

# DRUG INFORMATION, EVIDENCE-BASED MEDICINE, RESEARCH, AND HIPAA

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**Learning Objectives**

1. Differentiate between primary, secondary, and tertiary sources of information, and analyze these resources to answer questions related to clinical practice.
  2. List the pros and cons associated with primary, secondary, and tertiary sources of information.
  3. Identify commonly used primary, secondary, and tertiary literature sources.
  4. Describe the steps involved in a top-down and bottom-up evidence-based medicine (EBM) approach.
  5. Critically evaluate EBM resources.
  6. Critically evaluate clinical guidelines.
  7. Identify strategies available for seeking drug information resources on the Internet.
  8. List appropriate questions for evaluating Internet drug information websites and electronic applications.
  9. Define research and differentiate it from quality improvement activities.
  10. Define the composition, functions, and roles of the institutional review board (IRB).
  11. Define HIPAA (Health Insurance Portability and Accountability Act of 1996) regulations and their impact on clinical practice and research.
  12. Describe the various steps of the professional writing and peer-review processes.
3. An ambulatory care pharmacist is searching the Internet for appropriate diabetes education resources for one of her patients. Which is the best indicator that the website is reliable?
    - A. Health On the Net Foundation stamp of approval.
    - B. Does not give the most recent update or the authors of the articles.
    - C. References that include Wikipedia and [www.paulsdiabetesadvice.com](http://www.paulsdiabetesadvice.com).
    - D. Article that states personal opinions regarding diabetes treatment.

**Self-Assessment Questions**

*Answers and explanations to these questions may be found at the end of the chapter.*

1. Which statement best describes an example of primary literature?
  - A. A review article in *Pharmacotherapy*.
  - B. Dosing information from Lexicomp.
  - C. A study evaluating clopidogrel for the treatment of acute venous thromboembolism.
  - D. A PubMed search using the key words fluticasone furoate, vilanterol, and chronic obstructive pulmonary disease (COPD).
2. Which would NOT help you determine whether an Internet site likely contains reliable online health information?
  - A. Advertisements on the page.
  - B. Publication date.
  - C. Credentials of the author.
  - D. Publisher background.
4. A resident pharmacist in ambulatory care practice is asked by the attending physician whether any new studies have been published relative to the use of diuretics in heart failure since the most recent Cochrane review. Which is the best resource for the resident to use?
  - A. [www.guideline.gov](http://www.guideline.gov).
  - B. UpToDate.
  - C. DiPiro's *Pharmacotherapy*.
  - D. PubMed.
5. Which best describes the step in the process of evidence-based medicine (EBM) practice that includes use of the PICO (the patient problem or population, intervention, comparison, and outcome[s]) format?
  - A. Appraise.
  - B. Acquire.
  - C. Apply.
  - D. Ask.
6. Which best describes an individual who is required to be part of an institutional review board (IRB)?
  - A. Lawyer.
  - B. Individual with scientific expertise.
  - C. Patient advocate employed by the Institution.
  - D. Spiritual advisor.
7. Which best describes information that is considered protected health information (PHI)?
  - A. Town of residence.
  - B. Certificate and license numbers.
  - C. Age of a patient who is 46 years old.
  - D. State of residence.

## I. INTRODUCTION

- A. Why Do Pharmacists Need to Know About These Topics?
- B. As These Topics Pertain to You, Ambulatory Care Pharmacy Specialty Examination Content Outline
  - 1. *Domain 3*: Translation of evidence into practice (14%)
  - 2. Task statements:
    - a. Retrieve biomedical literature applicable to ambulatory care pharmacy practice
    - b. Interpret biomedical literature with respect to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions
    - c. Respond to requests for information from patients and health care professionals using evidence-based literature
    - d. Use the principles and strategies of project and research design to generate and disseminate information in ambulatory care
    - e. Enlist evidence-based strategies to effectively teach students, residents, pharmacists, and other health care professionals

