

REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports were presented by Alexander Ding, MD, MS, MBA, Chair.

1. DRUG SHORTAGES: 2021 UPDATE

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

American Medical Association (AMA) Policy H-100.956, “National Drug Shortages,” directs the Council on Science and Public Health (CSAPH) to continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2018 to August 2021, using the text term “drug shortages.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA), National Academies of Sciences, Engineering, and Medicine (NASEM), U.S. Department of Health and Human Services (HHS), American Society of Health-System Pharmacists (ASHP), Duke Margolis Center for Health Policy, and by direct contact with key FDA, ASHP, and University of Utah Drug Information Service (UUDIS) staff who monitor drug shortages and related issues daily.

BACKGROUND

CSAPH has issued eleven reports on drug shortages.¹⁻¹¹ The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15, “National Drug Shortages: Update.”⁴ The remainder of this informational report will provide an update on drug shortages since the 2020 report was developed, specifically commenting on issues associated with the drug supply chain that lead to drug shortages.

CURRENT TRENDS IN DRUG SHORTAGES

Drug shortages remain an ongoing public health concern in the United States and the AMA continues to monitor the situation and take action when appropriate. Overall, new drug shortages are decreasing; however, a large number of shortages are still ongoing and pose continued problems for patient care. Additionally, new shortages may occur as manufacturing capacity in the pharmaceutical industry is prioritized during the continuing COVID-19 public health emergency, specifically for the production of COVID-19 vaccines and treatments.

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Program at the FDA and the Drug Shortage Resource Center maintained by ASHP in cooperation with the UUDIS (see Box 1 for links to these resources).^{12,13}

ASHP and UUDIS

According to the most recent data compiled by ASHP and UUDIS, provided in Appendix 1 of this report, there were 129 new shortages reported in 2020 and 38 new shortages reported as of June 30, 2021; this is compared to the 166 new shortages reported for 2019. The number of active drug shortages has decreased to 236 in the second quarter of 2021 from 271 in quarter one of this year. In 2019, 39 percent of shortages were in injectable drugs; this increased to 50 percent in 2020 and is currently at 47 percent for 2021. The top five classes of drugs implicated in active drug shortages include CNS medications (43); cardiovascular medications (31); antimicrobials (26); chemotherapy agents (19); and hormonal agents (19).¹⁴

The reasons for drug shortages vary and unknown/unreported reasons account for 57 percent of drug shortages in 2020, down from 82 percent in 2019 (See Appendix for ASHP/UUDIS data).¹⁴ In the past year, significantly more suppliers did provide a reason for shortages. Additionally, “business decision” is included as a reason in 2020, with 14 percent of manufacturers reporting this as the reason for a shortage.

The ASHP Shortage Resource Center provides a list of shortages, guidance on managing critical shortages, as well as shortage metrics (Box 1).¹²

FDA

The FDA continues to utilize a mobile app to provide up-to-date access to information about drugs in shortage as well as notifications about new and resolved drug shortages. This mobile app also gives physicians the ability to report a drug shortage. The FDA Drug Shortages webpage includes a current shortages list, a link to the mobile app, and additional information (Box 1).¹³

The eighth annual report on drug shortages from the FDA to Congress published in early 2021 summarizes the major actions the FDA took in calendar year 2020 related to drug shortages.¹⁵ During the COVID-19 pandemic in 2020, FDA continued to closely monitor the medical product supply chain and, as expected, the supply chain was impacted by the pandemic, leading to supply disruptions or shortages of drug products in the United States. Appendix 2 includes a breakdown of the FDA’s calendar year 2020 metrics, including the number of expedited reviews (471) and expedited inspections (19).¹⁵

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law on March 27, 2020, to aid response efforts to the COVID-19 pandemic and to ease the economic impact of COVID-19.¹⁶ In addition, the CARES Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include authorities intended to enhance FDA’s ability to identify, prevent, and mitigate possible drug shortages by, among other things, enhancing FDA’s view into drug supply chains.¹⁷ Specific authorities to enhance FDA’s ability to identify, prevent, and mitigate drug shortages took effect on September 23, 2020 and include the following:¹⁸

- Amendments to expand the requirement for manufacturers of certain drugs to provide information on permanent discontinuances and interruptions in manufacturing that may lead to a meaningful disruption in supply to FDA.
- Amendments to require FDA to prioritize and expedite, as appropriate, the review of certain applications and inspections that could help mitigate or prevent a shortage of a drug covered by section 506C(a).
- The addition of a section of the code of federal regulations requiring manufacturers of drugs described in section 506C(a) of the FD&C Act or of any active pharmaceutical ingredient (API) or any associated medical device used for preparation or administration included in the drug to develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates the risks to the supply of the drug, as applicable, for each establishment in which the drug or API of the drug is manufactured.
- Amendments to require drug manufacturers registered under section 510 of the FD&C Act to annually report on the amount of each drug that they have “manufactured, prepared, propagated, compounded, or processed” for commercial distribution.

DRUG SHORTAGES AND COVID-19

The FDA reports that it has been closely monitoring the supply chain with the expectation that the COVID-19 pandemic would likely impact the medical product supply chain, including potential disruptions to supply or shortages of critical medical products in the United States. The COVID-19 pandemic has also increased the risks of shortages due to sudden increases in demand for drugs used in hospitalized patients, particularly the most critically ill. To respond to this risk, Drug Shortage Staff within the FDA’s Center for Drug Evaluation and Research (CDER) has asked manufacturers to evaluate their entire supply chain, including key starting materials, APIs, finished dose forms, packaging components, and any other components that may be impacted in any area of the supply chain due to the COVID-19 outbreak.

FDA reports proactively reaching out to manufacturers as part of an approach to identify potential disruptions or shortages and notes that the Agency will use all available tools to react swiftly and mitigate the impact to U.S. patients and health care professionals when a potential disruption or shortage is identified.

Actemra/RoActemra (tocilizumab)

Recently, Roche reported that the demand for Actemra/RoActemra (tocilizumab), a drug widely used to treat hospitalized patients with severe or critical COVID-19 around the world, has increased to unprecedented levels globally.¹⁹ Actemra/RoActemra is not approved for the treatment of COVID-19 in any country but was recently granted an Emergency Use Authorization in the United States for hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).²⁰ Additionally, tocilizumab has also now been included in the World Health Organization (WHO) Therapeutics and COVID-19 Living Guideline, based on the body of evidence that has been generated throughout the last 18 months. A statement from Roche acknowledges the increase in demand and the global shortage of the drug and also details the company's efforts to minimize the impact of global supply constraints.¹⁹ ASHP has developed an information sheet regarding the tocilizumab shortage.²¹

DRUG SUPPLY CHAIN AND DRUG SHORTAGES

Over the last several years, natural disasters, quality problems, manufacturer consolidation, and other issues have disrupted pharmaceutical manufacturing and have left the U.S. healthcare system on the brink of a significant public health crisis multiple times. The COVID-19 public health emergency further underscored the vulnerability of our nation's healthcare supply chain and stress-tested supply chains, highlighting the fragilities and deficiencies.

Considerable attention has been focused on supply chain resilience in the past several months. This year, the FDA has published several guidance documents related to supply chain security,²² the White House released a report and fact sheet on policies to support the creation of resilient supply chains,^{23,24} and The Duke-Margolis Center for Health Policy and the COVID Collaborative released a new white paper on challenges and potential solutions for resilient drug supply chains that complements the White House reports.²⁵ All of these publications address aspects of AMA policy regarding drug shortage, including calls for increased transparency, global cooperation, resiliency and redundancy in manufacturing capability, and the creation of a quality rating system.

CURRENT AMA DRUG SHORTAGE ACTIVITIES

AMA staff continue to remain engaged in drug shortage activities. Staff are involved in a multi-stakeholder effort to remain current on policies, drug shortage and supply chain issues, and to develop group recommendations on the topics. The effort includes the AMA, the ASHP, the American Hospital Association (AHA), the United States Pharmacopeia (USP), the American Society of Anesthesiologists (ASA), and the American Society of Clinical Oncology (ASCO). Earlier this year, the group sent a letter to the Secretary of Health and Human Services and leaders in the office of the Assistant Secretary for Preparedness and Response (ASPR) offering to assist the administration in its efforts to improve our nation's healthcare supply chains and specifically noting that:

For a number of years, we have worked collaboratively to address drug shortages. Recently, our organizations have begun developing consensus recommendations on a number of other supply chain issues, including Strategic National Stockpile (SNS) enhancement, visibility into supply chains, quality and manufacturing improvement (e.g., reducing contamination in finished pharmaceuticals), and medical supply and medical device supply chain reinforcement. We would welcome the opportunity to meet with you to share these recommendations, which are drawn from our members' expertise and their real-world experience with utilizing complex, and sometimes fragile, medical supply chains. We greatly appreciate the work ASPR and FDA are already undertaking on EO 14017, and we look forward to continuing to work closely with you.

SUMMARY

The rate of new medical product shortages is decreasing, but the current COVID-19 public health emergency requires continued diligence in monitoring any shortage or supply chain issues due to manufacturing capacity prioritization for COVID-19 vaccines and treatments.

The AMA's drug shortage policy is timely and already addresses a variety of issues that are under consideration by the White House, FDA, and other stakeholders including the improvement of quality assurance systems; expedited facility inspections and manufacturing changes/improvements; necessary resiliency and redundancy in manufacturing

capability; evaluation of root causes of drug shortages; transparent analysis of economic drivers and reasonable and sustainable payment rates for prescription drugs; greater transparency of the manufacturing process; and including drug manufacturing sites as part of the nation's critical infrastructure plan. Therefore, the Council feels that an update to AMA policy is not warranted at this time.

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Box 1. Resources available to assist in mitigation of drug shortages.

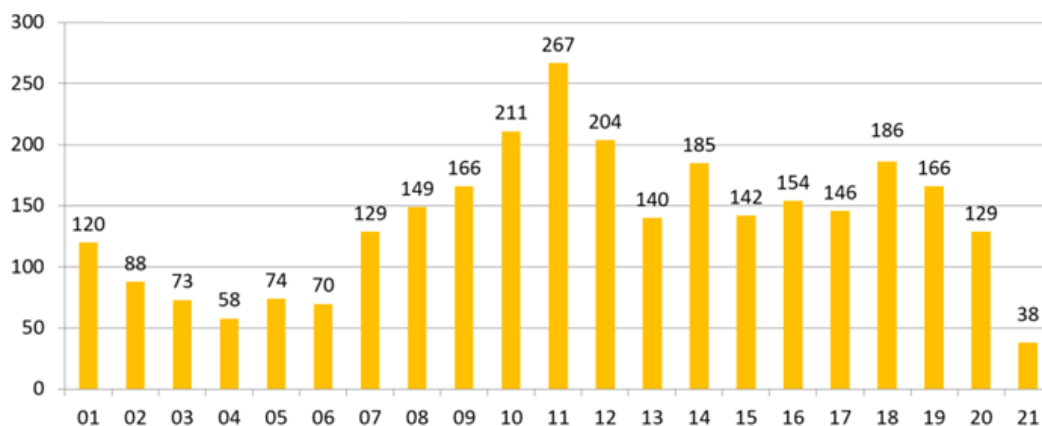
1. [ASHP Resource Center](#)
2. [ASHP list](#) of current shortages
3. [FDA Drug Shortages Page](#) (includes current shortages list, mobile app, and additional information)

APPENDIX 1 - ASHP/University of Utah Drug Information Service Drug Shortage Data

Figure 1.

National Drug Shortages: New Shortages by Year

January 2001 to June 30, 2021



Note: Each column represents the number of new shortages identified during that year.

University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, [@foxerinr](https://twitter.com/foxerinr) for more information.

Figure 2.

National Drug Shortages: Active Shortages by Quarter



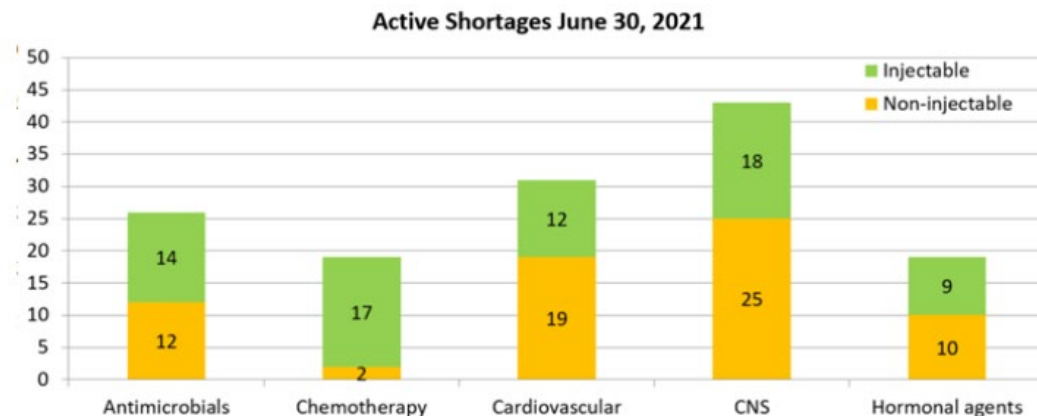
Note: Each point represents the number of active shortages at the end of each quarter.

University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, [@foxerinnr](https://twitter.com/foxerinnr) for more information.

Figure 3.

National Drug Shortages: Active Shortages Top 5 Drug Classes



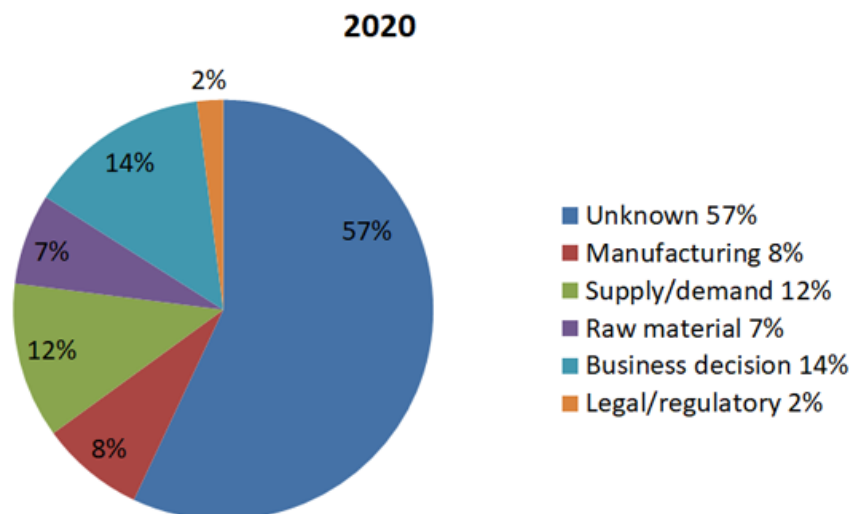
University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, [@foxerinnr](https://twitter.com/foxerinnr) for more information.

Figure 4.

National Drug Shortages

Reasons for Shortages as Determined by UUDIS During Investigation — 2020



University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, [@foxeirnr](https://twitter.com/foxeirnr) for more information.

APPENDIX 2 - FDA Drug Shortage Data

Breakdown of CDER's and CBER's Shortage Numbers, CY 2020

	CDER	CBER
New Shortages	43	0
Prevented Shortages	179	20
Ongoing Shortages	78	8
Notifications	473	39
No. of Manufacturers Notifying	93	29
ACTIONS TAKEN TO MITIGATE SHORTAGES		
Regulatory Flexibility and Discretion	110	1
Expedited Reviews	471	18*
Expedited Inspections	19	0

* This number includes expedited reviews for nine biologics license application (BLA)/BLA supplements and nine lot-release submissions for CBER-regulated products.

2. FULL COMMITMENT BY OUR AMA TO THE BETTERMENT AND STRENGTHENING OF PUBLIC HEALTH SYSTEMS (Resolution 401-JUN-21)

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 401-JUN-21
REMAINDER OF REPORT FILED
*See Policies TBD***

Policy D-440.922 adopted by the House of Delegates in November 2020 asked that:

Our AMA study the most efficacious manner by which our AMA can continue to achieve its mission of the betterment of public health by recommending ways in which to strengthen the health and public health system infrastructure.

Resolution 401-JUN-21, introduced by the Washington Delegation and referred by the House of Delegates asked that:

Our American Medical Association study the options and/or make recommendations regarding the establishment of:

1. a list of all essential public health services that should be provided in every jurisdiction of the United States;
2. a nationwide system of information sharing and intervention coordination in order to effectively manage nationwide public health issues;
3. a federal data system that can capture the amount of federal, state, and local public health capabilities and spending that occurs in every jurisdiction to assure that their populations have universal access to all essential public health services; and
4. a federal data system that can capture actionable evidence-based outcomes data from public health activities in every jurisdiction; and be it further

Our AMA prepare and publicize annual reports on current efforts and progress to achieve universal access to all essential public health services.

METHODS

This was a qualitative study in which semi-structured, in-depth interviews lasting 45 minutes were conducted with public health and physician experts (n=17) and members of the AMA Board of Trustees (n=11). Public health experts had federal, state, and local public health experience and were affiliated with governmental public health organizations, national public health organizations, schools of public health, public health foundations, and national medical specialty societies. Stakeholder organizations were identified by the members of the Council on Science and Public Health (CSAPH) and organizations were asked to identify a primary and alternate representative to participate in the stakeholder interview. Alternates were interviewed when there were difficulties scheduling with the primary representatives. Due to timing constraints and scheduling conflicts, some organizations were unable to participate. Members of the AMA Board of Trustees were asked to participate at the discretion of the Board Chair. The individuals who were interviewed provided verbal informed consent and received no financial compensation.

