REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports were presented by John T. Carlo, MD, Chair:

1. COUNCIL ON SCIENCE AND PUBLIC HEALTH SUNSET REVIEW OF 2015 HOUSE POLICIES

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED

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

1. As the House of Delegates adopts policies, a maximum 10-year time horizon shall exist. A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. Any action of our AMA House that reaffirms or amends an existing policy position shall reset the sunset "clock," making the reaffirmed or amended policy viable for another 10 years.

2. In the implementation and ongoing operation of our AMA policy sunset mechanism, the following procedures shall be followed: (a) Each year, the Speakers shall provide a list of policies that are subject to review under the policy sunset mechanism; (b) Such policies shall be assigned to the appropriate AMA councils for review; (c) Each AMA council that has been asked to review policies shall develop and submit a report to the House of Delegates identifying policies that are scheduled to sunset; (d) For each policy under review, the reviewing council can recommend one of the following actions: (i) retain the policy; (ii) sunset the policy; (iii) retain part of the policy; or (iv) reconcile the policy with more recent and like policy; (e) For each recommendation that it makes to retain a policy in any fashion, the reviewing council shall provide a succinct, but cogent justification (f) The Speakers shall determine the best way for the House of Delegates to handle the sunset reports.

3. Nothing in this policy shall prohibit a report to the HOD or resolution to sunset a policy earlier than its 10-year horizon if it is no longer relevant, has been superseded by a more current policy, or has been accomplished.

4. The AMA councils and the House of Delegates should conform to the following guidelines for sunset: (a) when a policy is no longer relevant or necessary; (b) when a policy or directive has been accomplished; or (c) when the policy or directive is part of an established AMA practice that is transparent to the House and codified elsewhere such as the AMA Bylaws or the AMA House of Delegates Reference Manual: Procedures, Policies and Practices.

5. The most recent policy shall be deemed to supersede contradictory past AMA policies.
6. Sunset policies will be retained in the AMA historical archives.

RECOMMENDATION

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

Fiscal Note: $1,000.

APPENDIX: RECOMMENDED ACTIONS

Policy Number	Title	Text	Recommendation
D-100.998	Combating Antibiotic Resistance Via Physician Action and Education: AMA Activities	Our AMA will continue to collaborate with the appropriate federal agencies, other medical specialty societies, and other appropriate public health organizations to address the urgent problem of increasing antimicrobial resistance and its impact on public health.	Retain, still relevant.
D-120.953	Treatment of Opioid Dependence	Our AMA will work to end the limitation of 100 patients per certified physician treating opioid dependence after the second year of treatment as currently mandated by the Drug Addiction Treatment Act.	Rescind. This requirement has been removed with the removal of the X-Waiver requirement.
D-120.975	Preserving Patients? Ability to Have Legally Valid Prescriptions Filled	Our AMA will: (1) work with state medical societies to support legislation to protect patients? ability to have legally valid prescriptions filled; (2) enter into discussions with relevant associations (including but not limited to the American Hospital Association, American Pharmacists Association, American Society of Health System Pharmacists, National Association of Chain Drug Stores, and National Community Pharmacists Association) to guarantee that, if an individual pharmacist exercises a conscientious refusal to dispense a legal prescription, a patient's right to obtain legal prescriptions will be protected by immediate referral to an appropriate dispensing pharmacy; and (3) in the absence of all other remedies, work with state medical societies to adopt state legislation that will allow physicians to dispense medication to their own patients when there is no pharmacist within a thirty-mile radius who is able and willing to dispense that medication.	Retain as amended. **Preserving Patients'~~?~~ Ability to Have Legally Valid Prescriptions Filled** Our AMA will: (1) work with state medical societies to support legislation to protect patients'~~?~~ ability to have legally valid prescriptions filled; (2) ~~enter into discussions~~ work with relevant associations (including but not limited to the American Hospital Association, American Pharmacists Association, American Society of Health System Pharmacists, National Association of Chain Drug Stores, and National Community Pharmacists Association) to guarantee that, if an individual pharmacist exercises a conscientious refusal to dispense a legal prescription, a patient's right to obtain legal prescriptions will be protected by immediate referral to an appropriate dispensing pharmacy; and (3) in the absence of all other remedies, work with state medical societies to adopt state legislation that will allow physicians to dispense medication to their own patients when there is no

			pharmacist within a thirty-mile radius who is able and willing to dispense that medication.
D-120.979	DEA Regulations and the Ability of Physicians to Prescribe Controlled Medication Rationally, Safely, and Without Undue Threat of Prosecution	Our AMA supports ongoing constructive dialogue between the DEA and clinicians, including physicians, regarding a proper balance between the needs of patients for treatment and the needs of the government to provide oversight and regulation to minimize risks to public health and safety.	Retain, convert to H-policy.
D-130.966	Domestic Disaster Relief Funding	1. Our American Medical Association lobby Congress to a) reassess its policy for expedited release of funding to disaster areas; b) define areas of disaster with disproportionate indirect and direct consequences of disaster as "public health emergencies"; and c) explore a separate, less bureaucratic process for providing funding and resources to these areas in an effort to reduce morbidity and mortality post-disaster. 2. Our AMA will lobby actively for the recommendations outlined in the AMA/APHA Linkages Leadership Summit including: a) appropriate funding and protection of public health and health care systems as critical infrastructures for responding to day-to-day emergencies and mass causality events; b) full integration and interoperable public health and health care disaster preparedness and response systems at all government levels; c) adequate legal protection in a disaster for public health and healthcare responders and d) incorporation of disaster preparedness and response competency-based education and training in undergraduate, graduate, post-graduate, and continuing education programs.	Retain as amended to remove outdated language (i.e. there is now a statutory definition of "public health emergency" that is not aligned to this recommendation) and references (AMA/APHA Linkages Leadership Summit) and convert to an H-policy. 1. Our American Medical Association lobby Congress to ~~a)~~ reassess its policy for expedited release of funding to disaster areas as well as a~~; b) define areas of disaster with disproportionate indirect and direct consequences of disaster as "public health emergencies"; and c) explore a separate,~~ less bureaucratic process for providing funding and resources to these areas in an effort to reduce morbidity and mortality post-disaster. 2. Our AMA will lobby actively for ~~the recommendations outlined in the AMA/APHA Linkages Leadership Summit including~~: a) appropriate funding and protection of public health and health care systems as critical infrastructures for responding to day-to-day emergencies and mass causality events; b) full integration and interoperable public health and health care disaster preparedness and response systems at all government levels; c) adequate legal protection in a disaster for public health and

			healthcare responders and d) incorporation of disaster preparedness and response competency-based education and training in undergraduate, graduate, post-graduate, and continuing education programs.
D-130.972	All Hazards Disaster Preparedness and Response	Our AMA will work with: (1) subject matter experts at the national level to quickly produce a provider manual on state licensure and medical liability coverage for physicians during disasters; (2) appropriate medical, public health, disaster response and relief organizations to improve plans, protocols, and policies regarding the provision of health care in mass evacuation shelters; and (3) appropriate state and local organizations to develop templates for private practice/office continuity plans in CD-ROM or web-based format that can be stored in state medical association offices on a server in the event of a disaster.	Retain as amended to reflect completed directives and convert to an H-policy. Our AMA encourages ~~will work with: (1) subject matter experts at the national level to quickly produce the creation of a provider manual on state licensure and medical liability coverage for physicians during disasters; (2)~~ appropriate medical, public health, disaster response and relief organizations to improve plans, protocols, and policies regarding the provision of health care in mass evacuation shelters ~~and (3) appropriate state and local organizations to develop templates for private practice/office continuity plans in CD-ROM or web-based a format that can be stored in state medical association offices on a server in the event of a disaster~~.
D-135.971	Evaluation of Canadian Underground Nuclear Waste Repository	Our American Medical Association, along with state and county medical societies, will urge Congress, the President, and the Secretary of State to invoke the participation of the International Joint Commission to evaluate the proposed underground nuclear waste repository in Ontario, Canada, and similar facilities.	Retain, still relevant.
D-135.972	Support Reduction of Carbon Dioxide Emissions	Our AMA will (1) inform the President of the United States, the Administrator of the Environmental Protection Agency (EPA), and Congress that our American Medical Association supports the Administration's efforts to limit carbon dioxide emissions from power plants to protect public health; and (2) working with state medical societies, encourage state governors to support and comply with EPA regulations designed to limit carbon dioxide emissions from coal fired power plants.	Retain as amended to rescind the directive that has been accomplished and convert to an H-policy. Our AMA ~~will (1) inform the President of the United States, the Administrator of the Environmental Protection Agency (EPA), and Congress that our American Medical Association~~ support ~~the~~

			~~Administration's~~ efforts to limit carbon dioxide emissions from power plants to protect public health; and (2) ~~working with~~ in collaboration with state medical societies, encourages state governors to support and comply with EPA regulations designed to limit carbon dioxide emissions from coal fired power plants.
D-145.996	Preventing Firearm-Related Injury and Morbidity in Youth	Our American Medical Association will identify and support the distribution of firearm safety materials that are appropriate for the clinical setting.	Retain, still relevant.
D-170.994	School Health Mentoring Program	Our AMA (1) encourages the Centers for Disease Control and Prevention (CDC) and other appropriate federal agencies to support the development of school health mentoring programs for allopathic and osteopathic volunteer physicians to work with teachers to educate children in grades K through 4 on the importance of good health habits; and (2) will work in collaboration with the Federation to lobby the US Congress for funds to teach early childhood health education in schools.	Retain, still relevant.
D-30.995	Increasing Taxes on Alcoholic Beverages	Our AMA will: (1) support increases in federal taxes on beer, wine, and liquor, with a substantial portion of the new revenues to be earmarked to the prevention of alcohol abuse and drunken driving, treatment of persons with alcohol use disorders or at-risk drinking patterns, and public health and medical programs that serve vulnerable populations; (2) encourage state and local increases in taxes on beer, wine, and liquor, with a substantial portion of the new revenues to be earmarked to the purposes noted above; (3) support, to the extent possible, state and local efforts to increase taxes on beer, wine, and liquor; (4) collaborate with other national organizations with an interest in this subject, including national medical specialty societies, the American Public Health Association, the Center for Science in the Public Interest, Mothers Against Drunk Driving, and the AMA Alliance; and (5) when state legislative efforts to increase alcohol taxes are stymied, encourage state medical societies to give consideration to the use of ballot initiatives in the states that allow such initiatives.	Retain as amended to update language and convert to an H-policy. Our AMA ~~will~~: (1) supports increases in federal taxes on beer, wine, and liquor, with a substantial portion of the new revenues to be earmarked to the prevention of alcohol misuse ~~abuse~~ and ~~drunken~~ driving while intoxicated, treatment of persons with alcohol use disorders or at-risk drinking patterns, and public health and medical programs that serve vulnerable populations; (2) encourages state and local increases in taxes on beer, wine, and liquor, with a substantial portion of the new revenues to be earmarked to the purposes noted above; (3) supports, to the extent possible, state and local efforts to increase taxes on beer, wine, and liquor; (4) supports collaboration ~~collaborate~~ with other national organizations with an interest in this subject, including national medical specialty

			societies, the American Public Health Association, the Center for Science in the Public Interest, Mothers Against Drunk Driving, and the AMA Alliance; and (5) when state legislative efforts to increase alcohol taxes are stymied, encourages state medical societies to give consideration to the use of ballot initiatives in the states that allow such initiatives.
D-30.997	Eliminate Underage Alcohol Consumption	Our AMA will support evidence-based public health/environmental policies to curtail destructive and high-risk drinking.	Retain as amended to update language and convert to an H-policy. Our AMA ~~will~~ supports evidence-based public health ~~/~~ and ~~environmental~~ policies to curtail ~~destructive and~~ high-risk drinking.
D-350.985	Addressing Sexual Violence and Improving American Indian and Alaska Native Women's Health Outcomes	1. Our AMA advocates for mitigation of the critical issues of American Indian/Alaska Native women's health that place Native women at increased risk for sexual violence, and encourages allocation of sufficient resources to the clinics serving this population to facilitate health care delivery commensurate with the current epidemic of violence against Native women. 2. Our AMA will collaborate with the Indian Health Service, Centers for Disease Control and Prevention (CDC), Tribal authorities, community organizations, and other interested stakeholders to develop programs to educate physicians and other health care professionals about the legal and cultural contexts of their American Indian and Alaska Native female patients as well as the current epidemic of violence against Native women and the pursuant medical needs of this population. 3. Our AMA will collaborate with the Indian Health Service, CDC, Tribal authorities, and community organizations to obtain or develop appropriate American Indian and Alaska Native women's health materials for distribution to patients in the spirit of self-determination to improve responses to sexual violence and overall health outcomes.	Retain, still relevant.
D-440.931	Encourage Autism Society to Support Vaccinations	Our American Medical Association will work jointly with the American College of Physicians, American Academy of Pediatrics and American Academy of Family Physicians to encourage the Autism Society of America to display on their website that based on current scientific evidence, autism is not caused by vaccinations and encourage vaccinations to promote better health for all our population.	Rescind, this directive has been accomplished. Other existing AMA policies including H-440.830, "Education and Public Awareness on Vaccine Safety and Efficacy," recognize the substantial body of scientific evidence that has disproven a

			link between vaccines and autism.
D-440.932	Preventing Allergic Reactions in Food Service Establishments	Our American Medical Association will pursue federal legislation requiring restaurants and food establishments to: (1) include a notice in menus reminding customers to let the staff know of any food allergies; (2) educate their staff regarding common food allergens and the need to remind customers to inform wait staff of any allergies; and (3) identify menu items which contain any of the major food allergens identified by the FDA (in the Food Allergen Labeling and Consumer Protection Act of 2004) and which allergens the menu item contains.	Retain as amended and convert to H-policy. Our American Medical Association supports~~will pursue~~ federal legislation requiring restaurants and food establishments to: (1) include a notice in menus reminding customers to let the staff know of any food allergies; (2) educate their staff regarding common food allergens and the need to remind customers to inform wait staff of any allergies; and (3) identify menu items which contain any of the major food allergens identified by the FDA (in the Food Allergen Labeling and Consumer Protection Act of 2004) and which allergens the menu item contains.
D-440.944	Disease Transmission Via Foods: Public Health Disaster in Waiting	Our AMA: (1) publicly calls for enhancement of the protocols, authority, oversight and funding, as well as encourages public health leadership at the federal agencies charged with regulation of the food industry and maintenance of a safer food supply and will monitor the success of such efforts.	Retain, still relevant.
D-440.961	Establishment of a Network of State Immunization Registries	Our AMA will work with the Centers for Disease Control and Prevention, the Department of Health and Human Services, the Public Health Service and other interested organizations to develop a network of state-based immunization registries that meet a set of minimum standards and allow for access at a national level, while ensuring the protection of the patient-physician relationship.	Retain, still relevant.
D-45.998	Reducing the Risk of Flight-Associated Venous Thrombosis	Our AMA will continue to monitor research on developments concerning the relationship between air travel and venous thromboembolism and respond appropriately when more definitive results become available, and urges the Federal Aviation Administration and individual airlines to provide more comprehensive educational modalities detailing DVT prevention for all long-duration domestic and international airline flights.	Retain, still relevant.
D-460.980	Scientific Integrity	Our AMA advocates the federal government should rely on sound medical science in formulating public health policies.	Retain, still relevant.
D-510.994	Health Care for Veterans and Their Families	Our AMA will: (1) work with all appropriate medical societies, the AMA National Advisory Council on Violence and Abuse, and government entities to assist	Rescind. The AMA National Advisory Council on Violence and Abuse no longer exists

		with the implementation of all recommendations put forth by the President's Commission on Care for America's Wounded Warriors; and (2) advocate for improved access to medical care in the civilian sector for returning military personnel when their needs are not being met by resources locally available through the Department of Defense or the Veterans Administration.	and specific elements of the policy, such as expansion of insurance benefits, recruitment of clinical staff, and support of PTSD and/or TBI research, are captured in other existing AMA policies, such as H-510.985, "Access to Health Care for Veterans," H-510.986, "Ensuring Access to Safe and Quality Care for our Veterans," D-510.990, "Fixing the VA Physician Shortage with Physicians," and H-510.988, "Supporting Awareness of Stress Disorders in Military Members and Their Families."
D-65.995	Health Disparities Among ~~Gay, Lesbian, Bisexual, Transgender and Queer~~ LGBTQ+ Families	Our AMA supports reducing the health disparities suffered because of unequal treatment of minor children and same sex parents in same sex households by supporting equality in laws affecting health care of members in same sex partner households and their dependent children.	Retain as amended to update language, convert to H-policy. Our AMA supports reducing the health disparities suffered because of unequal treatment of minor children and ~~same sex parents in same sex households~~ their parents in LGBTQ+ households by supporting equality in laws affecting health care of ~~members~~ LGBTQ+ families ~~in same sex partner households and their dependent children~~.
H-10.962	Encouraging Protocols to Assist with the Management of Patients with Obesity During Positioning and Transportation	Our American Medical Association encourages health care professionals to learn about techniques and devices to prevent potential injury and to provide safe and effective care for patients with obesity.	Retain, still relevant.
H-10.986	Use of Non-Toxic Aversive Additives	The AMA (1) in conjunction with other professional organizations, encourages individual manufacturers to consider adding non-toxic aversive products to either existent or newly introduced formulations when such have been deemed as having significant toxic potentials in order to provide safety in poison prevention; (2) believes that such actions should be publicized as intended to augment, but in no way replace, other poison prevention programs such as child-resistant containers, appropriate packaging and labeling, parental education, etc; and (3) supports continuing efforts by the household products and drug industries to identify methods of reducing the incidence of accidental poisonings.	Retain, still relevant.

H-100.952	Enhancing Antibiotic Stewardship in the Human Health Care Setting to Improve Patient Outcomes	Our AMA will: (1) support antimicrobial stewardship programs, overseen by qualified physicians, as an effective way to ensure appropriate antibiotic use to reduce the burden of antimicrobial resistance, to improve patient outcomes, and to reduce overall costs for health care facilities and systems. Antibiotic stewardship programs are systematic, multi-faceted, patient safety programs, and use evidence-based approaches to optimize antibiotic prescribing, encompassing components such as policy, guidelines, surveillance, education, epidemiology, process, and outcome measurement. Successful antibiotic stewardship programs monitor and direct antimicrobial use, providing a standard, evidence-based approach to judicious antibiotic use across the spectrum of care, including, but not limited to acute care hospitals, outpatient clinics, emergency departments and long-term care facilities; (2) support the development of antibiotic stewardship programs that allow flexibility so that adherence to national requirements does not limit the ability of providers to design programs based on local variables, such as health care facility size, patient population served, and care delivery setting (e.g., outpatient v. inpatient) and to address local antimicrobial stewardship and infection prevention challenges; (3) urge each health care facility's governing body to promote and support robust, physician-led antimicrobial stewardship and infection prevention programs as critical components of assuring safe patient care; and (4) support continued research into the impact of antibiotic stewardship programs on process outcomes and encourage increased research on the impact of such programs on patient-centered outcomes.	Retain, still relevant.
H-100.953	Establishment of Limited Population Antibacterial Drug Approval Pathway	1. Our AMA supports establishment of the Limited Population Antibacterial Drug (LAPD) mechanism to provide a predictable and feasible Food and Drug Administration approval pathway for pharmaceutical companies seeking to develop antibacterial drugs to treat serious and life-threatening infections where there is a lack of sufficient or satisfactory therapeutic options through legislative or regulatory means. 2. Should the LPAD be established, our AMA shall work with the Infectious Diseases Society of America, other medical societies, and the health care community to educate providers about LPAD products, including their benefits and risks.	Retain as amended with a change in title with recognition that LPAD has been established. ~~Establishment of~~ Limited Population Antibacterial Drug Approval Pathway 1. Our AMA supports ~~establishment of~~ the Limited Population Antibacterial Drug LPAD ~~LAPD~~) mechanism ~~to~~ which provides a predictable and feasible Food and Drug Administration approval pathway for pharmaceutical companies seeking to develop antibacterial drugs to treat serious and life-threatening infections where there is a lack of sufficient or satisfactory therapeutic options through

			legislative or regulatory means. 2. ~~Should the LPAD be established, our~~ Our AMA shall work with the Infectious Diseases Society of America, other medical societies, and the health care community to educate providers about LPAD products, including their benefits and risks.
H-100.960	The 10 x '20 Initiative (10 New Antibiotics by 2020)	Our AMA: (1) supports efforts to educate physicians, the Administration, Congress, and the public about the problem of antimicrobial resistance and the lack of new antibiotics in the drug development pipeline; and (2) endorses the 10 x '20 Initiative (10 new antibiotics by 2020) and supports efforts to bring together experts from the industrial, medical, scientific, policy, regulatory, and financial communities to determine and adopt the right combination of incentives needed to create a sustainable antibiotic research and development enterprise.	Retain as amended with a change in title. ~~The 10 x '20 Initiative (10~~ Incentivizing New Antibiotics ~~by 2020)~~ Our AMA: (1) supports efforts to educate physicians, the Administration, Congress, and the public about the problem of antimicrobial resistance and the lack of new antibiotics in the drug development pipeline; and (2) ~~endorses the 10 x '20 Initiative (10 new antibiotics by 2020) and~~ supports efforts to bring together experts from the industrial, medical, scientific, policy, regulatory, and financial communities to determine and adopt the right combination of incentives needed to create a sustainable antibiotic research and development enterprise.
H-100.971	Preserving the Doctor-Patient Relationship	The AMA and interested physicians will continue to work with the Food and Drug Administration to prevent the unnecessary intrusion of the government and other regulatory bodies into the doctor-patient relationship, especially as it concerns the prescription of medication.	Retain, still relevant.
H-100.973	Combating Antimicrobial Resistance through Education	Our AMA: (1) encourages the federal government, the World Health Organization, the World Medical Association, and the International Federation of Pharmacists to promote more effective education concerning the appropriate use of antibiotics; (2) strongly urges physicians to educate their patients about their antimicrobial therapy, the importance of compliance with the prescribed regimen, and the problem of antimicrobial resistance; (3) will continue to educate physicians and	Retain as amended to update relevant language as the "International Federation of Pharmacists" is now the "International Pharmaceutical Federation." Our AMA: (1) encourages the federal government, the World Health Organization, the World Medical Association, and the International

		physicians-in-training about the appropriate prescribing of antimicrobial agents; (4) encourages the use of antibiotic resistance management programs; these education-based programs should be multidisciplinary and cooperative (i.e., including infectious disease physicians, infection-control specialists, microbiology laboratory personnel, and clinical pharmacists); and (5) encourages continued scientific research on the issue of antibiotic resistance.	Pharmaceutical Federation ~~of Pharmacists~~ to promote more effective education concerning the appropriate use of antibiotics; (2) strongly urges physicians to educate their patients about their antimicrobial therapy, the importance of compliance with the prescribed regimen, and the problem of antimicrobial resistance; (3) will continue to educate physicians and physicians-in-training about the appropriate prescribing of antimicrobial agents; (4) encourages the use of antimicrobial~~biotic~~ resistance management programs; these education-based programs should be multidisciplinary and cooperative (i.e., including infectious disease physicians, infection-control specialists, microbiology laboratory personnel, and clinical pharmacists); and (5) encourages continued scientific research on the issue of antimicrobial~~biotic~~ resistance.
H-115.967	Addressing Drug Overdose and Patient Compliance with Targeted Pharmaceutical Packaging Efforts	Our American Medical Association supports research into, and development of, novel and affordable pharmaceutical packaging for dispensed medications, as well as abuse deterrent formulations in attempts to increase ease of use, improve patient adherence, and decrease the potential for misuse and abuse of controlled substances.	Retain as amended to update language with a change in title. Addressing Drug Overdose and Patient Adherence ~~Compliance~~ with Targeted Pharmaceutical Packaging Efforts Our American Medical Association supports research into, and development of, novel and affordable pharmaceutical packaging for dispensed medications, as well as abuse deterrent formulations in attempts to increase ease of use, improve patient adherence, and decrease the potential for the

			misuse ~~and abuse~~ of controlled substances.
H-115.971	Safety and Efficacy of Selective Serotonin Reuptake Inhibitors (SSRIs) in Children and Adolescents	Our AMA recognizes that the current product labeling (package insert) of antidepressant drugs, including the Black Box warnings, is a precautionary statement intended to reinforce the need for careful monitoring of patients with depression and other psychiatric disorders during the initiation of treatment. This product labeling should not be interpreted in a way that would decrease access for patients who may benefit from these drugs.	Retain, still relevant.
H-115.983	Expiration Dates and Beyond-Use Dates of Prescription and Over-the-Counter Drug Products	Our AMA: (1) supports the inclusion of expiration dates on the containers/labels of prescription and over-the-counter drug products and recommends that expiration dates be determined by pharmaceutical manufacturers using scientifically based stability testing with subsequent approval by the Food and Drug Administration (FDA); (2) urges the pharmaceutical industry, in collaboration with purchasers, the FDA, and the United States Pharmacopeia (USP), to determine whether lengthening of expiration dates will provide clinical and/or economic benefits or risks for patients and, if this is the case, to conduct longer stability testing on their drug products; (3) urges the FDA to work with the pharmaceutical industry and the USP to develop a schedule for the review and re-evaluation of expiration dates of prescription and over-the-counter drug products; (4) recommends that pharmacists place a beyond-use date on the labeling of all prescription medications dispensed to patients, and that the beyond-use date be based on the recommendations in the most recent edition of the United States Pharmacopeia and National Formulary; and (5) encourages the USP, in collaboration with pharmaceutical manufacturers, pharmacy organizations, and the FDA, to continue to explore the development of appropriate stability tests for the determination of scientifically sound beyond-use dates for repackaged products.	Retain, still relevant.
H-115.994	Prescription Product Labeling	1. The official labeling should not be regarded as the sole standard of acceptable or accepted medical practice nor as a substitute for clinical judgment or experience nor as a limitation on usage of the drug in medical practice. The official labeling statements approved by the FDA establish the parameters governing advertising or promotion of the drug product. 2. Our AMA will advocate that the FDA work to establish a process whereby the official drug labeling can be updated in a more expeditious fashion when new evidence becomes available affecting the clinical use of prescription medications and that evidence-based standards or peer-reviewed medical literature can add to legacy information contained in official	Retain, still relevant.

		drug labeling statements to guide drug administration and usage.	
H-120.956	Internet Prescribing	Our AMA will: (1) support the use of the Internet as a mechanism to prescribe medications with appropriate safeguards to ensure that the standards for high quality medical care are fulfilled; (2) work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications; (3) work with the Federation of State Medical Boards and others in endorsing or developing model state legislation to establish limitations on Internet prescribing; (4) continue to work with the National Association of Boards of Pharmacy and support their "Verified Internet Pharmacy Practice Sites" program so that physicians and patients can easily identify legitimate Internet pharmacy practice sites; (5) work with federal and state regulatory bodies to close down Internet web sites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States; and (6) keep pace with changes in technology by continually updating standards of practice on the Internet.	Retain as amended to update language. The National Association of Boards of Pharmacy use a different term to describe their accreditation. Our AMA will: (1) support the use of the Internet as a mechanism to prescribe medications with appropriate safeguards to ensure that the standards for high quality medical care are fulfilled; (2) work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications; (3) work with the Federation of State Medical Boards and others in endorsing or developing model state legislation to establish limitations on Internet prescribing; (4) continue to work with the National Association of Boards of Pharmacy and support their digital pharmacy accreditation ~~"Verified Internet Pharmacy Practice Sites"~~ program so that physicians and patients can easily identify legitimate Internet pharmacy practice sites; (5) work with federal and state regulatory bodies to close down Internet web sites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States; and (6) keep pace with changes in technology by continually updating standards of practice on the Internet.
H-120.965	Medication Errors	The AMA reaffirms its long-standing supportive efforts to curtail the problems of medication errors;	Retain, still relevant.

		and encourages physicians to add a brief notation of purpose (e.g., for cough, for constipation) on prescriptions, where appropriate, to avoid confusion on the part of either the pharmacists or the patients.	
H-130.942	Development of a Federal Public Health Disaster Intervention Team	1. Our AMA supports government efforts to: (a) coordinate and integrate federal medical and public health disaster response entities such as the Medical Reserve Corps, National Disaster Medical System, Public Health Services Commissioned Corps (PHSCC), as well as state-to-state sponsored Emergency Management Compact Systems, to strengthen health system infrastructure and surge capacity for catastrophic disasters (Incidents of National Significance) as defined by the Department of Homeland Security's (DHS) National Response Plan (NRP); and (b) place all federal medical and public health disaster response assets (with the exception of the Department of Defense) under authority of the Secretary of the Department of Health and Human Services (DHHS) to prevent significant delays and ensure coordination during a catastrophic disaster (Incident of National Significance). 2. Our AMA, through its Center for Public Health Preparedness and Disaster Response, will work with the DHHS, PHSCC, DHS, and other relevant government agencies to provide comprehensive disaster education and training for all federal medical and public health employees and volunteers through the National Disaster Life Support and other appropriate programs. Such training should address the medical and mental health needs of all populations, including children, the elderly, and other vulnerable groups. 3. Our AMA, through its Center for Public Health Preparedness and Disaster Response, will monitor progress in strengthening federal disaster medical and public health response capacity for deployment anywhere in the nation on short notice, and report back as appropriate.	Retain as amended to remove reference to the AMA's Center for Public Health Preparedness & Disaster Response and related work, which has ended. 1. Our AMA supports government efforts to: (a) coordinate and integrate federal medical and public health disaster response entities such as the Medical Reserve Corps, National Disaster Medical System, Public Health Services Commissioned Corps (PHSCC), as well as state-to-state sponsored Emergency Management Compact Systems, to strengthen health system infrastructure and surge capacity for catastrophic disasters (Incidents of National Significance) as defined by the Department of Homeland Security's (DHS) National Response Plan (NRP); and (b) place all federal medical and public health disaster response assets (with the exception of the Department of Defense) under authority of the Secretary of the Department of Health and Human Services (DHHS) to prevent significant delays and ensure coordination during a catastrophic disaster (Incident of National Significance). ~~2. Our AMA, through its Center for Public Health Preparedness and Disaster Response, will work with the DHHS, PHSCC, DHS, and other relevant government agencies to provide comprehensive disaster education and training for all federal medical and public health employees and volunteers through the~~

			~~National Disaster Life Support and other appropriate programs. Such training should address the medical and mental health needs of all populations, including children, the elderly, and other vulnerable groups~~. ~~3~~ 2. Our AMA~~, through its Center for Public Health Preparedness and Disaster Response,~~ will monitor progress in strengthening federal disaster medical and public health response capacity for deployment anywhere in the nation on short notice, and report back as appropriate.
H-130.946	AMA Leadership in the Medical Response to Terrorism and Other Disasters	Our AMA: (1) Condemns terrorism in all its forms and provide leadership in coordinating efforts to improve the medical and public health response to terrorism and other disasters. (2) Will work collaboratively with the Federation in the development, dissemination, and evaluation of a national education and training initiative, called the National Disaster Life Support Program, to provide physicians, medical students, other health professionals, and other emergency responders with a fundamental understanding and working knowledge of their integrated roles and responsibilities in disaster management and response efforts. (3) Will join in working with the Department of Homeland Security, the Department of Health and Human Services, the Department of Defense, the Federal Emergency Management Agency, and other appropriate federal agencies; state, local, and medical specialty societies; other health care associations; and private foundations to (a) ensure adequate resources, supplies, and training to enhance the medical and public health response to terrorism and other disasters; (b) develop a comprehensive strategy to assure surge capacity to address mass casualty care; (c) implement communications strategies to inform health care professionals and the public about a terrorist attack or other major disaster, including local information on available medical and mental health services; (d) convene local and regional workshops to share "best practices" and "lessons learned" from disaster planning and response activities; (e) organize annual symposia to share new scientific knowledge and information for enhancing the medical and public health response to terrorism and other disasters; and (f) develop joint educational programs to enhance	Retain as amended to remove an initiative the AMA is no longer involved in. Our AMA: (1) Condemns terrorism in all its forms and provides leadership in coordinating efforts to improve the medical and public health response to terrorism and other disasters. (2) ~~Will work collaboratively with the Federation in the development, dissemination, and evaluation of a national education and training initiative, called the National Disaster Life Support Foundation Program,~~ supports efforts to provide physicians, medical students, other health professionals, and other emergency responders with a fundamental understanding and working knowledge of their integrated roles and responsibilities in disaster management and response efforts. (3) Will join in working with the Department of Homeland Security, the Department of Health and Human Services, the Department of Defense, the Federal Emergency

		clinical collaboration and increase physician knowledge of the diagnosis and treatment of depression, anxiety, and post traumatic stress disorders associated with exposure to disaster, tragedy, and trauma. (4) Believes all physicians should (a) be alert to the occurrence of unexplained illness and death in the community; (b) be knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations; (c) be knowledgeable of procedures used to collect patient information for surveillance as well as the rationale and procedures for reporting patients and patient information; (d) be familiar with the clinical manifestations, diagnostic techniques, isolation precautions, decontamination protocols, and chemotherapy/prophylaxis of chemical, biological, and radioactive agents likely to be used in a terrorist attack; (e) utilize appropriate procedures to prevent exposure to themselves and others; (f) prescribe treatment plans that may include management of psychological and physical trauma; (g) understand the essentials of risk communication so that they can communicate clearly and nonthreateningly with patients, their families, and the media about issues such as exposure risks and potential preventive measures (e.g., smallpox vaccination); and (h) understand the role of the public health, emergency medical services, emergency management, and incident management systems in disaster response and the individual health professional's role in these systems. (5) Believes that physicians and other health professionals who have direct involvement in a mass casualty event should be knowledgeable of public health interventions that must be considered following the onset of a disaster including: (a) quarantine and other movement restriction options; (b) mass immunization/chemoprophylaxis; (c) mass triage; (d) public education about preventing or reducing exposures; (e) environmental decontamination and sanitation; (f) public health laws; and (g) state and federal resources that contribute to emergency management and response at the local level. (6) Believes that physicians and other health professionals should be knowledgeable of ethical and legal issues and disaster response. These include: (a) their professional responsibility to treat victims (including those with potentially contagious conditions); (b) their rights and responsibilities to protect themselves from harm; (c) issues surrounding their responsibilities and rights as volunteers, and (d) associated liability issues.	Management Agency, and other appropriate federal agencies; state, local, and medical specialty societies; other health care associations; and private foundations to (a) ensure adequate resources, supplies, and training to enhance the medical and public health response to terrorism and other disasters; (b) develop a comprehensive strategy to assure surge capacity to address mass casualty care; (c) implement communications strategies to inform health care professionals and the public about a terrorist attack or other major disaster, including local information on available medical and mental health services; (d) convene local and regional workshops to share "best practices" and "lessons learned" from disaster planning and response activities; (e) organize annual symposia to share new scientific knowledge and information for enhancing the medical and public health response to terrorism and other disasters; and (f) develop joint educational programs to enhance clinical collaboration and increase physician knowledge of the diagnosis and treatment of depression, anxiety, and post traumatic stress disorders associated with exposure to disaster, tragedy, and trauma. (4) Believes all physicians should (a) be alert to the occurrence of unexplained illness and death in the community; (b) be knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations; (c) be knowledgeable of procedures used to collect patient information for

		(7) Believes physicians and medical societies should participate directly with state, local, and national public health, law enforcement, and emergency management authorities in developing and implementing disaster preparedness and response protocols in their communities, hospitals, and practices in preparation for terrorism and other disasters. (8) Urges Congress to appropriate funds to support research and development (a) to improve understanding of the epidemiology, pathogenesis, and treatment of diseases caused by potential bioweapon agents and the immune response to such agents; (b) for new and more effective vaccines, pharmaceuticals, and antidotes against biological and chemical weapons; (c) for enhancing the shelf life of existing vaccines, pharmaceuticals, and antidotes; and (d) for improving biological chemical, and radioactive agent detection and defense capabilities.	surveillance as well as the rationale and procedures for reporting patients and patient information; (d) be familiar with the clinical manifestations, diagnostic techniques, isolation precautions, decontamination protocols, and chemotherapy/prophylaxis of chemical, biological, and radioactive agents likely to be used in a terrorist attack; (e) utilize appropriate procedures to prevent exposure to themselves and others; (f) prescribe treatment plans that may include management of psychological and physical trauma; (g) understand the essentials of risk communication so that they can communicate clearly and nonthreateningly with patients, their families, and the media about issues such as exposure risks and potential preventive measures (e.g., smallpox vaccination); and (h) understand the role of the public health, emergency medical services, emergency management, and incident management systems in disaster response and the individual health professional's role in these systems. (5) Believes that physicians and other health professionals who have direct involvement in a mass casualty event should be knowledgeable of public health interventions that must be considered following the onset of a disaster including: (a) quarantine and other movement restriction options; (b) mass immunization/chemoprophylaxis; (c) mass triage; (d) public education about preventing or reducing exposures; (e) environmental decontamination and sanitation; (f) public health

			laws; and (g) state and federal resources that contribute to emergency management and response at the local level. (6) Believes that physicians and other health professionals should be knowledgeable of ethical and legal issues and disaster response. These include: (a) their professional responsibility to treat victims (including those with potentially contagious conditions); (b) their rights and responsibilities to protect themselves from harm; (c) issues surrounding their responsibilities and rights as volunteers, and (d) associated liability issues. (7) Believes physicians and medical societies should participate directly with state, local, and national public health, law enforcement, and emergency management authorities in developing and implementing disaster preparedness and response protocols in their communities, hospitals, and practices in preparation for terrorism and other disasters. (8) Urges Congress to appropriate funds to support research and development (a) to improve understanding of the epidemiology, pathogenesis, and treatment of diseases caused by potential bioweapon agents and the immune response to such agents; (b) for new and more effective vaccines, pharmaceuticals, and antidotes against biological and chemical weapons; (c) for enhancing the shelf life of existing vaccines, pharmaceuticals, and antidotes; and (d) for improving biological chemical, and radioactive

			agent detection and defense capabilities.
H-130.952	Community-Wide Training in Basic Life Support and First Aid	Our AMA: (1) encourages education in (a) basic life support and first aid, and (b) effective interventions for reducing and preventing injuries and coronary heart disease; (2) urges state and local medical societies to participate in the development and promotion of community programs for adults, children, businesses, community groups, and public servants to increase awareness of the potential benefits of training in basic life support and first aid and to increase public knowledge, confidence, and motivation for responding to serious, or potentially serious illness and injury situations; and (3) encourages physicians to discuss with their patients: (a) how to recognize and respond to emergency situations; (b) proper utilization and activation of the local EMS system; (c) measures for reducing or eliminating potential risk factors for injuries and coronary heart disease; and (d) the availability and appropriateness of community programs in basic life support and first aid.	Retain, still relevant.
H-135.929	Banning Plastic Microbeads in Personal Care Products	Our AMA supports local, state, and federal laws banning the sale and manufacture of personal care products containing plastic microbeads.	Retain, still relevant.
H-135.930	Protecting Public Health from Natural Gas Infrastructure	Our AMA recognizes the potential impact on human health associated with natural gas infrastructure and supports legislation that would require a comprehensive Health Impact Assessment regarding the health risks that may be associated with natural gas pipelines.	Retain, still relevant.
H-135.955	Human Health and the Protection of Biodiversity	The AMA urges physicians and other health care professionals and the public to become more aware of the importance of protecting biological diversity and its relationship to human health.	Retain, still relevant.
H-135.989	Low Level Radioactive Waste Disposal	The AMA (1) believes that each state should be responsible for providing capacity within or outside the state for disposal of commercial, non-military low level radioactive waste generated within its border; and (2) urges Environmental Protection Agency action to ensure capacity for disposal of low level radioactive waste.	Retain, still relevant.
H-145.974	Increasing Toy Gun Safety	Our American Medical Association (1) encourages toy gun manufacturers to take further steps beyond the addition of an orange tip on the gun to reduce the similarity of toy guns with real guns, and (2) encourages parents to increase their awareness of toy gun ownership risks.	Retain, still relevant.
H-15.949	Auto Heat Deaths	Our American Medical Association supports efforts to reduce deaths of children left in unattended vehicles.	Retain, still relevant.
H-15.960	Motor Vehicle and Bicycle Safety	The AMA supports legislation that would make safety belt non-use by any occupants in automobiles and other enclosed motor vehicles a "primary offense" in all states; supports extension of motorcycle helmet laws to include motorized vehicles such as mopeds,	Retain, still relevant.

		scooters and all-terrain vehicles, and to cover all age groups; and supports legislation that would require helmet usage for riders of bicycles, including passengers.	
H-15.988	Modification of Three-Point Shoulder Harness Seat Belt to Enable Use by Small Children	The AMA (1) recognizes the value of using appropriately designed three-point safety belt restraints to reduce auto-related injuries and fatalities; (2) supports auto industry modifications in restraints for safe use by children and small adults; and (3) supports the development of standards required for such modifications by appropriate authorities.	Retain, still relevant.
H-150.941	Banning the Use of Artificial Trans Fat in the United States	Our AMA supports state and federal legislation that bans the use of artificial trans fats in the United States.	Retain, still relevant.
H-150.947	Mercury and Fish Consumption: Medical and Public Health Issues	AMA policy is that: (1) Women who might become pregnant, are pregnant, or who are nursing should follow federal, state or local advisories on fish consumption. Because some types of fish are known to have much lower than average levels of methylmercury and can be safely consumed more often and in larger amounts, women should also seek specific consumption recommendations from those authorities regarding locally caught or sold fish. (2) Physicians should (a) assist in educating patients about the relative mercury content of fish and shellfish products; (b) make patients aware of the advice contained in both national and regional consumer fish consumption advisories; and (c) have sample materials available, or direct patients to where they can access information on national and regional fish consumption advisories. (3) Testing of the mercury content of fish should be continued by appropriate agencies; results should be publicly accessible and reported in a consumer-friendly format.	Retain, still relevant.
H-150.959	Risk of Transmission of Bovine Spongiform Encephalopathy to Humans in the United States	The AMA: (1) supports the current FDA guidance/regulations regarding the treatment of products from bovine sources destined for human utilization, and the treatment of blood products from potential Creutzfeld-Jakob disease (CJD) donors; (2) recommends the FDA and the United States Department of Agriculture (USDA) continue to aggressively enforce regulations in place to prevent the occurrence/transmission of bovine spongiform encephalopathy (BSE) in the United States; (3) recommends the FDA, USDA, and Department of Health and Human Services continue to evaluate scientific data on transmissible spongiform encephalopathies (TSEs) and incorporate this information into their guidance and regulations; (4) recommends increased surveillance of new CJD cases as they arise in order to monitor for the possible appearance of new variant Creutzfeldt-Jakob disease (nv-CJD) via: (a) Referral of all deaths due to suspected CJD to an appropriately qualified pathologist for autopsy, with the submission of autopsy reports of confirmed cases to the Prion Disease Pathology Surveillance Center at Case	The AMA: (1) supports the current FDA guidance/regulations regarding the treatment of products from bovine sources destined for human utilization, and the treatment of blood products from potential Creutzfeld-Jakob disease (CJD) donors; (2) recommends the FDA and the United States Department of Agriculture (USDA) continue to aggressively enforce regulations in place to prevent the occurrence/transmission of bovine spongiform encephalopathy (BSE) in the United States; (3) recommends the FDA, USDA, and Department of Health and Human Services continue to evaluate scientific data on

		Western Reserve University, which is collaborating with the CDC. (b) Reporting of the diagnosis of CJD on the death certificate in all cases and the strengthening of the current system enabling health authorities to obtain clinical or pathologic data on the CJD cases of greatest public health concern. (c) Prompt notification of any case of new variant Creutzfeldt-Jakob disease to both the appropriate state health department and the CDC; and (5) recommends that well-controlled research be performed in the following areas: (a) Elucidation of the mechanism of disease of TSEs; (b) Elucidation of the infectivity, dose requirements, and clearance of the disease agent to provide more data for adequate risk analyses of disease transmission; (c) The risk of transmission via blood and blood products; (d) Alternatives to the use of bovine-derived products in drug manufacture and other biologic industries; (e) Antemortem diagnosis of BSE and nv-CJD and the detection and inactivation of the disease agent in blood supplies.	transmissible spongiform encephalopathies (TSEs) and incorporate this information into their guidance and regulations; (4) recommends increased surveillance of new CJD cases as they arise in order to monitor for the possible appearance of new variant Creutzfeldt-Jakob disease (nv-CJD) via: (a) Referral of all deaths due to suspected CJD to an appropriately qualified pathologist for autopsy, with the submission of autopsy reports of confirmed cases to the National Prion Disease Pathology Surveillance Center at Case Western Reserve University, which is collaborating with the CDC. (b) Reporting of the diagnosis of CJD on the death certificate in all cases and the strengthening of the current system enabling health authorities to obtain clinical or pathologic data on the CJD cases of greatest public health concern. (c) Prompt notification of any case of new variant Creutzfeldt-Jakob disease to both the appropriate state health department and the CDC; and (5) recommends that well-controlled research be performed in the following areas: (a) Elucidation of the mechanism of disease of TSEs; (b) Elucidation of the infectivity, dose requirements, and clearance of the disease agent to provide more data for adequate risk analyses of disease transmission; (c) The risk of transmission via blood and blood products; (d) Alternatives to the use of bovine-derived products in drug manufacture and other biologic industries; (e) Antemortem diagnosis of BSE and nv-CJD and the detection and inactivation of the disease agent in blood supplies.

