

OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinion was presented by Dennis S. Agliano, MD, Chair.

1. ETHICAL PHYSICIAN CONDUCT IN THE MEDIA

CEJA Opinion; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2017 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2-I-17, "Ethical Physician Conduct in the Media." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

E-8.12 – Ethical Physician Conduct in the Media

Physicians who participate in the media can offer effective and accessible medical perspectives leading to a healthier and better informed society. However, ethical challenges present themselves when the worlds of medicine, journalism, and entertainment intersect. In the context of the media marketplace, understanding the role as a physician being distinct from a journalist, commentator, or media personality is imperative.

Physicians involved in the media environment should be aware of their ethical obligations to patients, the public, and the medical profession; and that their conduct can affect their medical colleagues, other health care professionals, as well as institutions with which they are affiliated. They should also recognize that members of the audience might not understand the unidirectional nature of the relationship and might think of themselves as patients. Physicians should:

- (a) Always remember that they are physicians first and foremost, and must uphold the values, norms, and integrity of the medical profession.
- (b) Encourage audience members to seek out qualified physicians to address the unique questions and concerns they have about their respective care when providing general medical advice.
- (c) Be aware of how their medical training, qualifications, experience, and advice are being used by media forums and how this information is being communicated to the viewing public.
- (d) Understand that as physicians, they will be taken as authorities when they engage with the media and therefore should ensure that the medical information they provide is:
 - (i) accurate;
 - (ii) inclusive of known risks and benefits;
 - (iii) commensurate with their medical expertise;
 - (iv) based on valid scientific evidence and insight gained from professional experience.
- (e) Confine their medical advice to their area(s) of expertise, and should clearly distinguish the limits of their medical knowledge where appropriate.
- (f) Refrain from making clinical diagnoses about individuals (e.g., public officials, celebrities, persons in the news) they have not had the opportunity to personally examine.

- (g) Protect patient privacy and confidentiality by refraining from the discussion of identifiable information, unless given specific permission by the patient to do so.
- (h) Fully disclose any conflicts of interest and avoid situations that may lead to potential conflicts. (II, V, VII)

DRAFT

REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1–7, were presented by, Dennis S. Agliano, MD, Chair.

1. COMPETENCE, SELF-ASSESSMENT AND SELF-AWARENESS

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: REFERRED

The expectation that physicians will provide competent care is central to medicine. This expectation shaped the founding mission of the American Medical Association (AMA) and runs throughout the *AMA Code of Medical Ethics* [1-4]. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society [5]. The profession promises that practitioners will have the knowledge, skills, and characteristics to practice safely and that the profession as a whole and its individual members will hold themselves accountable to identify and address lapses [6-9].

Yet despite the centrality of competence to professionalism, the *Code* has not hitherto examined what the commitment to competence means as an ethical responsibility for individual physicians in day-to-day practice. This report by the Council on Ethical and Judicial Affairs explores this topic to develop ethics guidance for physicians.

DEFINING COMPETENCE

A caveat is in order. Various bodies in medicine undertake point-in-time, cross-sectional assessments of physicians' technical knowledge and skills. However, this report is not concerned with matters of technical proficiency assessed by medical schools and residency programs, specialty boards (for purposes of certification), or hospital and other health care organizations (e.g., for privileging and credentialing). Such matters lie outside the Council's purview.

The ethical responsibility of competence encompasses more than knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole. For purposes of this analysis, competence is understood as “the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and the community being served” and as “developmental, impermanent, and context dependent” [10].

Moreover, the Council is keenly aware that technical proficiency evolves over time—what is expected of physicians just entering practice is not exactly the same as what is expected of mid-career physicians or physicians who are changing or re-entering practice or transitioning out of active practice to other roles. Each phase of a medical career, from medical school through retirement, carries its own implications for what a physician should know and be able to do to practice safely and to maintain effective relationships with patients and with colleagues.

The concept that informs this report differs as well from the narrower definition of competence as the knowledge and skills an individual has to do a job. Rather, this report explores a broader notion of competence that encompasses deeper aspects of wisdom, judgment and practice that enable physicians to assure patients, the public, and the profession that they provide safe, high quality care moment to moment over the course of a professional lifetime.

FROM SELF-ASSESSMENT TO “INFORMED” SELF-ASSESSMENT

Health care institutions and the medical profession as a whole take responsibility to regulate physicians through credentialing and privileging, routinely testing knowledge (maintenance of certification, requirements for continuing education, etc.) and, when needed, taking disciplinary action against physicians who fail to meet expectations for competent, professional practice. However, the better part of the responsibility to maintain competence rests with

physicians' "individual capacity, as clinicians, to self-assess [their] strengths, deficiencies, and learning needs to maintain a level of competence commensurate with [their] clinical roles" [11].

Self-assessment has thus become "integral to many appraisal systems and has been espoused as an important aspect of personal professional behavior by several regulatory bodies and those developing learning outcomes for students" [12]. Undergraduate and graduate medical education programs regularly use self-assessment along with third-party evaluations to ensure that trainees are acquiring the knowledge and skills necessary for competent practice [5,10,13-16].

Yet how accurately physicians assess their own performance is open to question. Research to date suggests that there is poor correlation between how physicians rate themselves and how others rate them [5,12,13]. Various studies among health professionals have concluded that clinicians and trainees tend to assess their peers' performance more accurately than they do their own; several have found that poor performers (e.g., those in the bottom quartile) tend to over-estimate their abilities while high performers (e.g., those in the top quartile), tend to under-estimate themselves [5,12,17].

The available findings suggest that self-assessment involves an interplay of factors that can be complicated by lack of insight or of metacognitive skill, that is, ability to be self-observant in the moment. Similarly, personal characteristics (e.g., gender, ethnicity, or cultural background) and the impact of external factors (e.g., the purpose of self-assessment or whether it is designed to assess practical skills or theoretical knowledge) can all affect self-assessment [12,18]. The published literature also indicates that interventions intended to enhance self-assessment may seek different goals—improving the accuracy of self-assessors' perceptions of their learning needs, promoting appropriate change in learning activities, or improving clinical practice or patient outcomes [12].

Self-assessment tools alone are not sufficient measures of physicians' ability to provide safe, high quality care. Feedback from third parties is essential—or as one researcher has observed, "The road to self-knowledge may run through other people" [19]. However, physicians are often wary of assessment. They have indicated that while they want feedback, they are not sure how to use information that is not congruent with their self-appraisals [20]. Physicians can be hesitant to seek feedback for fear of looking incompetent or exposing possible deficiencies or out of concern that soliciting feedback could adversely affect their relationships with those whom they approach [20]. They may also question the accuracy and credibility of the assessment process and the data it generates [21].

To be effective, feedback must be valued both by those being assessed and by those offering assessment [14]. When there is tension between the stated goals of assessment and the implicit culture of the health care organization or institution, assessment programs can too readily devolve into an activity undertaken primarily to satisfy administrators that rarely improves patient care [20]. Feedback mechanisms should be appropriate to the skills being assessed—multi-source reviews ("360° reviews"), for example, are generally better suited to providing feedback on communication and interpersonal skills than on technical knowledge or skills—and easy for evaluators to understand and use [14]. High quality feedback will come from multiple sources; be specific and focus on key elements of the ability being assessed; address behaviors rather than personality or personal characteristics; and "provide both positive comments to reinforce good behavior and constructive comments with action items to address deficiencies" [22]. Beyond such formal mechanisms, physicians should welcome and seek out informal input from colleagues. They should be willing to offer timely comments to colleagues as well.

One study among physicians and physicians in training found that participants used a dynamic, multidimensional process to assess their own abilities. Under this process of what researchers identified as "informed self-assessment," participants interpreted and responded to multiple types of information, such as cognitive and affective data, from both formal and informal sources [23]. Participants described "critically reflecting 'in action,' that is, during an activity or throughout the day:"

I think we do a lot of it without thinking of it as reflection. We do it every day when we look at a patient's chart. You look back and see the last visit, "What did I do, or should I have done something different?" I mean that's reflection, but yet I wouldn't have thought of that as self-assessment or self-reflection, but we do it dozens of times a day [23].

EXPERTISE & EXPERT JUDGMENT

On this broad understanding of competence, physicians' thought processes are as important as their knowledge base or technical skills. Thus, understanding competence requires understanding something of the nature of expertise and processes of expert reasoning, themselves topics of ongoing exploration [24,25,26,27]. Prevailing theory distinguishes "fast" from "slow" thinking; that is, reflexive, intuitive processes that require minimal cognitive resources versus deliberate, analytical processes that require more conscious effort [26]. Some scholars take expertise to involve "fast" processes, and specifically decision making that involves automatic, nonanalytic resources acquired through experience [24]. Others argue that expertise consists in using "slow," effortful, analytic processes to address problems [24]. A more integrative view argues that expertise resides in being able to transition between intuitive and analytical processes as circumstances require. On this account, experts use automatic resources to free up cognitive capacity so that they maintain awareness of the environment ("situational awareness") and can determine when to shift to effortful processes [24].

Expert judgment is the ability "to respond effectively in the moment to the limits of [one's] automatic resources and to transition appropriately to a greater reliance on effortful processes when needed" [24], a practice described as "slowing down." Knowing when to slow down and be reflective has been demonstrated to improve diagnostic accuracy and other outcomes [26]. To respond to the unexpected events that often arise in a clinical situation, the physician must "vigilantly monitor relevant environmental cues" and use these as signals to slow down, to transition into a more effortful state [25]. This can happen, for example, when a surgeon confronts an unexpected tumor or anatomical anomaly during a procedure. "Slowing down when you should" serves as a critical marker for intraoperative surgical judgment [24].

INFLUENCES ON CLINICAL REASONING

Clinical reasoning is a complex endeavor. Physicians' capabilities develop through education, training, and experiences that provide tools with which to shape their clinical reasoning. Every physician arrives at a diagnosis and treatment plan for an individual in ways that may align with or differ from the analytical and investigative processes of their colleagues in innumerable ways. When something goes wrong in the clinic, it can be difficult to discern why. Nonetheless, all physicians are open to certain common pitfalls in reasoning, including relying unduly on heuristics and habits of perception, and succumbing to overconfidence.

Heuristics

Physicians often use various heuristics—i.e., cognitive short cuts—to aid decision making. While heuristics can be useful tools to help physicians identify and categorize relevant information, these time-saving devices can also derail decision making. For example, a physician may mistakenly assume that "something that seems similar to other things in a certain category is itself a member of that category" (the representative heuristic) [28], and fail to diagnose a serious health problem. Imagine a case in which a patient presents with symptoms of a possible heart attack or a stroke that the physician proceeds to discount as stress or intoxication once the physician learns that the patient is going through a divorce or smells alcohol on the patient's breath. Or a physician may miscalculate the likelihood of a disease or injury occurring by placing too much weight "on examples of things that come to mind easily, . . . because they are easily remembered or recently encountered" (the availability heuristic) [28]. For example, amidst heavy media coverage of an outbreak of highly infectious disease thousands of miles away in a remote part of the world, a physician seeing a patient with symptoms of what is actually a more commonplace illness may misdiagnose (or over diagnose) the exotic condition because that is what is top of mind.

Clinical reasoning can be derailed by other common cognitive missteps as well. These can include misperceiving a coincidental relationship as a causal relationship (illusory bias), or the tendency to remember information transferred at the beginning (or end) of an exchange but not information transferred in the middle (primary or recency bias) [28,29,30].

Habits of Perception

Like every other person, physicians can also find themselves prone to explicit (conscious) or implicit (unconscious) habits of perception or biases. Physicians may allow unquestioned assumptions based on a patient's race or ethnicity, gender, socioeconomic status, or health behavior, among other features, to shape how they perceive the

patient and how they engage with, evaluate and treat the individual. Basing one's interactions with a patient on pre-existing expectations or stereotypes demeans the patient, undermines the patient's relationship with the physician and the health care system, and can result in significant health disparities across entire communities [31]. This is of particular concern for patients who are members of minority and historically disadvantaged populations [31]. Physicians may fall victim to the tendency to seek out information that confirms established expectations or dismiss contradicting information that does not fit into predetermined beliefs (confirmatory bias) [28]. These often inadvertent thought processes can result in a physician pursuing an incorrect line of questioning or testing that then leads to a misdiagnosis or the wrong treatment.

No matter how well a patient may seem to fit a stereotype, it is imperative that the physician look beyond categories and assumptions to investigate openly the health issues experienced by the patient. Although all human beings exhibit both conscious and unconscious habits of perception, physicians must remain vigilant in not allowing preconceived or unexamined assumptions to influence their medical practice.

Overconfidence

Finally, another obstacle to strong clinical reasoning that physicians may encounter is overconfidence. Despite their extensive training, physicians, like all people, are poor at identifying the gaps in their knowledge [28,30]. Physicians may consider their skills to be excellent, when, in fact, their peers have identified areas for improvement [30]. Overconfidence in one's abilities can lead to suboptimal care for a patient, be it through mismanaging resources, failing to consider the advice of others, or not acknowledging one's limits [28,30].

To avoid falling into such traps, physicians must recognize that many factors can and will influence their clinical decisions [28]. They need to be aware of the information they do and do not have and they need to acknowledge that many factors can and will influence their judgment. They should keep in mind the likelihood of diseases and conditions and take the time to distinguish information that is truly essential to sound clinical judgment from the wealth of possibly relevant information available about a patient. They should consider reasons their decisions may be wrong and seek alternatives, as well as seek to disprove rather than confirm their hypotheses [28]. And they should be sensitive to the ways in which assumptions may color their reasoning and not allow expectations to govern their interactions with patients.

Shortcomings can be an opportunity for growth in medicine, as in any other field. By becoming aware of areas in which their skills are not at their strongest and seeking additional education or consulting with colleagues, physicians can enhance their practice and best serve their patients.

FROM INFORMED SELF-ASSESSMENT TO SELF-AWARENESS

Recognizing that many factors affect clinical reasoning and that self-assessment as traditionally conceived has significant shortcomings, several scholars have argued that a different understanding of self-assessment is needed, along with a different conceptualization of its role in a self-regulating profession [32]. Self-assessment, it is suggested, is a mechanism for identifying both one's weaknesses and one's strengths. One should be aware of one's weaknesses in order to self-limit practice in areas in which one has limited competence, to help set appropriate learning goals, and to identify areas that "should be accepted as forever outside one's scope of competent practice" [32]. Knowing one's strengths, meanwhile, allows a physician both to "act with appropriate confidence" and to "set appropriately challenging learning goals" that push the boundaries of the physician's knowledge [32].

