CASE STUDY 1

A hospital’s nutritionist is consulted and asked to develop a dietary plan for an 83-year-old man. Before visiting the patient, the nutritionist looks at his electronic medical record (EMR).

QUESTIONS

1. Should the nutritionist have access to the EMR?
2. If so, why?
3. Should the nutritionist have access to the entire record or just portions of it?
4. If the nutritionist had not been consulted, should he have access to the EMR?

DISCUSSION

Hospitals, clinics and physicians’ offices collect, use and store personal health information (PHI) to provide direct health care services to patients. PHI may be stored on paper or digitally. As no one health care profession provides complete care, others involved in direct care need information to diagnose, treat or care for the patient. The nutritionist must have access to PHI to develop a dietary plan, because, for example, the patient’s ability to swallow may be compromised because of a medical condition. Therefore, Principle 8 of the CMA’s Principles for the Protection of Patients’ Personal Health Information (privacy principles) is applicable, as the nutritionist needs to know details of the patient’s medical condition: “The use or disclosure of patient information within the ‘circle of care’ should be done solely on a need-to-know basis.”

Need to know is understood to mean that access to the PHI is necessary to conduct one’s professional duties. Even if one has all the necessary official approvals (such as a security clearance) to access certain information, one should not access PHI information unless one has a specific need for this information to provide direct care or treatment.

The nutritionist has the necessary approval and ability to access medical records or the EMR; however, if the nutritionist has not been consulted and, thus, is not providing a direct benefit to the patient, i.e., is not developing a diet plan, he has no need to access PHI, the patient’s chart or the electronic health record (EHR) or EMR. If the nutritionist accesses the chart or EMR of a patient he is not treating or caring for, he breaches the patient’s privacy rights and confidentiality has been broken.

ANSWERS

1. Should the nutritionist have access to the EMR?
   Yes.
2. Why?
   He needs access to the EMR to develop a dietary plan tailored to the patient.
3. Should access be granted to the full EMR or only portions?  
   The nutritionist should have access to the full EMR.
4. If the nutritionist had not been consulted, should he have access to the EMR?  
   No.

CASE STUDY 2

The mother of a surgeon working in a large urban hospital has requested that the treating team not disclose her diagnosis to anyone other than her husband, the surgeon’s stepfather. The surgeon is not her mother’s surrogate decision-maker, and her mother steadfastly refuses to disclose her medical condition to her surgeon-daughter. The surgeon accesses her mother’s EMR to discover the diagnosis, a list of medications and the prognosis.

QUESTIONS

PART ONE
1. Does the mother have the right to ask the health care team not to disclose PHI to her daughter?
2. Is her daughter part of the circle of care?
3. Does the daughter need to know her mother’s PHI?
4. Is there a conflict of interest and, if so, what is it?

PART TWO
1. Whose responsibility is it to ensure that only those who are part of the circle of care access PHI?
2. What obligations do the treating physicians have regarding access to the hospital’s EHR?

PART ONE DISCUSSION

When treating members of their immediate family, physicians are limited “to minor or emergency services and only when another physician is not readily available” (paragraph 20 of the CMA’s Code of Ethics). Thus, the surgeon is not and should not be involved in treating her mother and, therefore, is not providing a medical benefit (service) to her mother.

Although the surgeon believes she has a “need to know” her mother’s diagnosis, medications and prognosis, she has transgressed Principle 8 of the CMA’s privacy principles. The surgeon’s need to know is a personal need, not a professional one. She does not need to know her mother’s diagnosis to provide a health care service to her mother. She is not part of the health care team, i.e., she is not providing any “billable” services to her mother. She is not part of the circle of care, i.e., “those members of the health care team directly involved in the clinical care and management of the patient.”
The surgeon has acted both unprofessionally and unethically. Paragraph 33 of the CMA’s Code of Ethics is instructive: “Be aware of your patient’s rights with respect to the collection, use, disclosure and access to their personal health information.”

The surgeon-daughter is not respecting her mother’s right to control access to or disclosure of her PHI. In addition, the surgeon has a conflict of interest as she used a privilege of being a member of an institution and a profession (access to EHR) to further her personal interest in the status of her mother’s health. Although the surgeon may recognize this conflict of interest, she did not resolve it in her mother’s best interests. One assumes that her mother would have disclosed or allowed the health care team to disclose her PHI to her daughter if the mother considered it to be in her best interests to do so.

**ANSWERS**

**PART ONE**

1. Does the mother have the right to ask the health care team not to disclose PHI to her daughter?
   - Yes.

2. Is her daughter part of the circle of care?
   - No.

3. Does the daughter need to know her mother’s PHI?
   - No, not as a professional, as she is not a member of the circle of care.

