

## 6. THE ETHICS OF CASE REPORTING

### 6.1. Patient Ethics

It is important to understand that whenever we are dealing with patient data/information – and the more so when we intend to publish it – ethical codes of conduct apply. Where medical research is concerned, there are two types of potential harm for patients: 1) physical harm (for example in a trial assessing a new drug) and (2) informational harm (for example publishing a case of a patient with a stigmatizing illness who can be easily recognized). Since case reports are not experimental but observational studies, we are concerned with informational harm only. Although informational harm may appear less serious than physical harm it must not be taken lightly, because it constitutes potentially a serious breach of medical confidentiality.

As for all medical studies, a case report requires informed consent from the patient, meaning that the patient understands what it is to have a report on his/her illness described, written, and published irrevocably in an online journal accessible by any interested person (see Chapter 7). If the patient is literate, s/he should sign a consent form and if s/he cannot write and/or does not wish to have his/her name appear on any papers, then a witness should sign a consent form indicating that the patient has given his/her oral consent. Even if the patient gives his/her consent to publish his/her case, as healthcare providers we need in every case to guard the patient's privacy and safety by making efforts to leave out potentially identifying information or images when it is not absolutely essential for the understanding of the case. We must also protect the patient's dignity at all times. Just because a woman gives informed consent to describe a particularly challenging case of ectopic pregnancy, does not mean we should show a picture of the aborted foetus which brings nothing new to existing knowledge.

Case series may or may not require informed consent from the patients included in the study. If the case series is presented as aggregate data with no individual information, then it is not necessary to have consent from the patients, because it is impossible to recognize or identify them. On the other hand, if you are wishing to publish a small case series on a rare condition specific to a particular place

(e.g. an Ebola outbreak), you would want to have informed consent from the patients or their legal representatives (if they have died), because they could be potentially recognized.

Before you plan to publish, you need also to think about patient data protection. For example: does the country which the patients live in have specific patient data protection laws? Were any samples taken from patients (e.g. blood) sent abroad for diagnosis or research and was this validated? Have you checked whether that country has an Ethics Committee and what its rules are?

#### 6.1.1. Missing informed consent

There are two situations where informed consent from the patient may be missing. The first situation is when a patient has refused to give his/her consent after you have explained to him/her what it means to write and publish a case report. Refusal to give informed consent is irrevocable and should always be respected. On the other hand, it can happen that you do not have written informed consent from the patient because you forgot to ask, or because the patient is lost to follow-up, or because the patient has died. In such a situation, you should make all efforts to find the patient and/or his/her legal representative to secure the consent. But if this too proves impossible, then publishing without consent can be possible *providing all potential patient identifiers have been removed, including author name*. In such cases, a report would be authored by an “MSF physician” (giving the physician’s name could make it possible to locate the case), and the name of the country removed stating only, e.g. “a refugee camp in Africa” or “a Middle Eastern context” or “a conflict zone”. Because an author has a right to be recognized for his/her work and is accountable for its accuracy, having recourse to such anonymization should be exceptional.

#### 6.1.2. Written informed consent as an “obstacle” to treatment

There are illnesses and situations which are potentially stigmatizing and/or dangerous for the patient, his/her family, but also for the physician who looked after the patient and possibly the organization for which the physician works. For example, if a physician working for MSF carries out an abortion on a young girl who has been raped in a country where honour crimes are rampant and abortions illegal,

the danger for the patient, the healthcare provider, and the organization is very real. Such reports should be published only if a) it is deemed they are addressing a major gap in the literature or bring something exceptionally new, and b) all due precautions have been taken to remove patient and practitioner identifiers, including author name.

To sum up, here are some basic rules to follow with regard to patient consent and protection:

#### Rule 1

Wherever you are practicing, check if there exist any national ethical guidelines on publishing patient data.

#### Rule 2

Whether or not informed consent exists for a Case Report, remove potential identifiers which are not directly relevant to the occurrence/epidemiology or the clinical management of the disease/illness, if these identifiers could be associated with any theoretical or practical risk.

#### Rule 3

If for medical/epidemiological reasons it is necessary to include information (e.g. past medical history) which could serve as a possible patient identifier, consider submitting the report for publication only if there exists written or documented oral consent.

#### Rule 3

Regarding photographs, whether or not informed consent exists, include photographs only if all recognizable elements have been removed. Showing a face (even blacking out the eyes) should as a rule not occur – focus e.g. on the skin or tumor. Be sure no identifiable clothing appears in the photograph. Images such as X-rays are acceptable only if all potential identifiers (e.g. patient number) have been removed or masked. At all times and in all contexts, put the dignity of the patient first, including deceased patients.

## Rule 4

If for medical reasons it is necessary to show a potentially identifying part of the body (e.g. a hand with a tattoo), submit the report for publication only if there exists written or documented oral consent.

### **6.2. Seeking informed consent: guiding principles**

The purpose of this consent guideline is to guide you through the steps which ensure that consent from a patient or a patient's guardian is truly *informed*. For the consent form itself, see the Toolbox at the end of this Handbook.

For the publication of a case report, obtaining appropriate informed consent from the patient (or his/her legal representative) should be the rule.<sup>1</sup>

Informed consent implies that the person has been able to make a conscious choice to accept or refuse the proposed intervention (in this case the publication of his/her medical case report).

Therefore, necessary and comprehensive information should be given about the objective, the content, the risks and the benefits of publishing the medical case report in question.

The discussion around consent must be conducted in a language that the patient (or his/her legal representative) understands, using words that are culturally adapted and, in case of child assent, age specific. Remember that beyond language, different people have different degrees of health literacy. If translation is needed, then it is crucial to ensure the translation reflects correctly what is in the consent form.

