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Professionalism in the age of computerised medical records

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ABSTRACT

Electronic medical records have the potential to improve clinical care and to provide answers to important research questions. Research using existing medical records has provided important knowledge about the effectiveness and risks of widely-used medications. However, electronic medical records also raise ethical dilemmas regarding informed consent and confidentiality. Breaches of confidentiality with electronic records can be more severe than breaches with paper records. Furthermore, computerised health information raises new ethical dilemmas regarding direct advertisements of new drugs to patients, the impact of email on the doctor-patient relationship and the quality of outsourced radiology readings. Resolving these dilemmas may require new regulations and laws. In the interim, society will need to rely on physicians' professionalism to minimise the risks of electronic medical records and to ensure that the benefits outweigh the risks.

Keywords: computerised medical records, electronic medical records, ethical issues, healthcare information, informed consent, patient confidentiality

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I am honoured to be in Singapore today to present the annual Singapore Medical Association (SMA) lecture. As the SMA President, Dr Wong Chiang Yin, declared in his opening remarks, the profession of medicine faces many challenges today. In the digital era, electronic medical records (EMRs), email communication with patients, and outsourcing of radiology studies present new challenges to medical ethics. Although Singapore is considering legislation regarding EMRs, it is unlikely that the law will be able to keep pace with rapid advances in computerisation. Thus, when facing ethical dilemmas raised by the computer era, physicians will have to rely on their professional ethics, reinterpreting ethical principles in modern circumstances.

ELECTRONIC MEDICAL RECORDS (EMRs)

The University of California at San Francisco (UCSF), where I work, has instituted an EMR system. Physicians can access by computer the results of laboratory, radiology, and pathology tests, medications and their doses, the dates and diagnostic codes for outpatient visits, and narrative notes from some outpatient clinics. Inpatient records are completely electronic, including physicians' and nurses' narrative notes and flow sheets of vital signs. UCSF does not have computerised ordering of drugs, which some health centres have implemented.

The EMR has many benefits for patients and their healthcare providers[1,2]. Doctors can access health records through a secure Internet connection at any time. For example, an on-call physician can access records from home. The EMR enhances coordination of care, because all physicians caring for a patient can see each other's notes. An outpatient physician can obtain records from a patient's hospitalisation and the discharge medications. Electronic prescribing has been shown to reduce medication errors. Finally, the EMR facilitates quality improvement. Patients who are not receiving interventions that have been proven to be effective, such as cancer screening, influenza vaccine, statins for elevated cholesterol, and beta blockers after myocardial infarction, can be easily identified.

However, the EMR also presents practical problems and ethical issues. The benefits of the EMR may not be realised in a particular healthcare institution. An instructive case example is Cedars-Sinai Hospital in Los Angeles, which abandoned a $34 million EMR system after three months[3]. Physicians complained that the new EMR system increased time rather than saving it. Because of insufficient computer terminals in the hospital, physicians often had to wait to use the system. When the computer triggered an alert about

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a prescription, physicians rejected the alerts in over one-third of cases, because they believed that the alerts were not clinically meaningful. Furthermore, the computer did not accept common abbreviations and misspellings, forcing physicians to spend time making corrections.

At UCSF, in contrast to Cedars-Sinai, physicians were an integral part of the design and implementation of the EMR. Doctors designed electronic templates for the review of systems and the physical exam, two areas of the medical record where handwritten or dictated notes were falling short of the documentation required by health insurers. In other hospitals, physicians might suggest additional features for the EMR. For example, a geriatrics unit might want to include templates for physicians to document the functional status of the patient or stress in caregivers. The UCSF EMR had extensive pilot testing and was implemented in a stepwise manner into different clinical units.

