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Is the Glasgow Coma Scale score protected health information? The effect of new United States regulations (HIPAA) on completion of screening logs in emergency research trials

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The United States Department of Health and Human Services published final modifications to the Health Insurance Portability and Accountability Act (HIPAA) in August 2002. Full compliance was required as of 14 April 2003. This "privacy rule" regulates the way in which covered entities such as health care groups, organizations, and businesses should manage individually identifiable health information, known as protected health information (PHI). The HIPAA act is directly relevant to researchers as it establishes the conditions under which covered entities can use or disclose PHI [1]. It pertains to individually identifiable health information transmitted or maintained by electronic or any medium. Individually identifiable health information may relate to the past, present, or future physical health or mental health or condition of an individual; it includes demographic data, the provision of health care, payment for the provision of health care, and any other information for which there is a reasonable basis to believe that it might be used to identify the individual. The privacy rule is a response to public concern over potential abuse of the privacy of health information.

As such, the institution of HIPAA is timely and appropriate. However, its implementation may carry a risk of adversely influencing the quality and standards of clinical research. As an example, we experienced this as coordinating quality control and assurance center for an international multicenter phase III trial on the safety and efficacy of a neuroprotective agent in traumatic brain injury. We noted significant differences in completion of screening logs between European and United States centers. Obtaining accurate data on patients screened (but not enrolled) for participation in a randomized controlled trial (RCT) is necessary to monitor for selection bias and recommended in the consort statement. For this particular RCT, conducted in Europe, Australia, and the United States, over 7,000 patients were screened. All European sites, but only 5 of the 15 participating American sites, reported the actual age on the screening logs; the remaining 10 American sites only reported whether the patients met the age inclusion criteria for the study (e.g., 18–65 years). European sites provided data and time of injury, but 10 American sites only provided the date. Information on the occurrence of secondary insults such as hypoxia and/or hypotension as well as the admission Glasgow Coma Scale score were often omitted for reasons of privacy [2]. These data were essential in the context of this RCT to monitor for selection bias and performance of sites. Due to the deficiencies and incomplete information contained in the screening logs of United States sites such evaluation was incomplete for the American arm of the study.

The privacy rule was not intended to impede research using records within databases and repositories that include individual's health information, but the privacy rule does place new conditions on the use and disclosure of PHI by covered entities for research. The creation of a research database or repository and the use or disclosure of PHI from a database or repository for research may each be considered a research activity under the privacy rule [3]. The privacy rule permits a covered entity to use or disclose PHI for research, among other reasons, if the subject of the PHI has granted specific written permission through an authorization that satisfies section 164.508 of the HIPAA or under a "grandfathered" informed consent of the individual to participate in the research, an institutional review board waiver of such informed consent, or authorization or other express legal permission to use or disclose such information for research. A valid privacy rule authorization is an individual's signed permission that allows a covered entity to use or disclose the individual's PHI for the purpose and to the recipient stated in the authorization. When this is obtained for research, the HIPAA requires that it pertain only to a specific research study, not to future, unspecified projects. Researchers must additional provide written assurances that PHI will not be reused or disclosed, and must provide a written plan to destroy identifiers at the conclusion of the research, absent a legal justification to retain them [4]. Health care institutions may also gave permission to researchers to disclose limited data sets of information for research purposes. The HIPAA (section 164.514[e]) identified 16 identifiers which must be removed from the data sets. These include among others name, addresses, telephone numbers, medical record numbers and biometric identifiers. These data are usually of no interest for a coordinating quality control and assurance center for an international multicenter phase III trial.

In emergency and intensive care research obtaining written permission and authorization by the individual is not possible. Research in this field of health care is complicated by difficulty in obtaining informed consent for clinical research, since critical illness and its treatment may

impair or abolish competence and autonomy. It is not clear whether authorization for use of PHI can be given by a legal representative of an incompetent patient for the use of data obtained in emergency research in acute conditions. Further, it is not always clear which information should be seen as PHI and which not. For instance, should information on hypoxia, hypotension, or admission Glasgow Coma Scale, or even age be considered PHI, it is to us remarkable that two-thirds of the sites in the United States do not provide any such information, but the others appear to apply the regulations less strictly. We presume that this strict approach observed in 10 sites reflects caution or anxiety for persecution and that the differences observed reflect uncertainties in the interpretation of what may be considered PHI. We see no valid reason why such medical data should be seen as PHI.

The Consolidated Standards of Reporting Trials (CONSORT) statement was developed in the mid-1990s and revised in 2001 [5, 6]. It outlines procedures for reporting results of RCTs in a transparent manner, and includes a checklist for reporting clinical trials. This includes the number of patients excluded, with the reasons for exclusion. Confronted with the incomplete United States screening logs, precludes us checking accuracy of exclusion. This is not compatible with the widely accepted CONSORT statements.

Confidentiality of patient information is an important principle of clinical research, shared by both patients and healthcare providers. Several new regulations, such as the HIPAA and the European Union Directive on Clinical Research, may hinder emergency and intensive care research or even make it impossible [7]. This is of real concern for the future of emergency and intensive care research. In the case of the influence of HIPAA on emergency research, as we have experienced, this reflects caution or anxiety for persecution, and the differences which we observed reflect no less than uncertainties in the interpretation of what may be considered PHI. We absolutely see no valid reason why medical data as we describe should be seen as PHI under the HIPAA regulations.

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