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REPORTS OF ORIGINAL INVESTIGATIONS

Public perception of participation in low-risk clinical trials in critical care using waived consent: a Canadian national survey

Perception du public à l'égard de la participation à des études cliniques à faible risque en soins intensifs utilisant la renonciation au consentement : un sondage national canadien

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Abstract

Purpose *The acceptability of waiver of consent for participation in clinical research in intensive care unit (ICU) settings is uncertain. We sought to survey the Canadian public to assess levels of support, comfort, and acceptability for waived consent for low-risk clinical trials.*

Methods *We performed a prospective cross-sectional survey of the Canadian public aged 18 yr or older. The survey was conducted by Ipsos between 19 and 23 November 2020. The survey content was derived from a literature review and in consultation with a patient and family partnership committee. The survey focused on attitudes and beliefs on waived consent for participation in low-risk clinical trials in ICU settings. The survey contained 35 items focused on sociodemographics, general health status, participation in medical research, and levels of support and comfort with research and with waived consent. The survey used a case study of a low-risk clinical trial intervention in ICU patients. Analysis was descriptive.*

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Results *We included 2,000 participants, 38% of whom reported experience with ICU and 16% with medical research. Participation in medical research was more common among those with postsecondary education, those with chronic disease, and those who were employed in health care. Most (80%) would support a model of waived consent for low-risk clinical trials, citing medical benefits (36%) and low perceived risk (34%). Most (77%) were comfortable with personally participating in a low-risk clinical trial. Most (80%) believed waived consent approaches were acceptable. Half (52%) believed the waived consent process should provide information about the research and include the option of opting out. When asked whether participants should always give full informed consent, regardless of the practicality or level of risk, 74% and 72% agreed, respectively.*

Conclusions *There is public support for models of waived consent for participation in low-risk pragmatic clinical trials in ICU settings in Canada; however, this is not universal. This information can inform and guide education, ethics, policy, and legal discussion on consent models.*

Résumé

Objectif *L'acceptabilité de la renonciation au consentement pour la participation à la recherche clinique à l'unité de soins intensifs (USI) est incertaine. Nous avons cherché à sonder la population canadienne afin d'évaluer les niveaux de soutien, de confort et d'acceptabilité de la renonciation au consentement pour les études cliniques à faible risque.*

Méthode *Nous avons réalisé un sondage transversal prospectif auprès de la population canadienne âgée de 18 ans et plus. Le sondage a été réalisé par Ipsos entre le 19 et le 23 novembre 2020. Le contenu du sondage a été élaboré à partir d'une revue de la littérature et en consultation avec un comité de partenariat composé de patient·es et de familles. Le sondage portait sur les attitudes et les croyances à l'égard de la renonciation au consentement pour participer à des études cliniques à faible risque dans les unités de soins intensifs. Le sondage comportait 35 questions axées sur les données sociodémographiques, l'état de santé général, la participation à la recherche médicale et les niveaux de soutien et de confort à l'égard de la recherche et de la renonciation au consentement. Le sondage s'est appuyé sur une étude de cas d'une intervention d'étude clinique à faible risque chez des patient·es des soins intensifs. L'analyse était descriptive.*

Résultats *Nous avons inclus 2000 personnes, dont 38 % ont déclaré avoir eu des expériences en soins intensifs et 16 % en recherche médicale. La participation à la recherche médicale était plus fréquente chez les personnes ayant fait des études postsecondaires, celles atteintes de maladies chroniques et celles qui travaillaient dans le domaine des soins de santé. La plupart d'entre elles (80 %) appuieraient un modèle de renonciation au consentement pour les études cliniques à faible risque, citant les avantages médicaux (36 %) et le faible risque perçu (34 %). La majorité des personnes répondantes (77 %) étaient à l'aise à l'idée de participer personnellement à une étude clinique à faible risque. La plupart d'entre elles (80 %) croyaient que les approches fondées sur la renonciation au consentement étaient acceptables. La moitié (52 %) estimaient que le processus de renonciation au consentement devrait fournir des renseignements sur la recherche et inclure la possibilité de se retirer. Lorsqu'on leur a demandé si les participant·es devraient toujours donner un consentement éclairé complet, quel que soit l'aspect pratique ou le niveau de risque, 74 % et 72 % ont répondu par l'affirmative, respectivement.*

