INTRODUCTION

Patients have fundamental legal and ethical rights in determining what happens to their own bodies.[1] Valid consent to treatment is, therefore, absolutely central to all forms of healthcare, from providing personal care to more invasive interventions.[2] Seeking consent is also a matter of common courtesy between health professionals and patients.

It is not uncommon in pre-hospital situations for patients to refuse care or treatment. Although patients may refuse, there is still, in certain circumstances, an ongoing moral duty and legal responsibility for Ambulance Clinicians to provide further intervention,[3] particularly if life-threatening risk is involved. This procedure provides guidance on how these situations should be managed.

The Department of Health (DH)[1,2] and the Welsh Assembly Government[4] have issued guidance documents on consent, which may be consulted for good practice and legal guidance.

This guideline is applicable within England and Wales only. There are a number of laws and Acts in Ireland and Scotland that have a direct bearing on this guideline.

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- Duty of Care, Consent and Human Rights
- Advance Refusals of Treatment
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- Clinical Photography and Conventional or Digital Photography
- Exceptions to the Principles of Consent
- Consent and Research.

DEFINITIONS

Valid Consent – the voluntary and continuing permission of a patient to be given a particular examination, treatment, operation or examination. Consent is only valid when it is given by an appropriately *informed* person who has the *capacity* to consent to the intervention in question.

Informed Consent – a patient's consent to a clinical procedure (or to participation in a clinical study) after being advised of all relevant facts and all risks involved (***see below***).

Capacity to Consent – the ability to comprehend and retain information material to the decision, especially as to the consequences of having or not having the intervention in question, and ability to believe it and to use and weigh this information in the process used by a person in making a decision about whether to consent or to withhold consent.

Duration of Consent – the length of approval gained by valid consent being given. This generally remains valid unless it is withdrawn by the patient, however new information must be given to patients as it arises, and consent regained.

SEEKING CONSENT.

Before you examine, treat or care for patients you must obtain their consent. Valid consent can only be given by a patient, (or, where relevant, someone with parental responsibility for a child or young person – ***see Section 5***) or a validly appointed proxy (for adults without capacity, ***see Section 4***). Consent by a proxy is only valid if a fully completed Health Care Directive can be produced at the time.

Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them. Consent must be continuous, if previously unexplained treatment is recommended to be carried out, further consent must be gained beforehand.

Three basic tests are used[5] to ensure that consent is valid:

a. **Does the patient have capacity? –** is the patient able to comprehend and retain information material to the decision, believe it and use that information in making a decision while bearing the full consequences in mind?

b. **Is the consent given voluntarily?** – consent is only valid[6] if given freely, with no pressure or undue influence to accept or refuse treatment.

c. **Has the patient received sufficient information?** – the patient must understand, in broad terms, the nature and purpose of the procedure as well as the potential consequences of consenting to it or refusing to consent. Failure to provide all relevant information may render the carer liable to an action for negligence.[7]

The type of information that needs to be given by the ambulance clinician will vary depending on circumstance and urgency, but the following is a useful guide to the type of information the patient should receive prior to treatment:

- description and method of treatment, transport and ongoing care
- purpose and reason for treatment, transport and ongoing care
- possible complications and side-effects of treatment
- treatment options, including the option not to treat and the likely consequences
- explanation of likely benefits of treatment
- a reminder that the patient can change their mind about consent at any time.

In practice, patients also need to be able to communicate their decision. Care should be taken not to underestimate the ability of a patient to communicate, whatever their condition.[8,9] Many people with learning disabilities have the capacity to consent if time is spent explaining the issues in simple language, using visual aids. Ambulance Clinicians should take all steps that are reasonable in the circumstances to facilitate communication with the patient, using interpreters or communication aids as appropriate, while allowing for the urgency of the situation.

Adults are presumed to have capacity, but where any doubt exists, the ambulance clinician should assess the capacity of the patient to take the decision in question. This assessment and the conclusions drawn from it should be recorded in the clinical record.

Refusal and Withdrawal of Consent

If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment, or decides to withdraw their consent *at any time*, their decision must be respected. A patient is entitled to withdraw consent at any time. The ambulance clinician should stop the procedure, establish the patient's concerns, and explain the consequences of withdrawal. If, however, stopping a procedure at that point may reasonably be seen to put the patient's life at risk, then the ambulance clinician may continue until such risk no longer applies.

