

REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports, 1–9, were presented by Louis J. Kraus, MD, Chair:

1. CSAPH SUNSET REVIEW OF 2006 HOUSE POLICIES

Reference committee hearing: see report of [Reference Committee D](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

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

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

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

(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.

In this report, the Council on Science and Public Health (CSAPH) presents its recommendations on the disposition of the House policies from 2006 that were assigned to it. The CSAPH’s recommendations on policies are presented in the Appendix to this report.

RECOMMENDATION

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

APPENDIX - Recommended Actions on 2006 House Policies and Directives

Policy Number	Title	Recommended Action and Rationale
D-30-994	Take Action to End Alcohol Ads on College Sports Telecasts	Retain. Although the specific actions called for in this directive were accomplished, the NCAA does not yet ban alcohol ads for those products that contain less than 6% alcohol by volume.
D-120.968	Pharmacy Review of First Dose Medication	Sunset #1 – outdated and the standards have been revised. Retain #2 as stand-alone and change to AMA Policy as it is still relevant.
D-120.969	FDA Oversight of Bioidentical Hormone (BH) Preparations	Retain.
D-120.970	Prescription Requirements for Schedule II (C-II) Controlled Substance for a Hospice Patient	Sunset. Accomplished.
D-120.988	Inappropriate Actions by Pharmacies and Pharmacy Benefit Managers	Retain. AMA continues to work advocating for implementation of a standardized electronic process for pharmacy prior authorization.
D-130.981	Improving Regional Terrorism and Disaster Preparedness and Response	Sunset. Accomplished.
D-135.993	Contamination of Drinking Water by Pharmaceuticals and Personal Care Products	Sunset (1). Retain (2) in part to read as follows, and Change to AMA Policy: (2) encourage <u>AMA supports</u> the EPA and other federal agencies to engage in <u>engaging</u> relevant stakeholders, which may include, but is not limited to the AMA, pharmaceutical companies, pharmaceutical retailers, state and specialty societies, and public health organizations, in the development of guidelines for physicians and the public for the proper disposal of pharmaceuticals and personal care products to prevent contamination of drinking water systems.
D-150.986	Promotion of Healthy Lifestyles 1: Reducing the Population Burden of Cardiovascular Disease by Reducing Sodium Intake	Sunset (2) and (4). Retain 1, 3, and 5 and change to AMA Policy.
D-170.995	Human Papillomavirus (HPV) Inclusion in High School Education Curricula	Retain. Still relevant.
D-245.996	Standardization of Newborn Screening Programs	Sunset. Accomplished. Superseded by H-245.973.
D-440.957	Distribution and Administration of Vaccines	Sunset. Superseded by H-440.877.
D-440.959	Community-Associated Methicillin Resistant Staphylococcus Aureus	Sunset. Accomplished.
D-440.968	Expedited Partner Therapy (Patient-Delivered Partner Therapy)	Sunset (1), (2), (3). Accomplished. Retain (4) as stand-alone directive.
D-450.975	Centers for Excellence Designation	Sunset. Accomplished.
D-450.976	Patient Safety	Sunset. Accomplished.
D-450.977	Patient Adherence to Treatment Plans	Sunset. Superseded by AMA Policy H-373.993 – and a “Steps Forward” module has been created on medication adherence.
D-460.975	Tobacco Use or Exposure as a Variable in Clinical Research	Retain. Change to AMA policy.
D-475.998	Home Sedation for Children Undergoing Outpatient Procedures	Sunset. Accomplished.
D-490.979	Banning Smoking in All Workplaces	Retain. Still relevant. Not all workplaces are smoke-free.
H-10.974	Assurance of the Public’s Health Aboard Cruise Ships	Retain. Proposed legislation referred to as Cruise Passenger Protection Act of 2015 (CPPA), H.R. 3142, is currently pending in Congress.
H-15.978	Voluntary Highway Lights-On Campaign	Retain. Still relevant.
H-20.904	HIV/AIDS Education and Training	Retain in part. Retain (1) a), d), e), and f) Retain b) in part to read: b) <u>Can be a catalyst to bring the</u> Our AMA urges the communications industry, government officials, and the health care communities together to design and direct efforts for more effective and better targeted public awareness and information programs about HIV disease prevention through various public media, especially for those persons at increased risk of HIV infection; Sunset c) and g), (2) Retain a), sunset b), Retain c in part to

Policy Number	Title	Recommended Action and Rationale
		read: eb) Supports efforts to obtain adequate funding from local, state, and national sources for the immediate development and implementation of HIV educational programs as part of comprehensive health education in the schools. Retain (3) in part to read: (a) Our AMA supports continued efforts to work with other medical organizations, public health officials, universities, and others to foster the development and/or enhancement of programs to provide comprehensive information and training for primary care physicians, other front-line health workers (specifically including those in drug <u>addiction</u> treatment and community health centers and correctional facilities), and auxiliaries focusing on basic knowledge of HIV infection, modes of transmission, and recommended risk reduction strategies. Such efforts should assure: (i) educational programs covering practical and didactic aspects of universal precautions and infectious control procedures be conducted for all health care workers, and especially for physicians who practice invasive procedures; (ii) an easily accessible method of receiving the most current authoritative information on HIV; (iii) readily available training in HIV counseling and education; (iv) continuing education and training on techniques related to nonjudgmental history taking of sexual practices and drug use; (v) identification of effective ways to change those behaviors that place a person at risk of HIV infection; (vi) a review of methods other than education and counseling that might be effective in preventing the spread of HIV among intravenous drug users; Sunset b), c), d) e). Sunset (4) a), b) and c).
H-30.948	Thiamin Addition to Alcohol	Retain (1) with change in title to read: "Improving Nutritional State of Persons with Alcohol Use Disorder." Delete (2).
H-50.988	Autologous Blood Transfusions	Sunset. Outdated and impractical policy.
H-55.990	Cancer Risk of Pesticides in Agricultural Workers	Sunset. On September 28, 2015 EPA released its long-awaited improved rules for protecting farmworkers from on-the-job exposure to hazardous pesticides.
H-60.934	Internet Pornography: Protecting Children and Youth Who Use the Internet	Retain in part with title change to: "Internet Pornography: Protecting Children and Youth Who Use the Internet <u>and Social Media</u> ." Still relevant. Modify slightly to read (additions underlined): Our AMA: (1) Recognizes the positive role of the Internet in providing health information to children and youth. (2) Recognizes the negative role of the Internet in connecting children and youth to predators and exposing them to pornography. (3) Supports federal legislation that restricts Internet access to pornographic materials in designated public institutions where children and youth may use the Internet. (4) Encourages physicians to continue efforts to raise parent/guardian awareness about the importance of educating their children about safe internet <u>and social media</u> use. (5) Supports school-based media literacy programs that teach effective thinking, learning, and safety skills related to internet and social media use.
H-60.935	The National Children's Study	Sunset. The National Children's Study closed on December 12, 2014 following the advice of an expert review group.
H-60.951	Aspiration Hazard of Peanuts and Other Nuts	Sunset.
H-60.992	Missing and Exploited Children	Sunset. Outdated, predates the Internet.
H-65.974	Gender-Based Violence	Retain (1) and (3). Sunset (2).
H-75.996	Media Advertising and Public Service	Retain. Still relevant.

Policy Number	Title	Recommended Action and Rationale
	Announcements Regarding Contraception and Safe Sexual Practices	
H-95.985	Drug Screening and Mandatory Drug Testing	Retain pending Council update.
H-95.986	State Legislation to Monitor Prescription of Schedule II Drugs	Retain with change in title to read "State Legislation to Monitor Prescription of Controlled Substances Schedule II Drugs ". Still relevant.
H-100.988	Homeopathic Pharmacopoeia	Sunset. AMA supports review by the FDA.
H-115.985	Warning Labels on Over-The-Counter Iron Preparations and Dietary Supplements	Retain. Still an issue.
H-115.997	Patient Package Inserts	Sunset. Superseded by Policy H-115.969.
H-120.963	Epidemiology of Drug Errors	Retain. Still relevant.
H-125.985	Expanded Use of the AMA's Principles of a Sound Drug Formulary	Retain. Still relevant.
H-130.979	National Disaster Medical System	Retain. Still relevant.
H-130.981	The Heimlich Maneuver	Sunset due to variable guidelines.
H-135.945	Encouraging Alternatives to PVC/DEHP Products in Health	Retain. Still relevant.
H-135.954	Education and Prevention Programs Regarding Air Pollution Impact on Body Organs and Systems	Sunset. Not a strategic priority.
H-145.982	Prevention of Ocular Injuries from BB and Air Guns	Retain. Still relevant. Despite an April 2015 report from the American Association for Pediatric Ophthalmology and Strabismus encouraging stricter regulations on the use of air guns as well as greater usage of eye protection, the federal government doesn't regulate the sale of non-powder guns, and only 22 states restrict the ownership and use of these guns. This in spite of dramatic increases in eye injuries in children from air guns, BB guns and paintball guns.
H-150.979	Fast Food	Retain. Still relevant.
H-170.995	Healthful Lifestyles	Retain. Still relevant.
H-245.976	Hyponatremic Seizures Among Infants Fed with Commercial Bottled Drinking Water	Sunset. Multiple educational opportunities now exist regarding infant nutrition.
H-245.978	Impact of 24-Hour Postpartum Stay on Infant and Maternal Health	Sunset. National Conference of State Legislatures published final maternity length-of-stay rules and they became effective December 9, 2008 taking effect on January 2, 2009. Rules state 48 hour minimum post vaginal delivery, 96 hours post cesarean section.
H-365.990	Adverse Health Effects of Video Display Terminals	Sunset due to change in technology.
H-370.970	Umbilical Cord Blood Transplantation: The Current Scientific Understanding	Retain. The American Society of Hematology published article in 2013. Still relevant.
H-420.982	Standard Terminology for Reporting of Reproductive Health Statistics in the United States	Retain. Still relevant.
H-425.983	The Preservation of Guidelines for Adolescent Preventive Services (GAPS) in Current Practice	Sunset. Last updated 1998. No longer AMA project.
H-425.984	Clinical Preventive Services	Retain. Still relevant.
H-425.993	Health Promotion and Disease Prevention	Retain. Still applicable.
H-440.879	Expedited Partner Therapy (Patient-delivered Partner Therapy): An Update	Retain. Still relevant.
H-440.909	Regulation of Tattoo Artists and Facilities	Retain. Still relevant. A couple of states still do not regulate tattoo artists and facilities.
H-440.910	Medicine-Public Health Congress: Follow-Up Action	Sunset. No viable constituency has been established.
H-440.911	Medicine/Public Health Initiative	Sunset. Infrastructure not in place to support an activity of this magnitude.
H-440.948	Health Care Workers Infected with Hepatitis B Virus	Sunset # 1 and #3--CDC Guidelines now in place superseding these recommendations. Retain #2 in part to read as follows: All health care workers (<i>i.e.</i> , any person involved in patient care in a paid capacity or as a volunteer and as a student,

Policy Number	Title	Recommended Action and Rationale
		<u>resident, trainee, or trained worker</u>) who are at risk of infection with HBV should be fully immunized with HBV vaccine.
H-440.975	Community Control of Public Sources of Spread of Sexually Transmitted Diseases	Sunset. Outdated.
H-455.986	Radon in Homes	Retain. Still relevant.
H-455.987	Radioepidemiologic Tables	Sunset. Outdated and no longer relevant.
H-455.989	Involvement of Physician Expertise in Non-Military Radiation Emergencies	Retain with change in title to read: "Involvement of Physician Expertise in Non-Military Radiation Emergencies." Still relevant.
H-455.990	Safe Use of Radioactive Materials in Medical Practice	Sunset, no longer relevant. Federal, state and local agencies share responsibility for overseeing the uses of radiation in medicine. Radioactive material is regulated by the NRC or an Agreement State. There are 37 states that have signed agreements with the NRC allowing them to regulate the use of certain radioactive materials. These states issue licenses to and oversee medical users such as university medical centers, hospitals, clinics and doctors in private practice. The NRC similarly licenses and oversees medical uses in the 13 non-Agreement States, the District of Columbia, Puerto Rico and other US territories. The NRC is also responsible for ensuring the common defense and security of nuclear materials.
H-460.929	Expanded Public Education Program in Support of Animal Research	Retain, pending policy consolidation by CSAPH.
H-460.932	Increased Public Education Regarding Animal Research	Retain, pending policy consolidation by CSAPH.
H-460.957	Medical Research Involving Animals	Retain, pending policy consolidation by CSAPH.
H-470.964	Youth Training for Participating in Olympic Level Competition	Sunset. Accomplished. National Association for Sport and Physical Education published guidelines on this in 2010.
H-470.965	Ultimate and Extreme Fighting	Retain. Still continues.
H-470.977	Use of Protective Headgear During Equestrian Activities	Sunset. Professional Association of Therapeutic Horsemanship International requires all participants to wear protective headgear as of 2012 PATH standards.
H-480.967	Alternative Therapies for the Symptoms of Menopause	Sunset pending CSAPH Report.
H-480.983	Clinical Ecology	Sunset. Not necessary.
H-485.992	Support for Increased Educational Children's Television Programming	Retain. Still relevant.

2. HUMAN AND ENVIRONMENTAL EFFECTS OF LIGHT EMITTING DIODE (LED) COMMUNITY LIGHTING

Reference committee hearing: see report of [Reference Committee E](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**
See Policy H-135.927

INTRODUCTION

With the advent of highly efficient and bright light emitting diode (LED) lighting, strong economic arguments exist to overhaul the street lighting of US roadways.¹⁻³ Valid and compelling reasons driving the conversion from conventional lighting include the inherent energy efficiency and longer lamp life of LED lighting, leading to savings in energy use and reduced operating costs, including taxes and maintenance, as well as lower air pollution burden from reduced reliance on fossil-based carbon fuels.

Not all LED light is optimal, however, when used as street lighting. Improper design of the lighting fixture can result in glare, creating a road hazard condition.^{4,5} LED lighting also is available in various color correlated temperatures. Many early designs of white LED lighting generated a color spectrum with excessive blue

wavelength. This feature further contributes to disability glare, i.e., visual impairment due to stray light, as blue wavelengths are associated with more scattering in the human eye, and sufficiently intense blue spectrum damages retinas.^{6,7} The excessive blue spectrum also is environmentally disruptive for many nocturnal species. Accordingly, significant human and environmental concerns are associated with short wavelength (blue) LED emission. Currently, approximately 10% of existing US street lighting has been converted to solid state LED technology, with efforts underway to accelerate this conversion. The Council is undertaking this report to assist in advising communities on selecting among LED lighting options in order to minimize potentially harmful human health and environmental effects.

METHODS

English language reports published between 2005 and 2016 were selected from a search of the PubMed and Google Scholar databases using the MeSH terms “light,” “lighting methods,” “color,” “photic stimulation,” and “adverse effects,” in combination with “circadian rhythm/physiology/radiation effects,” “radiation dosage/effects,” “sleep/physiology,” “ecosystem,” “environment,” and “environmental monitoring.” Additional searches using the text terms “LED” and “community,” “street,” and “roadway lighting” were conducted. Additional information and perspective were supplied by recognized experts in the field.

ADVANTAGES AND DISADVANTAGES OF LED STREET LIGHTS

The main reason for converting to LED street lighting is energy efficiency; LED lighting can reduce energy consumption by up to 50% compared with conventional high pressure sodium (HPS) lighting. LED lighting has no warm up requirement with a rapid “turn on and off” at full intensity. In the event of a power outage, LED lights can turn on instantly when power is restored, as opposed to sodium-based lighting requiring prolonged warm up periods. LED lighting also has the inherent capability to be dimmed or tuned, so that during off peak usage times (e.g., 1 to 5 AM), further energy savings can be achieved by reducing illumination levels. LED lighting also has a much longer lifetime (15 to 20 years, or 50,000 hours), reducing maintenance costs by decreasing the frequency of fixture or bulb replacement. That lifespan exceeds that of conventional HPS lighting by 2-4 times. Also, LED lighting has no mercury or lead, and does not release any toxic substances if damaged, unlike mercury or HPS lighting. The light output is very consistent across cold or warm temperature gradients. LED lights also do not require any internal reflectors or glass covers, allowing higher efficiency as well, if designed properly.^{8,9}

Despite the benefits of LED lighting, some potential disadvantages are apparent. The initial cost is higher than conventional lighting; several years of energy savings may be required to recoup that initial expense.¹⁰ The spectral characteristics of LED lighting also can be problematic. LED lighting is inherently narrow bandwidth, with “white” being obtained by adding phosphor coating layers to a high energy (such as blue) LED. These phosphor layers can wear with time leading to a higher spectral response than was designed or intended. Manufacturers address this problem with more resistant coatings, blocking filters, or use of lower color temperature LEDs. With proper design, higher spectral responses can be minimized. LED lighting does not tend to abruptly “burn out,” rather it dims slowly over many years. An LED fixture generally needs to be replaced after it has dimmed by 30% from initial specifications, usually after about 15 to 20 years.^{1,11}

Depending on the design, a large amount blue light is emitted from some LEDs that appear white to the naked eye. The excess blue and green emissions from some LEDs lead to increased light pollution, as these wavelengths scatter more within the eye and have detrimental environmental and glare effects. LED’s light emissions are characterized by their correlated color temperature (CCT) index.^{12,13} The first generation of LED outdoor lighting and units that are still widely being installed are “4000K” LED units. This nomenclature (Kelvin scale) reflects the equivalent color of a heated metal object to that temperature. The LEDs are cool to the touch and the nomenclature has nothing to do with the operating temperature of the LED itself. By comparison, the CCT associated with daylight light levels is equivalent to 6500K, and high pressure sodium lighting (the current standard) has a CCT of 2100K. Twenty-nine percent of the spectrum of 4000K LED lighting is emitted as blue light, which the human eye perceives as a harsh white color. Due to the point-source nature of LED lighting, studies have shown that this intense blue point source leads to discomfort and disability glare.¹⁴

More recently engineered LED lighting is now available at 3000K or lower. At 3000K, the human eye still perceives the light as “white,” but it is slightly warmer in tone, and has about 21% of its emission in the blue-appearing part of the spectrum. This emission is still very blue for the nighttime environment, but is a significant improvement over

the 4000K lighting because it reduces discomfort and disability glare. Because of different coatings, the energy efficiency of 3000K lighting is only 3% less than 4000K, but the light is more pleasing to humans and has less of an impact on wildlife.

Glare

Disability glare is defined by the Department of Transportation (DOT) as the following:

Disability glare occurs when the introduction of stray light into the eye reduces the ability to resolve spatial detail. It is an objective impairment in visual performance.

Classic models of this type of glare attribute the deleterious effects to intraocular light scatter in the eye. Scattering produces a veiling luminance over the retina, which effectively reduces the contrast of stimulus images formed on the retina. The disabling effect of the veiling luminance has serious implications for nighttime driving visibility.¹⁵

Although LED lighting is cost efficient and inherently directional, it paradoxically can lead to worse glare than conventional lighting. This glare can be greatly minimized by proper lighting design and engineering. Glare can be magnified by improper color temperature of the LED, such as blue-rich LED lighting. LEDs are very intense point sources that cause vision discomfort when viewed by the human eye, especially by older drivers. This effect is magnified by higher color temperature LEDs, because blue light scatters more within the human eye, leading to increased disability glare.¹⁶

In addition to disability glare and its impact on drivers, many residents are unhappy with bright LED lights. In many localities where 4000K and higher lighting has been installed, community complaints of glare and a “prison atmosphere” by the high intensity blue-rich lighting are common. Residents in Seattle, WA have demanded shielding, complaining they need heavy drapes to be comfortable in their own homes at night.¹⁷ Residents in Davis, CA demanded and succeeded in getting a complete replacement of the originally installed 4000K LED lights with the 3000K version throughout the town at great expense.¹⁸ In Cambridge, MA, 4000K lighting with dimming controls was installed to mitigate the harsh blue-rich lighting late at night. Even in places with a high level of ambient nighttime lighting, such as Queens in New York City, many complaints were made about the harshness and glare from 4000K lighting.¹⁹ In contrast, 3000K lighting has been much better received by citizens in general.

Unshielded LED Lighting

Unshielded LED lighting causes significant discomfort from glare. A French government report published in 2013 stated that due to the point source nature of LED lighting, the luminance level of unshielded LED lighting is sufficiently high to cause visual discomfort regardless of the position, as long as it is in the field of vision. As the emission surfaces of LEDs are highly concentrated point sources, the luminance of each individual source easily exceeds the level of visual discomfort, in some cases by a factor of 1000.¹⁷

Discomfort and disability glare can decrease visual acuity, decreasing safety and creating a road hazard. Various testing measures have been devised to determine and quantify the level of glare and vision impairment by poorly designed LED lighting.²⁰ Lighting installations are typically tested by measuring foot-candles per square meter on the ground. This is useful for determining the efficiency and evenness of lighting installations. This method, however, does not take into account the human biological response to the point source. It is well known that unshielded light sources cause pupillary constriction, leading to worse nighttime vision between lighting fixtures and causing a “veil of illuminance” beyond the lighting fixture. This leads to worse vision than if the light never existed at all, defeating the purpose of the lighting fixture. Ideally LED lighting installations should be tested in real life scenarios with effects on visual acuity evaluated in order to ascertain the best designs for public safety.

Proper Shielding

With any LED lighting, proper attention should be paid to the design and engineering features. LED lighting is inherently a bright point source and can cause eye fatigue and disability glare if it is allowed to directly shine into human eyes from roadway lighting. This is mitigated by proper design, shielding and installation ensuring that no light shines above 80 degrees from the horizontal. Proper shielding also should be used to prevent light trespass into homes alongside the road, a common cause of citizen complaints. Unlike current HPS street lighting, LEDs have the

ability to be controlled electronically and dimmed from a central location. Providing this additional control increases the installation cost, but may be worthwhile because it increases long term energy savings and minimizes detrimental human and environmental lighting effects. In environmentally sensitive or rural areas where wildlife can be especially affected (e.g., near national parks or bio-rich zones where nocturnal animals need such protection), strong consideration should be made for lower emission LEDs (e.g., 3000K or lower lighting with effective shielding). Strong consideration also should be given to the use of filters to block blue wavelengths (as used in Hawaii), or to the use of inherent amber LEDs, such as those deployed in Quebec. Blue light scatters more widely (the reason the daytime sky is “blue”), and unshielded blue-rich lighting that travels along the horizontal plane increases glare and dramatically increases the nighttime sky glow caused by excessive light pollution.

POTENTIAL HEALTH EFFECTS OF “WHITE” LED STREET LIGHTING

Much has been learned over the past decade about the potential adverse health effects of electric light exposure, particularly at night.²¹⁻²⁵ The core concern is disruption of circadian rhythmicity. With waning ambient light, and in the absence of electric lighting, humans begin the transition to nighttime physiology at about dusk; melatonin blood concentrations rise, body temperature drops, sleepiness grows, and hunger abates, along with several other responses.

A number of controlled laboratory studies have shown delays in the normal transition to nighttime physiology from evening exposure to tablet computer screens, backlit e-readers, and room light typical of residential settings.²⁶⁻²⁸ These effects are wavelength and intensity dependent, implicating bright, short wavelength (blue) electric light sources as disrupting transition. These effects are not seen with dimmer, longer wavelength light (as from wood fires or low wattage incandescent bulbs). In human studies, a short-term detriment in sleep quality has been observed after exposure to short wavelength light before bedtime. Although data are still emerging, some evidence supports a long-term increase in the risk for cancer, diabetes, cardiovascular disease and obesity from chronic sleep disruption or shiftwork and associated with exposure to brighter light sources in the evening or night.^{25,29}

Electric lights differ in terms of their circadian impact.³⁰ Understanding the neuroscience of circadian light perception can help optimize the design of electric lighting to minimize circadian disruption and improve visual effectiveness. White LED streetlights are currently being marketed to cities and towns throughout the country in the name of energy efficiency and long term cost savings, but such lights have a spectrum containing a strong spike at the wavelength that most effectively suppresses melatonin during the night. It is estimated that a “white” LED lamp is at least 5 times more powerful in influencing circadian physiology than a high pressure sodium light based on melatonin suppression.³¹ Recent large surveys found that brighter residential nighttime lighting is associated with reduced sleep time, dissatisfaction with sleep quality, nighttime awakenings, excessive sleepiness, impaired daytime functioning, and obesity.^{29,32} Thus, white LED street lighting patterns also could contribute to the risk of chronic disease in the populations of cities in which they have been installed. Measurements at street level from white LED street lamps are needed to more accurately assess the potential circadian impact of evening/nighttime exposure to these lights.

ENVIRONMENTAL EFFECTS OF LED LIGHTING

The detrimental effects of inefficient lighting are not limited to humans; 60% of animals are nocturnal and are potentially adversely affected by exposure to nighttime electrical lighting. Many birds navigate by the moon and star reflections at night; excessive nighttime lighting can lead to reflections on glass high rise towers and other objects, leading to confusion, collisions and death.³³ Many insects need a dark environment to procreate, the most obvious example being lightning bugs that cannot “see” each other when light pollution is pronounced. Other environmentally beneficial insects are attracted to blue-rich lighting, circling under them until they are exhausted and die.^{34,35} Unshielded lighting on beach areas has led to a massive drop in turtle populations as hatchlings are disoriented by electrical light and sky glow, preventing them from reaching the water safely.³⁵⁻³⁷ Excessive outdoor lighting diverts the hatchlings inland to their demise. Even bridge lighting that is “too blue” has been shown to inhibit upstream migration of certain fish species such as salmon returning to spawn. One such overly lit bridge in Washington State now is shut off during salmon spawning season.

Recognizing the detrimental effects of light pollution on nocturnal species, US national parks have adopted best lighting practices and now require minimal and shielded lighting. Light pollution along the borders of national parks leads to detrimental effects on the local bio-environment. For example, the glow of Miami, FL extends throughout

the Everglades National Park. Proper shielding and proper color temperature of the lighting installations can greatly minimize these types of harmful effects on our environment.

CONCLUSION

Current AMA Policy supports efforts to reduce light pollution. Specific to street lighting, Policy H-135.932 supports the implementation of technologies to reduce glare from roadway lighting. Thus, the Council recommends that communities considering conversion to energy efficient LED street lighting use lower CCT lights that will minimize potential health and environmental effects. The Council previously reviewed the adverse health effects of nighttime lighting, and concluded that pervasive use of nighttime lighting disrupts various biological processes, creating potentially harmful health effects related to disability glare and sleep disturbance.²⁵

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) support the proper conversion to community-based Light Emitting Diode (LED) lighting, which reduces energy consumption and decreases the use of fossil fuels.
2. That our AMA encourage minimizing and controlling blue-rich environmental lighting by using the lowest emission of blue light possible to reduce glare.
3. That our AMA encourage the use of 3000K or lower lighting for outdoor installations such as roadways. All LED lighting should be properly shielded to minimize glare and detrimental human and environmental effects, and consideration should be given to utilize the ability of LED lighting to be dimmed for off-peak time periods.

REFERENCES

1. Municipal Solid State Street Lighting Consortium. <http://www1.eere.energy.gov/buildings/ssl/consortium.html>. Accessed April 4, 2016.
2. Illuminating Engineering Society RP-8 – Guide to Roadway Lighting. <http://www.ies.org/>? 2014. Accessed April 4, 2016.
3. LED Lighting Facts–A Program of the United States Department of Energy. <http://www.lightingfacts.com>. Accessed April 5, 2016.
4. Lin Y, Liu Y, Sun Y, Zhu X, Lai J, Heynderickx I. Model predicting discomfort glare caused by LED road lights. *Opt Express*. 2014;22(15):18056-71.
5. Gibbons RB, Edwards CJ. A review of disability and discomfort glare research and future direction. 18th Biennial TRB Visibility Symposium, College Station TX, United States, April 17-19, 2007.
6. Shang YM, Wang GS, Sliney D, Yang CH, Lee LL. White light-emitting diodes (LEDs) at domestic lighting levels and retinal injury in a rat model. *Environ Health Perspect*. 2014;122(3):269-76.
7. Lougheed T. Hidden blue hazard? LED lighting and retinal damage in rats, *Environ Health Perspect*. 2014;122(3):A81.
8. A Municipal Guide for Converting to LED Street Lighting, (<http://www1.eere.energy.gov/buildings/ssl/consortium.html>) 10/13/2013.
9. In depth: Advantages of LED Lighting. <http://energy.ltgovernors.com/in-depth-advantages-of-led-lighting.html>. Accessed April 5, 2016.
10. Silverman H. How LED Streetlights Work. HowStuffWorks.com. June 22, 2009. <http://science.howstuffworks.com/environmental/green-tech/sustainable/led-streetlight.htm>. Accessed April 7, 2016.
11. Jin H, Jin S, Chen L, Cen S, Yuan K. Research on the lighting performance of LED street lights with different color temperatures. *IEEE Photonics Journal*. 2015;24(6):975-78. <http://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=7328247>. Accessed April 7, 2016.
12. Morris N. LED there be light. Nick Morris predicts a bright future for LEDs. *Electrooptics.com*. <http://www.electrooptics.com/features/junjul06/junjul06leds.html>. Accessed April 7, 2016.
13. Mills MP. The LED illumination revolution. *Forbes Magazine*. February 27, 2008. http://www.forbes.com/2008/02/27/incandescent-led-cfl-pf-guru_in_mm_0227energy_inl.html. Accessed April 5, 2016.
14. Opinion of the French Agency for Food, Environmental and Occupational Health & Safety, October 19, 2010. <https://web.archive.org/web/20140429161553/http://www.anses.fr/Documents/AP2008sa0408EN.pdf>
15. U.S. Department of Transportation, Federal Highway Administration, 2005.
16. Sweater-Hickcox K, Narendran N, Bullough JD, Freyssinier JP. Effect of different coloured luminous surrounds on LED discomfort glare perception. *Lighting Research Technology*. 2013;45(4):464-75. <http://lrt.sagepub.com/content/45/4/464>. Accessed April 5, 2016.

17. Scigiano E. Seattle's new LED-lit streets Blinded by the lights. *Crosscut*. March 18, 2013. <http://crosscut.com/2013/03/streetlights-seattle-led/>. Accessed April 6, 2016.
18. Davis will spend \$350,000 to replace LED lights after neighbor complaints. CBS Local, Sacramento; October 21, 2014. <http://sacramento.suntimes.com/sac-news/7/138/6000/davis-will-spend-350000-to-replace-led-lights-after-neighbor-complaints>.
19. Chaban M. LED streetlights in Brooklyn are saving energy but exhausting residents. *NY Times*; March 23, 2015. http://www.nytimes.com/2015/03/24/nyregion/new-led-streetlights-shine-too-brightly-for-some-in-brooklyn.html?_r=0. Accessed April 5, 2016.
20. Vos JJ. On the cause of disability glare and its dependence on glare angle, age and ocular pigmentation. *Clin Exp Optom*. 2003;86(6):363-70.
21. Stevens RG, Brainard GC, Blask DE, Lockley, SW, Motta, ME. Breast cancer and circadian disruption from electric lighting in the modern world. *CA Cancer J Clin*. 2014;64:207-18.
22. Evans JA, Davidson AJ. Health consequences of circadian disruption in humans and animal models. *Prog Mol Biol Transl Sci*. 2013;119:283-323.
23. Wright KP Jr, McHill AW, Birks BR, Griffin BR, Rusterholz T, Chinoy ED. Entrainment of the human circadian clock to the natural light-dark cycle. *Curr Biol*. 2013;23:1554-8.
24. Energy Savings Estimates of Light Emitting Diodes in Niche Lighting Applications. Building Technologies Program, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy. January 2011. http://apps1.eere.energy.gov/buildings/publications/pdfs/ssl/nichefinalreport_january2011.pdf. Accessed April 7, 2016.
25. Council on Science and Public Health Report 4. Light pollution. Adverse effects of nighttime lighting. American Medical Association, Annual Meeting, Chicago, IL. 2012.
26. Cajochen C, Frey S, Anders D, et al. Evening exposure to a light-emitting diodes (LED)-backlit computer screen affects circadian physiology and cognitive performance. *J Appl Physiol*. 2011;110:1432-8.
27. Chang AM, Aeschbach D, Duffy JF, Czeisler CA. Evening use of light-emitting eReaders negatively affects sleep, circadian timing, and next-morning alertness. *Proc Natl Acad Sci USA*. 2015;112:1232-7.
28. Gooley JJ, Chamberlain K, Smith KA, et al. Exposure to room light before bedtime suppresses melatonin onset and shortens melatonin duration in humans. *J Clin Endocrinol Metab*. 2011;96:E463-72.
29. Koo YS, Song JY, Joo EY, et al. Outdoor artificial light at night, obesity, and sleep health: Cross-sectional analysis in the KoGES study. *Chronobiol Int*. 2016;33(3):301-14.
30. Lucas RJ, Peirson SN, Berson DM, et al. Measuring and using light in the melanopsin age. *Trends Neurosci*. 2014;37:1-9.
31. Falchi F, Cinzano P, Elvidge CD, Keith DM, Haim A. Limiting the impact of light pollution on human health, environment and stellar visibility. *J Environ Manage*. 2011;92:2714-22.
32. Ohayon M, Milesi C. Sleep deprivation/insomnia and exposure to street lights in the American general population. American Academy of Neurology Annual Meeting. April 15-21, 2016. Vancouver, BC.
33. Pawson SM, Bader MK. Led lighting increases the ecological impact of light pollution irrespective of color temperature. *Ecological Applications*. 2014;24:1561-68.
34. Gaston K, Davies T, Bennie J, Hopkins J. Reducing the ecological consequences of night-time light pollution: Options and developments. *J Appl Ecol*. 2012;49(6):1256-66.
35. Salmon M. Protecting sea turtles from artificial night lighting at Florida's oceanic beaches. In- Rich C, Longcore T (eds.). *Ecological Consequences of Artificial Night Lighting*. 2006:141-68. Island Press, Washington, DC.
36. Rusenko KW, Mann JL, Albury R, Moriarty JE, Carter HL. Is the wavelength of city glow getting shorter? Parks with no beachfront lights record adult aversion and hatchling disorientations in 2004. Kalb H, Rohde A, Gayheart K, Shanker, K, compilers. 2008. *Proceedings of the Twenty-fifth Annual Symposium on Sea Turtle Biology and Conservation*, NOAA Technical Memorandum NMFS-SEFSC-582, 204pp. <http://www.nmfs.noaa.gov/pr/pdfs/species/turtlesymposium2005.pdf>
37. Rusenko KW, Newman R, Mott C, et al. Using GIS to determine the effect of sky glow on nesting sea turtles over a ten year period. Jones TT, Wallace BP, compilers. 2012. *Proceedings of the Thirty-first Annual Symposium on Sea Turtle Biology and Conservation*. NOAA Technical Memorandum NOAA NMFS-SEFSC-631:32p.

Acknowledgement: The Council thanks George Brainard, PhD (Thomas Jefferson University); Richard Stevens, PhD (University Connecticut Health Center); and Mario Motta, MD (CSAPH, Tufts Medical School) for their contributions in preparing the initial draft of this report, and the commentary by Travis Longcore, PhD, on the ecological impact of nighttime electrical lighting.

3. THE PRECISION MEDICINE INITIATIVE

Reference committee hearing: see report of [Reference Committee E](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**
See Policy D-460.968

BACKGROUND

During the 2015 State of the Union address, the President announced the Precision Medicine Initiative (PMI), an ambitious project aiming to “bring us closer to curing diseases like cancer and diabetes and give all of us access to the personalized information we need to keep ourselves and our families healthier.”¹ The PMI has two overarching goals: intensified efforts toward the molecular characterization of cancers and development of targeted therapeutics; and the creation of a research cohort of over one million volunteers who will share genetic data, biological samples, and diet and lifestyle information, all linked to their electronic health records if they choose.² The Administration has tasked the National Institutes of Health (NIH), the National Cancer Institute (NCI), the Food and Drug Administration (FDA), and the Office of the National Coordinator for Health Information Technology (ONC) with carrying out various aspects of the PMI, and also has challenged private sector groups to assist in PMI efforts.³

In the context of the PMI, “precision medicine” is defined as prevention and treatment that takes into account individual variations in genes, environment, and lifestyle.² In some ways, physicians already are practicing “precision medicine” by managing each patient according to his or her unique symptoms, medical and family history, and preferences. However, recent technological advances such as the development of large-scale biologic databases (for example, the human genome sequence), powerful methods for characterizing patients (proteomics, metabolomics, genomics, cellular assays, and mobile health technologies), and computational tools for analyzing large sets of data have vastly improved the ability to apply precision medicine principles to patient care.⁴

Implementation of the PMI is in the early stages, but a roadmap of key activities is emerging. However, it is not yet clear how physicians will be affected by the PMI in the long term, and how they can contribute to its goals. The scale of the initiative, especially its goal of developing a large research cohort, means that physicians are likely to have clinical encounters with participants, and could view and use their patients’ genomic and other health data to inform ongoing care. They could also have the opportunity to recruit patients to become part of the cohort, and may be asked by patients about cohort enrollment and health data sharing. In the near future, successful PMI research projects that are translated into clinic practice will result in additional genomic and digital data that could influence patient management. The Council on Science and Public Health has initiated this report to inform physicians and the House of Delegates about the PMI and the potential ways that it could affect their practice and their patients.

METHODS

Literature searches were conducted in the PubMed database for English-language articles published between 2010 and 2016 using the search terms “precision medicine initiative” and “precision medicine.” These searches were intended to identify the impetus for the Precision Medicine Initiative and the reactions to it. To capture reports not indexed on PubMed, a Google search was conducted using the same search terms. Websites on the Precision Medicine Initiative, maintained by the White House, NIH, and NCI were consulted, as were reports by the Advisory Committee to the Director of the NIH and the Secretary’s Advisory Committee on Genetics, Health, and Society. Additional articles were identified by manual review of the references cited in these publications.

OBJECTIVES OF THE PMI

More and better treatments for cancer

The field of oncology is already making great strides in precision medicine. Risk assessment, diagnosis, prognosis and management can be tailored based on the genetic variations present in cancer cells. It has become standard practice to use multi-variant panel tests to determine risk of recurrence and magnitude of benefit of chemotherapy for certain breast cancers,⁵ and a number of similar multi-variant panels exist for characterizing other tumor types.⁶ Similarly, the availability and use of targeted therapeutics has increased. Nearly 50 oncology therapeutics targeted to

genetic variations have been approved by the FDA.^{7,8} However, too often, after remarkable results with a targeted therapeutic, cancer cells acquire resistance and stop responding. A deeper understanding of the molecular underpinnings of cancer is needed to develop more effective treatments, making the field of oncology a fitting candidate for the PMI.

The NCI has been tasked by the PMI with addressing obstacles that are commonly encountered in “precision oncology,” e.g., unexplained drug resistance, genomic heterogeneity of tumors, insufficient means for monitoring responses and tumor recurrence, and limited knowledge about the use of drug combinations.⁴ The NCI plans to address these obstacles by expanding precision medicine clinical trials focused on assigning patients to therapy targeted to the genetic alterations thought to be driving their cancer.⁹ An example of this type of trial already underway is NCI-MATCH, a large, multi-site trial that analyzes patients’ tumors to determine whether they contain genetic abnormalities for which a targeted drug already exists and assigns treatment based on the abnormality.¹⁰ A pediatric version of NCI-MATCH is expected to launch in 2016.¹¹ Under the PMI, the NCI also plans to increase its support of research on the development of new *in vitro* models of human cancers and better understand what drives the molecular response to immunotherapies; and establish a “knowledge network,” i.e., a national database that houses and integrates genomic information from tumors, including clinical response data and outcomes information, as a resource for scientists, health care professionals, and patients.

Creation of a voluntary national research cohort

For more than a decade, a case has been made for the development of a large US research cohort, which would enable prospective studies on a wide range of diseases.¹²⁻¹⁵ A research cohort is made up of a large number of individuals willing to provide access to their specimens and medical information and the collection of information about their environmental exposures (including physical, social, and behavioral information).¹⁴ Data stored in databases and specimens stored in repositories could then be accessed by qualified investigators for specific and approved research purposes.¹⁴ Large research cohorts have been created recently by several groups, the largest of which include the US Department of Veterans Affairs’ Million Veteran Program; Geisinger Health System’s MyCode Project; and Kaiser Permanente’s Research Program on Genes, Environment, and Health.