If self-assessment is to fulfill these functions, physicians need to reflect on past performance to evaluate not only their general abilities but also specific completed performances. At the same time, they must use self-assessment predictively to assess how likely they are to be able to manage new challenges and new situations. More important, physicians should understand self-assessment as an ongoing process of monitoring tasks during performance [3]. The ability to monitor oneself in the moment is critical to physicians' ethical responsibility to practice safely, at the top of their expertise but not beyond it.

Expert practitioners rely on pattern recognition and other automatic resources to be able to think and act intuitively. As noted above, an important component of expert judgment is transitioning effectively from automatic modes of thinking to more effortful modes as the situation requires. Self-awareness, in the form of attentive self-observation (metacognitive monitoring), alerts physicians when they need to direct additional cognitive resources to the

immediate task. For example, among surgeons, knowing when to “slow down” during a procedure is critical to competent professional performance, whether that means actually stopping the procedure, withdrawing attention from the surrounding environment to focus more intently on the task at hand, or removing distractions from the operating environment [25].

Physicians should also be sensitive to the ways that interruptions and distractions, which are common in health care settings, can affect competence in the moment [34,35], by disrupting memory processes, particularly the “prospective memory”—i.e., “a memory performance in which a person must recall an intention or plan in the future without an agent telling them to do so”—important for resuming interrupted tasks [35,36]. Systems-level interventions have been shown to help reduce the number or type of interruptions and distractions and mitigate their impact on medical errors [37].

A key aspect of competence is demonstrating situation-specific awareness in the moment of being at the boundaries of one’s knowledge and responding accordingly [33]. Slowing down, looking things up, consulting a colleague, or deferring from taking on a case can all be appropriate responses when physicians’ self-awareness tells them they are at the limits of their abilities. The capacity for ongoing, attentive self-observation, for “mindful” practice, is an essential marker of competence broadly understood:

Safe practice in a health professional’s day-to-day performance requires an awareness of when one lacks the specific knowledge or skill to make a good decision regarding a particular patient This decision making in context is importantly different from being able to accurately rate one’s own strengths and weaknesses in an acontextual manner. . . . Safe practice requires that self-assessment be conceptualized as repeatedly enacted, situationally relevant assessments of self-efficacy and ongoing ‘reflection-in-practice,’ addressing emergent problems and continuously monitoring one’s ability to effectively solve the current problem [32].

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills [32]. Self-aware physicians are also alert to how external stressors—the death of a loved one or other family crisis, or the reorganization of their practice, for example—may be affecting their ability to provide care appropriately at a given time. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient’s well-being.

MAINTAINING COMPETENCE ACROSS A PRACTICE LIFETIME

For physicians, the ideal is not simply to be “good” practitioners, but to excel throughout their professional careers. This ideal holds not just over the course of a sustained clinical practice, but equally when physicians re-enter practice after a hiatus, transition from active patient care to roles as educators or administrators, or take on other functions in health care. Self-assessment and self-awareness are central to achieving that goal.

A variety of strategies are available to physicians to support effective self-assessment and help physicians cultivate the kind of self-awareness that enables them to “know when to slow down” in day-to-day practice. One such strategy might be to create a portfolio of materials for reflection in the form of written descriptions, audio or video recording, or photos of encounters with patients that can provide evidence of learning, achievement and accomplishment [16] or of opportunities to improve practice. A strength of portfolios as a tool for assessing one’s practice is that, unlike standardized examinations, they are drawn from one’s actual work and require self-reflection [15].

As noted above, to be effective, self-assessment must be joined with input from others. Well-designed multi-source feedback can be useful in this regard, particularly for providing information about interpersonal behaviors [14]. Research has shown that a four-domain tool with a simple response that elicits feedback about how well one maintains trust and professional relationships with patients, one’s communication and teamwork skills, and accessibility offers a valid, reliable tool that can have practical value in helping to correct poor behavior and, just as important, consolidate good behavior [14]. Informal arrangements among colleagues to provide thoughtful feedback will not have the rigor of a validated tool but can accomplish similar ends.

Reflective practice, that is, the habit of using critical reflection to learn from experience, is essential to developing and maintaining competence across a physician’s practice lifetime [38]. It enables physicians to “integrate personal

beliefs, attitudes, and values in the context of professional culture,” and to bridge new and existing knowledge. Studies suggest that reflective thinking can be assessed, and that it can be developed, but also that the habit can be lost over time with increasing years in practice [38].

“Mindful practice,” that is, being fully present in everyday experience and aware of one’s own mental processes (including those that cloud decision making) [39], sustains the attitudes and skills that are central to self-awareness. Medical training, with its fatigue, dogmatism, and emphasis on behavior over consciousness, erects barriers to mindful practice, while an individual’s unexamined negative emotions, failure of imagination, and literal-mindedness can do likewise. Mindfulness can be self-taught, but for most it is most effectively learned in relationship with a mentor or guide. Nonetheless, despite challenges, there are myriad ways physicians can cultivate mindfulness. Meditation, which may come first to mind, is one, but so is keeping a journal, reviewing videos of encounters with patients, or seeking insight from critical incident reports [39].

“Exemplary physicians,” one scholar notes, “seem to have a capacity for self-critical reflection that pervades all aspects of practice, including being present with the patient, solving problems, eliciting and transmitting information, making evidence-based decisions, performing technical skills, and defining their own values” [39].

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted by society. To this end, medical schools, residency and fellowship programs, specialty boards, and other health care organizations regularly assess physicians’ technical knowledge and skills.

However, as an ethical responsibility competence encompasses more than medical knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Each phase of a medical career, from medical school through retirement, carries its own implications for what a physician should know and be able to do to practice safely and to maintain effective relationships with patients and with colleagues. Physicians at all stages of their professional lives need to be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole.

To fulfill the ethical responsibility of competence, individual physicians and physicians in training should strive to:

- (a) Cultivate continuous self-awareness and self-observation;
- (b) Recognize that different points of transition in professional life can make different demands on competence;
- (c) Take advantage of well-designed tools for self-assessment appropriate to their practice settings and patient populations;
- (d) Seek feedback from peers and others; and
- (e) Be attentive to environmental and other factors that may compromise their ability to bring appropriate skills to the care of individual patients and act in the patient’s best interest.

Medicine as a profession should continue to refine mechanisms for assessing knowledge and skill and should develop meaningful opportunities for physicians and physicians in training to hone their ability to be self-reflective and attentive in the moment.

REFERENCES

1. American Medical Association Code of Medical Ethics. Principle I. Available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed August 20, 2016.
2. American Medical Association Code of Medical Ethics. Opinion 11.2.1, Professionalism in health care systems. Available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed August 20, 2016.
3. American Medical Association Code of Medical Ethics. Opinion 1.2.3, Consultation, referral and second opinions. Available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed August 20, 2016.
4. American Medical Association Code of Medical Ethics. Opinion 1.1.6, Quality. Available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed August 20, 2016.
5. Gordon MJ. A review of the validity and accuracy of self-assessments in health professions training. *Acad Med.* 1991;66:762–769.
6. American Medical Association Code of Medical Ethics. Principle II. Available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed August 20, 2016.
7. American Medical Association Code of Medical Ethics. Opinion 9.4.2, Reporting incompetent or unethical behavior by colleagues. Available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed August 20, 2016.
8. American Medical Association Code of Medical Ethics. Opinion 9.4.3, Discipline and medicine. Available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed August 20, 2016.
9. American Medical Association Code of Medical Ethics. Opinion 8.6, Promoting patient safety. Available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed August 20, 2016.
10. Epstein RM, Hundert EM. Defining and assessing professional competence. *JAMA.* 2002;287(2):226–235.
11. Epstein RM, Siegel DJ, Silberman J. Self-monitoring in clinical practice: a challenge for medical educators. *J Contin Educ Health Professions.* 2008;28(1):5–13.
12. Colthart I, Bagnall G, Evans A, et al. The effectiveness of self-assessment on the identification of learner needs, learner activity, and impact on clinical practice: BEME Guide no. 10. *Medical Teacher.* 2008;30:124–145.
13. DA, Mazmanian PE, Fordis M, et al. Accuracy of physician self-assessment compared with observed measures of competence: a systematic review. *JAMA.* 2006;296:1094–1102.
14. Whitehouse A, Hassell A, Bullock A, et al. 360 degree assessment (multisource feedback) of UK trainee doctors: filed testing of team assessment behaviors (TAB). *Medical Teacher* 2007;29:171–178.
15. O'Sullivan P, Greene C. Portfolios: possibilities for addressing emergency medicine resident competencies. *Acad Emerg Med.* 2002;9(11):1305–1309.
16. Leigh IW, Smith IL, Bebeau M, et al. Competency assessment models. *Professional Psychology: Research and Practice* 2007;38(5):463–473.
17. Lipssett PA, Harris I, Downing S. Resident self-other assessor agreement: influence of assessor, competency, and performance level. *Arch Surg.* 2011;146(8):901–906.
18. Svirko E, Lambert T, Goldacre MJ. Gender, ethnicity and graduate status, and junior doctors' self-reported preparedness for clinical practice: national questionnaire surveys. *J Royal Society Med.* 2014;107(2):66–74.
19. Dunning D. Strangers to ourselves? *The Psychologist.* 2006;19(10):600–603.
20. Mann K, van der Vleuten C, Eva K, et al. Tensions in informed self-assessment: how the desire for feedback and reticence to collect and use it can conflict. *Acad Med.* 2011;86(9):1120–1127.
21. Sargeant J, Mann K, Ferrier S. Exploring family physicians' reactions to multisource feedback: perceptions of credibility and usefulness. *Medical Education* 2005;39:497–504.
22. Jackson JL, Kay C, Jackson WC, Frank M. The quality of written feedback by attendings of internal medicine residents. *J Gen Intern Med.* 2015;30(7):973–978.
23. Sargeant J, Amson H, Chesluk B, et al. The processes and dimensions of informed self-assessment: a conceptual model. *Acad Med.* 2010;85:1212–1220.
24. Moulton CE, Regehr G, Mylopoulos M, MacRae HM. Slowing down when you should: a new model of expert judgment. *Acad Med.* 2007;82(10 Suppl):S109–S116.
25. Moulton C, Regehr G, Lingard L, et al. Slowing down to stay out of trouble in the operating room: remaining attentive in automaticity. *Acad Med.* 2010;85(10):1571–1577.
26. Croskerry P. Achieving quality in clinical decision making: cognitive strategies and detection of bias. *Acad Emerg Med.* 2002;9(11):1184–1204.
27. Sklar DP. How do we think? can we learn to think? *Acad Med.* 2014;89:191–193.
28. Klein JG. Five pitfalls in decisions about diagnosis and prescribing. *BMJ* 2005;330:781–784.
29. Croskerry P, Petrie DA, Reilly B, Tait G. Deciding about fast and slow decisions. *Acad Med.* 2014;89:197–200.
30. Kadar N. Peer review of medical practices: missed opportunities to learn. *AJOG.* 2014; Dec:596–601.
31. Cooper LA, Roter DL, Carson KA, et al. The association of clinicians' implicit attitudes about race with medical visit communication and patient ratings of interpersonal care. *Am J Public Health.* 2012;102:979–987.

32. Eva KW, Regehr G. Self-assessment in the health professions: a reformulation and research agenda. *Acad Med*. 2005;80(10 Suppl):S46–S54.
33. Eva KW, Regehr G. Knowing when to look it up: a new conception of self-assessment ability. *Acad Med* 2007;82(10 Suppl): 581–584.
34. Rivera AJ, Karsh B-T. Interruptions and distractions in healthcare: review and reappraisal. *Qual Saf Health Care*. 2010;19(4):304–312.
35. Grundgeiger T, Sanderson P. Interruptions in health care: theoretical views. *Intl J Med Informatics* 2009;78:293–307.
36. Monsell S. Task switching. *TRENDS in Cog Sciences*. 2003;7(3).
37. Relihan E, O'Brien V, O'Hara S, et al. The impact of a set of interventions to reduce interruptions and distractions to nurses during medication administration. *Qual Saf Health Care*. 2010; May 28.
38. Mann K, Gordon J, MacLeod A. Reflection and reflective practice in health professions education: a systematic review. *Adv in Health Sci Educ*. 2009;14:595–621.
39. Epstein RM. Mindful practice. *JAMA*. 1999;282(9):833–839.

2. MERGERS OF SECULAR AND RELIGIOUSLY AFFILIATED HEALTH CARE INSTITUTIONS

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

See Policy H-140.832

Mergers between secular and religiously affiliated hospitals are changing the landscape of health care across the United States. This report by the Council on Ethical and Judicial Affairs (CEJA) offers ethics guidance to address the challenges such mergers can pose for patients, physicians, health care institutions and the communities they serve.

RELIGIOUSLY AFFILIATED HEALTH CARE INSTITUTIONS

The concept of the hospital as a facility providing inpatient care for the sick originated with the Catholic Church, with the original and enduring dual mission of healing the body and promoting spiritual well-being [1]. The mission of today's Catholic Health Association remains focused on the needs of those who are "poor, underserved, and most vulnerable" [2]. Although hospitals established by Protestant denominations and Jewish-identified facilities remain important segments of U.S. health care, Catholic facilities predominate among religiously affiliated institutions—U.S. Catholic Health Care is the largest nonprofit care provider in the country [2].

Since the 1990s, mergers between secular and religiously affiliated hospitals and health care institutions have been reshaping the landscape of health care in the United States, for both patients and physicians. Driven by economic considerations and changes in health policy, notably in recent years emphasis on accountable care organizations and bundled payments [1,3], mergers have enabled facilities in some cases simply to survive and in others to thrive within their communities. Consolidation has enabled hospitals to control a greater share of their local markets and to negotiate effectively with insurers [4].

Religiously affiliated hospitals and facilities benefit from the tax-exempt status of the religious institutions they represent and from other tax subsidies that derive from their mission to serve the poor and provide charitable care [5]. Although the majority of religiously affiliated hospitals remain nonprofit, the number of for-profit hospitals affiliated with religious institutions increased by 22 percent between 2001 and 2016 [6]. Religiously affiliated health care facilities—which encompass clinics, hospitals, and long-term care facilities—are also important employers. According to the Catholic Health Association, as of 2017 member facilities employed more than 500,000 full-time and 200,000 part time staff [2].

In some communities, religiously affiliated health care institutions may be the only providers [6]—as of 2015, 132 of the nation's approximately 1,300 critical access hospitals were members of U.S. Catholic Health Care [2]. In some areas, more than 40 percent of short-term, acute care beds are in Catholic facilities [6]. Nationwide, one in every six patients now receives care in a Catholic hospital [2].

