



ETHICS COMMITTEE

Recommendations on *Informed Consent* for European Emergency Departments

For Adults and Children

Summary of Recommendations

- *Informed consent* means that a patient with decision-making capacity freely agrees to a treatment plan or procedure after an explanation of the diagnosis, the relevant options for treatment (including no treatment) and any related risks and benefits important to him/her.
- In the Emergency Department, if it is not possible to find out a patient's wishes, treatment can be provided *without* his/her consent, as long as the treatment is immediately necessary to save the patient's life or to prevent a serious deterioration of his/her condition and it is in his/her best interests.
- In such situations, the physician should inform the patient or his/her legally designated representative at the earliest opportunity and obtain consent for any ongoing treatment.

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Scope

This is a guidance document for Emergency Physicians about obtaining *informed consent* for medical treatments and/or procedures or for participation in research in European adult and paediatric Emergency Departments.

Introduction

Informed consent to medical treatment is fundamental in both ethics and law. It is premised on the principle of self-determination as a fundamental human right and applies to every field of medicine. *Informed consent* is an important and challenging aspect of emergency medical care that ensures the protection of the right of patients to make informed decisions about proposed treatments and/or procedures. Even in emergency care situations, patients have the right to receive information about treatment options, so that they can make decisions about their care.

The objective of these recommendations is to encourage informed decision-making and provide a framework for consent in the adult and paediatric Emergency Department (ED) setting. As there are different legal frameworks across Europe it is recommended that Emergency Physicians (EPs) refer also to their local legal guidelines for definitive advice.

These recommendations have two levels of attainment. A *basic* one expressed as *must*, and a *quality improvement* one expressed as *should*, which are in accordance with international consensus about best practice.

Definition

Informed consent is the essential process by which a competent patient, after being properly and fully informed, learns about and understands the purpose, benefits, and potential risks of an examination, treatment or procedure and then acting voluntarily agrees to receive treatment and/or procedures, or to participate in a research trial, or even refuses these [2]. The patient may sign a document to this effect, known as a consent form. This is not essential. In emergency situations verbal consent is just as valid, but the clinician *must* document the discussion and that the patient has given consent.

SECTION 1: Ethical and Legal Issues of Informed Consent

Keeping patients informed has become ethically and legally essential because patients base their decisions about whether to risk their lives on what they are told by their physicians.

The ethical principles of informed consent are based on the protection of autonomous decision-making and the support of patient-defined goals as well as clinician beneficence.

The legal principle of informed consent is based on principles of human rights, protecting the legal rights of patients to determine what shall be done with their body and preventing unwanted procedures.

Autonomy

Patient autonomy, defined as the right of self-determination, refers to the ability of a competent patient to make and to carry out important decisions about his/her life, acting in his/her own “best interests”. It is a fundamental moral value that promotes patient wellbeing. *Respect for autonomy* requires the physician to recognise the patient’s-right to make independent choices, to hold certain views and to take certain actions based on personal values and beliefs [2,5].

Under the doctrine of informed consent patients with adequate decision-making capacity are allowed to make autonomous choices about their own health and health care, even choices, which may appear irrational to health care providers [7]. The principle of autonomy obliges physicians to respect patients’ decisions even when these decisions do not promote their physical well-being or conform with the physician’s medical judgment. Respecting patients’ autonomy also means respecting their wishes regarding what information is relevant to their decision and how much they want to participate in making their treatment decision [9].

Respect for patient autonomy is an essential feature of patient care in the ED, no less than in other treatment settings. However, Emergency Physicians face special challenges in demonstrating their respect for patient autonomy, as the ED setting imposes a variety of time restrictions on patient’s choices regarding where, by whom, and how they will be treated [20].

Beneficence

Beneficence is a central element of the Hippocratic Oath, written in the 5th century BCE, which compels physicians to act for the benefit of their patients. Informed consent upholds patient’s well-being by relying on the expertise of his/her physician about a range of treatment alternatives; and by allowing the patient to define his/her own welfare and to choose the alternative he/she prefers, based on the likely consequences of that treatment. This is generally a complex process since the overall effect of different treatments on a patient’s well-being depends greatly on how the patient ranks his/her own beliefs, values, and goals [20]. Thus, beneficence is compatible with respect for the well-being of patients lacking the capacity for

autonomous decisions. Beneficence unbounded by concerns for patient autonomy quickly turns into paternalism [9].

While the principles of autonomy and beneficence can complement one another, they can also be in conflict. In case a choice made autonomously conflicts with beneficence, autonomy would be deemed dominant over beneficence. Many physicians are able to provide a balance between promoting patient autonomy and leaving room for clinician beneficence. Demonstrating respect for patient autonomy does not require physicians to remain neutral sources of information in the care of their patients [9]. They *should* promote or advocate the treatment they see as best suited for their patient.

European Framework for Patients' Rights and Consent for Medical Practice

In the European Union Member States patients' rights and in particular the "*right to informed consent*" are embedded in individual human rights frameworks [13].

Treaty of Oviedo on Human Rights and Biomedicine

The European Convention on Human Rights and Biomedicine, known as the Treaty of Oviedo of 1997, is the first legally-binding international text designed to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances [11]. Article 5 of the Convention provides for the doctor's obligation only to carry out medical procedures with the consent of the patient and the patient's right to decline information:

"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time" [11].

In order to be valid, the consent *must* be given for a specific treatment or procedure or course of treatment.

