



Consent to external-beam radiotherapy

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ABSTRACT

Canadian law, and the physician's code of ethics, requires that informed consent be obtained before any medical act is performed. However, there are no rules about how consent is to be obtained and by whom, and how that consent is to be documented.

In April 2008, we asked the heads of all Canadian radiation oncology departments to tell us whether their centre uses a written consent form for external-beam radiotherapy and, if it did, to send us a copy of the form or forms used. Responses were received from 29 of the 38 centres contacted (76%). In 12 centres, all of them in British Columbia or Quebec, no written consent is obtained. Of the 17 centres (59%) that do seek written consent, 9 use a generic hospital or cancer centre form. Only 5 use a form specific to radiotherapy that mentions multiple visits, photographs in the treatment position, use of tattoos, and so on, and only 2 use a form that is specific to the tumour type or site irradiated and that explains the risks associated with treatment. The final centre of the 17 did not provide a form for review.

While current practice at the McGill University Health Centre is not out of line with that at other Canadian centres, the results of our survey suggest a need for dialogue on the subject of consent for external-beam radiotherapy.

KEY WORDS

Radiotherapy, consent

1. INTRODUCTION

Canadian law, and the physician's code of ethics¹, requires that informed consent be obtained before any medical act is performed. The choice to give consent is a patient right, and failure to obtain informed consent may be a significant factor in any action for medical negligence. However, practice ranges widely concerning

- the process of obtaining consent,
- which of the many health care professionals

- attending the patient may receive consent, and how consent is documented.

Written consent is routinely obtained for invasive medical procedures, but in many other situations, consent is based on an interpretation by the physician of the words and behaviour of a patient or the particular circumstances—that is, the consent is “implicit” rather than “explicit”².

For external-beam radiotherapy (EBRT), the fact that a patient attends for consultation and follows through on all of the multiple steps that lead up to the treatment itself is often interpreted as implicit consent for treatment. However, even though EBRT is not an obviously invasive procedure like surgery or brachytherapy, EBRT has an invasive character from the patient's perspective. Moreover, EBRT entails risks of varying degree depending on the clinical situation. Some would argue that, for those reasons, written consent should routinely be obtained before treatment. For example, although the Canadian Council on Health Facilities Accreditation and Accreditation Canada do not concern themselves with form content, they include questions about consent in their pre-survey questionnaire, and they may audit radiotherapy charts for the presence of consent forms during their visits.

For some years, policy at the McGill University Health Centre has required that discussions with a patient about radiotherapy treatment and likely outcome, including the risks and side effects associated with treatment, be documented by the responsible radiation oncologist in the patient's chart, usually in the consultation report. Concerned that such documentation may not be adequate, we initiated discussions within our department about both the need for written consent to EBRT and the content of a consent form. Those discussions elicited wide-ranging opinion on the subject from the radiation oncologists, the members of the radiation oncology quality assurance committee (which includes patient representatives, one of whom is a lawyer), and legal counsel for the hospital. With no consensus possible, we wanted to assess practice in other radiation oncology centres across the country.

2. MATERIALS AND METHODS

In April 2008, we asked the heads of all radiation oncology departments across Canada to tell us whether their centre uses a written consent form for EBRT and, if it did, to send us a copy of the form or forms used.

3. RESULTS

Table 1 shows the responses received from 29 (76%) of the 38 centres surveyed. In 12 centres, all of them in British Columbia or Quebec, written consent is not routinely obtained. Of the remaining 17 centres (59%), 9 use a generic hospital or cancer centre form that contains no information specific to radiotherapy. Another 5 use a form specific to radiotherapy that mentions multiple visits, photographs in the treatment position, use of tattoos for treatment set-up, and so on, but that gives no information specific to the proposed treatment or to the risks associated with that treatment. Only 2 centres use a form that is specific to the tumour type or site to be irradiated. One centre that uses a consent form did not provide a form for review.

4. DISCUSSION

The issues concerning informed consent are several:

- The right of the patient to inviolability and integrity of the person
- The right and the need of the patient to be informed about treatment options and outcomes
- The responsibility of the physician to impart to the patient all pertinent information regarding a proposed treatment, to ascertain that this information has been understood, and to answer the patient's questions.

