The College of Naturopaths of Ontario

Guidelines

Informed Consent

Adapted from the College of Kinesiologists of Ontario's Practice Guideline - Consent

Introduction

The ability to direct one's own health care needs and treatment is vital to an individual's personal dignity and autonomy. A key component of dignity and autonomy is choice. Regulated health professionals hold a position of trust and power with respect to their patients and can often exercise influence over a patient; however, decision making power must always rest with the patient, or in the case of incapacity, the patient's substitute decision -maker (SDM). It is the right of every patient or their SDM to receive full and frank information on his/her condition, the options available and to provide free and informed consent to any matters relating to their health.

The issue of consent in the health care context is so crucial that Ontario passed the *Health Care Consent Act (HCCA), 1996* to ensure there is a legal framework on establishing, maintaining and recording valid consent that is consistent in all settings.

This Guideline serves as a further explanation to the College's Practice Standard on Consent with specific focus on the HCCA. While it focuses on the provisions of the HCCA, members should remember the principle of choice and consent and that obtaining valid consent at all times is the ideal. Where there are exceptions to the need to obtain consent, these exceptions should only be applied if absolutely necessary. Consent should always be sought before action takes place or as soon as possible thereafter. When assessing the need for consent or when seeking to obtain consent, a member should not look at the situation through a legal or technical lens; consent is a broad concept and ultimately involves the person's inherent right to choose and their right to dignity and autonomy.

The Health Care Consent Act (HCCA), 1996

The HCCA was passed in 1996 and is multi-purpose in scope. It not only provides parameters on what, when and where consent should be obtained, but also establishes a framework for situations in which the patient is deemed incapacitated for the purposes of giving consent. In a broader sense, the act seeks to "promote communication and understanding between health practitioners and their patients or clients". By providing patients with all of the necessary information regarding their condition and treatment options, a practitioner is including the patient in the process, thereby strengthening the efficacy of the therapeutic relationship and the autonomy of the patient.

When does the Health Care Consent Act apply?

The HCCA outlines three major areas when consent is needed: 1) treatment; 2) admission to care facilities; and 3) the need for personal assistance services. Members will most often be operating under the treatment category. The

scope of the HCCA does not negate the need for consent in other matters such as disclosure of personal health information, which is dealt with under the *Personal Health and Information Privacy Act (*PHIPA), *2004.* The principles of the HCCA and the elements of consent outlined below should be followed in all situations where consent is needed, such as information patients about fees and billing etc…

Treatment

The HCCA defines treatment as "anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, and includes a course of treatment, plan of treatment or community treatment plan." The HCCA does provide a number of exceptions under the definition for treatment, which include, among others:

(a) the assessment, for the purpose of this act, of a person's capacity with respect to a treatment,
(b) the assessment or examination of a person to determine the general nature of the person's condition,
(c) the taking of a person's health history,
(d) the communication of an assessment,
(e) treatment that in the circumstances poses little or no risk of harm to the person.

However, a prudent member may still wish to seek consent even when not required to do so under the HCCA. It should also be noted that taking a person's health history is considered collection of personal health information and therefore the need for consent under PHIPA would apply.

What does consent look like under the HCCA?

The HCCA outlines the elements of consent to treatment as follows:

1. The consent must relate to the treatment.
2. The consent must be informed.
3. The consent must be given voluntarily.
4. The consent must not be obtained through misrepresentation or fraud.

1) The consent must relate to the treatment

Consent must be specific to the action the member proposes to take before the action takes place. This means that a member cannot obtain blanket consent for any and all assessments or treatments at the present time or in the future.

2) The consent must be informed

The HCCA defines informed consent as consent that is based on information which a reasonable person in the same circumstances as the patient would require in order to make a decision about the treatment. The HCCA specifies that the following matters must be discussed in order for the patient to provide informed consent:

1. The nature of the treatment.
2. The expected benefits of the treatment.
3. The material risks of the treatment.
4. The material side effects of the treatment.
5. Alternative courses of action.
6. The likely consequences of not having the treatment.

The Duty to Disclose

Informed consent is obtained by providing a patient or the SDM with full and frank disclosure of the items listed above, most notably the material risks and side effects of the proposed treatment. Providing this information is also often referred to as duty to disclose. The Supreme Court of Canada has held that the standard for disclosure is based on what information a reasonable person in the circumstances of the patient would require. The focus is on the patient.

