JOINT COUNCIL REPORTS

The following report was jointly presented by Jack McIntyre, MD, Chair, Council on Medical Service; and Stuart Gitlow, MD, Chair, Council on Science and Public Health:

COVERAGE FOR CHRONIC PAIN MANAGEMENT (RESOLUTION 112-A-14)

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATION ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 112-A-14 AND REMAINDER OF REPORT FILED
See Policy H-185.931

Resolution 112-A-14, submitted by the American Academy of Pain Medicine and referred by the House of Delegates asked:

> That our American Medical Association (AMA) and interested stakeholders advocate for a minimum set of health insurance benefits for people in pain severe enough to require ongoing therapy. At minimum, a proposed program of treatment categories should include:
>
> 1) Medical management
> 2) Evidence- or consensus-based interventional/procedural therapies
> 3) Ongoing behavioral/psychological/psychiatric therapies
> 4) Interdisciplinary care
> 5) Evidence-based complementary and integrative medicine (e.g., yoga, massage therapy, acupuncture, manipulation)
>
> That our AMA advocate for parity in coverage for people with pain, similar to that accorded people with mental-health disorders.
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> That our AMA and interested stakeholders advocate for an interdisciplinary clinical approach that recognizes the interdependency of treatment methods in the treatment of chronic pain.
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> That our AMA and interested stakeholders recommend and provide expertise for legislation to require that all payers offer coverage for a comprehensive, interdisciplinary pain program, which would include such care modalities as cognitive-behavioral therapy, for patients who have disabling pain and have failed more conservative therapy.

The House of Delegates voted to refer Resolution 112-A-14 because, although support was expressed for a comprehensive approach to chronic pain management and appropriate insurance coverage, questions were raised about the level and scope of coverage highlighted in the resolution. The resolution was assigned to the Council on Medical Service and the Council on Science and Public Health for development of a joint report.

BACKGROUND

Scope of the Problem

Chronic pain is a widespread and costly medical condition. According to a 2011 report published by the Institute of Medicine (IOM), approximately 100 million adults suffer from chronic pain in the United States, and chronic pain costs between $560 and $635 billion each year in medical costs and lost productivity.[1] Medical costs were based on an analysis of the Medical Expenditure Panel Survey, restricted to adults ages 18 years or older, who were civilians and noninstitutionalized; indirect costs were based on an analysis of individuals 24-65 years of age in an effort to capture the active labor force. Therefore, these figures are likely conservative estimates because they exclude the costs of pain affecting institutionalized individuals, military personnel, children under age 18, personal caregivers,

and productivity of both younger (<age 18) and older (>age 65) workers. The IOM estimates that a person with moderate pain generates approximately $4,516 more in health care expenditures annually than a person without pain, and a person with severe pain generates health expenditures $3,210 higher than those of a person with moderate pain.

Factors Influencing Opioid Prescribing

Analgesic strategies include pharmacologic, rehabilitative, psychological, interventional, surgical, neurostimulatory, and complementary/alternative approaches. Pharmacologic strategies are commonly used for the management of acute pain, pain related to trauma/injury, and in patients with cancer or other serious illness. During the last few decades, growing numbers of patients with persistent noncancer pain have been offered long-term opioid therapy. This change in prescribing behavior has been influenced by several competing interests. Undertreatment of cancer pain was identified as a significant issue, and the aggressive use of opioid analgesics was endorsed as the most effective approach to address patient suffering. With the advent of a new array of prescription opioid products, this approach was extended to patients with persistent noncancer pain, despite a lack of evidence from long term, randomized controlled trials. In both the hospital and outpatient settings, promotion of the concept of pain as the 5th vital sign, and the evolution of patient satisfaction surveys that include a focus on the extent to which a patient's pain is relieved, created a practice environment that promoted opioid use.[2] The adoption of the "pain standard" by The Joint Commission in accreditation processes for hospitals and other healthcare organizations also has been cited as a contributor to increased opioid prescribing by physicians.[3] Despite the substantial burden of chronic pain in the United States, access to multidisciplinary care and reimbursement for nonpharmacologic approaches are woefully inadequate, furthering contributing to the routine use of opioid analgesics.[4]

Harms Attributable to Opioid Analgesics

While some patients with persistent noncancer pain benefit from the use of opioid analgesics, an increase in the number of prescriptions for opioid analgesics has been paralleled by a large increase in adverse consequences, including drug abuse, addiction, diversion and unintentional overdoses and deaths. Drug overdose deaths in the United States have increased steadily and now exceed 38,000 annually; opioid analgesics are involved in more than 40% of such deaths.[5] During the past decade, the number of patients seeking substance abuse treatment for the primary abuse of prescription pain relievers has increased six-fold and the estimated number of emergency department visits related to the nonmedical use of opioid analgesics increased 79% from 201,280 in 2006 to 359,921 in 2010.[6] Opioid therapy for persistent noncancer pain in older adults also is associated with an increased risk of fall-related injuries, all-cause mortality, and hospital stays.[7,8] Additionally, nearly one-third of Medicare Part D recipients being treated with opioid analgesics have prescriptions from multiple prescribers.[9]

A recent systematic review issued by the Agency for Healthcare Research and Quality found a lack of evidence to support the long-term use of opioids for managing persistent noncancer pain.[10] In addition to the risks associated with long-term opioid therapy, patients who are unable to access effective, safe pain management services and/or those who have developed an opioid use disorder may find themselves engaging in nonmedical use of opioid analgesics and exposing themselves to additional risks associated with the use of illegal drugs. In particular, there has been resurgence in heroin use in recent years, leading to increases in overdoses and deaths from this substance.[11]

INTERDISCIPLINARY APPROACHES TO CHRONIC PAIN MANGEMENT

As noted in Resolution 112-A-14, there is increasing evidence that interdisciplinary, comprehensive approaches are more effective than surgical or pharmacological therapy alone for many patients who require treatment for chronic pain. As a perception, pain may or may not correlate with an identifiable source of injury, and the sensation of pain is modified by individual experiences, medical and psychiatric comorbidities, cognition, expectations, emotions and memory. As such, effective pain management strategies must be tailored to each individual, and are likely to require a multi-faceted approach.

