

REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports were presented by Noel Deep, MD, Chair:

1. OPPOSE SCHEDULING OF GABAPENTIN

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policies D-120.927, H-95.922, H-120.922 and H-120.988

American Medical Association (AMA) Policy D-120.927, “Oppose Scheduling of Gabapentin,” calls for the study of off-label use and potential risks and benefits of gabapentin to the general population as well as to those individuals with substance use disorders. This report investigates the evidence base for off-label prescribing of gabapentin, the regulatory landscape of gabapentin for maximizing patient access and minimizing stigma, and adverse events during the ongoing overdose crisis.

BACKGROUND

In February 2022, the U.S. Food and Drug Administration (FDA) received a petition from a consumer advocacy group requesting that gabapentin and gabapentin enacarbil be designated as schedule V under the Controlled Substances Act of 1970. In June 2022, Resolution 514-A-22 (now policy D-120.927) was adopted by the House of Delegates which called upon the AMA to oppose this petition and any other efforts to schedule gabapentin and its salts pending review of the risk and benefits of gabapentin use in the general public and those with substance use disorders.

METHODS

English language articles were selected from searches of PubMed, Cochrane Library and Google Scholar using the search terms “gabapentin OR Neurontin”, “gabapentin AND off-label”, “gabapentin AND controlled substance”, “gabapentin AND substance use disorder” and “gabapentin AND opioids”. Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

DISCUSSION

History of Gabapentin

Gabapentin, a gabapentinoid originally marketed under the trade name Neurontin by Parke-Davis, is an analog of the neurotransmitter gamma-aminobutyric acid. While the exact mechanism of action for gabapentin is not known, it is generally accepted that it binds to the $\alpha 2\delta$ subunit of calcium-activated ion channels.¹ It is hypothesized that this then further modulates neurotransmitter release, which may affect the dopaminergic pathways associated with reward-seeking behavior and substance use disorders.

Neurontin (gabapentin) was initially approved by the FDA in 1993 for adjunctive therapy of partial onset seizures in patients aged 12 or older.² In 2000, that indication was expanded by the FDA for pediatric patients over the age of three. In 2002, a second indication for post-herpetic neuralgia was approved by the FDA. It is currently available as a generic medication. Despite the relatively narrow scope of approved indications, Neurontin (gabapentin) was marketed by its manufacturer, Parke-Davis, for a variety of off-label indications such as neuropathic pain, epilepsy monotherapy, bipolar disorder, migraine, and attention-deficit disorder, due to data which showed improved outcomes in these disease states.³ It was estimated that prior to generic competition becoming available in 2004, Neurontin (gabapentin) products were grossing over \$3 billion a year in sales.

To maximize market penetration, Parke-Davis was accused of pursuing illegal strategies like the ethically dubious *quid pro quo* solicitation of ghost-written, pro-Neurontin editorials.⁴ As a result, Parke-Davis’s parent organization

Warner-Lambert (and ultimately Pfizer, after it acquired the company in 2000) pleaded guilty to two counts of violating the Food, Drug & Cosmetics Act and was required to pay \$430 million in both civil and criminal damages.⁵ A separate lawsuit for these marketing practices from Blue Cross Blue Shield of Louisiana, was settled for \$325 million, and a third lawsuit regarding anti-trust activity to prevent generic gabapentin off the market, was settled in 2014 for \$190 million.⁶ Pfizer did not admit wrongdoing in the latter two settlements.

It is critical to understand the history of Neurontin advertising when assessing the perception of off-label prescribing of gabapentin. A portion of off-label gabapentin prescriptions could be due to misleading marketing information. However, it should be noted that these were unethical and illegal *business* practices, and should be viewed separately from issues of safety, efficacy, or overall utility in patient care.

Gabapentin and its salts are FDA-approved to treat postherpetic neuralgia and adjunctive treatment of epilepsy with partial onset seizures, yet one study found that up to 95 percent of gabapentin prescriptions were for off-label uses such as fibromyalgia, bipolar affective disorder, and alcohol use disorder.⁷ Another study found that amongst 160 commonly prescribed drugs, gabapentin had the highest off-label prescription rate, and that 80 percent of the time, its off-label usage had little-to-no scientific support.⁸ As of a 2020 survey, seven states have made gabapentin a schedule V controlled substance, and 13 states have added it to their prescription drug monitoring programs (PDMP). At least three other states have considered scheduling or otherwise monitoring prescriptions of gabapentin.

Evidence for Off-Label Uses of Gabapentin

A title search for the term “gabapentin” of Cochrane Library reveals seven systematic reviews or meta-analyses of gabapentin uses, and over 1,700 individual trials. Gabapentin is currently only FDA approved for postherpetic neuralgia and adjunctive therapy in epilepsy, but trials have been conducted to evaluate gabapentin for a plethora of other indications. To give a sense of the sheer breadth of applications for which gabapentin has been investigated, a sample of the 1700 trials include, but are not limited to: diabetic neuropathy, restless leg syndrome (RLS), sleep, smoking cessation, alcohol use disorder, cocaine use disorder, cannabis use disorder, fibromyalgia, tinnitus, social phobia, carpal tunnel syndrome, post-surgery pain, uremic pruritis, radicular pain, migraine, bipolar disorder, delirium, surgery pretreatment, topical anti-itching, post-operative nausea, phantom limb pain, acute mania, hot flashes and postural tachycardia syndrome.

Due to the volume of studied off-label uses of gabapentin and the varying range of study quality, it is impossible to synthesize the evidence base for each indication. Table One, presented below, attempts to capture some of the most common off-label uses of gabapentin and the current understanding of the evidence for its use.

The current evidence shows that gabapentin may have some useful off-label applications primarily in the fields of pain management and mental health, such as diabetic neuropathy⁹, post-operative pain¹⁰, and conditional anxiety.¹¹ For some applications, such as fibromyalgia¹² or migraine prophylaxis¹³, the current evidence base is less compelling. This report should not be construed as clinical instructions or an endorsement of the off-label usage of gabapentin. Prescribers should utilize evidence-based decision-making when prescribing any medication for off-label uses.

Gabapentin and the Ongoing Overdose Epidemic

Proponents of scheduling gabapentin raise concerns over potential misuse, morbidity, and mortality associated with gabapentin.¹⁴ Overdoses solely attributed to gabapentin are described in the literature as “rare”.¹⁵ However, approximately 9.7 percent of overdose deaths examined in the United States between 2019-2020 detected gabapentin.¹⁶ Of those overdose deaths, almost 90 percent had at least one opioid (prescription or illicit) present in conjunction with gabapentin. Similar results were observed in a study of fatalities associated with gabapentin in England – of 913 deaths in which gabapentin was detected, opioids were co-detected in 91 percent.¹⁷ In 25 percent of cases in which gabapentin and an opioid (including methadone and buprenorphine) were present, the two medications were co-prescribed. Finally, they found that only one of 913 deaths could be attributed solely to gabapentin toxicity. Gabapentin is recognized as a ‘cutting’ agent for heroin.¹⁸ As such, gabapentin’s role appears to potentiate additional respiratory depression when used concomitantly with other drugs known to cause respiratory depression, such as opioids. In a 2019 warning from the FDA, they indicated that “[t]here is less evidence supporting the risk of serious breathing difficulties in healthy individuals taking gabapentinoids alone.”¹⁹

Gabapentin monotherapy misuse is less documented. Individuals may use high doses of gabapentin to induce euphoria but many, if not all, of these cases are observed in individuals with a history of substance use disorders.²⁰ In Germany (a country with a significantly lower overdose mortality rate than the United States), a survey of addiction medicine specialists placed gabapentin in a similar risk category as medications without misuse risk, such as non-steroidal anti-inflammatory drugs.²¹

It is difficult to assess the extent of gabapentin misuse. Online marketing surveys from the United Kingdom estimate that gabapentin misuse across the general population is as high as 1 percent.²² However, this number does not appear to be corroborated by clinical data, which found that there were only 576 reported cases of gabapentin misuse to the FDA's Adverse Events Reporting System across a 5-year period during which there were approximately 200 million prescriptions of gabapentin filled in the United States.²³

Rather, gabapentin misuse is often reported in the context of potentiating other substances, such as individuals under routine drug screens who potentiate buprenorphine and/or naloxone with gabapentin to induce euphoria while testing negative for opioids. Approximately 9 percent of individuals seeking treatment for opioid use disorders self-reported misuse of gabapentin upon entry into opioid use treatment clinics in the United States from 2019-2020.²⁴ Systematic reviews have found that the largest risk factor for gabapentin misuse is an opioid use disorder.²⁵

The growing rates of use of gabapentin and subsequent perception of its misuse are tied to the ongoing drug-related overdose epidemic. Based on the Centers for Disease Control and Prevention Clinical Practice Guidelines for Prescribing Opioids for Pain, utilization of multimodal pain management approaches is critical to supporting effective care.²⁶ As such, gabapentin has seen increases in prescribing as a key component of this multimodal approach, particularly in patients who have comorbidities that limit the use of other pain management medications.²⁷ In parallel to concerns with increased opioid use, despite clear evidence for improved outcomes, stigmatizing language of diversion and criminal activity is emerging surrounding gabapentinoid products. The AMA has significant policy, advocacy, and ongoing work supporting evidence-based decision making regarding the proper care of patients with pain and/or opioid use disorders. Research has shown repeatedly that the best outcomes are those which are patient-centric, recognizing that opioid use disorder is a medical diagnosis requiring treatment, not a criminal issue requiring incarceration.^{28,29}

REGULATING GABAPENTIN

Only a small number of states have chosen to pursue statutory or regulatory strategies specific to gabapentin. This includes classifying the medication as a schedule V controlled substance and requiring use of the PDMP; or requiring use of the PDMP without scheduling gabapentin. The Drug Enforcement Administration (DEA), with authority from the Controlled Substances Act, maintains a list of substances which are placed under increased regulatory scrutiny, including registration, production quotas, restrictions on research, and criminal or civil penalties for possession.³⁰ Substances are placed in different categories, or schedules, based on three factors: potential for misuse, whether there are accepted medical uses, and the potential for addiction. Schedule V is the lowest risk category, and are generally used for antidiarrheal, antitussive, and analgesic medications. Examples of schedule V drugs include Lomotil, Motofen, Parepectolin, and Lyrica (a gabapentinoid).

When the original resolution regarding gabapentin scheduling was presented at the House of Delegates at the 2022 Annual Meeting, testimony provided anecdotal evidence towards concerning patterns of misuse in non-prescribed gabapentin usage, particularly in incarcerated populations. Since potential for misuse is a key criterion for DEA scheduling, it is important to appreciate the magnitude of misuse. However, published literature on misuse of gabapentin is limited, and primarily in populations co-using with opioids. For example, in one study of individuals seeking inpatient opioid detoxification, 71 percent of respondents indicated that they were using gabapentin without a prescription for the purpose of reducing opioid withdrawal symptoms, and 58 percent reported they used gabapentin without a prescription to reduce their cravings for opioids.³¹ At the population-level, one study of law enforcement found 407 cases of diverted gabapentin between the years of 2002 to 2015, with a peak rate of 0.027 cases per 100,000 population.³² Another study found that 3 percent of commercially insured patients requested 3 or more prescription claims above the established dosage thresholds if they were seeking gabapentin on its own.³³ This number rose to 24 percent if they were seeking gabapentin co-prescribed with opioids. Due to the interconnectivity of gabapentin misuse with opioid use disorders – including instances which are intended to reduce opioid use – it is difficult to assess the true misuse risk of gabapentin.

Currently, gabapentin is not scheduled as a controlled substance by the DEA, but seven states (Alabama, Kentucky, Michigan, North Dakota, Tennessee, Virginia and West Virginia) have classified gabapentin as a schedule V controlled substance.³ While schedule V is the lowest risk categorization of the Controlled Substances Act of 1970 (although states may have different definitions under their own controlled substance regulations), it still requires physicians and other health care professionals who prescribe or dispense controlled substances to register with the DEA. Schedule V controlled substances are subject to restrictions on storage, security, and the amount, timing and frequency of refills.³⁴ A sub-population of patients particularly sensitive to changes in regulations are those within the carceral system, where prescribing of gabapentin is already heavily scrutinized, and the stigma and criminalization of pain treatment is highest.³⁵

There are 13 states, including Connecticut, Indiana, Louisiana, Ohio, Oregon, and Utah, that have required reporting of gabapentin prescriptions into their PDMPs. These requirements are meant, in part, to allow physicians, pharmacists and other health care professionals to view recent prescriptions and prescription patterns of gabapentin and other controlled substances, such as opioids and benzodiazepines, to support evidence-based prescribing decisions. The AMA and many others have long supported using PDMPs as part of the clinical decision-making process, but emphasized that information in a PDMP is only one of many factors a physician should consider when determining whether to prescribe controlled substances³⁶.

With respect to the question whether to add gabapentin as a Schedule V Controlled Substance, the role of the PDMP needs additional consideration. When PDMP requirements first came into vogue, the general argument for mandating their use was the potential to reduce opioid-related misuse and opioid-related mortality. There is some evidence showing use of PDMPs increased the ability of physicians and pharmacists to identify multiple prescriber events, that is, when an individual received three or more opioid prescriptions from three or more different prescribers or dispensers within a short time frame, typically 30 days.³⁷ Many states have reported reductions in these multiple prescription events, but as detailed in AMA Board of Trustees Report 3-I-16, merely identifying a multiple prescriber event is not sufficient to know whether a patient is engaging in aberrant behavior, someone who has uncoordinated care, or is pursuing illegal prescriptions. Thus, while reductions in multiple prescriber events are likely positive, it is not clear whether the reductions have led to improved patient outcomes. In addition, there has been no reduction in opioid-related mortality as PDMP use has increased. In 2022, physicians and other health care professionals used PDMPs more than 1.1 billion times while the overdose epidemic grew to more than 107,000 fatalities.³⁸ Furthermore, there is no compelling evidence suggesting that PDMPs helped improve outcomes for patients with pain. There also continues to be confusion about how to optimize PDMPs in clinical practice.³⁹

It is important to note that PDMPs have limitations. While different PDMP platforms claim to allow for interstate access of patient information, such retrieval is not always reliable if the user has not set the PDMP up to view all states—or even all neighboring states. There also continue to be challenges in reporting intervals from when a prescription is dispensed to when data is uploaded to the PDMP. Physicians and other health care professionals also continue to report frustration with PDMP-induced disruptions or poor interoperability with electronic health records.^{40,41} Given the absence of data suggesting that a PDMP reduces drug-related misuse or other harms, along with a clear-eyed view of PDMP limitations, it is unlikely that having gabapentin in the PDMP—by virtue of it being a Schedule V Controlled Substance—will improve outcomes, increase meaningfully available information, or improve patient outcomes.

In comparing states which designated gabapentin as a schedule V controlled substance and states which required gabapentin reporting to the PDMP alone, states that designated gabapentin a controlled substance (which includes automatic registration in the state PDMP), saw a significant decrease in the number of gabapentin prescriptions.⁴² By contrast, states which implemented a PDMP reporting-only approach saw little change in the number of gabapentin prescriptions.⁴³ This is not surprising as the requirements for prescribing a Schedule V controlled substance are greater than for a non-controlled substance.

Proponents of scheduling gabapentin as a controlled substance use this evidence, that designating gabapentin as a schedule V controlled substance reduces prescriptions, as a surrogate for decreasing patient harm.⁴⁴ The literature regarding scheduling gabapentin as a controlled substance lacks information regarding indication for use or patient oriented outcomes, such as pain control, increased functioning, prevalence of adverse events or evidence of decreases in misuse. Stigma and prescribing barriers have the potential to impede access to care, particularly pain management. When strategies simply aim to decrease the overall number of prescriptions, marginalized and/or underserved patients will often be turned away first. Black patients are at highest risk for receiving inadequate pain

treatment and are up to 36 percent less likely to receive *any* analgesic pharmacotherapy compared to white patients.^{45,46} In the event that they do present with a substance use disorder, Black patients covered by Medicaid have a 50 percent lower rate of prescribing buprenorphine compared to white patients when controlled against other clinical and demographic factors.⁴⁷ There are many reasons for this inequity, but at its core, the implicit bias and associations made between Black patients, pain medication, and criminal behavior is difficult to ignore.⁴⁸ It is likely that further stigmatization of gabapentin prescribing and emphasis on misuse and diversion could result in similar inequities.

In addition, the nation's overdose epidemic and its intense focus on reducing opioid prescriptions provide a useful point of comparison. In 2012-2013, physicians began to reduce opioid prescriptions in response to growing concerns about misuse. Between 2012-2021, opioid prescriptions have declined in every state—46.4 percent nationwide.⁴⁹ As noted above, this reduction has not led to reduced drug-related overdose or death. The inverse actually has occurred. This is not to say that reduction in opioid prescribing were not warranted in certain circumstances, but as noted by the AMA in comments to the CDC and others, the focus should always have been on ensuring patients with pain received the right care at the right time, which may include opioid therapy⁵⁰. The AMA supports continued efforts to enhance medical education and training, including those focused on medications that may be misused or used without a prescription. The AMA further supports efforts, including research and medical society collaboration to support effective pain care. These efforts could be interpreted to include gabapentin, but are certainly not limited to one medication and its potential uses, as noted above. These efforts already occur without having to increase the barriers to gabapentin by making it a Schedule V controlled substance. An end goal of simply reducing prescriptions is shortsighted and inappropriate.

Beyond regulatory solutions, best practices for prescribing gabapentin continue to evolve. The FDA is the appropriate agency to continue to evaluate drug safety. The AMA and organized medicine are the appropriate entities to support and encourage enhanced education about prescribing practices, including gabapentin.⁵¹

CONCLUSION

With the longevity of gabapentin on the market, combined with the incredibly wide range of trials, and the low incidence of adverse events, there is not a compelling reason to designate gabapentin as a controlled substance. The available evidence does not demonstrate that the benefits of scheduling gabapentin outweigh the risk of patient harm. Instead, strategies to increase prescriber awareness of gabapentin's potentiator effect and more thoughtful prescribing, particularly in groups at high-risk for overdose, will target increases in medication safety. The recognition of stigma and bias is critical for continued evidence-based decision-making and increased access to those in need.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted and the remainder of the report be filed.

1. That Policy D-120.927, "Oppose Scheduling of Gabapentin" be amended by addition and deletion to read as follows with recognition that several aspects of this directive have been accomplished:

Our AMA will:

1. actively oppose the placement of (a) gabapentin (~~2-[1-(aminomethyl)cyclohexyl]acetic acid~~), including its salts, and all products containing gabapentin (~~including the brand name products Gralise and Neurontin~~) and (b) gabapentin enacarbil (~~1-(((1R)-1-[(2-methylpropanoyloxy)ethoxy]carbonyl)amino)methyl)cyclohexyl)acetic acid~~), including its salts, (~~including the brand name product Horizant~~) into schedule V or other restricted class of the Controlled Substances Act;
2. ~~submit a timely letter to the Commissioner of Food and Drug for the proceedings assigned docket number FDA-2022-P-0149 in opposition to placement of gabapentin and gabapentin enacarbil into the schedule V of the Controlled Substance Act; and~~
3. ~~study the off label use and potential risks and benefits of gabapentin to the general population as well as to those individuals with substance use disorders.~~

2. affirm that given currently available data, the FDA and DEA have used the appropriate process for evaluating the safety, efficacy, and risk of misuse and dependency for gabapentin and its salts;
3. support the promotion of gabapentinoid-related research and education, particularly the risk of gabapentinoids when taken concomitantly with opioids and the potential for gabapentinoid withdrawal, in current clinical practice and undergraduate, graduate and post-graduate education.

2. That our AMA reaffirm Policies H-120.988, “Patient Access to Treatments Prescribed by Their Physicians”, H-120.922, “Improved Access and Coverage to Non-Opioid Modalities to Address Pain”, and H-95.922, “Substance Use and Substance Use Disorders.”

TABLE 1: SELECT STUDIES EVALUATING OFF-LABEL GABAPENTIN USES

Indication	# of Participants	Total Daily Dose Range (mg)	Clinical Measures Evaluated ^a	Favors Gabapentin Usage Over Risk of Use?	Reference
Diabetic neuropathy	5914	>1200	Substantial (>50%) or moderate (>30%) reduction in pain	Yes	9
Postoperative pain	370	250-500	Summed pain intensity difference	Yes	10
Conditional anxiety	934	300-1200	State-Trait Anxiety Inventory	Yes	11
Bipolar disorder	282	600-4800	Young Mania Rating Scale	No	11
Panic disorder	103	600-3600	Panic and Agoraphobia Scale	No	11
Depression	28	300-1800	Clinical Global Impressions-Severity Scale	Yes	11
Fibromyalgia	150	2400	50% reduction in pain	No	12
Migraine prophylaxis	1009	900-2400	Headache frequency	No	13
Sleep	4684	600-3600	Pittsburgh sleep quality index score	Yes	52
Cocaine use disorder	235	1600-2400	Report or evidence of use	No	53
Alcohol use disorder	269	600-1500	Report of heavy alcohol use	Yes	54
Hot flashes	600	1800	Frequency and severity of hot flashes	Yes	55

Restless leg syndrome	87	200	RLS rating scale and sleep quality	Yes	56
Chronic pelvic pain (women)	60	300-2700	Difference in pain score (vs. placebo)	Yes	57
Carpal tunnel syndrome	140	900	Global symptom score	No	58

^a – Some clinical measures used in studies were excluded from summary for brevity.

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2. IMPROVING RESEARCH STANDARDS, APPROVAL PROCESSES, AND POST-MARKET SURVEILLANCE STANDARDS FOR MEDICAL DEVICES

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policies H-120.988 and H-480.934

Resolution 523-A-22, "Improving Research Standards, Approval Processes, and Post-Market Surveillance Standards for Medical Devices" was referred by the House of Delegates (HOD). This report serves as the Council on Science and Public Health's (CSAPH) findings and recommendations regarding medical device regulation.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "medical device AND 510(k)" and "medical device AND post-market surveillance". Additional articles were

identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

BACKGROUND

In the context of regulatory oversight by the Food and Drug Administration (FDA), a medical device has a broad definition. According to the Food, Drug and Cosmetic Act:

a device is: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

[...]

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

As such, the breadth of items captured within this regulatory framework is expansive, ranging from tongue depressors and eyeglasses to x-ray machines and hip replacements. In addition to physical objects used as medical devices, software and algorithms are also captured within this definition. As such, the FDA classifies software into two broad categories: software *in* a medical device and software *as* a medical device (SaMD). CSAPH recognizes that software, particularly SaMD, is rapidly becoming a large part of medical care and may warrant further examination beyond the findings and recommendations of this report, which are intended to be generalizable to all medical devices.

DISCUSSION

The 510(k) Regulatory Pathway

When applying for a new medical device, the device is first evaluated for risk category: I (lowest risk), II (medium risk) or III (highest risk). Risk category is determined by a variety of factors, such as by comparing the device to a similar, known, device. If a device is found to be like a device already approved by the FDA, it may be classified as low (class I) or medium (class II) risk. Examples of devices commonly found to be class I include electric toothbrushes, tongue depressors, bandages, hospital beds, and non-electric wheelchairs. Examples of devices commonly found to be class II include catheters, pregnancy test kits, syringes, contact lenses, and surgical gloves. Examples of devices commonly found to be class III include breast implants, pacemakers, defibrillators, and cochlear implants. Approximately 1% of all new medical device applications from 2003 to 2017 were evaluated as high risk (class III).^{1,2}

If a medical device is found to be class I they are typically exempt from normal testing. If deemed a class II risk, manufacturers may submit a 510(k) application as pre-market notification (PMN) to the FDA. Class II risk devices are subjected to an equivalence evaluation comparing this product to one currently on the market through these 510(k) processes. 510(k) applications are processed within 90 days and once approved, the device is eligible for market. By contrast, class III devices must undergo pre-market approval (PMA) which requires two large clinical trials. According to a 2010 industry survey, pursuing pre-market approval in the United States takes on average 54 months to complete compared to 11 months in European countries.³

Medical device market approval differs from drug approval in a few critical ways, which may help illustrate why the 510(k) pathway is so desirable for medical device manufacturers. Table 1 in the appendix of this report highlights some of these differences. Clinical trial design for medical devices can be extremely difficult, and in some cases unethical. For example, a placebo control for a medical device could require a high-risk sham surgery. As such, subjecting all new medical devices to undergo clinical trials may substantially hinder innovation, particularly from physicians seeking small tweaks or customizations to products they use routinely.

But on the other hand, if a medical device does cause harm to a patient, one cannot simply discontinue having an implanted device without significant intervention unlike if they were experiencing adverse events to a new medication that could be quickly stopped. As such, the 510(k) pathway has been subject to intense public scrutiny, both in the media and by elected officials.⁴ Many recalls of medical devices are voluntarily initiated by the manufacturer due to liability concerns or public perception decreasing sales rather than by official FDA action.

The FDA has recently begun piloting a new program within the 510(k) framework, called the Safety and Performance Based Pathway. This pathway provides an alternative to the current equivalence evaluation for a small subset of devices that are highly studied and well-known. In the Safety and Performance Based Pathway, the FDA sets forth explicit benchmarks that medical devices must satisfy to demonstrate safety and efficacy to gain 510(k) approval.⁵ For example, if a resorbable surgical sutures manufacturer wished to market a new design, the FDA has guidance for the appropriate diameter, needle attachment, tensile strength, sterilization, shelf life and resorption profile for new suture designs to meet to receive 510(k) classification.⁶ This pathway provides added safety and efficacy requirements to this moderate risk class. However, participation in the Safety and Performance Based Pathway is currently optional.

Device Equivalence

To be eligible for the 510(k) approval, a manufacturer must first establish that their device is “substantially equivalent” to a previously known, FDA-approved predicate device.⁷ For the purposes of regulatory approval, the FDA considers both safety and functionality when determining equivalence. First, they investigate whether the device is to be used for the same primary purpose, and they then evaluate whether the device is expected to have a similar safety profile. For example, if a device were to change its power source (such as hardwired vs. rechargeable) with no other modifications, it would likely be deemed substantially equivalent. Similarly, if the material of the device were to change to another material known to be safe to the FDA, it is likely to be found substantially equivalent. A flowchart of the FDA decision making process has been included in the Appendix of this report.

However, there is a flaw with the approach of substantial equivalence. If a device is found to be unsafe after receiving market approval and then subjected to a recall, any *subsequent* devices which used the original, now-unsafe device as their predicate, are not subjected to any increased scrutiny or recalls. Recent analysis found that between the period of 2017 and 2021, the FDA initiated recalls of 156 devices using their highest risk categorization – devices with a reasonable probability to cause severe morbidity and mortality. Of those 156 devices recalled, 44.1 percent of them had received 510(k) approval using substantial equivalence to a device that had also been the subject of a recall.⁸ Further, 48.1 percent of devices recalled within the studied period have themselves been used as the predicate for another device’s 510(k) approval. This post marketing safety information and related devices draw significant attention to potential problems with the current 510(k) approval process with a lack of criterion for granting approval for devices outside the most well-studied and well-understood.

Post-Market Surveillance

It should be noted that the study described above only studied a cohort of devices which were the subject of FDA-initiated recalls. There are likely a non-trivial number of devices that are still being used as comparators for substantial equivalence that have been found to be unsafe and then production halted or voluntarily recalled by the manufacturer. However, there is limited publicly available information to monitor this risk. This scenario highlights the importance of rigorous post-market surveillance for devices that have been approved using the 510(k) pathway.

Among the post-market surveillance activities required by the FDA is the reporting of adverse events. Under Medical Device Reporting regulations (Title 21 Code of Federal Regulations part 803), manufacturers, importers, and device user facilities (such as a hospital, nursing home or outpatient treatment facilities) are mandatory reporters to the FDA regarding serious device malfunction, including death. Reports are made to the device manufacturer (if known) and the FDA. Health care professionals, patients, and caregivers are able to report suspected adverse events for medical devices using the FDA’s MedWatch portal.

