Rochester Epidemiology Project

Information for the

Community Advisory Board

Funded by the National Institutes of Health
Department of Health and Human Services

Challenges in research using medical records

This community advisory board will allow you to join with others to make recommendations to the leaders of the Rochester Epidemiology Project (REP). You will guide them in developing or improving policies about collection and use of medical records for research. We would like to identify community concerns and to engage the community in planning for the future of the REP.

The REP is funded by the U.S. National Institutes of Health.

The purpose of this booklet

This booklet is meant to provide basic information, including diverse perspectives.

Definitions of the technical terms used in this booklet are on pages 26-27. We use some abbreviations in this booklet:

HIPAA = Health Insurance Portability and Accountability Act
IRB = Institutional Review Board
NIH = National Institutes of Health
OMC = Olmsted Medical Center
REP = Rochester Epidemiology Project

Prepared by Rochester Epidemiology Project
August 2012

The importance of community engagement

People in our society are concerned about the conduct and regulation of research and technology. However, discussion about these concerns is shifting. In the past, experts told people what they needed to know about research and technology. Today, we recognize that all citizens should have a voice about how research is conducted. In particular, we all have important things to say about the use of our medical records for research.

Here, we aim to do two things: educate and seek advice. Our goal is to develop or improve research policies and practices by drawing on people from many different backgrounds and with many different opinions, needs, and expectations. By using the knowledge, insight, and advice of educated citizens, we can make better decisions and increase public trust.

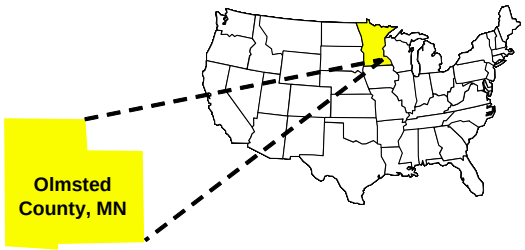
Photos from the REP deliberative community engagement in Rochester, 2011

Table of Contents

What is the Rochester Epidemiology Project (REP)?

In order to offer advice to the Rochester Epidemiology Project (REP), it is important for participants in the deliberative community engagement to have good background knowledge about the REP and its goals.

The REP is a medical records research collaboration among health care providers in Olmsted County, including Olmsted Medical Center, Mayo Clinic, Rochester Family Medicine Clinic, and other care providers. By working together and sharing medical data, researchers can better understand the causes of diseases and can develop new ways of preventing and treating diseases.
The REP was created in 1966. It is an initiative to collect and save medical information for the people living in Olmsted County, Minnesota. It is a unique resource for research in the U.S. It allows researchers to study people's health over time.



Goals of the REP

The overall goal of the REP is to improve community health through research. The REP allows researchers to review the records of patients from many settings, including the doctor's office, urgent care clinic, emergency department, and hospital. Patients can be followed regardless of where the care was delivered or whether they have insurance.

Collaborators

Olmsted Medical Center (OMC), Mayo Clinic, the Rochester Family Medicine Clinic, and other medical care providers in Olmsted County have agreed to work together to share information from their medical records with researchers.

This collaboration and sharing of medical information makes Olmsted County one of the few places in the U.S. where "population-based" research can be accomplished. For example, if a researcher wanted to know how many people respond to a treatment for diabetes, it is important to understand how many people have diabetes in a region and to know for sure who received treatment. Counting only those sick enough to go

to the hospital would give a false picture of diabetes care. It is important to study the full population to get accurate information to plan medical treatment.

The REP is unique because all care providers in Olmsted County are willing to work together.

Uses

The REP is important because research based on people who are seen by a single doctor or at a single clinic has many limitations. Using the REP, public health officials or researchers can figure out the true frequency of certain conditions (for example, how many patients develop heart disease each year) and the true success of treatments (for example, how many people will respond to a new anti-depressant medication). Policy makers can also determine how much it costs to treat a certain disease.

Good and accurate medical research requires that the majority of people living in a community participate in the research.

Funding

The REP has been supported by the NIH for nearly half a century. It is very rare for a project to be funded by the NIH for that long. This record of funding shows how important the REP is. It is currently supported by the NIH and by the Mayo Clinic.

How researchers use the REP

Prior to using any health information from the REP, all researchers must submit a protocol to independent review committees at both OMC and Mayo Clinic. A protocol is a plan that outlines the goals, design, methods, and statistical considerations of the study. The independent review committees, also known as Institutional Review Boards (IRBs), approve, monitor, and review medical research involving human participants. More detail on the process of protocol review and the function of IRBs will be discussed in the next sections.

