Knowledge of the legislation governing proxy consent to treatment and research

G Bravo, M Pâquet, M-F Dubois

Objective: To assess the knowledge of four groups of individuals regarding who is legally authorised to consent to health care or research involving older patients.

Design: A provincwide postal survey.

Setting: Province of Quebec, Canada.

Participants: Three hundred older adults, 434 informal caregivers of cognitively impaired individuals, 98 researchers in aging and 136 members of research ethics boards (REBs).

Measurements: Knowledge was assessed through a pretested postal questionnaire comprising five vignettes that describe hypothetical situations involving an older adult who requires medical care or is solicited for research. The respondent had to identify the person who is legally authorised to provide consent.

Results: Nearly 80% of all respondents provided the correct answer when the hypothetical scenario depicted a person who was competent to consent or incompetent but legally represented. Knowledge was worse (from 2% among older adults to 44% among REB members) for the scenario describing a research situation that involved an incompetent adult without a legal guardian.

Conclusion: The observed lack of knowledge raises doubts about the ability of current legislation to truly protect the rights of older adults with diminished decision making capacity. It points to the need for educational programmes aimed at increasing public awareness of the legislation put in place for those requiring special protection.
adults have completed advanced directives; 

doing so offers the opportunity to gain knowledge about current regulations that govern third party consent. Lastly, although researchers and REB members should be familiar with the laws that specify who can authorise enrolment of an incompetent individual in a research protocol, training in these matters is scarce. We surveyed the four groups of individuals listed above with the primary objective of assessing their knowledge of the Quebec legislation that currently governs the process of consent to treatment and research. As a secondary objective, we examined whether respondents’ knowledge varied with their sociodemographic characteristics and prior involvement in research.

METHODS

The study protocol was approved by the REB of the Sherbrooke University Geriatric Institute. Knowledge was assessed through a postal questionnaire mailed to a representative sample of each target population.

Sample selection

A random list containing the names, sex, and addresses of 700 adults was extracted from the provincial administrative database containing all beneficiaries of the Quebec universal health insurance plan. The sample was restricted to French speaking, community dwelling adults aged 65 and over who were presumed free of diseases affecting their ability to provide valid answers to a questionnaire. This latter criterion was operationalised by excluding any beneficiary with a diagnosis of mental illness (ICD-9, section V, codes 290 to 298, 300 to 305, 309 to 312), retardation (codes 317 to 319), or central nervous system diseases (section VI, codes 331 to 333).

Regional Alzheimer societies and memory clinics were used to access 700 informal caregivers of persons with dementia. Each participating centre was instructed to randomly select a predetermined number of caregivers in proportion to the size of their membership or clientele. Researchers in aging were identified from the latest version of the provincial directory of public researchers. Because the number of active researchers in aging is relatively small (160 were identified), sampling was considered unnecessary and every researcher was invited to participate in the survey.

Lastly, we identified the 44 REBs designated by the minister of health and social services. These are all based in a research centre affiliated to a university or a hospital. We then excluded seven committees that exclusively reviewed research protocols involving children or teenagers. Because the number of active researchers in aging is relatively small (160 were identified), sampling was considered unnecessary and every researcher was invited to participate in the survey.

After reporting the participation rate specific to each target population, we summarised the characteristics of the four groups of respondents using means and standard deviations or percentages. Using bar charts, we then display the percentage of correct answers for each vignette. Lastly, we present the results of multivariate (α = 0.05) logistic regression analyses on ordinal data aimed at identifying covariates linked to the respondent’s knowledge. In essence, these analyses compare the characteristics of the respondents who provided right answers to the queries with those who failed some of the questions. We started by examining one characteristic at a time, then examined simultaneously all respondents’ characteristics that were linked to the number of right answers. Multivariate analyses were restricted to the predictors that satisfied the proportional odds assumption.

Assuming a 60% response rate, we established at 700 the number of questionnaires to send to older adults and caregivers. We thus expected to analyse the responses of approximately 400 individuals from each of these two groups. A sample of that size would allow us to draw a precise picture of the respondents’ knowledge of the legislation governing consent to treatment and research. As mentioned earlier, all researchers in aging who could be identified and all members of eligible ethics committees were invited to take part in the study.