Conclusion *Il y a un appui public pour les modèles de renonciation au consentement quant à la participation à des études cliniques pragmatiques à faible risque dans les unités de soins intensifs au Canada; cet appui n'est toutefois pas universel. Ces renseignements peuvent éclairer et orienter l'éducation, l'éthique, les politiques et les discussions juridiques sur les modèles de consentement.*

Keywords bed capacity · health care provider · intensive care units · patient-centred care · physician-patient relations · quality

Learning health care systems aim to leverage "science, informatics, incentives, and culture" to systematically generate knowledge and apply evidence, to foster continuous improvement and innovation, and to promote refinement of care processes to improve decision-making in guiding clinical care.[1] There is a growing rationale for learning health care systems to contemplate alternative approaches to consent, including waiver of consent, for participation in low-risk comparative effectiveness research that poses no more than minimal risk to patients and respects clinician judgement.[2–4] From an ethical and legislative perspective, the acceptability of waived consent often depends on the specific nature and context of the research.[5]

A prior survey focused on assessing the public's attitudes towards consent models for participation in low-risk research found respondents wanted to be considered for research participation, even when no surrogate decision-maker was available, and were generally

comfortable with a waived consent model.[6] Nevertheless, this survey was performed more than 15 years ago among a small convenience sample in downtown Toronto and may not be representative of a broader Canadian population.

The recent update to the Canadian Tri-Council Policy Statement for the Ethical Conduct of Research Involving Humans (TCPS 2 [2022]), Chapter 3 (Articles 3.1 to 3.5) clearly articulates the default conditions for the individual consent to participate in research.[7] In Article 3.7A, conditions are outlined whereby research may seek alternative models of consent with research ethics board (REB) review and approval (Electronic Supplementary Material [ESM] eTable 1). While the TCPS 2 (2022) defers to the judgement of REBs for approval of alterations to consent requirements, this may exist at tension with jurisdictional legal frameworks.[5,8] Further, the consent process for research in ICU settings can have unique challenges, specifically due to impaired patient capacity and unavailability (or no availability) of surrogate decision-makers. As such, alternative consent models are commonly sought, particularly for low-risk pragmatic clinical trials evaluating standards of care or routine interventions where the perceived risk to patients is no more than minimal.[9] Currently, little is known about the relevant perceptions of patients, their families, or the general public.

Accordingly, we sought to perform a survey to: 1) assess public levels of support for waived consent for low-risk clinical trials in the ICU; 2) assess public comfort participating in low-risk clinical trials in the ICU that involve waived consent; 3) assess public acceptability to differing approaches of waived consent for research evaluating a low-risk treatment or approach to care that is routinely provided in the ICU; and 4) assess public attitudes towards waived consent for research evaluating routine low-risk treatments in the ICU.

Methods

This was a prospective cross-sectional survey, reported according to the Checklist for Reporting of Survey Studies (CROSS) statement (ESM eTable 2).[10] The target population was the Canadian public. Participants were adults aged 18 yr or older. The survey was conducted by Ipsos (Toronto, ON, Canada; https://www.ipsos.com/en-ca) between 19 and 23 November 2020. The study received approval by the REB at the University of Alberta (Edmonton, AB, Canada; File # Pro00085103; 7 November 2018).

The survey focused on attitudes and beliefs on consent for participation in low-risk clinical trials in ICU settings and derived content from a literature review and consultation with a patient and family partnership committee (ESM eTable 3). The term "low-risk" referred to participation in a clinical trial that posed no more than minimal risk, whereby the probability and magnitude of physical, psychological, emotional, social, or other harm and discomfort are no greater in and of themselves than would be expected to be encountered by participants during a typical admission and clinical course in an ICU.[11]

