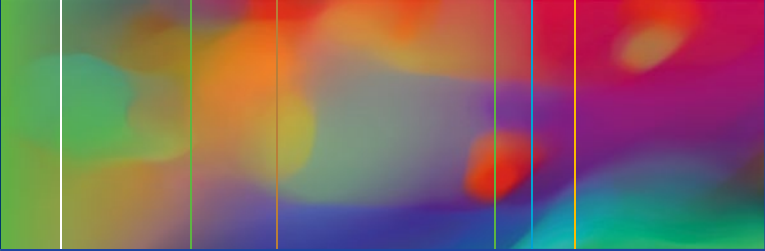


Matthew Z. Dudley · Daniel A. Salmon
Neal A. Halsey · Walter A. Orenstein
Rupali J. Limaye · Sean T. O'Leary · Saad B. Omer



The Clinician's Vaccine Safety Resource Guide

Optimizing Prevention of
Vaccine-Preventable Diseases
Across the Lifespan

 Springer

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Matthew Z. Dudley, PhD, MSPH
Epidemiologist, Institute for Vaccine Safety
Johns Hopkins Bloomberg School of Public Health
Baltimore, MD, USA

Neal A. Halsey, MD
Professor Emeritus, Department
of International Health
Johns Hopkins Bloomberg School
of Public Health
Professor Emeritus, Department
of Pediatrics
Johns Hopkins School of Medicine
Director Emeritus, Institute for Vaccine Safety
Johns Hopkins Bloomberg School
of Public Health
Baltimore, MD, USA

Rupali J. Limaye, PhD, MPH, MA
Associate Director for Behavioral
Research, Institute for Vaccine Safety
Johns Hopkins Bloomberg School of
Public Health
Baltimore, MD, USA

Saad B. Omer, MBBS, PhD, MPH
William H. Foege Professor
of Global Health
Professor of Epidemiology and
Pediatrics, Emory University
Atlanta, GA, USA

Daniel A. Salmon, PhD, MPH
Professor, Departments of International
Health and Health, Behavior and Society
Director, Institute for Vaccine Safety
Johns Hopkins Bloomberg School of
Public Health
Baltimore, MD, USA

Walter A. Orenstein, MD, DSc (Hon)
Professor of Medicine, Pediatrics, Global
Health, and Epidemiology
Emory University
Associate Director, Emory Vaccine Center
Director, Center of Excellence for
Influenza Research and Surveillance
(Emory-UGA CEIRS)
Former President, National Foundation
for Infectious Diseases (NFID)
Atlanta, GA, USA

Sean T. O'Leary, MD, MPH
Associate Professor, Pediatrics-Infectious
Diseases
University of Colorado School
of Medicine
Denver, CO, USA

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Foreword

Immunizations have had an enormous impact on public health. However, over the past decade, vaccine acceptance has been challenged by individuals and groups who question their benefit [1]. Increasing numbers of people are requesting alternative vaccination schedules [2, 3] or postponing or declining vaccination [4]. One of the main drivers for vaccine hesitancy has been concern over vaccine safety. In one survey of parents reporting concerns about vaccines, 26% worried about the development of autism or other potential learning difficulties after receiving vaccines, 13.5% expressed concern that vaccines could lead to chronic illnesses, and 13.2% stated that vaccines were not tested enough for safety prior to their use [5]. In another online survey of several thousand parents [6], most surveyed participants agreed that vaccines protected their children from diseases; however, more than half expressed concerns regarding serious adverse effects of vaccines. Overall, 11.5% of the parents had refused at least 1 recommended vaccine and the development of autism was often cited as the reason.

Therefore this book “The Clinician’s Safety Resource Guide: Optimizing Prevention of Vaccine Preventable Diseases Across the Lifespan” comes as a welcome publication to assist the healthcare provider in addressing vaccine safety concerns. The book is organized into a number of sections to aid in retrieving the needed information for routine

immunizations in the United States over the entire age spectrum including, children, adolescents, adults and pregnant women. The document also provides “evidence-based strategies for talking with patients about vaccines”; succinctly describes the vaccine safety system, and summarizes each of the recommended vaccines, the clinical manifestations and impact of the diseases they prevent, the official immunization recommendations, contraindications and precautions, information on vaccine effectiveness and safety, and standardized talking points for use with patients. The final section contains information on specific vaccine concerns and the scientific data to address these concerns.