## II. OVERVIEW OF DRUG INFORMATION RESOURCES

- A. Tertiary Literature
  - 1. Established knowledge or consensus of opinion; works that summarize, discuss, criticize, etc., the primary literature
  - 2. Pros
    - a. Provides an analysis and summary of the primary literature
    - b. Provides a discussion of studies that are thought to be well conceived and significant to the field
    - c. Usually easy to use; more concise, accessible, and convenient
  - 3. Cons
    - a. Significant lag time for updates – Primary literature publication outpaces tertiary literature.
    - b. Interpretation is dependent on the author's opinion, which may lead to incorrect interpretation of primary literature.
    - c. Incomplete; space limitations may exist
  - 4. Formats
    - a. Available as paper text, as CD/DVD-ROM, online, or as mobile applications (PDA [personal digital assistant], tablet, smartphone)
    - b. Electronic access online is generally considered the easiest to use, the most up to date, and the most accessible format to use from several locations.
    - c. The content of information in each format is not necessarily the same.
    - d. Mobile applications are a rapidly expanding area. The content of information for mobile applications is likely to be different from that in other formats of the same title because of storage and memory limitations.
  - 5. Evaluation of tertiary resources
    - a. Authors' experience/expertise relative to the topic; are they experts, with appropriate experience?
    - b. Is the information timely on the basis of its publication date, or is this a rapidly changing topic?
    - c. Is the conclusion of the author supported by the primary literature? And is the work properly cited?
    - d. Is the resource relevant and free of bias or blatant errors?
    - e. Quality of references used

6. Selected tertiary drug information resources for the ambulatory care clinical pharmacist
  - a. References selected are available electronically, are geared toward the health care professional, provide drug and alternative treatment monographs, and provide patient-oriented information. Many other appropriate references are available; this is only a partial list.
  - b. Clinical Pharmacology ([www.clinicalpharmacology.com](http://www.clinicalpharmacology.com))
  - c. Drug Facts and Comparisons ([www.factsandcomparisons.com](http://www.factsandcomparisons.com))
  - d. Lexicomp online ([www.lexi.com](http://www.lexi.com))
  - e. Micromedex Healthcare Series ([www.micromedex.com](http://www.micromedex.com))
    - i. Detailed Drug Information for the Consumer
    - ii. CareNotes System
  
- B. Secondary Literature
  1. Index or abstract of the primary literature and tertiary literature found in journals, with the goal of directing the user to the primary literature. Its primary purpose is to provide a rapid method for searching the primary literature and keep readers well informed on primary literature publications.
  2. Pros: Provides efficient and accessible access to the primary literature
  3. Cons
    - a. Different databases use different “vocabulary” or search strategies.
    - b. Only abstracts or citations are available; primary literature from the search must be obtained from alternative sources and is costly.
  4. Formats
    - a. Most secondary literature is electronic or in online databases.
    - b. Indexing system: Provides biographic citation information (e.g., title, author, citation)
    - c. Abstracting system: Provides biographic citation information and an abstract
  
- C. Primary Literature
  1. Original articles that have not been interpreted, condensed, or evaluated (except by peer review) by others
    - a. Research studies and reports; case studies/series published and unpublished
    - b. Review articles or editorials are not primary literature.
  2. Pros
    - a. Detailed, original articles
    - b. Direct access to the research reports and conclusions
  3. Cons
    - a. The reader must sift through methods, interpret the data and conclusions, and make decisions about the author’s conclusion.
    - b. The reader must have strong literature evaluation (e.g., statistics, clinical study) skills.
    - c. Time-consuming, both in the searching and in the evaluating

