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Report X

Contemporary Issues In Medicine: Education In Safe and Effective Prescribing Practices

Medical School Objectives Project

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July 2008

Association of
American Medical Colleges

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I. Introduction

The practicing physician in the 21st century is faced with many challenges. Among these is the difficult task of safely and effectively prescribing medications given the more specialized and powerful pharmaceutical armamentarium available today. In addition, the promise of personalized medicine and the growing recognition of patient variability in preferences, risk tolerance, and response to treatment require that the modern prescriber possess a new set of skills. As newer medications have become more "powerful" (often more effective, and sometimes more toxic), the clinical skills of making an accurate diagnosis, and individualizing drug treatment to fit the specific patient being treated, are becoming even more crucial.

Concern about medical students graduating without adequate training in therapeutics is not new. In 1903, the president of the American Therapeutic Society, Dr. Reynold W. Wilcox, expressed great concern about suboptimal education in clinical pharmacology and therapeutics in U.S. medical schools. During his presidential address, he stated that "…the day had come when something more is demanded of the practitioner or physician-consultant than a diagnosis…our obligation will not be satisfied until general principles have been fitted to the particular patient. The question is: How shall we teach the medical student so that he shall be best fitted to become a useful practitioner?"[1]

During the last 30 years or so, numerous clinical pharmacologists, basic pharmacologists, and other educators have stressed the importance of ensuring that all medical school graduates possess the attributes and qualities of a thoughtful, safe, and effective prescriber. A variety of suggestions have been put forward concerning what a core curriculum should contain, how such courses could be structured, and optimal times to teach such material to medical students. [2-18]

Prescribing medications for nearly any indication is one activity that distinguishes a physician from other health care professionals and is a privilege that carries serious responsibilities to patients, society, and the profession. For these reasons, it is important that medical students begin to understand all that is involved in becoming a safe and effective prescriber of pharmaceuticals (and related substances such as biologic vaccines or nutraceutical agents) before they become physicians and reach a pivotal event in their professional lives: the ability to prescribe independently, on their first day of residency training.

According to current tenets of U.S. consumer law, most consumer product manufacturers are legally responsible for informing the consumer of the risks associated with the use of their products. However, the pharmaceutical companies that develop, manufacture, and market prescription drugs rely on physicians to be their "learned intermediaries" in helping patients understand the risks associated with the use of their drug products. This, too, places a large responsibility on the shoulders of the young intern who writes his or her first prescription, without the need to have it cosigned.

The safe and effective prescribing of medications has been an ongoing topic of tremendous importance to those concerned with physician education. The report of the Institute of Medicine's Committee on Quality of Health Care in America, *To Err is Human*[19], issued in 1999, detailed concerns about the quality of American health care, including errors in interpreting laboratory tests and prescribing and medical errors.

The Association of American Medical Colleges (AAMC) has a longstanding interest in the quality of medical student education and patient care. In 2005, the AAMC and the U.S. Food and Drug Administration (FDA) convened a conference titled, *Drug Development Science: Obstacles and Opportunities for Collaboration.*[20] Conference participants agreed that too few physician (and veterinary) scientists with deep understanding of human diseases and drug intervention are being trained to lead necessary research initiatives in both the public and private sectors. Equally of concern, however, was a consensus that graduating medical students, residents in training, and practicing physicians lacked fundamental understanding and training in pharmacotherapy and rational prescribing. Participants felt that the situation would only grow more dire as the genomic revolution made personalized medicine a reality, and as more powerful and narrowly targeted therapeutics reach the market.

Pharmacology faculty, clerkship directors, residency program directors, and physicians in the pharmaceutical industry have expressed increasing concern that medical students are not

receiving sufficient education in prescribing. Specific concerns include a lack of knowledge about the process of drug discovery, clinical research, product development, regulation, and the knowledge and skills involved in safely prescribing these medications.

For the past 10 years, the AAMC has been engaged in the Medical School Objectives Project (MSOP). The first MSOP report, *Learning Objectives for Medical Student Education*, was issued in February 1998.[21] The goal of the initiative has been to enhance the relevance and thereby improve the quality of medical student education. The specific aim of the first report was to foster a consensus within the medical education community on the learning objectives for the general education of the physician graduate. The following principles guided the work of the advisory committee in developing the first report:

- *The combined purposes of undergraduate and graduate medical education are to educate physicians and to prepare them to meet their individual and collective responsibilities to patients and to the society at large.*
- *Medical schools should provide a general professional education that will allow students to acquire the knowledge, attributes, and skills that they ultimately will need for patient care responsibilities including an appreciation and dedication to continuous and life-long learning.*

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Report I is organized by physician attributes needed to meet society's expectations, and each attribute is followed by a set of learning objectives outlining a blueprint for medical student education. Report I is broad in scope and language and is not intended as a national curriculum.

Since publication of the first MSOP report, subsequent MSOP reports have each focused on specific, important, and contemporary issues in medical education, which set forth specific learning objectives and educational strategies to foster the learning objectives. These reports discuss educational issues such as medical informatics and population health, communication, basic science, clinical research, quality of care, genetics, musculoskeletal medicine, and the prevention and treatment of obesity. As with the first report, these later MSOP reports have been made available to medical schools for their consideration[22], but any implementation of the objectives remains the purview of the faculty members of each school. The MSOP reports have been used widely at medical schools as blueprints around which to organize medical student educational experiences.

Because of the ongoing importance and public interest in the topic, the MSOP approach was used to develop this report on the education of medical students in effective and safe prescribing.

To prepare this report, the AAMC convened a panel of academic and industry experts in drug therapy, pharmacology education, and pharmaceutical research and development. The panel was assembled by AAMC staff after consulting with various leaders in the medical education and pharmacology communities, including industry. The panel was charged to address three fundamental questions:

- *What should medical students learn in order to become knowledgeable, safe, and effective prescribers of medications?*
- *What is the ideal educational environment for learning about the optimal prescribing of medications?*
- *What kind of educational experiences would allow students to achieve those learning objectives?*

The panel was not charged with developing a specific course in safe and effective prescribing, but rather to consider the knowledge, skills, and attitudes necessary for all graduating medical students to understand and practice safe and effective prescribing with the ultimate goal of improved patient care.

The panel was aware of existing detailed pharmacology-oriented curricula, including *The Knowledge Objectives in Medical Pharmacology* initiative, first issued in 1985 under the leadership of James Fisher, Ph.D., and other senior medical school pharmacology faculty. A third edition was issued in 2005, under the leadership of Richard Eisenberg, Ph.D., and Gary Rosenfeld, Ph.D.[23] The panel was also aware of a number of published papers written by clinical pharmacology educators and consensus panels recommending various elements to create such a curriculum for medical students and residents.[4-18]

Panel members used the six core competencies recommended by the Accreditation Council for Graduate Medical Education (ACGME)[24] as the organizational structure for the objectives in this report. Those competencies include:

- *Medical Knowledge*
- *Patient Care*
- *Interpersonal and Communication Skills*
- *Professionalism*
- *Practice-based Learning and Improvement*
- *Systems-based Practice*

These competencies were used as a mechanism to frame the discussion of the objectives for a strong curriculum in safe and effective prescribing in medical student education.