ETHICAL CONCERNS ABOUT THE EMR

In addition to providing benefits to patients, EMR also raises ethical concerns[2]. First, patients have concerns about who has access to their identifiable health information. At a minimum, patients should be told how the EMR operates, who has access to their personal health information, and what protections are in place to protect personal information. Some patients may be reluctant to place personal health information into the EMR. However, individual approval to use the EMR may not be feasible. If a hospital uses a comprehensive EMR, it may not be possible for a physician to enter notes, order tests, retrieve tests results, or order medications without using the computerised system. Thus, patients wishing to receive care at that institution will need to accept use of the EMR. Under these circumstances, it is not realistic to suggest that patients have an option about the EMR or to seek their authorisation for use of the EMR.

Although it may not be realistic for patients to authorise use of the EMR for clinical care, healthcare organisations can still respect their concerns over access to personal information in the EMR. Employees in the hospital or clinic can be given access only to information which they need to carry out their job. For example, employees in the billing department need access only to the dates of service, the type of service, and the diagnosis, not to clinical notes. Furthermore, patients may block access to certain information in the EMR. For instance, patients may wish to restrict access to notes about psychotherapy or substance abuse treatment to the healthcare workers providing those services. Healthcare workers providing care for other problems could have access only to the diagnosis and medications.

Another major ethical concern is confidentiality of identifiable health information in the EMR[4]. In the US, several major breaches of confidentiality of electronic health records have occurred recently[5]. In Ohio, a medical school health centre mistakenly posted online treatment information, names, and addresses of 2,800 patients. In Florida, the names of 6,000 persons with HIV infection were mistakenly attached to an email sent to 800 employees in the county health department. Finally, in numerous episodes, laptops or CDs containing sensitive, personally identifiable information, including social security number, medical records and financial records were stolen or lost. This information was not encrypted. In light of these incidents, which occurred after the passage of federal regulations regarding health privacy, many patients may understandably be concerned that adequate precautions have not been taken to protect health information placed in EMRs.

Because the EMR provides greater access to information, breaches of confidentiality with EMRs can be more serious than breaches with paper medical records. A single electronic breach could affect more patients than a breach of confidentiality with paper records, because only one paper record can be accessed at a time. Furthermore, more data on each patient can be quickly retrieved in electronic format. Moreover, electronic records can be accessed from many computer terminals, providing more potential sites for breaches. Thus, the features of EMRs that provide clinical benefits also make breaches of confidentiality more serious.

Although computerised records offer opportunities for confidentiality to be breached, computers also allow protections that are not available with paper records[1]. Passwords, timed logouts, restricted access, encryption, and secure websites enhance the security of electronic records. However, such security measures involve a trade-off with ready access to the EMR when needed to provide clinical care. For instance, in the Cedars-Sinai Hospital example, physicians complained that delays in logging onto the EMR system made their work inefficient. Yet delays caused by password protection and timed logouts when no activity occurs at a terminal also thwart breaches of confidentiality.

In setting up and using an EMR, there is always a balance between protecting the confidentiality of personal information and allowing health information to be accessed in order to benefit patients. Physicians have an important role in helping to set this balance

in specific situations. To illustrate the issues that need to be considered, we analyse the use of EMR for advertising and for outcomes research.

USING THE EMR FOR ADVERTISING

Another ethical issue is using the EMR for purposes other than direct clinical care. We have already discussed how the EMR may be used for quality improvement, for example, to identify patients who have not received cancer screening and preventive interventions that have proven effective. However, information in the EMR can also be used for other purposes, whose benefits to patients are less clear. Because the direct benefit to patients may be questionable, the risk of breaches of confidentiality may not be acceptable.