**Table 1.** Examples of Primary, Secondary, and Tertiary Literature

Primary Literature	Secondary Literature	Tertiary Literature
Original articles (randomized controlled clinical trials; nonrandomized, prospective, clinical trials; cohort studies; case-control studies; case series; and case reports)	MEDLINE EMBASE PubMed Google Scholar IDIS Journal watch LexisNexis BIOSIS IPA Cochrane Library Current Contents CINAHL	General textbooks (e.g., Pharmacotherapy, Applied Therapeutics, Briggs' Drugs in Pregnancy and Lactation, Meyler's Side Effects of Drugs) General product information (e.g., American Hospital Formulary Service, Drug Facts and Comparisons, Physicians' Desk Reference, Drug Information Handbook, Clinical Pharmacology, UpToDate) Review articles Treatment guidelines Electronic textbooks and databases (McGraw-Hill ACCESS Pharmacy, STAT!Ref, Lippincott Health Sciences Library)

CINAHL = Cumulative Index to Nursing and Allied Health Literature; IDIS = Iowa Drug Information System; IPA = International Pharmaceutical Abstracts.

### III. INTERNET SOURCES OF DRUG INFORMATION

#### A. Introduction: Use of the Internet for Drug Information

1. Currently used as a drug information tool by most U.S. adults
2. In the past decade, an increased number of U.S. adults have used the Internet for drug information.
3. Institute of Medicine: "The Internet is a bit like the Wild West: It has vast amounts of unregulated territory and no one in charge."

#### B. Search Engines

1. Basic search engines (e.g., Google, Yahoo, Bing)
  - a. Search tool that sends the user's search request to a single search engine
  - b. Examples: Google, Yahoo, Bing, ASK.com
2. Metasearch engines
  - a. A search tool that sends the user's search request to several search engines and/or databases
  - b. Examples: Dogpile, MetaCrawler, WebCrawler
3. Boolean logic: Use of Boolean operators such as and, or, and not to help narrow searches
4. MEDLINE MeSH (Medical Subject Headings) terms
  - a. Standardized vocabulary used for indexing in MEDLINE
  - b. Content filters: Specific for a drug or disease being searched. Ensures that the searcher is looking for the most appropriate content (e.g., heart failure)
  - c. Validity filters: Use to narrow the search to only the highest-quality studies (e.g., randomized controlled trials, double-blind studies).

- C. Evaluating Information on the Internet
  1. Evaluation instruments
    - a. Medication Website Assessment Tool
    - b. Health On the Net Foundation Code of Conduct
    - c. Healthcare Website Assessment Tool (HWAT 3.0)
  2. National Institutes of Health tutorial: Tutorial geared toward patients

**Table 2.** Questions to Ask When Evaluating Websites

Variable	Questions
Source of information	What and who is responsible for the site, and is this information readily available on the site? What is the purpose of the site? Why was the website created, and what is the mission in providing the information?
Cost of access	Does the site want anything from you in return? If so, what and why? Does the site want your personal information, and if so, what will the site do with it? What personal information is required? Who is funding the site? Is there a site sponsor? Is the sponsorship readily available on the website and openly displayed? Does the sponsor gain any benefit?
Quality of information	Is the information current? Is the information correct? Has it been written and/or reviewed by appropriately trained health care professionals? Is the information based on opinion or high-quality controlled clinical trials? What is the editorial policy for the site?
Usability	Does the site provide information such as a site map, contact information, a mission/purpose statement, or the best way to use the site? Does the website make unbelievable claims or claim to be the answer to all questions or problems? Does it claim to be the only one to have true insight into the issues?

Adapted from: Murphy JE, Lee MW-N, eds. Pharmacotherapy Self-Assessment Program, 8th ed. Lenexa, KS: ACCP, 2013 [information abstracted from National Library of Medicine].

