

CONSENT IN PARAMEDIC PRACTICE

As the medicine is transforming, receiving patient centered care has been the expectation of the public from healthcare providers. Emergency care has evolved in a similar fashion. Patient autonomy is a well-established practice in the modern medicine practiced today. **Autonomy in medical perspective is defined as** the quality or state of being independent, free, and self-directing (Merriam-Webster). From ethical, legal and professional perspectives, paramedics must show respect to patients' right to make decisions on their own care whenever they are capable of doing so. In other words, paramedics have a duty to respect patient's autonomy. In Canadian practice, legal rights of patients to give or refuse consent to treatment has been outlined in the Health Care Consent Act (HCCA,1996).

Consider, for example, the case given below:

You are responding to a 56-year-old male complaining of dizziness. Following a thorough assessment on scene, you determine your patient is confused and very critical, presenting with a peri-arrest cardiac dysrhythmia which requires urgent intervention. As your partner gets ready to start an intravenous (IV) line, you explain your findings and planned treatment strategy to your patient's wife. After several unsuccessful attempts of getting an IV line, your partner turns to you to discuss alternatives. Patient's wife states her slightly obese husband has always been a hard stick. In order to deliver the much-needed antiarrhythmic drugs, you determine the next best alternative is an intraosseous (IO) line. As you ask your partner to prepare for an IO, your patient's wife asks what an IO is and what are you going to do to her husband. As you explain the procedure, she sees the IO needle your partner pulls out and asks "is that gonna hurt?". You again explain that it may hurt just as much as a regular IV stick, but that is the only way to deliver much needed lifesaving drugs under the existing circumstances, patient's spouse states she doesn't want her husband to be given anything, but instead taken straight to the hospital.

With an expected 25 minutes travel time to the hospital, you determine that the patient may never be able to reach there.

What would your response to the patient's wife be? What would you do?

Consent and Informed Consent

Consent in legal perspective is defined as the voluntary agreement or acquiescence by a person of age or with requisite mental capacity who is not under duress or coercion and usually who has knowledge or understanding (Merriam-Webster).

Consent is an integral part of medical care and must be obtained prior to any care given, except for some emergency situations. Furthermore, patients have the right to "informed consent".

There are two types of consent: implied and expressed.

Implied (Implicit) Consent

Implied consent is consent which is not explicitly given by the individual, but is inferred from the person's actions or inactions. For example, when a patient volunteers to answer questions regarding medical history or allows a paramedic to take a blood pressure by holding an arm out, it constitutes an implied consent. In fact, most patient care is based on implied consent. Another example of implied consent can be seen when a patient is unconscious but requires an emergent intervention to save his/her life. Paramedics then can assume that patient would have consented to the treatment they provide in order to save the patient's life or limb and can proceed. Unless stated otherwise prior to losing consciousness, a consent for these emergent procedures is considered given by the patient.

Expressed (Explicit) Consent

Whenever a patient care related activity, such as starting an intravenous line, becomes painful or carries risks, paramedic should ask the patient to express their consent. While most expressed consent is performed verbally, written consent should be sought by paramedics, especially when a certain procedure or treatment is refused by the patient.

Informed Consent

Informed consent is a form of expressed consent and can be defined as the decision made by the patient about their own treatment which is based on an understanding of the nature of the treatment, the risks inherent in it, the potential consequences of those risks or the refusal of treatment, and also what alternative treatments there may be.

Informed consent requires effective and patient-centered communication skills. Communicating with a patient who does not have a medical background and who might have doubts/concerns about their decisions on their health status is a challenging skill. Such communication should be neutral and balanced, and should not aim to sway the patient's mind toward a particular decision. A balanced and informative account of the paramedics' medical perspective on the particular health problem(s) and relevant outcomes should be clearly communicated with the patient. "If I were you..." sentences should be avoided. Direct but non-threatening communication should be preferred.