Documentation of the process used to obtain consent and of the discussion that took place with the patient may consist of a note in the chart, with or without the patient's signature, or of a completed

TABLE 1 Survey results: consent in radiation oncology in Canada

Centres surveyed (<i>n</i>)	38
Responding centres (<i>n</i>)	29
Consent form in use? [<i>n</i> (%)]	
No	12
	(all QC, BC)
Yes	17 (59)
Consent form type	
Generic to hospital/cancer centre	9
Specific to radiotherapy	5
Specific to tumour type	2
Unknown (sample not provided)	1

written consent form. The latter may be perceived as a "contract" with the patient that offers some measure of protection for the physician in the event of legal action, making it therefore necessary or at least highly desirable.

For centres such as our own that do not obtain written consent for EBRT, the discussion that takes place with the patient with respect to the benefits and risks of the treatment proposed is typically documented in the consultation report. Such a note, which is not usually seen by the patient, does not necessarily address the question of whether the patient has understood the issues discussed. The use of a generic form signed by the patient and treating physician (such as those used by 88% of the centres that responded to our survey) also does not guarantee understanding, but it creates a presumption to that effect. That presumption arises because such forms typically ask patients to acknowledge that they have understood the information provided and had the opportunity to ask questions. Such a form may also be somewhat reassuring to patients, who may subsequently feel more in control of their care, provided that their signature on the form was not obtained in a preemptory manner.

An alternative would be to develop consent forms specific to planned treatments. These forms would not only explain the risks of proposed treatments in general terms but also give estimates of their frequency (Table 1): for example, common (>50% of patients), less likely (10%–15% of patients), infrequent (<10% of patients), or rare (<5% of patients). These more specific forms would also state whether effects are likely to be permanent. Because patients are understandably often very anxious at the time of their first encounter with a radiation oncologist and because modern treatments are typically quite complex, often having alternative therapeutic options each bearing different risks, all of which need to be discussed with the patient, a detailed consent form specific to the treatment planned could be a very useful tool. It would give patients a document that could be reviewed at a later time when they are better able to assimilate the information provided. Such forms, currently used in a very few of the centres surveyed (2 of 28), would help to ensure that patients receive the information they need to make an informed decision and would provide better documentation of the discussions that take place between a patient and a treating radiation oncologist.

5. CONCLUSIONS

Current practice in most Canadian radiotherapy centres is likely less than ideal, and it may be useful to initiate a dialogue on the question, possibly with the involvement of, or even led by, the national specialty association. After much reflection on the subject, we at the McGill University Health Centre have reached

TABLE II Risks associated with radiation to the head-and-neck region

<i>Risk likelihood</i>	<i>Risk type</i>
Very likely (>50% of patients)	Sores in the mouth or throat (or both) that may be painful and that may make it difficult to chew and swallow food Mouth dryness or changes in taste and smell that may be permanent Hoarseness of voice Tanning or redness of the skin in the head-and-neck area being treated with radiation Ear pain or pressure (or both) Fatigue Weight loss Permanent hair loss in the area treated with radiation Loss of teeth, cavities in the teeth, hypersensitivity of the teeth
Less likely (10%–15% of patients)	Decrease in thyroid gland function that may require thyroid replacement medicine to prevent feelings of tiredness Difficulty with swallowing and eating for which a long-term or possibly permanent feeding tube might be required; possibility of inhaling food or liquids into the lungs, which could result in pneumonia Serious ear infections that may necessitate temporary tube insertions in the ears Hearing loss Damage to the spinal cord manifested by electric-like sensation in the upper and lower extremities associated with neck movements (a temporary side effect that may last for up to 3 months and that resolves spontaneously without need for any treatment) Permanent hair loss in the face, chin, or neck area treated with radiation
Infrequent (<10% of patients)	Permanent damage to the spinal cord or to nerves in the neck, jawbone, voice box, skin, or other parts of the head and neck that may require a major operation to correct and that may even be life-threatening on occasion
Rare (<5% of patients)	Blindness because of damage to the optic nerves (if in the radiation field) A second cancer

the conclusion that the best approach may be to use models from cooperative groups such as the Radiation Therapy Oncology Group and the Children's Oncology Group to develop forms specific to tumour types or sites that set out risks according to frequency (common, less likely, infrequent, rare) as is shown in Table II for head-and-neck radiotherapy. Such forms, which would need to be adapted as appropriate to ensure patient understanding, are currently under development at our centre by an inter-professional working group that includes patient and family representatives.

6. ACKNOWLEDGMENTS

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7. REFERENCES

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