Questionnaire

A preliminary version of the postal questionnaire was designed by the research team and examined by a committee composed of 12 experts representing the fields of bioethics, medicine, law, and research. Their comments were used to generate a revised version that was reviewed by a linguist and pretested on 4–13 subjects from each target population. Minor revisions led to the final version of the questionnaire. It comprises two main sections. Section one assesses the respondent’s knowledge of the Quebec legislation governing consent to treatment and research. This is achieved through five vignettes (see Appendix) describing hypothetical situations involving a person who requires care or whose participation in research is solicited. Following each vignette, the respondent is asked to identify the person who is legally authorised to provide consent. Section two collects sociodemographic information on the respondent and his/her prior experience in research as a member of an ethics committee.

Survey

The postal survey was conducted from November 2000 to May 2001. With the objective of maximising response rates, we followed Dillman’s Design Method whenever possible. Dillman’s method consists of a set of practical suggestions that cover the design of an attractive questionnaire, the ideal number of repeated mailings and the content of each mailing. Potential respondents received a first copy of the questionnaire with a personal covering letter that explained how they were chosen, stated the objective of the survey, and underscored the importance of their participation. The first mailing also contained a self addressed stamped envelope, a letter of support from an agency credible in the eyes of the respondent, and a postcard to be returned separately from the questionnaire. The postcard, which bore the respondent’s name, served two purposes: first to identify ineligible individuals and second to identify ethics committees who had returned the questionnaire anonymously. Space was provided on the postcard to indicate that the potential respondent did not satisfy our eligibility criteria. Two weeks later, a reminder postcard was mailed to all non-respondents. Finally, two months after the first mailing, individuals who had not returned their questionnaire received a replacement copy and a new personalised letter.

Mailings to the older adults and researchers were coordinated by the research team. In order to preserve the anonymity of their members and clients, Alzheimer societies and memory clinics preferred to manage the mailings themselves. They were provided with the required number of prepared envelopes and reminder postcards that they then distributed, by mail or in person, to the informal caregivers they had randomly chosen. The ethics committee chairs expressed the same desire. In this latter case, we forwarded the required number of questionnaires to their secretarial office, which was responsible for distributing them to their members. A reminder letter for distribution to all committee members was sent to the secretarial offices two weeks and one month later.

Analyses and sample size justification

After reporting the participation rate specific to each target population, we summarised the characteristics of the four groups of respondents using means and standard deviations or percentages. Using bar charts, we then display the percentage of correct answers for each vignette. Lastly, we present the results of multivariate (α = 0.05) logistic regression analyses on ordinal data aimed at identifying covariates linked to the respondent’s knowledge. In essence, these analyses compare the characteristics of the respondents who provided right answers to the queries with those who failed some of the questions. We started by examining one characteristic at a time, then examined simultaneously all respondents’ characteristics that were linked to the number of right answers.

Figure 1 provides an overview of the final sample. Because we did not entirely control the mailing of the questionnaires to the caregivers, only 632 questionnaires were distributed, instead of the target number of 700. Potential subjects were
classified as ineligible for various reasons that differed somewhat across the four groups. Ineligible older adults were either deceased, no longer living at the address we obtained, illiterate, or too ill or cognitively impaired to complete the questionnaire. Ineligible caregivers were individuals who had ceased to care for a relative suffering from dementia or health professionals who attended support groups offered by Alzheimer societies. Researchers excluded from the survey had moved outside the province, were deceased, or conducted research that did not place them in direct contact with human subjects. The six ineligible REB members were researchers in aging who had already completed the questionnaire. Following exclusion of ineligible individuals, response rates varied from 35% among ethics committee members to 75% among caregivers of persons lacking decision making abilities.

In the group of older adults, those who returned the questionnaire were younger (p = 0.005) and comprise a higher proportion of women (p = 0.003) than among non-respondents. Because little information was available on non-respondents from the other three target groups, we could not identify aspects on which they differed from those who returned the questionnaire. Characteristics of the four groups of respondents are summarised in tables 1 and 2.