Charter of Fundamental Rights of the European Union

The Charter of Fundamental Rights of the European Union, adopted in Nice in 2000, places the rights of patients within the framework of human rights throughout the European Union [14]. The "Right to Consent" clearly states that:

"Every individual has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health; this

information is a prerequisite for any procedure and treatment, including the participation in scientific research” [14].

Article 3 of the Charter establishes the duty of the physician to only act with the consent of the patient.

“In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law [14].

Legal Exceptions to Informed Consent in the ED

There are several exceptions to informed consent acknowledged by the legal system in most countries [19]:

- emergency situation (the urgency of patient care precludes timely discussion of the risk);
- prior patient knowledge (the patient already knows the risks);
- therapeutic privilege (the patient may be harmed by the consent process).

Emergency exception

An “emergency exception” applies when a patient is incapable of providing consent (unconsciousness, intoxication, delirium, intubation, traumatic brain injury, cardiac arrest, etc.) and when emergency treatment is immediately necessary to save life or to prevent a serious deterioration and preserve health. When there is no time to obtain informed consent or the patient is incapable of giving it, the Emergency Physician operates under the moral imperative of beneficence, acting in the “best interests” of the patient.

Under the “emergency exception,” immediate intervention can proceed without informed consent in order to prevent death or serious disability. The “emergency exception” is based on *consent implied in law*, the presumption that a reasonable person would consent to treatment to preserve life and health if he/she were able [16,19]. Thus, the “emergency exception” depends upon the patient's inability to provide consent as well as the medical urgency of their circumstances. The treatment provided *must* be the least restrictive of the patient's future choices.

If a decision is time-critical and a patient is unable to communicate his/her wishes, consideration *must* be made of whether the patient is likely to regain capacity in sufficient time to allow him/her to give consent. If not, and a delay in initiating treatment would likely be detrimental to the patient's wellbeing, a “best interest” decision *should* be reached [21]. Physicians *should* assume that the patient would want the most appropriate medical treatment,

and they would accept the risks of necessary procedures. In this situation, it is good practice to communicate with family members for their agreement, but if time is limited, physicians *must* proceed with treatment [19].

Article 8 of the European Convention on Human Rights and Biomedicine provides for such emergencies with inadequate time to obtain consent.

“When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned”[11].

There are some important qualifications to such an emergency situation. The physician *must* judge that treatment is necessary to preserve life or prevent significant harm, such as death, disability or severe suffering. He/she *must* judge that treatment cannot be safely delayed obtaining the patient’s informed consent. The presumption that the patient would consent to treatment can be defeated by clear indications to the contrary, such as an explicit refusal of treatment by a patient in the absence of any evidence that he/she lacks decision making capacity or an advance decision [20].

Therapeutic privilege

Some countries recognise withholding information under the principle of “therapeutic privilege”. This is when a patient can be expected to become so emotionally distraught upon disclosure that he/she will not be able to make a rational decision, and this may hinder his/her own treatment. It acknowledges that in some situations the disclosure of certain risks would not be in the patient’s best medical interest. This exception does not imply that the physician may withhold information simply because the patient will not agree with the preferred treatment (and later claim it was for the patient’s benefit) [19].

This principle is the exception most fraught with difficulty and potential abuse. It *should* be exercised with great care and discretion and *should* not be used as an excuse to withhold bad news. The notion of “therapeutic privilege” has been criticised in that it is extremely difficult to predict accurately when imparting information will cause significant harm or be more harmful than withholding that information from the patient. If a patient’s mental state is so precarious that the patient will be unable to cope with information about treatment choices, that circumstance in itself *must* raise serious questions about the patient’s capacity to give informed consent to treatment. Thus, the value of the principle of “therapeutic privilege” as an independent exception to informed consent is probably limited [20].

Patients lacking capacity

Legally, “capacity” refers straightforwardly to a person’s ability to understand the nature and quality of a transaction and to take actions or make decisions that influence his/her life. A decision that a patient “lacks capacity” is obviously a significant one, as it strips him/her of his/her right to control his/her life in relation to the decision in question [3].

Where patients “lack capacity”, other people will have to make the decision for them. The physician *must* consider the views of anyone the patient asks the physician to consult, or who has legal authority to decide on their behalf or has been appointed to represent them. Otherwise, the views of people close to the patient, who know the patient’s preferences, feelings, beliefs and values *should* be consulted to try to decide whether the proposed treatment would be in the patient’s “best interests”. If the patient regains “capacity”, he/she *must* be told what has been done and why [16].

Identifying the “best interests” for a patient can be challenging and depends on the situation. For elective interventions informed consent is always required, otherwise the intervention without consent is unlawful [26]. Emergency situations, on the other hand, that demand complex decisions to be made urgently with the benefits versus the risks of treatment to be weighed in short timeframes and the patient is not able to participate in decision making, or the patient’s legally designated representative is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician *must* inform the patient or his/her legally designated representative at the earliest opportunity and obtain consent for ongoing treatment in keeping with these recommendations [1]. However, the requirement for consent by a legally designated representative raises additional questions about identifying an appropriate representative and defining the scope of his/her authority [20].

In the UK it is very clear that the treating clinician *must* make the decision for an adult lacking capacity, unless there is someone else with the legal power to do so, such as a Lasting Power of Attorney (LPA). This is only applicable if they have an LPA for health. Even then it would have to be a decision made in the best interests of the patient. If there is no one with legal power then it is the clinician who decides, but that decision has to follow each country’s legislation and to be in the “best interests” of the patient, taking into consideration the opinions of the different people involved in the patient’s life and what they think the patient would have wanted.