II. Knowledge Objectives Summary

The six tables that follow contain the broad educational objectives which, in an ideal curriculum, would be taught and evaluated at each medical school to prepare all graduates to be thoughtful, effective, and safe prescribers by the time they are residents. Each broad competency domain, as outlined by the ACGME, is addressed by a table, which includes not only the broad educational objectives mentioned above, but also important subtopics, and a few illustrative examples of detailed content to illustrate the breadth and depth of an ideal undergraduate medical education curriculum. The level of mastery to be desired in each area is, in brief, the level of mastery that we would like all first-year residents to have attained before they write their very first independent drug order or prescription on their first day of residency.

These tables have some content overlap, which is unavoidable. For example, the ability to accurately tease out a patient's medication history, including an up-to-date medication list and a detailed list of previous adverse drug events and allergies, is both a communication skill and a skill necessary to deliver excellent patient care. In addition, the content within the tables has not been prioritized. These tables also do not explicitly describe how student mastery of each learning objective might best be assessed, leaving that to the judgment of faculty at each school, given their institution's culture and resources.

The panelists developed these six tables, after much discussion and learning from one another, to help all medical school faculty have a clearer sense of the breadth and depth of a curriculum that would help all graduates become the safe and effective prescribers that we would hope for when we become patients, and that our patients have a right to expect.

III. Safe and Effective Prescribing Knowledge Objectives

Table 1 - MEDICAL KNOWLEDGE: What each student needs to learn, understand, and be able to apply to become a competent resident prescriber. Medical students must demonstrate sufficient and appropriate knowledge about established and evolving biomedical, clinical, statistical, and social-behavioral sciences and apply this knowledge to patient care. As students receive their M.D. degree and prepare to prescribe medications without supervision, they need to understand:

Broad topic	Subtopics	Detailed examples or skills
A. Factors that make each patient unique	Age, gender, ethnicity, weight, pregnancy and breastfeeding status, liver function, kidney function, other concurrent diseases, concurrent medications, history of allergies or previous adverse drug reactions (ADRs), relevant pharmacogenetic background, environmental exposures	• Know effects of liver disease on drug choice • Know effects of renal function on choice and dosing of medications • Know effects of prior penicillin allergy on choice of antibiotic • Understand pharmacotherapy of acne in pregnant patients • Understand effects of smoking and diet on drug action and kinetics • Know hazards of polypharmacy in the elderly
B. Principles of clinically important pharmacokinetics	Absorption, distribution, metabolism, excretion, concepts of bioavailability, AUC (area under the curve), half-life, Tmax, Cmax, clearance, maintenance dose, loading dose, potential role of protein binding and free drug levels in some medications, plasma vs. biological half-life, effect of inadvertent or deliberate intermittent therapy (the issue of compliance)	• Calculate a loading dose and maintenance dose of gentamicin • Convert from an IV dose to an oral dose • Convert various opioids either from one route to another, or from one drug to another • Know implications of CYP 450 genotype • Know how to instruct a patient to resume dosing after a drug holiday
C. Drug treatment of common conditions and diseases, using frequently prescribed classes of drugs for the treatment and prevention of disease	Drugs used to treat common conditions such as hypertension, asthma, pneumonia, and other common infections; hyperlipidemia; gastrointestinal (GI) complaints; diabetes; obesity; arthritis and musculoskeletal conditions; acute and chronic pain; preventative drug treatment such as vaccines; role of known useful drug combinations such as those used in hypertensive or diabetes therapies	• Select optimal antihypertensive for patients with different concomitant medical problems • Know implications of local patterns of antibiotic resistance in choosing antibiotics for a patient • Understand mechanism of action of commonly prescribed medications • Develop treatment plan for terminal cancer patient with chronic pain • Know differences in dosing children
D. Management of less common but severe medical conditions and emergencies	Management of sepsis, shock, anaphylaxis, meningitis, myocardial infarction, drug overdose, malignant hypertension	• Understand optimal management of patient with acute overdose of aspirin, acetaminophen, etc. • Know specific steps in managing life-threatening anaphylaxis
E. Rules and regulations that govern prescribing	State/province board of pharmacy regulations, FDA/Health Canada, Drug Enforcement Administration (DEA), hospital formularies, hospital pharmacy and therapeutics (P&T) committees, prescribing medications for "off-label" indications	• Understand restrictions of prescribing Schedule II-III-IV-V drugs • Be aware of state/province rules for prescribing for self and family • Know that most children's medicine is "off label" • Understand compassionate use prescribing

Broad topic	Subtopics	Detailed examples or skills
F. Process and regulations governing drug discovery and development	Discovery, non-clinical testing, investigational new drug (IND) applications, Phase I-II-III, new drug applications (NDA)/ biologics license applications (BLA), approval, indications and marketing, Phase IV, postmarketing regulation, the importance of the balance of efficacy and safety in both discovery and commercialization of drugs	• Know limits of data about new drug at time of regulatory approval • Know how additional indications and warnings can be added post approval • Know recent changes in regulatory (e.g,. FDA in the United States, Health Canada in Canada) responsibilities and legal authority for post-approval follow-up • Know principles of clinical research (e.g., randomization, blinding, informed consent, and good clinical practice)
G. Diagnosis and management of patients with substance abuse problems	Alcohol abuse, smoking, opioids, cocaine, amphetamines, benzodiazepines, etc.; related terminology including tolerance, dependence, addiction, intoxication, withdrawal	• Know how to manage patient trying to quit smoking/drinking/abusing • Know how to manage patient acutely intoxicated with heroin • Undestand opioid maintenance therapy with methadone or buprenorphine • Know how to manage drug/alcohol acute withdrawal • Know implications for the newborn of a drug-addicted mother
H. How to find and use the most up-to-date information about drugs, biologics, and nutraceuticals	Drug compendia; electronic databases such as Clinical Pharmacology Online, Lexi-Comp, Epocrates, NIH and NCCAM websites, Sanford Guide of Antimicrobials, Micromedix, Neofax, Almedex, etc.	• Find drugs indicated for treatment of UTI in pregnant patient • Explore potential drug interactions when patient is receiving 6 different medications • Know drugs contraindicated in patients with G6PD deficiency
I. Medication errors	Frequency of medication errors, contribution to patient morbidity and mortality, root cause analysis, quality improvement efforts, confusion over abbreviations, avoiding misleading orders such as zero placed after decimal point	• Perform a root cause analysis on a patient who receives the wrong medication, or the wrong dose of a medication • Design system changes to improve a system that resulted in a patient receiving a potent anticancer drug via the incorrect route • Understand confusion between 5u of insulin and 50 units of insulin
J. Adverse drug reactions	Common ADRs for commonly used drugs, pharmacoepidemiology, assessing causality, avoiding ADRs in the first place, the role and reporting requirements of the MedWatch system; drug-food interactions	• Download and complete a MedWatch form from the FDA Web site • Discuss one patient you have cared for who experienced a serious or life-threatening ADR, and discuss how it might have been avoided • Capture ADRs accurately in an electronic medical record
K. Drug-drug interactions	Three common mechanisms of drug interactions (DI's) (pharmaceutical, pharmacokinetic, pharmacodynamic); searching a list of drugs for potential drug-drug interactions; potentially life-threatening drug interactions	• Search an electronic database and be able to find within 3 minutes all interactions between vancomycin, gentamicin, lisinopril, naproxen, alcohol, and foods • Identify and explain drug interaction between azathioprine and allopurinol • Know effects of certain foods on drug absorption