H-150.961	Irradiation of Food	It is the policy of the AMA to: (1) affirm food irradiation as a safe and effective process that increases the safety of food when applied according to governing regulations; and (2) consider the value of food irradiation to be diminished unless it is incorporated into a comprehensive food safety program based on good manufacturing practices and proper food handling, processing, storage, and preparation techniques.	Retain, still relevant.
H-150.980	Milk and Human Health	The AMA reaffirms its policy that all milk sold for human consumption should be required to be pasteurized.	Retain, still relevant.
H-170.964	Substance Use Education in Schools	Our AMA supports scientifically-based substance use education in schools.	Retain, still relevant.
H-170.980	Health Education	It is the policy of the AMA (1) to urge all state medical societies to urge their respective state departments of education to: implement model health education curricula, act as clearinghouses for data on curriculum development, work with local school districts to implement health education programs and to seek funding for these programs; and (2) that the health education programs contain provisions for educator training and development of local community health advisory committees.	Retain, as amended to update language. ~~It is the policy of~~ The AMA (1) ~~to~~ urges all state medical societies to ~~urge~~ advocate that their respective state departments of education ~~to:~~ implement model health education curricula, act as clearinghouses for data on curriculum development, work with local school districts to implement health education programs and to seek funding for these programs; and (2) that the health education programs contain provisions for educator training and development of local community health advisory committees.
H-170.988	Health Education Legislation	The AMA (1) reaffirms current policy which supports the establishment of a comprehensive health education program in the elementary and secondary schools; and (2) encourages state and specialty medical societies to consider the introduction of such model legislation in their state legislatures.	Retain, as amended to update language. The AMA (1) ~~reaffirms current policy which~~ supports the establishment of a comprehensive health education program in ~~the~~ elementary and secondary schools; and (2) encourages state and specialty medical societies to consider the introduction of such model legislation in their state legislatures.

H-170.989	Health Fairs	The AMA (1) urges that the emphasis of health fairs be primarily educational and informative; and (2) encourages the sponsors of health fairs and similar single-purpose screening programs to emphasize the importance of the establishment of a personal doctor-patient relationship.	Retain, still relevant.
H-175.997	Chelation Therapy	The AMA believes that chelation therapy for atherosclerosis is an experimental process without proven efficacy.	Retain, still relevant.
H-225.966	Medical Staff Role in the Development of Substance Abuse Policies and Procedures	1. Our AMA establishes the primacy of medical staff authority in substance abuse policy and procedures covering any pre-employment, credentialing, or other phases of physician evaluation. 2. Policy of the AMA states that medical staff must be involved in the development of the institution's substance abuse policy, including: (a) selection of analytical methods to ensure scientific validity of the test results, (b) determination of measures to maintain confidentiality of the test results, (c) in for-cause post-incident/injury testing, definition of standards for determining whether cause exists and which incidents and/or injuries will result in testing, and (d) development of mechanisms to address the physical and mental health of medical staff members. 3. The AMA believes all drug and alcohol testing must be performed only with substantive and procedural due process safeguards in place.	Retain as amended to update language. Medical Staff Role in the Development of Substance Misuse ~~Abuse~~ Policies and Procedures 1. Our AMA establishes the primacy of medical staff authority in substance misuse ~~abuse~~ policy and procedures covering any pre-employment, credentialing, or other phases of physician evaluation. 2. Policy of the AMA states that medical staff must be involved in the development of the institution's substance misuse ~~abuse~~ policy, including: (a) selection of analytical methods to ensure scientific validity of the test results, (b) determination of measures to maintain confidentiality of the test results, (c) in for-cause post-incident/injury testing, definition of standards for determining whether cause exists and which incidents and/or injuries will result in testing, and (d) development of mechanisms to address the physical and mental health of medical staff members. 3. The AMA believes all drug and alcohol testing must be performed only with substantive and procedural due process safeguards in place.
H-235.969	Responsibility for Infection Control	AMA policy states that: (1) the hospital medical staff should have a multidisciplinary committee to oversee the surveillance, prevention and control of infection; (2) the infection control committee should report to the hospital medical staff executive committee; and (3) the medical staff's role, responsibility and	Retain, still relevant.

		authority in the infection control activities should be included in the medical staff bylaws.	
H-25.988	Community-Based Falls Prevention Programs	Our American Medical Association will work with relevant organizations to support community-based falls prevention programs.	Retain, still relevant.
H-25.995	Exercise Programs for the Elderly	The AMA recommends that physicians: (1) stress the importance of exercise for older patients and explain its physiological and psychological benefits; (2) obtain a complete medical history and perform a physical examination that includes exercise testing for quantification of cardiovascular and physical fitness as appropriate, prior to the specific exercise prescription; (3) provide appropriate follow-up of patients' exercise programs; and (4) encourage all patients to establish a lifetime commitment to an exercise program.	Retain, still relevant.
H-295.879	Improving Sexual History Curriculum in the Medical School	Our AMA (1) encourages all medical schools to train medical students to be able to take a thorough and nonjudgmental sexual history in a manner that is sensitive to the personal attitudes and behaviors of patients in order to decrease anxiety and personal difficulty with sexual aspects of health care; and (2) supports public messaging that encourages patients to discuss concerns related to sexual health with their physician and reinforces its commitment to helping patients maintain sexual health and well-being.	Retain, still relevant.
H-30.939	Increasing Taxes on Alcoholic Beverages	It is AMA policy that federal, state, and local tax rates on alcoholic beverages be based on the grams of ethanol present in the beverage, not on the fluid volume of beverages such as beer, wine, and distilled spirits.	Retain, still relevant.
H-30.950	Alcoholism in the Elderly	It is the policy of the AMA to: (1) encourage medical educators to consider expanding instructional material on alcohol and aging at all levels of medical education, particularly in residency and/or postgraduate training; and (2) cooperate with other groups, such as the American Association of Retired Persons and appropriate government agencies, in public education programs for the elderly concerning alcohol-related problems.	Retain as amended to update language. ~~Alcoholism~~ Alcohol Use Disorder in Older Adults ~~the Elderly~~ ~~It is the policy of the~~ Our AMA ~~to~~: (1) encourages medical educators to ~~consider~~ expand~~ing~~ instructional material on alcohol and aging at all levels of medical education, particularly in residency and/or postgraduate training; and (2) cooperate with other groups, such as the American Association of Retired Persons and appropriate government agencies, in public education programs for ~~the elderly~~ older adults concerning alcohol-related problems.
H-365.991	NIOSH Cohort Mortality Studies	The AMA believes that physicians should (1) strive conscientiously to become familiar with the medical	Retain with change in title from “NIOSH Cohort

		fitness requirements, the environment and the hazards of the work done by those they serve, and with the health and safety aspects of the products and operations involved; (2) communicate information about health hazards in a timely and effective fashion to individuals or groups potentially affected, and make appropriate reports to the scientific community; and (3) communicate understandably to those they serve any significant observations about their health, recommending further study, counsel, or treatment when indicated.	Mortality Studies" to "Physicians and Occupational Health Hazards" to better reflect content of the policy.
H-373.993	Medication Adherence	Our AMA supports third parties in researching the effectiveness of personalized medication cards and other tools, including electronic reminders, intended to promote safe medication use, improve medication adherence, and improve health outcomes. Reminders should also be available in a variety of languages. Special attention should be devoted to reaching low literacy target audiences.	Retain, still relevant.
H-420.986	Maternal and Child Health Care	The AMA opposes any further decreases in funding levels for maternal and child health programs; encourages more efficient use of existing resources for maternal and child health programs; encourages the federal government to allocate additional resources for increased health planning and program evaluation within Maternal and Child Health Block Grants; and urges increased participation of physicians through advice and involvement in the implementation of block grants.	Retain, still relevant.
H-425.977	Encouraging Vision Screenings for Schoolchildren	Our AMA: (1) encourages and supports outreach efforts to provide vision screenings for school-age children prior to primary school enrollment; (2) encourages the development of programs to improve school readiness by detecting undiagnosed vision problems; and (3) supports periodic pediatric eye screenings based on evidence-based guidelines with referral to an ophthalmologist for a comprehensive professional evaluation as appropriate.	Retain, still relevant.
H-425.986	Challenges in Preventive Medicine	It is the policy of the AMA that (1) physicians should become familiar with and increase their utilization of clinical preventive services protocols; (2) individual physicians as well as organized medicine at all levels should increase communication and cooperation with and support of public health agencies. Physician leadership in advocating for a strong public health infrastructure is particularly important; (3) physicians should promote and offer to serve on local and state advisory boards; and (4) in concert with other groups, physicians should study local community needs, define appropriate public health objectives, and work toward achieving public health goals for the community.	Retain, still relevant.
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	Retain as amended to update language. Use of the Chokeholds and Carotid Restraints ~~Sleeper~~

		sleeper holds there should be timely medical surveillance of the inmate.	~~Hold~~ in ~~Prisons~~ in People who are Incarcerated The AMA (1) does not regard ~~the~~ chokeholds and ~~sleeper holds~~ carotid restraints 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 chokeholds and ~~sleeper holds~~ carotid restraints there should be timely medical surveillance of the ~~inmate~~ individual on which they were used.
H-440.827	Surveillance of Antibiotic Use and Resistance	Our AMA: (1) recognizes the importance of public health and veterinary health surveillance for antimicrobial resistance and antibiotic use; and (2) recommends that public health and veterinary health agencies be adequately funded, as outlined in the President's Council of Advisors on Science and Technology Report, to achieve the surveillance goals and objectives outlined in the National Action Plan for Combating Antibiotic Resistant Bacteria.	Retain as amended to update language. Our AMA: (1) recognizes the importance of public health and veterinary health surveillance for antimicrobial resistance and antibiotic use; and (2) recommends that public health and veterinary health agencies be adequately funded~~, as outlined in the President's Council of Advisors on Science and Technology Report,~~ to achieve the surveillance goals and objectives outlined in the National Action Plan for Combating Antibiotic Resistant Bacteria.
H-440.831	Protecting Patients and the Public Through Physician, Health Care Worker, and Caregiver Immunization	1. AMA policy is that, in the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues or threatens the availability of the health care workforce, particularly a disease that has the potential to become epidemic or pandemic, including influenza, and for which there is an available, safe, and effective vaccine, physicians, health care workers (HCWs), and family caregivers who have direct patient care responsibilities or potential direct exposure have an obligation to accept immunization unless there is a recognized medical reason to not be immunized. In scenarios in which there is a documented medical contraindication to immunization of a physician or HCW, appropriate protective measures should be taken. 2. Our AMA (a) encourages hospitals, health care systems, and health care providers to provide	Retain, still relevant.

		immunizations to HCWs against influenza and other highly transmissible diseases, at no cost to the employee, both for their own protection and to reduce the risk of infectious disease transmission to others; and (b) encourages health care institutions to develop mechanisms to maximize the rate of influenza immunization for HCWs, including the option of making immunization a condition of employment.	
H-440.833	Labeling and Recommended Protection for Sunglasses	Our American Medical Association recognizes, based on current evidence, that sunglasses that protect against 100% of both UVA and UVB radiation are currently the safest choice for consumers and recommends that manufacturers clearly label all sunglasses with the percentage of UVA and UVB radiation blocked so that consumers know the extent to which the glasses protect against both types of UV radiation.	Retain, still relevant.
H-440.834	Next Generation Infectious Diseases Diagnostics	1. Our American Medical Association supports strong federal efforts to stimulate early research and development of emerging rapid ID (infectious disease) diagnostic technologies through increased funding for appropriate agencies. 2. Our AMA supports the reduction of regulatory barriers to allow for safe and effective emerging rapid diagnostic tests, particularly those that address unmet medical needs, to more rapidly reach laboratories for use in patient care. 3. Our AMA supports improving the clinical integration of new diagnostic technologies into patient care through outcomes research that demonstrates the impact of diagnostics on patient care and outcomes, educational programs and clinical practice guidelines for health care providers on the appropriate use of diagnostics, and integration of diagnostic tests results into electronic medical records. 4. Our AMA supports efforts to overcome reimbursement barriers to ensure coverage of the cost of emerging diagnostics.	Retain, still relevant.
H-440.846	Antibiotic Use in Food-Producing Animals	Our AMA supports: (1) federal efforts to ban antibiotic use in food-producing animals for growth promotion purposes, including through regulatory and legislative measures; (2) a strong federal requirement that antibiotic prescriptions for animals be overseen by a veterinarian knowledgeable of the place and intended use of these drugs, under a valid veterinarian-client-patient relationship (VCPR); and (3) efforts to expand FDA surveillance and data collection of antibiotic use in agriculture.	Retain, still relevant.
H-440.851	Influenza Vaccine Availability and Distribution	Our AMA will: (1) continue efforts to communicate strongly to its partners involved in influenza vaccine production and distribution that physicians must receive influenza vaccines in a timely and equitable manner in order to help immunize all patients =6 months of age as recommended by the Center for	Retain as amended. Our AMA will: (1) continue efforts to communicate strongly to its partners involved in influenza vaccine

		Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP); (2) urge manufacturers and distributors of influenza vaccine to provide a dedicated ordering system for small- and medium-size medical practices to pre-order vaccine up to an appropriate volume threshold; (3) support federal actions to allow physicians (MDs and DOs) to form purchasing alliances to allow for competitive purchasing of influenza vaccine comparable to large purchasers currently supplying pharmacy and grocery chain stores with influenza vaccine; (4) communicate current ACIP recommendations on the influenza vaccine to physicians and assist the CDC in disseminating its informational letters and bulletins to physicians and other providers of the influenza vaccine when they become available in order to ensure compliance with the ACIP recommendations with respect to immunization of patients with influenza vaccine; (5) work with the CDC and other immunization partners to explore options to provide for timely influenza immunization of indigent or underserved populations, including exploring options to provide for the timely redistribution of state and federally funded influenza vaccines to facilities or groups within the state willing to appropriately manage, distribute, and administer the vaccine to indigent or underserved populations; (6) continue its collaboration with the CDC and other stakeholders in influenza vaccination to work to achieve the influenza immunization goals of Healthy People 2020, with particular attention to improving demand for vaccine and achieving stability in the vaccine supply; (7) work with local public health officers through the Federation to respond to community flu vaccine shortages and possible influenza outbreaks to protect the public health; and, (8) urge the federal government to support, as a national priority, the development of safe and effective influenza vaccines employing new technologies and to continue to support adequate distribution to ensure that there will be an affordable, available and safe supply of influenza vaccine on an annual basis.	production and distribution that physicians must receive influenza vaccines in a timely and equitable manner in order to help immunize all patients ~~=~~6 months of age and older as recommended by the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP); (2) urge manufacturers and distributors of influenza vaccine to provide a dedicated ordering system for small- and medium-size medical practices to pre-order vaccine up to an appropriate volume threshold; (3) support federal actions to allow physicians (MDs and DOs) to form purchasing alliances to allow for competitive purchasing of influenza vaccine comparable to large purchasers currently supplying pharmacy and grocery chain stores with influenza vaccine; (4) communicate current ACIP recommendations on the influenza vaccine to physicians and assist the CDC in disseminating its informational letters and bulletins to physicians and other providers of the influenza vaccine when they become available in order to ensure compliance with the ACIP recommendations with respect to immunization of patients with influenza vaccine; (5) work with the CDC and other immunization partners to explore options to provide for timely influenza immunization of those unable to pay ~~indigent~~ or underserved populations, including exploring options to provide for the timely redistribution of state and federally funded influenza vaccines to facilities or groups within the state willing to appropriately manage, distribute, and administer the vaccine to those

			unable to pay ~~indigent~~ or underserved populations; (6) continue its collaboration with the CDC and other stakeholders in influenza vaccination to work ~~to achieve the influenza immunization goals of Healthy People 2020, with particular attention to~~ on improving demand for vaccine and achieving stability in the vaccine supply; (7) work with local public health officers through the Federation to respond to community flu vaccine shortages and possible influenza outbreaks to protect the public health; and, (8) urge the federal government to support, as a national priority, the development of safe and effective influenza vaccines employing new technologies and to continue to support adequate distribution to ensure that there will be an affordable, available and safe supply of influenza vaccine on an annual basis.
H-440.856	Hospital Dress Codes for the Reduction of Health Care-Associated Infection Transmission of Disease	Our AMA encourages: (1) research in textile transmission of health care-associated infections (HAI); (2) testing and validation of research results before advocating for adoption of dress code policies that may not achieve reduction of HAIs; (3) all clinicians to assume "antimicrobial stewardship," i.e., adherence to evidence-based solutions and best practices to reduce of HAIs and HAI infection rates; and (4) all clinicians when seeing patients to wear attire that is clean, unsoiled, and appropriate to the setting of care.	Retain, still relevant.
H-440.881	Liability Protection for Adult Vaccines	Our American Medical Association supports the expansion of the Vaccine Injury Compensation Fund to include any vaccine encouraged or recommended by the Advisory Committee on Immunization Practices for routine use in the adult population.	Retain as amended to update language. Our American Medical Association supports the expansion of the Vaccine Injury Compensation Program ~~Fund~~ to include any vaccine ~~encouraged or~~ recommended by the Advisory Committee on Immunization Practices for routine use in the adult population.
H-440.908	Nosocomial Transmission of Disease via Stethoscope	The AMA advocates that health care providers frequently clean their stethoscopes and take all reasonable precautions with their other hand-held	Retain, still relevant.

		instruments in order to minimize the potential risk of nosocomial infection.	
H-440.918	Improving Public Awareness of Immunization Guidelines	The AMA encourages and supports the frequent and regular dissemination of the Recommended Childhood Immunization Schedule recommendations through appropriate media throughout the US.	Retain, still relevant.
H-440.925	Possible Repeal of the National Vaccine Injury Compensation Program	Our American Medical Association continues to support in principle the National Vaccine Injury Compensation Program.	Retain, still relevant.
H-440.939	Qualifications for State Health Directors	The AMA recommends to state medical societies that they advocate with their respective legislatures the adoption of statutory requirements that the qualifications for State Health Director include a doctoral degree in medicine or osteopathy, public health training or experience, and preparation, both academic and experiential, adequate for the management of a large and complex health agency.	Retain, still relevant.
H-440.941	High Cost and Shortage of Vaccines	The AMA seeks to ensure in an administratively efficient manner the ready availability of vaccines to immunize individuals at reasonable cost.	Retain, still relevant.
H-440.977	Hepatitis B Vaccine	The AMA urges the appropriate use of hepatitis B vaccine and the dissemination of professional educational materials to increase the use of the hepatitis B vaccine by physicians whose patients are in high risk groups, including physicians in training and other medical personnel who come into contact with blood and blood products, tissues, secretions and excretions demonstrated to be potential reservoirs of hepatitis B virus.	Retain, still relevant.
H-440.982	Centers for Disease Control Funding	The AMA supports funding for the Centers for Disease Control that is adequate to support its important and expanding public health activities.	Retain, still relevant.
H-440.991	Immunization Programs for Children	Our AMA (1) continues to support efforts toward the prevention of childhood disease through immunizations; (2) favors using its position in international health organizations to promote appropriate immunization programs for children throughout the world, especially in such critical and cost-effective areas as the prevention of poliomyelitis and measles; and (3) expresses the need for private and public research institutions to help develop more technically advanced products, such as new heat stable vaccines, necessary for the effective immunization of children throughout the world.	Retain, still relevant.
H-440.994	Sexually Transmitted Disease Prevention	Our AMA endorses the use of the condom as an effective method of prevention of sexually transmitted disease and urges state and county medical societies to endorse the display and sale of condoms of assured quality by the usual retail outlets for the prevention of sexually transmitted disease, and suggests that each package contain information about the hazards of sexually transmitted disease.	Retain as amended to remove unclear language. Our AMA endorses the use of the condom as an effective method of prevention of sexually transmitted disease and urges state and county medical societies to endorse the display and sale of condoms of assured quality by

			~~the usual~~ retail outlets for the prevention of sexually transmitted disease, and suggests that each package contain information about the hazards of sexually transmitted disease.
H-445.985	Physician and Health Institution Publicity and Responsibility	Our American Medical Association encourages physicians when engaged in public discourse related to health and medical science to disclose whether stated positions are based on peer-reviewed evidence, standard of care, or personal opinion.	Retain, still relevant.
H-45.989	Child Safety Restraint Use in Aircraft	Our AMA supports (1) the use of and education about appropriate restraint systems for all children on all commercial airline flights; and (2) working with the Federal Aviation Administration, International Air Transport Association and other appropriate aviation regulators to establish criteria for appropriate child restraint systems.	Retain, still relevant.
H-45.998	Aircraft Shoulder Harness	The AMA supports the National Transportation Safety Board position that the FAA take action to require the installation of approved shoulder harnesses for all seat locations in general aviation aircraft.	Retain, still relevant.
H-450.945	Science in Medicine and Quality of Care in Health System Reform	It is a critical role of the AMA to preserve, protect and enhance the quality of medical care now and in the future by: (1) advancing the art and science of medicine and the health of the public; (2) advocating for patients, physicians and the public; (3) enhancing the profile and priority within the AMA of science as the basis of medicine; and (4) bringing science advocacy to the forefront of health system reform.	Retain, still relevant.
H-460.899	The Value of Peer Review in the Scientific Process	Our AMA reaffirms our strong support for the value of peer review system in ensuring openness and fidelity in the scientific process.	Retain, still relevant.
H-460.900	The Value of Independent Scientific Advice	Our AMA reaffirms our strong support for the value of independent scientific advice provided by federal advisory panels.	Retain, still relevant.
H-460.904	The Next Transformative Project: In Support of the BRAIN Initiative	Our AMA: (1) supports the scientific and medical objectives of the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative of mapping the human brain to better understand normal and disease process; (2) encourages appropriate scientific, medical and governmental organizations to participate in and support advancement in understanding the human brain in conjunction with the BRAIN Initiative; and (3) supports the continued Congressional allocation of funds for the BRAIN Initiative, thus providing for research and innovation in technologies that will advance knowledge of neurologic function and disease.	Retain, still relevant.
H-460.912	Principles for Conduct and Reporting of Clinical Trials	Our AMA: (1) endorses the Association of American Medical Colleges' "Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials"; (2) commends the AAMC, the Centers for Education and Research in Therapeutics and the BlueCross BlueShield Association for the development and dissemination of these principles; (3) supports the	Retain as amended, to remove items that have been accomplished. Our AMA: (1) ~~endorses the Association of American Medical Colleges' "Principles~~

		timely dissemination of clinical trial data for public accessibility as permitted by research design and/or regulatory protocol; (4) supports the promotion of improved data sharing and the reaffirmation and enforcement of deadlines for submitting results from clinical research studies; (5) encourages the expansion of clinical trial registrants to ClinicalTrials.gov; and (6) will sign the petition titled "All Trials Registered; All Results Reported" at Alltrials.net that supports the registration of all past, present and future clinical trials and the release of their summary reports.	~~for Protecting Integrity in the Conduct and Reporting of Clinical Trials"; (2) commends the AAMC, the Centers for Education and Research in Therapeutics and the BlueCross BlueShield Association for the development and dissemination of these principles; (3)~~ supports the timely dissemination of clinical trial data for public accessibility as permitted by research design and/or regulatory protocol; (~~4~~2) supports the promotion of improved data sharing and the reaffirmation and enforcement of deadlines for submitting results from clinical research studies; and (~~5~~3) encourages the expansion of clinical trial registrants to ClinicalTrials.gov~~; and (6) will sign the petition titled "All Trials Registered; All Results Reported" at Alltrials.net that supports the registration of all past, present and future clinical trials and the release of their summary reports~~.
H-460.943	Potential Impact of Health System Reform Legislative Reform Proposals on Biomedical Research and Clinical Investigation	The AMA, to encourage and support the continuing development of new advances in science and medicine and the development and implementation of meaningful quality assurance programs essential to improving the delivery of medical and health care in the United States, advocates: (1) Strong support and funding for medical education programs at all levels to attract and stimulate gifted students and physicians to receive training and experience in, and to participate in, basic science or clinically-oriented research programs. (2) Strong financial and policy support for all aspects of biomedical science and research, including: basic science research (investigator initiated grant-funded research) in a wide variety of fields; laboratory-based clinical studies (including surgical studies); clinical studies and therapy trials; clinical outcomes research; behavioral science research, including studies to assess implementation of health promotion and/or disease prevention activities; and technology transfer research, with an emphasis on diffusing information about, training personnel in, and encouraging appropriate use of new technologies. (3) Adequate federal funding for biomedical science	Retain, still relevant.

		programs, including an appropriate balance of funding for basic, clinical, health service, and public health/prevention research. (4) Support and funding for evaluation and implementation research, including drug and technology assessment, medical device review, and developing and setting standards for computerized medical records.	
H-460.970	Maintaining Progress in Biomedical Research	Our AMA supports continued leadership by the Association in maintaining progress in biomedical research.	Retain as amended to clarify language. Our AMA supports continued leadership by ~~the~~ our Association in maintaining progress in biomedical research.
H-460.989	Animals as Experimental Subjects	The AMA encourages medical school faculty who use animals in the education of students to continue instruction of students on the appropriate use and treatment of animals.	Retain, still relevant.
H-460.998	Support of Biomedical Research	Our AMA endorses and supports the following ten principles considered essential if continuing support and recognition of biomedical research vital to the delivery of quality medical care is to be a national goal: (1) The support of biomedical research is the responsibility of both government and private resources. (2) The National Institutes of Health must be budgeted so that they can exert effective administrative and scientific leadership in the biomedical research enterprise. (3) An appropriate balance must be struck between support of project grants and of contracts. (4) Federal appropriations to promote research in specifically designated disease categories should be limited and made cautiously. (5) Funds should be specifically appropriated to train personnel in biomedical research. (6) Grants should be awarded under the peer review system. (7) The roles of the private sector and of government in supporting biomedical research are complementary. (8) Although the AMA supports the principle of committed federal support of biomedical research, the Association will not necessarily endorse all specific legislative and regulatory action that affects biomedical research. (9) To implement the objectives of section 8, the Board will establish mechanisms for continuing study,	Retain, still relevant.

		review and evaluation of all aspects of federal support of biomedical research. (10) Our AMA will accept responsibility for informing the public on the relevance of basic and clinical research to the delivery of quality medical care.	
H-470.953	Evaluating Green Space Initiatives	Our AMA supports appropriate stakeholders in conducting studies to evaluate different green space initiatives that could be implemented in communities to improve patients' health and eliminate health disparities.	Retain, still relevant.
H-470.955	Support of Protective Headgear (Helmets) in the Sport of Girls'/Women's Lacrosse	Our American Medical Association supports requiring approved protective headgear for all athletes participating in the sport of girls'/women's lacrosse.	Retain, still relevant.
H-470.956	Injuries in Cheerleading	Our AMA: (1) supports the designation of cheerleading as a sport; and (2) recognizes the potential dangers of cheerleading, including the potential for concussion and catastrophic injury, and supports the implementation of recommendations designed to improve its safety equivalent to those that apply to other athletic activities formally recognized as 'sports' by appropriate accrediting bodies. These include proper training of coaches, avoidance of inappropriate surfaces when performing stunts and adherence to rules for the proper execution of stunts.	Retain, with editorial amendments. Our AMA: (1) supports the designation of cheerleading as a sport; ~~and~~ (2) recognizes the potential dangers of cheerleading, including the potential for concussion and catastrophic injury~~,~~;and (3) supports the implementation of recommendations designed to improve its safety equivalent to those that apply to other athletic activities formally recognized as 'sports' by appropriate accrediting bodies. These include proper training of coaches, avoidance of inappropriate surfaces when performing stunts, and adherence to rules for the proper execution of stunts.
H-470.958	Head Injury Prevention in Hockey	Our AMA will encourage that all levels of hockey effectively prevent head hits and dangerous checking.	Retain, still relevant.
H-470.960	Soccer Injuries	Our AMA recognizes the problem of injuries in soccer and encourages additional studies into the incidence of soccer-related injuries and methods to reduce those injuries.	Retain, still relevant.
H-470.967	Safety in Youth Baseball and Softball	The AMA urges youth baseball and softball organizations to adopt policies for the use of protective equipment and encourages sponsors of organized youth sports activities to adopt written emergency and first responder plans.	Retain, still relevant.
H-470.971	Athletic Preparticipation Examinations for Adolescents	To promote the health and safety of adolescents, our AMA recommends that state medical societies work with appropriate state and local agencies to promote the following:	Retain, still relevant.

		(1) The development of standards for preparticipation athletic examinations that are consistent with consensus recommendations of the American Academy of Family Physicians, American Academy of Pediatrics, American Medical Society for Sports Medicine, American Orthopedic Society for Sports Medicine, and the American Osteopathic Academy of Sports Medicine. (2) Only licensed MDs, DOs, and licensed physician extenders practicing under the supervision of licensed MDs and DOs perform preparticipation examinations. (3) The decision of whether or not an adolescent is healthy and physically mature enough to participate in a particular sport is made by a qualified physician. (4) The decision of when an injured athlete resumes participation is made by a qualified physician. (5) The most current guidelines established by the American Academy of Pediatrics, American College of Cardiology, American College of Sports Medicine, and other appropriate medical specialty societies are used to determine eligibility for sports participation.	
H-470.974	Athletic Helmets	1. Our AMA urges the Consumer Product Safety Commission and other appropriate agencies and organizations to establish standards to ensure that athletic and recreational equipment produced or sold in the United States provide protection against head and facial injury. 2. Our AMA: (a) supports requiring the use of head and facial protection by children and adolescents while engaged in potentially dangerous athletic and recreational activities; (b) encourages the use of head and facial protection for adults while engaged in potentially dangerous athletic and recreational activities; (c) encourages physicians to educate their patients about the importance of head and facial protection while engaged in potentially dangerous athletic and recreational activities; and (d) encourages the availability of rental helmets at all commercial settings where potentially dangerous athletic and recreational activities take place.	Retain, still relevant.
H-470.979	Drugs and Athletes	The AMA favors cooperative efforts with the National Collegiate Athletic Association, the National Intercollegiate Athletic Association, the National Federation of High Schools and all other appropriate organizations to establish drug education, testing and treatment programs in all their respective athletic programs.	Rescind, as mostly accomplished and partly superseded by new data. At the college level, in 2024 the NCAA Sports Science Institute revised their "Substance Misuse Prevention and Intervention: An Athletics Tool Kit." The NCAA Sport Science Institute

			on behalf of the Committee on Competitive Safeguards and Medical Aspects of Sports issues yearly updates that include prevention, education, treatment, and recovery components. At the adolescent level, the American Society of Addiction Medicine issued guidelines on "Appropriate Use of Drug Testing in Clinical Addiction Medicine". This document includes recommendations about what level of risk justifies testing; consent and other procedural safeguards; and appropriate use of test data. At the high school level, the National Federation of State High School Associations (NFHS), published a 2024 opinion, "Revisiting Drug Testing in High Schools – Where Do We Stand" with a nuanced discussion of the "pros and cons" of drug testing in high school athletics and other optional activities. Because relevant organizations have recently published material that covers in detail all areas included in H-470.979, your Council on Science and Public Health recommends that H-470.979 be rescinded.
H-470.994	Non-Therapeutic Use of Pharmacological Agents by Athletes	Our AMA: (1) opposes the use of drugs for the purpose of enhancing athletic performance or sustaining athletic achievement. This action in no way should be construed as limiting a physician's proper use of drugs in indicated treatment of athletic injuries or clinical symptoms of individual athletes; and (2) endorses efforts by state level high school athletic associations to establish programs which include enforceable guidelines concerning weight and body fat changes on a precompetition basis for those sports in which weight management is a concern.	Retain, still relevant.

H-470.995	Athletic (Sports) Medicine	Our AMA believes that: (1) the Board of Education and the Department of Health of the individual states should encourage that an adequate Athletic Medicine Unit be established in every school that mounts a sports program; (2) the Athletic Medicine Unit should be composed of an allopathic or osteopathic physician director with unlimited license to practice medicine, an athletic health coordinator (preferably a NATABOC certified athletic trainer), and other necessary personnel; (3) the duties of the Athletic Medicine Unit should be prevention of injury, the provision of medical care with the cooperation of the family's physician and others of the health care team of the community, and the rehabilitation of the injured; (4) except in extreme emergencies, the selection of the treating physician is the choice of the parent or guardian and any directed referral therefore requires their consent; (5) the Athletic Medicine Units should be required to submit complete reports of all injuries to a designated authority; (6) medical schools, colleges, and universities should be urged to cooperate in establishing education programs for athletic health coordinators (NATABOC certified athletic trainers) as well as continuing medical education and graduate programs in Sports Medicine; (7) high school administrators, athletic directors, and coaches to work with local physicians, medical societies, and medical specialty societies, as well as government officials and community groups to undertake appropriate measures to ensure funding to provide the services of a certified athletic trainer to all high school athletes; and (8) not all high schools have the resources to procure the services of a certified athletic trainer and further recognizing that athletic trainers cannot be present at all practices and competitions, that the AMA encourage high school administrators and athletic directors to ensure that all coaches are appropriately trained in emergency first aid and basic life support.	Retain, still relevant.
H-480.955	"Keepsake" Fetal Ultrasonography	Our AMA: (1) supports the current Food and Drug Administration (FDA) policy on use of non-diagnostic fetal ultrasound, which views "keepsake" fetal videos as an unapproved use of a medical device; and (2) will lobby the federal government to enforce the current FDA position, which views "keepsake" fetal videos as	Retain, still relevant.

		an unapproved use of a medical device, on non-medical use of ultrasonic fetal imaging.	
H-495.978	Proper FDA Authority to Regulate Tobacco	Our AMA will continue to support federal legislation that would give the Food and Drug Administration strong regulatory authority over tobacco products.	Retain, still relevant.
H-495.987	Taxation of All Tobacco Products and Electronic Nicotine Delivery Systems (ENDS)	1. Our AMA will work for and encourages all levels of the Federation and other interested groups to support efforts, including education and legislation, to increase federal, state, and local excise taxes on all tobacco products and electronic nicotine delivery systems (ENDS), including e-cigarettes, in order to discourage use. 2. An increase in federal, state, and local excise taxes for such products should include provisions to make substantial funds available that would be allocated to health care needs and health education, and for the treatment of those who have already been afflicted by tobacco-caused illness, including nicotine dependence, and to support counter-advertising efforts. 3. Our AMA continues to support legislation to reduce or eliminate the tax deduction presently allowed for the advertisement and promotion of all tobacco products; and advocates that the added tax revenues obtained as a result of reducing or eliminating such advertising/promotion tax deduction be utilized by the federal government for expansion of health care services, health promotion and health education.	Retain as amended to update language. 1. Our AMA ~~will work for and~~ encourages all levels of the Federation and other interested groups to support efforts, including education and legislation, to increase federal, state, and local excise taxes on all tobacco products and electronic nicotine delivery systems (ENDS), including e-cigarettes, in order to discourage use. 2. Our AMA supports ~~A~~an increase in federal, state, and local excise taxes for ~~such~~ tobacco products and electronic nicotine delivery systems (ENDS) ~~should~~ that includes provisions to ~~make substantial funds available that would be~~ allocate~~d~~ substantial funds for ~~to~~ health care needs and health education, ~~and for~~ the treatment of those who have already been afflicted by tobacco-caused illness, including nicotine dependence, and to support counter-advertising efforts. 3. Our AMA continues to support legislation to reduce or eliminate the tax deduction presently allowed for the advertisement and promotion of all tobacco products; and advocates that the added tax revenues obtained as a result of reducing or eliminating such advertising/promotion tax deduction be utilized by the federal government for expansion of health care services, health promotion and health education.