Adverse events are viewable to health care professionals and the public using the FDA’s Manufacturer and User Facility Device Experience (MAUDE) portal.⁹ However, a 2019 exposé found that over 5 million incidents of reported adverse events were being kept from public view using an internal “alternative summary reporting” repository rather than the publicly available MAUDE database.¹⁰ Not only did this practice prevent physicians and

patients from knowing the real risks of currently approved medical devices, it also prevented manufacturers of new devices from knowing the risk profile of substantially similar predicate devices they were using for 510(k) approval. The FDA has stated that it has since abandoned this practice of internal incident report storage.¹¹

Health Equity Considerations

It should also be noted that implicit in the 510(k) substantial equivalence method of approval is that it tends to maintain the status quo. For example, most, if not all, pulse oximeters currently used in the United States are approved via the 510(k) pathway.¹² Pulse oximeters estimate blood oxygen saturation by shining light through the skin, typically on a fingertip or an ear lobe. Oxygenated blood absorbs red light more efficiently than de-oxygenated blood, thus allowing for estimates of oxygenation by simply measuring the amount of red light that passes through a tissue. However, oxygenated blood is not the only thing that absorbs red light – melanin, melanosomes, and melanocytes (ie, skin pigmentation), also absorb or scatter red light. A retrospective study found that practitioners missed hypoxemia diagnoses in 11.7 percent of Black patients compared to 3.6 percent of white patients due to pulse oximetry overestimating blood oxygenation.¹³

In the context of the COVID-19 pandemic, that suggests that excluding other factors, Black patients would be nearly 4-times less likely to receive oxygenation therapy such as a ventilator, which could prevent progression to acute respiratory distress syndrome.¹⁴ As a result of these findings, the FDA released a safety communication indicating oximeters may be less accurate in darker skin tones.¹⁵ The failure of pulse oximeters to accurately measure oxygen saturation in all skin tones is a clear example of how inequity enters the health care system from many sources and can cascade. For example, even if a provider wished to start a patient on oxygenation therapy, Medicare reimbursement for supplemental oxygen therapy is only approved if a patient has a blood oxygenation reading less than or equal to 89 percent, which is less likely in Black patients if a pulse oximeter is used.¹⁶ In November 2022, the FDA hosted an advisory committee meeting to discuss concerns of pulse oximeters and skin pigmentation. Dr. Jesse Ehrenfeld, president-elect of the AMA, was a participant of this meeting and delivered comments and recommendations on behalf of the AMA.

It is important to assess whether approving a new pulse oximeter design that reaches the same level of performance as a predicate device is appropriate as our appreciation of inequity grows and some categories of devices no longer match the values we wish to uphold.

Off-Label Use of Medical Devices

While the FDA has attempted to pilot programs, such as the Safety and Performance Based Pathway, that would improve the balance of fostering innovation and patient safety, they may not have the legislative authority or resources available to make these new programs mandatory. Without authority to pursue reforms to medical device regulation, there are concerns that the FDA may become more and more likely to begin regulating the practice of medicine to achieve similar goals.

The FDA has the authority to ban medical devices if they present a substantial deception to patients about the benefits or an unreasonable and substantial risk of injury. However, there are recent concerns of misuse of the banning process. In 2020, the FDA published a rule banning the use of electrical stimulation devices (ESD) for the treatment of self-injurious and/or aggressive behavior.¹⁷ The FDA reported that the use of ESDs for this indication was unsafe and could lead to significant physical and psychological harm. ESDs were still approved for other indications such as smoking cessation.¹⁸ The approval of devices for specific indications while banning the same device for others is, per AMA policy, the FDA regulating the practice of medicine. The AMA has extensive policy and significant history defending the rights of physicians to practice medicine and protect off-label prescribing of pharmaceuticals and devices.

Within the text of the FDA's rule on banning ESDs for aggressive behavior, they cite the 510(k) pathway as part of their justification for the banning of a specific indication, as they evaluate risk of a device based on its intended function, not on all potential functionalities. For example, daily wear vs. extended wear for gas permeable contact lenses are two separate risk categories. Evaluation of "substantially similar" for the purposes of 510(k) approval includes analysis of similar function. In 2021, the D.C. Circuit Court of Appeals overturned the ban, finding that the FDA was in fact regulating the practice of medicine, per the holdings of *Judge Rotenberg Educational Center v. United States Food and Drug Administration*.¹⁹

CONCLUSION

While the FDA has made strides in improving the 510(k) process for medical device approval, such as through the Safety and Performance Based Pathway, recent data have shown serious safety concerns. These safety concerns denote the need for the process to be re-examined to support the purpose and benefits of accelerated pathways along with providing the FDA with the statutory authority to address the larger, systemic issues without impeding on the practice of medicine.

RECOMMENDATIONS

The Council on Science and Public Health recommends the following be adopted, and the remainder of the report be filed:

1. Our AMA believes that to support innovation while protecting patient safety, approval pathways for medical devices should incorporate the following principles:
 - a. Evidence-based, measurable performance benchmarks, such as those used in the Safety and Performance Based Pathway, should be used wherever possible for classes of known, well-studied medical devices; and
 - b. For a subset of higher risk devices receiving approval but have not completed clinical trials, time-limited approvals may be appropriate, after which the manufacturer may be required to provide post-market data to support full device approval; and
 - c. Medical devices with known safety concerns should not be usable as predicate devices for the purposes of proving substantial equivalence. In the event safety concerns of predicate devices arise after approval has been granted, additional due diligence should be initiated as appropriate; and
 - d. Approval for medical devices should include criteria for adequate performance in racialized, minoritized, or otherwise historically excluded groups when feasible; and
 - e. ~~Reports of adverse events for medical devices should always be available in a publicly accessible, searchable database such as the Manufacturer and User Facility Device Experience.~~
2. That Policy H-120.988, “Patient Access to Treatments Prescribed by Their Physicians”, supporting a physician’s right to prescribe medical devices off-label, be reaffirmed.

Appendix

TABLE 1

Comparison of regulatory requirements for drugs, biologics, and devices

Modified from Congressional Research Service, “Medical Product Regulation: Drugs, Biologics, and Devices”, published September 29th, 2021. <https://sgp.fas.org/crs/misc/IF11083.pdf>.

	Drug	Biologic	Class II (Medium Risk) Device	Class III (High Risk) Device
Authorization Type	Approval	Licensure	Clearance	Approval
Submission to FDA	New Drug Application	Biologics License Application	510(k) notification	Pre-market approval
Clinical Trials?	Yes	Yes	No	Yes (few exceptions)
Evidence Required by FDA	Substantial evidence of effectiveness, adequate evidence of safety	Substantial evidence of effectiveness, adequate evidence of safety	Substantial equivalence to a known, approved device	Reasonable assurance that the device is safe and effective for its intended use(s)

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3. REGULATION AND CONTROL OF SELF-SERVICE LABS

Reference committee hearing: see report of Reference Committee E.

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

See Policies H-480.933 and H-480.941

At the 2022 Annual Meeting of the American Medical Association (AMA), the House of Delegates adopted Policy D-260.992, “Regulation and Control of Self-Service Labs.” That directive called for a study into “patient-directed self-service testing, including the accreditation and licensing of laboratories that sell self-ordered tests and physician liability related to non-physician-ordered tests”. This report serves as the Council on Science and Public Health’s (CSAPH) findings and recommendations regarding self-service testing, also known as direct access testing (DAT) or direct-to-consumer (DTC) testing. The Council has previously studied DTC genetic testing which shares many issues with DAT. For the purposes of this report, DAT refers solely to non-genetic, non-imaging based diagnostic testing.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms “direct access testing”, “self-service laboratory”, “direct to consumer laboratory”, and “self-service laboratory AND liability”. Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

BACKGROUND

Patient-directed testing has existed in the United States for decades, such as over-the-counter glucose testing kits available since the early 1980s. Currently, pharmacies sell a variety of at-home tests for pregnancy, illicit drug use, or other biomarkers. However, starting in the late 2010s, diagnostic companies began to offer a compilation of blood-based DATs such as hormone panels, electrolytes, heavy metal screening, metabolic panels, and prostate specific antigen (PSA). According to one estimate, the market for DAT in the United States currently exceeds \$350 million per year, up from just \$15 million per year in 2010.¹ Another source estimates that the DTC genetic and DAT lab services markets combined will exceed \$2.4 billion per year by 2025.² For the purposes of this report, DAT will refer to medical tests that are not available as over-the-counter kits and are performed by a laboratory after being purchased by an individual without a prescription.

The DAT business model removes the health care professional, often the primary care physician, from the care decision-making and allows an individual to directly purchase their test from the laboratory. Overall, there is limited literature on DAT, the model, and outcomes for patients and their care. According to the Frequently Asked Questions webpage of one DAT company, orders for these tests are provided by a licensed clinician upon demand, but these tests are not reimbursed by insurance as they are not the treating health care professional and they do not provide CPT codes.³

While the process may vary from company to company, they generally follow similar steps. First, a patient is presented with a menu of available testing options. They then select the test(s) they would like performed, and then pay up-front for the test. A licensed clinician then orders the test, which the companies claim does not constitute a patient-physician relationship. The patient then visits a nearby facility for their sample(s) to be taken, and they receive their results within a few days. Results are often reported in the same manner as they would from a prescribed test in the usual course of care— a single value with solely the reference range as context. Unlike tests that come from a prescribing physician within a health-system, DAT companies do not provide any diagnostic assessment, counseling, or guidance on laboratory results. Patients are encouraged to share their results with their physicians, but it is unclear if or how any DAT facilities enter results into the electronic medical record or otherwise to alert a health care professional that a test has been performed.

DISCUSSION

Patient Safety

The most obvious concern around DAT is patient safety. Assuming the patient identifies an appropriate test to measure the biomarker of interest, patients often receive a single numerical value and a reference range for their test results with no additional description or suggested next steps. However, interpreting medical tests is more than simply seeing if a number is within the reference range. Physicians have years of training and experience to incorporate the quantitative information of medical tests with the qualitative information collected from the patient, including past medical history or signs and symptoms. Take for example the measurement of thyroid stimulating hormone (TSH), which typically has a reference range listed of 1 to 4.5 mIU/L, depending on the assay. A non-trained individual may receive a result of 4.3 mIU/L, see that it is within the provided reference range, and assume they have healthy thyroid function. However, a trained physician may recognize that in combination with presenting symptoms or other risk factors, that this individual may have early hypothyroidism and can begin intervention.⁴

Risk assessment is a critical factor for interpreting and acting upon medical test results, but it is also a key consideration for prescribing the test in the first place. For example, for PSA screening the USPSTF recommends a shared decision-making model, in which men aged 55 to 69 should be informed of the potential risks and benefits of PSA screening before making the decision with their physician.⁵ PSA levels could be elevated from several non-cancer sources, such as benign prostatic hyperplasia or prostatitis, and that the risk of dying from prostate cancer was approximately 2.5 percent. Studies have found that approximately 80 percent of men who pursued aggressive clinical action such as brachytherapy due to elevated PSA levels experienced erectile dysfunction or incontinence as a result of treatment.⁶ In recommending a screening one needs to consider the risks of false positives and over-diagnosis of benign, non-fatal prostate cancers outweighed that may outweigh benefits of early detection. USPSTF has found that PSA testing outside of a very specific risk category offers poor or even negative value to the patient.⁷ This crucial risk-benefit analysis and discussion is missing when an individual can simply order a PSA test from a DAT website and may lead to unwanted outcomes. DAT companies do not follow any clinical guidelines for any test provided. They do not limit test offerings to those in the appropriate risk categories.

Legal Landscape

While the definition varies from state to state, the practice of medicine is typically defined as diagnosing, treating, or advising a patient on their symptoms or disease. It appears that DAT companies are pursuing a loophole – if they explicitly do not advise a patient on what their test results mean, or use a biomarker to diagnose, they contend it is not practicing medicine. Currently 37 states allow DAT with varying levels of restriction. It should be noted that depending on the state, DAT companies might utilize a dentist, nurse practitioner, physician assistant, naturopathic doctor, licensed acupuncturist, or chiropractor to order tests.

There are also concerns about the duty of the physician when a patient presents with DAT results and requests their physician take clinical action. While the Council does not intend to offer clinical guidance, it cannot identify any scenario in which the action by the physician, if they choose to act at all, can be anything but re-ordering the test through appropriate channels. This is especially true in instances where the patient may have ordered a test the physician is inexperienced with – how can they be expected to act upon, and be liable for, a test they would not have ordered themselves? Current AMA policy and the Code of Medical Ethics regarding direct-to-consumer diagnostic imaging services states that any physician ordering a test is the responsible party for diagnosis and subsequent patient counseling.⁸

Finally, there are also concerns about the regulations of the laboratories performing the tests. There are two main ways in which clinical testing is regulated in the United States. First, if a test is fully self-contained (ie, a test kit), then it is reviewed for medical claims by the Food and Drug Administration (FDA) as an in vitro medical device. For all other medical testing, such as laboratory developed tests, laboratories are regulated, inspected, and certified by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvements Amendment (CLIA). The FDA categorizes laboratory tests based on complexity, which CMS then uses to develop regulations. Depending on the categorization of test complexity, CLIA may require quality standards for facility administration, laboratory systems, personnel qualifications, quality assessment, and quality control. CLIA certification is provided by CMS-approved accrediting bodies, such as the Joint Commission or the College of

American Pathologists. Studies have found that the introduction of CLIA resulted in an increase in laboratory quality and customer satisfaction.⁹

There have been reports that some companies offering DAT skirt the CLIA certification process by claiming that since they only provide a context-free biomarker value, they are providing “health information” rather than a medical test.¹⁰ Ensuring that these tests are performed in CLIA-certified laboratories is critical for maintaining the accuracy of the results while also making sure patients’ samples and data are secure and stored appropriately.

Examining the Appeal

When assessing issues of DAT regulations, it is also important to understand the use-cases and surrounding ecosystem that has caused the market for DATs to flourish. DAT marketing often emphasizes a few key points: it is faster, the cost is upfront and known (ie, there is no unknown co-pay that will be administered later), and that an individual will be able to take control over their health. The first two claims are interconnected and point to the role health insurance companies play in reimbursement for testing. For example, studies have shown that when individuals enroll in a high deductible insurance plan, they are approximately 10 percent less likely to receive laboratory tests due to the financial disincentive.¹¹ It is also important to recognize that an insurance provider may require prior authorization, and then ultimately decline coverage, for outpatient laboratory testing which adds significant delays and cost uncertainty for a patient.

Additionally, there are several tests offered by DAT companies for conditions which unfortunately carry high levels of social stigma – particularly infectious diseases such as sexually transmitted infections or hepatitis. In these instances, availability of a test which can be ordered online and without an uncomfortable conversation with their physician may be attractive to many patients. Tests for influenza or other respiratory viruses that can be ordered for home sample collection may also reduce the risk of transmission in a hospital or clinic setting. However, those instances in which DATs may be an appealing option further underscore the need for ensuring DAT facilities are CLIA-certified and responsible for the appropriate patient counseling on result interpretation and any necessary lifestyle changes.

Finally, DATs are often marketed to the individual who is seeking to better understand and control their health. For example, DAT companies may offer cholesterol panel testing, which would be appealing to someone who has changed their diet or exercise routine and is eager to see results. While those goals should be applauded, there are multiple risks associated with this approach. First, if the test is inaccurate, the individual will be given a false understanding of changes in their health. Second, the individual may not properly understand the time it may take for their changes to have an impact on a clinical biomarker, nor may they appreciate the healthy fluctuation the biomarker levels may have from day-to-day, or the size of impact their lifestyle changes may have on the biomarker. In some instances, an individual could discontinue medication or other treatments if they are given inaccurate test results devoid of context. Again, this highlights the critical importance of physician counseling in health management, as none of this information is currently communicated to patients utilizing DAT companies.

CONCLUSION

In a system of complex insurance reimbursement and high out-of-pocket plans, DATs may appear appealing for patients. However, current DAT practices appear to skirt regulatory requirements, could easily be misinterpreted by patients, and lack appropriate diagnostic and counseling practices by a physician. Potential utilization of DAT may be warranted in the realm of infectious disease when immediate testing would be beneficial for public health; however, test results should still be carefully communicated to the patient and monitored by a physician who is responsible for the patient’s care.

RECOMMENDATIONS

The Council on Science and Public Health recommends the following recommendations be adopted, and the remainder of the report be filed:

1. Direct access testing, in which patients may order a diagnostic laboratory test on demand, should only be provided by teams which are physician-led, and performed in facilities that are CLIA-certified. Health care

- professionals who offer direct access testing services, for which a patient does not have a referral, recognize that agreeing to perform direct-to-consumer testing on request:
- a. establishes a patient relationship, with all the ethical and professional obligations such relationship entails; and
 - b. assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Health care professionals may choose to refer the patient for post-test counseling to an appropriate provider who accepts the patient, but they maintain ethical and professional responsibility until the patient has been seen by that provider; and
 - c. shall report all required findings to relevant oversight entities, such as state public health agencies, even if the patient and the laboratory are not co-localized in the same jurisdiction.
2. That Policy H-480.941, “Direct-to-Consumer Laboratory Testing,” calling for regulation of direct-to-consumer testing and education of patients of risks and benefits, be reaffirmed.

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4. SCHOOL RESOURCE OFFICER VIOLENCE DE-ESCALATION TRAINING AND CERTIFICATION

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 408
REMAINDER OF REPORT FILED
*See Policy H-60.902***

Resolution 416-A-22, referred for study by the House of Delegates, asked that our American Medical Association study the efficacy of School Resource Officer violence de-escalation training and certification.

BACKGROUND

A school resource officer (SRO) is a carefully selected, specifically trained, and properly equipped full-time law enforcement officer, trained in school-based law enforcement and crisis response, assigned to work in the school using community-oriented policing concepts.¹ Recently, the number of SROs has skyrocketed. An estimated 14,000 to 20,000 SROs now work in schools, and the number continues to grow.² Opponents argue that SROs damage school climate, criminalize relatively trivial student behavior, and fuel the school-to-prison pipeline.³ Proponents argue that SROs promote school safety, respond quickly to emergencies, and serve as mentors, role models, and law-related educators for students. One report concluded that for every dollar invested in the program, a minimum of \$11.13 of social and economic value was created.⁴

SRO officers may receive training in, among other things, mental health awareness, adolescent development and communication, implicit bias, trauma-informed care, conflict de-escalation, crisis intervention, cultural competence, and school-specific topics.⁵ However, within school systems, trainings vary in content and delivery. For example, some training courses include information on evaluation of the de-escalation and crisis response (e.g., support for staff and students after an incident). Further, some training may be a stand-alone curriculum, whereas others may include de-escalation as a topic within other training topics (e.g., classroom management, discipline policy, academic planning).

One main intervention, which has limited support in the research literature, is the use of de-escalation techniques and trainings for educational entities to mitigate the impact of peer aggression and promote the safety of the school environment.⁶ Across various professional fields, such as public health and education, de-escalation training involves learning strategies for the prevention and the management of aggression and violence. De-escalation may include training in early intervention practices, communication methods (i.e., verbal and non-verbal styles), appropriate responses in potentially violent situations, and the correct use of physical intervention techniques (e.g., restraint techniques, protection). The training is intended to reduce conflict, aggression, and harm. In an educational setting, de-escalation can be defined as a range of interconnected interventions that include verbal and non-verbal communication, self-regulation assessment, and actions taken while maintaining the safety of the those in the school.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms “school resource officer”, “school-based law enforcement,” and “school resource officers AND training”. Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by government agencies; applicable organizations were also reviewed for relevant information.

DISCUSSION

What are SROs?

The only definition of SRO in current federal law appears under the authorizing legislation for the Office of Community Oriented Policing Services (COPS Office), which is a component of the U.S. Department of Justice responsible for advancing the practice of community policing primarily through grant resources. This statute defines an SRO as “a career law enforcement officer, with sworn authority, deployed in community-oriented policing, and

assigned by the employing police department or agency to work in collaboration with schools and community-based organizations.”⁷ Although specific responsibilities and functions of SROs vary from place to place, the “triad” concept of school-based policing divides SRO responsibilities into three main areas of: teacher, informal counselor, and law enforcement officer.⁸

History of SROs

Since the 1900s, U.S. public schools have employed a growing number of SROs. In 1975, only 1 percent of schools reported having police officers on site, but by 2018, approximately 58 percent of schools had at least one sworn law enforcement official present during the school week.⁹ In response to school shootings in the 1990s, federal and state legislation spurred this rapid proliferation of SROs.

The first use of SROs in schools is reported to have been in Flint, Michigan, in the early 1950s.¹⁰ While police have had a presence in schools since then, it has only been over the past 20 years that the practice of assigning police officers to schools on a full-time basis has become more widespread. The number of SROs expanded significantly beginning in the 1990s due to legislative initiatives in response to concerns over a series of school shootings including the Columbine tragedy. The 1994 reauthorization of the Elementary and Secondary Education Act (ESEA) included provisions that established school safety as a core focus for the U.S. Department of Education (U.S. DOE).¹¹ It also included the Safe and Drug-Free Schools and Communities Act, which authorized federal support for police in schools via a grant program wherein local education agencies could use funds to hire and train SROs.^{7,12} Between 1994 and 2009, up to 40 percent of federal funding for this act could be used to hire and train school police and support other security measures.¹³ Overall, since 1998, the federal government has invested over \$1 billion to explicitly increase police presence in schools, and over \$14 billion to advance community policing, which can include SROs.^{10,14}

In recent years, federal funding and support for SROs has increased following tragic school shootings. Despite their concerns about the unintended negative consequences of SROs, the Obama Administration renewed funding to increase the number of SROs across the country after the 2012 shooting at Sandy Hook Elementary School in Newtown, Connecticut.¹⁵ Following the 2018 shooting at Marjory Stoneman Douglas High School in Parkland, Florida, the Trump Administration prioritized SRO positions in selecting COPS grants recipients.¹⁶

Federal Policy on SROs

Despite their growth and the substantial federal funding, there is very little federal policy explicitly defining the role of SROs. The absence of SROs from federal educational policy is in part due to the Obama administration’s concerns over unintended negative consequences of police presence in schools.¹⁷ The vagueness of federal law has led to large variation in the role, expectations, and accountability of police in schools. Moreover, federal-level data collection on SROs is also severely lacking. SROs are not required to register with any national database, police departments are not required to report how many of their officers work as SROs, and school systems are not required to report how many SROs they employ.¹ Since 2013-2014, the U.S. Department of Education has collected survey data every other year that details the number of student referrals and arrests made by school police (including SROs) in public schools, and which students are most affected.¹⁸ The data also include the number of counselors, social workers, school psychologists, and nurses that are in a school compared to the number of SROs.¹⁹ Given this overall lack of descriptive data there is little information on the roles of SROs nationally or how, if at all, SROs are trained. By failing to collect these data, it is difficult to monitor and evaluate the work of SROs and their impact.

State Policy on SROs

Federal policy and accompanied funding initiatives fueled the growth of SROs programs which are now operated in all 50 states.^{14,19} Yet, the lack of federal law on SROs has led to a patchwork of state policy. Out of all 50 states and Washington D.C., only 26 jurisdictions specifically define SRO in state statutes or regulations.¹⁹ These state-level definitions do not specify the role of SROs in schools. Most states encourage schools or districts to enter into a Memorandum of Understanding (MOU) with local law enforcement if they provide an SRO. For example, Connecticut, Massachusetts, Ohio, and South Carolina require MOUs to outline the role of the SRO.²⁰

The National Association of School Resource Officers (NASRO) suggests SROs receive at least 40 hours of specialized training in school policing prior to being assigned.²⁰ NASRO’s Basic SRO training is set up as a 5- day, 40-hour block of instruction and outlines evidence-based best practices for SRO programs.²⁰ This training covers the

following topics: constitutional and state law, armed response, crime prevention and mitigation, interview and interrogation techniques, investigations, crime prevention through environmental school design, patrol operations, advocacy within the juvenile justice system, and mandatory reporting.²⁰ Twenty-eight state statutes or regulations include language regarding training requirements for SROs, but these also vary widely and laws in only two states specify a required length of training.²¹ In several states, the training is simply what is required of traditional law enforcement, including firearm or active shooter training.²² Instruction regarding how to effectively interact with youth averages around four to six hours across all states.²² Training in sixteen states includes what is required of traditional law enforcement in addition to school-specific training. Few states explicitly require training in de-escalation or conflict resolution, mental health, youth development, or school climate.²² Only Maryland and Utah explicitly include provisions for training in “implicit bias and disability and diversity awareness with specific attention to racial and ethnic disparities” and “cultural awareness,” respectively.²² Therefore, across states there is wide variation in expectations regarding SRO training. Additionally, training is primarily standard police training, with little education on working in school settings and with youth.

Illinois is an example of this heterogeneity of approach. Illinois state law requires SROs to complete training within one year of assignment.²³ This training must cover juvenile developmental issues, youth mental health, how to prevent child abuse and exploitation, and various educational administrative issues. Illinois does not explicitly require implicit bias, disability training, or de-escalation training.

School District Policy on SROs

SRO training and duties vary across school districts. In general, SROs must enforce school rules and the law, as well as be visible authority figures in schools. They can also participate in mentorship programs, provide students with training on safety and violence, and promote a positive school environment.²⁴ SROs usually patrol school halls to discourage students from misbehaving, and when a student is caught breaking a school rule or the law, SROs step in to investigate and assist with student discipline. Certain school districts require SROs to follow zero tolerance policies when students are caught with drugs, meaning the SRO has zero discretion in how to respond. Other school districts allow SROs to use discretion to decide a disciplinary course of action.²²

Benefits of School Resource Officers

School resource officers can provide a variety of benefits not only to schools, but to individual students and local police departments. These benefits include promoting school safety, addressing the root causes of student misbehavior, and decreasing juvenile delinquency petitions where SROs are properly utilized.²⁵ Further, SROs can improve relationships between students and law enforcement, serve as protectors for victimized students, and reduce the burden on local law enforcement. Although there has been limited research, it is hypothesized that SROs can promote safety in schools by deterring criminal activity at schools, specifically more serious crimes including possession of a weapon and assault.²⁶ SROs can also aid in reducing the amount of fighting and bullying on campus through hallway patrols, which can allow SROs to intervene rather quickly when there is a fight.²⁶ Students may be less likely to break the rules or pick a fight when SROs are patrolling school grounds because of the increased probability of being caught.

Some districts have found that SROs can use their positions to identify the root cause of school misbehavior and help students address it. When SROs are properly utilized, they can potentially help offset the school-to-prison pipeline. For example, SROs in Franklin County, Virginia, often impose alternative methods of punishment to delinquency petitions, such as community service, school service, or mediation.²⁶ Once a student has completed his act of service, they are often encouraged to participate in afterschool extracurricular activities in order to create structure and prevent a second offense. In Franklin County, SROs only send a request for a delinquency petition to the state's attorney after all other avenues have been explored. A study of schools in this county that utilize this approach found a 64 percent decrease in potential delinquency petitions.²⁷

Research also reveals that SRO programs can improve relationships and build trust between students and law enforcement. A 2016 study that surveyed students from various schools in one southeastern U.S. school district analyzed how students' attitudes towards SROs change with increased interaction.²⁶ Overall, more student-SRO interactions were positively correlated with favorable feelings towards SROs. Other research shows that this improved trust can later help uncover previously unknown issues of abuse and neglect, because victims may feel more comfortable reporting the issue to law enforcement.²⁷ Additionally, SROs can sometimes serve as protectors

for students, which can make students feel more comfortable asking for help. This is especially true for students who are victims of various crimes, abuse, and bullying, and who may feel safer attending school knowing an SRO is available to protect them.²⁷ SROs have the unique ability to immediately intervene if a juvenile offender violates any court ordered condition, thereby increasing a victim's sense of safety at school. Finally, SROs can reduce the burden on law enforcement outside of the school. When officers are stationed at schools, the school often no longer needs to call 911 when a dangerous situation arises because it simply informs the SRO. This gives the school a quick response time while allowing patrol officers to focus on issues outside of schools. Overall, some of the benefits of SROs include:

- Increasing feelings of safety among students, teachers, and administrators,
- Deterring aggressive behavior, and empowering staff to maintain order and address behavioral issues in a timely fashion,
- Diminishing classroom time spent on discipline and behavioral disruptions,
- Improving school safety and reducing school-based crime,
- Increasing the likelihood that students report witnessing a crime, and help reduce community-wide criminality, and
- Improving relationships between law enforcement and youth.

