GLOBAL HEALTH CONSULTING

February 2024

The 7Ws approach to developing Use Cases for Vaccines, Diagnostics & Treatment of Neglected Tropical Diseases

We need a change in perspective

Achieving the goals of the **Immunization Agenda 2030** and **the Roadmap Neglected Tropical Diseases (NTD) 2030** requires:

- Increasing coverage of Mass Drug Administration (MDA) and Routine Immunization (the Zero-Dose Children's Agenda)
- Improving the ability and speed of measuring disease incidence and prevalence
- Addressing the root causes of vaccine hesitancy and MDA fatigue

Focusing on the users, those who ultimately use (or do not use) vaccines, drugs or diagnostics drugs will be necessary for initiating a dialogue that can trigger enhanced progress towards reaching these goals. The identification of use cases of these products is a necessary first step in this process.

"We cannot solve our problems with the same level of thinking that created them"

Albert Einstein

The goal of user research for Vaccines, Diagnostics and Treatments of NTDs

Developing a detailed understanding of all potential uses of a product or service **informs** various processes along the product or service life cycle.

For products in the early stage of development

Clinical trial design and choice of populations/sites

Forecasting of demand/and defining the commercial value proposition

Defining Target Product Profiles (TPP) and Preferred Product Characteristics (PPC)

For products moving towards the first marketing authorisation

Modelling of the health impact and estimate of the public health value proposition

Policy formulation

Programme design and identifying the most effective delivery strategies

User research requires a common understanding of some definitions

Fit

Use case

Persona

Implementation strategy

Archetype

The origin of the concept of use cases

Use cases : “all the ways of using a system to achieve a particular goal for a particular user”

- This original definition of use cases* aimed at clarifying what a system is going to do and, by intentional omission, what it is not going to do
- Over the years use cases have become the foundation for software development

Since then, the concept of use case has been adopted in social sciences (including public health) to describe the interaction between a user and a product or service

Introduced at the OOPSLA (Object-oriented Programming, Systems, Languages, and Applications) conference in 1987

Ivar Jacobson, Magnus Christerson, Patrik Jonsson, Gunnar Overgaard - Object Oriented Software Engineering: A Use Case Driven Approach - Addison-Wesley Professional; July 1992)

Ivar Jacobson, Ian Spence, Kurt Bittner - USE-CASE 2.0 The Guide to Succeeding with Use Cases, White Paper, IVAR Jacobsen International, December 2011

The definition of use cases for user research in healthcare settings

Use case

“A specific situation in which a medical product or service could potentially be used to accomplish a defined health goal”

“Improving the programme-fit of vaccines through the application of a design approach to the definition of vaccination policies and product guidance documents” (provisional title), S.Malvolti et. al., being finalized, 2024

