


BMJ Open Using human-centred design to tackle COVID-19 vaccine hesitancy for children and youth: a protocol for a mixed-methods study in Montreal, Canada

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ABSTRACT

Introduction To successfully combat COVID-19 vaccine hesitancy and increase uptake, research has demonstrated that interventions are most effective when tailored to meet local needs through active engagement and co-development with communities. This mixed-methods project uses a human-centred design (HCD) approach to understand local perspectives of COVID-19 vaccine hesitancy and develop strategies to enhance vaccine confidence for children and adolescents.

Methods and analysis Project ECHO (Étude Communautaire sur l'Hésitation vaccinale contre la COVID-19) combines population-based surveys of parents and adolescents with community-based participatory action research to design and pilot strategies to enhance COVID-19 vaccine confidence in two underserved and ethnoculturally diverse neighbourhoods of Montreal, Canada. Two surveys conducted 6 months apart through primary and secondary schools are used to monitor vaccine acceptance and its social determinants among children and youth. Analyses of survey data include descriptive and inferential statistical approaches. Community-led design teams of parents and youth from the two participating neighbourhoods, supported by academic researchers, design thinking experts and community partners, use an HCD approach to: (1) gather data to understand COVID-19 vaccine decision-making among parents and youth in their community and frame a design challenge (inspiration phase); (2) develop an intervention to address the design challenge (ideation phase) and (3) pilot the intervention (implementation phase). Strategies to evaluate the community-led interventions will be co-developed during the implementation phase.

Ethics and dissemination This study has been approved by the research ethics boards of the Sainte-Justine University Hospital Centre and the University of Montreal. Community design teams will be involved in the dissemination of findings and the design of knowledge translation initiatives that foster dialogue related to COVID-19 vaccination for children and adolescents among community, school and public health stakeholders. Findings will be disseminated through peer-reviewed

Strengths and limitations of this study

- Project ECHO (Étude Communautaire sur l'Hésitation vaccinale contre la COVID-19) responds to calls in the literature to address COVID-19 vaccine hesitancy and increase vaccine equity through active engagement and co-development of interventions with communities.
- Human-centred design (HCD) is integrated into this community-based participatory research project to support the design and implementation of innovative, accessible and effective solutions for addressing the complex issue of vaccine hesitancy.
- Involving community researchers in all steps of the research process and in the dissemination of findings will foster increased engagement with community, school and other stakeholders and promote dialogue about COVID-19 vaccination for children and adolescents.
- HCD can be a time-consuming process, especially when implemented by community design teams who are both learning and executing the process as the project unfolds.
- The COVID-19 pandemic and associated public health restrictions represent risks to our ability to implement the study as planned.

publications, conference presentations, community forums, policy briefs, and social media content.

INTRODUCTION

COVID-19 vaccination has been approved and is widely available in Canada for children aged 5 years and older—since May 2021 for 12–15 year olds and November 2021 for 5–11 year olds.¹ Vaccinating children and adolescents protects them against long-lasting effects of infection (ie, long COVID-19) and rare cases of multisystem inflammatory syndrome and severe paediatric COVID-19.¹ Moreover, ensuring high vaccination coverage among

young people is essential to reduce the population disease burden, ease pressure on healthcare systems and resume in-person schooling and other activities.²

In the Canadian province of Quebec, 59% of children aged 5–11 years had received at least one vaccine dose after the first 2 months of the vaccine campaign for children.³ Survey data suggest just 65% of Quebec parents intend to vaccinate their 5–11 year olds against COVID-19.² Parents with younger children report lower vaccine acceptance, as do parents from lower-income households, from racialised groups and those born outside Canada.^{4–6} In Quebec, there is also notably lower vaccine coverage among children living in more materially deprived neighbourhoods.^{3 7} Factors shown to contribute to disparities in COVID-19 vaccine coverage include inequitable access to vaccination services among disadvantaged populations, language and resource (eg, computer access) barriers and greater mistrust of governments and public health agencies among some equity-seeking groups.⁸