Impacts on Safety for Marginalized Youth

In the triad model concept advanced by NASRO, in addition to their law enforcement role, SROs will act as another mentor, educator, or counselor. However, this assumption ignores the fact that Black youth, Latinx youth, immigrant youth, indigenous youth, and youth living in poverty often come to school with harmful experiences with police that may perpetuate racial inequalities in educational, health, and social outcomes.²⁸ By placing SROs in schools, these traumatic issues can be exacerbated. SROs are more likely to reproduce broader patterns of police targeting and criminalizing Black, Indigenous, Latinx, and students of color.²⁹

Further, SROs are disproportionately placed in schools serving predominantly students of color, as opposed to schools serving predominantly white populations.³⁰ Among middle and high schools where more than 75 percent of students were Black, 54.1 percent had at least one SRO or security officer on campus.^{31,32} By comparison, among middle and high schools where over 75 percent of students were white, only 32 percent had SROs.^{32,33}

SROs Are Associated with Higher Rates of Exclusionary Discipline and Criminalization

Additionally, numerous studies show that the presence of SROs in schools is associated with higher rates of exclusionary discipline (suspensions and expulsions) which increases the risk of students being pushed into the “school to prison pipeline.”³³ Students of color across the nation are disproportionately subject to these exclusionary discipline practices.³⁴ For example, in Connecticut, suspension and expulsion rates for Black and Latino male students are two to three times that of their white counterparts.³⁵ The suspension rate for Black female students is around five times that of their white counterparts.³⁶

Additionally, SROs create the potential to escalate school disciplinary issues, even minor ones, into arrestable offenses.³⁶ In one survey of SROs, 77 percent reported that they had arrested a student to calm them down and 55 percent reported arresting students for minor offenses because the teacher wanted the student to be arrested.³⁷ The majority of school-based arrests are for non-violent offenses, such as disruptive behavior.³⁹ Further, studies show that the presence of an SRO increases the number of arrests for “disorderly conduct” – an often ambiguous, and subjective characterization of behavior.³⁸ Overall, research suggests that SROs’ potential to escalate conflicts puts students at risk.³⁹ For example, schools that employed police had an arrest rate 3.5 times that of schools without police.⁴⁰ As with exclusionary discipline, students of color are disproportionately subject to school arrests.⁴²

This pipeline extends further for undocumented students, as contact with SROs can put them at risk of detention and deportation.⁴¹ This risk is heightened in communities where local law enforcement is contracted with Immigration and Customs Enforcement under 287(g) agreements – which allows the Department of Homeland Security to deputize selected state and local law enforcement officers to enforce federal immigration law.⁴² Since 2013, COPS Grants have required recipients to sign a 287(g) agreement in order to receive funds. There are several documented cases of SROs putting immigrant students at risk of “school-to-deportation pipelines.”^{43,44}

Interference with Education

The presence of SROs and exclusionary discipline negatively impacts students' academic achievement and can accelerate future misbehavior, truancy, and drop-out rates.⁴⁷ Students who have contact with the criminal legal system through arrests and searches experience worse schooling outcomes than those who do not. Arresting students doubles their risk of dropping out.⁴⁵ The consequences of a school arrest extend far beyond a youths' public-school outcomes and include the loss of access to higher education and funding, job eligibility, access to public housing, and increasing both the likelihood and consequence of future law enforcement contact.⁴⁶ Further, trauma and anxiety symptoms can increase with the frequency of police contact, regardless of where that contact occurs. For many students of color, police presence in schools can cause re-traumatization given their negative experiences with law enforcement in their communities.⁵⁰

The presence of SROs can shift the focus from learning and supporting students to over-disciplining and criminalizing them. Regular police contact, even if this contact is in passing, affects how Black and Latinx youth perceive themselves, their school, and law enforcement.⁴⁷ Students of color have reported feeling the police are there to protect the school from them.⁴¹ Further, other research shows that the presence of SROs reduced students' feelings of school connectedness – the belief that adults and peers in the school care about them as humans.^{26,48} School connectedness is an important protective factor – young people who feel connected to their school are less likely to engage in behaviors that are harmful to themselves or others and are more likely to have better academic achievement, attendance, and persistence.⁵⁰ Research also demonstrates that racial and ethnic disparities in discipline are not the consequence of differences in rates or types of misbehavior by students of color and white students but rather racial and cultural biases.⁴⁴

Lastly, the focus on SROs has also diverted attention and funds from other areas of education that could support students. Between 1999 and 2015, the percentage of students who reported security guards or assigned police officers in their schools increased from 54 percent to 70 percent while the number of school counselors increased by only 5 percent, after adjusting for the growth in student enrollment.⁴² There are also more sworn law enforcement officers than social workers in schools across the U.S., with many states employing two-to-three times as many police officers in than social workers in schools.⁴⁹ Over 4,800 schools reported employing more school police and security than school-based mental health providers.⁵³ Across the country 1.7 million students are in schools with police but no counselors; 3 million are in schools with police but no nurses; 6 million students are in schools with police but no school psychologists; 10 million students are in schools with police but no social workers.⁴² Compared to white students, Latinx, Asian, and Black students are more likely to attend schools where the districts chose SROs over counselors.⁵⁰

Impact of SROs on School Shootings

There is limited evidence supporting the role of SROs in preventing school shootings.⁵¹ Research on averted school shootings – incidents planned by students and then prevented – suggests that the key is having trusted adults whom other students can inform.⁵² One study found that students are much more likely to report a planned shooting to school staff members; they rarely report this to a member of law enforcement.⁵⁶ There is also limited evidence on whether SROs can stop an active shooter or lower deaths or injuries when a school shooting happens. A recent study found that among all schools that experienced a school shooting between 1999 and 2018, the number of injuries and deaths was about 2.5 times higher in schools that had an SRO.⁵³ However, in at least one instance a school shooter deliberately selected an elementary school with no security personnel instead of the middle school they attended because their middle school had an armed security officer.⁵⁴ Further, one study found in one-quarter of the studied cases with an active shooter, the officer or SRO was able to make it to the scene of the attack within one minute. In three of the attacks (7 percent), it took between one and five minutes for the officer to respond, and for two attacks (5 percent), it took between five and ten minutes.⁵⁵ In sum, further research is needed to understand the role SRO's have in deterring school shooters.

Maximizing the Benefits of SRO Programs

Although there has been interest in encouraging the expansion of SRO programs to promote school safety, some are concerned about the negative effects SROs could have on the school environment. While research on the efficacy of particular program models or characteristics is limited, the COPS Office, has identified several elements of a

successful SRO program.⁵⁶ First, the COPS guide suggests that all schools should develop a comprehensive school safety plan based on their school safety goals and a thorough analysis of the problem(s) the school is facing before determining if it is necessary to employ an SRO.⁵⁹ In some instances, school safety plans might not require the deployment of an SRO. However, if after composing a school safety plan the school decides to use an SRO, there should be clear goals for the program. SROs should engage in problem-solving policing activities that directly relate to school safety goals and address identified needs, and data should be collected to determine whether the program is achieving its goals.

Second, the COPS guide suggests that schools and the law enforcement agencies that SROs work for should be aware of any pitfalls before agreeing to establish an SRO program.⁵⁹ There may be philosophical differences between school administrators and law enforcement agencies about the role of the SRO. Law enforcement agencies focus on public safety while schools focus on educating students. Establishing an agreed-upon operating protocol or MOU is considered a critical element of an effective school-police partnership. The MOU should clearly state the roles and responsibilities of SROs involved in the program.⁵⁹ However, most schools employing SROs do not enter into a MOU. Further, MOUs are not publicly available on school websites. This means that key stakeholders such as students and families lack easy access to information regarding their rights in relation to interacting with police in schools.⁶⁹

Third, the COPS guide suggests that selecting officers who are likely to succeed in a school environment—such as officers who can effectively work with students, parents, and school administrators; have an understanding of child development and psychology; and have public speaking and teaching skills—and properly training those officers are important components of a successful SRO program.⁵⁹ While it is possible to recruit officers with some of the skills necessary to be effective SROs, it is also important to provide training so officers can hone skills they already have or develop new skills that can make them more effective. The Police Foundation, for instance, recommends that training for SROs focus on the following:

- child and adolescent development, with an emphasis on the effect of trauma on student behavior, health, and learning,
- subconscious (or implicit) bias that can disproportionately affect youth of color and youth with disabilities or mental health issues,
- crisis intervention for youth,
- alternatives to detention and incarceration, such as peer courts, restorative justice, etc., and
- legal issues like special protections for students with disabilities.⁵⁷

Further, one study that surveyed educators, students, officers, and community members suggests that successful SRO programs can do the following:

- Increase feelings of safety among students, teachers, and administrators,
- Deter aggressive behavior, and empower staff to maintain order and address behavioral issues in a timely fashion,
- Diminish classroom time spent on discipline and behavioral disruptions,
- Improve school safety and reduce school-based crime,
- Increase the likelihood that students report witnessing a crime, and help reduce community-wide criminality, and
- Improve relationships between law enforcement and youth.⁵⁸

EXISTING AMA POLICY

AMA policy H-60.902, “School Resource Officer Qualifications and Training” encourages an evaluation of existing national standards to have qualifications through training and certification that includes child psychology and development, restorative justice, conflict resolution, crime awareness, implicit/explicit biases, diversity inclusion, cultural humility, and individual and institutional safety and others deemed necessary for school resource officers. It also encourages the development of policies that foster the best environment for learning through protecting the health and safety of those in school, including students, teachers, staff, and visitors.

CONCLUSIONS

Police stationed within K-12 schools, known as SROs, are a common feature of American schools. According to federal data, about half of schools had an SRO on school grounds at least once a week during the 2017-2018 school year.⁵⁹ In the same year, a national survey found that 80 percent of parents supported having police officers in schools, and some states, like Maryland, passed new laws mandating adequate law enforcement at all schools as a result of school shootings.^{60,61} However, since George Floyd's death in 2020, the U.S. has experienced an intensified debate about the proper role of police in communities, including schools. As a result, school districts, including Chicago and Los Angeles, have significantly cut their budgets for school policing.⁶²

Opponents of SROs often cite specific incidents of police violence against Black students in schools and link SROs to the broader concept of a school-to-prison pipeline, in which students' early experiences with school discipline and/or police in schools may directly or indirectly influence their lifetime involvement with the criminal justice system.⁶² Critics of SROs fear that having a police officer within a school makes it easier for a student to be formally arrested or referred to juvenile justice for minor acts of misconduct that would otherwise be handled through school discipline.⁶³ This criminalization of school misconduct disproportionately impacts students of color, as evidenced in the existing racial disparities in arrest and incarceration.⁴⁰

Proponents state that school districts often view SROs as the first line of defense against school shootings and other acts of school violence. SROs also aim to act as a specialized form of community policing, a model of policing designed to assign officers to permanent beats, involve students in decision-making, and problem-solve using non-criminal justice techniques such as mentoring and informal sanctions.⁶⁴ Consistent with this logic, research has shown that SROs may improve student attitudes toward the police and improve student and staff perceptions of school safety.²⁶

The current evidence is inconclusive on the effectiveness of de-escalation training for SROs. However, multi-faceted interventions are more likely to be effective, especially in school settings. Examples of evidence-based best practices include training on restorative justice, transformative justice, and trauma-sensitive or trauma-informed schooling.⁶⁵ At the center of each of these approaches is the development of: healthy relationships; processes that support the healing of harm and transformation of conflict; and just and equitable learning environments that confront oppressive structures and systems.⁶⁹

Further, establishing an agreed-upon operating protocol or MOU is considered a critical element of an effective school-police partnership. The MOU should include provisions addressing daily interactions between students and school personnel with school resource officers.⁶⁶ MOUs are widely considered important tools to clarify how SROs should operate in an educational environment.⁶⁷ However, most school districts employing SROs do not have a MOU in place. Research shows that an upfront MOU agreement can result in fewer court referrals, fewer violent offenses, and higher graduation rates.⁶⁸

It is also important to recognize that SROs are part of the school staff at large and shouldn't be considered a separate entity from school counselors, social workers, school psychologists, nurses, and schoolteachers. Their roles should therefore be defined within the team structure of the school. Finally, community-based policing practices ensure that the community plays a role in prioritizing and addressing public safety problems.⁶⁹ SRO programs employing these practices can be used to accomplish two interrelated goals of developing solutions to problems through collaborative problem solving and improving public trust.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted, and the remainder of the report be filed.

1. That our AMA amend Policy H-60.902, "School Resource Officer Qualifications and Training" as follows:
 1. Our AMA encourages: (1) an evaluation of existing national standards (and legislation, if necessary) to have qualifications by virtue of training and certification that includes child and adolescent psychology and development, trauma-informed care, restorative justice, peer mediation, conflict resolution, crime awareness, implicit/explicit biases, how to work with children with disabilities and special needs, diversity inclusion, cultural humility competence of

the distinct cultural groups represented at schools, de-escalation training, bullying and cyberbullying training, and individual and institutional safety and others deemed necessary for school resource officers; and (2) the development of policies that foster the best environment for learning through protecting the health and safety of those in school, including students, teachers, staff and visitors.

2. That our AMA encourage: (1) school districts initiating SROs develop and those with existing SROs maintain an up-to-date Memorandum of Understanding (MOU) that clearly outlines processes for officer selection and assessment, defines roles and responsibilities of SROs and their scope relative to school personnel, identifies data to be collected, and establishes a mechanism for program evaluation and oversight; (2) SROs to have access to local public health resources; (3) schools with SRO programs to collect and report data to help evaluate the impact of SROs in schools; ~~and~~ (4) federal and state grant programs which provide funding for SRO programs, require collection and reporting of data to inform policymaking on these programs; and (5) adequate federal funding to the Bureau of Indian Education to develop and implement SRO programs in consultation with tribal leaders.
3. That our AMA acknowledges that: (1) if a school chooses to utilize SROs, they are part of the school staff at large and their responsibilities should be defined within the context of the school team; and (2) community-based policing practices are essential for a successful SRO program.
4. That our AMA supports: (1) efforts to address physical and mental trauma experienced by children in preschool-12th grade by eliminating disproportionate punitive disciplinary actions and the involvement of law enforcement in student discipline; (2) transitions to restorative approaches that individually address students' medical, social, and educational needs; and (3) ensuring that any law enforcement presence in preschool-12th grade schools focuses on maintaining student and staff safety and not on disciplining students.

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5. INCREASING PUBLIC UMBILICAL CORD BLOOD-DONATIONS IN FACILITIES WITH OBSTETRIC SERVICES

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS AMENDED
REMAINDER OF REPORT FILED
TITLE CHANGED
See Policy H-370.956

INTRODUCTION

The first Resolve of Resolution 001-A-22, “Increasing Public Umbilical Cord Blood-Donations in Transplant Centers,” which was referred by the House of Delegates, asked that our American Medical Association (AMA) “encourage all hospitals with obstetrics programs to make available to patients and reduce barriers to public (altruistic) umbilical cord blood donation.”

BACKGROUND

Historically, umbilical cord blood (UCB) had no identified value and was disposed of with the placenta. UCB is now known to contain hematopoietic stem cells that have potential life-saving benefits. When used in hematopoietic stem cell transplantation, umbilical cord blood offers several distinct advantages compared with bone marrow or peripheral stem cells. Biologically, a greater degree of human leukocyte antigen (HLA) mismatch is tolerated by the recipient and the incidence of acute graft-versus-host reaction is decreased when umbilical cord blood is used compared with unrelated donor bone marrow.¹ The predominant disadvantage of umbilical cord blood use is that there is often a low yield of stem cells acquired per unit. Only 8–12 percent of umbilical cord blood units have sufficient cell volume for transplant to a person weighing 80 kg (176 lb).² In general, a private UCB bank is a for-profit company that allows storage of UCB for personal use. In contrast, public UCB banks offer gratuitous cord blood banking for individuals who meet the donation requirements. The benefits and limitations of public versus private UCB banking should be reviewed with the patient individually because they serve different purposes.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms “umbilical cord blood donation,” “public umbilical cord blood donation,” and “umbilical cord blood AND transplantation.” Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

DISCUSSION

Umbilical Cord Blood

UCB is the blood left over in the umbilical cord and placenta after delivery. Typically, the umbilical cord and placenta are thrown away as medical waste. UCB blood is similar to other sources of blood because it contains red and white blood cells, platelets and plasma. It also contains a special type of stem cell known as hematopoietic stem cells (HSCs) that can mature or grow into different types of blood cells such as red blood cells, white blood cells, or platelets. Billions of stem cells reside in just a few ounces of cord blood, which is collected painlessly from the umbilical cord after birth. HSCs are used in treating life-threatening malignant and non-malignant diseases of the blood and immune system.³ Researchers have found cord blood is effective in treating up to 80 conditions.⁴ Moreover, clinical studies have proved the pluripotent nature of cord blood cells, highlighting a wide range of possible clinical applications in neonatology, regenerative medicine, and immune modulation.

Umbilical Cord Blood Banking

UCB banking has grown significantly in the past two decades. The option to bank UCB was first made available in the 1990s following the discovery that cord blood is a rich source of stem cells.⁵ UCB banking consists of the collection and storage of the UCB from the placenta and umbilical cord, soon after childbirth.⁶

Three types of UCB banks currently exist: public, private, and hybrid. Public banks store UCB units received altruistically from donors, which are then listed on the Be The Match® Registry (The Registry) and made available for any potential recipient if they are an adequate HLA match.⁷ There is no cost to donate the baby’s cord blood to a public bank. Public banks follow strict quality assurance and FDA regulations and will only bank cord blood if it is sterile and contains enough stem cells to use in treatment. However, public cord blood banks do not allow directed storage. In contrast, private banks, also referred to as family banks, store UCB for exclusive future use either by the donor or a matched relative. When a baby’s cord blood is stored in a private cord blood bank, the donor pays collection and ongoing storage fees and the UCB is reserved for the donor’s use only. As the cord blood is being saved for personal use, private banks are not required to follow the same quality and sterility guidelines as a public bank.⁸ Hybrid banks offer combined public and private UCB storage solutions. In this scenario, either the private bank offers a public donation, or the public bank offers a private storage option.

Recruitment and Donor Education

Public UCB banks are required to process, and store collected units within 48 hours of collection. Therefore, collection tends to occur in geographically proximate hospitals, which is available in a limited number of hospitals in the United States.⁹ This, coupled with the lack of funding for marketing campaigns, means that recruitment and education of expectant parents provided by public UCB banks is minimal, mostly consisting of websites to provide education and guidance to expectant parents who want to donate their baby’s cord blood. Most public UCB banks rely on the voluntary participation of physicians, prenatal class instructors, and labor and delivery nurses to encourage expectant parents to donate, provide information about donation, and to collect the cord blood at the time of delivery. Some public UCBs maintain their own staff in collection hospitals to provide information and education about cord blood donation or consent-and-obtain information for the maternal questionnaire. Further, many states have laws requiring obstetricians to inform their patients about cord blood banking.¹⁰ However, most legislation does not specify whether public or private donation should be discussed.

Cord Blood Collection, Processing, and Storage

Families who decide to donate their newborn’s cord blood to a public UCB bank must provide a maternal health history and a maternal blood sample for infectious disease screening prior to delivery. Collected cord blood is then

packed, stored, and transported, typically in a temperature monitored environment, to a cell-processing laboratory. While in transit from the collection site to the processing and storage site, time and temperature affect the viability of the cord blood: One study reported a 1-percent drop in cell viability for every 4-hour increase in transit time.¹¹ After collection, but before further testing or processing, many public UCB banks perform an initial assessment of the collected unit to determine its weight and volume. Low weight or volume units are usually discarded or donated to research since they are unlikely to meet minimum cell count requirements for banking and use in transplants.¹²

At any point in the process, a cord blood unit may be identified as unsuitable for storage for any number of reasons, including low volume (i.e., not enough stem cells to use in a transplant), poor viability (i.e., there may be stem cells, but they may not be alive or appropriately functioning), poor results from infectious disease testing, or negative findings from the maternal health questionnaire. Some studies have demonstrated that for every one-hundred births eligible for cord blood donation in which cord blood collection is attempted, approximately forty-five are sent for processing and approximately ten are ultimately stored.¹³

Cord Blood Inventory Management and Withdrawal

Most cord blood stored in public banks in the United States are listed with the National Marrow Donation Program (NMDP), which runs The Registry and serves as a central site for patients seeking HSC transplants of all kinds.¹⁴ Many international banks' cord blood is also available through The Registry. Some public UCB banks may also offer units that do not meet qualifications for being listed on The Registry but may still have value to potential recipients (i.e., they may have lower cell counts, but represent rare HLA types). These are not available through The Registry, but rather are obtained directly through established relationships with UCB banks.

When a patient has a condition that necessitates treatment using an allogeneic HSC transplant, the patient's physician, whether in the United States or abroad, can search existing registries, including The Registry, for a potential match. More than 90 percent of UCB units distributed for transplant in the United States are distributed through The Registry.¹⁵

UMBILICAL CORD BLOOD REGULATION AND GOVERNMENT POLICIES

Federal Policies and Programs

In 1987, the National Bone Marrow Donor Registry (NBMDR) was initiated through a congressionally directed grant from the U.S. Department of the Navy and formally established in 1990 as a responsibility of the U.S. Department of Health and Human Services (HHS), with oversight initially by the National Institutes of Health (National Heart, Lung, and Blood Institute) and, since 1994, by the Health Resources and Services Administration (HRSA).¹⁶ In December 2005, Congress passed the Stem Cell Therapeutic and Research Act (Stem Cell Act 2005).¹⁷ The Stem Cell Act 2005 amended the Public Health Service Act and required the HHS Secretary, through HRSA, to rewrite the provisions that established and maintained the NBMDR. The provisions were rewritten to establish and maintain the C.W. Bill Young Cell Transplantation Program (CWBYCTP), the successor to the NBMDR.

The Stem Cell Acts of 2005, 2010, 2015, 2021 authorized the following:

- The Stem Cell Therapeutic and Research Act of 2005 established the CWBYCTP to replace the NBMDR. In so doing, the Act expanded on the previous requirements of the NBMDR to increase the numbers of marrow donors and cord blood units and continued to serve patients who need a bone marrow or umbilical cord blood transplant. The CWBYCTP also established an outcomes database to collect data and perform research, as well as offer patient and donor advocacy services, case management services, data collection on transplant outcomes, and educational activities.
- National Cord Blood Inventory (NCBI). The NCBI program contracts with cord blood banks to meet the statutory goal of building a public inventory of at least 150,000 new, high-quality, and genetically diverse UCB units.¹⁸ These UCB units are available for transplantation through the CWBYCTP. The Stem Cell Therapeutic and Research Reauthorization Acts of 2010 also required the U.S. Government Accountability Office to report on efforts to increase cord blood unit collection for the NCBI.

- Advisory Council on Blood Stem Cell Transplantation (ACBSCT). The goal of the ACBSCT is to advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services and the Administrator of HRSA on matters carried out by both CWBYCTP and the NCBI Program.¹⁹

HRSA

HRSA administers the CWBYCTP and manages its various components. HRSA provides funding for the collection of diverse cord blood units for NCBI through contracts to cord blood banks. There are 13 NCBI contractors who bid to provide a certain number of cord blood units of specified types (i.e., racial/ethnic groups).²⁰ Once NCBI-eligible cord blood units are listed on The Registry, public cord blood banks receive a subsidy for cord blood collection, processing, and storage. This subsidy does not cover the entire costs borne by cord blood banks for collection, processing, and storage, but it does help defray some of those costs.

National Marrow Donor Program (NMDP)

The NMDP provides the link between HRSA, UCB banks, and physicians for obtaining stem cells and, specifically, cord blood. The NMDP also acts as the financial intermediary between individual UCB banks and hospitals and provides education for patients and clinicians.²¹

FDA Oversight

The FDA regulates cord blood in a variety of ways, depending on the source, the processing, and the intended use. Cord blood stored in private banks (i.e., for autologous use or use in first- or second-degree relatives) does not need to go through FDA licensure because it is used on the individual from whom it was collected, or on a related individual. In contrast, public UCB banks store UCB units intended for use by a patient unrelated to the donor (i.e., for allogeneic use). Therefore, this use meets the legal definitions of both a “drug” and a “biological product,” which means that public UCB banks must adhere to additional requirements.^{22,23} Public banks are required to comply with good tissue practice regulations, conduct specific donor screening and infectious disease testing, conduct standardized testing on UCB units, and maintain international cellular therapy accreditation. Further, public UCB banks are required to hold licensure from the FDA. The costs and timeline for achieving FDA licensure are reportedly high, with many public UCB banks reporting a 12-to-24-month timeline, initial costs of approximately \$1 million, and ongoing annual costs of more than \$100,000.^{24,25}

It is also important to note that individual UCB units are licensed, not the UCB bank itself. Most public UCB banks in the United States were in operation before the FDA licensure mandate—the FDA issued guidelines for licensure in 2009 and issued the first license in 2011.²⁶ Licensed UCB units meet FDA standards, and unlicensed UCB units are collected and processed prelicensure or are post-licensure collections that do not meet the requirements specified by the FDA. Public UCB banks that have not achieved FDA licensure will produce only unlicensed UCBs. Finally, UCB units from international banks are also unlicensed. The use of an unlicensed UCB unit must go through the process of an Investigational New Drug (IND) application.²⁷ An IND may be submitted by the UCB bank, the transplant physician, the transplant center, a national or international cord blood registry involved in coordinating the distribution, or another qualified sponsor.²⁷ INDs are granted only for specific uses.²⁶

State Legislation

To date, 28 states have passed some form of cord blood education legislation, which represents 78 percent of the total annual US births.¹⁰ Several other states are in various stages of developing similar legislation to help inform health care professionals and expectant parents of all medically appropriate options for preserving cord blood stem cells.

ADVANTAGES AND DISADVANTAGES OF USING CORD BLOOD STEM CELLS

Advantages of Using Cord Blood Stem Cells Over Other Sources for Stem Cells

Physicians and patients balance trade-offs when choosing a suitable stem cell donation for transplant. In some cases, the urgency to perform the transplant makes cord blood stem cells the preferred choice because they are usually available for overnight transport once a suitable match is identified.²⁸ Other factors to consider include time to acquire the donation and quality of the potential stem cell sources, as well as the patient's age and disease. One major advantage to using cord blood stem cells is the fact that they are less differentiated than stem cells from adult sources (i.e., bone marrow or peripheral blood), and therefore are better able to develop into various cell types as they mature. This quality is an asset for transplantation because cord blood stem cells require less-stringent donor-recipient matching than adult stem cells and carry a lower risk for rejection by the recipient's body. Another advantage is that this less-strict matching also implicitly increases access to stem cells as a treatment source for those unable to find suitable matches among other sources.²⁹ This is especially important for racial and ethnic minorities who often have a hard time finding a suitable donor.

Bone marrow and peripheral blood stem cell collection also have disadvantages. Preparations for collection of bone marrow or peripheral blood, such as donor-recipient matching to minimize the chance of rejection, can take several weeks to complete. Collection itself requires the donor to undergo a procedure requiring sedation, typically done in an operating room, or take medication to stimulate stem cell production, both of which can be painful and can require recovery in the hospital.³⁰

Summary of Advantages for Patients

For certain patients, there may be advantages to using donor cord blood stem cells instead of donor peripheral blood or donor marrow stem cells. Some potential advantages include:

Availability. Cord blood stored in a public cord blood bank has been prescreened, tested and frozen and is ready to use. They are usually available for overnight transport once a suitable match is identified.³¹

Human Leukocyte Antigen (HLA) Matching. The outcomes of related and unrelated donor stem cell transplants are strongly affected by the degree of HLA matching between the transplant recipient and the donor cord blood. HLA matching plays an important role in successful engraftment, severity of graft-versus-host disease (GVHD) and overall survival. A close match between the patient and the cord blood unit can improve a patient's outcome after transplantation.³¹

Graft-Versus-Host Disease. Studies have found that after a cord blood stem cell transplant, fewer patients got GVHD and, among those patients who did develop GVHD, the complication tended to be less severe than it was in patients who had bone marrow or peripheral blood transplants. GVHD is a serious and sometimes fatal complication of allogeneic stem cell transplantation.³¹

Diversity. As a result of extending collection efforts to hospitals where births from diverse ethnic backgrounds are well represented, donated cord blood units have the potential to provide a source of stem cells that reflect racial and ethnic diversity.³¹

Infectious Disease Transmission. Cord blood stem cell transplants carry a lower risk of transmission of blood-borne infectious diseases compared with stem cells from the peripheral blood or marrow of related or unrelated donors.³¹

Disadvantages of Using Cord Blood Stem Cells Over Other Sources for Stem Cells

Although the U.S. government started a federal cord blood program in 2005 to help create a nationwide inventory of high quality and genetically diverse units of cord blood, the proportion of cord blood stem cell transplants relative to transplants using other types of stem cells, such as those from bone marrow, has been falling in recent years.³² The declining demand and increasing costs has led to some of the public UBC banks to struggle to operate financially.