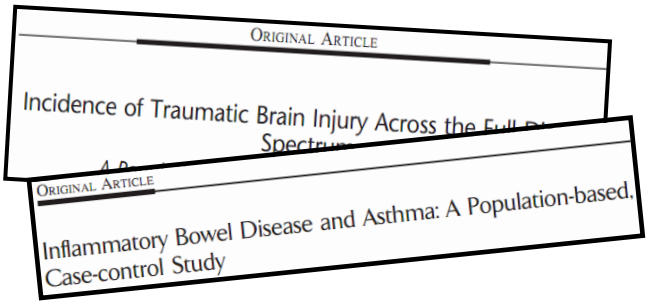
Medical records research around the world

Comprehensive population-based medical records systems have been developed in the United Kingdom, Australia, and Canada in collaboration with government institutions. Some examples include the Oxford Record Linkage Study, Scottish Record Linkage System, the Manitoba Population Health Information System, and the United Kingdom's General Practice Research Database. In addition, extensive records linking systems are available at the national level in Scandinavia.

In contrast, because there is no comprehensive national health care system in the U.S., such resources are limited in this country. Instead, large health care organizations have set up ways to store and use medical records for research. The REP, although funded by the nation, is independent. It is also not part of any single health care organization.

How does the REP work?

Since the beginning, the REP has supported many research projects. These projects have changed the way diseases are prevented and medicine is practiced. REP researchers have published over 2,000 research articles spanning almost every field of medicine.



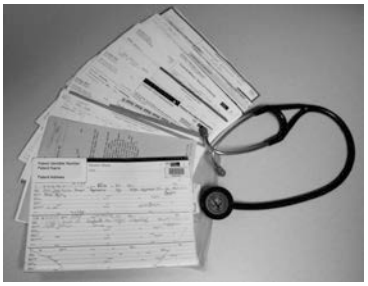
How is health information used in the REP?

Researchers use the REP for three types of activities: 1) chart review studies, 2) surveys, and 3) to identify research participants for special studies.

1. Chart review studies

We use the word "chart" to mean a medical record. Most studies supported by the REP do not involve any interaction with a patient. For example, the patient does not get a letter or phone call about the study. These chart review studies use information that was originally collected for routine medical care. Data include physician and nursing notes, ambulance and emergency room reports, hospital admission and discharge documentation, laboratory and diagnostic test reports, and other types of information, such as billing data.

Chart review studies are relatively inexpensive and allow important questions to be answered quickly. This type of study allows researchers to investigate medical conditions over time. For example, one REP study evaluated women 25 years after they had their ovaries removed. This study found that women who had this surgery were likely to die sooner than women who did not have their ovaries removed. This may help women make decisions about surgery in the future.



Such "no contact" research is convenient for both patients and researchers since the patient only needs to give permission for use of medical records once (as explained in the "Minnesota Research Authorization" section on page 12).

Otherwise, people with a common disease such as diabetes or high blood pressure might be invited to participate in many studies. However, if a patient has granted an authorization for use of medical record information for research, he or she will not need to be contacted for each new study. In this situation, the community will benefit from improved knowledge and there is no burden on the patient. This is not possible in studies that require a survey, an interview, or an in-person visit.

Some people, however, may think that privacy is much more important than convenience. They may prefer to know each time their record is used for research, or they may want to be contacted about each study.

2. Surveys

In some cases, medical records do not contain the types of information needed for a specific research question. If this occurs, researchers request permission from the Institutional Review Boards (see page 9) to ask people to answer questions on a survey. These studies may be conducted by telephone, by mail, face-to-face, or over the Internet. For example, surveys may ask about a person's diet, whether a person is in pain, or whether a person can perform daily tasks without assistance.

3. Special studies

Sometimes researchers need to collect information that is not routinely recorded as part of clinical care and cannot be obtained by a simple survey. For example, a researcher may ask participants to come to a research laboratory for a blood test. This type of study may discover whether a new blood test is useful to diagnose cancer. The researcher would first request permission from the Institutional Review Boards (see page 9) to invite people to participate in the study. Then, the researcher would use the REP database to find people with and without cancer. Next, the patients would be asked to volunteer for this particular study. To help make a decision, they would be given detailed information, including an informed consent document (see page 13).

The potential of the REP

The REP supports research in many diseases. The largest REP studies currently underway ask:

- What leads to hospitalization in patients with heart failure?

- How common is minor memory loss in the aging population?
- What causes blood clots to form in veins?
- Does bone loss that happens when people age cause fractures?

How is the REP governed?

"Governance" means the rules and practices used to manage the REP. It includes laws and institutional policies. Federal and state governments regulate research to guard against misuse of information and to build and maintain the public trust. The REP follows ethical principles for human subjects research as mandated by the government. The rules are enforced by an independent Institutional Review Board (IRB).

Role of the Institutional Review Board

An IRB is an independent committee that oversees research involving humans and protects their interests.