The book leaves the reader with an understanding that vaccines are comprehensively evaluated prior to their licensure. They are developed, tested, and regulated in a very similar manner to other drugs, but usually in much larger numbers of subjects and with comprehensive surveillance systems to assess any increase in adverse events after licensure. In addition the final section outlining the specific vaccine concerns, highlights that not all parents and patients have the same questions about vaccine safety and that the information must be tailored to the question. Addressing vaccine safety concerns is a time and effort consuming process [7]. With the assistance of this book, this task can be made more efficient and productive. We owe the authors our great appreciation for their work.

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Kathryn M. Edwards, MD
Sarah H. Sell and Cornelius Vanderbilt Chair
Professor of Pediatrics
Vanderbilt University Medical Center
Nashville, TN, USA

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Authors

Matthew Z. Dudley, PhD, MSPH Epidemiologist, Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

Daniel A. Salmon, PhD, MPH Professor, Departments of International Health and Health, Behavior and Society, Director, Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

Neal A. Halsey, MD Professor Emeritus, Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

Professor Emeritus, Department of Pediatrics, Johns Hopkins School of Medicine, Baltimore, MD, USA

Director Emeritus, Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

Walter A. Orenstein, MD, DSc (Hon) Professor of Medicine, Pediatrics, Global Health, and Epidemiology, Emory University, Atlanta, GA, USA

Associate Director, Emory Vaccine Center, Director, Center of Excellence for Influenza Research and Surveillance (Emory-UGA CEIRS), Atlanta, GA, USA

Former President, National Foundation for Infectious Diseases (NFID), Atlanta, GA, USA

Rupali J. Limaye, PhD, MPH, MA Associate Director for Behavioral Research, Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

Sean T. O’Leary, MD, MPH Associate Professor, Pediatrics-Infectious Diseases, University of Colorado School of Medicine, Denver, CO, USA

Saad B. Omer, MBBS, PhD, MPH William H. Foege Professor of Global Health, Professor of Epidemiology and Pediatrics, Emory University, Atlanta, GA, USA

Abbreviations

95%CI	95% Confidence Interval
AAAAI	American Academy of Allergy, Asthma, and Immunology
AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
AASLD	American Association for the Study of Liver Diseases
ACIP	Advisory Committee on Immunization Practice
ACNM	American College of Nurse-Midwives
ACOG	American College of Obstetricians and Gynecologists
ACP	American College of Physicians
ADEM	Acute Disseminated Encephalomyelitis
AEFI	Adverse events following immunization
aHR	Adjusted hazard ratio
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
aOR	Adjusted odds ratio
ASD	Autism spectrum disorder
BLA	Biologics License Application
CDC	Centers for Disease Control and Prevention
CFS	Chronic fatigue syndrome
cGMP	Current Good Manufacturing Practice

CIDP	Chronic Inflammatory Disseminated Polyneuropathy
CIN	Cervical Intraepithelial Neoplasia
CISA	Clinical Immunization Safety Assessment network
CMS	Centers for Medicare and Medicaid Services
CPSTF	Community Preventive Services Task Force
CRPS	Complex regional pain syndrome
CRS	Congenital Rubella Syndrome
DoD	Department of Defense
DSMB	Data Safety Monitoring Board
DTaP	Diphtheria, Tetanus and acellular Pertussis combination vaccine
DTP	Diphtheria, Tetanus and whole-cell Pertussis combination vaccine
EN	Erythema nodosum
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GBS	Guillain-Barré syndrome
H, as in H1N1	Hemagglutinin
HAV	Hepatitis A Virus
HBeAg	Hepatitis B e antigen
HBIG	Hepatitis B immune globulin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HHS	Department of Health and Human Services
Hib	<i>Haemophilus influenzae</i> type b
HPV	Human Papillomavirus
HR	Hazard ratio
HSCT	Hematopoietic stem cell transplantation
HSV	Herpes simplex virus
ID	Intradermal
IHS	Indian Health Services
IIV	Inactivated Influenza Vaccine
IM	Intramuscular
IND	Investigational New Drug
IOM	Institute of Medicine