Valid Consent

This definition itself underlines some of the key elements of consent. For consent to be considered valid, paramedics must ensure that:

- it is voluntarily given,
- the patient presents with mental competency (capacity) for consent,
- the patient is properly informed about the outcomes of decisions and all communication exchanged with the patient should be relevant to their existing condition.

A patient who consents or rejects a treatment should do so voluntarily, without any pressure or coercion. Paramedics must be convinced that the patient's own will is reflected in the decision. A decision provided under duress or influence from another may invalidate consent.

Very rarely, paramedics can encounter a situation where care must be provided to a patient despite an involuntary consent. A person who is in police custody and requires emergency life or limb saving care can be considered as an example. In this case, police have the power to give consent for emergent intervention. A patient who is under control of mental health officials can be treated in a similar manner.

Paramedics should be satisfied that the patient understands the nature of their medical problem and the anticipated effects of interventions/treatment as suggested by the paramedics and finally the consequences of refusing treatment. Determining the patient's capacity to consent is usually a straightforward process, however it can be challenging at times.

Generally, under the law, persons are presumed to be capable of making their own treatment decisions unless there are reasons to judge otherwise. Minors, patients with mental illnesses and patients under the influence of alcohol and/or drugs (therapeutic or recreational) constitute some of the examples who do not have the capacity to make a decision about one's own care.

Assessing the capacity of the patient essentially requires the steps taken to ensure that the patient has the general understanding of the decisions they need to make and the consequences of making or not making those decisions, the patient is able to understand and use the information provided to them relevant to their decisions and he or she is able to communicate his/her decisions with the paramedic.

Emotional stress, language and cultural barriers may affect the patient's comprehension of the information provided to him/her by the paramedics. Explanation of risks associated with proposed treatment or refusal thereof is not considered enough for informed consent. Further, paramedics should take reasonable steps (such as using an interpreter) to ensure the patient understands the information given.

Consent on Incapable Person's Behalf

At times when a patient is incapable of making decisions on his/her own care, a substitute decision maker can consent or refuse to consent to treatment. Patient's spouse, parents,

children, legal guardian(s) or others who are defined by law can be substitute decision makers. If the patient becomes capable once the treatment begins, his/her own decisions regarding the medical care provided must be taken into account.

Duration of Consent

Consent remains valid until the intervention is completed. However, any time during the patient care, patients may decide to withdraw consent. In that case, paramedics should communicate the possible consequences of the consent withdrawal decision and ensure the patient understand those consequences clearly.

In another example, a capable patient may not consent to any specific intervention and then loses consciousness. Unless there is a formal written directive for withholding care, paramedics should assume an implicit consent is present and proceed with critical interventions.

Refusing Treatment/Transport & Informed Refusal

Patient refusal of treatment or transport to a hospital is a common occurrence in paramedic practice. Patients who have the mental capacity have the right to refuse any medical assessment, care or transport to a hospital. By rule, any refusal expressed by the patient should be an informed refusal. In these cases, risks associated with their decision and consequences of refusal of care should be clearly explained to the patients. Also, reasonable alternatives to the treatment (such as referring patient to the family physician) should be given. Refusal is a stage where the patient does not agree with the paramedic's recommendations, therefore further insistence on obtaining consent should be avoided. On the other hand, upon direct explanation of risks and consequences and discussing alternatives, patients may change their minds and consent to receive recommended care.

Any refusal of paramedic intervention must be thoroughly documented. Information contained in this report must include risks clearly explained, questions answered (if any), and patient's understanding of the communication verified.

