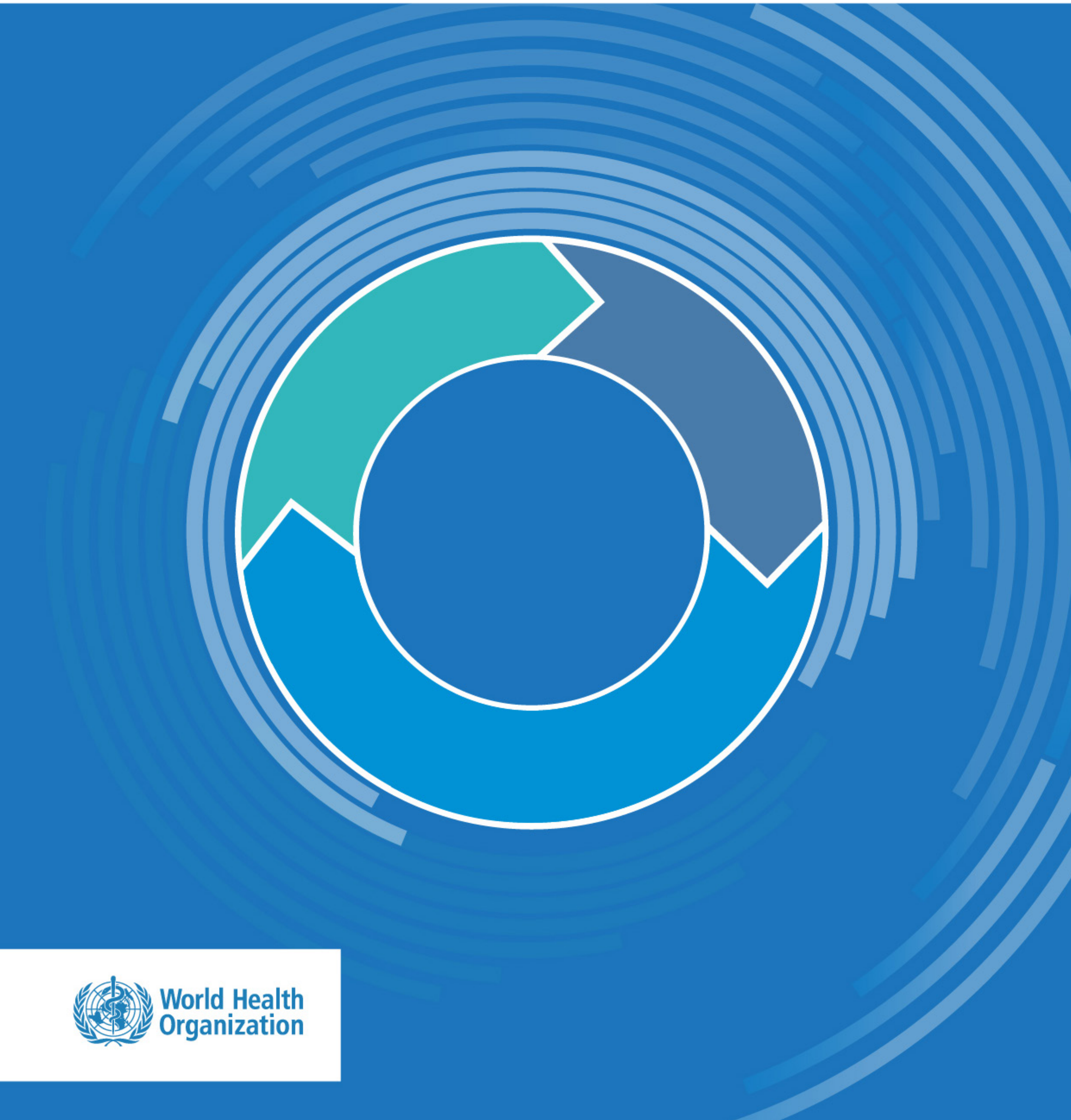
Norms, standards and processes underpinning development of WHO recommendations on vector control



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Note. The original title *Norms, standards and processes underpinning WHO vector control policy development* was changed to reflect recent changes to WHO's use of language regarding "policy" and "recommendations". The text has been updated accordingly.