H-505.964	International Tobacco Control Efforts	Our AMA: (1) supports the international tobacco control efforts of the World Health Organization and urges the appropriate bodies and persons within the U.S. government (including Congress, the State Department, the Department of Commerce, and the Department of Health and Human Services) to participate fully in international tobacco control efforts, including supporting efforts to bring to fruition a Framework Convention on Tobacco Control; (2) will work for the enactment of federal legislation or regulations that would prohibit the exportation of tobacco products to other countries. Pending the enactment of such legislation or regulation, our AMA (a) urges the U.S. government to alter trade policies and practices that currently serve to promote the world smoking epidemic; (b) continues to support the following activities: (i) federal legislation requiring health warning labels in the appropriate native language or symbolic form to be on packages of cigarettes exported and require foreign advertising by U.S. tobacco producers to be at least as restrictive as types of advertising permitted in the U.S.; (ii) labeling on tobacco products manufactured abroad to be at least as restrictive as those produced in the U.S.; (iii) opposition to efforts by the U.S. government to persuade countries to relax regulations concerning tobacco promotion and consumption; and (iv) encouragement of the World Health Organization to increase its worldwide anti-smoking efforts; (c) supports working with the World Medical Association as well as directly with national medical societies to expand activities by the medical profession to reduce tobacco use worldwide; (d) supports establishing close working relations with the World Health Organization to promote more physician involvement in anti-tobacco activities, particularly in developing and recently developed countries; (e) supports working with the Centers for Disease Control and Prevention's Office on Smoking and Health to promote worldwide anti-tobacco activities; (f) supports periodically monitoring the success of worldwide anti-tobacco efforts to control the growing worldwide smoking epidemic; and (g) supports the right of local jurisdictions to enact tobacco regulations that are stricter than those that exist in state statutes and encourages state and local medical societies to evaluate and support local efforts to enact useful regulations; and (3) opposes any efforts by the government or its agencies to actively encourage, persuade or compel any country to import tobacco products and favors legislation that would prevent the government from	Retain, still relevant.

		actively supporting, promoting or assisting such activities.	
H-515.963	Diagnosis and Management of Family Violence	Our American Medical Association recommends that questions to assess risk for family violence should be included within the context of taking a routine social history, past medical history, history of present illness, and review of systems as part of emergency, diagnostic, preventive, and chronic care management.	Retain as amended to update language. Our American Medical Association recommends that questions to assess risk for family and intimate partner violence should be included within the context of taking a routine social history, past medical history, history of present illness, and review of systems as part of emergency, diagnostic, preventive, and chronic care management.
H-515.973	Memories of Childhood Abuse	The AMA: (1) recognizes that few cases in which adults make accusations of childhood sexual abuse based on recovered memories can be proved or disproved and it is not yet known how to distinguish true memories from imagined events in these cases; (2) encourages physicians to address the therapeutic needs of patients who report memories of childhood sexual abuse and that these needs exist quite apart from the truth or falsity of any claims; and (3) encourages physicians treating possible adult victims of childhood abuse to subscribe to the *Principles of Medical Ethics* when treating their patients and that psychiatrists pay particular attention to the *Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry*.	Retain, still relevant.
H-515.995	Corporal Punishment in Schools	The AMA (1) supports the abolition of corporal punishment in schools; (2) encourages universities that train teachers to emphasize alternative forms of discipline during their training; (3) encourages physicians to work toward the abolition of corporal punishment in their communities; and (4) encourages state medical societies to support legislation prohibiting corporal punishment in their state.	Retain, still relevant.
H-60.920	Child Resistant Caps on Energy Drinks	Our American Medical Association urges that the US Food and Drug Administration and/or US Congress take legislative or regulatory action on the federal level to require child-resistant packaging on all high energy drinks manufactured in the United States.	Retain, still relevant.
H-60.983	Statement of Concern Regarding Destructive Themes Contained in Music	(1) The AMA is concerned about the possible impact of destructive themes depicted in certain types of popular music. The vivid depiction of drug and alcohol use, suicide, violence, demonology, sexual exploitation, racism and bigotry could be harmful to some young people, especially vulnerable children and adolescents who are socially alienated from traditional value systems and positive support groups. (2) The AMA urges four activities: (a) parents should be aware of the themes depicted in music; monitor the concerts their children attend, the music videos they	Retain, still relevant.

		watch, and the albums they purchase and discuss the potential harmful effects of music themes with their children; (b) physicians should know about potentially destructive themes in some forms of music, and should work to increase awareness of patients and communities about these themes; (c) members of the entertainment industry, including sponsors of concerts, agents, and entertainers, should exercise greater responsibility in presenting music to young people; and (d) all music industry companies should voluntarily label albums in compliance with recently agreed upon labeling standards.	
H-60.994	Herpes Simplex and School Children	The AMA reaffirms the rights of children with herpes infections to a quality education, condemns exclusion of such children from regular classes with other children, and encourages state legislation which would mandate that children with herpes not be excluded from regular classes.	Retain, still relevant.
H-95.979	Curtailing Prescription Drug Abuse While Preserving Therapeutic Use - Recommendations for Drug Control Policy	Our AMA (1) opposes expansion of multiple-copy prescription programs to additional states or classes of drugs because of their documented ineffectiveness in reducing prescription drug abuse, and their adverse effect on the availability of prescription medications for therapeutic use; (2) supports continued efforts to address the problems of prescription drug diversion and abuse through physician education, research activities, and efforts to assist state medical societies in developing proactive programs; and (3) encourages further research into development of reliable outcome indicators for assessing the effectiveness of measures proposed to reduce prescription drug abuse.	Retain, as amended to update language. Curtailing Prescription Drug Misuse ~~Abuse~~ While Preserving Therapeutic Use - Recommendations for Drug Control Policy Our AMA (1) opposes expansion of multiple-copy prescription programs to additional states or classes of drugs because of their documented ineffectiveness in reducing prescription drug misuse ~~abuse~~, and their adverse effect on the availability of prescription medications for therapeutic use; (2) supports continued efforts to address the problems of prescription drug diversion and misuse ~~abuse~~ through physician education, research activities, and efforts to assist state medical societies in developing proactive programs; and (3) encourages further research into development of reliable outcome indicators for assessing the effectiveness of measures proposed to reduce prescription drug misuse ~~abuse~~.

H-95.987	Using Controlled Substance Names in Commercial Products	The AMA opposes the advertising practice of naming products for controlled substances, implying that their use is exciting and desirable.	Retain, still relevant.

2. ADDRESSING SOCIAL DETERMINANTS OF HEALTH THROUGH CLOSED LOOP REFERRAL SYSTEMS

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See Policy H-160.896

INTRODUCTION

American Medical Association (AMA) Policy D-165.932 "Addressing Social Determinants of Health Through Closed Loop Referral Systems," as adopted by the House of Delegates (HOD), asked that our AMA study the effectiveness and best practices of closed loop referral systems in addressing social determinants of health.

BACKGROUND

Understanding Social Determinants of Health and Health-Related Social Needs

The way communities and individuals experience health and health care is not just based on access to medical services. It is also impacted by other factors that may support or create barriers to health and well-being. At a community level, these factors are referred to as social determinants of health (SDOH) and may also be referred to as "social drivers of health" (See APPENDIX 1 - Key Terms).[1] Examples of SDOH include economic stability, access to quality education and health care, the neighborhood, and built environment.[1] The specific factors that impact individuals directly are called health related social needs (HRSN).[2] Examples of HRSN include lack of stable or affordable housing and utilities, financial strain, lack of access to healthy food, personal safety, and lack of access to transportation.[1] While SDOH and HRSNs often coincide and overlap, the relationship between them can be complex. For example, a household with income below the federal poverty line (which could constitute an individual-level HRSN) that is living in an area with poor economic conditions (a community-level SDOH) is more likely to be exposed to housing that exacerbates health problems like asthma.[1] That household may be unable to afford living in areas with safer housing and may therefore benefit from various forms of housing assistance.[1] In this example, both the HRSN of having low income and the SDOH of living in an area with poor housing quality need to be addressed to holistically improve the household's situation and health outcomes.[1] Addressing SDOH and HRSNs requires implementing sets of policies and interventions involving community partners. Addressing both SDOH and HRSN is an important component of efforts to overcome disparities and achieve health equity for individuals and communities.[2]

A Closer Look at SDOH and HRSN in the U.S.

Systematic and structural inequities such as limited employment and educational opportunities, lack of affordable and safe housing, low availability of nutritious foods, high rates of exposure to environmental health hazards, and inadequate access to health care services, can jeopardize health and well-being.[3] Disparities resulting from these structural inequities often disproportionately impact historically underserved individuals such as Blacks, Latinx, members of Tribal Nations, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; persons who live in communities with environmental justice concerns; older persons; women and girls; and persons otherwise experiencing persistent poverty.[3] These disparities exist for many health outcomes, including infant and maternal mortality, heart disease, diabetes, hypertension, chronic illness, disability, cancer, mental illness, substance use, and overall life expectancy.[4–6] For instance, the life expectancy for Black Americans is four years shorter than White Americans.[6] People of color have higher rates of diabetes, hypertension, obesity, asthma, and premature death compared to non-Hispanic Whites, due in part to social and economic factors.[6,7] People living in rural areas are more likely than their urban counterparts to die from heart disease, cancer, unintentional injury, chronic

lower respiratory disease, and stroke.[6,8] Many of these disparities stem from differences in social and economic circumstances between these demographics.

An important contributor to health disparities is the inequitable distribution of social resources in localities across the country.[6,8] For example, a history of racialized practices and policies—housing discrimination, unequal educational opportunities, disproportionate incarceration rates, inequitable employment practices—has created inequities for many communities.[9] Inadequate access to social and health care services in many areas of the country has led to widening gaps in outcomes.[10] Notably, the cumulative impacts of environmental and climate factors have significant influence on health outcomes. Inequitable access to clean water, clean air, and natural green spaces with tree cover led to disproportionate environmental burdens for many communities.[11] These environmental injustices create new and exacerbate longstanding disparities in health outcomes. People who live in communities with environmental concerns may suffer from poorer health and have shorter life expectancies than those in other communities.[6,11] It is estimated that, on average, clinical care impacts only 20 percent of county-level variation in health outcomes, while SDOH affects as much as 50 percent of health outcomes.[6,8]

METHODS

English language articles will be selected from searches of PubMed and Google Scholar using the search terms "closed loop referral system", "United States Core Data for Interoperability (USCDI)," "closed loop referral system AND social determinants of health (SDOH)" and "United States Core Data for Interoperability AND SDOH". Additional articles will be identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies; applicable organizations will also be reviewed for relevant information.

DISCUSSION

What Is a Closed Loop Referral System?

Closed loop referral systems provide a means for health care professionals to send patient information to a CBO to help address a patient's needs that are typically better served outside of clinical workflows.[12] A CBO can provide an array of support programs within the community, including services that address a patient's social needs or address underlying causes of poor health outcomes with the goal of positively impacting the patient's overall health outcome(s).[12] The CBO can then provide feedback on the outcome of that referral to the referring individual/entity.[12] Closed loop referrals depend on an often-overlooked capability for the referral process to originate in a health care setting and progress to a CBO, and then for the CBO to further refer the patient to another CBO which may be better positioned to help that patient, with the whole care team then being able to follow the referral through that process and any other redirects that may occur.[13] At the core, a closed loop referral process represents a significant shift in the way systems, institutions, clinicians, communities, and families communicate.[13]

Lessons Learned from Early Adopters of Closed Loop Referral Systems

There is a growing body of evidence on the success of closed loop referral systems to improve health.[14] In a recent study examining 16 years of data from different communities, death due to cardiovascular disease, diabetes and influenza declined significantly among communities that expanded multisector networks supporting population health activities.[14,15] The first randomized control trial (RCT) to evaluate health outcomes of a clinic-based pediatric navigation program, demonstrated a significant decrease in reported HRSN and improved children's overall health status, as reported by caregivers.[14,16] An Eastern Massachusetts project of six pediatric practices engaged parents to create and use an online, interactive community resources map, results showed 76 percent of participants were physically active at new places, 57 percent shopped at new locations for groceries; and 71 percent reported they were very satisfied with the information they received.[14,17]

Studies have also looked at the role of the technology in screening and referrals.[14,16,18,19] A 2014 RCT comparing patient disclosure rates for unmet needs between electronic and face-to-face methods found significantly higher disclosure rates when employing electronic formats for sensitive issues (i.e., household violence, substance use) and marginally higher rates when used for less sensitive issues (i.e., financial insecurity, neighborhood and school safety), suggesting that technology has a role to play in solving challenges related to accurately identifying needs.[19] A separate study of youth found the majority willing to participate in a technology-based system for SDOH screening and that nearly half successfully addressed their priority concern.[18]

Care teams and health care organizations (HCOs) involved in implementing HRSN screening and referral programs have reported multiple challenges.[20] HCO staff reported that they were unfamiliar with the social services organizations in their communities or that the compiled lists of community resources were neither complete nor up to date.[20–23] Staff also reported having difficulty sending referrals to non–HCOs.[20,21,24] Many electronic health record (EHR) systems have historically lacked the capacity to document and track the delivery of care coordination services related to HRSN, as well as the outcomes of social services referrals.[20,25] Over the past decade a cluster of technology companies have developed software products to overcome these barriers to medical and social services coordination.[25]

The impetus to invest in closed loop referral technology systems was the result of a desire to be able to address patients' social needs more efficiently.[20,25] This included wanting to have centralized staff lists of community resources, send electronic referrals, and to receive updates on referral outcomes from community partners to improve their capacity to track patients' access to services across settings.[20] Some groups were motivated by external programs or value-based payment reforms that incentivized or required better care coordination with social services.[20] Examples included the Accountable Health Communities Model of the Centers for Medicare and Medicaid Services (CMS) Innovation Center, the CMS State Innovation Models initiative, and New York's Delivery System Reform Incentive Payment program.[20,26–28]

Implementors of closed loop referral systems described three funding sources used to cover platform licenses and implementation costs: grants and other short-term pilot funds, operational funds, and value-based health care transformation dollars.[20] Pilot funds typically originated from either foundations or demonstration projects sponsored by federal or state governments, such as the federal Accountable Health Communities Model, and State Innovation Model grants.[20,26,28]To facilitate community partners' use of the closed loop referral systems, HCOs either covered the cost of community partner organizations' software licenses or chose platforms that provided the product free of charge to affiliated CBOs.[20]

The most common challenge was recruiting CBOs to use the platforms, which was necessary for HCOs to be notified of referral outcomes.[20,29] HCOs generally attributed recruitment barriers to community partners' lack of resources and incentives.[20,29] Though community partners were almost universally provided with access to the closed loop referral system at no direct cost, implementation required indirect resources—for example, to train staff on using the closed loop referral system or to develop and maintain effective workflows for monitoring and responding to incoming referrals.[29] CBOs did not always have clear incentives for using the closed loop referral system, and the resources required for implementation prevented many organizations, especially very small ones, from adopting closed loop referral system.[20,29] As a result, many of the groups had not been able to track referral outcomes. Introducing a closed loop referral system could prove burdensome if CBOs were asked by different HCOs to use different platforms for different clients.[20,29] One solution was to use a common platform, as is the case in North Carolina.[20,30]

Among HCOs that reported success in recruiting community partners to use the closed loop referral system, three engagement strategies were cited. First, engaging CBOs in the platform selection process helped establish those partners' buy-in.[20,31] For example, one county health department established a coalition of thirty health care and community-based social services organizations.[20,31] The coalition undertook a joint assessment of platform referral functionalities, defined priority functionalities, and invited vendors to demonstrate their platforms. Once a shared platform was selected, subgroups within the larger coalition were assigned tasks such as designing the resource directory, referral system, and coalition wide release of information form.[20,31] Six months into distribution, the organizations started to exchange referrals through the platform, which was faster than most other organizations were able to implement this function.[20,31]

Second, CBOs were more accepting when HCOs clearly explored and articulated the potential benefits of the closed loop referral system during recruitment of CBOs.[20,32] Some HCOs reported that community partners became especially enthusiastic about the closed loop referral system when they learned that it could help them refer their clients to other organizations or health care professionals, in addition to increasing traffic and coordination for incoming referrals from health care systems.[20,32] Another powerful motivator for some CBOs was the potential to formally contract with and be reimbursed by health systems or payers for services rendered to referred patients, which could be more easily documented in the platform.[32]

Third, HCOs that successfully recruited CBOs as partners also described hiring staff to visit the organizations and stay in close contact to build rapport, support ongoing communication and coordination about the technology, and manage problems.[32] In one instance, a HCO had a network coordinator who published a biweekly electronic newsletter that

was sent to all referral partners to answer common questions and provide updates about what kinds of programs partner organizations offered and what new organizations had joined the network.[20,32]

Within HCOs, groups described the need to convey the rationale, vision, and goals for better integrating social care and medical care to internal health care end users; to develop workflows that matched the needs and demands of those users; and to monitor and manage staff expectations.[20,31] One health system hosted an internal planning session with designated end users and then developed a project workflow and selected a set of social risk screening questions for medical assistants to use.[20,31] Once staff started using the platform and were able to see positive effects on patients' lives, they became more enthusiastic about the technology.[20,31] It was also important to name staff champions, who tended to have experience with social interventions, to improve the internal process.[20,31,32] Staff champions could generate momentum when they endorsed the rationale for closed loop referral system adoption: having these champions helped convince other staff to stay involved as the organization worked to fold social risk screening and referral into workflows.[20,31,32]

A third set of challenges was clustered around the legal and privacy barriers to sharing data with external, non–HCOs.[20] This included the lack of clarity about what patient information could be shared, with whom, and how.[20] Overcoming these privacy concerns took longer when data were shared with multiple sectors, because each sector had different requirements for handling confidential data.[20,31–33] For example, substance use treatment programs cannot disclose any patient identities without consent.[20,31–33] One HCO used its platform only internally because the organization's legal department did not authorize sharing any data with external partners.[33] Patient consent protocols also took time to establish. In some cases, organizations have found ways to record consent over the phone or online to streamline the process.[20,32,33] Despite these important challenges, most groups reported overall satisfaction with the platform they had chosen, although implementation was slower than anticipated.[20,32,33]

Even if implementation challenges were overcome, HCOs and their community partners face the challenge of financially sustaining their platforms.[20] Promising models have emerged in places such as New York, where the Delivery System Reform Incentive Payment program financially incentivizes HCOs to establish partnerships with CBOs.[20,26,30] In California and Oregon, organizations that served Medicaid patients used health insurance benefits, bundled payment, and shared savings programs to support social services and build infrastructure to bridge the gap between medical and social care.[20,34] Continued expansion of state Medicaid social risk interventions could be a major driver of increased adoption of these technologies.[20,35] Health information exchanges, funded through a combination of public and private investment, are coming online and hold promise as infrastructure for closed loop referral systems.[14,36] In California, Oregon, New York, Washington, North Carolina and elsewhere, states are building upon previous Medicaid waivers and layering federal opportunities to establish more ambitious partnerships and programs addressing SDOH.[37–42] However, Medicaid waivers are a time-limited sources of innovation to test and pilot approaches for adoption by states, therefore sustainability of these efforts is uncertain.[26,34,39,41,42]

IMPLEMENTATION CONSIDERATIONS FOR CLOSED LOOP REFERRAL SYSTEMS

Localized Needs and Resource Availability

Historically, the U.S. has relied on CBOs to address social needs. With deep roots in the community and constrained geographical focus, CBOs are well-positioned to provide hyperlocal services that are uniquely tailored to a community's needs, yet this also means that addressing HRSN effectively requires an intimate understanding of local community resources and needs.[14,20,32] Each community is unique, with specific social challenges and available support services, which makes standardization difficult. For example, urban areas might have numerous CBOs, whereas resources in rural areas may be limited.[14,32] Service availability can also fluctuate based on state-level funding and policies, particularly under Medicaid.[26,28,39–41] CBOs may overlap in the types of services they provide or differ in which clients they serve or how they accept clients, and their capacity for new clients may also vary greatly.[14,32] The variability in local resources and needs means that a one-size-fits-all approach is impractical. Effective closed loop referrals must be tailored to the specific context of each community, which requires robust, localized directories and a deep understanding of community assets.[14]

Technological Disparities Among Organizations

The landscape of CBOs addressing HRSN is highly varied, with significant differences in technological capabilities. While some CBOs operate advanced technology platforms capable of seamless data exchange, others rely on paper-

based systems.[20,32] The variation in CBO funding means that some organizations can easily support 24/7 connectivity while others may not even be able to answer the phone consistently.[20,32] This disparity poses a fundamental challenge: the assumption that all organizations can conform to a unified standard is unrealistic. Effective patient referrals must navigate these technological gaps, which can vary dramatically across different local contexts.[20,32] For instance, a food pantry might operate on a basic, manual system, making integration with EHRs difficult.[20,32] Conversely, a large CBO might have the infrastructure to handle sophisticated digital referrals but is unable to communicate with less technologically advanced partners.[20,32] This fragmentation requires flexible expectations that can adapt to various levels of technological readiness.

Complexity and Variety of Referrals

Closed loop referrals to address HRSN are inherently complex and diverse.[20,32] Unlike medical referrals, which typically involve a single instance of care, HRSN referrals can range from short-term assistance, such as food vouchers, to long-term programs, such as job training.[20,32] The nature of these referrals varies significantly based on the needs of the individual. For example, a referral for emergency housing might involve multiple touchpoints and require ongoing support, whereas a referral for a one-time utility payment may be resolved quickly.[20,32] The ability to track and manage varied referrals necessitates a sophisticated data language that can represent different types of needs, interventions, durations, and outcomes.

Challenges of Feedback Mechanisms

Closed loop referrals rely on feedback mechanisms that inform referring clinicians about the status of the referral.[12,43] However, this feedback is not always necessary or feasible. Clinicians often express that receiving status updates on every referral can be overwhelming and counterproductive.[43] An emergency medicine clinician who refers the patient to a CBO is unlikely to have a long-term relationship with that patient that would benefit from regular updates, but if that emergency room is part of an accountable care organization, pooling data about referrals and outcomes is highly important.[43] Multiple approaches might be needed to accommodate varied use cases. For example, some use cases might benefit from a system where a clinician can check in on the fulfillment of the referral without being inundated with unnecessary information.[43] This balance requires thoughtful design of feedback systems to ensure they are informative without being burdensome.

Readiness for Standardization

Communicating the identified need, requested resources, and the status of the request requires shared standards. While USCDI v4 introduces many of the communications standards for SDOH, its implementation will take considerable time as EHRs are currently moving toward the required adoption of USCDI v3 (January 2026).[44,45] While essential, the push towards standardization – exemplified by the USCDI v4 – is insufficient on its own. While EHRs are making strides towards adopting these standards, many health systems are not yet ready to fully integrate the social care components required for addressing HRSN.[43] The health care delivery system is still evolving in its ability to formally represent and manage social needs.[43] A hybrid approach employing both traditional and innovative methods is necessary to bridge the gap between current capabilities and future requirements.[14,43] This includes supporting standards for closed loop referrals and accommodating the existing variability in readiness and infrastructure among CBOs.[14,43]

Grant and Funding Opportunities

Medicaid funding, including utilization of Medicaid 1115 waivers that offer opportunities for SDOH reimbursement, varies significantly across states.[35,40] This leads to a lack of uniformity in funding and support for HRSN initiatives, creates challenges for standardization, and complicates efforts to develop a consistent approach to closed loop referrals.[14,35] Incentivizing the development of closed loop referral systems through grants and funding is crucial. Similar to the Certified Community Behavioral Health Clinic (CCBHC) grants in the behavioral health sector, specific grants for developing HRSN referral capabilities could accelerate progress.[46] These funds would enable CBOs to invest in the necessary technology, infrastructure, and people skills to participate in closed loop referral systems.[14,46]

History of Collaboration and Backbone Organization Support

It can take several years of systematic effort to develop trust, shared vision, leadership structure, measures of success and cross-sector knowledge for successful collaboration.[14,32,43] Lack of funding support for a backbone organization to plan, convene, facilitate shared goals and track success is cited as a barrier to the more rapid development of closed loop referral systems.[14,43] A further complication is that the funding gap for community-wide collaborations can result in individual health care entities developing or purchasing point to point technology systems between one health plan or health system and CBOs.[14,43] Without a community approach, CBOs are concerned about the potential need to connect to multiple technology systems, complicating their ability to partner.[14,43] Finally, there are many competing priorities in the health care arena and investing effort in community collaborations is a more recent trend that may compete with other initiatives.[43]

Privacy, Security and Data Governance

Consent, access to information, data use agreements and data governance are all challenging hurdles to coordinated systems of care and closed loop technology implementation.[47] Capturing signed consent as far upstream as possible facilitates the greatest benefit for closed loop referral systems to exchange all relevant information; however, this requires dedicated attention and resources to implement and maintain.[47,48] Security is a separate and important consideration for closed loop systems to ensure information is protected from any breach.[47–49] Behavioral health information significantly increases the difficulty of sharing information given its specific privacy rules, and when children are the clients, issues of consent are even more challenging.[47–49] Legal questions, systems to obtain consent and other privacy considerations often prove a long and costly barrier and can delay development and implementation.[47–49] Templates for data security and governance could reduce the time and cost to implement health information exchange (HIE).[47–49]

RELATED FEDERAL INITIATIVES

While the following federal initiatives were current as of the time this report was drafted, their continuation under the current Administration is uncertain.

U.S Playbook to Address SDOH

On November 16, 2023, the White House released the "U.S. Playbook to Address Social Determinants of Health," which outlines an initial set of actions that federal agencies are
undertaking to support health by improving the social circumstances of individual and communities.[50] These actions were developed to serve as guideposts for other agencies and organizations to engage in efforts to address SDOH and HRSN. This playbook focuses on the following three pillars:

1. Expand Data Gathering and Sharing: Advance data collection and interoperability among health care, public health, social care services, and other data systems to better address SDOH with federal, state, local, tribal, and territorial support.[50]
2. Support Flexible Funding to Address Social Needs: Identify how flexible use of funds could align investments across sectors to finance community infrastructure, offer grants to empower communities to address HRSN, and encourage coordinated use of resources to improve health outcomes.[50]
3. Support Backbone Organizations: Support the development of community backbone organizations and other infrastructure to link health care systems to CBOs. Backbone organizations manage community-based partnerships formed across sectors such as health care, housing, social services care, nutrition assistance, employment training, and economic development to care for populations holistically.[50]

Centers for Medicare & Medicaid Services (CMS)

Though Medicaid rules limit spending on non-medical services, nearly all states have implemented at least some policies or initiatives to address HRSN through their Medicaid programs for various populations.[37] In January 2021, CMS issued a State Health Official letter identifying opportunities for states to better address SDOH under Medicaid and CHIP and to support states with improving outcomes and lowering costs by addressing SDOH.[51] Using a variety of mechanisms, including using section 1905(a) State Plan Authority, Home and Community Based Services (HCBS), section 1115 demonstrations, section 1945 Health, and managed care contract requirements, among others, states are addressing HRSN, including housing-related services and supports, non-medical transportation, home delivered

meals, educational services, employment, community integration and social support, and case management (See APPENDIX 2).[51]

Center for Medicare and Medicaid Innovation (CMMI) established the Accountable Health Communities (AHC) Model in 28 locations to promote clinical-community collaboration to address HRSN of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services.[28] The model, which focuses on five core HRSN of housing instability, food insecurity, transportation problems, utility difficulties, and interpersonal violence, found that 15 percent of the nearly 483,000 beneficiaries screened were eligible for navigation services, and more than half of these navigation-eligible beneficiaries reported more than one core HRSN.[52] CMMI is working to incorporate learnings from the AHC model into future models. As part of their Strategy Refresh, CMMI will require all new models to collect and report on data on HRSN and SDOH, as appropriate.[52] In addition, CMS will consider models that aim to address upstream, community-level SDOH.[52]

CMS has also worked to address HRSN and SDOH in the Medicare program. As of 2019, CMS expanded the definition of supplemental benefits in Medicare Advantage (MA) plans to better address SDOH.[53] As of 2019, MA plans can offer a broader array of benefits that are primarily health-related, such as transportation, meal delivery, and adult day care, and as of 2020, plans can offer non-primarily health-related benefits to the chronically ill, such as pest control.[53] In addition, Medicare ACOs provide high-quality care to Medicare beneficiaries to ensure that patients get the right care at the right time through care coordination.[53] In FY22, CMS also included a request for information in the final Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) rule that sought ideas to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable.[53] Inclusion of such measures in future payment rules would also build on the work of the CMMI AHC model.[54]

Administration for Community Living (ACL)

ACL funds a nationwide network of aging and disability organizations that provide access to a variety of local community-based services that address social needs.[55] Through this network, ACL provides 150 million home-delivered meals to over 883,000 individuals and 73.6 million congregate meals to more than 1.5 million seniors, funded through the OAA Nutrition Program.[55] In addition to meals, the program provides nutrition screening, assessment, education, and counseling, and provides connections to other in-home and community supports.[55] ACL also provides transportation services through their network, providing more than 20.4 million rides to doctor's offices, grocery stores, pharmacies, senior centers, meal sites, and other critical daily activities.[56]

In addition, ACL's Social Care Referrals Challenge is working to support health care systems and CBOs through health IT solutions.[57] The challenge seeks to cultivate care coordination, including the sharing of standardized data on SDOH, by developing or optimizing interoperable, scalable technology solutions that foster connections between community-based organizations and health care systems.[57] ACL is also supporting the infrastructure of 12 Network Lead Entities, or community hubs, that coordinate the activities of a broader network to efficiently contract health plans and providers to address social needs.[58] Increasingly, CBOs are organizing to form networks, allowing them to deliver a broad scope of services, expand populations served and geographic coverage, build stronger administrative functions, and offer a single point of contracting for payers.[58] As part of their support for their disability network, ACL also offers several grants to enhance the cultural and linguistic competency of the disability network to ensure that all people with disabilities can access ACL-funded programs and services.[58]

The Office of the National Coordinator for Health Information Technology (ONC)

ONC seeks to improve the health and well-being of individuals and communities using technology and health information, including SDOH information, that is accessible when and where it matters most.[59] Advancing the use and interoperability of SDOH data is important to improve the health and well-being of all individuals and communities.[59] ONC is focused on ensuring that both patients and providers understand what capabilities are possible and required by the 21st Century Cures.[59] Standardization of the way in which the data is obtained and exchanged will help providers more easily address non-clinical factors, such as food, housing, and transportation insecurities, which can have a profound impact on a person's overall health.[60] For example, as of March 2022, almost all hospitals and roughly 75 percent of physicians use EHRs certified through the ONC Health IT Certification Program, helping to enable widespread capabilities for the capture, reporting, exchange, and use of granular race and ethnicity data.[60] This functionality will extend to the widespread use of interoperable SDOH data that can be electronically captured, used,

and exchanged.[60] ONC works collaboratively with federal partners and the community to advance the electronic exchange and use of SDOH data to help improve individual and population health by guiding the development, dissemination, and adoption of health IT standards; informing the development of policies to overcome SDOH data interoperability challenges and data use; supporting states and local governments as they build the infrastructures for SDOH data; and driving innovation in care delivery by using health IT tools and standards to integrate SDOH data into workflows.[60]

STATE INITIATIVES IN IMPLEMENTING CLOSED LOOP REFERRAL SYSTEMS

North Carolina. NCCARE 360 is a statewide backbone organization that electronically connects North Carolinians who have unmet social needs to community resources.[61] It allows for feedback and follow-up through a shared technology network provided by Unite Us so that those seeking help are served.[61] The program includes a team of dedicated navigators to support referrals, as well as a community engagement team that works with community-based organizations, social service agencies, health systems, independent providers, and community members to create a statewide, coordinated care network.[61] NCCARE360 is available in all 100 counties across North Carolina and has multiple functionalities including:

- A team of dedicated Navigators with the expertise to support complex NCCARE360 referrals. Navigators support CBOs that are not able to stay with the client through the referral process, as well as self-referrals submitted by individuals through our website.[61]
- A robust statewide resource directory supported by a dedicated resource team at NC 211 who regularly verifies and updates programs and services in the NCCARE360 platform.[61]
- A shared technology platform powered by Unite Us that enables providers to assess for and identify unmet social needs, send and receive secure electronic referrals, and track outcomes.[61]
- Onboarding, training, and technical support provided by Unite Us. The NCCARE360 technology is robust and transformative so all network partners are trained and empowered to use it to better serve their patients and clients.[61]

New York. In 2024, the New York State Department of Health selected organizations to lead the Social Care Network (SCN) in their region.[62] SCN leads are accountable for maintaining a comprehensive network of CBOs that will be responsible for delivering and tracking services addressing HRSN to eligible Medicaid members.[62] Selections included five Unite Us partner organizations that serve nine regions, including Care Compass Collaborative, Health and Welfare Council of Long Island, Healthy Alliance Foundation Inc., Hudson Valley Care Coalition Inc., and Public Health Solutions.[62] Unite Us will serve as the infrastructure for collaboration in each region's network of CBOs, health care professionals, and managed care organizations, which together represent 72 percent of Medicaid members across the state.[62]

Washington. The Seattle Indian Health Board connects thousands of Seattle-area residents to health and social services across the region.[63] Funding from several foundations as well as from government is braided and blended to support the Board's programs.[63] One such program is the Gender-Based Violence programming that provides confidential services to individuals fleeing from or who are survivors of gender-based violence.[63]

New Jersey. In 2020, New Jersey established the Regional Health Hubs program to coordinate provision of person-centered health care.[64] This innovative model establishes a regional network of non-profit organizations that partner with Medicaid and State agencies to reduce health disparities and improve health outcomes by combining robust connections to social services and community resources at both the patient and organizational levels.[64] The state began with establishing four Regional Health Hubs and plans to expand.[64]

California. The California Advancing and Innovating Medi-Cal (CalAIM) Initiative to Support Children and Families Initiative is a series of initiatives and reforms, in which California's Department of Healthcare Services (DHCS) is advancing and innovating Medi-Cal to create a more coordinated, person-centered, and equitable health system that works for all Californians.[65] The CalAIM Initiative is set to introduce a transformative requirement in 2025 around a "Closed Loop Referral" policy.[65,66] This new referral policy is important to improve care for children under Medi-Cal for Kids & Teens, reduce disparities in children's and maternity care and improve depression screening and mental health follow-up rates.[65,67] Furthermore, this new policy shows promise as a critical tool in overcoming health access challenges that children and youth in foster care disproportionately face.[65,67] There are already several opportunities underway to build out the infrastructure that will be needed to support closed loop referrals.[65] For example, specifically for the rollout of the CalAIM Enhanced Care Management (ECM) and Community Supports benefits, Medi-Cal

Managed Care Plans (MCPs) can use Incentive Payment Program (IPP) payments to build out networks of providers, including community health workers, who can support opening and closing referral loops.[65,68]

For primary care providers (PCPs), the recently announced Equity and Practice Transformation (EPT) Payments present opportunities "to advance health equity and reduce COVID-19-driven care disparities by investing in up-stream care models and partnerships to address health and wellness and funding practice transformation.[69]" PCPs can use the EPT payments to build the infrastructure and staffing in their practice for closed loop referrals.[69] Further, MCPs and other interested parties can operationalize closed loop referral policies through memorandums of understanding (MOU) requirements.[70] Specifically, starting in January 2024, MCPs are required to enter MOUs with Third Parties (i.e., various programs and agencies) to facilitate care coordination and information exchange, including WIC agencies, county child welfare departments, and regional centers.[70]

BEST PRACTICES FOR IMPLEMENTATING CLOSED LOOP REFERRAL SYSTEMS

Require Clear Definitions and Standards

The term "closed loop referral" is not consistently understood or used in the same way across sectors, to the extent it is used at all.[71,72] Definitions and standards will be important for closed loop referral policies so that it is clear to all parties involved the role/responsibility of each entity/person, the information and actions that constitute a referral, and the key steps, sequences, and methodologies, that constitute the closing of a referral loop.[71,72] It is also important to identify which types of referrals are the highest priority for tracking and monitoring. These definitional standards need to be consistent statewide and will need to be incorporated into electronic interfaces, workflows, and staffing models across provider types.[71,72] HCOs and CBOs involved in referral loops will need clear directions for how to make referrals and a basic understanding of who is eligible for services that could be available to them.[71,72] Further, these definitions should consistently be codified in formal contracts and agreements, like MOUs, when developing standards and timelines, including processes for expediting closed loop referrals for urgent needs.[71,72]

Leverage Data and Integrate Technology

Data sharing is necessary for closed loop referrals, but data sharing is limited and varied. Experience suggests that "the future of resource database design should center on technology and solutions that strengthen pathways for coordination and communication between health care, community resources and community members."[71,73] Yet, there are many concerns and challenges around data literacy and how referral and service information will be shared in a timely way across systems and referral management platforms and vendors to close referral loops.[73] The field uses many platforms and resource directories for referrals that are not standardized, cohesively linked, up-to-date, or connected, especially with EHR systems or health plan data systems.[20,71,73] As a result, health care professionals navigate multiple referral systems depending on the patient's needs and what community support services and community partners are available to the patient.[20,71,73] Further, some platforms may not be able to fully capture and/or communicate all stages of a closed loop referral, much less share patient care plans or be used for ongoing quality improvement.[20,71] Patient/family access to their own referral information varies across systems designed towards connecting agencies or institutions, but thoughtful communication modalities and technologies like apps and text-messaging can help close the information gap in some instances.[20,71]

The variation in referral systems creates an unreasonable burden on the health care professionals who are responsible for opening and closing referral loops and may have preferred EHR systems or other data systems they use for their patient/client/member care.[20,71,73] Participants in some studies reported finding referral solutions, such as communicating with external partners through their Microsoft Teams communications platform or using the clinic's EHR system to fax referrals to community mental health providers.[20,71] Interoperable data systems and workflows will require training of health care professionals and staff and providers in community-based organizations on how to use them and ensure appropriate user permissions, and ideally these systems could track all stages of the closed loop referral in as real- time as possible.[20,71] There are also significant concerns about sharing personal identifiable and protected health information with other providers or agencies.[20,71] It should be noted there are initiatives to improve data interoperability such as through Regional Health Information Organizations (RHIO). The goal of RHIO is to oversee the means of information exchange within a geographical area among various provider settings, payers and government agencies.[74] This initiative may be a potential pathway to consider in addressing data interoperability in a closed loop referral system.[74]

Rely On Trusted Partnerships and Referral Pathways

While technology and electronic data-sharing is important for referrals, it does not replace interpersonal work, relationships, and interorganizational networks that are foundational to referrals.[75] Closed loop referrals are most effective in promoting equitable health outcomes when individuals are engaged in a timely manner (i.e., no scheduling delays or geographic barriers
to care) and in a meaningful way (i.e., the individual's preferred language, information provided is easy to understand, etc.).[75] Common barriers to closing the referral loop include the lack of collective and consistent use of referral platforms by the entities involved in referrals, as well as challenges finding available and qualified providers and resources (i.e., housing, food, culturally congruent providers, etc.) to refer individuals to.[75]

Health system partnerships with libraries, places of worship, laundromats, barber shops, fire departments, dollar stores, shopping malls, and other local sites offer the chance to connect with families who most need referral and navigation support in places within the community they already trust enough to meet their other basic needs.[76] Health care professionals will need to authentically engage clinics, local CBOs, county agencies, and other partners to support the establishment of effective workflows, data exchanges, legal agreements, and communication channels.[76] Work will need to be done to understand and address the needs and constraints of both the referring clinician and the receiving provider and provide ongoing training, technical assistance, monitoring, and financial resources or incentives to promote closed loop referrals.[76]

Further, it is important to remember that due to the past and ongoing impact of racism in health care, inclusive of systematic segregation, differential medical treatment based on race and ethnicity, and limited resources allocated to people and communities of color, there is wide variability in the availability of and access to local resources in communities.[75] In addition, many areas may lack reliable internet and broadband access needed for electronic referrals and data sharing.[75] Gaps in service area resources will need to be identified early to make the best use of available providers and map the places where service expansion will be needed.[75]

Training and Ongoing Support

It is critical to establish an efficient and compassionate referral network that meets the needs of individuals.[20,75,77] Best practices for this include assessing the need for initial and ongoing training for health care professionals and providers in CBOs on how to operationalize a closed loop referral system and coaching to foster a patient-centered approach to making referrals.[20,71,77] Operational training equips health care professionals and providers in CBOs with the skills to effectively navigate and utilize referrals in a digital landscape. Understanding the operational intricacies of a digital system, documentation requirements, referral initiation procedures, and tracking mechanisms is vital for ensuring that the referral process is seamless, efficient, and protective of sensitive information.[71,75,77] This training ensures health care professionals and providers in CBOs can use the system proficiently, thereby improving the accuracy, timeliness, and success of referrals they make, ultimately enhancing the quality of care.[71,75,77] Successful referrals are patient-centered, which often require cultural humility, empathetic communication, and a trauma-informed approach.[77] These skills should be integrated into closed loop referral coaching and support for all health care professionals and providers in CBOs.

To ensure referral-making is trauma-informed, health care professionals and providers in CBOs should be coached on how to prioritize creating a safe and supportive environment and respect the patient's autonomy and choices.[71,75,77]Health care professionals and providers in CBOs should understand how to consider the potential triggers and sensitivities related to the referral process, aiming to minimize retraumatization.[71,75,77] A patient-centered approach to referrals also considers the background and circumstances of the patient. Historically, patients of color and varying gender and sexual identities have been discriminated against and disrespected in health care settings.[71,75,77] It is critical that health care providers and staff and providers in community-based organizations understand the disparities that affect these communities and are culturally conscious in how they communicate during the referral process. Furthermore, the closed loop referral process should emphasize and acknowledge that health care professionals and providers in CBOs who are embedded in the community are best situated to make referrals.[71,75,77]

It is also important to note that studies have identified higher physician engagement in addressing HRSN were associated with a greater likelihood of burnout.[78] Specifically, high engagement in addressing HRSN was observed among physicians identifying as women or transgender women, those reporting Black or African American or other race and ethnicity, and those who frequently used non-English languages in patient communication.[78] This could be due to intrinsic factors, with physicians from certain racial and ethnic groups potentially feeling a stronger commitment

to addressing HRSN.[78] Importantly, these findings add an additional layer to diversity, equity, and inclusion efforts in medicine by critically considering the "minority tax"—the extra responsibilities that historically marginalized physicians often experience.[78,79] Recognizing patients' ongoing, unmet HRSN without being able to fully address them could potentially lead to a sense of helplessness, contributing to burnout.[78,80] Addressing HRSN necessitates interdisciplinary teamwork, such as HRSN screening often being led by nonphysician staff (i.e., nurses, social workers, and community health workers); therefore, training and education can be incorporated to help physicians effectively collaborate with interprofessional team members to address HRSN for patient populations.[78,81]

Resource and Monitor Referrals

The infrastructure to make closed loop referrals possible will need to be fully resourced and sustained. This goes beyond the high start-up costs of technological platforms or data integration but also applies to the ongoing needs to maintain a workforce (hiring, training, etc.) to manage referrals and ensure there are qualified providers available to receive referrals and deliver referred services.[20,32,71] This will require intentional and ongoing efforts and formalized relationships (i.e.,
contracts, MOUs, etc.) between health care professionals and community providers, as well as ongoing, cross-sector community reinvestment at state, local, and health system levels that are refined over time to fill in gaps and meet the changing needs of the patient population.[20,32,70,71] Furthermore, data captured on both successful and unsuccessful implementation of closed loop referrals should be used to fund and build local infrastructure to meet the needs of patients.[20,32,71]

EXISTING AMA POLICY

AMA policy H-165.822 "Health Plan Initiatives Addressing Social Determinants of Health," recognizes that social determinants of health encompass more than health care and encourages new and continued partnerships among all levels of government, the private sector, philanthropic organizations, and community- and faith-based organizations to address non-medical, yet critical health needs and the underlying social determinants of health. This policy also states that the AMA supports: continued efforts by public and private health plans to address SDOH in health insurance benefit designs; mechanisms, including the establishment of incentives, to improve the acquisition of data related to social determinants of health, while minimizing burdens on patients and physicians; and research to determine how best to integrate and finance non-medical services as part of health insurance benefit design, and the impact of covering non-medical benefits on health care and societal costs. Further, it encourages coverage pilots to test the impacts of addressing certain non-medical, yet critical health needs, for which sufficient data and evidence are not available, on health outcomes and health care costs.