The questionnaire items were iteratively reviewed and modified for clarity and comprehension. This process was replicated in consultation with Ipsos to further refine the survey for coherence. The final instrument contained 35 items and integrated questions focused on sociodemographics (age, gender, ethnicity, marital status, religious identity, education status, employment focus, employment status, geographic region), general health status (chronic disease, prior ICU exposure), participation in medical research (prior individual or family invitation to participate and/or participation) and level of support and comfort with research and with waived consent. Participants were further presented with a case study of a low-risk randomized clinical trial comparing two standard-of-care interventions for stress ulcer prophylaxis used in ICU patients receiving invasive mechanical ventilation.[9] Questions on levels of support and comfort for participation in a low-risk clinical trial used a Likert format (i.e., support/oppose: strongly support, somewhat support, somewhat oppose, strongly oppose; comfort: very comfortable, somewhat comfortable, somewhat uncomfortable, very uncomfortable). Participants were asked to provide reasons for supporting (or opposing) and reasons for being comfortable (or uncomfortable) participating in a low-risk clinical trial with waived consent. Reasons for supporting/being comfortable were themed on perceived importance to science, medical benefits, and minimal risk, while reasons for opposing/uncomfortable were themed on autonomy, trust, need to inform, and side effects. In the context of the scenario, participants were asked their beliefs on the minimum requirements for consent to participating in a low-risk clinical trial in the ICU (i.e., fully informed, waived consent with information provided and opt-out, and waived consent with no information). Finally, we inquired about the degree of support for several statements related to waived consent using a Likert format (i.e., strongly disagree, somewhat disagree, somewhat agree, strongly agree). The survey underwent pilot testing for clarity, comprehension, redundancy, and face validity (ESM eAppendix).

The survey was administered, and data managed by Ipsos using their standardized online platform. Sampling was performed through use of Ipsos' proprietary iSay panel of approximately managed 250,000 panelists across Canada. Ipsos' panelists sign a nondisclosure agreement

and can discontinue participation at any time. Ipsos manages their panel by only including those panelists who actively participate in online surveys at least once every six months. According to Ipsos, along with incentives, this guarantees high response rates to surveys (typically around 30–35%) and low drop-out rates.

The sample quota was 2,000. There was no prespecified sample size estimation. Purposive sampling was performed to ensure a weighted sample composition by age, gender, and geographic representation that reflected the Canadian adult population, based on the 2016 Canadian Census. Ipsos translated the survey into French to enable sampling of the French-speaking population in Quebec. There was no specific validation of the French version of the survey prior to implementation. Ipsos aimed to sample an estimated 75% of the French-speaking and 25% of the English-speaking participants from Quebec.

Analyses were descriptive.[12] No assumptions or imputations were made for missing data. Data were collated and presented as means (standard deviations) and proportions (%), rounded to the nearest percent. Responses across sociodemographics and health status were compared using Chi square tests as applicable. A P value of < 0.05 was considered statistically significant.

Results

A total of 2,000 members of the Canadian public were recruited over five days. The distribution across Canada included: British Columbia, 14% (n = 272); Alberta, 11% (n = 224); Saskatchewan/Manitoba, 7% (n = 130); Ontario, 38% (n = 768); Quebec, 24% (n = 470); and the Atlantic provinces, 7% (n = 136) (cumulative total = 101% due to rounding).

Of participants, 66% (n = 1,319) were aged 30–64 yr, 50% (n = 1,000) were female, 80% (n = 1,591) had completed postsecondary education, and 46% (n = 911) reported having a chronic health condition. The majority identified as having either Canadian or European ethnic background (87%). A full description of participant characteristics is shown in the Table.

In total, 38% of participants reported that they or a close family member had been admitted to the ICU in a Canadian hospital. This was more commonly reported among older participants (41% for participants $\geq$ 45 yr *vs* 36% for participants 18–44 yr; P = 0.045), those with chronic health conditions (59% *vs* 40%; $P < 0.01$) and those who had participated in a medical research study before (21% *vs* 12 %; $P < 0.01$).

Only 16% of participants reported that they or their family member had participated in a medical research study. Those more likely to report participation in a medical research study had postsecondary education (17% *vs* 12%; P = 0.01), were employed in health care (32% *vs* 16%; $P < 0.01$) and had a chronic health condition (23% *vs* 9%; $P < 0.01$). Of those who had participated in a medical research study, 18% reported this was in the ICU (extrapolates to $\sim$ 3% of the survey population). The most common reasons for participating were for general medical benefit (40%) (e.g., to advance science, for the greater good, and to develop new treatments) and for personal benefit (12%) (e.g., to gain access to new treatments, to understand their illness, and for potential benefit). Of those who had participated in a medical research study, 94% expressed being somewhat or very satisfied.