DATA COLLECTION AND ANALYSIS

The Council identified five objectives to guide the public health infrastructure research. The objectives were as follows:

- Understand the current challenges faced by public health professionals and health departments in preventing, detecting, and responding to emerging infectious disease threats and other public health crises.
- Understand physician and public health professionals' perspectives on what solutions need to be implemented to strengthen public health infrastructure to carry out the 10 essential public health services to improve disease and injury prevention and the health of the public

- Identify barriers and opportunities for improved and increased linkages between the public health and health care systems.
- Understand opportunities for the public health system to protect and promote the health of all people in all communities by removing systemic and structural barriers that have resulted in inequities.
- Identify opportunities for the AMA in supporting, developing, and implementing solutions.

The semi-structured interview guide (Appendix A) was developed with input from the members of CSAPH as well as AMA staff, including representatives from the Health, Science, and Ethics and the Center for Health Equity teams. The interview guide began by asking participants to define public health infrastructure, their experience, and the role of their organization in public health. The guide also asked individuals to identify challenges facing our nation's public health system, noting that these challenges could focus on the COVID-19 pandemic or challenges beyond the pandemic. The guide then aimed to give participants the opportunity to ideate possible solutions. Participants were then asked to identify how the AMA can best support solutions to strengthen public health infrastructure. A separate discussion guide was developed for the interviews with AMA trustees (Appendix B), which asked their reaction to the challenges and solutions identified by the external stakeholders and their perspective on the AMA's role in these efforts. The semi-structured interviews were conducted by C + R Research, an independent research firm. All interviews were recorded and transcribed. Transcripts were analyzed by the independent research firm for major themes. All personally identifiable information was removed from the transcripts prior to analysis. The findings of this research were presented to CSAPH and were shared to the Board of Trustees in July and serve as the basis for this report.

BACKGROUND

Public health has been defined as “what we do together as a society to ensure the conditions in which everyone can be healthy.”^{1(p0)} CSAPH believes that public health belongs to everyone and is everyone's responsibility. The public health system is broad and has been defined as “all public, private, and voluntary entities that contribute to the delivery of essential public health services within a jurisdiction”² This system includes public health professionals, health care professionals, employers, schools, parks and recreation, community-based organizations, non-governmental organizations, faith-based institutions and more (see Figure 1). However, for purposes of this report, when we talk specifically about strengthening our nation's public health infrastructure, we are talking about the work of governmental public health entities at the federal, state, territorial, local, and tribal levels.¹ The Council acknowledges that additional reports exploring the broader public health system are warranted in the near future.

10 Essential Public Health Services

The 10 Essential Public Health Services (EPHS), originally published in 1994, provide a framework by which the work of public health is to be accomplished in all communities. The 10 EPHS, which were revised in 2020, with input from the AMA, are as follows:

- Assess and monitor population health status, factors that influence health, and community needs and assets.
- Investigate, diagnose, and address health problems and hazards affecting the population.
- Communicate effectively to inform and educate people about health, factors that influence it, and how to improve it.
- Strengthen, support, and mobilize communities and partnerships to improve health.
- Create, champion, and implement policies, plans, and laws that impact health.
- Utilize legal and regulatory actions designed to improve and protect the public's health.
- Assure an effective system that enables equitable access to the individual services and care needed to be healthy.
- Build and support a diverse and skilled public health workforce.
- Improve and innovate public health functions through ongoing evaluation, research, and continuous quality improvement.
- Build and maintain a strong organizational infrastructure for public health.

Existing AMA Policy D-440.924, “Universal Access for Essential Public Health Services,” called for updating the 10 EPHS to bring them in line with current and future public health practice and encourages state, local, tribal, and territorial public health departments to pursue accreditation through the Public Health Accreditation Board (PHAB). The revised EPHS are central to the PHAB framework and inform PHAB standards, which provides a framework for health departments to evaluate their policies, procedures, and programs and to make meaningful improvements.

The Roles of Health Care and Public Health in Prevention

The Council also recognizes that the roles of health care and public health can seem indistinct. The role of health care in prevention is often described as increasing the use of evidence-based preventive services for individual patients and the role of public health is often described as focused on implementing interventions that reach the whole population or a population within a jurisdiction. There is also a shared responsibility for innovative clinical prevention provided outside of the clinical setting (see Figure 2). However, we recognize that there are public health agencies that provide clinical preventive services, particularly in rural communities where there may be a shortage of primary care physicians. There are also health care professionals involved in community-wide prevention efforts.

The COVID-19 Pandemic

Organizations representing U.S. governmental public health agencies have been cautioning for years that their ability to keep the population safe from disease and public health emergencies is constrained by the lack of dedicated and sustained funding.³ In addition to funding, our public health infrastructure has been threatened by high rates of staff turnover and obsolete data collection and reporting methods, which lead to delayed detection and response to public health threats of all types.^{4,5} The COVID-19 pandemic did not create these problems, but it inarguably exposed the cracks that had long existed in our public health infrastructure. For decades, public health professionals have been advocating for greater resources to plan and prepare for just such a crisis.

The challenges of the COVID-19 pandemic response have been well documented.^{6,7} While it is true that there certainly have been errors and omissions in the COVID-19 response, public health leaders should also be recognized for their successes and the tireless work that they have done under incredibly challenging circumstances.⁸ The development, authorization, distribution, and administration of over 300,000,000 doses of safe and effective vaccines in the United States in 20 months since the identification of the SARS-CoV-2 novel pathogen has been nothing short of remarkable.

RESULTS

The public health infrastructure interviews identified eight major gaps or challenges in the U.S. public health infrastructure. These include:

- (1) the lack of understanding and appreciation for public health;
- (2) the lack of consistent, sustainable public health funding;
- (3) legal authority and politicization of public health;
- (4) the governmental public health workforce;
- (5) the lack of data and surveillance and interoperability between health care and public health;
- (6) insufficient laboratory capacity;
- (7) the lack of collaboration between medicine and public health; and
- (8) the gaps in the public health infrastructure which contribute to the increasing inequities we see in health outcomes.

Lack of Understanding and Appreciation for Public Health

Challenge: When public health is working, it is invisible. Because of this, individuals outside of public health too often take it for granted and do not realize the way it impacts health and well-being on a daily basis. The public assumes the air is clean and their food and water is safe without giving the work of public health recognition for these accomplishments. As a result of this invisibility, public health is not prioritized or adequately funded.

There is broad consensus that the gaps we see in the public health infrastructure stem from a broad misunderstanding of what public health is and what it does. Some stakeholders indicated that public health is misunderstood by the public as “health care for poor people” and it is disregarded or devalued given this misjudgment. Others believe governmental and some health care organizations do not fully understand the role of public health professionals. Alternatively, health care is highly visible and well-regarded and is better understood by the public as it has a clear outcome (i.e., treating people when they are sick). Although health care’s mission is an important one, it does little to prevent people from becoming sick in the first place and health care is only one of several determinants of health.⁹

Solution: Prioritize public health by communicating about the work that public health agencies and practitioners do and their vital role in the health of our nation. Medical societies, at the county, state and national levels, can share their

power with public health and raise its visibility in their communities. At the individual level, physicians can become advocates for public health programs, activities, policies, and campaigns. Physician groups can encourage more physicians to go into public service roles and provide support for more physicians to specialize in preventive medicine and related disciplines.

“That white coat carries a lot of power with county commissioners and mayors, you know. I’ve worked in state legislatures, and I remember doctor days and you would just be like, oh man, you know, you’ve got 40 people walking around in white coats. People respect that, right? Physicians do have an exalted place in our society...so that’s a huge thing. We’ve just never been able to kind of crack that group...as a real advocate.” – Public Health Stakeholder

Existing AMA Policy: Our AMA should collaborate with national public health organizations to explore ways in which public health and clinical medicine can become better integrated; such efforts may include the development of a common core of knowledge for public health and medical professionals, as well as educational vehicles to disseminate this information (Policy H-440.912, “Federal Block Grants and Public Health”).

Lack of Consistent, Sustainable Funding

Challenge: Funding for public health is not consistent or sustainable. Stakeholders, in discussing public health funding referred to it as “anemic” and “emergency of the day” funding. In the past 20 years, the nation has responded to every public health crisis with temporary funding measures that have not provided state and local public health agencies with the people and the tools needed to build enduring programs and infrastructure which address the populations health and adequately prepare for or prevent future emergencies. Shoring up the system will take years of consistent effort by public health officials and policymakers. While billions are now coming from the Biden Administration in short-term funding to address the COVID-19 pandemic, the current infrastructure is ill equipped to handle the large influx of funds. Systems and administrative capabilities to distribute, manage and oversee spending quickly, adequately and equitably are lacking.

“The system has been so underfunded for so long that it’s sort of playing a constant catchup. And now that we have money coming into the system, you have to figure out how to absorb it.” – Public Health Stakeholder

Solution: Strong and consistent funding levels are necessary for our public health system to respond to everyday health needs, sustain hard-fought health gains, and prepare for and prevent unexpected public health emergencies. Consistent and sustainable funding is needed not just for public health programs, but also for foundational capabilities (i.e., communication and information technology). Similar to the way that the Federal Emergency Management Agency (FEMA) is consistently funded to prepare for and respond to the “unexpected crises” regardless of whether they occur, public health needs a strategy to fund for the long-term future of our population rather than focusing on the emergency of the day and after-the-fact. A shared common goal between health care and public health would drive more collaboration and shared funding between medicine and public health.

Existing AMA Policy: Our AMA urges Congress and responsible federal agencies to establish set-asides or stable funding to states and localities for essential public health programs and services, provide for flexibility in funding but ensure that states and localities are held accountable for the appropriate use of the funds; and involve national medical and public health organizations in deliberations on proposed changes in funding of public health programs. The AMA also supports the continuation of the Preventive Health and Health Services Block Grant, or the securing of adequate alternative funding, in order to assure preservation of many critical public health programs for chronic disease prevention and health promotion and will communicate support of the continuation of the Preventive Health and Health Services Block Grant, or the securing of adequate alternative funding, to the US Congress (Policy H-440.912 “Federal Block Grants and Public Health”). The AMA recognizes the importance of flexible funding in public health for unexpected infectious diseases to improve timely response to emerging outbreaks and build public health infrastructure at the local level with attention to medically underserved areas (Policy H-440.892, “Bolstering Public Health Preparedness”).

Legal Authority and Politicization of Public Health

Challenge: The COVID-19 pandemic raised concerns about the structure of our public health system due to the politicization of specific public health measures to mitigate the spread or impact of the pandemic. Concerns were

raised about the interference with the scientific guidance put out by the CDC and the impact that had on both public trust and the willingness to follow evidence-based recommendations. Concerns were also raised about collaboration and the lack of consistent messaging across the federal, state, territorial, local, and tribal levels. It was noted that at the state level, in some jurisdictions, public health leaders may have believed that requiring certain public health measures was the right thing to do (e.g., requiring masks or vaccines for returning college students), but they would not say it because the governor was not in favor of it.

“You must remember that public health is a confederated system. Based on the Tenth Amendment to the U.S. Constitution, the responsibility for public health falls to the states. Federal government can pump as much money as they’d like into it, but that money goes through governors’ offices. So, you have any number of governors...who have, throughout the pandemic, taken policy positions that were 180 degrees opposite public health practice recommendations.” – Public Health Stakeholder

Concerns were also raised that state legislatures have passed laws to severely limit the legal authority of public health agencies, necessary to protect the population from serious illness, injury, and death, which will lead to preventable tragedies.¹⁰ Public health is not in a position, on its own, to be able defend against the curtailing of public health authorities.

Solution: There was agreement among the stakeholders that public health agencies need to be able to communicate openly and make recommendations to protect and promote the health of the public based on the science. It was noted that some federal agencies seem to be able to navigate this better than others, including during the pandemic. How to best achieve this for the CDC and state health agencies in particular was not agreed upon. However, there was broad support for advocating for public health officials to have the authority they need to lead and make evidence-based decisions including emergency declarations. This includes defending against efforts by legislatures to strip that power away or efforts by governors to countermand evidence-based recommendations.

“I think the AMA and the state medical societies really need to take a strong stance on that. This is a health and medical issue. I mean, if you can’t act quickly to curtail...infectious disease outbreaks, or maybe environmental disasters...and, do that in an evidence-based way...we could find ourselves in serious trouble.” – Public Health Stakeholder

Existing AMA Policy: Our AMA: (1) recognizes the Office of the United States Surgeon General as the esteemed position of the “nation’s doctor;” and (2) calls for the Office of the United States Surgeon General to be free from the undue influence of politics, and be guided by science and the integrity of his/her role as a physician in fulfilling the highest calling to promote the health and welfare of all people (Policy H-440.863, “Restoring the Independence of the Office of the US Surgeon General”).

Workforce Shortages

Challenge: There is a growing public health workforce shortage at the local, state, and federal levels. Within the next few years, state and federal public health agencies could lose up to half of their workforce to retirement and to the private sector. Due to local and state budget crises and federal budget cuts, the potential for a shortage of highly skilled public health professionals has become more immediate and severe in scope. In addition, governmental public health salaries are not competitive with other industries. Recent public health graduates are opting for careers in other industries. Public health agencies struggle to attract and retain top talent because they cannot afford to pay them salaries comparable to the private sector.

“Even though schools of public health are producing a lot of public health-trained graduates, they’re not going into governmental public health where we need them at that federal, state and local level because of differences in pay parity with the private sector...it’s very difficult to get highly-trained individuals because of competition with private sector in areas, for example, like informatics that IT and informatics, which is a very large and growing area of public health.” – Public Health Stakeholder

Public health workers might be at risk for negative mental health consequences because of stresses associated with the prolonged demand for responding to the pandemic and for implementing an unprecedented vaccination campaign.¹¹ Among a survey of 26,174 state, tribal, local, and territorial public health workers, 53.0 percent reported symptoms of at least one mental health condition in the past 2 weeks (during the pandemic).¹¹ Symptoms were more

prevalent among those who were unable to take time off or who worked ≥ 41 hours per week.¹¹ The COVID-19 pandemic has been exceptionally challenging for the public health workforce due to the personal threats to their safety or even the safety of their family members that some public health officials have faced.

The turnover that we're experiencing right now is extraordinary. There are lots of things driving that, it's just been a horrific time to be in public health, in any capacity, given the attacks on individuals, the attacks on science, the undermining of authority, all of those things make these jobs incredibly challenging...and so we're now in a position where I'm seeing people leaving the field, leaving these positions and there is not a workforce at the ready to stand into those roles. So, figuring out what that pipeline of public health professionals is, is absolutely critical.” – Physician Stakeholder

Solution: To strengthen the workforce, the first step should be to raise the visibility of public health as a potential career choice and promote it as a valuable component to keeping populations healthy. In addition, providing competitive salaries would also help attract talent, as would student debt reduction or elimination programs and loan repayment programs. The public health workforce is aging and efforts to recruit young talent are direly needed. Supporting strengthening of the Commissioned Corps of the US Public Health Service, the Epidemic Intelligence Service Program and the expansion of preventive medicine residency programs and occupation and environmental health residency programs are also important solutions. There is also an important role for health care in standing up for science, against misinformation, and supporting health officials who are facing threats.

Existing AMA Policy: Our AMA will work to support increased federal funding for training of public health physicians through the Epidemic Intelligence Service program and work to support increased federal funding for preventive medicine residency training programs (Policy D-305.964 “Support for the Epidemic Intelligence Service (EIS) Program and Preventive Medicine Residency Expansion”). Our AMA strongly supports the continuation of the Commissioned Corps of the US Public Health Service (Policy H-440.989 “Continuation of the Commissioned Corps”). Our AMA supports investments that strengthen our nation’s public health infrastructure and the public health workforce (Policy H-440.820, “Vector-Borne Diseases”).

Our AMA: (1) acknowledges and will act to reduce the incidence of antagonistic actions against physicians as well as other health care workers including first responders and public health officials, outside as well as within the workplace, including physical violence, intimidating actions of word or deed, and cyber-attacks (Policy H-515.950, “Protecting Physicians and Other Healthcare Workers in Society”).

Antiquated Data Systems

Challenge: Public health data systems are outdated and in dire need of modernization. This issue was brought to light during the COVID-19 crisis. Many public health agencies did not have access to real-time data around testing results and incidence of infections and illness to efficiently respond to the emerging crisis. Health departments are often unable to access accurate, complete, and timely data to effectively surveil disease outbreaks and promote healthy communities. Many state and local public health departments rely on paper documents, phone calls, and faxes to communicate. Many also require manual input of data into systems with limited functionality. Consistency of demographic data collection has been particularly poor. Race and ethnicity data for infections, hospitalizations, and deaths have been missing, or slow to be published, in many states.

Financial investments were made to modernize the health care data infrastructure, but the same has not happened on the public health side. In health care, data is collected in the electronic health record (EHR) and despite there being requirements for data to be reported to public health, it can be days and weeks before public health is alerted. When public health receives case reports, they are often missing key information, including race and ethnicity data. Reports are also missing data elements like a patient’s address, so public health cannot geo-locate or map the cases to determine if there’s an outbreak occurring in a particular area. Case reports are also often missing a patient’s phone number, which is needed to conduct interviews for contact tracing. Furthermore, clinical medicine is not getting what it needs from public health. Clinicians should be able to work very closely with state and local health departments to get population-based data about their practice community.