One significant disadvantage to using cord blood stem cells is that the volume of collectible blood is small in comparison to that from an adult donor's bone marrow or peripheral blood. Fewer stem cells means that it takes approximately 10–15 days longer than other sources for the stem cells to establish themselves when introduced in the recipient's bone marrow.³³ This means longer recovery time in the hospital for the recipient. Since bone marrow and peripheral blood can provide more stem cells per donation, the cells usually engraft more quickly in the

recipient's bone marrow, so the recipient typically has a shorter recovery period. Further, bone marrow or other peripheral blood stem cells are not required to be licensed.

Summary of Disadvantages for Patients

Clinical Data. Cord blood stem cell transplantation is almost two decades old yet is a relatively new procedure in comparison to transplantation of peripheral blood or marrow stem cells. It is possible that genetic diseases may be present but not apparent at the time of birth and could be transplanted to a patient via donor cord blood stem cells. Procedures to track this possibility require follow-up until the donor infant is months or even years old, but such follow-up has proven difficult. A future approach to address this may be genetic testing for diseases that affect the blood and immune system and for certain metabolic diseases that might be transplantable.³¹

Storage. It is not known how long cord blood can be frozen and stored before it loses its effectiveness. Cord blood samples have been preserved for as long as 10 years and have still been successfully transplanted.³¹

Engraftment. The number of cells required to give a transplant patient the best chance for engraftment and for surviving the transplant is based on his or her weight, age and disease status. A cord blood unit might contain too few stem cells for the recipient's size. Due to the smaller number of stem cells in the cord blood unit, cord blood stem cell transplants engraft more slowly than stem cells from marrow or peripheral blood. Until engraftment occurs, patients are at risk of developing life-threatening infections due to immunosuppression from chemotherapy and/or radiation intended to prepare the recipient for the transplant. Thus, cord blood transplant recipients may be vulnerable to infections for an average of up to one to two months longer than marrow and peripheral blood stem cell recipients.³¹

CURRENT DEMAND FOR CORD BLOOD UNITS

Overall, stem cell transplants have been on the rise for several years. However, the number of transplants using cord blood has declined over time, from about 12 percent of all HSC transplants to about 8 percent from 2010 to 2015.³⁴ As of 2020, more than three-quarters (77%) of the unrelated transplants and three-quarters (80%) of related transplants were performed using peripheral blood.³⁵ One-seventh (14%) of unrelated transplants used bone marrow and 7% used cord blood units.³⁵ Other factors may contribute to the declining demand for cord blood, such as higher procurement and treatment costs or provider preferences. Over the short term, treatment costs are clearly higher for cord blood transplants relative to other stem cell transplants. This is primarily driven by longer engraftment periods, which translate into longer hospital stays. Research is still needed to determine whether cord blood recipients stay healthier over the long term than recipients of other stem cell types. Further, differences in collection costs are also unclear, as previous studies have tended to ignore the cost of harvesting adult stem cell sources, which can be significant.³⁴

Competition among public banks has increased as the net supply of cord blood units has grown. Private banks, in which individuals store cord blood for their own family use, also provide some competition because their units may not be released to the national inventory, keeping that segment of the market off-limits for most patients. In addition, international cord blood banks now supply about 24 percent of units used in the United States, up from 13 percent in 2004.³⁶ The fee that a bank charges a transplant center for a cord blood unit tends to be the same (about \$36,000) regardless of the unit's TNC count or genetic rarity.³⁴ The current market environment for public banks makes it difficult to break even. Costs for public banks include processing, testing, and storage costs; licensure by the U.S. Food and Drug Administration; and overhead costs. The total expenses vary widely, ranging from \$1 million to \$6 million, depending on the size of the operation.³⁷ Further, revenue primarily comes from fees, but also from the NCBI subsidies for registered units, donations, grants, or in-kind donations of services. Banks collect, on average, 8,500 units annually but ultimately store only 5 to 40 percent of those collections.³⁸ Among units that have been banked, a low-TNC-count unit has only about a 0.1-percent chance of being used in a given year, as opposed to a 3-percent chance for larger units.³⁷ Because banks collect fees only on units that are used, banks that store low-TNC-count units are more likely to lose money.

EQUITY CONSIDERATIONS

In the U.S., racial minorities are much less likely to find a suitable blood stem cell donor than White Americans. For example, a Black person has a 29 percent chance of finding a matched donor in the registry, while a white person has a 79 percent chance.³⁹ People who are American Indian and Alaska Native have a 60 percent chance of finding a registry match, Asian and Pacific Islander patients 47 percent, and Hispanic or Latino patients 48 percent.³⁹ People of color make up a small percentage of all donors, making it difficult to find matches for people with cancer who are not white or who are of mixed race and ethnicity.

HSCs from UCB offer the advantage of requiring less stringent HLA-matching criteria (i.e., six loci, rather than 10 as is the case for bone marrow derived HSCs). In addition, since these cells can be cryopreserved, this provides an off-the-shelf solution to patients in urgent need of transplantation. These factors are particularly advantageous for patients from non-Caucasian racial and ethnic groups, especially since this offers access to a worldwide inventory and increased the likelihood of finding a match.^{40,41}

As discussed above, one disadvantage of using UCB is the low yield of HSCs when compared to bone marrow or peripheral blood. Use of a suboptimal HSC cell dose results in delayed recovery, higher graft failure rates and risk of infection.^{45,42} This results in increased hospitalization times and a consequent increase in treatment costs. Double UCB transplantation is often employed to overcome this, causing significant financial burdens to the transplant recipient. The cost factor is particularly pertinent in the context of allogeneic UCB transplantation, when one considers that obtaining a single UCB unit can cost up to \$36,000.⁴³ The costs of double UCB unit transplantation and further manipulations can therefore be prohibitively expensive.

POTENTIAL COST CONSIDERATIONS

Limited information is available about the costs to set up an UCB donation systems in health care settings where a program currently does not exist. As noted above, public UCB banks are required to process, and store collected units within 48 hours of collection. This is essential to maintain the viability of the collected cells. Therefore, this may only be feasible when a public UCB bank is geographically proximate to the hospital. There are significant costs for hospitals to set up public UCB donation centers on site. One example of the potential fiscal cost comes from Connecticut which aimed to establish a public UCB bank between the Department of Public Health (DPH) and the University of Connecticut Health Center (UCHC).⁴⁴ The estimated costs were \$1.9 million, with ongoing annual operating costs of \$2.38 million for the subsequent years.⁴³ These estimates assumed a volume of 1,440 specimens to be collected and stored per year and included costs for personnel, equipment, training, accreditation, reagents, rent, vehicles for transport, freezers, testing, courier services, and computer maintenance.⁴³

Public UCB banks with donation systems in place incur both variable and fixed costs. Variable costs include costs of collection, testing, processing, storing, and distributing the unit.³⁷ Fixed costs include obtaining FDA licensure and overhead costs, such as rent.³⁷ Collection costs include costs of recruiting donors, collection kit supplies, and labor costs. These costs may vary based on the recruitment efforts conducted, as well as whether the bank uses volunteer CBU collectors, or whether it employs its own CBU collectors. There are also significant costs at the processing stage, including separation of the CBU components and HLA-typing to prepare the units for storage.³⁷ Further, the costs banks typically incur to obtain the FDA license are not publicly available. Therefore, average annual overhead costs—which consist of equipment costs, maintenance, rent, utilities, office supplies, and other related expenses—total from \$1.2 million to \$4.5 million, depending on the size and setup of the UCB bank.³⁷

Revenue comes primarily from fees, but also from the NCBI subsidies for registered units, donations, grants, or in-kind donations of services. Banks collect, on average, 8,500 units annually but ultimately store only 5 to 40 percent of those collections.³⁴ Because banks collect fees only on units that are used, banks that store low-TNC-count units are more likely to lose money. Banks have had to get creative with how they structure their businesses to remain viable. Some banks have adopted hybrid models, offering private family banking to cross-subsidize the nonprofit public banking operations under NCBI.³⁴ Some have also improved their financial situation by selling their processing or testing services to private banks.³⁴ Others are part of larger organizations, such as whole blood centers or hospitals, which can offer cheaper transportation and lab work.³⁴ Despite the current financial limitations, one study calculated that the average annual value of having a national public bank system range from \$883 million to

\$1.7 billion, far outweighing the aggregate industry operational costs of \$60 million to \$70 million to maintain the current system.³⁴

Other limitations to collecting UCB include the lack of delivery rooms, licensed obstetric nurses, and the need for more extended opening hours at the local public cord blood bank.⁴⁵ This highlights the other potential cost considerations that might increase UCB donations at current hospitals with existing systems set up.

FEDERATION OF MEDICINE POLICY

The American College of Obstetricians and Gynecologists support public UCB donations and state that public banking is the recommended method of obtaining cord blood. They further state that the routine use of private cord blood banking is not supported by available data.⁴⁶ In addition, the importance of contributions from all ethnicities and races to public banks is highlighted. The American Academy of Pediatrics also supports the use of public cord blood banking, and further state that it is the preferred method of collecting, processing, and using cord blood cells for use in transplantation in infants and children with fatal diseases, such as malignancies, blood disorders, immune deficiencies, and metabolic disorders.⁴⁷

Existing AMA Policy

The AMA has policy addressing the use of cord blood for transplantation. Code of Medical Ethics 6.1.5 “Umbilical Cord Blood Banking” states that cord blood is a potential source of stem and progenitor cells with possible therapeutic applications. Further it states that “physicians who provide obstetrical care should be prepared to inform pregnant women of the various options regarding cord blood donation or storage and the potential uses of donated samples.” It also encourages donation to a public bank. The Code of Medical Ethics 7.3.8 “Research with Stem Cells” urges physicians who conduct research using stem cells obtained from any source (established tissue, umbilical cord blood, or embryos) to adhere to institutional review board (IRB) requirements, ensure that the research is carried out with appropriate oversight and monitoring, ensure that the research is carried out with appropriate informed consent.

AMA Policy H-370.970 “Umbilical Cord Blood Transplantation: The Current Scientific Understanding” urges physicians to recognize the viability of UCB transplantation as an alternative to bone marrow transplantation. It also encourages the education of physicians and the public on UCB donation. Finally, AMA Policy H-370.956 “Increasing Public Umbilical Cord Blood-Donations in Transplant Centers” encourages the availability of altruistic cord blood donations in all states and access to public cord banking and the creation of public cord blood banks to support altruistic cord blood donation.

CONCLUSION

The UCB field has come a long way after 30 years of biomedical and clinical research supported by public and private cord blood banking. Over 40,000 UCB transplants have been performed, both in children and in adults, for the treatment of around 80 different medical disorders. Cord blood banking has been developed to the point that around 800,000 units are being stored in public banks and over 4 million units in private banks worldwide. Although UCB units are not the answer for every patient needing a bone marrow transplant, their availability is crucial for hundreds of patients every year who have no alternative treatment modality. Particularly, cord blood transplants can be critical for pediatric and minority populations. Although sometimes there are alternatives to cord blood, patients often have no appropriate alternative HSC source. In addition, the importance of getting treatment quickly for some patients can make UCB units the best choice compared with other HSC sources that require greater lead time.

Changes in technology or new research findings related to the use of HSCs might increase or decrease the future use of cord blood. Although clinical trials using cord blood typically address rare diseases, research efforts are underway studying new cord blood applications to treat diabetes, traumatic brain injury, stroke, cerebral palsy, and autism. Any new medical applications for cord blood could increase demand for UCB units. There is also research on HSC expansion and related technologies that could increase the utility of small CBUs.

Despite the benefits of UCB donations, multiple barriers exist for cord blood collection. One notable barrier is that public UCB banks are required to process, and store collected units within 48 hours of collection. This limits the

collection sites to proximally located hospitals. This provides a barrier for hospitals that lack the appropriate resources or infrastructure to UCB donations. This, coupled with the lack of funding for efforts to improve recruitment and education of expectant parents, leads to insufficient UCB donations and availability for transplant. Most public UCB banks rely on voluntary participation of staff to encourage expectant parents to donate, provide information about donation, and to collect the cord blood at the time of delivery. It should be noted that time of delivery is not optimal for appropriate consent, adding another limitation to umbilical cord blood donation. Further, some public UCBs maintain their own staff in collection hospitals with collection sites to provide information and education about cord blood donation.

RECOMMENDATIONS.

The Council on Science and Public Health recommends the following be adopted, and the remainder of the report be filed.

1. That our AMA amend Policy H-370.956 ~~“Increasing Public Umbilical Cord Blood Donations in Transplant Centers~~ Increasing Public Umbilical Cord Blood-Donations in Facilities with Obstetric Services” as follows:
 1. Our AMA encourages: (1) the availability of altruistic umbilical cord blood (UCB) donations in all states; and (2) access to public UCB cord-banking and the creation of public UCB cord-blood banks to support altruistic cord blood donation; (3) facilities that provide obstetrics services work to provide access to public (altruistic) UCB donation; (4) that when available, to reduce barriers through education of patients about altruistic UCB donation; and (5) that facilities providing obstetrics services and UCB banking facilities work together to create networks to expand access to and increase efficiency of altruistic UCB donations.
 2. Our AMA supports federal funding efforts to increase knowledge sharing across umbilical cord blood (UCB) banks and mentoring for centers, physicians, and staff with minimal experience in UCB collection.
 3. AMA advocates for increased federal and state funding for public umbilical cord blood (UCB) banks to create networks to expand access to and increase efficiency of altruistic UCB donations in areas lacking the appropriate infrastructure to effectively collect UCB donations.
 4. Our AMA supports efforts to educate physicians about best practices in collecting public umbilical cord blood donations.
 5. Our AMA encourages efforts to increase the diversity of the national inventory of umbilical cord blood (UCB) through funding that supports UCB banks to add collection sites where more racial and ethnic minority UCB units can be collected.

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6. STUDY OF BEST PRACTICES FOR ACUTE CARE OF PATIENTS IN THE CUSTODY OF LAW ENFORCEMENT OR CORRECTIONS

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 432 REMAINDER OF REPORT FILED

See Policy D-430.993, D-430.997, and H-420.957

American Medical Association (AMA) Policy D-430.993, “Study of Best Practices for Acute Care of Patients in the Custody of Law Enforcement or Corrections,” as adopted by the House of Delegates (HOD), asked that our AMA study best practices for interactions between hospitals, other acute care facilities, clinicians, and members of law enforcement or correctional agencies to ensure that patients in custody of such law enforcement or correctional agencies (including patients without decision-making capacity), their surrogates, and the clinicians caring for them are provided the autonomy and privacy protections afforded to them by law and in concordance with professional ethical standards and report its findings to the AMA House of Delegates by the 2023 Annual Meeting.

BACKGROUND

The U.S. has the highest incarceration rate in the world with 1.9 million people incarcerated nationwide.¹ People of color are incarcerated at higher rates in jails and prisons across the country, which causes disproportionate economic, health, and social harms.²

Incarcerated individuals typically have high rates of psychiatric conditions, communicable diseases, substance use disorders, and chronic diseases. Federal law mandates basic health care for individuals who are incarcerated. Correctional facilities offer a range of health care services from primary care to hospital-level care. Few states have stand-alone hospitals for incarcerated patients, and in some counties, health departments offer expanded on-site services in their jails, including urgent care facilities. However, when medical care required by an individual who is incarcerated exceeds the capabilities of the correctional facility's health care services, that individual is transferred to a contracted hospital or, in emergent cases, to the nearest health care institution. Health care professionals practicing outside of correctional facilities receive little dedicated training in the care of incarcerated patients, are unaware of guidelines for the treatment of patients in custody, and face unique medical, legal, and ethical issues.

This report is specifically focused on acute care of patients in custody. Acute care is defined as a patient who is treated for a brief but severe episode of illness, for conditions that are the result of disease or trauma, and during recovery from surgery.³ Acute care is generally provided in a hospital by a variety of clinical personnel using technical equipment, pharmaceuticals, and medical supplies to provide diagnosis, care and treatment of a wide range of acute conditions, including injuries.⁴

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms “acute care of patients in custody”, “acute care AND corrections,” and “acute care AND incarceration.” Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

DISCUSSION

Health of incarcerated populations

Compared to the general population, individuals with a history of incarceration have worse mental and physical health; they are more likely to have high blood pressure, asthma, cancer, arthritis, and infectious diseases, such as tuberculosis, hepatitis C, and HIV.^{4,5} Several factors contribute to the prevalence of mortality due to illness and disease in this population. The incarcerated population is largely drawn from the most disadvantaged segments of society, with significant health care needs but limited access to regular care.⁶ As a result, many incarcerated individuals arrive at correctional facilities in poor health with conditions that were previously undiagnosed.

Once incarcerated, the conditions of confinement often have a negative impact on health. Stress associated with institutional life, overcrowding, inadequate access to exercise, improper diet, exposure to infectious diseases, and poor sanitation and ventilation can all contribute to mortality. Further, while incarcerated individuals have a constitutional right to health care, the access to and the quality of the care in correctional facilities are variable.⁷ Insufficient resources play a key role here, especially limited budgets and regulations that require correctional facilities to prioritize treating certain diseases over others. Some facilities tend to focus on those medical conditions that have immediate and broad impact within the facility, such as HIV and tuberculosis, but also have the potential to spill over into the general population. As a result, treatment of other chronic conditions, such as diabetes and heart or kidney problems, may drop in priority.⁸ With few exceptions, nearly all chronic health conditions are more prevalent among incarcerated individuals than the general population. Finally, a major need is increased medical capacity in correctional facilities. Mortality could be reduced if facilities were better equipped to detect acute chronic conditions, such as elevated blood pressure, and respond with adequate care.⁹

Women with a history of incarceration face a greater burden of disease than men with a history of incarceration.^{10,11} For example, female offenders with a history of drug misuse were more likely than their male counterparts to suffer from conditions such as tuberculosis, hepatitis, and high blood pressure.^{21,22} Women with a history of incarceration are also at greater risk for HIV/AIDS, HPV, and other sexually transmitted diseases.^{21,22} Women with a history of incarceration are also more likely to have experienced childhood trauma and physical and sexual abuse than women

who are not involved in the criminal justice system, potentially explaining high levels of physical and mental health problems among women who are incarcerated.²²

The number of older adults (ages 50 years and above) in U.S. prisons is growing.^{12,13} Many correctional facilities, however, are not equipped to address the special health needs of these individuals.²³ While incarcerated, some older adults do not receive adequate treatment for their ailments, particularly mental health conditions.^{23,14} For example, one study found that only 18 percent of older adults who are incarcerated were prescribed medication to treat their mental health conditions.²⁵

Constitutional right to correctional health care

Incarcerated individuals oftentimes need medical attention for ailments, injuries, and diseases. However, there can be misconceptions about an incarcerated individual's medical rights among physicians, medical administrators, prison and jail staff, and law enforcement officials. There have been several landmark rulings regarding health care and incarceration. Two of the major cases are *Estelle v. Gamble*, (1976) and *Farmer v. Brennan*, (1994).^{15,16} In *Estelle*, the U.S. Supreme Court held that failure to provide adequate medical care to incarcerated people as a result of deliberate indifference violates the Eighth Amendment's prohibition against cruel and unusual punishment.⁵ The Supreme Court's decision in *Farmer* held that a prison official's deliberate indifference to a substantial risk to a prisoner violated the Eighth Amendment and resulted in cruel and unusual punishment.⁶ These two cases provide guidance regarding the legal standards for access to health care and deliberate indifference under the Eighth Amendment, but did not define the minimum standards of for medical care in prisons and jails, or a prisoner-patient's rights in medical decision-making.^{5,6} In practice, the standard for establishing an Eighth Amendment violation is very challenging to meet. Federal courts have stated that to constitute deliberate indifference, "treatment must be so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness."¹⁷

Clinical best practices

Best practices and management of medical conditions among hospitalized patients who are incarcerated or interact with law enforcement is limited and primarily focuses on the care of pregnant individuals. This demonstrates the need to create evidence-based guidelines in the acute care setting for individuals who are incarcerated or who interact with law enforcement, and these guidelines should balance the rights of the patient, the needs of the clinician, and the safety of the institution and law enforcement. Multiple agencies at federal, state, and local levels possess authority over correctional health care. The Federal Bureau of Prisons (BOP) oversees the provision of medical, dental, and mental health services in federal prisons. The vast majority of the incarcerated, however, are held in state prisons and county jails, where standards vary by state and by county. Some facilities are accredited by private organizations, but this accreditation process remains entirely voluntary, leaving the correctional health care system without a uniform set of standards.

National Commission on Correctional Health Care (NCCHC)

Several professional organizations, including the American Medical Association, the American Public Health Association, and later, the National Commission on Correctional Health Care (NCCHC), have since established national standards for correctional health care.²⁷ NCCHC's origins date to the early 1970s, when an American Medical Association study of jails found inadequate, disorganized health services and a lack of national standards. In collaboration with other organizations, the AMA established a program that in 1983 became the NCCHC, an independent, 501(c)(3) nonprofit organization.¹⁸ Forty years later, NCCHC remains dedicated to improving correctional health care quality. This is done by establishing rigorous standards for health services in correctional facilities, operating a voluntary accreditation program for institutions that meet those standards, offering certification for correctional health professionals, conducting educational conferences and webinars, and producing industry-specific publications and other resources.¹⁸

NCCHC's standards have provided uniquely valuable guidance to help correctional health professionals and administrators improve the health of their incarcerated populations (and the communities to which they return), increase efficiency of health services delivery, strengthen organizational effectiveness, and reduce the risk of adverse legal judgments.¹⁸ Established by health, mental health, legal, and corrections professions, NCCHC's

standards cover the areas of patient care and treatment, governance and administration, personnel and training, safety and disease prevention, special needs and services, and medical-legal issues.¹⁸ The NCCHC is impartial, unbiased, and dedicated only to recognizing and fostering quality in correctional health care. NCCHC is the only accrediting body authorized by the Substance Abuse and Mental Health Services Administration that focuses on corrections.¹⁸

Medicaid Inmate Exclusion Policy

The Medicaid Inmate Exclusion Policy, established in the 1965 Social Security Amendments, almost completely prohibits the use of federal Medicaid funding to care for incarcerated patients. As a result, there is no incentive for correctional facilities that seek accreditation, and voluntary accreditation rates remain low.¹⁹ Facilities often cite staff shortages and monetary and time costs as barriers to accreditation.²⁰ CMS has approved a first-of-its-kind Section 1115 demonstration amendment allowing Medicaid to fund limited services for people incarcerated in California state prisons, jails, and juvenile detention centers up to 90 days before their release.²¹ Under the amendment, the state will seek to increase coverage, continuity of care, and service uptake in carceral settings. Ten other states have applied for similar waivers, and bills in Congress seek to provide a pathway to Medicaid coverage for all incarcerated individuals approaching release.

Health care privacy

The year 1996, marked the enactment of the Health Insurance Portability and Accountability Act (HIPAA) which would later be amended to provide clear guidelines regarding the privacy of a patient's medical records.¹ A main purpose of the Act was the protection of patient health information (PHI) when it was electronically received, handled or shared among health care-related agencies and individuals. HIPAA specifies that certain entities that engaged in those processes are "covered entities."²² In general, a covered entity is defined as an agency that 1) electronically transmits health care information for the purpose of reporting; 2) requests to review PHI in order to secure authorization for the care of patients; and 3) electronically transmits PHI for the benefit of payment and claims from a public or private entity.²³ However, there is confusion regarding the privacy rights of incarcerated patients that needed clarification.

The unique circumstances of incarceration required a separate section under the Act. That section, titled "Correctional institutions and other law enforcement custodial situations," addresses permitted disclosures of PHI for prisoners.²⁴ The language in the section is very broad to permit disclosure in many circumstances. Covered entities may disclose the PHI of inmates without their authorization to correctional institutions or law enforcement officials who have lawful custody of an inmate for the purpose of providing health care to the inmate or for the health and safety of the inmate, other inmates, the officers and employees of the institution and others at the facility, and those responsible for inmate transfer.²⁵ Covered entities may also disclose the PHI of inmates without authorization for law enforcement purposes on the premises of an institution and for the administration and maintenance of the safety, security, and good order of the institution.⁹ These provisions apply only to the release of the PHI of current inmates.⁹

Situations where information may be released include:

- Court-Ordered Subpoenas, Warrants, or Summons: A hospital may release patient information in response to a warrant or subpoena issued or ordered by a court, or a summons issued by a judicial officer. The hospital may disclose only that information specifically described in the subpoena, warrant, or summons.¹⁷
- Grand Jury Subpoenas: A hospital also may disclose patient information in response to a subpoena issued by a grand jury. Only information specifically described in the subpoena may be disclosed.¹⁷
- Administrative Requests, Subpoenas, or Summons: An administrative request, subpoena, or summons is one that is issued by a federal or state agency or law enforcement official, rather than a court of law.¹⁷
- Disclosures for Identification and Location Purposes: In response to a request by a law enforcement official, a hospital may release certain limited information to the official for purposes of identification and location of a suspect, fugitive, material witness, or missing person.¹⁷
- Victims of a Crime: In response to a request by a law enforcement official, a hospital may disclose information to the official about a patient who may have been the victim of a crime, if the patient agrees to the disclosure. Such agreement may be oral but should be documented.¹⁷

- Custodial Situations: A hospital may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual information about such inmate or individual if the institution or official represents that such information is necessary for the health and safety of the individual.¹⁷

When inmates are released, they have the same privacy rights under HIPAA as all other individuals. Additionally, exclusions exist for safely transporting prisoners to and from medical facilities. Further, HIPAA also includes provisions regarding inmates' ability to exercise protections otherwise granted in the rule. Inmates are excluded from the right to receive notice of possible uses and disclosures of PHI and of their rights and a covered entity's duties with respect to PHI. HIPAA's notice requirement does not apply at all to correctional institutions that qualify as covered entities.²⁶ Inmates have no right to notice regarding PHI created during incarceration, and correctional institutions are not required to send notices to inmates after release.

Medical Decision-Making

All patients, including people who are incarcerated, have the right to make their own health care decisions, including the right to refuse medical care. They also have the right to designate who should make their medical decisions if they become incompetent or incapacitated.²⁷ All patients and their appointed surrogate medical decision-makers, have the right to be properly informed of medical conditions, prognosis, diagnosis, risk and treatment alternatives through the process of informed consent. Wardens, guards, sheriffs, and police officers are not court-appointed legal guardians and therefore cannot make medical decisions on behalf of incarcerated patients.¹²

Incarcerated individuals can appoint a surrogate medical decision-maker through a written advance directive, medical power of attorney, or an oral order.¹² Upon intake into a prison or jail, the incarcerated individual should be asked to list a medical decision-maker. If not asked by officials, the individual can request that such a decision-maker be listed in their medical records.¹² Physicians and medical staff have an ethical and legal duty to adhere to the patient's decisions, including through a surrogate decision-maker. Often, there is a misunderstanding among health care professionals, jail and prison administrators, and law enforcement officials that health care decisions can be made by wardens, sheriffs, guards, or police officers if an incarcerated patient is incapacitated. Under medical ethics and most state laws, those officials do not have medical decision-making authority for incapacitated prisoners. An area of frequent confusion in medical decision-making for people who are incarcerated involves a legally eligible or appointed surrogate decision-maker that is neither known and/or available.²⁸ This can be problematic when people are experiencing housing insecurity or are under the influence of drugs or alcohol when arrested. In cases when doctors and corrections officials do not know a legally eligible or appointed medical decision-maker, states have codified the legal hierarchy of medical-decision making through various statutes.¹³ Many states recognize that medical decisions for an incapacitated patient, without an appointed medical surrogate or proxy, should be made on a familial basis. If a legal appointed medical decision-maker cannot be located, then a court must appoint one on behalf of the patient through the legal guardianship process.