Where a patient has no one to make a decision on his/her behalf (in a country which endorses surrogate decision making), treatment can be provided, where it is necessary, in the patient’s best interests. A “*best interests*” decision is an objective test of what would be in the person’s actual best interests, taking into consideration all relevant factors. A “*best interests*” test

takes the patients' wishes into account where they are known, but they may not be determinative [3].

Article 6 of the European Convention on Human Rights and Biomedicine provides for the "protection of persons not able to consent":

"1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit. ...

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure." [11]

Advance decisions or directives and advance care planning

Competent patients over the age 16/18 can refuse specified treatment for a time in the future before they become incapacitated. This is called an "advance decision" or "advance directive" refusing treatment. Patients can only refuse treatment by means of an advance decision; they cannot commission treatment in advance. An "advance decision" specifies the specific treatment to be refused and the particular circumstances in which the refusal is to apply [3,4].

Article 9 of the European Convention on Human Rights and Biomedicine provides for those patients with "previously expressed wishes":

"The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account" [11].

SECTION 2: Fundamental Elements of Informed Consent of Adults in the ED

The conceptual framework of the process of obtaining patient consent for an intervention or treatment has several elements. Beauchamp classifies the seven key elements of informed consent into three components [2]:

- Threshold elements or preconditions:
 - *patient's capacity* to make decisions or a strong presumption of capacity;
 - *voluntariness* on the part of the patient to consent without coercion or duress;
- Information elements:

- *disclosure* of information by the medical practitioner on the proposed treatment, intervention, or procedure, including the expected benefits and risks, the likelihood (or probability) that the benefits and risks will occur, alternative treatments and their risks and benefits;
- *recommendation* of a plan by the medical practitioner, in order to give consent voluntarily and freely;
- *patient comprehension* of the above;
- *Consent* elements;
 - *decision* in favour of a plan;
 - *authorisation* of the chosen plan.

Patient Decision-Making Capacity

Autonomous decisions require the possession of mental “capacity”; that is a persons’ ability to take actions or make decisions that influence his/her life. “Capacity” implies understanding the purpose and potential consequences of both undergoing an intervention and also rejecting it. Every person is presumed to have “capacity”; unless demonstrated to be otherwise. The decision that an adult “lacks capacity” is a significant one involving the loss of fundamental human freedom. In contrast, failure to identify that a patient “lacks capacity” for autonomous choices, can expose him/her to serious harms.

The components of decision-making “capacity” consist of the patient’s ability [8]:

- to process and understand the information relevant to the decision;
- to understand the consequences of choosing each of the options;
- to retain the information long enough to be able to make the decision;
- to use the information to make and articulate a choice, evaluate the personal cost and benefit of each of the consequences and relate them to his/her own set of values and priorities;
- to communicate their decision by any means.

If an individual is unable to do any one of these, then he/she is deemed to “lack decision-making capacity”. The more complicated or serious the decision the greater the evidence of “capacity” required to make it and the more thorough and searching the assessment of “capacity”. However, decision-making “capacity” is not necessarily consistent over time; a patient’s mental status, his/her psychological status, or environmental factors may vary.

Disclosure of Information to the Patient

It is a physician's responsibility to give information to the patient about a specific treatment or procedure so that the patient can decide whether to undergo the treatment or procedure. In so doing, physicians *must* [16]:

- listen to patients and respect their views about their health;
- discuss with them what their diagnosis, prognosis, treatment and care involve;
- share with patients the information they want or need in order to make decisions;
- maximise patients' ability, to make decisions for themselves;
- respect patients' decisions.

The physician in charge of the treatment is obliged to ensure that the patient is given this information even if the patient has not explicitly asked for it. However, a signed consent form may not prove that proper consent was given.

Information to be disclosed

The current legal standards of disclosure in European countries are the "reasonable patient" standard and the "reasonable physician" standard of disclosure. The physician provides the patient with the information that a "reasonable physician" would disclose, or a "reasonable patient" would consider material, or that the particular patient would deem important in making the decision to undergo a medical procedure. Successful communication in the patient-physician relationship fosters trust and is central to good decision-making. It necessitates discussing with the patient their opinions on risks and outcomes as well as their concerns and preferences and allows the patient to weigh the risks and benefits presented. Working in partnership with their patients not only protects the physicians from exposure to liability but also encourages compliance with treatment.

Nevertheless, in this model the information goes just one way. The patient is usually deprived of the possibility to provide the physician with individual concerns or questions, or emotional preferences, if he/she desires to do so. The model that pleads for a two-way exchange of information is known as the "shared medical decision-making". It is defined as a process of communication in which the physician and patient use unbiased and complete information on the risks and benefits associated with all viable treatment alternatives, as well as information from the patient on personal factors that might make one treatment alternative better than the others. Achieving this model depends on building a good relationship, so that information is shared, and patients are supported to deliberate and express their preferences and views during the decision-making process. As a result, shared decision-making promotes both patient autonomy and clinician beneficence [9].

The necessary amount and details of information the EPs *should* share with their patients as part of the informed consent process varies according to the individual circumstances. It depends on the nature of the condition, as well as the patients' wishes. However, in some cases, an overwhelming amount of information may have negative ramifications, if confusing or intimidating to patients.

In the absence of an emergency, the physician *must* inform the patient about: [16, 21]:

- the diagnosis;
- the general nature of the contemplated treatment or procedure;
- the risks involved and their likelihood (or probability);
- the prospects of success of the recommended interventions or treatment;
- the prognosis if the procedure is not performed;
- alternative medical treatments or interventions;
- consequences and risks in case the patient declines or refuses treatment.

