

Sustainable Financing for Immunisation: MENA Countries share their lessons learnt on how to build an investment case Lessons learnt from the Vaccine Procurement Practitioners Network's Webinar held on 30 January 2024 Lessons

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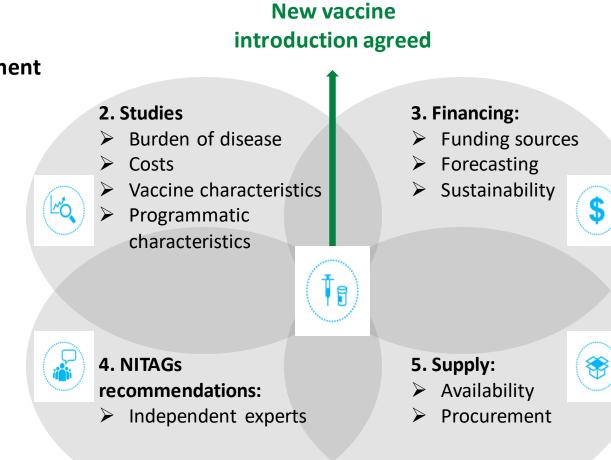
UNICEF PRESENTATION

How to create and use an investment case for new vaccine introduction



Decision-making for a new vaccine introduction Key factors to consider

- 1. Enabling environment
 - Social factors
 - Economic factors
 - Political factors
 - Regulatory/ Institutional factors
 - Stakeholders/ Interest groups



Adapted from: Burchett et al, 2012 National decision-making on adopting new vaccines: a systematic review | Health Policy and Planning | Oxford Academic (oup.com) and New vaccine adoption: qualitative study of national decision-making processes in seven low- and middle-income countries | Health Policy and Planning | Oxford Academic (oup.com)

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Decision-making for a new vaccine introduction – Key factors to consider:

- 1. To create an **enabling environment** for the introduction of a new vaccine, it is very important to consider political factors. The introduction of a vaccine can indeed become quite political and it is key to find the right moment to advocate for it.
- 2. The studies need to include a burden of disease, as only the vaccines, for which there is a prevalent burden of the particular disease, should be introduced. Both the costs of introducing the vaccine and the averted treatment costs should be estimated. The review of the vaccine characteristics should describe where the vaccine fits in the schedule. And for the programmatic characteristics, one should look at whether the vaccine needs to be delivered in schools or whether it can be added to the routine infant schedule.
- 3. Then, the **financing** needs to be analysed: what are the funding sources, the forecasting and how sustainable is the financing?
- 4. If there is a **NITAG** in the country, it should have the final say.
- 5. Finally, the supply availability and procurement options for the new vaccine should be assessed.

INVESTMENT CASE

- Useful for advocacy
- Contains an economic evaluation and broader topics:
 - Programmatic issues
 - Fiscal space
 - Rights-based and equity arguments
- Investment cases often include a costbenefit analysis or return on investment
 - This involves attaching a monetary value on morbidity and mortality, which is methodologically challenging

Ref: The UNICEF public finance toolkit https://www.unicef.org/documents/public-finance-toolkit

ECONOMIC EVALUATION

- Comparative analysis of alternative courses of action in terms of both their costs and their consequence
 - For instance, with and without a new vaccine

Three types of economic evaluation

Туре	Cost	Effect
	measurement	measurement
Cost-effectiveness	\$	Natural units
analysis		(cases, life years)
Cost-utility	\$	Healthy years
analysis		(QALYs/DALYs)
Cost-benefit	\$	\$
analysis		

An **investment case** always contains an economic evaluation. But it is broader than that, as it also considers programmatic issues, the fiscal space, etc.

