TMLT
Texas Medical Liability Trust

CME
VACCINES: A PRACTICAL GUIDE FOR PHYSICIANS

by Karin Zaner, JD

OBJECTIVES

Upon completion of this course, the physician will be able to:

1. discuss the FDA's process for vaccine development and approval;
2. list the required steps to become a vaccine provider;
3. explain the legal immunities associated with giving vaccinations; and
4. describe the AMA's position on a physician's responsibility regarding vaccines.

COURSE AUTHOR

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RELEASE/REVIEW DATE

This activity is released on May 17, 2021 and will expire on May 17, 2024.

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INTRODUCTION

As COVID-19 vaccinations continue across the United States, questions of best practices, patient priority, vaccine storage, and professional liability have all come into focus. One thing the COVID-19 vaccination effort has revealed is a need for clarity among the general public about how vaccinations are developed and used. This article offers physicians a deeper context on vaccinations to help them with patient interactions about this important topic.

Vaccination is a highly effective method for preventing or containing certain infectious diseases for adults and children. Many infectious diseases experienced by earlier generations, like polio and measles, are significantly less common today because of vaccine use.[1]

Immunization protects entire communities, as those who are not able to get vaccinated due to underlying health conditions or who choose not to be vaccinated rely on community (or "herd") immunity to protect them. Community immunity happens when enough people are immune to a disease, mostly through vaccination or prior illness, that the disease cannot effectively spread.

The percentage of people who need to be immune to achieve herd immunity varies with each disease. It is unknown what percentage of people need to be vaccinated for COVID-19 to achieve community immunity.[2]

Without adequate community participation in recommended vaccines, vulnerable populations such as senior adults, people with underlying conditions, immunocompromised people, and children are left at greater risk of exposure to serious infectious diseases.[3] Babies, children, adolescents, and adults are given vaccines to prevent infectious diseases, which means that safety and efficacy is of utmost importance.[4]

This article will provide an overview of the general structure of the vaccine approval and distribution system in the United States (including Emergency Use Authorization) as well as the protocols, guidelines, and best practices for providers in administering vaccinations.

This article will also discuss the federal statutes that provide important legal immunities (for providers, manufacturers, and other participatory third parties), as well as the legal framework for compensation to vaccine recipients who experience serious adverse effects.

Finally, this article will raise and explore some of the ethical issues facing vaccine providers.

THE U.S. VACCINE APPROVAL SYSTEM

The U.S. Food and Drug Administration (FDA) is the federal agency responsible for medical product regulation in the United States. The FDA states that "[e]nsuring the safety and effectiveness of vaccines is one of FDA's top priorities."[4] In order for a vaccine candidate to become available to the general public, it must first undergo rigorous safety and efficacy reviews by the FDA.

Vaccine manufacturers first collect and submit data to the FDA. The FDA's Center for Biologics Evaluation and Research (CBER) ensures that the FDA's rigorous scientific and regulatory processes are followed by vaccine developers and manufacturers.[4]

In addition, two separate committees independently review the safety and efficacy data. The first committee is the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), which evaluates data concerning safety, effectiveness, and appropriate use of vaccines and provides advice to the Commissioner of the FDA.[5] The second committee is the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC). The ACIP provides guidance to the Director of the CDC and recommendations on the use of vaccines based on disease epidemiology, vaccine safety, vaccine efficacy, quality of evidence reviewed, economic analyses, and implementation issues.[6]

STAGES OF VACCINE APPROVAL

Vaccine developers and manufacturers generally engage in the following stages for vaccine approval.