A physician is not required to provide information on issues that are considered to be common knowledge. He/she does not have to tell a patient about every possible thing that might happen as a result of a procedure or treatment, but only those risks that are important enough that other competent physicians would have informed the patient about. Certain fundamental risks, as for example a surgical incision causing a scar or infection, inherent in any operation are evident to any reasonable person. There is no obligation to communicate risks that persons of average sophistication are aware of [19].

Who should give the information?

It is the responsibility of the physician undertaking an investigation or providing treatment to discuss it with the patient, or alternatively it might be another with appropriate training and qualifications. This point is noted in the Declaration of Helsinki (paragraph 14):

"After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent" [13].

Emergency Physicians *must* work in partnership with their patients and respect their views about their health, and their right to make decisions about their care. They should discuss with them their condition and treatment options in a clear, concise and unambiguous way that will help patients to make informed decisions for themselves [16]. Information given about the risks of any proposed investigation or treatment *should* depend on the individual patient and what he/she wants or needs to know.

The EP *should* establish that any decision is truly that of their patient. Coercion (persuasion by threat, trickery, intimidation or other form of pressure or force) is unacceptable and invalidates consent. This would not be confused with appropriate reassurance concerning a specific treatment, or the highlighting of potential benefits of treatment on a patient's health [21].

Which procedures require written consent?

There are no standards that dictate which specific procedures require written consent in the ED. It has been suggested that written consent be obtained for certain emergency interventions, including invasive procedures such as lumbar puncture, arthrocentesis and others [18]. For routine ED minor procedures, such as physical examination, intravenous lines and blood drawing, small wound closure, ECG recording, X-rays, and splints or casts, the consent is implied or readily obtained by a simple question, for example "may I take a blood sample?"

Prior to significant interventions or more invasive procedures it is important that the risks, benefits, and alternative treatment options *should* be discussed with patients to be able to make an informed decision. Written documentation of the discussion of the procedure, risks, benefits, and alternatives is appropriate. Any questions *should* be fully explained, using consistent language that is easy and simple for the patient to understand.

Patient Comprehension

A patient needs to understand the nature and purpose of the specific treatment or intervention in order to give valid consent. Consent *must* be given voluntarily and freely, without pressure or undue influence being exerted on the patient to accept or refuse treatment.

In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), EPs *must*:

- assess the patient's "capacity" (or ability) to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision;
- present relevant information accurately and sensitively, including the expected benefits and risks, and the likelihood (or probability) that the benefits and risks will occur;
- make sure that the patient understands the relevant information and gives consent voluntarily, without coercion or duress.

Barriers to informed consent in the ED

For many ED patients, found in unfamiliar surroundings, and in a vulnerable state, there may be barriers to the informed consent process, besides impaired decisional capacity, including

impaired cognition, language barriers, illiteracy, insufficient time, problems with communication. It is the EP's responsibility to judge the subject's comprehension of the consent information. For such patients attention *should* be given to ensure adequate delivery of information, understanding of the proposed intervention and its risks and benefits, and the voluntariness of the informed consent.

The information given to the patient or his/her representative *must* be in language understandable to the subject or his/her representative. Poor literacy is a barrier to proper health care across all clinical areas as well as the informed consent process. Trust is an essential aspect of communication during the consent process and influences decision-making. Individuals are more likely to experience trust when the person seeking their consent shows respect for their cultural beliefs, language, perceptions of risks, and social and political history.

Patient Voluntariness to Consent

For an informed consent to be valid, the patient's choice of treatment *must* be voluntary. Consent obtained under duress or pressure, as when the patient is threatened with unacceptable consequences for failure to consent to treatment is a form of coercion. This is morally and legally unacceptable [20]. Coerced consent is invalid consent. Efforts by the professional obtaining consent to elicit a specific choice from the patient by limiting the information provided to the patient, framing the information in a specific way, or otherwise taking advantage of a patient's weakness, is manipulation.

Rosalind E. Ladd, a scholar in philosophy, argues that patients visiting the ED are "without choices", since the ED setting presents special difficulties for protecting and promoting patients' freedom of choice. She points out that many emergency patients do not choose their treatment sites, as they are routinely transported by EMS personnel to the nearest ED, or make their own way to the ED, because they lack health insurance and no obvious alternative source of health care. In the ED, the moral value of autonomy may come into conflict with other values, such as efficient operation of the department and patient well-being. So individual patient preferences at variance with protocols designed to maximise efficiency may not be honoured. Patients in need of care may have little choice but to comply with the system. Nevertheless, the principle of autonomy should strike a balance with other values in the ED as in non-emergency settings [17].

Informed Refusal of Medical Care

Legally competent patients have the legal and moral right to consent to care but also to refuse medical care. This is true even if the patient chooses to make a "bad decision" that may result in serious disability or even death. Patients may elect to refuse all treatment, or specific tests or therapies, as well as hospital admission. Refusing a test, treatment or procedure does not

necessarily mean that the patient refuses all care. The next best treatment should always be offered to the patient who refuses the recommended care. As with informed consent, informed refusal of care requires a similar disclosure of information and voluntary decision making. Informed refusal is a process, not merely a signature on a form.

If, in an emergency, a healthcare provider decides that a patient does not have decision-making “capacity”, the patient may not be able to refuse treatment. In this case, the law presumes that the average reasonable person would consent to treatment in most emergencies to prevent permanent disability or death.

Documentation of Consent by an Adult

The informed consent process *must* be documented thoroughly in writing in the medical records. The EPs *must* document the informed consent conversation and the patient’s or the surrogate’s decision. When the patient or the legally designated representative has provided specific written consent, the consent form *must* be included in the patient’s record.