An IRB is made up of doctors, nurses, pharmacists, scientists, ethicists, and at least one person from the local community. The IRB ensures that the appropriate steps are taken by researchers to develop well-planned, ethical studies. Most research involving people, including all REP research, requires IRB approval.

In the application to the IRB, researchers need to describe the purpose of the study and how they are going to do the research.

IRBs assess and evaluate how participants will be invited, the risks and potential benefits of the research, privacy and confidentiality considerations, and whether procedures are in place for patients to give informed consent. (Informed consent is discussed in detail on page 13.)

IRBs and medical records research

IRBs are responsible for the review and approval of research using medical records.

For chart review studies (where patients aren't directly contacted), the IRB requires that all study participants have granted "authorization" for their records to be used in research. There is a special law that regulates such

research in Minnesota (described in detail on page 12).

If the IRB feels that the study poses "minimal risk" to individual patients and that the appropriate protections are in place, it will allow the researchers to proceed with the study without requiring a formal informed consent process from every patient in the study (see page 13).

Unfortunately, IRBs have limitations:

- IRBs are overworked
- IRB members may not have expertise in particular research topics
- There is great inconsistency in how IRBs operate across the country

Gaining approval to use the REP

First, a researcher presents his or her idea to the REP leadership. If the research is approved, the researcher must obtain a formal "REP Collaborator" appointment. To get this appointment, a researcher must have appropriate education and experience. This appointment gives researchers space on the Mayo Clinic Rochester campus and access to REP resources.

All REP studies must be approved by both the Mayo Clinic and OMC IRBs. These approvals are necessary to make sure that research studies follow the state and federal rules about protecting people who participate in research.

After the IRBs approve a research study, the researcher can use REP computer tools and review patient medical records to find answers to his or her research questions.

What rules apply to medical records research?

Governance of the REP also includes federal and state laws related to privacy and use of medical records.

HIPAA and medical research

HIPAA stands for the Health Insurance Portability and Accountability Act. Since 2003, the federal HIPAA privacy rule has required that medical information about a person be kept confidential. It cannot be shared with anyone who is not authorized to get a patient's information.

"Somehow your medical records got faxed to a complete stranger. He has no idea what's wrong with you either."

A main purpose of HIPAA was to improve security when health information is transmitted electronically. This includes transfer of information from one doctor to another or from a hospital to an insurance company. HIPAA also requires that patients grant written approval before their health information is shared with others, like an insurance company or a researcher.

Before a health care institution shares records, patients need to sign a HIPAA authorization form. There are penalties for violating the rule. Also, when information about a patient is disclosed by accident, the law requires that the patient be informed.

In chart review studies, researchers may request a "HIPAA waiver" from the IRB, if the study would otherwise be difficult or impossible. If the waiver is granted, researchers do not need to contact each individual in the research study to obtain a signed HIPAA authorization form.

When is a HIPAA waiver granted?

If the researcher is not proposing to contact any patients, but only to review their medical charts for research using strict standards of confidentiality, the researcher can apply for a HIPAA waiver. In the application, the researcher must:

1. Describe the type of health information that will be used for the study.
2. Describe how the health information and the patients' identity will be protected from improper use and disclosure.
3. Explain how information will be destroyed at the earliest possible opportunity OR justify why health information that is linked to a certain person must be saved for future research.
4. Describe why the research would not be possible without the waiver. For example, it may be impractical or too expensive to contact the large number of people required for a study, and people who have moved may be difficult to find.

Is my medical record used for other purposes?

Health care providers use medical records for many purposes - we will only discuss research use. However, it is important to know that medical charts may be reviewed in order to improve the safety or quality of clinical services. For these uses, no informed consent or HIPAA authorization is required, and Minnesota Research Authorization does not apply.

Minnesota Research Authorization

In addition to the federal HIPAA privacy rule, Minnesota has a special privacy law for research with medical records. Since 1997, no one's medical information can be used for research purposes without his or her authorization. To our knowledge, no other state has a similar law about the use of medical records for research.

Protecting patient confidentiality is very important to the REP. All providers participating in the REP ask their patients to sign a Minnesota Research Authorization form at the time of their first visit. Some providers mail these forms to the homes of new patients. Some clinics ask the patients to sign the forms when they check in for their first visit.

The REP electronically links these responses with patients' names and addresses. If a person has said "no" on the Minnesota Research Authorization form, that person's medical record cannot be used for research. This means that a researcher cannot access any piece of information from that medical record, whether it is a paper record or whether it is electronically available through a computer system.

In Olmsted County, 93% of Mayo Clinic patients and 95% of OMC patients have authorized the use of their medical records for research.

How does Minnesota Research Authorization work?

Authorization forms contain "yes" and "no" check boxes. If a patient checks the "no" box, that patient's medical record at that institution may not be used for chart review studies.