As part of the PMI, the NIH has been tasked with creating a national research cohort. During much of 2015, a Working Group of the Advisory Committee to the Director of the NIH held public forums, solicited feedback, and developed plans around such issues as the unique scientific opportunities offered by the cohort, characteristics of already existing cohorts, effective mechanisms for analyzing large amounts of data, maximizing participant engagement, and using mobile and personal health technologies for data collection.¹⁶ The Working Group issued a report late in 2015 with its recommendations for creating the cohort.¹⁷ Among the recommendations were:

- **Cohort Assembly:** The PMI cohort should be a new, broadly accessible, national research resource of volunteers that reflect the diversity of the US. All potential participants in the cohort must agree to share their health data, provide a biospecimen (blood), and be recontacted for future research.
- **Cohort Recruitment:** Any individual living in America should have the opportunity to directly volunteer for the PMI Cohort Program or join through health care provider organizations (HPOs).
- **Participant Engagement:** The PMI Cohort Program should return to each participant their own results and aggregated results from its studies. Participants should be able to set preferences to dictate how much personal information they receive, and be able to change their preferences throughout their participation in the cohort.
- **Data Collection and Storage:** The PMI Cohort Program should anticipate and collect a diverse set of data types, beginning with a core set of high-value variables to be acquired during enrollment from all participants and stored centrally. The initial core data set should include data from electronic health records (EHRs), health insurance organizations, participant surveys, mHealth technologies, and biologic investigations.
- **Data Security and Access:** A data access control approach appropriate to the level of sensitivity of the data, from open-access for summary data to role-based access for individual level data, should be instituted. Data should be accessed and analyzed in de-identified forms, and secure computing environments should be used for data access and analysis.

INITIATIVES ENABLING THE PMI

To enable the PMI to proceed as the President has envisioned it, several improvements to research, regulatory, and data access infrastructures need to be instituted. Additionally, the innovative capabilities of private entities should be explored and applied to the PMI to solve current challenges.

Regulatory modernization

The Common Rule. The collection and use of data that straddle the research and patient care boundary, such as that likely to be generated in the PMI, should be subject to principles that both protect the participants and foster innovation.¹⁷ To that end, United States Department of Health and Human Services (HHS) announced late in 2015 proposed revisions to the Common Rule, the regulations governing the ethical conduct of research involving humans.^{18,19} The revisions have two central goals: enhance respect and safeguards for research participants, and increase research efficiency by reducing unnecessary burdens and calibrating oversight to the level of risk. A major step toward the latter goal was taken in February 2016 when the NIH announced that it is establishing a central PMI Cohort Program Institutional Review Board with expertise in mobile health technologies, bioinformatics, health disparities, epidemiology, genomics, and environmental health for oversight and review of the research conducted in the Cohort Program.²⁰

Next-generation sequencing. As part of the PMI, the FDA has begun to explore what type of oversight framework and resources would be appropriate for the clinical tests used to analyze the biological information provided by participants.²¹ Specifically, the FDA is focusing on the use of next-generation sequencing (NGS)-based technologies. NGS is a method for rapid and large-scale genomic sequencing; it is used in whole genome and whole exome sequencing, and often in panel-based tests that analyze dozens or even hundreds of genetic variants simultaneously.^{22,23} NGS is distinct from narrowly targeted tests because it is likely to reveal a large number of secondary findings, i.e., genetic variants not related to the phenotype under investigation but that might impact a patient's health.²⁴ Since the biospecimens contributed to the PMI will likely be genetically analyzed using NGS-based testing, the FDA has been exploring oversight mechanisms for it. The FDA has stated that because NGS tests are capable of detecting so many genetic variants that were not necessarily the initial targets of the tests, the traditional construct of evaluating the safety and efficacy of a targeted test that detects only one or a few variants may not be applicable to NGS.^{21,25}

The AMA has been active in its advocacy for genetic test oversight, including for NGS-based tests. The AMA supports a Clinical Laboratory Improvement Amendments (CLIA)-based laboratory oversight system along with appropriate third-party accreditation, and is opposed to FDA oversight of laboratory-developed testing services in all but the most narrow of circumstances.²⁶ Accordingly, the AMA has made public comments and statements for the record opposing FDA oversight that infringes on the practice of medicine, and has engaged with a broad group of stakeholders to support regulatory reform for genetic tests that promotes innovation and preserves patient access.²⁷⁻²⁹

Patient access to health data. The PMI has emphasized that the participants who volunteer to take part in the cohort will be treated as partners, including having access to the health data generated as a function of their participation. This includes returning personal results and information to individual participants and sharing aggregate findings from PMI investigations, and giving participants the opportunity to set preferences, and change those preferences at any time, to dictate how much personal health information they want to receive.¹⁷

Key to patient accessibility of health data generated in the PMI is the right of individuals to access and obtain a copy of their protected health information (PHI). In July of 2015, ONC and the Office for Civil Rights (OCR) announced they would work to address barriers that prevent patients from accessing their health data.³⁰ To honor that pledge, OCR in January 2016 issued guidance on the Health Insurance Portability and Accountability Act's provisions providing individuals with the right to access and receive a copy of their PHI held by healthcare providers and health plans.³¹ Additional efforts toward patient access to health information by improving interoperability and accessibility have been undertaken by health technology stakeholders, including the AMA. In February 2016, the AMA, along with dozens of health information technology developers, healthcare systems and physician health provider advocacy groups, pledged to work with HHS to improve the flow of electronic health information to patients and physicians to increase data sharing.^{32,33}

Public-private partnerships

The PMI will rely on partnerships with existing research cohorts, patient groups, and the private sector to develop the infrastructure that will be needed to expand the cancer genomics projects and to launch the Cohort Program.³ In February 2016, the Administration announced grant awards to several private sector and federal entities to begin implementation of the Cohort Program. Grants were awarded to Vanderbilt University and Verily (formerly Google Life Sciences) to develop a direct-volunteer pilot program that will explore the optimal approaches and systems for engaging, enrolling, and retaining participants; the Health Resources and Services Administration to begin partnerships with Federally Qualified Health Centers to develop, pilot, and refine approaches for bringing underserved individuals, families, and communities into the PMI Cohort Program; and ONC for a program called “Sync for Science” (“S4S”), which will pilot use of open, standardized applications to give individuals the ability to contribute their data to research.²⁰

Additionally, the Administration announced the commitments of more than 40 private sector organizations, including the AMA, health information technology companies, academic medical centers, biotechnology and pharmaceutical companies, research institutes, and advocacy groups, to assist in laying the foundation for the PMI, including patient access to their health data, engaging research participants as partners, improving data sharing, developing data security and privacy principles, and applying precision medicine to clinical practice.³⁴ The commitment of the AMA is:

The AMA commits to actively working in 2016 to improve patient access to their medical information and helping physicians leverage electronic tools to make health information more readily available, developing and disseminating a range of resources including toolkits, podcasts, and fact sheets. The AMA will also improve awareness of the Precision Medicine Initiative among physicians, including: creating articles in AMA digital publications; educational sessions at AMA meetings; emails/posts/tweets through social media channels; and information about the Precision Medicine Initiative Cohort and how to volunteer, once enrollment begins.

PHYSICIAN INVOLVEMENT IN COHORT PROGRAM RECRUITMENT

Currently, little is known about how physicians will be affected by the PMI, but the implementation plans announced for the Cohort Program suggest that physicians will play a key role in recruiting participants.

HPO participant recruitment

One of the two methods of recruiting participants for the Cohort Program will be through health care provider organizations (HPOs), which the PMI defines as institutions at which patients receive care over time resulting in a longitudinal record of care available in electronic format with ongoing, documented follow-up.¹⁷ Examples of HPOs include academic medical centers, Federally Qualified Health Centers, vertically integrated private health care organizations (e.g., Kaiser Permanente), and vertically integrated governmental organizations (e.g., VA).¹⁷ Accordingly, physicians practicing at these institutions likely will be expected to talk with their patients about the Cohort Program and should be prepared to answer patients’ questions about it. Topics may range from broad questions about what the Cohort Program is and what its goals are, to more specific questions about what type of information might be returned from the Cohort Program and how physicians might use it for patient management.

A baseline health exam and submission of a biospecimen (blood) will be required for participants; therefore physicians or their health professional team members will likely be performing the exams and collecting the biospecimens. Even if the exams are conducted by a separate entity within the HPO, the data from the exam will be deposited into the patient’s EHR and will be viewable and actionable by the patient’s physician. Participants also are expected to share with the PMI certain health information in their EHR. Physicians therefore may need to be prepared to talk with their patients about health data sharing, security, and privacy. When participants receive individual results from the PMI, physicians should be prepared to answer patients’ questions about what the results mean and how they could or should be applied to their care.

Direct volunteer enrollment

For those wishing to participate in the Cohort Program who do not have the opportunity to enroll through an HPO, a second mechanism for enrollment is through direct volunteerism.¹⁷ These participants could be recruited through a

number of technologies, such as Internet, social media, and mobile technologies, and through community and advocacy organizations and events. Participants volunteering must visit a health professional for a baseline exam and submission of a biospecimen. Physicians conducting these exams should be prepared to answer questions as discussed above, i.e., what the Cohort Program is and what its goals are; what type of information might be returned and how it might be applied to care; and what type of data sharing, security, and privacy protections are in place.

Participants volunteering outside of an HPO also must agree to share EHR data if they have it. The PMI envisions participants sharing their EHR using “Blue Button” technology, a term referring to patient online access to health care data with download ability and in some cases, transmittal to a third party application or service of the patient’s choice.^{17,35} Although this technology is not part of all EHR systems to date, public and private sector organizations have committed to make health information more easily available electronically to individuals and to encourage its use.³⁶ Physicians and their health professional team members may therefore be asked specifically about how to access and share health data from their EHR.

CHALLENGES AND UNANSWERED QUESTIONS FOR PHYSICIANS

Physician education about precision medicine and the PMI

Successful PMI research projects that are translated into clinical practice will result in additional genomic and digital data to inform patient management. But for these data to have a positive clinical impact, physicians need the skills and tools to understand them and use them in a meaningful way. The pace of genomic discoveries and subsequent clinical implementation has been so rapid that even those beginning practice just 10 years ago missed out on contemporary genomics training in medical school. As a result, many physicians report being inadequately prepared to use genomic information for patient care.³⁷⁻³⁹ This serves as a barrier to the implementation of genomic technologies into routine practice, and must be addressed to foster success for the PMI.^{40,41} Consequently, as the PMI begins, initiatives are needed to create genomics resources and tools that are integrated into clinical practice to enable non-geneticist physicians to become proficient in practicing precision medicine.

In addition to the educational demand required for the PMI to impact clinical care, improved awareness of and support for the initiative itself among physicians is needed. A number of articles in prestigious medical journals have introduced the PMI,^{4,41-44} but the necessary involvement of physicians in conducting baseline exams for patients enrolling, as well as the consequent role of the physician in answering patients’ questions about the PMI and applying returned results to patient care, creates an imperative to generate support for the PMI among the physician and health professional workforce. Studies have suggested that some physicians remain unsure that genomic information is clinically useful at this point in time,^{37,45,46} creating a potential challenge in convincing physicians that the PMI is a worthwhile endeavor. In addition, the majority of physicians in practice have other competing demands on their time, including implementing new delivery models, participating in quality reporting initiatives, fulfilling meaningful use requirements, and utilizing new digital medicine technologies. Physicians will need to be convinced that the PMI should be prioritized among these competing demands.

EHR and data challenges

EHR capabilities. The health data collected as part of the PMI’s national cohort has the potential to significantly impact clinical care—if it is accessible and meaningful to physicians. Robust and interoperable EHR systems and other health information technology (health IT) must be able to access and display longitudinal health data from each patient, no matter where that data is stored or whether it has been collected as part of the Cohort Program or by another health professional. Similarly, clinical decision support that will enable application of the data to care management is an essential component. However, many EHR systems in use today do not have such capabilities, and physicians are frustrated with the usability of EHR systems and report that they sometimes hamper safe and effective care.⁴⁷

Significant improvements in EHR capabilities are needed for the essential data collection and sharing components of the PMI. The PMI Working group has cited some aspects of Meaningful Use (MU) Stage 3 that could contribute to the necessary innovation to facilitate the Cohort Program.¹⁷ However, concern exists among physicians that the current MU program as well as Stage 3 create a significant barrier between the physician and patient by focusing on counting measure compliance and meeting arbitrary thresholds. Many, including the AMA, believe the Stage 3 MU proposal leaves many problems unanswered, diverts needed resources, and locks-in technology that will not assist

patients and physicians in moving forward.⁴⁸ A number of private sector companies and organizations have made commitments to work with ONC on its S4S initiative, made up of pilot projects that aim to demonstrate new models that enable EHR data access, control, and management; and that would consequently improve care coordination among health professionals and researchers.^{20,34} While S4S is an exciting opportunity for patients and PMI participants to manage their own complete medical record, MU requirements could stall the development of data standards and redirect EHR vendor priorities toward building systems based on a legacy framework.

Data accuracy and usability. While the PMI plans to return to each Cohort Program participant their own results and aggregated results from its studies, the participants' physicians may not automatically receive such results. Participants may have the opportunity to consent to sharing results directly with their physician. EHR capabilities may also dictate whether results will be deposited in the participant's EHR and are accessible to their physician. Physicians also will need to determine which of the returned results might impact patient care. Depending on the nature of the research being conducted, results may be applicable to patient care, for example, the results of a genetic test that identifies a clinically actionable variant; on the other hand, results may reveal the presence or absence of a biomarker that is still in experimental stages and not yet clinically informative. It is essential that physicians receive results that are applicable to patient care, and that mechanisms exist for physicians to receive other types of information should they desire and should the patient consent. Physician access to this data would ensure that it is appropriately explained to the patient in the context of his or her medical and family history, and that it is available to inform care when necessary.

Further, questions arise as to the quality and accuracy of the results, particularly those that are patient-generated. The PMI plans to collect behavioral and environmental data from participant self-reporting and from wearable sensors and applications.¹⁷ These data could include diet, physical activity, tobacco and alcohol use, heart rate, respiratory rate, location, and environmental exposures.¹⁷ While physicians may be interested in some of these measures, it will be difficult to verify the accuracy and quality of the data, and therefore to know whether it is trustworthy. An additional consideration is whether it belongs in the EHR and if so, how it would be deposited.

In addition, MU Stage 3 includes a requirement for physicians to accept patient-generated health data (PGHD), and certified EHRs must also support this function. PGHD are likely to play a role in precision medicine, yet methods for tagging and analyzing these data are still in development, and significant concerns exist about the privacy and security of this information. The mandate for PGHD also could mean that physicians will be required to purchase and implement poorly functioning EHRs and interpret voluminous, unstructured data that may not be accurate or clinically meaningful, detracting from the utility of health IT in the PMI.

CONCLUSIONS

The PMI is an ambitious initiative that holds great promise for improving patient care and outcomes. It will require the coordination and commitment of both the federal and private sectors, and rests on the interest and willingness of participants to enroll and share their health data.

The scale of the PMI means that physicians are likely to have clinical encounters with participants enrolled in the Cohort Program. Ensuring that physicians are well-informed about the PMI and have the educational and health IT resources needed for such an endeavor is vitally important. The Council believes that the AMA is well-positioned to improve awareness of the PMI among physicians and to act as a resource for physicians who have questions about how it will impact their patients.

RECOMMENDATIONS

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

1. That our American Medical Association work with the Precision Medicine Initiative to gather input from physicians to assist in the planning stages of the initiative and to improve awareness and willingness to recruit patients as participants.
2. That our AMA encourage the PMI to develop resources that will assist physicians in understanding the goals of the PMI, how to recruit and enroll patients, and how to best use the research results generated by it.

3. That our AMA continue to advocate for improvements to electronic health record systems that will enable interoperability and access while not creating additional burdens and usability challenges for physicians.

REFERENCES

1. The White House. State of the Union address, 2015. <https://www.whitehouse.gov/the-press-office/2015/01/20/remarks-president-state-union-address-january-20-2015>. Accessed March 7, 2016.
2. National Institutes of Health. Precision Medicine Initiative Infographic. <http://syndication.nih.gov/multimedia/pmi/infographics/pmi-infographic.pdf>. Accessed March 7, 2016.
3. The White House. Fact Sheet: President Obama's Precision Medicine Initiative. <https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative>. Accessed March 7, 2016.
4. Collins FS, Varmus H. A new initiative on precision medicine. *N Engl J Med*. 2015;372(9):793-5.
5. National Comprehensive Cancer Center. Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2016. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 7, 2016.
6. Marrone M, Filipski KK, Gillanders EM, Schully SD, Freedman AN. Multi-marker solid tumor panels using next-generation sequencing to direct molecularly targeted therapies. *PLoS Curr*. 2014;6.
7. Personalized Medicine Coalition. 2015 Annual Report: Education, Advocacy, Impact. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_2015_annual_report.pdf. Accessed March 7, 2016.
8. Personalized Medicine Coalition. 2015 Progress Report: Personalized Medicine at FDA. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/2015_Progress_Report_PM_at_FDA1.pdf. Accessed March 7, 2016.
9. National Cancer Institute. NCI and the Precision Medicine Initiative. <http://www.cancer.gov/research/key-initiatives/precision-medicine>. Accessed March 7, 2016.
10. National Cancer Institute. NCI-Molecular Analysis for Therapy Choice (NCI-MATCH) Trial. <http://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/nci-match>. Accessed March 7, 2016.
11. National Cancer Institute. Pediatric MATCH. <http://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/pediatric-match>. Accessed March 7, 2016.
12. Collins, FS. The case for a US prospective cohort study of genes and environment. *Nature*. 2004;429(6990):475-7.
13. Manolio TA, Bailey-Wilson JE, Collins FS. Genes, environment and the value of prospective cohort studies. *Nat Rev Genet*. 2006;7(10):812-20.
14. Secretary's Advisory Committee on Genetics, Health, and Society. Policy Issues Associated with Undertaking A New Large U.S. Population Cohort Study of Genes, Environment, and Disease (March, 2007). http://osp.od.nih.gov/sites/default/files/SACGHS_LPS_report.pdf. Accessed March 7, 2016.
15. National Research Council of the National Academies. Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease (2011). <http://www.nap.edu/catalog/13284/toward-precision-medicine-building-a-knowledge-network-for-biomedical-research>. Accessed March 7, 2016.
16. National Institutes of Health. Precision Medicine Initiative Events. <https://www.nih.gov/precision-medicine-initiative-cohort-program/events>. Accessed March 7, 2016.
17. Precision Medicine Initiative Working Group of the Advisory Committee to the Director of the NIH. The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine. (September 17, 2015) <https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf>. Accessed March 7, 2016.
18. Office for Human Research Protections. Notice of Proposed Rulemaking 2015: Summary. <http://www.hhs.gov/ohrp/humansubjects/regulations/nprm2015summary.html>. Accessed March 7, 2016.
19. Hudson KL, Collins FS. Bringing the Common Rule into the 21st Century. *N Engl J Med*. 2015;373(24):2293-6.
20. National Institutes of Health. The NIH Director: Preparing to Launch the Precision Medicine Initiative Cohort Program. <http://www.nih.gov/about-nih/who-we-are/nih-director/statements/preparing-launch-precision-medicine-initiative-cohort-program>. Accessed March 7, 2016.
21. Food and Drug Administration. Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests—Preliminary Discussion Paper. (December, 2014). <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM427869.pdf>. Accessed March 7, 2016.
22. Johansen Taber KA, Dickinson BD, Wilson M. The promise and challenges of next-generation genome sequencing for clinical care. *JAMA Intern Med*. 2014;174(2):275-80.
23. American Medical Association Council on Science and Public Health. Clinical Application of Next-Generation Genomic Sequencing. (2012). <http://www.ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-science-public-health/reports/2012-reports.page>. Accessed March 7, 2016.
24. Green RC, Berg JS, Grody WW, et al. ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing. *Genet Med*. 2013;15(7):565-74.
25. Lander ES. Cutting the Gordian helix--regulating genomic testing in the era of precision medicine. *N Engl J Med*. 2015;372(13):1185-6.
26. American Medical Association. Advocacy topics: personalized medicine. <http://www.ama-assn.org/ama/pub/advocacy/topics/personalized-medicine.page>. Accessed March 7, 2016.

27. American Medical Association. Statement of the American Medical Association for the Record: U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health Re: 21st Century Cures—Request for Feedback: A Modernized Framework for Innovative Diagnostic Tests. (January 2015) <https://download.ama-assn.org/resources/doc/washington/energy-commerce-ama-statement-ldt-ivd.pdf>. Accessed March 7, 2016.
28. American Medical Association. Comments on Food and Drug Administration Draft Guidance “Framework for Regulatory Oversight of Laboratory Developed Tests” and “Notification and Medical Device Reporting for Laboratory Developed Tests.” (February 2015) <https://download.ama-assn.org/resources/doc/washington/x-pub/fda-framework-regulatory-oversight-letter-02feb2015.pdf>. Accessed March 7, 2016.
29. American Medical Association. Multi-stakeholder letter to Energy and Commerce Committee and Health, Education, Labor, and Pensions Committee. (October 26, 2015). <https://download.ama-assn.org/resources/doc/washington/x-pub/clia-modernization-sign-on-letter-26oct2015.pdf>. Accessed March 7, 2016.
30. The White House. Fact Sheet: New Patient-Focused Commitments to Advance the President’s Precision Medicine Initiative. <https://www.whitehouse.gov/the-press-office/2015/07/08/fact-sheet-new-patient-focused-commitments-advance-president%20%80%99s-precision>. Accessed March 7, 2016.
31. U.S. Department of Health and Human Services. Individuals’ Right under HIPAA to Access their Health Information 45 CFR § 164.524. <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>. Accessed March 7, 2016.
32. American Medical Association. American Medical Association Continues Efforts to Improve Electronic Health Records <http://www.ama-assn.org/ama/pub/news/news/2016/2016-02-29-ama-improves-ehr.page>. Accessed March 7, 2016.
33. Office of the National Coordinator for Health Information Technology. Interoperability Pledge. <https://www.healthit.gov/commitment>. Accessed March 7, 2016.
34. The White House. Fact Sheet: Obama Administration Announces Key Actions to Accelerate the Precision Medicine Initiative. <https://www.whitehouse.gov/the-press-office/2016/02/25/fact-sheet-obama-administration-announces-key-actions-accelerate>. Accessed March 7, 2016.
35. Office of the National Coordinator for Health Information Technology. Blue Button. <https://www.healthit.gov/patients-families/your-health-data>. Accessed March 7, 2016.
36. Office of the National Coordinator for Health Information Technology. Who is Pledging IT? <https://www.healthit.gov/patients-families/pledge-members>. Accessed March 7, 2016.
37. Mikat-Stevens NA, Larson IA, Tarini BA. Primary-care providers’ perceived barriers to integration of genetics services: a systematic review of the literature. *Genet Med*. 2015;17:169-76.
38. Suther S, Goodson P. Barriers to the provision of genetic services by primary care physicians: a systematic review of the literature. *Genet Med*. 2003;5:70-6.
39. Klitzman R, Chung W, Marder K, et al. Attitudes and practices among internists concerning genetic testing. *J Genet Couns*. 2013;22:90-100.
40. Guttmacher AE, Porteous ME, McInerney JD. Educating health-care professionals about genetics and genomics. *Nat Rev Genet*. 2007;8:151-7.
41. Ashley EA. The precision medicine initiative: a new national effort. *JAMA*. 2015;313(21):2119-20.
42. Jaffe S. Planning for US Precision Medicine Initiative underway. *Lancet*. 2015;385(9986):2448-9.
43. Khoury MJ, Evans JP. A public health perspective on a national precision medicine cohort: balancing long-term knowledge generation with early health benefit. *JAMA*. 2015;313(21):2117-8.
44. Rubin R. Precision medicine: the future or simply politics? *JAMA*. 2015;313(11):1089-91.
45. Johansen Taber KA, Dickinson BD. Pharmacogenomic knowledge gaps and educational resource needs among physicians in selected specialties. *Pharmacogenomics Pers Med*. 2014;7:145-62.
46. Feero WG, Green ED. Genomics education for health care professionals in the 21st century. *JAMA*. 2011;306(9):989-90.
47. Friedberg MW, Chen PG, Van Busum KR, et al. Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. (2013). http://www.rand.org/content/dam/rand/pubs/research_reports/RR400/RR439/RAND_RR439.pdf. Accessed March 7, 2016.
48. American Medical Association. Letter to Centers for Medicare and Medicaid Services and Office of the National Coordinator for Health Information Technology on Meaningful Use Stage 3. (December, 2015). <https://download.ama-assn.org/resources/doc/washington/x-pub/meaningful-use-stage-3-comment-letter-15dec2015.pdf>. Accessed March 7, 2016.

4. POWDERED ALCOHOL (RESOLUTION 425-A-15)

Reference committee hearing: see report of [Reference Committee D](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**
See Policy H-30.935

Resolution 425-A-15, introduced by the Maryland Delegation and referred by the House of Delegates, asked:

That our AMA (1) adopt policy urging the ban of the distribution and sale of powdered alcohol and (2) lobby Congress and the Administration to ban by law or regulation the distribution and sale of powdered alcohol in the US.

METHODOLOGY

English-language articles were selected from a search of the PubMed and Google Scholar databases using the search terms “concentrated alcohol,” “crystalline alcohol,” “granulated alcohol,” “palcohol,” and “powdered alcohol” in the article title and/or abstract. Internet sites managed by federal and state agencies and relevant public health organizations were also reviewed. Additional articles were culled from the reference lists contained in the pertinent articles and other publications.

State laws were identified through a search conducted using the legal research database, LexisNexis, as well as publicly available websites featuring state legal compilations. The same search terms used in the literature review were also utilized to identify the laws.

BACKGROUND

Excessive alcohol use, including binge drinking, heavy drinking, and use by pregnant women and those under the age of 21, is the fourth leading preventable cause of death in the United States.¹ Excessive alcohol use led to approximately 88,000 deaths and 2.5 million years of potential life lost annually from 2006–2010.² According to the National Institutes on Alcohol Abuse and Alcoholism, alcohol negatively affects the brain and nervous system, heart and cardiovascular system, esophagus and gastrointestinal tract, liver, pancreas, other tissues and organs and the immune response, and increases the risk of several cancers.³

Alcohol continues to be the most common substance of abuse among American youth.⁴ Alcohol consumption patterns vary between adults and underage youth. Among youth who drink, the proportion that reports drinking heavily is higher than that of adult drinkers, increasing from 51% in 12-to 14-year-olds to 72% among 18-to 20-year-olds.⁵ In 2014, approximately 8.7 million underage Americans between the ages of 12 and 20 reported using alcohol during the past month, including 5.3 million who reported binge alcohol use and 1.3 million who reported heavy alcohol use.⁶

Excessive alcohol consumption contributes to more than 4,300 deaths among youth less than 21 years of age in the United States each year and accounts for more deaths than all other illicit drugs combined.^{2,4} Underage drinking contributes to a wide range of costly health and social problems, including motor vehicle crashes (the greatest single mortality risk for underage drinkers); suicide; interpersonal violence; unintentional injuries such as burns, falls, and drowning; impaired brain function and neurocognitive development; alcohol dependence; risky sexual activity; academic problems; and alcohol and drug poisoning.^{4,7,8} The adolescent brain is still developing and is more vulnerable to alcohol-induced brain damage and cognitive impairment than the adult brain.⁹ These changes in the adolescent brain make it more susceptible to both addiction and increased substance use severity.⁸

Powdered Alcohol

Powdered alcohol is defined as any powder or crystalline substance containing alcohol that is produced for direct use or reconstitution.¹⁰ To create powdered alcohol, alcohol is absorbed and encapsulated by a sugar derivative, such as dextrin.¹⁰ Powdered alcohol can be mixed with liquid to make an alcoholic beverage. Powdered alcohol dates back to the 19th century, with references in patent filings as early as 1877.¹¹ Several additional patents for powdered alcohol were approved in the 1960s and 1970s.^{12,13} In the 1970s, a Japanese company, Sato Foods, sold powdered alcohol as a food additive.¹⁰ However, these products were never used or marketed as a base for alcoholic beverages.¹⁰

Powdered alcohol, as a base for alcoholic beverages, has been available outside of the United States for more than a decade. In 2005, a German company briefly sold a powdered alcohol product called Subyou online and later in retail stores.¹⁴ Gerald Corporation, based in Panama, distributes Subyou Be True, which is “alcohol in powder.”¹⁵ It is available in several flavors including blood orange vodka, ron tropical, lime ron, and blackberry vodka.¹⁵ In 2007, Dutch students developed a product known as Booz2Go, but the product was never successfully marketed.¹⁶ In

2010, Pulver Spirits sought approval by the US Alcohol and Tobacco Tax and Trade Bureau (TTB) for an alcoholic powder product for retail sale, but ultimately decided not to proceed because of regulatory hurdles.¹⁷

In 2014, the TTB initially approved and then later retracted the labels for Lipsmark, LLC's powdered alcohol product, Palcohol. After minor labeling changes were accomplished, the TTB granted approval for the sale of Palcohol in the United States.¹⁸

PUBLIC HEALTH CONCERNS

A number of potential health harms led to calls for state and federal regulators to ban the sale of Palcohol. In Baltimore, pediatricians, emergency physicians, and public health leaders expressed concerns including:

[p]owdered alcohol is easier to conceal, facilitating use by youth ... [and making] oversight more difficult for parents, teachers, and law enforcement officials. Powdered alcohol may also lead to greater and unintentional alcohol consumption, which can lead to poisoning, motor vehicle accidents, and even death.¹⁹

Powdered alcohol differs from other alcoholic products, in that the final alcohol concentration will depend on the amount of powder or liquid used in mixing the beverage. Concerns have been raised that multiple packets of powdered alcohol could be mixed together or that powdered alcohol could be mixed with liquid alcoholic beverages instead of water to increase alcohol concentrations.^{20,21} Packets of powdered alcohol could also be mixed with energy drinks, a combination (caffeine and alcohol) that has previously raised safety concerns.

Furthermore, concerns have been raised that powdered alcohol will make it easy to "spike" nonalcoholic beverages.^{20,21} Since the product is in powdered form, it could be self-administered via nasal insufflation ("snorted") (as initially acknowledged though later retracted on Palcohol's website), to induce rapid intoxication.²¹ Palcohol flavors include rum, vodka, and three cocktail varieties, powderita, cosmopolitan, and lemon drop; some of these flavors may be more appealing to youth.

THE PALCOHOL RESPONSE TO PUBLIC HEALTH CONCERNS

Palcohol founder, Mark Phillips, posted a video on the product's website and wrote a letter to the editor, published in JAMA, disagreeing with public health concerns.^{22,23} Mr. Phillips specifically addressed snorting the product, which he argues is unlikely because it is painful and physically impossible to snort enough powder to equal one drink.^{22,23} In terms of spiking someone's drink, he argued that this will be difficult given the time it takes for the powder to dissolve.^{22,23} He also addressed the issue of the product being easy to conceal by showing a mockup of the product's container, which is designed to be used as a cup. The dimensions of the package are 4 inches by 6 inches with a 2 inch gusset.²² In terms of access by children, he argued that the product will only be sold in stores to individuals who are 21 years of age and older.²² Mr. Phillips addressed concentration issues by noting that Palcohol is only 10% alcohol by volume and "if multiple packets are added to less liquid, it becomes mush."²³

REGULATORY AUTHORITY AND ACTIONS

The 21st Amendment granted states the authority to create regulatory and enforcement systems for the sale and consumption of alcoholic beverages. However, the Federal government retains a role in the regulation of alcohol products given their authority to tax and regulate interstate commerce.

Federal

Federal authority to regulate alcohol is currently split among several agencies. In November 1987, the Bureau of Alcohol, Tobacco, and Firearms (now the TTB)^{*} signed a memorandum of understanding with the FDA clarifying the enforcement responsibilities of each agency with respect to alcoholic beverages considered adulterated under the Federal Food, Drug, and Cosmetic Act.²⁵ The TTB, which falls under the Department of Treasury, has the authority to review the formulation and labeling of distilled spirits products.²⁴ The FDA has the authority to take action with

^{*} The Bureau of Alcohol, Tobacco, and Firearms still exists within the Department of Justice, but was reorganized under the Homeland Security Act of 2002, with the tax functions being transferred to the Department of Treasury.

respect to adulterated food products, including alcohol.²⁵ The Federal Trade Commission regulates the advertising of alcoholic beverages.

As noted above and consistent with its authority, the TTB approved labels for Palcohol in 2015.¹⁸ The label indicates that the product is 58% alcohol by weight and 12% alcohol by volume.¹⁸ The label contains the standard government warning regarding drinking alcohol during pregnancy and the risk of birth defects as well as the fact that alcoholic beverages impair one's ability to drive a car or operate machinery and cause health problems.¹⁸

On March 12, 2015, Senator Charles Schumer (D-NY) introduced S.728, the Sober Truth on Preventing (STOP) Underage Drinking Reauthorization Act. In addition to reauthorizing the program to reduce underage drinking for FY2016 – FY2019, the bill would make it unlawful to “make, sell, distribute, or possess powdered alcohol.”²⁶ The bill provides a penalty for violators including a fine of not more than \$5,000, imprisonment for not more than 1 year, or both.²⁶ The STOP ACT, which has no cosponsors, was referred to the Committee on Health, Education, Labor, and Pensions.

On March 13, 2015, the FDA reported that consistent with the agency’s authority, they “evaluated the regulatory status of the non-alcohol ingredients” in these products.²⁷ The FDA concluded that the ingredients used were in compliance with FDA regulations and are “typical of ingredients found in many processed foods.”²⁷ Furthermore, the FDA indicated that it did not have concerns that the ingredients, when added to the alcoholic beverage products, would render the product as adulterated under the Federal Food, Drug, and Cosmetic Act.²⁷

State

States have the authority to regulate the production, sale, and distribution of alcohol within their borders. Alcohol laws and regulations vary widely from state to state, and may be more restrictive than federal regulations.²⁸ Although many states license private businesses to sell alcohol, 17 states control alcohol sales themselves.²⁹

In 1980, Alaska was the first state to prohibit the sale of alcohol unless it was in liquid form.¹⁰ The law was amended in 1995 to specifically prohibit alcohol in powdered form. In 2014, three states (Louisiana, South Carolina, and Vermont) enacted statutory bans on powdered alcohol. In 2015, approximately 90 bills were introduced in 40 jurisdictions on powdered alcohol.³⁰ Twenty-three states (Alabama, Connecticut, Georgia, Hawaii, Illinois, Indiana, Kansas, Maine, Maryland, Michigan, Minnesota, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Tennessee, Utah, Virginia, and Washington) enacted statutory bans on powdered alcohol in 2015. In 2016, Idaho, Massachusetts, and West Virginia enacted legislation banning powdered alcohol. California, Florida, Kentucky, Maryland, Missouri, and Rhode Island are currently considering legislation to ban the product (see Figure 1).

The laws enacted in Maryland and Minnesota are unique in that they provide for a temporary ban on the sale of powdered alcohol through June of 2016.³⁰ The Minnesota statute calls on the Director of the Division of Alcohol and Gambling Enforcement as well as the Commissioner of the Department of Health to make recommendations for legislation addressing any concerns.³¹ The Commissioner of Health subsequently recommended a ban on the manufacture, importation, distribution or sale of powdered alcohol in Minnesota.²⁰ The legislature, to date, has not taken action on this recommendation. Maryland is currently considering legislation that would establish a permanent ban on powdered alcohol.

Of the states that have enacted laws, 20 establish penalties for violating the ban on powdered alcohol. Several states also include provisions providing for the suspension and revocation of licenses and permits for violators. Twelve state statutes include an exemption allowing the use of powdered alcohol by groups (hospitals, state institutions, private colleges or universities, pharmaceutical or biotechnology companies) conducting *bona fide* scientific research. Several states have defined powdered alcohol for the purpose of regulating it. These states include California, Colorado, Delaware, and New Mexico. Colorado’s law authorizes the state licensing authority to adopt rules establishing a mechanism for regulating the manufacture, purchase, sale, possession, and use of powdered alcohol.³² It also authorizes the state’s Department of Revenue to promulgate rules concerning the excise tax applied to powdered alcohol at 60.26 cents per liter based on the recommended amount of water specified to be added by the manufacturer’s packaging.³²

In states that control alcohol sales themselves, legislative approval may not be required to ban powdered alcohol. For example, the state's liquor control boards in Maryland, Massachusetts, New Hampshire, and Pennsylvania made the decision to outlaw powdered alcohol products.³³⁻³⁶

DISCUSSION

As the federal agency responsible for regulating alcohol products, TTB has limited statutory authority and expertise to directly address public health and safety issues.²¹ Similarly, the FDA's role in regulating alcohol products involves reviewing the safety of the non-alcohol ingredients rather than examining the overall public health and safety issues related to use of the product.²¹ Therefore, decisions regarding the potential health and safety threat of alcohol products are often made at the state level.

Nevertheless, the FDA has previously acted to address harmful alcohol-containing products. For example, state and federal regulators were encouraged to act when young people became ill and died after consuming pre-mixed caffeinated alcohol drinks.³⁷ In 2010, after a year of studying the issue, the FDA sent warning letters to four companies marketing malt alcoholic beverages containing added caffeine.³⁸ The FDA warned that caffeine, as used in these products, is an "unsafe food additive" and therefore the product is "adulterated" under the Federal Food, Drug and Cosmetic Act.³⁸ In response, the four companies ceased adding caffeine to their products, and, by summer 2011, malt-based beverages with added caffeine were no longer available in the US.

In the case of powdered alcohol, the FDA does not have concerns regarding adulteration.²⁷ However, with 32 states banning the product either through the legislative process or by a decision of the state alcohol control board, concerns clearly exist regarding the potential harms of the product, particularly to minors. Although selling alcohol to youth under age 21 is illegal in all 50 states and the District of Columbia, underage youth find it relatively easy to acquire alcohol, often from adults.⁴ The creator of Palcohol touts the product as "light and compact," which will likely raise the attractiveness of the product to youth. The harms that could arise from mixing powdered alcohol with liquid alcohol or even with energy drinks raises the potential for dangerous patterns of use. A 2015 national poll found that 90% of adults are concerned that powdered alcohol will be misused by people under the age of 21 and 60% of adults favor a complete ban on powdered alcohol in their states.⁴⁰

Given the unavailability of the product, no research has been conducted to either substantiate or disprove these concerns. However, it has been argued that in the absence of data proving that the product is safe, the precautionary principle should be applied.²¹ The precautionary principle states that, "in cases of serious or irreversible threats to the health of humans or ecosystems, acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures."⁴¹

POLICY STATEMENTS

Current AMA policy does not address powdered alcohol. However, our AMA has numerous policies addressing the harmful effects of alcohol on youth (See Appendix A). AMA policy supports environmental strategies to reduce youth access to, and high consumption of, alcohol. Furthermore, AMA policy supports banning the marketing of alcohol products that appeal to youth under the age of 21. Among members of the Federation, the American College of Emergency Physicians adopted a resolution supporting a ban on powdered alcohol in 2015.⁴²

CONCLUSION

Alcohol is the most widely used substance of abuse among America's youth. Excessive alcohol use is responsible for 4,300 deaths among underage youth every year.⁴ Current AMA policy supports efforts to reduce youth access to and high consumption of alcohol. Previous experience with novel alcohol products that appealed to youth, including alcohol energy drinks, has demonstrated the potential for overuse and harm. For these reasons, the Council believes our AMA should support a ban on powdered alcohol.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following recommendation be adopted in lieu of Resolution 425-A-15 and the remainder of the report be filed.

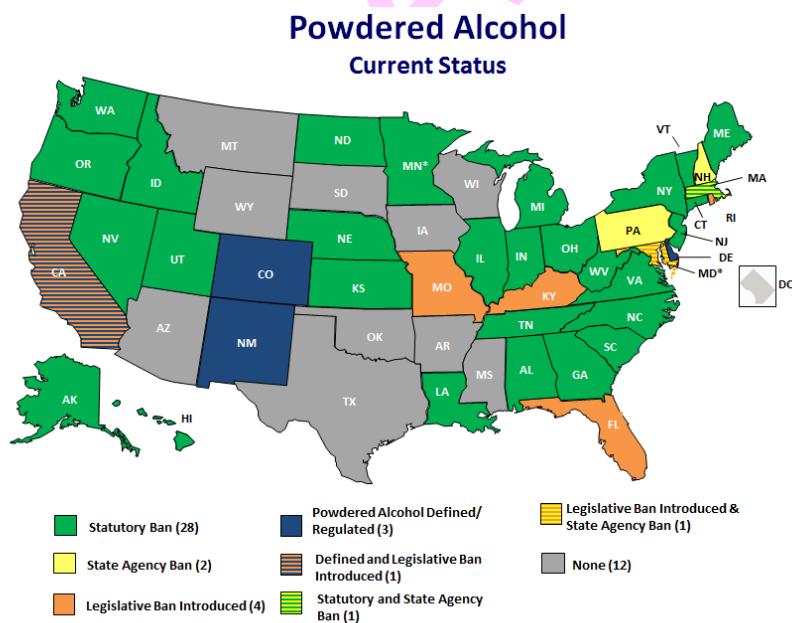
That our American Medical Associate supports federal and state laws banning the manufacture, importation, distribution, and sale of powdered or crystalline alcohol intended for human consumption.

