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The Effect of Prenotification on the Response Rate of a Postal Survey of Emergency Physicians: A Randomized, Controlled, Assessor-blind Trial

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The Effect of Prenotification on the Response Rate of a Postal Survey of Emergency Physicians: A Randomized, Controlled, Assessor-blind Trial

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Potential competing interests

Dr. Michael Hickey receives a salary as Hospital Donation Physician from Trillium Gift of Life Network, Ontario's organ donation organization, and Dr. Jeffrey Perry is supported by the Heart and Stroke Foundation of Ontario through a Mid-Career Award

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Dr. Michael Hickey is the first author and was responsible for the study design, data collection, statistical analysis and writing of the manuscript. Ms. Carly Hickey assisted with study design data collection and review of the manuscript. Drs. Jeff Perry, Lauralyn McIntyre, Monica Taljaard, Kasim Abdulaziz and Krishan Yadav provided methodological and statistical support in addition to manuscript review.

Keywords: Survey; emergency physician;

Abstract

Objectives: Response rates to physician surveys are typically low. The objective of this study was to determine the effect of a prenotification letter on the response rate of a postal survey of emergency physicians.

Design: We constructed a 24-item survey instrument using rigorous methodology informed by a modified Dillman's tailored design technique. The survey was to assess physician attitudes towards an intervention to encourage organ donation registration while patients and visitors are in the emergency department.

Participants: A random sample of 500 emergency physicians in Canada.

Setting: Participants were selected from the Canadian Medical Directory, a national medical directory which lists more than 99% of practicing physicians in Canada.

Interventions: Physicians were randomized in a concealed fashion to receive a prenotification letter approximately one week prior to the survey, or to not receive a prenotification letter. All physicians received an unconditional incentive of a \$3 coffee card with the survey instrument. In both groups, non-respondents were sent reminder surveys approximately every 14 days and a special contact using Xpresspost during the final contact attempt.

Results: 201 of 447 eligible physicians returned the survey (45.0%). Of 231 eligible physicians contacted in the prenotification group, 80 (34.6%) returned the survey and amongst 237 eligible physicians contacted in the no-prenotification group, 121 (51.1%) returned the survey (absolute difference in proportions 16.5%, 95% CI 2.5-30.5, $p=0.01$)

Conclusion: Inclusion of a prenotification letter resulted in a lower response rate in this postal survey of emergency physicians. Given the added costs, time and effort required to send a prenotification letter, this study suggests that it may be more effective to omit the prenotification letter in physician postal surveys.

Article Summary: Strengths and limitations of this study

- The survey instrument that this study was based on was robustly designed using cognitive interviews and pilot testing
- The participants in the survey were randomly selected from the most comprehensive database of Canadian physicians
- To our knowledge, this is the first study to evaluate the effect of a prenotification letter in postal physician surveys

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Introduction:

Physician surveys are an important method for obtaining information in research studies that aim to ultimately improve the delivery of healthcare. For a number of proposed reasons, adequate response rates remain difficult to achieve (1). Surveys of physicians typically have a response rate as low as ten percentage points less than that of the general population (2). Over the past decade, much emphasis in the literature has been placed on identifying strategies to improve response rates amongst physicians and other health providers (1, 3-6). Several strategies aimed at increasing physician survey response rates have been employed with variable success, including but not limited to unconditional financial incentives, design-based interventions, special envelope types and method of delivery (6-8). Dillman's tailored design method is a well-established technique that focuses on all aspects of internet and postal surveys with a goal that the respondent will believe that the expected benefits of responding outweigh the costs, and therefore increasing the likelihood of response (9). Practically, examples include using a clear and easily comprehensible survey instrument, implementing repeated contacts including a prenotification letter, utilizing a postage-paid, addressed return envelope, personalization of correspondence and an unconditional financial incentive (9). Postal surveys of physicians have had more favorable response rates than other modes, such as internet-based approaches (6, 10, 11). There exists little literature examining the effect of prenotification on the response rates of postal surveys of physicians. In an electronic web-based survey of 3550 general internists in the United States of America, a postal prenotification letter increased the response rate from 3.0% to 6.2% (12). However, the effect of prenotification on postal physician surveys, which have more favorable response rates, remains unclear. The objective of the current study is to determine the effect of prenotification on the response rate of a postal survey of emergency physicians in Canada.

Methods:

Study design and participants

This was an a priori sub-study of a national, self-administered postal survey of Canadian emergency physicians. The purpose of the original study was to examine emergency physicians' attitudes towards and acceptability of an intervention of promoting organ donation registration of patients and visitors while they await medical care in the emergency department. The current sub-study was then designed to assess the effect of survey prenotification on the response rate. To be eligible for the study, physicians needed to be currently practicing emergency medicine in Canada. The first contact occurred on December 12, 2019, with a reminder letter and

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3 additional copy of the survey every two weeks for a total of six weeks. The final contact was mailed on February 24,
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5 2020. We delayed the second contact by one week due to the date falling within the Christmas/New Year holiday
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7 season.

8 9 *Patient and Public Involvement:*

10 Neither patients nor the public were formally involved in the planning of the study.

11 12 13 *Outcome measure*

14 Our primary outcome was the survey response rate.

15 16 17 *Survey development*

18 The survey instrument was designed using rigorous methodology and with reference to Dillman's Tailored
19 Design technique (9). We conducted key-informant interviews with 12 experts with advanced knowledge in organ
20 donation and survey methodology which included critical care and emergency physicians, nurses and research
21 methodologists. The instrument was then drafted in English and translated into French based on physician language
22 preference according to the Canadian Medical Directory. We then conducted 10 cognitive interviews in both
23 languages with five attending and five resident emergency physicians whereby participants were directly observed
24 self-administering the survey. The questions were read aloud, and participants were encouraged to express thoughts,
25 comments or concerns while they completed the survey. In doing so, we were able to flag any potential problems
26 with regards to the content, flow, language and grammar of the survey, which took about 15 minutes to complete.
27 After minor adjustments, we conducted pilot surveys of 20 randomly selected emergency physicians from our
28 sample in an attempt to identify any issues with the postal procedure or completion of the survey. The final survey
29 instrument consisted of 24 questions divided into four sections, double-sided on two sheets of paper: demographic
30 and practice information, attitudes regarding organ donation, acceptability of using the emergency department to
31 promote organ donation and registration, and related perceived facilitators and barriers (Appendix 1). No
32 modifications were required following the pilot phase.

33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 *Ethics Statement*

48 This study was approved by the Ottawa Health Science Network Research Ethics Board. (Approval
49 20190178).

50 51 52 53 *Sample selection*

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3 From our sampling frame of 2,955 emergency physicians identified in the Canadian Medical Directory,
4 which claims to be Canada's most comprehensive directory of medical professionals, we used computer-generated
5 random numbers to randomly select 500 physicians with emergency medicine listed as a credential for the survey.
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7 Following this, an independent set of computer-generated random numbers were used to assign half of the
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9 physicians to receive a prenotification letter, and the other half to controls (no prenotification). Based on language
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11 preference, 77 of the total number of surveys were sent in French. From the sample of 500, we selected 20
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13 physicians located near our geographical area to receive the survey as pilot subjects (to minimize postal travel time)
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15 with intention to test the survey instrument and the postal procedure of distribution and return. Since the survey
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17 instrument did not require alteration once pilot participant responses were analyzed, these pilot surveys were
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19 included in the data analysis.
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22 *Intervention*

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24 Prenotification letters were hand-signed by the principal investigator and sent to half the randomly selected
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26 participants approximately one week prior to the first questionnaire mailout. The letter outlined the purpose of the
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28 study and emphasized the importance of the physicians' contribution. (Appendix 2). The other half did not receive
29
30 prenotification, and therefore were considered controls. All physicians in both groups received a \$3 Tim Hortons
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32 coffee card which was included with the first survey as an unconditional incentive.
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34 *Survey administration*

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36 Approximately one week following the prenotification letter that half the participants received, our survey
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38 instrument, an introductory letter, a \$3 Tim Hortons coffee card (national coffee shop) and an addressed, postage-
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40 paid return envelope was sent to all physicians, in either English or French languages, based on physician preference
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42 stated in the Canadian Medical Directory. A reminder letter and additional copy of the survey were sent to non-
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44 respondents approximately every two weeks for a total of six weeks. The final reminder was delivered via courier
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46 (Xpresspost), a trackable, larger special envelope delivered nationally within two business days.

47 *Data analysis*

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49 Using blinded outcome assessment, physician responses were analyzed using descriptive statistics. Although the
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51 response to the first item in the survey determined respondent eligibility (a binary question indicating current
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53 practice of emergency medicine in Canada), we included all physicians who did return the survey in the overall
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55 response rate. However, given that some respondents were ineligible to complete the subsequent items in the
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questionnaire, they were not included in further analysis. The randomized groups were compared using a chi-squared tests. The response rate was calculated in each group and compared using absolute difference in proportions with 95% confidence interval. Cumulative response rates were also reported after each reminder letter. We also assessed for non-response bias using chi-squared tests based on language preference and geographic region of Canada. Data were analyzed using SAS version 9.2 (SAS Institute, Cary, NC, USA).

Results:

Respondents

Demographic information for the respondents is shown in Table 1. The majority of respondents were male (62.7%), 33.3% were in the 35 to 44-year age range, and 72.1% have been in practice for 10 years or less. The majority of respondents practice in the most populous Canadian provinces: Ontario (41.3%), Quebec (22.9%) and British Columbia (17.4%).

Response rate

Of 500 physicians contacted (which included the 20 pilot participants), 26 were undeliverable. 27 physicians indicated that they were no longer practicing emergency medicine in Canada and were therefore considered ineligible to complete the survey. Of 474 physicians to whom a survey was delivered, 228 (48.1%) returned the survey and after assessment for eligibility, 45.0% of the total eligible respondents were included in the data analysis. Of 231 eligible physicians contacted in the prenotification group, 80 (34.6%) returned the survey and amongst 237 eligible physicians contacted in the no-prenotification group, 121 (51.1%) returned the survey (absolute difference in proportions 16.5%, 95% CI 2.5-30.5, $p=0.01$). The largest difference in response rate between prenotification and no prenotification was observed after the first contact (6.8% versus 32.4%; Figure 1). Small increases in response rate were observed with each contact in the prenotification group, but the response rate remained relatively unchanged with subsequent contacts in the no-prenotification group, despite consistent postal contact timing amongst the two groups.

We performed an assessment of potential non-response bias amongst known characteristics of non-responders using chi-squared test on language preference and region (Table 2). There were no differences detected amongst responders and non-responders with respect to language preference ($p=0.22$) or region in Canada ($p=0.45$).

Discussion:

We found that sending a prenotification letter prior to a postal survey of emergency physicians in Canada resulted in a significantly lower response rate. There exists very limited literature regarding the effect of prenotification of physicians prior to a questionnaire. One prior study found that a postal prenotification increased the response rate of an internet-based survey of general internists (12), however, we were unable to find any literature examining the effect of prenotification on postal surveys of physicians. In an attempt to optimize our response rate for this study, we decided to include a similar unconditional incentive to all participants which was received along with the first survey. This method was based on a previous study that examined the effect of including an unconditional incentive in a postal survey of emergency physicians in Canada (6). The authors observed a significant increase in response rates in those who received an incentive. We observed that those who did not receive a prenotification letter had a much higher response rate after the first contact. The incentive was not mentioned in the prenotification letter and it is unclear if this had an effect on the subsequent actions of physicians. It is possible that those who received prenotification and were not interested in taking part in the study did not open the first contact package containing the incentive, and therefore were unaware of it, leading to a lower response rate than the no prenotification group after the first contact.