- **Research and discovery:** Scientists develop a rationale for a vaccine based on how the infectious organism causes disease and conduct laboratory research to test such concepts.
- **Pre-clinical phase:** Additional laboratory research and testing in animals is conducted to obtain information about how the vaccine works, including whether it would be effective and safe for humans.
- **Clinical development:** This stage includes the submission of the Investigational New Drug application (IND), the FDA's assessment of the preclinical data, and then test Phases 1, 2, and 3 under the oversight of the FDA.
- **Manufacturing assessment:** Data is collected and submitted that supports the proposed manufacturing processes, facilities, and product characterization. Other submitted data includes a demonstration of lot-to-lot consistency, a review of "lot release protocol," a template of tests to be conducted on the vaccine post-approval, and inspections of facilities and operations by the FDA. All data submitted is to facilitate commercial-scale manufacturing.
- **Approval process:** Submission of Biologics License Application (BLA) to the FDA for approval to distribute and market the vaccine for use in the U.S., along with prescribing, indications, usage, dosing, and administration specifications.
- **FDA oversight:** Monitoring for safety and effectiveness and to identify uncommon adverse events or long-term complications, as well as other post-approval monitoring mechanisms such as "lot release."[4, 7]
- **Various other safety surveillance systems:** Review for approval may also be necessary from such systems as the Vaccine Adverse Event Reporting System (VAERS), the FDA BEST (Biologics Effectiveness and Safety) program and the FDA Sentinel Program, the FDA and Centers for Medicare & Medicaid Services (CMS) partnership, and the CDC's Vaccine Safety Datalink and Clinical Immunization Safety Assessment (CISA) Project 4.[8-13]

In addition, new systems have been developed for specific vaccines on an as-needed basis. For example, the v-safe smartphone-based tool uses text messaging to initiate internet-based survey monitoring and provides telephone follow up to anyone who reports medically significant adverse events related to COVID-19 vaccines.[14]

EMERGENCY USE AUTHORIZATIONS

In public health emergencies (PHE), such as the ongoing COVID-19 pandemic, the development process may be expedited given the urgent need for safe and effective vaccines. During a PHE, manufacturers may submit a request for Emergency Use Authorizations (EUA) to the FDA to facilitate the availability and use of their vaccine after meeting certain criteria.

An EUA generally contains the following data:

- chemistry, manufacturing, and controls information;
- nonclinical data and information;
- clinical data information; and
- administrative and regulatory information.

The FDA evaluates the need for pre-clinical studies and determines whether human trials can begin by considering all relevant data about the vaccine and closely related vaccines. The design of the specific clinical study for the vaccine is evaluated and considered before human trials begin.

Adaptive trial designs are intended to expedite clinical trial decisions based on preliminary results from earlier trials, which can facilitate efficient clinical development. This may reduce the size and duration of the trial and demonstrate an effect if one exists. The FDA states on its website: "There is no predetermined timeline for vaccine development. Typically, the better the scientific understanding of a pathogen and the disease it causes, the more efficient vaccine development." [4]

BECOMING A VACCINE PROVIDER

There are various required steps to becoming a vaccine provider. While requirements differ depending on the state and particular vaccine, such steps generally include the following. (Texas requirements for becoming a COVID-19 vaccine provider are included here to illustrate these steps.)[15]

1. **State registries:** In order to administer vaccines, a provider must enroll in the state immunization registry for the particular vaccine. In Texas, the Department of State Health Services (Texas DSHS) runs the registry,[16] and requires enrollment in ImmTrac2.[17]

   As part of this process, a provider needs to complete the CDC's Vaccination Program Provider Agreement for the specific vaccine at issue.[18] The provider should also list the health care providers at that location who will be responsible for vaccination.

   After completing enrollment, a provider will receive an email confirming registration. Once approved, a provider will receive another email confirming status as a vaccine provider for the vaccine.[19]

2. **ACIP requirements:** Providers must administer the vaccine in accordance with all requirements and recommendations of the CDC and the CDC's Advisory Committee on Immunization Practices (ACIP) for each type of vaccine.[20]

3. **Reporting to the CDC:** Certain reporting within a specific timeframe may be required by the CDC. For example, within 24 hours of administering a dose of COVID-19 vaccine, providers must document the vaccination in the recipient's record and report required information to the relevant state, local, or territorial public health authorities. Details of required information (Vaccine-Administration Data) for reporting can be found on the CDC's website at https://www.cdc.gov/vaccines/covid-19/reporting/overview/index.html.[21]

4. **Submission of data:** If the CDC requires it, providers must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction, or (2) another system designated by the CDC according to CDC documentation and data requirements.

