Informed Consent: Background, Requirements and Guidelines for Practice for Audiologists and Speech-Language Pathologists[1]

Consentement éclairé: Origine, exigences, et lignes directrices pour les audiologistes et les orthophonistes

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Abstract

Informed consent is an established legal doctrine in Canadian law. It is defined as the willing and uncoerced acceptance of a healthcare intervention by a client after adequate disclosure of the nature of proposed intervention, its risks and benefits, as well as of alternatives, with their risks and benefits (Klar, 1991). This article outlines the origins of informed consent, discusses the ethical-legal foundations, and provides guidelines for ensuring informed consent in the practice of audiology and speech-language pathology. Examples drawn from clinical practice and reference to the Canon of Ethics will serve to provide a framework for application of this legal requirement to the professions of audiology and speech-language pathology.

Abrégé

Le consentement éclairé est une doctrine établie dans le droit canadien. On le définit comme l'acceptation volontaire, sans contrainte, d'une intervention médicale par un client après divulgation des informations adéquates sur la nature de l'intervention, ses risques et ses avantages ainsi que sur les solutions de rechange, leurs risques et leurs avantages respectifs (Klar, 1991). Le présent article explique l'origine du consentement éclairé, en analyse les fondements déontologiques et juridiques et propose des lignes directrices sur la façon de l'obtenir dans la pratique de l'audiologie et de l'orthophonie. Des exemples tirés de la pratique clinique et des références au code d'éthique serviront d'encadrement à l'application de cette exigence juridique à l'audiologie et à l'orthophonie.

Informed consent can be defined as the willing and uncoerced acceptance of a healthcare intervention by a client after adequate disclosure of the nature of the intervention, its risks and benefits, and the alternatives available (Klar, 1990). In this article, we will explore the historical background, ethical foundations, and legal requirements of informed consent for clinicians in the fields of audiology and speech-language pathology.

We do not intend to present a detailed analysis of the issues surrounding informed consent (see Robertson, 1984, 1990 for discussion of issues). Rather, it is our intent to provide audiologists and speech-language pathologists with sufficient background and information to allow them to honour this ethical-legal principle in their practice.

Historical background

The legal doctrine of informed consent has its origins in English common law. The common law consists of judicial decisions made over the past 600 years. All Canadian provinces, except Québec, have imported the English common law, while Québec is governed by the Québec Civil Code.

The tort of battery, cited as early as 1767, established that expressed consent must be obtained from the patient before performing a medical procedure (Rose, 1986). Thus, competent adult patients had the right to accept or reject any proferred medical treatment. Treatment given in the absence of consent constituted a battery. "Battery" is defined as touching in the absence of consent (Klar, 1991). In 1914, Judge Cardoza of the New York Court of Appeals in *Schloendorff* v *Society of New York Hospital* stated: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."

The evolution of the informed consent doctrine is chronicled in the changes in the balance of power in the physician-patient relationship. Some writers, notably Katz (1984) and Rothman (1991), state that informed consent is the modern manifestation of "an erosion of trust,...a decline

in the deference given to doctors and to their professional judgements" (Rothman, p.10).

Until the late nineteenth century, the physician-patient relationship was characteristically an intimate one, in which both parties shared values, culture, and ethnicity. With the advent of improved sanitation and effective vaccinations along with the concomitant decline in deaths from infectious diseases, physicians were accorded increased respect and power. A social gulf was created, which elevated the physician above his or her patient (Storch, 1982; Rothman, 1991).

The Second World War and its aftermath brought antibiotics, a cure for tuberculosis, and increased prestige for medicine. This prestige further widened the gulf between the physician and the patient. One could no longer assume that physicians and patients shared similar values, culture, or socioeconomic status (Rothman, 1991).

Broader societal changes in the post-war era also contributed to the power imbalance in the physician-patient relationship. These changes included urbanization, bureaucratization, specialization, the transfer of private functions to government, and shifts in values. As a result, the population became concentrated in cities where healthcare services were delivered through large hospitals by specialists (Storch, 1982).

In these post-war years, it became increasingly apparent that the physician and patient were not equal partners in medical decision-making. Adhering to the ethical principle of beneficence, physicians chose to act without outside consultation, in their patients' best interests. Patients of this era demonstrated deference to physicians who were often strangers to them, and in command and control of new knowledge, drugs, and technology.

In response to changes in the patient-physician relationship, the concept of knowledgeable or "informed" consent emerged in the late 1950s in American law as a legal mechanism directed at redressing the imbalance in the physician-patient relationship (Rose, 1986). The standard for disclosure was the professional disclosure standard. This meant that the clinician's disclosures to the patient would be compared to the standard practice of one's peers in his or her professional community. If the clinician met this standard, no liability would ensue.