Our survey instrument for this study was designed using robust methodology and refined after performing cognitive interviews and pilot testing. As an a priori sub-study of a larger study regarding physicians' attitudes and acceptability of an intervention promoting organ donation registration in the emergency department, we were able to test the utility of including a prenotification letter in future surveys involving emergency physicians. The prenotification letter for postal surveys adds cost and additional time required to complete the study, as well as additional time and effort for participants to review it. Our study suggests that this step may not be necessary in physician postal surveys. The authors hypothesize that the reason for a lower response rate for the prenotification group may be twofold. It could be due to a displeasure that an overextended physician might experience during an additional contact to inform of a survey that has not yet begun. Another possibility may be that once the physician knows they will receive a survey about a certain subject, they may spend additional time considering the subject matter and decide against participating. An additional strength of our study is regarding the source we selected our sample from. The Canadian Medical Directory is a national medical directory which claims to list 91,000 practicing physicians in Canada. It is likely that future physician postal surveys will utilize this resource and therefore, we feel

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3 that the results of our study are generalizable for future surveys of emergency physicians. There also exists no other
4 comprehensive database that contains postal addresses for Canadian emergency physicians.
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7 Our study does have some weaknesses. As described, several physicians were not reachable at the noted
8 address, and several others reported to having ceased practice in emergency medicine. Also, our data regarding the
9 effect of prenotification may not apply to electronic or internet-based surveys, which are more commonly reported
10 in the literature and however often have very low response rates. Finally, given that this study was focused on a
11 specific area in organ donation, the results may not be generalizable to other subject areas or physician populations.
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14 Future research could assess the effect of electronic prenotification in electronic or internet-based surveys,
15 as well as in surveys sent to physicians in other specialties and based in various other realms of subject matter.
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18 **Conclusion:**

19 Inclusion of a prenotification letter resulted in a lower response rate in this postal survey of emergency
20 physicians. Given the added costs, time and effort required to send a prenotification letter, this study suggests that it
21 is more effective to omit the prenotification letter in future physician surveys.
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Table 1. Physician Respondent Demographics for Prenotification Group (N=80) and No Prenotification Group (N=121).

Characteristic	Prenotification Group N (%)	No Prenotification Group N (%)
Sex		
Male	49 (61.3)	77 (63.6)
Female	31 (38.8)	44 (36.4)
Language		
English	65 (81.3)	94 (77.7)
French	15 (18.7)	27 (22.3)
Age		
<35	6 (7.5)	8 (6.6)
35-44	27 (33.8)	40 (33.1)
45-54	20 (25.0)	39 (32.2)
55-64	17 (21.3)	22 (18.2)
>65	5 (6.3)	10 (8.3)
Unanswered	5 (6.3)	2 (1.7)
Years in Practice		
<5	31 (38.8)	40 (33.1)
5-10	30 (37.5)	44 (36.4)
11-20	13 (16.3)	26 (21.5)
>20	6 (7.5)	11 (9.1)
Religious affiliation		
Christian	42 (52.5)	61 (50.4)
None	26 (32.5)	41 (33.9)
Muslim	2 (2.5)	5 (4.1)
Other	5 (6.3)	4 (3.3)
Buddhist	2 (2.5)	3 (2.5)
Jewish	1 (1.3)	4 (3.3)
Sikh	0 (0.0)	3 (2.5)
Hindu	1 (1.3)	0 (0.0)
Unanswered	1 (1.3)	0 (0.0)
Location of practice		
Ontario	35 (43.8)	48 (39.7)
Quebec	17 (21.3)	29 (24.0)
British Columbia	15 (18.8)	20 (16.5)
Alberta	5 (6.3)	12 (9.9)
Manitoba	1 (1.3)	3 (2.5)
Newfoundland and Labrador	3 (3.8)	1 (0.8)
New Brunswick	2 (2.5)	1 (0.8)
Nova Scotia	1 (1.3)	2 (1.7)
Saskatchewan	0 (0.0)	3 (2.5)
Prince Edward Island	1 (1.3)	1 (0.8)
Unanswered	0 (0.0)	1 (0.8)

Table 2. Assessment of Non-response Bias

Characteristic	Respondents; N (%)	Non-respondents; N (%)	P-value
Geographic region			0.45
*Western Canada	59 (29.5)	76 (30.9)	
Ontario	83 (41.5)	99 (40.2)	
Quebec	46 (23.0)	53 (21.5)	
[§] Eastern Canada	12 (6.0)	18 (7.3)	
Survey language			0.22
English	159 (83.1)	209 (85.0)	
French	42 (16.9)	37 (15.0)	

* Alberta, British Columbia, Manitoba, Saskatchewan

[§] New Brunswick, Nova Scotia, Newfoundland, Prince Edward Island

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Figure Legend:

Figure 1. Response Rates for Prenotification and Non-prenotification Groups by Contact Number

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Author contributions:

Dr. Michael Hickey is the first author and was responsible for the study design, data collection, statistical analysis and writing of the manuscript. Ms. Carly Hickey assisted with study design data collection and review of the manuscript. Drs. Jeff Perry, Lauralyn McIntyre, Monica Taljaard, Kasim Abdulaziz and Krishan Yadav provided methodological and statistical support in addition to manuscript review.

Competing Interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: Dr. Michael Hickey receives a salary as Hospital Donation Physician from Trillium Gift of Life Network, Ontario's organ donation organization, and Dr. Jeffrey Perry is supported by the Heart and Stroke Foundation of Ontario through a Mid-Career Award. No other relationships or activities that could appear to have influenced the submitted work.

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Data Sharing: Requests for sharing of the data will be considered and reviewed by the study's steering committee. Requests can be made to Dr. Hickey.

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6 **Grantor Information:** The guarantor, Michael Hickey accepts full responsibility for the work and/or the
7 conduct of the study, had access to the data, and controlled the decision to publish. Dr. Hickey affirms
8 that this manuscript is an honest, accurate and transparent account of the study being reported and no
9 important aspects of the study have been omitted; and that any discrepancies from the study as planned,
10 have been explained. The corresponding author attests that all listed authors meet authorship criteria and
11 that no others meeting the criteria have been omitted.
12

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14 **Dissemination:** There is no formal plan to disseminate these results to study participants.
15

16 **Provenance and peer review:** Not commissioned; externally peer reviewed.
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Appendix 1. Survey instrument

Appendix 2. Prenotification letter

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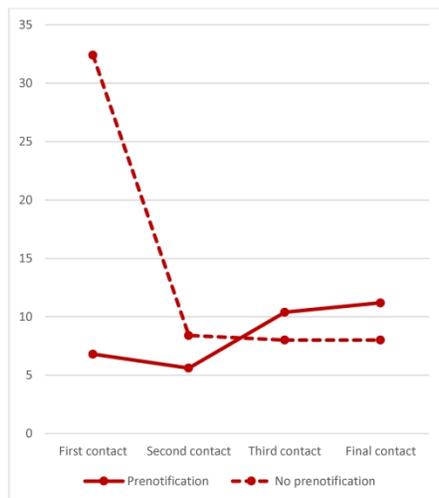


Figure 1. Response Rates for Prenotification and Non-prenotification Groups by Contact Number

215x279mm (300 x 300 DPI)

EMERGENCY PHYSICIAN ATTITUDES AND ACCEPTABILITY OF ORGAN AND TISSUE DONATION REGISTRATION IN THE EMERGENCY DEPARTMENT: A NATIONAL QUESTIONNAIRE

Are you currently practicing emergency medicine in Canada? Yes No

If **No**, please return the questionnaire in the postage paid envelope

If **Yes**, please complete and return the questionnaire in the postage paid envelope

A. Professional Status and Practice Setting

1. **Are you:** Female Male Other Prefer not to answer

2. **Year of birth:** 19____

3. **Province of practice:** _____

4. **How many years have you been practicing medicine independently?**

Less than 5 years Between 5 and 10 years Between 10 and 20 years Greater than 20 years

5. **To which religion do you most identify?**

Christian Buddhist Hindu Muslim Jewish Sikh Aboriginal Other (specify): _____ None

6. **In what setting do you perform MOST of your emergency medicine clinical activity?**

- Teaching hospital
 Community / District general hospital: Teaching
 Community / District general hospital: Non-teaching
 Other (specify): _____

7. **On average, how many patients shifts do you work per month?**

< 6 6-12 12-18 > 18

8. **What is your professional certification?**

FRCPC CCFP(EM) CCFP General practice Other

9. **Do you hold an official affiliation with a provincial organ donation organization?**

- Yes
 No

B. Attitudes and Acceptability

This section will explore your personal feelings regarding organ donation, and the acceptability of utilizing the ED as a venue to promote organ donation registration to patients who are capable and do not require immediate attention, and visitors.

1. **Are you personally registered as an organ and tissue donor?**

- Yes
 No

2. **If no, what is the reason?**

- I don't know how to register
 I don't have time to register
 I was not aware that it is possible to register as an organ donor
 Religious beliefs
 Personal beliefs
 Assumed non-suitability of organs due to medical problems
 I prefer not to donate my organs

Other (specify): _____

3. In general, do you support the concept of deceased organ donation?

- Strongly support
- Somewhat support
- Neutral
- Somewhat oppose
- Strongly oppose

4. Provincial organ donation organizations should attempt to increase the number of registered organ donors:

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

5. The emergency department waiting area is an acceptable setting to disseminate information regarding organ and tissue donation to capable patients who do not need immediate attention and visitors:

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

6. The emergency department waiting area is an acceptable setting to offer patients and visitors opportunity to register as an organ donor while they await medical care:

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

7. Emergency department patients and visitors would be open to receiving information regarding organ donation in ED waiting areas:

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

8. Emergency department patients and visitors would be open to being offered an immediate opportunity to register as an organ donor in ED waiting areas:

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

9. Emergency department patients and visitors would be open to being offered instructions on how to register as an organ donor in the future, following their ED visit:

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

10. If emergency department patients have an immediate opportunity to register as an organ donor, this should be facilitated by: (check all that are appropriate)

- Publicly posted signage with instructions
- Electronic devices available in waiting areas (iPad)
- Active approach by personnel
- Other: _____

11. There may be a number of individuals in the ED who may potentially approach patients and visitors regarding organ donation registration while they await medical care. As the attending physician in your ED, please describe your comfort level with the following categories of personnel should they facilitate the approach:

	Very uncomfortable	Somewhat uncomfortable	Don't know/Unsure	Somewhat comfortable	Very comfortable
a. ED physician / resident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Medical student	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. ED nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. ED administrative clerks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Provincial organ donation organization staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Hospital volunteer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional comments:

12. The following are potential facilitators to offering information regarding registration for organ donation in emergency department waiting areas. Please choose an option for each potential facilitator which you feel most appropriately describes the level of significance of the facilitator:

	Insignificant facilitator	Somewhat insignificant facilitator	Don't know/Unsure	Somewhat significant facilitator	Very significant facilitator
g. Strong organ donation culture at institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Societal/public importance of increasing organ donation rates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Patients' willingness to help others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Patients' previous awareness of organ donation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate any other facilitators not mentioned above:

13. The following are potential barriers to offering information regarding registration for organ donation in emergency department waiting areas. Please choose an option for each potential barrier which you feel most appropriately describes the level of significance of the barrier:

	Insignificant barrier	Somewhat insignificant barrier	Don't know/Unsure	Somewhat significant barrier	Very significant barrier
k. Staff or patient ethical barriers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Staff or patient religious barriers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. Lack of patient interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n. Time constraints	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o. Department flow/efficiency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. Availability of staffing / personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q. Hospital costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
r. Patient's privacy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
s. Staff confidence in ability to discuss organ donation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate any other barriers not mentioned above:

Additional comments regarding this topic or questionnaire:

Thank you for completing and returning this questionnaire in the postage-paid envelope.