Comprehensive chronic pain management approaches aim to achieve pain control, eliminate maladaptive pain-related behaviors, and improve coping for patients who suffer from chronic pain. While interventional or prescription treatments may address acute pain symptoms, behavioral treatments are designed to identify social and environmental factors that provoke pain or discourage healthy behaviors. In addition, patients who suffer from persistent pain experience higher rates of comorbid psychiatric disorders (e.g., depression, anxiety), as well as sleep

disturbances. These conditions must be managed concurrently in order to maximize the efficacy of treatments that specifically target the physical symptoms of pain. A particularly challenging clinical presentation is the individual with combined pain and addiction.

A comprehensive pain management plan generally requires a physician-led, interdisciplinary team approach to reduce symptoms and improve psychological and social functioning, reduce disability, and achieve rehabilitation.[12] A multimodal approach may require the combined efforts of: (1) physicians knowledgeable in pharmacologic and/or interventional procedures; (2) physicians or other health professionals trained to diagnose and/or treat mental health disorders or conditions that may result from, cause, or exacerbate pain and suffering; (3) physical therapists or rehabilitation specialists who can assess physical conditioning requirements; and (4) nurses knowledgeable about chronic pain management approaches. Team members can provide valuable assistance in sustaining patient optimism and participation in their own recovery. Other evidence-based complementary and integrative approaches (e.g., yoga, massage therapy, acupuncture, manipulation) may be beneficial in some patients and also should be reimbursable. In some cases, the services of an addiction medicine specialist are needed within the team approach.

Several studies have evaluated the clinical- and cost-effectiveness of multidisciplinary pain centers, supporting their efficacy.[13-17] A recent systematic review of multidisciplinary treatments for persistent pain showed they were effective in patients with chronic lower back pain and fibromyalgia, although they exhibited less robust effects in patients with persistent pain of mixed etiology.[18] Another investigation found that changes in depression and disability were associated concurrently with changes in pain beliefs and catastrophizing in patients undergoing multidisciplinary treatment.[19] Patients who are able to accept their condition are likely to benefit most from the treatment in terms of pain reduction, and such interventions also facilitate return to work.[18,20,21] Although the use of opioids for the long-term treatment of persistent noncancer pain remains controversial with many patients exhibiting poor outcomes, patients with severe pain and pain-related disability who are treated with opioids have been found to have better outcomes when managed in multidisciplinary pain clinics.[22]

BARRIERS TO ACCESS TO COMPREHENSIVE PAIN MANAGEMENT TREATMENTS

Although a broad consensus exists in the medical community that comprehensive, interdisciplinary approaches to chronic pain management are often more effective than single modality treatments, access to such care is limited. Lack of adequate insurance coverage has a significant impact on the affordability of such treatments. As noted in Resolution 112-A-14, health insurance policies generally provide coverage for prescription drugs or medical interventions (e.g., surgery for lower back pain) to treat chronic pain, but coverage for more comprehensive therapies that involve ongoing interdisciplinary care is more limited or difficult to access.[1] Patients and their physicians are often required to follow a step therapy approach, pursuing more traditional treatments before a plan will cover interdisciplinary care. Patients also may be subject to insurer "fail first" protocols that require a patient to try – and fail – on a particular course of treatment before the insurer will authorize the preferred course of treatment prescribed by the physician. In addition, plans may limit coverage for certain treatments, restricting access for patients who need ongoing pain management services.

A related but distinct barrier to patient access to appropriate chronic pain management treatment is a lack of professionals qualified to treat and manage patients with chronic pain, particularly in a physician-led, interdisciplinary framework. Despite the advantages of multidisciplinary pain care, access to such care is limited in the United States due to the fact that only about one such facility or clinic exists for every 670,000 patients with chronic pain in the United States.[23] Even if insurers provided full coverage for comprehensive chronic pain management therapies and services, the workforce does not currently have sufficient capacity to treat the population of patients in need of specialized care.

RELEVANT AMA POLICY

Policy D-160.981 expresses the AMA's strong commitment to better access and delivery of quality pain care through the promotion of enhanced research, education and clinical practice in the field of pain medicine. In particular, it encourages relevant specialties to collaborate in studying the body of knowledge encompassed by the field of pain medicine; the adequacy of medical education in the principles and practice of the field of pain medicine; and appropriate training and credentialing criteria for this multidisciplinary field of medical practice.

[1] See for example www.aetna.com/cpb/medical/data/200_299/0237.html; https://www.healthpartners.com/public/coverage-criteria/pain-programs/

Policy H-410.950 provides guidelines on invasive pain management procedures for the treatment of chronic pain. It defines interventional chronic pain management as the diagnosis and treatment of pain-related disorders with the application of interventional techniques in managing sub-acute, chronic, persistent, and intractable pain. The policy specifies that invasive pain management procedures require physician-level training, but that certain technical aspects of invasive pain management procedures may be delegated to appropriately trained, licensed or certified, credentialed non-physicians under direct and/or personal supervision of a physician.