Challenging Patient Groups

Even though the majority of the people paramedics care for fall into the capable adult category, there are certain subgroups of patients that may be more challenging for paramedics. Some of these patients include:

- Minors and mature minors
- Unconscious patients
- Patients under substance influence
- Adults with developmental disabilities
- Mental health
- Police custody

Minors and mature minors: *New Brunswick Medical Consent of Minors Act* states that minors 16 years or older can consent or refuse to consent to medical treatment or transport to a hospital just as adults can. The same Act also states that

The consent to medical treatment of a minor who has not attained the age of sixteen years is as effective as it would be if he had attained the age of majority where, in the opinion of a legally qualified medical practitioner, dentist, nurse practitioner, midwife or nurse attending the minor,

- a) the minor is capable of understanding the nature and consequences of the medical treatment, and*
- b) the medical treatment and the procedure to be used is in the best interests of the minor and his continuing health and well-being.*

Unconscious patients: Consent regarding unconscious patients is defined around implied consent and paramedics must act in the best interest of the patient, by usually providing the necessary treatment as they would do to a conscious and capable adult patient. The only exception to the standard care would be the presence of a substitute decision maker and their refusal of consent to care on behalf of the patient. Paramedics

must clearly communicate the informed refusal topics with the decision maker and document all communication, along with the substitute decision makers identity thoroughly.

Patients under substance influence: When rendering care for patients who are temporarily incapable of making decisions, such as those under the influence of alcohol/substance or those suffering from a medical condition (i.e. head injury), paramedics can confer with the implied consent principles and proceed with the needed actions for the well-being of the patient.

Mental health and adults with developmental disabilities: This patient group can be the most challenging when making decisions on the provision of urgent medical needs. *New Brunswick Mental Health Act* outlines the actions needed to be taken when providing care to patients with mental health issues. If the patient does not consent to treatment of their acute medical conditions, paramedics should consult the patient's physician (if any and whenever feasible) for the best course of action. Should a safety concern present because of the patient becoming violent or otherwise physically reactive, support from law enforcement should be sought. Paramedics should not attempt to restrain a violent/potentially violent patient, but otherwise should assist police or a physician who directly requests such measures. If a safety concern is present prior to patient transfer, paramedics should request police assistance for restraining the patient. If patient becomes violent during transport, paramedics should restrain the patient while police assistance is requested.

Police custody: Patients' under police custody have the same rights as all other patients whenever receiving medical care. If a patient in custody is fully capable and refuses medical care, then an informed refusal procedure should be completed with the police as a witness. If the police refuse medical care being provided to a patient in custody, paramedics should make their professional opinion known to the police and document

the event, including the communication with the police, in detail. In cases where the patient in custody requires urgent medical attention but refuses care, whenever police request care be delivered to the patient, consent will not be sought and care for the medical condition is to be delivered under police custody.

Conclusion

Legal actions against paramedics regarding consent in Canada is rare. However, paramedics are required to have a professional and working knowledge of the law as well as the ethical principles pertinent to their practice. As they become more competent in legal and ethical aspects of prehospital care, along with their clinical competency, their comfort level will increase when dealing with complex and challenging patient encounters.

Take Home Messages

- Signing of a consent form does not equate to consent being given.
- Any refusal must be informed refusal and be thoroughly documented.
- It is one of the fundamental duties of a paramedic to check and ensure the patient is competent to make decisions related to their care.
- Always take 'best interest of the patient' approach when delivering time critical treatment in emergency situations.
- Caring for challenging patients under complex situations require paramedics to utilize their professional judgements and act according to the law.

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Suggested Readings

New Brunswick Legislation

Mental Health Act

<http://laws.gnb.ca/en/ShowPdf/cs/M-10.pdf>

Medical Consent of Minors Act

<http://laws.gnb.ca/en/ShowPdf/cs/M-6.1.pdf>

Ambulance Services Act

<http://laws.gnb.ca/en/ShowPdf/cs/A-7.3.pdf>

Advanced Health Care Directives

<http://laws.gnb.ca/en/ShowPdf/cs/2016-C.46.pdf>

Self-Regulation

Self-regulation is a basic tenet of all professions, and few professions value that principle any more than the health care professions. But in today's world — where people are more skeptical of expertise, where conflicts of interest abound, where the public demands greater transparency from all professions, where news of a healthcare scandal can twitter around the entire earth in seconds — granting these groups complete control over their own ship is becoming a tougher sell.