In a US incident, a large chain of pharmacy outlets and a drug manufacturer formed a partnership to identify patients who might benefit from a new drug[6]. As the patent on the antidepressant fluoxetine was about to expire, the manufacturer introduced a new form of fluoxetine that could be taken once a week. To advertise this more convenient dosage, the manufacturers used the pharmacy chain's electronic records to identify patients who had received prescriptions for antidepressants. These patients were mailed samples of once-a-week fluoxetine. Although the pharmacy chain and the drug manufacturer believed this information would be welcome to patients, many recipients of the mailing were outraged. Many were angry that sensitive information about their psychiatric condition had been accessed without their knowledge or permission by an organisation they did not know. Furthermore, other patients were upset at receiving samples for a medicine that was not appropriate for them. One woman who received the sample had previously been unable to tolerate fluoxetine because of unacceptable side effects. A 16-year-old boy with no history of depression was sent samples prescribed by a physician he had never met. An investigative reporter found that the physician had allegedly signed blank prescriptions that were filled out by employees of the pharmacy chain. However, there were no laws or regulations forbidding such mailing of samples. Moreover, comprehensive federal health privacy regulations later enacted permitted this practice, after heavy lobbying by pharmaceutical manufacturers, health insurers, and pharmacy benefits plans.

This episode reveals the discrepancy between clinical and business views of the confidentiality of personally-identified health information. Moreover, conceptually it is important to distinguish between the use of the EMR for quality assurance by physicians, clinics and hospitals, and its use for advertising and promotions by for-profit companies selling healthcare products. It is reasonable to assume that almost all patients would agree to have their physicians and institutions where they receive healthcare, access their EMR to determine if they have failed to receive prevention interventions of proven benefit[7]. However, it is likely that many patients would not want their EMR to be used to send them advertisements for products that the manufacturer believes would benefit them. A crucial difference is that the physician or nurse leading a quality improvement project pledges to follow a professional code of ethics. In such professional codes, the best interests of the patient are paramount, and confidentiality is a strong presumption. In contrast, a drug manufacturer is seeking to maximise its profits and to enlarge its market share even if the new drug offers no decisive benefits over other similar drugs. Thus, the physician's professionalism, which leads them to recommend only interventions that will benefit patients, serves as an important protection for patients. When a situation is not covered by legislation or regulation, professional ethical standards take on additional importance in protecting the use of EMR from purposes whose benefit to patients is questionable.

USING THE EMR FOR OUTCOMES RESEARCH

The EMR in large healthcare organisations allows for important outcomes research to be carried out, for example to assess the safety of drugs as used in widespread clinical practice rather than in smaller controlled clinical trials. A good example of the potential public health benefits of outcomes research involving the EMR involves rofecoxib, a selective COX-2 inhibitor widely prescribed for arthritis and heavily marketed as having fewer gastrointestinal adverse effects than nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). In 2000, results from a clinical trial suggested that rofecoxib might increase heart attacks[8]. However, the investigators from that trial interpreted their data as showing that naproxen protected against heart attacks, rather than showing that rofecoxib increased the risk. A new clinical trial to address definitively the impact of rofecoxib on cardiac events, compared to other NSAIDs, would require many patients and several years of follow-up. Moreover, studying the impact of different doses or duration of therapy would require prohibitively large sample sizes. However, data from an EMR could address these issues, although not as rigorously as a randomised clinical trial.

A health maintenance organisation in Northern California, which provides care to almost a third of patients in the area, carried out research on the cardiac risk of rofecoxib. Using the EMR, researchers were able to identify 1.4 million prescriptions filled for NSAIDs and to analyse subsequent deaths, heart attacks, and strokes in patients who received such a prescription[9]. This study found that the adjusted odds-ratio for rofecoxib at doses greater than 25 mg daily, compared to celecoxib, was 3.58[9]. The adjusted odds-ratio for naproxen compared to remote NSAID use was not elevated. Even a study of this size, however, was not large enough to determine whether the risk of rofecoxib increases with time. This study could not have been carried out using paper records because of the sheer number of patients studied. The question of whether rofecoxib increases the risk of heart attack and stroke is important from a public health perspective. An estimated 100,000 persons in the US have suffered heart attacks attributable to this drug. This kind of outcomes research with EMRs, which can be carried out in a matter of months, has the potential to reduce the impact of adverse events due to drugs. Providing such benefits to society is a strong ethical justification for using the EMR to carry out outcomes research.