Public health department data and systems are siloed. They work independently of each other and do not have an easy way to share information across state lines or even, at times, between agencies within a given state, preventing them from efficiently supporting each other. It is important to note that even with public health data modernization, data

shared with public health agencies for review and action, will only be shared in accordance with applicable health care privacy and public health reporting laws. Improving antiquated data systems will overall improve data governance and security as well as improving access to vital surveillance data.

Solution: Data are the foundation to both population medicine and public health and rapid access to timely and accurate data are essential to drive decision-making. Priorities for public health data modernization should include automating the reporting of clinical and laboratory data from clinical health area data systems to public health. Clinicians should be incentivized to upgrade their EHR systems to support electronic case reporting and be incentivized to submit complete case reports and timely case reports. For example, if the case report is complete, including the race and ethnicity information, then clinicians should receive a bonus.

The U.S. also need to ensure interoperability among health care and public health as well as among core public health surveillance systems. There are core pieces of the public health data infrastructure that need to be modernized, such as the National Notifiable Diseases Surveillance System and the vital records systems which capture data from births and deaths annually and which can signal changes in trends, monitor urgent events and provide faster notification of cause of death. It is also important to support modernization of our syndromic surveillance system, so public health receives data in real-time from hospital emergency departments and urgent care centers to maintain a pulse on emergency-type visits and how the health care system is being impacted by emerging syndromes.

Existing AMA Policy: Our AMA recognizes public health surveillance as a core public health function that is essential to inform decision making, identify underlying causes and etiologies, and respond to acute, chronic, and emerging health threats and recognizes the important role that physicians play in public health surveillance through reporting diseases and conditions to public health authorities. The AMA supports increased federal, state, and local funding to modernize our nation's public health data systems to improve the quality and timeliness of data and supports electronic case reporting, which alleviates the burden of case reporting on physicians through the automatic generation and transmission of case reports from electronic health records to public health agencies for review and action in accordance with applicable health care privacy and public health reporting laws. The AMA will advocate for increased federal coordination and funding to support the modernization and standardization of public health surveillance systems data collection by the Centers for Disease Control and Prevention and state and local health departments and supports data standardization that provides for minimum national standards, while preserving the ability of states and other entities to exceed national standards based on local needs and/or the presence of unexpected urgent situations (Policy H-440.813, "Public Health Surveillance"). Our AMA encourages hospitals and other entities that collect patient encounter data to report syndromic (i.e., symptoms that appear together and characterize a disease or medical condition) data to public health departments in order to facilitate syndromic surveillance, assess risks of local populations for disease, and develop comprehensive plans with stakeholders to enact actions for mitigation, preparedness, response, and recovery (Policy H-440.892, "Bolstering Public Health Preparedness").

Insufficient Laboratory Capacity

Challenge: Our nation lacks the capacity to conduct adequate testing and surveillance of infectious diseases and other pathogens, including a lack of whole genome sequencing during the pandemic needed to identify SARS-CoV-2 variants. Public health labs have the technology to identify a wider range of diseases and are therefore expected to support clinical labs. However, public health labs often lack the resources needed to keep up with the workload, that has been especially true during the pandemic. Throughout the pandemic, all laboratories have faced challenges obtaining the necessary testing supplies. While public, commercial and hospital labs have shared resources throughout the pandemic, this has varied by jurisdiction and has occurred informally based on relationships among lab directors rather than systematically or consistently.

Solution: Our public health labs at the state and local level need to be better resourced and would benefit from more formal relationships between them and commercial labs, hospital and academic labs, and the CDC. The components of the laboratory community, though they may have different missions, need to see themselves as partners within a very interconnected system. As a nation, we need to do more whole genome sequencing, working with urgent care clinics, emergency departments, and hospitals, so that trends in virus variants can be identified and tracked. We also need to strengthen and broaden supplies within the Strategic National Stockpile and the capacity to ramp up production of supplies domestically; overreliance on international sources of supplies can be a national security issue.

Existing AMA Policy: Our AMA supports the Centers for Disease Control and Prevention's national Laboratory Response Network for communicating, coordinating, and collaborating with physicians and laboratory professionals on public health concerns (Policy H-440.891, "Support of the National Laboratory Response Network"). Our AMA: (1) encourages payers, regulators and providers to make clinical variant data and their interpretation publicly available through a system that assures patient and provider privacy protection; and (2) encourages laboratories to place all clinical variants and the clinical data that was used to assess the clinical significance of these results, into the public domain which would allow appropriate interpretation and surveillance for these variations that can impact the public's health (Policy D-460.971, "Genome Analysis and Variant Identification"). Our AMA urges Congress and the Administration to work to ensure adequate funding and other resources for the CDC, the National Institutes of Health (NIH), the Strategic National Stockpile and other appropriate federal agencies, to support the maintenance of and the implementation of an expanded capacity to produce the necessary vaccines, anti-microbial drugs, medical supplies, and personal protective equipment, and to continue development of the nation's capacity to rapidly manufacture the necessary supplies needed to protect, treat, test and vaccinate the entire population and care for large numbers of seriously ill people, without overreliance on unreliable international sources of production (Policy H-440.847, "Pandemic Preparedness").

Lack of Collaboration between Health Care and Public Health

Challenge: While the work of health care and public health are interconnected, the work is done in silos. Both physicians and public health practitioners that were interviewed expressed a strong desire for more collaboration. Some of the challenges in collaborating were mentioned previously around data modernization and the need to share information between health care and public health. Physicians also expressed frustration that they do not hear directly from their state and local health departments. During the pandemic, most physicians received updates on what is happening in their community through the news media. There is a desire for health departments to provide updates to clinicians in their jurisdictions directly. Beyond collaboration between health agencies and the physicians in their jurisdiction, there is also the desire for more collaboration between medicine and public health at the local, state and national levels among their professional organizations.

Solution: A critical component to improving public health infrastructure is to promote more collaboration and communication pathways between medicine and public health. There is a need to jointly arrive at the point of consensus that prevention is a shared goal which, if emphasized, will advance both fields. To that end, we need a "health" system--not divided between public health and health care, which unites in its shared goal of prevention. Greater collaboration also means that health-related jobs become easier, with fewer high-risk patients needing clinical care and more prevention activities to reduce demand on the health care system. The AMA should use some of its political capital, in collaboration with national public health organizations, to rebuild our public health infrastructure.

It is worth noting that in 1994, the AMA and the American Public Health Association (APHA) co-convened the Medicine and Public Health Initiative (MPHI).¹² In 1996, MPHI hosted a Congress inviting 400 representatives from Medicine & Public Health and provided grants at the state/local level to build sustainable, collaborative partnerships. By the year 2000, changes in leadership at the state and national level resulted in difficulty sustaining momentum. In 2002, following the September 11th attacks, the presidents of the AMA and APHA reiterated their dedication to MPHI. In 2004, the AMA and the CDC hosted the First National Preparedness Congress. This collaboration was not sustained due to shifting priorities. The Council urges consideration of the best way for clinical medicine and for our AMA and member organizations of the Federation of Medicine to collaborate with public health in a meaningful and sustainable way going forward.

Existing AMA Policy: Our AMA (1) encourages medical societies to establish liaison committees through which physicians in private practice and officials in public health can explore issues and mutual concerns involving public health activities and private practice; (2) seeks increased dialogue, interchange, and cooperation among national organizations representing public health professionals and those representing physicians in private practice or academic medicine; (3) actively supports promoting and contributing to increased attention to public health issues in its programs in medical science and education; (4) continues to support the providing of medical care to poor and indigent persons through the private sector and the financing of this care through an improved Medicaid program; (5) encourages public health agencies to focus on assessment of problems, assurance of healthy living conditions, policy development, and other related activities; and (6) encourages physicians in private practice and those in public health to work cooperatively, striving to ensure better health for each person and an improved community as enjoined in the Principles of Medical Ethics (Policy H-440.960, "Organized Medicine and Public Health Collaboration").

Ensuring Equity

Challenge: The gaps in the public health infrastructure mentioned previously all contribute to health inequities. The COVID-19 pandemic highlighted the equity gap in health outcomes for marginalized communities, as shown by the substantially higher rates of infection, hospitalization, and death in marginalized communities compared with White people. Incomplete data and fragmented access to data prevents public health from accurately identifying populations at greatest risk and prioritizing efforts and funding. Inadequate and inequitable funding means increased disparities in health outcomes because resources will not reach those in most need. The workforce needs to change so it has more people who are known and trusted in their communities, working on many of the issues that we face. These efforts require resources, and there are currently insufficient resources to support those kinds of meaningful efforts.

“Public health is for everybody. It’s just not for the poor. It’s not just for the rich. Public health is something that everyone should have access to. But some people need more help than others to get that access. And that’s got to be solved.” – Physician Stakeholder

Many practicing physicians lack the training to consider and address the social determinants of health with their patients. Limited time for patient visits contributes to doctors not having time to address social determinants during a regular visit even if they are trained in understanding and incorporating the social determinants of health. Physicians do not have to do this work alone; public health is here to address the social determinants of health in communities collaboratively, but we need a common language and a common understanding.

“I think as physicians, we increasingly realize that our patients’ diseases that we’re treating them for, diabetes, whatever, are being driven by risk behaviors that they’re taking that we don’t always feel like our counseling ... is effective ... without other interventions at the community level. Living conditions, social environment, institutional things, inequities that are happening, that are affecting their freedom, and housing, and transportation, ... are affecting the disease that shows up in our office.” – Physician Stakeholder

Solution: All of these gaps in the public health infrastructure contribute to the increasing inequities we see in health outcomes in the United States. Fragmented access to data prevents public health from accurately prioritizing efforts. Access to data is needed to inform equitable policy. Adequate funding is needed to decrease inequities in health outcomes and ensure resources reach those in most need. The workforce that is leading the charge against inequities needs to include more persons who look like the population it serves. Equity involves engagement with communities in an ongoing and meaningful way so those most affected by public health challenges are part of the conversations and part of the solutions.

Existing AMA Policy: Health equity, defined as optimal health for all, is a goal toward which our AMA will work by advocating for health care access, research, and data collection; promoting equity in care; increasing health workforce diversity; influencing determinants of health; and voicing and modeling commitment to health equity (Policy H-180.944, “Plan for Continued Progress Toward Health Equity”).

DISCUSSION

When public health stakeholders were asked about the work the AMA does in public health, there was little recognition of current public health activities. Some stakeholders referenced the work the AMA has done to address tobacco use and more were familiar with the AMA’s health equity strategy, which had been released around the time of the interviews. When asked about the AMA’s role in strengthening public health infrastructure, public health stakeholders highlighted the following as the strengths of the AMA and where the organization should focus its efforts:

- Communicating - Raise the visibility of public health to ensure the work public health professionals do is not invisible; share power--ensuring public health is at the table;
- Advocating - Elevate physicians’ and organized medicine’s influence in policy and support initiatives that focus more on public health; help build bi-partisan support for public health; and
- Educating - Help further emphasize public health and the social determinants of health in medical education, support training opportunities for medical students in health departments (see Appendix C, which outlines relevant existing activities).

Public health stakeholders encouraged the AMA to be a champion for public health while maintaining our brand position of being in the health care sector.

The AMA trustees who were interviewed as a part of this research strongly agreed with the challenges that were identified by the public health stakeholders as impacting our nation's public health infrastructure. There was also general agreement that these efforts would fit within the AMA's current strategic arcs. Trustees recommended solutions that are on-brand, fiscally responsible, and aligned with current strategy and operating goals. Some trustees cautioned that the AMA should not try to do all of these things, but to pick a few where the organization can be the most impactful. In addition to communicating, advocating, and educating, the trustees felt the AMA was well-equipped to be a convener and should focus on this while also engaging in other opportunities.

CONCLUSION

There is widespread recognition that our nation's public health infrastructure needs to be strengthened. The AMA already has extensive policy aligned with many of the challenges and solutions outlined in this report. These policies, adopted by the House of Delegates over the past decades, serve as the basis for the AMA to act. We recognize that there are many programs and initiatives happening across the organization that are relevant to this work. Members of the AMA Board of Trustees who participated in this process indicated that this work fits into the AMA's currently articulated strategic priorities. Therefore, your Council on Science and Public Health recommends that the AMA outline an organization-wide public health strategy, aligned with the findings of this report, to develop a clear roadmap of the work being done by the AMA in public health and to share accomplishments as the strategy is implemented. The Council also recommends new policy urging the AMA to actively oppose the limits being placed on the authority of health officials, recognizing the authority to implement evidence-based measures, including mandates, may be necessary to protect the health of the public. The Council also calls on the AMA to advocate for the solutions identified through this research, including sustainable funding to support public health infrastructure, incentives to help recruit and retain staff within the governmental public health workforce, public health data modernization and efforts to promote interoperability between health care and public health, and efforts to ensure equitable access to public health funding and programs. The Council also proposes new policy encouraging public health agencies to communicate directly with the health professionals licensed within their jurisdiction. We recognize that some jurisdictions are doing this well, but in many jurisdictions, there is little communication between health care professionals and their public health agency. Minor amendments are also suggested to further strengthen our existing public health policies based on the findings of this research.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 401-JUN-21 and the remainder of the report be filed.

1. That Policy D-440.922, "Full Commitment by our AMA to the Betterment and Strengthening of Public Health Systems" be amended by addition and deletion to read as follows:

Our AMA will: (1) champion the betterment of public health by enhancing advocacy and support for programs and initiatives that strengthen public health systems, to address pandemic threats, health inequities and social determinants of health outcomes; ~~and (2) study the most efficacious manner by which our AMA can continue to achieve its mission of the betterment of public health by recommending~~ (2) develop an organization-wide strategy on public health including ways in which the AMA can to strengthen the health and public health system infrastructure and report back regularly on progress; (3) work with the Federation and other stakeholders to strongly support the legal authority of health officials to enact reasonable, evidence-based public health measures, including mandates, when necessary to protect the public from serious illness, injury, and death and actively oppose efforts to strip such authority from health officials; (4) advocate for (a) consistent, sustainable funding to support our public health infrastructure, (b) incentives, including loan forgiveness and debt reduction, to help strengthen the governmental public health workforce in recruiting and retaining staff, (c) public health data modernization and data governance efforts as well as efforts to promote interoperability between health care and public health; and (d) efforts to ensure equitable access to public health funding and programs.

2. That Policy H-440.960, “Organized Medicine and Public Health Collaboration” be amended by addition and deletion to read as follows:

Our AMA (1) encourages medical societies to establish liaison committees through which physicians in private practice and officials in public health can explore issues and mutual concerns involving public health activities and private practice; (2) seeks increased dialogue, interchange, and cooperation among national organizations representing public health professionals, including representatives from governmental public health, and those representing physicians in private practice, ~~or employed in health systems, employed in~~ academic medicine, and working in other clinical settings; (3) actively supports promoting and contributing to increased attention to public health issues in its programs in medical science and education; ~~(4) continues to support the providing of medical care to poor and indigent persons through the private sector and the financing of this care through an improved Medicaid program;~~ (5) encourages public health agencies to focus on assessment of problems, assurance of healthy living conditions, policy development, and other related activities; and (6) encourages physicians in private practice and those in public health to work cooperatively, striving to ensure better health for each person and an improved community as enjoined in the Principles of Medical Ethics; and (6) encourages state and local health agencies to communicate directly with physicians licensed in their jurisdiction about the status of the population’s health, the health needs of the community, and opportunities to collectively strengthen and improve the health of the public.

3. That AMA Policy H-440.912, “Federal Block Grants and Public Health” which calls on the AMA to collaborate with national public health organizations to explore ways in which public health and clinical medicine can become better integrated and urges Congress and responsible federal agencies to: (a) establish set-asides or stable funding to states and localities for essential public health programs and services, (b) provide for flexibility in funding but ensure that states and localities are held accountable for the appropriate use of the funds; be reaffirmed.
4. That AMA Policy H-440.989, “Continuation of the Commissioned Corps,” be amended by addition to read as follows:

Our AMA strongly supports the expansion and continuation of the Commissioned Corps of the US Public Health Service and recognize the need for it to be adequately funded.

5. That our AMA reaffirm Policies D-305.964, “Support for the Epidemic Intelligence Service (EIS) Program and Preventive Medicine Residency Expansion,” D-295.327, “Integrating Content Related to Public Health and Preventive Medicine Across the Medical Education Continuum,” and D-305.974, “Funding for Preventive Medicine Residencies.”
6. That our AMA reaffirm Policy H-440.89, “Support of the National Laboratory Response Network,” and Policy D-460.971, “Genome Analysis and Variant Identification.”
7. That our AMA amend Policy H-440.813, “Public Health Surveillance” by addition and deletion to read as follows:

Our AMA: (1) recognizes public health surveillance as a core public health function that is essential to inform decision making, identify underlying causes and etiologies, and respond to acute, chronic, and emerging health threats; (2) recognizes the important role that physicians play in public health surveillance through reporting diseases and conditions to public health authorities; (3) encourages state legislatures to engage relevant state and national medical specialty societies as well as public health agencies when proposing mandatory reporting requirements to ensure they are based on scientific evidence and meet the needs of population health; (4) recognizes the need for increased federal, state, and local funding to modernize our nation’s public health data systems to improve the quality and timeliness of data; (5) supports the CDC’s data modernization initiative, including electronic case reporting, which alleviates the burden of case reporting on physicians through the automatic generation and transmission of case reports from electronic health records to public health agencies for review and action in accordance with applicable health care privacy and public health reporting laws; (6) will advocate for incentives for physicians to upgrade their EHR systems to support electronic case reporting as well as incentives to submit case reports that are timely and complete; ~~(67)~~ will share updates with physicians and medical societies on public health surveillance and the progress made toward implementing electronic case reporting; ~~(78)~~ will advocate for increased federal coordination and funding to support the modernization and standardization of public health surveillance systems data collection by the Centers for Disease Control and

Prevention and state and local health departments; and (8) supports data standardization that provides for minimum national standards, while preserving the ability of states and other entities to exceed national standards based on local needs and/or the presence of unexpected urgent situations.