“Self-regulation was originally instituted at the request of physicians because the body of knowledge in the profession was vast and unknown to the average citizen, and it would be difficult for external regulation to be as effective,” says Dr. Richard Cruess, a professor of surgery at McGill University's Centre for Medical Education in Montréal, Quebec. “But it was linked to the belief that the medical profession was altruistic.”

The problem with this form of regulation, however, is that professions can lean towards being protective of their members. This is not really that surprising; individuals belonging to any group tend to be protective of their own kind.

In medicine, historically, only the most egregious of professional lapses were considered worthy of a reprisal greater than a wrist slap. “Gross negligence would be punished, but a lot of small stuff got swept under the carpet,” says Cruess.

The need for external input may explain, in part, why the governing councils of provincial colleges, of all stripes, are increasingly compelled to have lay or non-profession specific members. The presence of nonexperts, after all, theoretically prevents members of a profession from speaking purely in their own language or acting strictly in the interests of the tribe. It helps keep an insular group connected to the public they serve. Though this is important, most professions would be quick to point out there is still no substitute for technical expertise in the regulation process.

What is Professional Self-Regulation?

Professional self-regulation is a regulatory model which enables government to have some control over the practice of a profession and the services provided by its members. Self-regulation is based on the concept of an occupational group entering into an agreement with government to formally regulate the activities of its members. The agreement typically takes the form of the government granting self-regulatory status. This is done through a piece of legislation which provides a framework for the regulation of a specified profession, and identifies the extent of the legal authority that has been delegated to the profession's regulatory body.

The specific legal authority transferred from government to the profession's regulatory body varies with different regulatory models. In exchange for the benefits of professional status, the regulatory body of a profession is expected to develop, implement, and enforce various rules. These rules are designed to protect the public by ensuring that services from members of the profession are provided in a competent and ethical manner. This legal authority often includes: the right to set standards for who may enter the profession; the right to set standards of practice for those working in the profession; and the right to create rules for when and how members may be removed from the profession, and the right and obligation to set educational institutional approval processes.

The self-regulatory model also generally requires that a regulatory body put in place a complaints and discipline system. Such a system permits members of the public to raise concerns about services a professional provides to them, as well as provides a process to investigate and, if necessary, discipline any member of a profession who fails to meet professional standards of practice. It is expected that all of a regulatory body's decisions and activities will be done in the "public interest." In other words, the primary purpose behind all regulatory body decisions is to protect the public from incompetent or unethical practitioners.

Approaches to professional self-regulation range from minimal to extensive control over a profession. Governments select from among different regulatory approaches, based on

the nature of the activities performed by a profession's members, and the extent to which the public might be harmed if an incompetent member of a profession provided services. Professional self-regulation may take the form of licensure, certification or registration.

Why Have Self-Regulation?

In Canada, professional self-regulation has been used as a means of controlling the practice of some professions for more than 200 years. Government authority delegated to these professions has provided them with a great deal of autonomy and authority in determining both how many, and who, would be allowed to enter each profession.

Canada has more than three-dozen self-regulating professions, ranging from physicians and lawyers to architects and veterinarians. The majority of these self-regulating professions are health professions. This high percentage makes sense since incompetent or unethical health professionals run a high risk of causing harm to the public. Nonetheless, practitioners of other occupations can also cause harm to the public. For example, incompetent engineers can cause buildings to collapse and unethical accountants could embezzle your life savings.

In the 1990's, criticism of self-regulating professions became increased. The public came to see the monopoly control these professions had as simply a means of increasing the personal wealth of their members, rather than as a way to protect the public from incompetent or unethical practitioners. During this time, formal models of self-regulation have undergone fairly dramatic transformations. The emphasis of self-regulation has shifted from a focus on protection of the profession, to a focus on protection of the public.

Despite this greater emphasis on making the self-regulating professions more responsive and accountable to the public, numerous occupational groups continue to seek government support to become self-regulated professions. This raises the questions: why is self-regulatory status so desirable and what exactly does a profession gain from this exercise? The reality is that when an occupational group is granted the privilege of self-regulation, it gains a great deal. This includes greater autonomy and control, professional prestige and, in many cases, financial rewards.

