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Brief Communication

Advance Consent in Acute Stroke Trials: Survey of Canadian Stroke Physicians

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ABSTRACT: Advance consent presents a potential solution to the challenge of obtaining informed consent for participation in acute stroke trials. Clinicians in stroke prevention clinics are uniquely positioned to identify and seek consent from potential stroke trial participants. To assess the acceptability of advance consent to Canadian stroke clinic physicians, we performed an online survey. We obtained 58 respondents (response rate 35%): the vast majority (82%) expressed comfort with obtaining advance consent and 92% felt that doing so would not be a significant disruption to clinic workflow. These results support further study of advance consent for acute stroke trials.

RÉSUMÉ : Consentement préalable et essais cliniques portant sur les AVC aigus : un sondage mené auprès de médecins canadiens spécialistes de l'AVC. Le consentement préalable constitue une solution potentielle au problème de l'obtention d'un consentement éclairé en ce qui regarde la participation à des essais cliniques portant sur les AVC aigus. À cet égard, les cliniciens qui œuvrent au sein des cliniques de prévention des AVC sont particulièrement bien placés pour identifier des patients potentiels à de tels essais et obtenir leur consentement. Pour évaluer l'acceptabilité du consentement préalable parmi les médecins des cliniques canadiennes spécialisées dans les AVC, nous avons effectué un sondage en ligne. Nous avons ainsi obtenu 58 réponses (taux de réponse : 35 %). À noter que la grande majorité des répondants (82 %) s'est dite à l'aise avec l'obtention d'un consentement préalable tandis que 92 % d'entre eux ont estimé que cette démarche ne perturberait pas de manière significative le flux de travail dans leur établissement. Ces résultats soutiennent donc la poursuite d'études portant sur le consentement préalable et des essais cliniques dans le cas d'AVC aigus.

Keywords: Consent; Advance directives; Research ethics

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Informed consent remains one of the most important tenets of medical research involving humans[1] but obtaining informed consent in hyperacute stroke research continues to pose a challenge given stroke's suddenness, its incapacitating nature, and the need to treat patients within minutes of their arrival in the emergency department.[2] In recent years, trial designs have incorporated various modifications to the consenting process, including surrogate consent, deferral of consent, and waiver of consent.[3] Each of these approaches has drawbacks, most important being the risk that patients may be enrolled into trials against their wishes.[4] Advance consent,[5] a practice accepted and used in dementia research,[6] could address some of the challenges experienced in acute stroke research by identifying at-risk patients in stroke prevention clinics, informing them about ongoing trials, and then inviting them to consent while they are capable of doing so. Their consent could then be documented in the health record, facilitating quicker trial participation for those who are willing and preventing enrollment for those who are not. This approach has potential for modest impact with about 7% of patients seen in our stroke prevention clinic with minor stroke/TIA presenting

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to the emergency department with acute stroke within 1 year of their clinic appointment.[7]

The concept of advance consent involves multiple stakeholders, including the physician seeking consent, the potential research participant giving it, and the organizations that oversee and fund research. Given the novel nature of this approach, assessing the perspectives of all key stakeholders is essential. In this paper, we report the results of a pragmatic survey we conducted with Canadian physicians who work in stroke prevention clinics. In future studies, we will assess the perspectives of patients and research ethics regulators. Our goal is to launch a feasibility study of advance consent in Canadian stroke prevention clinics. We hypothesized that stroke clinic physicians would generally feel comfortable seeking advance consent and would find it minimally disruptive to their normal clinic processes.