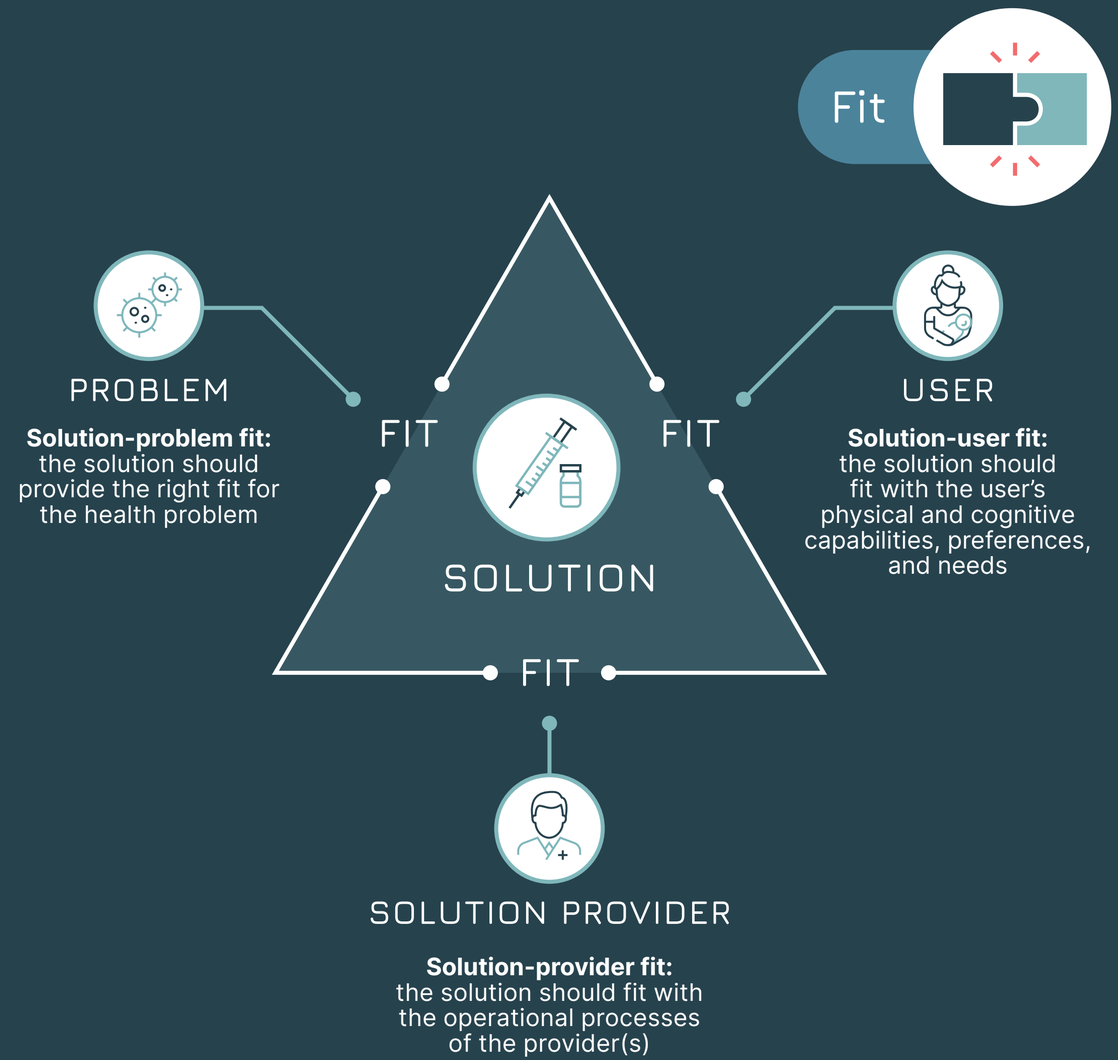
Defining the use cases requires focusing on how the product or service (the solution) can achieve the best FIT for the users

Fit is about appropriate products being timely administered to the targeted population

It is about moving from the current state (“as is”) to achieve the goal of a desired future improved state (“to be”)

The goal of user research is generating a fit across several different elements and not limiting the focus on the “technical” aspects of the health problem but focusing on the broader achievement of:

- The solution-problem fit
- The solution-provider fit
- The solution-user fit



Adapted from Leurs B., & Roberts I. (2017). What do we mean by design? https://www.nesta.org.uk/blog/what-do-we-mean-by-design/

The definition of the use cases starts from the analysis of the relevant Personae

The term **‘Persona’** was developed by Swiss psychoanalyst Carl Jung and refers to the version of oneself that we show to the world.

The concept has been adopted in market and user research to put the users at the centre and help to develop a better understanding of their needs, experiences, behaviours and goals.

Those factors, together with the country and programmatic context, influence Personae’s attitudes towards products or services, the way they interact with them and ultimately their use.