Figure 2 shows the percentage of respondents who provided the correct answers for each vignette. Overall, high rates of appropriate answers are observed when the vignette depicts a

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**Table 1** Characteristics of older adults and informal caregivers

<table>
<thead>
<tr>
<th></th>
<th>Older adults (n = 300)</th>
<th>Informal caregivers (n = 434)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (SD)</td>
<td>73.9 (SD6.7)</td>
<td>57.4 (SD11.9)</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>64.8%</td>
<td>78.2%</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>married</td>
<td>51.5%</td>
<td>74.3%</td>
</tr>
<tr>
<td>widowed</td>
<td>32.2%</td>
<td>5.3%</td>
</tr>
<tr>
<td>other</td>
<td>16.3%</td>
<td>20.4%</td>
</tr>
<tr>
<td>Years of schooling</td>
<td>8.8 (SD3.8)</td>
<td>13.0 (SD3.9)</td>
</tr>
<tr>
<td>Kinship to the cognitively impaired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>spouse</td>
<td>35.6%</td>
<td>56.3%</td>
</tr>
<tr>
<td>child</td>
<td></td>
<td></td>
</tr>
<tr>
<td>other</td>
<td>8.1%</td>
<td>55.9%</td>
</tr>
<tr>
<td>Legal guardian of the cognitively impaired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has drafted treatment advance directives</td>
<td>31.3%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Has drafted research advance directives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knows a cognitively impaired person</td>
<td>35.8%</td>
<td></td>
</tr>
<tr>
<td>General health status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>excellent</td>
<td>15.4%</td>
<td></td>
</tr>
<tr>
<td>very good</td>
<td>25.8%</td>
<td></td>
</tr>
<tr>
<td>good</td>
<td>40.3%</td>
<td></td>
</tr>
<tr>
<td>average or poor</td>
<td>18.5%</td>
<td></td>
</tr>
<tr>
<td>Previously invited to participate in research</td>
<td>11.4%</td>
<td>26.9%</td>
</tr>
<tr>
<td>Previously invited to provide a substituted consent for the cognitively impaired</td>
<td></td>
<td>25.6%</td>
</tr>
</tbody>
</table>
person who is clearly competent to consent (V1 and V2) or is incompetent but legally represented (V5). Rates are much lower when the hypothetical situation involves an incompetent person who does not have a legal guardian (V3 and V4). In general, researchers and REB members knew more about the legislation that regulates the process of consent than informal caregivers who, in turn, were more knowledgeable than older adults (all \( p < 0.001 \)). Surprisingly, the inverse was observed in the case of consent to treatment required by the health condition of an incompetent person (V3). Perhaps older adults have been exposed to a similar situation more frequently in the past than members of the other three study groups.

As shown in the lower part of figure 2, very few respondents correctly answered all five questions. Roughly half provided the right answer to the two vignettes describing a treatment situation. Fewer correctly answered all three questions depicting a research situation, especially among older adults and informal caregivers.

Respondents’ characteristics independently associated with greater knowledge are reported in table 3. Within each group, a few variables were found to influence the respondent’s ability to provide the correct answer, whether the scenario pertained to treatment or research. In part, this is due to the homogeneity of the responses: for many scenarios, the answers were heavily weighted in one direction or the other (see figure 2).

**DISCUSSION**

The main objective of this study was to determine whether concerned individuals from Quebec know who is legally authorized to provide informed consent to treatment or research on behalf of a person with diminished decision making capacity. The study reveals a lack of knowledge across the four study groups in situations where a cognitively impaired person in need of care or solicited for research is not legally represented (V3 and V4). Because knowledge may vary from one country to another, our study should be replicated in other jurisdictions, using the same questionnaire to facilitate international comparisons. Future studies could also survey other groups of concerned individuals, in particular, clinicians, who are responsible for treatment and often contribute to the recruitment of research subjects. Recent studies conducted in Australia and Great Britain showed that doctors in these countries were unaware of important aspects of the law related to substituted consent.

Returning to the current study, it is informative to focus attention on the respondents who failed to provide the correct answer to the third and fourth scenarios. Results show that a majority of older adults (53.2%) believed that legal consent to the care required by a cognitively impaired person could be given by the treating physician. One in five informal caregivers (20.9%) shared this view. Surprisingly, 34% of researchers and 58% of REB members wrongly thought that no one could consent to the care proposed by the clinician for an incapacitated person. The vast majority of respondents who gave the wrong answer to the fourth scenario thought that a caring family member was legally authorized to provide a substituted consent for research on behalf of a cognitively impaired relative (older adults: 85.1%; informal caregivers: 77.5%; researchers: 61.3%; REB members: 74.1%). The current legislation in Quebec prohibits enrolling mentally incapacitated individuals in research protocols if they are not legally represented. Clearly, most people are unaware of that.