1 Appendix 2.

2
3 **EMERGENCY PHYSICIAN ATTITUDES AND ACCEPTABILITY OF ORGAN AND TISSUE**
4 **DONATION REGISTRATION IN THE EMERGENCY DEPARTMENT: A NATIONAL SURVEY**
5

6 **Subject:** Invitation to participate in a study on Deceased Organ and Tissue Donation in the Emergency Department.

7
8 Dear Colleague,

9 This email is being sent to you by Dr. Michael Hickey who is an Emergency and Critical Care Physician at The
10 Ottawa Hospital. This e-mail is with regards to a research study that he is conducting.

11
12 The overall goal of this study is to assess how Canadian Emergency Physicians feel about utilizing the Emergency
13 Department (ED) for deceased organ and tissue donation registration for patients. We have initiated a program of
14 research to evaluate the acceptability, feasibility and barriers this endeavor, through all potential stakeholders who
15 would be involved in the process. The ED is an under-valued but promising venue to educate people about and
16 promote organ and tissue donation. As such, it is possible that **stable, CTAS 3, 4 and 5 patients who are in the**
17 **waiting areas of the ED** could be potentially approached and offered information about deceased organ and tissue
18 donation, and an immediate opportunity to register. Your participation is voluntary, and greatly appreciated.

19
20 You will receive this questionnaire by mail in approximately 1-2 weeks. This questionnaire should take about **15**
21 **minutes**. You may not like all the questions that you are asked. You may skip any questions that make you feel
22 uncomfortable or that you do not wish to answer.

23
24 There are no foreseeable risks or discomforts associated with your involvement in this study. Your participation is
25 completely voluntary. You can decide to stop at any time, even part-way through the questionnaire, for any reason.
26 If you decide to stop, the data submitted up to that point will not be included in the results. If you decide to
27 participate, you have the right to withdraw consent at any point without consequence.

28
29 Your responses will remain strictly confidential, and no participant identifiers will appear in any publication or
30 presentation resulting from this study. Please note that there will be no written consent for this study. Completion of
31 the questionnaire is the indication of your consent to participate.

32
33 The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research
34 study. If you have any questions about your rights as a study participant, you may contact the Chairperson of the
35 OHSN-REB at 613-798-5555, extension 16719.

36
37 If you have any questions regarding the study, please contact me, Dr. Michael Hickey at 613-798-5555 ext. 12067 or
38 mhickey@toh.ca.

39 Thank you for your time.

40
41 Sincerely,

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46 Michael Hickey, MD, FRCPC
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BMJ Open

The Effect of Prenotification on the Response Rate of a Postal Survey of Emergency Physicians: A Randomized, Controlled, Assessor-blind Trial

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3 The Effect of Prenotification on the Response Rate of a Postal Survey of Emergency Physicians: A Randomized,
4 Controlled, Assessor-blind Trial
5

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14

15 **Potential competing interests**

16 Dr. Michael Hickey receives a salary as Hospital Donation Physician from Trillium Gift of Life Network, Ontario's
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19

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22

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27

28 **Author contributions:**

29
30 Dr. Michael Hickey is the first author and was responsible for the study design, data collection, statistical analysis
31 and writing of the manuscript. Ms. Carly Hickey assisted with study design data collection and review of the
32 manuscript. Drs. Jeff Perry, Lauralyn McIntyre, Monica Taljaard, Kasim Abdulaziz and Krishan Yadav provided
33 methodological and statistical support in addition to manuscript review.
34

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Abstract

Objectives: Response rates to physician surveys are typically low. The objective of this study was to determine the effect of a prenotification letter on the response rate of a postal survey of emergency physicians.

Design: We constructed a 24-item survey instrument using rigorous methodology informed by a modified Dillman's tailored design technique. The survey was to assess physician attitudes towards an intervention to encourage organ donation registration while patients and visitors are in the emergency department.

Participants: A random sample of 500 emergency physicians in Canada.

Setting: Participants were selected from the Canadian Medical Directory, a national medical directory which lists more than 99% of practicing physicians in Canada.

Interventions: Physicians were randomized in a concealed fashion to receive a prenotification letter approximately one week prior to the survey, or to not receive a prenotification letter. All physicians received an unconditional incentive of a \$3 coffee card with the survey instrument. In both groups, non-respondents were sent reminder surveys approximately every 14 days and a special contact using Xpresspost during the final contact attempt.

Results: 201 of 447 eligible physicians returned the survey (45.0%). Of 231 eligible physicians contacted in the prenotification group, 80 (34.6%) returned the survey and amongst 237 eligible physicians contacted in the no-prenotification group, 121 (51.1%) returned the survey (absolute difference in proportions 16.5%, 95% CI 2.5-30.5, $p=0.01$)

Conclusion: Inclusion of a prenotification letter resulted in a lower response rate in this postal survey of emergency physicians. Given the added costs, time and effort required to send a prenotification letter, this study suggests that it may be more effective to omit the prenotification letter in physician postal surveys.

Article Summary: Strengths and limitations of this study

- The survey instrument that this study was based on was robustly designed using cognitive interviews and pilot testing
- The participants in the survey were randomly selected from the most comprehensive database of Canadian physicians
- The results may not be generalizable to all physician populations

For peer review only

Introduction:

Physician surveys are an important method for obtaining information in research studies that aim to ultimately improve the delivery of healthcare. For a number of proposed reasons, adequate response rates remain difficult to achieve (1). Surveys of physicians typically have a response rate as low as ten percentage points less than that of the general population (2). Over the past decade, much emphasis in the literature has been placed on identifying strategies to improve response rates amongst physicians and other health providers (1, 3-6). Several strategies aimed at increasing physician survey response rates have been employed with variable success, including but not limited to unconditional financial incentives, design-based interventions, special envelope types and method of delivery (6-10). Dillman's tailored design method is a well-established technique that focuses on all aspects of internet and postal surveys with a goal that the respondent will believe that the expected benefits of responding outweigh the costs, and therefore increasing the likelihood of response (11). Practically, examples include using a clear and easily comprehensible survey instrument, implementing repeated contacts including a prenotification letter, utilizing a postage-paid, addressed return envelope, personalization of correspondence and an unconditional financial incentive (11). Postal surveys of physicians have had more favorable response rates than other modes, such as internet-based approaches (6, 9, 12). Prenotification has previously been reported to increase the response rate of physician surveys. In 1991, Shiono et al. tested the effect of the response rate on a postal survey of resident physicians (i.e., doctors in training) and reported that the prenotification letter was not associated with an increase in response rate, and may have had a deleterious effect (13). In an electronic web-based survey of 3550 general internists in the United States of America, a postal prenotification letter increased the response rate from 3.0% to 6.2% (14). Additionally, a Cochrane systematic review from 2009 also reported that prenotification increased response in health related surveys, some of which included physician surveys (15). To the contrary, Gattellari et al. reported that the addition of a mailed or faxed prenotification letter to family physicians did not result in a change in the response rate (16). In addition, Xie and Ho reported that prenotification did not increase the response rate of a survey of nurses in Hong Kong (17). Interestingly, prenotification by letter has been previously shown to increase responses in the social sciences literature (18) and as such, it is of interest to investigate whether or not this translates into surveys of physicians. This certainly may not be the case, since the literature examining the effect of prenotification on physician surveys is quite mixed. The motivation to perform the current study is threefold. First, as described above, the literature reports mixed results with regards to prenotification and physician-survey response

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3 rates, and so equipoise remains. Secondly, most of the studies that have examined this were reported in an era where
4 the postal route was still the mainstay of communication, unlike the present day. Finally, the effect of prenotification
5 has been studied in some other populations, but not specifically emergency physicians. Since postal surveys are now
6 less frequently encountered, the effect of prenotification on a present-day postal survey is of considerable interest.
7
8 Given that prenotification adds time and cost to the development and administration of a survey, whether it can be
9 eliminated from future surveys is important to examine. The objective of the current study is to determine the effect
10 of prenotification on the response rate of a postal survey of emergency physicians in Canada. Specifically, the
11 present study tests the effect of a typed, hand-signed postal letter sent to emergency physicians via mail prior to
12 receiving the survey.
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20 **Methods:**

21 *Study design and participants*

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23
24 This was an a priori sub-study of a national, self-administered postal survey of Canadian emergency
25 physicians. The purpose of the original study was to examine emergency physicians' attitudes towards and
26 acceptability of an intervention of promoting organ donation registration of patients and visitors while they await
27 medical care in the emergency department. The current sub-study was then designed to assess the effect of survey
28 prenotification on the response rate. To be eligible for the study, physicians needed to be currently practicing
29 emergency medicine in Canada. The first contact occurred on December 12, 2019, with a reminder letter and
30 additional copy of the survey every two weeks for a total of six weeks. The final contact was mailed on February 24,
31 2020. We delayed the second contact by one week due to the date falling within the Christmas/New Year holiday
32 season.
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41 *Patient and Public Involvement:*

42
43 Neither patients nor the public were formally involved in the planning of the study.
44

45 *Outcome measure*

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47 Our primary outcome was the survey response rate. This was defined a priori along with the study protocol.
48

49 *Survey development*

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51 The survey instrument was designed using rigorous methodology and with reference to Dillman's Tailored
52 Design technique (11). We conducted key-informant interviews with 12 experts with advanced knowledge in organ
53 donation and survey methodology which included critical care and emergency physicians, nurses and research
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3 methodologists. The instrument was then drafted in English and translated into French based on physician language
4 preference according to the Canadian Medical Directory. We then conducted 10 cognitive interviews in both
5 languages with five attending and five resident emergency physicians whereby participants were directly observed
6 self-administering the survey. The questions were read aloud, and participants were encouraged to express thoughts,
7 comments or concerns while they completed the survey. In doing so, we were able to flag any potential problems
8 with regards to the content, flow, language and grammar of the survey, which took about 15 minutes to complete.
9 After minor adjustments, we conducted pilot surveys of 20 randomly selected emergency physicians from our
10 sample in an attempt to identify any issues with the postal procedure or completion of the survey. The final survey
11 instrument consisted of 24 questions divided into four sections, double-sided on two sheets of paper: demographic
12 and practice information, attitudes regarding organ donation, acceptability of using the emergency department to
13 promote organ donation and registration, and related perceived facilitators and barriers (see supplementary material).
14 No modifications were required following the pilot phase.