The following are the required elements for documentation of the informed consent discussion and included in the written consent form:

- the medical condition that warrants the test, procedure, or treatment;
- the nature of the procedure or treatment;
- the risks and benefits of the procedure or treatment;
- reasonable alternatives and their risks and benefits;
- the consequences of not accepting the test, procedure, or treatment;
- assessment of the patient's understanding of the above elements.

The consent form *should* be dated and signed both by the doctor and the patient.

SECTION 3: Consent to Treatment of Children in the ED

According to the United Nations Convention on the Rights of the Child (UNCRC) every person under the age of 18 years is considered a child [1]. This position is reflected throughout Europe. Children and young people are individuals with rights, which *must* be respected, and every physician has the duty to protect and to safeguard the health and wellbeing of children [2].

The following are the rights of children and young people regarding consent in the paediatric ED.

Principles and Criteria of Consent

For consent to be deemed valid, the young person giving consent *must* be competent and fulfil the following requirements [28,30,33]:

- understand the information given to them that is relevant to the decision;
- retain that information long enough to be able to make the decision;
- use or weigh up the information as part of the decision-making process;
- communicate that decision.

When applied to children further issues arise when one considers that different children will have different innate abilities to comply with some or all of these; and that this ability will change as the child ages and matures, i.e. the “capacity” to give consent. It is a necessary requirement to assess whether the child is able to understand the purpose and the consequences of investigations or treatment, and also the consequences of not receiving the treatment.

The EP obtaining consent needs to ensure that the patient is fully informed and that consent is given freely and voluntarily and has to be honest, fair and *must* not be biased [30,33].

Who can give consent?

Consent can be provided either by young persons themselves if they have capacity, or by their legal guardian if they do not [26,32]. If neither of these is possible, consent *must* be provided by judicial review if the decision is not time critical. In acute and emergency situations, where the child “lacks capacity” and no legal guardian is available, medical staff can act in the “best interests” of the child. This should not be an individual decision but made in contemporaneous consultation with relevant senior colleagues.

The age at which a person is considered capable of making his/her own decisions varies throughout European countries; in England and Wales this age is 18, while in Scotland it is 16 [32]. Children, however, are not a homogenous group. While a 15-year old person may well have the ability to participate in healthcare decision-making, this will not be the case in a 2-year old child [26].

Consent by age-group

Individuals 18 years

The age of 18 years is considered as the age of adulthood both in most European countries. Individuals at this age with capacity have the right to consent to and to refuse any treatment, irrespective of the outcome and potential consequences. A refusal of consent can only

be overridden when the patient lacks the ability to understand, retain and use the relevant information [26,28,30,32,33].

Individuals 16-17 years

Individuals between 16-17 years of age are expected to have capacity to consent to most forms of medical intervention [26,30,33]. However, this will vary between jurisdictions among European countries. If a person in this age group consents to a treatment that is clinically appropriate, parental refusal cannot override this [26]. However, when he/she lacks capacity to consent, again, the legal framework varies across jurisdictions throughout European countries.

In England, Wales, Northern Ireland and Ireland the legal guardian or those with parental responsibility can consent to medical interventions that are in the best interest of the young person [26,30,33].

Individuals younger than 16 years

In order to have the legal capacity to consent, individuals younger than 16 years old need to show that they are competent by showing “sufficient understanding and intelligence to enable them to understand fully what is being proposed”. In the UK this is known as ‘Gillick competence’ [26,30]. In this age group every person’s competence needs to be assessed individually on the complexity of the intervention. This needs to be done in a language the child understands and ideally in a surrounding where the child feels comfortable. Adequate time *should* be provided for questions to be asked by the patient [26,30].

It should be noted that there is a chance for developmental regression in children younger than 16 years in stressful situations or acute illness. If treatment has been refused in such a situation, which might have life-threatening consequences, the decision can be overruled by judicial intervention [33]. This only applies for the UK and varies across other European countries.

Children who “lack capacity”

In situations, where children “lack capacity” to consent, such as neonates or infants, decisions about investigations or treatment *must* be discussed with their parents and be in the child’s “best interest”. It is sufficient to have consent from one parent. However, in cases where more than one person holds parental responsibility, both should be encouraged to reach consensus. If that is not possible, then legal advice *should* be sought by applying for judicial review [30].

Those with parental responsibility are [30,32]:

- the child’s mother;
- the child’s father, provided that he was married to the child’s mother at the time of birth, and has been granted legal parental responsibility;
- adoptive parents;
- the child’s legally appointed guardians;
- a person or local authority that has been awarded an “Emergency Protection Order” or a “Care Order”.

Consent in a clinical emergency in the ED

In the setting of a clinical emergency in the ED, where an intervention or treatment with the intention to save lives or to prevent serious harm is indicated, and where it is not possible to explore the patient’s wishes, an intervention or treatment can be provided without consent [33]. If no one with parental responsibility is present or can be contacted and emergency treatment is deemed in the best interest of the child, it can be delivered without consent. In this case the doctrine of necessity is invoked.

Refusal of Treatment by Children in the ED

All individuals with capacity have the right to consent to, but also to refuse any treatment, irrespective of whether their choice might seem unwise or not. Hence, individuals over the age of 18 years have the right to refuse all treatment irrespective of the outcome and the potential consequences. A parental refusal cannot override this decision [26]. However, discussion between the care provider and the individual can be helpful to determine the reasons for refusal. Only when the patient lacks the ability to understand, retain and use the relevant information, can a refusal of consent be overridden in the best interest of the patient [26,28,30,32,33].