To successfully combat vaccine hesitancy, defined as ‘a delay in acceptance or refusal of vaccines’,⁹ and reduce inequities in vaccine uptake among children and adolescents, research has demonstrated that interventions are most effective when tailored to meet local needs through active engagement and co-development with communities.¹⁰ Community-based participatory research (CBPR) approaches have been widely used to develop solutions that improve community health and increase health equity through a process of co-learning and genuine partnership between researchers and communities.¹¹ Human-centred design (HCD) is a problem-solving approach that shares CBPR’s emphasis on co-creation and bidirectional exchange of knowledge between the design team and the project’s intended beneficiaries (‘users’). HCD engages with communities and their needs through an iterative process of building empathy with the experiences of individual users, generating ideas for how to solve problems, and designing and testing out prototypes. Traditionally used more in the private sector, HCD has in recent years been applied to numerous public health problems,^{12–14} including to develop mobile apps and education materials to bolster vaccine uptake.^{15 16} Emerging evidence suggests that the integration of HCD into CBPR projects may lead to more innovative, accessible and effective solutions to address complex health and social issues.^{17 18}

Study objectives

The ECHO study (Étude Communautaire sur l’Hésitation vaccinale contre la COVID-19) aims to understand local perspectives of COVID-19 vaccine hesitancy for children and adolescents in two underserved and ethnoculturally diverse Montreal neighbourhoods, and to co-develop tailored strategies with parents, youth and their communities to enhance vaccine confidence. Specific objectives and subobjectives of the study include:

Objective 1: to monitor COVID-19 vaccine acceptance and uptake for children and adolescents

- To estimate changes over time in COVID-19 vaccine acceptance for children and adolescents.
- To identify social factors associated with vaccine acceptance for children and adolescents.
- To explore behavioural and other characteristics associated with vaccine hesitancy.

Objective 2: to use HCD to develop and pilot community-driven solutions to enhance vaccine confidence among parents and adolescents.

- To train community-based design teams in the HCD approach.
- To design and pilot interventions to enhance vaccine decision-making and reduce other barriers to vaccine uptake.
- To evaluate feasibility and preliminary effectiveness of the interventions.
- To document and critically reflect on the use of HCD methodology in community-based vaccine hesitancy research.

METHODS AND ANALYSIS

Study design

This mixed-methods project combines population-based surveys to monitor vaccine acceptance and its determinants with CBPR to design and pilot strategies to enhance vaccine decision-making for children and youth.^{2 17} Parent-led and youth-led community-based design (CBD) teams are supported by researchers, design thinking experts, and community partners to apply an HCD approach to: (1) gather data to understand COVID-19 vaccine decision-making among parents and youth in their community and frame a design challenge (inspiration phase); (2) develop an intervention to address the design challenge (ideation phase) and (3) pilot the intervention (implementation phase) and evaluate acceptability and feasibility. The ECHO project is being conducted over a 12-month period (figure 1).

Study setting

The study takes place in two neighbourhoods of Montreal, Canada’s second largest city located in the French-speaking province of Quebec. Residents of the two neighbourhoods, Montréal-Nord and Parc Extension, have been disproportionately affected by the COVID-19 pandemic and have among the lowest rates of COVID-19 vaccination in the city, especially among children and teens.^{19–21} Montréal-Nord has approximately 84 000 residents and is one of Montreal’s poorest and most racially diverse neighbourhoods.²² Home to one of Canada’s largest Haitian communities and a sizeable North African population, two-thirds of the neighbourhood’s residents were either born abroad or have at least one parent who was born abroad.²² Parc Extension has a population just under 30 000 and is one of the densest, most culturally diverse and poorest neighbourhoods in Montreal. A neighbourhood

	Sept-Nov 2021		Dec-Feb 2022			Mar-May 2022			June-Aug 2022		
Preparations and ethics approvals	■	■									
Objective 1. Monitor vaccine acceptance and its determinants											
Online survey for parents and adolescents				■					■		
Objective 2. Human centered design projects											
Recruit community-based design teams		■	■								
Human centered design process											
<i>Inspiration phase</i>				■	■						
<i>Ideation phase</i>						■	■	■			
<i>Implementation phase</i>								■			
Process evaluation							■	■	■		
Knowledge dissemination						■	■			■	■

Figure 1 Timeline for ECHO study. ECHO, Étude Communautaire sur l'Hésitation vaccinale contre la COVID-19.

of choice among newcomers to Canada, 90% of residents were born outside Canada or have one or two immigrant parents, with most coming from South Asian countries (India, Pakistan and Bangladesh) and Greece.^{22 23} The mother tongue of two-thirds of Parc Extension residents is neither French nor English and 10% speak neither language.

