




BMJ Open Public reporting of clinical trial findings as an ethical responsibility to participants: a qualitative study

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ABSTRACT

Objective To understand how the experiences and views of trial participants, trial investigators and others connected to clinical trial research relate to whether researchers have a duty to participants to publicly report research findings.

Design Qualitative interview study.

Setting Semistructured interviews held in person or by telephone between March 2019 and April 2021 with participants in the Canadian provinces of Alberta, British Columbia and Ontario.

Participants 34 participants, including 10 clinical trial participants, 17 clinical trial investigators, 1 clinical research coordinator, 3 research administrators and 3 research ethics board members.

Analysis We conducted a thematic analysis, including qualitative coding of interview transcripts and identification of key themes.

Main outcome measures Key themes identified through qualitative coding of interview data.

Results Most clinical trial participants felt that reporting clinical trial results is important. Accounts of trial participants suggest their contributions are part of a reciprocal relationship involving the expectation that research will advance medical knowledge. Similarly, comments from trial investigators suggest that reporting trial results is part of reciprocity with trial participants and is a necessary part of honouring informed consent. Accounts of trial investigators suggest that when drug trials are not reported, this may undermine informed consent in subsequent trials by withholding information on harms or efficacy relevant to informed decisions on whether to conduct or enroll in future trials of similar drugs.

Conclusion The views of trial participants, trial investigators and others connected to clinical trial research in Canada suggest that researchers have an obligation to participants to publicly report clinical trial results and that reporting results is necessary for honouring informed consent.

INTRODUCTION

A systematic review indicated approximately 4 in every 10 randomised controlled trials included in trial registries were not reported in journal articles after a period of 2 or more years from study completion.¹ Clinical studies

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The use of qualitative interviews allowed for an in-depth exploration of experiences and views relating to clinical trial reporting as an ethical responsibility towards trial participants.
- ⇒ The study was strengthened by the inclusion of a range of participants, including past trial participants, trial investigators, research administrators and research ethics board members.
- ⇒ As the sample of past trial participants interviewed for this study was small, caution is warranted in generalising from these interviews.
- ⇒ The study focused on clinical trials in Canada, so it is not clear to what extent our findings apply to clinical trials in other countries.
- ⇒ It is possible that attitudes towards clinical trial reporting differed in those who participated compared with those who did not take part in the study.

with results favourable for the experimental treatment are more likely to be published, leading to bias in the medical literature.² Studies have also found low compliance with regulatory requirements for timely reporting of clinical trial results within ClinicalTrials.gov and the EU Clinical Trials Register.^{3 4} A study of clinical trials conducted in Canada, including trials registered in ClinicalTrials.gov and completed between 2009 and 2019, found that only 39% of trials had reported results in the registry by early October 2021.⁵ Moreover, the problem of non-publication of clinical trials has been documented across many areas of medicine^{6–10} and, although more frequent in earlier phase trials, for all phases of clinical trials.² Selective reporting of trials has led to less informed patient care, unnecessary harm to patients and a waste of research resources.^{11–13}

Advocates of full reporting of clinical trials have argued non-publication betrays trial participants and violates an implicit contract between participants and researchers.^{14–18} They reason that when individuals agree

to participate in trials, they expect their participation will contribute to medical knowledge and help future patients. When trial findings are not reported, this expectation is not fulfilled. More fundamentally, as individuals may reasonably expect trials to contribute to knowledge when deciding to participate in a trial, non-reporting of clinical trials may undermine informed consent.^{17 18}

Arguments that clinical trial investigators have a duty to trial participants requiring them to report findings are strengthened by previous research suggesting that motivations for participation in trials include altruism.^{19–22} In addition, a survey of non-critically ill patients in an emergency department setting found that most felt it was important to make clinical trial results publicly available.²³ However, trial participant views on the importance of reporting research findings and trial investigator views on the responsibility to report findings are unclear.

We conducted a qualitative study of clinical trial reporting in Canada. Our broader study aimed to investigate factors contributing to non-publication and publication bias in clinical trials and related ethical issues.^{24 25} The analysis reported in this paper aimed to understand how the experiences and views of trial participants, trial investigators and others relate to whether researchers have a duty to trial participants to publicly report research findings in journals or trial registries.