Figure 1

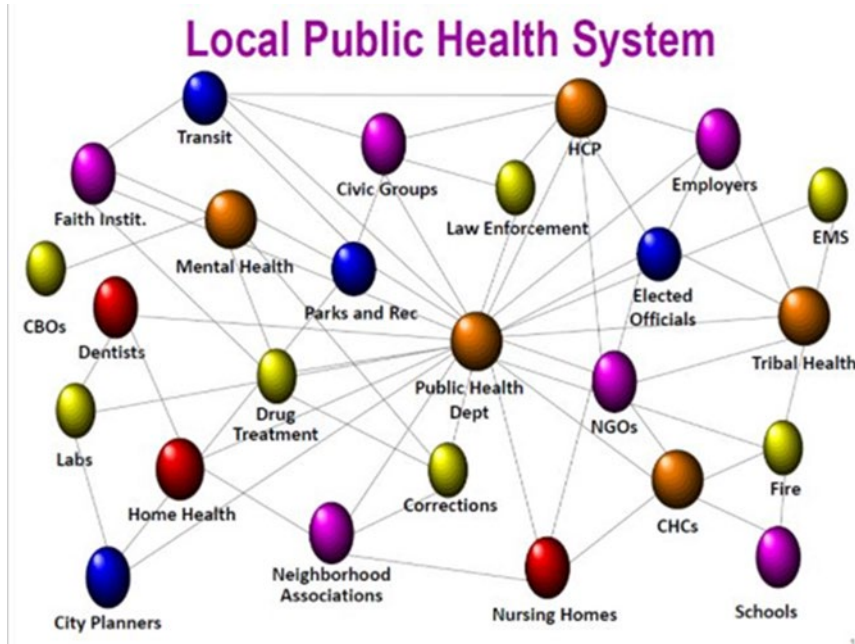
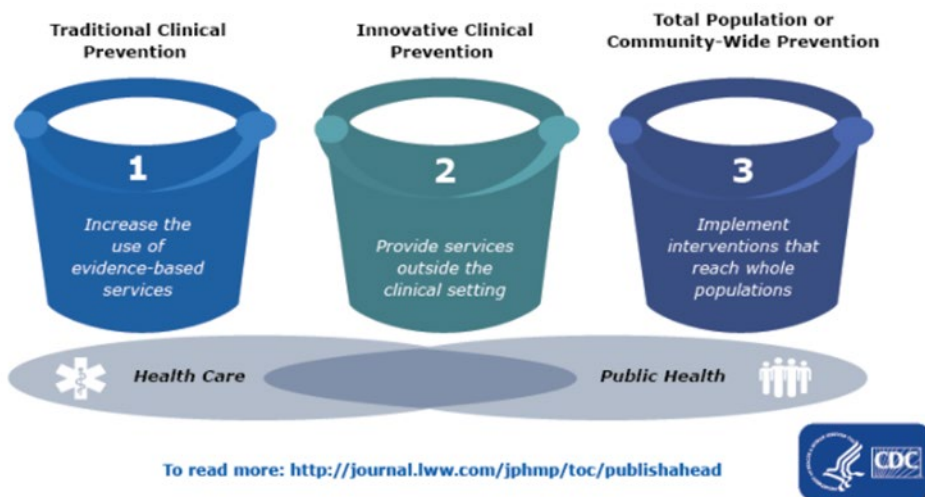


Figure 2



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APPENDIX A

#24495 Public Health Infrastructure Interviews

Background and Objectives

The American Medical Association's Council on Science and Public Health is assessing ways to strengthen our nation's public health infrastructure, and the AMA's role in supporting and improving public health systems. More specifically:

- Understand the current challenges faced by public health professionals and health departments in preventing, detecting, and responding to emerging infectious disease threats and other public health crises.
- Understand physician and public health professionals' perspectives on what solutions need to be implemented to strengthen public health infrastructure to carry out the 10 essential public health services to improve disease and injury prevention and the health of the public
- Identify barriers and opportunities for improved and increased linkages between the public health and health care systems.
- Understand opportunities for the public health system to protect and promote the health of all people in all communities by removing systemic and structural barriers that have resulted in inequities.
- Identify opportunities for the AMA in supporting, developing, and implementing solutions.

Methodology and Sample

N=30-33 External stakeholders

- Government and Public Health (n=10)
- National Public Health (n=6)
- Federation of Medicine (n=12)
- Foundations (n=2)

Note on in-depth interviews format:

Questions might not be asked in the order below and all questions will likely not be asked. Rather, they are used as a guideline for the discussion. We will aim to have a natural conversation with the interviewees and touch upon the topics as they become part of the discussion and as they are relevant to the interviewee.

Intros (2-3 minutes)

- C+R Research – independent market research firm
- Talking with Physicians and Public Health Professionals like you for research purposes but don't belong to any health organization – think of me as a neutral third-party
- No wrong answers!
- I'm a moderator, not an expert in this field, so I may ask you to clarify things along the way
- Documenting the interview with audio (for notetaking and report writing purposes only)
- Other C+R and AMA researchers may join your interview to observe your responses. They may also view session recordings or notes in the future. The AMA may publish research reports or articles that include your anonymous comments and experiences shared. C+R and the AMA will not provide any details with its use of the information resulting from the interview which would allow any third party to identify you, nor will it use this information in any way that can be damaging to you.
- Questions before we get started?

BACKGROUND AND CONTEXT
minutes

5

- First off, we mentioned that we would be talking about the public health infrastructure in our interview today. From your perspective, how do you define “public health infrastructure”?
 - Can you briefly describe your organization/your position and how long you have been in that role?
 - How would you describe your background in terms of your expertise or involvement in public health?
 - *Understand whether their focus is research, epidemiology, policy & management, environmental health, etc.*
 - *Understand primary issue/area of focus within the field of public health (e.g., immunizations, maternal health, gun violence, health equity, etc.)*
 - What previous roles have you had related to public health (in other organizations)? *Listen for if they were previously a state/local health official*
- For Governmental/National Public Health Organizations:*
- What is the role of your organization and/or members in the public health system?
 - Can you briefly **describe your location or jurisdiction/population of focus?**
- For physicians/primary care organizations:*
- How do you or your members support or interact with the public health system?
 - Can you briefly **describe your location or jurisdiction/population of focus?**

CURRENT CHALLENGES

15 minutes

Now I'd like to talk more about the challenges facing our nation's public health system. You are welcome to focus this conversation on COVID-19, as we understand it's likely a main part of what your organization is currently focused on, or you can consider challenges beyond the pandemic.

Successes + What Works Well

- **National Public Health Organizations:**
 - What are some “**big picture**” **successes** your organization/members/our public health system have had?
 - What's an example of a “**small success**” your organization/members/our public health system have had on a given day or week?
 - Please share some **examples of how your organization/members/the public health system has successfully collaborated** with physicians or healthcare delivery systems to address a public health issue.
 - *Probe: how do we sure the **10 Essential Public Health Services** are available to all people in all communities?*

- *Probe: is there an explicit strategy to advance equity?* Please describe any explicit **strategies to advance equity** that you/your organization/members use consistently.
- **National Physician Organizations:**
 - What are some **examples of how physicians/your members/health care systems have successfully collaborated** with public health agencies? Have these been sustained?
 - Please share an **example from your or your organization's perspective** of when the public health and healthcare sectors were in **alignment** on a significant public health issue in your local community and/or nationally.
 - *Probe: how do we sure the 10 Essential Public Health Services are available to all people in all communities?*
 - *Probe: Do you have an explicit strategy to advance equity?* Please describe any explicit **strategies to advance equity** that your organization/members use consistently.

Previous and/or Ongoing Challenges

- What would you say are the three to five **biggest challenges facing the nation's public health infrastructure** today?
 - Why do you think each of these is an important issue?
- How would you prioritize these issues?
 - *Probes: authority, communication, collaboration across levels of government, public health workforce, data modernization, linkages between health care and public health, ensuring equity*
 - **Physician Orgs:** How do challenges in public health infrastructure impact physician practices and patients?
- *Probes: for those who are former state/local health officials to think about what they needed when they were in that job and what would have been most beneficial.*
- **[For each challenge mentioned]** Tell me about a recent challenge the public health system faced. These challenges can be specific to the COVID-19 pandemic or on issues other than the pandemic.
 - What was the issue/challenge?
 - What made it challenging or difficult?
 - What was the plan to resolve this issue?
 - How was it implemented (whether successfully or unsuccessfully)?
 - What were the outcomes?
 - What was the impact on health equity?
 - What did you or your organization learn from this? What will be done differently in the future?

Repeat as time allows to understand multiple issues and their context.

IDEATE FUTURE SOLUTIONS

10-15 minutes

Now that we've talked about these challenges, I'd like to hear more from you about your thoughts on how these can be solved.

- From your perspective, what do you think **needs to be done to improve** the public health infrastructure?
- Thinking back to each of those challenges you have faced, what would have made these issues easier to solve?
- **National Public Health Organizations:**
 - What can help your **organization/members/the public health system** be more successful in their efforts?

- What can help you/your members/the public health be more successful in your/their job?
- What would improve collaboration between medicine and public health and lead to better health outcomes for patients and communities?
- **National Physician Organizations:**
 - What would improve collaboration between medicine and public health and lead to better health outcomes for patients and communities?
 - What is the perspective of physicians/your members on linking the principles of public health (upstream approaches) into the language and practice of medicine?
How do we move health care upstream to improve the structural and social drivers of health and equity?
- What's **one thing you'd want to change** that would make the work of the public health system easier, more effective and equitable tomorrow?
 - What about making the next few weeks/months easier more effective and equitable?
 - And the next few years?
- How would you **prioritize** these changes?
 - What should be focused on first? What is most important?
 - What are areas that could be addressed at a later time?
- What **goals** do you or your organization already have in place to address these in the future?
 - Which are more short-term, and which are longer term goals?
- Which organizations (for profit, not-for-profit, public, private) would be part of the solution to the U.S.'s public health infrastructure problems? What roles/contributions would they have in the solution?
- *If time allows.* Who would be a **reliable and trustworthy source** for you related to recommendations on how to better manage future public health issues?
 - Why are these sources more reliable than others? *Probe to get beyond simply peer reviewed research or the CDC.*

AMA POTENTIAL SOLUTIONS + WRAP UP minutes

10

I'd like to talk more specifically about how the AMA can **support efforts to strengthen public health infrastructure**.

- Public Health Orgs: In what way(s), does/do the AMA already help support you in your role/organization improve public health?
- Physician Orgs: In what ways does the AMA already support you in addressing the upstream factors that impact health?
- Thinking back to your previous challenges, how, if at all, can the AMA help with these?
 - What can the AMA do to help you face these challenges in a better way?
 - What would the AMA need to do? What would this solution look like?
 - What should the AMA provide?
- Do you have any **final words of advice** for those designing and implementing future public health policies, recommendations, and programs?

Moderator will check with back room for additional questions, thank and close

APPENDIX B

#24495 Public Health Infrastructure Interviews
FINAL GUIDE – Internal B.O.T. Interviews
45 minutes

Background and Objectives

The American Medical Association's Council on Science and Public Health is assessing ways to strengthen our nation's public health infrastructure, and the AMA's role in supporting and improving public health systems. More specifically:

- Understand the current challenges faced by public health professionals and health departments in preventing, detecting, and responding to emerging infectious disease threats and other public health crises.
- Understand physician and public health professionals' perspectives on what solutions need to be implemented to strengthen public health infrastructure to carry out the 10 essential public health services to improve disease and injury prevention and the health of the public
- Identify barriers and opportunities for improved and increased linkages between the public health and health care systems.
- Understand opportunities for the public health system to protect and promote the health of all people in all communities by removing systemic and structural barriers that have resulted in inequities.
- Identify opportunities for the AMA in supporting, developing, and implementing solutions.

Methodology and Sample

N=11 Internal B.O.T. Members

Note on in-depth interviews format:

Questions might not be asked in the order below and all questions will likely not be asked. Rather, they are used as a guideline for the discussion. We will aim to have a natural conversation with the interviewees and touch upon the topics as they become part of the discussion and as they are relevant to the interviewee.

Intros (2-3 minutes)

- C+R Research – independent market research firm
- Working with the AMA and talking with internal board members like you as well as external stakeholders in public health – think of me as a neutral third-party
- No wrong answers!
- I'm a moderator, not an expert in this field, so I may ask you to clarify things along the way
- Documenting the interview with audio (for notetaking and report writing purposes only)
- Other C+R and AMA researchers may join your interview to observe your responses. Just a reminder that this is all for research purposes and your responses will be reported back in the aggregate along with other board members like you.
- Questions before we get started?

BACKGROUND AND CONTEXT
 minutes

2-3

- Can you briefly describe **your role** as it relates to the AMA and how long you have been in that role?
- Today, we are going to be talking about the public health infrastructure as well as ways AMA can help. When I say **public health infrastructure**, I am talking about the governmental public health system at the federal, state, local, territorial and tribal levels.

Can you describe **your background** along with any previous involvement in efforts **related to public health** (if applicable)?

CURRENT CHALLENGES

10 minutes

As you may know, we just completed an initial round of interviews with external public health experts from a variety of organizations. They provided their perspective on what challenges are facing our nation's public health infrastructure today. But before we talk about what they told us, I'm curious what your perspective is.

Challenges (Unaided) – 3 minutes

- Just briefly, what would you say are the top three **biggest challenges facing the nation's public health infrastructure** today?
 - *Listen for and probe around any mentions of misperceptions of public health, funding, workforce, data modernization, collaboration between healthcare and public health, equity issues, etc.*
- How do these challenges **impact your practice or your patients?** *(do not ask if respondent is not a clinician)*

Challenges (Aided) – 7 minutes

- When we spoke with the external public health stakeholders, here are some of the **biggest challenges they mentioned**. I am curious to get your perspective on these and hear how you would prioritize them. *HAVE RESPONDENT RANK ORDER CHALLENGES FROM HIGHEST TO LOWEST PRIORITY*
 - Perception problems/lack of understanding of public health (i.e., public health is invisible)
 - Lack of consistent, sustainable funding
 - Workforce/staffing issues
 - Data modernization and lack of interoperability with health care
 - Lack of collaboration between healthcare and public health
 - Equity issues

IDEATE FUTURE SOLUTIONS

15 minutes

Now that we've talked about these challenges, I'd like to hear more from you about your thoughts on **how the AMA could help address each of these areas**.

- **[For each challenge mentioned, ask in order of priority] What could the AMA do** to help solve this challenge?
 - What would the potential solution(s) look like?
 - Who would need to be involved?
 - What would it take to accomplish this? (what would have to happen?)
- In addition to the solutions we just discussed, here are some other ideas the external stakeholders mentioned as **possible solutions, which include the AMA's role in strengthening the public health system**. I'd like to get your perspective on which of these the AMA feels best suited to support and why.
 - **Collaboration Between Medicine and Public Health**
For example, sharing of data across public health and healthcare, more communication between public health and health care, sharing the common goal of prevention, etc.
 - **Prioritizing Public Health**
For example, raising the visibility of our public health system to help ensure the work they do is not invisible and share power ensuring their voice is at the table.

- **Advocating for Sustainable Public Health Funding**

For example, advocating at the federal level for sustainable funding for the public health infrastructure (communications, IT, workforce) and services (immunizations, chronic disease, injury prevention to ensure that public health isn't only funded well in a crisis.

Working with state/county medical societies to advocate for evidence-based public health policies as well as support for public health authority during emergencies.

- **Data Modernization**

For example, supporting interoperability between health care and public health as well as incentives for health care professionals who report timely, accurate and complete data on notifiable conditions to public health agencies.

Supporting incentives for clinicians to upgrade the EHR systems to support electronic case reporting.

- **Strengthening the Public Health Workforce**

For example, supporting incentives for those who work in governmental public health so public health can attract the talent it needs to be successful. Prioritizing physician and medical student education in public health as well as education focusing on, equity and the social determinants of health.

Supporting residency programs for preventive medicine specialists.

- How would you **prioritize** these changes?
 - What should be focused on first? What is most important?
 - What are areas that could be addressed at a later time?

AMA POTENTIAL SOLUTIONS + WRAP UP

15 minutes

I'd like to talk more specifically about what else the AMA can do to **support efforts to strengthen public health infrastructure.**

- How does strengthening the public health system **fit into the AMA's current strategic plan and operating goals?** *Moderator may reference slide for strategic plan and operating goals*
- What do you think the AMA **should do** to further strengthen the public health infrastructure beyond what it is already doing?
 - What should the AMA do to strengthen collaboration between medicine and public health?
- What, if anything, would you **caution the AMA not to do or not to get involved in?**
- Do you have any **final words of advice** for those considering the AMA's role in strengthening public health infrastructure?