REFERENCES

1. Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the United States, 2000. *JAMA* 2005;293(3):293-4, 298.
2. Centers for Disease Control and Prevention. *Alcohol-Related Disease Impact (ARDI)*. Atlanta, GA. http://nccd.cdc.gov/DPH_ARDI/default/default.aspx. Accessed March 24, 2016.
3. National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, *Beyond Hangovers: Understanding Alcohol's Impact on Your Health*. NIH Publication No. 13-7604. Bethesda, MD, 2010.
4. Substance Abuse and Mental Health Services Administration, *Report to Congress on the Prevention and Reduction of Underage Drinking*. December 2013. <https://store.samhsa.gov/shin/content/PEP13-RTCUAD/PEP13-RTCUAD.pdf>. Accessed March 24, 2016.
5. Department of Justice, Office of Juvenile Justice and Delinquency Prevention. *Drinking in America: Myths, Realities, and Prevention Policy*. 1999. <http://www.lhc.ca.gov/lhc/drug/DrinkinginAmericaMosherSep26.pdf>. Accessed March 24, 2016.
6. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health (HHS Publication No. SMA 15-4927, NSDUH Series H-50). <http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>. Accessed March 24, 2016.
7. Miller JW, Naimi TS, Brewer RD, Jones SE. Binge drinking and associated health risk behaviors among high school students. *Pediatrics* 2006;119:76-85.
8. Siqueira L, Smith VC. Binge drinking. *Pediatrics*. 2015; 136(3): e718-e726.
9. Spanagel R. Alcoholism: a systems approach from molecular physiology to addictive behavior. *Physiol Rev*. 2009;89(2):649–705.
10. National Alcohol Beverage Control Association, *Powdered Alcohol: An Encapsulation*. September 2015. <http://www.nabca.org/assets/Docs/Research/PowderedAlcoholPaper.pdf>. Accessed March 24, 2016.
11. Improvement in Flavoring Powders, US 186712 A. <http://www.google.com/patents/US186712>. Accessed March 24, 2016.
12. Preparation of an alcohol-containing powder, US 3821433 A. <http://www.google.com/patents/US3821433>. Accessed March 24, 2016.
13. Preparation of an alcoholic dry beverage powder, US 3436224 A. <http://www.google.com/patents/US3436224>. Accessed March 24, 2016 .
14. Experts Warn About Powdered Alcohol, *Deutsche Welle*. May 27, 2005. <http://www.dw.com/en/experts-warn-about-powdered-alcohol/a-1596657-1>. Accessed March 24, 2016.
15. Geraldi Corp. *Subyou Be True*. <http://www.subyoux-mexico.com/en/subyou-be-true-blood.php>. Accessed March 24, 2016.
16. Just add water - students invent alcohol powder, Reuters. June 6, 2007. <http://www.reuters.com/article/us-dutch-drink-odd-idUSPAR64994620070606>. Accessed March 24, 2016.
17. The history of 'Palcohol': This isn't the first powdered booze, Fortune. April 23, 2014. <http://fortune.com/2014/04/23/the-history-of-palcohol-this-isnt-the-first-powdered-booze/>. Accessed March 24, 2016.
18. Department of Treasury, Alcohol and Tobacco Tax and Trade Bureau, *Palcohol Labels*. <http://www.bevlaw.com/bevlog/wp-content/uploads/2014/04/powder.pdf>. Accessed March 24, 2016.
19. Wen LS. et al. *Baltimore Statement on Dangers of Powdered Alcohol*. Baltimore City Health Department. <http://health.baltimorecity.gov/sites/default/files/Palcohol%20Statement.pdf>. Accessed March 24, 2016.
20. Ehlinger E. Minnesota Department of Health, Powdered Alcohol Testimony. <http://archive.leg.state.mn.us/docs/2016/mandated/160169.pdf>. Accessed March 25, 2016.
21. Naimi TS, Mosher JF. Powdered alcohol products: new challenge in an era of needed regulation. *JAMA* 2015; 314(2): 119-120.
22. Palcohol is Powdered Alcohol. <http://www.palcohol.com/home.html>. Accessed January 22, 2016.
23. Phillips M. Regulation of powdered alcohol. *JAMA*. 2015;314(21):2307.
24. U.S. Department of Treasury, Alcohol and Tobacco Tax and Trade Bureau, *TTB's Responsibilities - What We Do*. <http://www.ttb.gov/consumer/responsibilities.shtml>. Accessed March 25, 2016.
25. Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms, November 20, 1987. http://www.ttb.gov/main_pages/memo-understanding.shtml. Accessed March 25, 2016.
26. S.B. 728, 114th Congress (2015-2016).
27. Food and Drug Administration, *FDA Clarifies Its Role on "Palcohol"*, March 13, 2015. <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm438163.htm>. Accessed March 25, 2016.
28. Alcohol and Tobacco Tax and Trade Bureau, *Alcohol Beverage Authorities in United States, Canada, and Puerto Rico*. <http://www.ttb.gov/wine/state-ABC.shtml>. Accessed March 25, 2016.
29. National Alcohol Beverage Control Association, *The Control Systems*. <http://www.nabca.org/States/States.aspx>. Accessed March 25, 2016.
30. National Conference of State Legislatures, *Powdered Alcohol 2015 Legislation*, November 10, 2015. <http://www.ncsl.org/research/financial-services-and-commerce/powdered-alcohol-2015-legislation.aspx>. Accessed March 25, 2016.

31. MN SF 2338 (2015)
32. C.R.S. 12-47-503 (2015)
33. Franchot P. Comptroller of Maryland. (March 25, 2015). *Peter Franchot Announces Alcohol Industry's Voluntary Ban of Powdered Alcohol in Maryland*. March 25, 2015. http://comptroller.marylandtaxes.com/Media_Services/2015/03/25/peterGfranchotGannouncesGalcoholGindustryGVoluntaryGbanGofGpowderedGalcoholGinGmaryland/. Accessed March 25, 2016.
34. Alcoholic Beverages Control Commission, *Advisory Regarding Powdered Alcohol*. March 12, 2015. <http://www.mass.gov/abcc/pdf/ABCCAdvisoryPowderedAlcohol2015.pdf>. Accessed March 25, 2016.
35. New Hampshire Liquor Commission, *New Hampshire Liquor Commission Bans the Sale and Distribution of Powdered Alcohol in New Hampshire*. September 26, 2015. <https://www.nh.gov/liquor/enforcement/media/news/pr-2015-09-16-powdered-alcohol.htm>. Accessed March 25, 2016.
36. Pennsylvania Liquor Control Board. *The Pennsylvania Liquor Control Board Will Not Sell Powdered Alcohol Products in Fine Wine & Good Spirits Stores*. February 11, 2015. <http://www.lcb.state.pa.us/cons/groups/externalaffairs/documents/form/002548.pdf>. Accessed March 25, 2016.
37. FDA expected to act on alcoholic energy drinks, *The New York Times*, November 15, 2010. <http://www.nytimes.com/2010/11/16/us/16drinks.html?r=0>. Accessed March 25, 2016.
38. Food and Drug Administration. FDA Warning Letters issued to four makers of caffeinated alcoholic beverages, November 17, 2010. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm234109.htm>. Accessed March 25, 2016.
39. Public Health Service, Food and Drug Administration, Warning Letter, November 17, 2010. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm234023.htm>. Accessed March 25, 2016.
40. University of Michigan C.S. Mott Children's Hospital National Poll on Children's Health, *Majority of adults favor ban on powdered alcohol, concerned it would increase underage drinking*. June 15, 2015. <http://www.uofmhealth.org/news/archive/201506/powdered-alcohol>. Accessed March 2, 2016.
41. Martuzzi M, Tickner JA. The precautionary principle: protecting public health, the environment and the future of our children. World Health Organization. http://www.euro.who.int/_data/assets/pdf_file/0003/91173/E83079.pdf. Accessed March 25, 2016.
42. American College of Emergency Physicians, Report by Reference Committee B. <http://jdrblog.commpartners.com/docs/608/Ref%20B%20Report%20Final.docx>. Accessed January 22, 2016.

Figure 1.



APPENDIX A

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.

H-60.92 5 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.

H-30.961 Student Life Styles

Our AMA (1) supports educational programs for students that deal with the problem of alcoholism and drugs, and (2) encourages educational institutions to continue or institute efforts to eliminate the illegal and inappropriate use of alcohol and other drugs on their premises or at their functions.

D-60.973 Prevention of Underage Drinking: A Call to Stop Alcoholic Beverages with Special Appeal to Youths

1. Our AMA will advocate for a ban on the marketing of products such as alcops, gelatin-based alcohol products, food-based alcohol products, alcohol mists, and beverages that contain alcohol and caffeine and other additives to produce alcohol energy drinks that have special appeal to youths under the age of 21 years of age. 2. Our AMA supports state and federal regulations that would reclassify Alcops as a distilled spirit so that it can be taxed at a higher rate and cannot be advertised or sold in certain locations.

D-30.997 Eliminate Underage Alcohol Consumption

Our AMA will support evidence-based public health/environmental policies to curtail destructive and high-risk drinking.

D-170.998 Alcohol and Youth

Our AMA will work with the appropriate medical societies and agencies to draft legislation minimizing alcohol promotions, advertising, and other marketing strategies by the alcohol industry aimed at adolescents.

**5. AN EXPANDED DEFINITION OF WOMEN'S HEALTH
(RESOLUTION 604-A-15)**

Reference committee hearing: see report of [Reference Committee E](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

REMAINDER OF REPORT FILED

See Policies H-525.976, H-525.988 and H-525.991

Resolution 604-A-15, “A New Definition of Women’s Health,” submitted by the Women Physicians Section and referred by the House of Delegates asked that:

(1) future discussion within our American Medical Association of topics labeled as “women’s health” reflect this more accurate and inclusive definition; i.e., the term “women’s health” refers to all health conditions for which there is evidence in women, compared to men, of differing risks, presentations, and/or responses to treatment, as well as those reproductive issues exclusive to women; and

(2) our AMA encourage members to incorporate evidence-based information regarding the impact of sex and gender into their daily practices.

The topic of “women’s health” is broad, encompassing gynecologic and reproductive health as well as conditions for which risk, prevalence, or treatment are different in women compared to men. Resolution 604-A-15 brings attention to the health differences experienced by women that are not necessarily gynecologic or reproductive in nature. In this report, the Council briefly reviews the basis of sex differences in health and disease, selected disease areas in which sex differences are apparent, social and environmental factors that impact the health of men and women differently, and the role of women as clinical research participants. Of note, the Council comprehensively reviewed this topic more than 15 years ago;¹ additional information can be found in that report.

INTRODUCTION

The medical and scientific understanding of women’s health has changed substantially over time. Formerly focused mainly on reproductive issues such as pregnancy, childbirth, and disorders affecting the breasts and female reproductive tract, women’s health is now viewed more comprehensively to encompass diseases and conditions that are unique to women, more prevalent in women, more serious in women, and treated differently in women.^{2,3} Research over the last several decades has made it clear that sex and gender affect health through biologic mechanisms that impact the manifestation and pathophysiology of a large number of disease areas.⁴ In addition, social and economic factors contributing to general well-being now are recognized as impacting women’s health.²

Physicians are increasingly considering the role that sex and gender play in disease expression and health outcomes, especially as guidelines begin to acknowledge differences in risk assessment and treatment in women.

In 2001, The Institute of Medicine (IOM) published a nearly 300-page report entitled *Exploring the Biological Contributions to Human Health: Does Sex Matter?*⁵ The landmark report was a comprehensive review examining how sex differences affect human health, validating a field of research that, until that point, was considered nascent. The simplified message of the report was “every cell has a sex,” meaning that individual cells in males and females have basic biological differences that affect health. Although now more than 15 years old, the IOM report is still referenced as a fundamental resource in recognizing that sex differences play a role in health and that preventive, diagnostic, and therapeutic approaches should take sex differences into account. The growing knowledge base of the impact of sex differences on health is reflected in the scientific literature, with more than 10,000 articles covering sex and gender differences in clinical medicine, epidemiology, pathophysiology, clinical manifestations, outcomes, and management.⁴

It should be noted that *sex* and *gender* are defined differently. *Sex* is a biologic classification determined by the results of having two X chromosomes for females, or one X and one Y chromosome for males.⁵ Sex differences between males and females manifest at the reproductive level, and also are expressed at basic cellular and molecular levels. *Gender* is a person’s outward expression or behavior of being a man or woman, and is influenced by society, the environment, and personal cultural beliefs and experiences.⁵ The focus of this report is on sex differences in health and disease, i.e., differences that occur as a result of having two X chromosomes or one X and one Y chromosome. However, since health and disease are affected by social and environmental factors, sex and gender cannot be separated easily. Current knowledge about the diseases discussed in this report has been informed by focused research on sex differences, but because sex and gender are inextricably linked, differences in disease risk, prevalence, and severity cannot be attributed to sex or gender alone, but rather are a combination of the effects of both.

METHODS

Literature searches were conducted in the PubMed database for English-language articles published between 2006 and 2016 using the search terms “women’s health,” “sex differences in health,” and “sex differences in disease.” These searches were intended to identify the diseases and conditions that are experienced only by women, are more prevalent or more severe in women, or have different risk profiles or therapies for women. To capture reports not indexed on PubMed, a Google search was conducted using the same search terms. Reports developed by the Institute of Medicine, the United States Preventive Services Task Force (USPSTF), the National Institutes of Health (NIH) Office of Research on Women’s Health, and the Health Resources and Services Administration (HRSA) Office of Women’s Health were identified and reviewed. Additional articles were identified by manual review of the references cited in these publications, as well as manual review of articles published in *Gender Medicine*, the *International Journal of Women’s Health*, the *Journal of Women’s Health*, *Women’s Health*, *Women’s Health Care Journal*, *Women’s Health Issues*, and *Women’s Health Journal*.

SEX DIFFERENCES IN HEALTH AND DISEASE

How do sex differences affect health?

Multiple, ubiquitous differences have been discovered in the basic cellular biochemistry of males and females. Many of these differences are a direct result of the three primary types of genetic differences between the two sexes. First, and most apparent, is the fact that genes on the Y chromosome are expressed only in males, and most of these genes have no counterpart on the X chromosome or autosomes.⁵ Second, to equalize the dosage of X chromosome gene expression, one X chromosome is inactivated in almost every cell of the female, effectively creating a mosaic in which some cells express genes from the maternally inherited X chromosome and others express genes from the paternally inherited X chromosome.⁵ Third, the expression of many genes is influenced by hormones present in differing levels in males and females, resulting in patterns of gene expression in different tissues at different times.⁵

The ways that these chromosomal differences affect health and disease range from straightforward to complex. An example from the straightforward end of the spectrum is X-linked diseases that almost exclusively affect males. A pathogenic gene alteration carried on the X chromosome results in disease in males since they have no other X chromosome carrying an unaltered gene.⁶ Fragile X and Duchenne muscular dystrophy (DMD) are examples of X-

linked diseases, with 1/4,000-5,000 males and 1/8,000-9,000 females affected with Fragile X-associated intellectual disability,⁷ and approximately 1/5,000 males affected with DMD.⁸ The prevalence of females with DMD is close to zero since affected males usually do not live to reproductive age to pass down their X-linked gene alteration, although some female carriers will exhibit mild symptoms of DMD.⁹

On the more complex side of the spectrum, the hormonal milieu present in males and females controls a diverse and extensive number of processes involved in health and disease, including prenatal and pubertal development, behavioral characteristics such as cognition, risk for disease, severity of disease manifestation, and recovery from injury.⁵ For example, one theory accounting for the lower prevalence of Parkinson's disease in women is the effect of estrogen on dopaminergic neuron depletion.¹⁰ The nigrostriatal dopaminergic pathway plays a central role in regulating fine motor control; its degeneration leads to the primary motor symptoms of Parkinson's disease.¹¹ Estrogen-dependent gene expression in the substantia nigra is thought to result in the protection of dopaminergic neurons, thus attenuating the loss of neurons that might otherwise occur when estrogen levels are low or non-existent, as is the case in males.¹¹

Adding further complexity, more recent studies have found sex differences in epigenetic patterns, i.e., heritable alterations to DNA structure (not DNA sequence), such as methylation and histone modification, that alter gene expression and activity. The inactivation of X chromosomes in female cells that occurs to balance X chromosome gene expression is accomplished through an epigenetic mechanism of chromatin remodeling, silencing genes located on one of the X chromosomes of each cell. However, while perturbations to X-inactivation can be themselves the cause of disease, differences in epigenetic patterns beyond X-inactivation have been found in men and women, and some are thought to affect disease risk and severity.¹² Emerging research suggests that sex-specific DNA methylation occurring as a result of environmental stress may partially explain females' higher risk for depression and post-traumatic stress disorder.¹³

Diseases with different risk, prevalence, or severity in women

A comprehensive listing and discussion of every disease for which there is different risk, prevalence, or severity in women is not possible in this report. However, below are examples of diseases that are illustrative of sex differences for many diseases.

Cardiovascular disease (CVD). One of the most well known diseases exhibiting sex differences is CVD. Although CVD is the leading cause of death in both men and women, the annual mortality rate of CVD has been slightly higher for women than for men since the mid-1980s, and the absolute numbers of individuals living with and dying of CVD in the US are larger for women than for men.¹⁴⁻¹⁶ These numbers largely reflect the longer life expectancy of women and propensity of CVD to occur seven to ten years later in women than in men.¹⁶ Prevalence of CVD is slightly higher in men younger than age 79 years compared to women of the same age group; however, after that age, prevalence is higher in women.¹⁷

The unequal CVD burden is partially attributable to the differing prevalence of some risk factors. Both clinical risk factors (e.g., hypertension, type II diabetes, hyperlipidemia) and lifestyle risk factors (e.g., tobacco use, physical inactivity, overweight/obesity) for CVD are the same in men and women, but the prevalence of some clinical risk factors is higher in women.¹⁶ The number of women over age 65 years with hypertension is greater compared to men in the same age group.¹⁷ Similarly, more women age 20 years and older have total cholesterol greater than 240 mg/dL than do men age 20 years and older.¹⁷ Conversely, even though overall adherence to the heart-healthy lifestyle behaviors of smoking abstinence and appropriate nutrition (adequate fruit, vegetable, and whole grain intake, low sugar-sweetened beverage intake) is low for both men and women, women are more likely to adhere to such behaviors.^{16,17}

More men than women will experience acute myocardial infarction (AMI) during their lifetime, but more women than men will die within one and five years of a first AMI.^{17,18} Obstructive atherosclerotic disease of the epicardial coronary arteries remains the basic cause of AMI in both men and women, but plaque characteristics differ for women, and a greater role of microvascular disease in women has recently been suggested.¹⁸ Women with acute coronary syndromes are less likely to be treated with guideline-directed medical therapies, less likely to undergo cardiac catheterization, and less likely to receive timely reperfusion.¹⁸ One possibility for these differences in treatment may be the different presentation of AMI in women, which is more likely to include atypical symptoms

like pain in the upper back, arm, neck, and jaw, as well as unusual fatigue, dyspnea, indigestion, nausea/vomiting, palpitations, and weakness.¹⁸

Women account for nearly 60 percent of US stroke deaths, tend to have overall poorer recovery from stroke than men, and have an increased lifetime incidence of stroke compared to men largely due to a sharp increase in risk after menopause.^{17,19} In addition to stroke risk factors that are shared among men and women, migraine headaches with aura, atrial fibrillation, and hypertension are more common in women.^{20,21} Younger women may also have the risk factors of oral contraceptive use, pregnancy, preeclampsia, and gestational diabetes.²⁰

The differences in CVD risk and prevalence between men and women have resulted in clinical practice and prevention recommendations that differ for men and women. In 2014, the American Heart Association and American Stroke Association released for the first time a stroke prevention guideline that covers topics specific to women in more detail than in other prevention guidelines.²⁰ Similarly, the European Society of Cardiology lists female sex as an additional risk factor for stroke to be taken into account by physicians.²²

Autoimmune diseases. Most autoimmune diseases, a class of diseases in which the immune response to self-antigens results in damage or dysfunction of tissues, occur more commonly in women than in men. This sex bias can be small, as in the case of the approximately 2:1 female to male ratio of multiple sclerosis, or prominent, as in the case of the primary biliary cirrhosis, the female to male ratio of which has been reported to be as high as 22:1.^{23,24} Severity of an autoimmune disease, i.e., the degree of disability caused by the disease, also tends to be sex-dependent, although severity is not necessarily greater in the more frequently affected sex.²³

The predominance of autoimmune diseases in females is an area of active research, but has been theorized to occur for a number of reasons. One is the greater immune reactivity shown by females. While the overall number of lymphocytes in males and females is the same, females have more T lymphocytes, produce more B lymphocyte-mediated circulating antibodies, and produce a stronger humoral and cellular immune response to antigens.²³ Lymphocyte development and function is impacted by estrogen, yet the mechanisms by which this modulates autoimmunity are complex and generally unclear. Other sex-dependent mechanisms hypothesized to play a role are parental inheritance, mitochondrial inheritance, genomic imprinting and chromosomal inactivation.²³ Exposure to infectious agents and chemicals also is linked to the development of autoimmunity, and therefore differences in patterns of exposure (e.g., women more frequently use cosmetics, men have more unprotected exposure to the sun), as well as differences in responses to exposures, may partially account for the overall higher frequency of autoimmune disease in females.²³

One of the most common autoimmune diseases, systemic lupus erythematosus (SLE), is found in a 9:1 ratio of women to men; its peak incidence occurs in the early female reproductive years.²⁵ A leading theory explaining the sex difference involves the role of estrogen, which is thought to modulate inflammatory cytokine pathways. Elevation of the inflammatory cytokine interferon- α has been shown to be pathogenic in SLE, and women with SLE have abnormally high levels of estrogen metabolites, suggesting that autoimmunity and subsequent disease development are a result of hyperactive cytokine production in response to elevated levels of estrogen.²⁵ Conversely, estrogen is thought to be protective in Sjögren's syndrome (SS), which occurs in a 16:1 ratio of women to men.²⁶ SS is most commonly found in menopausal women, in whom estrogen levels are decreased compared to premenopausal women. Estrogen inhibits the proinflammatory action of NF- κ B; therefore, some hypothesize that the reduced inhibition that occurs when estrogen levels fall leads to the production of proinflammatory cytokines and the onset of autoimmunity.²⁶

Alzheimer's disease (AD). More women than men develop AD, partially because women have a longer life expectancy during which AD can arise. However, even after correcting for age, women are more likely than men to progress to cognitive impairment and have significantly greater deterioration of cognition than men.²⁷ Several hypotheses accounting for these differences are currently being studied. One is related to the influence of age-associated sex hormone reduction. Estrogen plays a neuroprotective role through a number of mechanisms; however, following menopause in women, estrogen levels are substantially diminished. In males, testosterone is converted to estrogen at a very low rate that continues throughout the lifespan, resulting in higher serum estrogen levels in elderly males than in post-menopausal females.²⁸ Study results have been inconsistent and difficult to interpret, but overall data from epidemiologic studies, observational studies, and clinical trials indicate that the decline in estrogen in post-menopausal women plays a role in the pathogenesis of cognitive decline and risk for AD.²⁸ In observational studies, postmenopausal women who used estrogen-only or estrogen-progestogen hormone

replacement therapy (HRT) showed slower declines in cognitive function and decreased risk of AD,²⁸ but other studies suggested that estrogens did not have a beneficial effect on dementia or cognitive function in older women.^{27,28} Newer studies are investigating whether estrogen therapy delivered only for a short duration during the peri-menopausal or immediate post-menopausal period may have cognitive benefit.²⁸

Another hypothesis accounting for the sex difference in AD involves a variant of the *apolipoprotein E (APOE)* gene. The *e4* allele of *APOE (APOE-4)* contributes up to half of the genetic basis for sporadic and late onset familial AD, but the risk of developing AD is higher in *APOE-4*-expressing females than in *APOE-4*-expressing males.²⁷ Female *APOE-4* carriers also show more pronounced AD-like changes in neuroimaging, neuropathological, and neuropsychological features than do male carriers.²⁹ The mechanism by which the *APOE-4* allele confers greater risk to women is unknown, although it is interesting to note that the risk of cardiovascular mortality also is higher in *APOE-4*-expressing females than in *APOE-4*-expressing males.^{27,30} The clinical value of genetic testing to determine one's *APOE-4* carrier status, both in the presence and absence of AD symptoms, has been an area of active debate.³¹

Mental illness. Differences in the prevalence of several common mental disorders have been observed among men and women. Women show higher prevalence rates of major depression, dysthymia, generalized anxiety disorder, panic disorder, social phobia, and specific phobia than do men (note: these data were generated using DSM-IV criteria).³²⁻³⁴ An estimated 8.5 percent of women aged 18 years and older reported experiencing a major depressive episode in the past year compared to 4.9 percent of men in the same age group.³²

Differences in depression prevalence begin to emerge during adolescence and persist through mid-life.³⁵ Differences in psychosocial and biological risk factors are thought to account for the difference in prevalence.³⁶ The higher prevalence in women may be partially due to a tendency in women to report symptoms of depression more often than do men.³⁷ Also, unhappy marriages, the presence of young children at home, and victimization or abuse (particularly during childhood) have been found to impact vulnerability to depression more so in women than in men.³⁵ The pubertal, pregnancy, post-partum, and postmenopausal phases of the reproductive cycle in women biologically influence risk for depression, mainly due to hormonal fluctuation during these periods.³⁸ For example, the post-partum time period is characterized by a rapid decline in estrogen concentration, affecting the serotonergic system and leading to an increased risk for depression.³⁵

Women with depression appear to have higher rates of comorbid disorders, most commonly, anxiety and eating disorders.³⁵ Comorbidities in depressed men are more commonly alcohol and substance abuse and dependence disorders.³⁵ Women with depression also have higher rates of comorbid CVD than men.³⁹ Emerging evidence suggests that women's greater exposure to chronic stressors, interpersonal stress responsiveness, and internalizing coping styles are associated with an elevated risk of CVD and/or depression through both behavioral and pathophysiological mechanisms.³⁹

Estrogen appears to play a role in the effectiveness of depression treatment. In a study comparing the effectiveness of a selective serotonin reuptake inhibitor (SSRI) versus a tricyclic antidepressant (TCA), women generally showed better response to the SSRI than the TCA.⁴⁰ However, when data were stratified by age, the response difference was apparent in premenopausal women but not in post-menopausal women.⁴⁰ It has therefore been hypothesized that estrogen either enhances the response to SSRIs or inhibits the response to TCAs; since estrogen level is higher in premenopausal women than in postmenopausal women, its effect on SSRIs and TCAs persists during the premenopausal period, but disappears after menopause.^{35,40}

Alcohol addiction. Women show lower prevalence rates of alcohol and drug dependence,³²⁻³⁴ with women nearly half as likely as men to have experienced a past-year substance use disorder (11.9 percent versus 6.9 percent respectively).³² For alcohol specifically, more women than men are lifetime abstainers, and those who drink tend to drink less than men.⁴¹ Women also are less likely to engage in problem drinking and to develop alcohol related disorders or withdrawal symptoms.⁴¹ Differences in alcohol use are influenced by mood and emotions, with women being more likely than men to drink heavily when experiencing unpleasant emotions, psychological distress, conflict with others, or to relieve internal tension.^{41,42} In contrast, men are more likely than women to consume alcohol in response to pleasant emotions and due to social pressure.^{41,42}

Although women are less likely than men to drink excessively, excessive drinking in women leads to severe medical problems more quickly than in men.⁴¹ Cirrhosis, alcohol-induced cardiomyopathy, and peripheral neuropathy develop after fewer years of heavy drinking in women than in men.^{43,44} In addition, women appear to be more

vulnerable to brain damage and the neurotoxic effects of alcohol than men.⁴³⁻⁴⁵ Both men and women with alcohol use disorder display reduced brain volume in comparison to nondrinking individuals, but brain atrophy and cognitive dysfunction develop more quickly in women than in men.⁴³⁻⁴⁷ Short-term memory impairment also appears to be more severe in women than in men with alcohol use disorder.^{43,45}

The telescoping effect, i.e., the faster onset of long-term adverse health effects in women, can be partially explained by sex differences in the absorption, distribution, and metabolism of alcohol.⁴³ Women have a lower proportion of total body water than men of similar body weight and therefore achieve higher blood alcohol concentrations after consuming equivalent amounts of alcohol.⁴¹ The smaller volume of distribution in women compared to men also is associated with longer persistence of high alcohol blood concentrations.⁴¹ Additionally, studies have suggested that women experience decreased first-pass metabolism because of lower levels of alcohol dehydrogenase in their gastric mucosa.^{41,43} Treatment of alcohol use disorder can be more difficult in women than in men because women with alcohol-use disorder are significantly more likely to have co-occurring mental health disorders that may serve to impede substance-use treatment efforts or make them more complex.^{41,42}

Osteoarthritis (OA). Several musculoskeletal conditions occur more frequently in women than in men. One of the most prevalent among older women is osteoporosis, caused partly by decreased estrogen levels during menopause. Among both men and women, osteoarthritis is the most common joint disorder and is one of the leading causes of physical functional impairment and disability, especially in older adults.⁴⁸ Sex differences in the joints affected are well known; women more often have OA of the knee, hip, and hands, while men more often have OA of the spine.^{49,50} Women also are more likely than men to report pain from OA⁵¹ and undergo more knee and hip replacement surgeries than men.⁵²

The underlying explanations for the differences are not completely clear, but evidence points to differences in biomechanics and alignment, lower extremity muscle strength, and for the knee, cartilage volume.^{51,53} Also, the overall higher rate of immune reactivity in women (see above discussion of autoimmune diseases) may contribute to the inflammatory features of OA.⁵⁴ OA often co-occurs with CVD, which itself is characterized by sex differences. Although the two conditions share risk factors such as obesity and advanced age, the high level of co-occurrence cannot be explained by common risk factors alone.⁵⁵ Some have suggested that the disability and reduced physical activity caused by OA contributes to CVD, while others have hypothesized that the low-grade inflammation present in OA can worsen the risk for CVD.⁵⁵

Emerging evidence in other disease. Many other disease areas show emerging evidence for differences in risk, prevalence, or severity in women. These include pulmonary diseases such as asthma, chronic obstructive pulmonary disease, and pulmonary embolism; nephrological conditions such as renal failure and polycystic kidney disease; gastroenterological diseases such as inflammatory bowel disease; neurological conditions such as epilepsy and pain perception; and non-reproductive cancers such as leukemia, lymphoma, and bladder, colorectal, pancreatic, and thyroid cancers.⁴ Continued research on sex differences in these and other diseases, followed by translation of research results to the clinic, is likely to impact the way that they are diagnosed, treated, and prevented in the future.

SOCIAL AND ENVIRONMENTAL SEX DIFFERENCES THAT AFFECT HEALTH

A complex relationship exists between sex and the social and environmental factors that underlie health differences in men and women. Sex influences health by modifying behavior. For example, testosterone levels are linked to aggressive and risk-seeking behavior.⁴ Behaviors that are often affected by a person's gender identity also can modify sex-controlled functions; for example, exposure to stress, environmental toxins, and poor nutrition can induce genomic and epigenetic changes that themselves manifest differently in men and women.⁴ Below is a discussion of some social and environmental factors that are known to affect life expectancy, mortality, and morbidity in males and females.

Sex differences in life expectancy and mortality

In almost all industrialized countries, women have longer life expectancies than men. In the US, life expectancy at birth is 81.2 years for females and 76.4 years for males.⁵⁶ While life expectancy for both sexes was far shorter in the late 19th and early 20th centuries, the disparity between the sexes was smaller. The increased disparity in more recent decades is partly explained by declining rates in maternal mortality.⁵⁷ Other biological explanations exist, such as differences in storage and metabolism of lipids, differences in combatting oxidative stress, skewing of X-

inactivation, and rates of telomere shortening associated with aging, but much of the difference in life expectancy is thought to be due to differences in behavior.⁵⁸

Sex differences in mortality persist at all age groups except for those older than age 80 years.⁵⁶ Sex differences in mortality are greatest among younger adults, in part because young males are more apt to take part in risky and aggressive behaviors that generally lessen with age.^{56,59} Males are more likely than females to engage in behaviors that result in unintentional injury and sometimes death, such as drug and alcohol use, firearm use, aggressive driving leading to traffic accidents, and participation in violent crime.^{32,57} Males also are more likely than women to die from suicide.⁵⁶ Cigarette smoking has affected life expectancy and mortality rates over time as well. Early in the 20th century, it was more socially acceptable for males than for females to smoke, leading to more smoking-related illness and death in males and likely explaining much of the disparity in life expectancy until the mid-20th century. As female smoking gained social acceptance, the difference in life expectancy due to tobacco-caused disease narrowed.⁵⁷

Social relationships account for sex differences in survival as well. Strong social relationships, such as those found in married individuals, reduce mortality risk by enhancing emotional and financial support and increasing compliance with medical regimens and healthy lifestyles.⁵⁹ Similarly, those who engage in religious activities have lower mortality risk, likely due to the social and emotional support offered in such settings. Both sexes benefit from marriage and religious relationships, but the overall marriage benefit is greater for females than for males due partly to the higher proportional income brought to marriage by males;⁵⁹ however, this marriage benefit can be attenuated by other factors, such as a large age gap between the woman and her male partner.⁶⁰ The religion benefit is higher for females because as a whole they are more likely than males to fully participate in religious activities, including those with a social aspect.⁵⁹

Another factor strongly associated with mortality risk is socioeconomic status (SES). High SES increases access to health care and health insurance coverage. It also improves the likelihood of strong social relationships and residing and working in safer neighborhoods, and creates a buffer against financial hardship.^{59,61} Males are more likely to be employed, earn higher incomes, and be covered by health insurance, but sex gaps in SES have narrowed over time with increased educational attainment among females, higher earnings, higher occupational statuses, and access to health insurance.^{32,59}

Sex differences in morbidity

Differences in morbidity between men and women are difficult to discern due to varying assessment mechanisms and interpretations of data. When assessed by expenditures on health care services, women utilize health care services more often than men,⁶² potentially implying that they seek out health care at earlier stages of disease, thus preventing disease onset or reducing severity and resulting in reduced morbidity. However, when assessed by questionnaires asking patients to rate their own health and by hospitalization events, women report worse health and experience more hospitalization episodes from early adolescence to late middle age than do men, suggesting higher morbidity in women.^{32,63} When considered with the fact that women are less likely than men to die at all ages, several explanations for these paradoxical morbidity findings have been offered. One is that women are more likely than men to perceive ailments that are often less serious, such as headaches or arthritis, as "poor health," and report it as such on questionnaires.⁶³ Another is that while the prevalence of chronic disease is not significantly different in men and women, the severity of certain chronic conditions may be higher in men; for example, men with respiratory cancer, cardiovascular disease, and bronchitis are more likely to die than women who suffer from the same chronic conditions, suggesting that they may experience more severe forms of these conditions.⁶³

Environmental and behavioral factors play a significant role in morbidity. Males are generally more likely to exercise and less likely to be obese, reducing their overall risk of chronic illness.⁵⁹ Related to physical activity, functional impairment is more common in females than in males. Females report higher rates of disability and restrictions in basic movement, which subsequently impact social activity, employment, and risk of accidents such as falls.⁵⁹ Elderly women are less likely to own a car and to drive than elderly men, further restricting activity outside of the primary dwelling.⁴

Many of the social and economic factors that narrow the gap in mortality between males and females also affect morbidity. For example, more females than males live below the poverty level, and more female-headed households than male-headed households experience food insecurity, both leading to adverse health consequences.³² Also, more

women than men are victims of intimate partner violence,³² which, in addition to injuries sustained during episodes of violence, can lead to an increased risk of unhealthy behaviors such as alcohol and drug misuse, eating and sleep disorders, physical inactivity, low self-esteem, post-traumatic stress disorder, smoking, self-harm, and unsafe sexual behavior.⁶⁴

WOMEN AS RESEARCH PARTICIPANTS

The application of sex differences knowledge to clinical practice has been hindered by a historical dearth of research focused on women. In 1985, the Public Health Service Task Force on Women's Health Issues concluded "the historical lack of research focus on women's health concerns has compromised the quality of health information available to women as well as the health care they receive."⁶⁵ Before that time, women were not commonly included as clinical research participants for reasons that included concern about ethical issues of possible fetal exposure to an experimental substance, the variability in hormonal status in women, comorbidities, and the assumption that results of research on men could be extrapolated to women.⁶⁵ In 1986, the National Institutes of Health (NIH) established a policy for the inclusion of women in clinical research; however, the policy was not well-communicated within the NIH, was applied inconsistently in the grant-review process, and applied only to extramural research.⁶⁵ The NIH Revitalization Act of 1993 required that NIH grantees include women and minority groups in human-subjects research and formalized the NIH Office of Research on Women's Health, charging it with reporting on progress related to the law throughout the NIH.⁶⁵

Also in 1993, the FDA reversed its policy that women of childbearing age be excluded from Phase I and II trials, and later amended its regulations to require safety and efficacy data on sex, age, and racial subgroups.⁶⁵ In some cases, new safety data has led to a change in product labeling to reflect differences in drug disposition or sensitivity in women (e.g., for zolpidem). The Government Accountability Office in 2001 reviewed the inclusion of women in clinical drug trials submitted to FDA and, while noting some ongoing concerns, found that women made up a majority (52 percent) of the trial participants in the new drug applications (NDAs) examined and that every NDA included enough women to make it possible to determine statistically whether the drugs were effective in women.⁶⁶

Although women now make up just over half of all NIH-funded clinical research participants, experimental design and analyses in cell and animal research have not followed suit, and publications often neglect sex-based considerations and analyses in preclinical studies.⁶⁷ To address this shortcoming, the NIH announced that beginning in January 2016, NIH-funded scientists will be required to account for the possible role of sex as a biological variable in vertebrate animal and human studies.⁶⁸

In 2010, the IOM released a comprehensive report on the progress of women's health research. It recognized the substantial research gains in knowledge of sex differences in a number of disease areas, but found that barriers exist to translating that research into clinical practice quickly and effectively.⁶⁵ Barriers identified included the complexity of the research, fragmentation in health care delivery and policies, challenges in communicating understandable and actionable messages, and consumer confusion and apprehension.⁶⁵ It recommended that "research be conducted on the best ways to rapidly translate research findings on women's health into clinical practice and public health policies," and suggested that "findings should be incorporated at the practitioner level and at the overall public health systems level through, for example, the use of targeted education programs for practitioners and the development of guidelines. Research on what messages women find confusing and how those messages could be delivered in a more effective manner is needed. As those programs and guidelines are developed and implemented, they should be evaluated to ensure effectiveness."⁶⁵

In 2015, the USPSTF issued a report to Congress highlighting high-priority issues affecting women for which there are substantial gaps in the data to inform clinical practice.² These women's health issues included intimate partner violence, illicit drug use, depression, suicide risk, thyroid function, vitamin D deficiency and supplementation, osteoporosis, breast cancer, ovarian cancer, and cervical cancer. The Task Force emphasized the need for continued research and funding on the issues so that findings could be effectively translated into clinical practice guidelines.²

DISCUSSION

Research over the last several decades has revealed differences in the health of men and women beyond those related to reproductive biology. Sex differences have been described in a wide number of disease areas, with some resulting in practice recommendations specific to women. Adding complexity to sex differences research and

application to care, health outcomes are influenced by factors other than biological sex, such as gender identity and developmental, cultural, environmental, and socioeconomic factors.² Physicians are challenged with considering these factors as they care for their patients. Resolution 604-A-15 proposed that AMA discussion of topics relating to women's health reflect the concept that many diseases have different risks, presentations, and treatments in women, and that evidence-based information regarding the impact of sex and gender be incorporated into practice. The Council supports the intent of Resolution 604-A-15, but also notes that in expanding the definition of women's health, care should be taken not to de-emphasize the importance of reproductive health and other "traditional" health services that are essential to women's health.