Individuals younger than 18 years of age in some jurisdictions can refuse medical intervention, once they have shown to have capacity [26,30,33]. In this regard there may be differences across jurisdictions among European countries and therefore it is recommended to refer to local guidelines.

Documentation of Consent by a Child or Legal Guardian

The evidence of having obtained consent from a child or a legal guardian *must* always be recorded. It needs to be documented [25]:

- that the child and/or parents were provided with sufficient and child-friendly information about the purpose and nature of the treatment, including risks and alternatives;

- the children’s views about treatment before starting treatment or what questions the child might have had;
- other available options and the advantages/disadvantages of each option if symptoms are not improving.

If the child or the parent refuses treatment, it *must* be recorded that the risks were considered and explored. The records *should* document the decisions made and why and signed by both the parents and the EP [25].

SECTION 4: Consent for Research in the Emergency Department

Informed consent is a central tenet of research ethics involving human beings. Historically, a major advance in the ethics of human experimentation was the *Nuremberg Code*, part of the judgment in the “Doctors Trial” at Nuremberg in August 1947, in the aftermath of World War II [35,37,39]. The *Code* specifies that, “the person involved should have legal capacity to give consent;” and:

“...be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, overreaching or other form of restraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision” [44].

The *Code* has become a landmark document and a legacy for medical ethics in human experiments and served as a blueprint for today's principles that ensure the rights of subjects in medical research [43]. In the 1950s, the newly founded World Medical Association proposed an ethics policy for research, which in 1964 became the *Declaration of Helsinki* [47]. In 1975, the Declaration was revised and expanded to include consent as a “basic principle” and to countenance minors as research subjects [37,46]. While the *Nuremberg Code* focuses on the human rights of research subjects, the *Declaration of Helsinki* focuses on the obligations of physician-investigators to research subjects [43].

Today, in the era of “evidence-based medicine” patients are required to give informed consent to be included in clinical trials. The European legislation on medical research is based on the EU Good Clinical Practice Directives 2001/20/EC and 2005/28/EC [10,12,15], which are now replaced by the European Parliament and Council Regulation 536/2014 on clinical trials on medicinal products for human use [15], with the aim to ensure greater harmonisation of the rules for conducting clinical trials throughout the EU.

Regulation 536/2014 defines “informed consent” for research as:

“a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial” [15].

The European countries' legislation about informed research consent varies widely depending on local institutional ethics committees and whether the patient is an adult or child.

Informed Consent for Research in Adults in the ED

In the setting of the ED consent becomes more complicated as many patients are not able to give consent. Patients in the ED are a vulnerable group whose critical faculties may be impaired by pain, fear, or therapeutic interventions. They *must* be afforded adequate time to reflect and consult on participation and *must* be acquainted with the nature, likelihood, and severity of any risks as well as the potential benefits [42].

Article 35 of the EU Regulation 536 of April 16, 2014 specifies “*clear rules concerning informed consent in emergency situations*” that *must* be fulfilled [15]:

“(a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical trial;

(b) there are scientific grounds to expect that participation of the subject in the clinical trial will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;

(c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;

(d) the investigator certifies that he or she is not aware of any objections to participate in the clinical trial previously expressed by the subject;

(e) the clinical trial relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical trial is of such a nature that it may be conducted exclusively in emergency situations;

(f) the clinical trial poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition."

Informed consent in "emergency situations"

EU Regulation 586/2014 relates to "*emergency situations*" when, for example, a patient has suffered a sudden life-threatening medical condition, such as multiple trauma, stroke or heart attack, necessitating immediate medical intervention. In such cases, intervention within an ongoing clinical trial, which has already been approved, may be permissible even if it is not possible to obtain informed consent prior to the intervention [15]. The Regulation sets clear rules whereby "such patients may be enrolled in the clinical trial under very strict conditions. In addition, the said clinical trial *should* relate directly to the medical condition, because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his/her legally designated representative. Any previously expressed objection by the patient *must* be respected" [15].

Information for research subjects

The following information *must* be provided to the research subject if time allows and he/she is not lacking capacity [15,36,38,42]:

- the purposes of the research explained in understandable terms;
- the expected duration of the subject's participation;
- a description of the procedure(s) or drug(s) that are going to be tested;
- identification of any procedure of an experimental drug;
- any reasonably foreseeable risks, discomfort or disadvantages;
- any benefits to the individual subject;
- appropriate alternative therapies that might be advantageous to the subject;
- a statement that participation is voluntary, and non-participation will have no influence on the quality of care;
- a description of measures taken to ensure that the subjects' medical and personal data will remain confidential, in compliance with rules on data protection;
- information on what will happen with the results;
- the process for withdrawal at any time;
- who is organising and funding the research project;
- name and contact address of researcher(s) to ask questions, if needed.

The researcher *must* exercise professional skill and judgement in deciding what constitutes adequate disclosure of potential risks and the patient *must* be warned of any

substantial or unusual risk or a danger special to him/her [42]. The research subject *must* be able to freely understand the information and express consent voluntarily. The information provided *must* be documented and signed. The informed consent form *must* be written in language that is easily understood.

Informed consent for subjects “lacking capacity”

For subjects with physical or mental incapacity that renders them incapable of giving informed consent the *Declaration of Helsinki* and Regulation 536/2014 allow for a “legally designated representative” to give their consent to an intervention, using prior knowledge of the subject’s decisions when competent. “Legally designated representative” means a natural or legal person, authority or body which, according to the law of the Member State concerned, is empowered to give informed consent on behalf of an incapacitated subject or a minor. The EP *must* disclose fully to the representative all available data on the risks and benefits of the proposed research intervention [11,15,42].