METHODS

Study design

We conducted a qualitative study involving semistructured interviews and thematic analysis of interview data to investigate experiences and views related to clinical trial reporting.²⁶ This study used a qualitative approach because this provided the flexibility to investigate emergent themes and to collect rich data regarding views and experiences relating to reporting of clinical trials—for example, through prompting interviewees to elaborate on unanticipated or important points raised in their responses.^{27 28} The research team for this project included a clinical trial investigator (SG), an expert in qualitative methods (GG), a health research analyst (RLM) and researchers in epidemiology and health policy (BM, MRL and CRD). The researchers had no prior relationship with those interviewed for the study.

Sampling

We sought to interview clinical trial participants, clinical trial investigators, clinical research coordinators, research administrators and research ethics board (REB) members (inclusion criteria are listed in [table 1](#)). We used a purposive sampling strategy to involve trial participants who had participated in trials for a range of treatments, trial investigators in diverse medical fields and others connected to clinical trial research to provide additional perspectives. Snowball sampling was used to as a complementary strategy to gain referrals to additional trial investigators and REB members. We chose to include

Table 1 Types of interviewees and inclusion criteria

| Interviewee type | Inclusion criteria | Rationale |
|-------------------------------|---|--|
| Past trial participant | Participated in ≥ 1 clinical drug trial while at least 18 years of age; participation in the 5 years prior to interview, but has now ended | Will have experience related to trial participation and trial reporting |
| Clinical trial investigator | Conducted ≥ 1 clinical drug trial | Will have experience relevant to trial reporting |
| Clinical research coordinator | Coordinated ≥ 1 clinical drug trial | May have experience relevant to clinical trial reporting |
| Research administrator | Knowledge of policy and practice related to dissemination of clinical trial findings and/or relations with trial sponsors | Contribute experience, knowledge and views from policy or administrative perspective |
| Clinical REB member | ≥ 1 year of experience as clinical REB member | Experience in ethical review and familiarity with practice and policy relating to clinical trial reporting |

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in our study sample both those who had participated in trials and those involved in the conduct, administration or ethical review of trials for two reasons: first, each type of interviewee might provide insights from a different perspective, and second, this would allow for triangulation of findings.²⁷

Recruitment

Strategies to recruit past trial participants included advertising in a free newspaper and requesting assistance from clinical research coordinators and managers, who sought consent from past trial participants for us to contact them about our study. We emailed or telephoned 11 individuals who expressed interest following the advertisement or consented to be contacted (10 participated and 1 did not respond). We identified other types of interviewees through online sources (ClinicalTrials.gov, Canadian Clinical Trials Asset Map database and websites of research institutions and REBs) and referrals. We invited participation from 61 trial investigators by email (17 investigators participated, 2 responded but were unavailable for an interview during the study, 36 did not respond and 6 declined). Investigators who declined stated they were too busy (n=1), not interested (n=1) or lacked relevant experience (n=4). A clinical research coordinator

who worked with a participating trial investigator also volunteered to take part in an interview. In addition, we emailed 12 research administrators (3 participated and 9 did not respond) and 15 REB members (3 participated and 12 did not respond). Trial participants and trial investigators were eligible to receive a US\$50 honorarium for participation.

Data collection

We conducted semistructured interviews from March 2019 to April 2021. Interview guides for each type of interviewee were used (online supplemental appendix). Interviews were primarily based on open-ended questions and allowed for exploration of unanticipated issues. Data collection included initial interviews in person or by telephone with 34 individuals and follow-up telephone interviews with 4 individuals to collect additional information. The duration of interviews was approximately 45–60 min for initial interviews and 20 min for follow-up interviews. In-person interviews were held in a public library meeting room or at the interviewee's workplace. RLM conducted the research interviews and coded the interview data. Data collection continued until the data allowed for a detailed analysis addressing the study's research questions.

Data analysis

Interviews were audiorecorded and transcripts were analysed using ATLAS.ti (V.8), including coding and deriving themes from the data. Analysis included initial coding with an open-ended approach, followed by additional analysis to retain and develop key themes for analysis.²⁶ Collection of data from different types of interviewees allowed for triangulation of data during analysis.²⁷ The Consolidated Criteria for Reporting Qualitative Studies checklist was used to guide reporting of findings.

