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# Ethical issues in videorecording patients lacking capacity to consent

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**Summary.** Videorecording of patients requires the utmost respect for the privacy and confidentiality of the patients. Consent should be requested from patients for all videorecording. When a mental disability or mental or physical illness prevents patients from giving their permission, agreement to recording from a legal representative or from a close relative or carer are necessary. Three documents on this subject issued in the United Kingdom, the United State of America and Italy are briefly summarized and discussed. The problem of consent for videorecording is addressed particularly in reference to persons incapable of making decisions on their own, such as persons in vegetative state. The general ethical framework is outlined and a few practical proposals are given.

*Key words:* bioethics, coma, informed consent, privacy.

**Riassunto** *(Problematiche etiche nella videoregistrazione di pazienti inabili al consenso)*. La videoregistrazione di pazienti richiede una particolare attenzione per la tutela dei dati personali e la protezione della confidenzialità. Il consenso dovrebbe essere richiesto ai pazienti per ogni videoregistrazione. Quando una disabilità mentale o una malattia mentale o fisica impediscono ai pazienti di dare personalmente il consenso, questo dovrebbe essere ottenuto da un rappresentante legale o da un familiare. Sono qui riassunti e discussi tre documenti sull'argomento pubblicati nel Regno Unito, negli Stati Uniti d'America e in Italia. Il problema del consenso è affrontato specialmente con riferimento a persone incapaci di esprimere personalmente il consenso, come le persone in stato vegetativo. Viene delineato il quadro dei principi etici di riferimento e sono proposti alcuni suggerimenti operativi.

*Parole chiave:* bioetica, coma, consenso informato, privacy.

## INTRODUCTION

Videorecording is becoming increasingly common in clinical use, especially in the field of psychiatry and as a research tool.

From an ethical perspective, two claims about the use of videorecording in medicine are especially debated.

The first claim is that videorecording may violate people's right to privacy, especially in case of misuse. The claim about privacy is pertaining to every situation. The advent of internet, digital imaging and electronic publishing allows storage, access, dissemination around the world with ease ad makes the problem of privacy particularly relevant.

The second claim is about the validity of informed consent, especially when the patient is unable of consenting for physical or legal condition (*e.g.* mentally disabled persons, minors).

The debate on these issues involves also public opinion since many years. For example, in 1996 a video showing real surgical operations was about to be sold through high street shops. The British Medical Association (BMA), the General Medical Council (GMC), and the Institute of Medical Illustrators were quick to condemn this commercial exploitation of sensitive and confidential material. A temporary injunction stopped the sale of the video. A subsequent court order permanently prevented its distribution. The film's producer claimed that the surgeons concerned had given their permission for the video to be disseminated, but it emerged that most of the patients had not [1].

The increasing debate on these issues led important institutions, societies and authorities to publish guidelines and recommendations on medical videorecording and subsequent use.

In the following paragraphs the main documents issued in the United Kingdom, the United State of America and Italy are briefly summarized and discussed.

In the discussion a specific attention to videorecording of persons affected by disorders of consciousness (DOC) is given. This condition includes mainly patients in coma or vegetative state. In these

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situations videorecording is often a powerful tool for diagnostic purposes, but the ethical problems about informed consent are tricky.

## THE GUIDANCE BY THE GENERAL MEDICAL COUNCIL

In May 2002 the GMC updated the guidance *Making and using visual and audio recordings of patients* [2].

The guidance sets four basic principles:

1. "When making recordings you must take particular care to respect patients' autonomy and privacy since individuals may be identifiable, to those who know them, from minor details that you may overlook";
2. "Where children who lack the understanding to give their permission are to be recorded, you must get permission to record from a parent or guardian. Children under sixteen who have the capacity and understanding to give permission for a recording may do so. You should make a note of the factors taken into account in assessing the child's capacity";
3. "When a mental disability or mental or physical illness prevents patients giving their permission, you must get agreement to recording from a close relative or carer (…)";
4. "People agreeing to recordings on behalf of others must be given the same rights and information as patients acting on their own behalf".