These additional data suggest an alternative interpretation of our results. It is possible that we did not really measure knowledge but rather what people thought made sense. Most respondents believed that a competent person was legally

| Table 2 Characteristics of researchers and research ethics board (REB) members |
|---------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|
|                                | Researchers in aging (n = 98) | REB members (n = 136) |
| Age (SD) 46.8 (8.9)            | 48.2 (11.8)          |
| Sex (female) 53.1%             | 53.7%               |
| Degree MD                      | 25.0%               |
| MSc or PhD                     | 86.3%               |
| Years in research              |                    |
| 1-5                             | 19.8%               |
| 6-10                            | 37.5%               |
| 11-15                           | 27.1%               |
| 16-19                           | 15.6%               |
| Months on the committee         |                    |
| 1-12                            | 23.5%               |
| 13-24                           | 21.3%               |
| 25-36                           | 16.9%               |
| 37+                             | 38.3%               |
| Area of specialisation          |                    |
| geriatrics                      | 10.9%               |
| rehabilitation                  | 8.7%                |
| public health                   | 20.7%               |
| mental health                   | 34.8%               |
| other                           | 25.0%               |
| Type of research                |                    |
| basic                           | 24.7%               |
| clinical                        | 59.8%               |
| epidemiological/evaluative      | 49.5%               |
| psychosocial                    | 30.9%               |
| Research involves individuals unable to consent 64.3% |
| Sits on the REB as               |                    |
| a researcher                    | 27.3%               |
| a health professional           | 48.5%               |
| an ethicist                     | 6.9%                |
| a jurist                       | 9.2%                |
| a representative of the public  | 16.0%               |
| other                          | 27.4%               |

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thought was the most sensible answer. This time, though, the
unwilling to tick “I don’t know”, they provided what they
research on behalf of an incompetent person (V3 and V4) and
of who is legally authorised to consent to treatment or

Figure 2 Knowledge about the person legally authorised to
provide consent to treatment and research. V1, a person able to
consent to treatment; V2 a person able to consent to research; V3, a
person unable to consent to treatment who does not have a legal
guardian; V4, a person unable to consent to research who does not
have a legal guardian; and V5, a person unable to consent to
research who has a legal guardian

unauthorised proxy consent. While some may argue that a
consent by a caring family member is acceptable on ethical
grounds, it none the less leads to derogation of current regu-
lations and disrespect for the legal process put in place to pro-
tect vulnerable individuals. Our findings also raise disturbing
questions about the ability of REBs to effectively accomplish
their mission of promoting and protecting the dignity,
interests, and integrity of human subjects. We acknowledge
that ethical approval of research protocols is based on consen-
sual decisions among REB members. Perhaps one knowledgeable
member per committee, a jurist for example, would be
enough to guarantee the protection of vulnerable individuals.
None the less, individual members of REBs must have a mini-
um amount of knowledge to make a significant contribution
to the committee’s deliberations.

The concerns raised above are justified in so far as the
respondents are representative of their respective populations.
In general, solicited respondents who fail to return a mailed
questionnaire have been shown to differ from those who respond.35 Because of a lack of information on non-
respondents, which is typical of anonymous postal surveys, we
were limited in our ability to detect significant differences
between respondents and non-respondents. We did observe
that older adult respondents were younger and included more
women than non-respondents. These differences are unlikely
to have biased the results as neither age nor sex was associated
with knowledge, at least among adult respondents aged 65
and over (see table 3).

In comparison to other postal surveys, response rates were
quite good for two of the populations surveyed—caregivers
and researchers—a little low among older adults, and
disappointing for the fourth group comprising REB
members.3738 Three reasons may explain the low response
rate of the last group. First, ethics committees are known to be
overburdened by the quantity and complexity of protocols
they have to review.3940 Second, with this group of respond-
ets, we were unable to fully apply Dillman’s method that has
been proven to maximise response rates. In particular, ethics
committee members did not receive a personalised covering
letter, a letter of support, and a replacement copy of the ques-
tionnaire. Last, but not least, REB members may have felt
threatened by our survey, which could—and did—reveal their
individual lack of knowledge regarding who is legally author-
ised to consent to research on incompetent individuals. If this
had a significant effect on the decision to participate in the
survey, then our results are overestimates and REB members’
knowledge is likely to be less than that shown in figure 2.