4. Is there a conflict of interest and, if so, what is it?
   - The conflict of interest is the surgeon’s interest as a daughter in her mother’s health and care and her mother’s interest in protecting her privacy. For the daughter, there is also a conflict between upholding her professional duties and her personal interest in the health of her mother.

**PART TWO DISCUSSION**

Principle 5 of the privacy principles stipulates: “Security safeguards must be in place to protect personal health information in order to ensure that only authorized collection, use, disclosure or access occurs.”

The organization is ethically obligated to protect patients’ privacy and ensure that PHI remains confidential. PHI may be disclosed or shared to provide treatment or care or to improve quality of care. EHR systems should facilitate information sharing, which should ensure quality of care and safety. However, the organization must ensure that the electronic system is secure and mechanisms are in place to monitor access.

Principle 13 of the privacy principles states: “Patients should be informed that the treating physician cannot control access and guarantee confidentiality for an electronic health record (EHR) system.”

If the data steward is a large organization, e.g., a hospital or a clinic, the physician collecting PHI should disclose, prior to collection, if he or she is not responsible for, or in control of, the EHR/EMR. Patients should be informed whether there is an audit system in place that allows the patient to monitor access to his or her EHR.
ANSWERS

PART TWO

1. Whose responsibility is it to ensure only those who are part of the circle of care access PHI?
   The hospital is the data steward and is, therefore, responsible for monitoring access and providing security safeguards.

2. What obligations do the treating physicians have regarding access to the hospital’s EHR?
   The treating physician must ensure that patients are informed that the physician is not the data steward for the EHR/EMR. As the hospital is the data steward, it is the hospital’s responsibility to inform patients of their privacy rights. Both obligations may be discharged by posters, flyers, handouts or similar means of communication.

CASE STUDY 3

A gerontologist has contracted with a pharmaceutical company to conduct a phase-2 clinical trial of a drug for dementia. The gerontologist works at a large urban hospital, and he has a private practice. The trial has received research ethics board approval. The gerontologist has to recruit 40 participants with dementia. He asks the hospital’s medical records department to “mine” the EHR system to identify potential recruits. He also asks the staff at his private practice to check his EMR system for potential recruits. He instructs both offices to pass the list of names to the study’s research assistant (RA), who will contact patients or their substitute decision-maker to assess interest in participating in the trial.

QUESTIONS

PART ONE

1. Must this study be reviewed by a research ethics board?
2. Are researchers considered part of the circle of care?
3. Is the gerontologist’s desire to access PHI for research an example of a valid need to know?
4. Would the gerontologist be considered a third party?
5. Would the RA be considered a third party?
6. Would accessing PHI for research purposes provide a direct benefit to patients?
7. If the research team does not provide a direct benefit to the patient, would the gerontologist’s and RA’s access to PHI be for primary or secondary purposes?
8. Should researchers and/or an RA have access to PHI in the absence of the patient’s explicit consent to disclose his or her PHI?
9. Would providing the names of potential recruits to the RA constitute a breach of privacy?
10. If the clinic’s staff share contact information with the RA without the patient’s explicit consent, is patient privacy breached and confidentiality broken?

**PART TWO**  
1. What process could be followed by the hospital and the clinic that would allow contact information to be shared with the RA and the research team?  
2. Should the gerontologist contact his own patients to recruit them?

**PART ONE DISCUSSION**

Although the gerontologist may have been a member of the hospital’s treating team and is definitely a member of his patients’ care team, in this instance, he is no longer acting as member of the circle of care. He does not wish to access the EHR “to provide the patient with direct health care and treatment” (Principle 8). The gerontologist, the research assistant and any representative of the pharmaceutical company sponsoring the research are considered third parties, and their need to access PHI is for secondary purposes.

Principle 7 would apply here: “The patient’s express consent is generally required to disclose any part or all of the patient’s personal health information in response to a third party request (e.g., insurance company, patient’s lawyer) that is not directly related to the patient’s health care or treatment.”

Principle 11 also applies: “Physicians should be aware of applicable requirements before collecting, using, or disclosing personal health information for research purposes.”

Because the use of PHI (a diagnosis of dementia) stored in the hospital’s EHR is for secondary purposes, if the gerontologist, the research assistant or a representative of the sponsoring company access any identifiable health information, privacy has been breached and confidentiality broken. However, as the gerontologist wishes to recruit patients from his practice, the situation is more complex. The gerontologist and members of his office are privy to his patients’ PHI; the research assistant and the sponsor, however, are not. If, without prior express consent of the clinic’s patients, staff of the clinic share contact information with the research assistant, then privacy has been breached and confidentiality broken.

**ANSWERS**

**PART ONE**  
1. Must this study be reviewed by a research ethics board?  
   - Yes.  
2. Are researchers considered part of the circle of care?  
   - No.  
3. Is the gerontologist’s desire to access PHI for research an example of a valid need to know?  
   - No.  
4. Would the gerontologist be considered a third party?  
   - Yes.
5. Would the RA be considered a third party?
   Yes.