The GMC distinguishes "recordings for which permission is not required" (X-rays, laparoscopic images, images of internal organs, ultrasound images) from "recordings for which permission is required". This second category includes: "recordings made as part of the assessment or treatment of patients" and "recordings made for the training or assessment of doctors, audit, research or medico-legal reasons". In all the situations for which permission is required the health professional must ensure that before the recording patients: "a) understand the purpose of the recording, who will be allowed to see it − including names if they are known − the circumstances in which it will be shown, whether copies will be made, the arrangements for storage and how long the recording will be kept; b) understand that withholding permission for the recording to be made, or withdrawing permission during the recording, will not affect the quality of care they receive; c) are given time to read explanatory material and to consider the implications of giving their written permission. Forms and explanatory material should not imply that permission is expected. They should be written in language that is easily understood. If necessary, translations should be provided". Moreover, the health professional must ensure that after the recording: "a) patients are asked if they want to vary or withdraw their consent to the use of the recording; b) recordings are used only for the purpose for which patients have given consent; c) patients are given the chance, if they wish, to see the recording in the form in which it will be shown; d) recordings are given the same level of protection as medical records against improper disclosure; e) if a patient withdraws or fails to confirm consent for the use of the recording, the recording is not used and is erased as soon as possible".

The GMC deals with the recording of unconscious patients together with recording of emergency treatments. According to the GMC in these two conditions:

- "If recordings are to be used only for training or clinical audit, you may record patients who need emergency treatment but cannot give their permission for the recording to be made. You do not need a relative's agreement before starting the recording but must stop it if a relative objects. Before these recordings are used, however, the patient's consent must be obtained or, if the patient has died, a relative must agree to it";
- "When no recording has been planned, but a record of an unexpected development would make a valuable educational tool, you may record patients undergoing treatment. If you cannot get permission at the time because, for example, the patient is anaesthetised, you must ensure the patient is later told about the recording and gives consent to its use";
- "With recordings made in these circumstances, you must follow patients' instructions about erasure or storage (…)";
- "Hospital policy on recording the treatment of unconscious patients should be adequately publicised, for example through notices in waiting areas".

In both the circumstances (unconsciousness and emergency) patients cannot give their permission for the recording to be made. Although in emergency often patients are unconscious, there are many unconscious patients that are not in emergency conditions (*e.g.*: coma, and vegetative state). In emergency situations physicians have to rapidly make decisions about treatments, while usually unconscious patients, after an initial emergency conditions, are treated in routinely conditions for very long times. Therefore, often the two conditions are very different. As a result, the claim that "You do not need a relative's agreement before starting the recording but must stop it if a relative objects" is questionable for patients who suffer long term disorders of consciousness. In such circumstances consent from a legal representative would be appropriate. We have discussed elsewhere the problem of informed consent and legal representation for persons with mental disability, highlighting in particular the crucial role of families [3].

## THE OPINIONS BY THE AMERICAN MEDICAL ASSOCIATION

The American Medical Association (AMA) issued two "Opinions" about videorecording patients: the

"Opinion 5.045 − Filming patients in health care settings" [4] and the "Opinion 5.046 − Filming patients for educational purposes" [5].

According to Opinion 5.045 "Filming patients without consent is a violation of the patient's privacy. Consent is therefore an ethical requirement for both initial filming and subsequent broadcast for public viewing. Because filming cannot benefit a patient medically and may cause harm, filming should be done only if the patient being filmed can explicitly consent. When patients cannot consent, dramatic reenactments utilizing actors should be considered instead of violating patient privacy". The AMA seems more exigent than GMC about informed consent. Moreover, the AMA considers the problem in a perspective different from the GMC's point of view: according to the AMA "consent by a surrogate medical decision-maker is not an ethically appropriate substitute for consent by the patient because the role of such surrogates is to make medically necessary decisions, and whether to film for public broadcast is not a medical decision". However, the AMA specify that "a possible exception exists when the person in question is permanently or indefinitely incapacitated (*e.g.* a patient in a persistent vegetative state) or is a minor child, in which case the consent should be obtained from a parent or legal guardian who has the authority to make non-medical decisions".

The AMA adds also a series of Recommendations. For example the AMA states: "The initial granting of consent does not preclude the patient from withdrawing consent at a later time. After filming has occurred, patients who have been filmed should have the opportunity to rescind their consent up until a reasonable time period before broadcast for public viewing. The consent process should include a full disclosure of whether the tape will be destroyed if consent is rescinded, and the degree to which the patient is allowed to view and edit the final footage before broadcast for public viewing". The possibility of withdrawing consent is important for unconscious patients in the event of recovery of consciousness.