Broad topic	Subtopics	Detailed examples or skills
L. Complementary and alternative therapies	Volume of consumption of various nutraceuticals in the general population; regulation of the production, sale, and advertising of vitamins, health supplements, etc.; potential for interactions with prescription drugs; value of acupuncture and non-pharmacologic therapies; which nutraceuticals have been shown to be effective; metabolism and drug-drug interactions of commonly used nutraceuticals	• Know current limitations on how such products can be advertised • Know safety and efficacy of alternate products • Know when regulatory authorities can become involved • Know why products containing ephedra were banned from sale • Explain interaction between cyclosporine and St. Johns wort
M. Statistical issues and trial design	Observational studies, interventional studies, Type I error, Type II error, power, advantages of blinding, utility of meta-analysis, sensitivity and specificity of diagnostic tests	• Know how to critically review the about clinical drug trials literature • Know how to eliminate bias in clinical research • Know hierarchy of evidence of clinical data (i.e., RCTs, observational studies, case reports, etc.) • Know what factors influence sample size in an intervention drug trial • Understand the methodological challenges in quantitative approaches to depiction of benefits and the balance of benefits to harm (risks)

Table 2 - CORE SKILLS FOR PATIENT CARE: What clinical skills each graduate needs to provide excellent pharmacotherapeutic care to his/her patients. Students must possess a wide variety of clinical skills to enable them to provide compassionate, appropriate, and effective patient care to treat health problems and promote health. Many skills relate specifically to prescribing medications. Students are expected to be able to:

Broad topic	Subtopics	Detailed examples
A. Communicate well with patients and families about drug-related topics	Form a therapeutic alliance, elicit patient preferences, counsel about new drugs and drug decisions, promote adherence, explain risks and benefits, monitor compliance	• Assess readiness to quit smoking • Explain risks and benefits of new drug • Elicit patient preference for two possible medications with different benefits, risks, and costs • Understand insurance coverage considerations
B. Obtain detailed and accurate drug history	Know prior medications, current Rx medications, over-the-counter (OTC) medications, topical medications, nutraceuticals; prior drug allergies and ADRs	• Elicit detailed information from a patient who believes he/she had a prior "allergy" to a medication (e.g., erythromycin-induced nausea) • Understand differences between allergic and nonallergic adverse drug reactions • Understand best ways to elicit a detailed drug history from different types of patients
C. Have a robust process for developing a sound drug therapy plan	Know the process of making accurate diagnosis, review disease pathophysiology, generate menu of therapeutic choices, select best choice for this patient (with consideration of patient expectations and preferences), select endpoints to follow, form a therapeutic alliance; elicit patient preferences, and patient understanding of risks; know principles of pharmaco-economics; understand applicable formularies (Medicare, private insurers, etc.) and existing restriction and substitution policies; understand the role of skipped doses in compliance, and what should be recommended if dose-skipping occurs	• Know optimal treatment choice of healthy outpatient with a UTI, vs. inpatient with urosepsis • Incorporate evidence-based guidelines for treatment of diabetic patients with an ACE inhibitor or an ARB • Select treatment for asthma
D. Use information technology resources to support clinical pharmacotherapeutic decisions	Know up-to-date drug information; how to access review articles, biomedical journals, electronic medical records, PubMed, OVID, Google, and drug information databases	• Find recent review article on drug management of hypertension • Be familiar with latest clinical trial of Angiotensin II Receptor Blockers (ARBs) in the treatment of diabetic nephropathy
E. Prescribe thoughtfully, unambiguously, and clearly	Know eight essential parts of a written prescription, when to use a DEA number, abbreviations to be avoided, DEA restrictions on renewals	• Write a clear, complete, and unambiguous prescription for an outpatient • Perform similar task for a written drug order for an inpatient • Keep a record (inpatient/outpatient) of written prescriptions
F. Find recent critical pathways and evidence-based medicine information	Know how to access Cochrane database, ACP Journal, other sources of critical pathways, and evidence-based medicine reviews	• Find evidence-based medicine (EBM) review of the value of antibiotic prophylaxis in neutropenic patients prior to development of fever • Be familiar with WHO guidelines for most important drugs

Broad topic	Subtopics	Detailed examples
G. Read and understand package inserts	Know information required by regulatory authorities; how different sections are labeled; difference between warning, precautions, contraindications, adverse reactions; regulatory authority-approved indications	• Prescribe for both regulatory authority approved and nonapproved indications • Know restrictions on drug advertising and detailing • Know how updates to the official package label are approved by regulatory authorities • Be aware of black box warnings
H. Use therapeutic drug monitoring effectively, when needed	Know therapeutic range, target concentration strategy, steady-state level, peaks and troughs, when physiologic endpoints are preferable, alterations in protein binding (free fraction), understand how to correctly perform therapeutic drug monitoring	• Know how to alter dosing of gentamicin based on peak or trough levels • Know effects of other drugs on steady-state levels of cyclosporine • Know appropriate timing for obtaining peaks and troughs • Know how to interpret levels that weren't drawn at a specific time
I. Interpret and use antibiograms effectively; understand principles of antibiotic coverage	Know how to interpret sensitive, low-grade resistance, high-grade resistance; outpatient strains vs. inpatient strains; trends over time	• Know how to select antibiotic of choice for empiric treatment of meningitis based on local antibiogram • Know how to narrow antibiotic spectrum once sensitivity patterns of current pathogen are known • Understand MIC's in context of achievable drug concentrations
J. Maintain accurate and useful medical records	Understand how to enter and maintain most accurate information about current medications, prior ADRs, prior allergies	• Know how to enter crucial information in local electronic medical record • Confirm and validate information previously entered by other providers • Know how best to elicit information from patients about drug compliance, reasons for discontinuation

Table 3 - INTERPERSONAL AND COMMUNICATION SKILLS: How medical students must be able to relate to, and communicate with, their patients and clinical colleagues to optimize the effectiveness of their therapeutic plans.
Medical students must be able to demonstrate interpersonal and communication skills that result in effective information exchange and teaming with patients, their patients' families, and professional associates. Students are expected to be able to:

Broad topic	Subtopics	Detailed examples
A. Communicate basic information about drug therapy to patients and their families, including purpose of medication, how it works, possible adverse drug reactions, potential drug interactions, cost, and necessary follow-up	Learn patient preferences for treatment, understand patient concerns and goals about disease and treatment, create partnership without conflicts of interest, forge therapeutic alliance	• Communicate to patients that their interests are primary • Elicit patient preferences for palliation or cure in diseases such as cancer
B. Use effective listening skills and elicit and provide information using nonverbal, explanatory, and questioning skills	Communicate well with patients who have different levels of health literacy; use listening skills to elicit patient concerns about delicate issues such as palliative care, or substance abuse; note the treatment of patients with concurrent disease and other potentially confounding factors for successful drug therapy	• Find out drinking history in patient reluctant to discuss • Elicit history of substance abuse in patient presenting with endocarditis or HIV
C. Work effectively with others as a member or leader of a health care team	Optimize relationships and communication with other physicians, registered nurses, practical nurses, pharmacists, and others	• Develop relationships with pharmacists that permit a partnership for patient care, with internal safety checks on doses, etc. • Communicate clearly with nurses, and in a manner that encourages questions and ability to spot medication errors • Partner with other staff members to reinforce patient education about important aspects of medication use
D. Develop sound skills to critically evaluate medical information	Develop skills to critically evaluate evidence presented by any source, including industry; understand what constitutes a conflict of interest or the appearance of a conflict of interest in professional relationships	• Learn how to get industry representatives to focus on providing peer-reviewed, published clinical trials • Realize need to focus on data supporting regulatory authority-approved indications • Know regulations and principles of professionalism that govern pharmaceutical representatives and physicians in promotion and detailing of pharmaceuticals. • Understand how receipt of gifts, payments, or other relationships can influence physician judgment and distort prescribing practices
E. Develop the ability to recognize errors and communicate effectively with patients about them	Recognize medication errors; understand root cause analysis, concept of team as a system, role of discussions with risk management; need to present information back to patient	• Know how to deliver news of an adverse event or error back to patient • Understand role of concern and apology • Obtain new information supporting more openness with patients about medical errors
F. Explain to patients drug information gathered through direct to consumer (DTC) advertising or Internet searching	Know extent of recent DTC advertising, legal limits and reviews of ads by regulatory authorities, requirement to provide adequate information about benefits and risks	• Know how to handle patient requests for a new drug or medication • Educate patients that "new" drugs are not necessarily more medically effective, safer, or cost effective

Broad topic	Subtopics	Detailed examples
G. Understand how cultural background can alter patient views of drug therapy and disease causation	Provide patient understanding of pathogenesis of disease, role of drug therapy, who must be consulted for permission to begin drug therapy	• Elicit patient's views about what is causing symptoms and disease • Understand how culturally related views of medication alter efficacy, compliance, etc.
H. Be aware of special communication issues related to drug research	Talk to patients about possible participation as human research subjects, obtain consent that is truly informed, help patients deal with risk and uncertainty, understand special challenges of performing clinical research in vulnerable populations	• Know essential elements for informed consent • Understand role of the IRB in approving patient information and informed consent documents • Be familiar with past flawed studies, such as the Tuskegee syphilis study • Understand that prisoners, children, and the mentally challenged are considered vulnerable populations and subject to enhanced human subject protections • When involving pregnant women, special consideration must be given due to risk to the fetus
I. Avoid collusion of anonymity	Understand need for one physician to oversee and coordinate all drug therapy; know confusion of roles in academic medical centers and problems with duplicative, interactive, or conflicting drug treatment plans	• Discuss role of residents on ICU team in which patient receives four consults from different services with different drug treatment recommendations • Understand role of resident as physician closest to patient, and often relied on by patient for advice

Table 4 - PROFESSIONALISM: Medical students must demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population. Students are expected to:

Broad topic	Subtopics	Specific examples
A. Demonstrate respect for patient, show compassion, and model integrity	Put patient needs first, avoid self interest and personal biases, realize importance of follow-up	• Refrain from judging patient with substance abuse problems • Find balance between pedestal and therapeutic partner
B. Commit to a habit of lifelong learning about drugs, and to therapeutic excellence	Know sources of unbiased information about new drugs as they are approved, how different drug compendia are assembled and organized, how changes in regulatory authority over time affect physician prescribing and safety of drugs, biologics, and nutraceuticals	• Demonstrate knowledge of how to access FDA or Health Canada Web sites • Subscribe to objective source of information about new drugs such as Medical Letter • Able to critically review the medical literature • Subscribe to FDA Updates for Health Professionals
C. Understand accountability to society and the profession	Responsible for discovering and reporting new knowledge, need to intervene when observing unethical behavior or substance-dependent physician	• Know how to file a Medwatch report of suspected serious ADR • Know how to file a report with the source pharmaceutical company of a suspected serious ADR • Know how to file accurate, detailed reports of ADRs that will be of greatest use and value • Know how to recognize risks of substance abuse in physicians, and how to spot and report an impaired physician
D. Show commitment to ethical principles	Provide or withhold clinical care, honor patient confidentiality and Health Insurance Portability and Accountability Act (HIPAA) provisions, employ ethical business practices, avoid real or potential conflicts of interest, be familiar with Declaration of Helsinki and the Belmont Report	• Plan to develop a lifelong, ethical, and professional relationship with drug and device companies • Understand how receipt of gifts, payments, or other relationships can influence the judgment of physicians and can distort prescribing practices • Know appropriate enrollment of subjects in drug trials
E. Demonstrate sensitivity and responsiveness to patients' culture, age, gender, and disabilities	Influence of patient background and culture on beliefs about disease and treatment; obtain true informed consent	• Know how to provide patients' drug information in different languages, written to an appropriate age level • Use of translator in discussions
F. Practice behaviors that support personal health and career fulfillment, and prevent burnout	Know state/province regulations that pertain to prescribing for self and family, work-related risk factors for substance abuse	• Know how states and provinces provide local additional rules and regulations to national DEA guidelines
G. Understand the importance of admitting error, and apologizing when appropriate	Know concept of each prescription as a therapeutic trial, realize importance of catching medical errors as early as possible, explain errors and risk to patient, act to prevent errors	• Know how to explain to patient in an understandable way the uncertainty related to making diagnosis, predicting efficacy of drug treatment, and potential for harm