Support for waived consent

The majority of participants (80%) would support, either somewhat (54%) or strongly (26%), a model of waived consent for low-risk clinical trials in ICU settings (Figure, panel a). Support was greater from male than from female participants (85% *vs* 77%; $P < 0.001$), and from participants who had prior experience with medical research (89% *vs* 79%; $P < 0.001$). There was no significant difference in the level of support when stratified by age, level of education, religious affiliation, or the presence of a chronic health condition. Among those who supported waived consent, the reasons provided included medical benefits (36%) (e.g., to support science, to advance health care, to benefit society, to test treatments, for personal medical benefits, and because benefits outweigh risk) and perceived low-risk (34%) (e.g., study "safe," no perceived harm, intervention given anyway, trust in medical professionals to act in patients' best interests, study part of routine or standard of care, and medicine already approved) (ESM eAppendix).

Alternatively, 19% opposed waived consent (15% somewhat and 5% strongly). There was a spectrum of reasons given for why participants opposed waived consent (e.g., need to ask consent [26%], need to inform [15%], risk of side effects [10%], and need to respect rights/freedom/autonomy [7%]). Of participants who opposed, 4% believed waived consent was unethical, untrusting, and did "not seem right" while 3% stated they did not want to be experimented on (ESM eAppendix).

Comfort with waived consent

When asked about their comfort being personally included in a low-risk clinical trial using waived consent, 77% of participants were comfortable (very, 28%; somewhat, 49%) (Figure, panel b). The reasons for being comfortable or uncomfortable were similar to those reported for support/opposition of waived consent.

Table Sociodemographic characteristics of Canadian respondents

Variable	Sample $N = 2{,}000$
Age (yr), *n*/total *N* (%)	
18–29	297/2,000 (15%)
30–44	612/2,000 (31%)
45–64	707/2,000 (35%)
65+	384/2,000 (19%)
Gender, *n*/total *N* (%)	
Female	1,000/2,000 (50%)
Male	960/2,000 (48%)
Other/prefer not to answer	40/2,000 (2%)
Ethnic origin,*† *n*/total *N* (%)	
European	885/2,000 (44%)
North American	860/2,000 (43%)
Asian	248/2,000 (13%)
Latin/Caribbean/Central/South American	62/2,000 (3%)
North American Aboriginal	52/2,000 (3%)
African	29/2,000 (1%)
Oceania	4/2,000 (< 1%)
Prefer not to answer	127/2,000 (6%)
Chronic health conditions, *n*/total *N* (%)	
Autoimmune disease	132/2,000 (7%)
Cancer	29/2,000 (1%)
Chronic lung disease	126/2,000 (6%)
Diabetes mellitus	194/2,000 (10%)
Cardiovascular disease	199/2,000 (10%)
Mental health disease	343/2,000 (17%)
Obesity	155/2,000 (8%)
Other chronic conditions	152/2,000 (7%)
Other	66/2,000 (3%)
None	1,020/2,000 (51%)
Prefer not to answer	70/2,000 (3%)
Marital status, *n*/total *N* (%)	
Single, never married	540/2,000 (27%)
In relationship, not living together	55/2,000 (3%)
Married/living with partner	1,153/2,000 (58%)
Separated/divorced	180/2,000 (9%)
Widowed	59/2,000 (3%)
Prefer not to answer	13/2,000 (1%)
Religious identity, *n*/total *N* (%)	
Roman Catholic	532/2,000 (27%)
Protestant or other Christian	465/2,000 (23%)
Muslim	40/2,000 (2%)
Jewish	43/2,000 (2%)
Hindu	40/2,000 (2%)
Sikh	13/2,000 (1%)
Buddhist	15/2,000 (1%)
Atheist/agnostic	11/2,000 (1%)
Other	45/2,000 (2%)
No religious identity	729/2,000 (36%)
Prefer not to answer	75/2,000 (4%)