The AMA has also involved in efforts aimed at improving patients' health by addressing SDOH. This includes but is not limited to being a founding member of the Gravity Project, a Robert Wood Johnson-funded initiative with more than 2,500 participants from organizations and entities representing health care, social services, payers, technology vendors, and government agencies working to develop consensus-driven data standards to support the collection, use and exchange of SDOH data.

CONCLUSION

Responding to compelling evidence that links social risks—such as food, housing, transportation, or economic insecurity—to health care outcomes, health care practices are considering how to improve patients' social conditions.[43,87] Several forces have spurred the momentum to act on evidence linking social risks and health care outcomes including the ongoing shift towards value-based care in the Affordable Care Act and beyond, campaigns advanced by clinician organizations such as the American Academy of Family Physicians, and influential reports by the National Academies of Sciences, Engineering, and Medicine and others.[43,88,89] As a result, health care practices report screening patients for at least one HRSN.[34,43,88] Information on patients' HRSN can be used by health care professionals to gain a deeper understanding of their patients' lives, to adjust patient's care plan (i.e., changes to medications or follow-up schedule), and to improve social conditions.[43,88] For many health care practices, the next step is providing patients with a referral to CBOs to address their social needs.[43,88] Closed loop referral platforms can be used to address this next step by allowing for efficient communication and coordination between health care professionals and CBOs.[12,13] It ensures that patient data and information are communicated to the right individuals at the right time, allowing for review, action, acknowledgment, and documentation.[12,13] The platform facilitates referrals from health care professionals to CBOs and enables reporting back on whether the patient's HRSN were addressed.[12,13]

There are many factors impacting the success of a closed loop referral system, including: technology (electronic referral, response and feedback), processes (effectiveness, efficiency), organizational (management, policy and planning, rules and regulations), and patient-centered individual characteristics (social capital, transportation, awareness, attitude, satisfaction, and social influence).[14,32,65,71,88] However, efforts have been underway to address these barriers to improve the effectiveness of the closed loop referral systems in improving social and health outcomes. Successful efforts thus far have incorporated four main best practices: (1) establishment of collaborative governance for shared decision-making processes, fostering trust, alignment, and transparency among organizations; (2) development of technology linkages between existing platforms to facilitate seamless referrals between organizations and ensure visibility of referral outcomes; (3) integration of regional resource directories into technology infrastructure to ensure resource accessibility/quality; and (4) evaluation of the system's impact on health equity, efficiency, and cost reduction.[12,14,32,65,71,75] It should be noted that more states are exploring the integration of closed loop referral systems to address SDOH which will continue to shape the best practices needed for successful implementation.[34,62,66,82]

RECOMMENDATIONS

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

1. Our AMA acknowledges closed loop referral systems are a mechanism to address social determinants of health (SDOH) through a community-level, system approach that connects clinicians and the patients they serve to health care services and social support services.
2. Our AMA supports the continued evaluation of closed loop referral systems in addressing SDOH and health-related social needs to identify best practices and improve health outcomes.
3. Our AMA supports continued research to streamline the workflow processes and ensure two-way communication for closed loop referrals between health care systems and community-based organizations to address SDOH and health-related social needs.
4. Our AMA supports: (a) using data to foster hospitals, health insurance, private sector, philanthropic organizations, and community- and faith-based organizations investment in addressing SDOH, (b) reducing barriers to using grants to address SDOH, and (c) promoting federal- and state- initiatives to expand funding for SDOH health-related social needs interventions.

Fiscal Note: less than $1,000

APPENDIX I – Key Terms

There are a few key terms that will be used throughout this report that are important to define because they are often used interchangeably when they have different definitions. These key terms are as follows:

- **Social determinants of health** (SDOH): The conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. SDOH refers to community-level factors.[90] They are sometimes called "social drivers of health."[90]
- **Health-related social needs** (HRSN): Social and economic needs that individuals experience that affect their ability to maintain their health and well-being.[2] They put individuals at risk for worse health outcomes and increased health care use. HRSN refers to individual-level factors such as financial instability, lack of access to healthy food, lack of access to affordable and stable housing and utilities, lack of access to health care, and lack of access to transportation.[2]
- **Health disparities**: Preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health, health quality, or health outcomes experienced by disadvantaged populations.[91]
- **Health equity**: The attainment of the highest level of health achievable for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[92]
- **Community-Based Organization** (CBO): A non-profit organization whose members represent a local community and focus on addressing the community's sociocultural conditions and lived experiences.[93] This can include improving the community members' social and health risks.[93]

- **Care Coordination Services**: A model of care approach aimed at connecting individuals to a full range of community health promotion services.[94]

APPENDIX II – CMS Waivers and Demonstration Programs for HRSN

- **Section 1905(a) State Plan Authority**: States have used Section 1905(a) to establish peer support and case management services, which are then used to link beneficiaries to HRSN supports. As of 2018, 19 states indicated that case management is a covered benefit in their program, and 36 indicated that targeted case management is a covered benefit (though this benefit may be provided under section 1915(g)*).[95,96]
- **Home and Community Based Services (HCBS)**: Several states have utilized HCBS to implement housing-related services, including 46 states with section 1915(c) waivers; † four states with section 1915(i) benefits; and eight states with section 1915(k) benefits as of 2021.[97] For example, Minnesota is using section1915(i) state plan authority to provide housing stabilization services to certain individuals that are experiencing homelessness or are at risk of becoming homeless.[98] In their first year, the state reported that they served 7,203 individuals.[97,98]
- **Section 1115 Demonstrations**: As of 2021, 25 states have utilized the flexibility provided by section 1115 demonstrations to address HRSN, such as housing-related services, nutrition, transportation, and interpersonal violence.[97,98] For example, CMS recently approved an 1115 waiver for California's Medicaid program (Medi-Cal) to launch California Advancing and Innovating Medi-Cal (CalAIM), which seeks to integrate the Medi-Cal program with other social services through a "no wrong door" approach that couples clinical care with Medicaid reimbursable nonmedical services, including housing supports, medical respite, personal care, medically tailored meals, and peer supports.[66] However, as of February 2022, four states have also used section 1115 demonstrations to waive NEMT, a benefit that is typically required.[99]
- **Section 1945 Health Homes**: As of April 2021, there are 37 Health Home models across 21 states and the District of Columbia, all of which must include comprehensive case management, individual and family support, and referrals to community and social services, among other required services.[100]
- **Managed Care Programs**: As of 2018, 37 states have implemented requirements in their managed care contracts related to HRSN and SDOH.[101]

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3. PROTECTIONS AGAINST SURGICAL SMOKE EXPOSURE

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policy H-365.975

INTRODUCTION

Resolution 404-A-24, "Protections Against Surgical Smoke Exposure," was referred. This resolution called for AMA to support efforts to limit surgical smoke in operation rooms. Testimony noted conflicting evidence as well as ergonomic and cost considerations of smoke evacuation technologies. This report provides a summary of the available evidence on the potential health impacts of surgical smoke, currently available preventive strategies, the landscape of legislative activity to limit surgical smoke, and a summary of potential concerns or barriers to effective prevention. While surgical smoke can also be of concern to patients, this report focuses on the issue from an occupational health and safety perspective for health care personnel.

BACKGROUND

Surgical smoke results from the use of energy-generating devices during surgery, including electric knives, ultrasonic scalpels, and lasers, which causes the temperature of tissue to rise to the point of tissue vaporization, released as surgical smoke. Surgical smoke has been estimated to be about 95 percent water vapor and five percent organic byproducts, the latter being responsible for potential adverse exposure risks.[1] Surgical smoke is a health concern as it may contain a number of known health hazards, including benzene, toluene, hydrogen cyanide, formaldehyde, viruses, and bacteria.[2] The potential negative impacts from surgical smoke are severalfold. First, surgical smoke may limit visibility within the operative field, affecting the safety of the surgical operation to some extent if it is not actively cleared. Second, surgical smoke can cause short-term discomfort and potential illness to surgical staff.[3,4] Depending on the size and types of particles released, surgical smoke can cause acute irritation of the eyes and throat while smaller particles in smoke can settle further in the lungs. Inhalation of particulate matter smaller than 2.5 micrometers ($PM_{2.5}$) has been associated with increased incidence of asthma, chronic obstructive pulmonary disease, lung cancer, and cardiovascular disease.[5] Lastly, surgical smoke may increase the risk of disease transmission through the presence of viral and bacterial pathogens in the smoke.[6]

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases using the search terms: “surgical smoke” AND “health” as well as “surgical smoke” AND “prevention.” Additional searches were performed on both effectiveness and cost concerns of current preventive measures. Legal websites were searched to identify which states have passed legislation on this topic. Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by federal agencies and applicable professional and advocacy organizations were also reviewed for relevant information.

DISCUSSION

Health hazards of surgical smoke

There are several different types of energy-generating devices utilized during surgery to cut and cauterize tissue, including electric knives, ultrasonic scalpels, and lasers. The composition of surgical smoke, particle size, and the amount produced is dependent on the device used and the type of tissue where it is employed. For example, the cauterization of solid organs or fat tissue versus muscle tissue has been found to create higher emissions.[7] In one study, much higher levels of ultrafine particulate matter were measured while operating on the liver compared to surgeries involving muscle, adipose tissue, and blood vessels.[3] Additionally, surgical smoke particles with the smallest size, generally less than 0.1 micrometers (µm), are produced by electrocautery, followed by laser tissue ablation (~0.3 µm) and ultrasonic scalpel usage (0.35–6.5 µm).[8] Particle sizes of less than five µm are of more concern as they are respirable, with smaller particles of sizes less than two µm being of the greatest concern as they can penetrate and be deposited deeper in the lungs.[8] Surgical smoke is a health risk for a range of health care staff. The Occupational Safety and Health Administration (OSHA) estimates that around half a million workers, including surgeons, nurses, anesthesiologists, gynecologists, perioperative practitioners, dermatologists, and surgical technologists, are exposed annually to surgical smoke.[9]

Concern over surgical smoke is driven by its composition as it may contain several known health hazards, including chemicals such as hydrogen cyanide, polycyclic aromatic hydrocarbons (PAHs), volatile organic compounds (VOCs – such as benzene, toluene, formaldehyde, etc.), pathogens (viruses and bacteria), and particulate matter.[1] However, the exposure to any of these health hazards may differ by specialty and profession, in terms of the type of surgeries they perform, as well as what role an individual has in the operating room. Additionally, exposure levels differ among staff members depending on where they stand during surgical procedures and the length of working hours. Coupled with the heterogeneity in the study methods used to assess risk and different types of surgery, it remains a challenge to obtain an accurate picture of exposure to surgical smoke to operating staff during procedures. While there have been a predominance of nonhuman studies assessing negative impacts of surgical smoke, human studies have yet to show a direct causal link between surgical smoke exposure and poor health outcomes besides acute irritative symptoms such as headache, eye irritation and watering, and throat irritation and cough.[3,4]

Studies assessing operating staff exposure to various chemicals in surgical smoke illustrate these multiple challenges. For example, there are concerns that surgical smoke contains VOCs such as benzene and formaldehyde, but studies conducted by the National Institute of Occupational Safety and Health (NIOSH) where they sampled surgical theaters found few VOCs. Even when detected, they were at levels below OSHA and NIOSH recommended exposure limit levels.[10] Another study has noted that VOCs were found to be higher during open surgery versus laparoscopic surgery.[3]

Nonetheless, due to the varied components in surgical smoke, there are several different biological mechanisms and pathways impacting health. Potential health impacts from surgical plumes are categorized into four main groups and are summarized below.

Respiratory impacts

There is a potential for ultrafine particles (particles 0.1µm in size) in surgical smoke plumes that can penetrate and be deposited deep in the lungs.[10] Known health impacts of particulate matter (PM) exposure include cardiovascular effects, including heart attacks, heart failure, and strokes, as well as respiratory effects, including asthma attacks and increased respiratory symptoms such as coughing, wheezing, and shortness of breath.[5] Data from the U.S. Nurses’ Health Study, an ongoing prospective cohort that started in 1976 with biennial surveys, have shown that operating room (OR) nurses have a higher risk of chronic obstructive pulmonary disease compared to nurses in administrative positions, but they were equivalent to those working in the emergency department or within in-patient hospital units.[11]

From this same study, OR nurses were also found to have lower incidence of asthma compared to those working in administrative positions.[12] On the other hand, other studies have noted OR staff have an increased risk of respiratory diseases, such as sinus problems, allergies, asthma, and bronchitis, compared to the general population.[13]

For PM, direct measurement of smoke in 100 laparoscopic surgeries found unhealthy concentrations of PM 2.5 but the measurement duration was not reported, which restricts comparisons with established standards that are used for other occupational settings or the U.S. Clean Air Act.[3] Multiple studies have found widely variable concentrations of PM levels, some over known Environmental Protection Agency (EPA) limits, others comparable to daily office exposure or lower than outdoor urban or rural environments, and still others found very brief but extremely high peaks in concentrations.[3,14] Another limitation that could explain wide variations in findings on PM levels is that studies examining surgical plumes for ultrafine particles have used devices that are unable to discern between water vapor and PM, a significant design flaw as living tissue has a high-water content.[10] As a whole, these data make it difficult to conclude whether surgical smoke contains levels of PM of concern for OR personnel.

Cancer risk

Several of the compounds found in surgical smoke are known carcinogens, notably benzene, 1,2-dichloroethane, and polycyclic aromatic hydrocarbons (PAHs).[15] In one study, the concentration of PAHs from 10 mastectomies were investigated to estimate cancer risk to surgical staff. Looking at the PAH concentrations within the breathing zones of surgical staff, the study authors found the concentrations to be 20 to 30 times higher than those in regular outdoor environments and thus their cancer risk was significantly higher than the benchmark set by EPA.[16] To note, even though measured PAH concentrations were higher by the surgeon, the anesthetic technologists had a higher cancer risk due to their longer working hours in operation rooms.[16] While the increased cancer risk may be greater than the general population, assessed exposure levels have varied from study to study, with some noting higher concentrations while others have noted they are within acceptable limits.[3] Due to the PM and carcinogenic compounds within surgical smoke, an increased risk of lung cancer is a concern among surgical personnel in the literature. Several studies have aimed to compare the carcinogenic risk of surgical smoke to smoking cigarettes, with comparisons ranging from exposure similar to smoking six cigarettes to inhaling the secondhand smoke of 27 to 30 unfiltered cigarettes a day.[17,18]

The first study on this was published in 1981. Utilizing electrosurgery tools on a canine tongue, smoke condensates was collected in a closed box system to assess the mutagenicity of the smoke using the Ames test (a well-established assay to evaluate the mutagenicity of agents) and found that the smoke from one gram of tissue was equivalent to those from three to six cigarettes in terms of total mutagenicity.[17] More recently, a study by plastic surgeons assessed ablated human and porcine tissue to determine how much tissue was destroyed over five minutes and then reviewed the total electrosurgery time in their operating room over a 44 day period to determine a daily average level of exposure. Using the one gram of tissue equivalency to six cigarettes assumption from the 1981 study, it was concluded that daily electrosurgery produced the equivalent of secondhand smoke of 27-30 unfiltered cigarettes.[18] Although these figures are often cited in the literature to demonstrate the hazards of surgical smoke, several researchers have called these findings into question. They argue that the methods used in the original 1981 study were limited in that the mutagenicity test was based on smoke produced in a close-system smoke chamber, which is not reflective of the surgical theater environment and exposure, and thus the concluded equivalency is faulty and misleading.[3,10,19]

Importantly, there is no evidence demonstrating that exposure to surgical smoke increases the risk of lung cancer. On the contrary, the Nurse's Health Study cohort, which focused on 87,000 nurses with and without operating room experience in 1984, showed no increase in lung cancer incidence at follow-up nearly 15 years later. In fact, the nurses with the longest operating room experience had significantly less incidence of lung cancer on follow-up, even after controlling for cigarette smoking history.[3]

Infectious diseases

Another concern with surgical smoke is the presence of viral fragments within the plume with some evidence demonstrating RNA or DNA fragments of SARS-CoV-2, human papillomavirus (HPV), hepatitis B, and human immunodeficiency virus (HIV) in surgical smoke.[20] Concern over HPV exposure in surgical smoke has been raised more frequently due to the common use of energy-generating devices in LEEP and anal wart ablative surgeries. While HPV particles have been detected in surgical smoke and inhalation of these particles into the upper airways has been detected, the evidence for transmission is more controversial.[21] The evidence of HPV-related disease in operation room staff following exposure to HPV is largely based on retrospective and survey data, which did not verify findings

through confirmatory testing, and a small number of case studies (n = 4).[6] Increased prevalence of HPV infection or HPV-related disease in operating room staff following occupational exposure to surgical smoke has not been convincingly demonstrated.[6]

For example, HPV DNA was detected in nasal epithelial cells of surgeons performing ablative surgery on HPV+ patients much more frequently than surgeons who do not conduct these types of operations. However, with a notable loss of follow-up, all became negative at two years.[21] The highest level of evidence and most cited studies have been case reports of laser surgeons diagnosed with HPV+ laryngeal papillomatosis (n = 1) and tonsillar cancer (n = 2), as well as an operating room nurse with papillomatosis who was frequently exposed to ablative excision of anogenital warts.[3] Another more recent study assessed HPV prevalence among operating room staff using post-surgery nasal swabs to detect whether HPV was present and in greater than 98 percent of samples, no HPV was present. The operating team had used a smoke evacuator system, and an overwhelming majority wore surgical masks, versus N95 masks. In the less than two percent of staff where HPV DNA was detected in nasal swabs, no HPV related disease was detected after 3-6 months of follow-up.[6] Researchers have noted that despite the limited evidence for HPV-related disease risk from surgical smoke, for cases where HPV lesions are to be cauterized, the use of smoke evacuators and/or N95 masks are reasonable precautionary measures.[10]

During the COVID-19 pandemic, concern over the transmissibility of human coronavirus during surgical procedures was also raised. A 2021 study evaluating the existence and infectivity of human coronavirus RNA in surgical smoke found that while viral RNA was present in the smoke, it was not demonstrated to be infectious and the study authors found that surgical masks were able to effectively reduce the amount of viral RNA by at least 99.8 percent.[20] Lastly, there have been no case reports of suspected transmission of HIV or viral hepatitis via surgical smoke.[10] Evidence for concern is solely based on existence of DNA fragments in surgical smoke.

Reproductive outcomes

Female surgeons have been shown to have higher rate of adverse pregnancy outcomes and infertility compared to the general population, but there have been no studies evaluating the direct effects of exposure of surgical smoke on reproductive outcomes.[7] However, other studies have demonstrated negative reproductive health outcomes from various components found in surgical smoke. For example, PM exposure has been linked to low birth weight and preterm labor. Toluene has been associated with cognitive impairment, congenital defects and infertility while benzene has been linked to an increased risk of childhood leukemia. Lastly, 1,2-Dichlorethane is associated with an increased risk of spontaneous abortion and infertility (but in animal studies only).[7] These are just a few of the 45 different chemicals that have been identified in surgical smoke. More research is needed to better understand whether OR exposure to surgical smoke could be related to negative reproductive health outcomes.

Known prevention strategies, evidence of effectiveness, and barriers to implementation

The issue of clinician exposure to surgical smoke was brought to the attention of the OSHA, the primary federal agency responsible for developing protective standards related to health care occupations, nearly 35 years ago but regulations were never formulated on the topic.[22,23] Despite the lack of a federal regulatory standard, OSHA, NIOSH, the American National Standards Institute, ECRI, and the Association of periOperative Registered Nurses (AORN) have developed recommendations on minimizing exposure to surgical smoke in the operating environment.[24–27] AORN has a Go Clear program, a comprehensive surgical smoke-free recognition program for facilities who want to ensure a smoke-free environment.[25] Across guidance documents, the most recommended preventive measure to limit exposure to surgical smoke in the operating rooms is utilizing smoke evacuation equipment to remove smoke near the surgical site where smoke is generated.[28] An operating room smoke evacuation system is designed to capture surgical smoke and includes a capture device (either free standing or fitted over an electrosurgical tool), a vacuum system, and some type of filtration unit capable of capturing contaminants.[1,29] Illustrative examples are provided at the end of this report.

Wearing personal protective equipment (PPE), including standard surgical masks or even N95 respirators and masks containing activated carbon have also been recommended. PPE can provide some level of protection but is not protective against all possible particles contained in surgical smoke, particularly particles less than 0.3 µm (the functional limit of N95 masks).[24] Additionally, having appropriate ventilation in the operation room to avoid any lingering presence of smoke in the operating environment is also recommended.[9] However, NIOSH determined that the Centers for Disease Control and Prevention's (CDC) recommended air exchanges per hour is insufficient on its

own for adequate surgical smoke evacuation.[7] Furthermore, in outpatient surgical settings there may be little to no ventilation in comparison to operating rooms, which are required to adhere to specific ventilation requirements.[24] From outside the U.S., the British Association of Dermatologists has called for smoke extractors to be made available in all settings where dermatology surgery takes places and further occupational health research on potential health risks from surgical plumes be conducted.[30]

Due to concerns of increased risk HPV infection and resulting oropharyngeal cancer in health care personnel, HPV vaccination of health care staff exposed to HPV through surgical smoke has been raised as a potential preventative strategy.[31] In the U.S., the American Society for Colposcopy and Cervical Pathology (ACSSP) has recommended the HPV vaccine for individuals working in gynecology routinely exposed to HPV.[32] However, the American College of Obstetricians and Gynecologists and CDC's Advisory Committee on Immunization Practices do not currently have similar recommendations for health care personnel to receive the HPV vaccine.[33,34] The AMA has sent a letter to the CDC asking them to review the available evidence for recommending the HPV vaccine for health care professionals to prevent health care related infection of HPV.

While implementing smoke evacuation systems is understood to be the most effective strategy for reducing surgical smoke exposure, their use is limited and inconsistent, with one study finding that only about 10 percent of surgeons consistently use them.[35] A number of barriers to implement effective preventive strategies, both at the individual and organizational level, have been identified.[36] At the individual level, barriers to usage include surgeon resistance, impaired surgical view, excessive noise, and lack of education.[7] To illustrate the lack of education among surgical staff, in a 2016 survey of dermatologist residents, nearly 72 percent had not received any education on the potential hazards of electrosurgery smoke during their medical training.[37] In terms of excessive noise, a 2021 study assessed the noise associated with 11 identified surgical smoke evacuators used during dermatologic surgery and found none of them had sound levels greater than the permissible upper limit as recommended by OSHA, and therefore would not be considered an occupational hazard based on a 8-hour exposure.[38]

Even if smoke evacuator noises do not exceed OSHA standards, operating team members may subjectively still find the noise excessive, a distraction, or an annoyance. Perceived excessive noise in the operation room can increase risk for error, by making it difficult to hear critical information or communicate effectively, and thus presents an unsafe environment the patient.[39] However, as the smoke evacuator would only need to be operational during the period in which smoke is being produced by electrosurgery tools, it could be assumed the noise would not be a constant and therefore minimally distracting.

At the organizational or hospital level, barriers include a lack of resources, associated costs with purchases smoke evacuation systems, and insufficient or nonexistent internal policies on the matter.[40] Improving awareness among health care staff around the potential harms of surgical smoke and the protective measures designed to minimize personal harm among health care workers could help improve personal and organizational uptake of appropriate preventive measures.

Legislation

As there is no federal standard or regulation around surgical smoke, some states have passed policy to require surgical smoke evacuation systems. Rhode Island was the first state to pass such a policy in 2018.[24] Based on a review of state laws in the summer of 2024, 18 states have passed surgical smoke legislation. In terms of countries that have passed legislation on this topic, Denmark was the first and remains one of the only countries in the world to pass national legislation requiring employers to install evacuation systems that remove smoke and other harmful substances as close as possible to the source in surgical theaters.[41] To date, there are no evaluation or implementation studies that have assessed the effectiveness or impacts of these state laws on reducing surgical smoke exposure.

AMA POLICY

Existing AMA policy does not address surgical smoke directly but supports the development of regulations to protect workers from occupational carcinogens using the best available scientific data and the protection of medical trainees from potential hazardous exposures.[42]

CONCLUSIONS

While more research is needed to better understand the potential health impacts associated with surgical smoke, there is currently no known safe level. In taking a public health precautionary principal approach, it is reasonable to take preventive measures even if health hazards are uncertain. There are several preventive measures that are recommended by multiple organizations and can be employed to reduce risk to personnel, which include the use of smoke evacuation equipment, having appropriate ventilation, and wearing appropriate PPE, which may include surgical masks or even N95 respirators. Additionally, increased education on the potential health risks of surgical smoke among health care personnel is needed, as many have not received any sort of training or education on the subject.

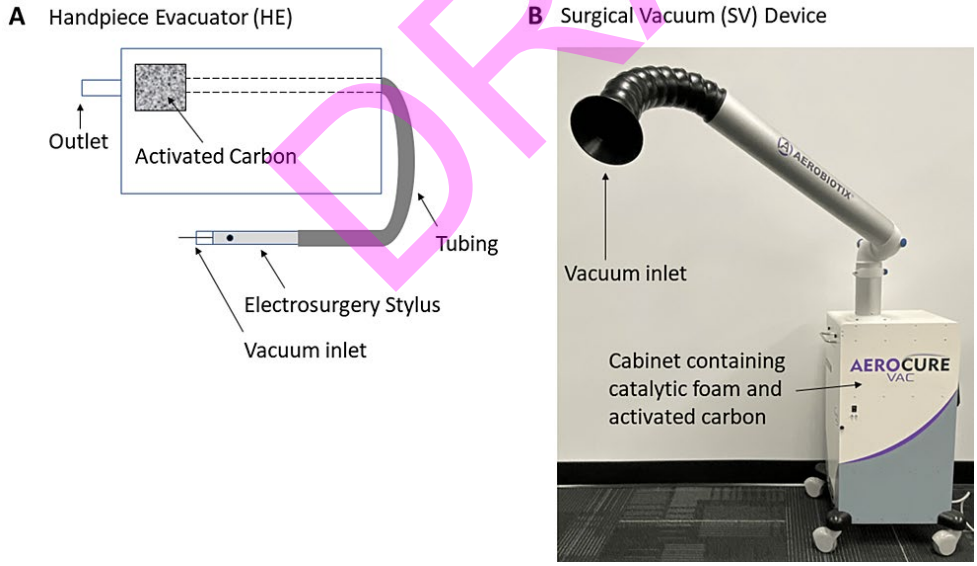
RECOMMENDATIONS

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

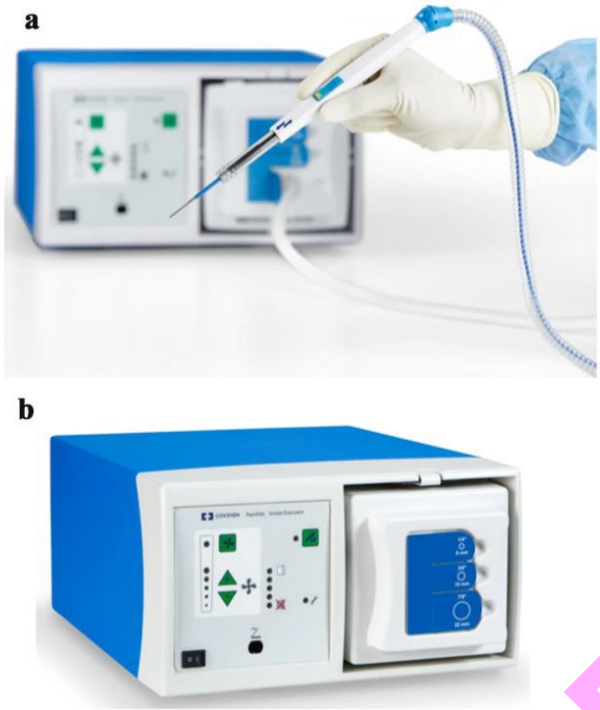
That our American Medical Association:
(1) supports efforts to limit surgical smoke exposure ~~in operating rooms~~, including where exposure to infectious diseases ~~such as human papillomavirus~~ may occur, using various methods such as smoke evacuators, appropriate ventilation, and/or appropriate personal protective equipment;
(2) recommends education on surgical smoke among medical students and health care professionals ~~that work and/or train in operating rooms~~ to improve awareness of the potential dangers of surgical smoke and preventive measures that can be taken; and
(3) encourages ongoing monitoring, data collection, and longitudinal research into the health impacts of surgical smoke to better inform understanding of potential health risks and evidence-based interventions to reduce risk.

Fiscal Note: less than $1,000

APPENDIX: Examples of Smoke Evacuation Systems. TO NOTE: The AMA does not endorse any specific smoke evacuation device or manufacturer. These are only included as illustrative of different types of systems.



Above: Two types of smoke evacuator systems, one as a freestanding unit and one with the vacuum inlet over the electrosurgery tool.[43]



Smoke evacuation device showing (a) electrosurgical pencil containing capture system surrounding protruding electrode connected to (b) vacuum-driven smoke evacuator with replaceable ULPA filtration unit. ©2020 Medtronic. All rights reserved. Used with permission of Medtronic

Above: Example of a smoke evacuation device with an electrosurgical pencil containing capture system.[1]

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4. CONDEMNING THE UNIVERSAL SHACKLING OF EVERY INCARCERATED PATIENT IN HOSPITALS

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policies H-420.957 and H-430.974

INTRODUCTION

Resolution 427-A-24, referred by the House of Delegates (HOD), asked that our American Medical Association (AMA):

> condemn the practice of universally shackling every patient who is involved with the justice system while they receive care in hospitals and outpatient health care settings; and
>
> advocate for the universal assessment of every individual who is involved with the justice system who presents for care, by medical and security staff in collaboration with correctional officers, to determine whether shackles are necessary or may be harmful, and, if restraint is deemed necessary, that the least restrictive alternative to shackling with metal cuffs is used when appropriate; and
>
> advocate nationally for the end of universal shackling, to protect human and patient rights, improve patient health outcomes, and reduce moral injury among physicians.

BACKGROUND

People who are justice system-involved have a higher prevalence of acute and chronic health conditions than the general U.S. population.[1] Federal law mandates the provision of health care for people who are incarcerated.[2,3] When an incarcerated patient requires medical care that exceeds the capacity of the correctional facility in which they are housed, they are transferred to a community hospital.[2] Health care professionals practicing outside of correctional facilities receive little dedicated training in the care of justice-system involved patients, may be unaware of guidelines for the treatment of justice-system involved patients, and practice in health care systems with varying policies toward these patients.[2,4–6] Hospitalized incarcerated patients are commonly shackled throughout their duration of treatment in community hospitals to prevent escape or harm to others.[7,8] While federal and state laws regulate shackling of pregnant people, no similar protections guide shackling of non-pregnant, incarcerated patients in the acute care setting.[7,9,10] As a result, health care professionals rarely unshackle incarcerated patients during routine hospital care.[9,9,10] Further it should be noted that shackling incarcerated patients in medical settings has been limited internationally. For example, in the Netherlands, shackles are never used on incarcerated patients in the medical setting and handcuffs are used only in exceptional circumstances.[11]

METHODS

English language articles were reviewed from searches of PubMed and Google Scholar using the search terms "shackling in health care settings", "shackling AND harm to health care professional" and "shackling AND harm". Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies such as the Department of Justice; applicable organizations were also reviewed for relevant information such as the National Commission on Correctional Health Care (NCCHC).

DEFINITIONS

The terms "restraint" and "shackling" are important to define because they are often used interchangeably despite having different definitions. These key terms may also have slightly different definitions depending on the source.

Restraint. (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or (B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. (C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).[12]

Shackling: the use of any physical restraint or mechanical device to control the movement of a prisoner's body or limbs, including handcuffs, leg irons, and belly chains.[2] The use of all devices which encircle the ankle or wrist of an incarcerated individual and restrict movement.[13]

DISCUSSION

Hospital Restraint Policies

It is important to differentiate shackling policies for patients who are incarcerated from hospital restraint policies for patients who are agitated or combative. The latter is governed by Centers for Medicare & Medicaid Services (CMS) guidelines requiring the least restrictive form of restraint that protects the physical safety of the patient, staff, or others.[2,14] Health care professionals are required to document the reason for restraint, form of restraint, reevaluations of continued restraint need, and any consequences for patient health.[2,14] However, no such policy exists for shackling in the hospital setting.[2] Shackles are not medically necessary and are often used "as a means of coercion, discipline, convenience, or retaliation."[15,16] It is up to the treating health care professional to determine whether appropriate care can be delivered with shackles in place.[2,15] Custody officials are then responsible for determining an alternative manner to safely secure, or not secure, a patient that allows for standards of medical care to be met.[2,15]

Applying Restraints to People Who Are Incarcerated

Federal regulations for the use of physical restraints on people who are incarcerated provide that staff are authorized to apply physical restraints necessary to "gain control" of an incarcerated individual "who appears to be dangerous" because the individual: assaults another individual; destroys government property; attempts suicide; inflicts injury upon self; or becomes violent or displays signs of imminent violence.[17] This regulation does not restrict the use of restraints in situations requiring precautionary restraints, particularly in the movement or transfer of incarcerated people (e.g., the use of handcuffs in moving incarcerated individuals to and from a cell in detention, escorting an incarcerated person to a Special Housing Unit pending investigation).[18] The restraint equipment or devices (e.g., handcuffs) may not be used in any of the following ways: as a method of punishment, through placement around an incarcerated individual's neck or face, or in any manner which restricts blood circulation or obstructs the incarcerated individual's airways, in a manner that causes unnecessary physical pain or extreme discomfort, to secure an incarcerated individual to a fixed object, such as a cell door or cell grill, except under certaincircumstances.[19] Further, all incidents involving the use of force and the application of restraints must be carefully documented.[20]

Summary of Types of Medical Restraints

It is important for health care professionals to have a solid working knowledge of their own health care facility's "least restrictive to most restrictive" spectrum of available physical restraints and restraint alternatives.[14] When restraint use is warranted, the least restrictive potentially effective measure should be considered first.[14,21] Examples of physical restraints are outlined in Appendix I. It is important to note that de-escalation techniques and diversionary devices should be tried before the decision is made to use any type of restraint.[14,22] Diversionary devices such as activity aprons and fidget sensory aids, for example, are designed to provide stimulating activities and textures for patients with decreased cognitive function and/or requiring tactile stimulation.[22]

Human Rights and Shackling

It has been argued that routine shackling of patients who are incarcerated violates foundational international human rights principles, including those contained in the Universal Declaration of Human Rights, the International Convention on the Elimination of All Forms of Racial Discrimination, and the International Covenant on Civil and Political Rights.[23–25] These principles were designed to protect human dignity and protect people from discrimination and cruel, inhuman, and degrading treatment.[23–25] It has been argued that shackling patients who are incarcerated who are critically ill or at the end of life are an affront to their human dignity and increase pain and suffering in this vulnerable time.[23–26] Routine shackling violates the United Nations Standard Minimum Rules for the Treatment of Prisoners (The Nelson Mandela Rules)—the internationally accepted standard for the treatment of people who are incarcerated.[27] These standards note that restraints are to be imposed only when no lesser form of control would be effective to address the risks posed by unrestricted movement; the method of restraint shall be the least intrusive method that is necessary and reasonably available to control the person's movement, based on the level and nature of the risks posed; and restraint shall be imposed only for the time required, and they are to be removed as soon as possible after the risks posed by unrestricted movement are no longer present.[27] Further, in accordance with the Mandela Rules and the Charter of Fundamental Rights of the European Union, the head of the British prison service has stated that the "shackling of patients in hospital[s] should not occur," emphasizing that "security is important, but it should never blind us to the overriding need for compassion and humanity."[28] In the Netherlands, shackles are never used and handcuffs are used only in exceptional circumstances.[11]

Legal Challenges to Shackling

The use of shackles during hospital visits has been challenged in U.S. courts and routinely upheld.[29] In one case, a patient who was incarcerated with renal failure received injuries after his leg edema was so severe that "at one point the shackles themselves were barely visible."[29,30] Though he was injured, the shackles were determined to have served a penological purpose outside of punishment, such as preventing escape, and the injuries were the result of the patient's guards not following protocol.[29,30] In the U.S. peripartum shackling of pregnant people who are incarcerated has been condemned. Though courts have had a mixed record on challenges, the practice has been banned in 23 states, though in most states significant exemptions exist.[31] Through the First Step Act of 2018, the federal government banned peripartum shackling for those in federal correctional facilities, but as most incarcerations are under state or local control, a considerable number of pregnant people who are justice system-involved can legally be shackled during their labor and deliveries.[32]

RATIONALE FOR SHACKLING PATIENTS WHO ARE INCARCERATED

Protecting Health Care Staff from Violence

The most frequently cited argument for shackling is that "not shackling people increases the risk of violence against health care staff," which is a legitimate concern.[15,33] Preliminary survey data suggest that violence against health care staff, such as nurses, escalated during the increased tension due to the COVID-19 pandemic.[15,34] However, there is currently no evidence suggesting that people who are incarcerated are contributors to these trends.[15,34] In fact, studies investigating the contributing factors to violence against health care staff reveal that hospital overcrowding, long waiting hours, staff shortages, and lack of staff training are key predictors of increased violence and that these factors point to a variety of strategies for addressing the issue.[15,35]

There is also a misconception that patients who are justice system-involved and have been convicted of a "violent" crime were convicted due to violent physical harm.[15] However, robbery (without assault) and drug-related offenses (such as stealing drugs and manufacturing methamphetamines) are considered violent crimes in many states.[15,36] Shackling to prevent violence in health care settings may result in unnecessary suffering of patients who may pose no risk of violence.[15] For instance, there have been reports of patients who are incarcerated being shackled while sedated and paralyzed.[37] There is also documentation of elderly patients who are incarcerated being shackled while dying, affecting dignity at the end of life.[38]

Protection Against Flight Risk

Data on the incidence of escape of patients who are incarcerated while hospitalized in community medical facilities is limited. A single study from 2011 using online media tracking identified 99 discrete incidents of patients who were incarcerated escaping medical facilities or medical transport over the course of a year.[7,39] This represents a minority of all individuals who are incarcerated and a small fraction of those seen within health care settings.[7,39] Articles in the press describe hospitalization and medical transport as times of vulnerability for law enforcement.[40] Press reports detail scenarios where shackles were removed prior to escape as well as instances in which shackles were in place during escape.[41] However, these reports do not demonstrate a relationship between indefinite shackling in health care settings and prevention of escape or harm to others.[39,41] Furthermore, the data show that escapes are few and far between in general but that if they are going to occur, it is most likely at the end of transportation back to the carceral facility after medical care has been received.[42] Systemic data identifying patient, incident, and facility-level contributing variables would allow better assessment of the use of shackles in the health care setting.[43]

Further, the risk of fleeing does not account for the fact that patients who are critically ill or under anesthesia are unable to flee. In several legal challenges against perinatal shackling instances, the court concluded that prepartum, peripartum, and postpartum patients were not in a medical state to flee.[15] For example, in the 1993 class action suit *Women Prisoners of District of Columbia Department of Corrections v. District of Columbia*, the court concluded that "the physical limitations of a woman in the third trimester of pregnancy…make complete shackling redundant and unacceptable in light of the risk of injury to a woman and baby.… While a woman is in labor and shortly thereafter, however, the Court holds that shackling is inhumane."[44] This case outlines the inhumanity in shackling patients whose medical status bars them from posing a flight risk.[44] In 2004, the court in *Nelson v. Correctional Medical Services* stated that "an incarcerated individual in the final stages of labor cannot be shackled absent clear evidence that she is a security or flight risk."[45] Yet again, this case references how patients' medical state dictates their inability to physically pose flight risk.[45] These same principles can be extended to nonpregnant patients who are incarcerated. Patients who are critically ill or sedated are physically unable to pose a security risk; thus, shackling is deemed not only inhumane but also wholly unnecessary.[46] Despite this limited evidence, many health care organizations have policies that call for shackling of patients who are incarcerated by default or lack protection against shackling by correctional staff.[46]

Shackling Facilitates the Work of Health Care Professionals by Ensuring Cooperation

Shackling patients who are incarcerated during procedures presents an increased risk for harm relative to performing the same procedures without shackles.[7] Shackling is a physical and psychological barrier to health care professionals providing the highest-quality medical care.[7] For those admitted with terminal diagnoses, shackles limit palliative providers' ability to provide dignity-driven end of life care.[38] Further, there is evidence of patients who are incarcerated being shackled while undergoing physical examinations, outpatient office procedures, inpatient bedside procedures

involving local or regional anesthesia and/or minimal to moderate sedation, and surgeries involving moderate to deep sedation or general anesthesia.[47]

Shackles manifest as a barrier for health care professionals in two ways. First, physical examinations and procedures are most effective and efficient with as few externally imposed movement restrictions as possible.[15] Shackles impede exam maneuvers, preventing full range-of-motion and other assessments that require the patient to move or turn over, and complicate positioning for procedures in clinics, hospital rooms, and operating rooms.[15,48] For example, a physician noted a time when they cared for a terminally ill 70-year-old female patient who was shackled to the bed.[15] The patient remained shackled during medical examinations and treatment despite being too weak to lift their leg against gravity.[15] The shackles made it more difficult for health care professionals to conduct comprehensive neurological exams and to roll the patient to prevent bed ulcers.[15] Second, shackling increases risk of medical complications.[7,15] Shackling sedated or anesthetized patients, for example, predisposes them to perioperative falls, tissue injury, and venous thromboembolism (VTE).[7,15] Patients who are sedated or anesthetized cannot maintain balance or request removal of shackles that compress their tissue.[7,15] As individuals recover from sedation or anesthesia, their immobility is already a risk factor for VTE, and being shackled exacerbates this risk.[7,15]

