



January 17, 2019

*****Public Comment Submitted Via Email*****

Office of Disease Prevention and Health Promotion
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Re: Public Comment for Healthy People 2030 Core, Developmental and Research Objectives.

The National Vaccine Information Center (NVIC), which was founded by parents of vaccine injured children in 1982, is the oldest and largest charitable non-profit organization advocating for the prevention of vaccine injuries and deaths through public education and the inclusion of safety and informed consent protections in U.S. vaccine policies and laws. We submit this public comment to request the addition and/or amendment of the proposed 2030 objectives and goals relating to Immunization and Infectious Disease (IID) and Public Health Infrastructure Goals.

In reviewing the mid-course review report provided by the Centers for Disease Control (CDC) for Healthy People 2020 IID goals and the Health People website, we note a lack of context and vaccine science data gaps, both in the report, webpages and the goals themselves.

For example, the IID overview webpage states that 42,000 adults and 300 children die of vaccine preventable disease annually in the U.S.¹ and notes that these figures include deaths from influenza. However, the CDC's website clearly states that they do not know how many people die from influenza annually and that their estimates include pneumonia deaths.² Further, reports produced by CDC Wonder of mortality rates due to "vaccine preventable diseases" do not appear to approach the figures quoted on the overview webpage.³

For transparency, these types of statements about infectious diseases should be clearly cited and put into context to separate verifiable facts from best guess estimates.

Additionally, like many of the proposed 2030 IID goals, the influenza vaccine uptake goal outlines desired increases in vaccination coverage while Public Health Infrastructure (PHI) goals call for improved informatics that include data-sharing and data exchange.

However, increased vaccine uptake does not necessarily equate to increased infectious disease prevention as demonstrated by the CDC's reports on influenza vaccine effectiveness. The CDC acknowledges that 80 percent of all respiratory infections that occur during flu season are not type A or B influenza. Since 2004, the effectiveness for influenza vaccine has ranged from 10 to 60 percent among those vaccinated.⁴ This lack of influenza vaccine effectiveness demonstrates a significant vaccine failure. We note that current vaccine failures are not confined to influenza in that the CDC acknowledges vaccine failures in recent pertussis⁵ and mumps⁶ outbreaks.

These failures highlight a critical deficit in the proposed 2030 IID goals and Public Health Infrastructure (PHI) goals, which is Healthy People 2030 does not contain goals to gather data on vaccine failures that would better inform goal feasibility. Nor are their educational communication goals to assist the public in making informed health decisions, including decisions about vaccination.⁷ Below are goals and objectives that NVIC believes would begin to address these deficits.

- communication, education and awareness goals about infectious disease incidence and the frequency and severity of complications to support informed decision making about treatment and prevention;
- communication, education and awareness goals about recognizing and reporting vaccine adverse events to address the gross underreporting of vaccine adverse events by doctors and other vaccine administrators^{8 9} in compliance with safety provisions in the National Childhood Vaccine Injury Act of 1986;¹⁰
- communication, education and awareness goals about the availability of federal vaccine injury compensation;¹¹
- education, awareness and research goals and objectives to close acknowledged vaccine safety knowledge gaps;^{12 13 14 15 16} and
- integration of informed consent protections throughout IID and PHI goals and objectives in recognition of the fact that vaccination is a medical procedure that involves a risk of injury and death, a risk which can be greater for some people and often cannot be predicted by physicians before administration of vaccines.

Correcting these deficits would begin to provide balance and valuable information to the public and those being asked to comply with government vaccine recommendations and mandates. Without accurate and complete information about vaccine benefits and risks, Healthy People 2030 goals lack transparency and fail to provide the basis for informed consent or trust in the credibility of public health policy and law.

NVIC co-founders worked with Congress to secure vaccine safety and research provisions in the National Childhood Vaccine Injury Act of 1986, a law that was historic acknowledgement by the U.S. government that vaccines are not 100 percent safe, vaccine injuries and deaths are real, vaccine safety reforms are needed in the vaccination system, and that the vaccine injured and their families should be financially supported. The 1986 law created a federal vaccine injury compensation program (VICP) to provide awards to those injured by vaccines.¹⁷

For almost four decades NVIC has been an organization of standing and a well-known vaccine stakeholder within federal and state health agencies. NVIC has represented the public's concerns

about vaccine safety and protecting informed consent rights by providing consumer representatives who served on the Advisory Commission on Childhood Vaccines, the National Vaccine Advisory Committee, the Institute of Medicine's Vaccine Safety Forum, the FDA Vaccines and Related Biological Products Advisory Committee, and the Vaccine Policy Analysis Collaborative. NVIC also continues to:

- Provide informed public comment to federal vaccine advisory committees and in response to federal rule making proposals that affect vaccine safety and the legal right to exercise informed consent to vaccination; and
- Give congressional testimony and testimony in state legislatures on vaccine science, policy and law; and

NVIC's long, credible and highly transparent record of public service representing vaccine consumers, including the vaccine injured, and working to institute vaccine safety and informed consent protections in US vaccine policies and laws is unmatched. Yet, NVIC was not contacted or included in what should have been an open, transparent and inclusive vaccine stakeholder public engagement process when Healthy People 2030 vaccine related goals and objectives were framed by government officials. Future framing of government's aspirational goals for protecting the public health should include input from a variety of vaccine stakeholders, including NVIC, to ensure balance and representation of different public perspectives.