5. **Preserve record for at least three years:** Providers must preserve the record for at least three years following vaccination, or longer if required by state or local law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.

6. **No cost to patient:** Depending on the vaccine, the CDC may prohibit providers from selling or seeking reimbursement for the vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to the provider. This has been the case with the COVID-19 vaccines.[15]

7. **Ability to pay:** Depending on the vaccine, the CDC may require providers to administer the vaccine regardless of the recipient's ability to pay vaccine administration fees. Again, this has been the case with COVID-19 vaccines.[15]

8. **Provide EUA/VIS fact sheets:** Providers must provide an approved EUA fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.[22] For the COVID-19 vaccine, providers must provide the applicable EUA for the specific vaccine given. Fact sheets for the following vaccines are found here:
   a. **Johnson & Johnson:** https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-Recipient-fact-sheet.pdf[23]
   b. **Moderna:** https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf[24]
   c. **Pfizer-BioNTech:** https://www.fda.gov/media/144414/download[25]

9. **Safe delivery:** To ensure safe delivery of the vaccine, providers must comply with any guidance for immunization services provided by the CDC for a particular vaccine.[26]

10. **Storage and handling:** Providers must comply with any CDC requirements for vaccine management and storage, which may include chain of custody and temperature, expiration dates, as well as the requirement for preservation of all vaccine records for a minimum of three years or longer if required by state or local law.[27]

11. **Unused, spoiled, expired, or wasted vaccines:** Providers may be required to report the number of doses of the vaccine that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction. This has been the case with the COVID-19 vaccines.

12. **Disposal:** Providers must comply with all federal instructions and timelines for disposing of vaccines, including unused doses.[28]

13. **VAERS reporting:** Providers must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/.

14. **Vaccination record card:** If required, providers must provide a completed vaccination record card to the vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. This is a requirement for COVID-19 vaccinations. All COVID-19 vaccine shipment containers include COVID-19 vaccination record cards.

15. **FDA and state vaccination laws:** Providers must comply with all applicable requirements as set forth by the FDA as well as all applicable state vaccination laws. For example, for the COVID-19 vaccines, providers must adhere to the requirements in the applicable EUA for the specific vaccine given.

In addition, the CDC has resources on individual vaccines, which are specifically designed to guide providers in vaccine education and administration. For example, all COVID-19 vaccine shipments include a specific quick reference guide for health care professionals detailing basic storage, preparation, and administration information.[29]

The CDC also provides specific tool kits for medical centers, clinics, pharmacies, and clinicians to educate their staffs; for health care professionals and pharmacists to educate patients; for long-term care facilities to educate staff, residents, and their families; and for public health departments and their partners to educate communities. These resources include sample messages for use on social media channels, as well as educational videos and other CDC resources that can be used or posted online.[30-33]

In particular, a CDC slide presentation from January 2021, "Building Confidence in COVID-19 Vaccines Among Your Patients" is a well-organized, fact-based, and concise example of the types of educational materials that the CDC makes available to providers during the ongoing pandemic. It is found at https://www.cdc.gov/vaccines/covid-19/downloads/VaccinateWConfidence-TipsForHCTeams_508.pdf.[34]

DISCUSSING COVID-19 VACCINATION WITH YOUR PATIENTS

With the introduction of vaccines for COVID-19, many patients are eager to become vaccinated and return to a more recognizable, pre-pandemic version of life — visiting family and friends in person, returning to the office and the classroom, and venturing into stores and restaurants.

However, other patients are feeling hesitant due to vaccination myths and misinformation. Here is a brief list of common concerns to address when speaking with those who are vaccine hesitant.[57, 58, 59]

Myth: The COVID-19 vaccines are not safe and have not been adequately tested.
According to the FDA, the COVID-19 vaccines are effective and safe. "The vaccines have undergone the most intensive safety monitoring in U.S. history, and vaccine developers followed all the necessary steps during clinical trials." The Pfizer and Moderna vaccines were developed with messenger RNA (mRNA) technology which allowed for faster vaccine development and has been in use for years.