In the event of a medical emergency, any contact, advance directive or guardianship information that corrections or law enforcement officials have for a prisoner-patient should be given to medical staff at the prison or jail infirmary or local hospital.²⁹ Prison and law enforcement officials must refrain from making medical treatment decisions on behalf of incarcerated patients, and doctors must refrain from following treatment decisions made by such officials. It may even be necessary for the hospital to use various means to attempt to determine the medical decision-maker if no information is available from the patient, such as requesting their prison or jail medical records or intake information.¹⁴ Regardless, physicians cannot delegate to prison and law enforcement officials a prisoner-patient's medical decision-making authority. Those officials can make recommendations regarding the safety of patients or physicians either in the prison or jail infirmary or local hospital, but such recommendations should not interfere with the patient's treatment protocol.¹⁴ If information is not available through an advance directive, appointed decision-making surrogate or lineage, the healthcare staff will have to default to the best medical interest standard for the prisoner-patient's care.

Forcible Medical Procedures

Several alarming cases of forced medical procedures performed on prisoners, in the form of surgery or body cavity searches, have been reported. In *Sanchez v. Pereira-Costillo*, the First Circuit Court of Appeals agreed with the plaintiff, that a surgical procedure conducted by doctors at the direction of corrections officials in Puerto Rico had

violated his rights.³⁰ Prison staff thought that the plaintiff had a cell phone hidden in his rectum. Despite X-rays and bowel movements indicating there was no phone, staff at the Río Piedras Medical Center performed exploratory surgery at the request of prison officials. The Court of Appeals noted in its opinion that “the exploratory surgery of his abdomen” violated the plaintiff’s rights under the Fourth Amendment.¹⁵ Furthermore, one issue that affects prisoners with respect to forced treatment, involuntary body cavity searches and medical decision-making is a doctor’s dual loyalties, which can be problematic in correctional health care.³¹ Physicians may work as employees or contractors at prisons and jails, and sometimes have conflicts of interest between their patients and employer.

Shackling

Shackling refers to a form of restraint using a physical or mechanical device to control the movement of an incarcerated individual’s body or limbs.³² It has been highlighted those conditions in which the limitations are imposed by shackling, such as the increased risk of thrombosis from reduced mobility, or related to the shackle itself could predispose patients to unnecessary harm.^{31,33} In addition to physical harm or discomfort, one study demonstrated that patient shackling was negatively associated with health care professional empathy toward patients who were incarcerated.³⁴ In the United States, particular attention has been focused on the shackling of incarcerated pregnant persons. The FIRST STEP Act of 2018 banned shackling of pregnant women in federal custody from the date on which pregnancy is confirmed until their postpartum recovery.³⁵ The majority of women, however, are incarcerated in state prisons.³⁶ Currently, 22 states and the District of Columbia prohibit or limit shackling of pregnant women. States vary in legislation, with some banning shackles during transport, childbirth, and postpartum, whereas other states ban shackles only during labor and birth.³⁷

Shackling policies for patients in custody should be differentiated from hospital restraint policies for patients who are agitated or combative. Since shackles are often placed for nonmedical reasons, the treating clinician should determine whether appropriate care can be delivered with shackles in place.³⁸ Custody officials are then responsible for determining an alternative manner to safely secure, or not secure, a patient who is incarcerated that allows for standards of medical care to be met.

Discharge Prescribing

Physicians may also be concerned that medications prescribed on discharge will be misused by patients in the correctional system, causing physicians to restrict or reconsider certain classes of medication in the hospital or on discharge.³⁹ Commonly diverted medications in the correctional setting include opioids, benzodiazepines, stimulants, antipsychotics, and γ -aminobutyric acid agonists.⁴⁰ A study of incarcerated individuals found that 51.5 percent of participants reported using illicit substances during incarceration, most commonly alcohol (35 percent) and cannabis (37.9 percent), followed by narcotics (14.6 percent).⁴¹ A variety of psychotropic medications are also misused in the correctional setting, although prescription medications lag behind more common substances, such as alcohol and cannabis. Another study examining opioid agonist therapies at a large jail, found that the medications for only 6 percent of patients were discontinued during a month because of diversion concerns.⁴² Further, there is no evidence that rates of diversion are increased among patients who are incarcerated relative to those in a community setting, and the monitored correctional environment may provide a safer setting for medications with diversion risk.⁴³

EXISTING AMA POLICY

AMA policy D-430.997 “Support for Health Care Services to Incarcerated Persons” supports NCCHC standards that improve the quality of health care services, including mental health services, delivered to the nation’s correctional facilities; encourages all correctional systems to support NCCHC accreditation; and encourages the NCCHC and its AMA representative to work with departments of corrections and public officials to find cost effective and efficient methods to increase correctional health services funding. This policy also calls on the AMA to work with an accrediting organization, such as NCCHC in developing a strategy to accredit all correctional, detention and juvenile facilities and will advocate that all correctional, detention and juvenile facilities be accredited by the NCCHC no later than 2025.

AMA policy H-315.975 “Police, Payer, and Government Access to Patient Health Information” advocates for protection of PHI but notably advocates “with respect to the final privacy rule or other privacy legislation that no government agency, including law enforcement agencies, be permitted access to medical records or individually identifiable health information (except for any discretionary or mandatory disclosures made by physicians and other health care providers pursuant to ethical guidelines or to comply with applicable state or federal reporting laws) without the express written consent of the patient, or a court order or warrant permitting such access.”

Further, AMA policy H-430.980 “Compassionate Release for Incarcerated Patients” supports policies that facilitate compassionate release for incarcerated patients based on serious medical conditions and advanced age. The Board of Trustees previously presented a report to the House of Delegates on compassionate release for incarcerated individuals.⁴⁴

CONCLUSION

The U.S. has the highest incarceration rate in the world. Compared to the general population, individuals with a history of incarceration are in worse mental and physical health. Incarcerated individuals typically have high rates of psychiatric conditions, communicable diseases, substance use disorders, and chronic diseases. The U.S. Supreme Court has indicated that failure to provide adequate medical care to incarcerated people as a result of deliberate indifference violates the Eighth Amendment’s prohibition against cruel and unusual punishment. However, in practice, federal courts have stated that to constitute “deliberate indifference,” treatment must be so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness.

The principles of privacy and confidentiality apply to all patients, including those who are incarcerated. HIPAA also equally applies to incarcerated individuals unless PHI disclosure is necessary for the provision of health care or safety of the patient, or other individuals in the facility.⁸ Hospital security policies may contravene this principle of confidentiality. The policy at many institutions requires that officers be permitted to always remain with a patient in custody, and although it is suggested that conversations be conducted out of hearing range, the officers must be allowed to remain within direct sight of the patient.⁴⁵

Information on best practices and management of medical conditions among hospitalized patients who are incarcerated or interact with law enforcement is limited and primarily focuses on the care of pregnant individuals. NCCHC remains the only national organization dedicated solely to improving correctional health care quality. This is done by establishing rigorous standards for health services in correctional facilities, operating a voluntary accreditation program for institutions that meet those standards, offering certification for correctional health professionals, conducting educational conferences and webinars, and producing industry-specific publications and other resources. AMA policy supports NCCHC standards. However, there is a need to incentivize correctional facilities to pursue accreditation.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted, and the remainder of the report be filed.

1. That our AMA amend policy D-430.993, “Study of Best Practices for Acute Care of Patients in the Custody of Law Enforcement or Corrections” to read as follows:

~~1. Our AMA will study best practices for interactions between hospitals, other acute care facilities, clinicians, and members of law enforcement or correctional agencies to ensure that patients in custody of such law enforcement or correctional agencies (including patients without decision-making capacity), their surrogates, and the clinicians caring for them are provided the autonomy and privacy protections afforded to them by law and in concordance with professional ethical standards and report its findings to the AMA House of Delegates by the 2023 Annual Meeting.~~

1. Our AMA supports the development of: (1) best practices for acute care of patients in the custody of law enforcement or corrections. (2) clearly defined and consistently implemented processes between health care professionals and law enforcement that (a) can best protect patient confidentiality, privacy, and dignity while meeting the needs of patients, health professionals, and law enforcement and (b) ensures security measures do not interfere with the capacity to provide medical, mental health, pregnancy, end of life care, palliative care, and substance use care, especially in emergency situations.

and (3) if conflict arises during an incarcerated individual's hospitalization that the hospital's bioethics committee should convene to address the issue and not a law enforcement liaison

2. That our AMA affirms that: (1) the adoption of best practices in the acute care of patients in the custody of law enforcement or corrections is an important effort in achieving overall health equity for the U.S. as a whole, and (2) it is the responsibility of the medical staff to ensure quality and safe delivery of care for incarcerated patients.
3. That our AMA reaffirm Policy D-430.997 "Support for Health Care Services to Incarcerated Persons" and Policy H-420.957 "Shackling of Pregnant Women in Labor."
4. That our AMA supports universal coverage of essential health benefits for all individuals in the custody of law enforcement or corrections and who are incarcerated.
5. That our AMA work with interested parties, including but not limited to, the American College of Emergency Physicians and the American College of Correctional Physicians, to develop model federal legislation requiring health care facilities to inform patients in custody about their rights as a patient under applicable federal and state law.

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7. SUPPORT REMOVAL OF BMI AS A STANDARD MEASURE IN MEDICINE AND RECOGNIZING CULTURALLY-DIVERSE AND VARIED PRESENTATIONS OF EATING DISORDERS AND INDICATIONS FOR METABOLIC AND BARIATRIC SURGERY

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policies H-150.965, H-440.866 and H-440.880

Resolution 407-A-22, referred by the House of Delegates (HOD), asked that our American Medical Association (AMA):

recognize the significant limitations and potential harms associated with the widespread use of body mass index (BMI) in clinical settings and supports its use only in a limited screening capacity when used in conjunction with other more valid measures of health and wellness; and

support the use of validated, easily obtained alternatives to BMI (such as relative fat mass, body adiposity index, and the body volume index) for estimating risk of weight-related disease; and

amend policy H-440.866, “The Clinical Utility of Measuring Body Mass Index and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity,” by addition and deletion to read as follows:

The Clinical Utility of Measuring Body Mass Index Weight, Adiposity, and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity, H-440.866

Our AMA supports:

(1) greater emphasis in physician educational programs on the risk differences ~~among ethnic and age~~ within and between demographic groups at varying weights and levels of adiposity ~~BMI~~ and the importance of monitoring waist circumference in all individuals ~~with BMIs below 35 kg/m²~~;

(2) additional research on the efficacy of screening for overweight and obesity, using different indicators, in improving various clinical outcomes across populations, including morbidity, mortality, mental health, and prevention of further weight gain; and

(3) more research on the efficacy of screening and interventions by physicians to promote healthy lifestyle behaviors, including healthy diets and regular physical activity, in all of their patients to improve health and minimize disease risks. (Modify Current HOD Policy); and

amend policy H-150.965, by addition to read as follows in order to support increased recognition of disordered eating behaviors in minority populations and culturally appropriate interventions:

H-150.965 – Eating Disorders

The AMA (1) adopts the position that overemphasis of bodily thinness is as deleterious to one’s physical and mental health as obesity; (2) asks its members to help their patients avoid obsessions with dieting and to develop balanced, individualized approaches to finding the body weight that is best for each of them; (3) encourages training of all school-based physicians, counselors, coaches, trainers, teachers and nurses to recognize unhealthy eating, binge-eating, dieting, and weight restrictive behaviors in adolescents and to offer education and appropriate referral of adolescents and their families for culturally-informed interventional counseling; and (4) participates in this effort by consulting with appropriate and culturally informed educational and counseling materials pertaining to unhealthy eating, binge-eating, dieting, and weight restrictive behaviors. (Modify Current HOD Policy)

While this report was in development, the HOD also referred Resolution 937-I-22, “Indications for Metabolic and Bariatric Surgery” for consideration within this report. That resolution asked that our AMA:

acknowledge and accept the new American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders indications for metabolic and bariatric surgery; immediately call for full acceptance of these guidelines by insurance providers, hospital systems, policy makers, and government healthcare delivery entities; and work with all interested parties to lobby the legislative and executive branches of government to affect public health insurance coverage to ensure alignment with these new guidelines.

BACKGROUND

Body mass index (BMI) is the ratio of weight to height, calculated as weight (kg)/height (m²), or weight (lb)/height (in²) multiplied by 703.¹ BMI is easy to measure, is inexpensive, has standardized cutoff points for overweight and obesity, and is strongly correlated with body fat levels as measured by the most accurate methods. However, BMI is an indirect and imperfect measurement as it does not distinguish between body fat and lean body mass. It is not as accurate of a predictor of body fat in the elderly and at the same BMI women on average have more body fat than men and Asians have more body fat than whites.¹ Further, when combined with measuring waist circumference, patients may be screened for possible health risks that come with being overweight and having obesity. If most of the fat is around the waist rather than at the hips, an individual is at a higher risk for heart disease and type 2 diabetes.¹ This risk goes up with a waist size that is greater than 35 inches for women or greater than 40 inches for men.

BMI is used because it is an inexpensive and easy tool. Research has shown that BMI is strongly correlated with the gold-standard method for measuring body fat known as dual-energy x-ray absorptiometry (DXA), and it is an easy way for clinicians to screen who might be at greater risk of health problems due to their weight.² Other methods to measure body fat include skinfold thickness measurements (with calipers), underwater weighing, bioelectrical impedance, and isotope dilution.² However, these methods are not always readily available, and they are either expensive or need to be conducted by highly trained personnel. Furthermore, many of these methods can be difficult to standardize across observers or machines, complicating comparisons across studies and time periods.

BMI is just one of several considerations to help determine a more specific and individualized course of action for patients. Some researchers are advocating for a new kind of classification system based on the concept of Adiposity-Based Chronic Disease (ABCD) — focusing more on the health issues associated with obesity rather than body size alone.³ The diagnostic term reflects both the pathophysiology and clinical impact of obesity as a chronic disease. The proposed coding system has four domains: pathophysiology, body mass index (BMI) classification, complications, and complication severity; and incorporates disease staging, specific complications that impact health, the basis for clinical intervention, individualized treatment goals and a personalized medicine approach.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms “Body Mass Index (BMI),” “alternatives to BMI,” “BMI and Eating Disorders,” “Bariatric Surgery,” and “BMI AND culturally diverse.” Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies; applicable organizations were also reviewed for relevant information.

DISCUSSION

Prevalence of obesity in the U.S.

In 2021, the CDC Adult Obesity Prevalence Map shows that obesity remains high. Nineteen states and two territories currently have an obesity prevalence at or above 35 percent, more than doubling from 2018.⁴ Adults with obesity are at increased risk for many other serious health conditions such as heart disease, stroke, type 2 diabetes, some cancers, and poorer mental health. Obesity also disproportionately impacts some racial and ethnic minority groups.⁴ Non-Hispanic Black adults had the highest prevalence of self-reported obesity (41.7 percent), followed by

non-Hispanic American Indian or Alaska Native adults (38.4 percent), Hispanic adults (36.1 percent), non-Hispanic White adults (31.0 percent), and non-Hispanic Asian adults (11.7 percent).⁴

Childhood obesity is a serious problem in the United States that puts children and adolescents at risk for poor health outcomes. From 2017-2020, the prevalence of obesity was 19.7 percent and affected about 14.7 million children and adolescents.⁵ Obesity prevalence was 12.7 percent among 2- to 5-year-olds, 20.7 percent among 6- to 11-year-olds, and 22.2 percent among 12- to 19-year-olds. Obesity prevalence was 26.2 percent among Hispanic children, 24.8 percent among non-Hispanic Black children, 16.6 percent among non-Hispanic White children, and 9.0 percent among non-Hispanic Asian children.⁵ Obesity-related conditions include high blood pressure, high cholesterol, type 2 diabetes, breathing problems such as asthma and sleep apnea, and joint problems.⁵

History of measures to calculate body weight (Body Build Index)

The concept of body fat as a major population-based medical issue gained popularity only shortly before 1900. Life insurance data accumulated at that time and subsequently indicated that body weight, adjusted for height (Wt/Ht), was an independent determinant of life expectancy, and in 1910, the effects of being overweight were noted to be greater for younger people than for the elderly.⁶ The Metropolitan Life Insurance Company in 1959 published tables of average body weights for heights (Wt/Ht), also known as body build, by gender and at different ages.⁷ This was based on data from 1935 to 1953 from more than 4 million adults, mostly men, insured by 26 different insurance companies. The risk for development of certain diseases as well as mortality data related to Wt/Ht differences also were analyzed and reported in the 1960 Statistical Bulletin of the Metropolitan Life Insurance Co.⁸

The Wt/Ht tables were used for many years as a reference for population-based studies. If a person's Wt/Ht was 20 percent above or below the mean for that height category, they were considered to be overweight or underweight, respectively.¹⁴ The insurance data also indicated the ratios of weights for heights at which mortality was lowest in adults. The latter was referred to as the "ideal" or later the "desirable" weight. From 1959 to 1983, the weight/height representing the lowest mortality had increased.^{9,10} However, a "desirable body" weight for height was invariably lower than the average weight for height in the insured population.^{15,16}

Challenges with the wt/ht (body build) index

Early on it was recognized that taller people had a lower death rate than shorter people with the same Wt/Ht ratio.¹¹ It also was recognized that a person's height in general and leg length could affect the calculated body mass adjusted for height. A person's bone mass could also affect the interpretation of this ratio. In general, it reflected whether one was narrowly or broadly built. Thus, efforts were made to eliminate lower limb length and frame size as variables.¹³ The strategy was to develop representations of body build, that is, charts of weight/height that were independent of these variables. The overall goal was to have the same distribution of Wt/Ht at each level of height.

Although not stated, the implicit goal in developing these tables was to define a person's fat mass as a proportion of their total mass, irrespective of their height or frame size.¹² Efforts were made to adjust for frame size (nonfat mass) by categorizing people as those with a small, medium, or large frame. Estimation of frame size was attempted using several measurements including shoulder width, elbow width, knee width, ankle width, and so on.¹³ None of these were widely adopted. Further, frame size based on elbow width was included in the Metropolitan Life weight/height tables, even though it was never validated.¹³

Adoption of the BMI as an index of obesity

In 1972, the validity of Metropolitan Life Insurance published data was criticized.¹⁴ Critics supported the use of the better documented weight for height data, which then popularized what is known as the Quetelet Index. The Quetelet Index was later known as an individual's body mass index (BMI). However, it was noted that even BMI rather poorly represents a person's percent of body fat.²⁰ Despite all the criticisms, the Metropolitan Life Tables criteria for defining obesity were widely used in the United States until the early 1990s.^{15,16} At about that time, the World Health Organization (WHO) classification of body weight for height, based on the BMI, was published, and later it was widely adopted.^{17,18} The distribution of BMIs in adult American men and women was determined in 1923 in 1026 individuals.¹⁹ The median BMI was 24, but the mean BMI was 25. The distribution curve indicated a skewing toward an increase in BMI, and this trend has continued.²⁴

WHO and the categorization of BMIs into quartiles

In 1993, the WHO assembled an Expert Consultation Group with a charge of developing uniform categories of the BMI. The results were published as a technical report in 1995.²⁰ Four categories were established: underweight, normal, overweight, and obese. An individual would be considered underweight if their BMI was in the range of 15 to 19.9, normal weight if the BMI was 20 to 24.9, overweight if the BMI was 25 to 29.9, and obese if it was 30 to 35 or greater.²⁶

At the time that the WHO classification was published, the National Institutes of Health (NIH) in the United States classified people with a BMI of 27.8 (men) and 27.3 (women) or greater as being overweight. If they were below this BMI, they were considered to be “normal.” This was based on an 85 percent cutoff point of people examined in the National Health and Nutrition Examination Study (NHANES) II.²¹ Subsequently, in 1998, the cutoff point between normal and overweight was reduced to a BMI of 25 to bring it into line with the 4 categories in the WHO guidelines.²² This then changed the categorization of millions of Americans from being “normal weight” to being “overweight.”

In Western population-based studies, the mean or median BMI was about 24 to 27.^{23,24} Therefore, the consequence of adopting the WHO classification resulted in approximately 50 percent or more of the general adult population being classified as overweight and obese. Indeed, the term “overweight” or particularly “preobesity” is prejudicial since people in this category were a major part of the expected normal distribution of BMI in the general population.

Advantages of BMI

A significant advantage of BMI is the availability of extensive national reference data and its established relationships with levels of body fatness, morbidity, and mortality in adults.²⁶ BMI is particularly useful in monitoring the treatment of obesity, with a weight change of about 3.5 kg needed to produce a unit change in BMI. In adults, BMI levels above 25 are associated with an increased risk of morbidity and mortality, with BMI levels of 30 and greater indicating obesity.²⁵ In children, BMI is not a straightforward index because of growth. However, high BMI percentile levels based on Centers for Disease Control and Prevention (CDC) BMI growth charts and changes in parameters of BMI curves in children are linked to significant levels of risk for adult obesity at corresponding high percentile levels.²⁶ Further, BMI is readily available, inexpensive, can be administered easily, and is understood easily by patients.²⁷ BMI can also be used as an initial screening tool to identify those at an elevated health risk because of excess body weight and poor distribution of fat mass.

Disadvantages of BMI

BMI as a determinant of body fat mass. BMI does not differentiate between body lean mass and body fat mass; a person can have a high BMI but still have a very low-fat mass and vice versa.^{28,29} From an anatomical and metabolic perspective, it has been proposed that the term obesity should refer to an excessive accumulation of body fat (triacylglycerols). The accuracy of the BMI as a determinant of body fat mass has been repeatedly questioned because it has limitations in this regard.^{30,31} Gender, age, ethnicity, and leg length are important variables not considered by BMI.^{32,33} It should also be noted that in population-based studies women generally have a BMI that is lower than that in men, even though their fat mass relative to their body build or BMI is considerably greater.

The relatively poor correlation between percent of body fat mass and BMI has been shown more recently in the NHANES III database in which bioelectrical impedance was used to estimate the fat component of body composition.³⁹ In subjects with a BMI of 25 kg/m², the percent of body fat in men varied between 14 percent and 35 percent, and in women it varied between 26 percent and 43 percent. Therefore, using the NIH criteria based on percent of body fat to define obesity, subjects with a BMI of 25, a group that would be considered “normal,” were associated with a body fat mass that varied between “low normal” to “obese.”

In addition, a recent study in individuals with or without diabetes in which the loss of lean body mass with aging was reported, the mean BMI in those without diabetes was 26.8. In those with diabetes, the BMI was 29.1. However, the percent of lean body mass was the same and therefore the increased BMI in those with diabetes was not due only to an excessive accumulation of fat.³⁴ Overall, although the correlation between the BMI and body fatness is strong, two people might have the same BMI, but the level of body fatness may differ.³⁵ Some examples of this include:

- Women tend to have more body fat than men,

- The amount of body fat may be higher or lower depending on the racial/ethnic group,³⁶
- Older people, on average, tend to have more body fat than younger adults, and
- Athletes have less body fat than do non-athletes.

BMI does not account for body fat location. BMI does not capture body fat location information, which is an important variable in assessing the metabolic as well as mortality consequences of excessive fat accumulation. This was first recognized in France by Dr Jon Vague in the 1940-1950s.³⁷ He noted that accumulation of fat in the upper part of the body versus the lower part of the body was associated with an increased risk for coronary heart disease, diabetes, and also gallstones and gout. Men tend to accumulate fat in the abdominal (upper body) area, whereas women tend to accumulate it in the peripelvic (gluteal) area and the thighs. A substitute for this information has been to determine the abdominal circumference or an abdominal/hip circumference ratio. Subsequent data indicate that the risk for development of diabetes as well as coronary heart disease, is more strongly related to the accumulation of upper body fat than lower body fat in both sexes.³⁸

More specifically, both visceral fat accumulation and an expanded girth have been associated with development of insulin resistance, diabetes, and risk for coronary heart disease and hypertension.³⁹ Accumulation of fat in the abdominal area appears to correlate best with triacylglycerols accumulating in the liver and skeletal muscle. Further, the relatively small accumulation of fat in these organs would not be detectable by BMI determinations, and they do not correlate with total body fat mass.⁴⁰

BMI does not account for the life cycle and location of accumulated fat caused by hormones. Girls tend to accumulate relatively large amounts of fat during and after puberty, particularly in the peripelvic and thigh region; boys do not. During and after puberty, boys accumulate a relatively large amount of lean mass (bone and muscle) but not fat mass. In both sexes, these changes are reflected in an increased BMI. With aging, both sexes tend to develop fat in the upper part of the body.⁴¹ The reason for these changes in amount and distribution is not completely understood. Generally, it is considered to be caused by hormonal changes. Further, a study noted BMI cutoffs fail to capture most postmenopausal women whose actual body fat percentage would classify them as obese.⁴² As women age, they tend to lose bone and muscle mass, which are heavier than fat. So even if a 65-year-old woman weighs the same as she did at 25 years of age, fat accounts for a larger share of her weight. The study suggested that to improve the sensitivity of BMI in identifying postmenopausal women at risk of obesity-related diseases, the obesity cutoff might need to be set to 24.9, which is currently the top of the normal BMI range for the general adult population.⁴²

BMI as a predictor of morbidity and mortality. The BMI classification system currently is being widely used in population-based studies to assess the risk for mortality in the different categories of BMI. Even when some comorbidities are considered, the correlation of mortality rates with BMI often does not take into consideration such factors as family history of diabetes, hypertension, coronary heart disease, metabolic syndrome, dyslipidemias, familial longevity or the family prevalence of carcinomas, and other genetic factors. For example, it has been reported that more than 50 percent of susceptibility to coronary artery disease is accounted for by genetic variants.⁴³

Frequently, when correlations are made, they also do not take into consideration a past as well as a current history of smoking, excessive alcohol use, serious and persistent mental illness or the duration of obesity, when in the life cycle it appeared, and whether the body weight is relatively stable or rapidly progressive. In most population-based studies, only the initial weight and/or BMI are given, even though weight as well as fat stores are known to increase and height to decrease with aging. In addition, the rate of weight gain varies among individuals, as does the loss of muscle mass.⁴⁴ Muscle mass has been correlated negatively with insulin resistance and prediabetes.⁴⁵ Lastly, population-based studies do not take into consideration the present and past history of a person's occupation, medication-induced obesity, and how comorbidities are being treated.