Cost-effectiveness, cost-utility and cost-benefit analyses are all part of an **economic evaluation**. Often, people require more than a cost-effectiveness analysis, and ask for a cost-benefit analysis also. The cost-benefit analysis is where a dollar value is put on a life, hence the return on investments. Methodologically, it is not so solid, but people like it and it is easy to

do. 🤳

EXAMPLES OF INVESTMENT CASES



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Contents lists available at sciencedirect.com journal homepage: www.elsevier.com/locate/jval

Systematic Literature Review

A Scoping Review of Investment Cases for Vaccines and Immunization Programs

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- 24 vaccine investment cases identified between 1980-2017
- 21 global analyses and only 3 country specific

(2 from Bangladesh, 1 from China)

- Audience: mainly donors and 'all stakeholders'
- 14 for licensed vaccines and 5 for pipeline vaccines (TB, malaria, ETEC)

COUNTRY SPECIFIC

Cost-effectiveness and budget-impact of sustaining Haemophilus influenzae type b, <u>rotavirus</u> and pneumococcal vaccination in the Sudan during and after transition from Gavi support

18th December 2020

Sudan investment case: Key findings

- Impact of Hib, rotavirus and PCV: Prevent ~80,000 deaths and ~US\$ 48 million disease treatment costs during 2022-2031
- Cost to the Government:
 - ~ US\$ 415 million in procurement costs during 2022-2031, assuming Sudan transitions from Gavi support in 2027
- After subtracting savings from averted healthcare:

~US\$22 million costs in 2022, increasing to around \$45 million annually during period of self-financing (2027-2031)

- > Converting benefits to monetary value:
 - Total value estimated as \$12 billion over the ten-year period
 - Increases to \$46 billion when using a higher "Value of Statistical Life"

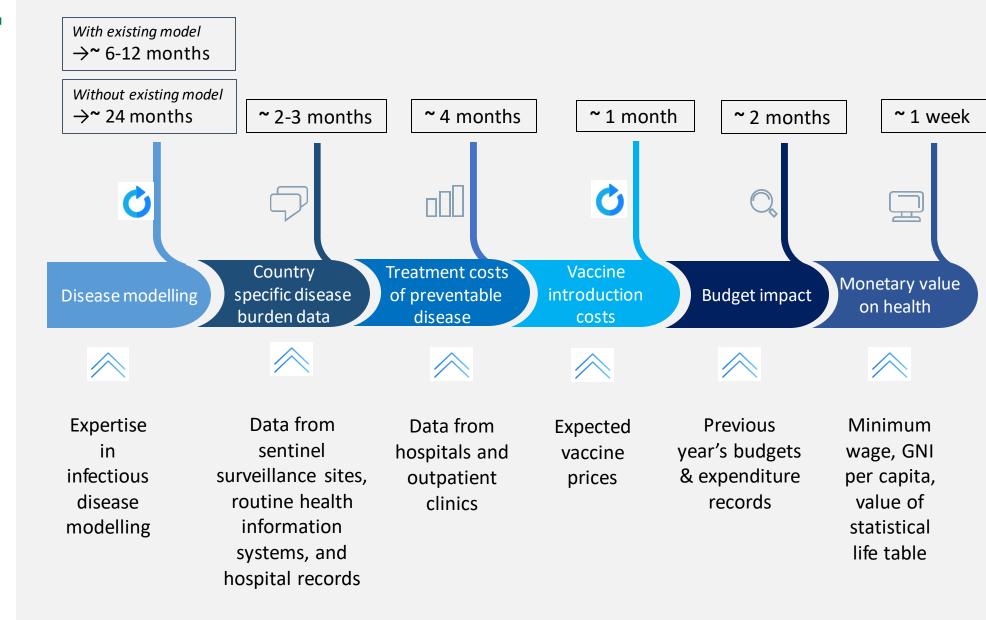
Examples of investment cases:

There was a systematic review of investment cases and it mainly concluded that most of them are actually global analyses. They only found 3 investment cases that were country specific.