THE DILEMMA OF MERGERS

The consolidation of a religiously affiliated institution with a secular health care facility raises challenges for all stakeholders—the facilities, their communities, their patients, and the physicians and other professionals who provide care. All religiously affiliated institutions seek to remain faithful to their defining mission and values, which can place them in tension with their secular counterparts. Catholic facilities, however, are embroiled in an increasingly public debate about the implications and effects of entering into arrangements with secular institutions as they seek to retain their identity and mission and still survive in the health care market place. Thus they offer a window through which to understand the ethical dimension of health care mergers.

As the Ethical and Religious Directives that govern care in Catholic health care facilities observe:

New partnerships can be opportunities to realign the local delivery system in order to provide a continuum of health care to the community; they can witness to a responsible stewardship of limited health care resources; and they can be opportunities to provide to poor and vulnerable persons a more equitable access to basic care.

On the other hand, new partnerships can pose serious challenges to the viability of the identity of Catholic health care institutions and services, and their ability to implement these Directives in a consistent way, especially when partnerships are formed with those who do not share Catholic moral principles (§VI)[7].

From this perspective, in the contemporary health care market place Catholic hospitals “are caught in an impossible bind” [1]. Like other hospitals, financial pressures drive them to consolidate with other institutions to become more economically efficient. Yet “competing in the aggressive world of the medical business industry” can put Catholic hospitals’ historical commitment to the poor at risk [1]. At the same time, gaining financial security may risk “imperceptibly compromising their traditional Catholic witness” when compromises are made with respect to Directives [1].

From the perspective of those they serve, a merger or consolidation may help guarantee the continued presence of health care in a community, but may also limit the range of services available to patients when the consolidated entity adheres to the Directives. Certain treatment choices for care at the end of life, reproductive health care services, and, by some reports, certain services for transgender individuals may all be affected [4,8,9]. Limitations on women’s health services have been a focus of concern for obstetricians and gynecologists associated with or employed by religiously affiliated hospitals [10], with reports of conflict over both elective and clinically indicated surgical sterilization [11,12], and management of miscarriage [13]. Restricted access to services can have a disproportionate impact on poor women, and women in rural areas where religiously affiliated institutions are the only providers of care [14].

From the perspective of physicians and other health care professionals affiliated with or employed by the entity that results from a merger can challenge professional commitments. A merger that results in loss of access to services for the community and requires physicians to follow the religious guidelines embodied in the Directives may result in “conflict with prevailing medical standards of care and ethical principles of health care professional” [15]. Physicians and other health care professionals who are not members of the faith tradition may find themselves contractually prohibited from providing care that is otherwise legal and, in their professional judgment, clinically appropriate and ethically permissible under the norms of medical professionalism.

THE RESPONSIBILITIES OF LEADERSHIP

As challenging as mergers between secular and religiously affiliated health care facilities may be for individual patients and physicians, addressing dilemmas of mission is pre-eminently a responsibility of hospital leadership.

For Catholic facilities merging with secular facilities (or facilities associated with other religious traditions), a touchstone is the principle of cooperation [16,17]. The principle, it is argued, is a necessity for business relationships in a pluralistic world, providing a way to address the reality that, for the faithful, “it is almost impossible to bring about good without brushing up against or even becoming somewhat involved in the wrongdoing of others” [16]. The principle of cooperation is understood “as a *limiting principle*, to avoid cooperating in evil” (original emphasis) [17].

The essential goal is to ensure that institutional arrangements allow the facility and its staff to “remain as removed as possible” from violations of the Directives and “not [to] contribute anything essential to make possible the wrongdoing’s occurring” [16]—e.g., essential employed staff or equipment for the performance of what under the Directives is an immoral procedure [17]. Whether services that would be otherwise prohibited by the Directives will or may be available through the merged entity is importantly a function of how caregiving is organized in the resulting composite system. The approval of the diocesan bishop is required for mergers involving facilities subject to his governing authority, and the diocesan bishop has final authority for assessing whether a proposed merger constitutes morally licit cooperation (§VI) [7].

Analogous discussions of the ethics of trusteeship, such as that offered by The Hastings Center, offer secular insight for thinking about the responsibilities of leaders in health care institutions. Trustees of not-for-profit health care organizations “regularly make decisions that affect the lives and well-being of a large number of people who are relatively powerless, relatively vulnerable, and in need of services or assistance” [18]. In light of the mission of such organizations, service on a board of trustees entails fiduciary duties to founders, benefactors, and donors and responsibility to ensure that the organization realizes the public benefits for which it enjoys tax exempt status.

Trustees are held to principles of fidelity to mission; service to patients, ensuring that the care is high quality and provided “in an effective and ethically appropriate manner”; service to the community the hospital serves, deploying hospital resources “in ways that enhance the health and quality of life” of the community; and institutional stewardship. They have a further responsibility to ensure that when there is conflict over fundamental values and principles, “all points of view are heard and taken seriously, that reasonable compromise is explored, and that consensus has time to form” [18].

The Principles of Integrated Leadership for Hospitals and Health Care Systems, developed in collaboration by the American Hospital Association (AHA) and the American Medical Association (AMA), address responsibilities of hospital leadership in the context of rapidly evolving models of integrated physician-hospital health care systems [19]. In addition to governance and management structure and leadership development, guidance identifies “cultural adaptation” as a key element for success, observing that:

Culture is the way an organization, institution or integrated health system does business, in a way that is predictable, known to all and consonant with the mission and values of the organization, institution or integrated health system. The creation of a common shared culture that includes an integrated set of values is important to serve as a guide to the entity and will serve as a touch point to help resolve the inevitable conflicts that will arise [19].

The AHA-AMA’s principles for *Integrated Leadership for Hospitals and Health Systems* urge integrated health systems to cultivate the characteristics of adaptive institutional culture, including a focus on the health of the entire population served; agreement to a common mission, vision, and values; mutual understanding and respect; and a sense of common ownership of the entity and its reputation [19].

INSIGHT FROM THE CODE OF MEDICAL ETHICS

As frontline clinicians, physicians (and other health care professionals) regularly confront the effects on patients’ lives and well-being of the institutional arrangements through which care is delivered. They have a responsibility to advocate for the resources patients need, as well as to be responsible stewards of the resources with which they are entrusted [20]. They must be able to make treatment recommendations in keeping with their best judgment as medical professionals [21]. And they are expected to uphold the ethical norms of medicine, including fidelity to patients and respect for patients as moral agents and decision makers [22].

Existing guidance on exercise of conscience by individual physicians suggests essential responsibilities of leadership in health care as well [22]. These include responsibility to engage in thoughtful consideration of the implications of institutional arrangements—whether arrangements sustain or risk undermining the personal and professional integrity of staff, cause moral distress, or compromise the ability to provide care. Leaders in health care institutions must be mindful that arrangements do not discriminate against or unduly burden individual patients or populations of patients, and of the burden arrangements may place on fellow professionals. And they must accept responsibility to take steps to ensure that services will be available to meet the patients and community the institution serves.

RECOMMENDATION

In light of this analysis, the Council on Ethical and Judicial Affairs recommends that the following be adopted, and the remainder of this report be filed:

The merger of secular health care institutions and those affiliated with a faith tradition can benefit patients and communities by sustaining the ability to provide a continuum of care locally in the face of financial and other pressures. Yet consolidation among health care institutions with diverging value commitments and missions may also result in limiting what services are available. Consolidation can be a source of tension for the physicians and other health care professionals who are employed by or affiliated with the consolidated health care entity.

Protecting the community that the institution serves as well as the integrity of the institution, the physicians and other professionals who practice in association with it, is an essential, but challenging responsibility.

Physician-leaders within institutions that have or are contemplating a merger of secular and faith-based institutions should:

- (a) Seek input from stakeholders to inform decisions to help ensure that after a consolidation the same breadth of services and care previously offered will continue to be available to the community.
- (b) Be transparent about the values and mission that will guide the consolidated entity and proactively communicate to stakeholders, including prospective patients, physicians, staff, and civic leaders, how this will affect patient care and access to services.
- (c) Negotiate contractual issues of governance, management, financing, and personnel that will respect the diversity of values within the community and at minimum that the same breadth of services and care remain available to the community.
- (d) Recognize that physicians' primary obligation is to their patients. Physician-leaders in consolidated health systems should provide avenues for meaningful appeal and advocacy to enable associated physicians to respond to the unique needs of individual patients.
- (e) Establish mechanisms to monitor the effect of new institutional arrangements on patient care and well-being and the opportunity of participating clinicians to uphold professional norms, both to identify and address adverse consequences and to identify and disseminate positive outcomes.

Individual physicians associated with secular and faith-based institutions that have or propose to consolidate should:

- (f) Work to hold leaders accountable to meeting conditions for professionalism within the institution.
- (g) Advocate for solutions when there is ongoing disagreement about services or arrangements for care.

REFERENCES

1. Guinan P. Catholic hospitals, are mergers the way to go? *Linacre Quarterly*. 2014;81(2):107–110.
2. Catholic Health Association. *U.S. Catholic Health Care 2017*. Available at <https://www.chausa.org/store/products/product?id=3455>. Accessed August 30, 2017.
3. Hill EL, Slusky DJG. Medically Necessary But Forbidden: Reproductive Health Care in Catholic-owned Hospitals, March 2017 [discussion paper]. Available at <https://economics.ku.edu/sites/economics.ku.edu/files/files/Seminar/papers1617/april%2026.pdf>. Accessed August 4, 2017.
4. American Civil Liberties Union. Health Care Denied, May 2016. Available at <https://www.aclu.org/mwg-internal/de5fs23hu73ds/progress?id=XGdSUFilEMNhTLIOIDDkVgjFI1WeJSEtthzNOu9Q8G0>. Accessed August 4, 2017.
5. Mencimer S. Charts: Catholic hospitals don't do much for the poor. *Mother Jones*. 2012;Dec 18. Available at <http://www.motherjones.com/politics/2013/12/catholic-hospitals-arent-doing-much-poor/>. Accessed August 3, 2017.
6. Uttley L, Khaikin C. Growth of Catholic Hospitals and Health Systems. *MergerWatch 2016*. Available at http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW_Update-2016-MiscarrOfMedicine-report.pdf?token=7BGsnPyq440GPR0AyWEgqOThYQ8%3D. Accessed August 4, 2017.

7. U.S. Conference of Catholic Bishops. *Ethical and Religious Directives for Catholic Health Services, 5th ed.* Washington, DC: USSCB 2009. Available at <http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf>. Accessed April 23, 2017.
8. Stulberg DB, Lawrence RE, Shattuck J, Curlin FA. Religious hospitals and primary care physicians: conflicts over policies for patient care. *J Gen Intern Med.* 2010;25(7):725–730.
9. Somashekar S. Transgender man sues Catholic hospital for refusing surgery. *Washington Post.* 2017;Jan 6. Available at https://www.washingtonpost.com/news/post-nation/wp/2017/01/06/transgender-man-sues-catholic-hospital-for-refusing-surgery/?utm_term=.08d436ce9705. Accessed August 3, 2017.
10. Stulberg DB, Dude AM, Dahlquist I, Curlin FA. Obstetrician-gynecologists, religious institutions, and conflicts regarding patient care policies. *Am J Obstet Gynecol.* 2012;207(1):73.31–73.e5.
11. Egelko B. Legal case tests religious hospitals' right to deny procedures. *San Francisco Chronicle.* 2015;Aug 25. Available at <http://www.sfchronicle.com/health/article/Lawsuit-tests-religious-hospitals-right-to-6461051.php>. Accessed August 1, 2017.
12. Stulberg DB, Hoffman Y, Dahlquist IH, Freedman LR. Tubal ligation in Catholic hospitals: a qualitative study of ob-gyns' experiences. *Contraception.* 2014;90(4):422–428.
13. Freedman LR, Landy U, Steinauer J. When there's a heartbeat: miscarriage management in Catholic-owned hospitals. *Am J Public Health.* 2008;98(10):1774–1778.
14. Sloboda M. The high cost of merging with a religiously-controlled hospital. *Berkeley J Gender, Law & Justice* 2013;16(1):140–156.
15. Uttley L, Reynertson S, Pawelko J, et al. Merging Catholic and non-sectarian hospitals: NYS models for addressing the ethical challenges [briefing paper]. *Merger Watch 2014.* Available at <http://static1.1.sqspcdn.com/static/f/816571/23042588/1372882137057/Models+of+Catholic-secular+hospitals+mergers+in+NYS.pdf?token=WMgcWaEMDP2zcdqKtRUngnSaaRQ%3D>. Accessed August 3, 2017.
16. Hamel R. Cooperation: a principle that reflects reality. *Health Progress.* 2012;Sept-Oct:80–82.
17. Cataldo PJ, Haas JM. Institutional cooperation: the ERDs. *Health Progress.* 2002;Nov-Dec:49–60.
18. Jennings B, Gray BH, Sharpe VA, et al. Ethics and trusteeship for health care [special supplement]. *Hastings Center Report.* 2002;Jul-Aug:S1–S27.
19. American Hospital Association, American Medical Association. *Integrated Leadership for Hospitals and Health Systems: Principles for Success, 2015.* Available at <http://www.aha.org/content/15/ahaaintegrleadership.pdf>. Accessed August 30, 2017.
20. American Medical Association. *Code of Medical Ethics.* Opinion E-11.1.2, Physician stewardship of health care resources. Available at <http://static1.1.sqspcdn.com/static/f/816571/23042588/1372882137057/Models+of+Catholic-secular+hospitals+mergers+in+NYS.pdf?token=WMgcWaEMDP2zcdqKtRUngnSaaRQ%3D>. Accessed August 8, 2017.
21. American Medical Association. *Code of Medical Ethics.* Opinion E-11.2.1, Professionalism in health care systems. Available at <http://static1.1.sqspcdn.com/static/f/816571/23042588/1372882137057/Models+of+Catholic-secular+hospitals+mergers+in+NYS.pdf?token=WMgcWaEMDP2zcdqKtRUngnSaaRQ%3D>. Accessed August 8, 2017.
22. American Medical Association. *Code of Medical Ethics.* Opinion E-1.1.7, Physician exercise of conscience. Available at <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-1.pdf>. Accessed August 8, 2017.

3. MEDICAL TOURISM

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**

See Policy H-140.834

Policy H-460.896(a), “Stem Cell Tourism,” adopted at the 2016 Annual meeting, calls on the American Medical Association (AMA) to encourage study of “appropriate guidance for physicians to use when advising patients who seek to engage in stem cell tourism and how to guide them in risk assessment.”

In keeping with this policy, the Council on Ethical and Judicial Affairs (CEJA) was asked to develop ethics guidance for physicians in this area. Based on its review of relevant literature and its deliberations, the council concluded that guidance focusing on the broader phenomenon of medical tourism, of which stem cell tourism is only one example, would better serve the profession. The following report and recommendations thus provide broad guidance for physicians who interact with patients who seek or have received medical care outside the U.S.