Myth: The vaccines were developed too quickly, and shortcuts were taken.
Neither science nor safety shortcuts were taken to develop the vaccines. They are a result of existing research, increased priority, unprecedented collaboration, and generous funding. The human clinical trials were also larger than usual for human trials, enrolling up to 45,000 participants, as opposed to a typical trial with less than 3,000 participants. All of these efforts contributed to the expedited development of safe and effective vaccines.

Myth: The vaccine will give me COVID-19.
None of the vaccines contain a live strain of the virus. Therefore, the vaccine will not give you COVID-19. The mRNA vaccine contains a "blueprint" of a small, non-living piece of the virus. Your body will use this blueprint to build antibodies to the actual virus should you ever become exposed to it.

You may experience side effects from the vaccine that will make you feel sick, but these symptoms are the result of your body working to strengthen your immune system. Should you become infected, your body will now know how to respond to the actual virus and fight it more effectively. Common side effects felt after receiving a COVID-19 vaccine are soreness at the injection site, fatigue, headache, body aches, or mild fever. But these side effects only last one to three days, if experienced at all.

Myth: The vaccine will alter my DNA.
Your DNA will not be altered. The vaccine's mRNA does not and cannot interact with your DNA because DNA is stored within your cells, and the vaccine does not enter your cells.

Myth: The vaccine will make me sterile or infertile.
There is no evidence that the COVID-19 vaccines could result in sterility or infertility. However, COVID-19 illness may pose a serious risk to an ongoing pregnancy and the mother's health. Pregnant patients should discuss getting the vaccine and any concerns they have with their physician.

Myth: The vaccines will not protect me against new variants of the coronavirus.
Data has found that the vaccines appear to be effective against several new strains of SARS-CoV-2. COVID-19 has less of a chance of spreading and being a health hazard when more people are vaccinated.

Myth: I've already had COVID-19, so I don't need the vaccine.
It is possible to become re-infected with COVID-19. Getting vaccinated will help minimize symptoms in the event you become re-infected.

It is also important to remind your patients that even though they have been vaccinated, they still need to follow current COVID-19 safety precautions.

LEGAL IMMUNITY AND COMPENSATION UNDER FEDERAL LAW

Any discussion of vaccines should include the legal remedies and defenses that exist for patients, providers, and manufacturers should a serious adverse reaction occur. While such legal remedies and defenses are state specific, there are federal statutes that preempt state laws in certain situations. Consult with various state resources and websites as well as legal counsel in your state to understand such specific state laws.

For patients adversely affected by vaccines, these federal laws may provide a certain framework for compensation that allows these patients to recover damages, sometimes even without a specific factual finding of causation. For providers, manufacturers, and others involved in providing vaccines, these federal laws provide legal immunities from liability under certain specific factual circumstances.

PREP ACT IMMUNITY FOR VACCINES IN PHEs

A primary federal law that provides legal immunity to providers (as well as manufacturers and others) for vaccines needed during a PHE is The Public Readiness and Emergency PREParedness Act (PREP Act). The PREP Act protects those involved in the development, manufacturing, and administration of vaccines from liability, as well as others involved in the necessary testing, diagnostic services, and other support services.[35]

The PREP Act was enacted by Congress in 2005 and signed into law by President George W. Bush in the wake of the avian influenza outbreak. The PREP Act preempts state vaccine safety laws when emergency declarations are made by the United States Department of Health and Human Services (HHS), as was done in January 2020 for COVID-19.[36]

Successful vaccination campaigns on a mass scale that are required during a PHE (now including COVID-19) would not be possible without some sort of legal immunity given to participatory third parties. Other vaccines covered by specific PREP Act declarations include smallpox and anthrax.[37, 38]

