Consent in Anaesthesia; An Irish Perspective

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“Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication about the proposed intervention” [1].

Consent may be implied, tacit or presumed and may be general or specific. Implicit consent is inferable from actions. Consent to a medical procedure may be implicit in a specific consent to another procedure, is it therefore possible to imply that by consenting to a surgical procedure that consent to anaesthesia can be inferred in the process. Tacit consent occurs passively through omissions in the case of consent for anaesthesia can consent just be ignored or omitted, do patients consider the risks of anaesthesia to be significant or are the merely preoccupied with the surgical outcome. In the anaesthesia induction room patients often express concern regarding the process of anaesthesia over and above their concern for the surgical procedure – Will I wake up during the procedure or will I wake up at all? Presumed consent to anaesthesia is subject to a variety of interpretations’ with many viewing it as part of the surgical process others’ as an entirely different entity. Beauchamp refers to "Informed consent is an individuals autonomous authorization of a medical intervention, second sense refers to the conformity to the social rules of consent that require professionals to obtain legally or institutionally valid consent from patients or subjects before proceeding with diagnostic, therapeutic or research procedures. The seven elements of informed consent include threshold elements (competence and voluntariness), information elements (disclosure, recommendation, and understanding) and consent elements (decision and authorization)” [2].

Is succumbing to general anaesthesia as part of consent for a surgical procedure ever autonomous?

What choices are made is there any alternative to this course of action, forgo the surgical procedure,consent to the surgical procedure without anaesthesia, which is near impossible in the vast majority of cases, bordering medical torture? We know that "The autonomous individual acts freely in accordance with a self chosen plan, having capacity for self governance including understanding, reasoning, deliberating, managing" [2]. Is it therefore the role of the anaesthesiologist to maximize the understanding of the patient? How much information would the reasonable patient require, would they willing and knowingly accept the albeit rare risk of death to ensure fully informed consent, would they prefer not to know. Is this ethical? Should the anaesthesiologist adopt a paternalistic approach? Ethically and legally we know that all significant and material risks should be disclosed to ensure informed consent. Paternalism represents the direct moral antithesis of autonomy. Whether the anaesthetist respects patient autonomy ahead of paternalistic action, or vice versa, depends on which of the competing duties is the most compelling, ultimately their own understanding of beneficence, does disclosing all material risks ultimately do more harm than good?

If so what constitutes valid and genuine consent to anaesthesia or is it merely implied as part of surgical consent?

Historically the nature and risks of anaesthesia were considered in generic terms as part of the general information given about the process of surgery. Anaesthesia however is associated with its own risks. Confusion exists in the literature and amongst medical practitioners about whether separate consent is needed for anaesthesia. It could be argued that patients do not have a choice, anaesthesia being a condition precedent to surgery thereby the voluntariness of their consent for anaesthesia is called into question. Studies have shown that surgeons have inadequate knowledge pertaining to the risks of anaesthesia and fail to provide sufficient information. Anaesthetists

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fail in documenting discussions about consent. It seems appropriate that the anaesthetist, with their expertise of anaesthetic risk, should be the responsible for obtaining consent.

Several recent guidelines have been published on the topic of consent including the HSE National Policy which states “For the consent to be valid, the service user must: have received sufficient information in a comprehensible manner about the nature, purpose, benefits and risks of an intervention/service or research project; not be acting under duress; and have the capacity to make the particular decision” [1]. This concept is reititerated in the Irish Medical Council Guidelines 33.1

National policy further states “The person who is providing a particular health and social care service or intervention is ultimately responsible for ensuring that the service user is consenting to what is being done” [1]. Therefore surely this implies that the anaesthetist is responsible for attaining consent for anaesthesia, however the policy also states “The task of providing information and seeking consent may be delegated to another professional, as long as that professional is suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed intervention and of the benefits and risks in order to be able to provide the information the service user requires” [1]. “If different aspects of care are to be provided by different professional disciplines, each should usually obtain consent for their particular intervention” [1]. There is distinct ambiguity within the guidelines making it difficult to interpret for health care professionals, who is ultimately responsible? Is consent obtained as part of surgical consent invalid with respect to provision of anaesthesia as it is the person providing the service with whom the duty lies to provide informed consent. Does a surgical senior house officer have sufficient knowledge are they suitably trained and qualified as a potential delegated individual to assume the responsibility of attaining consent for anaesthesia. Is the consent in fact invalid, as they are part of a different professional discipline governed by a different training body.

When should consent be sought is it appropriate that consent for anaesthesia is obtained in theatre reception or the anaesthesia induction room?

HSE policy explicitly states “The provision of information and the seeking and giving of consent should involve a continuing process of keeping service users up to date with any changes in their condition and the interventions proposed. It should not be a once-off, sometimes ‘eleventh hour’” [1]. “Asking a service user to provide consent just before the procedure is due to start, at a time when they may be feeling particularly vulnerable, or seeking consent from someone who is sedated, in pain or anxious, creates doubt as to the validity of the consent” [1].

Obtaining consent for anaesthesia in theatre reception or the anaesthesia induction room, does this represent an “eleventh hour” event, is this inappropriate albeit a somewhat common practice? It is clear that the patient does not have sufficient time to process the information in a comprehensible manner, could it even be that they under surgical duress, needing the surgery and therefore assimilating the risks associated with anaesthesia, do they have the capacity at this vunerable period to make these particular decisions at such a critical point. The Medical Council Guideline 37.2 state “it is not recommended to seek consent when a patient may be stressed, sedated or in pain and therefore less likely to make a calm and reasoned decision” [3]. Does this further render consent for anaesthesia invalid?

Given due process, what information should the prudent anaesthetist disclose?

