

Health Informatics and Institutional Review Board – Making Research Easier and Ethical

Arun-Kumar Kaliya-Perumal¹, Mohamad D. Awadalla^{2*}, Daniel G. Abate³
Yi-Fang Tsai⁴

Manual filing of medical records and retrieving data for research purpose is a tedious process. However, some hospitals still follow this long established procedure. If an integrated computer based system is not in place, then doctors need to maintain records of their clinical work and store it by their own means for research purposes. This data mostly includes patient information, clinical data, radiological images, investigational values and intraoperative pictures.

Why this is a problem?

When a doctor maintains such data personally, the risk of losing data or missing a potential confounding variable that may be needed later when the study is formulated will always be a possibility. Moreover, for a long term prospective study, it may be hectic for an individual to maintain complete data including follow-up for a large set of patients.

Another different perspective is when reporting a case; there may be a conflict among departments; especially if a patient is of interest to multidisciplinary team work, like radiology and orthopedics, or pathology and general surgery, or similar interrelated departments. In such cases doctors from both departments would have data of the same patient with intent to come out with a report or a study. If one goes ahead with a publication, the other would end up with copyright issues.

What needs to be done?

So an Institutional Review Board (IRB) is necessary to regulate this process. Firstly, data should be made available to health care professionals through software based digital means using hospital informatics^{1, 2, 3}. Hence the data will be available to an authorized person through the hospital intranet. This data can be of great value for education, to illustrate a situation, to raise awareness, or to act as evidence and contribute to advocacy. But when using the same data for research, IRB approval should be mandatory. The IRB should have access to the integrated digital system for verification purposes.

The digital means of maintaining hospital records will greatly reduce the researcher's burden of maintaining a personal collection of data and break down the time barrier associated with data retrieval. Also, the IRB can verify and approve the data that will prevent departments from conflict over reporting a particular case of interest in an international forum like a journal. It can also verify the intent of various departments to research a similar topic and suggest an alternative.

1. Department of Orthopaedics, Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research, Melmaruvathur, Tamil Nadu, India.

2. Department of Surgery, Faculty of Medicine, Gezira University, Sudan.

3. Department of Surgery, Jimma university, Jimma, Ethiopia.

4. Department of Orthopaedics, Chang Gung Memorial Hospital, Taoyuan, Taiwan.

*Correspondence to: Dr. Mohamad D. Awadalla, Department of Surgery, Faculty of medicine, Gezira University, Sudan. P.O: 20. Phone – 0088697317884. E- Mail – mohadaff22@gmail.com

The message:

Moving to digital means will be a giant leap but is highly necessary to maintain ethical research practice. Hospitals should start integrating medical records to digital software with specialty specific extensions which will efficiently reduce the burden of individual treating doctor from maintaining patient data by oneself. It will effectively reduce the costs and improve patient care^{2,4}. IRB should be the sole authority to approve or suggest changes to a study. Any proposal for publication should compulsorily go through IRB to prevent potential conflicts.

Thanks to “Sudan Journal of Medical Sciences” that quotes IRB approval is mandatory for any study involving human or animal subjects. We emphasize that, strict requirements for IRB approval and documentation in compliance with Declaration of Helsinki will increase ethical standards⁵.

REFERENCES:

1. Shekelle PG, Morton SC, Keeler EB. Costs and benefits of health information technology. *Evid Rep Technol Assess* 2006;132:1-71
2. Rothman B, Leonard JC, Vigoda MM. Future of electronic health records: implications for decision support. *Mt Sinai J Med*. 2012;79:757-68.
3. AEAM El-Nour, MK Elnimeiri, AMO Abbas. Towards a digitized and integrated health information system in Sudan: Assessment of readiness at state level. *Sudan J Med Sci*. 2016;11:55-60.
4. Becker SH, Arenson RL. Costs and benefits of picture archiving and communication systems. *J Am Med Inform Assoc*. 1994;1:361-371.
5. Roggin KK, Chwals WJ, Tracy TF. Institutional Review Board approval for prospective experimental studies on infants and children. *J Pediatr Surg*. 2001;36:205-8.