However, there are also ethical concerns about using the EMR for outcomes research. Although there is no physical risk to patients, there are psychosocial risks. Patients may be harmed if confidentiality of their personal health information is breached. For example, patients may suffer discrimination in employment if employers learn of health problems, even though they are able to carry out their job tasks. Patients may also feel that their freedom or autonomy is violated if they become subjects of research studies without their knowledge or consent. In particular, they might object to having information that was collected as part of clinical care used for another purpose, namely research. It is not feasible to obtain explicit consent for an outcomes research project from all the patients whose records would be reviewed. Moreover, it is scientifically important to have virtually full participation in such outcomes research. If some patients did not allow their data to be studied, the findings might be biased and inaccurate. For example, if sicker patients were less willing to participate than healthier patients, the risk might be underestimated.

In outcomes research using the EMR, there is a potential tension between two important ethical principles: On the one hand, well-designed research using the EMR should be carried out because it can benefit society. On the other hand, the autonomy and well-being of research participants must be respected. How can this tension be resolved? First, patient autonomy should be respected as far as this is possible. While consent for specific projects using the EMR may not be practicable, it is feasible to inform the public and patients seeking care at a particular healthcare institution that research using medical records is being carried out. The value of such research could also be explained. Moreover, the public should indicate its acceptance of the use of the EMR for research; for example, through legislation or regulations. Second, individuals whose medical information is used for research should be protected from inappropriate risks. For research using the EMR, this means adequate protection of confidentiality. In Singapore, the background paper on confidentiality of medical records states that persons whose records are used in research are "primarily protected by appropriate privacy safeguards, rather than … exercise of patient discretion in the use of information for the public good." Third, there should be an oversight of the research by an institutional review board that is independent of the researchers. This review helps to assure that the study has scientific merit and that persons whose records are used are adequately protected.

OTHER ETHICAL DILEMMAS IN THE DIGITAL ERA

In the digital era, other innovations that make clinical care more efficient or effective also lead to ethical dilemmas. Physicians and patients can use email to communicate, rather than talk on the phone or leave messages for each other. For patients, emails are often more convenient and efficient than an office visit or a telephone call. However, because the physician cannot see or examine the patient, some clinical decisions might be suboptimal. Confidentiality is another concern, because commercially-available email systems are not secure. However, these problems can be addressed. Physicians have experience deciding whether a more thorough evaluation is indicated. When taking a night or weekend call, doctors determine whether a patient's problem can be handled over the phone or whether an outpatient or emergency visit is indicated. Physicians can make similar judgments about email communications. Furthermore, confidentiality issues can be addressed by having secure websites for communication, which require password authorisation by the patient to retrieve email messages from physicians. Similar technology is used to protect online financial transactions.

Digitalised imaging studies raise additional ethical

issues. Digitalisation allows outsourcing of radiology readings to offsite locations. In the US, outsourcing radiology readings to another time zone allows studies to be read in a timely manner at night, when there is no radiologist in the hospital. Digital images can be sent immediately to Asia, to be read by a radiologist who can read them during normal business hours there. There are a number of ethical issues regarding such outsourcing. Concerns about the quality of services and the qualifications of the physicians doing the work can be resolved by requiring board certification and peer evaluations. A more serious concern concerns the confidentiality of the outsourced information. Can the US healthcare institution assure that the persons doing the readings are following appropriate standards for protecting confidentiality? Are the confidentiality protections that are required in the US enforceable in the other country? Once again, we see that increased access to information needs to be balanced with protecting confidentiality.

In summary, the era of digitalisation and computers allows healthcare information to be used in innovative ways that offer important benefits to patients and to the public. At the same time, such access to identifiable health information raises ethical concerns, particularly concerns about confidentiality. Because technological advances stimulate many innovative uses for health information, it is difficult for the legal protections to keep pace. Singapore is considering comprehensive regulation and legislation regarding electronic health information. A wise policy will provide assurance to patients and guidance for physicians and healthcare institutions. However, unforeseen situations and practices will inevitably arise, which are not covered by the law. In those situations, the physician's sense of professionalism will be the strongest protection for patients and the public.

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