IPV	Inactivated Polio Vaccine
IRB	Institutional Review Board
IRR	Incidence rate ratio
ITP	Immune thrombocytopenia purpura
IVS	Johns Hopkins Institute for Vaccine Safety
LAIV	Live Attenuated Influenza Vaccine
MBP	Myelin basic protein
MCO	Managed care organizations
MCV	Meningococcal conjugate vaccine
MI	Myocardial infarction
MIBE	Measles inclusion body encephalitis
mL	Milliliter
MMR	Measles, Mumps and Rubella vaccine
MMRV	Measles, Mumps, Rubella and Varicella combination vaccine
MPSV	Meningococcal polysaccharide vaccine
MS	Multiple sclerosis
N, as in H1N1	Neuraminidase
NAM	National Academy of Medicine
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NMO	Neuromyelitis optica
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
OMS	Opsoclonus myoclonus syndrome
OPV	Oral poliovirus vaccine
OR	Odds ratio
ORS	Oculorespiratory syndrome
PAN	Polyarteritis nodosa
PCV	Pneumococcal conjugate vaccine
pH1N1	Pandemic H1N1 influenza
POI	Primary ovarian insufficiency
PRISM	Post-Licensure Rapid Immunization Safety Monitoring Network
RIV	Recombinant influenza vaccine
RR	Relative risk/risk ratio
RV	Rotavirus vaccine

RZV	Recombinant zoster vaccine
SAb	Spontaneous abortion
SCID	Severe combined immunodeficiency
SFN	Small fiber neuropathy
SGA	Small for gestational age
SIDS	Sudden Infant Death Syndrome
SLE	Systemic lupus erythematosus
SSPE	Subacute sclerosing panencephalitis
Tdap	Tetanus, Diphtheria and acellular Pertussis booster vaccine
Th1	T helper type 1 cells
TIV	Trivalent inactivated influenza vaccine
US	United States
VA	Department of Veterans Affairs
VAERS	Vaccine Adverse Events Reporting System
VAMPSS	Vaccines and Medications in Pregnancy Surveillance System
VICP	National Vaccine Injury Compensation Program
VIP	Vaccine in Pregnancy Registry
VLP	Virus-like particles
VSD	Vaccine Safety Datalink
VZV	Varicella Zoster Virus
WHO	World Health Organization
ZVL	Zoster Vaccine, Live attenuated

Part I

Introduction

Chapter 1

Introduction



This book contains useful information on vaccines that are routinely recommended for most children, adolescents, adults and pregnant women in the United States. This information has been compiled and tailored for all vaccine providers and their staff.

First, evidence-based strategies for talking with patients about vaccines are described. Then, the vaccine safety system is discussed. The following section contains summaries of recommended vaccines along with the diseases they prevent. These summaries include official recommendations, contraindications and precautions, information on vaccine effectiveness and safety, and standardized talking points for use with patients. The final section contains summaries and talking points covering numerous potential vaccine adverse events and the current scientific evidence for associations (or non-associations) with vaccines.

Much of the information contained herein will be made available on the website for the Institute for Vaccine Safety at Johns Hopkins Bloomberg School of Public Health, found at the following link: <http://www.vaccinesafety.edu>. This content will also be available as an electronic searchable database in the associated app for smartphones, tablets and computers.

The website and app will be updated after each meeting of the Advisory Committee on Immunization Practices (ACIP),

to reflect any changes in recommendations made. The entire book will be updated regularly to incorporate new evidence as it arises. Feedback on the content of this book is encouraged and appreciated. To provide your feedback, please contact the authors at **info@hopkinsvaccine.org**.

We hope that having this information succinctly summarized and readily available will help providers and their staff be more comfortable and confident when answering questions and recommending vaccines to their patients.

Chapter 2

How to Talk with Patients About Vaccines



Conversations about vaccines with many patients can be easy. For some patients, vaccines can be a difficult topic. Talking with patients about uncomfortable topics can be challenging. However, it is part of providers' everyday interactions with patients. Within these interactions, the uneasiness surrounding certain topics more often emanates from the patient than the provider. In many cases, providers are able to overcome patients' uneasiness, as they have dealt with a particular topic frequently and are thus comfortable addressing it.

Talking about vaccines with patients who have concerns or questions can be difficult, given the unfortunate and abundant misinformation surrounding vaccines in the media and communicated by peers. Uneasiness can be more mutual when discussing vaccines. In this book, we provide many of the facts you will need to address both simple and complicated questions, including Advisory Committee on Immunization Practice (ACIP) recommendations, a description of the disease(s) being prevented, the vaccine(s) available, contraindications, vaccine effectiveness, and an overview of safety for the particular vaccine or combined vaccine. We include a section on important information for obstetric providers and considerations in pregnancy.

A presumptive approach to vaccinating on time should be the framework you use when you approach vaccination.