In conclusion, our findings underline the need to raise pub-
lic awareness of the legislation that currently governs consent
to treatment and research in Quebec. This statement raised
another issue: who should have this responsibility? Alzheimer
societies and memory clinics could assume this role with those
they serve, once they have gained sufficient knowledge them-
selves. How can older adults be reached? Perhaps through
their family physician if future surveys show that they have

<table>
<thead>
<tr>
<th>Table 3 Respondents’ characteristics linked to better knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dependent variable</td>
</tr>
<tr>
<td>Number of correct answers to the two questions pertaining to</td>
</tr>
<tr>
<td>treatment [V1 and V3]*</td>
</tr>
<tr>
<td>Number of correct answers to the three questions pertaining to</td>
</tr>
<tr>
<td>research [V2, V4, and V5]†</td>
</tr>
</tbody>
</table>

*An ordinal score ranging from 0 to 2.
†An ordinal score ranging from 0 to 3.
Knowledge of the legislation governing proxy consent to treatment and research

49
good knowledge of the rules governing proxy consent. Paradoxically, local ethics committees have been cited as ideal bodies to educate researchers about the ethical and legal conduct of research.11 Our results show that their members need to be better trained before they can assume an educational role in regard to researchers. It remains to be seen whether a similar need exists in other countries.

ACKNOWLEDGEMENTS

The authors thank the 12 experts who helped design the questionnaire, as well as the staff of the Alzheimer societies, memory clinics, and ethics committees for distributing the questionnaires. We also extend our deepest appreciation to the 968 individuals who took the time to answer our questionnaire. And we thank the Alzheimer Society of Canada for funding the project.

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REFERENCES


In this first section, we describe hypothetical situations. Please read each vignette carefully and respond to the best of your knowledge.

1. Mr Lawson is 84 years old. His health is generally good. He is bold and brash after his own affairs. He is scheduled to have a knee operation soon. Before the surgery, consent to the care must be obtained.

Who is legally authorized to accept or refuse the care proposed by Mr Lawson’s surgeon? (Check all the answers you think are appropriate.)

- Mr Lawson himself
- A member of his family
- The surgeon
- Other, please specify: ____________________________
- I don’t know

2. After his surgery, Mr Lawson spends a few days in a convalescent home. He is still as lucid as he was before the operation. A researcher is testing a new medication to relieve postoperative pain. The researcher asks Mr Lawson to participate in the study.

Who is legally authorized to decide if Mr Lawson will or will not participate in the study? (Check all the answers you think are appropriate.)

- Mr Lawson himself
- A member of his family
- The surgeon
- Other, please specify: ____________________________
- I don’t know

3. Mrs Bristol suffers from an advanced stage of Alzheimer’s disease. Since her husband died, she has lived with her daughter Amelia. Because of her disease, Mrs Bristol cannot understand when something is explained to her. As yet, no one has been officially appointed to make decisions on her behalf. Mrs Bristol is scheduled to have a hip operation soon. Before the surgery, consent to the care must be obtained.

Who is legally authorized to accept or refuse the care proposed by Mrs Bristol’s surgeon? (Check all the answers you think are appropriate.)

- No one
- Mrs Bristol herself
- Her daughter Amelia
- The surgeon
- Other, please specify: ____________________________
- I don’t know

4. Mrs Bristol is back at her daughter’s house. A researcher is doing a study to verify if classical music has a beneficial effect on people suffering from Alzheimer’s disease. This study does not involve any serious risk for the participants. The researcher would like Mrs Bristol to participate in the study.

Who is legally authorized to decide if Mrs Bristol will or will not participate in the study? (Check all the answers you think are appropriate.)

- No one
- Mrs Bristol herself
- Her daughter Amelia
- The surgeon
- Other, please specify: ____________________________
- I don’t know

5. Following a court decision, Amelia has been officially appointed to make decisions on her mother’s behalf. Amelia gets a call from another researcher who wants Mrs Bristol to participate in a study. This time, it is to test a new diet that could prevent weight loss in people suffering from Alzheimer’s disease. Like the previous study, this study does not involve any serious risk for the participants. The researcher would like Mrs Bristol to participate in the study.

Who is legally authorized to decide if Mrs Bristol will or will not participate in the study? (Check all the answers you think are appropriate.)

- No one
- Mrs Bristol herself
- Her daughter Amelia
- The surgeon
- Other, please specify: ____________________________
- I don’t know

* This is a translation of the questionnaire. All participants answered the French version

† The shaded square indicates the correct answer.

Section 1 of the questionnaire assessing knowledge

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