Moderator will check with back room for additional questions, thank and close

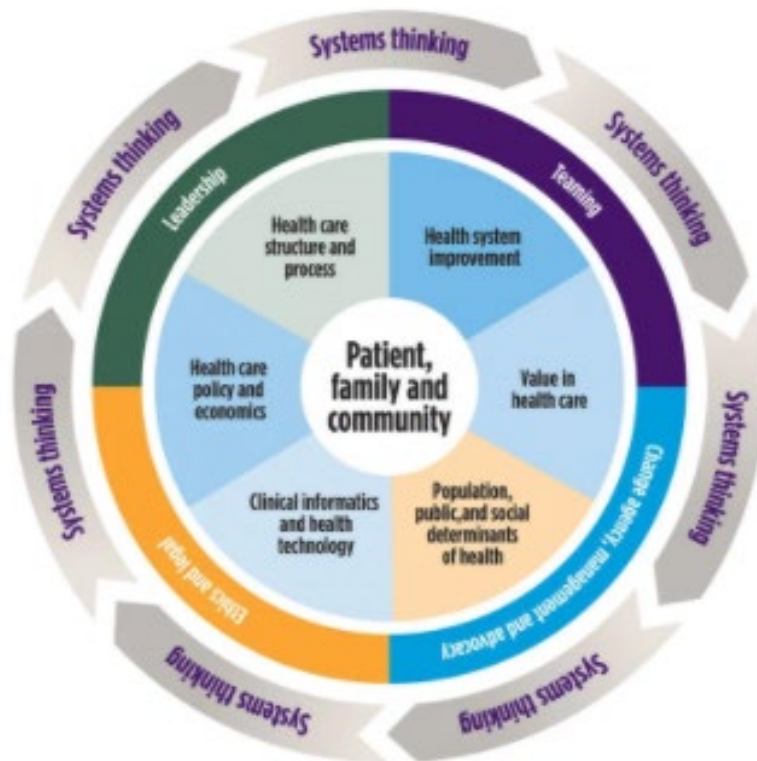
APPENDIX C

Health System Science

Health systems science (HSS) is the third pillar of medical science, along with the basic and clinical sciences. It involves understanding how care is delivered, how health care professionals work together to deliver that care and how the health system can improve patient care and health care delivery. It is critical for the successful functioning of a health system. Physicians need to

know the domains of health systems science, understand how it intersects with the basic and clinical sciences and explore how it can maximize health for patients and society.

The HSS curriculum includes issues related to how social determinants of health effect the entire population and the improvement strategies at the population health level to address gaps in care such as the organized assessment, monitoring or measurement of key health metrics necessary to improve health outcomes for a group of individuals.



Core functional, foundational, and linking domains of health systems science

AMA ACE Consortium

Relevant exemplar medical school efforts in the consortium, funded by AMA grants:

- Brown Warren Alpert School of Medicine established the Primary Care-Population Medicine in which students receive a Masters of Science in Population Medicine in addition to their MD <https://pcpm.med.brown.edu/curriculum/scm-curriculum>
- AT Still School of Osteopathic Medicine in Arizona embeds 2nd-4th year medical students in underserved communities where they perform needs assessments and work with community health center leadership and community stakeholders to perform community-based research, quality improvement or service projects that recognize the local, social and economic determinants of health.
- Florida International University Herbert Wertheim College of Medicine (FIU HWCOM) NeighborhoodHELP program places medical students on inter-professional teams that perform home visits that have resulted in increased use of preventive health services and a trend toward decreasing the use of the emergency department as a regular place of care. The program also allows for collaboration with local hospitals to improve population health outcomes.
- Similarly, University of Texas Rio Grande Valley School of Medicine (UTRGV) places medical students on inter-professional teams that serve colonias, impoverished rural settlements in unincorporated areas along the U.S./Mexico border, providing integrated care and connecting patients and families with public health services
- The University of California, Davis, School of Medicine (UC Davis) established a model three-year education track, the “Davis Accelerated Competency-based Education in Primary Care” (ACE-PC) that addresses pressing societal needs by including work with medically underserved populations and enhanced training in population management, chronic disease management, and preventive health skills

AMA Reimagining Residency initiative

The goal of the Reimagining Residency grant program is to transform residency training to best address the workplace needs of our current and future health care system. It supports bold and innovative projects that provide a meaningful and safe transition from undergraduate medical education to graduate medical education, establish new curricular content and experiences to enhance readiness for practice and promote well-being in training.

Examples of relevant projects:

- Montefiore is developing a curriculum in social determinants of health in four primary care residency programs.
- COMPADRE is a collaboration between OHSU and UC-Davis to address workforce in the predominantly rural and indigenous communities in the corridor between their institutions. They are providing training in those communities, so trainees understand the social context for care and the community resources available to support their work.
- The FIRST program at UNC expanding its 3+3+3 model (3 years of medical school, 3 years of residency, 3 years of early career mentorship) to 4 regions in the state (3 of them AHECs) and across disciplines. This is also an effort to link training and early career experience to community resources.
- Penn State is collaborating with Geisinger, Allegheny, and Kaiser Permanente to define the personal and learning environment characteristics that contribute the creation of “systems citizens” – those physicians who effectively navigate health systems and appropriately apply system and community resources to the care of their patients.

**3. PHYSICIAN INVOLVEMENT IN STATE REGULATIONS OF MOTOR VEHICLE
OPERATION AND/OR FIREARM USE BY INDIVIDUALS WITH COGNITIVE
DEFICITS DUE TO TRAUMATIC BRAIN INJURY
(Resolution 424-A-19)**

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 424-A-19
REMAINDER OF REPORT FILED
*See Policy TBD***

INTRODUCTION

Resolution 424-A-19, “Physician Involvement in State Regulations of Motor Vehicle Operation and/or Firearm Use by Individuals with Cognitive Deficits Due to Traumatic Brain Injury,” introduced by the American Academy of Physical Medicine and Rehabilitation and referred by the American Medical Association (AMA) House of Delegates (HOD) asked:

That our AMA reaffirm current AMA Policy H-145.999, stating it supports stricter enforcement of current federal and state gun legislation and that our AMA advocate for physician-led committees in each state to give further recommendations to the state regarding driving and/or gun use by individuals who are cognitively impaired and/or a danger to themselves or others.

This report summarizes the evidence around cognitive deficits, including traumatic brain injury (TBI), the legal landscape of cognitive impairment as it relates to firearm ownership and driving, and the role of the physician in adjudicating fitness. While the resolution specifically cites TBI, there is currently limited research available on TBI and driving or firearm ownership. As such, more well-studied cognitive deficits (such as dementias) are examined to provide context.

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases from January 2011 to July 2021 using the search terms “medical advisory board” and “gun” or “firearm” or “driver license” or “motor vehicle;” “cognitive impairment” or “dementia” or “traumatic brain injury” and “gun” or “firearm” or “driver license” or “motor vehicle.” Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal and state agencies and applicable regulatory and advocacy organizations were also reviewed for relevant information.

OVERVIEW OF COGNITIVE IMPAIRMENT

Cognitive impairment describes a durable characteristic in which an individual has difficulty concentrating, learning, remembering, or exercising sound judgment during everyday tasks due to illness or injury. Cognitive impairment is not limited to a specific condition or disease, but severe cases are typically associated with degenerative brain diseases, such as Alzheimer's, Parkinson's or Lewy Body disease. In these cases, cognitive impairment can be measured using the Global Deterioration Scale, which ranges from 1 (no cognitive impairment) to 7 (severe dementia).¹ Age is the primary risk factor for cognitive impairment. Current estimates suggest that there are approximately 44 million individuals worldwide living with dementia, nearly double the number of cases from 1990.² While a portion of this increase can be attributed to improved screening and awareness of dementia, it also is a key indicator of the impending "silver tsunami" as the baby boomer generation (birth years 1946-1964) ages.^{3,4}

It is generally accepted that individuals experiencing dementia, or other forms of cognitive impairment, may be at increased risk for harming themselves or others. To reduce injuries and deaths, while respecting their autonomy and rights, it is recognized that some activities, such as driving or firearm access, may need to be restricted in this population.

Traumatic Brain Injury

TBI is an emerging area of scrutiny, not only in the medical profession, but in the public sphere, raising questions as to whether individuals with TBI may be at higher risk of harming themselves or others. TBI occurs when an individual receives a blow to the head. It can be categorized broadly in two ways: mode of injury (closed/non-penetrative or open/penetrative) and severity (mild, moderate or severe).⁵ Secondary injuries from the initial impact may include increased intracranial pressure, decreased cerebral perfusion and intracranial hemorrhage. Persons with TBI commonly experience loss of consciousness, headache, nausea, fatigue, depression, mood swings and difficulty concentrating.⁶ In the most severe cases, persons with TBI may be left with persistent and severe cognitive impairment or they may remain in a comatose state long after their initial injury. While symptoms typically abate after approximately six months, many patients report lifelong complications from even a single, mild incident of TBI.⁷ Common causes of TBI include falls, motor vehicle crashes, sports injuries and gunshot wounds. Unlike other forms of cognitive impairment, persons living with TBI may recover and regain some or all cognitive function and motor skills, this is especially true in cases where rehabilitation is sought. This makes understanding symptom progression particularly difficult.⁸

It is estimated that approximately 1.1 percent of the U.S. population experiences life-long effects from TBI.⁹ Of particular interest to this report is the connection between TBI and later-in-life development of neurodegenerative disease such as dementias, including Alzheimer's and Parkinson's.¹⁰ Studies have suggested that patients who have experienced at least one incident of TBI in their life are up to 4 times more likely to develop Alzheimer's in their lifetime, with more severe incidents (such as those resulting in loss of consciousness) resulting in the highest risk.¹¹⁻¹³ One of the historic difficulties of diagnosing and treating TBI has been managing the sequelae that may not manifest until much later in life. For example, studies have shown that cognitive function post-TBI can steadily improve for up to 10 years only to be followed by a sharp decline.¹⁴

With regard to whether individuals with TBI may be at higher risk of harming themselves or others, data suggest TBI may be a risk factor for violent behavior and suicide. One study found that approximately 40 percent of patients monitored at 3, 6 and 12 months post-TBI presented signs of aggression.¹⁵ Similarly, several studies have shown TBI is a risk factor for intimate partner violence and violent criminal behavior,¹⁶⁻²¹ and a study of Vietnam war veterans with TBI found a correlation between lesions of the prefrontal cortex and a positive implicit attitude towards violence.²² Additionally, violent behavior may present as self-harm, as a 35-year retrospective study in Denmark found the absolute suicide rate was over double (41 vs 20 per 100,000 person-years) for patients with diagnosed TBI at any severity,²³ and this risk increases with subsequent head traumas.²⁴

DRIVER LICENSING

There is no constitutionally protected right to maintain a driver license, and there are clear guidelines for the role of the physician in protecting their patients from unsafe driving. In collaboration with the U.S. Department of Transportation and the National Highway Traffic Safety Administration, the AMA previously developed and

published guidance for physicians. While this guidance is presented in the context of an aging driver, potential cognitive and noncognitive impairment from a previous TBI can occur at any age.²⁵

In brief, the guidance suggests that physicians perform a battery of tests to assess driving skills (visual acuity, spatial awareness, dexterity, memory). If a physician believes that their patient is unfit to drive, they are advised to counsel the patient and their family or caregivers to voluntarily retire from driving and surrender their driver license, or they may refer the patient for occupational therapy. In the case of TBI, this is especially critical as surveys have shown that half of drivers recovering from mild TBI have no intention of self-moderating driving behavior.²⁶

Depending on the state, the physician may also have legal responsibilities as dictated by their medical licensing board. Some states, such as California, mandate that all physicians report to the Department of Motor Vehicles (DMV) any instances of patients with disorders resulting in loss of consciousness or severe impairment of motor vehicle operation. Other instances where a physician has a good faith belief that a driver is a risk to public safety are encouraged to be reported, but not required to do so. Some states, such as Kansas, explicitly do not require a physician to report this information and further require the physician to obtain written consent from the patient before releasing any information to the DMV. Additional state-level differences to be aware of include the legal protection (or liability) that a physician may be entitled to in the event of an accident from a known unsafe driver, and whether the physician may submit a DMV referral anonymously.

FIREARM OWNERSHIP

Firearm ownership in the United States is largely controlled by the Second Amendment to the Constitution, which indicates that “the right of the people to keep and bear Arms, shall not be infringed.” However, Supreme Court decisions in *District of Columbia v. Heller* (2008) and *McDonald v. City of Chicago* (2010) found that this right is not absolute and may be limited appropriately by federal, state and local governments.^{27,28} Limits to firearm ownership relevant to this report fall into two categories: cognitive impairment restrictions and risk-based removals.

It should be noted that instances of interpersonal firearm violence committed by people with mental illness often attract media and public scrutiny. However, only 4 percent of all interpersonal firearm violence in the United States can be attributed to individuals with mental illness.²⁹ By comparison, up to 74 percent of deaths by suicide are related to a diagnosed mental illness.³⁰

Firearm Ownership and Possession Restrictions

Federal law 18 U.S.C. § 922(d) prevents the sale of a firearm or ammunition to any person that “has been adjudicated as a mental defective or has been committed to any mental institution,” although all but 4 states (Colorado, Indiana, Kentucky and New Hampshire) have additional restrictions related to mental health and firearm ownership.³¹ The resulting patchwork of restrictions and regulatory authorities has been criticized for ineffectiveness. For example, the gunman responsible for the deaths of 32 people at Virginia Tech in 2007 had been found to be mentally unfit by a court in 2005 after accusations of stalking. The shooter was required by the court to attend treatment, but due to his treatment being on an outpatient basis, he was not prevented from purchasing the firearms used in the mass shooting, as federal law requires involuntary commitment.³²

All states but one (Hawaii) do not allow restrictions on firearm purchases on the basis of diagnosis alone. This practice of requiring an individual risk assessment is consistent with the recommendations of the American Psychiatric Association (APA).³³ While a practitioner may report the status of an individual’s diagnosis or treatment to a third party, that is not sufficient to bar the purchasing of a firearm (outside of Hawaii).

At the federal level, individuals adjudicated to be mentally unfit to own a firearm are reported to the National Instant Criminal Background Check System (NICS). Firearm dealers who hold a federal firearms license must process all potential buyers through NICS prior to selling them a firearm. Since 1998, firearm sales have been denied 1,970,264 times due to failing a NICS background check, but only 3 percent of them have been due to mental health concerns.³⁴ Several factors may have contributed to this relatively low rate of rejection, such as a lack of mandatory reporting of mental health data by states, the inability for states to report violations of their stricter purchasing restrictions, and a lack of clarity around NICS reporting and the Health Insurance Portability and Protection Act (which was clarified in 2016).^{35,36}

Firearm Removals

Once an individual has legally purchased a firearm, the primary means for removal are through extreme risk protection orders (ERPOs), although they may go by other names depending on the state, such as gun violence restraining orders (California), or risk warrants (Connecticut). Currently, 19 states (and the District of Columbia) have some version of ERPO law that allows for the petitioning of a court to remove firearms from the possession of someone deemed high risk.³⁷ ERPO laws have recently gained momentum, with 8 of the 20 states having passed legislation during the 2018 session immediately following the school shooting in Parkland, Florida. In June 2021, under the direction of President Biden, the Department of Justice released model legislation for states to follow if they wished to enact ERPO laws.³⁸ A 2018 report from this Council further discusses the role of the physician in firearm safety and ERPOs.³⁹ ERPO laws are still new, but research suggests that while public awareness remains low, California's approach has shown signs of success in removing firearms from individuals threatening mass shooting events.^{40,41}

By contrast, Oklahoma passed an anti-ERPO law in May 2020 which prohibits any county or local government from enacting ERPO laws. Texas, Alaska, Georgia, Minnesota and Kansas legislatures have all introduced anti-ERPO laws which have not passed at the time of writing. State legislators in these jurisdictions have argued that ERPO laws may infringe upon the First, Second, Fourth and Fifth Amendment, but in limited court proceedings, these arguments have been rejected.^{37,42-44}

The exact implementation of ERPO laws varies from state to state, but broadly they allow for a process in which a court can hear a petition to remove firearms and ammunition from the possession of an individual.⁴⁵ The laws largely differ in three major areas: who may petition the court, the burden of evidence required to approve the removal, and the duration of the removal and the overturning of the individual's rights to otherwise possess a firearm. The most narrowly drafted state legislation allows law enforcement officers or their agencies to petition a court to remove firearms, where other states allow some combination of household members, intimate partners, employers, coworkers, or school officials to additionally file an ERPO. Most relevant to this report, Maryland and the District of Columbia allow healthcare providers to file ERPO petitions as well, although professional groups have varying ways of defining and measuring risky behavior.⁴⁶ An individual may or may not be notified that a petition for an ERPO against them has been made, and law enforcement may be empowered to seize an individual's weapons within 24 hours and then to prevent the individual from regaining possession of their firearms until a hearing has been held, which, per some state statutes, can extend for up to a year.

Firearm Ownership and Cognitive Impairment

Studies have indicated that up to 60 percent of outpatients living with dementia are in households containing firearms, placing them at higher risk for death by suicide.^{47,48} Older adults die by suicide at rates disproportionate with the general population and firearms are the most common means.⁴⁹ Caregivers for those with dementia have been surveyed and over 70 percent feel that the caregiver plays a key role in firearm safety, but only 5 percent of caregivers had training or guidance.⁵⁰ The Veteran's Health Administration has developed guidance for counseling family or caregivers on creating a safe environment if firearms are accessible to a person living with dementia.⁵¹

As described above, the progression of TBI is unpredictable. Some report no behavioral or physical effects for many years only to be followed by a steep decline, while others report a full recovery of function. Currently, conditions such as chronic traumatic encephalopathy (CTE) from sports injuries can only be diagnosed posthumously which would make any blanket policy around TBI and firearm ownership difficult to craft and implement. However, TBI does increase the risk of developing other neurological conditions, such as dementias which have more established protocols for evaluating cognitive fitness.^{10,52-54} Depending on the progression of TBI, a similar approach to that used for dementia may be appropriate.

