a doctor for guidance and follow-up reasoning that this level of risk is akin to a diagnosis.
- Interviewees were adamant that well-defined procedures should be put in place to ensure quality and validity of procedures.
- While some were enthusiastic about the possibilities of telemedicine and telegenetics (e.g. the possibility of accessing genetic counseling remotely), others pointed out that this might not be helpful for remote areas that do not have access to high-speed Internet.



Mitigating complexity

- Effective communication tools
- Decision-making aids
- Healthcare staff training
- One-on-one pre-test counselling (with nurses)
- Relying on health literacy and numeracy best practices (e.g. plain language, pictures, translate percentage in absolute numbers, etc.)



Relative consensus on communication of results

Near population risk (screening starts at 50)

- By mail
- With possibility of phone contact for more information



Intermediate risk (screening starts early and may be more frequent)

- Doctor or nurses
- Face-to-face



High risk (prophylactic measures, genetic counselling)

- Doctor
- Face-to-face



Conclusions and further research agenda

- In a context of ongoing organizational changes, such as in Quebec's health system, pre-feasibility studies must anticipate how changing contexts could affect future implementation.

Further research:

- Regulatory issues associated with shift in professional roles and responsibilities (e.g. devolving responsibilities to nurses and genetic counsellors).
- Technical, legal and social dimensions associated with data collection, storage, and integration with Quebec's electronic health records.
- Analysis of the existing practices of current screening programs having a genetic component (e.g. Québec's newborn screening) regarding personal data and sample auto-collection.

Acknowledgements

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