Participants and methods

Objective 1: to monitor COVID-19 vaccine acceptance and uptake for adolescents and parental vaccine acceptance for children

We will use online questionnaires to collect data from parents of primary school students aged 5–11 years and from secondary school students aged 14–18 years in the two study neighbourhoods. Six public primary schools (out of 16 total) and 2 public secondary schools (out of 4 total), with an equal number of each per neighbourhood, were randomly selected to participate. We excluded a priori two public schools that serve unique student populations: one primary school for children with intellectual/developmental disabilities and one small secondary school that supports older students who had previous difficulties within the educational system. For the former, decision-making around vaccines likely involves different considerations for the parents of students with disabilities, while the latter school did not include our full age range of interest.

Students aged 14 years and older attending one of the two sampled secondary schools are eligible to participate in the online questionnaire. This age cut-off was selected because adolescents 14 years and older do not require the consent of a parent or guardian to be vaccinated in Quebec.²⁴ In addition, parents or guardians of all children aged 5–11 years attending one of the participating primary schools are eligible to participate. Surveys are being conducted in January 2022 (baseline) and June 2022 (follow-up). All questionnaires are available to participants in French and English, and the parent questionnaire is also available in Arabic, Urdu and Punjabi.

ECHO community design team members (ie, parent and adolescent ECHO team members from the two neighbourhoods) were involved in adapting, translating and piloting the questionnaires.

Questionnaires

The parent questionnaire focuses on assessing COVID-19 vaccine uptake and intentions and understanding the reasons parents are likely or unlikely to accept vaccination for their child (ren). It includes an adapted version of the 5C scale, which assesses 5 psychological antecedents of vaccination (confidence, complacency, constraints, calculation and collective responsibility).²⁵ Questions about household COVID-19 infections and vaccination status, knowledge about COVID-19 infection and vaccines, and sources of vaccine-related information are also included, along with basic parent and child health characteristics (eg, chronic diseases and mental health diagnoses). Where possible, questions are based on existing validated surveys and scales, including Statistics Canada's COVID-19 Vaccination Coverage Survey²⁶ and Quebec's National Institute for Public Health Surveys on vaccine acceptance for children.² Social determinants of interest include parental education, race/ethnicity, language(s) spoken at home and place of birth, which are measured using questions adapted from the Canadian Population Census.²⁷

The adolescent questionnaire measures vaccine uptake and focuses on understanding the reasons for receiving or not receiving the COVID-19 vaccine. The questionnaire includes basic sociodemographic and health questions for the adolescent and members of their family. As with the parent questionnaire, the adolescent questionnaire collects information about household COVID-19 infections and vaccination history, knowledge and beliefs about COVID-19 infection and vaccines, and sources of vaccine-related information. We further included questions to understand how the pandemic has impacted adolescents' mental health and quality of life. The youth

version of the MacArthur Scale of Subjective Social Status is used to assess socioeconomic status.^{28 29} Both questionnaires are available in online supplemental appendix 1.

Data collection and management

Questionnaire data is being collected and managed using the Research Electronic Data Capture application, a secure, web-based software platform designed to support data capture for research studies.³⁰ The surveys can be accessed through a unique web link or by scanning a QR code using a computer, tablet or smartphone. Only authorised personnel from the research team can access these data.