Broad topic	Subtopics	Specific examples
H. Know your own personal limitations in knowledge or therapeutic skills, and feel comfortable asking for help or advice	Know importance of general prescribing skills to the general physician, guidelines for seeking expert help with difficult-to-use or especially toxic drugs (e.g., chemotherapy, antiarrhythmic drugs)	• Be aware of local hospital rules about which physicians are allowed to prescribe specific classes of drugs • Know concept of a personal drug formulary, where physician has comfort level in prescribing
I. Balance commitment to the individual patient's welfare with societal concerns	Understand tension between selecting best drug for individual patient vs. needs of a larger group, overuse of antibiotics in specific patients leading to changes in resistance pattern for all patients, the role of "tiering" of prescription benefits to enable early use of generics in a "fail-first" paradigm to limit drug costs, tailored therapeutics or personalized medicine	• Recognize changes in strains of staphylococcus resistant to methicillin over past 15 years • Know how pharmacy budgets are developed in closed populations of patients (e.g., VA hospitals)

Table 5 - PRACTICE-BASED LEARNING AND IMPROVEMENT: Medical students must be able to review and evaluate their own patient care practices, appraise and assimilate scientific evidence, and find ways to improve their patient care outcomes. Students are expected to:

Broad topic	Subtopics	Specific examples
A. Analyze practice experience and perform practice-based improvement activities using a systematic methodology	Analyze critical pathways, evidence-based medicine, patient safety initiatives, medication errors, quality improvement initiatives, how patient-specific information (e.g., estrogen receptor status of tumor) can substantially alter treatment plans; participate in clinical research to learn more about drug action in the "real world" patient setting	• Perform root cause analysis of a medical error • Analyze why some practices have better compliance for aspirin, beta-blockers, ACE inhibitors S/P MI • Understand impediments to incorporating "best prescribing practices" in a patient practice • Understand issues and reasons for physician and patient noncompliance with practice guidelines and directions for use of medicines
B. Locate, appraise, and assimilate evidence from scientific studies related to patients' health problems	Able to read and understand primary drug trial literature, EBM sources, meta-analyses, best Web-based sources for primary sources and review; be familiar with the important components of the regulatory authority-approved official "package insert"	• Find latest references dealing with vancomycin-resistant enterococcus • Identify latest consensus guidelines for treatment of community-acquired pneumonia • Know how to interpret and apply population-based efficacy and/or safety data to individual patients (e.g., NSAID efficacy and safety data)
C. Obtain and use information about one's own population of patients and the larger population from which patients are drawn	Be familiar with community-based data regarding cancer risk, cardiovascular disease, obesity, and patterns of antibiotic resistance	• Find data at local hospital of the percentage of MI patients discharged on aspirin and a beta-blocker • Find data at a local hospital of the percentage of patients with DM receiving ACE inhibitor to protect renal function
D. Apply knowledge of study designs and statistical methods to the appraisal of clinical studies and other information on diagnostic and therapeutic effectiveness	Understand concepts of Type I error, Type II error, power analysis, confidence intervals, etc., to analyze recent published clinical trials; manage competing and sometimes conflicting information regarding the safety and efficacy of pharmaceuticals	• Read, analyze, and understand recent masked, controlled intervention trial • Read, analyze, and understand recent case-control observational study • Study related issues in the MSOP report on "Clinical Research in Medical Education"
E. Use information technology to manage information, access online medical information, and support their own education	Be familiar with PubMed, OVID, UpToDate, Cochrane, Clinical Pharmacology Online, MDConsult, EBM, electrical pharmaceutical databases	• Use a Web-based IT resource to access useful information about a recently approved drug • Access regulatory authority Web sites to review new information (indications, warnings, etc.) about approved drugs
F. Understand use of critical pathways and guidelines to standardize and optimize practice, using best EBM	Be familiar with Cochrane database of systematic reviews, Clinical Evidence, National Guideline Clearinghouse, ACP Journal Club, bmjupdates	• Find and assess a critical pathway for a common problem, such as management of hypertension • Know standard-of-care treatments of common illnesses
G. Know role of hospital pharmacy and therapeutics (P&T) committees	Know role of closed hospital formulary, therapeutic substitution, and formularies maintained by insurance companies	• Understand process whereby hospital P&T committee may select the "workhorse" drug of a given class • Understand the principles of populations-based cost/benefit/risk analyses • Know possible financial and adherence implications for the patient of a physician "blindly" prescribing newer, more expensive drugs

Table 6 - SYSTEMS-BASED PRACTICE: Medical students must demonstrate an awareness of and responsiveness to the larger context and system of health care and the ability to effectively call on system resources to provide optimal value care. Students are expected to:

Broad topic	Subtopics	Specific examples
A. Describe how their patient care affects other health care professionals, the health care organization, and the larger society	Prescribe drugs for approved and unapproved indications, understand nurse and pharmacist roles in drug therapy, realize costs and contributions of prescription and OTC drug products, be aware of implications for antibiotic resistance	• Know implications of excessive antibiotic prescribing on patterns of resistance • Understand under-prescribing of aspirin, beta-blockers for patients with recent MI • Realize importance of preventive care (i.e., vaccines)
B. Understand how various elements of the system affect practice	Understand pharmacist availability and the compounding of pharmaceuticals, nursing staff issues and verbal orders, insurance policies for drug coverage, prior approval for certain drugs, role of other providers (and implications for the supervising physician) regarding prescribing privileges	• Know why verbal orders in nonemergency situations can be problematic • Understand why insurance companies institute different levels of copayment for different medications • Understand scope of prescribing and limitations on prescribing by non-physician providers
C. Know how various delivery systems differ in controlling health care costs and allocating resources	Understand the role and use of formularies and the nature of coverage provided by appropriate insurance or government health care plans	• Know why and how different insurers select different ACE inhibitors as their "workhorse" agent • Know how to find out which drugs are on a particular formulary
D. Practice cost-effective health care and resource allocation that does not compromise quality of care	Know concepts of cost-effectiveness for diseases (such as hypertension) that have many possible drug choices, situations in which a more "expensive" drug choice may be optimal for a co-morbid condition, etc.	• Know the usual drugs of first choice in patients with simple essential hypertension • Know how these choices would be modified in patients with asthma, angina, DM, or who are members of various ethnic groups; or who are women or children/adolescents
E. Advocate for quality patient care and help patients deal with system complexities	Understand situations when a physician needs to become a patient advocate when a specific drug is medically necessary, based on best evidence, but disallowed by insurance coverage; help enroll needy patient on a company-sponsored free drug program	• Understand when generic drugs offer a cost-effective alternative to a brand-name product • Understand when a more expensive branded product may be more effective or safer than a generic product (e.g., patient allergy to excipient in a generic product, or use of a sustained-release product)
F. Understand roles of different professionals in the prescribe-transcribe-compound-dispense-administer chain	Understand roles of nurse, LPN, unit secretary, pharmacist, pharmacy benefits manager; confusion about look-alike and sound-alike pairs	• Describe the steps and safety checks when cancer chemotherapy is ordered within your hospital • Know the special steps and safety checks necessary for administration of intrathecal medications by the intern (e.g., double signatures at some institutions for safety)
G. Describe how prescribing practices can affect the health care system	Understand that prescription drugs account for about $250 billion per year of $2 trillion total health care costs, value to patients of avoiding surgery (e.g., ulcers), value to patients of treatments for previously untreatable diseases (e.g., CML), concepts of cost of QALY, etc.	• Analyze cost of years of life saved when treating MI with tPA • Know impacts on survival and costs of MI reperfusion with drugs (e.g., tPA) and immediate PTCA • Know the value of preventive care (i.e., iron deficiency screening, vaccines, and cholesterol screening)