Material risk

It is most often the potential risk(s), and/or the likelihood of the risk(s) occurring in relation to potential benefit(s) of a proposed treatment that is the deciding factor for a patient. A member should disclose all known risks or those that should be known of a proposed treatment. The latter requirement implies a duty on the member to be current with the state of science on the proposed treatment. Not all possible risks are material. However, if the risk is serious, or could result in permanent pain or injury, then the mere possibility of that risk may be material. The most notable example is risk of death. Even where death is only a remote possibility in a proposed treatment, its risk must always be disclosed. Another serious risk is the risk of a heart attack. A member who is assessing a person's cardiovascular performance, for example, should disclose the risk of a heart attack if it is at all present given the patient's condition.

Members should use caution when providing prepared lists of risks. Common problems with lists are that they may not be exhaustive, they can become outdated and they may not be fully relevant to a particular patient. What may be a material risk to one patient may not be relevant to another. For example, a course of treatment that could result in pain or injury to a person's joint functioning may be more relevant to a high-functioning athlete than a person who does not engage in much exercise.

Care should also be taken with respect to explaining to the patient the consequences of foregoing treatment. The consequences or risks involved should be realistic and patient-based. The same principles involved in disclosing material risks should be applied to this situation. It is important that the member does not attempt to influence or sway the patient into accepting treatment by mentioning alarming but remotely possible risks, unless they are very serious. Having undue influence over a patient's giving of consent, or being in a position of a conflict of interest, may invalidate the consent.

Communication

On-going dialogue and open communication between the patient or the SDM and the practitioner is essential for obtaining informed consent. Consent should be considered an ongoing process and not a single event. If the condition of the patient significantly changes or the member proposes a different treatment option, then consent should be obtained again. By the same token, members are encouraged to obtain consent to continue treatment where there has been no improvement in a patient's condition. The member should always be realistic with the patient when it comes to discussing the likelihood of future improvement. A member may assess a person's condition as unlikely to improve but treatment is considered necessary to prevent regression and this should be fully explained to the patient before proceeding.

The HCCA does set out two situations in which consent can be presumed: 1) if there is a variation in the treatment, but the expected benefits, material risks and material side effects are not significantly different from the original treatment; or 2) if the setting in which the treatment takes place changes, but there is no significant change in the expected benefits, material risks or material side effects of the treatment as a result of the change in the setting

During discussions about the patient's condition and treatment options, the member should provide opportunities for questions by the patient or the SDM. The member should seek to answer any questions when asked, if possible, or as soon as possible thereafter. If the discussion is lengthy and complex, the member should provide opportunities for questions throughout the conversation and should not always wait until the end of discussion to address questions. The patient may not be able to remember all of his/her questions if the discussion becomes complicated and prolonged.

Further, in ascertaining a patient's circumstances in order to determine an appropriate treatment plan, the member will have to collect personal information, including personal health information, from the patient, which also requires consent under PHIPA. It is therefore important that when asking the patient questions that the member explains the purpose of the questioning and ensures the confidentiality of the information provided. For example, a member may want to ascertain what a patient's family and financial situation is because this may affect their ability to take part in an expensive and time-consuming treatment program. Questions of this nature may at first seem irrelevant to a patient unless the member explains the purpose in relation to a proposed treatment.

Members must also be satisfied that the patient or the SDM understands the discussion about treatment. Every patient's ability to comprehend health matters varies, and the member should be mindful of any indications that the patient does not understand what is being said and should adjust their communication accordingly. If there is a language barrier, the member should consider having a colleague, staff member or a family member of the patient assist with translation. The use of diagrams or written information may also be helpful. The member can also consider having the patient explain back to the member, in his/her own words, the nature of the treatment and risks and benefits involved.

The member must also allow the patient time to provide consent. The patient may need a few days to think about the options or obtain a second opinion. Where a treatment poses greater risks, the member should encourage the patient to seek a second opinion from a relevant health care practitioner.

Withdrawal

Consent may be withdrawn at any time and this withdrawal should be respected by the member immediately. Moreover, patient should be informed of their right to withdraw consent at any time. The patient should be reminded of their right to withdraw consent every time consent is being sought.

Documentation

The signature of a patient or of the SDM on a consent form is not conclusive proof that the member obtained informed consent. This is true even if the consent form contains detailed information about the nature of the treatment and the risks involved. A signed consent form is only an indicator that a discussion surrounding consent took place. In addition to any consent form, the member should make detailed notes in the patient's records regarding the nature and content of the discussion around consent and follow all other documentation protocols and standards. In a situation where the member is relying on implied consent, the notes should be sufficient that a reasonable person could assume consent based on the circumstances outlined in the notes. Below is a discussion on implied consent.

Implied Consent vs. Express Consent

The HCCA allows for consent to treatment to be express or implied. Express consent is provided directly from the patient or SDM in explicit words or in writing. Therefore, express consent can be either verbal or written.