In the 1960s and 1970s, the civil rights movement and the bioethics movement challenged the authority of the healthcare professional, physicians in particular, in decision-making. Increasingly, debates over medical decision-making moved out of the private realm of physicians into the glare of public scrutiny as theologians, ethicists, lawyers, and policy-makers examined not only the decisions made by physicians, but unquestioned authority they had been given (Rothman, 1991). Patients, seeing themselves as consumers of healthcare, demanded increased participation in decisions regarding their health (Storch, 1982).

In Canada, the standard for disclosure was altered by the Supreme Court. Two 1980 Supreme Court decisions, *Hopp* v *Lepp* and *Reibl* v *Hughes*, amplified the doctrine of informed consent and changed the standard of disclosure in Canadian law to a "patient-centered" standard. The Supreme Court of Canada held that healthcare professionals must inform patients of the proposed treatment, its risks and benefits, along with those of any alternative treatment. They should also advise the patient of the consequences of leaving the condition untreated. As well, Laskin, C.J.C. in *Reibl*, stated that the healthcare professional should disclose information that would be important to the patient in his or her life circumstances, answer specific questions posed by the patient, and voluntarily disclose the risks, including those deemed *special* or *unusual*. Failure to make adequate disclosure could subject the healthcare professional to a legal action based upon negligent disclosure (Storch, 1982).

A recent review of cases based upon negligent disclosure (lack of informed consent) found that patients' claims were rarely successful (Pritchard, 1992). It was found that most patients could not prove that they would have refused treatment had a full explanation been provided.

Foundation of Informed Consent

The aforementioned societal changes in the post-war era contributed to the emergence of the ethical principle of respect for autonomy to the position of prominence it now has in healthcare deliberations (Rothman, 1991). Respect for autonomy forms the primary ethical foundation for the legal doctrine of informed consent. This ethical principle refers to the respect accorded individual choice. An individual is said to have made an autonomous decision if he or she acted with intention, understanding, and independent of controlling influence (Beauchamp & Childress, 1989). The autonomous choice of the patient must be respected even if that choice does not result in maximum benefit to the patient.

A related element of informed consent is veracity. Veracity refers to truth-telling. The rule of veracity is seen by ethicists as being derived from the principle of respect for autonomy (Beauchamp & Childress). Clients enter into a relationship with a healthcare professional with the expectation that they be told the truth. This relationship is founded on the assumption of trust. Trust is maintained in the relationship to the extent that the shared communication between the client and clinician is truthful.

Professional codes of ethics rarely explicitly deal with the obligation of veracity. This ethical obligation has become one of the issues debated in the topic of disclosure of medical mistakes.

The Legal Requirement of Consent

As has been stated, one of the most basic rights in our society is that every individual has the right to be free from bodily interference by others. This right has been recognized in Canadian common law and in Québec under the Civil Code.

The right to be free from non-consensual touching or treatment is also a right under the *Canadian Charter of Rights and Freedoms*. Under Section 7 of the Charter of Rights, treatment provided in the absence of consent may constitute an infringement of an individual's constitutional right to "security of the person".

The legal requirement of informed consent is stated in the Canadian Association of Speech-Language Pathologists and Audiologists' Canon of Ethics as follows:

> 12) A member shall provide to each client reasonable information regarding the nature and treatment of the client's communication disorders and the professional services that the member has provided or proposes to provide to the client.
>
> 14) Informed consent is required from the parent/guardian for the provision of direct service by audiologists and speech-language pathologists to children under the age of sixteen years and clients who are not competent to act on their own behalf.

The Provision of Treatment

There are three circumstances in which a healthcare professional may provide treatment: with the patient's consent, with statutory consent, or in emergencies. Regarding patient consent, a patient has the right to refuse treatment no matter how beneficial the treatment or unreasonable the refusal. For example, in a well-known Alberta case, *Mulloy* v *Hop Sang*, a physician amputated a patient's hand, although the patient had instructed him not to do so. The patient later sued the physician. While the court agreed that the surgery probably saved the patient's life and was competently performed, the physician was held liable in battery for performing an operation in the absence of consent.

A patient also has the right to withdraw consent. He or she may do so prior to the commencement of the treatment or during the treatment or procedure. This may cause practical difficulties for the healthcare professional, since it may be risky to stop once a procedure begins. However, once the patient demands or requests the treatment to cease, the healthcare professional must discontinue the treatment. This standard has particular relevance to audiologists administering procedures such as ABR or ENG, and to speech-language pathologists working in the areas of voice, resonance, and dysphagia. The clinician should explain to the patient that the risks increase as the procedure progresses, and that it may be dangerous to discontinue.