The general rule is to “provide information that a reasonable person in the service user’s situation would expect to be told” [1]. A risk may be seen as material/significant if a reasonable person in the patient’s position if warned of the risk would attach significance to it. The Medical Council refers to the “disclosure of all significant risks or substantial risks of grave adverse consequences” [3]. As per the Royal College of Anaesthetists [4] the following represent real risks pertaining to the provision of anaesthesia ranging from what may seem minor or even trivial to life threatening and death. The incidence of “dental damage to a tooth which requires subsequent repair or extraction happens in about 1 in 4,500 general anesthetics” [4]. The risk of corneal abrasion in about 1 in 2,800 general anesthetics” [4].
The chance of dying as a result of an anaphylactic reaction during anaesthesia is extremely rare, lying between 1 in 200,000 and 1 in 400,000 anesthetics [4] and around 1 death per 100,000 general anesthetics [4]. With regards to regional anaesthesia which may be offered as an alternative to general anaesthesia in certain circumstances or as an adjunct to general anaesthesia the risk of getting a post dural puncture headache after an epidural or spinal injection is between 1 in 100 and 1 in 500 procedures. "Peripheral nerve damage occurs uncommonly (less than 1 in 1,000). Spinal cord damage is exceptionally rare occurring in 1 in 50,000. With Peripheral nerve blocks short-term nerve damage (longer than 48 hours) occurs in less than 1 in 10 nerve blocks. The risk varies between the different blocks. The vast majority of those affected (92–97%), recover within four to six weeks. 99% of these people have recovered within a year. "Permanent nerve damage is rare estimate suggests it happens in between 1 in 2,000 and 1 in 5,000 nerve blocks" [4]. Should all of these material risks be disclosed to an already vulnerable patient, what is reasonable or unreasonable?

Medically, what information should be documented? Pertaining to the legal status of the consent form verbal consent is sufficient although written provides evidence that the patient has given consent although it is not a contract and the patient may withdraw consent at any time [5]. The AAGBI [5] have stated that express consent should be obtained for any procedure that carries a material risk although they saw no reason to sign a separate consent form they indicated that an entry should be made in the clinical notes of the patient to record ‘the anaesthetic techniques which have been discussed and agreed by the patient, and the material risks which have been explained’ [4]. Does this pertain to all, the risks may have been discussed but has the information been processed adequately, what is agreed is always subjective is there an objective measure, what is the alternative in all likelihood there isn’t any, abandon the procedure or forgo the risk. "The NAP 5 Study [6] has raised important issues regarding consent for both general anaesthesia and sedation stating anaesthesia as separate intervention, it is logical that some form of separate consent for the anaesthetic is necessary” [6]. NAP5 provides important information about complaint and litigation after reports of AAGA. "An analysis of litigation claims handled by the NHS between 1995 and 2007 suggested those cases of AAGA and ‘awake paralysis’ accounted for 12% of all anaesthetic-related claims and 20% of all claims relating to general anaesthesia. A high proportion of AAGA cases (87%) were settled in favour of the claimant, with average cost to the NHS of £30 000” [7]. Awareness is always a risk arising in rare incidences pertaining in certain circumstances in high risk cases or due to equipment failure, drug or human error.

In March 2015 the RCOA issued a statement stating It is important to be aware of the recent landmark Supreme Court judgment in the case of Montgomery v Lanarkshire Health Board which requires a doctor to take “reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternatives or varied treatments.” A doctor may be negligent in not providing relevant information before the patient gives consent for the procedure. In order to bring a successful action in negligence, the patient must prove that the doctor owed him a duty (e.g. agreed to take on the patient’s care), that the duty of care was breached (e.g. failed to deliver the correct form of treatment), and that the breach of duty caused harm to the patient.” [8].

There is considerable debate amongst lawyers and anaesthetists as to the quantity or quality of information that should be provided to patients in order to validate their consent. The legal position with regard to information disclosure in the UK has moved from the ‘reasonable doctor’ standard of Bolam towards the ‘reasonable patient’ standard suggested by Lord Scarman in Sideway, such that a doctor has a duty to warn a patient about a material risk. [8] the law equates significant material risk with a degree of risk to which a patient would attach relevance. The Bolam test is applied if a doctor” has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled on that particular art”. The courts have reluctant to give precise figures as to what risks should be disclosed.

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“Good clinical practice has moved in advance of the law with respect to paternalism and the withholding of information on the grounds of ‘therapeutic privilege’. Information must not be withheld because the anaesthetist feels it may deter a patient from undergoing a beneficial procedure conversely, any information which might lead a patient to cancel or defer a procedure should be considered significant” [9].

Special cases pertaining to consent in anaesthesia include the adult parturient who is presumed, like all adults, to have capacity [9]. Birth plans often include references to analgesia and anaesthesia. If a woman obviously loses capacity during labor, the birth plan should be treated as an Advance Decision, and any documented refusal of therapy must be respected. However, a presumption of capacity remains in these circumstances. Therefore, competent women who request epidural analgesia during labor, despite recording a refusal in their birth plan, should have their request respected; although they should be asked to countersign any documentation concerning consent for the procedure [9].

The topic of consent in anaesthesia raises several questions the vast majority of which seem to remain unanswered, should consent for anesthesia even be considered surely it is encompassed as part of consent to a surgical procedure, who would consent to a procedure without anaesthesia? Who should obtain consent, when is the correct time is the theatre reception an appropriate place to discuss and disclose all material risks including the risk of death. What would the prudent patient want to know? Is it better to compromise patient autonomy and adopt a paternalistic approach, what patient would want to consider death a possibility when faced with a surgical procedure? It is clear that consent in anaesthesia poses several ethical and legal dilemmas to the prudent anaesthetist. The HSE policy provides little guidance as to who is ultimately responsible.

Bibliography

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