BMI does not appropriately represent racial and ethnic minorities. The rise in obesity prevalence rates has disproportionately affected U.S. minority populations. For example, one longitudinal study of healthy women found that at the same BMI, Asians had more than double the risk of developing type 2 diabetes than whites; Hispanics and blacks also had higher risks of diabetes than whites, but to a lesser degree.⁴⁶ Increases in weight over time were more harmful in Asians than in the other ethnic groups: For every 11 pounds Asians gained during adulthood, they had an 84 percent increase in their risk of type 2 diabetes; Hispanics, blacks, and whites who gained weight also had higher diabetes risks, but again, to a much lesser degree than Asians.⁴⁶ Several other studies have found that at the

same BMI, Asians have higher risks of hypertension and cardiovascular disease than their white European counterparts, and a higher risk of dying early from cardiovascular disease or any cause.^{47,48}

Researchers are still assessing why Asians have higher weight-related disease risks at lower BMIs. One possible explanation is body fat. When compared to white Europeans of the same BMI, Asians have 3 to 5 percent higher total body fat.⁴⁹ South Asians, in particular, have especially high levels of body fat and are more prone to developing abdominal obesity, which may account for their very high risk of type 2 diabetes and cardiovascular disease.⁵⁰ In contrast, some studies have found that blacks have lower body fat and higher lean muscle mass than whites at the same BMI, and therefore, at the same BMI, may be at lower risk of obesity-related diseases.⁵¹ While genetic differences may be at the root of these different body fat patterns in Asians and other ethnic groups, environmental factors seem to be a much stronger force. For example, research suggests that under-nutrition during fetal life, such as during the Chinese famine of 1954 to 1964, raises the risk of diabetes in adulthood, especially when individuals live in nutritionally rich environments later in life.⁵²

BMI AND EATING DISORDERS

Eating disorders are behavioral conditions characterized by severe and persistent disturbance in eating behaviors and associated distressing thoughts and emotion. Types of eating disorders include anorexia nervosa, bulimia nervosa, binge eating disorder, avoidant restrictive food intake disorder, other specified feeding and eating disorders, pica and rumination disorder. Eating disorders affect up to 5 percent of the population, and most often develop in adolescence and young adulthood.⁵³ Evidence suggests that genes and heritability also play a part in why some people are at higher risk for an eating disorder.⁵³

Anorexia nervosa is an eating disorder characterized by self-starvation and weight loss resulting in low weight for height and age.⁵³ BMI is used to diagnose an individual with anorexia nervosa and is determined by an individual having a BMI of 18.5 or less.⁵³ Although BMI is used to diagnose anorexia nervosa, BMI does not accurately capture individuals with bulimia nervosa. Individuals with bulimia nervosa can be slightly underweight, normal weight, overweight or even obese.⁵³ Further, BMI is inaccurate in capturing individuals with other specified feeding and eating disorders. These include eating disorders or disturbances of eating behavior that cause distress and impair family, social or work function but do not fit the other categories. In some cases, this is because the frequency of the behavior does not meet the diagnostic threshold (i.e., the frequency of binges in bulimia or binge eating disorder) or the weight criteria for the diagnosis of anorexia nervosa are not met.⁵³ An example of another specified feeding and eating disorder is "atypical anorexia nervosa". This category includes individuals who may have lost a lot of weight and whose behaviors and preoccupation with weight or shape concerns and fear of fatness is consistent with anorexia nervosa, but who are not yet considered underweight based on their BMI because their baseline weight was above average.⁵³ Therefore, utilizing BMI can lead to substandard treatment, typically due to the use of BMI by insurance companies to cover inpatient treatment.⁵⁴ Further, as mentioned above, BMI is an inaccurate measure of obesity especially in children and adolescents and can therefore hinder access to eating disorder treatments.⁴¹

OTHER DIAGNOSTIC MEASURES FOR DIAGNOSING OBESITY

Abdominal Circumference

Obesity is commonly associated with increased amounts of intra-abdominal fat. A centralized fat pattern is associated with the deposition of both intra-abdominal and subcutaneous abdominal adipose tissue.⁵⁵ It should be noted that abdominal circumference is an imperfect indicator of intra-abdominal adipose tissue, as it also includes subcutaneous fat deposition, as well as visceral adipose tissue. This does not preclude its usefulness, as it is associated with specific health risks.⁵⁶ Persons in the upper percentiles for abdominal circumference are considered to have obesity and at increased risk for morbidity, specifically type 2 diabetes and the metabolic syndrome, and mortality.⁵⁷ The ratio of abdominal circumference (often referred to incorrectly as "waist" circumference) to hip circumference is a rudimentary index for describing adipose tissue distribution or fat patterning.⁵⁸ Abdomen-to-hip ratios greater than 0.85 represent a centralized distribution of fat. Most men with a ratio greater than 1.0 and women with a ratio greater than 0.85 are at increased risk for cardiovascular disease, diabetes, and cancers.⁵⁹

Skinfold Measurement

Skinfold measurements are used to characterize subcutaneous fat thickness at various regions of the body, but it should be noted that they have limited utility in people who are considered overweight or have obesity. The primary limitation is that most skinfold calipers have an upper measurement limit of 45 to 55 mm, which restricts their use to subjects who are moderately overweight or thinner.² A few skinfold calipers take large measurements, but this is not a significant improvement because of the difficulty of grasping and holding a large skinfold while reading the caliper dial. The majority of national reference data available are for skinfolds at the triceps and subscapular locations. The triceps skinfold varies considerably by sex and can reflect changes in the underlying triceps muscle rather than an actual change in body fatness. The statistical relationships between skinfolds and percent or total body fat in children and adults are often not as strong as that of BMI.⁶⁰ Further, the upper distribution of subcutaneous fat measurements remains unknown because most children and adults who have obesity have not had their skinfolds measured.

Waist-to-hip Ratio

The waist-to-hip ratio is often considered a better measurement than waist circumference alone in predicting disease risk. To calculate the waist-to-hip ratio, a measuring tape is used to measure waist circumference and hip circumference at its widest part. Observational studies have demonstrated that people with “apple-shaped” bodies, (who carry more weight around the waist) have greater risks for chronic disease than those with “pear-shaped” bodies, (who carry more weight around the hips). A study with more than twenty-seven thousand participants from fifty-two countries concluded that the waist-to-hip ratio is highly correlated with heart attack risk worldwide and is a better predictor of heart attacks than BMI.⁶¹ Abdominal obesity is defined by the World Health Organization (WHO) as having a waist-to-hip ratio above 0.90 for males and above 0.85 for females.

Visceral Adiposity Index (VAI)

The Visceral Adiposity Index (VAI) is an empirical-mathematical model, gender-specific, based on simple anthropometric (BMI and WC) and functional parameters (triglycerides (TG) and HDL cholesterol (HDL)), and indicative of fat distribution and function.⁶² It is an empirical-mathematical model that does not originate from theoretical assumptions, but from observation in a healthy normal/overweight population of a linear relationship between BMI and CV, from which a linear equation has been extrapolated. The main strength to consider is that the VAI is an indicator of early cardiometabolic risk in all borderline conditions in which overt metabolic syndrome is not present. This is explained by the fact that three of the variables making up the VAI (WC, TG, and HDL) are all expressed in the criteria for metabolic syndrome. An important limitation to consider is the application of the VAI in non-Caucasian populations and in patients aged less than 16 years.⁵⁸ This is because the mathematical modelling process was done on healthy Caucasian men and women, aged between 19 and 83 years.⁵⁸ A study which evaluated the VAI in children, found that the VAI should be extrapolated with caution in this age range.⁶³ Therefore, VAI is a useful measurement in the following populations: healthy or apparently healthy population with BMI < 40 kg/m², patients with one or two of the 5 components of the metabolic syndrome, women with PCOS, and patients with endocrine disorders (i.e., acromegaly, adult GH deficiency, hypogonadism, hyperprolactinemia, or abnormal thyroid function).⁵⁸

Relative Fat Mass (RFM)

Relative fat mass (RFM) is a simple linear equation based on height-to-waist ratio, and has promise as a potential alternative tool to estimate whole-body fat percentage in women and men 20 years of age and older. One study performed using nationally representative samples of the US adult population which allowed evaluation of the performance of RFM among Mexican Americans, European Americans, and African Americans.⁶⁴ The performance of RFM to estimate body fat percentage was overall more consistent than that of BMI among women and men, across ethnic groups, young, middle-age and older adults, and across quintiles of body fat percentage, although the accuracy of RFM was lower among individuals with lower body fatness.⁶⁰

Hydrostatic weighing (densitometry)

Hydrostatic weighing (underwater weighing), or densitometry, is the difference of the body weight in air and water is used to compute the body’s density.⁶⁵ Assuming a two-component model with different densities for fat mass and

fat-free mass and correcting for the air volume in the lungs, the total body fat percentage can be estimated. This technique, however, cannot give any measurements of the distribution of adipose tissue or lean tissue (LT).

Air displacement plethysmography (ADP)

ADP, also known under its commercial brand name as BOD POD, measures the overall body density, total body fat and lean tissue but not their distributions.⁶⁶ By putting the body in an enclosed chamber and changing the chamber's volume, the volume of the displaced air (i.e., the volume of the body) can be determined from the changes in air pressure.⁶⁰ Since ADP is based on the same two-component model as hydrostatic weighing, it is also affected by the same confounders, mainly variations in bone mineral content and hydration. Therefore, ADP, as well as hydrostatic weighing, is limited to gross body composition analysis, and not estimates of regional fat or muscles.

Bioelectrical impedance analysis (BIA)

BIA uses the electrical properties of the body to estimate the total body weight and from that the body fat mass.⁶⁷ The body is modeled as five cylindrical lean tissue compartments; the trunk and the four limbs, while fat is considered to be an insulator. The impedance is assumed to be proportional to the height and inversely proportional to the cross-sectional area of each compartment. BIA requires different model parameters to be used depending on age, gender, level of physical activity, amount of body fat, and ethnicity in order to be reliable.⁶⁸

Dual-energy X-ray absorptiometry (DXA)

DXA is a two-dimensional imaging technique that uses X-rays with two different energies. By using two different energy levels, the images can be separated into two components (i.e., bone and soft tissue). DXA is mainly used for bone mineral density measurements, where it is considered as the gold standard, but it can also be used to estimate total and regional body fat and lean tissue mass.⁶⁹ DXA has been found to be more accurate than density-based methods for estimating total body fat.⁷⁰ Due to its ability to estimate regional fat and measure lean tissue, in combination with relatively high availability, DXA has been used for body composition analysis in a wide range of clinical applications and is considered the gold standard for measuring body fat.⁷¹

Computed Tomography (CT) Scan

CT gives a three-dimensional high-resolution image volume of the complete or selected parts of the body, computed from a large number of X-ray projections of the body from different angles. As opposed to the previously described techniques, CT can accurately determine fat in skeletal muscle tissue and in the liver.⁷² In practice, however, CT-based body composition analysis is in most cases limited to two-dimensional analysis of one or a limited number of axial slices of the body. This approach, however, limits its precision since the exact locations of slices, in relation to internal organs, cannot be determined and will vary between scans. Regardless, CT, together with MRI, is today considered the gold standard for body composition analysis, which assessed the proportion of fat to fat-free mass in your body.

Magnetic resonance imaging (MRI)

MRI uses the different magnetic properties of the nuclei of certain chemical elements (normally hydrogen in water and fat) in the cells to produce images of soft tissue in the body. Several MRI-based methods for quantification of adipose tissue and muscles have been developed and implemented.⁷³ MRI is used to obtain precise measurements of regional adipose tissue and lean tissue, as well as diffuse fat infiltration in other organs. However, due to several undeterminable factors affecting the MR signal, an MR image is not calibrated on an absolute scale and therefore cannot be quantitative. But by using different postprocessing techniques, the image can be calibrated to quantitatively measure fat or adipose tissue.⁶⁹

CALCULATING OBESITY IN CHILDREN AND ADOLESCENTS

In the United States, obesity and severe obesity in children and adolescents are defined using threshold values from the 2000 CDC sex-specific body mass index-for-age growth charts.⁷⁴ In addition to defining obesity, BMI z-scores and percentiles are used to monitor children's weight status over time and to evaluate obesity treatments in research settings. Percentiles near the upper limit of 100 percent become less useful for detecting meaningful differences, and

therefore percentiles can be converted to z-scores that indicate the number of standard deviations of a value from the mean. However, BMI z-scores (BMIz) and percentiles based on the 2000 BMI-for-age CDC growth charts (BMIz and BMI percentiles) were never meant to be used to monitor children with extremely high BMI values, and significant limitations exist when they are used to monitor children with severe obesity.⁷⁵ Specifically, BMIz values corresponding to extremely high BMI values are compressed into a very narrow range. Studies on obesity prevalence, its impact, and the availability of effective treatment have highlighted the need for meaningful standardized measures to track extremely high values of BMI in clinical and research settings.

As a result of needing more standardized measures the CDC studied alternative BMI metrics which include:

- BMI (untransformed),
- BMI z-scores and percentiles (modified),
- BMI z-scores and percentiles (extended),
- Percent of 95th percentile BMI units or percent from median, and
- Adjusted BMI units or percent from median.⁷⁶

None of these metrics had the problem of compression at extremely high BMI values, but all had limitations, especially when applied across the weight status spectrum and a wide range of ages. The report however concluded that the extended method for calculating z-scores and percentiles stands out among the alternatives.⁷² First, the extended method improves the characterization of BMI distributions at very high values using nationally representative data, but all other BMI metrics that refer to a reference population (all alternative metrics except untransformed BMI) rely on extrapolating beyond this reference population.⁷² Second, below the 95th percentile, extended BMI z-scores and percentiles preserve CDC 2000 z-scores and percentiles that are currently in use, which allows seamless transitions from the current CDC z-scores and percentiles below the 95th percentile to extended z-scores and percentiles above the 95th percentile.⁷² Alternative BMI metrics other than extended BMIz and percentiles may be appropriate for use in certain scenarios, such as during adolescence when differences among the metrics are less pronounced, when transitions to or from obesity are minimal, or for monitoring BMI changes over short periods when adjusting for expected growth and development is less critical.

INDICATIONS FOR METABOLIC AND BARIATRIC SURGERY

During the HOD Interim meeting in 2022, Resolution 937 “Indications for Metabolic and Bariatric Surgery,” was introduced by the American Society for Metabolic and Bariatric Surgery, Society of American Gastrointestinal and Endoscopic Surgeons . This resolution called for adoption of the new American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders indications for metabolic and bariatric surgery. Given that these guidelines depend on BMI, they were referred for consideration in this report.

The American Society for Metabolic and Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) have convened to produce a joint statement on the current available scientific information on metabolic and bariatric surgery and its indications recommending the following updates:

- Metabolic and bariatric surgery (MBS) is recommended for individuals with a body mass index (BMI) ≥ 35 kg/m², regardless of presence, absence, or severity of co-morbidities.
- MBS should be considered for individuals with metabolic disease and BMI of 30-34.9 kg/m².
- BMI thresholds should be adjusted in the Asian population such that a BMI ≥ 25 kg/m² suggests clinical obesity, and individuals with BMI ≥ 27.5 kg/m² should be offered MBS.
- Long-term results of MBS consistently demonstrate safety and efficacy.
- Appropriately selected children and adolescents should be considered for MBS.⁷⁷

It should be noted that the AMA did not participate in the development of these guidelines and therefore cannot endorse these guidelines. AMA policies are also adopted for a period of 10 years with the option of renewal through the Sunset process, therefore it is important to not reference specific guidelines in policy which may change over time.

EXISTING AMA POLICY

Under existing AMA Policy H-440.866, “The Clinical Utility of Measuring Body Mass Index and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity” the AMA supports: (1) greater emphasis in physician educational programs on the risk differences among ethnic and age groups at varying levels of BMI and the importance of monitoring waist circumference in individuals with BMIs below 35 kg/m²; (2) additional research on the efficacy of screening for overweight and obesity, using different indicators, in improving various clinical outcomes across populations, including morbidity, mortality, mental health, and prevention of further weight gain; and (3) more research on the efficacy of screening and interventions by physicians to promote healthy lifestyle behaviors, including healthy diets and regular physical activity, in all of their patients to improve health and minimize disease risks.

Policy H-150.928, “Eating Disorders and Promotion of Healthy Body Image,” supports increased funding for research on the epidemiology, etiology, diagnosis, prevention, and treatment of eating disorders, including research on the effectiveness of school-based primary prevention programs for pre-adolescent children and their parents, in order to prevent the onset of eating disorders and other behaviors associated with a negative body image.

Policy H-150.965, “Eating Disorders” notes that the AMA (1) adopts the position that overemphasis of bodily thinness is as deleterious to one's physical and mental health as is obesity; (2) asks its members to help their patients avoid obsessions with dieting and to develop balanced, individualized approaches to finding the body weight that is best for each of them; (3) encourages training of all school-based physicians, counselors, coaches, trainers, teachers and nurses to recognize unhealthy eating, dieting, and weight restrictive behaviors in adolescents and to offer education and appropriate referral of adolescents and their families for interventional counseling; and (4) participates in this effort by consulting with appropriate specialty societies and by assisting in the dissemination of appropriate educational and counseling materials pertaining to unhealthy eating, dieting, and weight restrictive behaviors.

CONCLUSIONS

The most basic definition of obesity is having too much body fat, so much so that it presents a risk to health.⁷⁸ A reliable way to determine whether a person has too much body fat is to calculate the ratio of their weight to their height squared. This ratio, called the body mass index (BMI), accounts for the fact that taller people have more tissue than shorter people, and so they tend to weigh more. BMI is not a perfect measure, because it does not directly assess body fat. Muscle and bone are denser than fat, so an athlete or muscular person may have a high BMI, yet not have too much fat. Risk of developing health problems, including several chronic diseases such as heart disease and diabetes, rises progressively for BMIs above 21. There's also evidence that at a given BMI, the risk of disease is higher in some ethnic groups than others.

Critics of BMI note that body fat location is also important and could be a better indicator of disease risk than the amount body fat.⁷⁹ Fat that accumulates around the waist and chest (what is called abdominal adiposity) may be more dangerous for long-term health than fat that accumulates around the hips and thighs. Some researchers have further argued that BMI should be discarded in favor of measures such as waist circumference.⁷⁵ However, this is unlikely to happen given that BMI is easier to measure and has a long history of use. In adults, measuring both BMI and waist circumference may be a better way to predict someone's weight-related risk. In children, however, there is no good reference data for waist circumference, so BMI-for-age is currently the gold standard. Overall, BMI does not describe body fat distribution, so additional anthropometric parameters should be used to assess enhanced accumulation of visceral adipose tissue.

Further, the current BMI classification system is misleading regarding the effects of body fat mass on mortality rates. The role of fat distribution in the prediction of medically significant morbidities as well as for mortality risk is not captured by use of the BMI. Also, numerous comorbidities, lifestyle issues, gender, ethnicities, medically significant familial-determined mortality effectors, duration of time one spends in certain BMI categories, and the expected accumulation of fat with aging are likely to significantly affect interpretation of BMI data, particularly in regard to morbidity and mortality rates. Such confounders as well as the known clustering of obesity in families, the strong role of genetic factors in the development of obesity, the location in which excessive fat accumulates, its role in the development of type 2 diabetes and hypertension, and so on, need to be considered before promulgation of public health policies that are designed to apply to the general population and are based on BMI data alone. Further,

the use of BMI is problematic when used to diagnose and treat individuals with eating disorders, because it does not capture the full range of abnormal eating disorders. It should also be noted that the recent increase in fat transfer procedures may complicate BMI measurements and should be further studied.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted, and the remainder of the report be filed.

1. Our AMA recognizes:

1. the issues with using body mass index (BMI) as a measurement because: (a) of the historical harm of BMI, (b) of the use of BMI for racist exclusion, and (c) BMI cutoffs for underweight, normal, overweight, and obesity are based primarily on health risks in non-Hispanic White populations.
 2. the significant limitations associated with the widespread use of BMI in clinical settings and suggests its use be in a conjunction with other valid measures of risk such as, but not limited to, measurements of: (a) visceral fat, (b) body adiposity index, (c) body composition, (d) relative fat mass, (e) waist circumference and (f) genetic/metabolic factors.
 3. that BMI is significantly correlated with the amount of fat mass in the general population but loses predictability when applied on the individual level.
 4. that relative body shape and composition heterogeneity across race/ethnic groups, sexes, genders, and age-span is essential to consider when applying BMI as a measure of adiposity.
 5. that in some diagnostic circumstances, the use of BMI should not be used as a sole criterion for appropriate insurance reimbursement.
 6. that in some clinical circumstances BMI may have utility and that BMI > 35 should continue to be used for risk stratification.
 7. that BMI is a useful tool for population level surveillance of obesity trends due to its ease of use and low risk for application inconsistencies.
 8. that BMI is useful as an initial screener for metabolic health risks.
2. Our AMA supports further research on the application of the extended BMI percentiles and z-scores and its association with other anthropometric measurements, risk factors, and health outcomes.
 3. Our AMA supports efforts to educate physicians on the issues with BMI and alternative measures for diagnosing obesity.
 4. That our AMA amend policy H-440.866, “The Clinical Utility of Measuring Body Mass Index and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity,” to read as follows:

The Clinical Utility of Measuring Body Mass Index, Body Composition, Adiposity, and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity, H-440.866

Our AMA supports: (1) greater emphasis in physician educational programs on the risk differences ~~among ethnic and age~~ within and between demographic groups at varying levels of adiposity, BMI, body composition, and waist circumference and the importance of monitoring ~~these waist circumference~~ in all individuals ~~with BMIs below 35 kg/m²~~; (2) additional research on the efficacy of screening for overweight and obesity, using different indicators, in improving various clinical outcomes across populations, including morbidity, mortality, mental health, and prevention of further weight gain; and (3) more research on the efficacy of screening and interventions by physicians to promote healthy lifestyle behaviors, including healthy diets and regular physical activity, in all of their patients to improve health and minimize disease risks. (Modify Current HOD Policy).

5. That our AMA amend policy H-150.965, “Eating Disorders” to read as follows:

The AMA (1) adopts the position that overemphasis of bodily thinness is as deleterious to one’s physical and mental health as obesity; (2) asks its members to help their patients avoid obsessions with dieting and to develop balanced, individualized approaches to finding the body weight that is best for each of them; (3) encourages training of all school-based physicians, counselors, coaches, trainers, teachers and nurses to

recognize ~~unhealthy abnormal~~ eating behaviors, dieting, and weight restrictive behaviors in children and adolescents and to offer education and appropriate referral of adolescents and their families for evidence-based and culturally-informed interventional counseling; and (4) participates in this effort by consulting with appropriate, culturally-informed educational and counseling materials pertaining to ~~unhealthy abnormal~~ eating behaviors, dieting, and weight restrictive behaviors.

6. That our AMA not adopt Resolution 937-I-22, “Indications for Metabolic and Bariatric Surgery.”

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8. COUNCIL ON SCIENCE AND PUBLIC HEALTH SUNSET REVIEW OF 2013 HOUSE POLICIES

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

Policy G-600.110, “Sunset Mechanism for AMA Policy,” calls for the decennial review of American Medical Association (AMA) policies to ensure that our AMA’s policy database is current, coherent, and relevant. This policy reads as follows, laying out the parameters for review and specifying the needed procedures:

1. As the House of Delegates adopts policies, a maximum ten-year time horizon shall exist. A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. Any action of our AMA House that reaffirms or amends an existing policy position shall reset the sunset “clock,” making the reaffirmed or amended policy viable for another 10 years.
2. In the implementation and ongoing operation of our AMA policy sunset mechanism, the following procedures shall be followed: (a) Each year, the Speakers shall provide a list of policies that are subject to review under the policy sunset mechanism; (b) Such policies shall be assigned to the appropriate AMA councils for review; (c) Each AMA council that has been asked to review policies shall develop and submit a report to the House of Delegates identifying policies that are scheduled to sunset; (d) For each policy under review, the reviewing council can recommend one of the following actions: (i) retain the policy; (ii) sunset the policy; (iii) retain part of the policy; or (iv) reconcile the policy with more recent and like policy; (e) For each recommendation that it makes to retain a policy in any fashion, the reviewing council shall provide a succinct, but cogent justification (f) The Speakers shall determine the best way for the House of Delegates to handle the sunset reports.
3. Nothing in this policy shall prohibit a report to the HOD or resolution to sunset a policy earlier than its 10-year horizon if it is no longer relevant, has been superseded by a more current policy, or has been accomplished.
4. The AMA councils and the House of Delegates should conform to the following guidelines for sunset: (a) when a policy is no longer relevant or necessary; (b) when a policy or directive has been accomplished; or (c) when the policy or directive is part of an established AMA practice that is transparent to the House and codified elsewhere such as the AMA Bylaws or the AMA House of Delegates Reference Manual: Procedures, Policies and Practices.
5. The most recent policy shall be deemed to supersede contradictory past AMA policies.
6. Sunset policies will be retained in the AMA historical archives.

RECOMMENDATION

The Council on Science and Public Health recommends that the House of Delegates policies listed in the appendix to this report be acted upon in the manner indicated and the remainder of this report be filed. (Directive to Take Action)

APPENDIX: RECOMMENDED ACTIONS

Policy Number	Title	Text	Recommendation
D-135.974	Support Stricter OSHA Silica Permissible Exposure Limit Standard	Our AMA: (1) supports the Department of Labor's Occupational Safety and Health Administration's (OSHA's) proposed rule to establish a stricter permissible exposure limit (PEL) for respirable crystalline silica; (2) supports OSHA's proposed rule to establish a stricter standard of exposure assessment and medical surveillance requirements to identify adverse health effects in exposed populations of workers; and (3) will submit comments, in collaboration with respiratory and occupational health medical societies, in support of a stricter silica PEL. (Res. 916, I-13)	Rescind; completed. OSHA updated silica standards for industry, maritime, and construction settings in 2016.
D-135.975	Monitoring for Radiation in Seafood	Our AMA calls for the United States government to continue to monitor and fully report the radioactivity levels of edible ocean species sold in the United States. (Res. 414, A-13)	Retain; change to H-policy
D-135.980	Gulf Oil Spill Health Risks and Effects	Our AMA will encourage <u>supports efforts by</u> the National Institute of Environmental Health Sciences and the Natural Resource Damage Assessment program to: (1) continue to monitor health effects (including mental health effects) and public health surveillance activities related to the Gulf oil spill, and provide relevant information and resources as they become available; and (2) monitor the results of studies examining the health effects of the Gulf oil spill and report back as appropriate. (CSAPH Rep. 3, I-10; Modified: CSAPH Rep. 5, A-13)	Retain as amended; change to H-policy.
D-150.981	The Health Effects of High Fructose Syrup	Our AMA: (1) recognizes that at the present time, insufficient evidence exists to specifically restrict use of high fructose corn syrup (HFCS) or other fructose-containing sweeteners in the food supply or to require the use of warning labels on products containing HFCS; (2) encourages independent research (including epidemiological studies) on the health effects of HFCS and other added sugars sweeteners , and evaluation of the mechanism of action and relationship between fructose dose and response; and (3) in concert with the Dietary Guidelines for Americans, recommends that consumers limit the amount of added sugars calorie sweeteners in their diet. (CSAPH Rep. 3, A-08; Reaffirmation A-13)	Retain as amended and change to H policy. "Added sugars" is a more encompassing term for caloric sweeteners/sweeteners. The current Dietary Guidelines for American also references added sugars and not caloric sweeteners.

D-150.985	Folic Acid Fortification of Grain Products	Our AMA will : (1) <u>urges</u> the Food and Drug Administration to recommend folic acid fortification of all grains marketed for human consumption, including grains not carrying the "enriched" label; and (2) write letters to <u>supports</u> domestic and international producers of corn grain products, including masa, nixtamal, maize, and pozole, to advocate <u>advocating</u> for folic acid fortification of such products. (CSAPH Rep. 6, A-06; Reaffirmed: CSAPH Rep. 1, I-13)	Retain as amended; change to H-policy.
D-150.987	Addition of Alternatives to Soft Drinks in Schools	Our AMA will seek to promote the consumption and availability of nutritious beverages as a healthy alternative to high-calorie, low nutritional-content beverages (such as carbonated sodas and sugar-added juices) in schools. (Res. 413, A-05; Reaffirmation A-07; Reaffirmation A-12; Reaffirmation A-13)	Retain; still relevant.
D-20.992	Routine HIV Screening	Our AMA: (1) supports HIV screening policies which include: (a) routine HIV screening of adolescents and adults ages 13-64 <u>15-65</u> , and sexually active adolescents under age 15 <u>and adults over 65 at increased risk of infection should also be screened</u> ; (b) patients receive an HIV test as a part of General Medical Consent for medical care with option to specifically decline the test, and (c) patients who test positive for HIV receive prompt counseling and treatment as a vital part of screening; (2) supports that the frequency of repeat HIV screening be determined based on physician clinical judgment and consideration of identified risks and prevalent community experience; (3) supports the Centers for Disease Control and Prevention's (CDC) 2006 Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings ; (4) will <u>continues</u> to work with the CDC to implement the revised recommendations for HIV testing of adults, adolescents and pregnant people <u>women</u> in health care settings, including exploring the publication of a guide on the use of rapid HIV testing in primary care settings; (5) will <u>identify</u> legal and funding barriers to the implementation of the CDC's HIV testing recommendations and develop strategies to overcome these barriers; (6) will <u>publicize</u> its newly adopted HIV screening policies via its existing professional electronic and print <u>professional</u> publications and to the public via news releases and commentaries to major media outlets; and (7) will <u>formally request</u> all public and private insurance plans to <u>pay</u> the cost of routine HIV screening testing of all insured individuals who receive routine HIV testing in accordance with new recommendations. (CSAPH Rep. 2, I-06; Modified: Res. 927, I-10; Reaffirmation I-13)	Retain as amended to align with updated evidence-based guidelines.
D-220.970	Joint Commission Accreditation Standard for Pain Assessment	Our AMA urges <u>supports</u> efforts by The Joint Commission to <u>continuously</u> reevaluate its accreditation standard for pain assessment, including evidence on whether the standard improves pain management	Retain as amended; change to H-policy.

		practices, in order to ensure that the standard supports physician's abilities to select the most appropriate treatment options for their patients. (Sub. Res. 915, I-13)	
D-35.981	AMA Response to Pharmacy Intrusion Into Medical Practice	1. Our AMA deems inappropriate inquiries from pharmacies to verify the medical rationale behind prescriptions, diagnoses and treatment plans to be an interference with the practice of medicine and unwarranted. 2. Our AMA will work with pharmacy associations such as the National Association of Chain Drug Stores to engage with the Drug Enforcement Administration, the federal Department of Justice, and other involved federal regulators and stakeholders, for the benefit of patients, to develop appropriate policy for pharmacists to work with physicians in order to reduce the incidence of drug diversion and inappropriate dispensing. 3. If the inappropriate pharmacist prescription verification requirements and inquiry issues are not resolved promptly, our AMA will advocate for legislative and regulatory solutions to prohibit pharmacies and pharmacists from denying medically necessary and legitimate therapeutic treatments to patients. (Res. 218, A-13)	Retain as amended; change to H-policy.
D-440.935	Strategies to Increase Diabetes Awareness	Our AMA will organize a series of activities for the public in collaboration with health care workers and community organizations to bring awareness to the severity of diabetes and measures to decrease its incidence. (Res. 412, A-13)	Rescind; completed. Launched programs with the YMCA to provide screenings and awareness around diabetes prevention and supported referral of patients to Diabetes Prevention Programs, a lifestyle modification program designed to reduce the risk of developing type 2 diabetes.
D-455.998	Ionizing Radiation Exposure in the Medical Setting	Our AMA will: (1) collaborate with <u>Support</u> appropriate specialty medical societies and other interested stakeholders to convene a meeting <u>collaborate</u> (a) to examine the for feasibility of monitoring and quantifying the cumulative radiation exposure sustained by individual patients in medical settings; and (b) to discuss methods to <u>continue</u> to educate physicians and the public on the appropriate use and risks of low linear energy transfer radiation in order to reduce unnecessary patient exposure in the medical setting; (2) continue to monitor the National Academy of Sciences' ongoing efforts to study the impact of low levels of low linear energy transfer radiation on human health; (3) support education and standards for all providers and medical personnel using ionizing and non-ionizing radiation that includes awareness of, and methods to avoid, patient over-radiation;	Retain as amended; change to H-policy.