Personae are fictional characters representing the different user types that might use a service or a product

The provider and the recipient are the key personae in user research in healthcare

Persona

The **provider** who administers the medical product or service

The medical product or service used to address the health problem

The **recipient** who receives the medical product or service and their caregiver (where applicable)

Use cases vary depending on the programmatic context

The Implementation Strategies

How a medical product is used or a service is delivered depends on the **operational setting** in which it is embedded.

This context is generally addressed by specific implementation strategies.

Implementation Strategy

“Implementation strategies are methods or techniques used to enhance the adoption, implementation and sustainability of a clinical programme or practice”

Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012;8:217–226. doi: 10.1097/MLR.0b013e3182408812

Understanding the broader context is critical to refine the use cases

The archetypes

Contextual factors influence the use cases and their relative importance.

The importance of use cases may change considering different contexts (e.g., some may not be relevant in certain contexts).

The use of archetypes provides the ability to define common use case patterns across different contexts (e.g., geography, income, etc).

Archetpye

Archetypes are groupings of contextual factors sharing common characteristics in relation to the use of a specific medical product or service

METHOLOGY
THE 7 Ws APPROACH

A systematic approach to the definition of the use cases of a medical product or service

The use cases are influenced by:

- **the problem-solution relationship**
- **policy/programmatic aspects**
- **the context where the product is used**

Defining of use cases is an important step that should be included in the policy-making process.

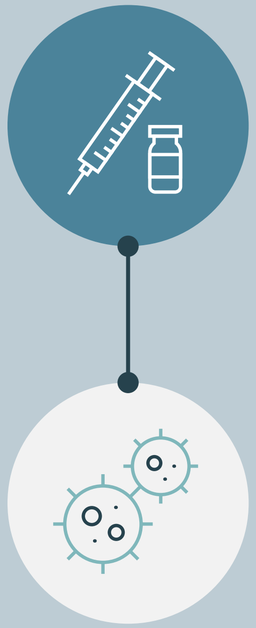
If use cases are defined before final policy recommendations (as issued at global, regional or country level), further refinement of the use cases will be required.

Identification of the use cases requires analysing six different dimensions of the health problem in a three-step process

STEP 1: clarification of the problem-solution relationship is needed to set the scene correctly

The characteristics of the medical product or service define its efficacy as a “solution” in addressing the problem.

Those characteristics determine the way in which the ”solution” is used by the users.