HARMS OF UNIVERSAL SHACKLING OF INCARCERATED PATIENTS

Shackles can cause proactive injury to patients who are incarcerated. Over-tightening of cuffs, potentially compounded by forced limb movement, has been shown to damage underlying structures leading to skin breakdown, compressive neuropathies, and fractures of the small bones of the hand.[7,49,50] When blanket shackling policies do not account for individual medical risk assessment, patients who are incarcerated with disabilities are disproportionately impacted.[7] For example, a shackled patient with hemiplegia may lose the ability to perform independent activities if their functional deficits are not accounted for in limb placement.[7] An inability to comply with continuous cuffed restraint can precipitate delirium in those with impaired cognition.[7]

Shackling also increases risk of emotional harm as it erodes trust between patients who are justice system-involved and clinicians.[15,51] Evidence shows that shackles can reinforce existing negative biases toward patients who are justice system-involved, setting the stage for inappropriate use of force by health care staff and security personnel.[2,15,52,53] Patients who experience discrimination and perceive stigma due to their criminal legal status are more likely to have poor health outcomes.[15,54] The harms of discrimination are further intertwined with issues of race, as people of color—who are overrepresented in the population who is justice system-involved—are less likely to trust their health care professionals.[15,54] Further, Black patients routinely report greater mistrust than White patients in the outcomes of care and the motivations of physicians, in large part due to past and current discrimination and the medical community's history of experimentation.[7,15] Incarcerated patients may therefore view their clinician and/or hospital as complicit with shackling, and health care professionals may act on internalized biases when treating shackled patients who are incarcerated.[15]

BEST PRACTICES TO PROVIDE COMPASSIONATE CARE

Allowing hospitalized patients who are incarcerated to remain indefinitely shackled during medical treatment can lead to harmful outcomes.[7] Despite the desire for compassionate care from health care professionals, patients remain in shackles as a default practice.[7,9] Health care professionals are taught to employ a risk–benefit analysis to any interventions affecting patient health.[7,9] However, by deferring the management of shackles in the acute care setting, health care settings are passively accepting a structure that perpetuates inequities in care for people who are justice system-involved - a population already at risk for poor health outcomes.[7,9] Health care professionals should work collaboratively with carceral facilities and hospital security to identify the least restrictive means available to secure a patient and correctional representatives should be tasked with proactively demonstrating a correctional necessity that requires a patient to be shackled.[7,9] In this way, health care professionals and institutions can deliver legally grounded care that prevents unnecessary physical harm, reduces prejudice towards patients who are incarcerated, and relinquishes an overreliance on shackles in favor of security measures tailored to the needs of patients, providers, and custody officers.[7,9] Health care professionals should also regularly examine restraint sites for injuries and assess inpatients for conditions particularly impacted by restraint.[9]

Further, health care professionals should familiarize themselves with state and facility policies, including contractual relationships.[7,9] If health care professionals encounter barriers to unshackling patients who are incarcerated during treatment or apprehension addressing custody officers, one starting point is to contact the patient's health care

professional at the referring correctional institution, who can offer context and patient advocacy.[7,9] Health care systems should standardize routes of communication between health care professionals and custody officers to facilitate collaborative relationships that ensure medical, and security needs are met.[7,55]

For health care systems, aligning policy on the shackling of patients who are incarcerated with policy guiding restraint of patients in general, creates parity and promotes the least restrictive form of restraint needed to secure a patient.[7] This change involves working from the assumption that all hospitalized patients should remain unshackled until a proven need for such restriction arises.[7] Such structural transformation mitigates the risks of active and passive harm to patients, lessens the prejudice shackles precipitate, and reflects shackling practices outside of health care settings.[7] Health care systems should also acknowledge the safety concerns of staff, real or perceived, as a barrier to care.[7] Examples of targeted interventions that address such concerns without reliance on shackles include individualized security risk assessments on admission, strategic room allocation, protocols for supervised patient-clinician interactions, and use of soft restraints when necessary.[7,9]

Boston Medical Group: A Successful Case Study

Recently, medical students spearheaded revision of the policy and clinical practice for the shackling of patients incarcerated patients at Boston Medical Center (BMC), the largest safety net hospital in New England.[26] The modified policy allows for individualized assessments and allows incarcerated patients to be unshackled if they meet defined criteria.[26] Changes pioneered at BMC led the Mass General Brigham health system to follow suit. Most importantly, a BMC patient who was incarcerated, sedated, and intubated was unshackled by correctional officers for the purpose of preserving human dignity.[26] This protocol identifies incarcerated patients who may be safely unshackled and provides a framework for restraint removal while ensuring safety.[26] It can be integrated into existing policy systems, electronic health record (EHR) flowsheets, and health care workflows, while also providing individualized care for incarcerated patients.[26] The next steps include continuation of staff training about the modified policy and EHR documentation.[26]

This process solicited input from key interested parties including nursing and medical staff, public safety, and general counsel, and collaborated with the local correctional facility to guide implementation.[26] The policy outlined a schematic for communication and decision-making among correctional facilities, hospital security, and the patient's healthcare team (Figure 1).[26] The protocol parallels existing clinical assessments of any patient who is restrained in the hospital for medical or behavioral reasons and is incorporated into theEHR.[26] The EHR identifies incarcerated patients and prompts a member of the healthcare team to perform a "Recurring Shackle Assessment." This functions to determine if a shackled, patient who is justice system-involved meets any "Special Circumstances" for shackle removal.[26] These include but are not limited to the following: sedation, significant weakness due to age or clinical condition, dependence on life-support, end-of-life care, or paralysis for any reason.[26] If the patient meets any "Special Circumstance," the EHR protocol prompts the health care team to determine whether shackle removal is appropriate. If appropriate, care team members first notify hospital public safety.[26] The attending physician directly calls the medical team at the correctional facility, requests the accompanying correctional officers to contact their commanding officer, or utilizes a contact at each local correctional facility to communicate with the commanding officer at the facility. The supervisor can then direct the accompanying correctional officers to remove shackles.[26] If there is a disagreement between the care team and the correctional facility about shackle removal, the care team follows an appeal process, escalating the request to hospital public safety leadership.[26]

Although this reform was successful, obstacles were noted and are important to understand for future implementation. The most common obstacles in adopting this policy change include parsing patient and physician rights, determining who can request the modification or removal of shackles, determining who wields the practical authority to approve or deny such requests, and identifying and engaging all appropriate interested parties.[26] Success was attributed to identifying written policies wherever possible, collaborating with colleagues from across clinical specialties and with hospital administration, and working directly with correctional facility leadership.[26]

New York City

New York City recently provided clear guidelines for the Department of Corrections, the Health Authority, and the Health and Hospitals Corporation regarding shackling of patients who are incarcerated seeking health care outside of secure medical wards of community hospitals.[15,56] The guideline discourages routine shackling of patients who are incarcerated, details medical circumstances in which patients should never be shackled, and outlines data reporting

recommendations.[15,56] The guideline also recommends that patients be shackled only at the direction of the chief correctional officer once he or she has reviewed evidence of custodial and safety risks posed by the patient and concedes that patients who behave violently and/or attempt escape may be shackled regardless of their medical condition.[15,56] However, the guideline attempts to dissuade correctional staff from shackling patients out of convenience by suggesting that the decision to shackle a patient be routinely reevaluated by the chief correctional officer.[15,56]

The guideline promotes patient advocacy among health care staff by recommending evaluating whether the shackles threaten the patient's life, in which case they can advocate for immediate shackle removal.[15,56] The guideline further recommends that health care staff routinely assess and communicate whether shackling is medically contraindicated and should be removed. The guideline also promotes increased data collection by recommending that health care organizations keep written records summarizing the reason for shackling, details of the shackling, and patient information.[15,56]

CURRENT AMA POLICY

AMA Code of Medical Ethics 1.2.7 "Use of Restraints" states that all individuals have a fundamental right to be free from unreasonable bodily restraint. It is noted that if health conditions may result in behavior that puts patients at risk of harming themselves, it may be ethically justifiable for physicians to order the use of chemical or physical restraint to protect the patient.
The code also states that patients should never be restrained punitively, for convenience, or as an alternative to reasonable staffing and physicians who order chemical or physical restraints should:
(a) Use best professional judgment to determine whether restraint is clinically indicated for the
individual patient; (b) Obtain the patient's informed consent to the use of restraint, or the consent of the patient's surrogate when the patient lacks decision-making capacity; and (c) Regularly review the need for restraint and document the review and resulting decision in the patient's medical record. Finally, the code notes that in certain limited situations, when a patient poses a significant danger to self or others, it may be appropriate to restrain the patient involuntarily and that the least restrictive restraint reasonably should be implemented, and the restraint should be removed promptly when no longer needed.

AMA policy D-430.997 "Support for Health Care Services to Incarcerated Persons" supports NCCHC standards that improve the quality of health care services, including mental health services, delivered to the nation's correctional facilities. AMA policy D-430.993, "Study of Best Practices for Acute Care of Patients in the Custody of Law Enforcement or Corrections," supports the development of clearly defined and consistently implemented processes between health care professionals and law enforcement that:
can best protect patient confidentiality, privacy, and dignity while meeting the needs of patients, health professionals, and law enforcement and ensures security measures do not interfere with the capacity to provide medical, mental health, pregnancy, end of life care, palliative care, and substance use care, especially in emergency situations. AMA policy H-420.957, "Shackling of Pregnant Patients in Labor," prohibits the use of shackles on pregnant people unless flight or safety concerns exist. The AMA advocacy resource center has also developed model legislation prohibiting shackling of pregnant people who are incarcerated.

American Public Health Association (APHA) and NCCHC Policies

APHA's policy 20233 "A Call to Stop Shackling Incarcerated Patients Seeking Health Care" called on state and federal legislatures to pass laws requiring health care organizations and correction agencies to implement policies that ban shackling of patients receiving health care and requests that the CMS and general assemblies enforce those regulations.[15] In the absence of shackling bans APHA outlines steps to end the practice of shackling during health care through: (1) legislative action, (2) national research efforts, (3) clinical guidance, and (4) clinical practice.[15]

The NCCHC remains the only national organization dedicated solely to improving correctional health care quality.[57] NCCHC's standards have provided uniquely valuable guidance to help correctional health professionals and administrators improve the health of their populations (and the communities to which they return), increase efficiency of health services delivery, strengthen organizational effectiveness, and reduce the risk of adverse legal judgments.[57] NCCHC's guidelines for "Use of Restraints for Nonmedical Purposes" notes that correctional health personnel should not participate in either the decision to restrain someone or in the placement of such restraints for nonmedical reasons. NCCHC standards explicitly prohibit health care staff from participating in this activity but recommend they monitor

the health status of individuals placed in security restraints.[58] If they observe conditions or practices that threaten a patient's health, their concerns should be communicated to the prison or jail administrator as soon as possible.[58] It is acknowledged that this may be a situation in which the underlying ethical principle is one of "doing the least harm," and that NCCHC's position is an approach that is likely to result in less harm to the incarcerated individual.[58]

CONCLUSION

The U.S. has the highest incarceration rate in the world.[2,59] Compared to the general population, individuals with a history of incarceration are in worse mental and physical health.[2,60] Incarcerated individuals typically have high rates of psychiatric conditions, communicable diseases, substance use disorders, and chronic diseases.[2] Correctional facilities offer a range of health care services from primary care to hospital-level care, but few states have stand-alone hospitals for patients who are incarcerated.[2,60,61] When medical care required by a person who is incarcerated exceeds the capabilities of the correctional facility's health system (for specialty care, diagnostics, or acuity of illness), that individual is transferred to a contracted hospital or, in emergent cases, to the nearest health care institution.[2,15] Clinicians practicing outside of correctional settings face unique medical, legal, and ethical issues surrounding the care of patients who are incarcerated.[2,15] One of those challenges is the harmful and discriminatory routine shackling of patients who are incarcerated and seeking care.

Shackling policies for patients who are incarcerated are different from hospital restraint policies for patients who are agitated or combative. The latter is governed by CMS guidelines mandating the least restrictive form of restraint and for the shortest duration of time needed to ensure patient and staff safety.[2,14] In contrast, case reports describe patients who are incarcerated are shackled with metal cuffs indefinitely, even while intubated, paralyzed, disabled, or in labor.[26] Most health care professionals are aware of the negative consequences of restricting patient movement during hospitalization, including delirium and venous thromboembolism, and although most hospital policies allow health professionals to request removal of shackles for medical necessity, such requests are rarely made.[2,6] Incarcerated patients often remain shackled for the duration of their hospitalization, independent of any individual risk assessment.[2,6]

One potential starting place for shackling reform is for hospital policy on shackling of patients who are incarcerated to align with internal policy on the restraint of persons who are nonincarcerated.[15,26] Hospital policy should delineate for clinicians when and how to communicate to security what is medically necessary to provide the standard of care.[15,26] Special circumstances should be defined in which shackles are prohibited, and procedures should be developed for compassionate removal.[15,26] Further, special considerations should be made for certain incarcerated populations such as older individuals, individuals who are disabled, individuals with serious mental illness, and individuals in the juvenile justice system. While this report does not directly address these specific populations, this is an area that warrants further study. It should be noted that AMA policy supports NCCHC standards and AMA's Code of Medical Ethics supports the use of the least restrictive restraint if it is appropriate to restrain a patient that the restraint should be removed promptly when no longer needed. However, this framework is currently not applied to patients who are incarcerated.[58,62]

RECOMMENDATIONS

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

1. Our AMA opposes the universal shackling of patients in medical settings who are incarcerated as a means of punishment, control, and oppression and believes shackling should only be used when there is an immediate and serious threat of self-harm, harm to others, or risk of elopement, that cannot be reasonably mitigated by other least restrictive means necessary.

2. Our AMA encourages health care facilities in collaboration with carceral facility leadership and hospital security, to develop and implement policies that eliminate or reduce universally shackling of patients who are incarcerated while receiving health care. Such policies should include:
   (a) individualized assessments that allow patients who are incarcerated to be unshackled when appropriate, particularly when incapacitating medical conditions are present such as weakness due to age or clinical condition, sedation, paralysis, dependence on life support, or while receiving end of life care;

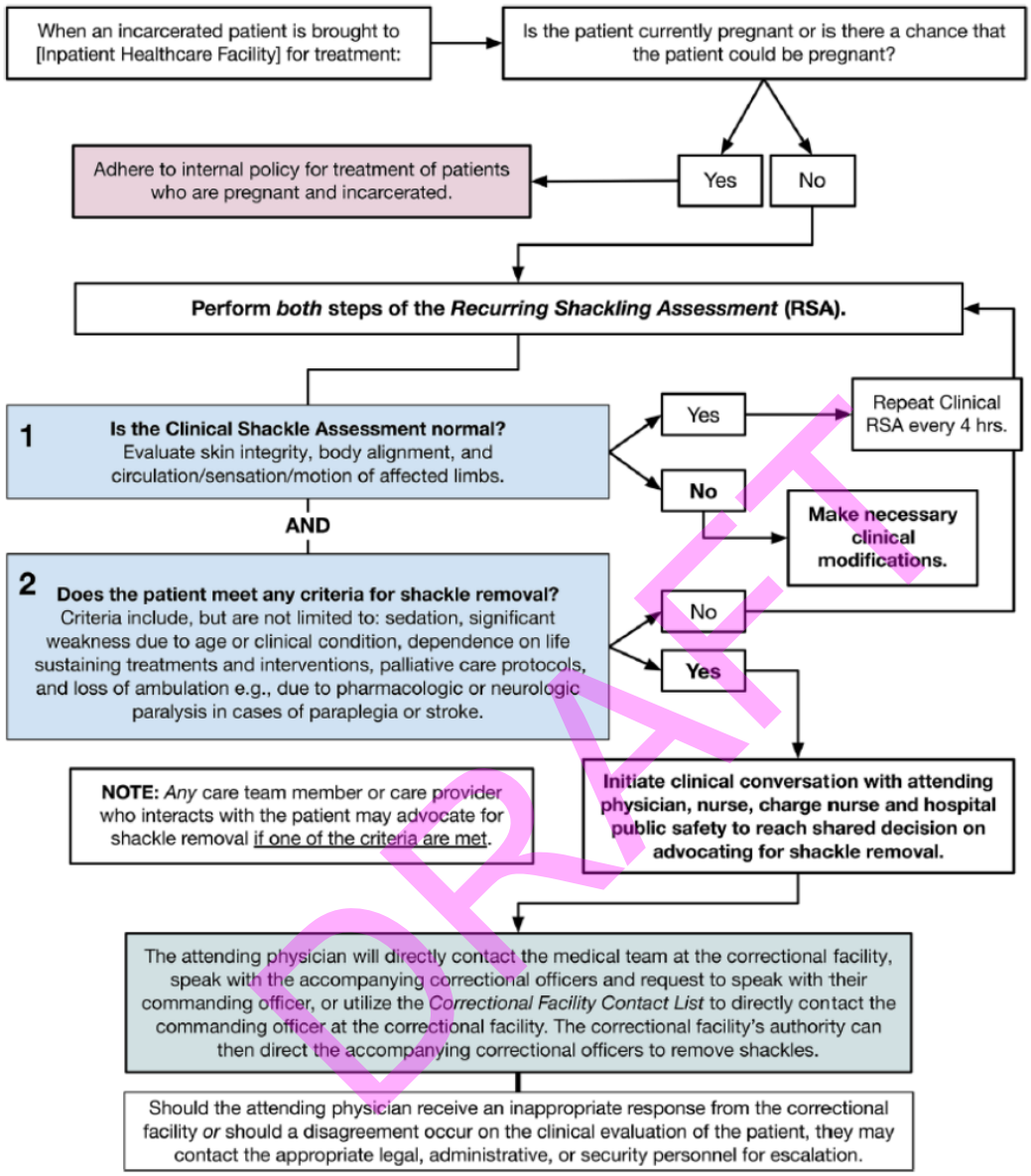
(b) clearly delineated procedures for shackle removal and/or replacement of shackles with the least restrictive means necessary; and
(c) expeditious procedures for health care professionals to communicate to and collaborate with the decision-making authority of carceral facilities and hospital security to allow timely shackle removal when medically necessary to provide the standard of care.

3. That our AMA reaffirm Policy H-420.957 "Shackling of Pregnant Women in Labor."

4. Our AMA urges through its representation on the National Commission on Correctional Health Care development and implementation of policies that eliminate or reduce universal shackling of patients who are incarcerated while receiving health care.

Fiscal Note – less than $1000

Figure 1: Generalizable protocol to supplement existing hospital policies for the care of patients who are incarcerated.[26]



APPENDIX I – Types of Restraints

Vest restraints	Designed to help prevent unassisted wheelchair, bed, and stretcher exits. These are considered one of the more physically restrictive types of patient restraints available for use.[22]
Limb restraints (limb holders)	Designed to limit the movement of wrists and/or ankles in patients assessed to be at risk of disrupting life-saving treatment, pulling lines/tubes, exacerbating skin conditions, compromising wound site integrity, or self-injury.[22] Sometimes these devices are referred to as being either soft restraints or hard restraints, depending on specific features such as cuff and strap materials and whether or not they can be locked.[22]
Belts	Designed for use with patients who need a reminder to call for assistance before exiting a hospital bed or wheelchair, for limiting unassisted exit and unwanted movement, or for patients who require a positioning device for added safety or to assist medical treatment.[22] Belts can be made from a variety of materials, can offer locking capabilities, and can be designed specifically to allow patients to self-release.[22] A belt's specific features help determine if it is considered a less restrictive or more restrictive device.[22] In some states and facilities, belts are not considered restraints.[22]
Hand mitts	Designed to help protect patients who are prone to disrupting medical treatment or to self-harm.[22] Mitts hinder picking and tube pulling and their construction and padding varies, as does the level of hand visibility afforded and the degree of finger movement permitted.[22] Mitts are generally considered to be less physically restrictive devices, and in some states and facilities they are not considered restraints.[22]
Multipurpose arm sleeves	Designed to limit or minimize patient arm movements without the use of rigid splints.[22] Multipurpose sleeves are in the least restrictive device category, and in some states and facilities they are not considered restraints.[22]
Enclosure beds	Designed to provide a safe, controlled environment for patients at risk of injury from an unassisted bed exit.[22] Although it's considered a restraint because it limits the patient's ability to get out of bed, an enclosure bed is less restrictive than other types of restraints.[63] Use of enclosure beds can help eliminate the need for more restrictive devices like limb holders or vest restraints.[22]

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5. SCREENING FOR IMAGE MANIPULATION IN RESEARCH PUBLICATIONS

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See Policies H-460.972 and H-460.980

INTRODUCTION

Resolution 506-A-24, Screening for Image Manipulation in Research Publications," introduced by the Medical Student Section was referred. It stated that "our American Medical Association support the creation of a nationally collaborative database of manipulated images from retracted publications to provide a test bank for researchers developing augmented intelligence-integrated image screening tools." While there was only limited testimony on this item, concerns around the feasibility and scope of the request resulted in its referral for further study. This report serves as the Council on Science and Public Health's response to that referral.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "image manipulation" and "AI image manipulation screening" and "generative adversarial networks." Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

BACKGROUND

In a time of rampant misinformation and disinformation around medical science, the integrity of academic journals is of the utmost importance and allegations of research misconduct should be taken very seriously. As artificial intelligence (AI) tools become more advanced and integrated into the toolkits of researchers, the potential role of AI in research fraud should also receive more scrutiny.

While retractions may be done for a variety of reasons that may not necessarily be caused by research misconduct, many publishers are alarmed by the increasing rate of fraudulent images resulting in retractions.[1,2] Per the publishing watchdog RetractionWatch, the retraction rate in 2014 was 3.5 retracted articles per 10,000 published articles and rose to 11.2 retractions per 10,000 in 2022, with over 10,000 papers being retracted in 2023.[3] Interestingly, the incidences of retractions are relatively centralized, with researchers in Saudi Arabia (30.6 retractions per 10,000 articles), Pakistan (28.1 per 10,000), Russia (24.9 per 10,000), and China (23.5 per 10,000) having more retractions than the global rate.[4] As a result, some countries, such as China, have initiated national audits of research integrity.[5] It should be noted, however, that these statistics reflect retractions for any cause, not just image manipulation.

Generally, researchers with retractions will only have one retraction in their career, however there are a small-subset of serial offenders with more than ten retractions.[4] For publishers, the inverse appears to be true; in 2022, 51 percent of all retracted articles were published in the same 34 journals, sparking concerns of "paper mills," in which a publisher intentionally maintains low standards to increase publishing fees revenue, or malicious researchers have identified a deficiency in a publisher's review process and specifically target them for fraudulent articles.[3]

Beyond instances of malicious fraud, AI-generated images can also produce misleading or incorrect images in publications even if well-intended. For example, researchers have probed anatomical illustrations created by AI programs and found deficiencies in both their accuracy and level of detail.[6]

The Role of AI

AI can be a powerful tool for helping researchers communicate their message to a broader audience. For example, AI can help generate graphical abstracts, summarize data sets, or make images more readable.[7] As such, many journals maintain policies where authors must disclose where and when they used AI tools for the editors to adjudicate its appropriateness.[8-10]

While these tools are promising, advancements in AI, such as generative adversarial networks (GANs), pose a unique threat to image manipulation detection. GANs were introduced in 2014 and excel in generating highly realistic images known as "deepfakes" (a portmanteau of 'deep learning' and 'fake'). For example, researchers have found that even trained experts only correctly identify whether a Western blot image was real or AI-generated at a 50 percent rate, no better than a random guess.[11] A sample image has been provided in Appendix 1. Even prior to the introduction of GANs, the Department of Health and Human Service (HHS) Office of Research Integrity reported that 67 percent of their closed research misconduct cases between 2011 and 2015 were a result of manipulated images.[12] It is expected that as artificial image generation technology grows more sophisticated and more accessible, its use in research misconduct will similarly increase.

Given that these fraudulent images are not duplicated from existing images in the public domain, modern image integrity detection software may struggle at detecting deepfakes. GANs, and other AI tools, have been used to generate false images or video for a variety of applications beyond research misconduct, including financial fraud, sowing political discontent, and even pornography.[13,14] The programs used to make these images are generally accessible and usable on desktop computers and do not require any specialized equipment.[15]

CURRENT APPROACHES

The original resolution requested a "nationally collaborative database of manipulated images from retracted publications" for researchers developing tools to combat research misconduct. It should be noted that resources which may satisfy these requirements currently exist. For example, the HHS, Office of Research Integrity maintains publicly available resources on image forensics, academic publishers regularly share open-source databases, and non-profit entities such as RetractionWatch maintain searchable databases of retracted publications.[16-18] While these resources may not fully accomplish the goals of the original resolution, they do point to the generally available nature of manipulated images from retracted articles.

Additionally, nearly all major journal publishers currently utilize detection software, suggesting that there are currently market forces to push these kinds of research and development efforts. While the use of AI technologies to conduct research fraud is new, the concept of manipulating images is not. As such, academic journals have generally been quick to adopt new technologies to keep up with the advances of malicious actors. For example, the AI image detection tool Proofig is currently partnered with journals published by Elsevier, Springer Nature, Science, the American Association of Cancer Research, the Royal Society of Chemistry, the American Society of Clinical Investigation, the Company of Biologists, Mary Ann Liebert, Inc., Compuscript Ltd, Sage Publishing, and the Taylor and Francis publishing group.[19] Proofig claims that approximately 25 percent of all manuscripts screened have been found to have some level of image manipulation, which can then be manually screened by an editor. Other tools, such as ImageTwin or Imachek, are also used by journal publishers to identify image manipulation. Other publishers, such as the PLOS family of journals, additionally require authors to submit raw image files prior to publication to detect image manipulation in their submissions.[20]

Finally, given the widespread accessibility of software to generate falsified images, it is unclear what value a centralized repository of retracted images would be. Technologies such as Deep AI are fully open source, meaning they are broadly available to the public for free use, or other programs such as DALL-E 3 or IMAGEN can be licensed at rates as low as 3 cents per image.[21,22] Particularly if a database were of specifically images from retracted publications, those are more likely to be generated using outdated technology, given the rapid rate of innovation in this space, or they were already detectable, given they were flagged for retraction. Additionally, it is unclear whether journal publishers retain the ownership rights for images after retraction, which may present intellectual property challenges for such a database.

Experts in the field of research misconduct describe the current publishing landscape as an "arms race," wherein generative software and detection software are both rapidly evolving to keep up with the developments of their counterpart.[23] This situation is likely unsustainable, and simply creating more sophisticated detection tools will likely only result in more sophisticated generation tools, and vice versa. Rather, some experts have argued that research misconduct is a symptom of the high pressures placed on researchers by the academic ecosystem, particularly the "publish or perish" mindset coming from the emphasis employers and funders place on academic publishing, and lack of interest in reproducibility.[24]

CURRENT AMA POLICY

Our AMA maintains robust policy on research misconduct, including through the Code of Medical Ethics. Full text of cited policies can be found in the appendix of this report.

Our AMA's opposition to research misconduct can be found in policy H-460.972, "Fraud and Misrepresentation in Science," which notes that "Our AMA supports the promotion, through AMA publications and other vehicles, of (a) A clear understanding of the scientific process, possible sources of error, and the difference between intentional and unintentional scientific misrepresentation. (b) Multidisciplinary discussions to formulate a standardized definition of scientific fraud and misrepresentation that elaborates on unacceptable behavior." This policy also notes that "Our AMA supports the development of specific standardized guidelines dealing with the disposition of primary research data, authorship responsibilities, supervision of research trainees, role of institutional standards, and potential sanctions for individuals proved guilty of scientific misconduct." Additionally, policy H-460.980, "Ethical and Societal Considerations in Research," states that "[e]ach institution should have a system both for monitoring the conduct of biomedical research and for investigating and reporting allegations of research misconduct."

Code of Medical Ethics, opinion 7.1.5, "Misconduct in Research," states "[b]iomedical and health research is intended to advance medical knowledge to benefit future patients. To achieve those goals physicians who are involved in such research maintain the highest standards of professionalism and scientific integrity." Additional opinions, including 7.1.1, "Physician Involvement in Research," ("[…] physicians who are involved in research should […] [a]dhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating results of the research"), and 7.2.1, "Principles for Disseminating Research Results," ("[…] physicians should […] [r]eport the results of research accurately, including subsequent negative findings. This is particularly important where the findings do not support the research hypothesis") further emphasize the importance of proper conduct by physicians performing research.

CONCLUSION

Research misconduct undercuts trust and has a corrosive impact on the practice of medicine. While cases of fraud have happened infrequently in the past, rising rates of retractions have resulted in concerns that widespread access to AI tools which quickly generate text and images are causing fraud to become more commonplace. Our AMA's stance on research misconduct is clear, robust, and supports the use of a variety of means to reduce its prevalence. While it is possible that the creation of a repository of falsified images for researchers to use may improve AI detection tools, it is also clear that these efforts are already underway, being developed by commercial entities, and utilized by many, if not all major journal publishers.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 506-A-24, and that the remainder of the report be filed:

1. AMA Policy H-460.972, "Fraud and Misrepresentation in Science," be amended by addition to read as follows:

    1. Our American Medical Association supports the promotion of structured discussions of ethics that include research, clinical practice, and basic human values within all medical school curricula and fellowship training programs;
    2. Our AMA supports the promotion, through AMA publications and other vehicles, of
        a. A clear understanding of the scientific process, possible sources of error, and the difference between intentional and unintentional scientific misrepresentation.
        b. Multidisciplinary discussions to formulate a standardized definition of scientific fraud and misrepresentation that elaborates on unacceptable behavior.
    3. Our AMA supports the promotion of discussions on the peer review process and the role of the physician investigator.
    4. Our AMA supports the development of specific standardized guidelines dealing with the disposition of primary research data, authorship responsibilities, supervision of research trainees, role of institutional standards, and potential sanctions for individuals proved guilty of scientific misconduct.
    5. Our AMA supports the sharing of information about scientific misconduct among institutions, funding agencies, professional societies, and biomedical research journals

6. Our AMA will educate, at appropriate intervals, physicians and physicians-in-training about the currently defined difference between being an "author" and being a "contributor" as defined by the Uniform Requirements for Manuscripts of the International Committee of Medical Journal Editors, as well as the varied potential for industry bias between these terms.
7. Our AMA supports policies requiring authors to disclose the use of generative artificial/augmented intelligence programs to best allow for content to be reviewed for intentional and unintentional scientific misrepresentation.
8. Our AMA supports efforts to disseminate accurate and valid research findings, and to combat research and publication fraud, in the face of rapidly advancing technology.

2. AMA Policy H-460.980, "Ethical and Societal Considerations in Research" be reaffirmed.

Fiscal Note: less than $1,000

RELEVANT AMA POLICY

AMA Publications G-630.090
Our American Medical Association policy on its publications includes the following:
1. JAMA and other AMA scientific journals should display a disclaimer in prominent print that the editorial views are not necessarily AMA policy.
2. Our AMA, in all of its publications and correspondence, will use the correct title for the medical specialist.
3. Our AMA recommends that medical journal articles using acronyms should have a small glossary of acronyms and phrases displayed prominently in the article.
4. The House of Delegates affirms that JAMA and The JAMA Network journals shall continue to have full editorial independence as set forth in the AMA Editorial Governance Plan.

Fraud and Misrepresentation in Science H-460.972
9. Our American Medical Association supports the promotion of structured discussions of ethics that include research, clinical practice, and basic human values within all medical school curricula and fellowship training programs;
10. Our AMA supports the promotion, through AMA publications and other vehicles, of
    a. A clear understanding of the scientific process, possible sources of error, and the difference between intentional and unintentional scientific misrepresentation.
    b. Multidisciplinary discussions to formulate a standardized definition of scientific fraud and misrepresentation that elaborates on unacceptable behavior.
11. Our AMA supports the promotion of discussions on the peer review process and the role of the physician investigator.
12. Our AMA supports the development of specific standardized guidelines dealing with the disposition of primary research data, authorship responsibilities, supervision of research trainees, role of institutional standards, and potential sanctions for individuals proved guilty of scientific misconduct.
13. Our AMA supports the sharing of information about scientific misconduct among institutions, funding agencies, professional societies, and biomedical research journals
14. Our AMA will educate, at appropriate intervals, physicians and physicians-in-training about the currently defined difference between being an "author" and being a "contributor" as defined by the Uniform Requirements for Manuscripts of the International Committee of Medical Journal Editors, as well as the varied potential for industry bias between these terms.

Ethical and Societal Considerations in Research H-460.980
1. Private organizations and academic institutions should jointly develop a means to continue and enhance broadly based study and discussion of ethical and societal issues in biomedical research.
2. The federal government should provide the resources to support new initiatives within the National Institutes of Health for the funding of research studies in bioethics. Existing federal programs that fund bioethical research studies should be preserved. Private foundations should be encouraged to provide resources to support research studies in bioethics.
3. A uniform set of federal regulations governing research with human subjects, based on the core regulations of the Department of Health and Human Services should be adopted by all federal agencies. Uniformity

should not preclude additions to Department regulations that do not conflict with the core regulations or that enhance the protection of research subjects.

4. Associations of regional institutional review boards (IRBs) should be formed to enhance IRB performance through the development of educational site visits and local workshops.
5. Each institution should have a system both for monitoring the conduct of biomedical research and for investigating and reporting allegations of research misconduct.
6. All investigators involved in research projects should be responsible for the clear articulation and enforcement of standards that ensure the integrity of scientific data and conclusions. Regardless of whether the research project is a result of individual or collaborative efforts, investigators should thoroughly understand the data and conclusions in research publications and studies.
7. As part of their formal training in research investigation, graduate, medical and postdoctoral students should be instructed on the importance of adhering to the ethical and scientific requirements in research conduct and in the reporting of research results.
8. Our American Medical Association encourages study of the inclusion of Socioeconomic Status (SES) data in clinical and public health research identify appropriate minimum standards for the inclusion of such data in research studies.
9. Our AMA:
    a. opposes policies requiring scientific disclosures of confidential medical records consistent with Policy H-315.983, "Patient Privacy and Confidentiality".
    b. supports the use of all credible scientific data in the development of public policy while safeguarding confidentiality of patient information.

7.1.5 Misconduct in Research

Biomedical and health research is intended to advance medical knowledge to benefit future patients. To achieve those goals physicians who are involved in such research maintain the highest standards of professionalism and scientific integrity.

Physicians with oversight responsibilities in biomedical or health research have a responsibility to ensure that allegations of scientific misconduct are addressed promptly and fairly. They should ensure that procedures to resolve such allegations:

(a) Do not damage science.

(b) Resolve charges expeditiously.

(c) Treat all parties fairly and justly. Review procedures should be sensitive to parties' reputations and vulnerabilities.

(d) Maintain the integrity of the process. Real or perceived conflicts of interest must be avoided.

(e) Maintain accurate and thorough documentation throughout the process.

(f) Maintain the highest degree of confidentiality.

(g) Take appropriate action to discharge responsibilities to all individuals involved, as well as to the public, research sponsors, the scientific literature, and the scientific community.

7.1.1 Physician Involvement in Research

Biomedical and health research is intended to contribute to the advancement of knowledge and the welfare of society and future patients, rather than to the specific benefit of the individuals who participate as research subjects.

However, research involving human participants should be conducted in a manner that minimizes risks and avoids unnecessary suffering. Because research depends on the willingness of participants to accept risk, they must be able to make informed decisions about whether to participate or continue in a given protocol.

Physician researchers share their responsibility for the ethical conduct of research with the institution that carries out research. Institutions have an obligation to oversee the design, conduct, and dissemination of research to ensure that scientific, ethical, and legal standards are upheld. Institutional review boards (IRBs) as well as individual investigators should ensure that each participant has been appropriately informed and has given voluntary consent.

Physicians who are involved in any role in research with human participants have an ethical obligation to ensure that participants' interests are protected and to safeguard participants' welfare, safety, and comfort.

To fulfill these obligations, individually, physicians who are involved in research should:

(a) Participate only in those studies for which they have relevant expertise.

(b) Ensure that voluntary consent has been obtained from each participant or from the participant's legally authorized representative if the participant lacks the capacity to consent, in keeping with ethics guidance. This requires that:

(i) prospective participants receive the information they need to make well-considered decisions, including informing them about the nature of the research and potential harms involved;

(ii) physicians make all reasonable efforts to ensure that participants understand the research is not intended to benefit them individually;
(iii) physicians also make clear that the individual may refuse to participate or may withdraw from the protocol at any time.
(c) Assure themselves that the research protocol is scientifically sound and meets ethical guidelines for research with human participants. Informed consent can never be invoked to justify an unethical study design.
(d) Demonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness for patients.
(e) Be mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants.
(f) Adhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating results of the research.

7.2.1 Principles for Disseminating Research Results

Physicians have an ethical responsibility to learn from and contribute to the total store of scientific knowledge. When they engage in biomedical or health research, physicians have obligations as scientists, which include disseminating research findings. Prompt presentation to scientific peers and publication of research findings are foundational to good medical care and promote enhanced patient care, early evaluation of clinical innovations, and rapid dissemination of improved techniques.
To fulfill their ethical responsibilities with respect to sharing research findings for the ultimate benefit of patients, physicians should:
(a) Advocate for timely and transparent dissemination of research data and findings. Physicians should not intentionally withhold information for reasons of personal gain.
(b) Report the results of research accurately, including subsequent negative findings. This is particularly important where the findings do not support the research hypothesis.
(c) Maintain a commitment to peer review.
(d) Disclose sponsorship and conflicts of interest relating to the research, in keeping with ethics guidance.
(e) Be responsible in their release of research results to the media, ensuring that any information the researcher provides is prompt and accurate and that informed consent to the release of information has been obtained from research participants (or participants' legally authorized representative when the participant lacks decision-making capacity) prior to releasing any identifiable information.
In rare circumstances, the potential for misuse of research results could affect the decision about when and whether to disseminate research findings. Physician-researchers should assess foreseeable ramifications of their research in an effort to balance the promise of benefit against potential harms from corrupt application. Only under rare circumstances should findings be withheld, and then only to the extent required to reasonably protect against misuse.

APPENDIX 1

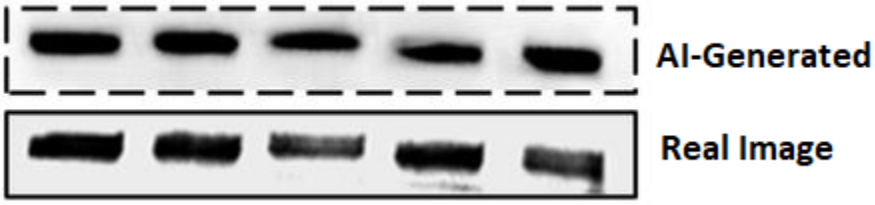

Figure 1. Sample of artificially generated (top) and real (bottom) Western blot images. When this specific image was provided to experts, only 4 of 23 participants were able to correctly identify the artificially generated image. For all images used in this study, experts had a 50 percent accuracy rate for detecting artificially generated images. Adapted from Qi et al.[11]

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6. FRAGRANCE REGULATION

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policy H-135.902

INTRODUCTION

Resolution 501-I-24, "Fragrance Regulations" was referred by the House of Delegates. This resolution asked that our AMA: (1) recognize fragrance sensitivity as a disability; (2) encourage fragrance-free policies in hospitals, outpatient clinics, urgent cares, and other patient care areas inclusive of medical schools; (3) advocate for governmental regulatory bodies to recommend fragrance-free policies; (4) work with relevant parties to support the appropriate labeling of fragrance-containing personal care products, cosmetics, and drugs; and (5) support increased identification of hazardous chemicals in fragrance compounds, as well as research focused on fragrance sensitivity.

METHODS

English language reports were selected from searches of PubMed and Google Scholar databases using the search terms: "fragrance sensitivity," "fragrance-free policies" AND "fragrance regulations." Additional articles were identified by manual review of the reference lists of pertinent publications. There was also a review of state and federal regulations on fragrance regulations as well as case law on fragrance sensitivity, multiple chemical sensitivity, and disability. Web sites managed by federal agencies and applicable professional and advocacy organizations were also reviewed for relevant information.

BACKGROUND

Humans are exposed to thousands of chemicals in complex and dynamic mixtures everyday through fragrance materials that are pervasive in personal care and household cleaning consumer products.[1–6] Although fragrance materials must be generally regarded as safe for the intended use and dose, the ubiquity of exposure coupled with the limited transparency about the chemical constituents and reports of adverse health impacts after exposure raises the concerns about: 1) the harmful effects of fragrance chemicals on the skin including allergic contact dermatitis, phototoxicity, and photoallergy; (2) toxic effects (e.g., cancer, endocrine disruption, respiratory, immune, cardiovascular, neurological, reproductive, and developmental harm, etc.) that might arise through transdermal absorption, inhalation, or ingestion of fragrance chemicals; and (3) environmental consequences of fragrance chemicals on waste water and air quality.[4,7]

DISCUSSION

What is fragrance sensitivity?

Multiple names have been used to describe sensitivity to fragrances, chemicals, and the environment more broadly including: multiple chemical sensitivity (MCS), idiopathic environmental intolerance (IEI), environmental illness (IE), chemical intolerance (CI), chemical sensitivity (CS), toxicant-induced loss of tolerance (TILT), and fragrance sensitivity (FS).[8–16] The specifics of each condition vary, but they share two key elements: (1) environmental exposure at relatively low doses (e.g., below thresholds of harm for the average person) and (2) consequent recurrent symptoms that affect multiple and variable organ systems.