A 7-question online survey (see Supplementary Material) was produced using Qualtrics® (Qualtrics International Inc., Provo, UT) to assess acceptability and physicians' comfort around obtaining advance consent in stroke prevention clinics. Four questions collected respondent demographics, and the final question prompted respondents to share any thoughts they had about the subject. Pilot testing was done locally utilizing both stroke physicians and residents. The survey was designed to be very brief and anonymous to maximize physician participation. No incentives were used to enhance recruitment. It was distributed via email invitation to 148 physician members of the Canadian Stroke Consortium, Canada's national organization of stroke physicians, once in September 2021 and again in May 2022. The research protocol was approved by the Ottawa Health Science Network Research Ethics Board. The survey was closed on June 6, 2022. Survey results remained anonymous. Descriptive analysis was planned. Quantitative data were analyzed using Microsoft Excel Version 2205 (Microsoft Corporation, Redmond, WA).

The survey obtained 58 responses (response rate 39%), of which 50 were complete. Only complete responses were included for analysis. Almost all (96%) respondents practice in Canada and 86% work in an academic institution (Table 1). Most respondents were male (66%) and under age 50 (70%).

The majority of respondents felt very comfortable (46%) or somewhat comfortable (36%) with approaching a patient to seek advance consent for an acute stroke trial (Figure 1A). None of the respondents expressed feeling very uncomfortable with this approach. While almost all respondents expected that obtaining advance consent would disrupt the flow of their regular clinic activities to some degree (Figure 1B), 40% of respondents felt this disruption would be minor. Only 8% of respondents expected that seeking advance consent would be "significantly disruptive" to their regular clinic activities.

Nine respondents provided free-text comments about advance consent, three of whom described advance consent as a "great" or "interesting" idea. Another four respondents explained that their comfort level would depend on whether advance consent would be specific to a particular trial or would be broad (i.e. applicable to any potential trial), with one respondent indicating that a trial-specific approach would be more acceptable. One respondent expressed the need for a research nurse to handle the consenting process.

As we hypothesized, the majority of respondents expressed comfort with the idea of obtaining advance consent in a stroke prevention clinic, despite acknowledging some potential disruption to their current workflow. This is an important first step in exploring advance consent as an alternative to existing consent approaches for emergency interventional research like acute stroke trials. Advance care planning for health care and research participation is widely recognized and has received significant support,[8] though only a small percentage of Canadians voice their care preferences and even fewer express preferences regarding research participation in the event of decisional incapacity.[9] While advance consent has been tried to a very limited extent for emergency conditions, a scoping review we performed as part of the conceptual design of this approach found no instances of its use for acute stroke research (Article in press). However, advance consent would appear to be well suited for stroke trials because patients at risk of stroke can be identified, and the condition renders patients incapable of providing their own consent at the time of candidacy for research. Advance consent might also be translatable to other sudden onset and incapacitating conditions for which at-risk patients can be identified, such as epilepsy or myocardial infarction.

Table 1: Demographics of survey respondents ($n = 50$)

		n	%
Age	25–39	16	32
	40–49	19	38
	50–59	12	24
	60+	3	6
Gender	M	33	66
	F	16	32
	Prefer not to say	1	2
Practice	Academic hospital	43	86
	Community hospital	7	14
Location	Canada	48	96
	Europe	1	2
	Australia	1	2

An important issue that arose in the physicians' comments is the distinction between broad and trial-specific advance consent. Broad consent, where a potential research participant gives their permission to participate in any given stroke trial, would likely necessitate generic disclosure; this practice reflects the way consent for tissue samples is commonly structured, though this is rarely done for interventional trials. On the other hand, trial-specific advance consent, where a potential research participant gives their permission only to participate in a specific trial, is the standard followed by current consent procedures in that disclosure is in-depth. This survey has taken into account Article 3.11 of the TCPS-2 that allows researchers to be "guided by advance research directives."[10] This suggests that the TCPS-2 is open to the idea that someone can express wishes to participate in a range of trials that they do not currently know and might lack the capacity to consent to in the future. Both approaches can be considered ethically acceptable under suitable circumstances.[11]

This study is limited in its sample size ($n = 58$) though the response rate of 39% is strong among surveys of physicians.[12] We are also unable to ascertain whether this sample is representative of stroke neurologists in Canada without a publicly available body of demographic information for this population. We chose to