If a patient doesn't fill out a Minnesota Research Authorization form, he or she must be asked a second time to fill out the form. According to the law, if the form is not signed after the second request, the patient's record can be used for research. At the back of this booklet you will find copies of the forms used by OMC and Mayo Clinic.

Can patients change their minds?

Health care institutions that work with the REP store patient decisions about Minnesota Research Authorization in their computer systems. A patient may change his or her mind. He or she may contact his or her health care institution at any time to change his or her response on the Authorization form.

Children and Minnesota Research Authorization

Parents or guardians sign for children. When children turn 18, they are asked to sign their own Minnesota Research Authorization forms. While the majority of diseases studied using the REP affect the elderly, some important discoveries have been made due to the inclusion of children in the REP. For example, one REP study found that if a mother needs anesthesia during a Cesarean delivery (C-section), this will not make the baby more likely to develop learning disabilities. Previously, there was concern about this.

When does Minnesota Research Authorization not apply?

This law applies primarily to chart review studies. Researchers may still invite a patient to participate in a special study that focuses on a specific disease, even if he or she refused the general research authorization. For example, a patient diagnosed with ovarian cancer may be invited to participate in a study of a new treatment. The reason for this exception is that people might want to participate in research about a specific disease that affects them or their relatives.

Some health care providers may interpret these rules more strictly. If a patient has said "no" to research authorization, these providers may not allow researchers to invite their patients to participate in any research.

Informed consent

The informed consent process is the primary way IRBs make certain that people understand what is involved in a study.

Listed below are the components of informed consent:

- The person must have the ability to consent. A person suffering from a condition that doesn't allow him or her to understand what is being proposed is incapable of providing informed consent. Severe Alzheimer disease is an example.

- Consent must be given voluntarily, without pressure from the researcher.

- The person must have all the relevant information. The person must be told the purpose of the

research, what will happen to him or her, the risks, any costs, and what potential benefits might result from the research. The person must be told about how his or her information will be kept confidential.

With this information, a person can make a decision to participate or not based on his or her own needs, values, and interests.

The REP and informed consent

Informed consent is not required for use of already existing information (like chart review studies). Consent is usually required when new information will be collected. For existing information, the Minnesota Research Authorization law applies.

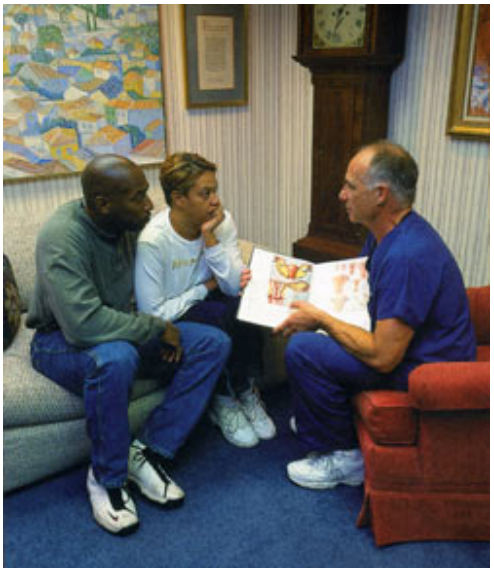
Because REP chart review studies use information that has already been collected, informed consent is not required. For REP research that uses existing information, only the Minnesota Research Authorization is required.

For surveys and special studies, the requirements are different. If researchers need to collect new information that is not already in the medical record, the researcher must ask participants for their consent. For example, a researcher might want to find patients with diabetes and have them give information about their exercise habits and a blood sample. The researcher could use the REP to find patients who have diabetes, but then these patients would need to give informed consent before the researcher could collect the additional information and collect blood.

If additional information is collected with a survey, the informed consent information usually is included with the survey itself.

Consent is more than just a form

The informed consent process is meant to ensure that patients understand what they are agreeing to when participating in research, including potential risks and benefits. It often involves a conversation with a researcher before signing the consent form. It is important that research participants have a chance to ask questions.



Legally, consent does not always require a form or a signature on a piece of paper. For example, consent for a telephone survey can be obtained verbally during a phone conversation.

Problems with consent

Some people are frustrated with the informed consent process. Consent forms are often long and complicated, and many patients find them confusing or overly time-consuming. Some patients may miss important details because they are overwhelmed by all the information. Other patients may feel pressure to sign the forms because they are used to following their doctor's instructions.

Can consent be withdrawn?

Participants can withdraw consent to participate in research at any time.

Comparing informed consent and research authorization

The Minnesota research authorization law requires health care providers to ask patients about using their records for research generally. If a patient authorizes access, then often that is the last time that a patient is asked about whether it is OK to use medical records for research. If a researcher wants to contact people later to respond to a survey or do something else (like have a blood test) for research, then the person will be notified and asked to consent to that specific survey or study.

How are privacy and confidentiality protected?