EMERGENCE OF MEDICAL TOURISM

Every year, a growing number of “medical tourists” cross borders to receive treatments and procedures, often treatments that are unaffordable or unavailable to them at home [1]. In its broadest sense, “medical tourism” refers to any occasion on which patients travel outside their home geographic area to receive medical care elsewhere—for example, traveling to a center of excellence in another city or state. As most commonly used today, however, medical tourism refers to traveling to a foreign country to receive care. It encompasses international travel by wealthy patients from lower wage countries to medical centers in higher wage countries, notably the U.S. [2]. Increasingly, however, medical tourism is understood as travel in the opposite direction, from higher wage countries to less affluent countries where medical services are available at lower cost [2,3].

Estimations of how many patients travel abroad for care vary considerably, but appear to exceed one million [4,5]. In some instances, patients travel abroad for care at the recommendation of their own physicians or under the auspices of programs initiated by their health plans or employers [2,6,7]. In others, patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies [2].

MEDICAL SERVICES OFFERED

Medical tourists travel to address what they deem to be unmet personal medical needs [8], prompted by issues of cost, timely access to services, higher quality of care or perceived superior services, or to access services that are not available in their country of residence [9,10]. Patients may also go outside their usual health care system to achieve other goals, for example, to preserve anonymity [11]; immigrant patients may return to their country of origin to receive care in culturally familiar settings [9]. The care medical tourists seek may be elective procedures; medically necessary standard care; or care that is unapproved or legally or ethically prohibited in their home system [12].

Elective Procedures: “Cosmetic Tourism”

A significant and expanding portion of the medical tourism industry is comprised of individuals who seek cosmetic procedures that are available in their home country but are offered at often considerably lower cost elsewhere [11,13,14]. For example, 2011 data indicate that breast implants that would have cost approximately \$6,000 in the U.S. were available for about 43 percent of that cost in Thailand (approximately \$2,600) and less than 25 percent (approximately \$1,248) in Cuba [11]. Because cosmetic procedures are generally not covered by insurance plans and patients must pay out of pocket, going abroad for a desired procedure can be an attractive option. However, as Australian researchers noted, “[t]he model of care by which these services are delivered limits preoperative assessment and follow up to a few days to a week” [14].

Medically Necessary Care: “Transplant Tourism”

Medical tourism also encompasses care that would be deemed “medically necessary,” such as cardiac care (coronary artery bypass grafts, heart valve replacements, angioplasty) and orthopedic surgery (hip and knee replacement, hip resurfacing, spinal fusion) [15]. Patients from publicly funded health care systems, such as Canada, Australia, or the U.K., cite long wait times at home as a primary reason for seeking care abroad [16], although they could receive needed care in their home system. Uninsured or underinsured patients in predominantly private health care systems, such as the U.S., travel to access needed care that would otherwise not be available to them [3].

Over the past decade “transplant tourism” has emerged as a particularly problematic form of medical tourism. As one critique noted, many of the patients who go abroad for an organ transplant are “middle-income Americans evading impoverishment by expensive, medically necessary operations” [17]. Self-insured employers may encourage transplant tourism in an effort to contain health care costs [18]. A study of transplant tourists who presented for follow-up care at one U.S. facility found that these patients “had a substantially lower mean dialysis time before transplantation” compared with patients who underwent transplant at the institution [19]. By one estimate, as of 2007 some 10 percent of transplants worldwide involved commercial sales of organs [20]. Organ trafficking and the exploitation of vulnerable donors in resource poor countries associated with transplant tourism led the international transplant community in 2008 to adopt principles intended to curb unethical transplant practices [20].

Unapproved/Investigational Therapies: “Stem Cell Tourism”

Other than therapies for blood disorders, there is no evidence that stem-cell-based interventions are efficacious. Yet the market in stem cell tourism continues to grow—by 2012 some 700 clinics worldwide offered stem cell therapy for spinal cord injury, cardiovascular disease, Parkinson’s and a host of other conditions [21]. For the most part, these therapies are unapproved and unregulated [21,22].

A recent case highlights the dangers of stem cell therapy. Richard Gass, a retired attorney in the U.S., suffered a stroke that left one arm paralyzed and one leg with weakness. Although he was able to live independently, he encountered a story about the miraculous physical recovery of a professional athlete who had traveled to Russia for stem cell treatments following a serious injury. Convinced of the promise stem cell treatments could bring, and undeterred by his family’s concerns about the dangers of these therapies, he traveled to Mexico to receive stem-cell injections. Despite improvement in his mobility early on, within months Gass became paralyzed from the neck down. When he sought follow-up care from his U.S. health care team, they discovered that a large, rapidly growing tumor along his spine derived from foreign cells that could not be completely removed [23].

In 2013, the International Society for Stem Cell Research called on governments and professional organizations to discourage commercial provision of (autologous) stem cell interventions outside of clinical trials [24]. Governments are moving to strengthen or more stringently enforce legal regulations where they exist [25]. For example, the U.S. Food and Drug Administration has issued draft guides that increase clarity and suggest that the U.S. Food and Drug Administration is preparing to take increased regulatory action in response to stem cell interventions offered domestically [26].

Proscribed Therapies: “Reproductive Tourism” (“Fertility Exile”)

As another area of medical tourism, travel for reproductive services highlights in particular issues involving access to services that for legal or ethical reasons are not available in the health care system where the patient(s) reside, or that are denied to certain categories of patients [27,28]. Hence the suggestion that such travel might better be described as “fertility exile” [29]. As reproductive tourists, patients may cross borders to receive services that are not legally available in their home health care system (e.g., pre-implantation genetic diagnosis); services for which they do not qualify in their home system by reason of age or marital status (e.g., in vitro fertilization); or services denied by their home health care institutions or health systems based on social rather than clinical considerations (e.g., gestational surrogacy for male same-sex couples) [28]. By one estimate, some 5,000 cross-border IVF treatment cycles were performed in 25 countries in 2008 [30].

Like transplant tourism, reproductive tourism raises concerns about the exploitation of vulnerable populations and the commercialization of human biological materials, as well as about discrimination against classes of patients [28,30,31]. Travel for unapproved or prohibited services can also exploit medical tourists themselves, of course, when it trades on false hope [12].

IMPLICATIONS FOR PATIENTS, PHYSICIANS & HEALTH CARE SYSTEMS

Many medical tourists receive excellent care, but data suggest that issues of safety and quality can loom large. Substandard surgical care, poor infection control, inadequately screening of blood products, and falsified or outdated medications in lower income settings of care can pose greater risks than patients would face at home [32,33]. Patients who develop complications may need extensive follow-up care when they return home; for those who return with infections, the differential diagnosis is often broader than in their home country, further complicating follow-up care [33]. The often short recovery periods following treatment abroad also mean medical tourists can face greater risk for deep vein thrombosis, pulmonary embolism, or other travel-related complications [5,14,33].

For example, in 2013, the Maryland Department of Health and Mental Hygiene dealt with the repercussions of medical tourists traveling outside the U.S. for cosmetic surgery. Public health officials, working with the CDC, identified 21 patients from six states who had traveled to the Dominican Republic for cosmetic procedures (liposuction, abdominoplasty, buttocks augmentation, breast augmentation, and breast reduction); 18 were confirmed to have rapidly growing *Mycobacterium abscessus* (RGM), likely because of poor sterilization procedures during their surgeries [13]. All patients were successfully treated, but their course of care was complicated. Among the nine patients for whom chart data were available, median onset of illness was 24 days after their surgical

procedure. Of the five from whom RGM culture was positive, median time to laboratory confirmation was 79 days after their first presentation for care in the U.S. Eight were hospitalized in the U.S., five of them on more than two occasions. All nine underwent at least one therapeutic surgical procedure; seven required courses of antibiotics for three months or longer; seven were prescribed more than five different classes of antibiotics [13].

Cost of post-surgical care can also be a concern. Of the patients who responded to requests for information about cost, 13 used medical insurance, although four indicated that their insurer had declined to cover some costs. Ten patients indicated the illness had caused financial problems; two reported that indirect costs, such as inability to work, compounded their financial difficulty [13]. A review of data for patients hospitalized at London's Royal Free Hospital between 2015 and 2017 following plastic surgery outside the U.K. found that among 21 patients, complications led to 18 in-patient admissions and 46 surgical procedures overall. The total cost of follow up care was £282,000 (U.S. \$368,600); cost per patient averaged £13,500 (slightly less than U.S. \$18,000) [34]. Chart review at Gold Coast University Hospital in Queensland, Australia, similarly found that between 2012 and 2013, the facility treated 12 patients for complications following cosmetic surgery abroad—including not only infection, but also pulmonary embolism—at a cost of AU\$151,172.52 (approximately \$115,800 U.S.) [14]. Similar additional costs are reported by U.S. facilities [5].

Medical tourism carries implications for patients' home communities as well. For example, the financial costs of needed follow-up care fall on health care institutions and health insurers [10,12,32], which may be especially problematic in publicly funded health care systems [10,14]. Medical travel poses public health risks, providing means for moving bacteria and resistant genes globally [33]. The fact that patients may return to multiple home institutions from a single destination treatment center underscores the need for tracking medical travel and outcomes that currently is not being met [14,33].

Additionally, medical tourism carries implications for destination communities and health care systems. It can foster dual systems of care, one catering to medical tourists, and one for the local population, a situation that risks exacerbating health inequity [10,32,35]. Development of commercial health care institutions to serve medical tourists risks creating, in the words of one author, "islands of medical excellence in a sea of medical neglect" [31]. Transplant and reproductive tourism in particular pose significant risk that vulnerable local populations will be exploited as donors of biological materials that benefit foreign patients [20,31].

GUIDANCE FROM PROFESSIONAL ORGANIZATIONS

In 2008, the American Medical Association adopted H-450.937, "Medical Care outside the United States," which advocates that entities that "facilitate or incentivize" medical care outside the U.S. ensure that such care is voluntary, take care that financial incentives neither limit the alternatives offered to patients nor restrict treatment or referral, and refer patients only to internationally accredited institutions. Policy further urges that local follow-up care and financing be coordinated prior to travel and that coverage include costs of necessary follow-up care in the U.S. Patients should be informed about their rights and legal recourse and should have access to information about the foreign facility and health care professionals, the potential risks of combining surgical procedures with travel, and outcomes data for the procedure(s) they will undergo. Transfer of medical records to and from facilities outside the U.S. should adhere to HIPAA requirements. Policy also supports reporting and tracking safety and quality data for procedures performed outside the U.S. Substantially similar guidelines were published by the American Society for Metabolic and Bariatric Surgery.

Also in 2008, the Transplantation Society and the International Society of Nephrology jointly developed the Declaration of Istanbul on Organ Trafficking and Transplant Tourism to promote and uphold ethical practice in organ transplantation internationally [20]. The following year, the American College of Surgeons issued a position statement on medical and surgical tourism that supports patients' right to choose where and from whom they receive care and encourages College Fellows to support informed decision making. The statement advises patients to consider not only medical, but also "social, cultural and legal implications of seeking treatment abroad," as well as to seek care at an accredited institution and to obtain a complete copy of their medical records before returning to the U.S. [36]. In 2013, the International Society for Stem Cell Research similarly issued a critique of commercial stem cell therapy and called for adherence to ethical standards regarding interventions whose clinical value has not yet been demonstrated [24].

Several professional medical organizations have published cautionary information for patients about medical tourism, including the American Academy of Facial and Plastic Surgery [37], the American Society of Hematology [38], the American Society of Plastic Surgery [39], and the American Society for Metabolic and Bariatric Surgery [40].

ETHICAL CHALLENGES OF MEDICAL TOURISM

Medical tourism can leave home country physicians in problematic positions: Faced with the reality that medical tourists often need follow-up when they return, even if only to monitor the course of an uneventful recovery; confronted with the fact that returning medical tourists often don't have records of the procedures they underwent and the medications they received, or contact information for the foreign health care professionals who provided services; asked to make right what went wrong when patients experience complications as a result of medical travel, often having not been informed about, let alone part of the patient's decision to seek health care abroad [41].

Many aspects of medical tourism confound core ethical expectations regarding patients' rights—to informed consent, continuity of care and access to their medical records (E-1.1.3)—and physicians' responsibilities—to promote quality of care (E-1.1.6) and patient safety (E-8.6), to be prudent stewards of health care resources (E-11.1.2). Patients' decisions to seek medical care abroad may also threaten trust [41] and the integrity of patient-physician relationships. These challenges are fundamentally systemic, yet patients often expect individual physicians to find ways to address them.

Informed Decision Making

Ensuring that patients make informed decisions about seeking care abroad is not possible unless patients let physicians know they are considering doing so. Expecting physicians to routinely screen patients for possible interest in becoming a medical tourist is not realistic, but when a patient expresses concern about access to certain services, or a desire to receive care that is generally not available in the community, physicians should recognize the possibility that the patient is contemplating going outside the local system of care and explore the patient's concerns and wishes more fully.

When patients' responses indicate interest in medical tourism, it is reasonable to expect physicians will help ensure that patients have the information they need to make well-considered decisions. Physicians might do so by addressing the pros and cons of medical tourism themselves when they have relevant knowledge, by referring the patient to a specialist who has relevant expertise, or by directing the patient to other resources on medical tourism for the procedure, such as specialty society or government information pages.

Continuity of Care

Arguably, the extent of individual physicians' ethical responsibility to provide after care for patients who have undergone a medical procedure abroad as a medical tourist will vary with the circumstances. Physicians have a responsibility to provide urgently needed care, or refer the patient appropriately (Principle VI), and to provide or refer for needed follow-up care when a current patient has received emergency medical care abroad. They are likewise expected to honor contractual obligations to provide care (E-1.1.2).

In other circumstances, however, physicians' ethical responsibility may be less stringent, particularly when patients have traveled for elective procedures. Physicians have stronger obligations to patients with whom they have a patient-physician relationship, especially one of long standing (E-1.1.7) [8]. Beyond carefully considering the likely effect on the individual patient's welfare, physicians should take into account whether they have the resources to provide the needed care safely and the likely effects providing care or declining to do so will have on their ability to meet the needs of other patients in their practice (E-1.1.2). Physicians have a further responsibility to reflect on the burden declining to provide follow-up care may impose on fellow professionals (cp. E-1.1.7), and on the likely impact on the health and resources of the community (E-11.1.2).

Preserving Trust

Patients may be hesitant to discuss medical tourism, fearing their physician's reaction [41]. Physicians have a responsibility to offer their best professional guidance about a patient's decision to become a medical tourist, just as

they would any other decision about care. This includes being candid when they deem a decision to obtain specific care abroad not to be in the patient's best interests and helping the patient understand why they believe that to be the case. To protect the trust on which an effective therapeutic relationship is grounded, physicians should acknowledge the patient's goal for seeking care. As patient advocates, they should help ensure that the patient has exhausted options for getting the desired care within their home health care system [42]. This includes encouraging patients who propose to travel for an unapproved therapy to enroll in appropriate clinical trials.