Statutory consent is prescribed by certain statutes found in provincial legislation. The authors have referred to Alberta legislation in this article. Readers should become familiar with the applicable legislation in the province in which they are practicing, since provincial legislation varies from province to province. Clinicians are advised to contact their provincial speech-language association in order to obtain this information.

In Alberta, the *Public Health Act* R.S.A. 1980 c. P-27.1, provides protection of the public from communicable disease specified in the schedules forming part of the Act. Under this type of statute, the consent of the individual is not required.

Substitute consent statutes, which vary across provincial jurisdictions, provide for those who lack the capacity to consent to treatment for themselves. In Alberta, for example, the *Child Welfare Act* R.S.A. 1980, c. A-38, provides a mechanism for obtaining consent for necessary healthcare for children whose parents are unavailable, unable, or unwilling to provide consent to treatment. The *Dependent Adults Act* R.S.A. 1980, C.D-32 and the *Mental Health Act* S.A. 1988, C. M-13.1 provided for substitute consent to treatment for adults who lack the capacity to consent to treatment.

In emergencies, a healthcare professional is authorized to provide treatment without first obtaining consent. The emergency exception is narrowly construed within the confines of specified criteria. Convenience and the best interest of the patient are not sufficient to protect the healthcare professional if the situation is not a true emergency.

Methods of Obtaining Consent

Consent can be either expressed or implied. Consider the following situation:

> Mr. MacDonald is a 54 year-old coal miner from Springhill. He underwent a laryngectomy and his physician is requesting a speech evaluation. Mr. MacDonald is illiterate.

Expressed consent is generally demonstrated in written or oral form; it is the client's response to the information

provided in the conversation between the client and the clinician. In Mr. MacDonald's case, expressed consent could be confirmed by a reliable and valid gestural communicative response, such as a headshake or head nod.

Consent may also be implied from what the client has said, written, or communicated by his actions. Thus, when a client opens his mouth at the request of the speech-language pathologist during an oral mechanism examination, consent to this procedure is implied.

Both types of consent are valid. However, it is often difficult, if consent later becomes an issue, for the client and the clinician to agree on the extent of an implied consent. There is no legal test to determine how much can be implied from what a client says or does, and thus each case will depend on its own facts. In Mr. MacDonald's case, it would be beneficial to have a witness to verify his consent.

Documenting Consent

Although the law does not require it, documentation of consent is, practically speaking, very important, particularly if consent is implied from a client's actions or is expressed orally. The practical reason for documenting the conduct or statements that are being relied upon as evidencing consent to treatment, is that the clinician is unlikely to remember the circumstances surrounding the obtaining of the consent. It may be years later before the issue arises in a trial and commonly the best evidence presented will consist of notes on the client's chart.

The primary "legal" purpose in documenting consent to any healthcare procedure is to provide evidence that the client actually consented. The consent form is intended to be evidence of the consent. It is *not* the consent.

If the client's consent is not valid for one reason or another, then the written documentation is meaningless and will be accorded little or no weight by a court. For example, if a client signs a consent form authorizing a specific procedure, and a different procedure had been proposed to the patient, that consent will not assist the clinician who claims that the client consented to the treatment that was actually given.

Criteria for a Valid Consent

There are four criteria necessary for a valid consent in Canadian law. If any one of these criteria is not present, then there is no consent.

The consent must be voluntary and genuine. A consent given under duress, compulsion, or fraud will invalidate the consent. For example, consider the following:

> Mr. McLeod is an 88 year-old widower who lives in a local nursing home. During her annual visit from California, Moire, Mr. McLeod's daughter, insists that her father be fitted with a hearing aid.

If Moire insists on having her father tested and fitted with a hearing aid, and Mr. McLeod, not wanting to antagonize his daughter, goes along with the audiological assessment, then a valid consent is not demonstrated. Only if Moire is Mr. McLeod's legally appointed guardian, with specific power to make healthcare decisions, would consent be seen as valid in this case.

Clinicians need to consider the family dynamics, as with the McLeods, and cultural norms in determining whether an individual has consented freely to the proposed assessment or treatment. Particular sensitivity to factors such as education, culture, and ethnicity is essential to the determination of a genuine and voluntary consent (Dickson, 1988).

The client must have the capacity to give valid consent. There are two issues that must be addressed in relation to the notion of capacity.