Table continued

Variable	Sample $N = 2{,}000$
Education, *n*/total *N* (%)	
High school or less	375/2,000 (19%)
Some postsecondary/trade certification	659/2,000 (33%)
Undergraduate degree	632/2,000 (32%)
Graduate degree	300/2,000 (15%)
Prefer not to answer	34/2,000 (2%)
Community size, *n*/total *N* (%)	
Unincorporated area (< 1,000 people)	101/2,000 (5%)
Small town/village (< 5,000 people)	181/2,000 (9%)
Small city (< 10,000)	134/2,000 (7%)
Medium city (< 100,000)	429/2,000 (21%)
Large city (< 1,000,000)	618/2,000 (31%)
Large metropolitan area (> 1,000,000)	496/2,000 (25%)
Don't know/prefer not to answer	42/2,000 (2%)
Employment status, *n*/total *N* (%)	
Employed full-time	824/2,000 (41%)
Employed part-time	193/2,000 (10%)
Self-employed full-time	79/2,000 (4%)
Self-employed part-time	75/2,000 (4%)
Retired	456/2,000 (23%)
Student	80/2,000 (4%)
Full-time parent/homemaker	80/2,000 (4%)
Military	4/2,000 (< 1%)
Currently unemployed	179/2,000 (9%)
Prefer not to answer	29/2,000 (1%)
Employment industry, *n*/total *N* (%)	
Health care	202/2,000 (10%)
Hospitality	110/2,000 (6%)
Energy sector	44/2,000 (2%)
Service industry/retail	224/2,000 (11%)
Agriculture/natural resources	35/2,000 (2%)
Construction/manufacturing	154/2,000 (8%)
Government/public service	201/2,000 (10%)
Education	173/2,000 (9%)
Professional (accounting; legal; engineering)	49/2,000 (2%)
Financial/banking/insurance	88/2,000 (4%)
Private companies	33/2,000 (2%)
IT/computer technology	69/2,000 (3%)
Driver/delivery/transportation	34/2,000 (2%)
Real estate/property management	20/2,000 (1%)
Other/retired/prefer not to answer	550/2,000 (28%)

Table continued

Variable	Sample $N = 2{,}000$
Household income (CAD), *n*/total *N* (%)	
Less than 30,000	270/2,000 (13%)
30,000 to < 60,000	519/2,000 (26%)
60,000 to < 90,000	451/2,000 (23%)
90,000 to < 120,000	303/2,000 (15%)
120,000 to < 150,000	149/2,000 (7%)
150,000 or more	132/2,000 (7%)
Prefer not to answer	176/2,000 (9%)

*Sum may exceed 100 because of participants providing more than one response

†This variable ("ethnic origin") is self-reported by survey participants and was defined by Ipsos using their standard question, "*What were the ethnic or cultural origins of your ancestors? An ancestor is usually more distant than a grandparent.*"

Minimum requirements for consent

When asked about the minimum requirements for consent approaches in the context of low-risk clinical trials, most participants (80%) believed a waived consent model was acceptable. About half (52%) believed consent should involve providing information about the clinical trial to patients/families and providing the option of opting out of participating, whereas only 11% believed waived consent with no additional information provided was acceptable. Nevertheless, 38% of participants believed fully informed consent prior to enrolment was the minimum requirement for low-risk clinical trials in the ICU.

Participant factors associated with greater acceptability for waived consent approaches included older age (67% for ≥ 45 yr *vs* 59% for 18–44 yr; $P < 0.001$), employment status (65% for employed *vs* 60% for not employed; $P = 0.04$) and prior admission to the ICU (65% *vs* 60%; $P = 0.04$). Participants with lower household income (59% for < CAD 60,000 *vs* 66% for ≥ CAD 60,000; $P = 0.04$) were less likely to accept a waived consent approach. There was no significant difference between the belief for fully informed compared with models of waived consent (including the option of opting out) when stratified by gender, level of education, religious affiliation, chronic health conditions, or prior involvement in medical research or geographic location.

Attitudes towards waived consent research

In the context of participating in low-risk clinical trials with a model of waived consent, most agreed (somewhat or strongly) with statements that participants should have the option of receiving the results (92%), that approval should be sought by the local REB (90%), and that approval should be approved by the ICU physicians (89%) (Figure, panel c). In the same context, when asked whether participants "should always give full informed consent" regardless of the "resources required" and the "level or risk," 74% and 72% either somewhat or strongly agreed.