25 26 *Ethics Statement*

27
28 This study was approved by the Ottawa Health Science Network Research Ethics Board. (Approval
29 20190178). All participants of the survey received an introductory letter stating that completion of the survey
30 indicated consent to participate in the study.
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34 35 36 *Sample selection*

37 From our sampling frame of 2,955 emergency physicians identified in the Canadian Medical Directory,
38 which claims to be Canada's most comprehensive directory of medical professionals, we used computer-generated
39 random numbers select a sample of physicians with emergency medicine listed as a credential for the survey. The
40 sample size was calculated based on a variance of 0.25 with 95% confidence and a margin of error of 0.07. This
41 resulted in 196 subjects. Based on an expected response rate of 40-50% from previous studies that surveyed the
42 same population (6, 12), we chose to randomly sample 500 physicians in order to achieve this goal. Following this,
43 an independent set of computer-generated random numbers were used to assign half of the physicians to receive a
44 prenotification letter, and the other half to controls (no prenotification) using a 50/50 allocation ratio. Randomization
45 was performed by an author who was not involved in data analysis. Based on language preference, 77 of the total
46 number of surveys were sent in French. From the sample of 500, we selected 20 physicians located near our
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3 geographical area to receive the survey as pilot subjects (to minimize postal travel time) with intention to test the
4 survey instrument and the postal procedure of distribution and return. Since the survey instrument did not require
5 alteration once pilot participant responses were analyzed, these pilot surveys were included in the data analysis.
6
7

8 9 *Intervention*

10
11 Prenotification letters were hand-signed by the principal investigator and sent to half the randomly selected
12 participants approximately one week prior to the first questionnaire mailout. The principal investigator was blinded
13 to the demographic information of the participants. The letter outlined the purpose of the study and emphasized the
14 importance of the physicians' contribution (see supplementary material). The other half did not receive
15 prenotification, and therefore were considered controls. All physicians in both groups received a \$3 Tim Hortons
16 coffee card which was included with the first survey as an unconditional incentive.
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24 *Survey administration*

25
26 Approximately one week following the prenotification letter that half the participants received, our survey
27 instrument, an introductory letter, a \$3 Tim Hortons coffee card (national coffee shop) and an addressed, postage-
28 paid return envelope was sent to all physicians, in either English or French languages, based on physician preference
29 stated in the Canadian Medical Directory. A reminder letter and additional copy of the survey were sent to non-
30 respondents approximately every two weeks for a total of six weeks. The final reminder was delivered via courier
31 (Xpresspost), a trackable, larger special envelope delivered nationally within two business days.
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40 *Data analysis*

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42 Using blinded outcome assessment, physician responses were analyzed using descriptive statistics. Although the
43 response to the first item in the survey determined respondent eligibility (a binary question indicating current
44 practice of emergency medicine in Canada), we included all physicians who did return the survey in the overall
45 response rate. However, given that some respondents were ineligible to complete the subsequent items in the
46 questionnaire, they were not included in further analysis. The randomized groups were compared using a chi-
47 squared tests. The response rate was calculated in each group and compared using absolute difference in
48 proportions with 95% confidence interval. Cumulative response rates were also reported after each reminder letter.
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We also assessed for non-response bias using chi-squared tests based on language preference and geographic region of Canada. Data were analyzed using SAS version 9.2 (SAS Institute, Cary, NC, USA).

Results:

Respondents

Demographic information for the respondents is shown in Table 1. The majority of respondents were male (62.7%), 33.3% were in the 35 to 44-year age range, and 72.1% have been in practice for 10 years or less. The majority of respondents practice in the most populous Canadian provinces: Ontario (41.3%), Quebec (22.9%) and British Columbia (17.4%).

Response rate

Of 500 physicians contacted (which included the 20 pilot participants), 26 were undeliverable and 7 surveys were returned incomplete (see Figure 1). 27 physicians indicated that they were no longer practicing emergency medicine in Canada and were therefore considered ineligible to complete the survey. Of 474 physicians to whom a survey was delivered, 228 (48.1%) returned the survey and after assessment for eligibility, 45.0% of the total eligible respondents were included in the data analysis of the main survey (reported separately). 3.1% of participants were not included in the data analysis because they indicated that they were not presently practicing emergency medicine in Canada. Of 231 physicians contacted in the prenotification group, 80 (34.6%) returned the survey and amongst 237 physicians contacted in the no-prenotification group, 121 (51.1%) returned the survey (absolute difference in proportions 16.5%, 95% CI 2.5-30.5, $p=0.01$; odds ratio 0.51, 95% CI 0.35-0.74; $p=0.0004$). The largest difference in response rate between prenotification and no prenotification was observed after the first contact (6.8% versus 32.4%; Figure 2). Small increases in response rate were observed with each contact in both groups.

We performed an assessment of potential non-response bias amongst known characteristics of non-responders using chi-squared test on language preference and region (Table 2). There were no differences detected amongst responders and non-responders with respect to language preference ($p=0.22$) or region in Canada ($p=0.45$).

Discussion:

We found that sending a prenotification letter prior to a postal survey of emergency physicians in Canada resulted in a significantly lower response rate. Prior literature regarding prenotification in physician surveys have reported mixed results. In an attempt to optimize our response rate for this study, we decided to include an unconditional incentive to all participants which was received along with the first survey. This method was based on a previous study that examined the effect of including an unconditional incentive in a postal survey of emergency physicians in Canada (6). The authors observed a significant increase in response rates in those who received an incentive. We observed that those who did not receive a prenotification letter had a much higher response rate after the first contact. The incentive was not mentioned in the prenotification letter and it is unclear if this had an effect on the subsequent actions of physicians. It is possible that those who received prenotification and were not interested in taking part in the study did not open the first contact package containing the incentive, and therefore were unaware of it, leading to a lower response rate than the no prenotification group after the first contact.

Our survey instrument for this study was designed using robust methodology and refined after performing cognitive interviews and pilot testing. As an a priori sub-study of a larger study regarding physicians' attitudes and acceptability of an intervention promoting organ donation registration in the emergency department, we were able to test the utility of including a prenotification letter in future surveys involving emergency physicians. The prenotification letter for postal surveys adds cost and additional time required to complete the study, as well as additional time and effort for participants to review it. The estimated cost of each prenotification letter (including stationery and postage was approximately \$1.29 CAD which for large surveys, can be costly. Our study suggests that this step may not be necessary in physician postal surveys. The authors hypothesize that the reason for a lower response rate for the prenotification group may be twofold. It could be due to a displeasure that an overextended physician might experience during an additional contact to inform of a survey that has not yet begun. Another possibility may be that once the physician knows they will receive a survey about a certain subject, they may spend additional time considering the subject matter and decide against participating. An additional strength of our study is regarding the source we selected our sample from. The Canadian Medical Directory is a national medical directory which claims to list 91,000 practicing physicians in Canada. It is likely that future physician postal surveys will utilize this resource and therefore, we feel that the results of our study are generalizable for future surveys of

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2
3 emergency physicians. There also exists no other comprehensive database that contains postal addresses for
4
5 Canadian emergency physicians.
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7 Our study does have some weaknesses. The difference in effect size of the response rates was much larger
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9 than anticipated and demonstrated statistical significance. We did not calculate an a priori sample size for the
10
11 randomized trial embedded within the larger survey study. However, with an available sample size of 250
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13 physicians per arm, there would be an 80% power to detect an absolute difference of 13% assuming a response rate
14
15 of 50% in one arm

16 As described, several physicians were not reachable at the noted address, and several others reported to
17
18 having ceased practice in emergency medicine. Also, our data regarding the effect of prenotification may not apply
19
20 to electronic or internet-based surveys, which are more commonly reported in the literature and however often have
21
22 very low response rates. Finally, given that this study was focused on a specific area in organ donation, the results
23
24 may not be generalizable to other subject areas or physician populations.
25

26 Future research could assess the effect of electronic prenotification in electronic or internet-based surveys,
27
28 as well as in surveys sent to physicians in other specialties and based in various other realms of subject matter.
29
30 Additionally, it would be helpful to undertake a follow up study using a mixed-methods approach to further
31
32 understand the results by contacting non-respondents in both arms of our study.
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34
35

36 **Conclusion:**

37 Inclusion of a prenotification letter resulted in a lower response rate in this postal survey of emergency
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39 physicians. Given the added costs, time and effort required to send a prenotification letter, this study suggests that it
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41 is more effective to omit the prenotification letter in future physician surveys.
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Table 1. Physician Respondent Demographics for Prenotification Group (N=80) and No Prenotification Group (N=121).

Characteristic	Prenotification Group N (%)	No Prenotification Group N (%)
Sex		
Male	49 (61.3)	77 (63.6)
Female	31 (38.8)	44 (36.4)
Language		
English	65 (81.3)	94 (77.7)
French	15 (18.7)	27 (22.3)
Age		
<35	6 (7.5)	8 (6.6)
35-44	27 (33.8)	40 (33.1)
45-54	20 (25.0)	39 (32.2)
55-64	17 (21.3)	22 (18.2)
>65	5 (6.3)	10 (8.3)
Unanswered	5 (6.3)	2 (1.7)
Years in Practice		
<5	31 (38.8)	40 (33.1)
5-10	30 (37.5)	44 (36.4)
11-20	13 (16.3)	26 (21.5)
>20	6 (7.5)	11 (9.1)
Religious affiliation		
Christian	42 (52.5)	61 (50.4)
None	26 (32.5)	41 (33.9)
Muslim	2 (2.5)	5 (4.1)
Other	5 (6.3)	4 (3.3)
Buddhist	2 (2.5)	3 (2.5)
Jewish	1 (1.3)	4 (3.3)
Sikh	0 (0.0)	3 (2.5)
Hindu	1 (1.3)	0 (0.0)
Unanswered	1 (1.3)	0 (0.0)
Location of practice		
Ontario	35 (43.8)	48 (39.7)
Quebec	17 (21.3)	29 (24.0)
British Columbia	15 (18.8)	20 (16.5)
Alberta	5 (6.3)	12 (9.9)
Manitoba	1 (1.3)	3 (2.5)
Newfoundland and Labrador	3 (3.8)	1 (0.8)
New Brunswick	2 (2.5)	1 (0.8)
Nova Scotia	1 (1.3)	2 (1.7)
Saskatchewan	0 (0.0)	3 (2.5)
Prince Edward Island	1 (1.3)	1 (0.8)
Unanswered	0 (0.0)	1 (0.8)

Table 2. Assessment of Non-response Bias

Characteristic	Respondents; N (%)	Non-respondents; N (%)	P-value
Geographic region			0.45
*Western Canada	59 (29.5)	76 (30.9)	
Ontario	83 (41.5)	99 (40.2)	
Quebec	46 (23.0)	53 (21.5)	
[§] Eastern Canada	12 (6.0)	18 (7.3)	
Survey language			0.22
English	159 (83.1)	209 (85.0)	
French	42 (16.9)	37 (15.0)	

* Alberta, British Columbia, Manitoba, Saskatchewan

[§] New Brunswick, Nova Scotia, Newfoundland, Prince Edward Island

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3 **Figure Legend:**
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5 **Figure 1. Participant Flow Diagram**
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For peer review only

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Figure Legend:

Figure 2. Response Rates for Prenotification and Non-prenotification Groups by Contact Number

For peer review only

Author contributions:

Dr. Michael Hickey is the first author and was responsible for the study design, data collection, statistical analysis and writing of the manuscript. Ms. Carly Hickey assisted with study design data collection and review of the manuscript. Drs. Jeff Perry, Lauralyn McIntyre, Monica Taljaard, Kasim Abdulaziz and Krishan Yadav provided methodological and statistical support in addition to manuscript review.

Competing Interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: Dr. Michael Hickey receives a salary as Hospital Donation Physician from Trillium Gift of Life Network, Ontario's organ donation organization, and Dr. Jeffrey Perry is supported by the Heart and Stroke Foundation of Ontario through a Mid-Career Award. No other relationships or activities that could appear to have influenced the submitted work.

Funding statement

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Data Sharing: Requests for sharing of the data will be considered and reviewed by the study's steering committee. Requests can be made to Dr. Hickey

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3 **Grantor Information:** The guarantor, Michael Hickey accepts full responsibility for the work and/or the
4 conduct of the study, had access to the data, and controlled the decision to publish. Dr. Hickey affirms
5 that this manuscript is an honest, accurate and transparent account of the study being reported and no
6 important aspects of the study have been omitted; and that any discrepancies from the study as planned,
7 have been explained. The corresponding author attests that all listed authors meet authorship criteria and
8 that no others meeting the criteria have been omitted.
9

10 **Dissemination:** There is no formal plan to disseminate these results to study participants.
11

12 **Provenance and peer review:** Not commissioned; externally peer reviewed.
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Supplementary Material consists of the prenotification letter, main survey introductory letter and survey instrument.