First, there is the concept of "legal" capacity. An adult person may have lost the capacity to consent to treatment for themselves. A typical example would be where a guardian has been appointed under dependent adult legislation. When such a guardian has been granted the authority by a court to make healthcare decisions on behalf of a dependent adult, that adult no longer has the legal capacity to consent to treatment; the clinician cannot obtain a valid consent from that individual, even if the individual appears to understand and appreciate the proposed treatment. In such cases, a legally valid consent must be obtained from the guardian. Guardianship orders are specific to the needs of the individual patient and the authority of the guardian will vary with each patient. The patient may retain decision-making capacity in some areas. Therefore, the clinician must be familiar with the scope of each guardianship order.

The second concept is that of "factual" capacity. For certain groups of clients, factual capacity presents a difficult issue for clinicians. Consider the following situations:

> Gerry Thibault is a 46 year-old man with a mental disability and severe cerebral palsy who was referred for an audiological assessment due to a suspected hearing loss. He lives in a group home. Mr. Thibault's parents are deceased.

> Mrs. Dachyshyn is a 64 year-old unilingual Ukrainian widow who had a stroke six months ago. She attends an outpatient treatment program. Mrs. Dachyshyn is apha-

sic. Her sister Lydia, who cares for her in their home, has noticed that Mrs. Dachyshyn is having difficulty swallowing. The speech-language pathologist is recommending an assessment of Mrs. Dachyshyn's oro-motor function and swallowing mechanism.

The fact that these individuals are communicatively disabled does not automatically mean that they lack the capacity to give a valid consent. Clinicians working with communicatively disabled individuals, particularly those who are brain-injured, aphasic, hearing-impaired, or mentally disabled, should recognize the legally assumed competence of these individuals and make reasonable attempts to obtain consent for assessment and treatment.

In Mr. Thibault's case, it would be important to clarify with his caregivers if a guardian has been appointed and, if so, what the terms of that guardianship order might include. In Mrs. Dachyshyn's case, the clinician should make a reasonable attempt, including providing Ukrainian translation, to obtain Mrs. Dachyshyn's consent. If Mrs. Dachyshyn's understanding of the information cannot be demonstrated in a reliable and valid manner, then the clinician may ask Lydia whether she has any indication of what her sister's wishes might be. Clients who are communicatively disabled are particularly vulnerable to violations of their right to informed consent. Clinicians must be aware that only a court can declare adults mentally incompetent and, therefore, unable to give consent.

Where children are concerned, it is important for the clinician to be aware of the applicable law governing the jurisdiction he or she is practising in. Some provinces have enacted legislation which stipulates the age at which a child or adolescent can consent to treatment. Other provinces, such as Alberta, have not enacted legislation, so the common law is applicable. According to common law, a child may consent to treatment provided that the child is capable of appreciating the nature and consequence of a particular treatment and the risks of foregoing treatment. It is up to the clinician to evaluate whether the particular child is capable of the necessary understanding and to document how that opinion was reached. Consider the following example:

> Ryan is a 15 year-old boy who sustained a closed head injury during a motor vehicle accident eight months ago. He attends an outpatient program for brain-injured adolescents. Ryan presents with dysarthria. He receives intensive speech therapy daily. Recently, Ryan has complained to his speech-language pathologist that he is tired of therapy and wants to stop. His mother, Sylvia, dearly wants her son's speech to improve and is unsure of what to do.

If Ryan is a resident of a province where common law is applicable and the speech-language pathologist is certain that his language comprehension is unimpaired, then he has the right to refuse speech therapy. His situation highlights the need for sensitivity and effective communication in addressing both Ryan's concerns regarding the unwanted burden of therapy and Sylvia's concerns regarding what she may feel is in her son's best interests. Hopefully, counselling will provide an avenue for resolution of this conflict.

The consent must be referrable to both the treatment and to the person who provides the treatment. Clinicians should ensure that a client has consented to the treatment or portion of the treatment plan that is provided by the professional in question. This is particularly true when a client is treated by a multidisciplinary team. A client who has consented to treatment by the physiotherapist may not have given a consent to the treatment provided by the speech-language pathologist. The speech-language pathologist cannot rely on the consent given for treatment provided by another healthcare professional.

The same criterion applies when consent has been obtained for one treatment. This consent is not transferrable to additional, subsequent, or different treatment.

In referring to assessment or treatment provided by students or other persons under the supervision of the audiologist or speech-language pathologist, the Canon of Ethics states:

> Members are responsible for all duties they delegate to personnel under their supervision and such duties must not contravene this Canon or the Laws of the Land.