Withholding or withdrawing *treatment* is not an option for Ambulance Clinicians unless consent is withdrawn, as *duty of care* and the patient's *human rights* would be jeopardised (***see Section 7***).

Patients often refuse treatment and remain at the location, as is their right. There is, however, a responsibility to provide treatment against a patient's wishes in specific circumstances.

ADULTS WITHOUT CAPACITY

Adults who usually have capacity may, especially in emergency situations, become temporarily incapable of having the three tests (Section 2) applied. In such circumstances it is permitted to apply treatments that are necessary and no more than is reasonably required in the patient's best interests pending the recovery of capacity. This includes any action taken to preserve the life, health or well-being of the patient, and can include wider social, psychological or welfare considerations.[10] Where possible, a general practitioner (GP) or professional carer should be fully involved if there is doubt concerning the patient's capacity.

A clinical record should be completed detailing advice and guidance given to the patient, or any referral to specialist staff, ideally signed by the patient (although this simply confirms their presence) and witnessed by a third party.

CHILDREN AND YOUNG PEOPLE

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults, in particular where treatment is being refused. Scotland and Ireland have different laws covering these areas.

Under the Children Act 1989, young people aged 16 and 17 years are presumed to have sufficient understanding and intelligence to be able to consent to their own medical treatment.[11] As with adults, Ambulance Clinicians must ensure that the consent of younger people of this age is valid, i.e. given voluntarily by an appropriately informed patient who is capable of consenting to the particular intervention. It is, however, good practice to involve the young person's family in the decision-making process, unless the young person specifically wishes to exclude them.[11]

Critical situations involving children and young persons involving a life threatening emergency may arise when consultation with either a person with parental responsibility is impossible, or the persons with parental responsibility refuse consent despite such emergency treatment appearing to be in the best interests of the child to prevent grave and irreversible mental or physical harm. **In such cases the Courts**

have stated that doubt should be resolved in favour of the preservation of life and it will be acceptable for all carers to undertake treatment to preserve life or prevent serious damage to health.[12] Section 3(5) of the Children Act 1989 also provides for emergency situations involving minors when a person with parental responsibility is not available.

With patients under the age of 16, those who have sufficient understanding and intelligence to understand fully what is proposed also have the capacity to consent to the intervention.[11] This means that the level of capacity of children varies with the complexity of the treatment/refusal and its consequences. There is no particular age when a child gains capacity to consent. In emergency care, consequences of non-treatment are usually evident, but must be fully explained to ensure that a refusal to give consent is fully informed.

Where possible, the child or young person should be given the opportunity to express their wishes. If this is not possible or feasible, Ambulance Clinicians should obtain consent from any person with parental responsibility.

If *valid*, *informed* consent is given by a young person, a parent or guardian cannot over-ride the decision.

As is the case where patients are giving consent for themselves, those giving consent on behalf of young patients must have the capacity to consent to the intervention in question, be acting voluntarily, and be appropriately informed and be acting in the best interests of the child.[12] In the absence of a person with parental responsibility and a child without capacity, Ambulance Clinicians must act in the child's *wider* best interest.[3] Again, Section 3(5) of the Children Act 1989 provides for these situations.

DUTY OF CARE, CONSENT AND HUMAN RIGHTS

There is professional, legal and moral consensus about the clinical duty to obtain valid informed consent. Patients may, however, have cognitive and emotional limitations in understanding clinical information. Social and economic variations are also important variables in understanding the practical difficulties in obtaining informed consent.[13] It is the duty of Ambulance Clinicians to act in a patient's best interest by overcoming such difficulties so that the patient has a clear, unbiased and informed view of the care that is being proposed.

- 'Duty of Care' may be defined as:

'The absolute responsibility of a healthcare professional to treat and care for a patient with a reasonable degree of skill and care'.

Negligence arises when that duty is breached and 'reasonably foreseeable harm' arises as a result. A lack of valid consent does not automatically absolve the carer of their duty of care, or risk of negligence.[14]

- The European Court of Human Rights has ruled that:

'Treatment without consent, invasive treatment contrary to a patient's best interest, and withholding medical care' can all be deemed 'inhuman or degrading treatment' in extreme cases.

This means that any carer who does *not* treat a needy patient because valid consent was not gained, could be deemed to be negligent if a genuine effort was not made to gain such consent.