Often, people want to keep information about their health private. They want to have control over who has access to personal details. Privacy is important for you as an individual and also for you as a member of a group.

We explained the HIPAA privacy rule and the Minnesota Research Authorization earlier in this booklet. Even before these laws were passed, both OMC and Mayo Clinic had strict privacy and confidentiality rules in place.

Sometimes rules that are intended to protect individual privacy create obstacles for researchers. Good and accurate medical research requires that the majority of people living in a community participate.

A recent example from the REP helps explain why. If men who experience urinary incontinence (leaking) after prostate cancer surgery refuse authorization due to embarrassment, then researchers might not learn that this is a common side effect. Therefore, it is important to find the right balance between privacy protection and research that can benefit the community.

Protecting medical record information by removing identifiable information

One way of protecting privacy is to remove all "identifiers" from patient information. Identifiers are pieces of information that reveal who a person is, such as names, birth dates, and addresses. Some researchers collect data using these identifiers, and later strip all identifying information from the collected data. This process is known as "de-identification."

For example, data are often collected in the format shown in the table below. (The examples below do not use real names.)

Last name	First name	Sex	Date of birth	Date of diagnosis
Peterson	Andrew	Male	10/21/1945	11/30/1992
Anderson	Jane	Female	02/17/1930	01/25/1987
Johnson	Michele	Female	06/05/1937	07/27/1990
Smith	Harry	Male	05/22/1940	03/09/1997

The process of de-identification would result in the table below:

Patient number	Sex	Age in 1990	Month disease was diagnosed
1	Male	45	11/1992
2	Female	60	01/1987
3	Female	53	07/1990
4	Male	50	03/1997

Patient identifiers are part of the medical record at all health care institutions. The REP uses these patient identifiers to link together medical records from multiple health care institutions. It is crucial that the links be correct.

In other types of medical records research, patient confidentiality is protected by removing all identifiers. This is not possible in the REP because it combines information from many medical records. That is the purpose of the REP and why it is different from other research.

Are paper or electronic records safer?

Some people believe that electronic health records create additional risk to confidentiality when compared with traditional paper medical records. Paper records can be locked up in file cabinets, in a locked room, etc. By contrast, electronic files seem to be more vulnerable to abuse.

VS.

Other people insist that electronic data can be protected to a much higher standard than any traditional method. One can add multiple passwords, security systems, and electronic tracking. It is easy to monitor electronic systems; it is harder to monitor the use of paper records.

"Group harms"

Groups of people may also be affected by disclosure of information. For example, if research looks at the rate of mental illness or alcoholism in a certain ethnic group, the entire group might be stigmatized. How to prevent harms to groups is an important consideration when debating how to govern the REP.

Informed consent is helpful when the potential harm is to a particular person. When a research project has implications for a group of people, or for an entire county, simply asking individuals may not be enough to make certain no one is harmed.

The REP has not experienced examples of group harms in the past, but community guidance for future research is needed.

REP data protection practices

The role of the Minnesota Research Authorization

As described before, each health care provider keeps careful records of which patients have said yes to research use of their medical record. This information is stored electronically with the record.

Some people may say "yes" at some health care institutions, but "no" at others. For example, if patients agree to have their OMC medical records used for research, but not their Mayo Clinic records, then a REP researcher can use the OMC records, but cannot use any information in the Mayo Clinic records.