Discussion

This cross-sectional survey of the Canadian public, 38% of whom were familiar with being in an ICU and 16% of whom had participated in medical research, indicates there is support and comfort among Canadians for the use of waived consent models (i.e., no consent) for low-risk clinical trials in ICU settings. Support was driven by willingness to contribute to medical science, by acknowledging the broader benefits to society, and by recognition that these routine treatments need rigorous evaluation and that the potential perceived benefits outweigh the risks. Nevertheless, support was not unanimous, with 19% opposing waived consent and 23% mentioning being uncomfortable with personally being included in a low-risk clinical trial in the ICU using waived consent. These perceptions were driven by concern for maintaining a respect for individual rights and autonomy, and the necessity for *a priori* disclosure, particularly for the associated risks with the intervention and participation. A small minority expressed concerns about trust in the health care system and that waived consent approaches were unethical. In this context, when asked about the minimum requirements, most believed waived consent was acceptable but would prefer to have information provided and be given the option to opt out of further participation.

For circumstances where fully informed consent is impossible or impracticable, most remained supportive and willing to personally participate, provided safeguards existed. These would, at minimum, include ethics review and approval, support and approval from the responsible ICU physician, transparent disclosure of information about the research being presented, and that an opportunity for opting out of participation be provided. Nevertheless, when probed with balancing questions, most participants stated they would prefer the opportunity to provide full informed consent prior to participation regardless of the circumstance or level of risk.

This survey extends prior work indicating the public would want to be considered for research participation, and would generally support and be comfortable with models of waived consent.[6] Prior work has shown comfort with waived consent, particularly in the absence of a surrogate decision-maker, provided their ICU physician supported