When patients inform them before they travel, physicians should advise the patient about the level of care they will or will not be able or willing to provide when the patient returns (cp. E-1.1.7). When a patient who did not inform the physician in advance returns seeking follow-up care for treatment received abroad, physicians must decide whether to provide that care. The obligation of compassion does not automatically translate into a duty to treat except in an emergency. However, before declining to provide needed after care to a medical tourist, physicians should carefully consider the effect that decision is likely to have on the patient's welfare, other health care professionals, and the community.

Oversight

The European Union has established formal guidelines for cross-border care among member countries [43], and entities such as the Joint Commission International and Accreditation Canada accredit international health care facilities [32], but at present, medical tourism is otherwise regulated only to the extent that medical practice in individual countries is regulated. Medical tourism companies as such are not regulated at all. Nor do medical tourism agents receive specific training or certification [32]. The absence of systematic collection and reporting of data about outcomes leaves patients, physicians, and health care systems in the dark, impeding informed decision making about medical tourism and obscuring potential risks to public health. Physicians have firsthand knowledge of the experience of individual patients who have become medical tourists and are well positioned to advocate for standards to improve quality of care and protect the interests of patients who seek care abroad.

RECOMMENDATION

In view of these considerations, the Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report filed:

Medical tourists travel to address what they deem to be unmet personal medical needs, prompted by issues of cost, timely access to services, higher quality of care or perceived superior services, or to access services that are not available in their country of residence. In many instances, patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies. The care medical tourists seek may be elective procedures, medically necessary standard care, or care that is unapproved or legally or ethically prohibited in their home system.

Many medical tourists receive excellent care, but issues of safety and quality can loom large. Substandard surgical care, poor infection control, inadequately screening of blood products, and falsified or outdated medications in lower income settings of care can pose greater risks than patients would face at home. Medical tourists also face heightened travel-related risks. Patients who develop complications may need extensive follow-up care when they return home. They may pose public health risks to their home communities as well.

Medical tourism can leave home country physicians in problematic positions: Faced with the reality that medical tourists often need follow-up when they return, even if only to monitor the course of an uneventful recovery; confronted with the fact that returning medical tourists often do not have records of the procedures they underwent and the medications they received, or contact information for the foreign health care professionals who provided services, asked to make right what went wrong when patients experience complications as a result of medical travel, often having not been informed about, let alone part of the patient's decision to seek health care abroad.

Physicians need to be aware of the implications of medical tourism for individual patients and the community.

Collectively, through their specialty societies and other professional organizations, physicians should:

- (a) Support collection of and access to outcomes data from medical tourists to enhance informed decision making.
- (b) Advocate for education for health care professionals about medical tourism.
- (c) Advocate for appropriate oversight of medical tourism and companies that facilitate it to protect patient safety and promote high quality care.
- (d) Advocate against policies that would require patients to accept care abroad as a condition of access to needed services.

Individually, physicians should:

- (e) Be alert to indications that a patient may be contemplating seeking care abroad and explore with the patient the individual's concerns and wishes about care.
- (f) Seek to familiarize themselves with issues in medical tourism to enable them to support informed decision making when patients approach them about getting care abroad.
- (g) Help patients understand the special nature of risk and limited likelihood of benefit when they desire an unapproved therapy. Physicians should help patients frame realistic goals for care and encourage a plan of care based on scientifically recognized interventions.
- (h) Advise patients who inform them in advance of a decision to seek care abroad whether the physician is or is not willing to provide follow-up care for the procedure(s), and refer the patient to other options for care.
- (i) Offer their best professional guidance about a patient's decision to become a medical tourist, just as they would any other decision about care. This includes being candid when they deem a decision to obtain specific care abroad not to be in the patient's best interests. Physicians should encourage patients who seek unapproved therapy to enroll in an appropriate clinical trial.
- (j) Physicians should respond compassionately when a patient who has undergone treatment abroad without the physician's prior knowledge seeks nonemergent follow-up care. Those who are reluctant to provide such care should carefully consider
 - (i) the nature and duration of the patient-physician relationship;
 - (ii) the likely impact on the individual patient's well-being;
 - (iii) the burden declining to provide follow-up care may impose on fellow professionals;
 - (iv) the likely impact on the health and resources of the community.

Physicians who are unable or unwilling to provide care in these circumstances have a responsibility to refer the patient to appropriate services.

REFERENCES

1. Wee S-L. China's ill, and wealthy, look abroad for medical treatment. *NY Times*. 2017;May 29.
2. Alleman BW, Luger T, Schacht Reisinger H, et al. Medical tourism services available to residents of the United States. *J Gen Intern Med*. 2010;26(5):492–97.
3. Kumar S, Brueing R, Chahal R. Globalization of health care delivery in the United States through medical tourism. *J Health Commun*. 2012;17:177–198.
4. Patients Beyond Borders. Medical Tourism Statistics & Facts. Available at <https://patientsbeyondborders.com/medical-tourism-statistics-facts>. Accessed September 22, 2017.
5. Adabi K, Stern CS, Weichman KE, et al. Population health implications of medical tourism. *Plast. Reconstr. Surg*. 2017;140:66–74.
6. Gan LL, Frederick JR. Medical tourism facilitators: patterns of service differentiation. *J Vacat Mark*. 2011;17:165–183.

7. American Medical Association, Council on Medical Service. Medical care outside the United States. *Proceedings of the House of Delegates*. 2008;June14:339–343.
8. Runnels V, Carerra PM. Why do patients engage in medical tourism? *Maturitas*. 2012;73:300–304.
9. Hanefeld J, Smith R, Horsfall D, Lunt N. What do we know about medical tourism? a review of the literature with discussion of its implications for the UK National Health Service as an example of a public health care system. *J Travel Med*. 2014;21:410–417.
10. Snyder J, Crooks VA, Johnston R. Perceptions of the ethics of medical tourism: comparing patient and academic perspectives. *Public Health Ethics*. 2012;5:38–46.
11. Franzblau LE, Chung KC. Impact of medical tourism on cosmetic surgery in the United States. *Plast Reconstr Surg Glob Open*. 2013;October 28:1–7.
12. Crozier GKD, Baylis F. The ethical physician encounters international medical travel. *J Med Ethics*. 2010;36:297–301.
13. Schnabel D, Esposito DH, Gaines J, et al. Multistate US outbreak of rapidly growing mycobacterial infections associated with medical tourism to the Dominican Republic, 2013–2014. *J Emerg Infect Dis*. 2016;22:1340–1347.
14. Livingston R, Berlund P, Eccles-Smith J, Saawhney R. The real cost of “cosmetic tourism” cost analysis study of “cosmetic tourism” complications presenting to a public hospital. *ePlasty*. 2015;15:313–319.
15. Lunt N, Smith R, Exworthy M, et al. Medical Tourism: Treatments, Markets and Health System Implications: A *Scoping Review*. OECD 2011. Available at <https://www.oecd.org/els/health-systems/48723982.pdf>. Accessed April 6, 2018.
16. Crooks VA, Turner L, Cohen G, et al. Ethical and legal implications of the risks of medical tourism for patients: a qualitative study of Canadian health and safety representatives’ perspectives. *BMJ*. 2013;3:e002302.
17. Milstein A, Smith M. America’s New Refugees — Seeking Affordable Surgery Offshore. *NEJM*. 2006;355:1637–1640.
18. Bramsted KA, Xu J. Checklist: Passport, Plane ticket, organ transplant. *Am J Transplant*. 2007;7:1698–1701.
19. Gill J, Madhira BR, Gjertson D, et al. Transplant tourism in the United States: a single-center experience. *Clin J Am Soc Nephrol*. 2008;3:1820–1828.
20. Danovitch GM, Chapman J, Capron AM, et al. Organ trafficking and transplant tourism: the role of global professional ethical standards: the 2008 Declaration of Istanbul. *Transplantation*. 2013;95:1306Y1312.
21. Einsiedel EF, Adamson H. Stem cell tourism and future stem cell tourists: policy and ethical implications. *Dev World Bioeth*. 2012;12:35–44.
22. Zarzeczny A, Caulfield T, Ogbogu U, et al. Professional regulation: a potentially valuable tool in responding to “stem cell tourism.” *Stem Cell Rep*. 2014;3:379–384.
23. Kolata G. A cautionary tale of ‘stem cell tourism’. *N Y Times*. 2016;June 22.
24. International Society for Stem Cell Research. ISSCR Statement on Delivery of Unproven Autologous Cell---based Interventions to Patients 2013. Available at <http://www.isscr.org/docs/default-source/policy-documents/isscr-acbistatement-091113-fl.pdf?sfvrsn=2>. Accessed October 30, 2017.
25. Master A, Zarzeczny A, Rachul C, Caulfield T. What’s missing? discussing stem cell translational research in educational information on stem cell “tourism.” *J Law Med Ethics*. 2013;Spring:254–268.
26. Bowman M, Racke M, Kissel J, Imitola J. Responsibilities of health care professionals in counseling and educating patients with incurable neurological diseases regarding “stem cell tourism”—caveat emptor. *JAMA Neurol*. 2015;72:1342–1345.
27. Gürtin ZB, Inhorn MC. Introduction: travelling for conception and the global assisted reproduction market. *Reprod BioMed*. Online 2011;23:535–537.
28. Pennings G. Reproductive tourism as moral pluralism in motion. *J Med Ethics*. 2002;28:337–341.
29. Matorras R. Reproductive exile versus reproductive tourism [ltr]. *Hum Reprod*. 2005;20:3571–3573.
30. Hudson N, Culley L, Blyth E, et al. Cross-border reproductive care: a review of the literature. *Reprod BioMed*. Online 2011;22:673–685.
31. Pfeffer N. Eggs-ploiting women: a critical feminist analysis of the different principles in transplant and fertility tourism. *Reprod BioMed*. Online 2011;23:634–641.
32. Turner LG. Quality in health care and globalization of health services: accreditation and regulatory oversight of medical tourism companies. *Int J Qual Health Care*. 2011;23:1–7.
33. Chen LH, Wilson ME. The globalization of healthcare: implications of medical tourism for the infectious disease clinician. *Emerging Infections*. 2013;December 15.
34. Gulland A. Plastic surgeons report surge in reoperations for patients treated abroad. *BMJ*. 2017;October 6.
35. Connell J. A new inequality? Privatisation, urban bias, migration and medical tourism. *Asia Pac Viewp*. 2011;52:260–271.
36. American College of Surgeons. Statement on Medical and Surgical Tourism 2009. Available at <https://www.facs.org/about-acs/statements/65-surgical-tourism>. Accessed September 22, 2017.
37. American Academy of Facial and Plastic Surgery. Planning Your Treatment, Near Or Far, Factors To Consider. Available at https://www.aafprs.org/patient/fps_today/vol27/02/pg1.html. Accessed October 19, 2017.
38. American Society of Hematology. Patient Advisory for Stem Cell Therapy and Medical Tourism 2013. Available at <https://www.cirm.ca.gov/about-cirm/newsroom/press-releases/08192013/patient-advisory-stem-cell-therapy-and-medical-tourism>. Accessed October 19, 2017.
39. American Society of Plastic Surgery Briefing Paper: Cosmetic Surgery Tourism. <https://www.plasticsurgery.org/news/briefing-papers/briefing-paper-cosmetic-surgery-touri...> Accessed February 20, 2018.
40. American Society for Metabolic and Bariatric Surgery What is Medical Tourism? Available at <https://asmbs.org/patients/medical-tourism>. Accessed October 19, 2017.
41. Crooks VA, Li N, Synyder J, et al. “You don’t want to lose that trust that you’ve built with this patient...”: (dis)trust, medical tourism, and the Canadian family physician-patient relationship. *BMC Fam Pract*. 2015;16:25.

42. Johnston R, Crooks VA, Snyder J, Dharamsi S. Canadian family doctors' roles and responsibilities toward outbound medical tourists. *Can Fam Physician*. 2013;59:1314–1319.
43. European Parliament. DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare. *Official Journal of the European Union*. 4.4.2011 L 88/45– L 88/65.

4. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**

See Policies H-140.833 and D460.967

Policy D-460.967(2), “Study of the Current Uses and Ethical Implications of Expanded Access Programs,” instructs our American Medical Association (AMA) to “study the ethics of expanded access programs, accelerated approval mechanisms, and payment reform models meant to increase access to investigational therapies, including access for infants and children.” This report by the Council on Ethical and Judicial Affairs (CEJA) examines ethical issues in relation to expanded access and offers guidance for physicians.

ACCESS TO INVESTIGATIONAL THERAPY

For some patients who face serious life-threatening or life-limiting conditions there are few or no approved therapies. For others, existing therapies are unlikely or have failed to be effective. In such situations, patients and their physicians may turn to as yet unapproved treatments as a last hope.

From a societal perspective, participating in a clinical trial is the most desirable way for patients to obtain access to therapies still in development [1,2]. But from the perspective of individual patients, enrolling in a randomized trial cannot guarantee access to the treatment they seek; some will not meet inclusion criteria to be accepted as trial participants even if they are willing to take the chance of being randomized to a control arm rather than the investigational therapy; still others may be unable to participate for other reasons. The expanded access program of the US Food and Drug Administration (FDA) allows patients in such circumstances to seek access to treatment with an investigational therapy outside a clinical trial.

Expanded Access (“Compassionate Use”)

“Expanded access” refers “the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient rather than to obtain the kind of information about the drug that is generally derived from clinical trials [3].

Following the thalidomide scandal of the late 1950s and early 1960s, in 1962 the US Congress mandated that the FDA validate the safety and effectiveness of new drugs based on substantial evidence collected from controlled clinical trials, which significantly lengthened the timelines for development of new drugs [4]. The FDA began allowing patients and physicians to petition for access to unapproved drugs [4], and in 1987 recognized “treatment IND [investigational new drug]” protocols in response to the HIV/AIDS crisis as dying AIDS patients sought access to the then-unapproved drug AZT [5].

With the push from advocacy groups such as ACT UP, the FDA agreed to allow pharmaceutical companies to offer access to other promising AIDS drugs through an “expanded access” (or “compassionate use”) protocol; Alzheimer and cancer patients and their advocates soon followed with similar demands for access to unproven therapies [5]. In 2009, the FDA substantially revised federal regulations (at 21 CFR 312), creating three categories for access to investigational therapies: use by individual patients, use by intermediate-sized patient populations (tens to hundreds), and widespread use after a clinical trial has been successfully completed but prior to FDA approval of the therapy [4,6].