The AMA has several policies that address the use of controlled substances in supporting pain relief and chronic pain management. Policy D-120.971 calls on the AMA to support a dialogue between the Drug Enforcement Administration and physician groups to assist in establishing a clinical practice environment that is conducive to pain management and the relief of suffering, while minimizing risks to public health and safety from drug abuse or diversion. Policy D-120.947 calls on the AMA to consult with relevant Federation partners and consider developing by consensus a set of best practices to help inform the appropriate clinical use of opioid analgesics, and to urge the Centers for Disease Control and Prevention to take the lead in promoting a standard approach to documenting and assessing unintentional poisonings and deaths involving prescription opioids, in order to develop the most appropriate solutions to prevent these incidents.

AMA policy is generally cautious with respect to supporting benefit mandates, which have the potential to increase the costs of health insurance and limit innovation in the health insurance market. For example, Policy H-185.964 opposes new health benefit mandates unrelated to patient protections, and Policy H-165.856 states that benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options. However, the AMA also supports value-based decision making at all levels of the health care system (Policy H-450.938). In particular, the AMA supports value-based insurance benefit designs, which balance the clinical benefit gained relative to the money spent (Policy H-185.939).

Consistent with an interdisciplinary approach to chronic care management, the AMA has developed extensive policy over the past two years supporting physician-led team-based care. Policy H-160.906 defines elements of a strong physician-led team-based care model, including a patient-centered focus that emphasizes teamwork and each member of the team taking responsibility for clearly defined roles and responsibilities consistent with his or her training and education.

DISCUSSION

It is acknowledged that pain, and in particular chronic pain, is a condition that should be evaluated and managed similar to other chronic medical conditions, like diabetes or hypertension. Since 2001, facilities accredited by The Joint Commission have been required to follow pain management standards, including recognizing the right of patients to appropriate assessment and management of pain; educating patients suffering from pain and their families about pain management; and addressing the individual's needs for symptom management in the discharge planning process. Yet there is general agreement that the approach to chronic pain management in the United State needs improvement, and that traditional treatment approaches combined with insurer-driven barriers do not provide sufficient relief to help patients effectively live with and manage their pain. In the context of ongoing concerns about prescription drug abuse it is critical that policymakers examine the barriers that prevent patients from receiving appropriate and comprehensive pain management services that may be safer and more effective than reliance on pharmacologic treatments alone.

The Councils believe that there should be an increased focus on comprehensive pain management approaches that are physician-led and recognize the interdependency of treatment methods in addressing chronic pain. In light of the evidence that comprehensive, interdisciplinary pain management approaches can be more clinically appropriate and cost-effective than traditional treatment options, expanding health insurance coverage to include these modalities seems likely to improve the value of spending on chronic pain care management, and may ultimately result in lower costs across the system for conditions related to chronic pain.

The Councils believe that our AMA should support health insurance coverage that gives patients access to the full range of evidence-based chronic pain management modalities, and that coverage for these services should be equivalent to coverage provided for medical or surgical benefits. However, pursuing legislative action to ensure coverage of specific chronic pain management benefits (as called for in the fourth resolve of Resolution 112-A-14)

could potentially limit the flexibility of health insurers to design and modify their pain management coverage options so that they reflect the maximum value to patients and are responsive to current and evolving evidence.

In addition to advocating for expanded insurance coverage for comprehensive chronic pain management services, efforts must be made to address the lack of professionals qualified to treat and manage chronic pain patients, and the limited availability of multidisciplinary centers of care. Accordingly, the Councils recommend that our AMA advocate for support for efforts to expand the capacity of practitioners and programs capable of providing physician-led interdisciplinary pain management services.

The Councils are aware that some state legislatures and regulators have introduced proposals that require physicians to follow certain protocols either prior to prescribing or in conjunction with opioid treatment.[2] On one hand, the AMA supports the development of voluntary guidelines that can help inform physician decision-making in the use of opioids to treat and manage pain. At the same time, the AMA has expressed concern that mandates on what physicians and patients must do for patients in chronic pain can have unintended consequences. The Councils note that these mandates may not be appropriate for all patients, and that patients' access to care may be limited by the current lack of coverage for these services, as well as the lack of professionals trained to provide comprehensive pain management services.

RECOMMENDATIONS

The Councils recommend that the following recommendations be adopted in lieu of Resolution 112-A-14, and that the remainder of the report be filed:

1. That our American Medical Association advocate for an increased focus on comprehensive, multidisciplinary pain management approaches that include the ability to assess co-occurring mental health or substance use conditions, are physician-led, and recognize the interdependency of treatment methods in addressing chronic pain.

2. That our AMA support health insurance coverage that gives patients access to the full range of evidence-based chronic pain management modalities, and that coverage for these services be equivalent to coverage provided for medical or surgical benefits.

3. That our AMA support efforts to expand the capacity of practitioners and programs capable of providing physician-led interdisciplinary pain management services, which have the ability to address the physical, psychological, and medical aspects of the patient's condition and presentation and involve patients and their caregivers in the decision-making process.

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The following report was jointly presented by Patrick W. McCormick, MD, Chair, Council on Ethical and Judicial Affairs; and Stuart Gitlow, MD, Chair, Council on Science and Public Health:

NON-MEDICAL EXEMPTIONS TO IMMUNIZATION

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

HOUSE ACTION: REFERRED

Policy D-440.936, "Immunization Exemptions," directs our American Medical Association (AMA) to review and address existing inconsistencies in its policies regarding immunization exemptions. While current AMA policy allows for immunization exemption for medical contraindications, AMA policy is not uniform regarding non-medical exemptions. Some policies recognize only non-medical exemptions based on religious beliefs, while others recognize non-medical exemptions based on both religious and philosophical objections:

- D-440.947, "Support for Immunizations," encourages states to enact more stringent requirements for parents/legal guardians to obtain personal belief exemptions from state immunization requirements.

- H-440.850, "Recommendations for Health Care Worker and Patient Influenza Immunizations," supports mandatory influenza vaccination for staff in long-term care facilities "absent a medical contraindication or religious objection."