Getting vaccines according to the ACIP schedule should be the default choice for your patients. The way physicians introduce vaccination can be very influential on patients' willingness to vaccinate [1, 2]. Instead of asking patients, "Would you like to get your influenza vaccine today?" changing that simple question into the statement, "It's time to get your influenza vaccine today" can make a dramatic difference. The latter phrasing presumes that vaccination will occur, and therefore frames vaccination as the default. Framing vaccine receipt as a routine procedure indicates to the patient that vaccination is expected, and it is the standard of care in your practice. It sets getting vaccinated on time as the default for the patient in the decision-making process. This phrasing does not take a patient's choice away. A patient always has the final say in deciding whether or not to vaccinate. The advantage to presuming vaccination is that it clearly and confidently indicates to the patient that vaccination is important and is the standard of care that you endorse for them.

While the majority of patients that you encounter may be accepting of the vaccines you recommend, some may be more reluctant. This reluctance can exist for a variety of reasons and may not always be due to a lack of awareness or knowledge of the recommended vaccines. Vaccine hesitancy often involves deeply held world views, misperceptions formed over time, or beliefs adopted from others in their family or social circles. When you encounter a patient who is hesitant about receiving vaccines, whether he/she has just a few specific questions or seems more reluctant overall, *how* you discuss vaccines is very important. Listen to the patient to understand what they believe and why.

Vaccine conversations can be broken down into message framing and message content. It is often intuitive when a patient has a misperception to attempt to counter or debunk that myth or misperception. However, correcting misinformation alone can, in fact, reinforce the misperception or backfire [3].

We provide a five-step strategy to work with vaccine hesitant patients:

- 1) Establish empathy and credibility
- 2) Briefly address specific concerns, if any
- 3) Pivot to disease risk
- 4) Convey vaccine effectiveness
- 5) Give a strong and personalized recommendation.

Establishing empathy and credibility with the patient is very important. This is especially important for patients with specific concerns that may stem from popular myths or claims from invalid research, as this approach allows you to connect on a broader sentiment or value that you both find important [4]. With this said, you must be very careful to not affirm a myth or misperception while attempting to make that connection. For example, if a patient says that he/she is concerned about getting a flu shot because the flu shot will cause the flu, don't attempt to connect with the patient by affirming this misconception with, "I understand why you are worried the flu vaccine might cause the flu." Restating the concern, even if later addressed in an effort to overcome it, can ultimately reinforce the false belief. Instead, connect first with the deeper desire to stay healthy since the patient is clearly interested in staying healthy. An empathetic and credible response to this concern might start with, "So what I hear you saying is that you want to avoid the flu and stay healthy." By connecting with the value or sentiment underpinning a misguided concern, you are likely to find common ground on the topic without affirming or confirming misguided beliefs.

For patients with specific concerns, it may be helpful to begin by borrowing a technique from the field of Motivational Interviewing – that is, asking permission to share. "I've looked into this a great deal. Would it be okay if I shared with you what I've found out about this?" By doing this, assuming the patient says yes, which most will, you have made the patient more receptive to your next statements.

After establishing an empathetic and credible conversation and obtaining permission to share, there is now an opportunity to discuss the specific concern or concerns originally

raised by the patient. The detail of your response may need to be tailored to the educational level of the patient and how much evidence they desire. You may find yourself walking a fine line between providing information and lecturing, which can be off-putting. Be careful about bringing up potential concerns the patient didn't raise in the first place, and in general, keep explanations simple. A simple myth is more cognitively attractive than an overcomplicated correction. Remember: "less is more."

Once you have respectfully acknowledged a patient's concern, the next important approach of message framing is pivoting to the disease. Instead of persisting in an attempt to dissuade them from a misguided belief, turn instead to emphasizing the susceptibility to and severity of the diseases vaccines protect against, since the risk of contracting a vaccine-preventable disease is much greater than the risk of suffering a severe adverse reaction from a vaccine [5]. This allows you to steer the conversation in an educational direction around a common enemy (i.e. the diseases) instead of toward a potentially adversarial back and forth about a specific vaccine or vaccine components. Because overall childhood vaccination rates are high in the US and have been for some time, patients are often not familiar with how dangerous some of these diseases can be for themselves and/or their children. Instead, they may be more familiar with, and more fearful of, highly publicized reports of rare adverse events or myths. It is important to emphasize that diseases like influenza and pertussis have not been eradicated and continue to pose a substantial risk. When pivoting to the disease, there is a fine line between informing a patient and intimidating or scaring a patient. The goal is not to scare patients into getting vaccinated but rather to shift the focus of the conversation from myths about vaccines to facts about the diseases they prevent.

Emphasize what can be done to protect from these diseases. Provide the patient with the fact that vaccination is a highly effective and very safe way to prevent these diseases.