The AMA underlines also that "Information obtained in the course of filming medical encounters between patients and physicians is confidential. Persons who are not members of the health care team, but who may be present for filming purposes, must demonstrate that they understand the confidential nature of the information and are committed to respecting it. If possible, it is desirable for stationary cameras or health care professionals to perform the filming. Physicians retain their responsibility to maintain professional standards whenever medical or surgical encounters are filmed for public broadcast. They should be mindful that the educational content of the finished product may become marginalized, potentially distorting the portrayal of the patient-physician encounter and of the medical procedures. Physicians should accurately convey the risks, benefits, and alternatives of treatments to an audience of prospective patients, and should refuse to participate in programs that foster misperceptions or are otherwise misleading". Moreover, the AMA considers the possibility of conflict of interest ("Due to the potential conflict of interest, informed consent should be obtained by a disinterested third party, and not a member of the film crew or production team") and recommends that "independent peer groups, such as medical specialty societies, also may help prevent misleading information from reaching the public by making themselves available to producers to assess the accuracy of program content. They may help dispel misperception by providing educational resources and, if necessary, taking corrective or disciplinary action. As advocates for their patients, physicians should not allow the care they provide or their advice to patients regarding participation in filming to be influenced by financial gain or promotional benefit to themselves, their patients, or their health care institutions".

## THE PROVISION BY THE ITALIAN DATA PROTECTION AUTHORITY

On 8 April 2010, the Italian Data Protection Authority (DPA) issued a provision on "Video surveillance" [6]. The rules to be followed in videorecording form part of the framework already outlined by the DPA in the "Personal data protection code"(DP Code) [7] and subsequent amendments (last amendment: 4 November 2010 [8]).

According to article 4.2 of the provision ("Hospitals and treatment centres"): "Surveillance in health care premises as well as the monitoring of patients that have been admitted to specific departments and/or areas (*e.g.* resuscitation units, medical isolation divisions) should only be implemented if it proves indispensable on account of specific treatment and health care requirements applying to the data subjects – taking account of the sensitive nature of many items of information that may be collected in this manner. Furthermore, all the additional precautions should be taken that are necessary to ensure a high level of protection of patients' privacy and dignity – partly in pursuance of the requirements laid down in the DPA's decision dated 9 November 2005 under the terms of section 83 of the DP Code. The data controller should make sure that only specifically authorised staff may access the images recorded for the above purposes – *e.g.* medical and/or nursing staff. Special attention should be paid to the arrangements whereby authorised third parties may access the video records; this applies to relatives, family members, and acquaintances/friends of patients hospitalised in divisions the said third parties are not allowed to access in person (*e.g.* resuscitation units). In that case, they should be enabled to only view the respective relatives/friends by means of the appropriate technical arrangements. Images suitable for disclosing health may not be

disseminated (…); on no account should images of patients be displayed on monitors located in publicly accessible premises. Failure to comply with the above requirements results into imposition of the administrative sanction set forth in (…) the DP Code. Dissemination of images in breach (..) of the DP Code is a criminal offence" and liable to the imposition of administrative sanction.

The general criteria, already stipulated in the DP Code, are confirmed in the Provision and seem more severe than those fixed by the GMC and the AMA.

## DISCUSSION: GENERAL ETHICAL PRINCIPLES FOR VIDEORECORDING IN CLINICAL SETTINGS

Videorecording is a useful tool in medicine and should be subject to the same general requirements as other confidential, patient identifiable material.

Autonomy is generally considered as one of the most important ethical principles for medical practice [9]. The main implications of autonomy for videorecording in clinical settings are to obtain consent and to protect confidentiality.

### *Consent and confidentiality*

As regards consent, according to the Convention on Human Rights and Biomedicine "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" [10]. Although videorecording is not properly an "intervention", the need of informed consent for making recording is unquestionable, particularly if the individual might be identifiable: a doctor should normally have the patient's consent before taking images and sharing that information with others beyond the healthcare team.

Further consent is required for the recording's use in an identifiable form in teaching, audit, or research. Additional consent is required for a wider dissemination to, for instance, medical video libraries.

Health care professionals have a legal and ethical duty to keep medical information private. Physicians, nurses, hospitals are required by law and professional codes to practice confidentiality [11]. The practice of confidentiality limits "the disclosure of non-public information within a fiduciary, professional or contractual relationship" [12]. Achieving confidentiality requires restricting information to persons belonging to a community of authorized recipients.

However, consent and confidentiality are not the only criteria to be considered: the specific characteristics of videorecording require further safeguards.

### *Publication and dissemination*

It has always been possible for the general public to have access to medical images by textbooks, but the various form of electronic dissemination are very different and require to face new challenges: the advent of digital imaging has allowed photographs and videorecordings to be stored, accessed, and distributed around the world with ease. Indeed, the publication of patients' images raises problems not only about confidentiality, but also about ownership.