- H-440.970, "Religious Exemption from Immunization," recognizes that religious exemptions endanger the health of the unvaccinated individual, the individual's group, and the community and "encourages state medical associations to seek removal of such exemptions."

- E-9.133, "Routine Universal Immunization of Physicians for Vaccine-Preventable Disease," holds that physicians have a professional ethical obligation to accept immunization "absent a recognized medical, religious or philosophic reason not to be immunized."

The Council on Science and Public Health (CSAPH) and Council on Ethical and Judicial Affairs (CEJA) deemed that a joint report would be the most prudent approach to implement Policy D-440.936 and convened a working group of members from both councils to prepare a comprehensive report on this topic.

BACKGROUND

Immunization benefits both the individuals who receive vaccines and the wider community. When people are immunized, they not only build up their own immune systems, they also help prevent the spread of disease to others who have not been immunized, for whom the vaccine has failed to provide protection, or for whom the vaccine is medically contraindicated. Herd immunity—high immunization rates that help minimize the transmission of disease through a population—protects unimmunized and under-immunized individuals and those who are at highest risk for severe infection, including pregnant women, infants, immunocompromised individuals, and patients with chronic disease.

Law and policy throughout the United States require immunizations or other documentation of immunity as a condition of public school attendance and, in some cases, as a condition of employment.[1] Historically, the US Supreme Court has held that states can mandate immunizations to protect public health, but, if they do, they also must allow medical exemptions. Courts have further held that the exemption process must not violate individuals' constitutional rights. Thus, most states also provide for non-medical exemptions to accommodate the religious beliefs of some individuals who oppose immunization. Some states also provide non-medical exemptions for individuals who oppose immunization for personal or philosophical reasons.

Many states also have laws providing for mandatory immunizations during a public health emergency or large-scale outbreak of a communicable disease.[1] Generally, the power to order such action resides with the governor of the state or with a state health officer. While exemptions may be permitted for medical, religious, or philosophical reasons, governments have the authority to quarantine unimmunized individuals during a public health emergency.

VACCINE MANDATES & EXEMPTIONS

Immunization programs in the United States, supported by state legal requirements and federal funding/oversight, are among the most cost effective and widely used public health interventions having controlled or eliminated the spread of epidemic diseases, including smallpox, measles, mumps, rubella, diphtheria, and polio.[2,3]

Medical exemptions from immunization are intended to prevent harm to individuals who are at increased risk of adverse events from the vaccine because of underlying conditions. Vaccines are medically contraindicated for individuals who have histories of severe allergic reactions from prior doses of vaccine. Many underlying conditions also place individuals at increased risk of complications from certain vaccines as well as from the diseases they prevent. For example, individuals who are severely immunocompromised should not be inoculated with vaccines containing live attenuated viruses, such as the varicella zoster (chicken pox or shingles) or measles, mumps, and rubella (MMR) vaccines.[4] Individuals for whom vaccines are medically contraindicated are protected from exposure to vaccine preventable diseases through herd immunity by ensuring high rates of coverage among the rest of the population.

Non-medical exemptions recognize the role of individual and, for childhood immunizations, parental autonomy in making decisions about immunization.[5] These exemptions are variously defined across the country, encompassing religious exemptions and exemptions for "personal belief," which may include philosophical or other strongly held non-medical reasons for objecting to immunization that are not associated with specific religious beliefs.

Childcare & School Entry Mandates

Every state and the District of Columbia (DC) has law requiring documentation of immunizations for entry into licensed childcare, Head Start, and school.[6] Various states also mandate immunizations for incoming college and university students. The CDC maintains a continuously updated online database of state laws pertaining to immunization requirements for childcare, kindergarten, middle school, and university/college attendance.[7] Institutions, such as colleges and private schools, may establish additional immunization policies for attendance or residence on campus. School entry coverage for most states is at or near national *Healthy People 2020* targets of maintaining 95% immunization coverage levels for all recommended vaccines.[8,9]

Requirements for exemptions from childcare and school entry vaccine mandates vary from state to state with regard to the child's age, school grades covered, the vaccines included, the processes and authority used to add or remove vaccines from school entry mandates, reasons for exemptions (medical reasons, religious reasons, philosophical or personal beliefs), and the procedures for granting exemptions.[10-12] Currently, 48 states allow a religious exemption (West Virginia and Mississippi are the only exceptions); 19 states also allow a "personal belief" exemption.[13] For the 2013-2014 school year, an estimated 90,666 exemptions were reported nationally among a total estimated population of 3,902,571 kindergarten-age children.[8] Exemption rates were less than 1% for eight states and greater than 4% for 11 states (range: less than 0.1% in Mississippi to 7.1% in Oregon; median 1.8%).

All states permit a medical exemption to immunization for children entering childcare and school. In states that report medical exemptions separately from non-medical exemptions, the median medical exemption rate for kindergarten-age children in the 2013-2014 school year was 0.2% (range: less than 0.1% in eight states to 1.2% in Alaska and Washington).[8]

Over the past two decades, the number of non-medical exemptions from school immunization requirements in the United States has increased considerably, from a state median of 0.98% in 1991 to 1.7% in 2014,[8,10,14-19] primarily among states that recognize exemptions based on personal or philosophical beliefs in addition to religious exemptions. In states that report medical exemptions separately from non-medical exemption rates, for the 2013-2014 school year, the median percentage of kindergarten-age children with non-medical exemptions was 1.7% (range: 0.4% in Virginia to 7.0% in Oregon); 11 states had non-medical exemptions levels of 4.0% or greater.[8]