Patient and public involvement

A patient advocate was consulted during the planning of this study regarding the importance of pursuing this research and strategies for recruiting past trial participants for interviews. All participants in this study who are interested will receive a summary of the study results, including past trial participants who took part in a research interview.

RESULTS

Overall, 34 individuals took part in the study, including 10 clinical trial participants, 17 clinical trial investigators, 1 clinical research coordinator, 3 research administrators and 3 REB members. (See table 2 for interviewee characteristics). The study included individuals from the Canadian provinces of Alberta, British Columbia and Ontario. Past trial participants varied by sex (three male; seven female), age (38–77 years at the time of their initial interview) and highest level of education completed (from elementary to university). They had taken part in trials of 6 months to 5 years in duration, testing treatments

Table 2 Interviewee characteristics

| Characteristic | Past trial participants (n=10) | | |
|--|--------------------------------|-------------------------------|-------------------|
| (A) Past trial participants | | | |
| Sex | | | |
| Female | | | 7 |
| Male | | | 3 |
| Age | | | |
| ≤65 years | | | 5 |
| >65 years | | | 5 |
| Education, highest level completed | | | |
| Elementary | | | 1 |
| Secondary | | | 3 |
| Community college | | | 1 |
| University | | | 5 |
| Province | | | |
| Alberta | | | 3 |
| British Columbia | | | 7 |
| (B) Trial investigators | | | |
| Characteristic* | Trial investigators (n=17) | | |
| Primary appointment | | | |
| University or academic teaching hospital | | | 10 |
| Other (eg, private practice, cancer centre) | | | 7 |
| Experience in role | | | |
| ≤5 years | | | 0 |
| >5 years | | | 17 |
| Province | | | |
| Alberta | | | 0 |
| British Columbia | | | 9 |
| Ontario | | | 8 |
| Types of funding | | | |
| Non-industry only | | | 0 |
| Industry only | | | 0 |
| Both industry and non-industry | | | 17 |
| Most senior role | | | |
| Principal investigator for site | | | 3 |
| Principal investigator for trial | | | 14 |
| Trial type | | | |
| Single site only | | | 0 |
| Multiple site only | | | 1 |
| Both single and multiple site | | | 16 |
| (C) Clinical research coordinators, research administrators and research ethics board (REB) members | | | |
| Characteristic | Research coordinator (n=1) | Research administrators (n=3) | REB members (n=3) |
| Primary appointment | | | |
| University or academic teaching hospital | 0 | 3 | 1 |
| Other (eg, private practice, cancer centre) | 1 | 0 | 2 |

Continued

**Table 2** Continued

| (C) Clinical research coordinators, research administrators and research ethics board (REB) members | | | |
|--|-----------------------------------|--------------------------------------|--------------------------|
| Characteristic | Research coordinator (n=1) | Research administrators (n=3) | REB members (n=3) |
| Experience in role | | | |
| ≤5 years | 0 | 0 | 1 |
| >5 years | 1 | 3 | 2 |
| Province | | | |
| Alberta | 0 | 1 | 1 |
| British Columbia | 1 | 0 | 2 |
| Ontario | 0 | 2 | 0 |

Table 2 was created by the authors. A version of table 2 has previously been published, and it is reprinted in a modified form with permission.²⁴
 *Classifications were based on those used for an investigator survey by Rochon *et al.*³⁹
 REB, research ethics board.

for cardiovascular disease, *Clostridioides difficile* infections, chronic pain, diabetes, eye disorders and multiple sclerosis. Among interviewees who were involved in the conduct, administration or ethical review of trials, some spoke about both conducting trials and playing a role in research administration or reviewing ethics applications. Trial investigators who took part in the study had conducted trials in cardiovascular medicine, endocrinology, hepatology, infectious diseases, oncology, psychiatry and rheumatology.

Our study results are presented below by theme. This includes themes relating to trial participant experiences and views (motivations for participating in a trial and trial participant views on reporting research findings), accompanied by quotations from trial participants (P1–P10). The findings below also include themes related to accounts from those involved in the conduct, administration or ethical review of trials (views on clinical trial reporting as a responsibility to research participants and linking clinical trial reporting to informed consent), presented with quotations from trial investigators (T1–T17).