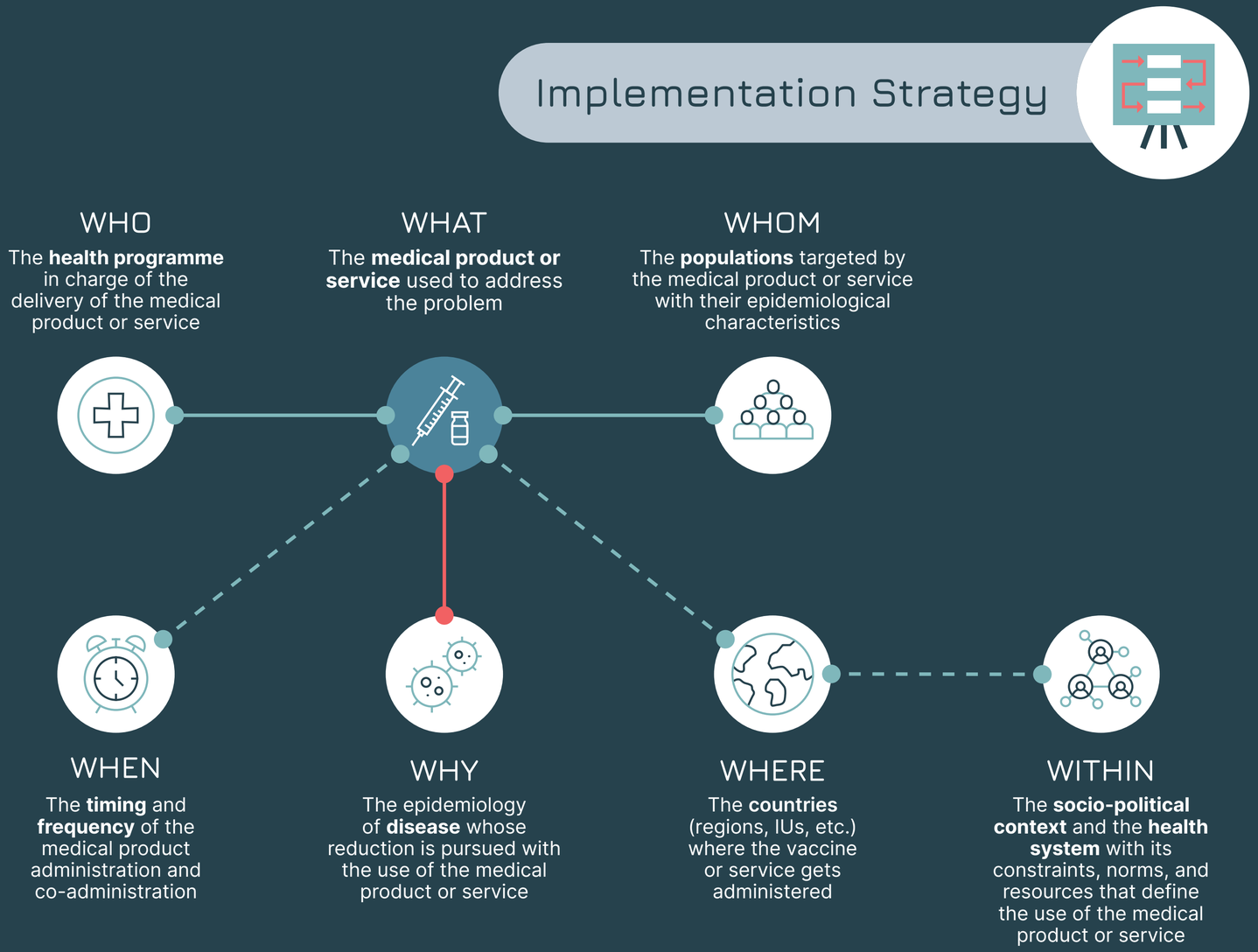
Solution WHAT

The medical **product or service** used to address the health problem

Problem WHY

The epidemiology of **disease** whose reduction is pursued with the use of the medical product or service

STEP 2: a programmatic/ policy lens is adopted to analyse contextual factors and identify implementation strategies



The output of step 2
A description of the implementation strategy

EXAMPLE OF AN IMPLEMENTATION STRATEGY

"A lyophilised measles-rubella combination vaccine indicated for infants from 9 months of age **(the what)** is administered during an outbreak response, **(the when)** by the EPI programme **(the who)** to a 9-month-old population **(the whom)** in Kano, Nigeria **(the where)**, in a decentralised health system, in an area with very low coverage and high vaccine hesitancy **(the within)**, to achieve the country goal of eliminating measles **(the why)**"

STEP 3: a product lens is adopted to analyse how the product is used in each implementation strategy and to assess the solution-user and solution-provider fits

Use case

WHAT

The **medical product or service** used to address the problem

WHO

The solution **provider** who administers the medical product or service

WHERE

The **location** where the medical product or service is administered

WHOM

The **recipient** who receives the medical product or service and their caregiver (where applicable)