IRBs have a role in protecting confidentiality

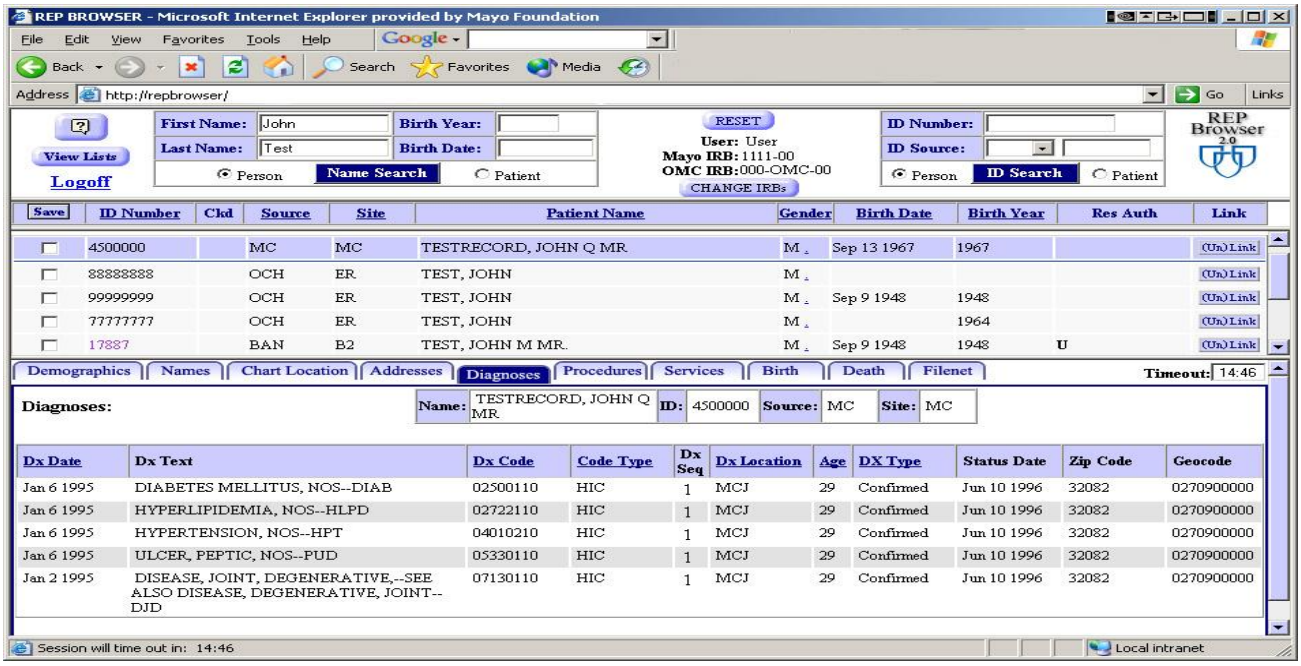
All researchers who wish to do a REP research study must receive approval from both Mayo Clinic and OMC IRBs (page 9). Every year, a researcher must submit a progress report and say whether he or she needs further time to complete the study. If the IRB approves the progress report, the researcher can continue to look at the medical record information.

REP training

Once researchers have received IRB approval from both OMC and Mayo Clinic, they must meet with REP staff for training sessions. During the training, the researchers are taught how to conduct a REP study, how information is tracked and documented, and how to use REP computer tools.

Security of REP data

The REP puts significant financial resources and effort into making sure that patient information is kept secure and that the confidentiality of data is maintained. Access to REP data is strictly controlled. Only personnel who have permission may use the medical records. The IRBs review the study to ensure that safeguards are in place to protect study participants. Once a researcher has final approval from the IRBs, he or she is given access to REP computer tools.



The REP Browser

The primary REP computer tool is called the "REP Browser." It allows researchers to see how many medical records a patient has and where those records are stored. This secure tool allows researchers to make lists of the medical records they need to review for their studies. The REP computer tools automatically block access to medical records where patients have said "no" to Minnesota Research Authorization. In addition, the computer tools track the researcher's unique username and password, and the two IRB numbers of the study (OMC and Mayo Clinic). This tracking system allows REP staff to determine which patient records were used for a specific study by a researcher.

In addition, patient information is locked behind several security layers and computer firewalls. The full REP database is only accessible to a small number of REP technical personnel. A special password is required. Passwords must be changed regularly.

Access to data is tracked for both researchers doing studies and REP staff who maintain the database. Each time a medical record is used, the REP electronically stores the time, the person who viewed the record, and the study title. This allows the REP staff to monitor any improper use. It is possible to determine which records were viewed by which researchers for which studies. This tracking system also makes it possible for individual patients to ask whether their records have ever been viewed for a research study.

What happens if a REP researcher looks at a friend or neighbor's medical record for a research study?

Since the REP is currently based in a single county in Southeast Minnesota, this increases the probability that a patient, researcher, or REP staff member has close ties with other community members. If an individual's medical history is accidentally "leaked," this could deeply affect his or her relationships, increasing the likelihood of prejudice or stigmatization.

Therefore, all people who work on research studies are required to complete training programs about protecting people who participate in research. For example, at Mayo Clinic the program is called "Protecting Human Research Participants Training." This program emphasizes that everyone who works on a research study is responsible for protecting the privacy of the people in the study, and for keeping all data completely confidential. Researchers must never disclose patient information to anyone who is not part of the study team, and all identifiable information must be carefully protected and stored securely.

Sometimes, a nurse or a researcher might be asked to review a medical record of someone they know personally, for example their child's teacher or their pastor. Researchers have been trained to make a careful decision about whether they should look at the record. If they decide they should not, they can ask another researcher to get the data for the study. They must maintain the confidentiality of the information, even if all they know is that they were asked to look at a record and declined.

What are the consequences of medical data misuse?

For the past three decades, the federal government has established many rules to protect human participants in research. The IRB is one example. The goal of these laws and rules is to minimize harm to people who participate in research. IRBs are asked to balance the risk to an individual versus benefit to society of research participation.

REP leadership understands that a person may be "wronged" by disclosure of information even if he or she is not "harmed" in any physical way. Violating the privacy of one's medical record, for example if a neighbor inadvertently finds out about a confidential matter, is a different sort of "harm" than a bad response to an experimental drug.