Medical Advisory Boards

Legal requirements and medical thresholds for firearm ownership and driver licensing in the event of cognitive impairment vary from state to state. To ensure that the physician's voice is heard in the process, states can implement a medical advisory board (MAB) at several different points: to create best practices guidelines, to perform the medical assessment, or to evaluate appeals for reinstatement.

MABs are much more commonly utilized in the case of driver licensing. A summary of MAB roles from state to state can be found in a 2017 NHTSA publication.⁵⁵ In brief, the MAB may be involved in all steps of the process. In New York, input from the MAB is given to the DMV for developing the regulations dictating a driver's fitness. Other states use their MABs on a case-by-case basis. Louisiana's MAB is forwarded complaints from the DMV for evaluation, whereas Maine's MAB is engaged only on driver appeal. Some states, like Montana, do not retain a MAB at all. It should also be noted that the function of state MABs are dependent not only on statutory authority but also on funding, which has historically not been consistent.

For firearm ownership, there are no known MABs in the country. In Texas, a MAB has been used to review cognitive fitness for concealed handgun licenses, but the MAB is not used for purchasing firearms or reviewing ERPOs. In 2020, a bill was introduced in the New York state legislature (S7065) to require anyone seeking to purchase a firearm to submit to a mental health screening, but it did not receive a vote in the committee that first had hearings on the bill. Countries as diverse as Argentina, Turkey, Ukraine, Croatia, France, Spain, Japan and Israel require either a mental health evaluation or access to medical records prior to purchasing any firearm.⁵⁶

Given the unpredictable nature of symptom progression in an individual living with TBI, including the potential for recovery, the role of a MAB in both driver licensing and firearm ownership becomes more critical. For example, many states utilize their MAB to develop a protocol for reinstating the driver's license of an individual living with epilepsy, a disease which can be managed with medication or other interventions. A typical procedure involves the revocation of the driver's license, followed by an appeals process in which the individual must go a set amount of time without a seizure event (3-18 months depending on the state) followed by an individual risk assessment performed by the MAB.⁵⁷ More research is needed to understand TBI as a risk factor for harming oneself or others in order to inform the development of policies and protocols for the revocation or reinstatement for the purposes of driver licenses and firearm ownership.

CURRENT AMA POLICY

The AMA has a multitude of policies regarding firearm violence, mental health and/or driver licensing as listed in the appendix of this report. AMA policy clearly defines firearm violence as a public health threat and aims to limit high-risk individuals from possessing firearms in order to protect themselves and others from morbidity and mortality. Most relevant to this report include AMA policies on "Medical Advisory Boards in Driver Licensing" (H-15.995), "Firearms and High-Risk Individuals" (H-145.972) and "Violence Prevention" (H-145.970).

DISCUSSION

When creating and implementing policy related to TBI, one must acknowledge the non-linear progression of even mild TBI. Many people who suffer a concussion will go on to live complication-free lives after their initial recovery, whereas others may be at risk of cognitive decline decades later. The potential for increased risk, even after long symptom-free periods, need to be balanced with individual dignity, constitutional rights, and physician liability.

With respect to driver licensing, AMA policy is clear, guidance has been published in collaboration with the U.S. Department of Transportation, and physicians are being utilized on MABs in 32 states as of 2015.⁵⁵ With respect to firearm ownership, the AMA supports the establishment of laws, such as ERPOs allowing family members, intimate partners, household members, and law enforcement personnel to petition a court for the removal of a firearm when there is a high or imminent risk for violence.

In CSAPH Report 4-A-18, "The Physician's Role in Firearm Safety," the Council identified those individuals considered to be high-risk of firearm violence to themselves or others and the report supported common-sense laws allowing for the removal of firearms in certain circumstances. In the case of TBI, where there can be a large range of severity, non-linear progression and a lack of conclusive diagnostic testing, a diagnosis alone may not be sufficient to quantify risk of harm to oneself or others.

With the Biden administration signaling an interest in passing a federal ERPO law and increasing pressure on states to pass standardized ERPO laws, opportunities may exist to develop guidance for physicians and courts, similar to the work previously done around driver licensing. The AMA has developed a CME module to prepare physicians to counsel their patients on firearm safety.⁵⁸ The module is designed to assist physicians in recognizing risk factors that

increase the potential for firearm injury and death, identifying barriers to communicating with patients about firearm safety, and effectively communicating with patients to reduce the risk of firearm injury and death.

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 encourages the National Institutes of Health and other funders to expand research on cognitive impairment, including traumatic brain injury (TBI), as a risk factor for harm to self or others that may impact driving and/or firearm ownership, and the role of the physician in policy advocacy and counseling patients so as to decrease the risk of morbidity and mortality.
2. That Policy H-15.995, “Medical Advisory Boards in Driver Licensing,” advocating for state governments to create and maintain medical advisory boards to oversee driver licensing, be reaffirmed.
3. That Policy H-145.972, “Firearms and High-Risk Individuals,” which advocates for ERPO laws and protocols for removing firearms from those deemed to be high-risk in the wake of a petition from concerned parties, be reaffirmed.
4. That Policy H-145.970, “Violence Prevention,” calling upon state and federal government entities to strengthen and promote the use of the NICS background check system, be reaffirmed.
5. That Policy H-145.976, “Firearm Safety Counseling in Physician-Led Health Care Teams,” which protects the right of a physician to counsel a patient and/or their family about the risks of gun ownership and appropriate safety measures, be reaffirmed.

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RELEVANT AMA POLICY

H-470.954, "Reduction of Sports-Related Injury and Concussion"

1. Our AMA will: (a) work with appropriate agencies and organizations to promote awareness of programs to reduce concussion and other sports-related injuries across the lifespan; and (b) promote awareness that even mild cases of traumatic brain injury may have serious and prolonged consequences.
 2. Our AMA supports the adoption of evidence-based, age-specific guidelines on the evaluation and management of concussion in all athletes for use by physicians, other health professionals, and athletic organizations.
 3. Our AMA will work with appropriate state and specialty medical societies to enhance opportunities for continuing education regarding professional guidelines and other clinical resources to enhance the ability of physicians to prevent, diagnose, and manage concussions and other sports-related injuries.
 4. Our AMA urges appropriate agencies and organizations to support research to: (a) assess the short- and long-term cognitive, emotional, behavioral, neurobiological, and neuropathological consequences of concussions and repetitive head impacts over the life span; (b) identify determinants of concussion and other sports-related injuries in pediatric and adult athletes, including how injury thresholds are modified by the number of and time interval between head impacts and concussions; (c) develop and evaluate effective risk reduction measures to prevent or reduce sports-related injuries and concussions and their sequelae across the lifespan; and (d) develop objective biomarkers to improve the identification, management, and prognosis of athletes suffering from concussion to reduce the dependence on self-reporting and inform evidence-based, age-specific guidelines for these patients.
 5. Our AMA supports research into the detection, causes, and prevention of injuries along the continuum from subconcussive head impacts to conditions such as chronic traumatic encephalopathy (CTE).
- CSAPH Rep. 3, A-15; Appended: Res. 905, I-16.

H-25.991, "Alzheimer's Disease"

- Our AMA: (1) encourages physicians to make appropriate use of guidelines for clinical decision making in the diagnosis and treatment of Alzheimer's disease and other dementias;
- (2) encourages physicians to make available information about community resources to facilitate appropriate and timely referral to supportive caregiver services;
 - (3) encourages studies to determine the comparative cost-effectiveness/cost-benefit of assisted in-home care versus nursing home care for patients with Alzheimer's disease and related disorders;
 - (4) encourages studies to determine how best to provide stable funding for the long-term care of patients with Alzheimer's disease and other dementing disorders;
 - (5) supports the use of evidence-based cost-effective technologies with prior consent of patients or designated healthcare power of attorney, as a solution to prevent, identify, and rescue missing patients with Alzheimer's disease and other related dementias with the help of appropriate allied specialty organizations;
 - (6) supports increased awareness of the sex and gender differences in incidence and etiology of Alzheimer's disease and related dementias; and
 - (7) encourages increased enrollment in clinical trials of appropriate patients with Alzheimer's disease and related dementias, and their families, to better identify sex-differences in incidence and progression and to advance a treatment and cure of Alzheimer's disease and related dementias.
- CSA Rep. 6, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Appended: Res. 503, A-16; Appended: Res. 915, I-16.

H-15.954, "Older Driver Safety"

- (1) Our AMA recognizes that the safety of older drivers is a growing public health concern that is best addressed through multi-sector efforts to optimize vehicle design, the driving environment, and the individual's driving capabilities, and:
 - (a) believes that because physicians play an essential role in helping patients slow their rate of functional decline, physicians should increase their awareness of the medical conditions, medications, and functional deficits that may impair an individual's driving performance, and counsel and manage their patients accordingly;

(b) encourages physicians to familiarize themselves with driver assessment and rehabilitation options, refer their patients to such programs whenever appropriate, and defer recommendations on permanent driving cessation until establishing that a patient's driving safety cannot be maintained through medical interventions or driver rehabilitation;

(c) urges physicians to know and adhere to their state's reporting statutes for medically at-risk drivers; and

(d) encourages continued scientific investigation into strategies for the assessment and management of driving safety in the clinical setting.

(2) Our AMA encourages physicians to use the Physician's Guide to Assessing and Counseling Older Drivers as an educational tool to assist them in helping their patients.

CSA Rep. 6, A-03; Reaffirmed: CSAPH Rep. 1, A-13.

Ethics Opinion 8.2, "Impaired Drivers & Their Physicians"

A variety of medical conditions can impair an individual's ability to operate a motor vehicle safely, whether a personal car or boat or a commercial vehicle, such as a bus, train, plane, or commercial vessel. Those who operate a vehicle when impaired by a medical condition pose threats to both public safety and their own well-being. Physicians have unique opportunities to assess the impact of physical and mental conditions on patients' ability to drive safely and have a responsibility to do so in light of their professional obligation to protect public health and safety. In deciding whether or how to intervene when a patient's medical condition may impair driving, physicians must balance dual responsibilities to promote the welfare and confidentiality of the individual patient, and to protect public safety.

Not all physicians are in a position to evaluate the extent or effect of a medical condition on a patient's ability to drive, particularly physicians who treat patients only on a short-term basis. Nor do all physicians necessarily have appropriate training to identify and evaluate physical or mental conditions in relation to the ability to drive. In such situations, it may be advisable to refer a potentially at-risk patient for assessment.

To serve the interests of their patients and the public, within their areas of expertise physicians should:

(a) Assess at-risk patients individually for medical conditions that might adversely affect driving ability, using best professional judgment and keeping in mind that not all physical or mental impairments create an obligation to intervene.

(b) Tactfully but candidly discuss driving risks with the patient and, when appropriate, the family when a medical condition may adversely affect the patient's ability to drive safely. Help the patient (and family) formulate a plan to reduce risks, including options for treatment or therapy if available, changes in driving behavior, or other adjustments.

(c) Recognize that safety standards for those who operate commercial transportation are subject to governmental medical standards and may differ from standards for private licenses.

(d) Be aware of applicable state requirements for reporting to the licensing authority those patients whose impairments may compromise their ability to operate a motor vehicle safely.

(e) Prior to reporting, explain to the patient (and family, as appropriate) that the physician may have an obligation to report a medically at-risk driver:

(i) when the physician identifies a medical condition clearly related to the ability to drive;

(ii) when continuing to drive poses a clear risk to public safety or the patient's own well-being and the patient ignores the physician's advice to discontinue driving; or

(iii) when required by law.

(f) Inform the patient that the determination of inability to drive safely will be made by other authorities, not the physician.

(g) Disclose only the minimum necessary information when reporting a medically at-risk driver, in keeping with ethics guidance on respect for patient privacy and confidentiality.

Issued: 2016

H-15.995, "Medical Advisory Boards in Driver Licensing"

Our AMA (1) endorses the establishment of state motor vehicle department medical advisory boards to improve licensure of vehicle operators and to reduce incidence of injury and death and (2) urges state medical associations to encourage establishment of such boards and to work actively with them.

Res. 2, A-72; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20.

H-160.972, "Physician Representation on State and National Health Care Advisory Bodies"

The AMA urges Congress, and others who select members of state and national health advisory bodies, to increase the proportion of physicians in active clinical practice serving on these bodies, with selected members being recommended by state or national medical associations.

Sub. Res. 110, A-88; Reaffirmed: Sunset Report, I-98. Reaffirmed: BOT Rep. 23, A-09; Reaffirmed: BOT Rep. 09, A-19

H-145.975, "Firearm Safety and Research, Reduction in Firearm Violence, and Enhancing Access to Mental Health Care"

1. Our AMA supports: a) federal and state research on firearm-related injuries and deaths; b) increased funding for and the use of state and national firearms injury databases, including the expansion of the National Violent Death Reporting System to all 50 states and U.S. territories, to inform state and federal health policy; c) encouraging physicians to access evidence-based data regarding firearm safety to educate and counsel patients about firearm safety; d) the rights of physicians to have free and open communication with their patients regarding firearm safety and the use of gun locks in their homes; e) encouraging local projects to facilitate the low-cost distribution of gun locks in homes; f) encouraging physicians to become involved in local firearm safety classes as a means of promoting injury prevention and the public health; and g) encouraging CME providers to consider, as

appropriate, inclusion of presentations about the prevention of gun violence in national, state, and local continuing medical education programs.

2. Our AMA supports initiatives to enhance access to mental and cognitive health care, with greater focus on the diagnosis and management of mental illness and concurrent substance use disorders, and work with state and specialty medical societies and other interested stakeholders to identify and develop standardized approaches to mental health assessment for potential violent behavior.

3. Our AMA (a) recognizes the role of firearms in suicides, (b) encourages the development of curricula and training for physicians with a focus on suicide risk assessment and prevention as well as lethal means safety counseling, and (c) encourages physicians, as a part of their suicide prevention strategy, to discuss lethal means safety and work with families to reduce access to lethal means of suicide.

Sub. Res. 221, A-13; Appended: Res. 416, A-14; Reaffirmed: Res. 426, A-16; Reaffirmed: BOT Rep. 28, A-18; Reaffirmation: A-18; Modified: CSAPH Rep. 04, A-18; Reaffirmation: I-18

D-145.995, “Gun Violence as a Public Health Crisis”

Our AMA: (1) will immediately make a public statement that gun violence represents a public health crisis which requires a comprehensive public health response and solution; and

(2) will actively lobby Congress to lift the gun violence research ban.

Res. 1011, A-16; Reaffirmation: A-18; Reaffirmation: I-18.

H-145.996, “Firearm Availability”

1. Our AMA: (a) advocates a waiting period and background check for all firearm purchasers; (b) encourages legislation that enforces a waiting period and background check for all firearm purchasers; and (c) urges legislation to prohibit the manufacture, sale or import of lethal and non-lethal guns made of plastic, ceramics, or other non-metallic materials that cannot be detected by airport and weapon detection devices.

2. Our AMA supports requiring the licensing/permitting of firearms-owners and purchasers, including the completion of a required safety course, and registration of all firearms.

3. Our AMA supports “gun violence restraining orders” for individuals arrested or convicted of domestic violence or stalking, and supports extreme risk protection orders, commonly known as “red-flag” laws, for individuals who have demonstrated significant signs of potential violence. In supporting restraining orders and “red-flag” laws, we also support the importance of due process so that individuals can petition for their rights to be restored.

Res. 140, I-87; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Modified: BOT Rep. 12, A-16; Appended: Res. 433, A-18; Reaffirmation: I-18; Modified: BOT Rep. 11, I-18

H-145.999, “Gun Regulation”

Our AMA supports stricter enforcement of present federal and state gun legislation and the imposition of mandated penalties by the judiciary for crimes committed with the use of a firearm, including the illegal possession of a firearm.

Sub. Res. 31, I-81; Reaffirmed: CLRPD Rep. F, I-91; Amended: BOT Rep. I-93-50; Reaffirmed: Res. 409, A-00; Reaffirmation A-07; Reaffirmed: BOT Rep. 22, A-17; Modified: Res. 401, A-17; Reaffirmation: I-18.

H-145.972, “Firearms and High-Risk Individuals”

Our AMA supports: (1) the establishment of laws allowing family members, intimate partners, household members, and law enforcement personnel to petition a court for the removal of a firearm when there is a high or imminent risk for violence; (2) prohibiting persons who are under domestic violence restraining orders, convicted of misdemeanor domestic violence crimes or stalking, from possessing or purchasing firearms; (3) expanding domestic violence restraining orders to include dating partners; (4) requiring states to have protocols or processes in place for requiring the removal of firearms by prohibited persons; (5) requiring domestic violence restraining orders and gun violence restraining orders to be entered into the National Instant Criminal Background Check System; and (6) efforts to ensure the public is aware of the existence of laws that allow for the removal of firearms from high-risk individuals.

CSAPH Rep. 04, A-18; Reaffirmed: BOT Rep. 11, I-18.

H-145.991, “Waiting Periods for Firearm Purchases”

The AMA supports using its influence in matters of health to effect passage of legislation in the Congress of the U.S. mandating a national waiting period that allows for a police background and positive identification check for anyone who wants to purchase a handgun from a gun dealer anywhere in our country.

Sub. Res. 34, I-89; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-07; Reaffirmed: BOT Rep. 22, A-17; Modified: Res. 401, A-17; Reaffirmation: A-18; Reaffirmation: I-18

H-145.970, “Violence Prevention”

Our AMA: (1) encourages the enactment of state laws requiring the reporting of all classes of prohibited individuals, as defined by state and federal law, to the National Instant Criminal Background Check System (NICS); (2) supports federal funding to provide grants to states to improve NICS reporting; and (3) encourages states to automate the reporting of relevant information to NICS to improve the quality and timeliness of the data.