Country-specific – Sudan investment case:

UNICEF did one country specific investment case for Sudan, including a cost-effectiveness analysis and return on investment of taking over the Hib, rotavirus and PCV vaccines when transitioning from Gavi support. It included the cost to the Government of sustaining the vaccines and subtracted savings from averted healthcare. The return on investment used the "value of statistical life" and estimated that the total value saved would amount to USD 12 billion over a ten-year period.

Time & resources needed to develop an investment case



Time & resources needed to develop an investment case:

The time needed for an investment case should not be underestimated, especially the economic evaluation part because it includes the disease modelling.

- 1. A **disease model** that estimates the vaccine's future impacts in terms of averted cases and deaths is always needed. It can be a sophisticated mathematical infectious disease model or it can be simpler, but it is a major piece of work. With an existing model, the whole exercise can take 6 to 12 months. Building the model will require 2 years.
- 2. Country-specific disease burden data are also necessary. It is always better to have data that are country-specific and not just picked from other countries, because decision-makers like to recognise where the data come from.
- 3. The averted treatment costs should also be collected from country data.
- 4. The vaccine introduction costs should include the expected vaccine prices that need to be compared with what is already paid for other vaccines and with the prices paid by other countries for the same vaccine.
- 5. The **budget impact** should look at what the government is already spending for vaccine procurement and what changes the new vaccine will make on the budget.
- 6. The monetary value on health is a simple calculation and represents just a week's work.

How to best use an investment case for decision-making

- Engage relevant decision makers during the process of developing the investment case
- Gather disease burden and cost data from local sources that decision makers recognize
- Engage local experts/academics in the process
- Ensure advocacy is linked to the budgetary process
- Link to any Health Technology Assessment organization in the country

The decision-making process is complex and political

- > Evidence influences decision makers at different points, which cannot be predicted
- It is often important to look for the right moments to advocate

The decision-making is quite political. Decision-makers have to be influenced at different times and it is hard to predict when is the best time to do so.

PANEL DISCUSSION



> a) Could you briefly describe the status of your immunisation programme? b) What vaccines have you introduced over the last 12 months? c) What vaccines are you planning to introduce in the near future?

	EGYPT	MOROCCO	TUNISIA
National Immunisation Schedule	 10 vaccines Bivalent oral polio vaccine and Salk vaccine Pentavalent vaccine against diphtheria, tetanus, pertussis (whooping cough), hepatitis B and Haemophilus influenzae type b Measles, mumps and rubella (MMR) 	 13 vaccines BCG Hepatitis B OPV DTwP-HepB-Hib IPV MR DTP Td 	 11 vaccines BCG Hepatitis B Pentavalent Polio (injectable and oral) PCV Measles and rubella (MR) Hepatitis A
Status of NVI (HPV, PCV, RV) Planned vaccine introductions	 HPV and RV – no timeline for introduction, priority is RV and then HPV PCV – 2024 	 PCV - 2010 RV - 2010 HPV - 2022 PCV 10 to PCV 13 - 2023 Hexavalent MMR Hepatitis A 	 PCV – 2019 HPV – academic year 2024/2025 RV – no timeline for introduction Tetraxim for 6-year-olds DTPa for school-age children and pregnant women HPV – 2024/2025 DTCa-VPI for 6-year-olds – 2024/2025 dTCa for pregnant women – 2024

Status of Immunisation Programme

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a) Could you briefly describe the status of your immunisation programme? b) What vaccines have you introduced over the last 12 months? c) What vaccines are you planning to introduce in the near future?

a) "We have 10 vaccines in Egypt.

- b) The Haemophilus influenzae vaccine was the last to be introduced in 2014. After that, we upgraded the doses of Salk vaccine, from a single dose for 4-month old babies in 2018 to 2 additional doses for 2-month and 6-month old babies since 2021.
- c) We are planning to introduce new vaccines, but under the government's condition that they are produced in Egypt. We are negotiating with pharmaceutical companies including Pfizer, Glaxo, Sanofi Pasteur, and others to introduce new vaccines, while localising the production in our country."

a) "The National Immunisation Programme includes 13 vaccines.

b) The latest introduced vaccine is in fact a switch: the transition from a PCV 10 to a PCV 13 which was made mid-2023. In 2022 we were able to introduce the HPV vaccine."