Progress in research on sex differences in health has been substantial, and the NIH policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies will further such research. However, translation of research findings has lagged. Guidelines are still typically based on a male standard and do not address important differences in women.⁶⁹ The IOM has made several recommendations to improve translation of women's health research findings, including encouraging examination of the best methods of incorporating guidelines into physician and public health practice, and the appointment of a task force to develop an evidence-based strategy to effectively communicate health messages to women.⁶⁵ Others have added that in order to increase awareness of how sex differences affect health and disease, a common knowledge basis and exchange between researchers of different disciplines should be developed, career opportunities for young scientists should be created, common training tools to introduce medical and research students to the discipline of women's health should be provided, and systematic sex- and gender-specific medicine research as an independent discipline should be established.⁶⁹

Our AMA recognizes the importance of education on women's health for both physicians in practice and in training. Policy H-295.890 encourages the teaching of women's health in medical school and participation in continuing medical education activities on women's health for practicing physicians. Additionally, the AMA supports inclusion of women in clinical research. Policies H-525.991 and H-525.988 support funding for research in women's health and the inclusion of women in clinical trials, the results of which will permit development of evidence-based prevention and treatment strategies for all women from diverse cultural and ethnic groups, geographic locations, and socioeconomic status. Policy H-525.988 further encourages that all medical/scientific journal editors require, where appropriate, a sex-based analysis of data.

Understanding sex differences that impact health and disease will lead to better care for both men and women. The Council recommends that the AMA adopt policy acknowledging the role that sex and gender play in health and supporting application of evidence-based information to practice.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted in lieu of Resolution 604-A-15 and the remainder of the report be filed.

1. That our American Medical Association (AMA) recognize the term "women's health" as inclusive of all health conditions for which there is evidence that women's risks, presentations, and/or responses to treatments are different from those of men, and encourage that evidence-based information regarding the impact of sex and gender be incorporated into medical practice, research and training.
2. That Policy H-525.991, Inclusion of Women in Clinical Trials, be amended by addition to read as follows:
 1. Our AMA encourages the inclusion of women, including pregnant women when appropriate, in all research on human subjects, except in those cases for which it would be scientifically irrational, in numbers sufficient to ensure that results of such research will benefit both men and women alike; 2. supports the National Institutes of Health policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies; and 3. encourages translation of important research results into practice.
3. That Policy H-525.988, Sex and Gender Differences in Medical Research, be reaffirmed.

REFERENCES

1. Council on Scientific Affairs. Women's Health: Sex- and Gender-Based Differences in Health and Disease. CSA Report 4-I-00. <https://download.ama-assn.org/resources/doc/csaph/x-pub/csai-00.pdf>. Accessed 2-25-16.
2. United States Preventive Services Task Force. Fifth Annual Report to Congress on High Priority Evidence Gaps for Clinical Preventive Services: Improving the Health of Women through Research. November, 2015. <http://www.uspreventiveservicestaskforce.org/Home/GetFile/6/300/2015annlrpt/pdf>. Accessed 2-8-16.
3. Kirchstein RL. Research on women's health. *Am J Public Health*. 1991;81(3):291-3.
4. Regitz-Zagrosek V. Sex and gender differences in health. Science & Society Series on Sex and Science. *EMBO Rep*. 2012;13(7):596-603.
5. Institute of Medicine. Exploring the Biological Contributions to Human Health: Does Sex Matter? 2001. <http://www.nap.edu/catalog/10028/exploring-the-biological-contributions-to-human-health-does-sex-matter>. Accessed 2-8-16.
6. National Library of Medicine. MedlinePlus: Sex-linked recessive. <https://www.nlm.nih.gov/medlineplus/ency/article/002051.htm>. Accessed 2-8-16.
7. National Center for Biotechnology Information. GeneReviews: *FMR1*-related disorders. <http://www.ncbi.nlm.nih.gov/books/NBK1384/>. Accessed 2-8-16.
8. Orphanet. Duchenne muscular dystrophy. http://www.orpha.net/consor/www/cgi-bin/OC_Exp.php?lng=EN&Expert=98896. Accessed 2-8-16.
9. National Center for Biotechnology Information. GeneReviews: Dystrophinopathies. <http://www.ncbi.nlm.nih.gov/books/NBK1119/>. Accessed 2-8-16.
10. Smith KM, Dahodwala N. Sex differences in Parkinson's disease and other movement disorders. *Exp Neurol*. 2014;259:44-56.
11. Gillies GE, Pienaar IS, Vohra S, Qamhawi Z. Sex differences in Parkinson's disease. *Front Neuroendocrinol*. 2014;35(3):370-84.
12. Singmann P, Shem-Tov D, Wahl S, et al. Characterization of whole-genome autosomal differences of DNA methylation between men and women. *Epigenetics Chromatin*. 2015;8:43.
13. Uddin M, Sipahi L, Li J, Koenen KC. Sex differences in DNA methylation may contribute to risk of PTSD and depression: a review of existing evidence. *Depress Anxiety*. 2013;30(12):1151-60.
14. Heron M. Deaths: Leading Causes for 2012. *Natl Vital Stat Rep*. 2015;64(10):1-93.
15. CDC/National Center for Health Statistics. National Vital Statistics Systems, Mortality 2013. http://www.cdc.gov/nchs/data/dvs/lcwk1_2013.pdf. Accessed 2-8-16.
16. Mosca L, Barrett-Connor E, Wenger NK. Sex/gender differences in cardiovascular disease prevention: what a difference a decade makes. *Circulation*. 2011;124(19):2145-54.
17. Mozaffarian D, Benjamin EJ, Go AS, et al. Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association. *Circulation*. 2016;133(4):e38-e360.
18. Mehta LS, Beckie TM, DeVon HA, et al. Acute Myocardial Infarction in Women: A Scientific Statement From the American Heart Association. *Circulation*. 2016 Jan 25; [Epub ahead of print].
19. Howe MD, McCullough LD. Prevention and management of stroke in women. *Expert Rev Cardiovasc Ther*. 2015;13(4):403-15.
20. Bushnell C, McCullough LD, Awad IA, et al. Guidelines for the prevention of stroke in women: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2014;45(5):1545-88.
21. Lundberg GP, Volgman AS. Burden of stroke in women. *Trends Cardiovasc Med*. 2016;26(1):81-8.
22. Camm AJ, Kirchhof P, Lip GY, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). *Eur Heart J*. 2010;31(19):2369-429.
23. Ngo ST, Steyn FJ, McCombe PA. Gender differences in autoimmune disease. *Front Neuroendocrinol*. 2014;35(3):347-69.
24. Smyk DS, Rigopoulou EI, Pares A, et al. Sex differences associated with primary biliary cirrhosis. *Clin Dev Immunol*. 2012;2012:610504.
25. Weckerle CE, Niewold TB. The unexplained female predominance of systemic lupus erythematosus: clues from genetic and cytokine studies. *Clin Rev Allergy Immunol*. 2011;40(1):42-9.
26. Brandt JE, Priori R, Valesini G, Fairweather D. Sex differences in Sjögren's syndrome: a comprehensive review of immune mechanisms. *Biol Sex Differ*. 2015;6:19.
27. Li R, Singh M. Sex differences in cognitive impairment and Alzheimer's disease. *Front Neuroendocrinol*. 2014;35(3):385-403.
28. Janicki SC, Schupf N. Hormonal influences on cognition and risk for Alzheimer's disease. *Curr Neurol Neurosci Rep*. 2010;10(5):359-66.
29. Ungar L, Altmann A, Greicius MD. Apolipoprotein E, gender, and Alzheimer's disease: an overlooked, but potent and promising interaction. *Brain Imaging Behav*. 2014;8(2):262-73.
30. Holland D, Desikan RS, Dale AM, McEvoy LK. Higher rates of decline for women and apolipoprotein E epsilon4 carriers. *Am J Neuroradiol*. 2013;34(12):2287-93.
31. Heger NE. Predictive testing and Alzheimer disease. *Clin Chem*. 2014;60(12):1585-6.
32. Health Resources and Services Administration. Women's Health USA 2013. December 2013. <http://mchb.hrsa.gov/whusa13/dl/pdf/whusa13.pdf>. Accessed 2-8-16.

33. Eaton NR, Keyes KM, Krueger RF, et al. An invariant dimensional liability model of gender differences in mental disorder prevalence: evidence from a national sample. *J Abnorm Psychol*. 2012;121(1):282-8.
34. Harvard Medical School. National Comorbidity Survey. <http://www.hcp.med.harvard.edu/ncs/>. Accessed 2-25-16.
35. Sagud M, Hotujac Lj, Mihaljević-Peles A, Jakovljević M. Gender differences in depression. *Coll Antropol*. 2002;26(1):149-57.
36. Affifi M. Gender differences in mental health. *Singapore Med J*. 2007;48(5):385-91.
37. Piccinelli M, Wilkinson G. Gender differences in depression. Critical review. *Br J Psychiatry*. 2000;177:486-92.
38. Soares CN, Zitek B. Reproductive hormone sensitivity and risk for depression across the female life cycle: a continuum of vulnerability? *J Psychiatry Neurosci*. 2008;33(4):331-43.
39. Möller-Leimkühler AM. Higher comorbidity of depression and cardiovascular disease in women: a biopsychosocial perspective. *World J Biol Psychiatry*. 2010;11(8):922-33.
40. Kornstein SG, Schatzberg AF, Thase ME, et al. Gender differences in treatment response to sertraline versus imipramine in chronic depression. *Am J Psychiatry*. 2000;157(9):1445-52.
41. Erol A, Karpyak VM. Sex and gender-related differences in alcohol use and its consequences: Contemporary knowledge and future research considerations. *Drug Alcohol Depend*. 2015;156:1-13.
42. Greenfield SF, Back SE, Lawson K, Brady KT. Substance abuse in women. *Psychiatr Clin North Am*. 2010;33(2):339-55.
43. Ceylan-Isik AF, McBride SM, Ren J. Sex difference in alcoholism: who is at a greater risk for development of alcoholic complication? *Life Sci*. 2010;87(5-6):133-8.
44. Hommer DW. Male and female sensitivity to alcohol-induced brain damage. *Alcohol Res Health*. 2003;27:181-5.
45. Prendergast MA. Do women possess a unique susceptibility to the neurotoxic effects of alcohol? *J Am Med Womens Assoc*. 2004;59(3):225-7.
46. Nixon SJ, Prather R, Lewis B. Chapter 16—sex differences in alcohol-related neurobehavioral consequences, in Handbook of Clinical Neurology (Sullivan EV, Pfefferbaum A eds). 2014;pp. 253-272. Elsevier, Amsterdam.
47. Alfonso-Loeches S, Pascual M, Guerri C. Gender differences in alcohol-induced neurotoxicity and brain damage. *Toxicology*. 2013;311(1-2):27-34.
48. Altman RD. Osteoarthritis, rev August 2015. Merck Manual. [http://www.merckmanuals.com/professional/musculoskeletal-and-connective-tissue-disorders/joint-disorders/osteoarthritis-\(oa\)](http://www.merckmanuals.com/professional/musculoskeletal-and-connective-tissue-disorders/joint-disorders/osteoarthritis-(oa)). Accessed 4-11-16.
49. Nelson AE, Golightly YM, Renner JB, et al. Brief report: differences in multijoint symptomatic osteoarthritis phenotypes by race and sex: the Johnston County Osteoarthritis Project. *Arthritis Rheum*. 2013;65(2):373-7.
50. Niu J, Zhang Y, LaValley M, et al. Symmetry and clustering of symptomatic hand osteoarthritis in elderly men and women: the Framingham Study. *Rheumatology (Oxford)*. 2003;42(2):343-8.
51. Srikanth VK, Fryer JL, Zhai G, et al. A meta-analysis of sex differences prevalence, incidence and severity of osteoarthritis. *Osteoarthritis Cartilage*. 2005;13(9):769-81.
52. Maradit Kremers H, Larson DR, Crowson CS, et al. Prevalence of Total Hip and Knee Replacement in the United States. *J Bone Joint Surg Am*. 2015;97(17):138697.
53. Plotnikoff R, Karunamuni N, Lytvynak E, et al. Osteoarthritis prevalence and modifiable factors: a population study. *BMC Public Health*. 2015;15:1195.
54. Pennell LM, Galligan CL, Fish EN. Sex affects immunity. *J Autoimmun*. 2012;38(23):J28291.
55. Fernandes GS, Valdes AM. Cardiovascular disease and osteoarthritis: common pathways and patient outcomes. *Eur J Clin Invest*. 2015;45(4):40514.
56. CDC/National Center for Health Statistics. Deaths: Final Data for 2013. http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf. Accessed 2-8-16.
57. Wisser O, Vaupel JW. The Sex differential in mortality: A historical comparison of the adult-age pattern of the ratio and the difference. Working papers of the Max Planck Institute for Demographic Research. June 2014. <http://www.demogr.mpg.de/papers/working/wp-2014-005.pdf>. Accessed 2-8-16.
58. Seifarth JE, McGowan CL, Milne KJ. Sex and life expectancy. *Gend Med*. 2012;9(6):390-401.
59. Rogers RG, Everett BG, Onge JM, Krueger PM. Social, behavioral, and biological factors, and sex differences in mortality. *Demography*. 2010;47(3):555-78.
60. Drehfahl S. How does the age gap between partners affect their survival? *Demography*. 2010;47(2):313-26.
61. Kalben BB. Why Men Die Younger: Causes of Mortality Differences by Sex. *North American Actuarial Journal*. 2000;4(4):83-111.
62. Mustard CA, Kaufert P, Kozyrskyj A, Mayer T. Sex differences in the use of health care services. *N Engl J Med*. 1998;338(23):1678-83.
63. Case A, Paxson C. Sex differences in morbidity and mortality. National Bureau of Economic Research Working Paper Series. August 2004. <http://www.nber.org/papers/w10653.pdf>. Accessed 2-8-16.
64. Langer A, Meleis A, Knaul FM, et al. Women and Health: the key for sustainable development. *Lancet*. 2015;386(9999):1165-210.
65. Institute of Medicine. Women's Health Research: Progress, Pitfalls, and Promise. 2010. <http://www.nap.edu/catalog/12908/womens-health-research-progress-pitfalls-and-promise>. Accessed 2-8-16.
66. Government Accountability Office. Women's Health: Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement. July 2001. <http://www.gao.gov/new.items/d01754.pdf>. Accessed 2-8-16.
67. Clayton JA, Collins FS. Policy: NIH to balance sex in cell and animal studies. *Nature*. 2014;509(7500):282-3.
68. National Institutes of Health. Consideration of Sex as a Biological Variable in NIH-funded Research. Notice Number: NOT-OD-15-102. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html>. Accessed 2-8-16.

69. Bairey Merz CN, Regitz-Zagrosek V. The Case for Sex- and Gender-Specific Medicine. *JAMA Intern Med.* 2014;174(8):1348-9.

**6. DELAYING SCHOOL START TIME TO ALLEVIATE ADOLESCENT SLEEP DEPRIVATION
(RESOLUTION 404-A-15)**

Reference committee hearing: see report of [Reference Committee D](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED**
See Policy H-60.930

INTRODUCTION

Resolution 404-A-15 “Altering School Days to Alleviate Adolescent Sleep Deprivation,” introduced by Medical Student Section at the 2015 Annual Meeting of the House of Delegates and referred to the Board of Trustees, asks:

That our American Medical Association (AMA) support appropriate entities in establishing clear evidence-based recommendations from existing research on adolescent sleep needs and school start times, and that our AMA support legislation congruent with those guidelines.

Current AMA policy identifies insufficient sleep and sleepiness as a public health issue, and supports education about sleep health as a standard component of care for adolescent patients (Policy H-60.930).

METHODOLOGY

English language reports published between 2005 and 2016 were selected from a search of the PubMed and Google Scholar databases using the search terms “school start time” and “sleep deprivation” combined with “adolescents,” “teenagers,” “schools,” “students,” and “adolescent behavior.” Additional articles were identified by manual review of the references cited in these publications. Further information was gathered from a 2014 policy statement issued by the American Academy of Pediatrics (AAP) and from Internet sites managed by relevant federal agencies and public health organizations.

BACKGROUND

Insufficient sleep among adolescents (aged 12-18 years) has been a concern for the past several decades. The AAP recommends that teenagers (aged 14-17 years) get 8.5 to 9.5 hours of sleep per night,¹ and an expert panel convened by the National Sleep Foundation (NSF) recommends that teenagers get 8 to 10 hours of sleep per night.² However, in 2013, only approximately 32 percent of teens in grades 9-12 reported getting at least 8 hours of sleep on an average school night.³ This proportion varied widely by sex, race/ethnicity, and grade level. In addition, approximately 40 percent of 9th graders reported at least 8 or more hours of sleep per night, compared to approximately 23 percent of 12th graders.³ Recognizing these patterns as a substantial concern, the topic of “Sleep Health” was incorporated into Healthy People 2020, with a specific objective to increase the overall proportion of students in grades 9-12 who get sufficient sleep (defined as 8 or more hours per night) to 33.1 percent by 2020.⁴

One contributor to insufficient sleep in adolescents is an early school start time.⁵⁻⁸ In the 1960s, to accommodate a large influx of baby-boomers, school districts began experimenting with staggered start times. By 1975, most high schools in the US started as early as 8:00 a.m.⁹ In the past few decades, high school start times have become increasingly early, with many high schools beginning at or before 7:30 a.m.^{9,10} Acknowledging a need to increase alertness and readiness to learn among high school students, many school districts have recently pushed back high school start times, and maintained those changes.¹¹ Delaying high school start times, while beneficial to the student, are often controversial within the school district and community.¹² This report builds on a 2014 AAP policy statement “School Start Times for Adolescents”¹¹ by briefly reviewing the health and academic consequences of decreased sleep in adolescents and examining more recent evidence for delaying school start times as a mechanism to address adolescent sleep deprivation.

DECREASED SLEEP AMONG ADOLESCENTS

The majority of adolescents do not get sufficient sleep (i.e., at least 8 hours) each night.^{3,4} Changes in circadian rhythm and sleep habits due to puberty, night-time distractions, and early school start times all contribute to insufficient sleep among adolescents.^{5,13}

Circadian rhythm

Puberty is accompanied by a biological delay or shift in circadian rhythm, contributing to later bedtimes among teens.^{1,14-17} With the onset of puberty, most adolescents experience a sleep/wake “phase delay,” resulting in both later sleep and wake times.¹ Pubertal influences on the circadian cycle occur among most mammals, and in humans, are cross-cultural.^{13,16}

Two primary biological factors contribute to changes in sleep regulation during adolescence.¹ First, the secretion of melatonin, a hormone that signals readiness for sleep, is delayed during puberty.¹⁴ On average, melatonin secretion in prepubescent individuals begins at approximately 9:30 p.m., but in adolescents, starts around 10:30 p.m.¹¹ Therefore, most teens are not ready for melatonin-triggered sleep until at least 11:00 p.m. or later.^{10,11} The preferred (natural) biological wake-time for 16-year-olds is estimated to be close to 8:00 a.m., while for 18-year-olds is estimated to be closer to 9:00 a.m. This is in contrast to the approximately 6:30 a.m. biological wake time for 10 year-olds.¹⁶ These differences in adolescent biology mean that a 7:00 a.m. wake up time for adolescents is roughly equivalent to a 4:30 a.m. wake-up time for a middle-aged adult.¹⁶ Second, an altered “sleep drive” occurs throughout adolescence, meaning that it can take much longer for teens to fall asleep.¹ Therefore, adolescents undergoing puberty will typically take longer to fall asleep when being awake for 14.5-18.5 hours compared to prepubertal teens.¹

The shifting circadian rhythm in teens results in loss of sleep on school days. Total sleep time on school days decreases significantly from ages 11 to 15 years, with 11-year-olds averaging 9 hours, 26 minutes of sleep, and 15-year-olds averaging 7 hours, 55 minutes of sleep.¹⁸ Total sleep time decreases even more as teens get older, with only 23.3 percent of 12th graders getting more than 8 hours of sleep on school days.³ On weekends, adolescents tend to shift bedtimes 1-2 hours later and rise times 1.5-4 hours later than during the week.¹⁴ Although this “catch-up sleep” can partially offset sleep deficits incurred during the week, circadian disruptions persist.¹

In a study examining the sleep/wake patterns for the Navy’s training camp, young recruits (aged 17-19 years) in the training camp were allowed six hours of sleep per night, 10:00 p.m. to 4:00 a.m.^{9,19} In order to address performance issues related to sleep deprivation, bedtime was moved to 9:00 p.m. Despite the extra hour of time allowed for sleep, the recruits were unable to fall asleep and no improvements in performance were noted. However, when sleep times changed from 10:00 p.m. to 6:00 a.m., sleep came more easily and substantial improvements were noted. In particular, standardized test scores increased and sick-calls were reduced by 70 percent.^{9,19}

Risk factors

In addition to circadian biology, several factors affect total sleep time among adolescents. Computer and electronic use, family dynamics, and social activities also influence bed time.²⁰ Night-time use of screen-based technologies (phones, televisions, computers, etc.) impact daytime sleepiness and academic performance. According to the NSF’s 2014 Sleep in America Poll, more than 70 percent of adolescents have at least one electronic device in the bedroom.²¹ Data from the Pew Research Institute show that over three-quarters of Americans between the ages of 12 and 17 years now own a mobile phone, almost half of which are smartphones.^{22,23} Nearly 85 percent of adolescents in the US who have a smartphone sleep with it in or near their bed, and in-bed use has been reported by more than 60 percent of adolescents.^{22,24} A recent study of more than 3,000 US middle and high school students found that mobile device use just before bed time or after lights-out is significantly associated with insomnia and daytime sleepiness and is correlated with poor academic performance, later bedtimes and fewer hours of sleep on school nights.²²

In addition to displacing sleep time, night-time use of some electronics further affects sleep patterns by suppressing melatonin. Exposure to the blue wavelength light found on screen-based technologies is associated with increased alertness and difficulty falling asleep.^{16,25,26} The short wavelength spectral light emitted by electronics inhibits the secretion of melatonin, delaying the melatonin-induced sleep process.^{13,27}

Other social factors such as a negative family environment (defined as an environment with conflict and/or chaos) and stress coping strategies that involve disengagement also impact the ability to fall asleep.^{25,28} Additionally, students working part-time jobs for more than 20 hours per week often have difficulty getting adequate sleep. For every 10 hours worked per week outside of school, students lose approximately 14 minutes of sleep per night.⁹

School start time is a large contributor to diminished sleep among adolescents.⁵⁻⁸ Students beginning school before 8:15 a.m. often are substantially sleep deprived.⁵ School start times typically remain constant or become earlier as students get older.²⁵ This is in juxtaposition to the changing sleep patterns and sleep/wake cycles of adolescents as they progress through puberty.¹⁶ The impact of school start times on adolescent health and performance is discussed in more detail later in this report.

Consequences of sleep deprivation

The proper amount of sleep is essential for healthy development during adolescence. Growth hormone is released during slow wave sleep and gonadotrophic hormones also are secreted during sleep.⁹ In addition, sleep impacts learning and memory.^{9,16} Adequate rapid eye movement (REM) sleep is essential for emotional processing and cognitive development.⁹ Inadequate REM is associated with poor memory performance, mood disorders, daytime sleepiness/unintended sleep, anxiety, decreased socialization, hypersexuality, mental fatigue, and decreased capability of handling complex tasks.^{5,9}

Several other negative health effects also are related to short sleep duration. For example, restricted sleep is associated with hypertension and metabolic disorders, including diabetes.¹⁶ Impaired immune function has been linked with short sleep duration; those with diminished sleep are more likely to have an increased susceptibility to viruses such as the common cold.^{16,29,30} A study assessing adolescents between the ages of 12 and 17 years found that cortisol levels and white blood cell, neutrophil, monocyte, and CD4+ lymphocyte counts were negatively correlated with short sleep duration.³⁰ Among females only, short sleep duration also was found to be negatively associated with pro-inflammatory cytokine levels.³⁰

Behaviors increasing risk for injury are more prevalent among US high school students who sleep less than 7 hours on an average school night compared to those who sleep 7-10 hours per average school night.³¹ These behaviors include infrequent bicycle helmet use, infrequent seatbelt use, riding with a driver who has been drinking, drinking and driving, and texting while driving.³¹ A higher risk of injury during after-school sporting activities also appears to be related to decreased sleep duration among adolescents.³²

Adolescents with decreased sleep often are cited as being less physically active.^{33,34} Body mass index (BMI) is believed to be directly related to inadequate sleep among adolescents.^{16,18,35-38} Adolescents aged 16 to 19 years who are underweight, overweight, or obese have shorter sleep durations than those who are normal weight.³⁵ However, sex differences in the relationship between obesity and decreased sleep may differ depending on the study design. Obesity is more likely among US adolescent girls getting less than 4 hours of sleep or more than 9 hours of sleep, but these effects were less consistently observed among adolescent boys.³⁸ In contrast, a more recent study found an association between obesity and short duration of sleep among adolescent boys, but not among adolescent girls.³⁵

Generally, a less positive attitude toward life and symptoms of depression and anxiety are more evident with short sleep duration.^{16,39} The association with mood and anxiety is most apparent among those getting less than 6 hours of sleep per night.⁹ Adolescents getting less than five hours of sleep per night are more likely to engage in other high risk behaviors, such as smoking, drug use, and high risk sexual activity.^{9,33,34,37} A negative or poorly structured family environment, which is itself a risk factor for shorter sleep duration, additionally contributes to these behaviors.^{9,25}

SCHOOL START TIMES IN THE UNITED STATES

School start times for high school students have become increasingly early over the past several decades.⁹ Nearly 10 percent of high schools in the US begin at or before 7:30 a.m.¹⁰ Recently, the Centers for Disease Control and Prevention (CDC) and the US Department of Education analyzed data from the 2011–2012 Schools and Staffing Survey (SASS).^{10,40} This survey assessed 39,700 public schools (middle, high, and combined schools), with an estimated total enrollment of 26.3 million students. The average start time for all middle, high, and combined schools in the US was 8:03 a.m.^{10,40} Average start time varied widely by state. The average start time for adolescent

students in Louisiana is approximately 7:40 a.m., whereas in Alaska and North Dakota, start times are almost an hour later at 8:33 a.m. and 8:31 a.m., respectively.^{10,40}

School start times vary by state, school size, whether the school is located in urban or rural locations, and the presence and type of the busing system. Schools with more than 1,000 students tend to start approximately 15 minutes earlier compared to smaller schools, and rural schools begin on average 15 minutes later than urban or suburban schools.¹⁰ Schools that do not have a tiered bus system start 15 minutes later than schools with two-tiered systems, or 20 minutes later than schools with three-tiered systems.⁴¹ Several school districts stagger the start times of their elementary, middle, and high schools, which accommodates large influxes of students and allows for the same bus drivers to serve multiple schools, thus reducing costs incurred by the school district.^{9,41,42}

Available data support a high school start time of 8:30 a.m. or later to ensure adequate essential sleep among adolescents.^{8,9,17} However less than 18 percent of public schools start at or later than 8:30 a.m.^{10,40} This percentage varies widely by state, with more than three-quarters of schools in North Dakota and Alaska starting later than 8:30 a.m., and no schools in Hawaii, Mississippi, or Wyoming starting at or later than 8:30 a.m.^{10,40} Forty-two states report that 75-100 percent of their public schools start before 8:30 a.m.^{10,40}

OUTCOMES DUE TO DELAYED SCHOOL START TIMES

As of 2009, more than 80 schools had delayed school start times in an effort to allow adolescents to attain extra sleep.¹¹ To date, schools in over 43 states have delayed school start times.⁴³ Several studies, including a systematic review, have evaluated the impact of delayed school start times.^{8,44-52} Benefits have been observed by parents, teachers, school administrators, and students, while few disadvantages or harmful effects have been noted.^{5,7,12,53} School districts that have delayed start times typically have not returned to their previous schedules.¹¹

Sleep duration

Several studies have compared patterns of sleep duration and the sleep/wake cycle among adolescents with earlier school start times to those with later school start times. One study compared students beginning school at 7:15 a.m. to students beginning school later, at 8:37 a.m.; students at both schools reported similar bedtimes, but students at the school with a later start time woke up an hour later on average on school days than students at the school with the earlier start time.⁴⁵ In addition, students at the school with the later start time experienced an average of 50 more minutes of sleep per night and reported less daytime sleepiness compared to their counterparts starting school more than one hour earlier.⁴⁵ A three year study that examined the effects of delayed school start times noted that schools starting after 8:30 a.m. allow for almost 60% of students to achieve a sleep duration of at least 8 hours per night on school days,⁸ nearly twice the proportion of 9th-12th grade students currently achieving 8 hours of sleep each night nationwide.³

In 1997, citing the negative effects of sleep deprivation, seven Minnesota high schools shifted school start time from 7:15 a.m. to 8:40 a.m. Prior to the change it was anticipated that students would adapt to the change in start time by delaying their bedtime.⁵ However, after several years of follow-up, bedtime remained unchanged from the years prior to the change in school start time; as a result, more students had increased total sleep duration each night.⁵ Other studies have observed the same, i.e., bedtime remains the same and sleep duration increases with delayed school start time.^{13,20,45-48} The average bedtime for teens (approximately 10:30 p.m.) has remained relatively constant for the past several decades.²⁰ Bedtimes of teens in 1981 were similar to those of bedtimes among teens in 2003-2006 despite drastic changes in school start times within this time frame.^{9,11,20}

Evidence that bedtime remains unchanged when school start time is delayed has not been completely consistent. A cross-sectional survey of 7,308 US adolescents aged 13 to 17 years found that those with later school start times went to bed later than students with earlier school start times.⁴⁹ Despite this difference, those with later school start times consistently obtained more sleep and were more likely to achieve the recommended 8-10 hours of sleep per night, compared to students attending schools with earlier start times.⁴⁹

Even modest changes in school start time induce positive changes in sleep duration.^{50,51} For example, a half-hour delay, from 8:00 a.m. to 8:30 a.m. was responsible for students gaining an average of more than 45 minutes of sleep per night.⁵⁰ Notably, reports of less than 7 hours of sleep per night were reduced by almost 80%.⁵⁰ Others also have

observed that a small delay in start time from 8:00 a.m. to 8:25 a.m. was associated with at least one half-hour increase in sleep duration, and more students experiencing at least 8 hours of sleep per school night.⁵¹

Social and physical outcomes

School districts that have delayed school start times have identified several changes in mood, behavior, and overall well-being among students. In particular, in the time period following institution of delayed start times, students were less likely to have self-reported depression, and more likely to report increased or improved motivation and increased energy level than before the delayed start times were instituted.^{9,13,45,50} Parents, teachers, and school administrators in schools with delayed start times also have noted improved student demeanor and significantly fewer disciplinary problems.^{5,42}

Two years following a delay in school start times by one hour in some Kentucky school districts, a notable decrease (16.5 percent) in motor vehicle crash rates among teens was observed in the geographic areas near the schools with delayed start times.⁵² In contrast, the motor vehicle crash rate for the rest of Kentucky increased by almost 8 percent during the same time period.⁵² This phenomenon has been observed elsewhere as well. In Virginia, teen crash rates were compared between geographically adjacent communities with vastly different high school start times, Virginia Beach, VA, and Chesapeake, VA.⁵⁴ School start time in Virginia Beach is 75-80 minutes earlier than in Chesapeake. For the two years studied, crash rates were significantly higher in Virginia Beach compared to Chesapeake.⁵⁴ Peak crash times occurred during teens' morning commute timeframe, but other factors, such as congestion rates, were not found to be associated with crash rates.⁵⁴ This trend has remained in other counties within the state of Virginia as well.⁵⁵ In addition, decreases in motor vehicle crashes among teenagers aged 16-18 years decreased between 65-70 percent after schools in both Minnesota and Wyoming delayed school start times.⁷

Extracurricular activities and responsibilities

While positive outcomes have been observed following delays in school start times, negative impacts also have been noted. Later end times to school affect the ability of students to participate in athletic and other extracurricular activities and to have part-time jobs.^{9,42} In addition, since it gets dark earlier during the fall and winter months, increased concern exists regarding students waiting for the school bus in the dark.^{56,57}

Traditionally, sports practice occurs at the end of the day. The consequent delay of practice and/or start times for games to accommodate a later school start time is a significant concern among parents, students, and coaches.^{5,56} Some schools with delayed start times have allowed for early dismissal from class to accommodate scheduling of sports games and practices.⁴² In addition, in order to minimize the reduced time allotted for sports practices, other schools have opted to hold practices in the morning, prior to school start, thus negating the reason for delaying school start times.^{41,56}

Two studies evaluating the effects of delayed school start times on whether students were too tired to play sports found no significant changes.^{43,51,52} Similarly, no significant differences in participation in music activities, volunteer work, or socializing with friends were noted after delayed start times were initiated.^{43,51,52}

Teachers also have after-school commitments, and for personal reasons, report mixed support for delayed school start times.^{5,12} The majority acknowledge that students are more alert during the day, and many appreciate the extra time in the morning for lesson planning before students arrive.⁵ But about half of teachers are concerned that the later end times mean less time for personal commitments, such as having a second job, and longer commutes home due to rush hour traffic.¹²

Academic performance and attendance

Selected markers of academic performance indicate that decreased sleep duration is associated with poorer academic performance among adolescents.^{33,58,59} When school start times are delayed, improvements in academic performance are noted.^{8,9,60} Specifically, when classes begin after 8:35 a.m., substantial improvements in grades in math, English, and social studies are observed, and improvements in performance on academic achievement tests at both the state and national level are apparent.⁸ In addition, when teens begin school before 8:00 a.m., they tend to perform more poorly throughout the day, compared to teens beginning school later.⁵⁹ However, when grades or grade point average (GPA) alone are considered, data on academic performance and school start times are less clear.^{8,9,13,57,60} For

example, little to no association has been found between GPA and decreased sleep.^{57,60} Confounding factors, such as student selection of coursework and specific instructors may bias any association between grades or GPA and decreased sleep.

Improvements to attendance also have been noted when school start time is delayed. Fewer students are tardy or absent from school, and fewer truancies occur.^{8,13,15,41,48}

Bus schedule impact

Costs associated with changes to school bus schedules often are cited as a major reason to not delay school start times.^{5,42} However, evidence from school districts that have instituted delays does not support this view. Schools in Minnesota that implemented a change in school start time from 7:15 a.m. to 8:40 a.m. had no changes in transportation costs.⁵ In these schools, buses and bus routes remained the same, yet the time the buses used the routes was delayed.⁵

If schools with tiered bus systems opt to dismantle the tiered schedule as a result of later school start times, then increases in transportation costs can be expected. However, the costs may not be as high as previously imagined. Eliminating a three-tiered bus schedule is estimated to cost approximately \$150 per student per year.⁴¹ In contrast, reducing class size by one-third to allow for a more enriched learning environment and an increase in standardized test scores is estimated to cost roughly \$2,151 per student per year, about seven times the cost of eliminating the tiered bus system to accommodate a delayed school start, with an almost equivalent benefit to students.⁴¹

Impacts on family schedules

In school districts considering delaying start times, parents have reported concern about the impact that the later start times could have on their work and family schedules.⁵ Some parents have jobs with inflexible start times, so a delay in school start time may require them to arrange for alternative transportation to get their children to and from school. For families with younger siblings, a delay in high school start time may mean that the schedules of younger children will be offset, creating the need for multiple trips to drop off and pick up children from school. Similarly, older siblings are often counted on to provide after-school care for younger siblings, so a shift in school end times may leave parents with the need to find alternative care for those children.^{9,42} However, many parents who express concern about the impact of delayed school start times on their family's schedule still support later start times because of the anticipated positive impact on students' health and learning.⁵

CURRENT LEGISLATION

In 1998, the Zzz's to A's Act was introduced in the US House of Representatives, advocating for later school start times. Newer versions and revisions have occurred over the past decade and a half. The Act directs the Secretary of Education to study the effect of delaying school start times for adolescents and present the findings to Congress. The Act's sponsor believes that the study will help local school districts to recognize the impact that school start times can have on the well-being of adolescents.⁶¹

The newest version of the Act, H.R. 1306, was introduced in the House in March of 2015. As of April 2015, it has been referred to the Subcommittee on Early Childhood, Elementary and Secondary Education, which is part of the House Education and Workforce Committee.⁶² The Act has several original cosponsors and is supported by both the National Sleep Foundation and Start School Later, Inc.⁶¹

ROLE OF PHYSICIANS, PARENTS, AND EDUCATORS

Adolescent sleep hygiene is highly influenced by parents.¹⁶ Significant concordance exists between parent and adolescent sleep time; adolescents sleep more or less on days in which their parents sleep more or less, respectively.⁶³ Parents can therefore impact sleep patterns by establishing a sleep routine for the family and by modeling adequate sleep duration and appropriate sleep behavior.⁶³

School-based education programs on sleep hygiene have generally improved students' knowledge of appropriate sleep practices, but have resulted in improved sleep behavior only on weekends, not weeknights.^{64,65} However, a

positive outcome from one education program was a decrease in behaviors that can negatively impact sleep, such as caffeine intake and hyperactivity.⁶⁵

School administrators, parents, and community members involved in the process of delaying school start times can become overwhelmed by the available data, and the process can be emotionally charged.¹² Lack of sufficient community support to delay start times has led to controversy and worry about the cascade of transportation and athletic/extracurricular activity consequences that could result from a schedule change.¹²

School start time delays have generally been unsuccessful when only partial facts are explained, implementation is too rapid, and incorrect assumptions are conveyed.⁵ Physicians and medical professionals can assist school districts that are considering delaying school start times. The AAP recommends that pediatricians and other health professionals educate adolescents, parents, educators, athletic coaches and other stakeholders about the biological and environmental factors that contribute to sleep deprivation in youth.¹ Further, the AAP recommends that health professionals provide scientific information, evidence-based rationales, guidance, and support to educate school administrators, parent-teacher associations, and school boards about the benefits of instituting a delay in start times as a potentially highly cost-effective countermeasure to adolescent sleep deprivation and sleepiness.¹ The presence of physicians, particularly sleep medicine specialists and pediatricians, at public meetings on delaying school start times has been influential.^{1,56,66-69} Support from other professionals has been similarly influential. In Kentucky, support from a child psychologist and the school's legal counsel were helpful in the decision to delay school start times.⁵⁶

CONCLUSIONS

Adolescent sleep health is an important public health topic. Decreased total sleep time among teens is strongly associated with several negative outcomes including decreases in emotional processing and memory, metabolic disorders, impaired immune function, depression and anxiety, high risk behaviors, increased injury from sport activities, unhealthy BMI, and decreased academic performance.^{5,9,16,18,29-39,44,58,59} Evidence strongly suggests that allowing adolescents more time for sleep results in improvements in health, academic performance, behavior, and general well-being. Overwhelming evidence exists that sleep duration in adolescents can be significantly increased when school start time is delayed, particularly past 8:30 a.m.^{7-9,13,20,45,47-51,69} The AAP and the National Association of School Nurses and the Society of Pediatric Nurses support a delay in school start times to allow more adolescents to achieve the recommended sleep duration of 8-10 hours per night.^{1,69}

Implementing a delayed school start can be an emotional and potentially stressful issue among members of the community. No “one size fits all” approach to delaying school start times will be appropriate for all school districts.¹² However, the Council on Science and Public Health believes that the benefits of delaying school start times to allow for adequate sleep among adolescents outweigh the potential consequences. The Council believes that physicians, as well as parents and educators, should work together to convey the benefits of increased sleep among teens and support later start times for schools.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted in lieu of Res 404-A-15 and the remainder of the report be filed.

That our American Medical Association:

1. Encourage school districts to aim for the start of middle schools and high schools to be no earlier than 8:30 a.m., in order to allow adolescents time for adequate sleep.
2. Encourage physicians, especially those who work closely with school districts, to become actively involved in the education of parents, school administrators, teachers, and other members of the community to stress the importance of sleep and consequences of sleep deprivation among adolescents, and to encourage school districts to structure school start times to accommodate the biologic sleep needs of adolescents.

3. Reaffirm Policy H-60.930, Insufficient Sleep in Adolescents, identifying adolescent insufficient sleep and sleepiness as a public health issue and supporting education about sleep health as a standard component of care for adolescent patients.
4. Encourage continued research on the impact of sleep on adolescent health and academic performance.