#### IV. EVIDENCE-BASED CLINICAL PRACTICE

- A. Introduction to Evidence-Based Pharmacy/Medicine (EBM)
  1. EBM uses the scientific method as an important source of knowledge. In addition to the scientific method, other sources of knowledge are listed below.
    - a. Reference to tradition: Accepting certain truths or facts as givens
    - b. Reference to authority: Placing trust in those who are experts in a given area
    - c. Trial and error: Making several attempts to solve a problem by chance. Used when no other basis for making a decision is possible
    - d. Logical reasoning: Deductive reasoning
    - e. Scientific method: Applying a logical process to identify a problem, collecting data, and developing a conclusion
  2. Definitions
    - a. “The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients while integrating clinical experience with the best available evidence from a systemic search” (BMJ 1996;213:71-2)



- b. EBM is the integration of clinical expertise, patient values, and the best research evidence into the decision-making process for patient care. Clinical expertise refers to the clinician’s cumulated experience, education, and clinical skills. The patient brings to the encounter his or her own personal preferences and specific concerns, expectations, and values. The best research evidence is usually found in clinically relevant research that has been conducted using sound methodology (Sackett 2000).
- c. Process of making disease management decisions by evaluating and rating the quality of studies
- d. Criticisms of EBM
  - i. “Cookbook” or reduced clinician autonomy
  - ii. Too difficult to apply to individual patients
  - iii. Limited data to suggest that evidence-based guidelines translate to improved care
- 3. Summary of factors that influence the medical decision
  - a. Clinical evidence
  - b. Clinical experience
  - c. Patient circumstance
  - d. Patient desires
- 4. Five-step process of EBM practice
  - a. Assess the patient: Start with a question that comes from the clinical care of a patient.
  - b. Ask the question: Develop an answerable question that reflects the clinical dilemma posed. PICO format:
    - i. (P)roblem/patient/population
    - ii. (I)ntervention
    - iii. (C)omparison
    - iv. (O)utcome
  - c. Acquire the evidence: Gather and assemble the data needed to make a conclusion.
  - d. Appraise the evidence: Use literature evaluation skills to assess the quality, quantity, and applicability of the data collected.
  - e. Apply to the patient: Incorporate the evidence into clinical practice.
  - f. Act on and assess your decision.
- 5. EBM approaches
  - a. Top-down: Describes the EBM process, which requires resources and time. This approach is best suited for situations in which decisions are made about groups of patients (e.g., evidence-based guidelines).
  - b. Bottom-up: Describes the EBM process with fewer resources and limited time. This approach is best suited for individual patient decisions when resources and time are limited (e.g., day-to-day decisions that clinicians must make).

**Table 3.** Levels of Evidence Based on Several Evaluation Scales

Ranking	Type of Evidence	CEBM Scale	USPSTF Scale	ACC Scale
Highest	RCT	1 <sup>a</sup>	I	A
	Nonrandomized, prospective, CT	—	II-1	B
	Cohort studies	2 <sup>a</sup>	II-2	C
	Case-control studies	3 <sub>a</sub>	II-2	C
	Case series	4	II-3	C
Lowest	Expert opinion	5	III	—

<sup>a</sup>A systematic review of these study types ranks higher than individual studies.

ACC = American College of Cardiology; CEBM = Centre for Evidence-Based Medicine; CT = clinical trial; RCT = randomized controlled trial; USPSTF = United States Preventive Services Task Force.

From: Shumock G, Brundage DM, Chapman MM, et al., eds. Pharmacotherapy Self-Assessment Program, 5th ed. Kansas City, MO: ACCP, 2005.

**B. Evaluating Clinical Guidelines**

1. Agency for Healthcare Research and Quality
  - a. National Guidelines Clearinghouse ([www.guidelines.gov](http://www.guidelines.gov))
  - b. Allows a comparison of guidelines
2. Appraisal of Guidelines for Research and Evaluation (AGREE)
  - a. Evaluates the process of practice guideline development and the quality of reporting
  - b. [www.agreetrust.org/](http://www.agreetrust.org/)
3. Bandolier
  - a. “Evidence-based thinking about healthcare”
  - b. Independent group based in Oxford, UK
  - c. [www.medicine.ox.ac.uk/bandolier/index.html](http://www.medicine.ox.ac.uk/bandolier/index.html)