Some people fear that they won't have jobs or insurance if employers and

insurers find out sensitive medical information, such as mental illness or drug abuse. Because the REP is a research activity, it never releases information to insurance companies or other clinics. Although rare, it is possible that a court of law may issue a subpoena for information in a research database.

What are the penalties when confidentiality is violated?

There are serious consequences for unauthorized use or disclosure of patients' medical information. The people who work most extensively with REP information are employees of either OMC or Mayo Clinic. Both organizations have very strict policies about who may look at another person's medical records.

All use of medical records for both regular clinical care and for research is carefully monitored. There are examples of employees being fired because they looked at a medical record for personal curiosity rather than because of a professional need. Also, if information is disclosed inappropriately, health care organizations like OMC and Mayo Clinic may be disciplined or fined by the federal or state government.

Federal law requires that all patients be notified if their information is accidently or inappropriately shared with someone who should not have it.

What about researchers from outside?

Sometimes researchers who do not work for OMC or Mayo Clinic are allowed permission to use the REP for research. First, the proposal must be approved by the REP Steering Committee. Second, the researcher must secure a sponsor, generally another researcher from Mayo Clinic. Third, he or she must formally apply for "Research Collaborator" status at Mayo Clinic. A committee at Mayo Clinic reviews the researcher's credentials to make sure he or she is qualified to conduct the planned study. A background check is required. Once approved, outside

researchers must follow the same steps as any applicant to use the REP.

Should Olmsted County residents be concerned about the security of health records?

No security system is fool-proof. Several recent "high profile" examples of data loss remind us of this fact. One widely reported example is the theft of a laptop from a Veterans Administration (VA) employee. This laptop included personal information from 26.5 million veterans and military personnel. Another example occurred this year at Stanford University Medical Center. A large database, including information about all patients who had received care in the hospital emergency room, was posted on a public website.

Closer to home, in Minneapolis, Fairview Hospital and North Memorial Hospital issued an apology when 14,000 patient records were stolen from a laptop computer left in an employee's car. The Minneapolis hospitals required that all data stored on a computer be "encrypted," meaning that information is disguised. But the policy was violated. Human error is always a possibility.

The REP guards against such breaches of data security. Information is only stored in a central computing facility. REP employees are not allowed to download data onto laptops. Making paper copies of medical records is never allowed.

Info, info everywhere …

Privacy of health information is often hotly debated. Nevertheless, we give out our personal information every day to people we don't even know. For example, when shopping online certain pieces of information are automatically collected, stored, and redistributed, such as our names, contact information and even details of our financial information. Every time we purchase our food at the grocery store with a debit card, our personal information is stored in the grocery store's database.

Have problems occurred with REP data?

Of course, no system of data protection is perfect. There are two root causes of data misuse. First, human error will occur, although it may not lead to harm or loss of confidentiality. Second, data may be stolen for criminal purposes.

To our knowledge, in the last 47 years, no patient data have been released by mistake or misused by the REP. However, there are several other concerns that have been raised by

Olmsted County residents. Below are some specific examples:

1. A woman residing in Olmsted County received a letter of invitation to participate in a REP study. The letter was signed by a Mayo Clinic researcher. Because she receives her care from OMC, the letter was unexpected and confusing. The woman called OMC and asked for an explanation, since she could not understand why Mayo Clinic would know about her diagnosis. To avoid this type of misunderstanding, the REP encourages that letters of invitation be co-signed by researchers from both Mayo Clinic and OMC.

2. In a study about the costs of epilepsy, researchers telephoned people known to have a diagnosis of epilepsy in Olmsted County. However, a few of those called were unaware of having epilepsy. One person was concerned that the diagnosis was in the medical record and that the record was available to researchers. He stated that he had asked his doctor not to write the diagnosis in the record. (Physicians are required to include such information in the medical record.)

3. The most common situation is that a person gets invited to participate in a study, but he or she does not know his or her exact diagnosis or the name of the disease. This problem is hard to avoid in studies that require an interview or in-person clinic visit.

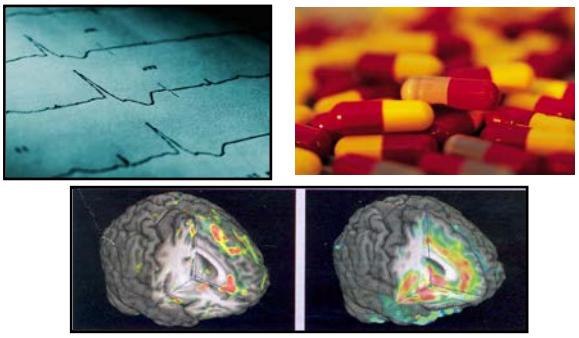
What are the plans for the REP?