REFERENCES

1. American Academy of Pediatrics. School start times for adolescents. *Pediatrics*. 2014;134(3):642-9.
2. Hirshkowitz M, Whiton K, Albert SM, et al. National Sleep Foundation's sleep time duration recommendations: methodology and results summary. *Sleep Health*. 2015;1(1):40-3.
3. Kann L, Kinchen S, Shanklin SL, et al. Youth Risk Behavior Surveillance – 2013. *MMWR Surveill Summ*. June 13, 2014;63(4):1-47.
4. HealthyPeople 2020. Sleep Health. <http://www.healthypeople.gov/2020/topics-objectives/topic/sleep-health/objectives>. Accessed February 16, 2016.
5. Wahlstrom K. Changing times: Findings from the first longitudinal study of later high school start times. *NASSP Bulletin*. 2002;86(633):3-21.
6. Dexter D, Bijwadia J, Schilling D, Applebaugh G. Sleep, sleepiness and school start times: a preliminary study. *WMJ*. 2003;102(1):44-6.
7. Wahlstrom K. School start time and sleepy teens. *Arch Pediatr Adolesc Med*. 2010;164(7):676-7.
8. Wahlstrom K, Dretzke B, Gordon M, et al. Examining the impact of later high school start times on the health and academic performance of high school students: A multi-site study. 2014. <http://conservancy.umn.edu/handle/11299/162769>. Accessed February 16, 2016.
9. O'Malley EB, O'Malley MB. Chapter 7: School Start Time and Its Impact on Learning and Behavior. In Ivanenko, A ed. *Sleep and psychiatric disorders in children and adolescents*. CRC Press; 2008.
10. National Center for Education Statistics. Schools and Staffing Survey. Average start time for public high schools and percentage distribution of start times in public high schools, by selected school characteristics: 2011–12. https://nces.ed.gov/surveys/sass/tables/sass1112_201381_s1n.asp. Accessed February 16, 2016.
11. Lamberg L. High schools find later start time helps students' health and performance. *JAMA*. 2009;301(21):2200-1.
12. Wahlstrom KL. The prickly politics of school starting times. *Phi Delta Kappan*. 1999;80:344-7.
13. Owens J, Adolescent Sleep Working Group, Committee on Adolescence. Insufficient sleep in adolescents and young adults: an update on causes and consequences. *Pediatrics*. 2014;134(3):e921-32.
14. Crowley SJ, Acebo C, Carskadon MA. Sleep, circadian rhythms, and delayed phase in adolescence. *Sleep Med*. 2007;8(6):602-12.
15. Hagenauer MH, Perryman JI, Lee TM, Carskadon MA. Adolescent changes in the homeostatic and circadian regulation of sleep. *Dev Neurosci*. 2009;31(4):276-84.
16. Kelley P, Lockley SW, Foster RG, Kelley J. Synchronizing education to adolescent biology: 'let teens sleep, start school later'. *Learning, Media and Technology*. 2015;40(2):210-26.
17. Hasler BP, Clark DB. Circadian misalignment, reward-related brain function, and adolescent alcohol involvement. *Alcohol Clin Exp Res*. 2013;37(4):558-65.
18. Leger D, Beck F, Richard JB, Godeau E. Total sleep time severely drops during adolescence. *PLoS One*. 2012;7(10):e45204.
19. Miller L, Dyche J, Andrews C, Lucus T. The impact of additional sleep on test scores at U.S. Navy boot camp. *Sleep*. 2004;27:A164.
20. Knutson KL, Lauderdale DS. Sociodemographic and behavioral predictors of bed time and wake time among US adolescents aged 15 to 17 years. *J Pediatr*. 2009;154(3):426-30.
21. National Sleep Foundation. 2014 Sleep in America Poll. <https://sleepfoundation.org/sites/default/files/2014-NSF-Sleep-in-America-poll-summary-of-findings---FINAL-Updated-3-26-14-.pdf>. Accessed February 16, 2016.
22. Polos PG, Bhat S, Gupta D, et al. The impact of Sleep Time-Related Information and Communication Technology (STRICT) on sleep patterns and daytime functioning in American adolescents. *J Adolesc*. 2015;44:232-44.
23. Madden M, Lenhart A, Duggan M, Cortesi S, Gasser, U. Teens and technology 2013. Pew Research Center. 2013. <http://www.pewinternet.org/2013/03/13/teens-and-technology-2013>. Accessed February 16, 2016.
24. Lenhart A, Ling R, Campbell S, Purcell K. Teens and mobile phones. Pew Research Center. 2010. <http://www.pewinternet.org/2010/04/20/teens-and-mobile-phones>. Accessed February 16, 2016.
25. Bartel KA, Gradisar M, Williamson P. Protective and risk factors for adolescent sleep: A meta-analytic review. *Sleep Med Rev*. 2015;21:72-85.
26. Gamble AL, D'Rozario AL, Bartlett DJ, et al. Adolescent sleep patterns and night-time technology use: results of the Australian Broadcasting Corporation's Big Sleep Survey. *PLoS One*. 2014;9(11):e111700.
27. American Medical Association Council on Science and Public Health. Report 4-A-12. Light Pollution: Adverse Health Effects of Nighttime Lighting. <http://www.ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-science-public-health/reports/2012-reports.page>. Accessed March 24, 2016.
28. Matthews KA, Hall MH, Cousins J, Lee L. Getting a Good Night's Sleep in Adolescence: Do Strategies for Coping With Stress Matter? *Behav Sleep Med*. 2015;15:1-11.

29. Prather AA, Janicki-Deverts D, Hall MH, Cohen S. Behaviorally Assessed Sleep and Susceptibility to the Common Cold. *Sleep*. 2015;38(9):1353-9.

30. Perez-de Heredia F, Garaulet M, Gomez-Martinez S, et al. Self-reported sleep duration, white blood cell counts and cytokine profiles in European adolescents: the HELENA study. *Sleep Med*. 2014;15(10):1251-8.

31. Wheaton AG, Olsen EO, Miller GF, Croft JB. Sleep Duration and Injury-Related Risk Behaviors Among High School Students - United States, 2007-2013. *MMWR Morb Mortal Wkly Rep*. 2016;65(13):337-41.

32. Milewski MD, Skaggs DL, Bishop GA, et al. Chronic lack of sleep is associated with increased sports injuries in adolescent athletes. *J Pediatr Orthop*. 2014;34(2):129-33.

33. Stea TH, Knutson T, Torstveit MK. Association between short time in bed, health-risk behaviors and poor academic achievement among Norwegian adolescents. *Sleep Med*. 2014;15(6):666-71.

34. McKnight-Eily LR, Eaton DK, Lowry R, et al. Relationships between hours of sleep and health-risk behaviors in US adolescent students. *Prev Med*. 2011;53(4):271-3.

35. Suglia SF, Kara S, Robinson WR. Sleep duration and obesity among adolescents transitioning to adulthood: Do results differ by sex? *J Pediatr*. 2014;165(4):750-4.

36. Sivertsen B, Pallesen S, Sand L, Hysing M. Sleep and body mass index in adolescence: results from a large population-based study of Norwegian adolescents aged 16 to 19 years. *BMC Pediatr*. 2014;14(1):204.

37. Meldrum RC, Restivo E. The behavioral and health consequences of sleep deprivation among US high school students: Relative deprivation matters. *Prev Med*. 2014;63:24-8.

38. Lowry R, Eaton DK, Foti K, et al. Association of sleep duration with obesity among US high school students. *J Obes*. 2012;2012:476914.

39. Perkinson-Gloor N, Lemola S, Grob A. Sleep duration, positive attitude toward life, and academic achievement: the role of daytime tiredness, behavioral persistence, and school start times. *J Adolesc*. 2013;36(2):311-8.

40. Wheaton AG, Ferro GA, Croft JB. School Start Times for Middle School and High School Students — United States, 2011–12 School Year. *MMWR Morb Mortal Wkly Rep*. 2015;64(30):809-13.

41. Edwards F. Early to rise? The effect of daily start times on academic performance. *Economics of Education Review*. 2012;31(6):970-83.

42. Kirby M, Maggi S, D'Angiulli A. School Start Times and the Sleep Evaluation of Available Evidence. *Educational Researcher*. 2011;40(2):56-61. □Wake Cycle of Adolescence

43. Start School Later, Inc. Success Stories. <http://www.startschoollater.net/success-stories.html>. Accessed February 16, 2016.

44. Minges KE, Redeker NS. Delayed school start times and adolescent sleep: A systematic review of the experimental evidence. *Sleep Med Rev*. 2015;28:82-91.

45. Wolfson AR, Spaulding NL, Dandrow C, Baroni EM. Middle school start times: the importance of a good night's sleep for young adolescents. *Behav Sleep Med*. 2007;5(3):194-209.

46. Vedaa O, Saxvig I, Wilhelmsen-Langeland A, Bjorvatn B, Pallesen S. School start time, sleepiness and functioning in Norwegian adolescents. *Scandinavian J Educ Res*. 2012;56(1):55-67.

47. Short MA, Gradisar M, Lack LC, et al. A cross-cultural comparison of sleep duration between US And Australian adolescents: the effect of school start time, parent-set bedtimes, and extracurricular load. *Health Educ Behav*. 2013;40(3):323-30.

48. Lufi D, Tzischinsky O, Hadar S. Delaying school starting time by one hour: some effects on attention levels in adolescents. *J Clin Sleep Med*. 2011;7(2):137-43.

49. Paksarian D, Rudolph KE, He JP, Merikangas KR. School Start Time and Adolescent Sleep Patterns: Results From the US National Comorbidity Survey Adult Behavior Health 2005. *J Clin Sleep Med*. 2011;105(7):1351-7.

50. Owens JA, Belon K, Moss P. Impact of delaying school start time on adolescent sleep, mood, and behavior. *Arch Pediatr Adolesc Med*. 2010;164(7):608-14.

51. Boergers J, Gable CJ, Owens JA. Later school start time is associated with improved sleep and daytime functioning in adolescents. *J Dev Behav Pediatr*. 2014;35(1):11-7.

52. Danner F, Phillips B. Adolescent sleep, school start times, and teen motor vehicle crashes. *J Clin Sleep Med*. 2008;4(6):533-5.

53. Start School Later, Inc. Reports and Case Studies: How Have Schools Managed to Delay Bell Times? <http://www.startschoollater.net/case-studies.html>. Accessed February 16, 2016.

54. Vorona RD, Szklo-Coxe M, Wu A, et al. Dissimilar teen crash rates in two neighboring southeastern Virginia cities with different high school start times. *J Clin Sleep Med*. 2011;7(2):145-51.

55. Vorona RD, Szklo-Coxe M, Lamichhane R, et al. Adolescent crash rates and school start times in two central Virginia counties, 2009-2011: a follow-up study to a southeastern Virginia study, 2007-2008. *J Clin Sleep Med*. 2014;10(11):1169-77.

56. Hamiduzzaman S, Phillips B. High school start times and death on the road. *J Clin Sleep Med*. 2014;10(11):1179-80.

57. Eliasson A, Eliasson A, King J, Gould B, Eliasson A. Association of sleep and academic performance. *Sleep Breath*. 2002;6(1):45-8.

58. Perez-Lloret S, Videla AJ, Richaudeau A, et al. A multi-step pathway connecting short sleep duration to daytime somnolence, reduced attention, and poor academic performance: an exploratory cross-sectional study in teenagers. *J Clin Sleep Med*. 2013;9(5):469-73.

59. Ming X, Koransky R, Kang V, et al. Sleep insufficiency, sleep health problems and performance in high school students. *Clin Med Insights Circ Respir Pulm Med*. 2011;5:71-9.

60. Carrell SE, Maghakian T, West JE. A's from Zzzz's? The causal effect of school start time on the academic achievement of adolescents. *American Economic Journal: Economic Policy*. 2011;3(3):62-81.
61. U.S. House of Representatives. Lofgren introduces Zzz's to A's Act to protect student health, well-being, and performance. <https://lofgren.house.gov/news/documentsingle.aspx?DocumentID=397886>. Accessed February 16, 2016.
62. Congress.gov. H.R. 1306: ZZZ's to A's Act. Available at: <https://www.congress.gov/bill/114th-congress/house-bill/1306>. Accessed February 15, 2016.
63. Fuligni AJ, Tsai KM, Krull JL, Gonzales NA. Daily concordance between parent and adolescent sleep habits. *J of Adolesc Health*. 2015;56(2):244-50.
64. Kira G, Maddison R, Hull M, Blunden S, Olds T. Sleep education improves the sleep duration of adolescents: a randomized controlled pilot study. *J Clin Sleep Med*. 2014;10(7):787-92.
65. Wing YK, Chan NY, Man Yu MW, et al. A School-Based Sleep Education Program for Adolescents: A Cluster Randomized Trial. *Pediatrics*. 2015;135(3):e635-e643.
66. Minneapolis Star Tribune. Wayzata schools debate start times. <http://www.startribune.com/wayzata-schools-debate-start-times/330439211/>. Accessed February 16, 2016.
67. Portland Press Herald. Later start times for southern Maine middle and high schools proposed. <http://www.pressherald.com/2016/02/16/later-start-times-for-southern-maine-middle-and-high-schools-proposed/>. Accessed February 16, 2016.
68. Connecticut News Junkie. School Officials Want The State To Take The Lead On Changing School Start Times. http://www.ctnewsjunkie.com/archives/entry/schoolOfficials_want_the_state_to_take_the_lead_on_changing_school_start_time/. Accessed February 16, 2016.
69. Fogg N, Johnson A. Child and Adolescent Sleep Patterns and Early School Start Times: Recognizing the Role of the Pediatric Nurse. *J Pediatr Nurs*. 2015;30(4):628-31.

7. PREVENTING VIOLENT ACTS AGAINST HEALTH CARE PROVIDERS

Reference committee hearing: see report of [Reference Committee D](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

REMAINDER OF REPORT FILED

See Policies H-215.978, H-515.957, H-515.966 and D-515.983

INTRODUCTION

Policy D-515.983, "Preventing Violent Acts Against Health Care Providers," asks in part that our American Medical Association work with other appropriate organizations to study mechanisms to prevent acts of violence against health care providers and improve the safety and security of providers while engaged in caring for patients, and that our AMA widely disseminate the results of this study.

This report updates and expands upon information contained in CSAPH 2-I-10, Violence in the Emergency Department, and Board of Trustees Report 2-I-12, Surveying Violence in the Non-hospital Work Environment. The Council's 2010 report has previously been made available to relevant stakeholders.

METHODS

English language reports were selected from a search of the PubMed and Google Scholar databases using the search terms "prevalence" and "workplace violence," "violence" and "health care worker," "workplace violence" and "health," "workplace violence" and "prevention," and "firearms" and "hospitals." Additional articles were identified by manual review of the references cited in these publications. Further information was gathered from internet sites managed by relevant federal agencies and health care organizations.

BACKGROUND

For more than 15 years, violence has been among the top four causes of death in US workplaces.¹ According to the World Health Organization, health care workers are at high risk of violence worldwide.² Recent media coverage of tragic, violent events in the health care setting has raised awareness and resulted in some added requirements for employers to take in preventing harm and death from workplace violence.^{3,4}

Workplace violence is defined as violent acts (including physical assaults and threats of assaults) directed toward persons at work or on duty.⁵ The spectrum of workplace violence ranges from offensive or threatening language to

homicide.⁵ Examples include threats (verbal or written expressions of intent to cause harm), physical assaults (hitting or muggings), the use of weapons, rape, and homicide.⁵ Based on the perpetrator's profile, four types of workplace violence have been described and applied to data collection and research studies. One is the result of criminal activity, in which the perpetrator has no relationship to the workplace (Type I). Another involves perpetrators who are customers or clients (in this case patients or visitors) who become violent while being served by the worker (Type II). A third category involves perpetrators who are employees or past employees (Type III). When the perpetrator has a personal relationship with an employee, this is defined as type IV violence. The most commonly reported form of violence in health care is the result of a disruptive patient or the patient's family member (Type II).⁶

A number of risk factors place health care workers at risk of workplace violence. These include contact with the public, the delivery of services, working with unstable or volatile persons, working alone or in small numbers, working late at night or during early morning hours, and working in community-based settings.⁷ Workplace violence occurs across a range of health care settings. While much of the focus has been on hospitals and emergency departments, health care workers in residential and home health care settings and treatments centers for those who are aged, cognitively impaired, or mentally ill, also are at risk and could benefit from workplace violence prevention programs.⁸ While a need exists to address workplace violence across a range of health care settings, interventions should be developed based on hazard risk assessments and respond to identified risks.

CURRENT AMA POLICY

The AMA has a number of policies addressing the prevention of violence in the health care workplace (see Appendix A). The AMA condemns acts of violence against physicians involved in the practice of medicine and supports efforts of the International Association for Healthcare Security and Safety, the American Hospital Association, and The Joint Commission to develop guidelines and/or standards regarding hospital security issues. The AMA encourages all health care facilities to adopt policies to reduce and prevent all forms of workplace violence and abuse, and to manage reported occurrences of workplace violence and abuse. The AMA also encourages hospitals to incorporate, within their security policies, specific provisions on the presence of firearms in the hospital setting.

The AMA urges hospital safety committees to include physicians, encourages physicians to work with their hospital safety committees to address security issues and to become familiar with their own institution's policies and procedures. Training courses on workplace violence prevention and reduction should be widely available and states should work to increase criminal penalties for assaults against health care providers.

PREVALENCE OF WORKPLACE VIOLENCE IN THE HEALTH CARE SETTING

Data from the United States Bureau of Labor Statistics (BLS) confirm that violence is an ongoing threat to workers in health care settings. While significant attention has been directed to workplace homicides, the majority of workplace violence incidents are non-fatal.⁹ BLS data show that the majority assaults in the workplace resulting in missed work days occur in health care and social services settings. Between 2011 and 2013, reported workplace assaults ranged from 23,540 to 25,630 annually, 70 to 74% of which occurred in health care and social service settings.⁹ For health care workers, assaults comprise 10-11% of workplace injuries involving days away from work, compared with a 3% rate in all private sector employees.⁹ Preliminary data from the Census of Fatal Occupational Injuries found that overall fatal work injuries due to violence decreased slightly from 2013 to 2014.¹⁰ The number of workplace homicides were similar to the previous year.¹⁰ In 2014, 13 health care professionals were the victims of workplace homicide.¹¹

Recent studies corroborate BLS data on the high levels of violence against health care workers. For example, an anonymous survey of hospital workers (n=11,000) found that the 12-month prevalence of type II violence was 39%.¹² This included 1,180 physical assaults, 2,260 physical threats, and 5,576 incidents of verbal abuse.¹² However, only 19% of these events were captured by official reporting systems.¹² A survey of nurses (n=762) found that over the past year, 76% had experienced violence involving patients or visitors.¹³

High-Risk Practice Areas

Emergency department (ED), mental health, and long-term care providers are among the most frequent victims of patient and visitor attacks. Perpetrator characteristics or circumstances that influence this pattern of violent events include altered mental status, dementia and behavioral issues, pain/medication withdrawal, and dissatisfaction with care.^{12,13}

EDs are high-risk due to their 24-hour accessibility, the presence of a high-stress environment, and the lack of adequate security or trained staff.¹⁴ A nationwide survey of emergency medicine residents and attending physicians (n=263) found that 78% of respondents had reported at least one workplace violence act in the previous year and 21% had reported more than one type of violent act.¹⁵ The most common types of violence reported were verbal threats (75%) and physical assaults (21%).¹⁵ A nationwide survey of nurses found that ED nurses experienced a significantly higher number of incidents than nurses in other practice settings.¹³

Another study of nurses (n=248) in eight acute locked psychiatric units of the Veterans Health Administration (VHA) found that the overall weekly incident rate was 0.60/nurse for verbal aggression and 0.19 for physical aggression.¹⁶ A study of substance use disorder counselors found that more than half of counselors had personally experienced violence, 44% had witnessed violence, and 61% had knowledge of violence directed at a colleague.¹⁶

Hospital-Based Shootings

A 2012 study examining US hospital-based shootings occurring between 2000 and 2011 identified 154 events involving 148 hospitals and affecting 235 victims.¹⁸ Of the 154 events, 91 (59%) occurred inside the hospital building and 63 (41%) occurred outside on hospital grounds.¹¹ Of those occurring inside the hospital, 31 (34%) occurred in the ED and 29 (32%) occurred in patient rooms.¹⁸ The majority of shooters (91%) were men.¹⁸ The most frequent motives were grudge or revenge (27%), suicide (21%), and ending the life of an ill relative (14%).¹⁸ Hospital staff were relatively infrequent victims (physicians 3% and nursing staff 5%).¹⁸

From 2011-2013, 47 gun discharge events were recorded in US hospitals resulting in 39 deaths and 19 injuries.¹⁹ Sixty eight percent of these events occurred at hospitals with a trauma designation; sites with Level I trauma centers (36%) experienced the highest number of events.¹⁹ The majority of events occurred in a nursing unit, with 30% occurring on an inpatient floor or in a patient room and 23% occurring in the ED.¹⁹ Hospital gun discharge events are not random; in most instances (78%) the shooter had a specific intended target.¹⁹

REPORTING

Health care workers experience high rates of workplace violence, but such events are widely underreported. Reasons for not reporting can be as simple as health care workers not knowing what constitutes an act of workplace violence or a reporting process that is too cumbersome and time-consuming.¹⁴ Other reasons for not reporting include a perception that workplace violence is "normal" or a part of the job, fearing the response they may receive when reporting these events (blaming the victim), and lacking support from leadership to encourage reporting.^{14, 20} Steps should be taken to mitigate barriers to reporting. Accurate data are important to help identify patterns of assaults and near misses in order to implement appropriate controls or measures to reduce and/or prevent workplace violence.⁹

REQUIREMENTS TO PREVENT VIOLENCE AGAINST HEALTH CARE WORKERS

Occupational Safety and Health Administration (OSHA)

OSHA falls under the US Department of Labor. This agency was established by Congress in 1970 to assure safe and healthy working conditions by setting standards, providing assistance, outreach, education and training, and enforcement.²¹ OSHA currently does not have specific standards for workplace violence.²² However, the courts have interpreted Section 5(a)(1) of the Occupational Safety and Health Act of 1970 (the General Duty Clause), to mean that:

an employer has a legal obligation to provide a workplace free of conditions or activities that either the employer or industry recognizes as hazardous and that cause, or are likely to cause, death or serious physical harm to employees when there is a feasible method to abate the hazard.²²

Therefore, workplace violence must have taken place or the employer must be aware of threats or other signs that the potential for violence exists, in order to be held accountable under the General Duty Clause.

In April 2015, OSHA released an updated version of *Guidelines for Preventing Workplace Violence for Health Care and Social Service Workers*.⁹ The revised guidelines stress the importance of developing a written workplace violence prevention program. The five components of this prevention program remain largely unchanged from the previous version: management commitment and employee participation, worksite analysis, hazard prevention and control, safety and health training, and recordkeeping and program evaluation.⁹ In December 2015, OSHA released *Preventing Workplace Violence: A Road Map for Health care Facilities* to complement the *Guideline* document by providing examples of workplace violence policies and procedures that have been put into practice by health care facilities.²³

OSHA also has advised its staff that inspections of hospitals and nursing home facilities should include the review of potential hazards from workplace violence and to that end, released policy guidance and procedures for field offices to utilize in responding to incidents of workplace violence.²⁴ OSHA appears to be utilizing the General Duty clause to hold facilities accountable for failing to protect staff from workplace violence. For example, one OSHA inspection documented at least 40 incidents of workplace violence between February 7 and April 12, 2014 at Brookdale University Hospital and Medical Center in Brooklyn, New York.²⁵ OSHA cited Brookdale for one willful violation, with a proposed fine of \$70,000, for failing to develop and implement adequate measures to reduce or eliminate the likelihood of physical violence and assaults against employees by patients or visitors.²⁵

OSHA-Approved State Plans and Hospital Licensing Requirements

Currently, 28 OSHA-approved state plans provide operational oversight for state-wide occupational safety and health programs (see Figure 1).²⁶ State plans are required to have standards and enforcement programs that are considered to be at least as effective as OSHA's, although states can have different or more stringent requirements. Six of the state plans only cover state and local government workers.²⁶ Jurisdictions operating under OSHA-approved state plans have an opportunity to provide stronger protections against workplace violence.

Ten states currently have workplace violence prevention requirements in place for hospitals and other facilities. Many of these requirements were established through state legislation and are not necessarily tied to OSHA-approved state plans. Common themes among these state laws include requirements for a hazard assessment, development of a violence prevention plan, and employee training within 90 days of their start date. Some plans address the need to have a system in place for employees to report incidents and establish requirements for record retention (five years) and the reporting of assaults to authorities within 24 hours (with some exceptions). Some states require the establishment of workplace safety committees, which provides an opportunity for employee input. Figure 2 outlines the workplace violence requirements by state as of August 2015 and includes the health care settings in which they apply.

Subsequently, Minnesota enacted legislation requiring all hospitals to design and implement preparedness and incident response action plans to acts of violence and to submit an annual report to the Commissioner of Health. Hospitals must establish a violence prevention committee that includes health care workers employed by the hospital as well as nonclinical staff.²⁷ The law also requires hospitals to provide training on safety measures during acts of violence to all health care workers who are employed or contracted with the hospital.²⁷ The Minnesota Medical Association, the state department of health, the state nurses association, and the state hospital association formed a coalition to develop a gap analysis to help health care facilities implement best practices in preventing violence against health care providers and hospital staff.²⁸ The coalition also has gathered training resources to educate health care workers about violence prevention.²⁹

Three states are currently considering legislation requiring health care facilities to establish violence prevention plans. In Massachusetts, legislation would require each health care employer to annually perform a risk assessment, develop a written violence prevention plan, provide training to employees, and develop a system for the ongoing reporting and monitoring of incidents and situations involving violence or the risk of violence.³⁰ Each health care employer also would be required to designate a senior manager responsible for the development and support of an in-house crisis response team for employee-victims of workplace violence.³⁰ In New Hampshire, legislation would require hospitals, nursing homes, state or county psychiatric hospitals, and state developmental centers to establish a violence prevention committee.³¹ The committee would develop and maintain a written violence prevention plan and

conduct annual violence risk-assessments.³¹ Facilities would be required to conduct annual violence prevention training, maintain records of all violent acts against employees at work, and establish a post-incident response system that provides in-house crisis response for victims and their co-workers.³¹ Vermont's legislation is specific to social and mental health workers and would require the Agency of Human Services and each of its departments to establish and maintain a written workplace violence prevention and crisis response policy.³² The legislation also requires a system for centrally recording all incidents or credible threats of workplace violence and a training program to educate employees providing direct services to clients.³²

The Joint Commission

In the United States, Joint Commission accreditation and certification is recognized as a symbol of quality that reflects an organization's commitment to meeting certain performance standards.³³ Systems to ensure patient safety have been a concern for a number of years. A number of Joint Commission standards relevant to workplace violence exist in the areas of leadership development, environment of care, emergency management, and human resources.³⁴ (See Appendix B)

In 2010, The Joint Commission published a Sentinel Event Alert on preventing violence in the health care setting. The purpose of the alert was to specifically address assault, rape, or homicide of patients and visitors.³⁵ The alert notes that existing standards require health care facilities to address and maintain a written plan describing how an institution provides for the security of patients, staff and visitors.³⁵ Institutions also are required to conduct risk assessments to determine the potential for violence, provide strategies for preventing instances of violence, and establish a response plan that is enacted when an incident occurs.³⁵

INTERVENTIONS AND THEIR EFFECTIVENESS

The National Institute for Occupational Safety and Health (NIOSH), an agency within the Centers for Disease Control and Prevention, works to develop knowledge in the field of occupational safety and health and translate that knowledge into practice.³⁶ NIOSH conducts research and makes recommendations to prevent work-related illness and injury; some evaluations of existing interventions have been conducted.³⁷

Workplace Violence Prevention Plans

Workplace violence prevention plans based on OSHA's guidance are often viewed as model programs. In fact, most states that require workplace violence prevention plans incorporate major components of the OSHA guidelines. Although workplace violence prevention plans seem like a common sense approach, evaluations of their impact on reducing incidents of violence or harms associated with violence are limited.

An evaluation of Washington State's efforts to reduce workplace violence in the health care industry found that their approach led to lower injury rates and reduced workers' compensation costs.³⁸ From 1997 to 2007, the state's average annual rate of workers' compensation claims, associated with workplace violence in the health care and social assistance industry, was 75 per 10,000 full-time equivalent workers (FTEs).³⁸ From 2007 to 2013, the rate had fallen to 54 claims per 10,000 FTEs--a 28% decrease.⁸ This improvement coincides with Washington's 2009 rule that required hazard assessments, training, and incident tracking for workplace violence.

NIOSH funded a study to evaluate New Jersey's regulations requiring workplace violence prevention programs in health care facilities. In addition to conducting interviews to measure compliance with the regulations and surveying nurses to evaluate the training they receive, the study also will collect and compare facility violent event reports 3 years pre-regulation (2009-2011) and 3 years post-regulation (2012-2014).³⁹ The results of this study are expected to be published in 2016.³⁹

Training in Workplace Violence Prevention

The majority of health care professionals, whether entering the profession or experienced, have not received training in workplace violence prevention strategies.²⁰ A number of stand-alone training courses are available for health care workers to help them prevent and respond to an incident of workplace violence. Courses range from verbal de-escalation training to active shooter scenarios. Studies investigating the impact of such training have had mixed results and contain significant limitations.⁴⁰

NIOSH developed an on line educational course, *Workplace Violence Prevention for Nurses*, that provides the basis for a comprehensive workplace violence prevention program. Focus groups found the content to be appropriate for both novice and senior nurses.²⁰ To date, 17,000 health care professionals have received continuing education credits for completing the course.⁶ A broader evaluation of the course is planned to determine the impact that such a course can have in preventing workplace violence.²⁰ The course content also is applicable to health care workers who are not nurses, but continuing medical education (CME) is not currently available for physicians who might complete the NIOSH training.

Patient Record Flags

The VHA has implemented patient record flags as a means of identifying patients who may pose a threat to themselves, staff, or others.⁴¹ Notations are placed in the patient's electronic health record to serve as an alert to clinical staff. VHA uses two types of flags. Category I flags identify patients at high-risk for violent or disruptive behavior and are shared across all VHA facilities.⁴¹ Events that can trigger a Category I flag include a history of violence towards staff or patients, documented acts of repeated violence, credible verbal threats, the possession of weapons, or the use of objects as weapons.⁴¹ Category II flags identify patients at high risk for other reasons, such as drug-seeking behavior, history of wandering, or spinal cord injuries.⁴¹ Category II flags are local, meaning they are not shared across facilities.⁴¹ Flags also include a narrative that describes the reason for the flag and may include some suggested actions for staff to take when they encounter the patient.⁴¹ VHA facilities have Disruptive Behavior Committees, which make final decisions about flagging patient records. In order for flags to be most effective, they need to be assigned in a timely manner following a triggering incident.

Magnetometers in Hospitals

The use of firearms in hospitals is rare but can make an attack more lethal. Some hospitals have installed magnetometers (metal detectors) at their entrances to prevent individuals from bringing weapons into facilities. Henry Ford Hospital in Detroit confiscated 33 handguns, 1,324 knives, and 97 chemical sprays within the first six months of screening.⁴² Other hospitals, including Johns Hopkins Hospital in Baltimore, have suggested that widespread use of magnetometers is impractical given the many entrances most hospitals have. In addition, armed guards manning magnetometers could be the source of weapons used in hospital-based shootings. The 2012 study on hospital-based shootings determined that less than half (30-36%) of events could have been prevented by the use of a magnetometer.¹⁸ Furthermore, in 23% of shootings examined within the ED, the weapon was a security officer's gun taken by the perpetrator.¹⁸

Strengthening Criminal Penalties

More than 30 states have increased penalties for those who commit acts of violence against health care workers.⁴³ In addition to increasing the penalty, Nebraska law requires every hospital and health clinic to display, in a prominent place, a sign reading, "warning: assaulting a health care professional who is engaged in the performance of his or her official duties is a felony."⁴⁴ Despite widespread adoption of these laws to deter violent acts against health care workers, no evaluation of their effectiveness has been conducted. California Governor Jerry Brown recently vetoed legislation to increase the sentence for such offenses. In his veto message he said "[i]f there were evidence that an additional six months in county jail...would enhance the safety of these workers or serve as a deterrent, I would sign this bill. I doubt that it would do either."⁴⁵

DISCUSSION

While often viewed as a sanctuary from violent events, health care settings can be high-stress, emotional environments, which can contribute to violence. Given that health care workers represent a significant portion of the victims of workplace violence, health care facilities and other clinical settings should take appropriate steps to prevent this known risk. While OSHA has taken steps to address workplace violence, the absence of a federal requirement for employers to implement workplace violence prevention programs has resulted in some states filling the gap by establishing their own requirements, often in response to serious workplace violence incidents.

Workplace violence can result in negative outcomes for health care workers. In addition to physical injuries, it can result in low morale, decreased productivity, increased stress, and turnover.²⁰ Although more research is needed to determine the effectiveness of interventions to prevent workplace violence in health care settings, helpful resources

are available from the Joint Commission, OSHA, NIOSH, and others to guide employers in addressing this issue. Furthermore, health care providers should be proactive in seeking out training, becoming familiar with their organization's policies and procedures, and reporting incidents of workplace violence.

CONCLUSION

Health care workers face a significant risk of workplace violence and more research is needed regarding the effectiveness of interventions to prevent workplace violence in the health care setting. OSHA has taken steps to encourage employers to enact workplace violence prevention plans to protect health care workers from acts of violence. However, given the risk, these actions do not go far enough. A number of states require health care facilities to implement workplace violence prevention plans. A federal standard would help ensure that health care employers across the country are prepared to address workplace violence.

RECOMMENDATIONS

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

That our AMA:

1. Encourage the Occupational Safety and Health Administration to develop and enforce a standard addressing workplace violence prevention in health care and social service industries.
2. Encourage Congress to provide additional funding to the National Institute for Occupational Safety and Health to further evaluate programs and policies to prevent violence against health care workers.
3. Encourage the National Institute for Occupational Safety and Health to adapt the content of their online continuing education course on workplace violence for nurses into a continuing medical education course for physicians.
4. Amend Policy H-515.966, "Violence and Abuse Prevention in the Health care Workplace," by addition and deletion to read as follows:

Our AMA encourages all health care facilities to: adopt policies to reduce and prevent all forms of workplace violence and abuse; develop a reporting tool that is easy for workers to find and complete; and develop policies to assess and manage reported occurrences of workplace violence and abuse; and will advocate that make training courses on workplace violence prevention available to employees and consultants and reduction be more widely available; and include physicians in safety and health committees.

5. Amend Policy H-215.978, "Guns in Hospitals," by addition and deletion and a change in title to better reflect the content of the policy to read as follows:

Workplace Violence Prevention

Our AMA: (1) supports the efforts of the International Association for Healthcare Security and Safety, the AHA, and The Joint Commission to develop guidelines or standards regarding hospital security issues and recognizes these groups' collective expertise in this area. As standards are developed, the AMA will ensure that physicians are advised; (2) encourages physicians to work with their hospital safety committees to address the security issues within particular hospitals; and also encourages physicians to become aware of and familiar with their own institution's policies and procedures; encourages physicians to participate in training to prevent and respond to workplace violence threats; encourages physicians to report all incidents of workplace violence; and encourages physicians to promote a culture of safety within their workplace; and (3) urges that hospital safety committees include physicians and that emergency departments be recognized as high risk environments for violence.

6. Amend Policy D-515.983, "Preventing Violent Acts Against Healthcare Providers," by addition and deletion to read as follows (as it has been implemented in part):

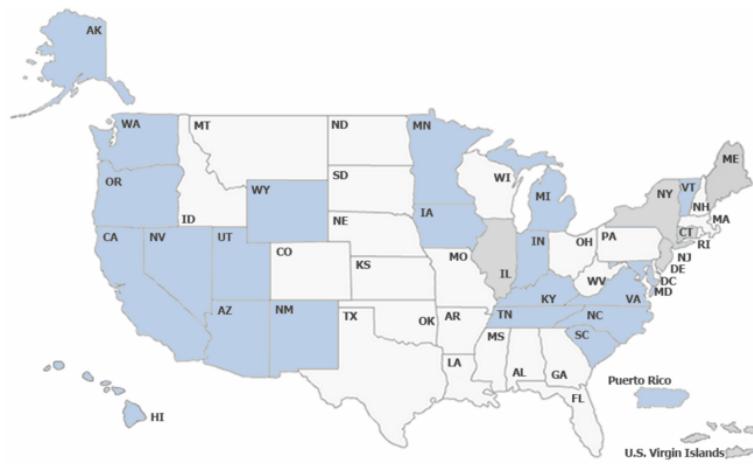
1. Our AMA will make ~~CSAPH Report 2 I-10, Violence in the Emergency Department, available to hospitals, emergency medicine departments, emergency physicians, mental health physicians, patient advocates, and law enforcement organizations as a resource designed to assist in the implementation of procedures to protect students, trainees, physicians, nurses, and other health care staff in the Emergency Department environment and to assure optimal care for patients, including those with psychiatric or behavioral conditions.~~ 2. Our American Medical Association will: (a) continue to work with other appropriate organizations to study mechanisms to prevent acts of violence against health care providers and improve the safety and security of providers while engaged in caring for patients; and (b) widely disseminate information on effective workplace violence prevention interventions in the health care setting as well as opportunities for training the results of this study.

REFERENCES

1. U.S. Department of Labor, Occupational Safety and Health. OSHA Instruction: Enforcement Procedures for Investigating or Inspecting Workplace Violence. September 8, 2011.
2. World Health Organization, Violence and Injury Prevention, Violence Against Health Workers. http://www.who.int/violence_injury_prevention/violence/workplace/en/. Accessed March 7, 2016.
3. Volpe T. Attack on nurses points to growing risk of Minnesota hospital violence. MPRNews, November 17, 2014. <http://www.mprnews.org/story/2014/11/07/maplewood-hospital-attack-points-to-growing-risk-of-hospital-violence>. Accessed March 16, 2017.
4. Rosenbaum L. Being like Mike – Fear, trust, and the tragic death of Michael Davidson. *NEJM* 2015; 372(9): 798-9.
5. Centers for Disease Control and Prevention, National Institute for Occupational Health and Safety. *Violence Occupational Hazards in Hospitals*. April 2002. <http://www.cdc.gov/niosh/docs/2002-101/>. Accessed March 16, 2017.
6. Hartley D. National Institute for Occupational Health and Safety Science Blog. *Violence in Health care*. <http://blogs.cdc.gov/niosh-science-blog/2015/03/27/violence-in-health-care/>. Accessed March 16, 2016. (Updated data provided by the author in 2016).
7. National Institute for Occupational Safety and Health, *Violence in the Workplace, Risk Factors and Prevention Strategies*, Current Intelligence Bulletin 57, July 1996. <http://www.cdc.gov/niosh/docs/96-100/risk.html>. Accessed April 13, 2016.
8. The Joint Commission. *Improving Patient and Worker Safety: Opportunities for Synergy, Collaboration and Innovation*. Oakbrook Terrace, IL. Nov 2012. <http://www.jointcommission.org/assets/1/18/tjc-improvingpatientandworkersafety-monograph.pdf>. Accessed April 13, 2016.
9. U.S. Department of Labor, Occupational Safety and Health Administration. *Guidelines for Preventing Workplace Violence for Health care and Social Service Workers*. 2015.
10. U.S. Department of Labor, Bureau of Labor Statistics. *Census of Fatal Occupational Injuries Summary, 2014*. September 17, 2015. <http://www.bls.gov/news.release/cfoi.nr0.htm>. Accessed March 15, 2016.
11. U.S. Department of Labor, Bureau of Labor Statistics. *Census of Fatal Occupational Injuries Summary, 2014, Table 3: Fatal occupational injuries by occupation and selected event or exposure, 2014*. September 17, 2015. <http://www.bls.gov/news.release/cfoi.t03.htm>. Accessed March 15, 2016.
12. Pompeii LA, Schoenfisch AL, Lipscomb HJ, Dement JM, Smith CD, Upadhyaya M. Physical assault, physical threat, and verbal abuse perpetrated against hospital workers by patients or visitors in six U.S. hospitals. *Am J Ind Med*. 2015;58:1194-1204.
13. Speroni KG, Fitch T, Dawson E, et al. Incidence and cost of nurse workplace violence perpetrated by hospital patients or patient visitors. *J Emerg Nurs*. 2014;40(3): 218-28.
14. Stene J, Larson E, Levy M, et al. Workplace violence in the emergency department: Giving staff the tools and support to report. *The Permanente Journal*. 2015;19(2):e113-116.
15. Behnam M, Tillotson RD, Davis SM, et al. Violence in the emergency department: a national survey of emergency medicine residents and attending physicians. *J Emerg Med*. 2011; 40(5):565-79.
16. Ridenour M, Lanza M, Hendricks S, et al. Incidence and risk factors of workplace violence on psychiatric staff. *Work*. 2015;51(1):19-28.
17. Bride BE, Choi YJ, Olin IW, et al. Patient Violence Towards Counselors in Substance Use Disorder Treatment Programs: Prevalence, Predictors, and Responses. *J Subst Abuse Treat*. 2015;57:9-17.
18. Kelen GD, Catlett CL, Kubit JG, et al. Hospital-based shootings in the United States: 2000-2011. *Ann Emerg Med*. 2012;60(6):790-98.
19. Harnum J. Hospital gun discharge events. *J Health Care Protection Management*. 2014;30(2): 36-46.
20. Hartley D, Ridenour M, Craine J, et al. Workplace violence prevention for nurses on-line course: Program development. *Work*. 2015;51(1):79-89.
21. U.S. Department of Labor, Occupational Safety and Health Administration, *About OSHA*, <https://www.osha.gov/about.html>. Accessed March 15, 2016.
22. U.S. Department of Labor, Occupational Safety and Health Administration, *Enforcement*. <https://www.osha.gov/SLTC/workplaceviolence/standards.html>. Accessed March 15, 2016.