Broad topic	Subtopics	Detailed examples or skills
H. Understand how the system can support or hinder complex prescribing, such as for substance abuse, palliative care, and home treatment with antibiotics	Know rules, regulations, and social acceptance of treatments for substance abuse (methadone, buprenorphine); high-dose opioids for palliative care; home-based treatment for DVT or infection	• Know new rules and regulations enabling office-based treatment of opioid dependence with buprenorphine • Know the choices of inpatient- and outpatient-based treatment of new onset DVT or pulmonary embolism • Understand hospice care prescribing
I. Describe the role of regulatory authorities and how it could be strengthened and improved	Know the current process for approving IND and NDA/BLA, regulation of marketing and advertising, DTC advertising, reviews and regulations of nutraceutical products, postmarketing surveillance, process for requiring new warning in package insert, process of sharing post-marketing information between industry and FDA/Health Canada, process of applying for new indications, implications of recent laws altering regulatory authority for reviewing drugs and nutraceuticals, laws regulating advertising of pharmaceutical products to physicians and directly to consumers	• Understand process by which ephedra-containing products were banned by the FDA and other regulatory authorities • Review recent episodes of post-marketing discovery of unexpected toxicity resulting in removal of drug from marketing (e.g., rofecoxib, troglitazone) • Understanding importance of regulatory agencies in studying safety of drugs for use in children and pregnant women (e.g., chloramphenicol toxicity, thalidomide tragedy) and how the FDA can encourage drug development to include studies of drugs in children (through extended exclusivity)

IV. Different Models for Providing Clinical Pharmacology Education

Virtually all medical schools accredited by the LCME offer a course in basic medical pharmacology in Year 1 or (more commonly) in Year 2 of the M.D. curriculum. These introductory courses usually are sequenced to coordinate with other discipline-based basic science courses, integrated basic science courses, organ- or system-based pathophysiology courses, or problem-based learning-based curricula. In any of these formats, medical pharmacology courses introduce students to the major classes of drugs for clinical use and their mechanisms of action. The importance of mastering this material during the first two years is currently reinforced by the inclusion of a significant number of questions related to basic medical pharmacology on Step 1 of the USMLE exam sequence.

Traditionally, medical students take their clinical clerkships during Year 3 of medical school, and then pursue more advanced clinical experiences (e.g., subinternships) and electives during Year 4. Most students are then in the best position to study clinical pharmacology and therapeutics *after* completion of their introductory pharmacology courses, and *after* having experienced the major clinical clerkships. Some schools have attached clinical pharmacology and therapeutics course material to the end of the basic medical pharmacology course, but many students do not have an adequate grasp of clinical medicine at that time to fully benefit from this material.

Medical schools incorporating clinical pharmacology and therapeutics material into their curricula have found it helpful to include this material in Year 3 or Year 4 of medical school, *after* students have completed some or all of their core clinical clerkships. Various formats for including such clinical pharmacology core material have been tried, such as:

- Clinical pharmacists participating on team rounds to ensure that therapeutics are discussed in a patient-centered manner, on some or all clerkships. (This model is especially common at medical schools that have schools of pharmacy on the same campus.)
- Including a clinical pharmacology course longitudinally throughout Year 3, or included in intersession courses between clerkships during Year 3.
- Integrating lectures or other teaching methods into existing clerkships, often the internal medicine clerkship. This model has the advantage of being "piggybacked" onto a strong existing clerkship, but often is very time limited and not a comprehensive curriculum in clinical pharmacology.
- Offering electives at some schools during Year 4. While some of these electives have been of high quality, and taken by a large segment of the senior class, such electives have the major disadvantage of not reaching all graduating seniors.
- Requiring a clinical pharmacology and therapeutics course during Year 4 is a very powerful learning experience for senior students, building on Year 2 pharmacology knowledge, Year 3 clinical knowledge and skills, and Year 4 student desire to prepare for internship. February of Year 4 can be an especially effective time given what students are focused on at that time of the year (thinking ahead to becoming a good and safe intern, and looking ahead to Match Day). However, it is difficult to "obtain" curriculum time in Year 4, and this model is in use at very few U.S. schools, perhaps fewer than five. Also, many medical schools may not have a core of clinical pharmacology faculty to organize and help teach such a course.
- Since most allopathic U.S. and Canadian medical schools do not have clinical pharmacology physician faculty on site, perhaps use of shared teaching models or Web-based curricular materials might be helpful. This model is currently very successful for the clinical pharmacology course offered for fellows within the National Institutes of Health (NIH), and shared with fellows at training programs across the country. A similar model of a national clinical pharmacology curriculum developed specifically for senior medical students, offered to students at all medical schools in a Web-based format, has been implemented recently in Australia.[16]

Just as there are several models for providing a clinical pharmacology and therapeutics curriculum to medical students, there are several models for teaching the curriculum. Faculty at various schools have employed lectures, case-based large-group instruction (similar to the case method used in law school or business school), small-group problem-based learning cases, small-group conferences, tutorials, clinical (patient-centered) electives, etc. Combinations of these have been used as well. Teaching/learning formats have often been determined by logistical limitations of faculty availability on site, size of the medical school class, and related factors.

Ultimately, each medical school must decide the minimal level of knowledge and skill that its graduates must possess in these (and other) competency domains. Most schools pursue a four-year curriculum, with many competing demands for curricular time and attention. Development of a robust, broad, and deep curriculum in pharmacotherapeutics is the ideal; creation of a briefer curriculum that "covers the basics" to help graduates become thoughtful, safe, and effective prescribers" may be a more realistic goal for most schools. Pursuit of "great" should not prevent implementation of "good." This is especially important because we are in a time of important advances in drugs (i.e., monoclonal antibodies) and technology (i.e., online drug information databases), overwhelming amounts of information, and increased time constraints on physicians and other health care providers.

V. Summary

Recent reports from the Institute of Medicine about the quality chasm and medical errors, and recent post-marketing data about major health risks of several prescription drugs, remind us that modern pharmaceuticals are more powerful and effective than ever before, but a challenge to prescribe in a manner that optimizes both efficacy and safety. Every medical school is obligated to ensure its graduates' competency to prescribe medications in a manner that maximize drug efficacy, minimize drug toxicity, recognize the factors that make each patient unique, and provide the greatest value overall to each patient and to society. Every medical school graduate will begin prescribing drugs on the first day of residency, often without direct supervision of each inpatient drug order or outpatient prescription.