Statistical considerations

Sample size calculations are based on vaccine uptake data for children and adolescents living in the two neighbourhoods.²¹ Averaged across the two neighbourhoods, 58% of children aged 5–11 years are unvaccinated. Based on this, we estimate that a sample size of 187 parents will enable detection of a 25% decrease in the per cent of children unvaccinated between baseline and follow-up surveys. Similarly, as 26% of adolescents are unvaccinated in the two neighbourhoods,²¹ an estimated sample size of 586 is needed to detect a 25% decline in the per cent of unvaccinated teenagers between baseline and follow-up. Both calculations are based on power of 80% and a two-sided significance level of 95%. Using the eligible student populations of the sampled primary and secondary schools, we require response rates of 6% and 28% among parents and adolescents, respectively, which are reasonable targets based on our previous COVID-19 research in Montreal schools.³¹

We will use descriptive and inferential approaches to analyse survey data. Analyses will describe and compare rates of vaccine acceptance and uptake for children and youth between baseline and follow-up. We will examine reasons for non-vaccination among adolescents and parents and reasons parents are likely or unlikely to vaccinate their children, as well as the psychological antecedents of vaccination. Exploratory analyses will examine socio-demographic (eg, socioeconomic status, parental education level, race/ethnicity and primary language spoken) and other determinants of vaccine acceptance.

Objective 2: to use HCD to develop and pilot community-driven solutions to enhance vaccine-related decision-making among parents and adolescents

Recruitment and training of community-based design teams

We recruited 2 youth CBD teams, each comprised of 4 students aged 14–17 years from the participating secondary schools, and 2 parent CBD teams, each comprised of 4 parent residents from each neighbourhood. The positions were advertised through local community organisations and schools, and via social media. Interested parents and youth participated in 15-minute interviews with the study team to gauge their motivation, relevant lived experiences and sense of service to their schools

and communities. The 8 students and 8 parents selected as CBD team members receive compensation for their work on the project (approximately 5 hours/week for a 6-month period) and are considered study collaborators. Team members reflect the diversity of their neighbourhoods—many are immigrants from different parts of the world (eg, Algeria, Ivory Coast, Palestine, Afghanistan and India) and together they speak at least 12 different languages. Each of the 4 CBD teams has a dedicated mentor from the study team who coordinates team communication and meetings and provides dedicated support for their team's project. The mentors are public health graduate students from diverse backgrounds who bring expertise in qualitative and CBPR methods and lived experiences in the project neighbourhoods.

In-person and virtual HCD workshops for the CBD teams are held approximately monthly through the various stages of the 6-month HCD process (see [figure 2](#)). Workshops are led by a collaborator with design thinking expertise, with support from academic researchers and other individuals with relevant local and substantive expertise.

HCD process

CBD teams and their community-based and academic partners engage in a three-step HCD process,³² as depicted in [figure 2](#) and as described below.

Inspiration phase

During the first phase, CBD teams begin by gathering information to better understand COVID-19 vaccine decision-making in their communities using existing data and local resources. Teams then collect primary data via semi-structured interviews. Parent teams conduct interviews with parents of unvaccinated children aged 5–11 years and youth CBD teams interview unvaccinated youth aged 14–18 years, all from their respective communities. Recruitment of interview participants uses different types of purposive sampling, including convenience and snowball sampling.³³

CBD team members are trained on interviewing techniques and prepare interview guides with the support of the research team. Interviews are conducted in pairs (one interviewer and one note taker) and take place in person or via Zoom depending on public health guidelines. Interviews are audio recorded with the permission of participants. The choice of interviewers, use of translators and other factors are always considered to ensure privacy and confidentiality and increase the validity of interview findings. Each CBD team completes 12–15 interviews.