6. Would accessing PHI for research purposes provide a direct benefit to patients?
   No, research is undertaken to generate new knowledge, not to provide treatment. If a patient directly benefits from participating, this is a side-effect and is not the primary intent of the research study.

7. If the research team does not provide a direct benefit to the patient, would the gerontologist’s and RA’s access to PHI be for primary or secondary purposes?
   Their access is for a secondary purpose.

8. Should researchers and/or an RA have access to PHI in the absence of the patient’s explicit consent to disclose his or her PHI?
   No.

9. Would providing the names of potential recruits to the RA constitute a breach of privacy?
   Yes.

10. If the clinic’s staff share contact information with the RA without the patient’s explicit consent, is patient privacy breached and confidentiality broken?
    Yes.

**PART TWO DISCUSSION**

It is advisable to have another data custodian contact potential recruits or their surrogates to obtain consent to share PHI. There are two options for hospital patients; 1) the treating physician (or another member of the circle of care) contacts potential recruits, introduces the clinical trial and obtains consent to share contact information with the research assistant. The research assistant would then follow up with potential study participants. 2) A member of the circle of care contacts potential recruits, introduces the clinical trial and if the patient is interested in participating, the recruit is given the research assistants’ contact information.

For the patients of the clinic, a staff member who is not involved in the study should contact potential recruits, introduce the study and obtain consent to share PHI with the research assistant (or as above gives the recruit the research assistant’s contact information). A disinterested staff member — not the gerontologist — should contact the clinic’s patients so as to manage the gerontologist’s conflict of interest and ensure that patients are not unduly influenced because their physician is asking them to participate in a clinical trial.¹

**ANSWERS**

**PART TWO**

1. What process could be followed by the hospital and the clinic that would allow contact information to be shared with the RA and the research

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¹ This process should mitigate the danger of patients agreeing because they believe they will benefit from participating (the therapeutic misconception.)
Have a member of the circle of care contact the patient seeking permission to share contact information so the RA can contact them or provide the RA’s contact information so that, if interested, the patient can contact the RA.

Should the gerontologist contact his own patients to recruit them?

No, recruiting one’s patients could unduly influence their decision, as they may believe their physician is recruiting them because they would directly benefit.

CASE STUDY 4

New guidelines for treating vascular dementia have been published. Treating physicians receive a report of the findings, which references the new guidelines and includes a recommendation for follow-up with patients if deviations are identified.

A gerontologist, who is working at a large urban hospital and also has a private practice, undertakes a chart review. He asks the hospital’s medical records department and his staff to “mine” the EHR/EMR to identify patients with vascular dementia. The gerontologist reviews the records to assess whether, in light of the new standard of care, follow-up care or treatment is necessary.

QUESTIONS

PART ONE
1. Would the gerontologist be considered a member of the circle of care, justifying access to PHI on a need-to-know basis?
2. If not, why not?
3. Should this study be considered research?
4. Must a research ethics board review this study?
5. Would this use of PHI constitute a primary or secondary purpose?
6. Would the gerontologist be considered a third party?
7. Are there obligations, which if previously met, could mitigate the need to obtain a patient’s explicit consent to access his or her PHI?

QUESTIONS

PART TWO
1. Who is responsible for meeting these obligations?
2. What conflict does this situation present?
3. In cases where obligations conflict with privileges, which should prevail?
4. What are the obligations associated with this scenario?
5. What are the privileges associated with this scenario?
6. Is there an option available to the gerontologist that would allow him to access PHI for quality-assurance studies without patients’ express consent?
7. Must the gerontologist obtain express consent from his patients to review the clinic’s EMR?
8. If not, why not?
9. If his staff performs the chart review, are there any other obligations?
10. If so, what would they be?

PART ONE DISCUSSION

Privacy principles 4, 4(c), 4(f), 5, 6, 7, 8 (discussion), 11 and 13 are instructive in this case. According to Principle 8, the use or disclosure of patient information within the circle of care should be done solely on a need-to-know basis. In this instance, the hospital is custodian of the PHI and the gerontologist is not part of the circle of care. Therefore, the institution and the gerontologist may not rely on Principle 62 to justify access to PHI without the expressed consent of the patient; the gerontologist is considered a third party.

Principle 7 states: “The patient’s express consent is generally required to disclose any part or all of the patient’s personal health information in response to a third-party request (e.g., insurance company, patient’s lawyer) that is not directly related to the patient’s health care or treatment.”

The hospital and the gerontologist could invoke Principle 4: “Physicians3 play an important role in educating patients about possible consensual and non-consensual uses and disclosures that may be made with their personal health information.”

According to Principle 4, “Prior to the collection of health information, the patient should be informed through means such as websites, letters, posters, flyers or conversations that their personal health information… (c) may be used for health system planning and research… and (f) where possible, personal health information may be either deidentified or anonymized for any secondary purposes.”