The output of step 3
The description of the use case

EXAMPLE OF A USE CASE

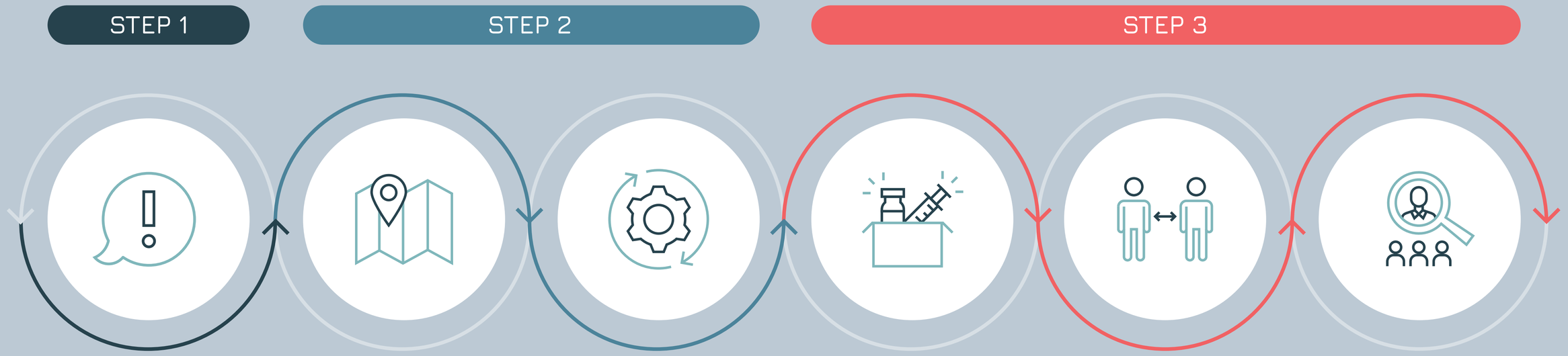
"As part of an outbreak response activity **(the implementation strategy)**, a lyophilised measles-rubella combination vaccine indicated for infants from 9 months of age in a vial containing 5 doses and requiring refrigeration at 2-8°C and to be prepared with a diluent **(what)** is administered by a community health worker **(who)** to a 9-month-old infant accompanied by the mother **(whom)** in a remote village health post without cold chain or storage capacity **(where)**"

For each implementation strategy, all use cases can be summarised in one synthetic view

	Fixed Health Facility (e.g., hospital, health centre, health post)	Setting with limited health services (e.g., schools)	Setting with no health services (e.g., home, workplace)
Delivery strategy:	Fixed site with full cold chain capacity	Outreach/campaigns in areas with reduced cold chain	Outreach or campaigns with limited cold chain and/or cold boxes
 <2 year old	1 Delivery by HW or CHW in Fixed Health Post Infant, accompanied by a caregiver, is vaccinated in a health post with full cold chain	2 Delivery by HW or CHW in settings with limited health services Infant, accompanied by a caregiver, is vaccinated in a community setting with reduced cold chain	3 Delivery by HW or CHW in setting with no health service Infant is vaccinated in the community with no cold chain by a HW/non-HW during a mobile session
 2- to 15-year-old 24 months-15 years	4 Delivery by HW or CHW in Fixed Health Post or a setting with limited/no health services Pre and school-age child is vaccinated as part of supplemental immunization activity at a health post with full cold chain or in a school with reduced cold chain, or as part of a campaign in the community with no cold chain by HW/non-HW		
 Adolescents & adults >15 to 45 years, including special populations*	*No use case - deprioritised due to low likelihood*		
 Military	5 Delivery by HW in Fixed Health Post Military personnel is vaccinated at military health facility with full cold chain by a HW		
 Travellers	6 Delivery by HW or CHW in Fixed Health Post or a setting with limited health services Adult traveller to an endemic typhoid area is vaccinated at a travel clinic or pharmacy with full or reduced cold chain by a HW or CHW		

* Special populations include food handlers and laboratory workers

The three operational steps of the process



Clarification of the Solution-Problem Ws

Mapping and selecting influential dimensions at programmatic and policy level

Defining the implementation strategies

Mapping and selecting influential dimensions at product level for each implementation strategy

Defining use cases for each implementation strategy

Consolidation and prioritisation of use cases across the different implementation strategies

GLOBAL HEALTH CONSULTING

This methodology has been developed by MMGH Consulting GmbH

Layout and design by Studio Miko

Read the full Method Paper at: www.mmghconsulting.org

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