ADVANCE REFUSALS OF TREATMENT

Patients may have a 'living will' or 'advance directive' although it is not legally necessary for the refusal to be made in writing or formally witnessed (check your service's policy in this area). This specifies how they would like to be treated in the case of future incapacity. Case law is now clear that an advance refusal of treatment that is made voluntarily by an appropriately informed person with capacity *and applicable to subsequent circumstances in which the patient lacks capacity*, is legally binding.[15,16] Ambulance Clinicians should respect the wishes stated in such a document.

In a pre-hospital emergency environment, there may be situations in which there is doubt about the validity of an advance refusal. If Ambulance Clinicians are not satisfied that the patient had made a prior and specific request to refuse treatment, they should continue to provide all clinical care in the normal way.

SELF-HARM

Cases of self-harm present particular difficulties for health professionals. Where the patient is able to communicate, an assessment of their mental capacity should be made as a matter of urgency. If the patient is judged not to have capacity, they may be treated on the basis of temporary incapacity, as outlined above. Similarly, patients who have attempted suicide and are unconscious should be given emergency treatment in all circumstances.[17]

In a pre-hospital setting, an instance of self-harm may require urgent intervention, such as in the case of a toxic drug overdose. If the patient refuses treatment, and the delay caused to clinical intervention is tolerable, the patient's GP should be urgently

requested to attend the patient and fully assess their level of capacity. If the incident is more critical and there is insufficient time to arrange the attendance of additional healthcare professionals, crews currently overcome most situations with commendable determination to act in the best interests of the patient. These practices should continue, but strict determination of the patient's capacity must be made.

Ambulance Clinicians usually act intuitively to assess whether they perceive a patient is at risk of suicide. An assessment tool is provided in the ***mental disorder guideline*** (in Scotland this is part of the Mental Health First Aid programme). It should be realised that this is only an **additional** support, designed to assist in identifying specific areas to be aware of when deciding to leave a patient on scene. It must be noted that this advice must be used in conjunction with, and adherence to, the Mental Health Act 1983, the various sections of which must be understood and applied appropriately.

CLINICAL PHOTOGRAPHY AND CONVENTIONAL OR DIGITAL PHOTOGRAPHY

Any type of photography of a patient is not permitted unless it is directly to benefit the patient's treatment. It is, therefore, seen as 'treatment' in itself, and requires valid consent. Photographs should be retained in the patient's hospital file and no other copies are permissible. Once taken, these photographs form part of the patient's hospital record.

EXCEPTIONS TO THE PRINCIPLE OF CONSENT

An unborn foetus has no rights under consent case-law. A pregnant mother has every right to refuse treatment for herself or her foetus, irrespective of the potential harm that may arise to the foetus.[16,18]

The Public Health (Control of Disease) Act 1984 provides that, on an order made by a magistrate or sheriff, persons suffering from certain notifiable infectious diseases can be medically examined, removed to, and detained in a hospital without their consent. Similarly, Section 47 of the *National Assistance Act 1948 (or similar legislation in Scotland and Ireland)* provides for the removal to suitable premises of persons in need of care and attention without their consent. Such persons must either be suffering from grave chronic disease or be aged, infirm or physically incapacitated and living in unsanitary conditions. These situations are extremely rare and Ambulance Clinicians should request a sector officer to attend such incidents.

If a patient refuses decontamination treatment, for example following a chemical, biological radiological or nuclear incident, responsibility lies with the Ambulance Officer in charge of the incident, in liaison with the Police, Health Protection Agency and Public Health Laboratories to decide on an appropriate course of action. Powers lie within these groups to take action for the public good.

Treatment involving mentally disordered patients is covered by the Mental Health Act 1983, provided that the patient is formally detained under that Act. Exceptions under the Act only relate to treatment for the mental disorder itself, and not for other illnesses or conditions.[19] This means that any patient detained under the Mental Health Act has every right to impart and deny consent for treatment for physical disorders that are not directly related to his/her mental illness.[20] It is very likely that specialist nursing advice will be available in such circumstances.

CONSENT AND RESEARCH

Research Governance procedures should be in place in each service, and these should include guidance on consent.

As a very brief guide, research subjects must enter a study voluntarily, be informed about risks and benefits, and understand the difference between experiment and treatment.[21] Post-decision questionnaires should be developed, adapted to individual studies, and used to assess the voluntariness and understanding of all research subjects.[22] Applications to Research Ethics Committees must include evidence of valid consent for every research subject.