For medical schools that would like to strengthen their curricula in safe and effective prescribing practices, this MSOP report provides an outline of what such a core curriculum might look like, organized by the six major competency domains first proposed by the ACGME. Curriculum time at every medical school is precious, and finding the optimum time to "cover" this subject is a challenge. Assessing whether students have adequately mastered each learning objective to an appropriate degree likewise remains an educational challenge with many possible solutions. We describe several models that have been successful at various medical schools for incorporating this important material. A particularly effective approach to achieving the desired competencies may be to offer structured instruction in clinical pharmacology/therapeutics in Year 4 of undergraduate medical education, in addition to core instruction in basic pharmacology in Year 1 or Year 2.

Each medical school has its own local constraints and learning climate and will need to find its own local solution to help its students achieve an appropriate level of mastery of these different competencies. Because most current residents (and faculty) graduated from medical schools that did not emphasize training in these areas, it becomes even clearer that society expects our medical schools to ensure that each graduate is ready on Day 1 of residency to prescribe medications safely and effectively, and with appropriate skill and knowledge.

References Cited In Text

1. RW Wilcox. The teaching of therapeutics. Trans Am Ther Soc 1903;25–26.
2. H Gold. A blueprint for the expansion of human pharmacology in the medical curriculum. J Clin Pharmacol 1968;8:74–78.
3. KL Melmon and HF Morrelli. The need to test the efficacy of the instructional aspects of clinical pharmacology. Clin Pharmacol Ther 1969;10:431–435.
4. AH Neims and CS Watson. The need for a longitudinal plan in teaching clinical pharmacology. J Clin Pharmacol 1981;21:258–259.
5. RR Spector and RJ Roberts. Commentary: physician education and drug therapy. J Clin Pharmacol 1983;23:491–493.
6. KL Melmon and TF Blaschke. The undereducated physicians' therapeutic decisions. N Eng J Med 1983; 308:1473–1474.
7. RK Ferguson and PH Vlasses. Clinical pharmacology for fourth-year medical students. J Clin Pharmacol 1984;24:271–272.
8. DW Nierenberg and TA Stukel. The effects of a required fourth-year clinical pharmacology course on student attitudes and subsequent performance. Clin Pharmacol Ther 1986;40:488–493.
9. DW Nierenberg. Clinical pharmacology instruction for all medical students. Clin Pharmacol Ther 1986;40:483–487.
10. RD Feldman, R Spector, GD Park, M Albanese, R Roberts. Clinical pharmacology and therapeutics education for senior medical students. J Clin Pharmacol 1987;27:682–684.
11. CM Lathers and CM Smith. Teaching clinical pharmacology: coordination with medical pharmacology courses. J Clin Pharmacol 1989;29:581–597.
12. AJ Ingenito, CM Lathers, HJ Burford. Instruction in clinical pharmacology: changes in the wind. J Clin PHarmacol 1989;29:7–17.
13. DW Nierenberg and The Council for Medical Student Education in Clinical Pharmacology and Therapeutics. A core curriculum for medical students in clinical pharmacology and therapeutics. Clin Pharmacol Ther 1990;48:606–610.
14. D Nierenberg: Consensus for a core curriculum in clinical pharmacology for medical students. Clin Pharmacol Ther 1990:48:603–605.
15. S Maxwell, T Walley: Teaching safe and effective prescribing in UK medical schools: a core curriculum for tomorrow's doctors. Br J Clin Pharmacol 2003;55:496–503.
16. A Smith, T Tasioulas, N Cockayne, G Misan, G Walker, G Quick: Construction and evaluation of a web-based interactive prescribing curriculum for senior medical students. Br J Clin Pharmacol 2006;62:653–659.
17. C Candler, M Ihnat, G Huang: Pharmacology education in undergraduate and graduate medical education in the United States. Clin Pharmacol Ther 2007;82:134–136.
18. A Smith: Competency for new prescribers. Australian Prescriber 2007;30:58–59.

19. Institute of Medicine, To Err Is Human: Building a Safer Health System. 1999. Accessible at http://books.nap.edu/openbook.php?isbn=0309068371.

20. AAMC and the FDA, Drug Development Science: Obstacles and Opportunities for Collaboration Among Academia, Industry and Government 2005. Accessible at http://www.aamc.org/publications/.

21. AAMC. Medical School Objectives Project Report I: Learning objectives for medical student education. 1998. Accessible at http://www.aamc.org/meded/msop/.

22. These MSOP reports are accessible at: http://www.aamc.org/meded/msop/.

23. R Eisenberg, G Rosenfeld. Knowledge Objectives in Medical Pharmacology, 2005. Accessible at http://www.aspet.org/AMSPC/Knowledge_Objectives/default.asp.

24. ACGME Common Program Requirements: General Competencies (known as the ACGME Core Competencies). Accessible at http://www.acgme.org/outcome/.

Annotated Reference Sources

C Candler, M Ihnat, G Huang: Pharmacology education in undergraduate and graduate medical education in the United States. Clin Pharmacol Ther 2007;82:134–136.

Authors: The authors work at the AAMC (MedEdPORTAL project), and at two U.S. medical schools
Subject: Review of pharmacology instruction in medical schools (as posted in the AAMC curriculum database CurrMIT) and residency training programs
Conclusions: Clinical pharmacology instruction in the clinical years of medical school is not well documented, and seems to be haphazard and accidental during residency. The recent movement towards competency-based teaching and assessment is likely to permeate both undergraduate (medical school) and graduate (residency) training programs and, along with the driving force of the patient safety movement, lead to better and more formal instruction in clinical pharmacology and therapeutics.

R Eisenberg, G Rosenfeld. Knowledge objectives in medical pharmacology, 2005. www.aspet.org/AMSPC/Knowledge_Objectives/default.asp.

Authors: Members of the Association for Medical School Pharmacology Chairs (AMSPC), which includes chairs of departments of pharmacology at U.S. medical schools
Subject: A description of the competencies in pharmacology that should be obtained by students completing their basic medical education.
Conclusions: This document is a detailed description of an optimal curriculum in basic medical pharmacology, but also includes some discussion of recommended curricular content in clinical pharmacology and therapeutics as well.

S Maxwell, T Walley: Teaching safe and effective prescribing in U.K. medical schools: a core curriculum for tomorrow's doctors. Br J Clin Pharmacol 2003;55:496–503.

Authors: The authors work at the University of Edinburgh and the University of Liverpool, and also hold leadership positions in the British Pharmacological Society.
Subject: Recent changes in curricular design in U.K. medical schools has made it harder to organize specific courses in clinical pharmacology. Therefore, the general objectives related to training in clinical pharmacology and therapeutics now need to be translated into more specific learning outcomes. Core knowledge and skills related to safe prescribing are outlined.
Conclusions: For most doctors, drug therapy is the main tool they have for influencing the health care of their patients. Modern drugs bring great patient benefits, but at the risk of causing great harm. Therefore, it is crucial that medical students become competent to prescribe safely and effectively before they graduate, and that they should be able to assimilate new information about new drug developments throughout their professional careers.