It is of great concern to us that the Healthy People 2020 and 2030 goals, which are supposed to be aspirational and do not have statutory authority, are being used to incentivize public health agencies to implement these "goals" through block grants.¹⁸ Inflexible implementation of these goals without the necessary informed consent protections noted in this public comment result in one-size-fits all vaccine mandates that place an unequal higher vaccine risk burden on vaccine vulnerable individuals. Lack of information and inflexible implementation of government vaccination goals and objectives also threatens an individual's ability to exercise the human right to informed consent, which includes the ability to delay or decline a vaccination without being sanctioned.

Ultimately, the health of the public is only as strong as the health of individual members. We request that NVIC's concerns and suggestions be considered as 2030 Health People goals and objectives are finalized.

Sincerely,

Theresa Wrangham,
Executive Director

References

¹ HealthyPeople.gov. [Immunization and Infection – Overview](#). Jan. 17, 2019.

² CDC. [Estimating Seasonal Influenza-Associated Deaths in the United States](#). Jan. 29, 2018.

³ CDC. National Center for Health Statistics. [Underlying Cause of Death 2007-2017 on CDC WONDER Online Database, released December, 2018](#). Accessed at <http://wonder.cdc.gov/ucd-icd10.html> on Jan 14, 2019 12:17:27 PM

⁴ CDC. [Seasonal Influenza Vaccine Effectiveness, 2004-2018](#). Nov. 15, 2018.

⁵ CDC. [ACIP Presentation – Pertussis Epidemiology and Vaccination in the United States](#). Clark, T. Feb. 2012.

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- ⁶ CDC Stacks. ACIP Presentation - [Update on Mumps Epidemiology, United States](#). Slide 4. Dec 20, 2017.
- ⁷ HealthyPeople.gov. [Proposed Objectives for Inclusion in Healthy People 2030](#).
- ⁸ Lazarus R. [Electronic Support for Public Health-Vaccine Adverse Event Reporting System \(ESP:VAERS\)](#). Harvard Pilgrim Health Care, Inc. 2011.
- ⁹ Government Publishing Office. 42 U.S.C. §§ 300aa-25 [National Childhood Vaccine Injury Act of 1986 – Recording and reporting of information](#). 2016 edition.
- ¹⁰ Lazarus R. [Electronic Support for Public Health-Vaccine Adverse Event Reporting System \(ESP:VAERS\)](#). Harvard Pilgrim Health Care, Inc. 2011.
- ¹¹ <https://www.nvic.org/PDFs/ACCV/BanyonReport-VICPResearchReport.aspx>
- ¹² Institute of Medicine Vaccine Safety Committee. Adverse Effects of Pertussis and Rubella Vaccines: [Executive Summary, Research Needs](#) (p. 8) and [Afterword on Research Needs](#) (p. 206-207). Washington, DC. *National Academy Press* 1991.
- ¹³ Institute of Medicine Vaccine Safety Committee. [Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality: Need for Research and Surveillance](#) (p. 305-308). Washington, D.C. *National Academy Press* 1994.
- ¹⁴ Institute of Medicine Vaccine Safety Forum. [Summaries of Two Workshops: Detecting and Responding to Adverse Events Following Vaccination and Research to Identify Risks for Adverse Events Following Vaccination: Biological Mechanisms and Possible Means of Prevention](#). *National Academies Press* 1997.
- ¹⁵ Institute of Medicine Committee to Review Adverse Effects of Vaccines. Adverse Effects of Vaccines: Evidence and Causality: [Evaluating Biological Mechanisms of Adverse Events](#) (p. 57-102) and [Concluding Comments](#) (p. 629-632). Washington, DC: *The National Academies Press* 2012.
- ¹⁶ Institute of Medicine Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule. The Childhood Immunization Schedule and Safety Stakeholder Concerns, Scientific Evidence and Future Studies: [Summary: Health Outcomes](#) (p. 5-6) and [Conclusions About Scientific Findings](#) (p. 11) and [Review of Scientific Findings](#) (p. 75-98). Washington, D.C. *The National Academies Press* 2013.
- ¹⁷ NVIC. [The National Childhood Vaccine Injury Act of 1986](#).
- ¹⁸ CDC. [Public Health Professionals Gateway. National Allocation of Funds for Health People 2020: 2017](#). Sep. 14, 2018.