In many cases identification is most unlikely, such as from a photograph of a small area of skin or from a chest radiograph. It could be argued that if patients cannot possibly be recognised from a picture they have no right to restrict its use. This has been the position taken in a number of discussions about written information [13] and is presumably the principle behind Smith's conclusion: "If we have an epidemiological paper with data on 5000 individuals will we require consent from all of these people? The answer will always be no when, as is usual, the data are presented in a combined form: no individual is identifiable" [14]. However, it is important to consider that apparently insignificant features may still be capable of identifying the patient to others.

Moreover, patients may have rights akin to ownership, rather than confidentiality, over an image of themselves.

According to the International Committee of Medical Journal Editors "Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication" [15].

Images could be categorised into those from which patients can be identified, those from which identification is unlikely, and those form which identification is impossible.

Although anonymisation in not always possible, it is recommended that this procedure be followed wherever feasible. A traditional way of preserving anonymity when a photograph includes a patient's face is by blacking out the eyes. It is questionable whether this successfully disguises identity. Digital imaging can distort features a little more effectively, but what seems unidentifiable to a doctor may not be so to patients and their family or friends. Moreover, patients' facial expressions are very important for some purposes, such as studies with persons in vegetative state.

### *Videorecording of mentally incapacitated subjects*

Decisions concerning treatment and research activities are often called for in the case of unconscious patients. "Persons without the capacity to consent can be identified as those who, for reasons internal to themselves, do not have the capacity to make autonomous choices irrespective of their external circumstances. Various groups of people have been traditionally labelled in this way. They include people with learning difficulties, the mentally ill, children, confused elderly and unconscious people" [16]. This article does not intend to discuss the specific problem of legal representation of minors. Elsewhere we have discussed the problem of informed consent other categories of persons incapable of making decisions on their own [3].

As regards the specific problem of consent for videorecording, four main issues should considered: advance directives, presumed consent, surrogate consent and legal representation.

Advance directives are "documents written by patients to help direct they care if they become incapable of making their own health care decisions" [17]. According to the Council of Europe "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" [10]. Difficult questions arise when advance directives refuse treatments in the terminal stages of illness. This problem lies outside the interests of this article. Although the availability of advance directives is expected to become more frequent, it is very unlikely that doctors have direct access to what seem to be the express wishes of the unconscious patient about the specific problem of videorecording. Therefore, probably advance directive are not helpful for our purposes. The possibility of relying on "presumed consent" or "implied consent", is questionable. This possibility which is raised in the GMC guidelines, particularly in the 1997 edition of the Guidance: "Patient's consent to recording being made may be implicit in their consent to treatment, for example in laparoscopic surgery" (art. 3) [18]. However "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" [10]. Moreover, it is prudent to engage family and friends in decisions.A health care proxy ("the agent") is an individual designated to decide what medical procedures should be taken if a patient ("the principal") becomes incapacitated or incompetent. Typically, a proxy is chosen while the principal is healthy, but a proxy may need to be assigned after the patient becomes unable to make decisions if none was chosen previously. Proxy decision-makers can only guide treatments according to one's interest as far as they know them. In practice, in many countries relatives, or proxy decision makers, authorise videorecording of patients in vegetative state when necessary. Even when their authorisation has not basis in the law, most medical societies considers to be an acceptable practice for videorecording.

According to European Directive 2001/20/EC "The notion of legal representative refers back to existing national law and consequently may include natural or legal persons, an authority and/or a body provided for by national law" [19]. In the current Italian normative context, the are three main forms of legal representation: interdiction, disqualification and administrative support [20, 21].

In the absence of a legal representative it is reasonable to allow certain other individuals to express informed consent on behalf of incapacitated subjects for videorecording. For example individuals listed in article 408 of the Italian Civil Code as preferable candidates for supporting administrator might be allowed to express consent without explicit appointment by a tutelary judge: spouse (not legally divorced), stable cohabitating partner, father, mother, child, brother, sister, or any relative not more distant than fourth degree.

### *A summary*

- Audio and videorecording form part of health records.
- Consent should be requested before recording are made and for the subsequent use of the images, whether or not they patients can be identified by the images.
- Specific consent should be obtained if an image will be used in electronic publishing.
- When consent is not available because patient lacks capacity, recording may be made when this is not contrary to the patient's interests and authorisation is given by parents or people close to the patient.
- When the patient is temporarily incapacitated, consent must be sought for the use of recording once the patient regains capacity.
- Images from which it is impossible to identify the patient may be used for teaching, audit, or research without consent, but such use of identifiable images requires consent.

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