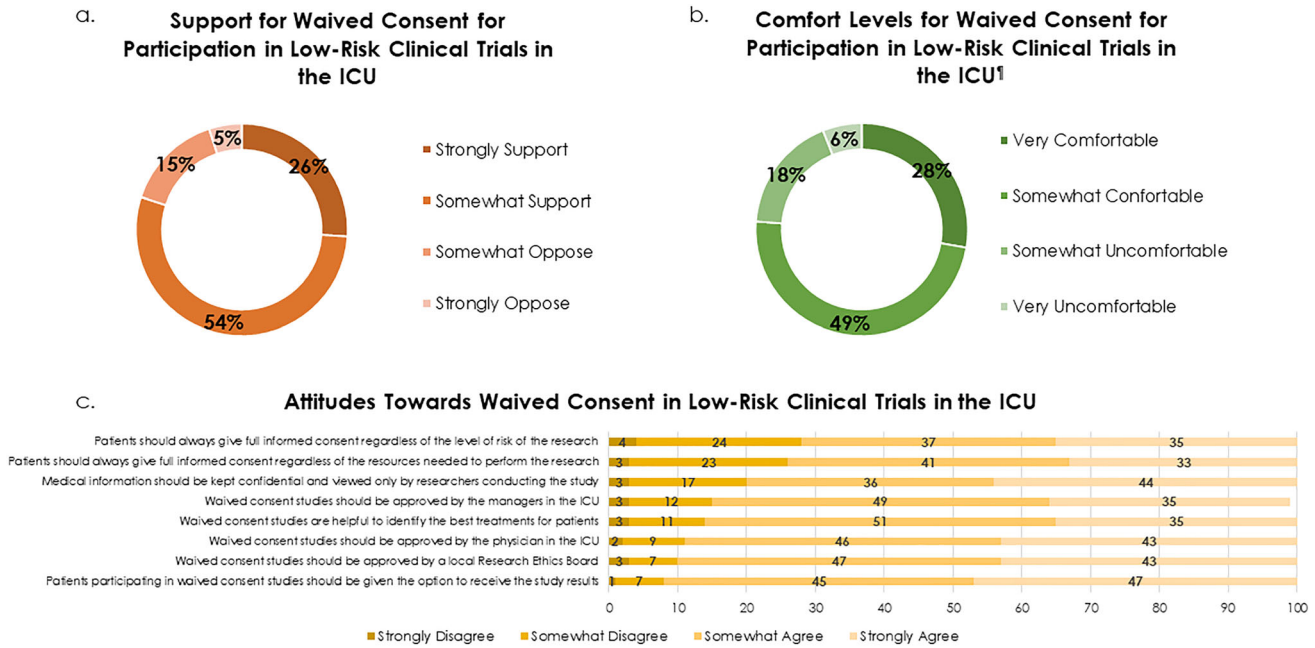

Figure Summary of beliefs and attitudes towards waived consent in low-risk clinical trials in intensive care unit settings from a sample of the Canadian public. Panel a: distribution of support levels; panel b: distribution of comfort levels; and panel c: attitudes towards waived consent. In panel b, because of one missing response (n = 1,999) and rounding to the nearest full percentage, the cumulative total is 101%.

their participation.[6] Research in ICU settings has unique challenges that can compromise enrolment of eligible participants, including impaired patient capacity, limited availability of surrogate decision-makers or research personnel, and narrow time-windows for inclusion.[13] This can inadvertently prolong the process of evidence generation and implementation into practice.

While models of waived consent in ICU settings can enhance recruitment into clinical trials; such models are not likely to have universal applicability.[14] Nevertheless, for low-risk comparative-effectiveness trials, specifically when evaluating standards of care within health systems where clinical care and research are embedded (i.e., learning health care systems), waived consent would appear clinically and ethically justifiable. Nevertheless, similar support from a health information legislative framework remains uncertain and would require further exploration.[5]

Observations in our survey imply there may be disconnect in the public's perceptions and understanding of the research process, particularly for participation in clinical trials that pose no more than minimal risk and are aimed at evaluating treatments or interventions within the scope of current standards of care. Specifically, as applied to the example in this survey, where a routine treatment may lack rigorous evaluation and where the prescription or administration of the treatment is not driven by specific patient-care indications, but rather variations in clinician practice or institutional culture.[2] This is compounded by not only the unique challenges of performing clinical trials in ICU settings (e.g., patients lacking capacity) but also the uncertainty in the quality of communication (i.e., poor comprehension of the details of specific clinical trial and the research process) and in decision-making about research participation by surrogates.[6,15] Misunderstanding or misrepresentation of such low-risk clinical trials and the process for participation may propagate further risk of public mistrust in health care institutions or precipitant decisional regret or posttraumatic symptoms among patients or surrogate decision-makers (i.e., family).[16]

This survey also reinforces the necessity for a broader campaign aimed at informing the public on the importance, rationale and relative benefits and risks (societal and individual) for low-risk clinical trials in ICU settings, specifically when focused on mitigating the random variations in standards of care. Moreover, the clinical, ethical, and legal framework for models of waived consent may further require reappraisal following the COVID-19 pandemic.

There are several limitations to consider. First, while the sampling frame was nationally representative, the public understanding and context with ICU-related research was relatively low (only $\sim$ 3% exposed). In addition, Ipsos did not disclose the total number of iSay panelists approached to achieve the target sample size, precluding an estimate of response rate. Second, Ipsos provided translation of the survey into French to enable sampling of the French-speaking population in Quebec. The French version of the survey was not validated prior to implementation and Ipsos

did not disclose the proportion of respondents from Quebec that were French-speaking. Third, the survey framing may have inadvertently contributed to biased responses by participants favouring acceptance of a waived consent model for participation in low-risk ICU research. Fourth, the survey instrument was not designed to specifically explore barriers and facilitators to support greater comfort and acceptance with the use of models of waived consent for low-risk clinical trials in ICU settings. Fifth, we recognize this survey targeted a representative population in Canada but may not necessarily reflect individuals who would (or may never) have the opportunity to participate either directly or indirectly (through family) in ICU research, including low-risk clinical trials. Finally, the survey leveraged the infrastructure and network of Ipsos, limiting the extent of detail that could be included. This precluded an expanded probing of perceptions of additional approaches to consent for participation in low-risk clinical trials in ICU settings.

In conclusion, there would appear to be public support for models of waived consent for participation in low-risk pragmatic clinical trials in ICU settings in Canada. Nevertheless, this was not universal among respondents and, when prompted, most would prefer models of consent that are fully informed. This information can inform and guide ethics, policy, and legal discussion on consent models.

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