**C. Sources of Clinical Guidelines (Note: These are only examples, not a complete list.)**

1. National Library of Medicine (PubMed) ([www.pubmed.gov](http://www.pubmed.gov))
2. Agency for Healthcare Research and Quality ([www.ahrq.gov](http://www.ahrq.gov))
3. National Institute for Clinical Evidence
  - a. [www.nice.org.uk/](http://www.nice.org.uk/)
  - b. UK National Health Service
4. Cochrane Collaboration ([www.cochrane.org/](http://www.cochrane.org/))
5. Association websites
  - a. American Heart Association ([www.heart.org](http://www.heart.org))
  - b. American College of Cardiology Foundation ([www.acc.org](http://www.acc.org))
  - c. American Society of Clinical Oncology ([www.asco.org](http://www.asco.org))
  - d. American Academy of Family Physicians ([www.aafp.org](http://www.aafp.org))
  - e. The American Society of Health-System Pharmacists ([www.ashp.org/bestpractices](http://www.ashp.org/bestpractices)) provides links to best practice policies and guidelines.

**V. INSTITUTIONAL REVIEW BOARD/HUMAN SUBJECTS’ RESEARCH****A. Definitions**

1. Research: “Systematic investigation (i.e., research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge”
2. Human subject: “Living individual about whom an investigator obtains data through intervention or interaction with the individual OR identifiable private information”
3. Quality improvement versus research
  - a. In general, if the results of a project are presented outside an organization (i.e., contributes to generalized knowledge), either as a publication or a presentation, it is defined as research.
  - b. If the results of a project are to be used internally, and not meant to contribute to generalized knowledge, the activities will fall under quality improvement. Ideally, the IRB makes this decision.

**B. History and Development of Research Ethics**

1. Nuremberg Code (1948)
  - a. Subjects should give informed voluntary consent.
  - b. The benefits of research must outweigh the risks.

2. Declaration of Helsinki (1964)
  - a. Governs international research ethics
  - b. Defines rules for “research combined with clinical care” and “nontherapeutic research”
  - c. Basis for good clinical practices used today
3. Tuskegee Syphilis Study (1972)
  - a. The study did not minimize risks to human subjects. In fact, it increased their risks.
  - b. These issues heightened awareness of the need to protect human subjects and to ensure their informed voluntary consent.
4. Belmont Report (1978): Prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
  - a. Summarizes the basic ethical principles identified in its deliberations
  - b. Serves as a statement of basic ethical principles and guidelines that assist in resolving the ethical problems that surround the conduct of research with human subjects
5. Code of Federal Regulations (CFR) (1981): The Department of Health and Human Services (DHHS) and the U.S. Food and Drug Administration (FDA) issued regulations according to the Belmont Report:
  - a. DHHS: CFR Title 45 (public welfare), Part 46 (protection of human subjects)
  - b. FDA: CFR Title 21 (food and drugs), Parts 50 (protection of human subjects) and 56 (IRBs)
6. Common Rule (1991)
  - a. Obtaining and documenting informed consent
  - b. IRB membership, function, operations, review of research, and recordkeeping
  - c. Additional protections for certain vulnerable research subjects: Pregnant women, prisoners, children, individuals with impaired capacity
  - d. Ensuring compliance by research institutions
    - i. All institutions that conduct federally sponsored research must provide the federal government an “assurance” that states the institution’s principles for protecting the rights and welfare of human subjects.
    - ii. Multiple project assurance is the most common approach to this.
7. IRB review of studies: Reviewed at one of three levels, depending on the level of risk to the human subjects. These are the federal guidelines that define the categories of review, which are as follows:
  - a. Exemption from full IRB review
    - i. Categories
      - (a) Research conducted in established or commonly accepted educational settings
      - (b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior
      - (c) Research involving the collection or study of existing data, documents, records, pathologic specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects
      - (d) Research and demonstration projects that are conducted by or subject to the approval of department or agency heads
    - ii. Projects are not assigned an expiration date.
    - iii. The IRB makes the final decision on exemption; a staff member usually reviews the proposal.
    - iv. Review usually takes a few days.
  - b. Expedited IRB review
    - i. Minimal risk to participant
    - ii. Minor change to previously approved study
    - iii. Chairperson or designee reviews the proposal.
    - iv. Review usually takes a few weeks.