In emergency situations the EP *must* act in the patient’s best interest and *presume* consent based on necessity. Clearly this is only appropriate for interventions that will benefit the patient directly. A research intervention *must* be part of a protocol approved by an independent institutional ethics committee and *should* represent no more than minimal risk to the patient [15,42]. Where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the clinical trial *must* be obtained from the subject as soon as he/she is capable of giving informed consent. The informed consent procedure *should* be considered a continuous one.

In emergency situations, informed consent can be waived under strict conditions as stated in the Regulation 536/2014 or informed consent can be sought a posteriori. Conceptually, three conditions have to be met, namely: impracticability, always acting in the patient’s best interest, the clinical relevance and public health importance being potentially high. The institutional ethics committee *must* examine such a waiver demand in detail, with special attention given if the subjects are pregnant women, prisoners, war victims or psychosocial vulnerable subjects.

Informed Consent for Research in Children

Research involving children is subject to the same ethical consent principles that apply to adult research [26]. Research can be either therapeutic (where treatment might directly benefit the research subject) or non-therapeutic (where research outcomes might be beneficial to the population but not the research subject in particular) and it is acceptable for children to be involved in any of these [30].

It is important to involve the child in discussions about their inclusion in research. Formal consent, either verbal or written, *must* be obtained and documented [30,41].

For consent to be informed, the researcher *must* discuss the following with the patient or those with parental responsibility [45]:

- the purpose of the research,
- the nature of each procedure,
- the potential benefits and harms,
- the name of the researcher and his contact details if questions arise,
- provide, as a minimum, a written patient information document about the research.

In situations where the child lacks capacity a person with parental responsibility or guardianship may provide consent [30]. In a situation where the legal guardian initially provided consent, but the child subsequently wishes to withdraw consent, then the child's decision *must* be respected [30].

Research in emergencies in children

Research in emergency situations *should* only be undertaken if necessary and where non-urgent research will not resolve uncertainties [41].

Challenges arising in such situations are the difficulty of obtaining consent in the sick child. In these circumstances a child will, by definition, not have capacity to make decisions. Even parents, if present, might be in "situational incapacity" because of the distressing situation due to the condition of their child [41]. In situations like these, it is acceptable to enrol into the research without parental consent, provided consent is obtained retrospectively immediately afterwards. This is the concept of "deferred consent" [41].

In situations where no legal guardian is available, the concept of "substitute acceptance" might apply, where the doctors responsible for the care of the child, confirm eligibility of the patient to participate in the research project and provides consent as a legal representative, provided that the physician is not involved in the research study [41].

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References

Ethical & Legal Issues

1. AMA. Code of Medical Ethics: Consent, Communication & Decision Making. Available from: <https://www.ama-assn.org/delivering-care/informed-consent> (Accessed 21.6.2019)
2. Beauchamp T. *Informed consent*. In: Veatch R, ed. *Medical Ethics*. 2nd ed. Sudbury, MA: Jones and Bartlett Publishers, 1997, pp. 185–208.
3. British Medical Association. Consent to treatment - adults who lack capacity. Available from: <https://www.bma.org.uk/advice/employment/ethics/medical-students-ethics-toolkit/7-consent-to-treatment-lacking-capacity> (Accessed 22.6.2019).
4. Butler M, Ratner E, McCreedy E, Shippee N, Kane RL. Decision aids for advance care planning: an overview of the state of the science. *Ann Intern Med* 2014;16;161(6):408-418.
5. Delany C. Making a difference: incorporating theories of autonomy into models of informed consent. *J Med Ethics* 2008; 34:e3.
6. Department of Health. *Liberating the NHS: No decision about me, without me*. Crown Copyright, December 2012. Available from: <http://data.parliament.uk/DepositedPapers/Files/DEP2012-1873/LiberatingtheNHS-Nodecisionaboutmewithoutme.pdf> (Accessed 17.7.2019).
7. Larkin GL, Marco CA, Abbott JT. Emergency Determination of Decision-making Capacity: Balancing Autonomy and Beneficence in the Emergency Department. *Acad Emerg Med* 2001;8:282–284.
8. Mental Capacity Act 2005. Charter 9. UK: The Stationery Office Limited, 2005. Available from: https://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf (Accessed 22.6.2019).
9. Moulton B, King JS. Aligning ethics with medical decision-making: the quest for informed patient choice. *J Law Med Ethics* 2010; 38(1):85-97.

European Framework

10. Commission directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance). *Official Journal of the European Union* 2005;L91:13–21.

11. Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, CETS 164, Oviedo 1997.
12. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. *Official Journal of the European Union* 2001; L 0020:1-19.
13. European Commission. *Patients' Rights in the European Union*. Mapping eXercise. Final Report. Luxembourg: Publications Office of the EU, 2016.
14. European Parliament, Council and Commission. Charter of Fundamental Rights of the European Union (7.6.2016). *Official Journal of the European Union* 2016; C 202:389-405.
15. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC. *Official Journal of the European Union* 2014; L158:1-76.