Before a patient can legally receive an investigational therapy outside of a clinical trial, the FDA must approve the expanded access application submitted by the physician who will oversee treatment (21 CFR312.305). To be

granted, a request must demonstrate that the patient(s) for whom access is requested has a “serious or immediately life-threatening” condition for which there is no satisfactory alternative therapy; that the potential benefit to the patient justifies the risk of the investigational therapy; and that the potential risks of the investigational therapy “are not unreasonable in the context of the disease or condition to be treated” (21 CFR 312.305). To protect the scientific integrity of clinical trials, it must also be shown that providing the investigational therapy “will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use” (21 CFR 312.305).

The regulations further set evidentiary thresholds for risk that are more stringent the greater number of patients involved and the less serious the condition. For single patient use, a physician need only conclude that the investigational therapy poses no greater risk than the disease itself (21 CFR 312.310), while for intermediate-size patient populations, there must be evidence that the drug is safe “at the dose and duration” proposed for expanded access use and that there is “at least preliminary clinical evidence of effectiveness” (or plausible pharmacologic effect) to make use under expanded access “a reasonable therapeutic option” for the intended patient population (21 CFR 312.315). Thus, patients who receive investigational therapies outside clinical trials don’t have the same protections as do enrolled participants, such as monitoring by institutional review boards and data and safety monitoring boards, which can halt trials when significant concerns arise [7]. Because patients receiving investigational therapies under expanded access are not connected to a particular trial site, “the potential for rigorous safety monitoring is greatly reduced” [7].

Under the 2009 regulations, the treating physician must determine that the proposed use meets FDA criteria for expanded access and is also responsible for obtaining IRB approval for use of the investigational therapy for the patient, which can be particularly challenging for physicians outside academic medical centers [4]. Physicians who treat patients with investigational therapies under expanded access must comply with the responsibilities for investigators set out elsewhere in federal regulations governing clinical trials. In 2017, the FDA took steps to streamline the process of applying for expanded access, simplifying the single patient application form and modifying the requirement for IRB approval to allow review by a single member of the IRB rather than the fully convened board [8]. FDA has indicated that further simplification is being considered [8].

Sponsors are not required to provide investigational therapies for use under expanded access, and FDA has no authority to mandate that a drug be made available by an unwilling sponsor [7]. Sponsors decline to participate in expanded access for a variety of reasons, including limited supply of the investigational therapy, limited capacity to produce additional supplies, or the cost of making the therapy available outside an ongoing clinical trial [1,4]. Sponsors who provide an investigational therapy under expanded access face additional administrative burdens—among other requirements, regulations mandate that they ensure that physicians are qualified to administer the therapy and submit investigational new drug safety reports for the expanded access use, including reporting adverse events (21 CFR 312.305).

One concern is that adverse events reported for expanded access use may in fact not be associated with the investigational therapy and could jeopardize development of it [1,9]. Patients who receive an investigational therapy outside clinical trials may have more advanced disease than trial participants, have other concurrent medical conditions, or be receiving other concurrent treatment, which can make it more difficult to determine the cause of an adverse event. Responding to this concern, the FDA recently clarified expectations for reporting negative effects, permitting sponsors to report only those events for which “there is evidence to suggest a causal relationship between the drug and the adverse event” [8].

Impact of Expanded Access

Applications for expanded access use for both drugs and biologics have grown steadily—from just under 1,100 in 2010 to more than 1,700 in 2016 (with a high total of 1,999 in 2014) [10]. Overall, the Center for Drug Evaluation and Research received nearly 11,000 applications between 2005 and 2014, of which 99.7% were approved [1]. The majority of requests were in “therapeutic areas where products were being developed to treat life-threatening illness with significant unmet medical need,” such as hematologic and solid organ malignancies [1].

Less is known about whether requests for expanded access use are granted by sponsors or whether investigational therapies provided through expanded access have received FDA approval. A review of found 398 expanded access programs registered at ClinicalTrials.gov as of July 2016 [11]. Of the 210 unique experimental drugs for which data

were reviewed, 76 percent had ultimately received approval. As the authors note, this suggests that “we cannot entirely eliminate safety and efficacy questions in expanded access and compassionate use” [11].

The Future of Expanded Access

Provisions of the 21st Century Cures Act enacted in December 2016 address the challenges patients and physicians face in obtaining information about investigational therapies that may be available through expanded access. The act requires manufacturers and distributors of investigational drugs intended to treat serious diseases to “make public and readily available” their policies for evaluating and responding to requests for expanded access use (Pub L 114-255). The act further requires that such policies include contact information for the manufacturer or distributor, procedures for making requests and general criteria used to evaluate requests for individual patients, and a link or other reference to clinical trial information about the investigational therapy. The act does not, however, require a manufacturer or distributor to guarantee access to an investigational therapy in development.

In addition to simplifying application forms for single patient use and procedures for IRB approval, in July 2017 FDA launched a new online [Expanded Access Navigator](#) in conjunction with the Reagan-Udall Foundation to assist patients and physicians in finding information about expanded access [8].

ETHICAL CHALLENGES IN EXPANDED ACCESS

Although ongoing efforts to simplify expanded access programs will likely enable more patients to receive treatment with investigational therapies, ethical concerns remain. Key among them are issues of informed consent and decision making, fairness in access to investigational therapies, and possible negative effects for the conduct of clinical trials.

Informed Consent

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and to ask questions about recommended treatments so that they can make well-considered decisions about care ([E-2.1.1](#)). Treatment with an investigational therapy poses special challenges in this regard. Patients who face serious, life-threatening illnesses for which approved therapies have not been effective or for which there are no approved therapies may be particularly vulnerable to holding out false hope for investigational therapy [12]. Promoting truly informed decisions about whether to request expanded access is critical, but can be difficult, both because information about an investigational therapy is often incomplete or difficult to obtain, and because patients may be prone to misinterpreting what information is available.

In the early stages of development, relatively little may be known about an investigational therapy’s efficacy or possible adverse effects [4,13]. Information about therapies still in development is often proprietary and thus not readily available, making it difficult for patients and physicians to assess whether the risk of disease outweighs the risk of the investigational therapy for purposes of requesting expanded access [4]. Moreover, terminally ill patients do not always evaluate risks and benefits objectively—they tend to overestimate likely benefit and underestimate the burdens of as yet unproven therapies [12,14]. They may be under a “therapeutic misconception” and fail to appreciate that the therapy has not been demonstrated to be effective [15], or be “unrealistically optimistic” and expect that their personal outcomes will be more positive than the outcomes of others in similar situations [14,16].

FDA acknowledges that patients who are candidates for expanded access use “are a particularly vulnerable population” and “should be afforded a rigorous informed consent process that effectively communicates the risks and potential benefits of any investigational therapy to be used for treatment use [sic] in a way that does not raise false expectations about a positive outcome from treatment and makes clear what is unknown about the drug” [6]. Expanded access regulations mandate that the treating physician (“investigator” in the language of the regulations) ensure that the consent requirements of the Common Rule are met (21 CFR 305(c)(4)), including informing the patient that the therapy is investigational and that there is uncertainty as to its safety and effectiveness [3].

FDA also mandates that the sponsor of an investigational therapy provide the treating physician “with the information needed to minimize the risk and maximize the potential benefits of the investigational drug (the investigator’s brochure must be provided if one exists for the drug)” (21 CFR 312.305(c)(5)) as a requirement for expanded access use. It is essential that the treating physician have as much information as possible about an

investigational therapy to provide appropriate patient care. An investigator's brochure "provides insight to support the clinical management of the study subject" [17]—or, in the instant case, the patient receiving the investigational therapy under expanded access—by compiling both clinical and nonclinical information about the therapy.

Financial Barriers to Expanded Access

Issues of equity also arise with respect to expanded access programs. Sponsors may provide investigational therapies at no cost for expanded access use, but they are not required to do so. Current FDA regulations permit sponsors to recover direct costs of providing an investigational therapy for expanded access use (21 CFR 312.8(d)(1)), either directly from patients or by billing third-party payers. For the most part, insurance plans do not reimburse the costs of therapies not yet approved for marketing [14,18]. Although most sponsors shoulder the cost burden, when they do not patients may be unable to afford to pay out of pocket, even when they have been approved for expanded access use. It has been argued that expanded access "favors the rich or well-connected" [4].

Effects on Clinical Trials/Implications for Public Health

Expanded access programs may also adversely affect the successful completion of clinical trials and marketing approval of clinical trials. Permitting patients to obtain not yet approved therapies by means of expanded access may delay enrollment in trials of the therapy or jeopardize retention of participants, undermining efforts to demonstrate the safety and efficacy of the investigational therapy [9]. This in turn thwarts society's interest in the development and approval of new therapies for populations of patients [2,9]. The extent to which expanded access programs in fact have this effect is not clear. Before FDA will approve a request for expanded access use, patients and physicians must demonstrate that the patient is not a candidate for a clinical trial, for example, because the individual fails to meet inclusion criteria or existing trials are geographically inaccessible to the individual.

RECOMMENDATION

In light of these considerations, the Council on Ethical and Judicial Affairs recommends that Policy D-460.967(2), "Study of the Current Uses and Ethical Implications of Expanded Access Programs," be rescinded, the following be adopted, and the remainder of the report be filed:

Physicians who care for patients with serious, life-threatening illness for whom standard therapies have failed, are unlikely to be effective, or do not exist should determine whether questions about access to investigational therapy through the U.S. Food and Drug Administration's "expanded access" program are likely to arise in their clinical practice. If so, physicians should familiarize themselves with the program to be better able to engage in shared decision making with patients.

When a patient requests expanded access to an investigational therapy, physicians should:

- (a) Assess the patient's individual clinical situation to determine whether an investigational therapy would be appropriate, including:
 - (i) whether there is a satisfactory alternative therapy available to diagnose, monitor, or treat the patient's disease or condition;
 - (ii) the nature of potential risks of the investigational therapy and whether those risks are not unreasonable in the context of the patient's disease or condition;
 - (iii) whether the potential benefit to the patient justifies the risks of the investigational therapy;
 - (iv) whether the patient meets inclusion criteria for an existing clinical trial of the investigational therapy.
- (b) As part of the informed consent process, advise the patient (or parent/guardian if the patient is a minor) that the investigational therapy has not yet been demonstrated to be effective in treating the patient's condition and may pose as yet unknown risks. Physicians should explain the importance of clinical trials, encourage patients who meet inclusion criteria to participate in an existing trial rather than seek access to

investigational therapy through the FDA expanded access program, and direct patients who wish to participate in research to appropriate resources.

- (c) Decline to support an application for expanded access to an investigational therapy when:
- (i) the physician judges the treatment with the investigational therapy not to be in the patient's best interest, and explain why; or
 - (ii) the physician does not have appropriate resources and ability to safely supervise the patient's care under expanded access.

In such cases, physicians should refer the patient to another physician with whom to discuss possible application for expanded access.

- (d) Discuss the implications of expanded access for the patient and family and help them form realistic expectations about what it will mean to be treated with the investigational therapy outside a clinical trial. Physicians should alert patients:
- (i) to the possibility of financial or other responsibilities associated with receiving an investigational therapy through expanded access;
 - (ii) to the lack of infrastructure to systematically monitor and evaluate the effects of the investigational therapy outside a clinical trial;
 - (iii) that they need information about how to contact the manufacturer for guidance if they seek emergency care from a health care professional who is not affiliated with a clinical trial of the investigational therapy;
 - (iv) that the physician has a responsibility to collect and share clinical information about the patient's course of treatment with the investigational therapy, as well as to report any adverse events that may occur over the course of treatment;
 - (v) to the conditions under which the physician would recommend stopping treatment with the investigational therapy.

REFERENCES

1. Jarow JP, Lemery S, Bugin K, et al. Expanded access of investigational drugs: the experience of the center of drug evaluation and research over a 10-year period. *Ther Innov Regul Sci*. 2016 November;50:705–709.
2. Leonard EW. The public's right to health: when patient rights threaten the commons. *Washington U Law Rev*. 2009;86:1335–1396.
3. US Food and Drug Administration. Expanded access to investigational drugs for treatment use—questions and answers; guidance for industry; availability. *Fed Register*. 2016;81: 35778–35779.
4. Darrow JJ, Sarpatwari A, Avorn J, Kesselheim AS. Practical, legal, and ethical issues in expanded access to investigational drugs. *NEJM*. 372:279–286.
5. Sanghavi DM. The pills of last resort. *NY Times*. 2013;October 13.
6. US Food and Drug Administration. Expanded access to investigational drugs for treatment use. *Fed Register* 2009; 74: 40900–40945.
7. Shah S, Zettler P. From a constitutional right to a policy of exceptions: Abigail Alliance and the future of access to experimental therapy. *Yale J Health Policy, Law, Ethics*. 2013;10:137–196.
8. Gottlieb S. Expanded access: FDA describes efforts to ease application process. *FDA Voice*. 2017;October 3.
9. Rosenblatt M, Kuhlík B. Principles and challenges in access to experimental medicines. *JAMA*. 015;313:2023–2024.
10. FDA Expanded Access INDS and Protocols 2009 – 2016. Available at <https://www.fda.gov/newsevents/publichealthfocus/expandedaccesscompassionateuse/ucm>. Accessed October 11, 2017.
11. Miller JE, Ross JS, Moch KI, Caplan AL. Characterizing expanded access and compassionate use programs for experimental drugs. *BMC Res Notes*. 2017;10:350.
12. Dresser R. “Right to try” laws: the gap between experts and advocates. *Hastings Center Report*. 2015;May-June:9–10.
13. Jacob JA. Questions of safety and fairness raised as right-to-try movement gains steam. *JAMA*. 2015; 314:758–760.
14. Bunnik E, Aarts N, van de Vathorst S. The changing landscape of expanded access to investigational drugs for patients with unmet medical needs: ethical implications. *J Pharm Policy, Practice*. 2017;10:10. Available at

- <https://joppp.biomedcentral.com/track/pdf/10.1186/s40545-017-0100-3?site=joppp.biomedcentral.com>. Accessed October 11, 2017.
15. Bateman-House A, Kimberly L, Redman B, et al. Right-to-try laws: hope, hype, and unintended consequences. *Annals Intern Med.* 2015;163:796–797.
 16. Crites J, Kodish E. Unrealistic optimism and the ethics of phase 1 cancer research. *J Med Ethics.* 2013;39:403–406.
 17. International Conference on Harmonisation. *Good Clinicap Practice. Guideline 7–investigator’s brochure.* <http://ichgcp.net/7-investigator’s-brochure>. Accessed April 6, 2018.
 18. Jerome RN, Edwards TL, Boswell HC, et al. Recommendations to facilitate expanded access to investigational therapies for seriously ill patients. *Acad Med.* 2016;91:305–309.