- c. Full IRB review: More than minimal risk
  - i. Review protocol and supporting documents.
  - ii. Lengthy process, usually months
  - iii. Full IRB reviews the proposal.

**Table 4.** Examples of IRB Review Categories

Type of Review	Examples
Exemption from review	Epidemiologic study with NHANES data Study of changes in the number of days requiring antibiotics, using de-identified institutional data
Expedited review	Cross-sectional study of patients with heart failure measuring a biomarker, requiring a single blood sample Case-control study of the relationship between admission to the hospital and drug use
Full review	Randomized controlled trial of a new drug or device for heart failure therapy Cross-sectional study requiring bronchoscopy after administration of methacholine

IRB = institutional review board; NHANES = National Health and Nutrition Examination Survey.

8. IRB composition

- a. At least five members
  - i. Chairperson
  - ii. Scientific member
  - iii. Nonscientific member
  - iv. Layperson unaffiliated with the institution
  - v. Practitioner
- b. Sufficient qualifications through the experience, expertise, and diversity of its members and backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects
- c. Membership must be able to ensure protection of vulnerable populations.
- d. Membership must come from more than one profession.

9. Informed consent

- a. Informed consent is a process, not a form. Information must be presented to the individual (or representative) to enable that person to make a voluntary decision to participate as a research subject.
- b. Components
  - i. Description of any reasonably foreseeable risks or discomforts
  - ii. Description of any benefits to the subject or to others that may reasonably be expected
  - iii. Disclosure of appropriate alternative procedures or courses of treatment, if any
  - iv. Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
  - v. For research involving more than minimal risk, an explanation about whether any compensation, and an explanation about whether any medical treatments, will be available if injury occurs
  - vi. Contact information for answers to questions about the research and research subjects' rights; whom to contact if the subject has a research-related injury
  - vii. A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits, and the subject may discontinue participation at any time without penalty

- c. Waiver or alteration of consent: An IRB may waive/alter informed consent if the following are met:
  - i. No more than minimal risk
  - ii. Will not adversely affect the rights and welfare of the subjects
  - iii. The research could not practicably be carried out without waiver.
  - iv. Subjects will be provided additional pertinent information after participation.
- d. An IRB may also waive informed consent in a limited class of research in emergency settings.

## VI. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)

- A. Health Care Access, Portability, and Renewability (Title I): Ensures that individuals moving from one health plan to another or to another type of health plan (individual vs. group) will have continuity of coverage and will not be denied coverage under preexisting condition clauses or other reasons
- B. Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform (Title II)
  - 1. Privacy rule
  - 2. Transactions and code set rules: Simplify transactions.
  - 3. Security rule: Administrative, physical, and technical standards
  - 4. Enforcement rule: Increases the federal government's fraud enforcement authority in many areas
  - 5. Unique Identifiers Rule (National Provider Identifier)
- C. Sets a National Standard for Accessing and Handling Medical Information. Privacy is now the law rather than an ethical issue.
- D. Covered Entities
  - 1. Health care providers who conduct certain financial and administrative transactions (billing, fund transfers) electronically
  - 2. Health plans and health care clearinghouses
- E. Protected Health Information (PHI): 18 identifiers
  - 1. Name
  - 2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, and zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if one of the following applies according to the current publicly available data from the Bureau of the Census:
    - a. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and
    - b. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
  - 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death; and all ages older than 89 years and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 years or older
  - 4. Telephone numbers
  - 5. Fax numbers
  - 6. Electronic mail addresses
  - 7. Social Security numbers

