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INFORMED CONSENT

A Refresher

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AGENDA

1. General Overview
2. Application to Health Professionals
3. Application after Change in Circumstances
4. Application in Elective Procedures
5. Application in Research

GENERAL OVERVIEW

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GENERAL OVERVIEW

Reibl v. Hughes [1980] 2 S.C.R. 880

- Battery
  - When no consent is given at all
  - When treatment goes beyond that which was consented to; or
  - When consent is obtained through serious or fraudulent misrepresentation

- Absent an emergency, a physician is legally responsible for the consequences of procedures performed without consent even when the physician has acted in what in their opinion is the best interest of the patient *(Muhsina v. Orstein,* 2012 ONSC 6678 at para 35*)*

- A claim in battery is actionable "'without actual proof of damages' (Campion & Dimmer, at p. 9-17) and 'can succeed even where the treatment performed was done properly, was not harmful and may have helped the patient'" (at p. 9-18.1). (*Gerelus v. Lim et al.*, 2008 MBCA 89 at para 25)

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- A failure to adequately inform a patient gives rise to a claim in negligence but does not vitiate a patient's consent to the actual procedure (*Reibl v. Hughes,* at pp 890-891)

NEGLIGENCE

- The court in *Reibl v. Hughes* outlined a two part test in order to determine whether negligence had been established.

    I. Did the practitioner discharge his duty to make disclosure to the patient of all material risks;

    II. If not, what would a reasonable person in the patient's position have done if there had been proper disclosure of the attendant risks

- The standard of disclosure is measured by what a reasonable person in the patient's position would want to know and generally should "answer any specific questions posed by the patient as to the risks involved and should without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation" (at pp 891-892)

- The duty to disclose has also been expanded and includes relevant alternative treatment options and the likely prognosis of not having the procedure (*Groves v. Morton,* [2006] O.J. No 4772 (QL) at para. 11)

- In deciding whether to advise of a particular risk or not, the doctor must balance the likelihood of the risk materializing against the gravity of the harm that could ensue if it were to materialize (*Hopp v. Lepp*, [1980] 2. S.C.R. 192 at para. 32)

- Who has the duty to disclosure?
  - Individual performing each treatment is ultimately responsible for ensuring the patient is properly informed (*Thiessen v. Hota*, 2005 MBQB 248 (Master))
  - Individual responsible for prescribing or authorizing the treatment is ultimately responsible for ensuring the patient is properly informed

- In order to satisfy the second part of the test, the failure to disclose must be shown to have caused the plaintiff's damages (modified objective test)
    - Plaintiff must prove that the plaintiff subjectively would likely have not consented to the procedure
    - Court must assess whether a reasonable person in the plaintiff's circumstances likely would have consented to treatment if the required disclosure had been made

HEALTH PROFESSIONALS

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HEALTH PROFESSIONALS

- The Doctrine of Informed Consent has broad application to Health Professionals
- Most Governing Bodies include a requirement to obtain informed consent prior to treating patients in their governing materials such as their Standards of Practice or Code of Ethics
- The Government of Manitoba's website lists 21 Health Regulators on its website, who have the responsibility to ensure their members practice in a manner that meets the public interest

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HEALTH REGULATORS

- Audiologists and Speech-Language Pathologists
- Chiropractors
- Dental Hygienists
- Dentists
  - Dental Assistants
- Denturists
- Licensed Practical Nurses
- Medical Laboratory Technologists
- Midwives
- Naturopathic Doctors
- Occupational Therapists
- Opticians
- Optometrists
- Pharmacists
- Physicians and Surgeons
  - Clinical Assistants
  - Physician Assistants
- Physiotherapists
- Podiatrists
- Psychologists
- Registered Dietitians
- Registered Nurses
  - Nurse Practitioners
- Registered Psychiatric Nurses
- Registered Respiratory Therapists