Conceptually, FS is the most narrowly defined, with a focus on fragranced chemicals.[16] MCS, CS, CI, and TILT are more expansive as they focus on chemicals which may or may not to be expressly fragranced. Finally, IEI and IE are the broadest definitions acknowledging any potential environmental exposure (e.g. fragrances, chemicals, electromagnetic forces, and radio signals). Additionally, while some researchers maintain that MCS, CS, and CI are really the same disorder, others suggest MCS is a more severe form of CI, and still others suggest that TILT is a two-stage disease mechanism (e.g., initiation and trigger), which can be used to explain and unite MCS, CS, CI, IEI, and IE.[14,17,18] There is still no consensus regarding naming; however, some researchers suggest that CI and TILT are being

used with greater frequency now and that MCS, EI, and IEI are descriptive phases of the constellation of allergy-like symptoms, rather than distinct diseases.[14] Arguably, this naming inconsistency is indicative of the lack of consensus in the field, which ironically facilitates further uncertainty. For the purposes of this report, fragrance sensitivity is used as an umbrella term; however, when citing specific studies, deference is given to the language of the authors.

Diagnostic Criteria

One of the most important problems when diagnosing fragrance sensitivity is the variability of symptoms, the lack of symptomatic patterns in relation to frequency, sex or age of onset, and the breadth of distinct, but very similar conditions with similar and overlapping diagnostic criteria.[19] Despite over 50 years of research on the topic, including advances in understanding potential underlying mechanisms, there is also no single biomarker or test that can be used to definitively diagnose fragrance sensitivity.[15,20–23] The most frequently referenced diagnostic method for this disease is the QEESI (Quick Environmental Exposure and Sensitivity Inventory).[19,24–29] The instrument has four scales: Symptom Severity, Chemical Intolerances, Other Intolerances, and Life Impact. Each scale contains 10 items which are scored from 0 = "not a problem" to 10 = "severe or disabling problem."[30]

Prevalence of Fragrance Sensitivity

Extensive self-reported data suggests exposure to fragrances and chemicals is associated with a variety of adverse health impacts including respiratory, eye, and skin irritation, mucosal symptoms, headaches and migraine, asthma exacerbation, and respiratory, cardiovascular, neurological, gastrointestinal, musculoskeletal, immune, and endocrine issues.[16,19,31–42] However, estimates of fragrance sensitivity prevalence vary. This is likely a product of: (1) the lack of consensus on what condition is being assessed (e.g., MCS, IEI, TILT, CI, CS, and FS); (2) variable study methods (e.g., reliance on self-report symptoms vs evidence of formal diagnosis); (3) environmental exposure variations based on socioeconomic, cultural, and societal differences; and (4) potential prevalence changes over time.

One international study comprised of nationally representative self-report surveys conducted between 2016 and 2017 in the U.S., Australia, the UK, and Sweden found that 34.7 percent, 33.0 percent, 28.7 percent, and 33.1 percent of the population, respectively, reported at least one adverse health effects from exposure to fragranced products.[32,37,39] The same survey found that across these four countries 19.9 percent of the population report chemical sensitivity, 7.4 percent report medically diagnosed MCS, 21.2 percent report chemical sensitivity and/or medically diagnosed MCS, and 32.2 percent report fragrance sensitivity.[37,39] These findings are emblematic of the overall variability of prevalence data due to uncertainty around disease definition (e.g. MCS, CS, CI, TILT, IEI, IE, and FS) and use of different methods (self-report of symptoms vs. diagnosis). For example, other self-report studies published between 1998 and 2015 in the U.S., Canada, Germany, Sweden, Finland, Australia, Korea and Japan found chemical intolerance prevalence estimates of 9–16 percent with lower rates of 0.5–3.9 percent reported for doctor-diagnosed MCS.[1,43–52] Additionally, it is possible some of the variability is a result of increases over time. Nationally representative U.S. population surveys conducted between 2002-2003, 2005-2006, and 2016-2017, by the same researchers who performed the study of international prevalence, found that self-reported chemical sensitivity and medically diagnosed MCS may have increased by more than 200 percent and 300 percent respectively, with chemical sensitivity prevalence increasing from (11.1-11.6 percent) to 26 percent and medically diagnosed MCS increasing from (2.5-3.9 percent) to 13 percent.[1,14,16,37,39,40]

There are also several demographic differences. Women are more likely to report fragrance sensitivity and chemical intolerance as are middle-aged individuals, and those who renovated their home in the past seven years.[13,19,27,42,53–57] There also appear to be high rates of self-reported CI and FS among individuals with asthma/asthma-like conditions and autism/autism spectrum disorder.[33,37,39,58] Finally, the evidence regarding socioeconomic status is mixed. A cross-sectional study of Danish adults showed increased risk of MCS among individuals with lower socioeconomic and subjective social status.[53] Other studies appear to suggest that on average individuals with MCS tend to be well-educated, of higher socioeconomic status, and middle aged.[42]

Sources of Fragrance Exposure

Fragrances are complex mixtures of organic chemicals – solvents, fixatives, essential oils, stabilizers, and preservatives – nearly all of which are either aromatic volatile organic compounds (VOCs) (e.g., ester, aldehydes, and alcohols) like limonene, alpha-pinene, beta-pinene, ethanol, acetone, and acetaldehyde that produce aromas, or semi-volatile organic compounds (SVOCs) like phthalates and parabens.[41,59,60] The complex and variable nature of

fragrance means that the fragrance industry uses more than 3,000 chemical substances, both synthetic and naturally occurring, in personal care and other consumer products - a single perfume or fragrance may contain up to 300 different molecules.[4,31,41]

Most people are exposed to fragrance ingredients daily from personal care (e.g., perfumes, lotions, shampoos, bar soaps), air care (e.g., candles, environment fresheners), fabric care (e.g., detergents, fabric softeners), and home care products (kitchen, bathroom, and other household cleaners).[61,62] Scented products represent 89 percent of laundry, 79 percent of surface cleaning, and 99 percent of dish washing product sales in the U.S. and mouthwashes, toothpastes, soaps, and shampoos are the most frequently used scented products.[61,63,64] Fragrance exposures occur via direct contact, skin absorption, inhalation, and ingestion and once inside the body, the materials can impact any organ or system.[41,65]

Hazardous chemicals in consumer goods

There are more than 80,000 chemicals in thousands of regularly used consumer products and hazardous chemicals are commonly found in consumer products in the U.S.[36,66,67] One study used quantitative high throughput exposure assessment to evaluate the chemical content in common household products and found substantial risks associated with paints, paint strippers, pesticides, leave-on personal care products, and cleaning products.[67] Additionally, many of the ingredients commonly found in consumer goods are associated with asthma exacerbation, endocrine disruption, reproductive and developmental harm, cancer, immune system issues, nervous system damage, and headaches.[36,59]

Hazardous chemicals in fragranced consumer goods

Multiple studies have found evidence of endocrine disrupting chemicals (e.g., parabens and phthalates, bisphenol A), triclosan, and VOCs (e.g., ethanolamines, alkylphenols, fragrances, glycol ethers, cyclosiloxanes) in fragranced cleaners, synthetic detergents, fabric softeners, air fresheners, sunscreen, and deodorants for preservative properties.[34,68–80] Studies also suggest fragrance products have a higher concentration of these chemicals compared to non-fragranced products and that these chemicals are the most important contaminants in perfumes and colognes.[34,59] Furthermore, more frequent use of personal care products was associated with higher urinary concentrations of parabens.[68,72–74,77–80] Finally, exposures happen despite existing regulations and many detected chemicals were not listed on product labels.[34]

Social, cultural, and socioeconomic impacts on exposure

As noted earlier, social, cultural, and socioeconomic differences facilitate wildly disparate exposures and consequently risk from these exposures are not equally distributed.[36] Multiple studies have demonstrated that women have higher exposure to scented products than men, which may be driven by sociocultural forces that influence women to use more cosmetic, personal care, and cleaning products than men.[31,36,64,81,82] There is also some evidence of age differences, with individuals aged 40 years and older showing a significant lower exposure to scented products.[64] Additionally, individuals in The Netherlands and Germany had higher levels of exposure to scented products than individuals in Sweden.[64] Finally, there is evidence that products with more toxic ingredients are often marketed to marginalized communities, including racial minorities and low-income populations.[35,4036,83]

Workplace environments also impact exposure. Custodial professionals may use general-purpose cleaners, degreasers, detergents, and other household products more frequently than others.[36,41] Similarly, individuals working in the cosmetics industry including beauticians, nail and hair salon professionals, and aromatherapists are likely exposed to VOCs emitted from shampoos, styling products, lotions, nail products, cosmetics, and sanitizers.[36,41] The same is true for home and automobile maintenance and repair professionals who experience cumulative exposure to heavy-duty cleaners, degreasers, adhesives, lubricants, sealants, caulks, and paint strippers.[36] The highest intensity of VOC exposures in the workplace is expected during the use of floor strippers and general-purpose cleaners because they contain the highest concentrations of VOCs in the bulk.[84] Finally, there is some evidence of increased risk of fragrance allergy among individuals in professions with high workplace VOC exposure.[41,85,86]

A historical perspective on fragrance exposure

A brief look at history provides helpful context regarding the increased prevalence of exposures over time. MCS was first described in the 1950s, around the same time as the post-WWII expansion of the petrochemical industry including

widespread production of organophosphate pesticides, solvents, dyes, and fragrances.[8,14] Sick building syndrome was first described in the 1970s, with MCS, IEI, and EI entering the popular press shortly thereafter to describe the myriad of symptoms reported internationally from exposures like: (1) employment in the U.S. Environmental Protection Agency (EPA) headquarters during renovation in 1987; (2) participation in the Gulf War in the 1990s; and (3) the World Trade Center tragedy.[14] By 1994, U.S. synthetic organics production reached over 460 billion pounds per year.[14] Moreover, as VOCs were becoming increasingly prevalent, people transitioned to spending more time indoors and building envelopes of homes and workplaces became better sealed to improve energy efficiency resulting in less fresh air circulation.[1,87,88] Consequently, indoor air quality is often worse than outdoor air quality with VOC concentrations approximately four times higher inside compared to outside.[88] Notably, mixed VOCs and SVOCs, followed by pesticides and combustion products were most prevalent across CI, MCS, and TILT initiation events.[1,14]

HEALTH, ENVIRONMENTAL, AND SOCIOECONOMIC IMPACTS

Self-report evidence suggests exposure to fragrances and chemicals are associated with a variety of adverse health impacts including skin irritation, mucosal symptoms, headaches and migraines, asthma exacerbation, and respiratory, cardiovascular, neurological, gastrointestinal, musculoskeletal, immune, cognitive and neurological issues (see Table 1).[16,16,19,31–40,42,89–96] Yet, understanding the potential health, environmental, and socioeconomic impacts of exposure to fragrances is extremely difficult because of the complexity of exposures, methodological limitations, and significant comorbidities and overlapping conditions. Currently, the strength of the evidence varies depending on the symptoms and organ system impacted.

Skin irritation and contact allergies

There is strong evidence that exposure to fragrances can cause skin irritation, contact dermatitis, contact urticaria, photosensitivity, phototoxicity, and photoallergy.[4,31,41,61,65,97–101] The prevalence of fragrance allergy appears to range between 1 and 9 percent depending on the population and the allergen test used.[41,97,98,102] In one meta-analysis, an estimated 4.5 percent of the general adult population was estimated to be allergic to fragrance materials (e.g., fragrance mix 1), and 1.9 percent has clinically relevant fragrance contact allergies.[41,103] Another systematic review found that the overall prevalence of sensitization to fragrance mix I (FM I) was 6.81 percent and FM II was 3.64 percent and among pediatric dermatitis patients, sensitization prevalence for FM I and FM II was 4.09 percent and 2.17 percent.[98]

The strong, consistent evidence of contact allergy associated with fragrances is not surprising considering more than 150 fragrance ingredients used in personal care and household cleaning products are known to cause contact allergies.[41,97,104] Nevertheless, neither the U.S. nor the European Union requires disclosure for all 150 known allergens. In the U.S., the Food and Drug Administration (FDA) has identified fragrance allergies, but has not yet published the list of allergens that must be included on labels, despite the original proposed June 2024 release date.[105–108] In contrast, the European Union recently updated the list of fragrance allergies required on labels from 26 products to 82.[102] There is also evidence that endocrine disrupting chemicals, many of which are found in fragranced products, may cause skin sensitization and allergic responses.[75,76]

Comorbid conditions, overlapping symptoms, and shared triggers

An important factor that complicates the ability to understand the health impacts of fragrance exposure is that there are numerous comorbid conditions (e.g., fibromyalgia, Sjogren's, autism, chronic fatigue, asthma, and migraine) with overlapping symptoms (e.g., fatigue, nausea, headache, etc.), and shared triggers.[1,1,8,13,31,42,59,109–115]
For instance, there are conditions like migraine that have osmophobia, sensitivity to odor, as a symptom, as well as exposure to fragrance as a trigger.[31,35,60,60,91,114,115] Specifically, there is evidence from retrospective comparison and cross-sectional studies of migraine patients that fragrances trigger migraine at high rates (70 percent and 90.2 percent), with perfume being the most common trigger (95.1 percent), followed by cleaning products (81.3 percent), cigarette smoke (71.5 percent), and motor vehicle exhaust (70.5 percent).[113–115]

Similarly, fragrance and fragranced consumer products have been linked to asthma, asthma exacerbation, and respiratory reactions in the respiratory tract that range from acute temporary upper airway irritation to obstructive lung disease.[16,31,34,39,54,61,65,97,116] As noted earlier, patients with asthma report that fragrances, in particular perfumes (56 percent), air fresheners (32 percent), and scented detergent (28 percent), can worsen their asthma symptoms.[31,117]

There is also some evidence that MCS patients often have comorbid autoimmune diseases (e.g., Hashimoto's thyroiditis, systemic lupus erythematosus (SLE), Sjogren's syndrome).[8,118] Similarly, autoimmunity may be linked to postural tachycardia syndrome (POTS) and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), which are associated with IEI and SBS.[119] One study found close correspondence between symptom patterns for mast cell activation syndrome (MCAS) and TILT such that as the likelihood of patients having CI increases, so did the likelihood of having MCAS.[120] This suggests that mast cell sensitization could be an underlying cause for both TILT and MCAS.[121,122]

Finally, there are extensive studies showing an association between mental illness and MCS, CI, CS, and FS.[9,13,15,42,123–131] Some research suggests that roughly half of MCS subjects meet the criteria for at least one mental health condition in their lifetime as well as significantly higher rates of depression and anxiety.[13,17] Additionally, one study found that 68 percent of the chemically intolerant women surveyed reported a past diagnosis of depression, anxiety, or panic disorder, which was significantly higher than those without chemical intolerance.[13,17,132] Likewise, a cross-sectional study of the association between MCS and mental illness among Canadian adults also found that individuals with MCS were more likely to have major depressive disorder, generalized anxiety disorder, major depressive disorder and generalized anxiety disorder, severe distress, and languishing/moderate mental wellbeing.[13]

Although the evidence on comorbidities, overlapping symptoms, and shared triggers does not provide much additional clarity on fragrance sensitivity, it does shed light on potential mechanism (e.g., inflammatory sensitization, immune dysfunction), illustrate some of the challenges in studying and understanding complex conditions like fragrance sensitivity, and highlight the value of efforts to reduce exposure to fragrances – as it may improve the health and well-being of individuals with shared triggers and comorbid conditions.

Epidemiological evidence of health impacts

Fragranced products often contain endocrine disruptors, carcinogens, and other toxic materials; however, the evidence connecting exposure to these materials in consumer and personal products to health impacts is limited and often weak or attenuated. There is limited evidence suggesting the ingredients in fragranced household products are associated with increased cancer risk as sixty percent of the chemical combinations in household products have hazard quotients exceeding 1, and 9 percent have lifetime cancer risks exceeding 10.[4,67] Similarly, there are epidemiological associations between MCS and tachycardia, arrhythmia, a mitral valve prolapses and electrocardiogram abnormalities.[8,133–135] Finally, there is some epidemiological evidence that MCS is associated with endocrinological disorders (i.e., hyposurrenalism, dysthyroidism and hyperprolactinemia).[8,136–139] Similarly, endocrine disrupting chemicals (EDCs), which are often found in fragranced products, may have synergistic endocrine disruption.[75,76] However, aside from the evidence that synthetic musks have been shown to have estrogenic effects, the evidence connecting EDCs in fragranced personal care and household cleaning products to endocrine disorders and disruption is weak.[34,140–142] However, in each of these examples the evidence is weak and attenuated.

Environmental Impacts

In addition to the multiple direct and immediate health risks associated with exposure to fragrances, there are also environmental impacts. One study found that fragrance substances are continuously discharged in large amounts into the environment, especially via wastewater.[143] Furthermore, fragrances and in particular musks are ubiquitous, persistent, bioaccumulative pollutants that can be highly toxic.[35,143] Yet, evaluating the overall impact is difficult because data on persistence, bioconcentration, and aquatic toxicity is only available for ~0.2 percent, one percent, and 11 percent respectively of chemicals registered in the European Union.[144–148] There is also concern that because many fragrance compounds are identical to those which are signal substances of environmental organisms at very low concentrations it is potentially impacting the ecosystem balance.[143,145,146] Additionally, fragrance VOCs and SVOCs contribute to air pollution and decrease air quality.[35,65]

Social and economic impacts

There is strong self-reported evidence that people with fragrance sensitivities report avoiding certain places because of potential exposure.[32,33,91,111,149]Specifically, individuals who experienced chemicals triggering adverse physical

symptoms avoided social and occupational settings because of widespread use of chemicals.[149] Similarly, there is self-reported evidence suggesting that exposure to fragrances results in stigma, missed work, loss of income, and occasionally loss of employment.[111,149] One study found that those with fragrance sensitivity reported missing 7.4 workdays on average due to illness from fragranced product exposure in the workplace.[32] Moreover, one study found that of the individuals surveyed with a hypersensitivity to fragrance, 13.5 percent (1.8 percent of the entire sample) reported losing their jobs because of their hypersensitivity.[111]

PATHOPHYSIOLOGICAL THEORIES OF FRAGRANCE SENSITIVITY

Fragrance sensitivity is a complex condition and despite decades of research there is no consensus around a unified theory of fragrance sensitivity pathophysiology. However, there are multiple rationally grounded hypotheses about the underlying mechanisms of fragrance sensitivity (e.g., neural sensitization/hyperresponsivity/central sensitization, limbic system dysfunction, neurogenic inflammation, immune system dysregulation, and psychological theories) as well as cross-cutting themes and common ground for many of these theories (e.g., the importance of genetic and immune factors, altered metabolic capacity, and oxidative stress). [1,8,12,14,15,17,42,109,110,112,121,150,151]

Neurogenic Inflammation

Neurogenic inflammation is a type of inflammation that is triggered by the activation of sensory neurons. Under the neurogenic inflammation hypothesis, fragrances trigger the responses of unmyelinated c-fiber neurons in the respiratory mucosa, leading to central nervous system (CNS) inflammation, and eventually symptoms like headache or tachycardia.[42,152–158]

Limbic system dysregulation and neural sensitization

Limbic system dysregulation and neural sensitization are parallel processes that involve acquired hyper-responsiveness manifested in several body systems. Limbic system dysfunction hypothesis focuses on hyper-responsiveness in the limbic system. Specifically, recurrent low-level intermittent exposure to chemicals, could produce something similar to kindling, where an increased electrical response in the brain following repeated low-level electrical stimulations of limbic structures can permanently lower the seizure threshold.[42,150,159–164] Neural sensitization, sometimes referred to as hyperresponsivity or central sensitization, also involves increased responsiveness of neurons, but with a focus on non-limbic areas in the CNS. For instance, with neural sensitization increased EEG activity and changes in skin conductance occurred after repeated intermittent exposures to chemicals in chemically sensitive women compared to normal controls.[42,137,165,166] There is some evidence of both sensitization events and clear cellular-level impacts from fragrance and chemical exposure in the central and peripheral nervous and immune systems.[1,14,167] This is grounded in the notion that the olfactory nerve acts as a vector for neurotoxic agents to be transported into the central nervous system bypassing the blood brain barrier.[150,159] Neuroimaging studies support the idea that the development of MCS may be attributed to neural sensitization.[1,153,168–173] [150,173]

Immune dysregulation

Allergic response and immune system dysregulation is another proposed etiological mechanism to explain fragrance sensitivity.[8,112,119,121,150,174] Some researchers theorize that mast cell degranulation and mediator release, caused by indoor air contaminants (e.g., volatile organic chemicals outgassing from new construction and remodeling materials, pesticides, mold, disinfectants, and cleaning agents) at extremely high levels, could provide an explanation for the myriad illnesses and symptoms associated with MCS, TILT, and IEI as well as the comorbid and often overlapping conditions (e.g., fibromyalgia, chronic fatigue, depression, asthma, eczema, and neurodivergence).[120–122,175–177] One study demonstrated that individuals with MCS displayed a distinct systemic immune mediator profile suggestive of low-grade systemic inflammation, as plasma levels of interleukin-1β, -2, -4, and -6 were significantly increased in the MCS group compared with controls.[112]

Psychogenic theory

The psychogenic theory of MCS hypothesizes that MCS patients, who often have high levels of depression, anxiety, and mental distress, have a greater sensitization towards environmental stimuli, which they then focus their attention on to explain their psychological symptoms.[9,13,15,26,42,95,123–129,131,178–180] This is further complicated by the fact that some psychiatric disorders (e.g., panic disorder, and PTSD) share many of the same symptoms or features of MCS.

Other common factors to consider

Although not expressly tied to a given pathophysiological theory, there is also consistent evidence of the importance of genetic and immune factors, altered metabolic capacity, and oxidative stress. For instance, the clinical manifestations of MCS may be associated with a variety of genetic polymorphism many of which result in alterations in metabolic capacity.[19,181 8,18,23,109,150,182–186] There is also some evidence suggesting these polymorphisms could increase oxidative stress.[8,15,17,18,183,186–188] Therefore, it is possible that gene expression is epigenetically modulated by exposure, leading to potential hypersensitivity and MCS.[8,182–186]

LEGISLATIVE AND REGULATORY LANDSCAPE

Federal Legislation and Administrative Oversight

Historically there have been few regulations regarding fragrances and a patchwork of federal agencies that have authority over different products with fragrances. The FDA has the authority to regulate the safety of food, drugs, medical devices, and cosmetics. Additionally, The Fair Packaging and Labeling Act (FPLA or Act) directs the Federal Trade Commission (FTC) and the FDA to issue regulations requiring that all "consumer commodities" be labeled to disclose net contents, identity of commodity, and name and place of business of the product's manufacturer, packer, or distributor.[189] In the U.S., most cleaning products are regulated by the Consumer Product Safety Commission, which does not require full fragrance ingredients or even the presence of fragrances on either the product label or the material safety data sheet (MSDS).[65] Personal care products are regulated by the FDA, which requires ingredients on the product label, but not on the MSDS. Notably, the FDA does not require companies to disclose “trade secrets,” of which fragrance formulas are likely to be. Consequently, fragrance ingredients were simply listed as “fragrance,” rather than disclosed on an individual basis.[7,190,191] In short, the FDA required finished cosmetic products to be safe when used by customers in accordance with product labeling or customary usage and to not be misbranded or adulterated while the FPLA required cosmetics marketed on a retail basis to consumers in interstate commerce to be honestly and informatively labeled.[65,190] Together the FDCA and FPLA were the primary pieces of federal legislation governing fragrance chemicals in personal care products, cosmetics, and consumer goods until the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) was passed.

The goal of MoCRA was to expand the FDA’s authority to regulate cosmetics. Specifically, the new powers provided to the FDA under MoCRA include: (1) expanded adverse event reporting and transparency; (2) recall authority; (3) requiring manufacturers and processors to register with the FDA; (4) good manufacturing processes (GMP); (5) expanded labeling requirements (e.g., contact for adverse event reporting and disclosure of fragrance allergens); (6) maintenance records supporting safety substantiation; (7) screening Talc-containing products for asbestos; and (8) assessment of per- and polyfluoroalkyl substances (PFAS) safety in personal care products (e.g., summary report in collaboration with National Center for Toxicological Research) issued within three years.[190,192,193] Many of the new requirements became effective on December 29, 2023, but FDA delayed enforcement until July 1, 2024.[194,195]

Despite the improvements brought by MoCRA, there are still clear gaps and areas of improvement. First, although the new label requirements include the disclosure of fragrance allergens, which is a step in the right direction, as of the writing of this report, the FDA has not published a list of fragrance allergens. Additionally, fragrance ingredients that are not on the list of allergens may still be identified only as, “fragrance” to protect company trade secrets. Second, there are some exemptions under MoCRA. Specifically, certain small businesses (e.g., companies whose average gross annual sales of cosmetic products in the U.S. for the past three years is less than $1 million) are exempt from compliance with GMP, registration requirements, and adverse event record retention. However, the exemption does not apply to facilities that manufacture or process products that: (1) regularly come into contact with the mucus membrane of the eye; (2) are injected; (3) are intended for internal use; or (4) are intended to alter appearance for more than 24 hours.[194] MoCRA does preserve the authority of states to ban or regulate chemicals of concern in personal care products. Thus, the hard work of regulating specific ingredients now falls to the states.[193]

State Legislation

Currently, twenty states have passed laws limiting certain substances in cosmetics, including California, Colorado, Florida, Hawaii, Illinois, Iowa, Maryland, Minnesota, Montana, Mississippi, Nevada, New Jersey, New Mexico, New York, Ohio, Oregon, Vermont, Virginia, Washington and Wisconsin.[193] These states have stricter limits on some

chemicals (e.g. 1,4-dioxane, cadmium, color additives, formaldehyde, mercury, parabens, PFAS, phthalates, methyl alcohol and methyl methacrylate) due to concerns about their potential health effects.[193]

California is a leader in consumer safeguards, specifically, regarding protection against harmful substances in personal care products, and therefore the best example of successful fragrance regulation at the state level. In 1986, the state passed Proposition 65, the Safe Cosmetics Act, which required manufacturers to reveal the presence of Proposition 65 chemicals. The Prop 65 list currently includes 624 carcinogens and 323 reproductive/developmental toxicants; however, it does not include other hazard endpoints, such as neurotoxicity, asthmagenicity, or endocrine disruption.[36,66] Then California passed the Professional Cosmetics Labeling Requirements Act, which mandated ingredient labels on professional salon products. Next, in 2020 the Toxic-Free Cosmetics Act banned 24 toxic chemicals sold in California and the Cosmetic Fragrance and Flavor Ingredient Right to Know Act was passed, requiring disclosure of fragrance mixture ingredients in personal care products. Finally, in 2022, California banned intentionally added PFAS chemicals from personal care products, effective on January 1, 2025.

Industry Self-Regulation

The final regulatory mechanism is industry self-regulation. The Research Institute for Fragrance Materials (RIFM) and the International Fragrance Association (IFRA) make up the international self-regulation system for the fragrance industry.[4] RIFM was formed as a member-supported nonprofit organization in 1966 and in 1967 RIFM established their Expert Panel for Fragrance Safety as an independent team of researchers and academics (e.g., dermatologists, pathologists, toxicologists, and environmental scientists) that review and approve all RIFM work. This includes the RIFM database which provides information (e.g., chemical features, safety assessment, genotoxicity, repeated dose and reproductive toxicity, skin sensitization, photoirritation and photoallergenicity, local respiratory toxicity, mutagenicity, carcinogenicity, metabolism and toxicokinetics, and environmental consequences) on 7,000 raw fragrance materials. However, RIFM does not evaluate final fragrance formations and the database is only available to members.[4,65] IFRA was founded in 1973 and acts as the official representative body of the international fragrance industry. As such they represent the collective interests of the industry. The primary activity of IFRA is the publication of the list of usage standards for fragrance materials, based on the findings of RIFM. The most recent publication (the 51st Amendment) was implemented in January 2024 and updates are scheduled to occur every three years.[196] Ultimately, industry self-regulation is helpful, but labeling transparency and disclosure of all fragrance ingredients in consumer products may not be in their best interest.

Although the enactment of MoCRA and state legislation to either prohibit or provide notice of certain harmful ingredients in personal care and household cleaning consumer goods are actions that will likely help reduce exposure to potentially harmful chemicals and fragrances, other mechanisms may yield better results.

LEGAL LANDSCAPE AROUND FRAGRANCE SENSITIVITY AND DISABILITY

In the absence of more stringent state and federal legislation around fragrance regulation, the most likely tool to reduce exposure to fragrances for those who experience fragrance sensitivity is either: (1) exercising rights under the Americans with Disabilities Act (ADA) or (2) relying on organizations to pursue self-regulation and implementation of fragrance-free policies.[197]

ADA and third-party accommodations

Under the ADA, a disability means: (1) a physical or mental impairment that substantially limits one or more major life activities of such individual; (2) a record of such an impairment; or (3) being regarded as having such an impairment.[198]

The ADA uses the concept of reasonable accommodation to establish a form of positive rights. Specifically, the ADA affirmatively requires public and private entities to make reasonable modifications to physical environments, rules, and policies to make spaces accessible.[197] Generally, interpretation of what constitutes reasonable accommodation focuses on two parties, the individual seeking the accommodation to achieve equitable access and the employer or public/private actor who is being asked to engage in or refrain from certain behaviors. However, fragrance-free policies would require third-party accommodations, because other individuals using the shared space would also need to accommodate.[197] Third-party accommodation can be both passive behaviors (such as prohibiting peanuts in schools)

as well as active behaviors (such as washing hands or wearing a mask).[197] In the case of fragrance-free policies, the accommodation would require multiple third parties to refrain from using certain fragranced products.

Often the criticism of third-party accommodations (and disability accommodations in general), is that they may be viewed as special rights that infringe on the rights of third parties. However, there are examples of successful third-party accommodation, starting with smoke-free policies that paved the way as both a disability accommodation as well as a general public health practice.[197,199] This provides hope for the potential success of other third-party accommodations.

Smoke-free policies as accommodations

Historically, courts have been sympathetic to claims of secondhand smoke-related disabilities and acknowledged employers should have granted reasonable accommodation such as prohibition of smoking on the job or inside the building.[197,200] Importantly, the standard courts have taken to evaluate the reasonableness of third-party accommodations, is whether the accommodation creates undue burden for others. For instance, smoke-free workplace policies and laws have been considered reasonable because they are inexpensive to implement and do not harm or burden businesses that have implemented them.[197,201]

Food allergy bans and mask requirements as accommodations

As with smoke-free policies, there has been evolution over the years with respect to accommodating food allergies and mask requirements – particularly in education, air travel, and the workplace. Section 504 is the primary statutory framework used to accommodate students with disabilities in schools and it has been used to accommodate students with food allergies and immune conditions.[197,202] Regarding food allergies, reasonable accommodations include allergen-free lunch tables, handwashing requirements, an allergen-free classroom, and self-carry epinephrine (EpiPen).[197,203] Although, there has been occasional resistance from parents of non-allergic kids, generally food bans as accommodations are well accepted and practiced with many schools banning nuts schoolwide.[197,199] In contrast, mask requirements in schools as a reasonable disability accommodation have had mixed results with circuit courts split.[197] One researcher theorizes that some courts are resistance to blanket mask requirement policies because they lack flexibility, applying mask requirements to everyone regardless of whether they come into contact with the student in need of accommodation. In contrast, a third-party accommodation argument and more importantly policy, which can be tailored to the specific needs of the individual being accommodated as well as the other parties, may be more successful in these circuits.[197]

Food allergies and self-regulation to avoid tort liability

The airline industry has shown similar successes regarding making planes safer for individuals with food allergies (specifically peanuts); however, it has taken the form of self-regulation. In the absence of federal or industry regulation banning peanuts, many airlines (but not all) decided to stop serving them to prevent potential tort liability.[197,204] Consequently, the current landscape theoretically gives consumers enough room to choose the safest airline for them. However, this sort of informal self-regulation, which is driven by the desire to avoid potential tort liability, has not been perfect – with reports of families being removed from planes when they raise questions regarding exposure or situations when the airline determines the severity of an allergy made it unsafe for them to fly.[197,205,206] In this way, the airline industry provides a cautionary example for informal self-regulation as opposed to formal regulation.

Third-party accommodations and fragrance sensitivity?

Smoke-free policies, mask requirements, and bans on food allergens provide a potential roadmap for fragrance sensitivity. Moreover, in many ways the current situation with fragrance sensitivity mirrors what was going on with food allergies 70 years ago. People with fragrance sensitivity experience symptoms when exposed to fragrances, but there is not a proven biological mechanism or clear clinical biomarker. Likewise, prior to the discovery of immunoglobulin E (IgE) as an indicator allergy in the mid-1960s, food allergy was considered a controversial condition.[197,207] This is particularly interesting as successful ADA and Section 504 challenges for food allergy

accommodations helped normalize narrowly applied third-party accommodations such that more widespread nut bans in schools are now more well accepted. At the same time, to avoid liability, the airline industry has relied on self-regulation to give consumers choice. It is not yet clear whether fragrance-free policies will have a similar divide.

ADA cases involving fragrance sensitivity

Initial efforts of individuals with MCS to exercise their rights under the ADA were largely unsuccessful. A study of 17 early ADA cases involving MCS (between 1995 and 2003) found that motions for summary judgment by the defendant were granted or affirmed in 14 cases.[197,208] Similarly, a review of cases involving MCS prior to the 2008 Americans with Disabilities Act Amendments Act (ADAAA), which broadened the definition of disability, demonstrate that courts regularly questioned whether the plaintiffs were truthful about the presence or severity of their condition.[197,209] Moreover, in 2022, with the ADAAA in place for some time, the Eastern District Court of Virginia still excluded from evidence a medical diagnosis of the condition because it "lacked reliability and the medical community has not accepted MCS as a diagnosis."[197,210,211] This suggests courts are reticent to acknowledge MCS as a condition meriting accommodation.

Moreover, even in cases where courts acknowledge fragrance sensitivity as a disability meriting accommodation, there remains the question of whether fragrance-free policies are considered a reasonable accommodation that does not unduly burden third parties. For instance, the Minnesota District Court decided that fragrance-free policies "impose an undue financial and administrative burden on employers, because they are very difficult to enforce."[197,212] Similarly, when evaluating the reasonableness of a fragrance-free policy in a public school, the court determined that, "a public school could never be free from any objectionable smell or any deodorant, perfume, cologne, hand lotion, or cleaning products."[197,211] At the same time there have been some successful ADA cases involving MCS.[213–216] In short, while there is a pathway under the ADA to ensure accommodations for individuals with fragrance sensitivity, evidence suggests the court system may not be the best tool to achieve equity.

Self-regulation and implementation of fragrance-free policies

Fragrance-free policies, which often apply to both individuals and spaces, aim to make spaces more accessible for individuals with MCS, as well as those with other conditions with symptoms that may be triggered by fragrance.[217] For instance, efforts are taken to promote the use of fragrance-free cleaning products, and people coming into those spaces asked to avoid or limit wearing perfume, using fragranced laundry detergent/dryer sheets, applying personal care products that contain fragrances, or refrain from using fragranced products when in fragrance-free spaces.[217]

As illustrated above, some blanket fragrance-free policies have been struck down by courts. Consequently, it is important to consider what sorts of fragrance-free policies might be the most successful.

Where are fragrance-free policies being implemented?

Fragrance-free polices are gaining traction in workplaces and schools. Since 2009, the Centers for Disease Control (CDC) has encouraged employees to be as fragrance-free as possible.[218] The rational for the policy was to establish guidance and procedures to protect and maintain safe indoor environmental quality for all CDC employees at all CDC work areas. Importantly, the policy does not expressly prohibit individuals from using fragranced products, but it does prohibit carrying or using such products inside the CDC.[218] Therefore, it is a good example of a flexible policy. There have also been efforts to implement and advocate for fragrance free spaces and product options elsewhere by the CDC, the American Lung Association, the Job Accommodation Network (JAN), and the U.S. EPA.[218–221] Additionally, University of Illinois Chicago (UIC) and University of California Los Angelas both advocate and provide resources for implementing fragrance-free policies on their campuses and Portland was the first city to ban fragrance.[141,217,222,223] Importantly, Portland's ban, like CDC's policy, is flexible. It applies only to City of Portland employees who are asked, "to refrain from the use of personal scented products in the workplace where the sole purpose is to produce a scent, such as perfume, after shave, and cologne and to avoid the use of strongly scented personal hygiene products such as laundry soap, dryer sheets hand lotion, powder, hair spray, and deodorant."[223]

It is not clear if increased implementation of fragrance-free spaces is based predominantly on the strength of the scientific evidence, the precautionary principle, or the legal landscape regarding MCS as a disability. However, currently fragrance-free policies appear to be the most effective method for reducing exposure to fragrances, particularly when the policies are flexible, creative, and voluntary rather than focusing on strict bans.[224]

CURRENT AMA POLICY

Our AMA does not currently have any policy related to fragrance regulations or fragrance-free policies. However, policy H-440.855, "National Cosmetics Registry and Regulation," does support the creation of a publicly available registry of all cosmetics and their ingredients. Additionally, although it is not a formal policy the AMA does discuss the complex medical and legal nature of disability. For instance, HOD policy supports the designation of alcohol use disorder as a disability and opposes the classification of obesity as a disability.

CONCLUSION

Fragrance sensitivity is a controversial, unexplained, and complex disorder. There is extensive self-report evidence suggesting that fragrance sensitivity is a serious problem for a significant portion of the population. Yet, the heterogeneity of symptoms and exposures coupled with the sheer volume of ingredients in fragranced products (and consumer products more broadly) makes understanding the relationship between fragrance exposure and health impacts extremely difficult. Most of the evidence, which varies wildly in quality, falls into three categories: (1) self-report of exposure to fragrance followed by a constellation of symptoms; (2) toxicological and epidemiological associations between chemicals found in fragranced products and potential risk of harm; and (3) analysis of potential mechanisms in individuals with a diagnosis of fragrance sensitivity. It is possible to connect the evidence to form a compelling narrative of how exposure to harmful chemicals from personal care and household cleaning products causes serious adverse health effects through several plausible mechanisms. However, the throughline between these categories of research is often attenuated, weak, or based on limited data.

This clearly illustrates the need for more research on fragrance sensitivity (e.g., diagnostic tools, mechanisms, health impacts, impacts of fragrance on other diseases, and fragrance-free interventions). Although more research is needed, inaction means that those with fragrance sensitivity will continue to be misdiagnosed, offered health care solutions with limited or no effect, or be met with mistrust and doubt. Furthermore, efforts to reduce exposure to fragrances and other chemicals will likely benefit individuals with fragrance sensitivity, as well as those with comorbidities and shared triggers that are also negatively impacted by exposure to fragrances. Therefore, it is worth pursuing efforts to reduce exposure.

It is unlikely that either federal regulation or industry self-regulation will bring significant changes or improvements regarding labeling transparency or ingredient bans, but some states have been making promising progress in these areas suggesting this may be an area worth more focus. Likewise, there is a viable mechanism for accommodation under the ADA, though decisions are mixed. Instead, the most effective approach has been self-regulation in the form of implementation of fragrance-free policies. Notably the most successful fragrance-free policies and third-party accommodations appear to be those that afford flexibility and creativity rather than blanket bans.

RECOMMENDATIONS

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

Our American Medical Association:
(1) recognizes that some environmental exposures may have the potential to substantially limit major life activities of an individual with fragrance sensitivity and related disorders.
(2) encourages health care facilities, government agencies, and nonprofit organizations to adopt and promote fragrance-free policies that recommend individuals avoid or limit use of fragrances and support the use of fragrance-free products when feasible in consultation with relevant medical specialists when possible.
(3) encourages research on fragrance sensitivity to (a) improve diagnostic tools; (b) understand the impact of fragrances on other diseases; (c) evaluate the impact of fragrances on health; and (d) evaluate the impact of fragrance-free intervention.

(4) supports the identification of fragrance allergens and disclosure of fragrance ingredients as part of labeling of personal care products, cosmetics, and drugs.

Fiscal Note: less than $1,000

Table 1. Variations is self-report symptom prevalence (%) across different populations and subgroups

	Steinemann*					Steinemann*	Steinemann*	Caress*	Fares-Medina*		Andersson**	Caress**	Hausteiner**	Borchein***	Klasche****		
	US	AU	UK	SE	AVG	US	US	US	ES-w	ES-m	nr	US	DE	nr	DE-FS	DE-Autists	DE-Asthmatics
Migraine headaches	15.7	10	8.4	16.1	12.6	8.4	15.7	7.2	19		66	88	58	33	25.1	22.4	12
Asthma attacks	8	7.6	6.8	5.5	7	6.8	8	4.7		29	59				16.9	20.4	13.8
Neurological problems (e.g., dizziness, seizures, head pain, fainting, loss of coordination)	7.2	4.5	3.7	5	5.1		7.2	3.2	10		22	7.2-46	22	19	27.4	30.6	11.1
Respiratory problems (e.g., difficulty breathing, coughing, shortness of breath)	18.6	16.7	11.6	20	16.7	11.6	18.6	9.5		47-60					55.3	30.6	24.4
Skin problems (e.g., rashes, hives, red skin, tingling skin, dermatitis)	10.6	9.5	9.8	6.5	9.1	9.8	10.6	5.7	15	1	30		19		32	34.7	16
Cognitive problems (e.g., difficulties thinking, concentrating, or remembering)	5.8	4.1	2.8	4.5	4.3	2.8	5.8		2-9		21-51	32	17-46	13-27	18.7	28.6	12.4
Mucosal symptoms (e.g., watery or red eyes, nasal congestion, sneezing)	16.2	14	9.2	13.5	13.2	9.2	16.2	7.6	42	2	22-65	59-77	11	12	35.6	28.6	14.2
Immune system problems (e.g., swollen lymph glands, fever, fatigue)	4	3.3	1.9	1.5	2.7	1.9	3.8					17.4			13.2	38.8	9.3
Gastrointestinal problems (e.g., nausea, bloating, cramping, diarrhea)	5.5	3.3	3	3.5	3.8	3	5.5		20	2	25-26		30	15	21.9	24.5	10.2
Cardiovascular problems (e.g., fast or irregular heartbeat, jitteriness, chest discomfort)	4.4	3	3.2	2.1	3.2	3.2	4.4		3		21-30	46-55	14-27	19-Dec	14.6	24.5	8
Musculoskeletal problems (e.g., muscle or joint pain, cramps, weakness)	3.8	2.6	2	1.5	2.5	2	1.7		17	2		30.4		19-21	9.6	24.5	6.7
Other	1.7	1.9	2.1	2.2	2		1.7					50.7			3.2		1.3

nr = not reported, AVG = average

*General population/nationally representative sample

**Individuals with self reported chemical intolerance

***Individuals with a diagnosis of MCS

****German subpopulations (FS = fragrance sensitive individuals, autists, and asthmatics)

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7. ADDRESSING THE HEALTH ISSUES UNIQUE TO MINORITY COMMUNITIES IN RURAL AREAS

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See Policies H-135.905 and H-350.937

INTRODUCTION

Resolution 433 was adopted at the 2024 Annual Meeting resulting in policy H-350.937, "Improving Healthcare of Minority Communities in Rural Areas." Item five of this policy asks that "our American Medical Association (AMA) will research and study health issues unique to minority communities in rural areas, such as access to care difficulties."