8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate and license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Medical device identifiers and serial numbers
14. Internet universal resource locators
15. Internet protocol (IP) addresses
16. Biometric identifiers (fingerprints and voiceprints)
17. Full-face photographic images and comparable images
18. Any other unique identifying number, characteristic, or code (may assign a code for de-identified information to be re-identified)

F. Business Associates Agreement

1. PHI belongs to the covered entity, but another person (nonemployee hospital health care personnel providing service to the covered entity) is using or disclosing the PHI to perform a function or activity on behalf of the covered entity
2. Providing services to the covered entity if the provision of the service involves the disclosure of PHI to the service provider

G. Patient Information

1. Patients must be notified if their health information is used and disclosed, and they must be notified of their right to privacy under HIPAA.
2. Usually, by a Notice of Privacy Practices (letter or brochure)

H. Responsibilities as a Health Care Provider

1. If you use or share health information that is not work related, you could be subject to disciplinary action (loss of privileges, dismissal) or civil and/or criminal penalties.
2. You can share patient information for work-related reasons.
  - a. Treatment: Provide, coordinate, manage health or related services; consultations; referral
  - b. Payment: Obtain payment or reimbursement for providing health care services: Determining eligibility, adjusting insurance rates, handling billing and claims management, handling collections, handling preauthorizations, and determining medical necessity
  - c. Health care operations – Things that we do to run and that improve our business
  - d. Authorized by the patient: If patients give permission to use or disclose their PHI, we can share the minimum amount of information necessary to accomplish our purpose.
3. Day-to-day activities
  - a. Be mindful of bulletin boards, white boards, desks, computer monitors without privacy screens, etc.
  - b. Discussions with patients/families: Draw curtain, speak quietly; find an empty room or other private area.
  - c. Do not discuss what you see and hear at work or in places such as hallways or elevators.
  - d. Use shredders or place in HIPAA-compliant locked recycling bins. Do not place in garbage or unlocked bins.
  - e. Printers and fax machines should be in appropriate locations. Many fax machines and copiers have hard drives.
  - f. Do not share user accounts when PHI is accessible (or ever).
  - g. Electronic mail is usually not secure; encryption and password protection varies by organization.
  - h. Cloud-based storage locations: Dropbox, Dox, Google, etc. Check with your institution. Smartphones, USB storage drives, laptops, and tablets: Major concerns for privacy

I. Research/Quality Improvement Under HIPAA

1. Research: Approved by the IRB
  - a. HIPAA authorization: Permission from individuals to use their PHI. Certain statements are required on the informed consent. Some statements depend on local IRB requirements.
  - b. De-identified data
  - c. Limited data sets
2. If you are reviewing a patient record for anything other than a need to know the basis for the care of a patient, you need to determine whether it is quality improvement or research and take the appropriate action.
3. Quality improvement: Work with internal committees. For example, a review of adverse drug reactions usually takes place under the authority of the pharmacy and therapeutics committee (a medical staff–authorized quality improvement activity).

J. Penalties for Violations

1. Civil penalties: Accidental disclosure: \$100/person/violation, up to \$25,000 per year
2. Criminal penalties
  - a. Knowing misuse of information: \$50,000 and 1 year in jail
  - b. False pretenses: \$100,000 and 5 years in jail
  - c. Harmful intent, sell information: \$250,000 and 10 years in jail

K. Health Information Technology for Economic and Clinical Health Act (HITECH Act)

1. Title XIII of the American Recovery and Reinvestment Act of 2009
2. Purpose is to promote and expand the adoption of health information technology.
3. Anticipates the increase in electronic transactions of PHI, thus increasing the scope of privacy and security protections
4. Civil penalties for willful neglect up to \$250,000 with repeat or uncorrected up to \$1.5 million
  - a. Breach notification: Notify patient of all breaches.
  - b. Breach notification: Notify DHHS and the media if there are greater than 500 patients.
5. If provider has an electronic health record system, individuals may obtain their PHI electronically (ePHI); the individual can also designate a third party to receive the ePHI.