**5. STUDY AID-IN-DYING AS END-OF-LIFE OPTION /
THE NEED TO DISTINGUISH “PHYSICIAN ASSISTED SUICIDE” AND “AID IN DYING”
(RESOLUTIONS 15-A-16 AND 14-A-17)**

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: REFERRED

At the 2016 Annual Meeting, the House of Delegates referred Resolution 15-A-16, “Study Aid-in-Dying as End-of-Life Option,” presented by the Oregon Delegation, which asked:

That our American Medical Association and its Council on Judicial and Ethical Affairs, study the issue of medical aid-in-dying with consideration of (1) data collected from the states that currently authorize aid-in-dying, and (2) input from some of the physicians who have provided medical aid-in-dying to qualified patients, and report back to the HOD at the 2017 Annual Meeting with recommendation regarding the AMA taking a neutral stance on physician “aid-in-dying.”

At the following Annual Meeting in June 2017, the House similarly referred Resolution 14-A-17, The Need to Distinguish between ‘Physician-Assisted Suicide’ and ‘Aid in Dying’” (presented by M. Zuhdi Jasser, MD), which asked that our AMA:

(1) as a matter of organizational policy, when referring to what it currently defines as ‘*Physician Assisted Suicide*’ avoid any replacement with the phrase ‘*Aid in Dying*’ when describing what has long been understood by the AMA to specifically be ‘*Physician Assisted Suicide*’; (2) develop definitions and a clear distinction between what is meant when the AMA uses the phrase ‘*Physician Assisted Suicide*’ and the phrase ‘*Aid in Dying*’; and (3) fully utilize these definitions and distinctions in organizational policy, discussions, and position statements regarding both ‘*Physician Assisted Suicide*’ and ‘*Aid in Dying*.’

This report by the Council on Ethical and Judicial Affairs (CEJA) addresses the concerns expressed in Resolutions 15-A-16 and 14-A-17. In carrying out its review of issues in this area, CEJA reviewed the philosophical and empirical literature, sought input from the House of Delegates through an I-16 educational program on physician-assisted suicide, an informal “open house” at A-17, and its I-17 Open Forum. The council wishes to express its sincere appreciation for participants’ contributions during these sessions and for additional written communications received from multiple stakeholders, which have enhanced its deliberations.

The council observes that the ethical arguments advanced today supporting and opposing “physician-assisted suicide” or “aid in dying” are fundamentally unchanged from those examined in CEJA’s 1991 report on this topic [1]. The present report does not rehearse these arguments again as such. Rather, it considers the implications of the legalization of assisted suicide in the United States since the adoption of [Opinion E-5.7](#), “Physician-Assisted Suicide,” in 1994.

“ASSISTED SUICIDE,” “AID IN DYING,” OR “DEATH WITH DIGNITY”?

Not surprisingly, the terms stakeholders use to refer the practice of physicians prescribing lethal medication to be self-administered by patients in many ways reflect the different ethical perspectives that inform ongoing societal debate. Proponents of physician participation often use language that casts the practice in a positive light. “Death with dignity” foregrounds patients’ values and goals, while “aid in dying” invokes physicians’ commitment to

succor and support. Such connotations are visible in the titles of relevant legislation in states that have legalized the practice: “Death with Dignity” (Oregon, Washington, District of Columbia), “Patient Choice and Control at the End of Life” (Vermont), “End of Life Options” (California, Colorado), and in Canada’s “Medical Aid in Dying.”

Correspondingly, those who oppose physician provision of lethal medications refer to the practice as “physician-assisted suicide,” with its negative connotations regarding patients’ psychological state and its suggestion that physicians are complicit in something that, in other contexts, they would seek to prevent. The language of dignity and aid, critics contend, are euphemisms [2]; their use obscures or sanitizes the activity. In their view such language characterizes physicians’ role in a way that risks construing an act that is ethically unacceptable as good medical practice [3].

The council recognizes that choosing one term of art over others can carry multiple, and not always intended messages. However, in the absence of a perfect option, CEJA believes ethical deliberation and debate is best served by using plainly descriptive language. In the council’s view, despite its negative connotations [4], the term “physician assisted suicide” describes the practice with the greatest precision. Most importantly, it clearly distinguishes the practice from euthanasia [1]. The terms “aid in dying” or “death with dignity” could be used to describe either euthanasia or palliative/ hospice care at the end of life and this degree of ambiguity is unacceptable for providing ethical guidance.

COMMON GROUND

Beneath the seemingly incommensurate perspectives that feature prominently in public and professional debate about writing a prescription to provide patients with the means to end life if they so choose, CEJA perceives a deeply and broadly shared vision of what matters at the end of life. A vision that is characterized by hope for a death that preserves dignity, a sense of the sacredness of ministering to a patient at the end of life, recognition of the relief of suffering as the deepest aim of medicine, and fully voluntary participation on the part of both patient and physician in decisions about how to approach the end of life.

Differences lie in the forms these deep commitments take in concrete decisions and actions. CEJA believes that thoughtful, morally admirable individuals hold diverging, yet equally deeply held, and well-considered perspectives about physician-assisted suicide that govern how these shared commitments are ultimately expressed. For one patient, dying “with dignity” may mean accepting the end of life however it comes as gracefully as one can; for another, it may mean being able to exercise some measure of control over the circumstances in which death occurs. For some physicians, the sacredness of ministering to a terminally ill or dying patient and the duty not to abandon the patient preclude the possibility of supporting patients in hastening their death. For others, not to provide a prescription for lethal medication in response to a patient’s sincere request violates that same commitment and duty. Both groups of physicians base their view of ethical practice on the guidance of [Principle I](#) of the *AMA Principles of Medical Ethics*: “A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.”

So too, how physicians understand and act on the goals of relieving suffering, respecting autonomy, and maintaining dignity at the end of life is directed by identity-conferring beliefs and values that may not be commensurate. Where one physician understands providing the means to hasten death to be an abrogation of the physician’s fundamental role as healer that forecloses any possibility of offering care that respects dignity, another in equally good faith understands supporting a patient’s request for aid in hastening a foreseen death to be an expression of care and compassion.

IRREDUCIBLE DIFFERENCES IN MORAL PERSPECTIVES ON PHYSICIAN-ASSISTED SUICIDE

How to respond when coherent, consistent, and deeply held beliefs yield irreducibly different judgments about what is an ethically permissible course of action is profoundly challenging. With respect to physician-assisted suicide, some professional organizations—for example, the American Academy of Hospice and Palliative Medicine [5]—have adopted a position of “studied neutrality.” Positions of studied neutrality neither endorse nor oppose the contested practice, but instead are intended to respect that there are irreducible differences among the deeply held beliefs and values that inform public and professional perspectives [5,6], and to leave space open for ongoing discussion. Nonetheless, as a policy position, studied neutrality has been criticized as being open to unintended

consequences, including stifling the very debate it purports to encourage or being read as little more than acquiescence with the contested practice [7].

CEJA approaches the condition of irreducible difference from a different direction. In its 2014 report on exercise of conscience, the Council noted that “health care professionals may hold very different core beliefs and thus reach very different decisions based on those core beliefs, yet equally act according to the dictates of conscience. For example, a physician who chooses to provide abortions on the basis of a deeply held belief in protecting women’s autonomy makes the same kind of moral claim to conscience as does a physician who refuses to provide abortion on the basis of respect for the sanctity of life of the fetus” [8].

Importantly, decisions taken in conscience are not simply idiosyncratic; they do not rest on intuition or emotion. Rather, such decisions are based on “substantive, coherent, and reasonably stable” values and principles [8]. Physicians must be able to articulate how those values and principles justify the action in question.

The ethical arguments offered for more than two decades by those who support and those who oppose physician participation in assisted suicide reflect the diverging “substantive, coherent, and reasonably stable” values and principles within the profession and the wider moral community. While supporters and opponents of physician-assisted suicide share a common commitment to “compassion and respect for human dignity and rights” (AMA Principles of Medical Ethics, I), they draw different moral conclusions from the underlying principle they share. As psychiatrist Harvey Chochinov observed with respect to the stakeholders interviewed by Canadian Supreme Court’s advisory panel on physician-assisted death, “neither those who are strongly supportive nor those who are opposed hold a monopoly on integrity and a genuine concern for the well-being of people contemplating end of life. Equally true: neither side is immune from impulses shaped more by ideology than a deep and nuanced understanding of how to best honor and address the needs of people who are suffering” [9].

THE RISK OF UNINTENDED CONSEQUENCES

From the earliest days of the debate, a prominent argument raised against permitting physician-assisted suicide has been that doing so will have adverse consequences for individual patients, the medical profession, and society at large. Scholars have cited the prospect that boundaries will be eroded and practice will be extended beyond competent, terminally ill adult patients; to patients with psychiatric disorders, children; or that criteria will be broadened beyond physical suffering to encompass existential suffering; or that stigmatized or socioeconomically disadvantaged patients will be coerced or encouraged to end their lives. Concerns have also been expressed that permitting the practice will compromise the integrity of the profession, undermine trust, and harm the physicians and other health care professionals who participate; and that forces outside medicine will unduly influence decisions.

The question whether safeguards—which in the U.S. jurisdictions that permit assisted suicide, restrict the practice to terminally ill adult patients who have decision-making capacity and who voluntarily request assisted suicide, along with procedural and reporting requirements—can actually protect patients and sustain the integrity of medicine remains deeply contested. Some studies have “found no evidence to justify the grave and important concern often expressed about the potential for abuse—namely, the fear that legalized physician-assisted dying will target the vulnerable or pose the greatest risk to people in vulnerable groups” [10], others question whether the available data can in fact support any such conclusions, finding the evidence cited variously flawed [11], inadequate [12], or distorted [13].

Although cross-cultural comparisons are problematic [14], current evidence from Europe does tell a cautionary tale. Recent findings from studies in Belgium and the Netherlands, both countries that permit euthanasia as well as physician-assisted suicide, mitigate some fears but underscore others [15]. For example, research in the Netherlands has found that “requests characterized by psychological as opposed to physical suffering were more likely to be rejected, as were requests by individuals who lived alone,” mitigating fears that “solitary, depressed individuals with potentially reversible conditions might successfully end their lives.” At the same time, however, among patients who obtained euthanasia or assisted suicide, nearly 4 percent “reported only psychological suffering.” At the level of anecdote, a description of a case of euthanasia in Belgium elicited widespread concern about the emergence of a “slippery slope” [16].

Studies have also raised questions about how effective retrospective review of decisions to provide euthanasia/assisted suicide is in policing practice [17,18]. A qualitative analysis of cases that Dutch regional euthanasia committees determined had not met legal “due care criteria” found that such reviews focus on procedural considerations and do not “directly assess the actual eligibility” of the patients who obtained euthanasia [17]. A separate study of cases in which psychiatric patients obtained euthanasia found that physicians’ reports “stated that psychosis or depression did or did not affect capacity but provided little explanation regarding their judgments” and that review committees “generally accepted the judgment of the physician performing EAS [euthanasia or physician-assisted suicide]” [18]. It remains an open question whether reviews that are not able to assess physicians’ reasoning truly offer the protection they are intended to provide. To the extent that reporting and data collection in states that permit physician-assisted suicide have similar limitations, oversight of practice may not be adequate.

Medicine must learn from this experience. Where physician-assisted suicide is legalized, safeguards can and should be improved—e.g., “[t]o increase safeguards, states could consider introducing multidisciplinary panels to support patients through the entire process, including verifying consent and capacity, ensuring appropriate psychosocial counseling, and discussing all palliative and end-of-life options” [19]. Both the state and the medical profession have a responsibility to monitor ongoing practice in a meaningful way and to address promptly compromises in safeguards should any be discovered. It is equally important that strong practices be identified and encouraged across all jurisdictions that permit physicians to assist suicide. Health care organizations in California and Canada, for example, have shared richly descriptive reports of practices adopted in response to the recent legalization of “aid in dying” in those jurisdictions that seek to address concerns about quality of practice and data collection [20,21].

Medicine must also acknowledge, however, that evidence (no matter how robust) that there have not yet been adverse consequences cannot guarantee that such consequences would not occur in the future. As a recent commentary noted, “[p]art of the problem with the slippery slope is you never know when you are on it” [15].

SAFEGUARDING DECISIONS AT THE END OF LIFE

CEJA has found that just as there are shared commitments behind deep differences regarding physician-assisted suicide, there are also shared concerns about how to understand the available evidence. For example, in the council’s recent Open Forum, both proponents and opponents of physician-assisted suicide observed that in the U.S., debate occurs against the backdrop of a health care system in which patients have uneven access to care, including access to high quality end-of-life care. They also noted that patients and physicians too often still do not have the conversations they should about death and dying, and that too few patients are aware of the range of options for end-of-life care, raising concern that many patients may be led to request assisted suicide because they don’t understand the degree of relief of suffering state-of-the-art palliative care can offer. Participants who in other respects held very different views concurred as well that patients may be vulnerable to coercion, particularly patients who are in other ways disadvantaged; and expressed concern in common that forces external to medicine could adversely influence practice.

These are much the same concerns the Institute of Medicine identified in its 2015 report, *Dying in America* [22]. They are concerns echoed in a February 2018 workshop on physician-assisted death convened by the National Academies of Science, Engineering and Medicine [23]. They underscore how important it is to understand *why* a patient requests assisted suicide as a starting point for care.

Patient requests for assisted suicide invite physicians to have the kind of difficult conversations that are too often avoided. They open opportunities to explore the patient’s goals and concerns, to learn what about the situation the individual finds intolerable and to respond creatively to the patient’s needs other than providing the means to end life—by such means as better managing symptoms, arranging for psychosocial or spiritual support, treating depression, and helping the patient to understand more clearly how the future is likely to unfold [4,24]. Medicine as a profession must ensure that physicians are skillful in engaging in these difficult conversations and knowledgeable about the options available to terminally ill patients [25]. The profession also has a responsibility to advocate for adequate resources for end-of-life care [14,25], particularly for patients from disadvantaged groups. The availability of assisted suicide where it is legal must not be allowed to interfere with excellent care at the end of life.

CONCLUSION

At the core of public and professional debate, the council believes, is the aspiration that every patient come to the end of life as free as possible from suffering that does not serve the patient's deepest self-defining beliefs and in the presence of trusted companions, including where feasible and when the patient desires, the presence of a trusted physician. As Timothy Quill noted more than 20 years ago, "dying patients do not have the luxury of choosing not to undertake the journey, or of separating their person from their disease" [24]. Decisions about how to approach the end of life are among the most intimate that patients, families, and their physicians make. Respecting the intimacy and the authenticity of those relationships is essential if our common ideal is to be achieved.