Views of clinical trial participants

Motivations for participating in a clinical trial

Most trial participants stated they were motivated to take part in the clinical trial in part to help future patients. Patients with a less urgent need to improve their health condition were more likely to identify helping future patients as their primary reason for joining a trial. For example, a patient with type 1 diabetes recalled that she had joined multiple clinical trials over time because she ‘figured if there isn’t research being done to help people, then nothing is ever going to improve.’ (P7) Patients who were in more urgent need to improve their health condition were more likely to identify access to treatment as their primary reason for participating in a trial. However, they also often wanted to help future patients and conceived of their participation as an act of solidarity with others like them. A patient who had experienced a

recurring *C. difficile* infection recalled that at the time of joining a clinical trial she had told family members: ‘Nobody should have to suffer this way, and if there’s anything that I can do to help medical science move forward so that other people don’t have to suffer like this in the future, I’m all for it.’ (P6) Although most participants were motivated to join a trial in part to help others, this was not always the case. One trial participant, who joined a trial to access treatment after suffering from a sudden deterioration of her vision due to an eye disorder, recalled that her initial motivation was solely to address her own health needs. Trial participants typically had multiple reasons for participating in a trial. Motivations varied among participants but included access to free medication or medical supplies, access to better care and helping one’s health provider or researchers.

Trial participant views on reporting research findings

Most past trial participants felt it was important for the results of clinical trials to be published. Trial participants stated various reasons they felt publishing research findings was important. Some suggested if results were not published, this would represent a waste of time or resources. A patient who had participated in a trial to test a treatment for *C. difficile* felt it was important to avoid wasting the effort and resources invested in a trial: ‘If we’re doing the work, spending the dollars and not using that information to further medical science, then what was the point of doing all that work in the first place?’ (P6) Another patient, who had taken part in a trial to test a treatment for relapsing-remitting multiple sclerosis, emphasised the importance of reporting results to help future patients: ‘If you don’t publish... then how is it to be paid forward to help other people?’ (P5) Some trial participants stated it was important to publish trials to learn from negative or incomplete trials, inform the medical community, demonstrate transparency and improve future research. However, not all patients stated that publishing trial results was important. One patient felt it was hard for her to judge whether it was important to publish results from a trial suggesting a treatment did not work. Another patient spoke about how he would feel about publication of results of the trial he participated in, rather than about the importance of reporting in general, saying: ‘I would feel a little better knowing that my participation helped in something.’ (P9)

When some participants described the value of clinical trial reporting, they highlighted the contribution of trial participants to research. A patient with type 1 diabetes felt it was important to publish trial results, ‘because of a lot of effort that a lot of people put into it—not just the researchers, but the people that were participating in the trial.’ (P7) Similarly, another trial participant said she felt it was important to publish trial results in part because ‘people were gracious enough to be part of it.’ (P2) One trial participant reflected that she was quite willing to be a ‘guinea pig’, but she would feel ‘cheated’ if the trial she had participated in were not published, because she

had participated ‘not just for me.’ (P5) Taken together with statements from a larger number of trial participants that they had participated in part to help other patients, these comments suggest reporting the results of trials is important as a form of reciprocity between researchers and trial participants. However, none of the trial participants was aware of whether the results of the trial they had participated in had been published, although in some cases the trials they had taken part in were either ongoing or so recent that it would be reasonable that results might not have been published at the time of their interview. In effect, reciprocity between trial participants and researchers may require reporting of trial results, but trial participants may often not be able to observe whether this is fulfilled.

Views of those involved in the conduct, administration or ethical review of trials

Clinical trial reporting as a responsibility to research participants

Among investigators, administrators and REB members interviewed for this study, many felt researchers have an obligation to trial participants to report the results of clinical trials. Comments highlighted that trial participants contribute their time and expose themselves to risk, yet may not directly benefit through their participation. Several comments suggested reporting results is necessary as a kind of reciprocity, or to fulfil an implicit agreement, between trial participants and researchers. A trial investigator who studied treatments for infectious diseases felt publishing was important as a responsibility to trial participants: ‘Well, they’ve spent their time ... There’s a potential risk of entering a clinical trial, so I think as researchers we have a responsibility to hold true to their commitment and altruism to enter into a clinical trial.’ (T16) An endocrinologist who conducted clinical trials said: ‘I think most people understand that this may or may not benefit them, but hopefully this will benefit society... If it’s not even published, then we’re not fulfilling our side of the bargain.’ (T14) Similarly, a couple of investigators suggested that a ‘contract’ between participants and researchers obligated researchers to report results. Notably, the chronology of this reciprocity or ‘bargain’ involves the trial participants contributing their time and exposing themselves to risk without knowing whether researchers will fulfil their implicit obligation to report the research findings. This was reflected in the comment of one trial investigator, who noted: ‘People have volunteered, given their time, given their samples *in good faith* that some science is going to come out of it.’ (T7, emphasis added)