Immunization of Health Care Personnel

The CDC recommends that all health care personnel be immunized appropriately.[20] A number of states require employees of certain health care facilities, such as hospitals and nursing homes, to be immunized against diseases such as measles, mumps, rubella, varicella zoster, hepatitis B, and influenza. Such laws, which vary widely,

generally contain opt-out provisions if a vaccine is medically contraindicated or if the vaccine is against the individual's religious or philosophical beliefs.[21] As of 2014, approximately 30% of health care personnel reported that their employers required influenza immunization as a condition of employment.[22]

As of July 2014, three states (Alabama, Colorado, and New Hampshire) mandated influenza immunizations for health care personnel.[23] Even without a state mandate, hospitals and health care systems in 45 states have implemented institutional policies mandating influenza immunization, although these policies vary in their requirements and penalties.[24]

For the 2013-2014 influenza season, 75% of health care personnel overall reported having had an influenza immunization,[22] which is below the *Healthy People 2020* annual goal of 90% influenza vaccine coverage for this group.[9] By occupation, immunization coverage was 92% among physicians, 90.5% among nurses, 90% among nurse practitioners and physician assistants, 87% among other clinical personnel, and 69% among nonclinical personnel.[22] Immunization coverage was 90% among health care personnel working in hospitals and 63% among those working in long-term care facilities.

IMMUNIZATION STATUS & THE RESURGENCE OF VACCINE PREVENTABLE DISEASES

A growing number of parents are seeking non-medical exemptions to delay or refuse some or all vaccines for their children.[22-27] The ease of obtaining non-medical exemptions is associated with higher rates of exemptions,[12,18,28] and there is reason to believe that parents may use non-medical exemptions out of convenience rather than deeply held belief.[12,18,28] A study of non-medical exemptions permitted between 1991 to 2004, found that the increase in exemption rates was not uniform.[18] Exemption rates for states that allowed only religious exemptions remained at approximately 1% during this time period; however, in states that allowed exemptions for philosophical or personal beliefs, the mean exemption rate increased from 1% to 2.5%. Additional studies suggest that states that allow philosophical exemptions for school-age children have significantly higher estimated rates of unimmunized children.[8,10,16-19,28,29]

Overall, about 90% of all non-medical exemptions for states that permit both religious and philosophical exemptions for school entry were philosophical exemptions.[8] Some states require membership in a recognized religion, whereas others merely require an affirmation of religious or philosophical opposition. States in which individuals can obtain vaccine exemptions for non-religious "philosophical" reasons generally have the highest immunization opt-out rates in the nation.[8,19,29]

There is ample evidence that where immunization rates are low, especially where children are under-immunized or not immunized at all, outbreaks of vaccine preventable disease are more frequent.[30-35] Studies have shown an increase in the local risk of vaccine preventable diseases (notably pertussis, measles, and mumps) when individuals who refuse immunization cluster geographically within school districts, communities, and counties.[18,19,33-39]

In Colorado, for example, the county-level incidence of measles in immunized children from 1987 through 1998 was associated with the frequency of exemptions in that county.[33] Vaccine exempt children were 22 times more likely to acquire measles and 6 times more likely to acquire pertussis than immunized children. At least 11% of nonexempt children who acquired measles were infected through contact with an exempt child. The mean exemption rate among schools with pertussis outbreaks was 4.3% compared with 1.5% for schools that did not have an outbreak.

From January 1, 2014 to April 3, 2015, the United States has experienced a dramatic increase in the number of measles cases. During this time, the CDC confirmed 827 measles cases. In 2014, there were 668 cases in 27 states stemming from 23 outbreaks. Many of these outbreaks began with unimmunized individuals who were exposed to the virus while abroad, particularly those who travelled to the Philippines which experienced a large measles outbreak. One large outbreak included 383 cases in unimmunized Amish communities in Ohio. As of 2015, 159 cases of measles have been confirmed in 18 states and the District of Columbia. These cases have grown out of 4 major outbreaks, with 117 cases (74%) from a large multi-state outbreak linked to an amusement park in California. The majority of all of these cases occurred in persons who were unimmunized.[40,41]

VACCINE REFUSAL

While the vast majority of parents in the United States have their children immunized in accordance with the ACIP-recommended vaccine schedule, it has been estimated that almost 1 in 8 parents (12%) have refused at least one vaccine recommended by their physician.[42] Studies indicate that underimmunized children are likely to have missed some immunizations because of factors related to the health care system or socioeconomic characteristics, whereas children who are not immunized at all are likely to belong to families that intentionally refuse vaccines.[10]

Decisions about immunization are influenced by the individual's perception of health, beliefs about and experience of childhood diseases, and perceptions about the risks of diseases, as well as perceptions about vaccine safety and effectiveness and vaccine components and level of trust in institutions.[43-51] Even when they do not outright reject immunization, many parents have become "vaccine hesitant."[52,53] Having had little or no experience with most of the vaccine preventable diseases because the prevalence of those diseases is very low (or nonexistent), parents' concerns that a vaccine will adversely affect their child can often outweigh their concerns about disease risk. Additionally, lack of understanding about how vaccines work combined with the fear of being injected with a disease agent contribute to reluctance to undergo immunization. In surveys, parents consistently cite vaccine safety, including concerns about autism, as the most frequent reason for not vaccinating their children. [10,43-45,49,50,54] The evidence that originally purported to show a link between autism and immunization was proven to be fraudulent and was retracted and its author censured.[55] An extensive body of credible scientific evidence continues to support the safety and effectiveness of vaccines. [56-59]

Parents who refuse immunization for their children may also rely more on guidance from family, friends, and their broader social network, including popular media, than on physicians' recommendations.[60] The influence of such social guidance is evident in the persistence of the anti-immunization movement in the United States,[61] and the geographical clustering of families with similar attitudes and beliefs about immunizations.[18,19,33-39]

Decisions may also be influenced by physicians' attitudes toward immunization and the guidance they offer to patients/parents.[10,43-48] Physicians can play an important role in engaging and supporting vaccine hesitant parents to understand and address their concerns. Disconcertingly, however, objections to immunization are offered by health care personnel as well as the public.[62] For example, although physicians generally have favorable attitudes toward vaccines, those who provide care for unimmunized children are more likely to have safety concerns and may themselves be less likely to view vaccines as beneficial to society.[48]

THE CHALLENGE OF NON-MEDICAL EXEMPTIONS to IMMUNIZATION

It is not ethically problematic to exempt from immunization an individual with medical contraindications. Ethical concerns arise when individuals are allowed to decline immunizations (for themselves or their children) for other, non-medical reasons. The rationale for non-medical exemptions must strike a prudent balance among multiple interests and values, including the welfare of individuals, groups and communities; respect for civil liberties and autonomy; and fairness.