## VII. PROFESSIONAL WRITING: THE PUBLICATION PROCESS

A. Primary Literature

1. Experimental studies
2. Observational studies
3. Descriptive reports

B. Publication Process

1. Journal selection
  - a. Topic
  - b. Journal quality
    - i. Impact factor
    - ii. Immediacy index
  - c. Open access

2. Preparation of submission: Paper parts
  - a. Title page
  - b. Abstract
  - c. Introduction/background
  - d. Methods
  - e. Results
  - f. Discussion
3. Editorial and peer review
  - a. Types of reviews
    - i. Single-blind review: The reviewer's identity is hidden from the author, but the reviewer knows the author.
    - ii. Double-blind review: Both reviewer and author are blinded.
    - iii. Open review: Reviewer and author are known to each other.
    - iv. Published review: Reviewers' comments are published together with the paper.
  - b. Role of reviewer
    - i. Does the scientific content have value and originality?
    - ii. Is the paper consistent with journal guidelines?
    - iii. Are the methods appropriate?
    - iv. What changes should be made or additional experiments conducted?
    - v. Make a recommendation (accept, revise, reject) to the editor.
4. Revision process
5. Poor-quality research: Why?
  - a. Academic scientists need to publish.
  - b. Poor training or investigators/writers
  - c. Lack of reviewers with sufficient knowledge or time to review
  - d. Least publishable unit: Several publications from same study
  - e. Other influences
    - i. Current political issues and hot topics
    - ii. Industry
      - (a) Design and funding of studies
      - (b) Comments during publication stage
      - (c) Ghost writers
      - (d) Promotional activities



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**ANSWERS AND EXPLANATIONS TO SELF-ASSESSMENT QUESTIONS****1. Answer: C**

Answers A and B, a review article in *Pharmacotherapy* and dosing information from Lexicomp, are examples of tertiary literature, one printed and one electronic. Answer D, a PubMed search using the key words fluticasone furoate, vilanterol, and COPD, is an example of secondary literature. Answer C, a study evaluating clopidogrel for the treatment of acute venous thromboembolism, is correct.

**2. Answer: B**

Although advertisements (Item A is correct) do not always indicate an unreliable Web site, each of the other distractors is a reasonable indicator that some attention is being paid to the content.

**3. Answer: A**

The responses in Answers B–D should all be viewed with skepticism when reviewing a website. The Health On the Net Foundation seal of approval (Answer A) is an external tool that is useful in assessing the quality of a website.

**4. Answer: D**

Answer A would provide the most up-to-date guideline and a tertiary source, but using it would likely take the longest time when incorporating the most recent studies. Answers B and C, UpToDate and *Pharmacotherapy*, respectively, are both tertiary sources, and although they would include studies, they would not provide the most recent new evidence for this condition because the chapter and review article would both have a time delay between writing and publication. Answer D, PubMed, would allow the searching of the primary literature to locate the most recent studies in this area.

**5. Answer: D**

The PICO format is associated with the ASK step of the five-step EBM process. Each of the other options is associated with one of the other steps in the process.

**6. Answer: B**

Federal law guidance for IRB membership simply states that membership must contain a chairperson, a scientific member, a nonscientific member (Item B is correct), a layperson unaffiliated with the institution,

and a practitioner. There is no requirement for the others indicated.

**7. Answer: B**

Eighteen items are identified as PHI in federal law. A town (Item A) or state (Item D) of residence is not one of them and are incorrect. Similarly, the age of a patient (Item C) (unless > 90) is not PHI