CBD teams are trained to synthesise data from the interviews in a collective sense-making approach using empathy maps ([figure 3](#)).³⁴ Teams use empathy maps to create personas that capture the needs, motivations and pain points of a potential group of users with shared characteristics. The empathy maps are also used to develop point-of-view statements that include information about users, needs and insights (eg, (user) needs a way to (verb)

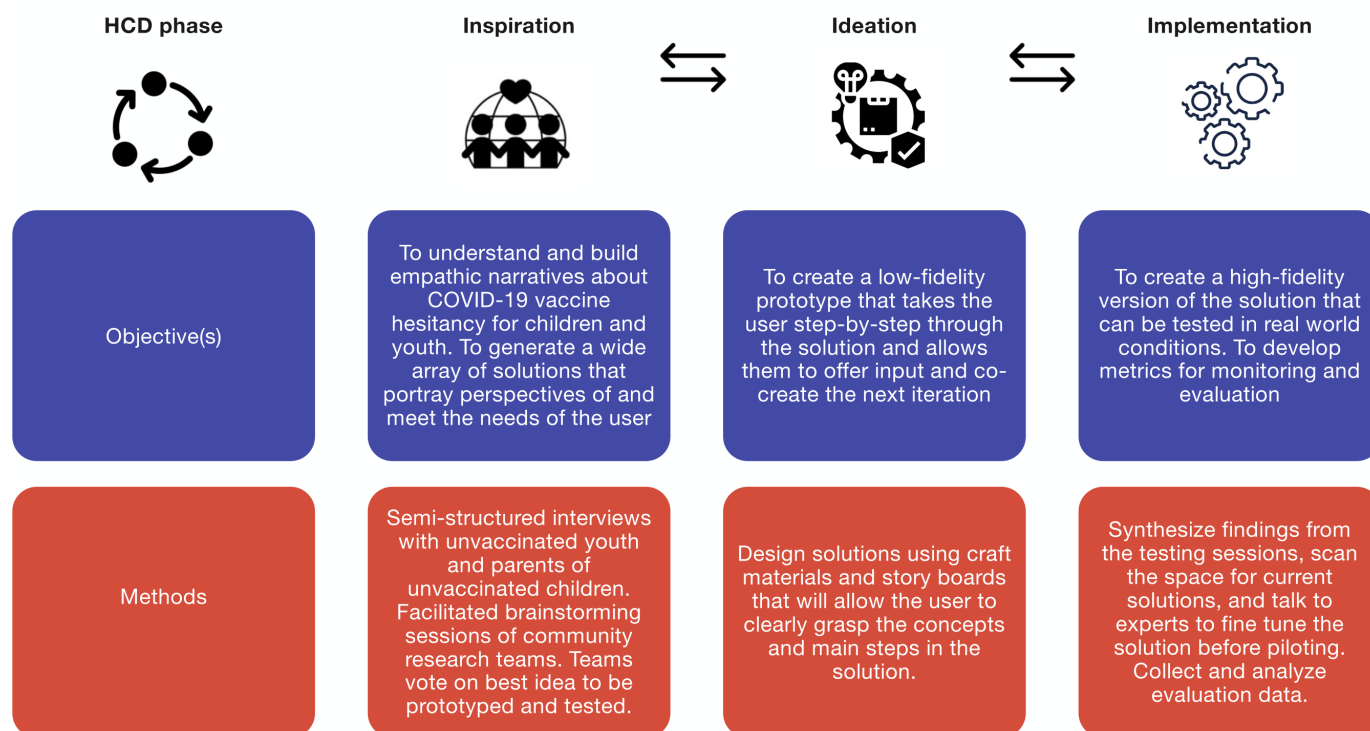


Figure 2 HCD phases for the ECHO study. ECHO, Étude Communautaire sur l'Hésitation vaccinale contre la COVID-19; HCD, human-centred design.

because (surprising insight)). Once the teams clearly articulate their users' points of view, they can begin to define the design challenge that needs to be addressed.

Ideation phase

With the design challenge and personas' points of view firmly in mind, the teams then move into the solution space. Teams generate ideas during facilitated brainstorming sessions that encourage a wide array of ideas to stimulate innovative solutions. Through a democratised decision-making process, teams vote on the ideas they want to prototype and test with users.

Initial prototypes are made rapidly using craft materials and storyboards. Storyboards develop visual representations of a user's journey through a possible solution to a problem.¹⁸ The first low-fidelity prototypes allow the teams to test the major concepts of their solution and engage the user in a process of co-creation whereby their input is solicited and incorporated in further iterations. The prototypes are tested with 12–15 users per team. A second round of testing is undertaken with a subset of the first round of users and additional new users, again targeting 12–15 users per team.