As stated in the discussion section under Principle 13, “Every institution with a role to play in the EHR environment (e.g., health authorities, hospitals, clinics and governments) must play a part in educating patients and the public about the use of the EHR to store and share personal health information.”

This could lead one to believe that, once disclosure has occurred and if the patient did not object (opt out of a particular use), the hospital and gerontologist could access PHI in the EMR without express consent for this use. However, this access to and use of the hospital’s EMR is for a secondary purpose and the gerontologist is considered a third party. In addition, quality-assurance studies (such as this example case) qualify as research even though the intent is that past, present and future patients directly benefit from improved care and follow-up is included as part of the protocol.

However, the ethical obligation outlined in Principle 7 conflicts with the privilege of relying on inferred or tacit consent if patients have been informed of potential uses. A concern remains that the requisite

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2 Principle 6: “Under certain circumstances, physicians may rely on a patient’s implied informed consent to share personal health information.”

3 Where the term physician is used, it is meant to refer to the custodian of the medical record, which in the case of institutions may not be the treating physician.
disclosure did not occur, e.g., the patient did not read the poster, or that patients did not understand or know that they could refuse or how they would register a refusal.

Hence Principle 11 is operable: “Physicians should be aware of applicable requirements before collecting, using or disclosing personal health information for research purposes.”

ANSWERS

PART ONE

1. Would the gerontologist be considered a member of the circle of care, justifying access to PHI on a need-to-know basis?
   No.

2. If not, why not?
   He is not providing a medical service to the patient; the patient does not receive a direct benefit.

3. Should this study be considered research?
   Yes.

4. Must a research ethics board review this study?
   Not necessarily. Quality-assurance studies may be conducted without such approval. If publication of results is planned, this may constitute research and approval may be necessary, as most journals require proof of research ethics board approval. It is advisable to seek a waiver from the research ethics board.

5. Would this use of PHI constitute a primary or secondary purpose?
   Secondary.

6. Would the gerontologist be considered a third party?
   Yes.

7. Are there obligations, which if previously met, could mitigate the need to obtain a patient’s explicit consent to access his or her PHI?
   Yes.

PART TWO DISCUSSION

Because this use of PHI is for quality-assurance purposes, (presumably is not shared with those not a member of the circle of care) the requirement for express consent to access and use PHI for secondary purposes (research) may be waived; a waiver should be discussed with the research ethics board. In addition, if treating physicians have told their patients about the possible uses and disclosures of their PHI or that patients may opt out and are told how to do so, then this use may qualify for an exemption from the need for express consent.

The gerontologist may rely on inferred consent to review the EHR of his patients because he is part of the circle of care (Principles 6 and 8), but his patients should be aware of the possible uses he may make of their PHI (Principle 4). The intention of this quality-assurance study is to provide a direct benefit to his patients — to ensure that he provides the new standard of care and treatment.
A gerontologist who asks a member of his staff to conduct the chart review may infer that his patients understand that staff members may access their PHI for legitimate purposes — in this instance, helping to ensure that patients receive quality care. However, the gerontologist is obligated to ensure (Principle 5) that “Security safeguards [are]... in place to protect personal health information in order to ensure that only authorized collection, use, disclosure or access occurs.”

**ANSWERS**

**PART TWO**

1. **Who is responsible for meeting these obligations?**
   
The data steward is responsible.

2. **What conflict does this situation present?**
   
The conflict is between the interests of the gerontologist as a physician and those as a researcher. The other conflict is between physicians’ obligations and researchers’ privileges.

3. **In cases where obligations conflict with privileges which should prevail?**
   
Obligations should prevail.

4. **What are the obligations associated with this scenario?**
   
Maintaining confidentiality and disclosure to patients of permitted and/or potential secondary uses of their PHI without their express prior consent.

5. **What are the privileges associated with this scenario?**
   
Accessing PHI and relying on inferred consent to access PHI for secondary purposes.

6. **Is there an option available to the gerontologist that would allow him to access PHI for quality-assurances studies without patients’ express consent?**
   
Yes, having the research ethics board waive the requirement for explicit consent to access PHI for secondary purposes.

7. **Must the gerontologist obtain express consent from his patients to review the clinic’s EMR?**
   
Not necessarily.

8. **If not, why not?**
   
If patients have been informed that their PHI may be accessed for quality-assurance/standard-of-care checks, then explicit consent is not required.

9. **If his staff performs the chart review, are there any other obligations?**
   
Yes.

10. **If so, what would they be?**
    
The obligation to ensure that patients understand that staff will need to access their PHI for secondary purposes. The obligation to ensure that the clinic’s staff understand the obligation to maintain confidentiality. There is an obligation to ensure that only appropriate staff access PHI for the quality-assurance check.