Some faith communities oppose immunization as a violation of core tenets of their religion. In general, society respects individuals' freedom to make health care decisions for themselves in keeping with their religious commitments. However, society constrains the freedom to make decisions for others on the same basis, especially if those decisions may lead to foreseeable harm. Parents are expected to make decisions in the best interests of their minor children and when there is no foreseeable harm or possible harms are minor, society generally respects the decisions parents make for their children. Because there is no foreseeable harm (only potential harm) to an unimmunized child, allowing parents to claim the religious exemption on behalf of their children respects the autonomy of parents and the faith commitments of the family.

Within limits, society also respects individuals' freedom to make decisions for themselves based on personal beliefs that are not encoded in specific religious doctrine per se. Ideally, those beliefs will comprise a "substantive, coherent, and relatively stable set of values and principles" to which the individual is genuinely committed and that are reflected broadly in the individual's decisions and actions.[63]

Physicians' Duty to Be Immunized

Physicians have long-recognized obligations to promote health and prevent disease for the well-being of individual patients and the community at large.[64] Physicians likewise have an obligation not to put patients at undue risk of harm. These fundamental obligations encompass responsibilities to subordinate their own interests to those of their patients and to protect their own health and well-being in the interests of their individual patients as well as the community at large in ensuring adequate availability of care. [65,66]

Taken together, these considerations argue strongly for a duty for physicians and other health care personnel to be immunized against vaccine preventable diseases—unless there are compelling reasons for not receiving a specific vaccine. As the Council on Ethical and Judicial Affairs noted in its 2010 report on routine universal immunization of physicians, the relative strength of a duty to be immunized is conditioned on several factors, including how readily a given disease is transmitted; what medical risk the disease represents for patients, colleagues, and others; risk of occupational exposure; the safety and efficacy of available vaccine(s); effectiveness and appropriateness of immunization relative to other strategies for preventing disease; and the medical value or possible contraindication of immunization for the individual.[67] Unless medically contraindicated, the more readily transmissible the disease and the greater the risk to patients and others with whom the physician comes into contact relative to risks of immunization to the physician, the stronger the physician's duty to accept immunization.

Although the presumption is that physicians have a responsibility to be immunized, there are certain circumstances in which they should refrain from being immunized; for example, if the receipt of a live virus vaccine would put immunocompromised or never-immunized patients at risk during the time the physician may transmit the attenuated virus. Physicians should take appropriate measures to protect themselves and their patients. This may include refraining from direct patient care for that period of time.

In light of physicians' professional commitments, non-medical exemptions for physicians (and other health care personnel) are ethically problematic. Physicians and other health care personnel providing direct patient contact should rightly expect their individual autonomy to be respected when their personal health choices do not put others at risk of harm.[62] However, with certain limited exceptions, physicians and other health care personnel who decline to be immunized do put others at risk for vaccine preventable disease. Physicians and other health care personnel who consider declining immunization on grounds of deeply held personal beliefs must carefully consider what is at stake for patients and others in order to strike an ethical balance between their diverging commitments as moral individuals and as medical professionals. Those who cannot or choose not to be immunized have a responsibility to take other steps to protect themselves and those to whom they may transmit a vaccine preventable disease.

Arguably, physicians' responsibility to protect patients' well-being extends to ensuring that all staff in their own practices are immunized, absent medical contraindication, or take steps to protect themselves and patients. At a minimum, physician-leaders in practices and health organizations should require that staff who come into contact with high risk patients take appropriate protective measures.

The lay public cannot be said to have a duty to be immunized in the same sense. However, immunization especially for highly transmissible vaccine preventable diseases and those with significant morbidity and mortality, is surely in the self-interest of individuals and should rightly be encouraged in the interest of protecting oneself, one's close associates, and one's community. Parents are expected to make health care decisions in the interests of their children, so ensuring their children are immunized is a logical part of a protective parental role, which is enhanced when parents are themselves immunized.

Physicians' Duty to Persuade

Although physicians who treat children have an obligation to promote their patients' interests and well-being separate from what the child's parents or guardian want, with certain exceptions parental permission is required before any intervention is carried out with an unemancipated minor patient.[67-69] Unless the course of action selected by a child's parents/guardian places the patient at substantial risk of harm, physicians must respect the health care decisions parents/guardians make on behalf of their children. However, this does not mean that physicians should not advocate strongly on behalf of their patients and attempt to dissuade parents/guardians from decisions that in the physician's professional judgment are not in the patient's best interest.

As trusted sources of information and guidance, physicians can play a significant role in shaping their patients' perspectives about vaccines and the decisions patients make about immunizing themselves and their families.[16, 43-48] Physicians have a responsibility to educate parents/guardians about the risks of forgoing or delaying a recommended immunization,[70] and help them better understand the long-term preventive benefits that childhood immunizations convey.