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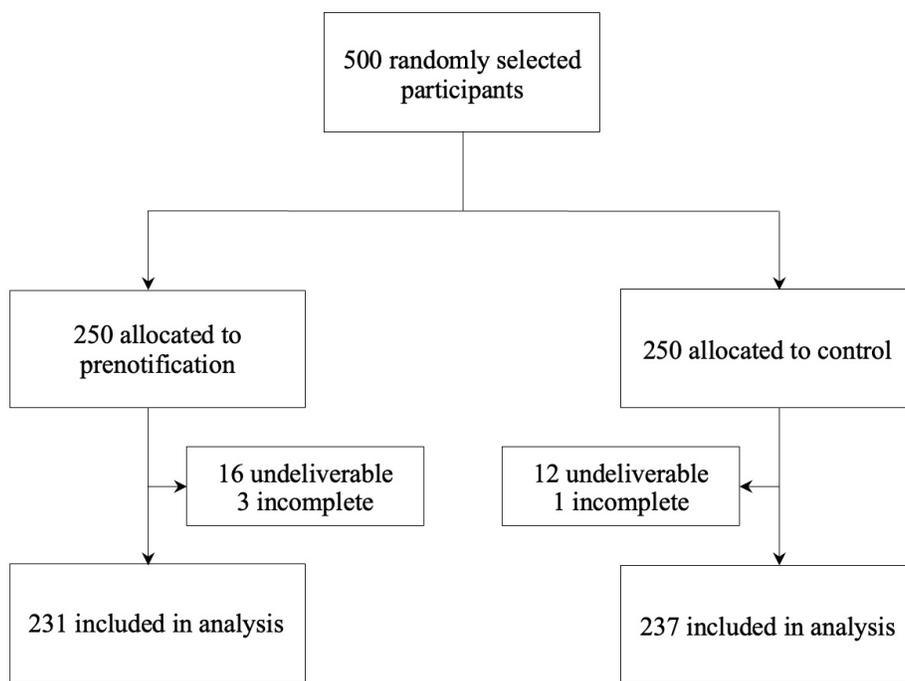


Figure 1. Participant Flow Diagram

224x165mm (144 x 144 DPI)

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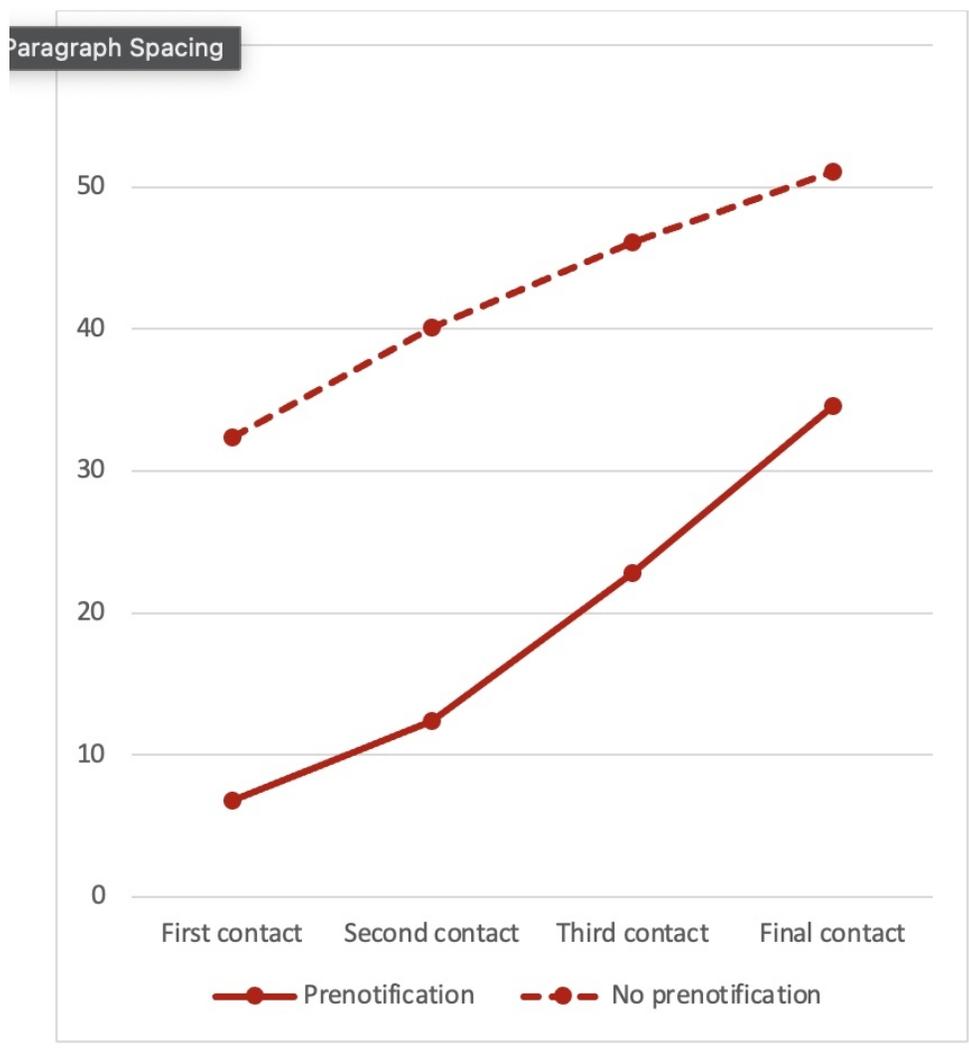


Figure 2. Response Rates for Prenotification and Non-prenotification Groups by Contact Number
156x170mm (144 x 144 DPI)

EMERGENCY PHYSICIAN ATTITUDES AND ACCEPTABILITY OF ORGAN AND TISSUE DONATION REGISTRATION IN THE EMERGENCY DEPARTMENT: A NATIONAL SURVEY

Subject: Invitation to participate in a study on deceased organ and tissue donation registration in the Emergency Department (ED).

Dear colleague:

This letter is being sent to you by Dr. Michael Hickey who is an Emergency Physician at the University of Ottawa, regarding a research study that he is conducting. We have undertaken an important research endeavor investigating deceased organ donation registration in the Emergency Department (ED), and your participation is extremely important.

The overall goal of this study is to assess how Canadian Emergency Physicians feel about utilizing the ED for deceased organ and tissue donation registration for patients. We have initiated a program of research to evaluate the acceptability, feasibility and barriers of this endeavor, through all potential stakeholders who would be involved in the process. The ED is an under-valued but promising venue to promote and educate the public about organ and tissue donation. As such, it is possible that **stable, CTAS 3, 4 and 5 patients who are in the waiting areas of the ED** could be approached and offered information about deceased organ and tissue donation, and given an immediate opportunity to register.

In approximately one week from now, you will receive a questionnaire by mail, and should take about **15 minutes** to complete. I am writing to let you know in advance as some people like to know ahead of time that they will be contacted. Your participation is voluntary, and greatly appreciated.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. If you have any questions about your rights as a study participant, you may contact the Chairperson of the OHSN-REB at 613-798-5555, extension 16719. If you have any questions regarding the study, please contact me, Dr. Michael Hickey at 613-798-5555 ext. 12067 or mhickey@toh.ca.

Thank you for your attention.

Sincerely,

Michael Hickey, MD FRCPC
University of Ottawa / The Ottawa Hospital

EMERGENCY PHYSICIAN ATTITUDES AND ACCEPTABILITY OF ORGAN AND TISSUE DONATION REGISTRATION IN THE EMERGENCY DEPARTMENT: A NATIONAL SURVEY

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This questionnaire should take about **15 minutes**. You may not like all the questions that you are asked. You may skip any questions that make you feel uncomfortable or that you do not wish to answer.

There are no foreseeable risks or discomforts associated with your involvement in this study. Your participation is completely voluntary. You can decide to stop at any time, even part-way through the questionnaire, for any reason. If you decide to stop, the data submitted up to that point will not be included in the results. If you decide to participate, you have the right to withdraw consent at any point without consequence.

Your responses will remain strictly confidential, and no participant identifiers will appear in any publication or presentation resulting from this study. Please note that there will be no written consent for this study. Completion of the questionnaire is the indication of your consent to participate.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. If you have any questions about your rights as a study participant, you may contact the Chairperson of the OHSN-REB at 613-798-5555, extension 16719.

If you have any questions regarding the study, please contact me, Dr. Michael Hickey at 613-798-5555 ext. 12067 or mhickey@toh.ca.

Thank you for your attention.

Sincerely,

Michael Hickey, MD FRCPC
University of Ottawa / The Ottawa Hospital

EMERGENCY PHYSICIAN ATTITUDES AND ACCEPTABILITY OF ORGAN AND TISSUE DONATION REGISTRATION IN THE EMERGENCY
DEPARTMENT: A NATIONAL QUESTIONNAIRE

Are you currently practicing emergency medicine in Canada? Yes No

If **No**, please return the questionnaire in the postage paid envelope

If **Yes**, please complete and return the questionnaire in the postage paid envelope

A. Professional Status and Practice Setting

1. Are you: Female Male Other Prefer not to answer

2. Year of birth: 19____

3. Province of practice: _____

4. How many years have you been practicing medicine independently?

Less than 5 years Between 5 and 10 years Between 10 and 20 years Greater than 20 years

5. To which religion do you most identify?

Christian Buddhist Hindu Muslim Jewish Sikh Aboriginal Other (specify): _____

None

6. In what setting do you perform ***MOST*** of your emergency medicine clinical activity?

Teaching hospital

Community / District general hospital: Teaching

Community / District general hospital: Non-teaching

Other (specify): _____

7. On average, how many patients shifts do you work per month?

< 6 6-12 12-18 > 18

8. What is your professional certification?

FRCPC CCFP(EM) CCFP General practice Other

9. Do you hold an official affiliation with a provincial organ donation organization?

Yes

No

B. Attitudes and Acceptability

This section will explore your personal feelings regarding organ donation, and the acceptability of utilizing the ED as a venue to promote organ donation registration to patients who are capable and do not require immediate attention, and visitors.

1. Are you personally registered as an organ and tissue donor? Yes No**2. If no, what is the reason?** I don't know how to register I don't have time to register I was not aware that it is possible to register as an organ donor Religious beliefs Personal beliefs Assumed non-suitability of organs due to medical problems I prefer not to donate my organs Other (specify): _____**3. In general, do you support the concept of deceased organ donation?** Strongly support Somewhat support Neutral Somewhat oppose Strongly oppose**4. Provincial organ donation organizations should attempt to increase the number of registered organ donors:** Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree**5. The emergency department waiting area is an acceptable setting to disseminate information regarding organ and tissue donation to capable patients who do not need immediate attention and visitors:** Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree**6. The emergency department waiting area is an acceptable setting to offer patients and visitors opportunity to register as an organ donor while they await medical care:** Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree

7. Emergency department patients and visitors would be open to receiving information regarding organ donation in ED waiting areas:

- Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree

8. Emergency department patients and visitors would be open to being offered an immediate opportunity to register as an organ donor in ED waiting areas:

- Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree

9. Emergency department patients and visitors would be open to being offered instructions on how to register as an organ donor in the future, following their ED visit:

- Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree

10. If emergency department patients have an immediate opportunity to register as an organ donor, this should be facilitated by: (check all that are appropriate)

- Publicly posted signage with instructions
- Electronic devices available in waiting areas (iPad)
- Active approach by personnel
- Other: _____

11. There may be a number of individuals in the ED who may potentially approach patients and visitors regarding organ donation registration while they await medical care. As the attending physician in your ED, please describe your comfort level with the following categories of personnel should they facilitate the approach:

	Very uncomfortable	Somewhat uncomfortable	Don't know/Unsure	Somewhat comfortable	Very comfortable
a. ED physician / resident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Medical student	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. ED nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. ED administrative clerks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Provincial organ donation organization staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Hospital volunteer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional comments:

12. The following are potential facilitators to offering information regarding registration for organ donation in emergency department waiting areas. Please choose an option for each potential facilitator which you feel most appropriately describes the level of significance of the facilitator:

	Insignificant facilitator	Somewhat insignificant facilitator	Don't know/Unsure	Somewhat significant facilitator	Very significant facilitator
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1	g.	Strong organ donation culture at institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2							
3	h.	Societal/public importance of increasing organ donation rates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4							
5							
6	i.	Patients' willingness to help others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7							
8	j.	Patients' previous awareness of organ donation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9							
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11							

12 Please indicate any other facilitators not mentioned above:

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16 **13. The following are potential barriers to offering information regarding registration for organ donation in emergency department waiting areas. Please choose an option for each potential barrier which you feel most appropriately describes the level of significance of the barrier:**

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19		Insignificant barrier	Somewhat insignificant barrier	Don't know/Unsure	Somewhat significant barrier	Very significant barrier
20						
21	k.	Staff or patient ethical barriers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22						
23	l.	Staff or patient religious barriers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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25						
26	m.	Lack of patient interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27						
28	n.	Time constraints	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29						
30	o.	Department flow/efficiency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31						
32	p.	Availability of staffing / personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33						
34	q.	Hospital costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35						
36	r.	Patient's privacy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37						
38	s.	Staff confidence in ability to discuss organ donation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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42 Please indicate any other barriers not mentioned above:

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48 Additional comments regarding this topic or questionnaire:

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54 Thank you for completing and returning this questionnaire in the postage-paid envelope.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5-7
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6,7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

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			N/A
1		assessing outcomes) and how	
2	11b	If relevant, description of the similarity of interventions	
3	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
4		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
5			
6	Results		
7	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and
8	diagram is strongly		were analysed for the primary outcome
9	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons
10	Recruitment	14a	Dates defining the periods of recruitment and follow-up
11		14b	Why the trial ended or was stopped
12	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
13	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was
14			by original assigned groups
15	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its
16	estimation		precision (such as 95% confidence interval)
17		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
18	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing
19			pre-specified from exploratory
20	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
21			
22	Discussion		
23	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
24	Generalisability	21	Generalisability (external validity, applicability) of the trial findings
25	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
26			
27	Other information		
28	Registration	23	Registration number and name of trial registry
29	Protocol	24	Where the full trial protocol can be accessed, if available
30	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders
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32			N/A
33			N/A
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37 *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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BMJ Open

The Effect of Prenotification on the Response Rate of a Postal Survey of Emergency Physicians: A Randomized, Controlled, Assessor-blind Trial

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3 The Effect of Prenotification on the Response Rate of a Postal Survey of Emergency Physicians: A Randomized,
4 Controlled, Assessor-blind Trial
5

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16 Dr. Michael Hickey receives a salary as Hospital Donation Physician from Trillium Gift of Life Network, Ontario's
17 organ donation organization, and Dr. Jeffrey Perry is supported by the Heart and Stroke Foundation of Ontario
18 through a Mid-Career Award
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22

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29 **Author contributions:**

30 Dr. Michael Hickey is the first author and was responsible for the study design, data collection, statistical analysis
31 and writing of the manuscript. Ms. Carly Hickey assisted with study design data collection and review of the
32 manuscript. Drs. Jeff Perry, Lauralyn McIntyre, Monica Taljaard, Kasim Abdulaziz and Krishan Yadav provided
33 methodological and statistical support in addition to manuscript review.
34

35 **Keywords:** Survey; emergency physician
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Abstract

Objectives: Response rates to physician surveys are typically low. The objective of this study was to determine the effect of a prenotification letter on the response rate of a postal survey of emergency physicians.

Design: This was a sub-study of a national, cross-sectional postal survey sent to emergency physicians in Canada. We randomized participants to either receive a postal prenotification letter prior to the survey, or to no prenotification letter.

Participants: A random sample of 500 emergency physicians in Canada. Participants were selected from the Canadian Medical Directory, a national medical directory which lists more than 99% of practicing physicians in Canada.

Interventions: Using computer-generated randomization, physicians were randomized in a concealed fashion to receive a prenotification letter approximately one week prior to the survey, or to not receive a prenotification letter. All physicians received an unconditional incentive of a \$3 coffee card with the survey instrument. In both groups, non-respondents were sent reminder surveys approximately every 14 days and a special contact using Xpresspost during the final contact attempt.

Outcome: The primary outcome was the survey response rate.

Results: 201 of 447 eligible physicians returned the survey (45.0%). Of 231 eligible physicians contacted in the prenotification group, 80 (34.6%) returned the survey and amongst 237 eligible physicians contacted in the no-prenotification group, 121 (51.1%) returned the survey (absolute difference in proportions 16.5%, 95% CI 2.5-30.5, $p=0.01$).

Conclusion: Inclusion of a prenotification letter resulted in a lower response rate in this postal survey of emergency physicians. Given the added costs, time and effort required to send a prenotification letter, this study suggests that it may be more effective to omit the prenotification letter in physician postal surveys.

Article Summary: Strengths and limitations of this study

- The survey instrument that this study was based on was robustly designed using cognitive interviews and pilot testing
- The participants in the survey were randomly selected from the most comprehensive database of Canadian physicians
- The results may not be generalizable to all physician populations

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Introduction:

Physician surveys are an important method for obtaining information in research studies that aim to ultimately improve the delivery of healthcare. For a number of proposed reasons, adequate response rates remain difficult to achieve (1). Surveys of physicians typically have a response rate as low as ten percentage points less than that of the general population (2). Over the past decade, much emphasis in the literature has been placed on identifying strategies to improve response rates amongst physicians and other health providers (1, 3-6). Several strategies aimed at increasing physician survey response rates have been employed with variable success, including but not limited to unconditional financial incentives, design-based interventions, special envelope types and method of delivery (6-10). Dillman's tailored design method is a well-established technique that focuses on all aspects of internet and postal surveys with a goal that the respondent will believe that the expected benefits of responding outweigh the costs, and therefore increasing the likelihood of response (11). Practically, examples include using a clear and easily comprehensible survey instrument, implementing repeated contacts including a prenotification letter, utilizing a postage-paid, addressed return envelope, personalization of correspondence and an unconditional financial incentive (11). Postal surveys of physicians have had more favorable response rates than other modes, such as internet-based approaches (6, 9, 12). Prenotification has previously been reported to increase the response rate of physician surveys. In 1991, Shiono et al. tested the effect of the response rate on a postal survey of resident physicians (i.e., doctors in training) and reported that the prenotification letter was not associated with an increase in response rate, and may have had a deleterious effect (13). In an electronic web-based survey of 3550 general internists in the United States of America, a postal prenotification letter increased the response rate from 3.0% to 6.2% (14). Additionally, a Cochrane systematic review from 2009 also reported that prenotification increased response in health related surveys, some of which included physician surveys (15). To the contrary, Gattellari et al. reported that the addition of a mailed or faxed prenotification letter to family physicians did not result in a change in the response rate (16). In addition, Xie and Ho reported that prenotification did not increase the response rate of a survey of nurses in Hong Kong (17). Interestingly, prenotification by letter has been previously shown to increase responses in the social sciences literature (18) and as such, it is of interest to investigate whether or not this translates into surveys of physicians. This certainly may not be the case, since the literature examining the effect of prenotification on physician surveys is quite mixed. The motivation to perform the current study is threefold. First, as described above, the literature reports mixed results with regards to prenotification and physician-survey response

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3 rates, and so equipoise remains. Secondly, most of the studies that have examined this were reported in an era where
4 the postal route was still the mainstay of communication, unlike the present day. Finally, the effect of prenotification
5 has been studied in some other populations, but not specifically emergency physicians. Since postal surveys are now
6 less frequently encountered, the effect of prenotification on a present-day postal survey is of considerable interest.
7
8 Given that prenotification adds time and cost to the development and administration of a survey, whether it can be
9 eliminated from future surveys is important to examine. The objective of the current study is to determine the effect
10 of prenotification on the response rate of a postal survey of emergency physicians in Canada. Specifically, the
11 present study tests the effect of a typed, hand-signed postal letter sent to emergency physicians via mail prior to
12 receiving the survey.
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20 **Methods:**

21 *Study design and participants*

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24 This was an a priori sub-study of a national, self-administered postal survey of Canadian emergency
25 physicians. The purpose of the survey was to examine emergency physicians' attitudes towards and acceptability of
26 an intervention of promoting organ donation registration of patients and visitors while they await medical care in the
27 emergency department. The current sub-study was then designed to assess the effect of survey prenotification on the
28 survey response rate. To be eligible for the study, physicians needed to be currently practicing emergency medicine
29 in Canada. The first contact occurred on December 12, 2019, with a reminder letter and additional copy of the
30 survey every two weeks for a total of six weeks. The final contact was mailed on February 24, 2020. We delayed the
31 second contact by one week due to the date falling within the Christmas/New Year holiday season. While the study
32 was conducted based on a protocol written a priori (see supplementary material), it was not registered.
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41 *Patient and Public Involvement:*

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43 Neither patients nor the public were formally involved in the planning of the study.
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45 *Outcome measure*

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47 Our primary outcome was the survey response rate, which was determined a priori.
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49 *Survey development*

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51 The survey instrument was designed using rigorous methodology and with reference to Dillman's Tailored
52 Design technique (11). We conducted key-informant interviews with 12 experts with advanced knowledge in organ
53 donation and survey methodology which included critical care and emergency physicians, nurses and research
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3 methodologists. The instrument was then drafted in English and translated into French based on physician language
4 preference according to the Canadian Medical Directory. We then conducted 10 cognitive interviews in both
5 languages with five attending and five resident emergency physicians whereby participants were directly observed
6 self-administering the survey. The questions were read aloud, and participants were encouraged to express thoughts,
7 comments or concerns while they completed the survey. In doing so, we were able to flag any potential problems
8 with regards to the content, flow, language and grammar of the survey, which took about 15 minutes to complete.
9 After minor adjustments, we conducted pilot surveys of 20 randomly selected emergency physicians from our
10 sample in an attempt to identify any issues with the postal procedure or completion of the survey. The final survey
11 instrument consisted of 24 questions divided into four sections, double-sided on two sheets of paper: demographic
12 and practice information, attitudes regarding organ donation, acceptability of using the emergency department to
13 promote organ donation and registration, and related perceived facilitators and barriers (Supplement 1). No
14 modifications were required following the pilot phase.

25 26 *Ethics Statement*

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28 This study was approved by the Ottawa Health Science Network Research Ethics Board. (Approval
29 20190178). All participants of the survey received an introductory letter stating that completion of the survey
30 indicated consent to participate in the study.