Key Points – Consent

- Gaining valid consent is central to all forms of healthcare.
- Patients can change their minds and withdraw consent at any time.
- Consent is only valid if it is given freely by a person who has all the relevant facts, is able to assimilate them, and can fully understand the implications of their decision.
- Young persons who have the intelligence to fully understand the proposed treatment also have the capacity to consent to such treatment.
- The rules of consent do not absolve clinicians of their duty of care, nor do they affect the human rights of patients.

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METHODOLOGY

Refer to methodology section; see below for consent search strategy.

Consent search strategy

Electronic databases searched:

CINAHL(Ovid) – years search 82 – 05

EMBASE (Ovid) – years search 96 – 05

MEDLINE (Ovid) – years search 66-95

MEDLINE (Ovid) – years search 66-05

ERIC (Ovid) – years search 66-05

EBM Review – years search All

Health Management NELH – years search: all years.

Search strategy:

MEDLINE	CINAHL	OTHERS
1. controlled.ab. 2. design.ab. 3. evidence.ab. 4. extraction.ab. 5. randomized controlled trials/ 6. meta-analysis.pt. 7. review.pt. 8. sources.ab. 9. studies.ab 10. or/1-9 11. letter.pt. 12. comment.pt. 13. editorial.pt. 14. or/11-13 15. consent 16. 10 not 14 17. 15 and 16	1. meta analysis/ 2. systematic review/ 3. systematic review.pt. 4. (metaanaly$ or meta-analy$).tw. 5. metanal$ 6. nursing interventions.pt. 7. (review$ or overview$).ti. 8. literature review/ 9. exp literature searching/ 10. cochrane$.tw. 11. synthes$.tw. adj3 (literature$ or research$ or studies or data).tw. 12. (medline or medlars or embase or scisearch or psycinfo or psychinfo or psyclit or psychlit).tw,sh. 13. pooled analy$.tw. 14. ((data adj2 pool$) and studies).tw. 15. ((hand or manual$ or database$ or computer$) adj2 search$).tw. 16. reference databases/ 17. ((electronic$ or bibliographic$) adj2 (database$ or data base$)).tw. 18. (review or systematic-review or practice-guidelines).pt. 19. (review$ or overview$).ab. 20. (systematic$ or methodologic$ or quantitativ$ or research$ or literature$ or studies or trial$ or effective$).ab. 21. 18 and 20 22. 19 adj10 20 23. or/1-17,21,22 24. editorial.pt. 25. letter.pt. 26. case study.pt. 27. record review/ 28. peer review/ 29. (retrospective$ adj2 review$).tw. 30. (case$ adj2 review$).tw. 31. (record$ adj2 review$).tw. 32. (patient$ adj2 review$).tw. 33. (patient$ adj2 chart$).tw. 34. (peer adj2 review$).tw. 35. (chart$ adj2 review$).tw. 36. (case$ adj2 report$).tw. 37. exp case control studies/ 38. exp prospective studies/ 39. case studies/ 40. human studies/ 41. "edit and review"/ 42. (adults$ or children).tw. 43. or/24-42 44. 43 not (43 and 23) 45. 23 not 44 46. consent and pre-hospital 47. 46 and 45	1. meta.ab. 2. synthesis.ab. 3. literature.ab. 4. randomized.hw. 5. published.ab. 6. meta-analysis.pt. 7. extraction.ab. 8. trials.hw. 9. controlled.hw. 10. search.ab. 11. medline.ab. 12. selection.ab. 13. sources.ab. 14. trials.ab. 15. review.ab. 16. review.pt. 17. articles.ab. 18. reviewed.ab. 19. english.ab. 20. language.ab. 21. comment.pt. 22. letter.pt. 23. editorial.pt. 24. animal/ 25. human/ 26. 24 not (24 and 25) 27. consent 28. 27 not (21 or 22 or 23 or 26) 29. or/1-20 30. 28 and 29

Additional sources searched:

Scotland's Health On the Web – http://www.show.scot.nhs.uk

National Library of Medicine – http://www.nlm.nih.gov

Department of Health – http://www.dh.gov.uk/Home/fs/en

General Medical Council – http://www.gmc-uk.org/guidance/library/consent.asp

Age of Consent – http://www.avert.org/aofconsent.htm

British Journal of Cancer – http://www.nature.com/bjc/journal/index.html

British Medical Journal – http://bmj.bmjjournals.com