The consent procedure should be conducted in a room/space that permits full confidentiality and puts the person at ease without giving any impression of coercion. It should be made very clear that acceptance or refusal of consent is completely unrelated to the quality and extent of the care that will be provided to the patient. Ideally, the consent procedure should be conducted by a staff member who is not involved in the care, to avoid any misconceptions around patient agreement or refusal and

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level of care. Requesting informed consent is also usually better at the end of the care process (for example before discharge) but can happen at any moment the clinical team deems appropriate.

All should be done to obtain informed consent before the patient is discharged (or deceased).

Contacting the patient (or his/her legal representative) after exit needs to be carefully considered as this can lead to a breach of patient privacy (one does not want the community or relatives to know that the patient has sought health care services) or even a breach in confidentiality (whenever the project is vertical - for example: HIV/AIDS). Contacting patients (or their legal representative) after exit is not problematic but only if consent was given to do so (for example in a project where consent was given by the patient to be contacted subsequently for test results or follow-up consultations).

### **Who should give informed consent?**

- The patient should give consent if in capacity to do so (fully conscious, emotionally stable, no mental or neurologic impairment) and:
  - the patient is adult ( $\geq 18$  years of age)
  - the patient is an emancipated adolescent<sup>2</sup> ( $\geq 15$  years).
- The legal representative (parent or legal guardian<sup>3</sup>) whenever:
  - the patient is a minor ( $< 18$  years of age)
  - the patient is not in capacity to give consent (not fully conscious, emotionally unstable, mentally or neurologically impaired)
  - the patient is deceased.

Regarding proxy consent via a legal representative, wherever possible the national ethics committee (if it exists) should be consulted. Proxy consent, in particular as regards impairment of consciousness, should be decided on a case by case basis, always keeping the patient's best interest in mind.

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<sup>2</sup> Emancipation is when a minor has achieved independence from his or her parents, such as by getting married before reaching age 18 or by becoming fully self-supporting. This concept is country-dependent and should be used only if national regulations allow for it.

<sup>3</sup> A legal guardian is appointed whenever a minor is an orphan or none of the parents are in capacity to (e.g. Out of the country, in prison, on duty, not competent etc.) to make care decisions or take care of a minor.

Children above the age of 12 years should receive age and culturally adapted explanations about the case reporting. They need to be given the possibility to ask questions and to give their assent for their case report to be published. In case the child does not give his/her assent, the case report cannot be published, even if the parent (or legal guardian) has given consent.

### **How is informed consent documented?**

The Consent Form is an official paper document that contains the essential information for which the patient (or his/her legal representative) gives consent and the name and signature of the person who is conducting the consent procedure. The Consent Form should be dated and signed by the patient (or his/her legal representative). In case the patient (or his/her legal representative) is illiterate, the consent can be oral as long as all the information is given to and understood by the patient (or his/her legal representative) and that a witness signs that the patient (or his/her legal representative) has agreed and given his/her consent. The witness should be literate, understand the patient's (or legal representative's) language and not be a member of staff directly involved in case management.

### **What should be done if informed consent is no longer possible?**

When the idea of a case report comes after a patient has been discharged (or died) and the patient (or his/her legal representative) can or should not be contacted, obtaining informed consent will not be possible.

In this scenario, it is important to determine the relevance of the medical case and the benefit of publishing it together with the feasibility of true "anonymity" of the report.

Publication of a case report without informed consent is acceptable only when no direct or indirect identification is possible: this includes removing all direct identifiers (name, address, phone number, pictures with identifiable images, individual numbers like patient number, national number, GPS coordinates) and all indirect identifiers that, when combined, make it possible to identify the person. Depending on the context and the medical topic this might also include removal of the country's and the author's name (replacing it for example by "working group" or "task force" or "medical team").

Once all identifiers have been removed, it needs to be determined if the case report still has sufficient elements to be relevant and that the risk-benefit analysis is clearly in favor of publishing.

### **Specifics around images:**

Medical imagery (like X-Ray, Ultrasound, Scan, etc.) as well as pictures from the patient(s) or his/her environment can be very useful to illustrate a case report and reduce the number of words in the description. However, images can be very identifiable.

For the patient's dignity, consent must be requested before taking any picture/photograph. Consent should include what exactly will be photographed and what use will be made of the picture/photograph (including how long it will be stored and with whom it will be shared). This consent can be oral but should be documented in the medical file with the name of the person who obtained the consent.

Identifiable body parts and regions that are intimate should be avoided as much as possible: only the specific topic/lesion should be photographed.

Beware that pictures/photographs can include indirect identifiers such as the surroundings or a date.

In medical imagery often patient identification and some clinical data is included. Any kind of identifiable information that is in an image must be removed or masked before it is shared or published.

Additionally, the use of any picture/photograph or any medical imagery as illustration for a case report should be clearly notified to the patient (or his/her legal representative) and the image shown to him (or his/her legal representative) for approval. The fact that a picture will be published must figure in the consent form that the patient (or his/her legal representative) will be asked to sign.

### **6.3. Research and publication ethics**

Beyond ethical considerations around patient data, there are also rules to follow in relation to research and publication ethics. These include:

Honest reporting: describe the patient and the case management based on facts and to the best of your knowledge. Do not hypothesize unless you are doing so openly in the “Discussion” part of the case report. Do not hide any of the relevant patient information that you have unless such information is potentially dangerous. Provide enough detail so that another clinician could replicate the same procedures as you describe.

Accountability: even when you have informed consent, you are accountable to your patient for sharing his/her case in the interest of future patients. You are also accountable to all those who will be involved in the writing and publication process: your co-authors, editors, and peer reviewers will all spend a considerable amount of time reading and revising your paper. This means that you should be sure as to why you want to publish a given case and prepare your draft manuscripts as best and as accurately as possible.