Implementation phase

In this phase, CBD teams finalise their prototypes, fabricate them to a higher fidelity and pilot their interventions. Prior to finalising their prototypes, teams analyse current solutions to address vaccine hesitancy in the community and speak to experts in the field for additional learnings. The interventions developed by parent teams will be pilot

tested among parents at the two primary schools and those developed by the youth teams will be pilot tested among students at their secondary schools.

Teams also develop plans for monitoring and evaluation during the implementation phase. This includes reflecting on the team's theory of change about how the prototype will create positive change and defining a set of indicators to measure effectiveness. Both quantitative and qualitative indicators are included. Quantitative indicators may rely on survey data collected for objective 1, which provides pre-intervention and post-intervention information on knowledge and attitudes around vaccination from a sample of parents and students. Each team will have a budget of \$C15 000 to design, implement and evaluate their intervention.

In addition to evaluation of the four interventions developed using HCD, we will use field notes, document reviews (eg, meeting minutes and weekly mentor activity reports), briefings and qualitative data collection techniques to document and critically reflect on the use of the HCD methodology in community participatory research on vaccine hesitancy. Focus groups and in-depth interviews with CBD team members and mentors, respectively, will be carried out to understand experiences and lessons learnt in applying HCD in this project.

Data management and analysis

Interview data collected by CBD teams will include audio recordings and notes taken during interviews. Password protected files containing participant contact information