The consent must be informed. In order for a client to give a valid consent to treatment, he or she must be given sufficient information upon which to base his or her decision. The law imposes the duty of disclosure on healthcare professionals to disclose information that a client in a position similar to this client would want to know in order to make a decision regarding assessment or treatment.

As discussed earlier in this paper, the clinician must answer any specific questions posed by the client, and should also disclose any alternatives to the proposed treatment, the risks associated with each, and the consequences of leaving the condition untreated. In assessing the risks that should be disclosed, the law provides that the more serious the potential risk, the greater the obligation to disclose it, even if it is a mere possibility. Clinicians should be aware that the scope of disclosure is greater for treatment that can be characterized as experimental or innovative in nature. Regarding disclosure of risks, consider the following case:

> Ms. Chang is a 24 year-old graduate student who is experiencing balance problems and vertigo. The ENT has requested an audiological assessment including an ENG.

The audiologist should disclose to Ms. Chang the risk of experiencing nausea associated with the procedure involved. Mere disclosure of the information may not be sufficient. Clinicians also have a responsibility to ensure that the client comprehends the information that is given. This is an important concern for clinicians in the field of human communication disorders, where determination of language comprehension is within the profession's scope of practice. Decisions regarding comprehension may rest with the information from the speech-language pathologist's assessment.

Also, the increasing number of new Canadians who do not speak one of the official languages poses a new dilemma for determining comprehension. Special care should be taken in cases where translators are used, particularly if the translation is provided by a family member.

Given the option, the client may decide to waive disclosure. He or she has the right to do so, but the clinician should carefully document the waiver. In very rare cases, a client may be unwilling or unable to deal with the information that the clinician would ordinarily disclose. The clinician may decide to impart less detail than he or she would otherwise disclose. This is known as therapeutic privilege. It should be pointed out that Canadian courts have construed this doctrine very narrowly and it should rarely be utilized.

Finally, is there an obligation to disclose mistakes? During the last few years the courts have placed an increasing responsibility of disclosure on healthcare professionals. The trend is to require the healthcare professional to disclose mistakes. Generally, clients will appreciate the healthcare professional who honestly discloses a mistake and wants to rectify it. It should be seen as part of effective communication that is required by professional ethics and law.

Guidelines for the Process of Obtaining Informed Consent

Numerous guidelines have been proposed for obtaining informed consent (Picard, 1984; Rozovsky,1980). The following guidelines have been adapted from Evans (1990).

1. It is important for audiologists and speech-language pathologists to familiarize themselves with the criteria for a valid consent, as it is within a legal framework that informed consent will be determined.

2. Clinicians should discuss the details of the proposed assessment or treatment, its benefits, and any risks in non-technical language. Since clinicians are dealing with clients who demonstrate communication difficulties, they must be sensitive to potential comprehension problems.

3. In discussing treatments, clinicians should also advise the client about the rationale for choosing the proposed treatment, as well as the alternatives including benefits and risks. The option of no treatment should also be discussed.

4. Clients must be free to ask any questions. Clinicians should be attentive to the specific concerns expressed by the client.

5. Clinicians should exercise caution in accepting waivers from clients, particularly if they suspect that the client may be confused, coerced, or experiencing stress.

6. In obtaining consent for treatments that are either innovative or experimental, clinicians should be aware that full explanations of the known and/or potential risks, harms, and inconvenience to the client be provided, since a more stringent standard of disclosure is expected by the courts.

7. As stated in the CASLPA Canon of Ethics, Section 7d, the results of treatment cannot be guaranteed.

8. It is important to inform the client if all or part of the treatment will be provided by a student clinician or other person under the supervision of the clinician. This provision is stated in Section 3 of the Canon of Ethics.

9. Clinicians should record the details of the consent conversation on the client's chart, with reference to specific information, in the event that questions or concerns arise regarding the consent at a later time.

Conclusion

Informed consent is a legal requirement in the provision of services by audiologists and speech-language pathologists. With the trend toward private practice in audiology and speech-language pathology, and the widening scope of liability of healthcare professionals in general, it is important for clinicians to familiarize themselves with this requirement.

Informed consent is an ongoing process which ensures that the client is kept informed of the intervention process. As a process, informed consent has the potential to change the dynamic of the client-healthcare professional relationship, recognizing the client's right to make healthcare decisions on his or her own behalf. For the audiologist or speech-language pathologist, it offers an opportunity to honour ethical obligations, to convey care and trust, and to share responsibility for decision-making.

Author Note

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