Some trial investigators felt a responsibility to trial participants to publicly report trials results existed but it could be difficult or less important to publish in certain circumstances. A cardiovascular investigator, who spoke about the difficulty of publishing incomplete trials, stated: ‘To me, not publishing is unethical, but I can see some situations where it’s just not possible.’ (T10) He also suggested trials stopped early following a decision by

an industry sponsor to halt development of a drug could be less important to publish due to a lack of statistical power and lack of relevance. Similarly, some interviewees mentioned that trials which are unable to recruit many patients may not be published and that it can be difficult to make inferences from or publish an incomplete trial. In addition, some investigators highlighted that a lack of time or resources may be a factor contributing to non-reporting or delays in reporting. While trial results could be reported in trial registries such as ClinicalTrials.gov, which could be particularly helpful if results were difficult to publish in a journal, not all trial investigators were aware of the possibility of reporting results in registries.

Linking clinical trial reporting to informed consent

Several investigators linked an obligation to report trial results in a journal or trial registry to informed consent. In some cases, consent forms signed by trial participants actually indicate research findings will be published. More generally, trial participants may reasonably expect or be told a trial will contribute to medical knowledge. An investigator in hepatology trials suggested this requires researchers to report their findings: ‘We specifically say the benefit will be greater knowledge to the scientific and medical community, which will hopefully benefit other people in the future. So if we’re not sharing the results of the study, then that’s not true... We are not honouring that consent.’ (T15)

When trials showing drug harms or a lack of efficacy, including early phase trials, are not reported, this may also undermine informed consent in future trials. An investigator noted that trials identifying safety concerns may provide information relevant to future trials of similar drugs. Although another investigator was less concerned about this issue because drugs in the same class would not necessarily be associated with the same adverse effect, in some cases information about harms of one drug in a class is deemed important enough to add to consent forms used in trials of drugs in the same class. Similarly, a trial investigator and an REB member involved in conducting trials each highlighted that publishing trials showing harms may inform other trialists that trials of the same or similar drugs would expose patients to excessive risk. In addition, the REB member commented that non-publication of negative trials may lead to redundant research which unknowingly involves patients in trials of drugs lacking efficacy.

DISCUSSION

The accounts of trial participants, trial investigators and others connected to clinical trial research suggest that when researchers enrol patients in clinical trials there is often an implicit understanding among researchers and trial participants involving an obligation to publicly report research results. Most trial participants were motivated to enter clinical trials in part to advance science, and most felt that reporting the results of clinical trials is



important. Trial participant accounts suggest their contributions are part of a reciprocal relationship involving the expectation that research will advance medical knowledge. Similarly, comments from trial investigators suggest that reporting trial results is part of reciprocity with trial participants and is a necessary part of honouring informed consent. In addition, when trials are not reported, this may undermine informed consent in subsequent trials by withholding information on harms or efficacy relevant to informed decisions on whether to conduct or enrol in future trials of similar drugs.

Comparison with existing literature

Our finding that many trial participants were motivated to join trials in part to help future patients is consistent with previous studies on reasons for participation in trial research.^{19–22} Our study adds that even patients who are strongly motivated to participate by the opportunity to access treatment may feel it is important to help future patients out of a sense of solidarity with others like them.

A survey of non-critically ill patients in an academic emergency department in the northeastern USA found that most felt it was important to report trials results.²³ Our study indicated most individuals who had recently taken part in a clinical trial felt it was important to report trial results, while highlighting trial participants may view their own contributions as part of a reciprocal relationship involving the expectation that trials will contribute to medical knowledge. However, this reciprocity which involves a responsibility for researchers to report trial results may be weakened for various reasons. First, trial participants may often not find out whether trial results are published by the researchers, which might diminish a researcher's sense of the obligation to publish as a responsibility to the trial participants. Second, trial participants might be unlikely to question whether results have been reported, due to losing contact with researchers who are not their regular health providers, respect for the authority and expertise of the researchers, or gratitude for other benefits received in the trial (such as access to treatment or greater medical attention).