Implied consent is consent that is inferred from signs, actions, or facts or by inaction or silence. The standard that is applied to whether implied consent was obtained is based on whether a reasonable person in the same circumstances would believe that consent was given. An example of implied consent might be where a patient holds out their arm and tells the practitioner that they have pain in their wrist. This may imply that they consent to the practitioner looking at and touching their wrist.

Members should exercise great caution when relying on implied consent. Implied consent is subject to interpretation, which can lead to misunderstanding. Interpretation of someone else's actions may not take into account that person's religious or cultural customs, personal habits or behaviours or the inherent power imbalance between the member and the patient. For instance, a patient may have a nervous habit of nodding their head during a conversation, but this may not mean they are consenting to the proposed action of the member. Further, there are certain circumstances where implied consent should not be relied upon. The more serious an intervention or invasive a procedure being proposed is, the greater the need for express consent. Members should also be acquainted with the need for express consent with respect to the disclosure of personal health information as outlined in Section 18(3) of the Personal Health Information Protection Act, 2004.

3) The consent must be given voluntarily

Consent must also be voluntary, which means that it must be given free of undue influence or duress. As stated previously, members should be mindful of their own influence over the patient. Where the power imbalance is greater, the patient may want the member to make the decision or feel they have to accept the member's recommendation.

Members must also ensure that any other person, such as a family member or other representative, is not pressuring the patient. There may be situations where a patient relies on another person to help them understand the

information that is being provided by the practitioner; however, this does not mean that the patient is unable to consent freely on his/her own behalf.

Members should inform the patient that consent to treatment is their choice and that they should make it freely without any pressure from anyone else.

4) The consent must not be obtained through misrepresentation or fraud

In providing the information about the treatment to a patient, the member must be frank and honest. The member should not be in a conflict of interest when making recommendations. If the member is recommending any course of treatment or product where the member has a relationship with another provider, this should be disclosed and alternatives provided as well.

Where does the HCCA apply?

The HCCA applies to all settings in which a regulated health professional may be practicing, even if the setting is non-clinical in nature. As a regulated health professional, a member is expected to obtain consent for all treatment matters wherever they occur. A member who practices in a private gym would be subject to the provisions of the HCCA as would a member working in a hospital. A member who is conducting an assessment on behalf of an employer or insurance company should also seek the consent of the individual they are assessing. Despite the fact that a member may be hired by a company or insurance firm for the purposes of an assessment, the member enters into a therapeutic relationship with the person they are assessing and all standards of the profession, including the requirement for consent, apply. Consent in the health care context takes place between the practitioner and the patient. A third party cannot provide consent on behalf of the patient.

However, a member can delegate the consent discussion in certain circumstances, if appropriate. For example, an administrator of a facility might obtain consent for an assessment at an initial appointment on behalf of the member. The person conducting the consent discussion must be knowledgeable about the assessment and be able to answer any questions from the patient. However, the member retains the responsibility at all times of ensuring that there is valid and informed consent. If treatment involves a more invasive procedure or touching of a sensitive nature, the member should discuss and obtain consent from the patient directly.

Incapacity

There are situations in which a patient may not be able to provide informed consent because they are incapacitated. The HCCA sets out rules with respect to obtaining consent from the Substitute Decision Maker (SDM), while still including the patient as much as possible. Making a determination that someone is incapacitated for the purposes of consent is a very serious matter and goes to the very heart of an individual's autonomy and dignity.

The HCCA states that a person is capable with respect to a treatment if the person is able to understand the information that is relevant to making a decision about the treatment and is able to appreciate the reasonably and foreseeable consequences of a decision or lack of a decision.

All persons are presumed to be capable. A member may not presume that a person is incapable solely on the basis of any one of the following reasons:

- The existence of a psychiatric or neurological diagnosis;
- A refusal of a proposed service that is contrary to the member's advice or the advice of another practitioner;
- A request for an alternative service;
- The person's age;
- The existence of a disability, such as a hearing impairment; and/or
- The mere fact that a SDM is in place.

A patient may be in a situation that impedes their ability to process or understand information, but is still capable of providing consent. For example, where a patient has a hearing impairment, it is the duty of the member to ensure the

patient receives all the information necessary to provide informed consent. The member might adjust the volume of his/her voice, move to a quieter setting or use a different method of communication, such as pen and paper.

The HCCA, as well as PHIPA, also explicitly state that a patient's incapacity with respect to one matter may not necessarily mean that they are incapable to make other decisions. For example, a patient may be able to consent to an initial assessment, but may not be able to consent to a treatment plan because they are unable to understand the more complex information provided with respect to the treatment. Also, a patient may be incapable at one time and capable at another time with respect to treatment. When a patient is deemed to be capable again, consent must be sought from the patient.