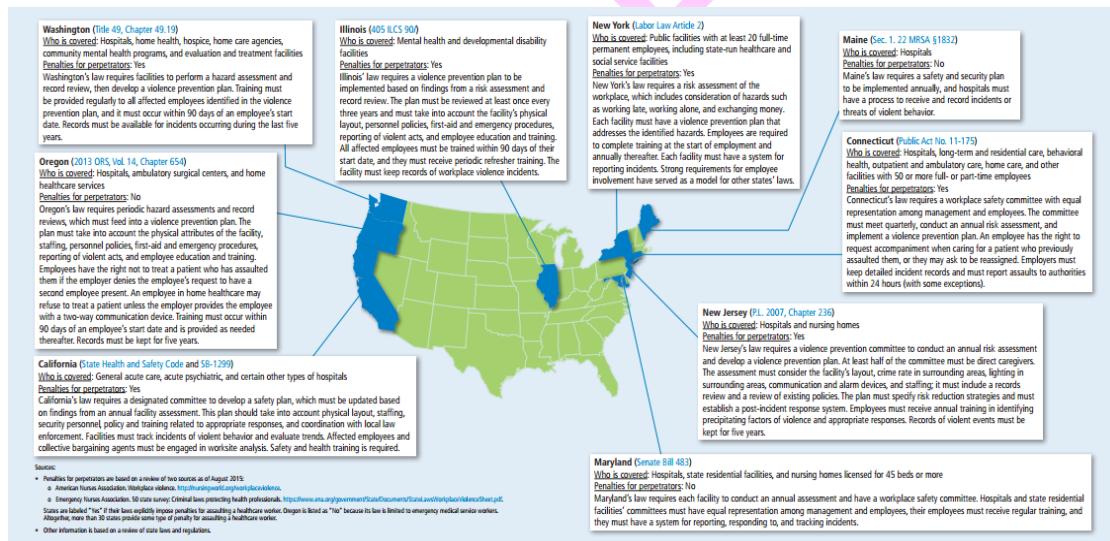
23. U.S. Department of Labor, Occupational Safety and Health Administration, *Preventing Workplace Violence: A Roadmap for Health care Facilities*. December 2015. <https://www.osha.gov/Publications/OSHA3827.pdf>. Accessed March 15, 2016.
24. U.S. Department of Labor, Occupational Safety and Health Administration, *Enforcement Procedures for Investigating or Inspecting Workplace Violence*. September 8, 2011.
25. U.S. Department of Labor, Occupational Safety and Health Administration, *Brooklyn medical facility cited by US Department of Labor's OSHA for inadequate workplace violence safeguards*. August 11, 2014. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=26514. Accessed March 16, 2016.
26. U.S. Department of Labor, Occupational Safety and Health Administration. *Office of State Programs*. <https://www.osha.gov/dcsp/osp/index.html>. Accessed March 16, 2016.
27. Minnesota Department of Health, *Violence Against Health care Workers*. <http://www.health.state.mn.us/patientsafety/preventionofviolence/violencebillfactsheet.pdf>. Accessed March 16, 2016.
28. Minnesota Department of Health, *Preventing Violence in Health care: Gap Analysis*. <http://www.health.state.mn.us/patientsafety/preventionofviolence/preventingviolenceinhealthcaregapanalysis.pdf>. Accessed March 16, 2016.
29. Minnesota Department of Health, *Violence Prevention and Response Training Options*, <http://www.health.state.mn.us/patientsafety/preventionofviolence/violenceprevresptrngoptions.pdf>. Accessed March 16, 2016.
30. MA HB 1687 and SB 1313 (2016).
31. NH SB 516 (2016).
32. VT HB 74 (2016).
33. The Joint Commission, *About the Joint Commission*. http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx. Accessed March 16, 2016.
34. U.S. Department of Labor, Occupational Safety and Health Administration. *Safety and Health Management Systems and Joint Commission Standards: A Comparison*. https://www.osha.gov/dsg/hospitals/documents/2_2_SHMS_JCAHO_comparison_508.pdf. Accessed March 16, 2016.
35. The Joint Commission. Preventing Violence in the Health care Setting. *Sentinel Event Alert*. Issue 45, June 3, 2010. http://www.jointcommission.org/assets/1/18/sea_45.pdf. Accessed March 16, 2016.
36. National Institute for Occupational Safety and Health. *About NIOSH*. <http://www.cdc.gov/niosh/about/default.html>. Accessed March 16, 2016.
37. McPhaul KM, London M, Lipscomb JA. A framework for translating workplace violence intervention research into evidence-based programs. *The Online Journal of Issues in Nursing* 2013;18(1):1-13.
38. Foley M, Rauser E. Evaluating progress in reducing workplace violence: Trends in Washington State workers' compensation claims rates, 1997–2007. *Work*. 2012;42:67–81. (Updated data provided by the authors in 2015.)
39. National Institute for Occupational Safety and Health. *Occupational Violence*. http://www.cdc.gov/niosh/topics/violence/traumaviol_research.html#nji. Accessed March 16, 2016.
40. Nachreiner NM, Gerberich SG, McGovern PM, et al. Impact of training on work-related assault. *Research in Nursing and Health*. 2005;28:67-78.
41. Department of Veterans Affairs, Office of Inspector General. *Health care Inspection: Management of Disruptive Patient Behavior at VA Medical Facilities*. Washington, DC. March 7, 2013.
42. Nelson R. Tackling violence against health-care workers. *The Lancet*. 2014;383:1373-4.
43. Emergency Nurses Association, *50-State Survey: Criminal Laws Protecting Health Professionals*. <https://www.ena.org/government/State/Documents/StateLawsWorkplaceViolenceSheet.pdf>. Accessed March 16, 2015.
44. NE LB 677 (2012).
45. Office of the Governor, Veto Statement on AB 172. October 10, 2015. https://www.gov.ca.gov/docs/AB_172_Veto_Message.pdf. Accessed March 16, 2015.

Figure 1.



** Note: Twenty-six states, Puerto Rico, and the Virgin Islands have OSHA-approved State Plans. Twenty-two State Plans (21 states and one U.S. territory) cover both private and state and local government workplaces. The remaining six State Plans (five states and one U.S. territory) cover state and local government workers only. This map requires javascript to be enabled. A [text version](#) is also available.

Figure 2.



APPENDIX A

H-5.997 Violence Against Medical Facilities and Health care Practitioners and Their Families

The AMA supports the right of access to medical care and opposes (1) violence and all acts of intimidation directed against physicians and other health care providers and their families and (2) violence directed against medical facilities, including abortion clinics and family planning centers, as an infringement of the individual's right of access to the services of such centers.

H-515.966 Violence and Abuse Prevention in the Health care Workplace

Our AMA encourages all health care facilities to adopt policies to reduce and prevent all forms of workplace violence and abuse and to develop policies to manage reported occurrences of workplace violence and abuse and will advocate that training courses on workplace violence prevention and reduction be more widely available.

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.

D-515.983 Preventing Violent Acts Against Health care Providers

1. Our AMA will make CSAPH Report 2-I-10, Violence in the Emergency Department, available to hospitals, emergency medicine departments, emergency physicians, mental health physicians, patient advocates, and law enforcement organizations as a resource designed to assist in the implementation of procedures to protect students, trainees, physicians, nurses, and other health care staff in the Emergency Department environment and to assure optimal care for patients, including those with psychiatric or behavioral conditions. 2. Our American Medical Association will: (a) work with other appropriate organizations to study mechanisms to prevent acts of violence against health care providers and improve the safety and security of providers while engaged in caring for patients; and (b) widely disseminate the results of this study.

H-215.977 Guns in Hospitals

The policy of the AMA is to encourage hospitals to incorporate, within their security policies, specific provisions on the presence of firearms in the hospital. The AMA believes the following points merit attention: (1) Given that security needs stem from local conditions, firearm policies must be developed with the cooperation and collaboration of the medical staff, the hospital security staff, the hospital administration, other hospital staff representatives, legal counsel, and local law enforcement officials. Consultation with outside experts, including state and federal law enforcement agencies, or patient advocates may be warranted. (2) The development of these policies should begin with a careful needs assessment that addresses past issues as well as future needs. (3) Policies should, at minimum, address the following issues: a means of identification for all staff and visitors; restrictions on access to the hospital or units within the hospital, including the means of ingress and egress; changes in the physical layout of the facility that would improve security; the possible use of metal detectors; the use of monitoring equipment such as closed circuit television; the development of an emergency signaling system; signage for the facility regarding the possession of weapons; procedures to be followed when a weapon is discovered; and the means for securing or controlling weapons that may be brought into the facility, particularly those considered contraband but also those carried in by law enforcement personnel. (4) Once policies are developed, training should be provided to all members of the staff, with the level and type of training being related to the perceived risks of various units within the facility. Training to recognize and defuse potentially violent situations should be included. (5) Policies should undergo periodic reassessment and evaluation. (6) Firearm policies should incorporate a clear protocol for situations in which weapons are brought into the hospital.

H-215.978 Guns in Hospitals

Our AMA: (1) supports the efforts of the International Association for Health care Security and Safety, the AHA, and The Joint Commission to develop guidelines or standards regarding hospital security issues and recognizes these groups' collective expertise in this area. As standards are developed, the AMA will ensure that physicians are advised; (2) encourages physicians to work with their hospital safety committees to address the security issues within particular hospitals and also encourages physicians to become aware of and familiar with their own institution's policies and procedures; and (3) urges that hospital safety committees include physicians and that emergency departments be recognized as high risk environments for violence.

APPENDIX B - The Joint Commission Standards Relevant to Workplace Violence

LD.02.03.01	The governing body, senior managers and leaders of the organized medical staff regularly communicate with each other on issues of safety and health.
LD.03.01.01	Leaders create and maintain a culture of safety throughout the hospital.
LD.03.01.01, EP8	All individuals who work in the hospital, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality.
LD.03.03.01	Leaders use hospital-wide planning to establish structures and processes that focus on safety and quality.
LD.04.04.04, EP6	Leaders provide and encourage the use of systems for b lame-free internal reporting of a system or process failure, or the results of a proactive risk assessment.
EC.01.01.01, EP3	The hospital has a written plan for managing...the environmental safety of patients and everyone who enters the hospital's facilities.
EC.02.01.01, EP1	The hospital identifies safety and security risks associated with the environment of care that could affect patients, staff, and other people coming into the hospital's facilities.
EC.02.01.01, EP3	The hospital takes action to minimize or eliminate identified safety and security risks in the physical environment.
EC.03.01.01, EP1	Staff and licensed independent practitioners can describe or demonstrate methods for eliminating and minimizing physical risks in the environment of care.
EC.03.01.01.2	Staff and licensed independent practitioners can describe or demonstrate actions to take in the event of an environment of care accident.
ED.04.01.01, EP1	The hospital establishes a process(es) for continually monitoring, internally reporting, and investigating the following: injuries to patients or others within the hospital's facilities; occupational illnesses and staff injuries; and security incidents involving patients, staff or

	others within its facilities.
EM.01.01.01, EP2	The hospital conducts a hazard vulnerability analysis (HVA) to identify potential emergencies that could affect demand for the hospital's services or its ability to provide those services, the likelihood of those events occurring, and the consequences of those events.
HR.01.04.01, EP2	The hospital orients its staff to the key safety content before staff provides care, treatment, and services.
HR.01.05.03, EP7	Staff participate in education and training that includes information about the need to report unanticipated adverse events and how to report these events.

8. JUVENILE JUSTICE SYSTEM REFORM (RESOLUTION 205-I-14)

Reference committee hearing: see report of [Reference Committee D](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

See Policies H-60.919, H-60.922, H-60.986 and D-430.997

INTRODUCTION

Resolution 205-I-14, introduced by the Minority Affairs Section and referred by the House of Delegates, asked:

That our American Medical Association advocate for the Department of Justice to work towards the elimination of the school to jail pipeline which disproportionately affects African American youth; and that our AMA lobby the US Department of Health and Human Services and the Department of Justice to ensure that youth incarcerated in short-term and long-term correctional facilities receive medical and mental health care consistent with community standards in order to improve their health outcomes; and that our AMA advocate for the Department of Housing and Urban Development to reconsider banning non-violent juvenile offenders from public housing thereby preventing a minor child from returning to their family.

METHODS

English language reports were selected from a search of the PubMed and Google Scholar databases using the search terms “adolescent brain development,” “zero tolerance,” “disproportionate minority contact,” “solitary confinement,” “transfer or waiver” and “adult or criminal court,” “mental health” and “juvenile justice,” “substance abuse” and “juvenile justice,” “community-based alternatives,” “reentry and aftercare” and “juveniles,” and “health” and “juvenile justice.” Additional articles were identified by manual review of the references cited in these publications. Further information was gathered from Internet sites managed by relevant federal agencies, foundations including the Annie E. Casey Foundation and the MacArthur Foundation, and other national, non-profit organizations involved in juvenile justice reform.

CURRENT AMA POLICY

The AMA has numerous policies related to the juvenile justice system, with most addressing the health of juveniles within the system (see Appendix). AMA policy encourages state and county medical societies to become involved in the provision of adolescent health care within detention and correctional facilities. Policy also discourages the detention and incarceration of youth for reasons related to mental illness, the detention and incarceration of children and youth in adult jails, and the use of experimental therapies (not supported by scientific evidence) to alter behavior. Specific policies also address preventing assault and rape by custodial staff, nutrition and dietary guidelines, tobacco use, the prevention and control of HIV and tuberculosis, and sexually transmitted infections among incarcerated populations. AMA policy also addresses the use of restraints on pregnant women and encourages correctional facilities to offer training in parenting skills to all female inmates with children in preparation for their release and return home.

AMA policy 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 health treatment programs. AMA policy calls

for correctional and detention facilities to provide medical, psychiatric, and substance misuse care that meets prevailing community standards, including appropriate referrals for ongoing care upon release from the correctional facility in order to prevent recidivism. The AMA supports the accreditation standards promulgated by the National Commission on Correctional Health Care (NCCCHC) and encourages all correctional systems to seek NCCCHC accreditation. The AMA also opposes the use of solitary confinement except in extraordinary circumstances.

Policy D-430.994, "Health Care While Incarcerated," directs the AMA to study mental health and health care for incarcerated juvenile and adult individuals and identify the best mental health and health care models for local, state and federal facilities. The Council on Medical Service is preparing a report for I-16 to implement this directive.

BACKGROUND

Prior to the early 19th century, children as young as 7 could be tried in criminal court in the United States and, if convicted, sentenced to prison or even to death.¹ The Progressive Era (1890s–1920s) brought an increased focus on reforming young offenders. Treating children and adolescents as adult criminals was viewed as negatively impacting young offenders and reducing the likelihood that they would be reformed.¹ This sentiment led to the development of separate juvenile courts, the first of which opened in Chicago in 1899. Juvenile courts differ from adult courts in that the proceedings are civil rather than criminal, thereby allowing juvenile courts to focus on rehabilitation. By 1925, a functioning juvenile court existed in every state except Maine and Wyoming.² By 1945, all states had juvenile courts.

The juvenile justice process varies greatly by jurisdiction, but the general stages of delinquency case processing are outlined in the case flow diagram (Figure 1).³ Because the focus of the juvenile system originally was not on punishment, constitutional rights and due process procedures afforded in adult criminal proceedings were not extended to youth. This changed in the 1960s when a series of US Supreme Court decisions introduced formal due process protections into the juvenile system making it (for better or worse) more like criminal courts.⁴ In the late 1980s and early 1990s, increases in violent crime by juveniles led to criticism that the juvenile system was too lenient.⁴ In response, a number of state-level reforms were enacted including mandatory sentencing requirements and the automatic transfer of youth to adult criminal courts under certain circumstances. Rather than rehabilitation, the purpose of juvenile proceedings became more about holding juvenile offenders accountable, deterring crime, protecting the public, and making sure the punishment was consistent with the seriousness of the crime.⁴

By 1995, the number of youth in confinement peaked at more than 107,000.⁵ While that number has decreased, the United States still leads the industrialized world in youth confinement rates.⁵ In most states, a juvenile is defined as a youth when they are at or below the upper age of original juvenile court jurisdiction. For the large majority of states, that age is 17, although in some states the upper age is only 15 or 16 years old.⁶ Some jurisdictions have suggested increasing the age of original juvenile court jurisdiction to 20.⁷

Today, 40% of juvenile detentions and confinements are due to technical violations of probation, drug possession, low-level property offenses, public order offenses, and status offenses or actions prohibited to minors.⁵ African-American youth are nearly 5 times more likely to be confined as their white peers.⁵ Latino and American Indian youth are between 2 and 3 times more likely to be confined.⁵ These disparities in confinement rates reflect a system that treats youth of color, particularly African Americans and Latinos, more punitively.

As tragic cases of justice-involved youth garner national attention, a growing consensus exists on the need to reform the juvenile justice system.^{8,9} Research has improved our understanding of adolescent brain development as well as the impact of trauma on adolescent behavior and overall health, but the law has been slow to apply these scientific findings to the juvenile justice system. Youth advocacy groups, foundations, and professional organizations have been advocating for a return to a juvenile system that focuses on rehabilitating justice-involved youth, providing young offenders with comprehensive and quality care, reducing confinement, and effectively addressing disparities throughout the process.

ADOLESCENT BRAIN DEVELOPMENT

Adolescence* is a distinct period of development between childhood and adulthood characterized by increased risk taking, heightened sensitivity to peers, the formation of personal identity, and a reduced ability (compared with adults) to make judgments requiring future orientation.¹⁰ Magnetic resonance imaging studies strongly suggest that these behavioral findings are associated with biological immaturity of the brain. The frontal lobe undergoes substantial modification between early adolescence and young adulthood.¹¹ The prefrontal cortex, which governs advanced functions such as integrating information from the senses, reasoning, and other “executive” functions, is the last area of the brain to mature.¹² Research indicates that, for most youth, the period of risky experimentation does not extend beyond adolescence and young adulthood, ceasing as identity becomes settled with maturity.¹⁰ The application of these scientific findings has gradually resulted in changes in the juvenile justice system.

United States Supreme Court Decisions Related to Adolescent Differences

In 2005, the Supreme Court ruled in the landmark decision of *Roper v. Simmons* that the Eighth Amendment’s prohibition against cruel and unusual punishments forbids the imposition of the death penalty on offenders who were under the age of 18 when their crimes were committed.¹³ Justice Kennedy, writing for the majority, cited the “lack of maturity and underdeveloped sense of responsibility” of youth as well as their susceptibility “to negative influences and outside pressures” and personality traits that are more transitory.¹³ In 2010, in the case of *Graham v. Florida*, the Court held that the Eighth Amendment’s cruel and unusual punishment clause does not permit a juvenile offender to be sentenced to life in prison without parole for a non-homicide crime.¹⁴ In 2012, the Court held that the Eighth Amendment forbids a sentencing scheme that mandates life in prison without the possibility of parole for juvenile homicide offenders.¹⁵ In 2016, the Court ruled in *Montgomery v. Louisiana* that the ban on mandatory life-without-parole sentences for juvenile offenders applied retroactively.¹⁶

The AMA submitted amicus briefs in the cases of *Roper v. Simmons*, *Miller v. Alabama*, and *Graham v. Florida* arguing that the science confirms adolescent offenders exhibit insufficiencies warranting their exclusion from the harshest punishments.¹⁷

Scientists have found that adolescents as a group, even at later stages of adolescence, are more likely than adults to engage in risky, impulsive, and sensation-seeking behavior. This is, in part, because they overvalue short-term benefits and rewards, and are less capable of controlling their impulses making them susceptible to acting in a reflexive rather than a planned voluntary manner. Adolescents are also more emotionally volatile and susceptible to stress and peer influences. In short, the average adolescent cannot be expected to act with the same control or foresight as a mature adult.¹⁸

SCHOOL-TO-JAIL PIPELINE

The school-to-jail pipeline refers to the growing pattern of removing students from educational institutions, primarily via zero tolerance policies, and directly or indirectly into the juvenile or adult criminal justice systems.¹⁹ Schools punish inappropriate behavior both to deter the behavior and to promote safe school environments. Over the past 25 years school discipline has become much more formal with schools adopting zero tolerance policies, involving law enforcement personnel, and mandating the removal of students from school under specific circumstances.²⁰

Zero Tolerance Policies

Zero tolerance policies represent an administrative response to weapons, drugs, and violent acts by students, which resulted in mandated, predetermined consequences such as suspension or expulsion.²¹ The Gun-Free Schools Act of 1994 helped give rise to the zero tolerance approach by requiring that states, in order to qualify for federal funding, have a law in place mandating the expulsion of students for at least one year for bringing a weapon to school.²⁰ Some states and local jurisdictions have extended zero tolerance policies to cover a wider range of student

* Defined age ranges for adolescence vary by source, but generally include those aged 10 to 18 years of age. Some sources, including the American Academy of Pediatrics, extend the upper age to 21. Adolescence is followed by early or young adulthood, which is typically defined to end at age 24.

misconduct.²¹ By 1997, approximately 79% of schools had adopted zero tolerance policies for violence.²⁰ Between 1997 and 2007, the number of US high schools with armed security guards tripled.²⁰

Student discipline now goes beyond the school administrative process with increasing referral to the juvenile justice or criminal justice system.²² The lack of discretion by school administrators in determining punishments or penalties under zero tolerance policies precludes consideration of intent or extenuating and mitigating circumstances.²² The result has been the suspension and expulsion of youth for relatively minor, non-violent offenses.²³ These forms of zero tolerance discipline exclude students from the classroom and academic opportunity.²⁴ A health impact assessment on school discipline policies found that exclusionary discipline, such as zero tolerance policies, led to negative health outcomes via declining educational attainment, a lack of social cohesion, direct mental health impacts, increased violence and drug use, and recurring discipline events and incarceration.²⁵

Zero tolerance policies result in the disproportionate exclusion of minority students from the classroom.²⁴ Although African American students represent approximately 15% of the general student population in the United States, they account for nearly 40% of all discipline referrals in the public school system.²⁶ Researchers have noted that zero tolerance policies have a history of discriminating against black males, resulting in their suspension and incarceration at alarming rates.²⁷ In May 2015, the President's Task Force on 21st Century Policing called on education and criminal justice agencies to work collaboratively to reform policies that collectively have pushed youth into the juvenile justice system.²⁸

CHARACTERISTICS OF JUSTICE-INVOLVED YOUTH

Some youth become involved with the juvenile justice system because they are accused of committing a delinquent or criminal act. Others come into contact with the system for status offenses, which are defined as “actions that are illegal only because of a youth’s age—such as truancy, underage drinking, and running away from home.”²⁹ In 2010, law enforcement agencies in the United States arrested 1.6 million persons under the age of 18.³⁰ Approximately two-thirds of all arrested youth were referred to a court with juvenile jurisdiction.³⁰ Juvenile courts formally process more than 1 million delinquency and status offense cases annually.³⁰

Disproportionate Minority Contact (DMC)

DMC occurs when the proportion of “disadvantaged ethnic minority youth at any given stage of the juvenile justice process exceeds the proportion of their respective group in the general population and exceeds white youth at the same stage in the juvenile justice process.”³¹ DMC may occur at any decision point in the system—arrest, referral to juvenile court, diversion, secure detention, petition (charges filed), delinquent findings, probation placement, secure confinement, and transfer to adult court.³² African American, Hispanic/Latino, Native American, Southeast Asian American and Pacific Islander youth are represented disproportionately at every stage of the juvenile justice system.³¹ In 2010, African American youth constituted 16% of the juvenile population but 33% of the delinquency caseload.³⁰ Even when referred for the same offenses, African American youth are more likely than white youth to be formally charged, sentenced to residential facilities, and waived to adult courts.³¹

In 1988, Congress added a requirement to the Juvenile Justice and Delinquency Prevention Act (JJDPA) requiring states that received funding to ascertain the proportion of minority youth in confinement compared with the general population and to implement plans to address disproportionate minority confinement.³³ When the JDDPA was reauthorized in 1992, Congress raised the status of disproportionate minority confinement making it a core requirement for states to address to receive grant funding.³⁴ In 2002, Congress broadened the focus further by requiring states to focus on “contact” rather than just “confinement.”³⁵

Despite these and other efforts to address disparities, DMC remains a problem for the juvenile justice system.¹⁰ Little objective evidence exists regarding the effectiveness of interventions in reducing DMC. However, efforts by the Annie E. Casey Foundation’s Juvenile Detention Alternatives Initiative (JDAI), the W. Haywood Burns Institute, and the MacArthur Foundation’s Models for Change initiative have shown some promise.¹⁰

Behavioral Health Disorders

Fifty to seventy percent of youth in the juvenile justice system meet the diagnostic criteria for a mental health disorder, and 60% meet the criteria for a substance use disorder.^{36,37} Among youth with co-morbid mental health and

substance use disorders, nearly one-third experience severe impairment compromising their ability to function.³⁶ Many youth who get into trouble with the law have problems with substance use, and their offenses are tied to their involvement with drugs or alcohol.³⁸ However, the services typically available to youth in the juvenile justice system to address mental health and substance use disorders are often inadequate or simply unavailable.³⁹

The MacArthur Foundation's Models for Change initiative has been working to better respond to the needs of such youth through early identification of mental health needs, diversion from the system where appropriate, and timely access to treatment.⁴⁰ Today, standardized mental health screening protocols have been widely adopted in the juvenile justice system. While a number of screening tools exist, the most widely adopted tool is the Massachusetts Youth Screening Instrument, Second Version (MAYSI-2).⁴¹ MAYSI-2 is a 52-question self-report instrument that helps identify existing mental health and substance abuse problems among youth.⁴¹ A number of screening tools are also available to identify substance use disorders specifically. One that is widely used, the SASSI-A2, is designed to identify individuals who have a high probability of having a substance use disorder, including substance dependence.⁴² The SASSI-A2 incorporates both obvious and subtle items that have no apparent relationship to substance use, in order to identify individuals who are unwilling or unable to acknowledge substance misuse or symptoms associated with it.⁴²

Formal diagnostic assessments should be conducted by clinicians for youth with positive screening results. Assessments can verify the presence or absence of mental health needs, help inform psychiatric diagnoses and treatment, and assist with developing recommendations for longer range interventions including initiation of medical treatment and counseling as needed.⁴³ Most youth with mental health needs would be better served in community-based settings that offer opportunities for family engagement and provide access to evidence-based treatments.⁴⁴ The youth for whom diversion to community settings is deemed inappropriate deserve access to effective treatment within the juvenile justice system.⁴⁴

Trauma Histories and Traumatic Stress

Child traumatic stress occurs when children and adolescents are exposed to traumatic events or situations where this exposure overwhelms their ability to cope with what they have experienced.⁴⁵ Exposure to trauma (physical abuse or assault, sexual abuse or assault, victimization by sex trafficking, emotional abuse, neglect, domestic violence, traumatic loss, community violence, school violence, disasters, etc.) is common among detained youth.⁴⁶ Up to 90% of justice-involved youth report exposure to some type of traumatic event.⁴⁵ The Northwestern Juvenile Project, a prospective longitudinal study of youth detained at the Cook County Juvenile Temporary Detention Center in Chicago, IL, documented the prevalence of trauma and post-traumatic stress disorder among juvenile detainees. In the study sample, 92.5% of youth had experienced at least one trauma, 84 % had experienced more than one, and 56.8% were exposed to trauma six or more times.⁴⁷ These exposure levels may not be generalizable to other settings.

Youth exposed to traumatic events exhibit a wide range of symptoms such as depression or anxiety, aggression, conduct problems, and oppositional or defiant behavior.⁴⁸ It is possible that traumatic stress symptoms worsen as a result of juvenile justice system involvement. Accordingly, juvenile justice system staff who have direct and consistent contact with justice-involved youth should be trained to understand trauma and post-traumatic reactions to facilitate a better understanding and anticipation of problems that may arise.⁴⁵

Girls

Girls make up the fastest growing segment of the juvenile justice system population.²⁹ Many girls experience violence, trauma, poverty, and racial, ethnic and gender bias that can lead to their involvement in the juvenile justice system.⁴⁹ Girls in the juvenile justice system have disproportionately been victims of sexual violence.⁵⁰ The rate of sexual abuse for girls entering the juvenile justice system is 4 times higher than that of boys, and girls' rate of complex trauma (five or more adverse childhood experiences) is nearly twice as high as the rate for boys.⁵¹ The involvement of girls in the juvenile justice system has been referred to as the "sexual abuse to prison pipeline."⁵⁰

Girls are far more likely than boys to be detained for non-serious offenses such as status violations.⁴⁹ The violations for which girls are most often arrested – running away, substance abuse, and truancy – are warning signs of abuse.⁵⁰ For many adolescent girls, links appear to exist among the experience of abuse and neglect, the lack of appropriate treatment, and the behaviors that led to arrest.⁵² Among those who are exposed to trauma, girls are more likely than boys to develop mental health problems.⁵² The Northwestern Juvenile Project found that almost three-quarters of

detained girls had one or more mental health disorders, 57% met the diagnostic criteria for two or more disorders, and 47% had a substance use disorder.⁵³

Because of their high incidence of victimization, detained and incarcerated girls are also at high risk for sexually transmitted infections and pregnancy. However, the juvenile justice system may fail to address trauma and sexual abuse, as well as medical needs including access to gynecological and obstetric care.⁵⁰ Detained, pregnant juveniles have reported shackling, frequent hunger, lack of access to prenatal vitamins and prenatal or parenting classes, improperly fitted uniforms, and miscarriages.⁵⁴ For an incarcerated mother, being separated from her child is extremely difficult and has implications for the child's well-being and development.⁵⁵

As a group, girls involved in the juvenile justice system have a critical need for services, but they generally do not pose a significant threat to public safety.⁵⁶ Not only does the juvenile justice system typically fail to address trauma and abuse but exacerbation may also occur, re-traumatizing youth who have experienced abuse and reducing opportunities for positive development.⁵⁰ Helping girls heal from trauma and abuse and ensuring that they receive appropriate medical care are critically important, but many juvenile justice agencies were designed around the male population and lack the capacity to assist girls in their recovery.

Lesbian, Gay, Bisexual, Transgender, Questioning, and Intersex (LGBTQI)

LGBTQI youth also often experience systemic disparities of care in the juvenile justice system. It is estimated that LGBT youth account for 5 to 7% of the nation's overall population, but comprise 13 to 15% of those currently in the juvenile justice system.⁵⁷ Gay and transgender youth entering the juvenile justice system are twice as likely to have experienced family conflict, child abuse, and homelessness as other youth.⁵⁷ Despite the disproportionately high rates of gay and transgender youth entry, the juvenile justice system is not equipped to manage the challenges that these young people face.⁵⁷ The Annie E. Casey Foundation has developed a practice guide to help juvenile justice facilities meet their obligations to ensure the safety and well-being of LGBT youth involved in the juvenile justice system.⁵⁸

PROSECUTION OF YOUTH IN ADULT COURTS

While the goal of the juvenile system is treatment and rehabilitation, some youth are less amenable to these goals.³ Relevant factors in determining responsiveness to rehabilitation include but are not limited to age, prior record, and seriousness of the offense committed. In order to address these cases, a transfer process was established whereby the juvenile system grants jurisdiction over the youth's case to the adult criminal system.⁵⁹ Several types of transfer mechanisms exist. Judicial waiver authorizes a judge to use his or her discretion to waive juvenile court jurisdiction and send the case to adult criminal court. Prosecutorial discretion allows the prosecutor to determine where to file the charges. Statutory exclusion laws require cases involving specified offenses to be filed in criminal court.

In the 1980s and early 1990s, many states amended their laws to decrease the age and/or expand the types of offenses for which juveniles may be sent to criminal court.⁶⁰ Previously, waiver was primarily at the discretion of the judge, but increasingly that power shifted to the prosecutor or became automatic due to statutory requirements.⁶¹ Predictably, more youths were convicted in criminal courts and incarcerated in adult correctional facilities.⁶²

Transfer policies disproportionately impact older males and youth of color who have substantial needs for mental health and substance use disorder services.⁶¹ Transferred juveniles experience high rates of pretrial detention. They are often detained or incarcerated in adult facilities placing them at high risk for assault and abuse. Youth detained in adult facilities are also typically detained for longer periods of time than those detained in juvenile facilities. Transfer policies have no proven deterrent effect and cause sharp increases in recidivism.⁶²

Based on a systematic review of the literature, the Community Preventive Services Task Force recommended against policies facilitating the transfer of juveniles from juvenile to adult criminal justice systems for the purpose of reducing violence.⁶³ This recommendation is based on strong evidence that these laws and policies are associated with increased subsequent violent behavior among transferred youth.⁶³ Evidence is insufficient to determine whether juveniles in the general population are deterred from violent crime by strengthened juvenile transfer policies.⁶³ Current AMA policy does not address transfer or waiver to adult criminal court, but discourages the detention and incarceration of children and youth in adult jails.

CONDITIONS WITHIN JUVENILE FACILITIES AND STANDARDS

Youth may be held in detention centers while awaiting trial or inside correctional facilities to serve their sentence. Detaining or confining youth widens the gulf between the youth and positive influences such as family and school, and places them in an environment where their only peer group is other anti-social youth.⁶⁴ Incarceration in secure settings is associated with short-term declines in temperance and responsibility.⁶⁴ The amount of time incarcerated in residential treatment facilities has a negative effect on the developmental trajectory of psychosocial maturity.⁶⁴ Research on traditional confinement in large centers has also found high recidivism rates.⁶⁵

A substantial body of law establishes the rights of detained and incarcerated youth and protects them from dangerous conditions.⁶⁶ However, a report commissioned by the Department of Justice (DOJ) Office of Juvenile Justice and Delinquency Prevention (OJJDP) found several substantial problem areas for juvenile facilities including living space, health care, security, and control of suicidal behavior.⁶⁷ Specific to suicide, the report found that only 25% of confined juveniles were in facilities that conformed to suicide prevention assessment criteria.⁶⁷ This finding was corroborated by a national survey of juvenile suicide in confinement, which found that nearly 80% of suicides occurred in facilities that did not have all the components of a comprehensive suicide prevention program in place.⁶⁸ These components include a written policy, intake screening, training, CPR certification, observation, safe housing, and mortality review.⁶⁸ The OJJDP report also noted troubling indicators in the areas of educational and treatment services and the use of room confinement and restraints.⁶⁷

The Department of Justice Civil Rights of Institutionalized Persons Act (CRIPA) aims to eliminate unlawful conditions of confinement for detained and incarcerated youth.⁶⁷ CRIPA authorizes the DOJ to bring actions against state or local governments to remedy systemic problems that violate the civil rights of persons institutionalized in publicly operated facilities.⁶⁷ While liability is one way to deter dangerous conditions, a number of organizations have also established standards to provide guidance to facility administrators regarding expected approaches.

General Standards

The Council of Juvenile Correctional Administrators launched Performance-based Standards (PbS) in 1995. PbS is a program for juvenile justice agencies, facilities and residential care providers to identify, monitor and improve conditions and services provided to youth by applying national standards and outcome measures.⁶⁹ In addition to developing a set of goals and standards, PbS collects data through semi-annual self-assessments; the data are used to develop reports identifying areas in need of improvement.⁷⁰ As of 2011, 198 facilities across 27 states were utilizing PbS.⁷⁰

The Annie E. Casey Foundation's JDAI emphasizes the importance of maintaining safe and humane conditions in juvenile detention facilities. Beginning in 2004, officials at participating JDAI sites began assessing and monitoring the conditions in their facilities based on the JDAI standards.⁷¹ The standards were based on case law, consent decrees, federal statutes, model state laws, professional standards, best practices, and expert opinion.⁷¹ The Foundation revised its standards in June 2014 to recognize significant changes in legal and professional practices, including the issuance of the Prison Rape Elimination Act regulations for juvenile facilities.⁷¹

Health Standards

The NCCHC, a national non-profit organization that sets standards for health services in correctional facilities, grew out of a program started by the AMA in the 1970s.⁷² In addition to the AMA, a number of medical specialties, law enforcement, corrections, and public health organizations are represented on the NCCHC's board of directors.⁷³ NCCHC's nationally recognized standards lay the foundation for constitutionally acceptable health service systems and serve as the basis for voluntary accreditation. The 2015 edition of the *Standards for Health Services in Juvenile Detention and Confinement Facilities* addresses nine general areas: governance and administration, safety, personnel and training, health care services and support, patient care and treatment, health promotion, special needs and services, health records and medical-legal issues.⁷⁴

SOLITARY CONFINEMENT

Solitary confinement, defined as the confinement of a prisoner alone in a cell for all, or nearly all, of the day with minimal environmental stimulation and minimal opportunity for social interaction, can cause severe psychiatric

harm.⁶⁵ The potential psychiatric consequences of prolonged solitary confinement include depression, anxiety, and psychosis.⁶⁵ Juvenile offenders are at particular risk for such adverse reactions.⁷⁵ Furthermore, the majority of suicides in juvenile correctional facilities occur when the individual is isolated or in solitary confinement.⁶⁸

Solitary confinement continues to gain national attention. In 2012, the American Academy of Child and Adolescent Psychiatry adopted policy “oppos[ing] the use of solitary confinement in correctional facilities for juveniles.”⁷⁶ AMA policy adopted in 2014 opposes the “use of solitary confinement in juvenile correction facilities except for extraordinary circumstances when a juvenile is at acute risk of harm to self or others” and opposes the “use of solitary confinement of juveniles for disciplinary purposes in correctional facilities.” The Annie E. Casey Foundation’s JDAI passed solitary confinement standards in June 2014. The standards set a clear limit on isolation in juvenile detention facilities.⁷⁷ The revised JDAI Detention Facility Standards prohibit the use of room confinement for discipline, punishment, administrative convenience, retaliation, staffing shortages, or reasons other than as a temporary response to behavior that threatens immediate harm to a youth or others.⁷⁷ The Council of Juvenile Correctional Administrators has developed a toolkit, which includes steps that can be taken to reduce the use of isolation.⁷⁸

In 2015, President Obama announced that Attorney General Loretta Lynch was conducting a review of “the overuse of solitary confinement across American prisons” in part to develop strategies for reducing the use of this practice throughout our nation’s criminal justice system.⁷⁹ The DOJ released its report in January 2016, including recommendations for banning solitary confinement for juveniles and in response to low-level infractions, expanding treatment for the mentally ill, and increasing the amount of time inmates in solitary confinement can spend outside of their cells.⁷⁹ President Obama adopted the DOJ’s recommendations for reform of the federal prison system with the expectation that the reforms will serve as a model for state and local corrections.⁸⁰

COMMUNITY-BASED ALTERNATIVES

Community-based and home-based programs are designed to protect public safety while avoiding the harmful outcomes associated with incarceration by allowing youth to receive in-home or out-of-home services in their community. Many juvenile justice systems use risk assessment tools to identify youth who are at the highest risk to reoffend and make placement decisions accordingly.⁸¹

According to the OJJDP:

Community-based programs are cost-effective solutions for a large number of delinquent youth. These alternatives to secure detention and confinement are intended to reduce crowding, cut the costs of operating juvenile detention centers, shield offenders from the stigma of institutionalization, help offenders avoid associating with youth who have more serious delinquent histories, and maintain positive ties between the juvenile and his or her family and community.⁸²

Blueprints for Healthy Youth Development, within the Center for the Study and Prevention of Violence at the University of Colorado at Boulder, identifies evidence-based prevention and intervention programs that are effective in reducing anti-social behavior and promoting a healthy course of youth development.⁸³ The most commonly recognized, evidence-based approaches include the following:

Multisystemic Therapy (MST): This approach is an intensive family- and community-based treatment that addresses environmental systems (homes, families, schools, neighborhoods, and friends) that impact chronic and violent juvenile offenders.⁸⁴ The MST therapist meets with the family and other people in the youth’s life regularly and is on call 24 hours a day, seven days a week.⁸⁴

Family Functional Therapy (FFT): This approach is a short-term, family-based therapeutic intervention for delinquent youth at risk for institutionalization and their families.⁸⁵ FFT is designed to improve family communication and supportiveness while decreasing intense negativity and dysfunctional patterns of behavior.⁸⁵ Parenting skills, youth compliance, and cognitive, emotional, and behavioral domains are targeted for change based on the specific needs of each family.⁸⁵

Treatment Foster Care Oregon (TFCO): In this program, community families are recruited, trained, and closely supervised to provide youth with treatment and intensive supervision at home, in school, and in the community.⁸⁶

TFCO utilizes a behavior modification program based on a three-level point system by which the youth are provided with structured daily feedback.⁸⁶ As youth accumulate points, they are given more freedom from adult supervision. Individual and family therapy is provided, and case managers closely supervise and support the youth and their foster families through daily phone calls and weekly foster parent group meetings.⁸⁶

REENTRY AND AFTERCARE

Each year approximately 100,000 youth exit the juvenile justice system.⁸⁷ Reentry is the process of preparing and planning for youth who have been in out-of-home placements to transition back into their communities.⁸⁸ The planning process should begin at intake and continue after release. Aftercare refers to the post-release services, supervision, and supports that help youth reintegrate safely and successfully into the community and help prevent recidivism.⁸⁸ In some jurisdictions, more than half of released youth reoffend.⁸⁷ However, providing them with strong family and community support systems can decrease the likelihood of risky behavior and increase their ability to make good decisions.⁸⁹

Reentry and aftercare services should concentrate on the needs of each individual. In addition to reconnecting with family or guardians, focus areas should include ensuring school reenrollment, access to health care including treatment for mental health and substance use disorders, health insurance, structured workforce preparation, housing support, and intensive case management.⁹⁰ Although a number of reentry and aftercare programs exist, evidence of their effectiveness is sparse; while some have promising results, the sample sizes are often small and/or lack comparison with a control group.^{91,92}

Education and Training

Juvenile adjudications can hinder the ability of youth to reintegrate in their community. Education and employment are both strong predictors of recidivism rates. However, many juvenile facilities do not provide adequate education or job training while youth are incarcerated.⁸⁸ Furthermore, laws vary by jurisdiction, but they may prohibit adjudicated youth from re-enrolling in school and restrict their ability to work in certain types of positions.⁸⁸ Individuals who take the General Education Development (GED) test are more likely to find a job upon their release and less likely to reoffend.⁹³ In 2014, changes to the GED test made it more academically challenging and more costly, and it is now only available in a computer-based testing format.⁹³ While these changes were designed to keep the test meaningful and in line with employer expectations, those working in the justice system have expressed concerns about the impact these changes may have on recidivism rates.