Exploring with vaccine hesitant parents/guardians their reasons for declining or delaying recommended immunizations for their children is crucial. Vaccine hesitant parents commonly misunderstand physicians' motivation for urging immunization. Parents who are reminded that their child's physician is motivated first and foremost by the welfare of their child instead of public health concerns are more receptive to considering immunization.[70] As with all parents, candor, willingness to listen, encouraging questions, and respectfully acknowledging parents' concerns are essential elements of conversations with vaccine-hesitant parents.[70]

Physicians also serve as role models for their patients, consciously or otherwise. Physicians who adhere to immunization requirements and recommendations for themselves and their children can be powerful motivators for patients, colleagues, and others in the community to pursue immunization.[71] Physicians can take advantage of their power to motivate by communicating that they themselves have been immunized—for example, by wearing a button proclaiming "I've Been Immunized" or other informal means. By the same token, physicians who fail to follow their own advice risk compromising patients' trust and undermining their credibility as advisors.

Parents/guardians of minor patients who continue to refuse immunization for their children, as well as adult patients who refuse immunization for themselves, pose a health risk to others. Because physicians have an obligation to protect the health of the other patients in the practice and the practice staff, physicians must take action to protect those who will come in contact with unimmunized individuals in the office, clinic, or other health care setting.

Some clinicians have ended or considered ending their relationship with patients or families or refuse immunization. However, these patients/families still have other important medical needs that must be met and terminating the patient-physician relationship should be a last resort. If the relationship has been irrevocably damaged by the disagreement over immunization, termination may be unavoidable and in the best interests of all parties. If so, physicians should give the patient/family appropriate notice and facilitate transfer to another health care professional willing to provide care when possible, in keeping with ethical guidelines.[70,71,73]

Physicians' Duty to Advocate

In light of their professional responsibility to promote the health of both their individual patients and the community, physicians have a responsibility to advocate for effective, fair, consistently implemented immunization programs. Through their state and specialty societies, physicians can have a voice in shaping scientifically and ethically sound policy concerning immunization requirements and exemptions.

A majority of states do not specifically define what constitutes a religious or personal exemption; when they do, how strictly the exemption is defined does not appear to determine how strictly the exemption is applied.[22] In some states, a parent can claim personal exemption simply by signing a prewritten statement on the school immunization form.[20] Often this is perceived as easier than completing a school immunization form that requires a health care professional to provide details of immunization from the child's medical record. Some states that offer religious or personal belief exemptions have additional administrative requirements, such as requiring a signature from a local health department official, annual renewal, notarization, or a personally written letter from the parents explaining the reasons for vaccine refusal. Research supports a relationship between rates of non-medical exemptions and the process in place for obtaining them: the easier the process, the higher the rate of exemptions.[28] Moreover, exemption rates are higher in states that permit non-medical exemptions for personal and philosophical, rather than solely religious, reasons.[28]

The important public health goals of immunization policies and programs argue in favor of greater consistency and clarity among states in how they define non-medical exemptions and greater stringency in implementing such exemptions, while still allowing a role for individual autonomy in decisions about immunization. Accurate, easily understood information about the scientific basis for vaccine safety, the benefits of immunization, and the implications of refusing immunization for the individual and for vulnerable persons in the community who must rely

on herd immunity to protect them from disease, also must be readily available to help patients and parents make informed decisions about immunization.

Supporting more uniform procedures for obtaining non-medical exemptions that are neither unduly burdensome nor simply pro forma can also help achieve public health goals while protecting autonomy and promoting fair implementation of immunization policies. Requiring individuals who seek a non-medical exemption to demonstrate in some way that they understand and meet clearly defined criteria for such an exemption is ethically justifiable and can help promote prudent use of exemptions.

Just as clinicians, school officials, and state health officials are responsible for ensuring that medical exemptions are granted appropriately,[74] so too do they have a responsibility to advocate for immunization policies that clearly articulate when exemptions based on deeply held personal beliefs will be granted and that set out fair practices for obtaining a non-medical exemption.

CONCLUSION

Decisions about immunization rest on one's assessment of the relative risks and benefits of accepting or refusing vaccine. The very success of immunization programs over time has resulted in a situation in which many individuals, including physicians, have no memory of the devastating effects of infectious diseases such as poliomyelitis, measles, and pertussis against which to appreciate the benefits of immunization. As these diseases become rare, concern among some has shifted from preventing disease transmission to worries about the safety of vaccines.

The reemergence of various vaccine preventable diseases argues for looking carefully at the use of non-medical exemptions to immunization mandates. Where exemption rates are high, herd immunity may be compromised and the number of unimmunized individuals might become sufficient to permit transmission of vaccine preventable diseases, if introduced. When people decide not to be immunized, they put others at risk as well as themselves.

Protecting community health requires that individuals not be permitted to opt out of immunization solely as a matter of convenience, whim, or misinformation. Non-medical exemptions should protect individuals' right to make choices about what happens to their bodies or to their children's bodies. However, with the right to choose comes a responsibility to consider the consequences of those choices for others. Public policies that limit non-medical exemptions to circumstances in which refusals are based on well-considered, deeply held beliefs and require individuals who seek exemptions to demonstrate that they meet those criteria can balance public health and civil liberties.

Physicians have an important role to play in protecting individual patients and the health of communities. They have a responsibility to help educate patients and parents about the risks of vaccine preventable diseases and the safety and effectiveness of vaccines. Such information can help ensure that individuals make well-informed decisions for themselves and their children. Physicians who administer vaccines also need to stay up-to-date on the recommendations of the Advisory Committee on Immunization Practices and use sound professional judgment in granting medical exemptions. In their own practices and through their state and professional medical societies, physicians have a responsibility to support limited, prudent use of non-medical exemptions and to advocate for exemption policies that are transparent and fair.