		<p>(4) support policies that promote the safe use of medical imaging devices, informed clinical decision-making regarding the use of procedures that use radiation, and patient awareness of medical radiation exposure; and</p> <p>(5) encourage the continued development and use of standardized electronic medical record systems that will help physicians track the number of imaging procedures a patient is receiving, in both the in-patient and out-patient settings, which will help physicians discuss the potential dangers of high level of radiation exposure with patients.</p> <p>CSAPH Rep. 2, A-06; Appended: Res. 921, I-11; Reaffirmation A-13</p>	
D-455.999	Monitoring Patient Exposure to Ionizing Radiation	<p>1. Our American Medical Association will work with the <u>support</u> public health, radiology and radiation oncology specialty societies and all other interested parties to <u>study monitor</u> the issue of radiation exposure by <u>to</u> the American public and develop a plan, if appropriate, to allow the ongoing monitoring and quantification of radiation exposure sustained by individual patients in medical settings.</p> <p>2. Our AMA: (a) will work with the American College of Radiology, the Radiological Society of North America, and other appropriate specialty medical societies and stakeholders to develop recommendations for a common format for monitoring, quantifying, documenting, and communicating the cumulative radiation exposure sustained by individual patients in medical settings that could be incorporated into a patient's personal health record and present their findings to industry; (b) recommends dissemination and use of the Physician Consortium for Performance Improvement (PCPI) 2007 Radiology Performance Improvement Measures that pertain to radiation exposure monitoring for CT scanning and fluoroscopy; and that the PCPI continue to incorporate radiation exposure issues in future performance measurement sets; and (c) supports physician and patient education on the appropriate use and risks of radiation in the medical setting.</p> <p>Res. 521, A-05; Appended: BOT Rep. 12, I-09; Reaffirmation A-13</p>	<p>Retain as amended; change to H-policy.</p> <p>Part two of the resolution is complete.</p>
D-460.983	Translating Biomedical Research to the Bedside	<p>Our AMA will: (1) give high priority to bringing promising biomedical research to the bedside; and (2) advocate for the elimination of unreasonable barriers to bedside care using new research.</p> <p>(Res. 812, I-03; Modified: CSAPH Rep. 1, A-13)</p>	Retain; change to H policy.
D-490.983	Annual Tobacco Report 2003	<p>Our AMA will continue to produce the Annual Tobacco Report.</p> <p>(BOT Rep. 7, I-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.
D-515.985	Elder Mistreatment	<p>Our AMA:</p> <p>1. Encourages all physicians caring for the elderly to become more proactive in recognizing and treating vulnerable elders who may be victims of mistreatment through prevention and early identification of risk factors in all care settings. Encourage physicians to</p>	Retain; change to H policy.

		<p>participate in medical case management and APS teams and assume greater roles as medical advisors to APS services.</p> <p>2. Promotes collaboration with the Liaison Committee on Medical Education and the Association of American Medical Colleges, as well as the Commission on Osteopathic College Accreditation and American Association of Colleges of Osteopathic Medicine, in establishing training in elder mistreatment for all medical students; such training could be accomplished by local arrangements with the state APS teams to provide student rotations on their teams. Physician responsibility in cases of elder mistreatment could be part of the educational curriculum on professionalism and incorporated into questions on the US Medical Licensing Examination and Comprehensive Osteopathic Medical Licensing Examination.</p> <p>3. Encourages the development of curricula at the residency level and collaboration with residency review committees, the Accreditation Council for Graduate Medical Education, specialty boards, and Maintenance of Certification programs on the recognition of elder mistreatment and appropriate referrals and treatment.</p> <p>4. Encourages substantially more research in the area of elder mistreatment.</p> <p>5. Encourages the US Department of Health and Human Services, Office of Human Research Protections, which provides oversight for institutional review boards, and the Association for the Accreditation of Human Research Protection Programs to collaborate on establishing guidelines and protocols to address the issue of vulnerable subjects and research subject surrogates, so that research in the area of elder mistreatment can proceed.</p> <p>6. Encourages a national effort to reach consensus on elder mistreatment definitions and rigorous objective measurements so that interventions and outcomes of treatment can be evaluated.</p> <p>7. Encourages adoption of legislation, such as the Elder Justice Act, that promotes clinical, research, and educational programs in the prevention, detection, treatment, and intervention of elder abuse, neglect, and exploitation.</p> <p>(CSAPH Rep. 7, A-08; Reaffirmed: CMS Rep. 8, I-13)</p>	
D-55.998	Encourage Appropriate Colorectal Cancer Screening	Our AMA, in conjunction with interested organizations and societies, will supports educational and public awareness programs to assure that physicians actively encourage their patients to be screened for colon cancer and precursor lesions, and to improve patient awareness of appropriate guidelines, particularly within minority populations and for all high risk groups. (Res. 510, A-03; Modified: CSAPH Rep. 1, A-13)	Retain as amended; change to H policy.
H-10.966	Prevention of Fires Related to Cigarette Smoking	The AMA (1) supports studies to determine the feasibility and practicality of establishing a standard for self-extinguishing cigarettes and requiring cigarette manufacturers to meet that standard; (2) supports the concept of self-extinguishing cigarettes for the purpose	Retain; still relevant.

		of reducing fire related deaths, injuries and loss of property; and (3) reiterates its opposition to all smoking. (Sub. Res. 6, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	
H-10.981	Prohibition on the Public Sale of Fireworks	Our AMA (1) encourages accurate reporting of fireworks related injuries, deaths, and fires; (2) supports all efforts designed to prohibit the public sale, including those by mail order, of all fireworks; (3) supports existing efforts to educate physicians, parents, children, and community leaders about the dangers of fireworks; and (4) encourages the adoption of federal legislation prohibiting the sale of fireworks and their use, with the exception of those used for professional displays. (Res. 419, A-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-10.995	Use of Technology to Prevent Explosions	The AMA encourages manufacturers of automobiles, boats, and other vehicles, as well as makers of containers of volatile liquids and gases, to incorporate appropriate safety technology into the development of their products. (Res. 59, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-100.976	Benzodiazepine Education	Our AMA encourages physicians interested in the addictive nature of benzodiazepines and their rational use to seek information from appropriate sources. (CSA Rep. E, A-92; Amended: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-130.992	Proposed Crisis Relocation and Shelter Plans	Patients must be treated regardless of how they are injured, and planning for treatment is an important part of good medicine. The AMA, therefore, is committed to working with the federal government to provide advice concerning development of sound medical planning for disasters and catastrophes of any and all magnitude. (BOT Rep. I, I-82; Reaffirmed: Res. 34, A-83; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Rescind; duplicative of more comprehensive policy (H-130.942 , D-130.972 , and D-130.974).
H-130.993	Use of Emergency Medical Information Aids	The AMA (1) endorses and encourages the use of effective medical information aids by which appropriate individual medical information can be brought to the attention of emergency personnel; and (2) supports continued review of existing medical information aids to determine appropriate steps to encourage greater use of those information aids which are considered effective. (Res. 57, I-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Retain as amended.
H-135.948	Toxicity of Computers and Electronics Waste	Our AMA (1) encourages its members and US health institutions to adopt purchasing or leasing contracts only with electronics manufacturers and distributors who are committed to safely handling the products at the end of life, meaning that they reuse and recycle to the greatest extent possible, do not export hazardous electronic waste to developing countries and safely	Retain; still relevant.

		dispose of the waste that <u>cannot</u> be reused or recycled; (2) encourages its members and US health institutions to provide purchasing/leasing preferences to electronics manufacturers that minimize the use of toxic and hazardous constituents, use recycled content and design products that can be easily recycled in order to minimize the adverse public health impacts from electronic waste; and (3) supports policies that hold electronics manufacturers and distributors responsible for taking back their products at the end of life, with the objective of redesigning their products for longevity and reduction of harmful materials. (Res. 423, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	
H-135.961	Risks of a High-Level Radioactive Waste Repository	The AMA (1) strongly encourages the U.S. Nuclear Regulatory Commission and the Nuclear Waste Technical Review Board of the National Research Council to include representatives of the appropriate state medical societies/associations, the AMA, and appropriate medical specialty groups with expertise in the field to advise and/or act as consultants to those entities; and (2) urges the U.S. Congress to establish a site for a high-level radioactive waste repository. (BOT Rep. A, I-92; Amended: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-145.978	Gun Firearm Safety	Our AMA: (1) recommends and promotes the use of trigger locks and locked gun <u>firearm</u> cabinets as safety precautions; and (2) endorses <u>supports</u> standards for firearm construction reducing the likelihood of accidental discharge when a gun is dropped and that standardized drop tests be developed. (Res. 425, I-98; Reaffirmed: Res. 409, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmation A-13)	Retain as amended; still relevant. Terminology updated for consistency.
H-145.988	AMA Campaign to Reduce Firearm Deaths	The AMA supports educating the public regarding methods to reduce death and injury due to keeping <u>firearms</u> guns , ammunition and other explosives in the home. (Res. 410, A-93; Reaffirmed: CLRPD Rep. 5, A-03; Reaffirmation A-13; Modified: CSAPH Rep. 1, A-13)	Retain as amended; still relevant. Terminology updated for consistency.
H-15.954	Older Driver Safety	(1) Our AMA recognizes that the safety of older drivers is a growing public health concern that is best addressed through multi-sector efforts to optimize vehicle design, the driving environment, and the individual's driving capabilities, and: (a) believes that because physicians play an essential role in helping patients slow their rate of functional decline, physicians should increase their awareness of the medical conditions, medications, and functional deficits that may impair an individual's driving performance, and counsel and manage their patients accordingly; (b) encourages physicians to familiarize themselves with driver assessment and rehabilitation options, refer their patients to such programs whenever appropriate, and defer recommendations on permanent driving cessation until establishing that a patient's driving safety cannot be maintained through medical interventions or driver rehabilitation;	Retain; still relevant.

		<p>© urges physicians to know and adhere to their state’s reporting statutes for medically at-risk drivers; and (d) encourages continued scientific investigation into strategies for the assessment and management of driving safety in the clinical setting.</p> <p>(2) Our AMA encourages physicians to use the Physician’s Guide to Assessing and Counseling Older Drivers as an educational tool to assist them in helping their patients. (CSA Rep. 6, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	
H-15.964	Police Chases and Chase-Related Injuries	<p>The AMA encourages (1) communities, aided by government officials and medical scientists, to develop <u>and implement</u> guidelines on the use of police vehicles that indicate when, how, and how long pursuits should be carried out and to address other key aspects of police pursuit; and (2) responsible government agencies to develop, test, and use instruments and techniques with advanced technologies, for example, coding and tracking devices, to discourage, eliminate, or replace high-speed chases.</p> <p>(CSA Rep. C, A-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)</p>	Retain as amended. In 2015, a model policy was created by the International Association of Chiefs of Police. In it, the policy states, “Pursuit is authorized only if the officer has a reasonable belief that the suspect, if allowed to flee, would present a danger to human life or cause serious injury. In general, pursuits for minor violations are discouraged”
H-150.966	FDA Regulations Regarding the Inclusion of Added L-Glutamic Acid Content on Food Labels	<p>Until such time as L-glutamic acid in any form has been shown to pose a significant public health hazard or until biological non-equivalence of monosodium glutamate and L-glutamate has been demonstrated, the AMA supports the exclusion of L-glutamic acid released from hydrolyzed protein from food product labeling requirements.</p> <p>(CSA Rep. D, A-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.
H-170.965	Education on Condom Use	<p>Our AMA: (1) Supports joining with appropriate medical and public health organizations and federal agencies in endorsing the use of condoms in reducing the risk of HIV/AIDS and other sexually transmissible diseases among the population; (2) Encourages the production of condom education materials that meet standards of accuracy, completeness, social appropriateness, clarity, and simplicity; (3) Supports cooperating with other medical societies, the public health community, government agencies, and the media to develop standards for public service announcements regarding condom use in prevention of HIV/AIDS and other sexually transmissible diseases; and (4) In cooperation with state, county, and specialty medical societies, encourages physicians to educate their patients about the role of condom use in reducing the risk of sexually transmissible diseases, including HIV disease. While such counseling may not be appropriate for all patients, physicians should be encouraged to provide this information to any patient who may benefit from being more aware of the risks of sexually transmissible diseases.</p> <p>(CSA Rep. 4, A-03; Modified: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.

H-170.966	Human Sexuality Education	Our AMA encourages physicians to assist parents in providing human sexuality education to children and adolescents. (CSA Rep. 4, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Rescind; Duplicative of policy H-170.968
H-170.967	Rehabilitative Programs, Mental Health, and Educational Services for Girls in the Juvenile Detention System	Our AMA supports comprehensive health education for female delinquents, including information on responsible sexual behavior, the prevention of sexually transmissible diseases and HIV/AIDS, and also supports the availability of intervention programs for girls who have been victimized. (Res. 411, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Rescind; more recent policy exists including D-60.994 , D-430.997 , and H-515.981 .
H-175.992	Deceptive Health Care Advertising	Our AMA (1) encourages and assists all physicians and medical societies to monitor and report to the appropriate state and federal agencies any health care advertising for which there is a reasonable, good-faith basis for believing that said advertising is false and/or deceptive in a material fact, together with the basis for such belief; and (2) encourages medical societies to keep the Association advised as to their actions relating to medical advertising. (Sub. Res. 102, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: BOT Rep. 13, I-01; Reaffirmed: CSAPH Rep. 1, A-11; Reaffirmed in lieu of Res. 6, A-13)	Retain; still relevant.
H-20.899	HIV Testing	Our AMA endorses routine HIV screening/testing for individuals on admission to the hospital, visit to the emergency room or doctor's office as deemed appropriate by the attending physician. It is AMA policy that: (1) this testing should be a voluntary program in which patients may opt out if they desire not to be tested; (2) HIV screening permission be incorporated into general health care consent forms and that separate written consent is not recommended; (3) prevention counseling should not be a requirement for this testing program; (4) when tests are positive, appropriate public health measures be instituted for surveillance, prevention of transmission and dissemination of the virus; and (5) when positive HIV patients are identified, appropriate linkage to HIV care be established. (Res. 2, A-07; Reaffirmation I-13)	Rescind; Duplicative of H-20.920
H-20.903	HIV/AIDS and Substance Abuse	Our AMA: (1) urges federal, state, and local governments to increase funding for drug treatment so that <u>people who use drugs</u> abusers have immediate access to appropriate care, regardless of ability to pay. Experts in the field agree that this is the most important step that can be taken to reduce the spread of HIV infection among <u>persons who inject drugs</u> intravenous drug abusers ; (2) advocates development of regulations and incentives to encourage retention of HIV-positive and AIDS-symptomatic patients in drug treatment programs so long as such placement is clinically appropriate; (3) encourages the availability of opioid maintenance for persons addicted to opioids. Federal and state regulations governing opioid maintenance and treatment of drug dependent persons should be reevaluated to determine whether they meet the special needs of <u>persons who inject drugs</u> intravenous drug	Retain as amended; updating language.

		<p>abusers, particularly those who are HIV infected or AIDS symptomatic. Federal and state regulations that are based on incomplete or inaccurate scientific and medical data that restrict or inhibit opioid maintenance therapy should be removed; and (4) urges development of educational, medical, and social support programs for persons who inject drugs intravenous drug abusers and their sexual or needle-sharing partners to reduce risk of HIV infection, as well as risk of other bloodborne and sexually transmissible diseases. Such efforts must target (a) pregnant people who inject drugs intravenous drug abusers and those who may become pregnant to address the current and future health care needs of both mothers and newborns and (b) adolescent substance abusers-users, especially homeless, runaway, and detained adolescents who are <u>living with HIV seropositive or AIDS symptomatic</u> and those whose lifestyles with risk factors place them at risk for contracting HIV infection.</p> <p>(CSA Rep. 4, A-03; Modified: CSAPH Rep. 1, A-13)</p>	
<p>H-20.907</p>	<p>Financing Care for HIV/AIDS Patients</p>	<p>Our AMA:</p> <p>(1) Believes that current private insurance and existing public programs, coupled with a significant expansion of state risk pools, provide the best approach to assuring adequate access to health expense coverage for HIV-infected persons and persons with AIDS. However, as the disease patterns and costs become more defined, it may be necessary to reevaluate this conclusion. Continued study of this issue is imperative;</p> <p>(2) Supports the development of a clinical staging system based on severity of HIV disease as a replacement for the AIDS diagnosis as a basis for determining health, disability, and other benefits;</p> <p>(3) Supports increased funding for reimbursement and other incentives by public and private payers to encourage (a) expanded availability for therapies and interventions widely accepted by physicians as medically appropriate for the prevention and control of HIV disease and (b) for alternatives to in-patient care of persons with HIV disease, including intermediate care facilities, skilled nursing facilities, home care, residential hospice, home hospice, and other support systems;</p> <p>(4) Supports government funding of all medical services that are deemed appropriate by both the patient and physician for pregnant seropositive women lacking other sources of funding;</p> <p>(5) Supports broad improvements in and expansion of the Medicaid program as a means of providing increased coverage and financial protection for low-income AIDS patients;</p> <p>(6) Supports, and favors considering introduction of, legislation to modify the Medicaid program to provide for a yearly dollar increase in the federal share of payments made by states for care of all patients in proportion to the amount of increase in costs incurred by each state program for care of HIV-positive</p>	<p>Retain as amended; still relevant.</p>

		<p>individuals and patients with AIDS over the preceding year;</p> <p>(7) Encourages the appropriate state medical societies to seek establishment in their jurisdictions of programs to pay the private insurance premiums from state and federal funds for needy persons with HIV and AIDS; and strongly supports full appropriation of the amounts authorized under the Ryan White CARE Act of 2000;</p> <p>(8) Supports consideration of an award recognition program for physicians who donate a portion of their professional time to testing and counseling HIV-infected patients who could not otherwise afford these services.</p> <p>(CSA Rep. 4, A-03; Reaffirmation I-11; Reaffirmation I-13)</p>	
H-20.910	HIV-Infected Children	<p>Our AMA:</p> <p>(1) Supports day-care, preschool, and school attendance of HIV-infected children;</p> <p>(2) Encourages the physician responsible for care of an HIV-infected child in a day-care, preschool, or school setting to receive information from the school on other infectious diseases in the environment and temporarily remove the HIV-infected child from a setting that might pose a threat to his/her health;</p> <p>(3) Encourages that HIV-infected children who are adopted or placed in a foster-care setting have access to special health care benefits to encourage adoption or foster-care.</p> <p>(CSA Rep. 4, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.
H-20.916	Breastfeeding and HIV Seropositive Women <u>People</u>	<p>Our AMA believes that, where safe and alternative nutrition is widely available, HIV seropositive women <u>people</u> should be counseled not to breastfeed and not to donate breast milk. HIV testing of all human milk donors should be mandatory, and milk from HIV-infected donors should not be used for human consumption.</p> <p>(CSA Rep. 4, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Retain as amended to include gender-neutral language.
H-20.917	Neonatal Screening for HIV Infection	<p>Our AMA: (1) urges the U.S. Public Health Service, other appropriate federal agencies, private researchers, and health care industries to continue to pursue research, development, and implementation of diagnostic tests and procedures for more accurate demonstration of HIV infection in the newborn; and supports the widespread use of such tests in early diagnosis; (2) favors giving consideration to rapid HIV testing of newborns, with <u>maternal consent of the gestational parent</u>, when the maternal <u>individual's</u> HIV status has not been determined during pregnancy or labor; and (3) supports mandatory HIV testing of all newborns in high prevalence areas.</p> <p>(CSA Rep. 4, A-03; Modified: CSAPH Rep. 1, A-13)</p>	Retain as amended.
H-20.919	Patient Disclosure of HIV Seropositivity	<p>Our AMA encourages patients who are HIV seropositive to make their condition known to their physicians and other appropriate health care providers.</p> <p>(CSA Rep. 4, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.

H-245.983	Baby Walkers	The AMA strengthens its policy on baby walkers by urging <u>urges</u> the Consumer Product Safety Commission to ban infant walkers as a mechanical hazard. (Res. 403, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Retain as amended; still relevant.
H-245.985	Mandatory Labeling for Waterbeds and Beanbag Furniture	The AMA urges the Consumer Product Safety Commission to require waterbed manufacturers and manufacturers of similar type furnishings to affix a permanent label and to distribute warning materials on each waterbed and other furnishings sold concerning the risks of leaving an infant or handicapped child, who lacks the ability to roll over, unattended on a waterbed or beanbag. (Res. 414, A-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-280.958	Pain Control in Long-Term Care	Our AMA will work: (1) to promote promulgate clinical practice guidelines for pain control in long term care settings and support educational efforts and research in pain management in long term care; and (2) to reduce regulatory barriers to adequate pain control at the federal and state levels for long term care patients. (Res. 715, A-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed in lieu of Res. 518, A-12; Reaffirmation A-13)	Retain as amended to clarify the AMA's role in clinical practice guidelines.
H-365.996	Regulation of Occupational Carcinogens	The AMA endorses the principle of <u>supports</u> using the best available scientific data, including data derived from animal models, as a basis for regulation of occupational carcinogens. (Sub. Res. 81, I-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Retain as amended; still relevant.
H-370.984	Organ Donation Education	Our AMA encourages all states and local organ procurement organizations to provide educational materials to driver education and safety classes. (Res. 504, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSA Rep. 4, I-02; Reaffirmed: CSAPH Rep. 1, A-12; Modified: Res. 3, A-13)	Retain; still relevant.
H-420.991	Fetal Effects of Maternal Alcohol Use	The AMA believes that (1) The evidence is clear that a woman <u>person</u> who drinks heavily during pregnancy places her <u>their</u> unborn child at substantial risk for fetal damage and physical and mental deficiencies in infancy. Physicians should be alert to signs of possible alcohol abuse use and alcoholism <u>alcohol use disorder</u> in their female patients of child-bearing age, not only those who are pregnant, and institute appropriate diagnostic and therapeutic measures as early as possible. Prompt intervention may prevent adverse fetal consequences from occurring in this high-risk group. (2) The fetal risks involved in moderate or minimal alcohol consumption have not been established through research to date, nor has a safe level of maternal gestational <u>maternal gestational</u> alcohol use been established. One of the objectives of future research should be to determine whether there is a level of maternal gestational <u>maternal gestational</u> alcohol consumption below which embryotoxic and teratogenic effects attributable to alcohol are virtually non-existent. (3) Until such a determination is made, physicians should inform their patients as to what the research to	Retain as amended; still relevant.

		<p>date does and does not show and should encourage them to decide about drinking in light of the evidence and their own situations. Physicians should be explicit in reinforcing the concept that, with several aspects of the issue still in doubt, the safest course is abstinence.</p> <p>(4) Long-term longitudinal studies should be undertaken to give a clearer perception of the nature and duration of alcohol-related birth defects. Cooperative projects should be designed with uniform means of assessing the quantity and extent of alcohol intake.</p> <p>(5) To enhance public education efforts, schools, hospitals, and community organizations should become involved in programs conducted by governmental agencies and professional associations.</p> <p>(6) Physicians should take an active part in education campaigns. In so doing, they should emphasize the often overlooked consequences of maternal gestational drinking that are less dramatic and pronounced than are features of the fetal alcohol syndrome, consequences that are at least indicated, if not sharply delineated, by some of the research that has been conducted in several parts of the world with diverse populations. (CSA Rep. E, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	
H-425.971	Celiac Disease Screening	Our AMA: (1) recognizes undiagnosed celiac disease as a public health problem; and (2) supports the formal establishment of evidence-based celiac disease screening recommendations and high-risk population definitions for general and pediatric populations by appropriate stakeholders. (Res. 419, A-13)	Retain; still relevant.
H-430.988	Prevention and Control of HIV/AIDS and Tuberculosis in Correctional Facilities	<p>(1) Medical Testing and Care of <u>Individuals who are Incarcerated Prisoners</u> a) Federal and state correctional systems should provide comprehensive medical management for all entrants, which includes voluntary testing for HIV infection and mandatory testing for tuberculosis followed by appropriate treatment for those infected; b) <u>Individuals who are incarcerated, prisoners</u> should be tested for HIV infection as medically indicated or on their request; c) All <u>individuals who are incarcerated</u> and staff should be screened for tuberculosis infection and retested at least annually. If an increase in cases of tuberculosis or HIV infection is noted, more frequent retesting may be indicated; d) Correctional institutions should assure that informed consent, counseling, and confidentiality procedures are in place to protect the patient, when HIV testing is appropriate; e) During their post-test counseling procedures, HIV-infected <u>individuals who are incarcerated</u> should be encouraged to confidentially notify their sexual or needle-sharing partners; and f) Correctional medical care must, as a minimum, meet the prevailing standards of care for HIV-infected persons in the outside community at large. Prisoners <u>Individuals who are incarcerated</u> should have access to approved therapeutic drugs and generally employed</p>	Retain as amended; updating language to be consistent with current policy.