31 32 33 *Sample selection*

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35 From our sampling frame of 2,955 emergency physicians identified in the Canadian Medical Directory,
36 which claims to be Canada's most comprehensive directory of medical professionals, we used computer-generated
37 random numbers select a sample of physicians with emergency medicine listed as a credential for the survey. The
38 sample size necessary for the survey was calculated based on a key question around participants support for organ
39 donation registration in the emergency department. It was based on a variance of 0.25 with 95% confidence and a
40 margin of error of 0.07. This resulted in 196 subjects. Based on an expected response rate of 40-50% from previous
41 studies that surveyed the same population (6, 12), we chose to randomly sample 500 physicians in order to achieve
42 this goal. Following this, an independent set of computer-generated random numbers were used to assign half of the
43 physicians to receive a prenotification letter, and the other half to controls (no prenotification) using a 50/50
44 allocation ratio. Randomization was performed by a member of the study team who was not involved in data
45 collection or analysis. Based on language preference, 77 of the total number of surveys were sent in French. From
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3 the sample of 500, we selected 20 physicians located near our geographical area to receive the survey as pilot
4 subjects (to minimize postal travel time) with intention to test the survey instrument and the postal procedure of
5 distribution and return. Since the survey instrument did not require alteration once pilot participant responses were
6 analyzed, these pilot surveys were included in the data analysis.
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10 *Intervention*

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12 Prenotification letters were hand-signed by the principal investigator and sent to half the randomly selected
13 participants approximately one week prior to the first questionnaire mailout. The principal investigator was blinded
14 to the demographic information of the participants. The letter outlined the purpose of the study and emphasized the
15 importance of the physicians' contribution. (Supplement 2). The other half did not receive prenotification, and
16 therefore were considered controls. All physicians in both groups received a \$3 Tim Hortons coffee card which was
17 included with the first survey as an unconditional incentive.
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24 *Survey administration*

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26 Approximately one week following the prenotification letter that half the participants received, our survey
27 instrument, an introductory letter, a \$3 Tim Hortons coffee card (national coffee shop) and an addressed, postage-
28 paid return envelope was sent to all physicians, in either English or French languages, based on physician preference
29 stated in the Canadian Medical Directory. A reminder letter and additional copy of the survey were sent to non-
30 respondents approximately every two weeks for a total of six weeks. The final reminder was delivered via courier
31 (Xpresspost), a trackable, larger special envelope delivered nationally within two business days.
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38 *Data analysis*

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40 Using blinded outcome assessment, physician responses were analyzed using descriptive statistics.
41 Although the response to the first item in the survey determined respondent eligibility (a binary question indicating
42 current practice of emergency medicine in Canada), we included all physicians who did return the survey in the
43 overall calculation of the response rate. However, given that some respondents were ineligible to complete the
44 subsequent items in the questionnaire (because they reported to not be currently practicing emergency medicine in
45 Canada), they were not included in further data analysis other than the response rate calculation. The randomized
46 groups were compared using a chi-squared tests. The response rate was calculated in each group and compared
47 using absolute difference in proportions with 95% confidence interval. Cumulative response rates were also reported
48 after each reminder letter. We also assessed for non-response bias using chi-squared tests based on language
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3 preference and geographic region of Canada. Data were analyzed using SAS version 9.2 (SAS Institute, Cary, NC,
4 USA).

7 **Results:**

8 *Respondents*

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10 Demographic information for the respondents is shown in Table 1. The majority of respondents were male
11 (62.7%), 33.3% were in the 35 to 44-year age range, and 72.1% have been in practice for 10 years or less. The
12 majority of respondents practice in the most populous Canadian provinces: Ontario (41.3%), Quebec (22.9%) and
13 British Columbia (17.4%).

14 *Response rate*

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16 Of 500 physicians contacted (which included the 20 pilot participants), 26 were undeliverable and 7
17 surveys were returned incomplete (see Figure 1). 27 physicians indicated that they were no longer practicing
18 emergency medicine in Canada and were therefore considered ineligible to complete the survey. Of 474 physicians
19 to whom a survey was delivered, 228 (48.1%) returned the survey and after assessment for eligibility, 45.0% of the
20 total eligible respondents were included in the data analysis of the main survey (reported separately). 3.1% of
21 participants were not included in the data analysis because they indicated that they were not presently practicing
22 emergency medicine in Canada. Of 231 physicians contacted in the prenotification group, 80 (34.6%) returned the
23 survey and amongst 237 physicians contacted in the no-prenotification group, 121 (51.1%) returned the survey
24 (absolute difference in proportions 16.5%, 95% CI 2.5-30.5, $p=0.01$; odds ratio 0.51, 95% CI 0.35-0.74; $p=0.0004$).
25 The largest difference in response rate between prenotification and no prenotification was observed after the first
26 contact (6.8% versus 32.4%; Figure 2). Small increases in response rate were observed with each contact in both
27 groups.
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31 We performed an assessment of potential non-response bias amongst known characteristics of non-
32 responders using chi-squared test on language preference and region (Table 2). There were no differences detected
33 amongst responders and non-responders with respect to language preference ($p=0.22$) or region in Canada ($p=$
34 0.45).
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Discussion:

We found that sending a prenotification letter prior to a postal survey of emergency physicians in Canada resulted in a significantly lower response rate. Prior literature regarding prenotification in physician surveys have reported mixed results. To optimize our response rate for this study, we decided to include an unconditional incentive to all participants which was received along with the first survey. This method was based on a previous study that examined the effect of including an unconditional incentive in a postal survey of emergency physicians in Canada (6). The authors observed a significant increase in response rates in those who received an incentive. We observed that those who did not receive a prenotification letter had a much higher response rate after the first contact. The incentive was not mentioned in the prenotification letter and it is unclear if this had an effect on the subsequent actions of physicians. It is possible that those who received prenotification and were not interested in taking part in the study did not open the first contact package containing the incentive, and therefore were unaware of it, leading to a lower response rate than the no prenotification group after the first contact.

Our survey instrument for this study was designed using robust methodology and refined after performing cognitive interviews and pilot testing. As an a priori sub-study of a larger study regarding physicians' attitudes and acceptability of an intervention promoting organ donation registration in the emergency department, we were able to test the utility of including a prenotification letter in future surveys involving emergency physicians. The prenotification letter for postal surveys adds cost and additional time required to complete the study, as well as additional time and effort for participants to review it. The estimated cost of each prenotification letter (including stationery and postage was approximately \$1.29 CAD which for large surveys, can be costly. Our study suggests that this step may not be necessary in physician postal surveys. The authors hypothesize that the reason for a lower response rate for the prenotification group may be twofold. It could be due to a displeasure that an overextended physician might experience during an additional contact to inform of a survey that has not yet begun. Another possibility may be that once the physician knows they will receive a survey about a certain subject, they may spend additional time considering the subject matter and decide against participating. An additional strength of our study is regarding the source we selected our sample from. The Canadian Medical Directory is a national medical directory which claims to list 91,000 practicing physicians in Canada. It is likely that future physician postal surveys will utilize this resource and therefore, we feel that the results of our study are generalizable for future surveys of

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3 emergency physicians. There also exists no other comprehensive database that contains postal addresses for
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5 Canadian emergency physicians.
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7 Our study does have some weaknesses. The difference in effect size of the response rates was much larger
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9 than anticipated and demonstrated statistical significance. We did not calculate an a priori sample size for the
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11 randomized trial embedded within the larger survey study. However, with an available sample size of 250
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13 physicians per arm, there would be an 80% power to detect an absolute difference of 13% assuming a response rate
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15 of 50% in one arm.

16 As described, several physicians were not reachable at the noted address, and several others reported to
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18 having ceased practice in emergency medicine. Also, our data regarding the effect of prenotification may not apply
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20 to electronic or internet-based surveys, which are more commonly reported in the literature and however often have
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22 very low response rates. Finally, given that this study was focused on a specific area in organ donation, the results
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24 may not be generalizable to other subject areas or physician populations.
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26 Future research could assess the effect of electronic prenotification in electronic or internet-based surveys,
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28 as well as in surveys sent to physicians in other specialties and based in various other realms of subject matter.
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30 Additionally, it would be helpful to undertake a follow up study using a mixed-methods approach to further
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32 understand the results by contacting non-respondents in both arms of our study.
33

34 **Conclusion:**

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36 Inclusion of a prenotification letter resulted in a lower response rate in this postal survey of emergency
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38 physicians. Given the added costs, time and effort required to send a prenotification letter, this study suggests that it
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40 is more effective to omit the prenotification letter in future physician surveys.
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Table 1. Physician Respondent Demographics for Prenotification Group (N=80) and No Prenotification Group (N=121).

Characteristic	Prenotification Group N (%)	No Prenotification Group N (%)
Sex		
Male	49 (61.3)	77 (63.6)
Female	31 (38.8)	44 (36.4)
Language		
English	65 (81.3)	94 (77.7)
French	15 (18.7)	27 (22.3)
Age		
<35	6 (7.5)	8 (6.6)
35-44	27 (33.8)	40 (33.1)
45-54	20 (25.0)	39 (32.2)
55-64	17 (21.3)	22 (18.2)
>65	5 (6.3)	10 (8.3)
Unanswered	5 (6.3)	2 (1.7)
Years in Practice		
<5	31 (38.8)	40 (33.1)
5-10	30 (37.5)	44 (36.4)
11-20	13 (16.3)	26 (21.5)
>20	6 (7.5)	11 (9.1)
Religious affiliation		
Christian	42 (52.5)	61 (50.4)
None	26 (32.5)	41 (33.9)
Muslim	2 (2.5)	5 (4.1)
Other	5 (6.3)	4 (3.3)
Buddhist	2 (2.5)	3 (2.5)
Jewish	1 (1.3)	4 (3.3)
Sikh	0 (0.0)	3 (2.5)
Hindu	1 (1.3)	0 (0.0)
Unanswered	1 (1.3)	0 (0.0)
Location of practice		
Ontario	35 (43.8)	48 (39.7)
Quebec	17 (21.3)	29 (24.0)
British Columbia	15 (18.8)	20 (16.5)
Alberta	5 (6.3)	12 (9.9)
Manitoba	1 (1.3)	3 (2.5)
Newfoundland and Labrador	3 (3.8)	1 (0.8)
New Brunswick	2 (2.5)	1 (0.8)
Nova Scotia	1 (1.3)	2 (1.7)
Saskatchewan	0 (0.0)	3 (2.5)
Prince Edward Island	1 (1.3)	1 (0.8)
Unanswered	0 (0.0)	1 (0.8)

Table 2. Assessment of Non-response Bias

Characteristic	Respondents; N (%)	Non-respondents; N (%)	P-value
Geographic region			0.45
*Western Canada	59 (29.5)	76 (30.9)	
Ontario	83 (41.5)	99 (40.2)	
Quebec	46 (23.0)	53 (21.5)	
[§] Eastern Canada	12 (6.0)	18 (7.3)	
Survey language			0.22
English	159 (83.1)	209 (85.0)	
French	42 (16.9)	37 (15.0)	

* Alberta, British Columbia, Manitoba, Saskatchewan

[§] New Brunswick, Nova Scotia, Newfoundland, Prince Edward Island

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3 **Figure Legend:**
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5 **Figure 1. Participant Flow Diagram**
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Figure Legend:

Figure 2. Response Rates for Prenotification and Non-prenotification Groups by Contact Number

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Supplementary Material: Uploaded as "Supplementary Material"; this file includes the study prenotification letter, the survey introductory letter and the survey instrument.

Author contributions:

Dr. Michael Hickey is the first author and was responsible for the study design, data collection, statistical analysis and writing of the manuscript. Ms. Carly Hickey assisted with study design data collection and review of the manuscript. Drs. Jeff Perry, Lauralyn McIntyre, Monica Taljaard, Kasim Abdulaziz and Krishan Yadav provided methodological and statistical support in addition to manuscript review.

Competing interests:

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: Dr. Michael Hickey receives a salary as Hospital Donation Physician from Trillium Gift of Life Network, Ontario's organ donation organization, and Dr. Jeffrey Perry is supported by the Heart and Stroke Foundation of Ontario through a Mid-Career Award. No other relationships or activities that could appear to have influenced the submitted work.

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Data sharing:

Requests for sharing of the data will be considered and reviewed by the study's steering committee. Requests can be made to Dr. Hickey

Ethics statement:

No human participants were included in this study. This study was approved by the Ottawa Health Science Network Research Ethics Board. (Approval 20190178).