Health

Youth with mental health or substance abuse disorders may receive inadequate treatment while confined and could have difficulty accessing care when released due to lack of health insurance coverage, providers, and resources.⁸⁸ Federal law prohibits Medicaid payments for care or services for adult and juvenile inmates of public institutions (other than medical institutions).⁹⁴ As a result, many Medicaid agencies terminate eligibility as a youth moves into and out of custody. However, progress has been made in some state correctional systems, which now suspend rather than terminate benefits such as Medicaid while individuals are incarcerated and then immediately restart their benefits post-release.³⁶ This policy helps to ensure access to health care upon release.

Housing

Finding housing can also be challenging upon release. Youth may lose their foster care placement, be unable to return to their parents due to conflict or abuse, or be ineligible to live in public housing.⁸⁸

In President Clinton's 1996 State of the Union address, he called upon public housing authorities to take a "one strike and you're out" approach for residents who commit crimes and sell drugs to prevent them from "destroying the lives of decent tenants."⁹⁵ That same year, Clinton signed the Housing Opportunity Program Extension Act (Extension Act) of 1996 into law.⁹⁶ The Extension Act granted public housing agencies the authority to terminate tenancy in public housing units for illegally using a controlled substance or abusing alcohol in a manner determined to "interfere with the health, safety, or right to peaceful enjoyment of the premises by other residents."⁹⁶ In 2002, the US Supreme Court held that the Anti-Drug Abuse Act of 1988 grants local public housing authorities the discretion to evict tenants for the drug-related activity of household members and guests whether or not the tenant knew, or

should have known, about the activity.⁹⁷ As a result, an entire family could be evicted from public housing based on the actions of their child.

In 2015, the Department of Housing and Urban Development (HUD) announced updated public housing arrests guidance, which states that “arrest records may not be the sole basis for denying admission, terminating assistance or evicting tenants. HUD also reiterated that it does not require [public housing authorities] and owners to adopt ‘One Strike’ policies.”⁹⁸ HUD’s updated guidance is a step in the right direction. However, more needs to be done to encourage local public housing agencies to use discretion in making housing decisions, including consideration of the juvenile’s rehabilitation efforts. Homelessness can exacerbate health problems and increase the likelihood of recidivism.⁹⁵

RECENT STATE AND FEDERAL ACTIONS

Juvenile justice programs are administered by the states, though the federal government has had significant influence on this issue through judicial, executive, and congressional actions. While recent significant actions at the state level and on the federal level by the Supreme Court and the President are noted throughout this report, there has been little activity in Congress to address juvenile justice reform.

Federal Legislation

The JJDPA, first authorized in 1974, has three main components: it established the OJJDP within the DOJ to coordinate and administer federal juvenile justice efforts; it established grant programs to assist the states; and it promulgated core mandates that states must adhere to in order to be eligible to receive grant funding.¹⁰⁰ The JJDPA has been due for reauthorization since 2007. In the 114th Congress, Senators Grassley (R-IA) and Whitehouse (D-RI) introduced S. 1169 and Representative Scott (D-VA) introduced H.R. 2728 to reauthorize the JJDPA. The House of Representatives and the Senate have yet to pass the legislation. Federal funding for juvenile justice programs has continued to decline, peaking in Fiscal Year (FY) 2002 at \$565 million. In FY 2016, Congress appropriated \$270.2 million for these programs.¹⁰⁰ The President’s FY 2017 budget proposal included \$334.4 million for juvenile justice programs.¹⁰⁰

State Legislation

In recent years, states have reexamined policies developed 25-30 years ago that were intended to hold young offenders accountable through adult sentencing options, in an effort to produce more effective responses to youth crime and improve the juvenile justice system.¹⁰¹ Trends include: (1) reforming transfer, waiver and direct file statutes, and raising the age of juvenile court jurisdiction; (2) addressing delinquency prevention and diverting non-violent youth from the juvenile justice system; (3) increasing due process and defense reforms, including the right to “quality” counsel; (4) limiting or prohibiting solitary confinement; (5) requiring proper mental health screening and assessment to ensure treatment; (6) addressing racial and ethnic disparities; and (7) improving aftercare support for juveniles for successful reentry into the community.¹⁰¹

The decline in federal funding and status of state budgets has led some jurisdictions to consider innovative funding models to support juvenile justice system reform. Specifically, some jurisdictions are looking to social impact bonds (SIBs), which are financing mechanisms to raise funding from private investors for social and public health interventions (see Figure 2), in order to address juvenile justice reform.¹⁰² For example, with support from Goldman Sachs, New York City is working on a SIB project to reduce recidivism among youth ages 16-18 at Rikers Island, a jail complex in New York City.¹⁰² Massachusetts is engaged in a \$27 million dollar SIB project aiming to reduce recidivism and increase employment rates among young men ages 17-24 who are at risk of reoffending, on probation, or leaving the juvenile justice system.¹⁰² The results of these projects are not yet available.

CONCLUSION

The prefrontal cortex, the area of the brain that governs advanced functions such as integrating information from the senses, reasoning, and other “executive” functions, continues to develop throughout adolescence into young adulthood. While recognized differences in cognitive function and decision-making between adolescents and adults have led to some changes in the juvenile justice system, the United States still leads the industrialized world in the rate at which young people are confined. The disparities in youth confinement rates reflect a system that treats youth

of color, particularly African Americans and Latinos, more punitively. Many youth who get in trouble with the law have not only been negatively impacted by adverse childhood events and trauma, but also suffer from mental health or substance use disorders and would benefit from treatment.

Policies enacted in the 1980s and early 1990s, which focused the juvenile system more on punitive measures, have done little to ensure public safety and prevent recidivism. Similarly, zero tolerance policies, which disproportionately impact minorities, have resulted in youth being removed from the classroom, mostly for minor offenses, and into the juvenile justice system. Today, a growing consensus exists regarding the need to return to a juvenile system focused on rehabilitating justice-involved youth. Community-based alternatives to residential placement have shown promise and should be prioritized particularly for youth who do not pose a threat to public safety. Youth confined in juvenile facilities should be protected from dangerous conditions and receive access to quality services, including comprehensive health care. Gender-specific and trauma-informed policies and programs should be adopted throughout the juvenile justice system. Comprehensive reentry and aftercare services should be prioritized to assist youth in reintegrating in the community.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 205-I-14, and the remainder of the report be filed.

That our American Medical Association:

1. Reaffirm policies H-60.922, “Solitary Confinement of Juveniles in Legal Custody,” D-430.997, “Support for Health Care Services to Incarcerated Persons,” and H-60.986, “Health Status of Detained and Incarcerated Youth.”
2. Support school discipline policies that permit reasonable discretion and consideration of mitigating circumstances when determining punishments rather than “zero tolerance” policies that mandate out-of-school suspension, expulsion, or the referral of students to the juvenile or criminal justice system.
3. Encourage continued research to identify programs and policies that are effective in reducing disproportionate minority contact across all decision points within the juvenile justice system.
4. Encourage states to increase the upper age of original juvenile court jurisdiction to at least 17 years of age.
5. Support reforming laws and policies to reduce the number of youth transferred to adult criminal court.
6. Support the reauthorization of federal programs for juvenile justice and delinquency prevention, which should include incentives for: (1) community-based alternatives for youth who pose little risk to public safety, (2) reentry and aftercare services to prevent recidivism, (3) policies that promote fairness to reduce disparities, and (4) the development and implementation of gender-responsive, trauma-informed programs and policies across juvenile justice systems.
7. Encourage juvenile justice facilities to adopt and implement policies to prohibit discrimination against youth on the basis of their sexual orientation, gender identity, or gender expression in order to advance the safety and well-being of youth and ensure equal access to treatment and services.
8. Encourage states to suspend rather than terminate Medicaid coverage following arrest and detention in order to facilitate faster reactivation and ensure continuity of health care services upon their return to the community.
9. Encourage Congress to enact legislation prohibiting evictions from public housing based solely on an individual’s relationship to a wrongdoer, and encourages the Department of Housing and Urban Development and local public housing agencies to implement policies that support the use of discretion in making housing decisions, including consideration of the juvenile’s rehabilitation efforts.

REFERENCES

1. National Research Council and Institute of Medicine. *Juvenile Crime, Juvenile Justice*. Panel on Juvenile Crime: Prevention, Treatment, and Control. 2001, Washington, DC: National Academy Press. <http://www.nap.edu/read/9747/chapter/7#157>. Accessed February 25, 2016.
2. Geraghty TF, Drizin SA. *The Debate Over the Future of Juvenile Courts: Can We Reach Consensus?* 1997. *J Crim Law Criminol.* 88;Article 1(Issue 1)(Fall). <http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=6941&context=jclc> Accessed April 19, 2016.
3. Office of Juvenile Justice and Delinquency Prevention, *Juvenile Justice System Structure and Process, Case Flow Diagram*. http://www.ojjdp.gov/ojstatbb/structure_process/case.html. Accessed February 25, 2016.
4. Juvenile Offenders and Victims: 1999 National Report, *Juvenile Justice System Structure and Process*. <https://www.ncjrs.gov/html/ojjdp/nationalreport99/chapter4.pdf>. Accessed February 25, 2016.
5. Annie E. Casey Foundation, *Youth Incarceration in the United States*. <http://www.aecf.org/m/resourcedoc/aecf>YouthIncarcerationInfographic-2013.pdf>. Accessed February 25, 2016.
6. Office of Juvenile Justice and Delinquency Prevention, *Statistical Briefing Book: Jurisdictional Boundaries*. 2014. http://www.ojjdp.gov/ojstatbb/structure_process/qa04101.asp. Accessed March 16, 2016.
7. Barr S. *Connecticut Governor Suggests Raising the Age to 20*. Juvenile Justice Information Exchange. November 6, 2015. <http://jje.org/connecticut-governor-suggests-raising-the-age-to-20/150489/>. Accessed March 16, 2016.
8. Gonnerman J, Browder K. 1993-2015, *The New Yorker*, June 7, 2015. <http://www.newyorker.com/news/news-desk/kalief-browder-1993-2015>. Accessed February 25, 2016.
9. Sanders T. *Jacksonville Teen Dies from Bacterial Meningitis While in Department of Juvenile Justice Custody*, The Florida Times Union, February 24, 2015. <http://jacksonville.com/news/crime/2015-02-24/story/jacksonville-teen-dies-bacterial-meningitis-while-department-juvenile>. Accessed February 25, 2016.
10. National Research Council. *Reforming Juvenile Justice: A Developmental Approach*. Committee on Assessing Juvenile Justice Reform. 2013. Washington, DC: The National Academies Press. <http://www.nap.edu/read/14685/chapter/1#ii>. Accessed February 25, 2016.
11. ER Sowell, PM Thompson, CJ Holmes, et al. In vivo evidence for post-adolescent brain maturation in frontal and striatal regions. *Nature neuroscience*. 1999;2(10):859-861.
12. National Institute of Mental Health, *Imaging Study Shows Brain Maturing*, May 17, 2004. <http://www.nimh.nih.gov/news/science-news/2004/imaging-study-shows-brain-maturing.shtml>. Accessed February 25, 2016.
13. *Roper v. Simmons* 543 U.S. 551 (2005)
14. *Graham v. Florida* 130 S. Ct. 2011 (2010)
15. *Miller v. Alabama* 132 S.Ct. 2455 (U.S. 2012)
16. *Montgomery v. Louisiana* 577 U. S. ____ (2016).
17. American Medical Association, *Litigation Center Cases on Minor Rights*. <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/litigation-center/case-summaries-topic/minors-rights.page?>. Accessed February 26, 2016.
18. Brief for American Medical Association and American Association of Child and Adolescent Psychiatry as Amici Curiae Supporting Neither Party, *Graham v. Florida*. 130 S. Ct. 2011 (2010). <http://www.ama-assn.org/resources/doc/legal-issues/x-pub/graham-v-florida.pdf>.
19. Heitzeg NA. *Criminalizing Education: Zero Tolerance Policies, Police in the Hallways and The School to Prison Pipeline*. http://www.hamline.edu/uploadedFiles/Hamline_WWW/HSE/Documents/criminalizing-education-zero-tolerance-police.pdf. Accessed February 29, 2016.
20. Kang-Brown J, Trone J, Fratello J, et al. *A Generation Later: What We've Learned About Zero Tolerance in Schools*. The Vera Institute for Justice, December 2013. <http://www.vera.org/sites/default/files/resources/downloads/zero-tolerance-in-schools-policy-brief.pdf>. Accessed February 29, 2016.
21. Hanson A. Have zero tolerance school discipline policies turned into a nightmare? The American dream's promise of equal educational opportunity grounded in *Brown v. Board of Education*. *UC Davis Journal of Juvenile Law & Policy*. 2005(9): 289-378.
22. Lamont JH for the American Academy of Pediatrics, Council on School Health. Out of School Suspension and Expulsion. *Pediatrics* 2013; 131(3):1000-1007. <http://pediatrics.aappublications.org/content/131/3/e1000>. Accessed February 29, 2016
23. The Civil Rights Project and the Advancement Project. *Opportunities Suspended: The Devastating Consequences of Zero Tolerance and School Discipline Policies*. June 1, 2000. <http://civilrightsproject.ucla.edu/research/k-12-education/school-discipline/opportunities-suspended-the-devastating-consequences-of-zero-tolerance-and-school-discipline-policies/>. Accessed February 29, 2016.
24. Russ E. Zero tolerance zero benefits: The discipline gap in American public K-12 education. George Mason University, *New Voices in Public Policy*, Volume VIII, Spring 2014.
25. Human Impact Partners, *Health Impact Assessment of School Discipline Policies*. <http://www.cadre-la.org/core/wp-content/uploads/2013/07/HIA-Summary.English.pdf>. Accessed March 3, 2016.
26. McNeil M, Shah N, Hung CC. Student expulsion and suspension data, 2009-2010 School Year, *Education Week* (2013). <http://www.edweek.org/ew/qc/2013/ocrdata.html?intc=EW-QC13-EWH>. Accessed February 29, 2016.
27. Skiba R, Peterson R. The dark side of zero tolerance: Can punishment lead to safe schools? *Phi Delta Kappan*. 1999;80(5):372-382.

28. Final Report of The President's Task Force on 21st Century Policing, May 2015. http://www.cops.usdoj.gov/pdf/taskforce/taskforce_finalreport.pdf. Accessed March 7, 2016.
29. Youth Involved with the Juvenile Justice System, <http://www.youth.gov>. Accessed February 26, 2016.
30. Office of Juvenile Justice and Delinquency Prevention. *Juvenile Offenders and Victims: 2014 National Report*. <http://www.ojjdp.gov/ojstatbb/nr2014/downloads/NR2014.pdf>. Accessed February 26, 2016.
31. Gillis AJ, Bath E. *Adjudicated Youth: Child and Adolescent Psychiatric Clinics of North America*. Chap. 1. *Demographics*. Edited by Kraus LJ and Trivedi HK. Volume 25, Number 1. January 2016.
32. Rovner J for The Sentencing Project, *Disproportionate Minority Contact in the Juvenile Justice System*, May 2014. http://sentencingproject.org/doc/publications/ji_Disproportionate%20Minority%20Contact.pdf. Accessed February 26, 2016.
33. Juvenile Justice and Delinquency Prevention Act as amended, Pub. L. No. 93-415 (1988).
34. Juvenile Justice and Delinquency Prevention Act as amended, Pub. L. No. 93-415 (1992).
35. U.S. Department of Justice, The Office of Juvenile Justice and Delinquency Prevention, *Disproportionate Minority Contact*, November 2012. <http://www.ojjdp.gov/pubs/239457.pdf>. Accessed February 28, 2016.
36. Substance Abuse and Mental Health Services Administration, *Criminal and Juvenile Justice*, Last Updated December 7, 2015. <http://www.samhsa.gov/criminal-juvenile-justice>. Accessed February 29, 2016.
37. Teplin LA, Abram KM, McClelland GM, Dulcan MK, Mericle AA. Psychiatric disorders in youth in juvenile detention. *Arch Gen Psychiatr*. 2002;59(12):1133-1143.
38. Mulvey EP, Schubert CA, Chassin L. *Substance Use and Delinquent Behavior Among Serious Adolescent Offenders*, OJJDP Juvenile Justice Bulletin, December 2010. <https://www.ncjrs.gov/pdffiles1/ojjdp/232790.pdf>. Accessed February 29, 2016.
39. U.S. Department of Justice, *Department of Justice Activities Under the Constitutional Rights of Institutionalized Persons Act Fiscal Year 2010*. https://www.justice.gov/sites/default/files/crt/legacy/2011/07/12/split_cripa10.pdf. Accessed February 29, 2016.
40. MacArthur Foundation, Models for Change, *Mental Health*, <http://www.modelsforchange.net/reform-areas/mental-health/index.html>. Accessed February 29, 2016.
41. Models for Change, *Mental Health Screening within the Juvenile Justice: The Next Frontier*. November 15, 2007. <http://www.modelsforchange.net/publications/198>. Accessed February 29, 2016.
42. Substance Abuse and Mental Health Services Administration, *Examples of Screening and Assessment Tools for Substance Use Disorders*. https://ncsacw.samhsa.gov/files/SAFERR_AppendixD.pdf. Accessed April 18, 2016.
43. Technical Assistance Partnership for Child and Family Mental Health, *Screening and Assessment in Juvenile Justice Systems: Identifying Mental Health Needs and Risks of Reoffending*. http://www.tapartnership.org/docs/jjResource_screeningAssessment.pdf. Accessed March 6, 2016.
44. National Center for Mental Health and Juvenile Justice, *Better Solutions for Youth with Mental Health Needs in the Juvenile Justice System*. <file:///C:/Users/agarcia/Downloads/Better%20Solutions%20for%20Youth%20with%20Mental%20Health%20Needs%20in%20the%20Juvenile%20Justice%20System.pdf>. Accessed February 29, 2016.
45. Dierkhising CB, Ko SJ, Woods-Jaeger B, Briggs EC, Lee R, Pynoos RS. Trauma histories among justice-involved youth: findings from the National Child Traumatic Stress Network. *European Journal of Psychotraumatology*. 2013;4:10.3402.
46. The National Child Traumatic Stress Network. *Defining trauma and child traumatic stress*. (2006). www.nctsn.org/nccts/nav.do?pid=faq_def. Accessed April 19, 2016.
47. Abram KM, Teplin LA, King DC et al. PTSD, trauma, and co-morbid psychiatric disorders in detained youth. OJJDP. *Juvenile Justice Bulletin*. June 2013. <http://www.ojjdp.gov/pubs/239603.pdf>.
48. Caporino N, Murray L, Jensen P. The impact of different traumatic experiences in childhood and adolescence. 2003. *Emot Beh Disord Youth*. Summer: 63-64, 73-76.
49. Zavlek S, Maniglia R. Developing correctional facilities for female juvenile offenders: Design and programmatic considerations. 2007. *Corrections Today*; Aug:58-63. http://justicesolutionsgroup.com/uploads/pdfs/zavlek_maniglia-prog_des_consid.pdf. Accessed February 29, 2016.
50. Saar MS, Epstein R, Rosenthal L, et al. *The Sexual Abuse to Prison Pipeline: The Girls' Story*. http://rights4girls.org/wp-content/uploads/r4g/2015/02/2015_COP_sexual-abuse_layout_web-1.pdf. Accessed March 28, 2016.
51. Baglivio MT, Epps N, Swartz K, Sayedul Huq M, Sheer A, Hardt NS. The prevalence of Adverse Childhood Experiences (ACE) in the lives of juvenile offenders. *Juv. Justice* 2014;3(2). <http://www.journalofjuvenilejustice.org/JOJJ0302/article01.htm>. Accessed April 19, 2016
52. Hennessey M, Ford JD, Mahoney K, et al. *Trauma Among Girls in the Juvenile Justice System*, Nat'l Child Traumatic Stress Network, 2004. http://www.nctsnet.org/nctsn_assets/pdfs/edu_materials/trauma_among_girls_in_jjssys.pdf. Accessed March 28, 2016.
53. Teplin LA, Abram KM, Washburn JJ, Welty LJ, Hershfield JA, Dulcan, MK. *The Northwestern Juvenile Project: Overview*. 2013. Washington, DC: U.S. Department of Justice, Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention.
54. Acoca L. Are those cookies for me or my baby? Understanding detained and incarcerated teen mothers and their children. *Juvenile and Family Court Journal* 2004;55:65-80.
55. Parke RD, Stewart KA. *From Prison to Home: The Effect of Incarceration and Reentry on Children, Families, and Communities*. Office of the Assistant Secretary for Planning and Evaluation, Washington, DC. 2001

56. Watson L, Edelman P. *Improving the Juvenile Justice System for Girls: Lessons from the States*. October 2012. http://www.law.georgetown.edu/academics/centers-institutes/poverty-inequality/upload/jds_v1r4_web_singles.pdf. Accessed February 29, 2016.

57. Hunt J, Moodie-Mills AC. *The Unfair Criminalization of Gay and Transgender Youth An Overview of the Experiences of LGBT Youth in the Juvenile Justice System*. June 29, 2012.

58. Wilber S. *A Guide to Juvenile Detention Reform: Lesbian, Gay, Bisexual and Transgender Youth in the Juvenile Justice System*. Annie E. Casey Foundation, 2015. <http://www.aecf.org/m/resourcedoc/AECF-lesbiangaybisexualandtransgenderyouthinj-2015.pdf>. Accessed April 4, 2016.

59. The Office of Juvenile Justice and Delinquency Prevention, *Juvenile Justice Reform Initiatives in States 1994-1996*. Chapter 2. http://www.ojjdp.gov/pubs/reform/ch2_j.html. Accessed March 2, 2016.

60. U.S. General Accounting Office, *Juvenile Justice: Juveniles Processed in Criminal Court and Case Dispositions*. August 1995. Washington, DC. GAO/GGD-95-170. <http://www.gao.gov/assets/230/221507.pdf>. March 2, 2016.

61. UCLA School of Law Juvenile Justice Project, *The Impact of Prosecuting Youth in the Adult Criminal Justice System: A Review of the Literature*. July 2010. <http://www.campaignforyouthjustice.org/documents/UCLA-Literature-Review.pdf>. Accessed March 2, 2016.

62. Redding RE for the Office of Juvenile Justice and Delinquency Prevention. *Juvenile Transfer Laws: An Effective Deterrent to Delinquency?* June 2010. <https://www.ncjrs.gov/pdffiles1/ojjdp/220595.pdf>. Accessed March 2, 2016.

63. Task Force on Community Preventive Services. Recommendation against policies facilitating the transfer of juveniles from juvenile to adult justice systems for the purpose of reducing violence. *Am J Prev Med* 2007;32 (4S):S5-6.

64. Dmitrieva J, Monahan KC, Cauffman E, et al. Arrested development: The effects of incarceration on the development of psychosocial maturity. *Develop Psychopath*. 2012 (24): 1073-1090.

65. Grassian S. Psychiatric Effects of Solitary Confinement, 22 *Wash. U. J. L. & Pol'y* 325 (2006).

66. The Office of Juvenile Justice and Delinquency Prevention, *Civil Rights of Institutionalized Persons Act in Juvenile Correctional Facilities*. <http://www.ojjdp.gov/pubs/walls/sect-01.html>. Accessed March 6, 2016.

67. Parent DL et al. *Conditions of Confinement: Juvenile Detention and Corrections Facilities: Research Report*. August 1994. <https://www.ncjrs.gov/pdffiles1/ojjdp/1FrontMat.pdf>. Accessed March 3, 2016.

68. Hayes L. *Juvenile Suicide in Confinement: A National Survey*. The Office of Juvenile Justice and Delinquency Prevention. Washington, DC. 2009. <https://www.ncjrs.gov/pdffiles1/ojjdp/213691.pdf>. Accessed April 19, 2016.

69. Council of Juvenile Corrections Administrators, *Performance-based Standards*. <http://cjca.net/index.php/initiatives/performance-based-standards-pbs>. Accessed March 3, 2016.

70. Performance-based Standards: Safety and Accountability for Juvenile Corrections and Detention Facilities. http://pbstandards.org/cjcaresources/93/PbS_InfoPacket2011.pdf. Accessed March 3, 2016.

71. Annie E. Casey Foundation, *Juvenile Detention Facility Assessment: 2014 Update*. <http://www.aecf.org/m/resourcedoc/aecf-juveniledetentionfacilityassessment-2014.pdf>. Accessed March 3, 2016.

72. The National Commission on Correctional Health Care, *About Us*. <http://www.ncchc.org/about>. Accessed March 3, 2016.

73. The National Commission on Correctional Health Care, *Board of Directors*. <http://www.ncchc.org/supporting-organizations>. Accessed March 3, 2016.

74. The National Commission on Correctional Health Care, *Juvenile Standards 2015: What's New*. <http://www.ncchc.org/juvenile-standards-2015-what%20%99s-new>. Accessed March 3, 2016.

75. Mitchell J, Varley C. Isolation and restraint in juvenile correctional facilities. *Am. Acad. Child Adolesc Psychiatry*. 1990;29(2):251-5.

76. American Academy of Child and Adolescent Psychiatry, Juvenile Justice Reform Committee. *Solitary Confinement of Juvenile Offenders*. April 2012. https://www.aacap.org/aacap/policy_statements/2012/solitary_confinement_of_juvenile_offenders.aspx. Accessed March 23, 2016.

77. Juvenile Detention Alternatives Initiative, *Juvenile Detention Facility Assessment*, 2014 Standards. <http://www.aecf.org/m/resourcedoc/aecf-juveniledetentionfacilityassessment-2014.pdf#page=103>. Accessed March 2, 2016.

78. Council of Juvenile Correctional Administrators Toolkit: Reducing the Use of Isolation. March 2015. <http://cjca.net/attachments/article/751/CJCA%20Toolkit%20Reducing%20the%20Use%20of%20Isolation.pdf>. Accessed April 18, 2016.

79. U.S. Department of Justice, *Report and Recommendations Concerning the Use of Restrictive Housing*. January 2016, Washington, DC. <https://www.justice.gov/dag/file/815551/download>. Accessed March 2, 2016.

80. Obama B. Why we must rethink solitary confinement. The Washington Post, January 25, 2016. https://www.washingtonpost.com/opinions/barack-obama-why-we-must-rethink-solitary-confinement/2016/01/25/29a361f2-c384-11e5-8965-0607e0e265ce_story.html. Accessed March 2, 2016.

81. Altschuler D, Bilchik S. *Critical Elements of Juvenile Reentry in Research and Practice*. Council of State Governments. April 21, 2014. <https://csgjusticecenter.org/youth/posts/critical-elements-of-juvenile-reentry-in-research-and-practice/>. Accessed March 6, 2016.

82. Austin J, Johnson KD, Weitzer R. Alternatives to the secure detention and confinement of juvenile offenders. *Juvenile Justice Bulletin*. 2005(Sept). <https://www.ncjrs.gov/pdffiles1/ojjdp/208804.pdf>. Accessed April 19, 2016.

83. University of Colorado at Boulder. *Blueprints for Healthy Youth Development*. <http://www.colorado.edu/cspv/blueprints/>. Accessed March 3, 2016.

84. University of Colorado at Boulder, Blueprints for Healthy Youth Development. *Multisystemic Therapy*, <http://www.blueprintsprograms.com/factsheet/multisystemic-therapy-mst>. Accessed March 3, 2016

85. University of Colorado at Boulder, Blueprints for Healthy Youth Development. *Family Functional Therapy*. <http://www.blueprintsprograms.com/factsheet/functional-family-therapy-fft>. Accessed March 3, 2016.
86. University of Colorado at Boulder, Blueprints for Healthy Youth Development. *Treatment Foster Care Oregon*. <http://www.blueprintsprograms.com/factsheet/treatment-foster-care-oregon>. Accessed March 3, 2016.
87. HN Snyder. An empirical portrait of the youth reentry population. *Youth Violence and Juvenile Justice*. 2004;(2):139-55.
88. Juvenile Justice Information Exchange, *Re-entry key issues*. <http://jje.org/hub/reentry/key-issues/>. Accessed March 3, 2016.
89. Cahn ES. *How the Juvenile Justice System Reduces Life Options of Minority Youth*, Joint Center for Political and Economic Studies Health Policy Institute, Washington, DC. 2006. http://www.oaklandnet.com/documents/drc_how_juvenilez_justice_rReduces_lofm.pdf. Accessed February 28, 2016.
90. Moeser J, Thomas RL, Walsh TB, et al. Chapter Two: Equipping for Reentry Success: Partnerships, Coalition-Building and Independence-Building in *Desktop Guide to Reentry for Juvenile Confinement Facilities*, East Lansing, MI: The National Partnership for Juvenile Services, July 2004
91. National Criminal Justice Reference Service, *Promising Aftercare Programs*, <https://www.ncjrs.gov/html/ojjdp/201800/page4.html>. Accessed March 7, 2016.
92. OJJDP. *Aftercare/Reentry*. <http://www.ojjdp.gov/mpg/litreviews/Aftercare.pdf>. Accessed March 7, 2016.
93. Tran NP. *National Debate on 2014 GED Changes*. The Council of State Governments. December 13, 2013. <https://csgjusticecenter.org/reentry/posts/national-debate-on-2014-ged-changes/>. Accessed April 3, 2016.
94. Zemel S, Mooney K, Justice D, et al. *Facilitating access to Health Care Coverage for Juvenile Justice-Involved Youth, Models for Change*. National Academy for State Health Policy. http://www.nashp.org/sites/default/files/Facilitating_Access_to_Health_Care_Coverage.pdf. Accessed April 4, 2016.
95. Clinton B. 1996 State of the Union Address, in 142 CONG. REC. H768-71 (1996).
96. Public Law 104-120. March 28, 1996. <https://www.congress.gov/104/plaws/publ120/PLAW-104publ120.pdf>. Accessed April 4, 2016.
97. *Department of Housing and Urban Development v. Rucker et al.* 535 U.S. 125 (2002).
98. U.S. Department of Justice, *The Justice Department and U.S. Department of Housing and Urban Development Announce New Juvenile Re-Entry Assistance Program*. November 2, 2015. <https://www.justice.gov/opa/pr/justice-department-and-us-department-housing-and-urban-development-announce-new-juvenile-re>. Accessed March 3, 2016.
99. National Health Care for the Homeless Council. *Homeless & Health: What's the Connection?* June 2011. http://www.nhchc.org/wp-content/uploads/2011/09/Hn_health_factsheet_Jan10.pdf. Accessed April 4, 2016.
100. Finklea K. *Juvenile Justice Funding Trends*. Congressional Research Service, January 8, 2016. <https://www.fas.org/sgp/crs/misc/RS22655.pdf>. Accessed March 7, 2016.
101. Brown SA. *Trends in Juvenile Justice State Legislation: 2011-2015*. September 2015, National Conference of State Legislatures, Denver, CO. http://www.ncsl.org/documents/cj/Juvenile_Justice_Trends_1.pdf. Accessed March 7, 2016.
102. Tran NP. *Social Impact Bonds Gain Momentum in the Criminal Justice Field*. The Council of State Governments, February 18, 2014. <https://csgjusticecenter.org/reentry/posts/social-impact-bonds-gain-momentum-in-the-criminal-justice-field/>. Accessed March 7, 2016.

Figure 1. (Source OJJDP)

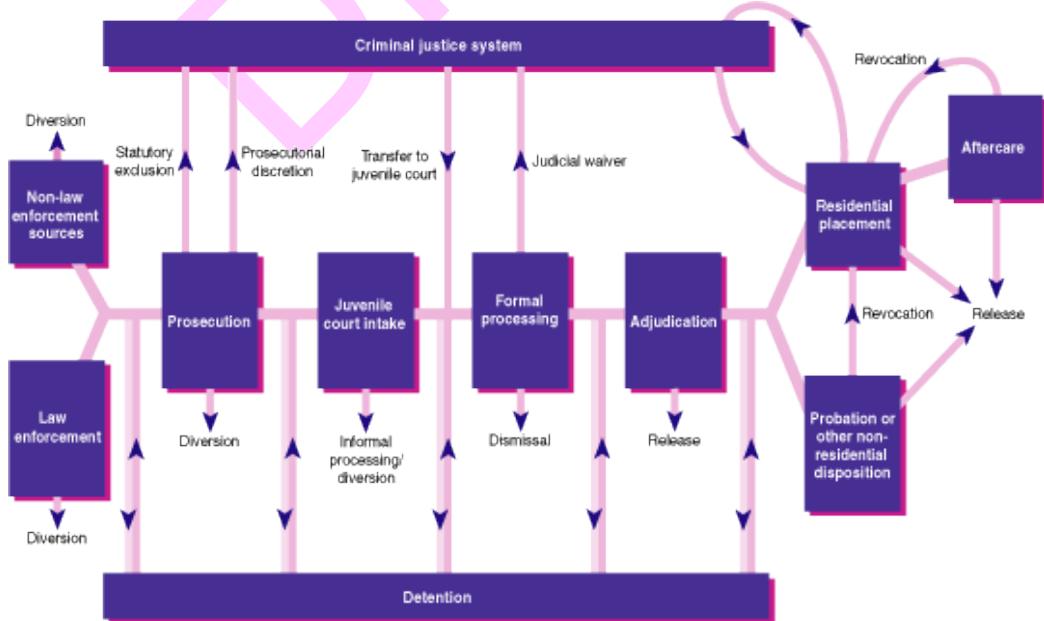
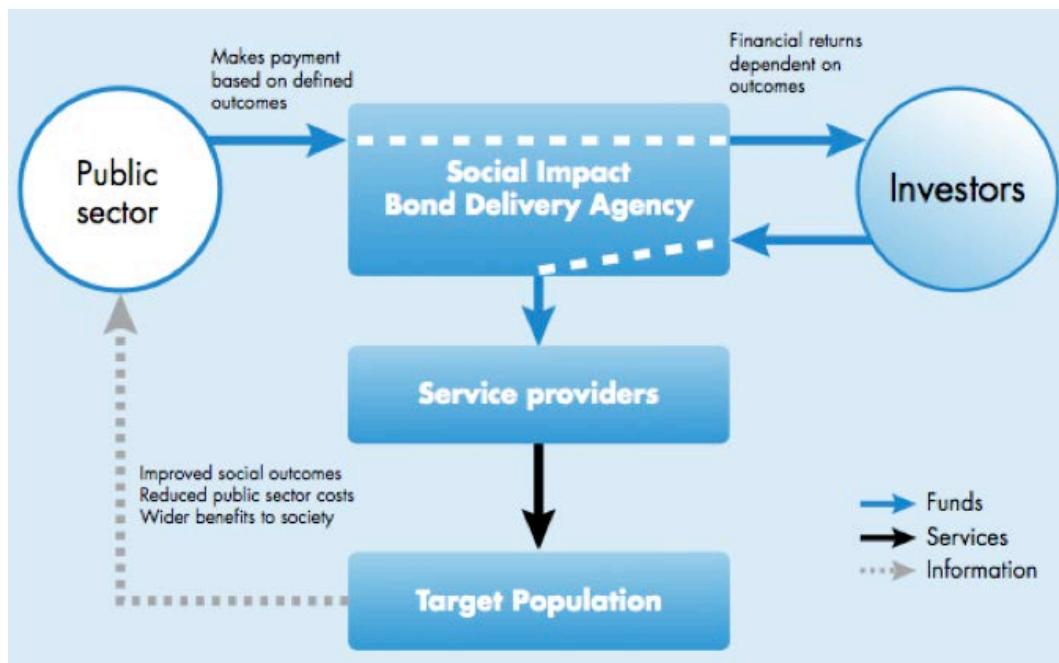


Figure 2. (Source: Next Billion: Development through Enterprise)



APPENDIX

H-60.922 Solitary Confinement of Juveniles in Legal Custody

Our AMA: (1) opposes the use of solitary confinement in juvenile correction facilities except for extraordinary circumstances when a juvenile is at acute risk of harm to self or others; (2) opposes the use of solitary confinement of juveniles for disciplinary purposes in correctional facilities; and (3) supports that isolation of juveniles for clinical or therapeutic purposes must be conducted under the supervision of a physician.

H-60.986 Health Status of Detained and Incarcerated Youth

Our AMA (1) encourages state and county medical societies to become involved in the provision of adolescent health care within detention and correctional facilities and to work to ensure that these facilities meet minimum national accreditation standards for health care as established by the National Commission on Correctional Health Care; (2) encourages state and county medical societies to work with the administrators of juvenile correctional facilities and with the public officials responsible for these facilities to discourage the following inappropriate practices: (a) the detention and incarceration of youth for reasons related to mental illness; (b) the detention and incarceration of youth in adult jails; and (c) the use of experimental therapies, not supported by scientific evidence, to alter behavior. (3) encourages state medical and psychiatric societies and other mental health professionals to work with the state chapters of the American Academy of Pediatrics and other interested groups to survey the juvenile correctional facilities within their state in order to determine the availability and quality of medical services provided. (4) advocates for increased availability of educational programs by the National Commission on Correctional Health Care and other community organizations to educate adolescents about sexually transmitted diseases, including juveniles in the justice system. (CSA Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Appended: Res. 401, A-01; Reaffirmed: CSAPH Rep. 1, A-11)

H-420.957 Shackling of Pregnant Women in Labor

1. Our AMA supports language recently adopted by the New Mexico legislature that an adult or juvenile correctional facility, detention center or local jail shall use the least restrictive restraints necessary when the facility has actual or constructive knowledge that an inmate is in the 2nd or 3rd trimester of pregnancy. No restraints of any kind shall be used on an inmate who is in labor, delivering her baby or recuperating from the delivery unless there are compelling grounds to believe that the inmate presents: an immediate and serious threat of harm to herself, staff or others; or a substantial flight risk and cannot be reasonably contained by other means. If an inmate who is in labor or who is delivering her baby is restrained, only the least restrictive restraints necessary to ensure safety and security shall be used. 2. Our AMA will develop model state legislation prohibiting the use of shackles on pregnant women unless flight or safety concerns exist.