Consent of Adults in the ED

16. General Medical Council UK. Consent: patients and doctors making decisions together. GMC, 2008. Available from: https://www.gmc-uk.org/-/media/documents/Consent_English_0617.pdf 48903482.pdf (Accessed 21.6.2019)
17. Ladd RE. Patients without choices: The ethics of decision making in emergency medicine. *J Emerg Med* 1985; 3:149-156.
18. Marco CA. Informed consent for emergency department procedures. *Acad Emerg Med* 2003; 10:462.
19. Moore GP, Matlock AG, Kiley JL, Percy KD. Emergency Physicians: Beware of the Consent Standard of Care. *Clin Pract Cases Emerg Med* 2018;2(2):109-111.
20. Moskop JC. Informed consent in the emergency department. *Emerg Med Clin N America* 1999; 7:327-40.
21. The Royal College of Emergency Medicine. Consent in Adults, Adolescents and Children in Emergency Departments. London, Revised January 2018. Available from: [https://www.rcem.ac.uk/docs/RCEM%20Guidance/Consent%20guidance%20\(revised%20Dec%202017\).pdf](https://www.rcem.ac.uk/docs/RCEM%20Guidance/Consent%20guidance%20(revised%20Dec%202017).pdf) Accessed 20.6.2019
22. Wooley S. Jehovah's Witnesses in the Emergency Department: What are their rights? *Emerg Med J* 2005; 22:869-871.

Consent for Children in the ED

23. Academy of Medical Royal Colleges. *Ethical issues in paediatric organ donation* – A position paper by the UK Donations Ethics Committee (UKDEC). London: AMRC, June 2015. Available from: https://www.aomrc.org.uk/wp-content/uploads/2016/04/Paediatric_organ_donation_position_0615-2.pdf (Accessed 4.3.2019).
24. American Academy of Paediatrics. Policy Statement—Consent for Emergency Medical Services for Children and Adolescents. *Pediatrics* 2011; 128:427–433.
25. Care Quality Commission. Brief guide: capacity and competence to consent in under 18s. CQC, December 2017. Available from: https://www.cqc.org.uk/sites/default/files/20180228_briefguide-capacity_consent_under_18s_v2.pdf (Accessed 4.2.2019).
26. Casby C, Lyons B. Consent and Children. *Anaesth Intens Care Med* 2019; 20(1):52-55.
27. Gardiner DC, Nee MS, Wootten AE, et al. Critical Care in the emergency department: organ donation. *Emerg Med J* 2017; 34:256-263.
28. General Medical Council. Guidance for all doctors - 0-18 years. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/0-18-years> (Accessed on 1.2.2019).
29. Hawkins KC, Scales A, Murphy P, et al. Current status of paediatric and neonatal organ donation in the UK. *Arch Dis Child* 2018;103:210-215.
30. Jenkins JA, Wellesley H. Consent in children. *Anaesth Intens Care Med* 2012;13(5):240-242.
31. O'Malley P, Barata I, Snow S, et al. Death of a child in the emergency department. *Paediatrics* 2014;134(1):e313-e330.
32. Palmer R, Gillespie G. Consent and capacity in children and young people. *Arch Dis Child Educ Pract Ed* 2014;99:2–7.
33. The Royal College of Emergency Medicine. Consent, Capacity and restraint of adults, adolescents and children in Emergency Departments. RCEM, July 2013. [https://www.rcem.ac.uk/docs/RCEM%20Guidance/Consent%20guidance%20\(revised%20Jan%202018\).pdf](https://www.rcem.ac.uk/docs/RCEM%20Guidance/Consent%20guidance%20(revised%20Jan%202018).pdf) (Accessed 1.2.2019).
34. United Nations Human Rights. *Convention on the Rights of the Child*. New York, 20 November 1989. <https://www.ohchr.org/en/professionalinterest/pages/crc.aspx> (Accessed on 1.2.2019).

Consent for Research in the ED

35. Askitopoulou H, Vgontzas AN. The relevance of the Hippocratic Oath to the ethical and moral values of contemporary medicine. Part I: The Hippocratic Oath from antiquity to modern times. *Eur Spine J* 2018;27:1481–1490.
36. Coats TJ, Shakur H. Consent in emergency research: new regulations. *Emerg Med J* 2005;22:683–685.
37. Foëx BA. The problem of informed consent in emergency medicine research. *Emerg Med J* 2001;18:198–204.
38. Furyk JS, Lawton LD, Ting JY, Taylor D. Informed consent in emergency care research: An oxymoron? *Emerg Med Australas* 2017;29(1):110–112.
39. Katz J. The consent principle of the Nuremberg Code: its significance then and now. In: Annas G, Grodin M, eds. *The Nazi Doctors and the Nuremberg Code*. New York: Oxford University Press, 1992:227–239.
40. Mentzelopoulos SD, Mantzanas M, van Belle G, Nichol G. Evolution of European Union legislation on emergency research. *Resuscitation* 2015;91:84–91.
41. Modi N, Vohra J, Preseton J et al. Guidance on clinical research involving infants, children and young people: an update for researchers research ethics committees. *Arch Dis Child* 2014; 99:887–891.
42. Nee PA, Griffiths RD. Ethical considerations in accident and emergency research. *Emerg Med J* 2002;19:423–427.
43. Shuster E. Fifty Years Later: The Significance of the Nuremberg Code. *N Engl J Med* 1997; 337:1436–1440.
44. The Nuremberg Code (1947). *Br Med J* 1996;313(7070):1448.
45. The Royal College of Paediatrics and Child Health: Ethics Advisory Committee. Guidelines for the ethical conduct of medical research involving children. *Arch Dis Child* 2000; 82:177–182.
46. World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Available from: www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (Accessed 21.6.2019).
47. World Medical Association. Human experimentation. Code of ethics of the World Medical Association. *BMJ* 1964;2:177.