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Although worded slightly differently, some examples of the duty imposed by health regulators include:

a) Denturists

- *The patient has the right to receive from the denturist information necessary to give informed consent prior to the start of any procedure and/or treatment. The patient has the right to be informed of significant alternatives for dental care or treatment, where they exist.*
- *The patient has the right to refuse treatment to the extent permitted by law, and to be informed of the consequences of those actions. (Denturist Association of Manitoba, Patient's Bill of Rights, #3 and #4)*

b) Chiropractors

- *Chiropractors must discuss with patients treatment recommendations including benefits, prognosis and significant risks, as well as reasonable alternatives and associated costs to enable patients to make an informed decision with regard to any proposed chiropractic care. (Manitoba Chiropractors Association, Code of Ethics, A.a)*

c) Dentists

- *A professional has a duty to inform the patient of their treatment options including the advantages, disadvantages and significant risks and costs. The patient has the final choice of treatment, as long as this choice is within accepted treatment standards. (The Manitoba Dental Association, Code of Ethics, First Fundamental Principle)*
- *Dentists must discuss with patients treatment recommendations including benefits, prognosis and significant risks, as well as reasonable alternatives and associated costs to allow patients to make an informed choice. Dentists shall also inform patients if the proposed oral health care involves treatment techniques or products which are not generally recognized or accepted by the dental profession. (The Manitoba Dental Association, Code of Ethics, Article 5)*

d) Audiologist and Speech-Language Pathologists

- *Having sufficient dialogue with the client about his or her condition, the nature of the treatment and the treatment options, including the risks, benefits and efficacy of the options, to enable informed decision-making on the part of the client. (The College of Audiologists and Speech-Language Pathologists of Manitoba, Standards of Practice, 5.1.b.ii)*

Massage Therapists

- *Not yet a regulated health professional but has applied to become self-regulated under the Regulated Health Professions Act* (anticipated sometime in 2020)
- *Currently has a Code of Ethics which includes a requirement to obtain informed consent*
  - *Patient autonomy is demonstrated by providing complete and accurate information in a sensitive and timely fashion to enable patients, or when necessary a patient's Power of Attorney or substitute decision-maker, to make informed choices; and*
  - *Encouraging and being responsive to patients' choices to accept, augment, modify, refuse or terminate treatment; (Massage Therapy Association of Manitoba, Code of Ethics, Principle 1: b) and d).*

CHANGES IN CIRCUMSTANCES

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CHANGE IN CIRCUMSTANCES

- Health care professionals must be careful when there is a change in circumstances during a procedure
- Could lead to claim in battery
- In *Muhsina v. Orstein, 2012 ONSC 6678,* the plaintiff consented to a cystectomy on the right ovary, however there were complications during surgery which led to Dr. Ornstein placing two Filshie clips on the left fallopian tube to avoid the future risk of an ectopic pregnancy.
    - *Dr. Ornstein could not establish that placing the Filshie clips was a continuation of the procedure for which additional consent was not required and as such was found liable in battery*

- *Or* to a claim in negligence
- In *Husain v. Daly*, 2012 ONSC 919, the plaintiff consented to a myomectomy to remove fibroids and during the procedure the defendant converted the procedure into a hysterectomy and removed the patient's uterus as she believed it to be in the patient's best interests.
  - *Plaintiff established that the risk of a non-emergency hysterectomy might be performed had not been disclosed*
  - *Plaintiff established that she would not have consented if she had been provided the disclosure*
  - *Plaintiff's desire to have a baby was known to the defendant and not unreasonable*

- In *Pridham et al v. Nash*, [1986] O.J. No. 1243 (Ont. H.C.J.) the court held that "[t]he surgeon would have been required to consult further with the patient and obtain a further consent to a major operation. However, this case, in my view is different. From a practical point of view it would be foolish for Dr. Nash to wait for Mrs. Pridham to come out of anesthesia and then seek her consent to go through the same incision again to cut the two adhesions. The additional curative surgery was of such a minor nature that it falls practically in the same category as taking a sample for a biopsy." (at para 22).

ELECTIVE PROCEDURES

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ELECTIVE PROCEDURES

- For over 40 years there has been debate as to whether the fact that a procedure is elective elevates the duty of disclosure
- There have been comments in obiter that "[w]here an operation is elective, as this one was, even minimal risks must be disclosed to patients, since 'the frequency of the risk becomes much less material when the operation is unnecessary for his medical welfare' (See Grange J. in *Videto v. Kennedy* (1980), 27 O.R. (2d) 747 at 758)" (*White et al. v. Turner et al.* (1981), 15 C.C.L.T. 81 at p. 103)