D Nierenberg, T Stukel. The effects of a required fourth-year clinical pharmacology course on student attitudes and subsequent performance. Clin Pharmacol Ther 1986;40:488–493.

Authors: Clinical pharmacologist and biostatistician at a U.S. medical school
Subject: Description of goals and content of a required Year 4 course in clinical pharmacology, student evaluation, and improvement in student performance on Step 2 of the national board examination.
Conclusions: Eighty-nine percent of senior medical students felt that such a course was "essential" to their future careers as physicians. As interns, 80 percent of the graduates who responded found that the course had been frequently useful or essential during their internships. Average student scores on Step 2 of the NBME exams in clinical pharmacology-related questions increased from 38th percentile to 74th percentile (comparison to historical control group), compared to an increase from 48th to 52nd percentile on all topics over the same period of time.

D Nierenberg, A Atkinson, D Brater, J Drayer. The American Society for Clinical Pharmacology and Therapeutics: programs to support education in clinical pharmacology. Clin Pharmacol Ther 1990;47:262–269.

Authors: Four clinical pharmacologists, three from U.S. medical schools and one from a private clinical pharmacology consulting company.

Subject: Efforts of a national clinical pharmacology academic society to support medical student education in the field, including conducting a survey of all U.S. medical schools in 1985 concerning their teaching of the field.

Results: Sixty-nine percent of all U.S. medical schools responded to the survey. All U.S. schools offered a required course in basic medical pharmacology, usually taught in the second year (98 percent). Only 14 percent of schools offered required courses in clinical pharmacology; many other schools taught clinical pharmacology material as part of the basic pharmacology course.

D Nierenberg and the Council for Medical Student Education in Clinical Pharmacology and Therapeutics. Clin Pharmacol Ther 1990;48:606–610.

Authors: Clinical pharmacologists from several U.S. and Canadian medical schools who held a workshop to develop a core curriculum for medical student education in clinical pharmacology. The faculty were representing four societies interested in clinical pharmacology education—the American Society for Clinical Pharmacology and Therapeutics (ASCPT), the American Society for Pharmacology and Experimental Therapeutics (ASPET), the Association for Medical School Pharmacology (AMSP), and the American College of Clinical Pharmacology (ACCP).

Subject: Consensus guidelines for a core curriculum in clinical pharmacology and therapeutics for medical students in core information, core skills, and core attitudes, along with discussion of how such a curriculum could be implemented.

Conclusions: Details of a core curriculum are presented in the "older language" of core knowledge, skills, and attitudes. These aspects of a core curriculum map fairly easily into the newer perspective of having a competency-based curriculum based on the six competency domains originally suggested by the ACGME. Implementation by different medical schools has been difficult, for a variety of reasons.

D Nierenberg: Consensus for a core curriculum in clinical pharmacology for medical students. Clin Pharmacol Ther 1990:48:603–605.

Author: Clinical pharmacologist at a U.S. medical school

Subject: How the consensus guidelines cited in the article above were formulated.

Conclusions: Given the recent emphasis on widespread problems of mis-medication, overmedication, drug toxicity, and irrational prescribing, it is an opportune time for medical schools to consider adding required courses in clinical pharmacology. Faculty owe it to the public to make sure that medical students graduate with a firm understanding of how to practice rational therapeutics throughout their professional careers.

A Smith: Competency for new prescribers. Australian Prescriber 2007;30:58–59.

Author: Emeritus professor of clinical pharmacology at University of Newcastle, New South Wales, Australia

Subject: New regulations granting nurses the license to prescribe any licensed medicine for any medical condition "within their competence" has focused attention on the adequacy of training and continued professional development of any prescriber.

Conclusions: Students will prescribe medication 200,000 times during their career. Such an important task requires adequate training (in school) and ongoing professional development.

A Smith, T Tasioulas, N Cockayne, G Misan, G Walker, G Quick: Construction and evaluation of a Web-based interactive prescribing curriculum for senior medical students. Br J Clin Pharmacol 2006;62:653–659.

Authors: Physicians in Australia from the National Prescribing Service and several medical schools.

Subject: The development, implementation, and results of a national, voluntary, Web-based, case-based educational program for helping senior medical students learn about prescribing medications optimally for common problems to be encountered during internship year.

Conclusions: Such a national curriculum designed for senior medical students, developed cooperatively from faculty at all medical schools and from a national prescribing resource group, was found to be very valuable by students and faculty at all schools who used it. High use at a school was found to be related to an enthusiastic faculty champion at that school. Some schools felt that their curriculum time was too crowded to permit adoption of this program. Student utilization was highest at schools that formally assessed the content of the program.

Abbreviations and Acronyms

This report necessarily uses a variety of abbreviations and acronyms. While most of these are well known to medical school faculty, a listing is provided for the convenience of all readers.

AAMC	Association of American Medical Colleges
ACCP	American College of Clinical Pharmacology
ACGME	Accreditation Council for Graduate Medical Education
ACP	American College of Physicians
ADR	Adverse drug reaction
AMSP	Association for Medical School Pharmacology (now AMSPC)
AMSPC	Association of Medical School Pharmacology Chairs
ARB	Angiotensin Receptor Blocker (anti-hypertension drug)
ASCPT	American Society for Clinical Pharmacology and Therapeutics
ASPET	American Society for Pharmacology and Experimental Therapeutics
AUC	Area under the curve
BLA	Biologics License Application (application to the FDA)
Cmax	Maximum drug concentration in plasma
CML	Chronic myeloid leukemia
CurrMIT	AAMC's Curriculum Management & Information Tool
DEA	Drug Enforcement Administration
DI	Drug interaction
DM	Diabetes mellitus
DTC	Direct to consumer
EBM	Evidence-based medicine
FDA	Food and Drug Administration
GI	Gastro-intestinal
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	Human Immunodeficiency Virus
ICU	Intensive care unit
IND	Investigational New Drug (application to the FDA)
IRB	Institutional Review Board
LCME	Liaison Committee on Medical Education
MI	Myocardial infarction

MIC	Minimum inhibitory concentration
MSOP	Medical School Objectives Project
NBME	National Board of Medical Examiners
NCCAM	National Center for Complementary and Alternative Medicine
NDA	New Drug Application (application to the FDA)
NIH	National Institutes of Health
NSAID	Non-Steroidal Anti-Inflammatory Drug
OTC	Over the counter
P&T	Pharmacy and therapeutics
PTCA	Percutaneous transluminal coronary angioplasty
QALY	Quality-adjusted life year
RCT	Randomized clinical trial
S/P MI	Status post myocardial infarction
Tmax	Time to maximum plasma concentration
tPA	Tissue plasminogen activator
USMLE	U.S. Medical Licensing Examination
UTI	Urinary tract infection
VA	Department of Veterans Affairs
WHO	World Health Organization

AAMC

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