

## STATEMENT OF POLICY

### Vaccine Safety

#### Policy

Confidence in the safety of vaccines is critical to assuring that they are used as widely, effectively, and appropriately as possible to protect the residents and visitors of our nation. Assuring this safety, from manufacturing to administration, is a shared responsibility of all levels of public health, the medical community, and the private sector. In order to attain and sustain the necessary level of assurance, the National Association of County and City Health Officials (NACCHO) urges the following:

- Rigorous post-licensure safety monitoring and sharing of available safety-related data with local health departments for all vaccines on the market in a timely manner.
- Transparency and proactive communication with local health departments about vaccine safety to ensure cohesive messaging to the public.
- Increased training and ongoing support to help local health departments utilize vaccine administration and disease incidence data to identify gaps in vaccine use patterns.
- Increased federal funding and support to local health departments to improve their ability to identify and understand vaccine safety and hesitancy concerns among populations within their jurisdictions; including translating research, developing effective messaging, and implementing evidence-based interventions to counter vaccine hesitancy.
- Increased federal funding and support to help local health departments translate research on vaccine hesitancy, develop effective messaging, and institute evidence-based interventions to counter vaccine hesitancy due to safety concerns.
- Increased federal funding for locally driven educational efforts geared towards physicians and other health care personnel regarding the safety of vaccines, true contraindications, the risks of delayed vaccine schedules, and the process for, and importance of, reporting adverse events. This should include information on safety monitoring systems, including how data is collected and analyzed, how evidence-based conclusions are drawn, and how results are disseminated.
- Increased federal funding and support for local health departments to educate medical care providers as well as the public about safety monitoring systems, including how data is analyzed and disseminated.
- Increased federal capacity to conduct standardized clinical evaluations of reports to the Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), MedWatch, V-Safe, and other vaccine safety reporting systems. Expand VSD coverage of the U.S. population and increase opportunities for independent research studies involving vaccine risks by credible parties other than the Centers for Disease Control and Prevention (CDC), and create mechanisms by which local health departments and healthcare providers can access the subsequent results.



## **Justification**

Vaccines are the best defense against many infectious diseases. Their widespread availability and acceptance have prevented a large burden of disease, complications, and deaths from polio, measles, pertussis, tetanus, and other serious diseases.<sup>1</sup> Vaccines are extensively tested and monitored to ensure that they are safe and effective.

There are two mechanisms under which vaccines can be approved for use. Vaccines may be fully approved and licensed by the US Food and Drug Administration (FDA) after a manufacturer submits an application with various safety, efficacy, and other data and the FDA determines that the benefits outweigh the risks for the population the vaccine is indicated for.<sup>2</sup> Vaccines may also be authorized under an Emergency Use Authorization (EUA). Vaccines may be authorized under an EUA during public health emergencies if they have not yet gone through the full FDA approval process but have been shown to prevent serious and life-threatening conditions and have benefits that outweigh the risks when there is no alternative available.<sup>3</sup> Examples of vaccines issued under EUA include an anthrax vaccine in 2005, an mpox vaccine in 2022, and multiple COVID-19 vaccines in 2020-2021.<sup>3-5</sup> Vaccines authorized under an EUA are still required to meet certain safety and efficacy standards and no steps in the process are skipped.<sup>3</sup>

The CDC monitors and assesses vaccine safety for both fully approved and licensed vaccines and those authorized under an EUA in a number of ways, including: (1) The Vaccine Adverse Event Reporting System (VAERS), an early warning system that monitors reports of possible vaccine side effects and adverse events from patients, parents, health care professionals, and vaccine manufacturers;<sup>6</sup> (2) Vaccine Safety Datalink (VSD), a collaboration with managed care organizations that monitors adverse events following vaccination in near real time and contains comprehensive medical and immunization histories of more than nine million people;<sup>7,8</sup> (3) thorough monitoring of certain populations by other federal agencies such as the Department of Defense, the Department of Veterans Affairs, the Indian Health Service, and the Centers for Medicare and Medicaid Services; (4) special studies and reviews (including those conducted by the Institute of Medicine) designed to investigate whether a relationship exists between vaccination and certain health problems;<sup>9,10</sup> (5) the Clinical Immunization Safety Assessment (CISA) project, which conducts clinical research to identify adverse events risk factors and offers consultation to help healthcare professionals with vaccine decision-making and;<sup>11</sup> (6) V-Safe, a smartphone based tool developed to enable people to report any side effects experienced after receiving a COVID-19 vaccine.<sup>12</sup>

The vast majority of vaccine adverse events reported and evaluated through these systems are minor and temporary. Severe vaccine adverse events are extremely rare and significantly less likely to occur than the clinical repercussions caused by the associated disease. However, despite the strong safety record of vaccines, vaccine hesitancy has been increasing. This is reflected in the rise of non-medical exemptions to school immunization requirements and findings from cross-sectional surveys.<sup>13,14</sup> The kindergarten vaccine exemption rate in the US has been steadily increasing since the 2019-2020 school year. In that year, the national exemption rate was 2.5%.<sup>15</sup> During the 2023-2024 school year, the exemption rate increased to 3.3%, with 14 states having exemption rates over 5% (medical exemptions accounted for 0.2% of exemptions).<sup>13</sup> In an attempt to explain some of this increase, a 2024 KFF poll found that 31% of parents said it was definitely or probably true that the MMR vaccine has been proven to cause autism, despite extensive evidence that there is no link.<sup>16,17</sup> Such concerns can lead to vaccine refusals, which have been associated with outbreaks of vaccine-preventable diseases, including measles,

pertussis, and varicella.<sup>16</sup> Particularly for those vaccines authorized under an EUA during a public health emergency, it is vital to develop messaging about their safety and the EUA process to prevent vaccine hesitancy. It is important that public health and healthcare providers educate the public to ensure they understand the process, that no safety measures are overlooked, and that, as with other vaccines, safety and efficacy data is continuously collected and evaluated.

When questions about vaccine safety arise, the FDA, CDC, and other agencies must communicate with local health departments before a public announcement. This allows them to provide accurate information, combat misinformation, and educate the public and healthcare providers on safety monitoring systems. It's crucial for marginalized communities with medical mistrust to understand these measures, helping build trust in the public health system.

It is imperative that greater support is made available to local health departments to increase their surveillance of vaccine coverage locally to identify gaps in coverage; understand vaccine safety concerns and their impact; and to develop and implement evidence-based interventions to decrease vaccine hesitancy and increase vaccine confidence and uptake. This support can help to close gaps in a community's immunity against diseases that, despite the record low incidence levels, are not yet relegated to the pages of history books.

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### **Record of Action**

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