H-430.987 Opiate Replacement Therapy Programs in Correctional Facilities

Our AMA endorses: (1) the medical treatment model of employing opiate replacement therapy (ORT) as an effective therapy in treating opiate-addicted persons who are incarcerated; and (2) ORT for opiate-addicted persons who are incarcerated, in collaboration with the National Commission on Correctional Health Care and the American Society of Addiction Medicine.

H-430.988 Prevention and Control of HIV/AIDS and Tuberculosis in Correctional Facilities

(1) Medical Testing and Care of Prisoners 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) During incarceration, prisoners should be tested for HIV infection as medically indicated or on their request; c) All inmates 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 inmates 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 should have access to approved therapeutic drugs and generally employed treatment strategies. (2) HIV/AIDS Education and Prevention Our AMA: a) Encourages the inclusion of HIV-prevention information as a regular part of correctional staff and inmate education. 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 inmates; 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 inmates 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.

H-430.989 Disease Prevention and Health Promotion in Correctional Institutions

Our AMA urges state and local health departments to develop plans that would foster closer working relations between the criminal justice, medical, and public health systems toward the prevention and control of HIV/AIDS, substance abuse, tuberculosis, and hepatitis. Some of these plans should have as their objectives: (a) an increase in collaborative efforts between parole officers and drug treatment center staff in case management aimed at helping patients to continue in treatment and to remain drug free; (b) an increase in direct referral by correctional systems of parolees with a recent, active history of intravenous drug use to drug treatment centers; and (c) consideration by judicial authorities of assigning individuals to drug treatment programs as a sentence or in connection with sentencing.

H-430.990 Bonding Programs for Women Prisoners and their Newborn Children

Because there are insufficient data at this time to draw conclusions about the long-term effects of prison nursery programs on mothers and their children, the AMA supports and encourages further research on the impact of infant bonding programs on incarcerated women and their children. The AMA recognizes the prevalence of mental health and substance abuse problems among incarcerated women and continues to support access to appropriate services for women in prisons. The AMA recognizes that a large majority of female inmates who may not have developed appropriate parenting skills are mothers of children under the age of 18. The AMA encourages correctional facilities to provide parenting skills training to all female inmates in preparation for their release from prison and return to their children. The AMA supports and encourages further investigation into the long-term effects of prison nurseries on mothers and their children.

H-430.994 Prison-Based Treatment Programs for Drug Abuse

Our AMA: (1) encourages the increased application to the prison setting of the principles, precepts and processes derived from drug-free residential therapeutic community experience; and (2) urges state health departments or other appropriate agencies to take the lead in working with correction and substance abuse agencies for the expansion of such prison-based drug-free treatment programs.

H-430.997 Standards of Care for Inmates of Correctional Facilities

Our AMA believes that correctional and detention facilities should provide medical, psychiatric, and substance misuse care that meets prevailing community standards, including appropriate referrals for ongoing care upon release from the correctional facility in order to prevent recidivism.

H-430.998 Use of the Choke and Sleeper Hold in Prisons

The AMA (1) does not regard the choke and sleeper holds as casually applied and easily reversible tranquilizers, but as the use of deadly force with the potential to kill; and (2) advocates that with all incidents involving the application of choke and sleeper holds there should be timely medical surveillance of the inmate.

H-440.931 Update on Tuberculosis

It is the policy of the AMA that: (1) All prison inmates 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 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.

H-490.915 Tobacco Use in Prison Populations

It is the policy of our AMA to (1) recognize and promote the policy that all anti-smoking policies that apply to the general population should apply equally to persons who are incarcerated in local jails, state prisons, and federal prisons; (2) work actively to stop the manufacture of cigarettes by any prison or jail system in the United States; (3) work actively to stop the subsidy of cigarette sales in all jail and prison systems; (4) ensure that the prohibition of smoking by minors be enforced in the correctional system; (5) be committed to smoking cessation programs in correctional facilities and encourage physicians working in correctional systems to include smoking cessation counseling and programs for their patients who smoke; (6) work through its representative to the National Commission on Correctional Health Care to ensure that smoking cessation counseling be made a national standard for correctional medicine; (7) develop model legislation providing for smoke-free prison areas for all inmates, and particularly that common areas including cell blocks and recreation areas not be smoking areas; and (8) support legislation banning smoking in prisons and jails. (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)

H-515.981 Family Violence-Adolescents as Victims and Perpetrators

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 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)

D-60.994 Sexually Transmitted Infections Among Adolescents, Including Incarcerated Juveniles

Our AMA will increase its efforts to work with the National Commission on Correctional Health Care to ensure that juveniles in correctional facilities receive comprehensive screening and treatment for sexually transmitted infections and sexual abuse. (Res. 401, A-01; Modified: CSAPH Rep. 1, A-11)

D-430.995 Dietary Intake of Incarcerated Populations

Our AMA: 1) urges the National Commission on Correctional Health Care, the American Correctional Association, and individual states to mandate adherence to the current Dietary Reference Intakes and Dietary Guidelines for Americans (with adjustments, as needed, for special populations) as a criterion for accreditation and/or standards compliance, until national dietary guidelines specific for adolescent and adult incarcerated populations becomes available; and 2) urges the Food and Nutrition Board of the Institute of Medicine to examine the nutrient status and dietary requirements of incarcerated populations and issue guidelines on menu planning for adolescent and adult incarcerated populations. (CSAPH Rep. 4, A-11)

D-430.994 Health Care While Incarcerated

Our AMA will study mental health and health care for incarcerated juvenile and adult individuals and identify the best mental health and health care models for local, state and federal facilities.

D-430.997 Support for Health Care Services to Incarcerated Persons

Our AMA will:

(1) express its support of the National Commission on Correctional Health Care Standards that improve the quality of health care services, including mental health services, delivered to the nation's correctional facilities; (2) encourage all correctional systems to support NCCHC accreditation; (3) encourage 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; and (4) continue support for the programs and goals of the NCCHC through continued support for the travel expenses of the AMA representative to the NCCHC, with this decision to be reconsidered every two years in light of other AMA financial commitments, organizational memberships, and programmatic priorities. (Res. 440, A-04; Amended: BOT Action in response to referred for decision Res. 602, A-00; Reaffirmation I-09; Reaffirmation A-11)

D-430.999 Preventing Assault And Rape Of Inmates By Custodial Staff

Our AMA urges: (1) that all states have legislation that protects prisoners from sexual misconduct and assault; and (2) physicians who work within prisons to ensure procedures are followed for preventing sexual misconduct and assault of prisoners by staff and appropriately managing prisoners if abuse or assault does occur; the investigation of sexual misconduct should be confidential with information disclosed only to those individuals involved in the process.

9. INCREASING AWARENESS OF NOOTROPIC USE

Reference committee hearing: see report of [Reference Committee E](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED

See Policies H-95.935 and D-100.969

INTRODUCTION

American Medical Association (AMA) Policy D-100.969, “Increasing Awareness of Nootropic Use,” holds that nootropic use may be a potential health problem and that our AMA will research the demand, use, and adverse effects of nootropics used individually and in combination.

The term nootropic was introduced in 1972 by a Romanian psychologist and chemist, Corneliu E. Giurgea, from the Greek words *vouç* (nous) or “mind,” and *τρέπειν* (trepein) meaning to “bend or turn.”¹ Nootropics (also called “smart drugs”) are prescription drugs, supplements, or other substances that are claimed to improve cognitive functions of healthy individuals, particularly executive function, memory, learning, or intelligence.^{1,2} The term “smart pill” was first introduced in the 1960s, referring to a drug that increases the cognitive ability of anyone taking it, whether the user is cognitively impaired or normal. In their best-selling book, *Smart Drugs and Nutrients*, Dean and Morgenthaler (1990) reviewed a large number of synthetic and natural substances that have been used by healthy individuals for the intended purpose of increasing cognitive abilities.³ Other descriptive terms that have been used by both popular media and academicians include “neuroenhancement,” “cognitive enhancement,” “pharmacological cognitive enhancement,” and “cosmetic neurology,” each with variations in their definitions, depending on the source.

Nootropic use has invoked increasing media scrutiny in many countries around the world, with special emphasis placed on the nonmedical use of prescription stimulant drugs by college students. Media portrayals have featured a growing trend in the personal use of nootropics, with less attention devoted to safety or adverse events.⁴ The movie “Limitless” and television series based on the same theme have encouraged re-examination of the possibility that pharmacologic enhancement of mental acuity and cognitive function may be a near-term reality. Many studies have been conducted on attempts to improve cognitive function in individuals with cognitive decline, and in those who have suffered traumatic brain injuries or who have other mental or neurological disorders. This report addresses the use of putative nootropics by otherwise normal, healthy individuals with the intention of improving memory, learning or other aspects of cognition.

METHODS

English-language articles were selected from a search of the PubMed database through April 30, 2016 using the search terms for various putative nootropics according to the following format (for example): “methylphenidate” AND “cognition,” NOT “Alzheimers” NOT “ADHD.” In some cases, alternate disease exclusions were applied (e.g., “narcolepsy” when searching for modafinil). The Cochrane Controlled Trial register and library of systematic reviews also were searched using specific nootropic candidate names. Additionally, articles were selected from a search of the PubMed and Google Scholar databases using the search terms “nootropic,” “smart drug,” and “cognitive enhancement.” Various internet sites managed by manufacturers and purveyors of nootropic products and formulations also were consulted and the Consumer Healthcare Products Association was contacted in search of market information. Additional articles were culled from the reference lists contained in the pertinent articles and other publications.

HOW ARE NOOTROPICS EVALUATED?

Testing Protocols

Virtually all of the published research on nootropics has been done in laboratory settings where various aspects of cognitive function have been tested using a wide array of validated psychological paradigms. Executive function is a collection of cognitive processes essential for higher order mental function.^{5,6} Two major aspects of executive function are working memory and cognitive control. Executive function is responsible for the maintenance of information in a short-term active state to guide task performance and inhibit irrelevant information or responses, respectively. Related executive abilities (i.e., planning, fluency, and reasoning) also have been the subject of published studies.⁵

Categories of Cognitive Enhancers

Cognition enhancers such as prescription stimulants influence primary psychological states, including arousal and alertness which affect cognitive operations.⁶ Some potential enhancers may act directly on cognitive operations (e.g., memory, attention) while others influence neural systems underlying long-term potentiation, which is critical for learning and memory consolidation.⁷ Conceptually, a third category affects integrated cognitive operations. Substances that target fast excitatory synaptic transmission mediated by glutamate receptors are of theoretical interest for the latter.⁷ Examples include substances activating subtypes of cholinergic nicotinic receptors or those that allosterically modulate glutamate receptors (so-called ampakines).^{8,9} Brain imaging in primates has shown that ampakines expand cortical networks activated by a complex task.¹⁰

PATTERNS OF USE

The nonmedical use of prescription drugs for cognitive enhancement has been extensively investigated (see below). International sales of non-prescription supplements exceed \$1 billion annually and are growing.¹¹ A subset of consumers and Internet-based purveyors appear to be highly engaged, but information on the use of specific products or a systematic analysis of individuals engaged in self-treatment with putative cognition enhancers is not available.

PRIMARY NOOTROPIC DRUGS AND COMPOUNDS OF INTEREST

Prescription Stimulants

Methylphenidate, dexmethylphenidate, and mixed amphetamine salts act in various ways to augment neurotransmission involving dopamine and/or norepinephrine, affecting cortical and subcortical systems that enable people to focus and flexibly deploy attention. They are FDA-approved to treat attention-deficit hyperactivity disorder. Recent systematic reviews have evaluated the putative cognitive effects of these drugs.¹²⁻¹⁷ Because of its role in executive function, the effects of these drugs on working memory have been extensively studied. The evidence concerning the effects of prescription stimulants on working memory is mixed and task-dependent. The preponderance of evidence indicates that effects on “learning” in normal individuals is limited to situations where testing involves delayed recall and recognition, suggesting effects on memory consolidation. Positive effects of prescription stimulants on attention, inhibition, and planning are more evident in subjects with lower than optimal baseline performance. The pattern of evidence also is mixed with respect to the effects of prescription stimulants on overall executive function. Prescription stimulants do not routinely improve more complex cognitive processing in normal individuals, and sometimes their use interferes. Accordingly, the cognitive effects of stimulants appear to be highly variable among individuals, are dose-dependent, and limited or modest at best.

Many adverse events are associated with prescription stimulants including the potential for substance misuse and dependence, exacerbation of other mental health and neurologic disorders including seizures, and elevated cardiovascular risks (i.e., blood pressure, cardiac arrhythmias, peripheral vasculopathies) and rarely sudden death.

Modafinil

Modafinil is a wakefulness promoting agent that is distinct from amphetamine derivatives in terms of its neurochemical effects and behavioral profile; its precise mechanism of action is not well established.^{18,19} In addition

to its wakefulness-promoting effects, modafinil produces psychoactive and euphoric effects, and some alterations in perception that are typical of central nervous system stimulants in humans. Modafinil is FDA-approved for the treatment of excessive daytime sleepiness in narcolepsy, shift work sleep disorder, and obstructive apnea/hypopnea syndrome. Although a substantial portion of the published literature on the effects of modafinil involves sleep-deprived subjects, recent reviews also have evaluated the cognitive effects of modafinil in otherwise healthy subjects.¹⁷⁻²² The cognitive effects of a related drug, armodafinil (R-modafinil; Neuvigil™), have not been well-studied in healthy individuals. A prodrug of modafinil (adrafinil) was an approved drug in France until 2011 and remains available via Internet-based sites. The cognitive effects of this agent have not been published, but because it is converted to modafinil in the body, its pharmacological profile is reported to resemble that of modafinil.

Modafinil consistently improves attention and vigilance in non-sleep deprived as well as sleep-deprived healthy individuals.¹⁷⁻²⁰ In particular, experiments have shown improvements in sustained attention and selective attention and motivation in a manner that “may make unappealing tasks more appealing.”²³ Such tasks therefore may be undertaken and completed more easily. The effects of modafinil on memory are less clear. Some studies report beneficial effects of modafinil on spatial and numeric working memory.²² However, a review of 31 randomized controlled studies reported no significant changes in memory.¹⁷ The cognitive effects of modafinil strongly depend on the individual baseline performance. Similar to methylphenidate, modafinil appears to positively affect low-performing individuals to a greater extent than high-performing individuals.

In placebo-controlled clinical trials, the most common adverse reactions ($\geq 5\%$) associated with the use of modafinil were headache, nausea, nervousness, rhinitis, diarrhea, back pain, anxiety, insomnia, dizziness, and dyspepsia.²⁴ Rarely the drug may cause serious skin rashes including Stevens-Johnson syndrome, psychiatric symptoms, and cardiovascular events.

Patterns of Prescription Stimulant Use Among Students. Many surveys have been conducted on the nonmedical use of prescription stimulants by high school and college age students. Evidence supports the view that American high school and college students (and their European counterparts) have embraced the nonmedical use of prescription stimulants, and some information exists on the demographics of students most likely to use prescription stimulants for cognitive enhancement. The source of these drugs is most commonly diversion from a peer who has a prescription. Among high school seniors, the lifetime prevalence of both medical and nonmedical use of prescription stimulants is 9.5%.²⁵ Based on large, self-administered, cross-sectional web-based surveys (N >26,000), the past year diversion and nonmedical use of prescription stimulants in college-age students increased from 5.4% in 2003 to 9.3% in 2013.²⁶ Most nonmedical users take prescription stimulants sporadically, with higher rates of use among Caucasians, fraternity/sorority members, and males, and at institutions with more competitive admissions criteria.²⁷ In one survey of medical students, 18% had used prescription stimulants at least once, with the first use usually occurring in college; approximately 11% reported use during medical school training.²⁸

Increases in the nonmedical use of prescription stimulants are concerning not only because of their potential for misuse, but also their association with other adverse events and behavioral consequences including depression, sleep deprivation, irritability, and headache.²⁶ Individuals who engage in patterns of nonmedical stimulant use are more likely to smoke, binge drink, use cocaine, and screen positive for substance use disorders.²⁹ In one study, nonmedical use of prescription stimulants for studying was associated with alcohol and cannabis use disorders, and academic decline.³⁰ College students who use stimulants for cognitive enhancement also display higher levels of trait impulsivity and novelty seeking, and lower levels of social reward dependence and cognitive empathy.

Motivations for Prescription Stimulant Use. Less sophisticated information is available on the reasons for use, especially for cognitive enhancement. Key national surveys on drug use (e.g., National Survey on Drug Use and Health; Monitoring the Future) do not seek information on the use of stimulants for cognitive enhancement, just “nonmedical” use. Reported motivations for stimulant use among students include increased wakefulness, alertness, energy, and increased motivation; improved concentration; and a perceived ability to better cope with memorizing and study.^{27,29} The peak periods of stimulant use are before tests, during certain high demand academic assignments, and during finals week.

OTHER PUTATIVE NOOTROPIC AGENTS

More than 130 (mostly nonprescription) putative nootropic agents are listed or described on various websites promoting their use.³¹⁻³³ In addition to prescription stimulants and wakefulness-promoting agents, other primary

categories are “racetams,” cholinergic derivatives/acetylcholinesterase inhibitors, botanical products sold as dietary supplements, ampakines, and various substances influencing the neurotransmitters dopamine, serotonin, or gamma-aminobutyric acid, as well as certain hormones, metabolic “enhancers,” neuroprotective agents, and nutrients. The most common categories of putative nootropic agents across websites are briefly discussed below.

Piracetam and Derivatives

More than 50 years have passed since the discovery of piracetam.³⁴ Piracetam and several chemical analogues (phenylpiracetam, pramiracetam, aniracetam, oxiracetam, etiracetam, nefiracetam, rolziracetam) are available in other countries or via the Internet. Many of these products are being marketed as dietary supplements. No generally accepted mechanism of action has emerged, but the “racetams” appear to modulate ion flux (e.g., Na^+ , Ca^{2+} , K^+) through various membrane channels or modify ion transport mechanisms; antioxidant and neuroprotective features also have been described.³⁴ Some racetams, in particular aniracetam, exhibit ampakine-like properties (see below). A newer agent marketed as an antiepileptic drug in the United States (levetiracetam) reduces the activity of negative modulators of GABA- and glycine-gated currents and partially inhibits N-type calcium currents in neuronal cells. Levetiracetam also binds to a synaptic vesicle protein, SV2A, thought to be involved in the regulation of neurotransmitter release.

Noocept (N-phenylacetyl-L-prolylglycine ethyl ester) is a dipeptide derivative of piracetam promoted and prescribed in Russia and neighboring countries as a nootropic. It is a prodrug for the endogenous peptide cycloprolylglycine. The registered brand name Noopept™ is trademarked by the manufacturer JSC LEKKO Pharmaceuticals. The compound is patented in both the United States and Russia. It is sold as a dietary supplement in the United States and as a prescription medication in other countries. It is sometimes grouped with the “racetams” because it shares some similarities. Much of the published literature is not in English and that literature was not evaluated.

The majority of the published literature on the “racetams” has been on their use in animal models or in patients with various conditions including cognitive or memory disorders, epilepsy and seizures, traumatic brain injury, neurodegenerative diseases, stroke/ischemia, and anxiety disorders.^{35,36} A Cochrane Review from 2001 concluded evidence was insufficient to support the view that piracetam improves cognitive impairment or dementia.³⁷ The cognitive effects of the “racetams” have not been studied in a controlled fashion in normal healthy individuals.

Cholinergic Derivatives

The most popular agents in this category include choline, α -glycerophosphatidyl choline, centrophenoxine (meclofenoxate), 5'-cytidine diphosphate choline (citicholine), and acetyl-L-carnitine. These products are being marketed and sold as dietary supplement products in retail stores and on the Internet. These substances have been studied based on the view that boosting cholinergic function improves memory and cognition because loss of cholinergic pathways is predominant in the early stages of Alzheimer’s disease. Citicholine is a precursor in the synthesis of phosphatidylcholine, a cell membrane component that may be degraded during cerebral ischemia/hypoxia. Acetyl-L-carnitine has some activity at cholinergic neurons, stabilizes neuronal membranes, and enhances mitochondrial function. Many studies have evaluated the effects of cholinergic agents in animal models of dementia, and they have been used in various disease states associated with cognitive impairment.^{38,39} The potential for acute cognitive enhancing effects in normal individuals also has been examined, but only in a limited manner.^{38,40-42}

Botanical Products

Major putative botanical nootropics are *Ginkgo biloba*, *Panax ginseng*, *Bacopa monnieri* (brahimi), and *Centella asiatica* (gotu kola). One systemic review and one meta-analysis of ginkgo concluded that it is not a cognition enhancer in normal healthy individuals.^{43,44} Similarly, a Cochrane review on ginseng concluded that this substance does not enhance cognition in healthy participants.⁴⁵ *Bacopa monnieri* is a traditional Ayurvedic herb used to “sharpen intellect and attenuate mental deficits.”⁴⁶ An analysis of six randomized controlled trials of 12 weeks duration suggested that daily administration of *Bacopa monnieri* may improve free memory recall but no other aspects of cognitive performance.⁴⁷ A meta-analysis of randomized controlled trials indicated that chronic treatment with *Bacopa monnieri* improved speed of attention and decision reaction time, but further large scale studies are required to confirm significant cognitive effects.⁴⁸ Recent single dose studies of this botanical indicate some modest cognitive effects based on standard cognitive test batteries and multitasking performance measurements.^{49,50} Other

botanical compounds of interest include *Huperzia serrata*, which contains a substance (Huperzine A) that inhibits acetylcholinesterase, periwinkle extract (vinpocetine) and “sage oil” (*Salvia lavandulifolia*). All of these botanical substances are readily available for purchase in retail stores or on the Internet. They can be purchased as single substances or as components of complex blends.

Ampakines

The α -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid receptor (also known as the AMPA receptor) is a non-NMDA-type ionotropic transmembrane receptor for glutamate that mediates fast synaptic transmission in the central nervous system. Its name is derived from its ability to be activated by the artificial glutamate analog AMPA. Glutamate is the most common excitatory neurotransmitter in the mammalian central nervous system. Ampakines are currently being investigated as potential treatments for a range of conditions involving mental disability and pathologies such as Alzheimer’s disease, Parkinson’s disease, schizophrenia, treatment-resistant depression and ADHD. Many synthetic AMPA receptor agonists are available via chemical supply companies. Interest in these compounds is prompted by the role played by NMDA receptors in synaptic plasticity and long term potentiation, a neurobiological mechanism fundamental to long term memory formation. Aniracetam (N-anisoyl-2-pyrrolidinone) is one of the parent compounds in the ampakine class; it is available for purchase in dietary supplement formulations. Sunifiram (1-benzoyl-4-propanoylpiperazine) is another ampakine-like substance available online. None of these compounds has been formally studied for cognitive effects in otherwise healthy patients.

COMBINATIONS

Even though high quality evidence is lacking to establish persistent nootropic effects for most of the substances discussed above, Internet purveyors and discussion boards commonly discuss the concept of “stacking” nootropics for use, either by purchase of pre-formulated combinations or providing instructions on building your own stacks. Users are commonly instructed to select a racetam, choose a choline supplement, and then add a natural or herbal nootropic to the mix. No controlled data are available on the efficacy or safety of this practice, only testimonials and blogs from satisfied customers. The Appendix lists four such formulations and their ingredients. With few exceptions,⁵¹ none of these formulations has been subjected to randomized controlled studies.

ETHICAL CONCERNS

The ethics of pharmacological cognitive enhancement has been extensively debated in the academic literature and by several national ethics advisory bodies including the U.S. President’s Council on Bioethics.⁵²⁻⁵⁴ Some issues include whether the safety profile of nootropics justifies restricting (or permitting) their elective use, and whether individuals could be coerced into using nootropics by explicit/implicit pressures in order to compete at school or the workplace. Additionally, does unequal access to nootropics have implications for distributive justice, and does their use constitute cheating in competitive contexts? Some colleges have established policies that the nonmedical use of prescription stimulants constitutes cheating in the academic environment. A full discussion of the ethical issues is beyond the scope of this report and the attached policy recommendation is based on lack of evidence of safety and efficacy.

GUIDANCE FOR PHYSICIANS ON PRESCRIBING NOOTROPICS

The American Academy of Neurology has developed guidance for responding to requests from adult patients for “neuroenhancement” medications. The guidance denotes the concept that “the medical principles for prescribing medications (to normal adult patients) for neuroenhancement are identical to those for prescribing medications to treat medical conditions.”⁵⁵ The adoption of this guidance has been opposed, with some emphasis placed on the fact that off-label use of prescription stimulants for cognitive enhancement is inadvisable for a number of reasons.^{56,57} High-level concerns include meeting regulatory standards for prescribing controlled substances and the high potential for misuse of these substances.^{56,57} Limited analysis of physician prescribing of methylphenidate for cognitive enhancement suggests that physicians place greater weight on safety concerns than on “benefits” when considering whether to offer pharmacological cognitive enhancement.⁵⁸

CONCLUSIONS

Existing evidence suggests that putative nootropics are used by otherwise healthy individuals to pursue a competitive advantage at school or work, to maintain levels of attention and performance when sleep-deprived, and to improve task-related motivation. Experimental studies of cognitive effects are based on laboratory evaluations using standardized psychometric measures. It is uncertain how these findings translate to activities of daily living. Prescription stimulants and wakefulness-promoting agents are commonly used off-label by students and others. Such use is associated with a variety of adverse mental health conditions and patterns of substance misuse. Only a limited amount of information is available on the patterns of use of nonprescription substances used for cognitive enhancement, and their safety and efficacy have not been systematically examined. Evaluation of these issues is complicated by availability of a multitude of proprietary blends and by the fact that individuals create their own combinations. The recommendation to oppose the prescribing of stimulants and modafinil for cognitive enhancement is based on the increase in nonmedical use which has occurred over the last decade, the harms attributable to such use, and a need for physicians to comport with the requirements of the Controlled Substances Act which holds that a “prescription for a controlled substance must be issued for a legitimate medical purpose in the usual course of practice.”

RECOMMENDATIONS

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

1. That our American Medical Association (AMA): (a) opposes the prescription of controlled substances, including stimulants and wakefulness-promoting agents, for the purpose of cognitive enhancement in otherwise normal, healthy individuals; and (b) discourages the nonmedical use of prescription drugs, including stimulants and wakefulness-promoting agents for cognitive enhancement at all levels of education and in the workplace.
2. That our AMA encourages continued research into the risks and benefits of drugs and other substances for improving function in patients undergoing cognitive decline or who are experiencing cognitive impairment.
3. That our AMA encourages more research into the patterns of use, as well as risks and benefits, of dietary supplements (including herbal remedies) being promoted for cognitive enhancement.
4. That our AMA urge the Federal Trade Commission to examine advertisements for dietary supplements and herbal remedies that claim cognitive enhancement to ensure that they are truthful and not misleading, and are substantiated.
5. That AMA Policy D-100.969, “Increasing Awareness of Nootropic Use” be rescinded.

REFERENCES

1. Lanni C, Lenzken SC, Pascale A, et al. Cognition enhancers between treating and doping the mind. *Pharmacol Res.* 2008;57(3):196-213.
2. Kennedy D. Just treat, or enhance? *Science.* 2004;304:17.
3. Dean W, Morganthaler J. *Smart Drugs & Nutrients: How to Improve Your Memory and Increase Your Intelligence Using the Latest Discoveries in Neuroscience.* January 1, 1991.
4. Aprtiridge BJ, Bell SK, Lucke JC, Yeates S, Hall WD. Smart drugs “as common as coffee”: Media hype about neuroenhancement. 2011. *PLoS ONE* 6(11):e28416. doi:10.1371/journal.pone.0028416.
5. Smith ME, Farah MJ. Are prescription stimulants “smart pills”? *Psychol Bull.* 2011;137(5):717-741. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3591814/pdf/nihms442605.pdf>. Accessed April 26, 2016.
6. Logue SF, Gould TJ. The neural and genetic basis of executive function: attention, cognitive flexibility, and response inhibition. *Pharmacol Biochem Behav.* 2014;August:45-54. doi:10.1016/j.pbb.2013.08.007.
7. Lynch G, Palmer LC, Gall CM. The likelihood of cognitive enhancement. *Pharmacol Biochem Behav.* 2011;99(2):116-129.
8. Wezenberg E, Verkes RJ, Ruigt GS, Hulstijn W, Sabbe BG. Acute effects of an ampakine faramator on memory and information processing in healthy elderly subjects. *Neuropsychopharmacology.* 2007;32:1272-83.
9. Loughhead J, Ray R, Wiley E, et al. Effects of the alpha⁴beta² partial agonist varenicline on brain activity and working memory in abstinent smokers. *Biol Psychiatry.* 2010;67:7115-21.
10. Facilitation of task performance and removal of the effects of sleep deprivation by an ampakine (CX717) in nonhuman primates. Porrino LJ, Daunais JB, Rogers GA, Hampson RE, Deadwyler SA. *PLoS Biol.* 2005 Sep;3(9):e299.
11. Chinthapalli K. The billion dollar business of being smart. *BMJ.* 2015;351:4829.

12. Wood S, Sage JR, Shuman T. Psychostimulants and cognition: A continuum of behavioral and cognitive activation. *Pharmacol Rev.* 2013;66:193-221.
13. Ilieva IP, Hook CJ, Farah MJ. Prescription stimulants' effects on health inhibitory control, working memory, and episodic memory: A meta-analysis. *J Cognitiv Neurosci.* 2015;27(6):1069-89.
14. Bagot KS, Kaminer. Efficacy of stimulants for cognitive enhancement in non-attention deficit hyperactivity disorder youth: a systematic review. *Addiction.* 2014;109(4):547-57.
15. Linssen AM, Sambeth A, Vuurman EF, Riedel WJ. Cognitive effects of methylphenidate in healthy volunteers: a review of single dose studies. *Int J Neuropsychopharmacol.* 2014;17(6):961-77.
16. Sahakian BJ, Bruhl AB, Cook J, et al. The impact of neuroscience on society: cognitive enhancement in neuropsychiatric disorders and in healthy people. *Phil Trans R Soc B.* 370:20140214. <http://dx.doi.org/10.1098/rstb.2014.0214>. Accessed April 16, 2016.
17. Repantis D, Schlattmann P, Laaisney O, Heuser I. Modafinil and methylphenidate for neuroenhancement in healthy individuals: a systematic review. *Pharmacol Res.* 2010 Sep;62(3):187-206.
18. Minzenberg MJ, Carter CS. Modafinil: A review of neurochemical actions and effects on cognition. *Neuropsychopharmacol.* 2008;33:1477-1502.
19. Rasetti R, Mattay VS, Stankevich B, et al. Modulatory effects of modafinil on neural circuits regulating emotion and cognition. *Neuropsychopharmacol.* 2010;35:2101-09.
20. Mereu M, Bonci A, Newman AH, Tanda G. The neurobiology of modafinil as an enhancer of cognitive performance and a potential treatment for substance use disorders. *Psychopharmacol.* 2013;229(3):415-34.
21. Battleday RM, Brem AK. Modafinil for cognitive neuroenhancement in healthy non-sleep-deprived subjects: A systematic review. *Eur Neuropsychopharmacol.* 2015;25(11):1865-81.
22. Caviola L, Faber NS. Pills or push-up? Effectiveness and public perception of pharmacological and non-pharmacological cognitive enhancement. *Frontiers in Psychology.* 2015;6:1852. doi: 10.3389/fpsyg.2015.01852.
23. Package insert. Modafinil. <https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=modafinil>. Accessed May 2, 2016.
24. Muller U, Rowe JB, Rittman T, et al. Effects of modafinil on non-verbal recognition, task enjoyment and creative thinking in healthy volunteers. *Neuropharmacology.* 2013;64:4990-5.
25. McCabe SE, West BT. Medical and nonmedical use of prescription stimulants: results from a national multicohort study. *J Am Acad Child Adolesc Psychiatry.* 2013;52(12):1272-80.
26. McCabe SE, West BT, Teter CJ, Boyd CJ. Trends in medical use, diversion, and nonmedical use of prescription medication among college student from 2003 to 2013: Connecting the dots. *Addict Behav.* 2014;39(7):1176-82.
27. Weyandt LL, Marraccini ME, Gyda B, et al. Misuse of prescription stimulants among college students: a review of the literature and implications for morphological and cognitive effects on brain functioning. *Exp Clin Pharmacol.* 2013;21(5):385-407.
28. Emanuel RM, Frellsen SL, Kashima KJ, et al. Cognitive enhancement drug use among future physicians: Findings from a multi-institutional census of medical students. *J Gen Intern Med.* 2012;28(8):1028-34.
29. Sepulveda DR, Thomas LM, McCabe SE, Cranford JA, Boyd CJ, Teter CJ. Misuse of prescribed stimulant medication for ADHD and associated patterns of substance use: preliminary analysis among college students. *J Pharm Pract.* 2011;24(6):551-60.
30. Arria AM, Wilcox HC, Caldeira KM, et al. Dispelling the myth of "smart drugs": Cannabis and alcohol use problems predict nonmedical use of prescription stimulants for studying. *Addictive Behaviors.* 2013;38(3):1643-50.
31. Mental Health Daily. Mental Health Blog. <http://mentalhealthdaily.com/2014/11/26/extensive-list-of-nootropics-130-smart-drugs/>. Accessed May 3, 2016.
32. pureNootropic. <http://purenootropic.com>. Accessed May 3, 2016.
33. Nootriment. <http://nootriment.com/samrt-drugs/>. Accessed May 3, 2016.
34. Gouliaev AH, Senning A. Piracetam and other structurally related nootropics. *Brain Res Brain Res Rev.* 1994;19:180-222.
35. Winblad B. Piracetam: A review of pharmacological properties and clinical uses. *CNS Drug Reviews.* 2005;11(2):169-82.
36. Malykh AG, Sadaie MR. *Drugs.* 2010;70(3):287-312.
37. Flicker L, Grimley Evans G. Piracetam for dementia or cognitive impairment. *Cochrane Database Syst Rev.* 2001;(2)CD001011.
38. Leermakers ET, Moreira EM, Kieft-de Jong JC. Effects of choline on health across the life course: a systematic review. *Nutr Rev.* 2015;73(8):500-22.
39. Gareri P, Castagna A, Cotreneo AM, Putignano S, DeSarro G, Bruni AC. The role of citicoline in cognitive impairment: pharmacological characteristics, possible advantages, and doubts for an old drug with new perspectives. *Clin Intervention Aging.* 2015;10:1421-1429.
40. Bruce SE, Werner KB, Preston BF, Baker LM. Improvements in concentration, working memory and sustained attention following consumption of a natural citicoline-caffeine beverage. *Int J Food Sci Nutr.* 2014;65(8):1003-7.
41. Knott V, Smith D, de la Salle S, et al. CDP-choline: effects of the procholine supplement on sensory gating and executive function in healthy volunteers stratified for low, medium and high P50 suppression. *J Psychopharmacol.* 2014;28(12):1095-108.
42. [No author]. Citicholine. Alternative Medicine Review. 2008;13(1):50-57. <http://www.anaturalhealingcenter.com/documents/Thorne/monos/CiticolineMono13-1.pdf>. Accessed May 4, 2016.
43. Caner PH, Ernst E. Ginkgo biloba is not a smart drug: an updated systematic review of randomised clinical trials testing the nootropic effects of G. biloba extracts in healthy people. *Hum Psychopharmacol.* 2007;22(5):265-78.

44. Laws KR, Sweetnam H, Kondei TK. Is Ginkgo biloba a cognitive enhancer in healthy individuals? A meta-analysis. *Hum Psychopharmacol*. 2012;27(6):527-33.

45. Geng J, Dong J, Ni H et al. Ginseng for cognition. *Cochrane Database Syst Rev*. 2010;dec 8;(120:CD007769. Doi: 10.1002/14651858.CD007769.pub2

46. Aguiar S, Borowski T. Neuropharmacological review of the nootropic herb *Bacopa monnieri*. *Rejuvenation Res*. 2013;16:313-26.

47. Pase MP, Kean K, Sarris J, Neale C, Scholey AB, Stough C. The cognitive-enhancing effects of *Bacopa monnieri*. A systematic review of randomized controlled human clinical trials. *J Alternative Complem Med*. 2012;18(7):1-6.

48. Kongkeaw C, Dilokthornsakul, Thanarangsarit, Limpeanchob N, Scholfield CN. Meta-analysis of randomized controlled trial on cognitive effects of *Bacopa monnieri* extract. *J Ethnopharmacol*. 2014;151:528-35.

49. Benson S, Downey LA, Stough C, Wetherell M, Zangara A, Scholey A. An acute, double-blind, placebo-controlled cross-over study to 320 mg and 640 mg doses of *Bacopa monnieri* (CDRI-08) on multitasking stress reactivity and mood. *Phytother Res*. 2014;28(4):551-9.

50. Downey LA, Kean J, Nemeh F, et al. An acute, double-blind, placebo-controlled crossover study of 320 mg and 640 mg doses of a special extract of *Bacopa monnieri* (CDRI 08) on sustained cognitive performance. *Phytother Res*. 2013;27(9):1407-13.

51. Solomon TM, Leech J, deBros GB, et al. A randomized, double-blind, placebo controlled, parallel group, efficacy study of alpha BRAIN® administered orally. *Hum Psychopharmacol*. 2016;31(2):135-43.

52. President's Council on Bioethics. *Beyond Therapy*. 2003. Washington D.C: U.S. Government Printing Office.

53. Shaw D. Neuroenhancing public health. *J Med Ethics*. 2014;40(6):389-91.

54. Cakic V. Smart drugs for cognitive enhancement: ethical and pragmatic consideration in the year of cosmetic neurology. *J Med Ethics*. 2009;35(12):738.

55. Larriviere D, Williams MA, Rizzo M, Bonnie RJ on behalf of the AAN Ethics, Law and Humanities Committee. Responding to requests from adult patients for neuroenhancements. Guidance of the Ethics, Law and Humanities Committee. *Neurology*. 2009;73:1406-12.

56. Boot BP, Partridge B, Hall W. Better evidence for safety and efficacy is needed before neurologists prescribe drugs for neuroenhancement to healthy people. *Neurocase*. 2012;18(3):181-4.

57. Drabiak-Syed K. Reining in the pharmacological enhancement train: We should remain vigilant about regulatory standards for prescribing controlled substances. *J Law Med Ethics*. 2011;Summer:272-78.

58. Ponnet K, Wouters E, Van Hal G, Heinman W, Walrave M. Determinants of physicians' prescribing behavior of methylphenidate for cognitive enhancement. *Psychol Health Med*. 2014;19(3):286-95.

Appendix - Ingredient list for selected nootropic formulation stacks

Alpha Brain®

Vitamin B6
L-tyrosine
L-theanine
L-leucine
Phosphatidylserine
L-alpha glycerylphosphorylcholine,
Bacopa monniera extract
Uncaria tomentosa extract
Avena sativa extract
Huperzia serrata extract
Vinpocetine
Pterostilbene

Neurofuse®

Vitamin D3
Vitamin B6
Vitamin B12
Caffeine anhydrous
L-theanine
Choline bitartrate
Phosphatidyl serine
Alpha-lipoic acid
DMAE bitartrate
Rhodiola rosea extract
Vinpocetine
Huperzine A

NeuroEnhance™

Ginko biloba extract
Gingoxine
St. John's Wort extract
L-glutamine hydrochloride
Phosphatidylserine
Bacopa monnieri extract
Dimethylaminoethanol bitartrate
L-acetyl carnitine
Vinpocetine

OptiMind®

Tyrosine
Caffeine
Phosphatidylserine
Vinpocetine (from periwinkle)
Huperzine A (from *Huperzia*)
Bacoside A (from *Bacopa*)