RECOMMENDATION

Over the past two years, the Council on Ethical and Judicial Affairs has reviewed the literature and received thoughtful input from numerous individuals and organizations to inform its deliberations, and is deeply grateful to all who shared their insights. CEJA engaged in extensive, often passionate discussion about how to interpret the *Code of Medical Ethics* in light of ongoing debate and the irreducible differences in moral perspectives identified above. After careful consideration, CEJA concludes that in its current form the *Code* offers guidance to support physicians and the patients they serve in making well-considered, mutually respectful decisions about legally available options for care at the end of life in the intimacy of a patient-physician relationship. The Council on Ethical and Judicial Affairs therefore recommends that the *Code of Medical Ethics* not be amended, that Resolutions 15-A-16 and 14-A-17 not be adopted and that the remainder of the report be filed.

REFERENCES

1. Council on Ethical and Judicial Affairs. Decisions near the end of life. *JAMA* 1992;267:2229–2233.
2. Vamos MJ. Physician-assisted suicide: saying what we mean and meaning what we say. *ANZJP* 2012;46:84–86.
3. Herx L. Physician-assisted death is not palliative care. *Curr Oncol* 2015;22:82–83.
4. Quill TE, Back AL, Block SD. Responding to patients requesting physician-assisted death: physician involvement at the very end of life. *JAMA* 2016;315:245–246.
5. American Academy of Hospice and Palliative Medicine. *Statement on Physician-Assisted Dying*, June 24, 2016. Available at <http://aahpm.org/positions/pad>
6. Quill TE, Cassel CK. Professional organizations' position statements on physician-assisted suicide: a case for studied neutrality. *Ann Intern Med* 2003;138:208–211.
7. Johnstone M-J. Organization position statements and the stance of "studied neutrality" on euthanasia in palliative care. *J Pain Symptom Manage* 2012;44:896–907.
8. Crigger BJ, McCormick PW, Brotherton SL, Blake V. Report by the American Medical Association's Council on Ethical and Judicial Affairs on physicians' exercise of conscience. *J Clin Ethics* 2016;27:291–226.
9. Chochinov HM. Physician-assisted death in Canada. *JAMA* 2016;315:253–254.
10. Battin MP, van der Heide A, Ganzini L, van der Wal G, Onwuteaka-Philipsen B. Legal physician-assisted dying in Oregon and the Netherlands: evidence concerning the impact on patients in vulnerable groups. *J Med Ethics* 2007;33:591–597.
11. Finlay IG, George R. Legal physician-assisted suicide in Oregon and The Netherlands: evidence concerning the impact on patients in vulnerable groups—another perspective on Oregon's data. *J Med Ethics* 2010;37:171–174.
12. Golden M, Zoanni T. Killing us softly: the dangers of legalizing assisted suicide. *Disability and Health Journal* 2010;3:16–30.
13. U.S. Conference of Catholic Bishops. *Assisted Suicide Laws in Oregon and Washington: What Safeguards?* September 22, 2016. Available at http://www.usccb.org/search.cfm?site=newusccb&proxystylesheet=newusccb_frontend&q=assisted+suicide&lang=eng. Accessed October 27, 2016.
14. Ganzini L, Back AL. The challenge of new legislation on physician-assisted death. *JAMA Intern Med* 2016;176:427–428.
15. Lerner BH, Caplan AL. Euthanasia in Belgium and the Netherlands: on a slippery slope? *JAMA Intern Med* 2015;175:1640–1641.
16. Aviv R. The death treatment. *New Yorker*;2015:June 22.
17. Miller DG, Kim SYH. Euthanasia and physician-assisted suicide not meeting due care criteria in the Netherlands: a qualitative review of review committee judgments. *BMJ Open* 2017;7: e017628.
18. Doernberg SN, Peteet JR, KIM SYH. Capacity evaluation of psychiatric patients requesting assisted death in the Netherlands. *Psychosomatics* 2016;57:556–565.
19. Gostin LO, Roberts AE. Physician-assisted dying: a turning point? *JAMA* 2016;315:249–250.
20. Nguyen HQ, Gelman EJ, Bush TA, Lee JA, Kanter MH. Characterizing Kaiser Permanente Southern California's experience with the California End of Life Option Act in the first year of implementation [research letter]. *JAMA Intern Med* 2017;December 26.
21. Li M, Watt S, Escaf M, et al. Medical assistance in dying: implementing a hospital-based program in Canada. *N Engl J Med* 2017;376:2082–2088.

22. Institute of Medicine. *Dying in America: Improving Quality and Honoring Individual Preferences near the End of Life*. Washington, DC: The National Academies Press; 2015.
23. National Academies of Science, Engineering and Medicine. “Physician-Assisted Death: Scanning the Landscape and Potential Approaches” Workshop, February 12–13, 2018. <http://www.nationalacademies.org/hmd/Activities/HealthServices/PADworkshop/2018-FEB-12.aspx>.
24. Quill TE. Doctor, I want to die. will you help me? *JAMA* 1993;270:870–873.
25. Petrillo LA, Dzung E, Smith AK. California’s End of Life Option Act: opportunities and challenges ahead. *J Gen Intern Med* 2016;31:828–829.

6. CEJA’S SUNSET REVIEW OF 2008 HOUSE POLICIES

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS EDITORIALY CORRECTED BY CEJA REMAINDER OF REPORT FILED

At its 1984 Interim Meeting, the House of Delegates (HOD) established a sunset mechanism for House policies (Policy G-600.110). Under this mechanism, a policy established by the House ceases to be viable after 10 years unless action is taken by the House to retain it.

The objective of the sunset mechanism is to help ensure that the American Medical Association (AMA) policy database is current, coherent, and relevant. By eliminating outmoded, duplicative, and inconsistent policies, the sunset mechanism contributes to the ability of the AMA to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of HOD deliberations.

At its 2012 Annual Meeting, the House modified Policy G-600.110 to change the process through which the policy sunset review is conducted. The process now includes the following steps:

- Each year the House policies that are subject to review under the policy sunset mechanism are identified.
- Policies are assigned to appropriate Councils for review.
- For the Annual Meeting of the House, each Council develops a separate policy sunset report that recommends how each policy assigned to it should be handled. For each policy it reviews, a Council may recommend one of the following actions: (a) retain the policy; (b) sunset the policy; (c) retain part of the policy; (d) reconcile the policy with more recent and like policy. A justification must be provided for the recommended action to retain a policy.
- A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. A reaffirmation or amendment to policy by the House of Delegates resets the sunset clock, making the reaffirmed or amended policy viable for another 10 years.

Although the policy sunset review mechanism may not be used to change the meaning of AMA policies, minor editorial changes can be accomplished through the sunset review process.

2008 POLICIES

In this report, the Council on Ethical and Judicial Affairs presents its recommendations regarding the disposition of 2008 House policies that were assigned to or originated from CEJA.

DUPLICATIVE POLICIES

On the model of the Council on Long Range Planning & Development (CLRPD)/CEJA Joint Report I-01 and of subsequent reports of CEJA’s sunset review of House policies, this report recommends the rescission of House policies issued since June 2008. As noted previously, the intent of this process is the elimination of duplicative ethics policies from PolicyFinder. The process does not diminish the substance of AMA policy in any sense. Indeed, CEJA Opinions are a category of AMA policy.

MECHANISM TO ELIMINATE DUPLICATIVE ETHICS POLICIES

The Council continues to present reports to the HOD. If adopted, the recommendations of these reports continue to be recorded in PolicyFinder as House policy. After the corresponding CEJA Opinion is issued, CEJA utilizes its annual sunset report to rescind the duplicative House policy.

For example, at the 2007 Interim Meeting, the HOD adopted the recommendations of CEJA Report 8-I-07, "Pediatric Decision-Making." It was recorded in PolicyFinder as Policy H-140.865. At the 2008 Annual Meeting, CEJA filed the corresponding Opinion E-2.026, thereby generating a duplicative policy. Under the mechanism to eliminate duplicative ethics policies, CEJA recommended the rescission of Policy H-140.865 as part of the Council's 2009 sunset report.

The Appendix provides recommended actions and their rationale on House policies from 2008, as well as on duplicate policies.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the House of Delegates policies that are listed in the Appendix to this report be acted upon in the manner indicated and the remainder of this report be filed.

APPENDIX - Recommended Actions

Policy No.	Title	Recommended Action & Rationale
H-15.997	Elderly's Eligibility for Automobile Insurance and Licensure	Retain: Policy remains relevant.
H-25.997	Dignity and Self Respect	Retain in part, with the deletion as shown: The AMA believes that medical care should be available to all our citizens, regardless of age or ability to pay, and believes ardently in helping those who need help to finance their medical care costs. But the AMA does not believe that tax dollars of the working people of America should be used to finance medical care for any person who is financially able to pay for it. Furthermore, the AMA believes in preserving dignity and self-respect of all individuals at all ages and believes that people should not be set apart or isolated on the basis of age. The AMA believes that the experience, perspective, wisdom and skill of individuals of all ages should be utilized to the fullest.
H-160.961	Caring for the Poor	Rescind: Policy is superseded by Opinion E-11.1.4, Financial Barriers to Health Care Access adopted as modernized in June 2016.
H-160.998	Health Care	Rescind: Policy has been superseded by the following: H-165.838 Health System Reform Legislation H-165.888 Evaluating Health System Reform Proposals H-165.920 Individual Health Insurance
H-230.962	Subspecialists Functioning as Primary Care Physicians	Retain: Policy remains relevant; edit to remain timely It is the policy of the AMA that clinical privileges in primary care be granted to physicians that have demonstrated capability through education, training, experience and current competence, and that the practice of

		managed care organizations to arbitrarily deny denying primary care privileges to physicians because of subspecialty or second specialty training be opposed by the AMA.
H-265.997	AMA-ABA Statement on Interprofessional Relations for Physicians and Attorneys	Retain: Policy remains relevant.
H-315.981	Privacy of a Physician's Personal Medical Records	Retain: Policy remains relevant.
H-35.999	Medicine and Pharmacy Relations	Retain: Policy remains relevant
H-350.971 H-350.975	Initiatives Regarding Minorities Improving Healthcare of Hispanic Populations in the United States	Defer recommendation to 2018 Interim meeting pending report on consolidation of AMA policy addressing issues of disparities and the health of minority populations: H-160.991 Health Care Needs of Gay, Lesbian, Bisexual and Transgender Populations H-295.878 Eliminating Health Disparities—Promoting Awareness and Education of Lesbian, Gay, Bisexual and Transgender (LGBT) Issues in Medical Education H-350.957 Addressing Immigrant Health Disparities H-350.958 Hispanic Population and Access to the US Healthcare System H-350.959 Guiding Principles for Eliminating Racial and Ethnic Health Care Disparities H-350.961 Improving the Health of Minority Populations H-350.966 Health Initiatives on Asian-Americans and Pacific Islanders H-350.971 AMA Initiatives Regarding Minorities H-350.972 Improving the Health of Black and Minority Populations H-350.974 Racial and Ethnic Disparities in Health Care H-350.976 Improving Health Care of American Indians H-440.869 Establishment of State Commission/Task Force to Eliminate Racial and Ethnic Health Care Disparities D-350.996 Strategies for Eliminating Minority Health Care disparities D-55.997 Cancer and Health Care Disparities among Minority Women D-65.995 Health Care Disparities among Gay, Lesbian, Bisexual and Transgender Families
H-350.978	Minorities in the Health Professions	Retain: Policy remains relevant.
H-370.967	Ethical Procurement of Organs for Transplantation	Retain: Policy remains relevant.
H-375.965	Principles for Incident-Based Peer Review and Disciplining at Health Care Organizations	Retain: Policy remains relevant.
H-375.969	Physician Access to Performance Profile Data	Retain: Policy remains relevant.
H-375.970	Professional Review Organization Peer Review	Retain: Policy remains relevant.
H-405.999	Physicians in Public Affairs	Retain: Policy remains relevant.

H-465.988	Educational Strategies for Meeting Rural Health Physician Shortage	Retain: Policy remains relevant
H-465.994	Committee on Rural Health	Retain: Policy remains relevant; revise title for clarity "Improving Rural Health Care"
H-475.987	Freedom of Speech in Medical Information	Rescind: Policy addresses litigation concluded in 1997 and is outdated.
D-478.992	Health Information Technology Purchasing Guidance	Rescind: Directive is accomplished through extensive resources available online at: https://www.ama-assn.org/practice-management/improving-digital-health

7. JUDICIAL FUNCTION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS: ANNUAL REPORT

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

At the 2003 Annual Meeting, the Council on Ethical and Judicial Affairs (CEJA) presented a detailed explanation of its judicial function. This undertaking was motivated in part by the considerable attention professionalism has received in many areas of medicine, including the concept of professional self-regulation.

CEJA has authority under the Bylaws of the American Medical Association (AMA) to disapprove a membership application or to take action against a member. The disciplinary process begins when a possible violation of the Principles of Medical Ethics or illegal or other unethical conduct by an applicant or member is reported to the AMA. This information most often comes from statements made in the membership application form, a report of disciplinary action taken by state licensing authorities or other membership organizations, or a report of action taken by a government tribunal.

The Council rarely re-examines determinations of liability or sanctions imposed by other entities. However, it also does not impose its own sanctions without first offering a hearing to the physician. CEJA can impose the following sanctions: applicants can be accepted into membership without any condition, placed under monitoring, or placed on probation. They also may be accepted, but be the object of an admonishment, a reprimand, or censure. In some cases, their application can be rejected. Existing members similarly may be placed under monitoring or on probation, and can be admonished, reprimanded or censured. Additionally, their membership may be suspended or they may be expelled. Updated rules for review of membership can be found at ama-assn.org/governing-rules.

Beginning with the 2003 report, the Council has provided an annual tabulation of its judicial activities to the House of Delegates. In the appendix to this report, a tabulation of CEJA's activities during the most recent reporting period is presented.

APPENDIX CEJA Judicial Function Statistics, April 1, 2017 – March 31, 2018

Physicians Reviewed	SUMMARY OF CEJA ACTIVITIES
3	Determinations of no probable cause
37	Determinations following a plenary hearing
11	Determinations after a finding of probable cause, based only on the written record, after the physician waived their plenary hearing right
Physicians Reviewed	FINAL DETERMINATIONS FOLLOWING INITIAL REVIEWS
11	No sanction or other type of action
8	Monitoring
12	Probation
6	Revocation
12	Suspension
2	Application denied
11	Censure
1	Reprimand
Physicians Reviewed	PROBATION/MONITORING STATUS
12	Members placed on Probation/Monitoring during reporting interval
8	Members placed on Probation without reporting to Data Bank
4	Probation/Monitoring concluded satisfactorily during reporting interval
1	Memberships revoked due to non-compliance with the terms of probation
46	Physicians on Probation/Monitoring at any time during reporting interval who paid their AMA membership dues
26	Physicians on Probation/Monitoring at any time during reporting interval who did not pay their AMA membership dues