



WHO Preferred Product
Characteristics for
Next-Generation
Influenza Vaccines



WHO preferred product characteristics for next generation influenza vaccines

ISBN 978-92-4-151246-6

© World Health Organization 2017

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. WHO preferred product characteristics for next generation influenza vaccines. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Public domain cover image courtesy of CDC/Douglas Jordan.
Website: <https://phil.cdc.gov/phil/home.asp>

Printed in Geneva, Switzerland

WHO Preferred Product Characteristics for Next-Generation Influenza Vaccines

**Department of Immunization,
Vaccines and Biologicals**

Contents

Abbreviations & acronyms	<i>ii</i>
Introduction	1
1. WHO preferred product characteristics	4
1.1 Background and purpose	4
1.2 Target audience for WHO preferred product characteristics	5
1.3 Improved influenza vaccines: strategic priorities for WHO	5
1.4 Assumptions regarding vaccine research and immunization services	7
1.5 Global unmet public health need and strategic goals for improved influenza vaccines	10
1.6 Target groups, immunization strategies, and use case	11
1.7 Clinical endpoints	12
2. PPC for improved influenza vaccines	13
3. PPC for universal-type influenza A vaccines	18
4. Considerations on programmatic suitability	23
5. References	25
Appendix 1. Definitions of terms	28
Appendix 2. Assumptions regarding vaccine research and immunization systems	31
Acknowledgements	33

Abbreviations & acronyms

GVAP	WHO Global Vaccine Action Plan
HA	Influenza hemagglutinin glycoprotein
IVR	WHO Initiative for Vaccine Research
LMIC	Low and middle income country
PPC	Preferred product characteristic
TPP	Target product profile
VPPAG	WHO Vaccine Presentation and Packaging Advisory Group
WHO	World Health Organization

Introduction

The World Health Organization (WHO) recommends that persons at high risk for severe influenza illness should be vaccinated annually against influenza.¹ However, many low and middle income countries (LMICs) do not have national influenza vaccination programmes.² The absence of such programmes can be partly explained by the challenges associated with current vaccines which need to be reformulated up to twice each year to match the anticipated circulating strains in the northern and southern hemisphere influenza seasons, are generally of moderate efficacy against ambulatory influenza illness, and provide protection of limited duration. There is therefore a public health need for improved influenza vaccines conferring broader and longer protection against severe illness, particularly in LMICs.

To encourage innovation in influenza vaccine development to address these needs, WHO has developed *Preferred Product Characteristics for Next-Generation Influenza Vaccines*. Preferred product characteristics (PPCs) describe WHO preferences for vaccine parameters, primarily the indications, target groups, immunization strategies, and clinical data for assessment of safety and efficacy.³ These preferences are shaped by the global unmet public health need in a WHO priority disease area.

This document is designed to provide early guidance for the improvement of current influenza vaccines and the development of new influenza vaccines. It addresses vaccine research and development within five and ten year time horizons. WHO encourages studies and data collection most relevant to LMIC policy-making but does not advocate for specific vaccine formulations for use in those settings. WHO encourages product development that results in a dual market for both high income country and LMIC settings to facilitate commercial development, affordable pricing, and global distribution. The PPCs indicate to product developers the influenza vaccine characteristics that are most useful to policy-makers in LMICs. PPCs do not provide clinical evaluation guidance, regulatory guidance, or data thresholds for policy-making, and do not quantify explicit performance thresholds which may introduce barriers to improvement and innovation.

WHO convened an advisory group of international experts on influenza vaccines and public health to develop the PPC document. This PPC Advisory Group prepared a consensus statement on the global public health need for improved influenza vaccines: *Safe and well-tolerated influenza vaccines that prevent severe influenza illness, provide protection beyond a single year, and are suitable for programmatic use, are needed for low and middle income countries.*

The WHO position on influenza vaccines and the global unmet public health need define a use case that is prioritized throughout this document – the prevention of severe seasonal influenza illness through annual immunization of population groups at high risk in LMICs which have existing systems for vaccine delivery. The groups for which improved influenza vaccines are most needed are young children and elderly adults, as influenza vaccine effectiveness is suboptimal in both of these populations. Given the limitations in immunization systems for adults in low-resource settings, the priority target group of this document is young children, with immunization of other risk groups as a secondary target.

The PPC primary immunization strategy is the direct protection of immunized persons against influenza illness. Other important influenza immunization strategies, including vaccination of children to reduce transmission and influenza incidence at the household or community level, immunization of pregnant women to prevent influenza illness in infants, prevention of ambulatory influenza to ensure a healthy workforce, and responding to influenza pandemics, are discussed but are not considered to be part of the primary use case for the PPC document. However, technologies for production of improved influenza vaccines to address these different use case scenarios are likely to be similar.

Strategic goals for five and ten year time horizons and the preferred vaccine characteristics to address each strategic goal were defined by the PPC Advisory Group. The PPC development was guided by evidence-based assumptions with regard to vaccine research and development as well as availability of immunization services within these time horizons. Many technical achievements may be required for a product to meet all of the WHO preferred characteristics; however, attaining even some of them would be of value for public health.

This document highlights influenza vaccine preferences for LMICs for consideration by vaccine developers and by manufacturers of licensed products. Substantial global resources and effort have been dedicated to the development of a next generation influenza vaccine that would decrease the need for annual reformulation and vaccination. If these efforts are successful, and if such products are affordable and programmatically suitable for LMIC use, they could make an important contribution towards meeting this public health need.

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_26458