BACKGROUND

As of 2020, around 46 million Americans, or 14 percent of the U.S. population, lived in rural areas.[1] Rural Americans face numerous health disparities compared with their urban counterparts. Rural Americans are more likely to die from heart disease, cancer, unintentional injury, chronic lower respiratory disease, and stroke than their urban counterparts.[2] Unintentional injury deaths are approximately 50 percent higher in rural areas than in urban areas, partly due to greater risk of death from motor vehicle crashes and opioid overdoses.[3,4] In general, residents of rural areas in the U.S. tend to be older and sicker than their urban counterparts.[2,5]

While rural America is still overwhelmingly White (constituting about 76 percent of the rural population), it has become more ethnically and racially diverse over the last twenty years.[1] Despite limitations in available data and health studies, it has been well established that racial and ethnic minority populations in rural areas often experience disparities in health status, rates of chronic disease, life expectancy, and rates of unintentional injury compared to their White rural counterparts.[6–8] As an example, in a recent study, rural counties with a majority non-Hispanic Black or American Indian/Alaska Native (AI/AN) residents were found to have a higher premature death rate compared to rural counties with a majority of non-Hispanic White residents.[9] In places where race and ethnicity overlay with rural geography, residents often experience dual disparities and face some of the worst outcomes in the nation. Poor health outcomes for rural minority populations are a result of intersecting social determinants of health factors, which are further elucidated in this report.

In 2022, the AMA's Council on Science and Public Health (CSAPH) authored a report on improving rural public health infrastructure, which found that rural local health departments are often limited by budgets, staffing, and capacity constraints in providing public health services, limiting their ability to respond to national public health and health care policy initiatives and emergencies. With less funding and fewer staff, rural local health departments are often not able to meet the needs of a sicker population over a larger geographical area, contributing to the lack of essential public health services offered in rural areas. Building from the previous CSAPH report, this report provides a summary of the available evidence on health disparities within minority rural populations, with a focus on Black/African American, Hispanic/Latinx, AI/AN, as well as gender and sexual minority populations. Additionally, the report explores the historical and current contributors to ongoing health disparities, such as the social determinants of health and structural racism.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "rural" AND "minority"; "rural" and "health disparities", and "rural" and "health inequities." Additional articles were identified by manual review of the reference lists of pertinent publications and as new areas of exploration were revealed through identified articles. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

DISCUSSION

Rural minority populations are not a homogeneous group of individuals and ethnic and racial diversity within rural America has increased significantly within the past twenty years.[1] For the purposes of this report, rural minority populations are grouped into four general categories: African American/Black, Hispanic/Latinx, AI/AN, and the LGBTQ+ community. To note, the non-Hispanic multiracial population has also increased in rural areas as of the 2020 Census, now representing 3.9 percent of the rural population.[1] However, due to the recency of this population increase and little information in the literature on the health issues of this population, this report focuses primarily on the four above noted categories.

Data from the Behavioral Risk Factor Surveillance System (BRFSS), an annual state-based, random-digit–dialed telephone survey of the noninstitutionalized U.S. population aged 18 years or older, demonstrates that rural minority populations have poor health outcomes across multiple measures compared to their White rural counterparts.[6] For example, as of 2017, close to 30 percent of AI/ANs, non-Hispanic blacks, and Hispanics self-reported poor or fair health compared to only about 18 percent of non-Hispanic Whites.[6] While many rural racial minority populations suffer worse health outcomes and have poorer health care access compared to their White rural counterparts, each group experiences a unique set of challenges.[6] The following sections summarize health challenges unique to each of the four minority groups.

Non-Hispanic African American/Black. As of the 2020 Census, rural African Americans account for about 7.7 percent of nonmetropolitan inhabitants, with a concentrated population in the rural south.[1] This geographic concentration is an artifact of our countries' history of chattel slavery, as many black families stayed in the south following emancipation and the Civil War despite the large migration to other regions of the country in the early 20th century. The history of slavery in the U.S. is an important social determinant influencing the health disparities experienced by rural African Americans today (discussed further below). Rural African Americans have significantly lower rates of health care coverage (73.2 percent) compared to White populations (83.9 percent) and almost one in four (24.5 percent) have not seen a doctor in the past 12 months due to cost.[6] Based on BRFSS data, rural African Americans are significantly more likely to have two or more chronic health conditions (40.3 percent prevalence), are more likely to be severely obese (12.1 percent have a BMI greater than or equal to 40 kg/m2), and are more likely to get no leisure-time physical activity (38.2 percent prevalence) compared to non-Hispanic White populations (36.0 percent prevalence of two or more chronic conditions, 5.0 percent prevalence of severe obesity, and 27.7 percent prevalence of no leisure time physical activity).[6] As a result, rural African American communities are particularly impacted by cardiovascular disease, hypertension, stroke, and diabetes.[7] Rural African Americans are 20 percent more likely to be diagnosed with diabetes compared to urban residents and also tend to have poorer diabetes disease control, leading to increased rates of complications that arise from diabetes.[7]

Poor control of hypertension among rural African American communities is also high, which may be linked to the high rates of stroke found in this population. The high rate of stroke is so stark that southern states where many rural African Americans reside have been nicknamed "The Stroke Belt."[7] Lastly, due to barriers faced in accessing preventive services in rural areas, cancer disparities are more acutely felt among rural African Americans.[7,10] For example, African American women in rural areas have the highest breast cancer mortality rate compared to other racial and ethnic populations in the U.S.[7] The high prevalence of poorly managed chronic disease, lack of access to preventive services and care, ultimately lead to higher mortality rates among rural African Americans. Based on one study, the age-adjusted mortality rates estimated across a five year period (2013-2017) were highest among rural African Americans compared to all other minority groups, in both rural and urban settings (981.3 deaths per 100,000).[8]

Hispanic/Latinx. As of the 2020 census, Hispanics represent the largest share of the rural minority population, with a population of about 4.1 million or 9.0 percent.[1] Since 1980, Hispanics have been the fastest growing population in rural America, often relocating for employment opportunities in the agriculture, construction, and manufacturing sectors.[7] A result of the intersection of largely being immigrants (26.7 percent of rural Hispanics were born outside of the U.S.) and working in lower skilled jobs, rural Hispanics have the lowest prevalence of health care coverage among rural minority populations (61.1 percent) and nearly a quarter have not seen a doctor in the past 12 months due to cost (23.1 percent).[6] In terms of health conditions, rural Hispanics are impacted by a high prevalence of diabetes compared to rural White populations and urban Hispanic populations, as well as a higher burden of hypertension, heart disease, and stroke.[7] Rural Hispanics with diagnosed diabetes and/or hypertension are significantly less likely to be managing their conditions.[7] Significant barriers to accessing care unique to the rural Hispanic community are lack of bilingual staff or qualified medical interpreters within health care settings.[7] Despite higher prevalence and burden of some health

conditions, rural Hispanics have a lower age-adjusted mortality rate compared to their African American, AI/AN, and White rural counterparts (580.7 per 100,000) but it is significantly higher than urban Hispanic populations (522.7 per 100,000).[8]

American Indian/Alaskan Native. AI/AN populations are largely rural in composition, with approximately 54 percent living in rural areas of small towns, and 68 percent living on or near their tribal homelands.[11] AI/AN communities have a significantly higher prevalence of depressive disorder (23.2 percent), obesity (38.5 percent), and are more likely to be current smokers (36.7 percent) compared to non-Hispanic Whites (20.3 percent prevalence of depressive disorders, 32.0 percent obese, and 24.7 percent are current smokers).[6] Rural AI/AN communities also have the highest rate of death by unintentional injury compared to all other racial/ethnic groups, both urban and rural (101.9 deaths per 100,000).[8] Notable health conditions of concern in AI/AN community include high rates of diabetes and hypertension, substance use, suicide, as well as respiratory health conditions such as tuberculosis, asthma, pneumonia, and more recently, COVID-19.[7,12] As a result of the numerous health disparities experienced by the AI/AN community, they have a lower life expectancy compared to all other racial groups in the U.S. population (65.2 years in 2021 compared to 76.4 for White populations).[12] While life expectancy declines from the COVID-19 pandemic were experienced among the entire population, AI/AN groups experienced the largest decline which is reflective of the disproportionate burden of excess deaths from COVID-19 experienced in this community.[12]

LGBTQ+ community. While exact numbers of the LGBTQ+ population in rural areas are difficult to assess compared to racial and ethnic minorities as there is no standardized method for collecting this information, (such as the Census) and ongoing stigma targeted at the LGBTQ+ community makes self-reporting unreliable, it is estimated that there are approximately three to four million LGBTQ+ individuals living in rural areas.[7,13] Data is limited in terms of unique health conditions experienced in this community. However, it has been documented that self-reported health among rural LGBTQ+ populations is more likely to be poor or fair and they are more likely to report having three or more chronic conditions compared to urban LGBTQ+ populations.[14] Sexual minority populations are at an elevated risk for substance use and substance use disorders compared to heterosexual populations, which has been associated with chronic stress and use of substances as a coping mechanism.[15] Rural LGBTQ+ populations may experience more stress due to continued stigmatization and prejudice, with reduced access to supportive communities, leading to higher levels of anxiety and depression.[13,14] It has also been estimated that rural sexual minorities have lower access to substance use disorder treatment, but few studies have evaluated this issue.[15]

Causes of Rural Minority Health Disparities: Intersecting Social Determinants of Health

Rural minorities are functionally impacted by two overlapping disparity processes - disparities associated with their rural geography and disparities associated with being a member of a particular minority group, which can be exponential, not just additive.[7] In other words, existing rural health disparities are a product of a complex intersection and interplay of many social and structural determinants of health. Among the various social determinants of health, a lack of education, economic stagnation, and lack of investment within rural communities are notable as they have led to disproportionate rates of poverty in rural areas, leading to lower tax bases that limit the ability for educational and health systems to thrive.[7] As a result, upstream social and economic determinants are negatively impacted, including housing, food security, access to places to be physically active, and health care access.[16,17]

While many consider housing shortages and affordability an urban issue, many rural areas are also facing similar challenges caused by an overall lack of housing development over many decades as well as the growth in seasonal and recreational use of available housing.[18,19] These issues were exacerbated by the COVID-19 pandemic, when urban dwellers and remote workers moved to rural areas.[20] Housing shortages and affordability not only impact low-income minority populations but also makes recruitment and retention of rural health care professionals even more challenging.[18,19] Multi-modal transportation infrastructure, such as public transportation, sidewalks, and biking-walking trails, is also lacking in rural areas compared to most urban and suburban municipalities.[21,22] Combined with long distances between destinations, this reduces the availability of daily opportunities for physical activity and creates a reliance on personal automobiles to access daily needs and services.

To understand how the current social determinants of health were created, it is useful to look from a structural and historical perspective. The relationship between rural minority groups and current poor health outcomes is rooted in centuries of discrimination, racism, violence, as well as disinvestment and injustice.[23] Structural racism in the U.S. is defined as "the totality of ways in which societies foster racial discrimination through mutually reinforcing systems…These patterns and practices in turn reinforce discriminatory beliefs, values and distribution of resources."[24]

Structural racism plays a critical role in the existing health disparities experienced by minority rural populations as it has influenced housing and lending discrimination, cultural stigma, forced migration, occupational inequalities, and xenophobic immigration policies.[25] For Black Americans in the rural South and AI/AN populations, the historical legacy of land dispossession is a critical structural determinant in understanding the current context of high poverty levels and poor health.

In the rural South, particularly the Mississippi Delta area (an area defined as the northwest section of the U.S. that lies between the Mississippi and Yazoo rivers), 98 percent of black agricultural landowners have lost ownership of their land, equating to a loss of 12 million acres over the last century.[26] Following the civil war and during the Reconstruction era, Black ownership of land increased and even outnumbered White landowners in some southern counties. At the beginning of the 20th century, it was estimated that African Americans owned as much as 14 million acres of farmland.[27] That changed starting during the Great Depression and through the 1960s when federal agencies and policy directives, implemented in a structurally discriminatory manner, transformed the nature of farm ownership and increased racial disparities in farm owner acreage. As an example, Black farmland in Mississippi totaled 2.2 million acres in 1910. Fifty years later, according to the Census of Agriculture, black farmers lost almost 800,000 acres of land over a fourteen-year period. This was largely a result of discriminatory loan servicing and loan denial practices by the USDA and other federal and financial institutions (as found by major audits and investigations).[26] Coupled with the onset of Jim Crow laws in the late nineteenth and early twentieth century, rural African American communities have struggled economically, with the long-term effects on health clear today.

Among indigenous communities in the U.S., the overall level of land dispossession is even more staggering. The colonization and imperial expansion by Western European countries of North America led to the displacement and forced migration of indigenous communities across the U.S., the erosion of their languages and culture, and dismantling of their social structures.[28,29] It is estimated that there has been an aggregate reduction in historical indigenous lands of about 98.9 percent.[29] The eviction of indigenous people from their ancestral lands has had long-term intergenerational impacts on indigenous families and community. For both the African American and AI/AN communities, the dispossession of their lands has led to an overwhelming loss of actual and potential net wealth that could have been passed on between generations. For African Americans, it has been estimated that as of 2013 the median net wealth of their households is $11,200, while it is thirteen times greater for White households.[30] For ancestral AI/AN lands, one study estimated that the total worth of the transfer of land resources was equivalent to approximately half a billion dollars.[30] Overall, loss of land has been found to have stemmed from "discrimination in federal and state programs, swindles by lawyers and speculators, unlawful denials of private loans, and even outright acts of violence or intimidation."[26] Considering the extreme level of poverty experienced by these rural minority communities today, the importance of this historical loss of wealth cannot be overstated. Additionally, current lands where indigenous populations have been relocated to are more exposed to climate change risks and hazards, including more extreme heat and less precipitation.[29]

Occupational Hazards

In the Hispanic/LatinX rural population, occupational health hazards represent an important and unique social determinant of health which intersects with low pay for the work they do, few regulatory protections, limited services, as well as discrimination and harassment.[16] Hispanic migrants make up an overwhelming majority of hired crop workers in the U.S. One estimate is that they account for around 83 percent of hired U.S. farm workers. Rural Hispanics are also overly represented in the workforce of large scale agricultural processing facilities (e.g., poultry processing).[31] Working in the agricultural sector, rural Hispanics face numerous environmental and physical threats, including chemical hazards from pesticides and air pollutants, physical hazards such as those from occupational injuries and the effects of extreme heat, as well as biological hazards from inadequate access to drinking water and basic sanitation.[32,33]

Pesticides are not only a source of injury and acute illness among farm workers, but long-term exposure is also linked to several chronic health effects. Acute, short-term health impacts of pesticide exposure depend on the type of chemicals used but can include eye and skin irritation, nausea, dizziness, and diarrhea.[34] Chronic health effects from pesticide exposure can include cancer, birth defects and reproductive harm, neurological and developmental impacts, and disruptions to the endocrine system.[34] Farm workers are also exposed to numerous air pollutants, including black carbon, particulate matter, carbon monoxide, nitrogen dioxide, sulfur dioxide, and diesel-related emissions from farm activities, such as tractor driving, maintenance and repair of machinery and equipment, and agricultural crop residue

burning.[32] An emerging threat to farm worker health is exposure to smoke, dust, and poor air quality from wildfires, which are expected to increase in frequency and intensity in the coming years because of climate change.[35]

Machine related injuries are another top occupational risk for farm workers as well as musculoskeletal injuries from physical exertion and repetitive motions.[16,32,36] Bacterial and viral threats from working in agriculture are also unique to farm workers and there are several recent examples of this. During the COVID-19 pandemic, farm workers were considered essential and had to keep working, thus increasing their risk of COVID exposure.[32] Most recently with the spread of highly pathogenic avian influenza A (H5N1) in dairy cows, the small number of cases that have occurred in farm workers has affected primarily Latino migrants.[37] Despite working on farms and harvesting food, the combination of low wages and living in highly rural areas with a low density of available supermarkets means that food insecurity is especially high among migrant workers in the rural/agricultural sector.[5] Additionally, there is a lack of quality housing for migrant workers and available low-cost housing is limited. Reports have consistently found high rates of overcrowded and substandard housing among migrant workers.[32]

Environmental Conditions

Increased risk of exposure to hazardous environmental exposures and conditions are not limited to the rural Hispanic community. Rural Black and AI/IN populations also experience similar but unique environmental justice issues. For example, intensive livestock operations, such as large hog farms, are disproportionately located near rural, low-income African American communities, which results in wide range of adverse health impacts including eye irritations, respiratory ailments, cardiovascular issues, mental health issues, and noxious odors.[38] Additionally, low-income, African American communities are disproportionately exposed to toxic air pollution from the fossil fuel industry, with more than 1 million African Americans living within a half-mile of oil and natural gas wells, processing, transmission and storage facilities.[39] Abandoned hard rock mining operations in the Western U.S. are disproportionately located on American Indian lands, creating an increased likelihood that American Indians living near these mines are exposed to high levels of toxic metals, which are associated with increased risk of kidney disease, hypertension, and other chronic diseases.[40]

Concerns over water quality and waste management in rural African American and AI/AN communities are also prevalent, as many of these communities are not connected to larger municipal water and sewage treatment systems but rather rely on wells and septic systems.[41] One report estimates that 48 percent of households on American Indian reservations lack clean water or adequate sanitation.[42] Another study found that American Indians, Black, and Hispanic households are much more likely to live in a household without indoor plumbing and running water and "plumbing poverty" is geographically clustered in Alaska, the U.S. Southwest, the Upper Midwest, the Northeast (especially northern Maine and New Hampshire), and the Allegheny and Appalachian regions of Pennsylvania and West Virginia.[43] Moreover, for those with access, particularly well water, they are still at risk of contamination. The Hopi Tribe estimates 75 percent of its community members are drinking contaminated water.[44] Similarly, multiple studies documented home well contamination with the Navajo nation exposed to uranium and arsenic in their well water and 39 percent of Tribal families' wells on the Crow Reservation showing unsafe levels of metals and/or nitrate.[45]

Fear of Deportation

Lastly, for migrant and immigrant Hispanic communities, the fear of and experience of deportation is an ongoing concern with both mental and physical health consequences, to the individuals themselves, their families, and their communities. If arrested and targeted for deportation, a person is held within an immigration detention center. In recent years, U.S. immigration detention centers have seen increasing reports of civil and human rights abuses as well as preventable in-custody deaths.[46] One study of detained immigrants in California found that greater exposure to confinement conditions within detention facilities increased the likelihood of one or more negative health conditions, but researchers also found a cumulative negative effect on their overall health.[47] Not only are the conditions of detention centers inhumane, but immigrants may fear what sort of conditions and punishment they will face upon return to their home country.[48]

Deportation efforts also separate individuals from their families and social support networks, often breaking up families that may have mixed immigration status. Large scale deportation efforts can be economically devastating for families, potentially plunging millions of families into poverty, increasing housing instability and food insecurity.[49] Mass deportation efforts also negatively impact communities. After deportation raids, communities are often more

fearful and less trusting of public institutions, are less likely to participate in social and cultural activities, are less likely to seek health care, and are more reluctant to report crime to the police.[48]

Health Care Access

There are longstanding disparities in health care access within rural areas, which suffer from a shortage of health care professionals, the need to travel long distances to health care facilities and a lack of public transportation options for those who do not own cars, lower rates of health insurance coverage, as well as an increase in rural hospital closures.[5,50–55] Intersecting with these longstanding challenges, racial and ethnic segregation also impact access to health care in rural areas. While rural areas have lower proportions of racial and ethnic minorities compared to urban areas, estimates of residential segregation patterns are similar.[56] Segregation can perpetuate existing disparities by restricting various health promoting opportunities, such as education, employment, concentrating poverty, as well as access to health care resources. More than half of rural counties are estimated to be either whole or partially within a health primary shortage area, and those in this designation are more likely to be in counties that are majority Hispanic and/or African American.[56] In a study assessing residential segregation and health care access, both African American and Hispanic segregation were negatively associated with having a usual source of care but higher levels of segregation were also positively associated with health care needs being reported as met.[56] This second finding, as the study authors note, "underscores the need to identify assets and sources of resilience on which racial/ ethnic minority communities rely," in order to meet health care needs.[56]

Southern states, which have the highest populations of rural Black populations, were less likely to accept Medicaid expansion following the Affordable Care Act (ACA), therefore limiting the ability for lower-income minority rural patients to have access to health insurance coverage.[10] Medicaid plays an important role in rural areas for those who are low-income and unemployed (or underemployed). Medicaid coverage rates tend to be higher in rural areas versus urban areas and the expansion of Medicaid under the ACA has been instrumental in expanding insurance coverage in rural America. It has also been demonstrated that Medicaid expansion decisions have been racialized as there are large differences in support for Medicaid expansion across different races. For example, state adoption decisions have been positively related to White opinion and do not respond to non-White support levels. Additionally, evidence indicates that when the size of the Black population increases and White support levels are low, states were significantly less likely to expand Medicaid.[57]

Outside of hospital settings, community health centers play an important role in providing primary care in rural areas that have a shortage of health care professionals. There are two federal programs which help to meet this gap – the Rural Health Clinics program and the Federally Qualified Health Centers program.[58] In terms of distance to health care facilities, one study found that rural zip code tabulation areas with a high proportion of Black or Hispanic residents tended to have better geographic access, defined as shorter distances, to both Rural Health Centers and Federally Qualified Health Centers compared to White populations, but those distances were still longer than urban minority populations.[55] However, in this study AI/AN populations had the poorest geographic access to Rural Health Centers and Federally Qualified Health Centers, with the longest distances, and areas with higher minority populations have been found to be more likely to have experienced a decline in Rural Health Centers compared to low-minority communities.[55,58]

The growing use of telemedicine has been hailed as a potential solution to help improve health care access and utilization, but evidence of a rural/urban and ethnic/racial digital divide has made equitable access to telemedicine challenging.[59] One study looking at the utilization of telemedicine amid the COVID-19 pandemic found that both adults living in rural areas and minority race/ethnicity groups were less likely to use telemedicine.[60] This may be due to the fact that ethnic minorities, particularly rural African Americans, report less access to a computer or laptop with high-speed internet, smartphone with a data plan, or any digital access compared to non-Hispanic Whites based on 2019 American Community Survey data.[61,62] According to one estimate, there are approximately 3 million people living in rural areas without adequate broadband access or healthcare, and these populations are geographically concentrated in the rural South, Appalachia, and the remote West.[63] In addition to the challenges of internet access in rural areas, telemedicine has limits in terms of the types of medical issues that can be addressed, such as physical exams or medical testing. Thus, if accessing health care in-person is too far or expensive for rural minority communities, then telemedicine can only do so much to meet the existing health care needs.

Other barriers to accessing health care include stigma and cultural practices inherent to the current health care system.[59] Among LGBTQ+ populations in rural areas, stigma around seeking mental health care was a concern.[59] In particular,

transgender and gender-diverse individuals living in rural areas face numerous barriers to accessing health care, including systemic transphobia and lack of health care professionals with sufficient training in gender-affirming care.[64] Another instance where stigma around gender and sexual identity intersects with health care access is the current epidemic of HIV in the South which has shifted towards rural areas.[65,66] Rurality has been associated with lower availability of HIV testing, prevention education, and Pre-Exposure Prophylaxis, which leads to later HIV diagnosis, later adoption of antiretroviral therapy, and increased HIV-related mortality.[66,67] To give an example, in one national study, HIV testing rates were 66 percent for nonurban participants versus 88 percent for urban participants.[66] Additionally, on top of all the other challenges in health care access, there is also a lack of access to clinicians with HIV expertise.[66] Based on the most recent data from the Centers for Disease Control and Prevention (CDC), nearly half of all new HIV infections were in the Southern region of the U.S., and the most affected subpopulations were Hispanic/LatinX men and African American men who had male-to-male sexual contact.[65] Thus, individuals who have multiple minority identities coupled with HIV diagnoses may experience even more significant stigma and discrimination in their interactions with the health care system, which may negatively impact their willingness to seek treatment or manage their health conditions.

Reproductive Health Care Access

The impacts of the reversal of *Roe v. Wade*, in terms of limiting access to reproductive health care, may be especially acute for minority women in rural areas. Pregnant and postpartum women in rural areas already experience worse health outcomes, with one study finding that rural women had a 9 percent greater probability of severe maternal morbidity and mortality compared to urban residents.[53] State abortion bans exacerbate existing workforce shortages based on location and specialty, with OB/GYN, trauma and emergency medicine, and primary care in rural areas being most adversely impacted.[68] Consequently, an increasing number of rural women travel long distances to see health care professionals and have more nonindicated induction and C-sections.[69] Moreover, areas with more abortion restrictions also have fewer social safety net and maternal and child health resources.[70,71] Minority women are thus seriously impacted by intersecting barriers to care including long travel distances and maternity care deserts, waiting periods, parental consent, and financial burden.[69,72,73]

Strategies to Improve Rural Minority Health

The challenges facing rural minority populations are immense, multigenerational and multifactorial, and as such require targeted investment and resources across multiple sectors. Reversing the health care professional shortages and trends in hospital closures in high minority rural areas would be an initial step but bolstering public health and preventive services would need to occur simultaneously. However, due to the historical and entrenched poverty in many rural minority communities, changes in available economic and housing opportunities, investment in education, improved environmental regulation and clean-up, as well as stronger occupational regulations would also be needed to reverse the historical and ongoing trauma of disinvestment and injustice.

There have been federal agency initiatives aimed at improving rural minority health disparities. In 2023, the National Institute on Minority Health and Health Disparities in the National Institutes of Health started an initiative to address gaps in scientific knowledge and support research that addresses multilevel and multiple domains influences related to health disparities experienced by people who live in rural communities.[74] In 2022, the Centers for Medicare & Medicaid Services published their Framework for Advancing Health Care in Rural, Tribal and Geographically Isolated Communities, which has six priority areas that aim to support, strengthen, and improve data collection efforts, health care professionals, health care coverage, as well as medical and communication technology in these communities.[75] Additionally, in 2023 the CDC established the Office of Rural Health and in 2024 published its Rural Public Health Strategic Plan, FY 2024-2029. The Strategic Plan has four key priorities: (1) advance results-based engagement with partners and communities to address rural public health challenges, (2) strengthen rural public health infrastructure and workforce, (3) advance rural public health science, and (4) improve rural public health preparedness and response capacity.[76] With all that being said, changes to federal priorities with the election of a new administration in 2024 may impact the existence or scope of these initiatives moving forward.

CURRENT AMA POLICY

There are over 20 existing AMA policies pertinent to rural health and health care. The most relevant, AMA Policy H-350.937, "Improving Healthcare of Minority Communities in Rural Areas," was adopted in parallel with this request for study. In addition to a study, the policy (1) encourages health promotion, access to care, and disease prevention

through educational efforts and publications specifically tailored to minority communities in rural areas; (2) encourages enhanced understanding by federal, state and local governments of the unique health and health-related needs, including mental health, of minority communities in rural areas to improve their quality of life; (3) encourages the collection of vital statistics and other relevant demographic data of minority communities in rural areas; (4) states AMA will advise organizations of the importance of minority health in rural areas; (5) states AMA will channel existing policy for telehealth to support minority communities in rural areas, and lastly (6) encourages AMA's Center for Health Equity to support minority health in rural areas through programming, equity initiatives, and other representation efforts. AMA also recently adopted policy in 2024 (D-135.963) supporting access to water and adequate sanitation, water treatment, and environmental support and health services in AI/AN communities.[77]

CONCLUSION

Despite more limited data compared to urban minority populations, it is clear rural minority populations experience a disproportionate burden of adverse health outcomes compared to rural White populations or urban minority populations. Rural minority residents experience dual disparities and poor health outcomes as a result of intersecting structural and social determinants of health. There are also longstanding disparities in health care access within rural areas in general, which are compounded by additional barriers experienced by rural minority populations, including racial and ethnic segregation, limited transportation options, lower rates of health insurance coverage, poor internet and broadband coverage which limits the ability for expanded telemedicine, as well as stigma and discrimination.

RECOMMENDATIONS

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

1. That Policy H-350.937, "Improving Healthcare of Minority Communities in Rural Areas" be amended by addition and deletion to read as follows:

1. Our American Medical Association encourages health promotion, access to care, and disease prevention through educational efforts and publications specifically tailored to minority communities in rural areas.
2. Our AMA encourages enhanced understanding by federal, state and local governments of the unique health and health-related needs, including mental health, of minority communities in rural areas in an effort to improve their quality of life.
3. Our AMA encourages the collection of vital statistics and other relevant demographic data of minority communities in rural areas.
4. Our AMA will advise organizations of the importance of minority health in rural areas.
~~5. Our AMA will research and study health issues unique to minority communities in rural areas, such as access to care difficulties.~~
~~6.~~ 5. Our AMA will channel existing policy for telehealth to support improved broadband internet access in minority communities in rural areas to increase the availability of telemedicine where clinically appropriate.
~~7.~~ 6. Our AMA ~~encourages our Center for Health Equity to~~ supports minority health in rural areas through programming, equity initiatives, and other representation efforts.
7. Our AMA encourages the development of strategies and mechanisms for communities to share resources and best practices to serve their rural minority populations.

2. That Policy H-135.905, "Furthering Environmental Justice and Equity H-135.905" be amended by addition and deletion to read as follows:

1. Our American Medical Association supports prioritizing greenspace access and tree canopy coverage for communities that received a "D" rating from the Home Owners' Loan Corporation, otherwise known as being "redlined," or those that have been impacted by other discriminatory development, loan servicing, and building practices with full participation by the community residents in these decisions.
2. Our AMA supports measures to protect frontline communities from the health harms of proximity to historical and current harmful industrial and mining operations, including fossil fuel extraction, refining and combustion, and large-scale agriculture, such as using the best available technology to reduce local pollution exposure ~~from oil refineries~~, or health safety buffers from ~~oil extraction~~ industrial operations.

Fiscal Note: less than $1,000

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8. EXPLAINABILITY OF ARTIFICIAL/AUGMENTED INTELLIGENCE AND MACHINE LEARNING ALGORITHMS

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policies D-480.954 and H-480.940

INTRODUCTION

In continuance of the American Medical Association's (AMA) interest in the oversight and regulation of augmented intelligence (AI) and machine learning (ML) algorithms in the medical system, the Council on Science and Public Health have has initiated this report to examine the concept of explainability. To keep the focus of this report narrow, it is the Council's intent to regularly examine issues relevant to AI/ML's intersection with science and public health

and develop policy recommendations as necessary. This report will also serve as an opportunity to define key concepts related to AI in a field where groups are using different definitions of the same term, leading to confusion.

Briefly, "explainable AI" (XAI) describes algorithms whose decisions would be understandable to an expert in the field and can be evaluated for accuracy or other external factors. AI/ML tools in the medical setting can take a variety of forms, ranging from those which interpret images, make diagnostic recommendations, or have a conversation with a patient using a large-language model (LLM). All of these tools would theoretically be able to be developed using an XAI framework. An example of this includes an algorithm trained to distinguish between pictures of wolves and huskies to help track endangered species.[1] The program became very good at detecting wolves, but when researchers probed deeper, they discovered that their AI had instead learned to identify pictures of snow, which just so happened to be present in every picture of a wolf (see Appendix 1). Had the algorithm been required to present its explanation, any expert would have been able to discard the results as identifying snow. When translating this example to the medical ecosystem, some experts have questioned whether physicians and patients will ever fully be able to trust or implement AI decision-making tools in the clinic if the output is not explainable for fear of misdiagnosis or improper treatment plans.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "AI explainability," "black box algorithm," and "white box algorithm." Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

BACKGROUND

Prior to the 2000s, most augmented/artificial intelligence (AI) applications were a series of "if, then" statements in which an end user could conceivably recreate the program's logic, albeit in a more time-intensive manner.[2] In 2000, researchers began to develop what was known as "machine learning" (ML), which was a much more complex network of equations that began to obscure the logic used to arrive at conclusions, even to the designers of ML programs.[3] While orders of magnitude more powerful than previous iterations of AI tools, the inability for many ML tools to describe their decision-making process has resulted in significant discussion as to the value of XAI.

At its core, the implementation and use of XAI places physician autonomy in question. In instances where algorithms can explain their decision-making, they may be useful tools for assessing huge data sets and recognizing patterns that are imperceptible to a clinician. In those cases, those algorithms are augmenting the physician's skillset by consolidating large volumes of data, with outputs which can support a physician's decision-making or be discarded if the physician's training and expertise disagree with the conclusion. However, if clinical AI/ML algorithms are not explainable, the clinician's training and expertise is removed from decision-making, and they are presented with information they may feel compelled to act upon without knowing where it came from or being able to assess quality and accuracy of the conclusion.

To help readers conceptualize the concepts of XAI, this report discusses several simplified, hypothetical scenarios. However, to best convey the utility of XAI, these hypotheticals will often describe instances where AI performed poorly or resulted in negative patient outcomes. This focus, however, should not be construed as a blanket criticism of AI in the clinic, but rather highlight opportunities where the physician voice can be used to push for development of safe, responsible, and impactful products for patients.

Trustworthiness of Outputs

Briefly, trustworthiness describes what a person (or in this case, an AI tool) has done to demonstrate that they can be trusted. Historically, AI developers have used accuracy or other performance measures as a proxy for trustworthiness, but experts have argued that this alone is insufficient.[4] Physicians and their patients may have many concerns about AI in medicine beyond accuracy, including privacy or fairness. One of the steps proposed by ethics researchers and regulatory bodies to demonstrate AI trustworthiness is through explainability.[5]

Take for example, a hypothetical AI/ML algorithm that provides recommendations on whether to prescribe antibiotics for patients with a bacterial infection. If that algorithm were not explainable, also known as a "black box" algorithm,

then an output may be a simple 'do not treat' versus 'treat'. In this situation, the physician may feel pressured to defer to the AI/ML algorithm, as a specialized tool designed to determine the appropriateness of an antibiotic and accept the recommendation. If the patient were to ask why they were not getting treatment, the physician would have a challenging time communicating the reasoning due to the lack of explainability of the AI/ML algorithm, undercutting the physician's role as a trusted expert.

By contrast, if that algorithm were explainable, also known as a "white box" or "glass box" algorithm, then the same hypothetical output would provide more context and may read "When compared to 5000 patients of similar age, sex, weight, social history, body temperature, and presence of headache, the patient is 80 percent likely to have a mild viral infection and a five percent chance of having a severe bacterial infection. Given the risk for adverse side effects and antibiotic resistance, it is not recommended to initiate antibiotics." This explanation provides the physician with information about the size of population being compared, the demographics being compared, the inputs it considered, and the risks it balanced – but potentially contains several mistakes, inaccuracies, or extraneous information or misses important context to the patient case. When presented with this explanation, a physician could recognize that a culture is most useful to differentiate between a viral and bacterial infection, or that locally there has been a significant prevalence of viral infections increasing the likelihood of a viral over bacterial infection where antibiotics may be warranted. In this instance, a physician could give this AI recommendation lower value in their differential diagnosis, but could still glean some useful insights, such as recognizing that in a similar patient population, their patient is generally perceived as low risk for severe infection.

Generally, humans have low trust of AI, particularly when it is involved in decision-making. In one study, even when participants were explicitly told that an automated decision-making tool was performing better than them, 81 percent of participants still chose to ignore the tool's inputs.[6] The researchers posit that this response may come from an innate feeling that humans use "perfected automation," meaning humans perform the same calculations as the AI/ML tool but without error. Thus, the majority of AI tool users will only ever incorporate an AI tool's output into their own decision making, rather than solely rely on it.[7] As such, explainability for AI/ML systems may assist to overcome this hesitance for use. Even when the stakes are far lower than someone's health, studies have found that people are more likely to accept an algorithm's movie recommendation if it comes with an explanation as to why (such as, it is similar to other movies you have watched), and even more when the reason for the recommendation is easily understandable and conveys high value information (it has your most frequently viewed actor in it).[8]

In the hypothetical example of an algorithm recommending against prescribing antibiotics, if the patient were to develop a severe bacterial infection, then the importance of explainability for trustworthiness is further amplified. If the algorithm were a black box algorithm and simply got the recommendation wrong, trust is fractured. Studies have found the human response to AI/ML algorithms is that a single failure from a black box algorithm causes a person to severely underestimate the algorithm's level of accuracy in the future, often fully disregarding recommendations in perpetuity.[6] However, with a white box algorithm, even though the logic may be flawed, the user can see the decision-making process, understand what its limitations are, and may still feel comfortable using it in the future, albeit with more caution.[9] This trend also matches the perceptions of patients; in studies where AI is a black box, or otherwise removes their physician's experience and training from their decision-making, patient trust decreases and concerns about liability increase.[10-12]

It is unclear how the use and recommendations for AI will be disclosed to patients or documented. Current AMA policy calls for "a risk- and impact-based approach that considers the unique circumstance of AI and its use case. The need for transparency and disclosure is greater where the performance of an AI-enabled technology has a greater risk of causing harm to a patient." In instances where AI tools are aiding in diagnosis but do not provide explanations (or the explanation is inadequate for non-experts), disclosure of an AI recommendation into a patient's medical record could have serious implications such as insurance reimbursement or on the patient-physician relationship, particularly in instances where the physician does not agree with the AI recommendation that their patient can view.

This tension further escalates as the conditions of interest become more serious. For example, in the mid-2010s, the electronic health record vendor Epic released a module for the detection of sepsis which utilized a proprietary, black box model. When external researchers probed the performance of the model, they found that while it did detect seven percent of true sepsis cases that clinicians missed, the software had a 67 percent false negative rate across all sepsis cases.[13] Further, the model had a high false-positive rate, generating electronic alerts on 18 percent of *all* hospitalized patients (compared to the true positive sepsis rate of seven percent), resulting in significant "alert fatigue" in clinicians.

After working with the model for prolonged periods of time, it is possible that clinicians would begin to ignore the alerts and instead rely on traditional clinical signs for sepsis diagnosis.

Technical Feasibility

While XAI is highly appealing for building trust in this new technology, it is less clear that it is implementable for medical applications. A common fallacy when evaluating AI/ML algorithms is to assume that it approaches problems and datasets in the same way a human would. While the field of human cognition is vast and complicated, two simple techniques that humans use to assess information and make decisions are linear logic and inference.[14] Briefly, humans often rely on linear logic (if A is true, then B is true) to understand information, then use intuition and experience to fill in (or infer) where there are information gaps. For example, if a 50-year old patient with a family history of colon cancer were to present with occult blood in their stool, a physician is likely to infer from a constellation of risk factors, signs and symptoms to assess that the patient is at high risk of having colon cancer. They would then use a confirmatory test, such as a colonoscopy with biopsy, to create a linear logic chain to confirm their diagnosis.

AI/ML algorithms do not process information in the same way humans do.[15] Thinking is a purely biologic process and cannot currently be replicated by any artificial technique. As such, AI/ML cannot infer. In a typical ML model, every single input is assigned a specific weight, and the output is a sum or other computation of those weights. Weights are based on datasets used to "train" the algorithm and are often dynamic and/or non-linear. These systems are generally referred to as "neural networks" to invoke the imagery of the hundred billion neurons and their interconnectivity similar to the human brain.[16] To help visualize the complexity of these connections, a neural network diagram for a simple AI/ML algorithm used to differentiate between 10 unique digits (0 through 9) from handwriting samples is included as Appendix 2.[17] Due to the complexity of the computations, even the developers of AI/ML algorithms may not fully comprehend how their programs arrived at an output when the process is too complex, and would thus argue that explainability is an unrealistic expectation humans have of AI/ML.[18]

Building Bridges to Explainability

While there may never be a way to truly convert the computation of an AI/ML algorithm into a comprehensible form for human interpretation, there are promising techniques being developed that do provide the user with *more* information to build confidence in AI, albeit incomplete. Some of these techniques include Locally-Interpretable Model-agnostic Explanation (LIME),[19] Gradient-weighted Class Activation Mapping (Grad-CAM),[20] and Occlusion Sensitivity (OS).[21]

Consider a hypothetical AI/ML algorithm that has been designed to detect lung tumors. In this example, the physician inputs a chest MRI for their patient, and the program returns a score for the likelihood a malignant tumor has been detected. In instances where the score is high, the obvious follow-up is: how can you tell? What factors is the algorithm using to distinguish between malignant and benign? In this hypothetical, the algorithm is only trained to calculate a "likelihood of tumor" value from millions of interconnected calculations and report "malignant" if the value is above a pre-determined value, or "benign" if the value is below.