H-145.976, “Firearm Safety Counseling in Physician-Led Health Care Teams”

1. Our AMA: (a) will oppose any restrictions on physicians’ and other members of the physician-led health care team’s ability to inquire and talk about firearm safety issues and risks with their patients; (b) will oppose any law restricting physicians’ and other members of the physician-led health care team’s discussions with patients and their families about firearms as an intrusion into medical privacy; and (c) encourages dissemination of educational materials related to firearm safety to be used in undergraduate medical education.

2. Our AMA will work with appropriate stakeholders to develop state-specific guidance for physicians on how to counsel patients to reduce their risk for firearm-related injury or death, including guidance on when and how to ask sensitive questions about firearm ownership, access, and use, and clarification on the circumstances under which physicians are permitted or may be required to disclose the content of such conversations to family members, law enforcement, or other third parties.

Res. 219, I-11; Reaffirmation A-13; Modified: Res. 903, I-13; Appended: Res. 419, A-17; Reaffirmed: CSAPH Rep. 04, A-18.

H-145.971, “Development and Implementation of Recommendations for Responsible Media Coverage of Mass Shootings”

Our AMA encourages the Centers for Disease Control and Prevention, in collaboration with other public and private organizations, to develop recommendations and/or best practices for media coverage of mass shootings, including informed discussion of the limited data on the relationship between mental illness and gun violence, recognizing the potential for exacerbating stigma against individuals with mental illness.

Res. 212, I-18; Modified: Res. 934, I-19.

4. PHARMACOVIGILANCE (Resolution 518-A-19)

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 518-A-19
REMAINDER OF REPORT FILED
*See Policy TBD***

INTRODUCTION

Resolution 518-A-19, “Chemical Variability in Pharmaceutical Products,” introduced by the American College of Cardiology and referred by the House of Delegates (HOD) asked:

That our American Medical Association (AMA) do a study and report back by the 2019 Interim Meeting regarding the pharmaceutical variability, both in active pharmaceutical ingredient and dissolution, the impact on patient care and make recommendations for action from their report findings; that our AMA advocate for legislation requiring independent testing and verification of the chemical content of batches of pharmaceuticals; and that our AMA advocate for the logging of batches at the patient level, so the batches can be traced and connected to patient outcomes or adverse events.

In addition, two resolutions were introduced and debated at I-19 on the topic of pharmaceutical production and quality. At both A-19 and I-19, there was confusion about several concepts detailed in the resolutions and the concept of pharmacovigilance (PV) in general. Your Council on Science and Public Health (CSAPH) noted that there are several issues related to PV, track and trace, and testing and verification of pharmaceuticals that could benefit from further study. This report summarizes and explains the current state of PV for medications taken by patients in the United States; describes the role of the U.S. Food and Drug Administration (FDA) in PV; explains Drug Supply Chain and Security Act (DSCSA, also called “track and trace”) and its implementation; clarifies testing and verification procedures for medications; comments on issues associated with the pharmaceutical supply chain related to medication safety and quality; and provides recommendations related to PV policy. Additionally, CSAPH acknowledges the delay in this report due to the COVID-19 public health emergency and shifting of priorities for Council staff. This report from the Council also includes new developments related to pharmaceutical quality that have arisen during the COVID-19 public health emergency.

METHODS

English-language articles were selected from a search of the PubMed database through August 2021 using the search terms “pharmacovigilance,” “pharmaceutical/drug quality,” and “pharmaceutical/drug impurities.” Additional articles

were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society and international, national, and local government agency websites were conducted to identify clinical guidelines, position statements, and reports.

BACKGROUND

PV is defined by the World Health Organization (WHO) as comprising the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects and other drug-related problems.¹ PV is described as a systematic process involving the collection of information about the nature, severity, clinical characteristics, and outcomes of adverse effects of medicinal products; documentation and analysis of the collected adverse-effects data to detect a causal link between the medicinal product and adverse effect; remedial actions to eliminate (or minimize) hazards posed by adverse effects of medicinal products, and continued monitoring of the impact of any such remedial actions.² The field of PV has undergone rapid growth over the last two decades.³

Various medicinal product-related safety issues not attributable to the pharmacologic properties of the product are also a part of PV. Safety issues include dosage form problems such as contamination, physical defects, abnormal odor or taste; product packaging issues such as broken seals, leaking bottles, and incorrect fill amount; labeling problems such as missing labels, missing lot numbers, and missing expiration dates; and counterfeit medicines. Upon learning about issues, regulatory authorities ask manufacturers to take remedial actions, for example, product recalls. This report addresses many aspects of adverse events and the tracking of those, but also drug product supply chains and recent and ongoing efforts to improve the tracking of medicinal product production, distribution, shipping, and location.

Terminology

PV is a growing field and mounting concern in healthcare, which aims to enhance patient care and patient safety in relation to the use of medicines. However, often in healthcare, the terms including adverse event, adverse drug reaction, and side effect are used interchangeably. Experts note that standardization of medication-safety-related terminology is an important goal of PV. With that in mind, the following terms are provided for clarity:^{4,5}

Adverse event (AE). All undesirable events occurring after the use of a medicinal product that may not necessarily be ascribed to the product are AEs.

Adverse drug reaction (ADR). A response to a drug which is noxious and unintended, and which occurs at doses normally used for the prophylaxis, diagnosis, or therapy of disease, or used for modifications of physiological function, is an ADR.

AEs or ADRs are considered unexpected if it is not consistent with applicable product information or characteristics of the drug. Serious AEs or ADRs are untoward medical occurrences that at any dose results in death, are life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, and/or results in persistent of significant disability or incapacity.

Side effect. An unintended effect, regardless of dosage, that occurs related to the pharmacological properties of a medication, is considered a side effect; side effects are not necessarily adverse and are often foreseen.

PHARMACOVIGILANCE AT THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA has several offices dedicated to drug quality, surveillance, and epidemiology. The aim of FDA PV processes is to collect information about various broad aspects of medicinal product safety. These aspects are listed in the FDA's guidance document on good PV practices.⁶ Specifically, the document provides guidance on safety signal identification, pharmacoepidemiologic assessment and safety signal interpretation, and PV plan development. The FDA also hosts an informational website that provides and outlines resources related to pharmaceutical quality.⁷

FDA Office of Surveillance and Epidemiology (OSE)

The FDA's Office of Surveillance and Epidemiology (OSE) monitors and evaluates the safety profiles of drugs using a variety of tools and disciplines throughout the life cycle of the drugs.⁸ OSE has four core functions:

pharmacovigilance; pharmacoepidemiology; medication error prevention and analysis; and risk management. The Office operates across multiple disciplines to review and assess the safety of medicines and maintains a system of postmarketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug development process. OSE evaluates more than 1.5 million adverse event reports (AERs) submitted every year to the FDA's MedWatch program,⁹ part of the FDA Adverse Event Reporting System (FAERS)^{10,11} or Safety Reporting Portal (SRP).¹²

OSE is part of the Center for Drug Evaluation and Research (CDER) and houses the Office of Pharmacovigilance and Epidemiology (OPE) as well as the Office of Medication Error Prevention and Risk Management. OPE's Division of PV (DPV) evaluates the safety of drug and therapeutic biologic products, engages in monitoring/surveillance, analyzes safety signals, recommends regulatory actions, and communicates relevant safety information. OPE and DPV recognize that pre-approval clinical trials of drugs have limitations and that the pharmaceutical industry and the FDA must rely on postmarket surveillance and AE reports to monitor medications and monitor for safety signals. OSE and its office and divisions are responsible for:

- Postmarketing safety surveillance for all marketed drug and therapeutic biologic products;
- Conducting active drug safety surveillance;
- Reviewing drug safety-related epidemiologic study protocols and study reports;
- Ensuring that the postmarketing requirements conducted by sponsors meet the best practices in epidemiology and can provide robust and actionable evidence to inform regulatory decision making following initial approval;
- Procuring, managing, and analyzing pharmaceutical sales and health care data to describe and characterize drug utilization levels and treatment patterns in the United States;
- Working with drug companies to reduce medication errors related to confusing labels, labeling, drug packaging, and drug names that look alike or sound alike; and
- Providing risk management expertise on development and implementation of programs and initiatives to support policies related to Risk Evaluation and Mitigation Strategies (REMS).

In May 2021, OSE issued its first annual report highlighting the key OSE initiatives to detect, assess, prevent, and monitor the risks of medicines, with a special focus on its efforts to respond to the COVID-19 pandemic.¹³

FDA Office of Pharmaceutical Quality (OPQ)

FDA's CDER also houses the Office of Pharmaceutical Quality (OPQ) which works to assure that quality medicines are available for the American public.¹⁴ OPQ integrates assessment, inspection, surveillance, policy, and research activities to strengthen pharmaceutical quality on a global scale. OPQ oversees the quality of marketed drugs over the entire drug lifecycle and monitors the state of quality for all regulated manufacturing sites and drug products by establishing quality standards, including current good manufacturing practices (cGMP); identifying quality problems which require corrective action; and encouraging the adoption of emerging technologies to enhance pharmaceutical quality. OPQ works closely with other FDA offices if enforcement decisions need to be made and strives to balance potential quality risks with the risk of a patient not getting a needed medication. It also attempts to anticipate quality problems before they develop so as to help prevent drug shortages.

The OPQ 2019 annual report described activities in 2019 and over the office's five-year life, including efforts in drug assessment, inspection, surveillance, policy, and research. The report also detailed the number of additional FDA staff hired to work on pharmaceutical quality.¹⁵ The 2020 annual report on the state of pharmaceutical quality contains select quality indicators and trends that provide insight into the quality of the U.S. drug supply chain and includes an analysis of the impact of the COVID-19 public health emergency on the pharmaceutical supply chain and on the quality of drugs.¹⁶

Facility Inspections

A U.S. Government Accountability Office (GAO) report from December 2019, *Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections*, noted that more than 60 percent of drug manufacturers for the United States market are located overseas. The FDA inspects foreign and domestic drug manufacturers to ensure drug safety and effectiveness; however, the number of inspections of foreign drug manufacturers has declined since FY 2016 and most foreign inspections are preannounced. The report notes concerns about FDA's ability to oversee the global supply chain.¹⁷

In March 2020, at the beginning of the COVID-19 public health emergency, the FDA made the decision to pause most foreign and domestic facility inspections, with the exception of mission-critical inspection work. This decision was made in response to federal guidelines to mitigate the spread of the COVID-19 virus. The Agency relied on alternative tools such as inspection reports from foreign regulators, records requests, and product sampling to complement its oversight activities.

The FDA acknowledges that the pandemic had an impact on inspection work in a report titled “Resiliency Roadmap for FDA Inspectional Oversight,” which outlines the effect of the public health emergency on inspection activities and the detailed plan for inspections and operations moving forward. The report notes that a significant backlog of both domestic and international inspections that are likely to persist through much of the next calendar year.¹⁸

FDA Drug Quality Sampling and Testing Programs

FDA Drug Quality Sampling and Testing Programs help assure that only safe and effective drugs are sold.¹⁹ The FDA tests drugs in FDA laboratories and through research contracts and grants. This includes active pharmaceutical ingredients (API) used to make the product and the finished drug product sold to consumers. FDA tests drugs using the same standards that are part of the drug approval process for identity, strength, purity, and bioavailability, which is also used to establish bioequivalence. Although some research has indicated batch-to-batch variability,²⁰ FDA offices and labs evaluate these issues and take corrective action as necessary, including recalls.²¹

DRUG SUPPLY CHAIN

Of note when discussing the topic of PV is overall pharmaceutical supply chain issues. Because of the way API are distributed in the supply chain, one source of contaminated API can impact multiple products from multiple manufacturers. At times, because of a lack of transparency in the supply chain, it is difficult and time-consuming to determine all links in the supply chain.

Recently, considerable attention has been focused on supply chain resilience. In 2021, the FDA published several guidance documents related to supply chain security,²² the White House released a report on policies to support the creation of resilient supply chains,^{23,24} and The Duke-Margolis Center for Health Policy and the COVID Collaborative released a new white paper on challenges and potential solutions for resilient drug supply chains that complements the White House report.²⁵ All of these publications include aspects of AMA policy regarding drug shortage including calls for increased transparency, global cooperation, resiliency and redundancy in manufacturing capability, and the creation of a quality rating system. While advanced manufacturing, including continuous manufacturing,²⁶ is an important component to drug quality, the specifics regarding implications and implementation of advanced manufacturing are outside of the scope of this report.

Additionally, a recent report from the National Academies of Sciences, Engineering, and Medicine, *Stronger Food and Drug Regulatory Systems Abroad*, recommends strategies and a framework that regulatory agencies worldwide can adopt to support the availability of good quality, safe food and medicines globally and to identify areas of greatest risk. The report also recommends ways that U.S. government agencies, international development donors, and the WHO can strengthen the capacity of food and drug regulators, particularly those in low- and middle-income countries. Such investments should prioritize the expansion of WHO’s approval and quality control processes for priority medicines and vaccines; the development of tools for rapidly screening food and drug quality; and improving the evaluation of how well regulatory agencies are performing.²⁷

PHARMACEUTICAL IMPURITIES

The FDA, the International Conference on Harmonization (ICH), and the United States Pharmacopeia (USP) define an impurity as “any component of a drug substance that is not the chemical entity defined as the drug substance and in addition, for a drug product, any component that is not a formulation ingredient.”²⁸⁻³⁰ Impurities in a drug substance (i.e., an API) or a drug product that can arise due to synthetic/manufacturing processes (process-related impurities [PRIs]) and degradation (degradation-related impurities [DRIs]), or due to factors such as storage conditions, containers, excipients, or contamination. In addition, impurities can be categorized as identified or unidentified, volatile or nonvolatile, or organic or inorganic species. Figure 1 provides a flowchart that details the categories of impurities.³¹

Nitrosamine Impurities

Unacceptable levels of nitrosamine impurities in some batches of the angiotensin II receptor blocker (ARB) valsartan were first detected in 2018. Subsequently, impurities were found in other ARBs, as well as unrelated drugs, including ranitidine, nizatidine, metformin, varenicline, rifampin and rifapentine.³²⁻³⁴

Nitrosamines are a group of chemical compounds, some of which can pose a risk to patients and public health due to their mutagenic properties. They are well known to be present in foods, such as smoked or grilled meats and fish, and they are also present in mainstream and sidestream air from combusted tobacco in cigarettes, cigars and pipes. Nitrosamines or their precursors can also be present in a wide variety of manufactured and natural products. Nitrosamines generally are not intentionally added to foods or consumer products but are formed from constituents of the foods or products that are either naturally present or added during production. When they are metabolized, nitrosamines are converted to alkylating agents. Some of these are known to damage DNA and have been linked to an increased risk of cancer if a patient is exposed to unacceptable levels of the impurity for an extended period of time.³⁵

FDA testing found the levels of the nitrosamine N-nitrosodimethylamine (NDMA) increased under normal storage conditions and increase in samples stored at higher temperatures. FDA testing also determined that levels of NDMA present in drugs is similar to levels a person is exposed to through consuming grilled meats. The Agency has established “interim limits” for three nitrosamine compounds: NDMA, NDEA and NMBA.³⁶ The FDA also noted that the identification of nitrosamine impurities in tested drug samples may not reflect an emerging regulatory problem, but is an evolution of scientific methods that are capable of detecting the impurities at significantly lower levels than in the past.³⁷

In numerous updates, the FDA notes that they continue to work with manufacturers to investigate the source of nitrosamines in drug products and whether they are at a level that may pose risks to human health. The FDA and manufacturers are testing samples of certain medications that may contain nitrosamines and will continue to take rapid and appropriate action when needed.^{36,38-40} Additionally, the FDA held a public workshop on nitrosamine impurities to educate about nitrosamine chemistry and toxicology, on the finding of nitrosamines as impurities in drugs, data gaps and research needs to address uncertainties in nitrosamine safety assessment, and about how to prevent or minimize their presence in drugs, as well as to provide a forum for an open discussion of questions.⁴¹

Manufacturers are held responsible for understanding their manufacturing processes and following cGMP, which includes identifying and preventing the presence of unacceptable impurities. This involves developing new predictive approaches, along with using suitable methods to detect and control these impurities as well as others that may arise when making changes to manufacturing processes. The FDA issued and then revised an immediately-in-effect Guidance for Industry on the *Control of Nitrosamine Impurities in Human Drugs* which describes steps manufacturers of active pharmaceutical ingredients and drug products should take to detect and prevent objectionable levels of nitrosamine impurities in pharmaceutical products. The Guidance also describes conditions that may introduce nitrosamine impurities. Material in the Guidance is consistent with recommendations from the ICH on the assessment and control of mutagenic impurities.⁴² USP has also provided information on the topic and has developed a new general chapter to provide information useful for ensuring the appropriate control of nitrosamine impurities in drug substances which becomes official on Dec 1, 2021.⁴³⁻⁴⁵

POSTMARKET SURVEILLANCE

The FDA outlines risk-based best practices for conducting ongoing postmarket safety surveillance activities for drugs and biological products in the document, “Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff,” which was required under a provision of the 21st Century Cures Act.⁴⁶ The document includes considerations that inform the frequency and extent of systematic drug and biologic safety monitoring; considerations based on specific product types and patient populations; safety signal identification based on screening and data mining of the FDA’s AE reporting system and other data sources, including general practices for the frequency and extent of screening these data sources, as well as prioritizing identified signals; a multidisciplinary, comprehensive evaluation of the identified safety signal that integrates the cumulative data gathered from all available sources; an assessment of the causal association between the identified AE and the product; and an overview of regulatory and other actions that can be taken in response to identified safety signals.