Greater autonomy and control translates into independence of individual members of a profession to carry out activities with less or no supervision. It also means more autonomy and control for the profession as a whole. Under professional self-regulation, the regulatory body for a profession is able to set entry requirements and standards for practicing the profession, rather than having government, or another profession, impose requirements on the profession. In addition, the regulatory body provides the profession with a means of gaining access to government, which allows it to express its point of view and even negotiate for additional authority.

Prestige comes from attaining “professional” status and all of the benefits that go along with that status. Financial rewards resulting from self-regulation are difficult to quantify and they generally take several years to accrue. The financial benefits to professional’s stem, in part, from the increase in demand for the services of a profession due to the public’s greater assurance that these professionals meet high standards.

Governments can also gain a great deal from allowing an occupational group to self-regulate. This form of regulation allows government to demonstrate that they have acted to protect the public, but in a way that minimizes the government’s role. Regulating through a regulatory body also allows for greater flexibility in the regulatory process as rules can often be developed more quickly. The government saves the expense of hiring experts to assist with creating unique rules and standards for the profession. The self-regulatory model also transfers the cost of regulating from government to the profession itself. Most importantly, the self-regulatory model helps to insulate government from the actions of individual members of a profession or the rules put in place by its regulatory body.

One of the most persuasive arguments in favour of self-regulation is that an occupational group has evolved over time and developed a specialized body of knowledge which makes members of the group experts. Because the knowledge these members have is so specialized, it would be difficult and expensive, for the government to determine and monitor standards of practice for the profession. It is therefore thought that members of a

profession are in the best position to set standards and to evaluate whether they have been met.

The regulatory body of a profession has significant autonomy from government in regulating its profession. Nonetheless, since a regulatory body's legal authority is delegated from government, there needs to be some mechanism to ensure public accountability. This accountability of a profession is often facilitated through a reporting requirement to the government, usually through the Minister from the department which sponsored the legislation giving the group self-regulatory status. While the government generally has an arms-length relationship with the self-regulating profession -that is, it is not expected to interfere directly with the regulatory bodies decision making process - it often retains some ability to direct the regulatory body to do as it wishes under threat of removal of the profession's self-regulatory status.

Another common method of holding a regulatory body accountable to the public is through the appointment of members of the public to its governing Board. Some organizations may have only one token public member, while others can have a majority of the Board appointed by government. In Ontario, self-regulatory legislation for the health professions mandates that just under half of each Board is composed of public appointees. Some would argue that such a large proportion of Board members need to be public members in order to ensure that there is effective public participation and that the organization makes its decisions in the public interest, as well as remains accountable to the public. Others would argue that having such a large proportion of public representatives on a regulatory body's Board runs contrary to the principle of self-regulation. They would argue that only members of the profession, with specialized knowledge of the profession, are able to make decisions about the practice of the profession.

Qualifying for Self-Regulation

The move towards self-regulation is typically a long journey. In order to qualify for self-regulation, governments tend to consider several factors. First, government considers whether there is a risk of harm to the public from members of the occupational group. The

basic philosophy of the self-regulatory model is that if there is no risk of harm to the public, there is no need for any form of government intervention, including self-regulation, which might limit who can provide a service. Under this circumstance, the greater choice of service provider the public has the better.

Second, the occupational group needs to be large enough to have adequate resources to implement a self-regulatory model. The resources required for self-regulation is quite significant. This means having adequate financial resources, as well as the commitment of enough members of the profession to assist with creating the standards and rules that will be necessary for the self-regulatory process to be implemented. Almost all self-regulating professions are expected to finance these activities through fees paid by members, who are required to maintain their memberships in order to practice the profession. As a result, it is uncommon for governments to allow smaller occupational groups to become self-regulated.

Lastly, the occupational group needs to have a defined body of knowledge that may be attained through specified education and does not overlap significantly with another occupational group. If the body of knowledge is too esoteric, or is already possessed by other occupational groups, it becomes impractical to set standards of practice for the profession.