To bridge the gap between the complex AI/ML algorithm and an explainable, interpretable result, a technique such as OS can be utilized. OS analysis highlights the area of an image that is being utilized in a computation for human assessment of accuracy.[21] Using the OS technique, the same MRI is entered into the algorithm hundreds more times, but each time with a slight modification – typically by systematically removing a subunit of the image, like a single pixel. Then, the "likelihood of tumor" output is compared to the original image; if the modified image has a lower likelihood value than the original image, you can infer that the missing pixel was strongly associated with the tumor. This process is repeated multiple times, with each run removing a different pixel and assessing its impact on the tumor likelihood value. Then, a heat map can be generated and overlaid on the original MRI to highlight what regions of the image were most strongly associated with the tumor by the AI. The physician can then interpret the findings, use their experience, and evaluate whether the highlighted area is in fact likely a tumor. Appendix 3 visualizes a hypothetical workflow for how OS explanations in a program identifying dog breeds from an image can improve useability, accuracy, and trust.

Another model, LIME, uses a similar approach, in which it slightly changes the inputs and assesses how the output changes. However, using LIME, the model then attempts calculate a linear regression between how each new input and the matching output.[19] This allows LIME to then generate a series of numerical weights to convey how important

each changed input may be. These weights could be used to generate a similar heat map to OS if the input was an image, but it also allows the user greater flexibility in the inputs it considers, including text. For example, if LIME were used in the above MRI example, it may be possible for it to additionally tell the physician how important factors from the patient's medical record (age, weight, sex, etc.) were to its interpretation of the MRI. While approaches like LIME may be more flexible, they do rely on simplifying the complex calculations of an AI/ML algorithm to simple linear equations, which may make it more prone to failure the further an individual case gets from the typical cases used in the algorithm's training set.

OS and other explainability methods have been utilized for applications such as identifying prostate cancer in histopathological samples, distinguishing lung diseases from a radiograph, predicting risk for psoriatic arthritis from the electronic health record, and more.[22-24] Beyond heat maps or other visualization tools, some tools can also provide simple written outputs (such as "clean margin") or link to data from its training set that the tool found to be most similar to the input. This provides an opportunity for the AI/ML user to utilize their own expertise in deciphering the accuracy of the output. While true explainability may never be possible for AI algorithms, models like OS, LIME, and Grad-CAM are promising efforts to make these systems more trustworthy. However, some experts in the field question: is explainability the right bar to hold AI to?[25]

Other Black Boxes in Medicine

When looking at other aspects of medicine, it is not uncommon to find black boxes or unclear processes that physicians and patients trust. For example, the analgesic mechanism for acetaminophen is not fully known and debated frequently in the literature, yet it is widely available over-the-counter in the United States.[26] Similarly, many genetic tests rely on genome wide association studies (GWAS), which often do not have a known, underlying biologic mechanism, but correlate certain genetic mutations with an increased risk of disease.[27] Yet these, and many other aspects of medicine, are routinely utilized in practice despite not truly being explainable, because they have been found to be safe and effective using rigorous scientific testing.

Randomized clinical trials (RCTs) are recognized as the gold standard or high level for evidence development in medicine, whether the intervention is explainable or not.[28] By carefully controlling variables and often utilizing a placebo, RCTs allow researchers, physicians, and regulators to best assess safety and efficacy of an intervention – but notably they do not necessitate a known mechanism of action, but often a theoretical hypothesis. When evaluating a new drug, the U.S. Food and Drug Administration (FDA) prefers, but ultimately does not require, a drugmaker to know how their drug works; they simply must prove that it is safe and effective for a specific disease in its target population before approval.[29] True explainability may never be achievable for AI, but there is no reason to believe that an individual AI tool could not be found to be safe and effective using an appropriately designed RCT model. This raises the question as to why humans intrinsically view explainability for AI to be more important than in other black boxes or unexplainable processes in medicine, and if that will always remain a barrier to trust, but that philosophical debate reaches beyond the scope of this report.

Using explainability as a strict requirement for clinical adoption could additionally exclude applications of AI which rely on noticing patterns for which current medical knowledge cannot explain. The hypothetical examples described thus far in this report (antibiotic prescribing recommendations and image interpretation) describe devices that aim to improve or build upon current best practices in medicine. However, there are many researchers actively seeking to discover *new* methods or treatments from the vast amounts of medical data available. For example, one study used a ML algorithm to diagnose patients with type-2 diabetes mellitus (T2DM) based on recordings of their speech – a completely novel approach.[30] The authors of the study hypothesized several potential causes, such as the influence of blood glucose levels on vocal cord elasticity, or pitch modulation caused by myopathy, but as of writing, this correlation would be considered unexplainable using current medical knowledge. Despite that limitation, the authors reported over 70 percent accuracy in detecting T2DM just from audio recordings of a mere 11 words. Given the low level of invasiveness, low cost and prevalence of smart phones, similar tools could be desirable for routine screening applications despite the inability for patients and their physicians to comprehend how T2DM changes the voice. In those instances, transparency around the relative risks and benefits could be more useful for developing trust, which could be derived from a RCT.

CURRENT REGULATORY APPROACHES

In Medicine

As described in BOT 01-I-24, "Augmented Intelligence Development, Deployment, and Use in Health Care," the regulatory landscape for AI in the United States is inconsistent, and relevant health care regulatory agencies do not currently have a comprehensive strategy for oversight of AI. The FDA has been reviewing and approving algorithm-based devices since 1995, with over 1000 devices that utilize AI/ML being approved as of January 2025.[31] Applications for these devices vary, including triage and diagnostics, and cross multiple specialties.

In June 2024, the FDA, in collaboration with Health Canada and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA), released their 10 guidelines for "good machine learning practice," which have been listed in Appendix 4.[32] These guidelines are non-binding, but give insight as to how regulators are thinking about AI oversight. None of the guidelines specifically mention explainability, however recommendations 7 ("Focus Is Placed on the Performance of the Human-AI Team"), and 9 ("Users Are Provided Clear, Essential Information") are generally supportive of the concept. Of note, under recommendation 9, device manufacturers are suggested to provide "the basis for decision-making when available." Interestingly, this phrasing could have two interpretations: (1) decision-making is not always present in AI tools, but an explanation is required whenever it is; or (2) explanations of decision-making are preferred, but ultimately not required if they are too complex to derive or no external explainability model is available. While ultimately the specific interpretation of this recommendation is moot, as they are non-binding, it does underscore the level of uncertainty in potential regulations for explainability moving forward.

In January 2025, the FDA released a draft Guidance for Industry that has yet to be formalized at the time of writing.[33] In it, the FDA further describes the types of data they wish to see in submissions from AI tool developers. Within this guidance, the FDA describes explainability as a "risk control" to mitigate potential harm. Additionally, they further expound on explainability and visualization tools such as those described in this report, stating "[…] explainability tools or visualizations can be valuable in increasing model transparency and a user's confidence in a model's output and could be developed as part of the user interface. However, if not well designed and validated for the target user group, explainability tools or visualizations could also significantly mislead users. Therefore, sponsors should develop and validate explainability metrics and visualizations through appropriate testing." However, the guidance does not ultimate require explainability for a device submission.

In a scoping review of FDA-approved AI devices from 1995 to 2023 (692 total devices), researchers found that only 46 percent of device sponsors provided the FDA with the results of performance studies, and only 37 percent provided information on their testing sample size.[34] Given these gaps in disclosed information, the researchers concluded that "[their] current findings suggest that evaluation [of explainability] cannot be comprehensively conducted across approved FDA devices." A similar study, investigating 104 FDA-cleared AI tools to aid in medical imaging interpretation, found that less than half provided an explanation of their output.[35]

At the 2024 Interim Meeting of the House of Delegates, the AMA adopted policy stating that regulation should be "a risk-based approach where the level of scrutiny, validation, and oversight should be proportionate to the overall potential of disparate harm and consequences." While a lack of explainability does not increase the risk of a tool per se, removing a physician's ability to contextualize information from the output using their expertise should be considered a risk factor.

In 2024, the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) enacted policies to advance AI transparency through electronic health record (EHR) regulation, requiring disclosure of source attributes, data elements, and decision-making roles in AI technology embedded in EHRs. While not specifically focusing on explainability, ASTP/ONC's intent is to empower physicians to make informed choices, ensuring AI tools enhance rather than override clinical judgment. Eplainability is not explicitly mandated, yet ONC's emphasis on transparency will likely foster trust by clarifying how predictive models operate and assist physicians in interpreting AI outputs. These policies are intended to promote responsible AI adoption, reinforcing physician autonomy and incentivizing the development of fair, effective, and safe AI-driven tools in healthcare.

Some manufacturers and scholars have raised concerns that by disclosing or otherwise visualizing an explanation of AI computational processes, they may be exposing their intellectual property (IP) to competitors.[36,37] There remains

ambiguity as to what is patentable with regards to AI-enabled medical devices. For example, the software driving the algorithm is generally patentable, as it is considered a finished product. However, the Supreme Court found in *Gottschalk v. Benson* that mathematical formulas are generally not patentable as they represent abstract concepts, which leave algorithms unprotected.[38] In a January 2025 report on AI and copyrightability, the U.S. Copyright Office concluded that current laws and regulations adequately address AI copyright concerns, and did not recommend any legislative changes.[39] The recent release of the Chinese-based AI DeepSeek has highlighted the difficulty in protecting IP in the rapidly growing AI/ML space. Briefly, the American-based company OpenAI claim that DeepSeek developers used the outputs of OpenAI models to reverse engineer or otherwise train a model that would be a market competitor.[40] While explanations of AI/ML tool outputs make the outputs more trusted, they may also make the underlying system more vulnerable to rival companies.

As such, other fields which have utilized algorithms (like banking and finance) rely on a "trade secrets" model for protecting their IP, in which algorithms are deemed proprietary and are hidden from the user. This is a similar approach to how food manufacturers protect their recipe yet disclose their ingredients for food products. However, if this approach were to continue, medical AI developers may be pitting innovation against a patient's right to transparency and autonomy in their medical decision-making.

Outside of Medicine

Given the rapid expansion of AI, other fields grapple with similar issues of explainability in their regulatory oversight. For example, the Equal Credit Opportunity Act of 1974 requires that financial institutions provide written descriptions explaining why they made an adverse decision (such as denying a loan application), and explicitly protecting certain traits (such as race or sex) from being the basis for those decisions. However, as financial institutions began incorporating more and more automated AI tools in their decision-making, explanations for adverse decisions became increasingly more abstract, and many worried that protected traits were being used by black box algorithms.

In response, the Consumer Financial Protection Bureau (CFPB) released a memo in 2023 clarifying that even in instances where black box AI tools "[made] it difficult — if not impossible — to accurately identify the specific reasons for denying credit or taking other adverse actions," customers are still legally owed an explanation of those specific reasons they were denied, and thus does not permit unexplainable algorithms to be used.[41] The CFPB went further, stating that even estimations or proxies of the AI tool's logic may not be acceptable if they are not specific enough. For example, if a financial institution did not know the logic their AI tool used to make decisions, a simple explanation of "the applicant has insufficient income" would be deemed inadequate. This approach mirrors legislation in states such as Colorado, New York, California, and Connecticut, which limit insurance companies' ability to use unexplainable, black box algorithms when making insurance coverage determinations.[42]

Outside the United States, the European Union's 2018 General Data Protection Regulation (GDPR) is generally regarded as one of the first attempts at comprehensive regulations of AI and other digital technologies and is the basis for many international regulations. The GDPR contains several regulations for the development and use of algorithms, but its position on explainability is less clear. Under Article 15 of the GDPR, it states that algorithms are required to disclose "meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject."[43] Some scholars have interpreted this text to mean that the GDPR establishes a "right to explanation," however this right has yet to be asserted and adjudicated in a European court.[44]

Additional Considerations

When regulating the explainability of AI, it is critical to establish both who is owed an explanation, and where the explanation comes from. In the medical context, there are several potential audiences, such as the physician, the patient, or external groups such as payors. If, for example, a "right to explanation" was proposed – who has the right? In the United States, the Health Insurance Portability and Accountability Act (HIPAA) generally establishes that patients have a right to access their clinical data.[45] However, as discussed above, there are significant gaps in the ability of most AI tools to explain their outputs in a layperson fashion, and most models to approximate explanations (such as OS, LIME, and Grad-CAM) are targeted to a physician-type expert for contextualization and action.

When discussing the disclosure of test results, the Code of Medical Ethics states that "[test] results [should be] conveyed sensitively, in a way that is understandable to the patient/surrogate, and the patient/surrogate receives information needed to make well-considered decisions about medical treatment and give informed consent to future

treatment[.]" In a hypothetical situation where a physician receives an AI tool's explanation, but then uses their own words to convey that information to their patient, it is unclear if that would suffice under some scholarly interpretations of a GDPR-styled "right to explanation."

CURRENT AMA POLICY

The AMA maintains extensive policy on AI generally. Board of Trustees (BOT) Report 15-I-24, "Augmented Intelligence Development, Deployment, and Use in Health Care," provided a comprehensive overview of the regulatory landscape and the AMA's history in AI governance. A brief summary of relevant sections of AMA policies are as follows (full text of policy available at the end of this report):

H-480.931, "Assessing the Intersection Between AI and Health Care"

- "Health care AI must be designed, developed, and deployed in a manner which is ethical, equitable, responsible, accurate, and transparent."
- "Health care AI requires a risk-based approach where the level of scrutiny, validation, and oversight should be proportionate to the overall potential of disparate harm and consequences the AI system might introduce."
- "Clinical decisions influenced by AI must be made with specified human intervention points during the decision-making process. As the potential for patient harm increases, the point in time when a physician should utilize their clinical judgment to interpret or act on an AI recommendation should occur earlier in the care plan. With few exceptions, there generally should be a human in the loop when it comes to medical decision making capable of intervening or overriding the output of an AI model."
- "Medical specialty societies, clinical experts, and informaticists are best positioned and should identify the most appropriate uses of AI-enabled technologies relevant to their clinical expertise and set the standards for AI use in their specific domain."
- "Purchasers and/or users (physicians) should carefully consider whether or not to engage with AI-enabled health care technologies if […] information is not disclosed by the developer. As the risk of AI being incorrect increases risks to patients (such as with clinical applications of AI that impact medical decision making), disclosure of […] information becomes increasingly important."
- "Individuals impacted by a payor's automated decision-making system, including patients and their physicians, must have access to all relevant information (including the coverage criteria, results that led to the coverage determination, and clinical guidelines used)."

H-480.939, "Augmented Intelligence in Health Care"

- "Oversight and regulation of health care AI systems must be based on risk of harm and benefit accounting for a host of factors, including but not limited to: intended and reasonably expected use(s); evidence of safety, efficacy, and equity including addressing bias; AI system methods; level of automation; transparency; and, conditions of deployment."
- "Physicians should not be penalized if they do not use AI systems while regulatory oversight, standards, clinical validation, clinical usefulness, and standards of care are in flux."
- "[Our AMA will advocate that] AI is designed to enhance human intelligence and the patient-physician relationship rather than replace it."

H-480.940, "Augmented Intelligence in Health Care"

- "[Our AMA will seek to promote] development of thoughtfully designed, high-quality, clinically validated health care AI that […] is transparent[.]"

CONCLUSION

Ironically, the concept of explainability is hard to explain. It is complex, nuanced, and asks profound questions on human cognition and the meaning of trust. While this report primarily focused on hypothetical instances where AI/ML performs poorly to highlight the opportunities and challenges for explainability, the responsible usage of well-designed AI/ML tools has already had a profoundly transformative impact on medicine, building efficiency in practice, increasing the breath of data integration, and increasing communication capabilities, such as the use of a LLM. The appeal and need for some level of explainability for AI/ML tools in medicine is clear, where decisions can have life or death consequences. Physicians are trained to utilize a broad compilation of information for medical decision-making, including context and seeing the whole patient's clinical picture; a binary "yes/no" output from an AI/ML tool is restrictive and lacks nuance.

However, explainability struggles in practice in part due to the disconnect between how humans and computers process information. AI does not think, nor can it guess, infer, or intuit, all of which are core processes for how a physician would make a clinical determination. Some models, such as occlusion sensitivity, are being developed to allow for insight into the inner workings of an AI tool, but they generally still require expert interpretation, and risk being an oversimplification of the true computational process.

Medicine is experienced in handling unexplainable phenomena and utilizing data through research and evaluation verify safety and efficacy. Understanding the mechanism of action of a drug, biologic process, or otherwise is crucial for building trust, troubleshooting, and advancing medical practice, but it generally has not been the barrier to clinical *entry*. By the same token, however, physicians should feel confident that the tools they use in the clinic are safe, based on sound science, and can be discussed appropriately with their patients, so they can engage in shared decision-making.

RECOMMENDATIONS

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

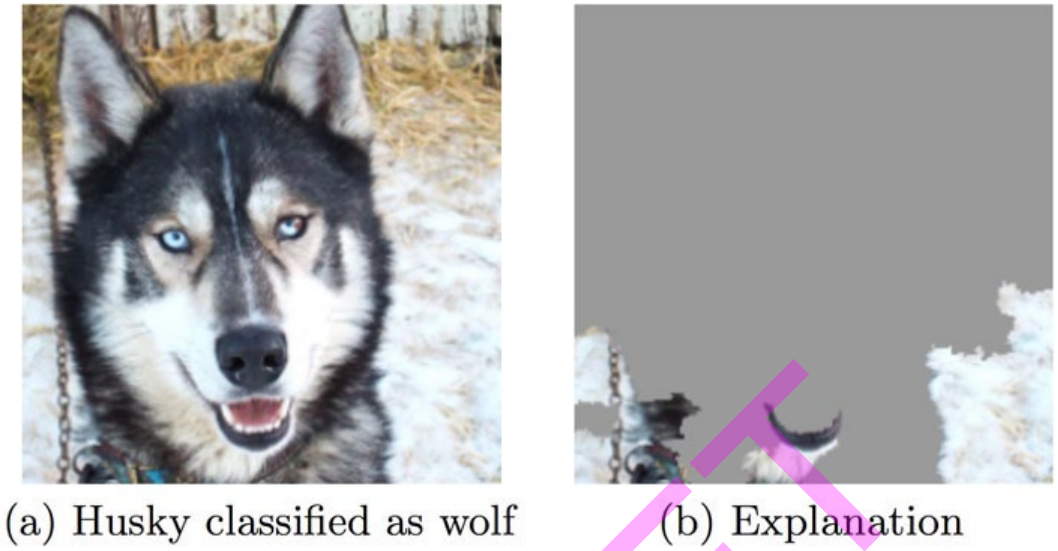
1. To maximize the impact and trustworthiness of augmented intelligence and machine-learning (AI/ML) tools in clinical settings, our AMA recognizes that:
    a. Explainable AI with safety and efficacy data should be the expected form of AI tools for clinical applications, and exceptions should be rare and justified and require at minimum safety and efficacy data prior to their adoption or regulatory approval.
    b. To be considered "explainable," an AI device's explanation of how it arrived at its output must be interpretable and actionable by a qualified human. Claims that an algorithm is explainable should be adjudicated only by independent third parties, such as regulatory agencies or appropriate specialty societies, rather than by declaration from its developer.
    c. Explainability should not be used as a substitute for other means of establishing safety and efficacy of AI tools, such as through randomized clinical trials.
    d. Concerns of intellectual property (IP) infringement, when provided as rationale for not explaining how an AI device created its output, does not nullify a patient's right to transparency and autonomy in medical decision-making. While intellectual property should be afforded a certain level of protection, concerns of infringement should not outweigh the need for explainability for AI with medical applications.

2. That our American Medical Association will collaborate with experts and interested parties to develop and disseminate a list of definitions for key concepts related to medical AI and its oversight.

3. That policies H-480.931, "Assessing the Intersection Between AI and Health Care," H-480.939, "Augmented Intelligence in Health Care," and H-480.940, "Augmented Intelligence in Health Care" be reaffirmed.

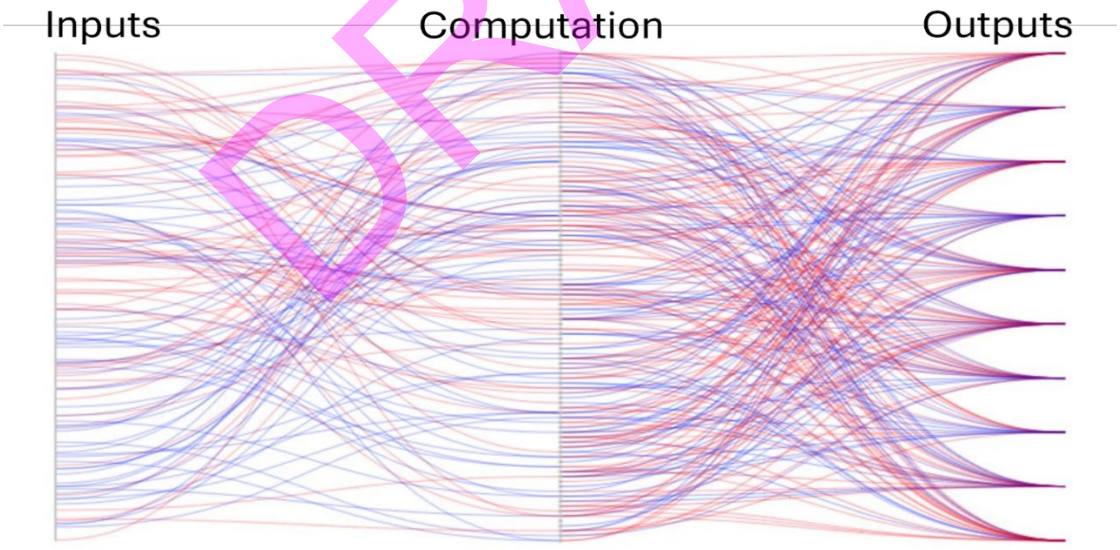
APPENDIX

Appendix 1 – Sample AI Explainability



Appendix 1 – A sample of an AI system processing an image (left) and providing an explanation (right) for how it determined whether the input was a picture of a husky or a wolf. In this case, the system mistook a husky for a wolf due to the presence of snow, which was present in most images of wolves used for the AI's training set.

Appendix 2 – Visualization of Neural Networks



Appendix 2 – Visualization of the complexity in a sample neural network used to detect the digits 0 through 9 from handwriting samples. Each line on the left side represents an input considered by the algorithm, and each position on the right side represents a potential output (the digits 0 through 9). The middle visualizes the interconnectivity and how the algorithm sorts inputs into outputs. Image adapted from https://www.i-am.ai/neural-numbers.html.

Appendix 3 – Sample Occlusive Sensitivity Workflow

INPUT

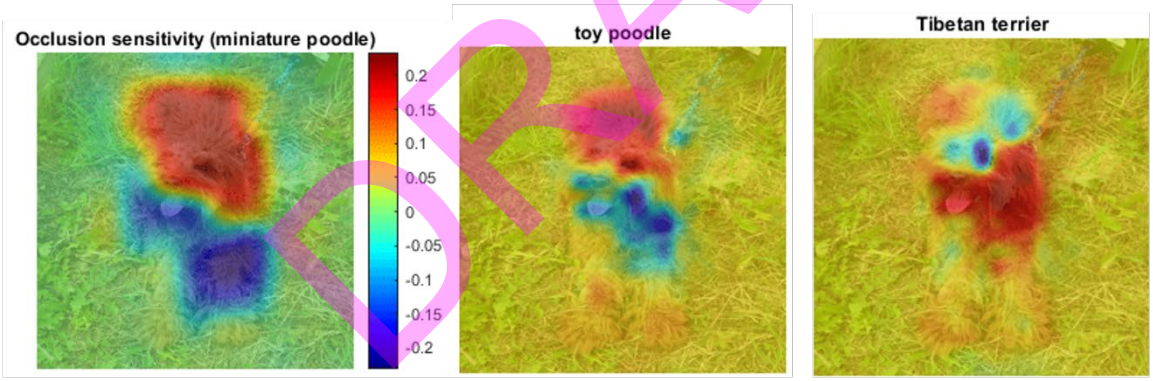
User inputs image of a poodle / cocker spaniel mixed breed dog, and asks AI tool to estimate the breed

OUTPUT

Breed Scores
Miniature Poodle: 23%
Toy Poodle: 17%
Tibetan Terrier: 11%

AI tool outputs ranked scores of dog breeds, struggling to identify the dog's breed. The user wants to troubleshoot and wonders if the dog is blending in with the grass.

OCCLUSION SENSITIVITY "EXPLANATION"



In these images, red coloration indicates the portions of the image that contributed more heavily to the breed's score. The user could thus infer that the algorithm is correctly differentiating grass from fur. However, in the miniature and toy poodle images, the back is likely incorrectly being grouped with the top of the head. The user discards the results and picks a new image from a different angle.

Apendix 3 – Hypothetical workflow of a user using an AI/ML tool to identify a dog breed. By using occlusion sensitivity, the user can identify that the tool was mischaracterizing key body features, thus explaining the poor results but allowing the user to modify their input to improve accuracy. Images adapted from https://www.mathworks.com/help/deeplearning/ug/understand-network-predictions-using-occlusion.html.

Appendix 4 – FDA Good Machine Learning Practice for Medical Device Development: Guiding Principles

Taken from: https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

1. **Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle:** In-depth understanding of a model's intended integration into clinical workflow, and the desired benefits and associated patient risks, can help ensure that ML-enabled medical devices are safe and effective and address clinically meaningful needs over the lifecycle of the device.
2. **Good Software Engineering and Security Practices Are Implemented:** Model design is implemented with attention to the "fundamentals": good software engineering practices, data quality assurance, data management, and robust cybersecurity practices. These practices include methodical risk management and design process that can appropriately capture and communicate design, implementation, and risk management decisions and rationale, as well as ensure data authenticity and integrity.
3. **Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population:** Data collection protocols should ensure that the relevant characteristics of the intended patient population (for example, in terms of age, gender, sex, race, and ethnicity), use, and measurement inputs are sufficiently represented in a sample of adequate size in the clinical study and training and test datasets, so that results can be reasonably generalized to the population of interest. This is important to manage any bias, promote appropriate and generalizable performance across the intended patient population, assess usability, and identify circumstances where the model may underperform.
4. **Training Data Sets Are Independent of Test Sets:** Training and test datasets are selected and maintained to be appropriately independent of one another. All potential sources of dependence, including patient, data acquisition, and site factors, are considered and addressed to assure independence.
5. **Selected Reference Datasets Are Based Upon Best Available Methods:** Accepted, best available methods for developing a reference dataset (that is, a reference standard) ensure that clinically relevant and well characterized data are collected and the limitations of the reference are understood. If available, accepted reference datasets in model development and testing that promote and demonstrate model robustness and generalizability across the intended patient population are used.
6. **Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device:** Model design is suited to the available data and supports the active mitigation of known risks, like overfitting, performance degradation, and security risks. The clinical benefits and risks related to the product are well understood, used to derive clinically meaningful performance goals for testing, and support that the product can safely and effectively achieve its intended use. Considerations include the impact of both global and local performance and uncertainty/variability in the device inputs, outputs, intended patient populations, and clinical use conditions.
7. **Focus Is Placed on the Performance of the Human-AI Team:** Where the model has a "human in the loop," human factors considerations and the human interpretability of the model outputs are addressed with emphasis on the performance of the Human-AI team, rather than just the performance of the model in isolation.
8. **Testing Demonstrates Device Performance during Clinically Relevant Conditions:** Statistically sound test plans are developed and executed to generate clinically relevant device performance information independently of the training data set. Considerations include the intended patient population, important subgroups, clinical environment and use by the Human-AI team, measurement inputs, and potential confounding factors.
9. **Users Are Provided Clear, Essential Information:** Users are provided ready access to clear, contextually relevant information that is appropriate for the intended audience (such as health care providers or patients) including: the product's intended use and indications for use, performance of the model for appropriate subgroups, characteristics of the data used to train and test the model, acceptable inputs, known limitations, user interface interpretation, and clinical workflow integration of the model. Users are also made aware of device modifications and updates from real-world performance monitoring, the basis for decision-making when available, and a means to communicate product concerns to the developer.
10. **Deployed Models Are Monitored for Performance and Re-training Risks are Managed:** Deployed models have the capability to be monitored in "real world" use with a focus on maintained or improved safety and performance. Additionally, when models are periodically or continually trained after deployment, there are appropriate controls in place to manage risks of overfitting, unintended bias, or degradation of the model (for example, dataset drift) that may impact the safety and performance of the model as it is used by the Human-AI team.

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9. RARE DISEASE ADVISORY COUNCILS

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policy H-460.880

INTRODUCTION

Resolution 231-A-24, "Supporting the Establishment of Rare Disease Advisory Councils," was referred by the House of Delegates (HOD). It stated that "that our American Medical Association will support state legislation for the establishment of Rare Disease Advisory Councils in each state." While there was general support for Rare Disease Advisory Councils (RDACs), there was some concern expressed in testimony regarding the undue influence of pharmaceutical companies and the need to help ensure the participation of appropriate physician specialists. This report serves as the Council on Science and Public Health's response to that referral.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "rare disease advisory councils." Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

BACKGROUND

In the United States, the term "rare disease" is defined by the Orphan Drug Act of 1983 to mean any disease which impacts fewer than 200,000 people in the country.[1] Despite its name, an estimated 1-in-10 Americans will be diagnosed with a rare disease in their lifetime. Conditions covered by the Orphan Drug Act span from those that are well-studied, such as cystic fibrosis or amyotrophic lateral sclerosis (ALS), to the highly obscure, such as CANDLE syndrome, of which there have only been 30 recorded cases in the world.[2,3] Per a 2024 landscape analysis, approximately 80 percent of rare diseases are believed to be genetic in origin with 70 percent presenting in childhood.[4]

Patients with rare diseases face many unique obstacles to care. First, patients with rare diseases often experience significant delay between symptom onset and a diagnosis, known as the "diagnostic odyssey."[5] Rare disease patient groups estimate that the *average* diagnostic odyssey length is six years, requires an average of seven specialist visits, and typically costs $220,000 from medical expenses and reduced ability to work.[6]

Once a diagnosis has been made, patients may then further struggle to access the care they need. Currently, less than five percent of all rare diseases have a medication approved by the U.S. Food and Drug Administration (FDA).[4] Of those that do, many are amongst the most expensive therapies on the market. Per one analysis, 8 of the 10 most expensive drugs in the United States treat rare diseases.[7] For example, an FDA-approved gene therapy for spinal muscular atrophy (SMA), onasemnogene abeparvovec (brand name Zolgensma), costs approximately $2.1 million per dose, which at the time of its FDA approval, set the record for the world's most expensive drug.[8] Given the price tag, access, and coverage to treatment for SMA patients has resulted in ethical controversies. For example, Zolgensma's manufacturer Novartis utilizes a medication lottery to give out 100 doses each year at random.[9] In Brazil, governmental drug reimbursement analysis recommended that the Brazilian government should pay 77 percent less than the manufacturer's price, resulting in Novartis withdrawing Zolgensma from Brazilian markets and subsequent lawsuits.[10]

Additionally, rare disease specialty care can often be geographically centralized, resulting in patients having to travel long distances for care. A study in Europe found that 25 percent of rare disease patients have to leave their geographic region to receive care, with 2 percent having to leave their country entirely.[11]

In a system where resources are limited, investing in research and development for treatments of rare diseases can be too risky and inefficient for some companies. By definition, an individual rare disease has few patients, resulting in fewer opportunities for a company to recoup its investment, but also creates challenges in the design and implementation of clinical trials for recruiting and allocating patients. Clinical trials for rare disease treatments have

lower enrollment, and therefore are frequently designed to utilize more nonrandomized, unblinded trial designs or to measure surrogate endpoints rather than patient-centered clinical outcomes. These trial designs, although often necessary in smaller studies, limit regulators' confidence in researchers' efficacy and safety conclusions.[12] As a result, there is an ongoing debate around the development and approval of treatments for rare disease: how can rare disease treatments be given the regulatory flexibility they need around clinical trial design, while avoiding providing patients with false hope at an ultra-high price point?[13]

RARE DISEASE ADVISORY COUNCILS

Given the complexities, nuances, and equity concerns when allocating resources for patients with rare diseases, many state governments have opted to utilize RDACs to provide guidance. The first RDAC was established by the North Carolina legislature in 2015, and while composition of the Council has evolved over time, it currently consists of:[14]

- two physicians,
- one registered nurse,
- one academic researcher,
- a hospital administrator,
- two adults diagnosed with a rare disease,
- two caregivers for patients with rare diseases,
- one representative from a patient advocacy group,
- one pharmacist,
- one member of a pharmaceutical or life sciences company developing rare disease treatments,
- two representatives of payors,
- a genetic counselor,
- and three personal appointees of elected officials

Compositions of RDACs vary from state-to-state but generally have a similar cross-section of representatives. Currently 27 states have formed a RDAC, and at least two others have approved legislation to establish one.[15] After manual review of the current landscape of state authorizing legislation, no RDAC currently requires the participation of a medical ethicist, which could provide value.

RDACs may have different requirements but generally are enacted to provide guidance for the state legislature and its executive branch. RDACs tend to focus on state-level barriers to access, such as reimbursement from state Medicaid or other state-regulated insurance programs, protecting and/or expanding newborn screening programs, out-of-pocket drug prices, telehealth flexibilities, easing of step therapy requirements, and access to medical nutrition, which many rare metabolic syndromes require.[16-18] Other functions of RDACs may include advocacy for research funding, performing state-wide needs assessments, maintaining rare disease patient registries, creating awareness campaigns for clinical trial recruitment, or collaborating with academic centers to align research priorities.

Influence of Pharmaceutical Companies

To help understand the influence of pharmaceutical companies on the outputs of an RDAC, a review of their authorizing laws was conducted (summarized in Appendix). Of the 27 states with an RDAC, only one state (Ohio) had more voting seats designated for pharmaceutical industry representatives than physicians. In that state, the overall voting power of pharmaceutical industry representatives was low (two of 25 total votes, or eight percent of voting share). Nine states had zero voting seats designated for pharmaceutical company representatives.

It should also be noted that this analysis may not represent the actual make-up of any given state's RDAC. Several positions delineated by state law (such as hospital administrator or academic researcher) could also be filled by a licensed physician or someone from a pharmaceutical company. For example, the state of Pennsylvania calls for three physicians and two pharmaceutical industry representatives. However, when looking at the membership of their RDAC (as of January 2025), there are eight members with MD or DO credentials, and an additional policy specialist from the state's medical society.[19] One of the two pharmaceutical industry representatives has been filled by a member of a manufacturer's patient advocacy group. However, it is also difficult to ascertain the level of financial involvement that members have with the pharmaceutical industry, given the intertwined nature of medical research. Despite these limitations, there has been no evidence identified which would suggest that commercial interests have had an outsized, undue, or otherwise problematic influence on the work of RDACs to date, although the risk still exists.

RDACs can also provide an informational venue for representatives to receive scientific and technical knowledge from scientists from the pharmaceutical industry. The risk/reward balance of investing in rare diseases can often result in pharmaceutical companies simply choosing to avoid developing treatments. Additionally, there are serious difficulties in the recruitment and powering clinical trials for rare diseases, which are the kinds of issues that legislatures should be made aware of. By providing a venue for industry to interface with other interested parties, it gives an opportunity for patient advocates and their physicians to have a larger voice in guiding research priorities. Finally, when treatments are available, legislators need to be able to hear about the benefits and make tough decisions when looking to cover the sometimes-ultra-costly rare disease treatments.

CURRENT AMA POLICY

AMA Policy, H-460.880 "Recognizing the Burden of Rare Disease" recognizes the under-diagnosis, under-treatment, and financial burden of rare disease to the health care system and affected individuals. The policy notes the AMA's support of efforts to increase awareness of patient registries, improve diagnostic and genetic tests and incentivize drug and device companies to develop novel treatments.

More broadly, our AMA also generally supports physician participation in decision-making bodies where possible. For example, H-225.983 "Physician Representation on Hospital Governing Boards" and H-405.953 "Participation of Physicians on Healthcare Organization Boards" encourage physician membership in advisory boards and note that conflict-of-interest policies should be robust.

CONCLUSION

Ensuring that patients with rare diseases have access to the diagnosis, specialists, and treatments they need is a delicate balancing act. States may struggle to identify who and what conditions require prioritization within their borders and often benefit from external advisement. Rare Disease Advisory Councils (RDACs) are a useful tool for states and other entities to adopt to provide a wide array of voices for decision makers. It should be noted that while the original resolution sought support for solely state-based RDACs, it is possible that similarly beneficial groups could exist in other forms, including municipal, regional, multi-state, or federal.

After reviewing the current landscape, there has been no evidence to suggest that those with monetary interests have an outsized or unethical voice in RDACs, but legislatures should be cognizant of the risk and include appropriate guardrails to maintain the goal of RDACs serving the public interest. With such guardrails in place, RDACs provide the opportunity to best support patients with rare disease by removing barriers across the spectrum, from diagnosis to reimbursement.

RECOMMENDATIONS

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

That Policy H-460.880, "Recognizing the Burden of Rare Disease" be amended by addition to read as follows:

H-460.880, "Recognizing the Burden of Rare Disease"

1. Our American Medical Association recognizes the under-treatment and under-diagnosis of orphan diseases, the burden of costs to health care systems and affected individuals, and the health disparities among patients with orphan diseases.
2. Our AMA supports efforts to increase awareness of patient registries, to improve diagnostic and genetic tests, and to incentivize drug companies and medical device companies to develop novel therapeutics and devices to better understand and treat orphan diseases.
3. Our AMA supports the study, approval, and coverage of implantable medical devices and therapeutics via FDA Humanitarian Device Exemption for treatment of orphan diseases.
4. Our AMA supports the establishment of Rare Disease Advisory Councils to inform policymakers and other interested parties about the unique challenges faced by patients with rare diseases and their caregivers. Rare Disease Advisory Councils should include voting representation from patients with rare disease and a range of physicians who specialize in the diagnosis and/or treatment of rare disease, among other interested parties.

5. Our AMA recommends Rare Disease Advisory Councils should develop guidance on management of conflicts of interest (especially financial conflicts) and appropriate conditions for recusal from discussions and decisions.

APPENDIX – OVERVIEW OF PHYSICIAN AND PHARMACEUTICAL INDUSTRY MEMBERSHIP OF RDACS

State	Total RDAC Members	Number of Physicians* (%)	Number of Pharmaceutical Industry (%)
Alabama	17	6 (35%)	0 (0%)
Colorado	12	2 (17%)	1 (8%)
Connecticut	12	2 (17%)	1 (8%)
Delaware	14	2 (14%)	1 (7%)
Florida	22	3 (14%)	1 (5%)
Georgia	16	3 (19%)	1 (6%)
Illinois	11	3 (27%)	0 (0%)
Indiana	15	1 (7%)	1 (7%)
Kentucky	20	NR	NR
Louisiana	12	3 (25%)	0 (0%)
Maine	20	4 (20%)	1 (5%)
Maryland	21	2 (10%)	1 (5%)
Massachusetts	28	3 (11%)	2 (7%)
Minnesota	24	4 (17%)	1 (4%)
Missouri	11	6 (55%)	0 (0%)
Nevada	15	3 (20%)	0 (0%)
New Hampshire	11	1 (9%)	0 (0%)
New Jersey	20	2 (10%)	1 (5%)
New York	NR	NR	NR
North Carolina	21	2 (10%)	1 (5%)
Ohio	25	1 (4%)	2 (8%)
Pennsylvania	24	3 (13%)	2 (8%)
South Carolina	11	1 (9%)	1 (9%)
Tennessee	11	3 (27%)	0 (0%)
Utah	16	5 (31%)	0 (0%)
Virginia	21	3 (14%)	1 (5%)
West Virginia	11	3 (27%)	0 (0%)

NR = No Restriction
* = Includes positions described as board-certified geneticists

CITED AMA POLICY

Recognizing the Burden of Rare Disease H-460.880

1. Our American Medical Association recognizes the under-treatment and under-diagnosis of orphan diseases, the burden of costs to health care systems and affected individuals, and the health disparities among patients with orphan diseases.
2. Our AMA supports efforts to increase awareness of patient registries, to improve diagnostic and genetic tests, and to incentivize drug companies and medical device companies to develop novel therapeutics and devices to better understand and treat orphan diseases.
3. Our AMA supports the study, approval, and coverage of implantable medical devices and therapeutics via FDA Humanitarian Device Exemption for treatment of orphan diseases.

Physician Representation on Hospital Governing Boards H-225.983

1. It is the policy of the AMA that physicians who are members of the medical staff shall be eligible for, and should be included in, full membership on hospital governing bodies and their action committees in the same manner as are other knowledgeable and effective individuals. Other physicians also should be considered eligible for membership on the governing body. The hospital medical staff should have the right of representation at all meetings of the governing body by medical staff members elected by the medical staff having the right of attendance, voice and vote. Compensation to medical staff members for service to the hospital should not preclude the physician's membership on the hospital governing board.
2. Hospital conflict of interest policies should include physician medical staff members of hospital governing boards.

Participation of Physicians on Healthcare Organization Boards H-405.953

1. Our American Medical Association will advocate for and promote the membership of physicians on the boards of healthcare organizations including, but not limited to, acute care providers; insurance entities; medical device manufacturers; and health technology service organizations.
2. Our AMA will promote educational programs on corporate governance that prepare and enable physicians to participate on health organization boards.
3. Our AMA will provide physicians, the public, and health care organizations information on the positive impact of physician leadership.

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