Adverse Event Reporting

Regulatory authorities are interested in receiving reports of serious and unexpected AEs and ADRs on an urgent and priority basis.⁴⁷ All reporting by physicians is voluntary and also strongly recommended; the FDA gives extra credence to physician reports. The Safety Reporting Portal (SRP)¹² streamlines the process of reporting product safety issues to the FDA and the NIH, formerly done through FAERS^{10,11} and MedWatch⁹ Online Voluntary Reporting Form. The SRP can be used by manufacturers, health care professionals, researchers, public health officials, and patients.⁴⁸

DRUG SUPPLY CHAIN AND SECURITY ACT

The Drug Supply Chain and Security Act (DSCSA) also called “track and trace,” enacted as part of the Drug Quality and Security Act of 2013, includes extensive requirements related to supply chain participants and regulated products. The law outlines the steps manufacturers, repackagers, wholesale distributors, dispensers (i.e., pharmacies), and third-party logistics providers need to take to develop an electronic, interoperable system that tracks a drug at the unit-level throughout the drug supply chain.⁴⁹⁻⁵¹ For the tracking component, each supply chain entity should be able to see a valid chain of custody for any product. The tracking component will allow FDA the ability to follow the chain of custody of a product back to its point of origin.

DSCSA includes provisions on product identification and verification, data sharing, detection and response to suspect any illegitimate products, recordkeeping, and unified licensure standards for wholesale distributors and third-party logistics providers. The schedule of milestones has been broken down into three phases:

- Phase 1: Lot-level traceability and verification of products and transactions (2015)
- Phase 2: Drug product serialization and enhanced verification of serialized products (2017-2020)
- Phase 3: Unit-level traceability (2023)

Requirements for Phase 1 are thus already in effect. In January 2015, the FDA expected dispensers to have established a system for verification and handling of suspect or illegitimate products, and to confirm that trading partners (i.e., manufacturers, wholesale distributors) are appropriately registered or licensed with the FDA or the appropriate state authority. As of March 2016, the FDA began enforcing the requirement. In addition, dispensers must maintain such information for no less than 6 years after the date of the transaction. Currently with a product transaction, the ability to track and trace the product down to the lot level is possible.

By 2023, electronic package-level tracing information using a product identifier will be required. A recent presentation from FDA’s CDER provided updates on implementation of these security requirements for enhanced drug distribution security.⁵² The stated goals are to implement interoperable, electronic tracing of products at the package level by 2023 that will enable secure tracing of products at the package level; use product identifiers to verify products at the package level; enable prompt response to suspect and illegitimate products when found; and improve efficiency of recalls. National standards for licensure for wholesale distributors and third-party logistics providers will be established by 2023 as well.

Additionally, four guidance documents describing key details of how the FDA plans to secure the pharmaceutical supply chain were recently released. The documents relate to various aspects of the “track and trace” system.⁵³ *Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act* provides recommendations on the system attributes necessary for enabling the secure tracing of drug product at the package level, defined as the smallest individual salable unit of drug product for distribution by a manufacturer or repackager.⁵⁴ *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry* lays out the FDA’s current understanding of terms used to define “suspect” and “illegitimate” products.⁵⁵ *Product Identifiers under the Drug Supply Chain Security Act - Questions and Answers* clarifies information for industry.⁵⁶ *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry* is intended to aid certain trading partners in identifying a suspect product and specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain.⁵⁷

CURRENT AMA POLICY

AMA has several policies on the topic of PV (see appendix for full text). AMA Policy H-100.946, “Source and Quality of Medications Critical to National Health and Security,” supports studies of United States dependency on foreign components, legislative and regulatory initiatives to ensure proper domestic capacity, production, and quality of pharmaceuticals, and encourages the development and enforcement of standards that make the sources of pharmaceuticals and their chemical substrates used in the United States transparent to prescribers and the general public. Policy H-100.969, “Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals,” addresses the safety and quality of foreign manufactured pharmaceuticals and supports inspection of all products entering the United States and surveillance inspections of foreign manufacturers. Policy D-100.977, “Pharmaceutical Quality Control for Foreign Medications,” advocates that the Congress and the FDA use their authorities to ensure safe imported drugs. Policy H-100.995, “Support of American Drug Industry,” supports pharmaceutical manufacturing industry efforts to develop and market pharmaceutical products meeting proper standards of safety and efficacy. Policy D-125.987, “Biosimilar Product Naming and Labeling,” supports appropriate PV for biosimilar products.

Policies D-100.988, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals,” H-100.966, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals,” and D-100.985, “Federal Regulation and Computerized Tracking of Pharmaceuticals During Shipping and Handling from Manufacture Until Ultimately Received by Patient,” support pharmaceutical tracking systems, identification and eradication of illegal activities in the pharmaceutical industry and punishment of pharmaceutical counterfeiters. Policy H-120.958, “Supporting Safe Medical Products as a Priority Public Health Initiative,” supports reporting of adverse events; a coding system for prescription medicine packaging to improve patient safety; and the need for public health infrastructure and local consortiums to work on problems related to medical product safety.

Policy H-100.956, “National Drug Shortages,” notes several relevant themes including: supporting the improvement of manufacturing quality systems; requiring drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible; urging the development of a comprehensive independent report on the root causes of drug shortages, which includes the number of manufacturers, economic factors and contracting practices; and urging the FDA to require manufacturers to provide greater transparency regarding production locations of drugs and to provide more detailed information regarding the causes and anticipated duration of drug shortages.

CONCLUSION

The originally referred resolution that initiated this report was in response to the recalls of multiple drug products because of impurities present in the medications. These impurities were identified by the FDA and partner testing. The FDA subsequently informed the public about the problem, continues to investigate the issue, and continues to take corrective action. The source of detected impurities is linked to manufacturing issues and subsequent inspections revealed systemic problems of supervision that could have created the conditions for quality issues to arise; corrective action is underway. Importantly, FDA procedures identified the issue.

PV is a continuous process requiring active participation and combined efforts from physicians, other authorized prescribers, the pharmaceutical industry, government regulators, public health officials, clinicians, and health care organizations. Informed participation by all in PV processes is necessary to continually improve drug product safety, maintain drug supply chain integrity, and to identify safety signals. The AMA already has significant, relevant, and well-written policy related to PV and drug quality. Therefore, your Council recommends updating two outdated policies and reaffirmation of several existing policies.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 518-A-19 and the remainder of the report be filed:

1. That Policy D-100.988, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals” be amended by addition and deletion to read as follows:

Our AMA will support the Food and Drug Administration’s efforts to evaluate and facilitate implementation of effective tracking systems for pharmaceuticals, including all outlined implementation phases of the Drug Supply Chain and Security Act (DSCSA, Public Law 113-54) also called “track and trace,” which contains extensive requirements and provisions related to supply chain participants and regulated products.

2. That Policy H-120.958, “Supporting Safe Medical Products as a Priority Public Health Initiative” be amended by addition and deletion to read as follows:

Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt methodology to help prevent “look alike-sound alike” errors in giving new drugs generic names;

(2) continue participation in ~~the National Patient Safety Foundation’s~~ efforts to advance the science of safety in the medication use process, including and likewise work with the National Coordinating Council for Medication Error Reporting and Prevention;

(3) support the FDA’s Medwatch program by working to improve physicians’ and pharmacists’ knowledge and awareness of the program and encouraging proper reporting of adverse events;

(4) vigorously work to support the Drug Supply Chain and Security Act (DSCSA, Public Law 113-54), including provisions on product identification and verification, data sharing, detection and response, and encourage efforts to create and expeditiously implement a national machine-readable coding system for prescription medicine packaging in an effort to improve patient safety;

(5) participate in and report on the work of the Healthy People ~~2010~~ 2030 initiative in the area of safe medical products especially as it relates to existing AMA policy; and

(6) seek opportunities to work collaboratively within the Medicine-Public Health initiative (H-440.991), with pharmacy associations, and with the Food and Drug Administration (FDA), National Institutes of Health (NIH), United States Pharmacopoeia (USP) and Centers for Disease Control and Prevention (CDC) the Agency for ~~Health Care Policy and Research (AHCPR)~~ Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) to provide information to individual physicians, pharmacists, other clinicians, and state medical societies on the need for public health infrastructure and local consortiums to work on problems related to medical product safety.

3. That Policy D-100.977, “Pharmaceutical Quality Control for Foreign Medications,” that calls upon Congress to provide the FDA with the necessary authority and resources to ensure that imported drugs are safe for American consumers and patients, be reaffirmed.
4. That Policy D-100.985, “Federal Regulation and Computerized Tracking of Pharmaceuticals During Shipping and Handling from Manufacture Until Ultimately Received by Patient,” opposing illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting, be reaffirmed.
5. That Policy D-100.988, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals,” supporting the FDA’s efforts to evaluate and facilitate implementation of effective tracking systems for pharmaceuticals, be reaffirmed.
6. That Policy H-100.946, “Source and Quality of Medications Critical to National Health and Security,” supporting legislative and regulatory initiatives that help to ensure proper domestic capacity, production and quality of pharmaceutical and chemical substrates as a matter of public well-being and national security and encouraging the development and enforcement of standards that make the sources of pharmaceuticals and their chemical substrates used in the United States of America transparent to prescribers and the general public, be reaffirmed.

7. That Policy H-100.969, “Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals,” supporting the inspection of all foreign manufacturers of pharmaceutical chemicals and products which are exported to the United States to assure compliance with U.S. standards, be reaffirmed.
8. That Policy H-100.995, “Support of American Drug Industry,” supporting the American pharmaceutical manufacturing industry in its efforts to develop and market pharmaceutical products meeting proper standards of safety and efficacy for the benefit of the American people, be reaffirmed.

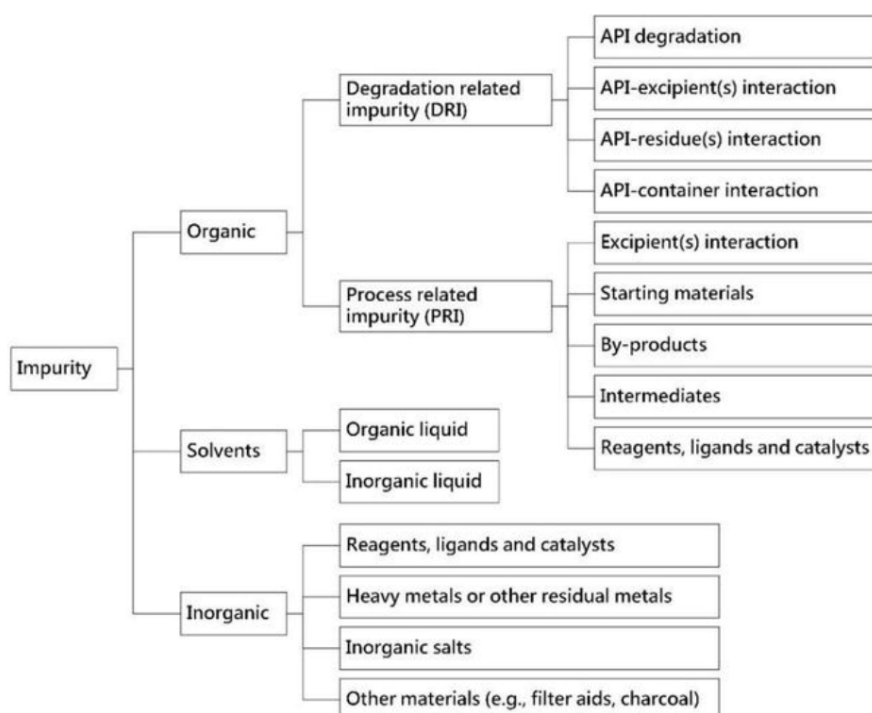
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Figure 1. Categorization of impurities from FDA and USP (figure from ³¹).



APPENDIX: AMA Policies Related Pharmacovigilance

D-100.977, “Pharmaceutical Quality Control for Foreign Medications”

Our AMA will call upon Congress to provide the US Food and Drug Administration with the necessary authority and resources to ensure that imported drugs are safe for American consumers and patients. Res. 508, A-08

D-100.985, “Federal Regulation and Computerized Tracking of Pharmaceuticals During Shipping and Handling from Manufacture Until Ultimately Received by Patient”

Our AMA will: (1) continue to actively oppose illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting; and (2) work with the Congress, the Food and Drug Administration, the Drug Enforcement Administration, and other federal agencies, the pharmaceutical industry, and other stakeholders to ensure that these illegal activities are minimized. Res. 501, A-04; Reaffirmation I-06; Reaffirmed: BOT Rep. 06, A-16; Reaffirmed: CMS Rep. 01, I-18

D-100.988, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals”

Our AMA will support the Food and Drug Administration’s efforts to evaluate and facilitate implementation of effective tracking systems for pharmaceuticals. Res. 924, I-03 Reaffirmation I-06 Reaffirmed: BOT Rep. 06, A-16

D-125.987, “Biosimilar Product Naming and Labeling”

Our AMA urges the FDA to finalize Guidance on the naming and labeling conventions to be used for biosimilar products, including those that are deemed interchangeable. Any change in current nomenclature rules or standards should be informed by a better and more complete understanding of how such changes, including requiring a unique identifier for biologic USANs would impact prescriber attitudes and patient access, and affect post marketing surveillance. Actions that solely enhance product identification during surveillance but act as barriers to clinical uptake are counterproductive. However, because of unique product attributes, a relatively simple way to identify and track which biosimilar products have been dispensed to individual patients must be established. If unique identifiers for biosimilar USANs are required to support pharmacovigilance, they should be simple and the resulting names should reinforce similarities by using the same root name following standards for nonproprietary names established by the USAN Council. CSAPH Rep. 4, A-14

H-100.946, “Source and Quality of Medications Critical to National Health and Security”

Our AMA: (1) supports studies that identify the extent to which the United States is dependent on foreign supplied pharmaceuticals and chemical substrates; (2) supports legislative and regulatory initiatives that help to ensure proper domestic capacity, production and quality of pharmaceutical and chemical substrates as a matter of public well-being and national security; and (3) encourages the development and enforcement of standards that make the sources of pharmaceuticals and their chemical substrates used in the United States of America transparent to prescribers and the general public. Res. 932, I-19

H-100.956, “National Drug Shortages”

1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients. 2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion. 3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage. 4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant. 5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages. 6. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The federal Centers for Medicare & Medicaid Services (CMS) should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages. 7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons. 8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer’s purchase history. 9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs. 10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages. 11. Our AMA urges the FDA to require manufacturers to provide greater transparency regarding production locations of drugs and provide more detailed information regarding the causes and anticipated duration of drug

shortages. 12. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes. 13. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities. 14. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan. CSAPH Rep. 2, I-11; Modified: CSAPH Rep. 7, A-12; Modified: CSAPH Rep. 2, I-12; Modified: CSAPH Rep. 8, A-13; Modified in lieu of Res. 912, I-13; Modified: CSAPH Rep. 3, A-14; Modified: CSAPH Rep. 2, I-15; Appended: CSAPH Rep. 04, I-17; Modified: CSAPH Rep. 02, A-18

H-100.966, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals”

Our AMA supports legislation making the production and distribution of counterfeit pharmaceuticals a felony. Res. 924, I-03; Reaffirmation I-06; Reaffirmed: BOT Rep. 06, A-16

H-100.969, “Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals”

Our AMA supports: (1) the inspection of all foreign manufacturers of pharmaceutical chemicals and products which are exported to the United States to assure compliance with U.S. standards; and (2) periodic surveillance inspections of all foreign pharmaceutical manufacturers with timely follow-up inspection of all foreign manufacturers that have been identified as having serious manufacturing deficiencies. Res. 512, A-99 Reaffirmation I-06 Reaffirmation A-08 Reaffirmed: Res. 508, A-08 Reaffirmation A-09

H-100.995, “Support of American Drug Industry”

Our AMA continues to support the American pharmaceutical manufacturing industry in its efforts to develop and market pharmaceutical products meeting proper standards of safety and efficacy for the benefit of the American people. Sub. Res. 20, A-74; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10

H-120.958, “Supporting Safe Medical Products as a Priority Public Health Initiative”

Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt methodology to help prevent “look alike-sound alike” errors in giving new drugs generic names; (2) continue participation in the National Patient Safety Foundation’s efforts to advance the science of safety in the medication use process and likewise work with the National Coordinating Council for Medication Error Reporting and Prevention; (3) support the FDA’s Medwatch program by working to improve physicians’ knowledge and awareness of the program and encouraging proper reporting of adverse events; (4) vigorously work to support and encourage efforts to create and expeditiously implement a national machine-readable coding system for prescription medicine packaging in an effort to improve patient safety; (5) participate in and report on the work of the Healthy People 2010 initiative in the area of safe medical products especially as it relates to existing AMA policy; and (6) seek opportunities to work collaboratively within the Medicine-Public Health initiative (H-440.991) and with the Food and Drug Administration (FDA), National Institutes of Health (NIH), United States Pharmacopoeia (USP) and Centers for Disease Control and Prevention (CDC) the Agency for Health Care Policy and Research (AHCPR) and the Centers for Medicare & Medicaid Services (CMS) to provide information to individual physicians and state medical societies on the need for public health infrastructure and local consortiums to work on problems related to medical product safety. Res. 416, A-99; Appended: Res. 504, I-01; Reaffirmation A-10