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RECENT CASE LAW

- In *Solomon v. Ali*, 2018 ONSC 3287:
  - *Defendant recommended and performed a surgery which would even if performed correctly not meet the patient's goals*
  - *Judge confirmed that informed consent is a process*
  - *"For elective surgery, all material risks must be disclosed. The legal standard of disclosure does not vary, but the scope of disclosure does. 'In other words, in deciding whether a risk is "material" the elective nature of the procedure is a relevant (and significant) factor. A risk is much more likely to be characterized as material (that is something that a reasonable patient would want to know about) if the procedure is elective'"* (at para 136)

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ISSUES WITH DISCLOSURE

1. Failure to Know Needs, Lifestyle of Patient
2. Inadequate Description of the Surgery
3. Failure to Explore the Surgical Options Suggested by Plaintiff
4. Failure to Clearly Warn that the Fusion Surgery would Eliminate all Movement
5. Failure to Describe Material Risks
6. Failure to Describe other Surgical Option (relied on expert evidence)

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- *In Jesperson v. Karas*, 2019 ONSC 5841
  - *Plaintiff, a dentist, was nearsighted and had to wear glasses but wanted corrective surgery in order to avoid glasses while playing sports*
  - *"[i]t is generally accepted that the scope of disclosure is greater where the procedure is elective" quoted from Legal, Liability of Doctors and Hospitals in Canada, 5th ed. (Toronto: Carswell, 2017) with approval by Justice D.A. Wilson*
  - *Court found that as a dentist, a reasonable person in the plaintiff's position would not have accepted the risk*

RESEARCH

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RESEARCH

- The requirements for conducting research on humans are detailed in the Tri-Council Policy Statement, a Policy Statement prepared and agreed to by The Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Science and Humanities Research Council of Canada (endorsed by Justice G. Dow in *Stirrett v. Cheema*, 2018 ONSC 2595, at para 5)

- Chapter 3 of the Tri-Council Policy Statement sets out the ethical requirements for consent in research involving humans.

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GENERAL PRINCIPLES

1) Consent Shall be Given Voluntarily
2) Consent Shall be Informed
3) Consent Shall be an Ongoing process
4) Consent Shall Precede Collection of, or Access to, Research Data

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VOLUNTARILY

- Without undue influence
- Without coercion
  - *More force than undue influence*
- Incentives
  - *Cannot be of a nature which would "encourage reckless disregard of risks"*
- Ability to withdraw
  - *Unless practically not possible*
  - *Without retaliation and with return of materials*

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INFORMED CONSENT

- 12 separate obligations including
  - *The purpose of research and details of the research to be conducted (Article 3.2 (b))*
  - *Description of all reasonably foreseeable risks and potential benefits, both to the participant and in general (Article 3.2 (c))*
  - *An assurance that the prospective participants:*
    - Are under no obligation to participate and can withdraw
    - Will be given in a timely manner information relevant to their decision to continue
    - Will be given information on right to withdraw date or human material from the study (Article 3.2 (d))

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ONGOING PROCESS

- Article 3.3 sets out that "[c]onsent encompasses a process that begins with the initial contact… and carries through the end of participants' involvement in the project"
- Researchers have an "ongoing legal and ethical obligation to bring to participants' attention any changes to the research project that may affect them"

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CASE LAW

- "The subject of medical experimentation is entitled to full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent" (*Halushka v. University of Saskatchewan* (1965), 53, D.L.R. (2d) 436 (Sask. CA) at para. 29)

- "The obligation of a researcher to the participant when it involves human is more strict than a doctor to patient relationship." (*Stirrett v. Cheema*, 2018 ONSC 2595, at para 47)

- A failure to provide the information necessary to obtain informed consent can be found to be a breach of a fiduciary duty. (*Stirrett v. Cheema*, 2018 ONSC 2595, at para 47)

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STIRRETT V. CHEEMA

- Case against physicians performing procedure dismissed
- Qualified ethicist to give expert evidence
  - *"anything which would influence the decision of a prospective patient or participant should be disclosed. Further, the patient or participant should be updated on new information as it develops" (para 35)*
- While the changes to the study may not have been significant or changed the risk of harm was not for Dr. Strauss to decide, his obligation was to pass on the information

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- Dr. Strauss breached his fiduciary duty in not disclosing the changes to the study
- A "finding of a fiduciary duty and the breach of that duty removes causation from the analysis on whether there will be recovery" (at para. 52)
- "The physician is pledged by the nature of his calling to use the power the patient cedes to him exclusively for her benefit. If he breaks that pledge, he is liable" (at para. 53)

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Q&A

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THANK YOU

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