

Title: Paper or Plastic? From Paper Records to Electronic Database

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Description: Dr. Edwards has developed an electronic database to manage patient records. He is beginning to use the database as a research tool, but his patients have never consented to having their data used for research purposes.

Headings: Privacy and Confidentiality; Storage of data

Case Type: Decision Making

Paper or Plastic? From Paper Records to Electronic Database

Dr. Edwards is very excited about the database he has developed. He has been a clinical psychologist and researcher for fifteen years and has strongly advocated for the use of computers in his field since his med school days. Several years ago, looking at the shelves and drawers filled with patient files, he began to think about data management. He came up with the idea of developing a multimedia, fully integrated database that would allow physicians and researchers to store, analyze and query patient/subject information quickly and easily. Through such a resource, he thought, he could maximize the utility of large collections of data, allowing researchers to ask questions currently impossible to address, due to the logistics of handling such large, heterogeneous data sets. Edwards envisioned a database that would allow researchers to record and track all aspects of an experiment including patient samples and records (everything from name and address to CAT scans), experimental reagents, protocols, raw data and primary analysis. It is a fantastically powerful tool with tremendous potential.

The Medusa database (**M**ultimedia **D**ata **S**torage and **A**nalysis) was developed in Edwards's lab, at a prominent teaching hospital, using data from his own studies of ADHD and bipolar disorder. Medusa is fairly robust for his data set, but needs to be beta-tested with a range of data types and formats that are not commonly encountered in clinical psychology (e.g., DNA sequence data or results from animal breeding experiments). He meets with several labs on the medical campus and gives presentations on Medusa in an effort not only to advertise, but also to recruit high-profile labs in which to beta-test his product. During demonstrations, all patient names are encrypted and family relationships obscured. Edwards navigates through Medusa, showing off the ease with which one can toggle between a patient's blood chemistries and the results of behavioral tests. He convinces three labs with large ongoing projects to import their data into Medusa, helping him work out bugs and continue to develop the design and utility of his database. He knows that if all goes well, his name and that of Medusa will be mentioned in future publications out of the beta-labs, which will be important when he takes his database to market.

When Edwards began developing Medusa, he did not inform his patients or ask their permission to be included. He believes that storing the data in Medusa is equivalent (if not superior) to storing it in folders in file cabinets and is simply the best way for him to provide care to his patients.

Currently, the database is located in Edwards's lab on only one computer, which is accessible over the web. The bioinformatics staff of the respective beta-labs must learn the data structures and file formats used in Medusa, as well as how to manipulate the encryption utility. That will enable them to devise ways to import their own labs' data, which may be markedly different than the data from Edwards's lab. In order to import the data, a few individuals must have full access to the database, which means that they also have full access to Edwards's data set. To avoid this exposure, Edwards would have had to set up a complete duplicate database, which would be onerous and time-consuming. Edwards provides each beta-lab programmer with the encryption key; Amy is one such database programmer. While learning Medusa, Amy has access to complete patient files and experimental data stored in the database, although she has no need to look through these files. Periodically, her supervisor asks her to update the rest of the lab on her progress. During her lab presentations, it is easier to demonstrate much of Medusa's functionality without the encryption in place; although Edwards is working on it, the key currently must be entered each time a query is submitted, which is cumbersome and slow for demonstration purposes.

Is Edwards' use of Medusa ethical, particularly as compared with paper records?

Questions for Further Reflection

Is there a substantive difference between paper records and Medusa?

Is Edwards justified in using patient information for database development and promotion? Why or why not?

If Edwards *had* sought his patients' informed consent for use in the database, what would the consent form look like? E.g., what risks and benefits would have to be disclosed?

Given this additional information, do you feel differently about Edwards's use of patient information in the development and promotion of Medusa? Why or why not?

Where is the line between legitimate sharing of information and breach of physician-patient confidentiality?