Importantly, our study strengthens empirical support for arguments that when trial results are not reported, this violates an implicit agreement or contract between researchers and participants and undermines informed consent.^{15–18} Trial participants may consent to enter a trial with the understanding that research will benefit future patients. However, this consent is not respected when trial results are not reported and this potential benefit is not fulfilled. In effect, the core ethical principle of respect for persons is undermined, as informing trial participants of the risks and benefits of research is part of respecting their autonomy as research participants.^{29 30}

Notwithstanding the responsibility to publicly report trial findings, some investigators noted it may be difficult to complete a trial due to low recruitment or other reasons, and it may be difficult to publish certain findings such as those from an incomplete trial. Estimates of the

rate of discontinuation of clinical trials vary, but discontinued trials are less likely to be published.^{31–33} A focus group study of biomedical researchers found that many felt it was difficult to publish negative or 'no difference' results.³⁴ It may even appear questionable to report a trial that encountered problems such as difficulty in recruitment or high drop-out rates. However, trial registries provide an avenue to report trials that might be difficult to publish in a journal, and may, like ClinicalTrials.gov, allow authors to provide reasons for early termination of a trial and to describe limitations or caveats regarding a trial's results.³⁵

Policy implications

While the analysis reported in this paper highlights an ethical responsibility to report research results, this responsibility does not lie with trial investigators alone. Previously reported findings from our broader study of clinical trial reporting, based on the same interviews analysed for this paper, indicated that industry sponsors of clinical trials may exert influence on whether results are reported and that clinical trial reporting practices are shaped by incentives within the research system favouring publication of positive or negative trials, such as funding opportunities and academic promotion, bonuses and recognition.^{24 25} Similarly, a survey study found researchers were 'aware of being the main culprits of non-publishing or selective publishing of results from clinical trials' but felt that 'blame rested not solely with them but with the system that encourages and supports practices that lead to publication bias—from funders and research institutions to journals and trial registries.'³⁶ The responsibility to ensure trials are publicly reported is shared by trial investigators with other actors in the research system who shape the context in which trial reporting takes place.

Stronger regulatory measures could improve clinical trial reporting policy or practices of research institutions, sponsors and individual investigators. In Canada, it is important to adopt regulatory measures to require reporting of clinical trial results within a recognised trial registry. While phase 1 trials are largely excluded from current regulatory reporting requirements in the USA and European Union,^{4 37} our study highlights reporting early phase trials is necessary for fulfilling informed consent. The effectiveness of mandatory reporting requirements depends on both enforcing existing requirements and expanding their scope to cover all clinical trials of drugs and biologics.^{3 4 38}

Strengths and limitations of this study

The use of qualitative interviews allowed for an in-depth exploration of experiences and views relating to clinical trial reporting as an ethical responsibility towards trial participants. A strength of our study was the inclusion of a range of participants, including past trial participants, trial investigators, research administrators and REB members. Our study also had limitations. As the sample of past trial participants interviewed for this study was

small, caution is warranted in generalising from these interviews. However, this limitation was mitigated by triangulation of findings among different types of interviewees regarding reciprocity between researchers and trial participants and the responsibility to report results. More generally, it is not clear to what extent our findings apply to clinical trial settings outside Canada, as experiences and views of clinical trial reporting might vary due to differences in funding, policy or healthcare systems. In addition, it is possible that attitudes towards clinical trial reporting differed in those who participated compared with those who did not take part in the study.

CONCLUSIONS

The views of trial participants, trial investigators and others connected to clinical trial research in Canada suggest that researchers have an obligation to research participants to report clinical trial results and that reporting of results in registries or journals is necessary for honouring informed consent. This highlights the need for Health Canada to adopt regulatory measures to require timely reporting of clinical trial results within a recognised trial registry. Future studies could investigate views on clinical trial reporting in other countries.

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agencies, the Canadian Institutes of Health Research and Alberta Innovates; no other relationships or activities that could appear to have influenced the submitted work

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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