If a patient was judged to be incapable and a SDM provided consent and the patient later becomes capable again, then the patient's own decision to give or refuse consent governs.

How to assess capacity

A member may use the following observations as possible indicators of incapacity:

- The person shows evidence of confused or delusional thinking;
- The person appears unable to make a settled choice about service;
- The person is experiencing severe pain or acute fear or anxiety;
- The person appears to be severely depressed;
- The person appears to be impaired by alcohol or drugs; and/or
- Any other observations which give rise to a concern about the person's capacity, including the person's behaviour or communication.

What to do when a determination of incapacity is made

Under section17 of the HCCA, it is mandated that the College set out guidelines to its members regarding the type of information that must be provided at a minimum to a patient about the consequences of a finding of incapacity. The College recommends the following courses of action following a finding of incapacity:

- Inform the patient that the member believes that the patient is incapable of providing consent to the proposed treatment unless:
    - there is a substantial risk of serious harm to the patient or another individual if the member informs the patient; or
    - the patient's incapacity is to such a degree that they would be unable to understand the fact of the finding or the member's reasoning;
- Inform the patient that he/she may still be able to consent to other matters if he/she is deemed capable with respect to those matters;
- Inform the patient that an SDM will be responsible for making decisions on the patient's behalf and the name of the SDM;
- Inform the patient of his/her right to appeal the finding to the Consent and Capacity Review Board (CCRB);
- If the patient objects to the particular SDM, the member should inform the patient that another person can be appointed by the CCRB;
- Inform the patient that his/her incapacity will continue to be reassessed and when capacity returns, he/she will be able to consent to treatment;
- Provide the information to the patient in a manner that the patient is best able to understand; for example, using simple language or providing a written information sheet; and/or
- Inform the patient that the finding of incapacity will be documented in the patient's health record. The member must document the discussion thoroughly in the patient's record

If a patient has indicated to the member that they plan to appeal the member's decision to the CCRB, then the member must not begin treatment.

Substitute decision makers

When a patient is deemed to be incapable of providing informed consent, the member must seek consent from a Substitute Decision Maker (SDM). The hierarchy of substitute decision makers is as follows:

1. Guardian

2. Attorney for personal care
3. A representative appointed by the Consent and Capacity Review Board
4. Spouse or partner (including a same-sex spouse)
5. Child, parent or children's aid society. This does not apply to a parent who has only a right of access
6. Parent with right of access only
7. A brother or sister
8. Any other relative
9. The Public Guardian and Trustee

The stipulations of the HCCA, the College's Practice Standard on Consent and this Guideline all apply to obtaining consent from the SDM.

In order to qualify as a substitute decision maker, a person must meet all of the following criteria:

- Be capable to consent to the treatment;
- Be at least 16 years old. The only exception is if the person under 16 is the incapable person's parent;
- Not be prohibited by a court order or separation agreement from having access to the incapable person or from giving or refusing consent on the incapable person's behalf;
- Be available; and
- Be willing to assume the responsibility of giving or refusing consent

A SDM must make decisions on behalf of the patient that are in accordance with the patient's known wishes or that are in the patient's best interests. The HCCA outlines the factors that a SDM should take into account before making a decision on behalf of the patient. If the member does not believe that the SDM is acting in the best interests of the patient, the member can make an application to the CCRB.

Emergency treatment

Members cannot make decisions about a patient's treatment without their consent except in certain emergency situations. An emergency situation is defined in the HCCA as when a person for whom the treatment is proposed is apparently experiencing severe suffering or is at risk, if the treatment is not administered promptly, of sustaining serious bodily harm. Where practicable, consent should still be sought from the patient or his/her SDM, but not if the delay required in obtaining consent would prolong the suffering or put the person at risk of serious bodily harm. In the case of a person who is capable of providing consent but cannot do so due to a language barrier or disability, the member should attempt to find a way to communicate with that person and obtain consent. If the member is unable to communicate with the person and there is no reason to believe that the person does not want the treatment, then the member can perform emergency treatment without consent.

For example, if a member is assessing range of motion and the patient collapses from an apparent heart attack, the member should ascertain whether the patient is conscious and capable of providing consent. If the member determines that the patient is incapable of providing consent and no SDM is available, the member should proceed to provide CPR or other appropriate treatment, as may be required.

The member should document any treatment provided in an emergency in the patient's health record as soon as possible. Consent should be sought as soon as possible from either the patient or SDM after the emergency treatment has been administered.

Suggested Reading

Professional Misconduct Regulation;
General Regulation;
Health Care Consent Act;
Standard of Practice for Conflict of Interest;
Standard of Practice for Consent;

Standard of Practice for Record Keeping

Approval

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