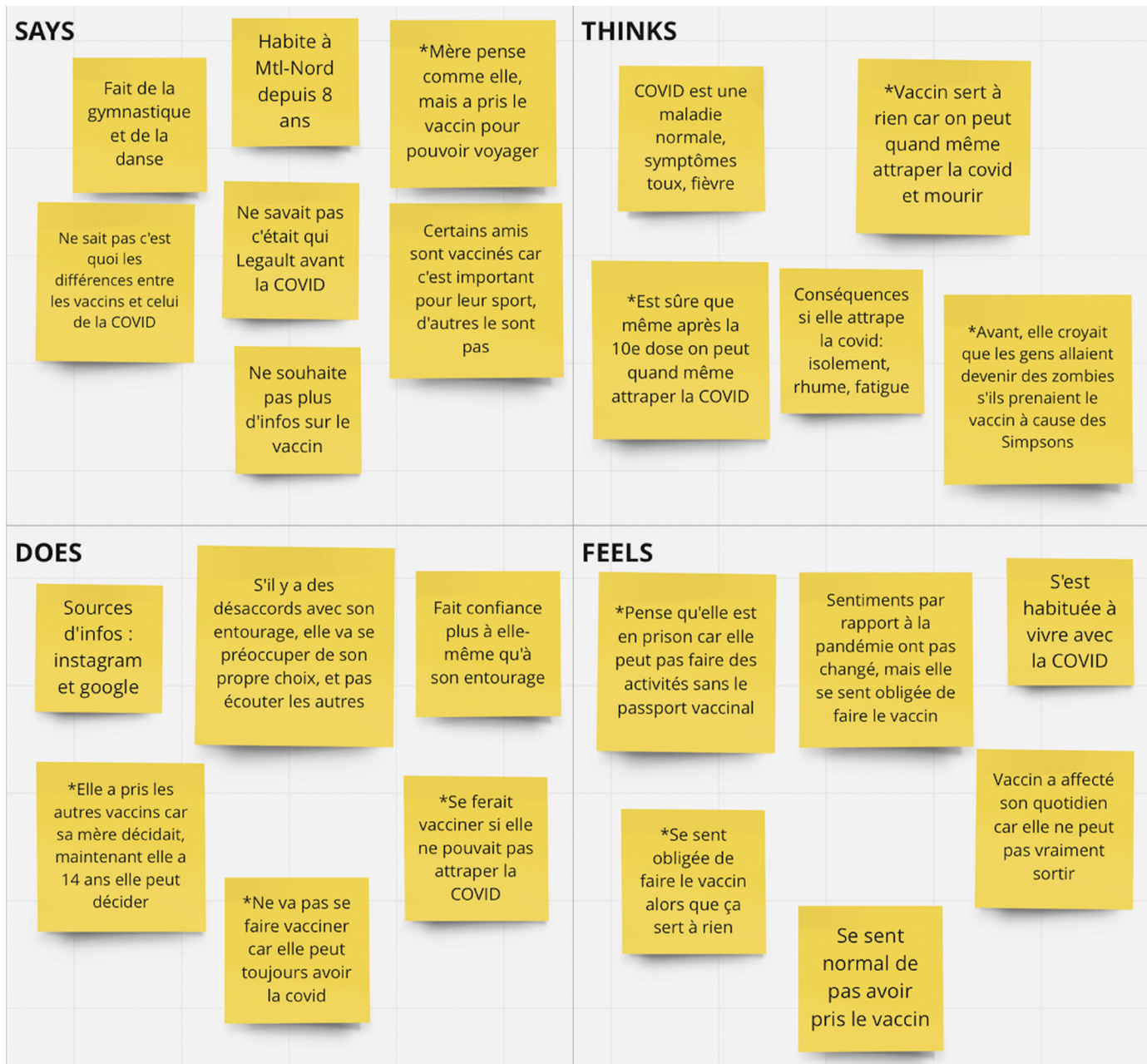


Figure 3 Empathy map example from the ECHO study. ECHO, Étude Communautaire sur l'Hésitation vaccinale contre la COVID-19.

(name, email and phone number) are kept separately from interview notes and audio recordings and linked only via a numeric identifier. Only authorised personnel from the research team can access interview data.

Data are analysed through the HCD process by identifying themes and translating these themes into design opportunities.³² Empathy maps, inspiring stories and other information collected from users are shared among team members to identify key themes by identifying patterns, compelling insights, surprises, etc. Themes are then used to develop insight statements: short, memorable phrases that ascribe meaning to the themes and help identify important elements of the solution. These insight statements are translated into design opportunities,

which describe key elements of the solution and that will be further refined as teams begin to build and test their prototypes.

Patient and public involvement

Parents and adolescents from the two project neighbourhoods are involved as co-researchers throughout the study. They are integral members of the research team, whose activities include designing interview guides, conducting interviews with community members, participating in co-design sessions, assisting with survey preparation and recruitment, and designing and supporting knowledge translation activities. Additional community members—parents, adolescents, health professionals

and community leaders—are also involved in co-design sessions during the ideation and implementation stages of the project.

ETHICS AND DISSEMINATION

This study has been approved by the research ethics boards (REBs) of the Saint-Justine University Hospital Centre (MP-21-2022-3733), the University of Montreal (2021–1315) and, for the survey, the three participating school boards. Due to the iterative nature of the research process, amendments to the current research protocol are submitted to the REBs as data collection tools and evaluation strategies are developed. Standard procedures for obtaining informed consent prior to any data collection are followed for all survey and interview participants. Youth participants aged 14 years and older provide their own consent to participate.

Knowledge translation (KT) for the study will promote dialogue related to COVID-19 vaccination for children and adolescents and raise awareness about COVID-19 vaccine inequities. Parent and youth CBD teams will be involved in the dissemination of findings and the design of KT initiatives that foster dialogue among community, school and public health stakeholders. Dissemination strategies will leverage technology, including webinars, social media platforms, research snapshots and policy briefs, and will engage new and existing community organisation and public sector partners. Study findings will also be disseminated in reports, conference presentations and peer-reviewed publications. Community researchers will be given the opportunity to be included as co-authors on any publications that include data from their projects.

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Contributors The study design and concept were conceived by BM, KZ, AV, CQ, ED, CTN and NB. BM wrote the first draft of the protocol. All other authors (KA, AV, ED, CTN, NB, GF, MP, JS, JA-m, MAB, CQ and KZ) were involved in revising the paper for important intellectual content, approving the final version of the manuscript and agreeing to be accountable for all aspects of the work.

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