Once a specific PREP Act declaration is issued by the HHS secretary, legal immunity from liability is provided for "claims of loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a [PREP Act] declaration...has been issued with respect to such countermeasure." [39]

PREP Act immunity applies to diseases, threats, and conditions determined by the HHS secretary to constitute "a credible risk" of a future public health emergency. By virtue of its definitions, the PREP Act broadly protects entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures.[39]

For example, the PREP Act immunity applies to any "covered person," defined as individual persons and entities, including (at the HHS secretary's discretion), manufacturers, distributors, program planners, and qualified persons who prescribe, administer, or dispense countermeasures (e.g., licensed health care professionals).[39]

The scope of PREP Act immunity includes the following: "design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasures." Covered countermeasures include vaccines, drugs, and medical devices to be used against chemical, biological, radiological, and nuclear agents or terrorism, epidemics, and pandemics.[39, 40]

PREP Act immunity covers tort liability for death (except in cases of willful misconduct for which the plaintiff has the burden to show), as well as physical, mental, or emotional injury, illness, or disability, and also can provide legal immunity for allegations tied to fear of any of these conditions. The framework for litigating and recovering for "willful misconduct" is set forth in the PREP Act as well.[39]

In addition to the PREP Act statute, additional guidance is provided through advisory opinions by HHS's office of general counsel, although such guidance is advisory only and not a final agency action or order (meaning there is "no force or effect of law").[41]

The PREP Act also created the Countermeasures Injury Compensation Program (CICP), which provides benefits to certain individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures under a PREP Act declaration. The CICP "substitutes a no-fault, speedy compensation system in place of expensive and uncertain litigation." [41]

The regulations implementing the CICP specify which serious injuries that warrant hospitalization are covered.[42] Injuries that are not covered include emotional injuries, fear of injury, business losses, and other types of claims for which immunity is provided.[41] Information about the CICP and filing a claim are available at the toll-free number 1-855-266-2427 or the CICP website at https://www.hrsa.gov/cicp.[43]

CHILDHOOD VACCINES UNDER THE NCVIA

The federal National Childhood Vaccine Injury Act of 1986 (NCVIA) provides certain legal immunity to providers, manufacturers, and others for the routine administration of CDC-recommended vaccines to children.[44] This act facilitated the creation of the National Vaccine Injury Compensation Program (VICP), a no-fault alternative to the traditional legal tort compensation system in court.[45]

The VICP was established after lawsuits against vaccine manufacturers and health care providers threatened to cause vaccine shortages and reduce vaccination rates. The VICP is designed to be an "accessible and efficient forum" to provide compensation to people injured by certain vaccines. The NCVIA was amended in 2016 to update and expand the vaccines covered by the VICP.[45] The PREP Act clearly provides that nothing in it "shall be construed to affect the [VICP]."[39]

The NCVIA mandates that all health care providers must report certain adverse events following vaccination to VAERS.[8, 12, 46] The NCVIA requires that all health care providers who administer certain vaccines (e.g., vaccines against diphtheria, tetanus, pertussis, polio, mumps, rubella, hepatitis B, Haemophiles influenzae type b, and varicella) must provide a Vaccine Information Statement (VIS) to the vaccine recipient, their parent, or legal guardian before each dose. Current versions of all VIS are available at https://www.cdc.gov/vaccines/hcp/vis/index.html.[47]

A VIS must be given with every vaccination, including each dose in a multi-dose series. Each VIS contains a brief description of the disease, as well as the risks and benefits of the vaccine. Each VIS is developed by the CDC and distributed to state and local health departments, as well as individual providers.