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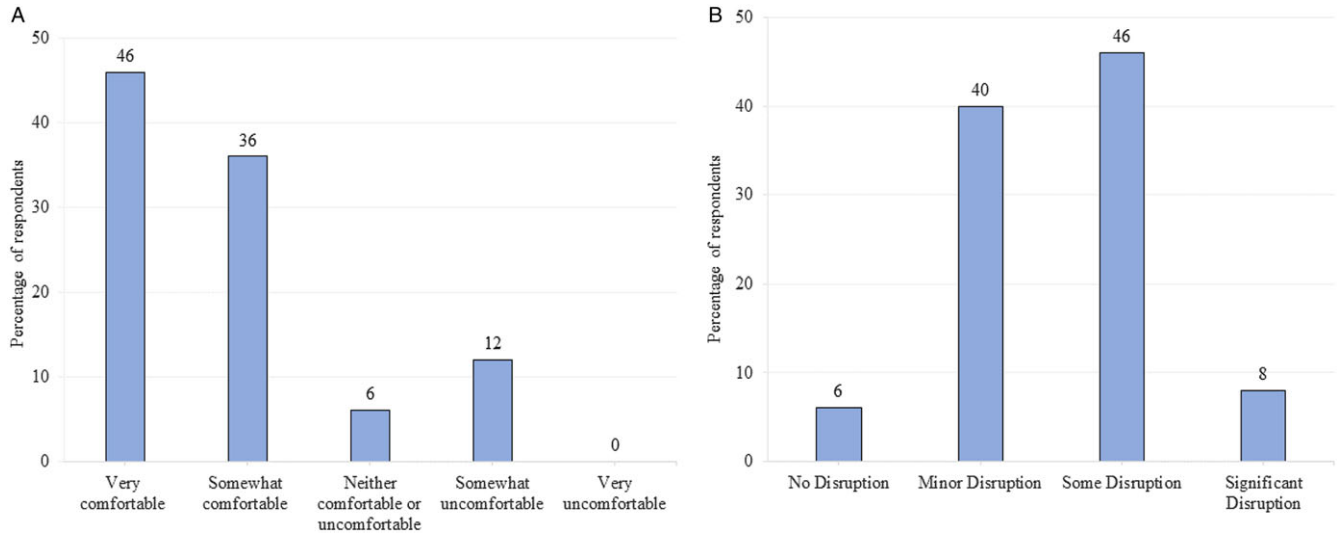

Figure 1: (A) Percentage of respondents and their level of comfort approaching a patient to seek advance consent (n = 50). (B) Percentage of respondents and their perception on the level of disruption seeking advance consent will be to regular clinic activities (n = 50).

focus exclusively on Canadian physicians as we intend to develop advance consent in the Canadian regulatory environment. Finally, there is a potential for self-selection bias in this survey where respondents who participated were more likely to be interested in the subject. We also acknowledge that this work is preliminary and is only one part of a program that will explore the attitudes of people with lived experience and research ethics board chairpeople towards both broad and trial-specific approaches. Based on these data, we intend to design a model of advance consent that can be piloted in a clinical trial. We will also explore the utility and cost-effectiveness of having dedicated research staff available to assist with screening patients and consenting them.

Ultimately, developing systems to improve consenting practices for acute stroke research will enhance opportunities to respect and enact patient wishes regarding research participation, making for a more equitable and efficient approach to clinical trial participation.

Supplementary material. For supplementary material accompanying this paper visit https://doi.org/10.1017/cjn.2023.12

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Statement of Authorship. All authors made significant contributions to this manuscript. MS, BD, and DD contributed to the development of the survey. MS identified and facilitated contact of potential participants. UU analyzed the survey responses. UU wrote the initial draft of the manuscript. All authors reviewed and revised the manuscript.

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