RECOMMENDATIONS

In light of the foregoing analysis, the Council on Science and Public Health and the Council on Ethical and Judicial Affairs recommend that the following recommendations be adopted, including revisions in Opinion E-9.133 proposed by the Council on Ethical and Judicial Affairs in Recommendation 2 below, and that the remainder of the report be filed.

1. That Policy H-440.970, "Religious Exemption from Immunization," be amended by substitution to read as follows:

SUPPORT FOR ROUTINE, UNIVERSAL IMMUNIZATION

Recognizing that immunization is one of the most cost-effective interventions available to protect the health of individuals, including individuals for whom immunization is not medically appropriate and those who do not respond to immunization, and the community against vaccine preventable diseases, our American Medical Association:

(1) Supports routine, universal immunization in accordance with Advisory Committee on Immunization Practices (ACIP) recommendations and consistent with professional guidelines, absent medical contraindications, for appropriate patients, health care personnel, and other at-risk populations. Routine, universal immunization against influenza and pertussis is particularly important given the high number of deaths attributed annually to influenza and the potential for harm from pertussis.

(2) Urges the Centers for Disease Control and Prevention to work with appropriate health agencies and organizations to disseminate scientifically well grounded, easy to understand information about vaccine safety, the benefits of immunization for individuals and for populations, and the implications of refusing immunization for the individual and vulnerable persons in the community with whom the individual comes in contact in order to encourage immunization and counter misinformation about immunization that may exist in the community.

(3) Urges education to enhance knowledge and understanding among physicians and other health care professionals about the importance of taking an immunization history from all patients, of considering vaccine preventable diseases as a differential diagnosis, and of effective communication strategies to address individuals who resist immunization.

(4) Urges physicians and other health care professionals to

a. reinforce key points about vaccines with patients and caregivers;
b. inform parents/guardians about state immunization requirements pertaining to entry into school or childcare, which might require that unimmunized children remain at home during outbreaks of vaccine preventable disease;
c. document vaccine-related discussions in the medical record, including patients' or parents'/guardians' informed refusal of immunization for themselves or their children; and
d. issue medical exemptions for immunization only in accordance with ACIP recommendations and consistent with professional guidelines and sound professional judgment.

(5) Urges hospitals, other health care facilities, and physicians in their own practices to ensure that they, their staff, and their own close associates are up to date on personal immunizations in keeping with ACIP recommendations and appropriate professional guidelines.

(6) Encourages all hospitals, health care systems, and skilled nursing facilities to implement systems for measuring and maximizing immunization rates among health care personnel.

(7) Will work with state medical associations to oppose any vaccine legislation that deviates from ACIP recommendations and appropriate professional guidelines.

(8) Encourages state medical associations to advocate for more stringent requirements for non-medical exemptions from immunization to promote public and individual welfare while ultimately respecting personal autonomy by working with state legislatures and public health authorities to promote

a. clear definitions of accepted grounds for non-medical exemptions that prudently limit such exemptions;
b. implementation of fair, reasonable procedures for granting non-medical exemptions; and
c. vigorous, consistent enforcement of laws and policies concerning non-medical exemptions.

(9) Encourages physicians and local medical associations to work with state and local public health officials to inform patients and community groups about the benefits of vaccines and the risk to personal and public health if adults decline to be immunized or do not immunize their unemancipated minor children.

(10) Encourages state and local medical associations to work with public health officials to develop contingency plans for controlling outbreaks of vaccine preventable diseases in exempt populations and intensify efforts to enhance immunization rates in communities with a high proportion of individuals who have non-medical exemptions from immunization.

2. That E-9.133, "Routine Universal Immunization of Physicians," be amended by addition and deletion to read as follows:

As professionals committed to promoting the welfare of individual patients and the health of the public and to safeguarding their own and their colleagues' well-being, physicians have an ethical responsibility to take appropriate measures to prevent the spread of infectious disease in health care settings. Conscientious participation in routine infection control practices, such as hand washing and respiratory precautions is a basic expectation of the profession. In some situations, however, routine infection control is not sufficient to protect the interests of patients, the public, and fellow health care workers.

In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues, or threatens the availability of the health care workforce, particularly a disease that has the potential to become epidemic or pandemic, and for which there is an available, safe, and effective vaccine, in general physicians have an obligation to accept immunization absent a medical contraindication or when a specific vaccine would pose a risk to the physician's patients.

Physicians who consider seeking exemption from immunization on the grounds of well-considered, deeply held beliefs have a responsibility to

(a) Uphold their responsibility to provide objective information about the benefits and burdens of immunization to patients, independent of the physician's personal decision to seek non-medical exemption.

(b) ~~Accept immunization absent a recognized medical, religious, or philosophic reason to not be immunized.~~ Thoughtfully consider the implications of a decision not to be immunized for their patients, their families, colleagues, and others whom they may expose, taking into account the medical risk the disease represents, the risk of occupational exposure, the safety and efficacy of the available vaccine, the effectiveness and appropriateness of immunization relative to other strategies for preventing disease, and the possible impact on their role and credibility as health advisors.

(c) Seek an exemption only when they conclude ~~that the risk immunization poses for their personal integrity or deeply held beliefs balances the risks to themselves and others declining to be immunized~~ immunization cannot be reconciled with their deeply held beliefs as a lesser evil when balanced with the risk to their patients and others.

(d) Accept a decision of the medical staff leadership or health care institution, or other appropriate authority, to adjust practice activities to protect patients when the physician is ~~if~~ not immunized or has recently been immunized and is potentially harmful to immunocompromised patients (e.g., wear masks or refrain from direct patient care). It may be appropriate in some circumstances to inform patients about immunization status. (I, II)

3. That Policies H-440.850, "Recommendations for Health Care Worker and Patient Influenza Immunizations," D-440.947, "Support for Immunizations," and D-440.936, "Immunization Exemptions," be rescinded.

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