Those filing claims under the VICP are not required to prove negligence on the part of the health care provider or manufacturer to receive compensation.[48] Also, the VICP publishes a Vaccine Injury Table that contains a listing of covered vaccines and associated injuries that makes it easier for some patients to receive compensation. The table lists and explains injuries and/or conditions that are presumed to be caused by vaccines unless another cause is proven.[49]

Funding to compensate vaccine-related injury or death petitions for covered vaccines administered on or after October 1, 1988 are paid for by the Vaccine Injury Compensation Trust Fund, which is funded by a $0.75 excise tax on each vaccine dose (i.e., those vaccines recommended by the CDC for routine administration to children). The VICP is administered by the HHS. Information about the VICP and filing a claim are available at the toll-free number 1-800-338-2382 or by email at vaccinecompensation@hrsa.gov.[45]

A vaccine manufacturer or administrator may be afforded certain protections from liability if the vaccine is covered under the VICP. Under the NCVIA, persons with petitions of vaccine-related injuries or deaths resulting from covered vaccines must first exhaust their remedies under the VICP before they can pursue legal actions against vaccine manufacturers or administrators.

To exhaust the remedies available under the VICP and pursue a legal action outside the VICP, a VICP petitioner must either withdraw a petition or reject the judgment under the VICP. Although the Act provides liability protections, these protections are not absolute. For example, a petition requesting damages of $1,000 or less will be allowed in state or federal court without first filing a petition in the VICP. Also, if the VICP has paid a petitioner for a vaccine-related injury, the VICP may be able to pursue its own action against a vaccine manufacturer or administrator using its subrogation rights.[50]

AMA'S CODE OF ETHICS POLICY ON VACCINES

The American Medical Association (AMA) Code of Ethics Opinions provides important guidance relating to vaccinations generally, as well as for use during the current COVID-19 pandemic. AMA Code of Ethics Opinion 8.7 ("Routine Universal Immunization of Physicians") specifically states that (emphasis in bold added):

> "[P]hysicians have an ethical responsibility to encourage patients to accept immunization when the patient can do so safely, and to take appropriate measures in their own practice to prevent the spread of infectious disease in health care settings. Conscientious participation in routine infection control practices, such as hand washing and respiratory precautions is a basic expectation of the profession. . .
>
> In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues, or threatens the availability of the health care workforce, particularly a disease that has potential to become epidemic or pandemic, and for which there is an available, safe, and effective vaccine, **physicians have a responsibility to accept immunization** absent a recognized medical contraindication or when a specific vaccine would pose a significant risk to the physician's patients.
>
> Physicians who are not or cannot be immunized have a responsibility to voluntarily take appropriate action to protect patients, fellow health care workers and others. They must adjust their practice activities in keeping with decisions of the medical staff, institutional policy, or public health policy, **including refraining from direct patient contact** when appropriate. . .
>
> Physician practices and health care institutions have a responsibility to proactively develop policies and procedures for responding to epidemic or pandemic disease with input from practicing physicians, institutional leadership, and appropriate specialists. Such policies and procedures should include robust infection control practices, provision and required use of appropriate protective equipment, and a process for making appropriate immunization readily available to staff. During outbreaks of vaccine-preventable disease for which there is a safe, effective vaccine, institutions' responsibility **may extend to requiring immunization of staff**. Physician practices and health care institutions have a further responsibility to limit patient and staff exposure to individuals who are not immunized, **which may include requiring unimmunized individuals to refrain from direct patient contact**." [51]

Further, the AMA Code of Ethics Opinion 8.4 ("Ethical Use of Quarantine & Isolation") specifically states that:

> A physician's "long-recognized public health responsibility. . .in the context of infectious disease [may also] include the use of quarantine and isolation to reduce the transmission of disease and protect the health of the public. In such situations, physicians **have a further responsibility to protect their own health to ensure that they remain able to provide care**. These responsibilities potentially conflict with patients' rights of self-determination and with physicians' duty to advocate for the best interests of individual patients and to provide care in emergencies.
>
> With respect to the use of quarantine and isolation as public health interventions in situations of epidemic disease, **individual physicians should**:

(a) Participate in implementing scientifically and ethically sound quarantine and isolation measures in keeping with the duty to provide care in epidemics.
(b) Educate patients and the public about the nature of the public health threat, potential harm to others, and benefits of quarantine and isolation.
(c) Encourage patients to adhere voluntarily to quarantine and isolation.
(d) **Support mandatory quarantine and isolation** when a patient fails to adhere voluntarily.
(e) Inform patients about and comply with mandatory public health reporting requirements.
(f) Take appropriate protective and preventive measures to minimize transmission of infectious disease from physician to patient, **including accepting immunization for vaccine-preventable disease**, in keeping with ethics guidance.
(g) Seek medical evaluation and treatment if they suspect themselves to be infected, including adhering to mandated public health measures.
The medical profession, in collaboration with public health colleagues and civil authorities, has an ethical responsibility to:
(h) Ensure that quarantine measures are ethically and scientifically sound:
(i) use **the least restrictive means** available to control disease in the community while protecting individual rights;
(ii) without bias against any class or category of patients.
(i) Advocate for the highest possible level of confidentiality when personal health information is transmitted in the context of public health reporting.
(j) Advocate for access to public health services to ensure timely detection of risks and implementation of public health interventions, including quarantine and isolation.
(k) Advocate for protective and preventive measures for physicians and others caring for patients with communicable disease.
(l) Develop educational materials and programs about quarantine and isolation as public health interventions for patients and the public." [52]

The AMA Code of Ethics Opinion 8.3 ("Physician's Responsibilities in Disaster Response & Preparation") specifically states that:

"Because of their commitment to care for the sick and injured, **individual physicians have an obligation to provide urgent medical care during disasters. This obligation holds even in the face of greater than usual risks to physicians' own safety, health, or life.**

However, the physician workforce is not an unlimited resource. Therefore, when providing care in a disaster with its inherent dangers, **physicians also have an obligation to evaluate the risks of providing care to individual patients versus the need to be available to provide care in the future.**

With respect to disaster, whether natural or manmade, individual physicians should:
(a) **Take appropriate advance measures**, including acquiring and maintaining appropriate knowledge and skills **to ensure they are able to provide medical services when needed.**

Collectively, physicians should:
(b) Provide medical expertise and work with others to develop public health policies that:
(i) are designed to improve the effectiveness and availability of medical services during a disaster;
(ii) are based on sound science;
(iii) are based on respect for patients.

(c) Advocate for and participate in ethically sound research to inform policy decisions." [53]

The AMA Code of Ethics Opinion 8.8 (Required Reporting of Adverse Events) specifically states that:

"Spontaneous reports of adverse events, especially rare or delayed effects or effects in vulnerable populations **are irreplaceable** as a source of information about the safety of drugs and devices. . . [P]hysicians are best positioned to observe and communicate about adverse events.
. . . A physician who **suspects that an adverse reaction to a drug or medical device has occurred has an ethical responsibility to:**

(a) Communicate that information to the professional community through established reporting mechanisms. (b) **Promptly report serious adverse events requiring hospitalization, death, or medical or surgical intervention** to the appropriate regulatory agency." [54]

Generally, these regulatory frameworks and statutes for vaccines enable providers to comply with these various ethics opinions, although situations can arise that challenge such ethical principles or put them in conflict. However, by reviewing and internalizing these ethics opinions as well as any others that might address the specific situation, a provider is best prepared to make good, sound decisions if or when such issues arise in their practice.

CONCLUSION

Issues surrounding vaccinations are especially critical to review and understand during the current COVID-19 pandemic. But even when the pandemic subsides, these issues will remain, including a provider's role in ensuring that their communities are vaccinated at appropriately safe levels. The National Foundation for Infectious Diseases (NFID) sets forth on its website its "10 Reasons to be Vaccinated," and these reasons will continue to exist even after the COVID-19 pandemic.[55]

The NFID website also shares "real stories" of "real people" whose lives and loved ones have been seriously affected by their choice to vaccinate or not. Continued efforts at all levels as well as vigilance by providers to educate, prepare, and administer vaccinations is required to control the spread of serious diseases that can be prevented or mitigated by vaccination. And perhaps in doing so, such cautionary tales will save the lives of other "real people" in the future.[56]

SOURCES AND NOTES

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