What Does a Regulatory Body Do?

Regulatory bodies are expected to act in the public interest and not in the interest of the profession they regulate. In many situations, the public interest and the profession interest may be the same. In situations where they are not the same, it is the role of the professional association to represent the interests of the profession, while the regulatory body considers the public. Because of the conflict between making decisions in the interest of the public versus that of the profession, governments often requires a separation between regulatory body and professional association. Despite this potential conflict, in some circumstances, such as the profession is newly regulated, fairly small, or the risk of harm to the public is relatively low, government may allow both the professional

association and regulatory body to co-exist as one organization. Nonetheless, the public interest is expected to take precedence in making decisions related to regulatory functions. Failure to do so leaves the profession open to losing its self-regulatory status and potentially being regulated directed by government.

The main functions of a regulatory body include: (1) setting requirements for individuals to enter the profession; (2) setting requirements for the practice of the profession; (3) setting up a disciplinary process; and (4) setting up a process to evaluate the on-going competence of members. For most occupational groups that are seeking professional self-regulation, they have already determined entry requirements and have developed standards of practice. In most cases, these requirements will have evolved over time and become informally adopted within the profession, despite lacking the same legal authority they will have under a regulatory body. Likewise, more advanced occupational groups will also already have a process in place for removing undesirable members. However, under a self-regulatory model, this process will probably have to become more formal and transparent.

Finally, a new regulatory body will need to implement some mechanism to assess the on-going competence of members. Again, more advanced occupational groups may have some form of quality assurance already in place. Determining a method for evaluating continuing competence is often the most controversial activity performed by a regulatory body. There is controversy because quality assurance has such a dramatic impact on the individual members of a profession, due to the stress associated with complying with any requirements. Should a member fail to comply with the quality assurance process, or fail to meet current competency standards, the member might be compelled to undergo additional training or run the risk of being removed from the profession.

Quality assurance programs can also be controversial due to their high costs. One of the most common approaches to quality assurance has been to require a minimum number of education credits. This approach is the easiest to implement and is therefore often a starting point for new professions. Professions which use this approach are numerous and include health professions, lawyers, and real estate agents, to name a few. However,

research questioning the value of this education credit approach is gaining support. While proponents see the education credit system as a good way of ensuring that professionals continue to expose themselves to ongoing education, critics argue that these systems are too focused on the process of education without having any knowledge of whether professional actually learn anything when they attend educational events.

One of the most popular methods of overcoming the deficit of credit systems has been to require professionals to maintain a professional portfolio. This portfolio not only documents a professional's attendance at educational events, but also includes documentation of how those educational events relate to his or her specific educational needs as well as how what he or she learned is translated into the daily practice. While this professional portfolio approach to continuing competence is more proactive than the educational credit approach, it has been argued that it fails to adequately protect the public from members of the profession who are good at maintaining a professional portfolio but actually have not maintained their competence.

To address this dilemma, in some professions, where the potential risk of harm to the public is relatively high, the competence of professionals may be re-assessed on an ongoing basis. This may be done through a peer assessment process, where a professional is observed in his or her normal work environment, or a more formal assessment process, which re-evaluates competence in simulated environments. Examples of professions which undergo this more intensive assessment of their continuing competence include physicians, pharmacists and airline pilots. Where the potential risk of harm to the public is not as high, more cost effective and less stressful approaches to assessing continuing competence may be more appropriate.

Conclusion

Attaining self-regulated status not only sends a message to society about the expertise and professionalism of an occupational group, but also provides members of the profession a priceless opportunity to gain control over their future and that of the entire profession. In the absence of self-regulation, at best, occupational groups can expect to

be relegated to the status of a trade or occupation, in a world which has come to highly value professionals. Making the move towards professional self-regulation is one which each occupational group will have to make after thoughtful deliberation. Ultimately, self-regulation has tremendous benefits – but with those benefits come costs and responsibilities.

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