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3 **Grantor Information:** The guarantor, Michael Hickey accepts full responsibility for the work and/or the
4 conduct of the study, had access to the data, and controlled the decision to publish. Dr. Hickey affirms
5 that this manuscript is an honest, accurate and transparent account of the study being reported and no
6 important aspects of the study have been omitted; and that any discrepancies from the study as planned,
7 have been explained. The corresponding author attests that all listed authors meet authorship criteria and
8 that no others meeting the criteria have been omitted.
9

10 **Dissemination:** There is no formal plan to disseminate these results to study participants.
11

12 **Provenance and peer review:** Not commissioned; externally peer reviewed.
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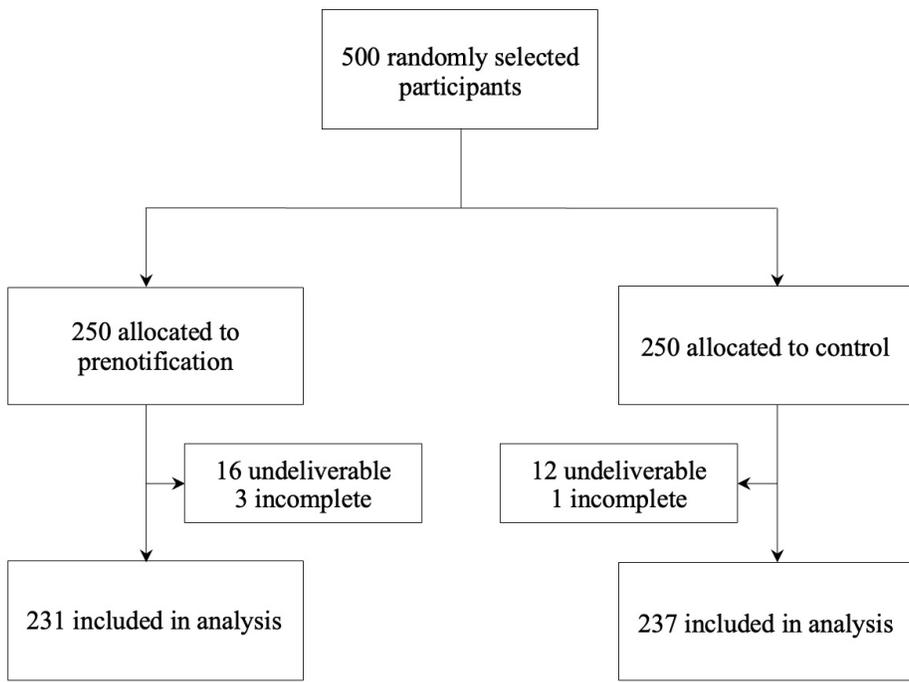


Figure 1. Participant Flow Diagram
224x165mm (144 x 144 DPI)

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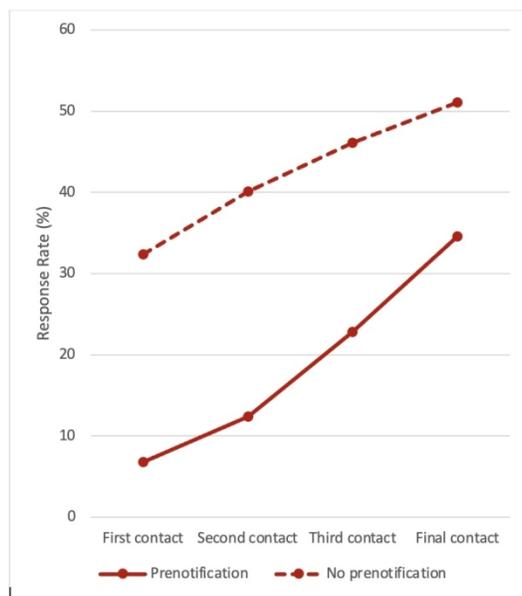


Figure 2. Response Rates for Prenotification and Non-prenotification Groups by Contact Number

Figure 2. Response Rates for Prenotification and Non-prenotification Groups by Contact Number

273x190mm (144 x 144 DPI)

EMERGENCY PHYSICIAN ATTITUDES AND ACCEPTABILITY OF ORGAN AND TISSUE DONATION REGISTRATION IN THE EMERGENCY DEPARTMENT: A NATIONAL QUESTIONNAIRE

Are you currently practicing emergency medicine in Canada? Yes No

If **No**, please return the questionnaire in the postage paid envelope

If **Yes**, please complete and return the questionnaire in the postage paid envelope

A. Professional Status and Practice Setting

1. Are you: Female Male Other Prefer not to answer

2. Year of birth: 19____

3. Province of practice: _____

4. How many years have you been practicing medicine independently?

Less than 5 years Between 5 and 10 years Between 10 and 20 years Greater than 20 years

5. To which religion do you most identify?

Christian Buddhist Hindu Muslim Jewish Sikh Aboriginal Other (specify): _____
 None

6. In what setting do you perform ***MOST*** of your emergency medicine clinical activity?

Teaching hospital

Community / District general hospital: Teaching

Community / District general hospital: Non-teaching

Other (specify): _____

7. On average, how many patients shifts do you work per month?

< 6 6-12 12-18 > 18

8. What is your professional certification?

FRCPC CCFP(EM) CCFP General practice Other

9. Do you hold an official affiliation with a provincial organ donation organization?

Yes

No

B. Attitudes and Acceptability

This section will explore your personal feelings regarding organ donation, and the acceptability of utilizing the ED as a venue to promote organ donation registration to patients who are capable and do not require immediate attention, and visitors.

1. Are you personally registered as an organ and tissue donor? Yes No**2. If no, what is the reason?** I don't know how to register I don't have time to register I was not aware that it is possible to register as an organ donor Religious beliefs Personal beliefs Assumed non-suitability of organs due to medical problems I prefer not to donate my organs Other (specify): _____**3. In general, do you support the concept of deceased organ donation?** Strongly support Somewhat support Neutral Somewhat oppose Strongly oppose**4. Provincial organ donation organizations should attempt to increase the number of registered organ donors:** Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree**5. The emergency department waiting area is an acceptable setting to disseminate information regarding organ and tissue donation to capable patients who do not need immediate attention and visitors:** Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree**6. The emergency department waiting area is an acceptable setting to offer patients and visitors opportunity to register as an organ donor while they await medical care:** Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree

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2 **7. Emergency department patients and visitors would be open to receiving information regarding organ donation**
3 **in ED waiting areas:**

4 Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree
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8 **8. Emergency department patients and visitors would be open to being offered an immediate opportunity to**
9 **register as an organ donor in ED waiting areas:**

10 Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree
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13

14 **9. Emergency department patients and visitors would be open to being offered instructions on how to register as**
15 **an organ donor in the future, following their ED visit:**

16 Strongly agree Somewhat agree Neither agree nor disagree Somewhat disagree Strongly disagree
17
18
19

20 **10. If emergency department patients have an immediate opportunity to register as an organ donor, this should be**
21 **facilitated by: (check all that are appropriate)**

22 Publicly posted signage with instructions

23 Electronic devices available in waiting areas (iPad)

24 Active approach by personnel

25 Other: _____
26
27
28
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31 **11. There may be a number of individuals in the ED who may potentially approach patients and visitors regarding**
32 **organ donation registration while they await medical care. As the attending physician in your ED, please**
33 **describe your comfort level with the following categories of personnel should they facilitate the approach:**

	Very uncomfortable	Somewhat uncomfortable	Don't know/Unsure	Somewhat comfortable	Very comfortable
34 a. ED physician / resident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35 b. Medical student	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36 c. ED nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37 d. ED administrative clerks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38 e. Provincial organ donation organization staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39 f. Hospital volunteer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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52 **Additional comments:**

53 **12. The following are potential facilitators to offering information regarding registration for organ donation in**
54 **emergency department waiting areas. Please choose an option for each potential facilitator which you feel most**
55 **appropriately describes the level of significance of the facilitator:**

	Insignificant facilitator	Somewhat insignificant facilitator	Don't know/Unsure	Somewhat significant facilitator	Very significant facilitator
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1	g.	Strong organ donation culture at institution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2							
3	h.	Societal/public importance of increasing organ donation rates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4							
5							
6	i.	Patients' willingness to help others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7							
8	j.	Patients' previous awareness of organ donation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9							

Please indicate any other facilitators not mentioned above:

13. The following are potential barriers to offering information regarding registration for organ donation in emergency department waiting areas. Please choose an option for each potential barrier which you feel most appropriately describes the level of significance of the barrier:

	Insignificant barrier	Somewhat insignificant barrier	Don't know/Unsure	Somewhat significant barrier	Very significant barrier	
21						
22	k.	Staff or patient ethical barriers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23						
24	l.	Staff or patient religious barriers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25						
26	m.	Lack of patient interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27						
28	n.	Time constraints	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29						
30	o.	Department flow/efficiency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31						
32	p.	Availability of staffing / personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33						
34	q.	Hospital costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35						
36	r.	Patient's privacy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37						
38	s.	Staff confidence in ability to discuss organ donation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39						
40						

Please indicate any other barriers not mentioned above:

Additional comments regarding this topic or questionnaire:

Thank you for completing and returning this questionnaire in the postage-paid envelope.

EMERGENCY PHYSICIAN ATTITUDES AND ACCEPTABILITY OF ORGAN AND TISSUE DONATION REGISTRATION IN THE EMERGENCY DEPARTMENT: A NATIONAL SURVEY

Subject: Invitation to participate in a study on deceased organ and tissue donation registration in the Emergency Department (ED).

Dear colleague:

This letter is being sent to you by Dr. Michael Hickey who is an Emergency Physician at the University of Ottawa, regarding a research study that he is conducting. We have undertaken an important research endeavor investigating deceased organ donation registration in the Emergency Department (ED), and your participation is extremely important.

The overall goal of this study is to assess how Canadian Emergency Physicians feel about utilizing the ED for deceased organ and tissue donation registration for patients. We have initiated a program of research to evaluate the acceptability, feasibility and barriers of this endeavor, through all potential stakeholders who would be involved in the process. The ED is an under-valued but promising venue to promote and educate the public about organ and tissue donation. As such, it is possible that **stable, CTAS 3, 4 and 5 patients who are in the waiting areas of the ED** could be approached and offered information about deceased organ and tissue donation, and given an immediate opportunity to register.

In approximately one week from now, you will receive a questionnaire by mail, and should take about **15 minutes** to complete. I am writing to let you know in advance as some people like to know ahead of time that they will be contacted. Your participation is voluntary, and greatly appreciated.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. If you have any questions about your rights as a study participant, you may contact the Chairperson of the OHSN-REB at 613-798-5555, extension 16719. If you have any questions regarding the study, please contact me, Dr. Michael Hickey at 613-798-5555 ext. 12067 or mhickey@toh.ca.

Thank you for your attention.

Sincerely,

Michael Hickey, MD FRCPC
University of Ottawa / The Ottawa Hospital

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This questionnaire should take about **15 minutes**. You may not like all the questions that you are asked. You may skip any questions that make you feel uncomfortable or that you do not wish to answer.

There are no foreseeable risks or discomforts associated with your involvement in this study. Your participation is completely voluntary. You can decide to stop at any time, even part-way through the questionnaire, for any reason. If you decide to stop, the data submitted up to that point will not be included in the results. If you decide to participate, you have the right to withdraw consent at any point without consequence.

Your responses will remain strictly confidential, and no participant identifiers will appear in any publication or presentation resulting from this study. Please note that there will be no written consent for this study. Completion of the questionnaire is the indication of your consent to participate.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. If you have any questions about your rights as a study participant, you may contact the Chairperson of the OHSN-REB at 613-798-5555, extension 16719.

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Sincerely,

Michael Hickey, MD FRCPC
University of Ottawa / The Ottawa Hospital



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5-7
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6,7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	N/A
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
			N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomisation, together with reasons	7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	6
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	7
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	8
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8
Other information			
Registration	23	Registration number and name of trial registry	N/A
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.