Continue to maintain and build the REP

The REP has received funding from both the NIH and Mayo Clinic to continue adding new medical records to the REP system from current partners (OMC, Mayo Clinic, and the Rochester Family Medicine Clinic).

Adding new types of health data

The REP will also make some types of medical record information more easily available to researchers. In particular, it will add results of laboratory tests (such as throat cultures), procedures (such as mammograms and colonoscopies), and has recently added electronic medication prescriptions.

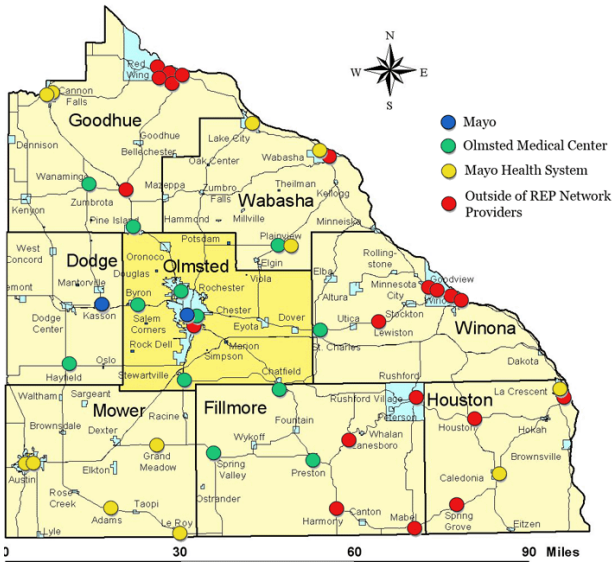


These types of information are already part of the medical record. However, it is difficult to identify people who have

received a prescription or who have had a procedure. The REP will make these pieces of information available so that it is easier for researchers to conduct studies.

Expansion of the REP population

The REP will expand its partnership to other health care providers in southeastern Minnesota. In the next five years, sites that are part of the Mayo Clinic Health System will become REP partners. Additionally, the REP is discussing collaboration with clinics in Winona and Owatonna. Including more health care providers and clinics in the REP will allow researchers to study less common diseases.



Glossary

Confidentiality: The promise made by someone, for example by your physician, that medical information will only be disclosed to authorized users at specific times of need.

Data: A collection of factual information, often in the form of numbers, that is used as a basis for reasoning or calculation. In health research data include things like age, sex, or symptoms of disease.

Data security: The processes and mechanisms used to control the disclosure of information. It is the protection of computer-based information from unauthorized access, destruction, modification, or disclosure.

Deliberation: Respectful discussion in which participants offer views, reasons and questions in an attempt to understand each other and determine agreements and disagreements.

De-identification: The process of removing information from research data or from medical records so that it can no longer link to a particular person. An example is removal of a medical record number or date of birth.

Deliberative Democracy: A form of representative democracy which involves groups of citizens who discuss and make recommendations about policy issues; an approach focused on enhancing political participation.

Electronic Medical Record: This is a computer-based record, collected over time, of a patient's medical information. It replaces the paper chart. It includes patient details, such as age, sex, disease history, physician notes, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. These records are usually kept by a hospital or physician group. It is sometimes called the Electronic Health Record.

Epidemiology: The study of how often diseases occur in different populations and why.

Governance: The policies and practices used to accomplish the management of an institution or project.

Health Information Portability and Accountability Act (HIPAA): Also, known as the "HIPAA privacy rule," this 2003 federal law established standards for data security of electronic health information and for sharing of personal health information.

Informed Consent: The process of informing a patient of the nature of a research study and the potential risks and benefits of being involved.

Institutional Review Board (IRB): A committee that performs ethical review of research with human subjects. Committees must meet standards set by the Office of Human Research Protections, part of the Department of Health and Human Services. When the IRB is not satisfied that the protocol meets established ethical standards, it can prevent the research from starting or, where concerns arise in relation to ongoing research, from continuing.

Mayo Clinic Health System: The health system is a regional network of clinics and hospitals dedicated to serving the health needs of people in 70 counties throughout Iowa, Minnesota, and Wisconsin. Many of the clinics provide primary care.

Minnesota Research Authorization: A state-wide policy that requires institutions engaging in medical records research to request permission from patients prior to using their records.

Population-based research: Research that includes all of the inhabitants of a given geographic area, like a country or city, as a group.

Population health: The measures of health, including lack of disease, longevity and other factors, across the members of a group.

Privacy: The claim of an individual to decide what information about himself or herself should be known by others.

REP: The Rochester Epidemiology Project, created in 1966, is a research collaboration among the Olmsted Medical Center, the Mayo Clinic, the Rochester Family Medicine Clinic, and other medical care providers in Olmsted County, MN.

Stigmatization: To characterize or brand as disgraceful or undesirable. Many diseases carry stigma, such as AIDS, tuberculosis, or mental illness. The specific conditions that are stigmatized change over time.