		<p>treatment strategies. (2) HIV/AIDS Education and Prevention Our AMA: a) Encourages the inclusion of HIV-prevention information as a regular part of <u>the education</u> of correctional staff and individuals <u>who are incarcerated</u>. AIDS education in state and federal prisons should stress abstinence from drug use and high-risk sexual practices, as well as the proper use of condoms as one way of decreasing the spread of HIV; b) Will pursue legislation that encourages state, local, and federal correctional institutions to make condoms available to <u>individuals who are incarcerated</u>; and c) Urges medical personnel in correctional institutions to work closely with state and local health department personnel to control the spread of HIV/AIDS, tuberculosis, and other serious infectious diseases within and outside these facilities. (3) Prison-based HIV Partner Notification Program Our AMA: a) Urges state health departments to take steps to initiate with state departments of correctional services the development of prison-based HIV Partner Notification Programs for <u>individuals who are incarcerated</u> convicted of drug-related crimes and their regular sexual partners; and b) Believes that all parties should recognize that maximum effectiveness in an HIV Partner Notification Program will depend on the truly voluntary participation of inmates and the strict observance of confidentiality at all levels. (CSA Rep. 4, A-03; Modified: CSAPH Rep. 1, A-13)</p>	
H-440.842	Recognition of Obesity as a Disease	Our AMA recognizes obesity as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention. (Res. 420, A-13)	Retain; still relevant.
H-440.843	Health Risks of Sitting	Our AMA recognizes that there are potential risks of prolonged sitting, encourages efforts by employers, employees, and others to make available alternatives such as standing work stations and isometric balls, and encourages educational efforts regarding ways to minimize this risk. (Res. 413, A-13)	Retain; still relevant
H-440.866	The Clinical Utility of Measuring Body Mass Index and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity	<p>Our AMA supports:</p> <p>(1) greater emphasis in physician educational programs on the risk differences among ethnic and age groups at varying levels of BMI and the importance of monitoring waist circumference in individuals with BMIs below 35 kg/m²;</p> <p>(2) additional research on the efficacy of screening for overweight and obesity, using different indicators, in improving various clinical outcomes across populations, including morbidity, mortality, mental health, and prevention of further weight gain; and</p> <p>(3) more research on the efficacy of screening and interventions by physicians to promote healthy lifestyle behaviors, including healthy diets and regular physical activity, in all of their patients to improve health and minimize disease risks.</p> <p>(CSAPH Rep. 1, A-08; Reaffirmed: CSAPH Rep. 3, A-13)</p>	Retain; still relevant.

H-440.898	Recommendations on Folic Acid Supplementation	<p>Our AMA will:</p> <p>(1) encourage the Centers for Disease Control and Prevention (CDC) to continue to conduct surveys to monitor nutritional intake and the incidence of neural tube defects (NTD);</p> <p>(2) continue to encourage broad-based public educational programs about the need for women of child-bearing potential to consume adequate folic acid through nutrition, food fortification, and vitamin supplementation to reduce the risk of NTD;</p> <p>(3) encourage the CDC and the National Institutes of Health to fund basic and epidemiological studies and clinical trials to determine causal and metabolic relationships among homocysteine, vitamins B12 and B6, and folic acid, so as to reduce the risks for and incidence of associated diseases and deficiency states;</p> <p>(4) encourage research efforts to identify and monitor those populations potentially at risk for masking vitamin B12 deficiency through routine folic acid supplementation of enriched food products;</p> <p>(5) urge the Food and Drug Administration to increase folic acid fortification to 350 µg per 100 g of enriched cereal grain; and</p> <p>(6) encourage the FDA to require food, food supplement, and vitamin labeling to specify milligram content, as well as RDA levels, for critical nutrients, which vary by age, gender, and hormonal status (including anticipated pregnancy); and</p> <p>(7) encourage the FDA to recommend the folic acid fortification of all refined grains marketed for human consumption, including grains not carrying the "enriched" label. (CSA Rep. 8, A-99; Modified: CSAPH Rep. 6, A-06; Reaffirmed: CSAPH Rep. 1, I-13)</p>	Retain; still relevant.
H-440.931	Update on Tuberculosis	<p>It is the policy of the AMA that: (1) All prison <u>individuals who are incarcerated</u> should be tuberculin skin-tested upon arrival and annually thereafter. Those who are positive should be managed as medically appropriate, contact tracing performed, and provisions made for the continued treatment and follow-up of those who are released prior to the completion of their therapy. (2) Staff of both prisons and jails should be tuberculin-tested upon employment and annually thereafter. Those who are positive should be managed as medically appropriate and contact tracing performed. (3) Both public and health care worker education about TB, its transmission, and the necessity for preventive as well as therapeutic treatment should be increased. (4) Current CDC guidelines for the prevention of tuberculosis in congregate settings should be fully implemented. The protection of persons who are immunocompromised needs to be addressed especially by treatment centers housing such persons. (5) While powered air-purification respirators may be useful for the protection of HIV-infected and other immunocompromised health care workers who care for patients with infectious TB, their routine use for the</p>	Retain as amended; updating language.

		prevention of the nosocomial transmission of TB is uncalled for in health care facilities where CDC guidelines are fully implemented. (6) States should review their TB control laws using current CDC recommendations and recent legal and ethical publications as guidelines. Where necessary to further protect the public health from the disease, existing laws should be modified and/or new ones added. (BOT Rep. JJ, A-93; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	
H-440.934	Adequacy of Sterilization in Commercial Enterprises	The AMA requests that state health departments ensure the adequacy of sterilization of instruments used in commercial enterprises (tattoo parlors, beauty salons, barbers, manicurists, etc.) because of the danger of exchange of infected blood-contaminated fluids. (Sub. Res. 409, I-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-440.966	Elimination of Tuberculosis as a Public Health Problem	The AMA (1) endorses the Strategic Plan for the Elimination of Tuberculosis, as developed by the CDC Division of Tuberculosis Elimination Advisory Committee for the Elimination of Tuberculosis ; (2) supports cooperative efforts with other national medical and public health organizations to help implement the policies of the Strategic Plan for the Elimination of Tuberculosis; (3) supports the promulgation of information on the appropriate methods for evaluating, diagnosing, treating, and preventing tuberculosis; (4) encourages and assists state and county medical associations to work with state, county and city health officials to achieve the long-range objective of reducing the incidence of active tuberculosis in the United States to one case per million before the year 2010 ; and (5) supports use of a tuberculosis risk assessment questionnaire in US school aged children when appropriate, with follow-up TB testing based on the results of that TB risk assessment. (Res. 75, A-88; Reaffirmed: Sunset Report, I-98; Modified and Reaffirmed: CSAPH Rep. 2, A-08; Appended: Res. 515, A-13)	Retain as amended; updated language to be consistent with the current goals.
H-455.980	National Biomedical Tracer Facility	The AMA supports the establishment of a National Biomedical Tracer Facility with federal funding to serve as a national resource for clinical medicine, research and education. (Res. 513, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-455.994	Risks of Nuclear Energy and Low-Level Ionizing Radiation	Our AMA supports the following policy on nuclear energy and low-level ionizing radiation: (1) Usefulness of Nuclear Energy: Energy produced by nuclear reactors makes an important contribution to the generation of electricity in the US at present, and it will continue to do so in the foreseeable future. Investigation and research should continue in order to develop improved safety and efficiency of nuclear reactors, and to explore the potential of competing methods for generating electricity. The research should include attention to occupational and public health	Retain as amended; still relevant.

		<p>hazards as well as to the environmental problems of waste disposal and atmospheric pollution.</p> <p>(2) Research on Health Effects of Low Level Radiation: There should be a continuing emphasis on research that is capable of determining more precisely the health effects of low level ionizing radiation.</p> <p>(3) Uranium Mill Tailings: Uranium mill tailings should be buried or otherwise covered.</p> <p>(4) Radioactive Waste Disposal: There should be acceleration of pilot projects to evaluate techniques for the disposal of high-level radioactive wastes. The decommissioning of nuclear reactors is a source of nuclear waste which requires accelerated technological investigation and planning. Local laws should be modified to allow the disposal of low level radioactive waste materials in accordance with AMA model state legislation.</p> <p>(5) Occupational Safety: The philosophy of maintaining exposures of workers at levels "as low as reasonably achievable (ALARA)" is commended. The present federal standards for occupational exposure to ionizing radiation are adequate. The responsibilities of the various federal agencies regarding workers in the nuclear energy industry should be clarified; these agencies include the Departments of Energy, Defense, HHS, Labor and Transportation; and the NRC, VA and EPA.</p> <p>(6) Minimizing Exposures to Radiation: Each physician should attempt to minimize exposures of patients to ionizing radiation in accord with good medical practice.</p> <p>(7) Radiation Exposure Standards: The present standards for exposure of populations to ionizing radiation are adequate for the protection of the public.</p> <p>(8) Emergencies and Governmental Readiness: Government agencies at all levels should be prepared to respond to nuclear energy-related emergencies. There is need for improved public planning by the several federal agencies involved, including the Federal Emergency Management Agency (FEMA) and the agencies of state and local governments. Responsible officials should develop skills and undergo periodic retraining in order to be able to act appropriately during major radiation emergencies. Because emergency planning is a complex task involving aspects of health as well as problems related to utilities, state and local governments and the federal government (FEMA) would benefit from the cooperation of physicians and others in the health sciences.</p> <p>(9) Federal Radiation Emergency Planning Responsibilities: Federal groups such as the NRC and FEMA must work together closely to fulfill responsibilities in radiological emergency preparedness and in crisis management. There is a need for NRC and FEMA to define better the roles of community hospitals and of physicians.</p> <p>(10) Reactor Operators and Radiation Inspectors: There is a need for better training of operating personnel with</p>	
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H-460.903	Commercialized Medical Screening	<p>Our AMA supports the funding of well-designed, large-scale clinical trials aimed at determining the safety, value, and cost-effectiveness of screening imaging procedures.</p> <p>(CSA Rep. 10, A-03; Modified: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.
H-460.915	Cloning and Stem Cell Research	<p>Our AMA: (1) supports biomedical research on multipotent stem cells (including adult and cord blood stem cells); (2) supports the use of somatic cell nuclear transfer technology in biomedical research (therapeutic cloning); (3) opposes the use of somatic cell nuclear transfer technology for the specific purpose of producing a human child (reproductive cloning); (4) encourages strong public support of federal funding for research involving human pluripotent stem cells; and (5) will continue to monitor developments in stem cell research and the use of somatic cell nuclear transfer technology.</p> <p>(CSA Rep. 5, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.
H-470.972	Medical and Nonmedical Uses of	<p>Our AMA (1) reaffirms its concern over the nonmedical use of drugs among athletes, its belief that drug use to</p>	Retain; still relevant.

	Anabolic-Androgenic Steroids	enhance or sustain athletic performance is inappropriate, its commitment to cooperate with various other concerned organizations, and its support of appropriate education and rehabilitation programs; (2) actively encourages further research on short- and long-term health effects, and encourages reporting of suspected adverse effects to the FDA; and (3) supports continued efforts to work with sports organizations to increase understanding of health effects and to discourage use of steroids on this basis. (CSA Rep. A, I-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: Res. 501, A-01; Modified: CSA Rep. 9, A-03; Modified: CSAPH Rep. 1, A-13)	
H-480.956	Commercialized Medical Screening	AMA policy is that relevant specialty societies continue to evaluate the validity and clinical use of screening imaging procedures that are advertised directly to the public and make available to the broader physician community unbiased evaluations to help primary care physicians advise their patients of the risks and benefits of these procedures. (CSA Rep. 10, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-480.966	Multiplex DNA Testing for Genetic Conditions	Policy of the AMA is that: (1) tests for more than one genetic condition should be ordered only when clinically relevant and after the patient or parent/guardian has had full counseling and has given informed consent; (2) efforts should be made to educate clinicians and society about genetic testing; and (3) before genetic testing, patients should be counseled on the familial implications of genetic test results, including the importance of sharing results in instances where there is a high likelihood that a relative is at risk of serious harm, and where the relative could benefit from early monitoring or from treatment. (CEJA Rep. 1, I-96; Appended: BOT Rep. 16, I-99; Modified: CSA Rep. 3, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-480.978	Medical Innovations	It is the policy of the AMA to continue to publicly support adequate funding for the development and implementation of medical innovations, and that the reasoning behind this position be communicated to physicians, the public, and appropriate policymakers. (Sub. Res. 508, I-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-485.995	TV Violence	The AMA reaffirms its vigorous opposition to television violence and its support for efforts designed to increase the awareness of physicians and patients that television violence is a risk factor threatening the health of young people. (Res. 19, I-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmation A-13; Reaffirmed: CSAPH Rep. 1, A-13)	Retain, still relevant.
H-490.906	Enhanced Education for Abrupt Cessation of Smoking	Our AMA encourages research and evaluation on promising smoking cessation protocols that promote abrupt cessation of smoking without reliance on pharmaceuticals. (Res. 408, A-13)	Retain; still relevant.

H-490.914	Tobacco Prevention and Youth	<p>(1) (a) urges the medical community, related groups, educational institutions, and government agencies to demonstrate more effectively the health hazards inherent in the use of tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco); (b) encourages state and local medical societies to actively advise municipalities and school districts against use of health education material sponsored or distributed by the tobacco industry; and (c) publicly rejects the tobacco industry as a credible source of health education material;</p> <p>(2) opposes the use of tobacco products of any kind in day care centers or other establishments where pre-school children attend for educational or <u>childcare</u> purposes;</p> <p>(3) advises public and private schools about the very early smoking habits observed in children and encourages appropriate school authorities to prohibit the use of all tobacco products in elementary through senior high school by anyone during the school day and during other school-related activities;</p> <p>(4) (a) supports the concept that a comprehensive health education program stressing health maintenance be part of the required curriculum through 12th grade to: (i) help pre-teens, adolescents, and young adults avoid the use of tobacco products, including smokeless tobacco; and (ii) emphasize the benefits of remaining free of the use of tobacco products; (b) will work with other public and private parties to actively identify and promote tobacco prevention programs for minors and encourages the development, evaluation, and incorporation of appropriate intervention programs, including smoking cessation programs, that are tailored to the needs of children; and (c) recommends that student councils and student leaders be encouraged to join in an anti-smoking campaign.</p> <p>(5) urges state medical societies to promote the use of appropriate educational films and educational programs that reduce tobacco use by young people;</p> <p>(6) (a) favors providing financial support to promising behavioral research into why people, especially youth, begin smoking, why they continue, and why and how they quit; (b) encourages research into further reducing the risks of cigarette smoking; and (c) continues to support research and education programs, funded through general revenues and private sources, that are concerned with health problems associated with tobacco and alcohol use;</p> <p>(7) opposes the practice of tobacco companies using the names and distinctive hallmarks of well-known organizations and celebrities, such as fashion designers, in marketing their products, as youth are particularly susceptible;</p> <p>(8) supports working with appropriate organizations to develop a list of physicians and others recommended as speakers for local radio and television to discuss the</p>	Retain as amended; still relevant.
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		harmful effects of tobacco usage and to advocate a tobacco-free society; and (9) commends the following entities for their exemplary efforts to inform the Congress, state legislatures, education officials and the public of the health hazards of tobacco use: American Cancer Society, American Lung Association, American Heart Association, Action on Smoking and Health, Inc., Groups Against Smoker's Pollution, National Congress of Parents and Teachers, National Cancer Institute, and National Clearinghouse on Smoking (HEW). (CSA Rep. 3, A-04; Modified: Res. 402, A-13)	
H-495.985	Smokeless Tobacco	Given that the use of smokeless tobacco (snuff and chewing tobacco) is associated with health risks, our AMA: (1) supports publicizing the increasing evidence that the use of snuff or chewing tobacco is associated with adverse health effects and encourages ongoing research to further define the health risks associated with snuff and chewing tobacco, including the risk of developing cardiovascular disease, and the effectiveness of cessation and prevention programs; (2) objects strongly to the introduction of "smokeless" cigarettes; (3) opposes the use of smokeless tobacco products by persons of all ages; (4) urges that the same requirements and taxes placed on cigarette sales and advertising be applied to smokeless tobacco products; (5) supports legislation to prohibit the sale of smokeless tobacco products to minors and encourages states to enforce strictly the prohibition on purchasing and distributing all tobacco products to individuals under the age of 21 years; (6) supports public and school educational programs on the health effects of smokeless tobacco products; (7) urges the commissioners of professional athletic organizations to discourage the open use of smokeless tobacco by professional athletes and recommends that professional athletes participate in media programs that would discourage the youth of America from engaging in this harmful habit; and (8) is committed to exerting its influence to limit exposure of young children and teenagers to advertising for smokeless tobacco and look-alike products, and urges that manufacturers take steps to diminish the appeal of snuff and chewing tobacco to young persons. (CSA Rep. 3, A-04; Reaffirmation A-13)	Retain; still relevant.
H-5.985	Fetal Tissue Research	The AMA supports the use of fetal tissue obtained from induced abortion for scientific research. (Res. 540, A-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-50.975	Safety of Blood Donations and Transfusions	Our AMA: (1) Supports working with blood banking organizations to educate prospective donors about the safety of blood donation and blood transfusion;	Retain; still relevant.

		<p>(2) Supports the use of its publications to help physicians inform patients that donating blood does not expose the donor to the risk of HIV/AIDS;</p> <p>(3) Encourages physicians to inform high-risk patients of the value of self-deferral from blood and blood product donations; and</p> <p>(4) Supports providing educational information to physicians on alternatives to transfusion.</p> <p>(CSA Rep. 4, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	
H-50.976	Blood Bank Look-Back Programs	<p>Our AMA supports the concept of blood bank look-back recipient notification programs as a means of protecting patients and reducing the possible spread of infections.</p> <p>(CSA Rep. 4, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.
H-50.977	Blood Donor Recruitment	<p>Our AMA: (1) supports the establishment of a national volunteer blood donor education and recruitment campaign to assure an adequate and readily available blood supply; and (2) supports scientifically-based policies that ensure the safety of the nation's blood supply.</p> <p>(Sub. Res. 401, A-02; Modified: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.
H-50.982	Autologous Blood Transfusions	<p>The AMA (1) supports the collection of autologous blood from candidates for elective surgery who are without contraindications to phlebotomy and when such donations are medically indicated because transfusion is likely to be needed; and (2) supports efforts to remove economic barriers to the collection and use of autologous blood for transfusion, in order to promote its wider use.</p> <p>(CSA Rep. A, I-92; Modified: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Retain; still relevant.
H-515.981	Family Violence-Adolescents as Victims and Perpetrators	<p>The AMA (1) (a) encourages physicians to screen adolescents about a current or prior history of maltreatment. Special attention should be paid to screening adolescents with a history of alcohol and drug misuse, irresponsible sexual behavior, eating disorders, running away, suicidal behaviors, conduct disorders, or psychiatric disorders for prior occurrences of maltreatment; and (b) urges physicians to consider issues unique to adolescents when screening youths for abuse or neglect. (2) encourages state medical society violence prevention committees to work with child protective service agencies to develop specialized services for maltreated adolescents, including better access to health services, improved foster care, expanded shelter and independent living facilities, and treatment programs. (3) will investigate research and resources on effective parenting of adolescents to identify ways in which physicians can promote parenting styles that reduce stress and promote optimal development. (4) will alert the national school organizations to the increasing incidence of adolescent maltreatment and the need for training of school staff to identify and refer victims of maltreatment. (5) urges youth correctional facilities to screen incarcerated youth for a current or prior history of abuse or neglect and to refer maltreated youth to appropriate medical or mental</p>	Retain; still relevant.

		health treatment programs. (6) encourages the National Institutes of Health and other organizations to expand continued research on adolescent initiation of violence and abuse to promote understanding of how to prevent future maltreatment and family violence. (CSA Rep. I, A-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	
H-515.982	Violent Acts Against Physicians	Our AMA (1) condemns acts of violence against physicians involved in the legal practice of medicine; (2) will continue to take an active interest in the apprehension and prosecution of those persons committing assaults on physicians as a result of the physician's acting in a professional capacity; (3) will continue to monitor state legislative efforts on increased criminal penalties for assaults against health care providers; and (4) will continue to work with interested state and national medical specialty societies through all appropriate avenues, including state legislatures, when issues related to workplace violence inside and outside of the emergency department arise. (Res. 605, A-92; Reaffirmation I-99; Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed in lieu of Res. 608, A-12; Modified: BOT Rep. 2, I-12; Reaffirmed in lieu of Res. 423, A-13)	Retain; still relevant.
H-60.925	Effects of Alcohol on the Brains of Underage Drinkers	Our AMA supports creating a higher level of awareness about the harmful consequences of underage drinking. (CSA Rep. 11, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-60.926	Prevention of Falls Through Windows	Our AMA: (1) supports the use of window guards and devices that prevent children from falling through windows; and (2) supports public education regarding the risks of children falling through windows. (Res. 415, A-13)	Retain; still relevant.
H-60.941	Effects of Alcohol on the Brains of Underage Drinkers	Our AMA encourages increased medical and policy research on the harmful effects of alcohol on adolescents and young adults and on the design and implementation of environmental strategies to reduce youth access to, and high consumption of, alcohol. (CSA Rep. 11, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Retain as amended; still relevant.
H-60.945	Neonatal Male Circumcision	1. Our AMA: (a) encourages training programs for pediatricians, obstetricians, and family physicians to incorporate information on the use of local pain control techniques for neonatal circumcision; (b) supports the general principles of the 2012 Circumcision Policy Statement of the American Academy of Pediatrics, which reads as follows: "Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks and that the procedure's benefits justify access to this procedure for families who choose it. Specific benefits identified included prevention of urinary tract infections, penile cancer, and transmission of some sexually transmitted infections, including HIV." and (c) urges that as part of the informed consent discussion, the risks and benefits of pain control techniques for circumcision be thoroughly discussed to aid parents in making their decisions.	Retain as amended; still relevant.

		2. Our AMA encourages state Medicaid reimbursement of neonatal male circumcision. (CSA Rep. 10, I-99; Reaffirmed: CSAPH Rep. 1, A-09; Modified: Res. 503, A-13)	
H-60.963	Preventable Airway Obstructions in Children	The AMA supports educational programs to apprise the public of the dangers of airway obstruction hazards in children and on methods to prevent these hazards. (Res. 412, A-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-60.973	Provision of Health Care and Parenting Classes to Adolescent Parents	1. It is the policy of the AMA (A) to encourage state medical and specialty societies to seek to increase the number of adolescent parenting programs within school settings which provide health care for infant and mother, and child development classes in addition to current high school courses and (B) to support programs directed toward increasing high school graduation rates, improving parenting skills and decreasing future social service dependence of teenage parents. 2. Our AMA will actively provide information underscoring the increased risk of poverty after adolescent pregnancy without marriage when combined with failure to complete high school. (Res. 422, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11; Appended: Res. 422, A-13)	Retain; still relevant.
H-60.975	Political Influence and the NIH	Our AMA (1) reaffirms its support for the long standing, uniformly accepted and merit-based scientific peer review system utilized by federal research agencies, including the National Institutes of Health; and (2) deplors the use of political influence to override decisions to support research proposals when those decisions were derived from scientific peer review. (Res. 526, I-91; Modified: Sunset Report, I-01; Reaffirmed: Res. 725, I-03; Modified: CSAPH Rep. 1, A-13)	Retain; still relevant.
H-75.994	Contraception and Sexually Transmitted Diseases Infections	Our AMA, in cooperation with state, county, and specialty medical societies, encourages physicians to educate their patients about sexually transmitted diseases <u>infections</u> , including HIV disease, and condom use. While such counseling may not be appropriate for all contraception patients, physicians should be encouraged to provide this information to any contraception patient who may benefit from being more aware of the risks of sexually transmitted diseases <u>infections</u> . (BOT Rep. E, A-89; Reaffirmation A-99; Reaffirmed and Title Change: CSA Rep. 4, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	Retain as amended; still relevant.
H-90.977	Impairment and Disability Evaluations	It is the policy of the AMA: (1) that in settings where impairment and disability evaluations are required, physicians should determine medical impairment and their functional consequences, including those associated with HIV infection, using medically established and approved guidelines; and (2) to	Retain; still relevant.

		encourage physicians to contribute their medical expertise to disability determinations. (CSA Rep. 8, I-99; Reaffirmed and Title Change: CSA Rep. 4, A-03; Reaffirmed: CSAPH Rep. 1, A-13)	
H-95.954	The Reduction of Medical and Public Health Consequences of Drug <u>Use Abuse</u>	Our AMA: (1) encourages national policy-makers to pursue an approach to the problem of drug <u>misuse</u> abuse aimed at preventing the initiation of drug use, aiding those who wish to cease drug use, and diminishing the adverse consequences of drug use; (2) encourages policy-makers to recognize the importance of screening for alcohol and other drug use in a variety of settings, and to broaden their concept of addiction treatment to embrace a continuum of modalities and goals, including appropriate measures of harm reduction, which can be made available and accessible to enhance positive treatment outcomes for patients and society; (3) encourages the expansion of opioid maintenance programs so that opioid maintenance therapy can be available for any individual who applies and for whom the treatment is suitable. Training must be available so that an adequate number of physicians are prepared to provide treatment. Program regulations should be strengthened so that treatment is driven by patient needs, medical judgment, and drug rehabilitation concerns. Treatment goals should acknowledge the benefits of abstinence from drug use, or degrees of relative drug use reduction; (4) encourages the extensive application of needle and syringe exchange and distribution programs and the modification of restrictive laws and regulations concerning the sale and possession of needles and syringes to maximize the availability of sterile syringes and needles, while ensuring continued reimbursement for medically necessary needles and syringes. The need for such programs and modification of laws and regulations is urgent, considering the contribution of injection drug use to the epidemic of HIV infection; (5) encourages a comprehensive review of the risks and benefits of U.S. state-based drug legalization initiatives, and that until the findings of such reviews can be adequately assessed, the AMA reaffirm its opposition to drug legalization; (6) strongly supports the ability of physicians to prescribe syringes and needles to patients <u>who inject drugs</u> with injection drug addiction in conjunction with addiction counseling in order to help prevent the transmission of contagious diseases; and (7) encourages state medical associations to work with state regulators to remove any remaining barriers to permit physicians to prescribe needles for patients. Res. 416, A-00; Reaffirmation I-00; Reaffirmed: CSAPH Rep. 1, A-10; Modified: CSAPH Rep. 2, I-13)	Retain as amended; still relevant.
H-95.956	Harm Reduction Through Addiction Treatment	The AMA endorses <u>supports</u> the concept of prompt access to treatment for chemically dependent patients, regardless of the type of addiction, and the AMA will work toward the implementation of such an approach nationwide. The AMA affirms that addiction treatment is a demonstrably viable and efficient method of	Retain as amended; still relevant.

		<p>reducing the harmful personal and social consequences of the inappropriate use of alcohol and other psychoactive drugs and urges the Administration and Congress to provide significantly increased funding for treatment of alcohol use disorders alcoholism and other drug dependencies <u>substance use disorders</u> and support of basic and clinical research so that the causes, mechanisms of action and development of addiction can continue to be elucidated to enhance treatment efficacy.</p> <p>(Res. 411, A-95; Appended: Res. 405, I-97; Reaffirmation I-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	
H-95.961	Policy on Legal <u>Illicit</u> Drug Use	<p>The AMA discourages and condemns illegal <u>illicit</u> drug use, and encourages physicians to do all in their power to discourage the use of illegal <u>illicit</u> drugs in their communities and to refuse to assist anyone in obtaining drugs for non-medical use.</p> <p>(Res. 523, A-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13)</p>	Rescind based on stigmatizing language and discordance with more recent policy.
H-95.984	Issues in Employee Drug Testing	<p>The AMA (1) reaffirms its commitment to educate physicians and the public about the scientific issues of drug testing; (2) supports monitoring the evolving legal issues in drug testing of employee groups, especially the issues of positive drug tests as a measure of health status and potential employment discrimination resulting therefrom; (3) takes the position that urine alcohol and other drug testing of employees should be limited to (a) preemployment examinations of those persons whose jobs affect the health and safety of others, (b) situations in which there is reasonable suspicion that an employee's (or physician's) job performance is impaired by alcohol and/or other drug use, (c) monitoring as part of a comprehensive program of treatment and rehabilitation of substance use disorders, and (d) urine, alcohol and other drug testing of all physicians and appropriate employees of health care institutions may be appropriate under these same conditions; and (4) urges employers who choose to establish alcohol and other drug testing programs to use confirmed, positive test results in employees primarily to motivate those employees to seek appropriate assistance with their alcohol or other drug problems, preferably through employee assistance programs.</p> <p>(CSA Rep. A, A-87; Reaffirmed: Sub. Res. 39, A-90, CSA Rep. D, I-90; BOT Rep. I, A-90; CSA Rep. 2, I-95; Reaffirmed: BOT Rep. 17, I-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed: Res. 817, I-13)</p>	Retain; still relevant.
H-95.997	Cannabis Intoxication as a Criminal Defense	<p>Our AMA believes a plea of cannabis intoxication not be a defense in any criminal proceedings.</p> <p>(BOT Rep. J, A-72; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Modified: CSAPH Rep. 2, I-13)</p>	Retain; still relevant.