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INTRODUCTION

In 2018, the World Health Organization (WHO) reviewed its processes for developing and disseminating guidance and recommendations spearheaded by a detailed analysis conducted within the Global Malaria Programme (GMP). The review identified areas for improvement, one of which is the better communication of the norms, standards and processes underpinning these recommendations. Better communication will ensure that product developers and researchers are fully aware of the WHO's requirements for assessing and ultimately recommending interventions for vector control. In this context, a vector control intervention is defined as a tool, technology or approach/strategy, and thus is not limited to products (see Annex 1 for glossaries of terms).

The current evaluation process for vector control was first communicated in 2017, following the transition from the WHO Pesticide Evaluation Scheme (WHOPES) to a process co-managed by the WHO Prequalification Team for Vector Control Products (PQT-VCP) and the two technical departments involved in vector control: GMP and the Department of Control of Neglected Tropical Diseases (NTD). While PQT-VCP assesses the safety, quality and efficacy of all vector control products and interventions, the three departments together support the Vector Control Advisory Group (VCAG), which is tasked with evaluating the public health value of novel interventions for which no WHO recommendation exists.

Since this first communication, the evaluation process and associated communication have been refined and continue to evolve. The implementation of the new process for developing WHO recommendations provides an opportunity to communicate these developments within the overarching framework of the WHO revised process, while highlighting the elements specific to vector control.

This document is mainly aimed at manufacturers and procurers of vector control products, and at researchers generating data, technologies and approaches/strategies. However, it is also envisaged that this document will provide reassurance to WHO Member States regarding the rigour applied by WHO in formulating recommendations, considering that such recommendations are used by Member States to inform the development of national policy and implementation of strategies.

The document provides a detailed overview of the norms, standards and processes underpinning the development of WHO recommendations for vector control interventions.[1] It also includes high-level information on the prequalification process, which is complementary to and coordinated with development of WHO recommendations. Detailed information on prequalification requirements and processes are available on the PQT-VCP website (https://www.who.int/pq-vector-control/en/).

In addition, this document provides an overview of the roles and responsibilities of the two technical departments involved in the development of vector control recommendations, namely GMP and NTD, and how they interact with PQT-VCP, which oversees the prequalification process in this area (see Annex 2). A RACI matrix is used to describe the various roles in completing the required tasks or deliverables for the vector control evaluation process the associated norms, standards and process of developing WHO recommendations. RACI is an acronym derived from the four key responsibilities most typically used: Responsible, Accountable, Consulted and Informed.

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[1] This document replaces: The evaluation process for vector control products. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/255644/WHO-HTM-GMP-2017.13-eng.pdf) and Malaria vector control policy recommendations and their applicability to product evaluation. Geneva: World Health Organization; 2017.

THE PROCESS OF DEVELOPING WHO RECOMMENDATIONS

A revised process for developing WHO recommendations is being rolled out across WHO departments beyond GMP, structured around three high-level steps:

- **Better anticipate:** This step involves activities that build up to and trigger the process for developing WHO recommendations, including horizon scanning and developing or endorsing preferred product characteristics (PPCs)/target product profiles (TPPs), in order to stimulate innovation, guide product development and provide predictability to manufacturers with respect to the evaluation process anticipated for these new tools.

- **Develop recommendations:** In this step, activities are undertaken to develop WHO recommendations, including recommendations based on the generation of evidence by manufacturers and/or research groups to demonstrate that an intervention has public health value; the assessment of these data by the relevant WHO advisory groups; and the formulation of recommendations by WHO.

- **Optimize uptake:** WHO guidance and recommendations are disseminated and use monitored.[2]

As outlined in Fig. 1, these process enhancements enable WHO to identify and communicate unmet public health needs; develop recommendations through an open and transparent process with shortened timelines; and optimize uptake through the use of tools such as digital technology.

This document outlines the links between the evolution of the process for developing WHO recommendations and the evolution of the evaluation process for vector control interventions. It also describes how the outputs from this evaluation process inform the development of new WHO recommendations. Topics covered include the determination of the evaluation pathways (Prequalification Pathway or New Intervention Pathway), detailed steps to be followed by applicants, and key epidemiological evaluation standards for vector control interventions, including study design and WHO requirements for trials.

OVERVIEW OF THE EVALUATION PROCESS FOR VECTOR CONTROL INTERVENTIONS

The WHO process for evaluating vector control interventions consists of two separate yet complementary pathways (Fig. 2). To decide which pathway an intervention will follow, the WHO Pre-submission Coordination Committee (PCC)[3] determines whether or not a new submission falls into an existing intervention class, based on the categorization of interventions