- a) "The Tunisian immunisation programme includes 11 vaccines.
- b) We have not changed it over the last 12 months. There was just a switch in March 2023 from the oral polio vaccine to the injectable one.

c) Looking ahead, we are planning in 2024 the introduction of the HPV vaccine and acellular DTCa-VPI for 6-year old children in schools as well as acellular dTCa for pregnant women."

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What process do you go through to introduce a vaccine? Using your latest vaccine introduction as an example, could you highlight: a) the process' recurring steps b) the challenges you face c) the best practices you have found?

 a) "We are not a Gavi eligible country so the introduction of new vaccines is the responsibility of our government. For the last introduced vaccine, the IBV, we started with one dose after ensuring the financial support from the Ministry of Finance. Of course, it's a long process that includes increasing the capacity of cold chain equipment and training healthcare workers. We will go through the same process to introduce the pneumococcal vaccine.

b) We are currently negotiating **partnerships with Egyptian companies working in pharmaceutical industries**. For other issues like cold chain equipment, we are relying on partners such as WHO and UNICEF in Egypt who are playing a very important role in supporting us with technical areas."

 a) "The vaccine introduction process includes the burden of the disease, its consequences and the risks of not introducing the vaccine. On top of this, we also analyse the financial accessibility, the technical feasibility of introducing the vaccine on programmatic and operational levels and the vaccine's acceptability by the population.

b) The main challenges are generally linked with the lack of national data to properly justify the introduction and of long-term visibility on the sustainability of the financing. For the vaccines prices, we use data from WHO, UNICEF and other partners. This allows us to make important benchmarks and plans.

 c) For the HPV introduction, we followed this process: we analysed what would be the consequences of not introducing the vaccine in terms of death increase. We consulted WHO and UNICEF to get an idea of the products availability and direct costs. We also studied the technical feasibility and programmatic aspects."

a) "There are **3 important steps**: first the Technical Immunisation Committee's recommendation to introduce a new vaccine. Second, the Health Minister's agreement. And third, the Ministry of Finance's agreement on the budget.

- b) Based on our latest experience, we do not really face any challenges for vaccine introductions. Above all, we have to examine whether the State budget allows for them. We put together advocacy case files which need to be accepted by the Ministers of Health first and of Finance then.
- c) In terms of **best practice**, the preliminary steps are key. First, learned societies or epidemiology services must appeal to the Technical Immunisation Committee. The Committee then needs to designate a group to work on the advocacy case file, including the disease's epidemiological state, recent studies in the country and experience of countries which have already introduced the vaccine."

Lessons SERIES Learnt Do you complete an investment case for a new vaccine introduction? If yes, what is it useful for and what are the key requirements for a good investment case? If no, would an investment case or other evidence be useful?

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"Yes, investment cases are done but not in the presented form. Our investment cases gather economic information and benchmarks, without country-specific data because we are missing a number of them.

Putting together an investment case as described above requires a lot of time and expertise that we don't have. We use data gathered in other similar middle-income countries."

"Yes. The key element of a good investment case is to ensure that the financing is sustainable. There is no point in investing in a new vaccine if it cannot be guaranteed in the long run.

Once the new vaccination line is introduced into the budget, it cannot be removed. The Health Minister's agreement is therefore very important because the vaccine budget line cannot be diverted to another public health priority."

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How can UNICEF support you when talking about new vaccines introduction? Would a process framework or more sharing of other countries' experience be helpful? "UNICEF has a good impact with its support for countries. In Egypt, UNICEF is the main partner for the vaccination programme.

For the introduction of new vaccines, we work with UNICEF country office, which supports us in **preparing an action plan** and helps with **community awareness**. It also helps us with the **training of healthcare workers**."

"UNICEF data on vaccine availability is especially important for planners as it allows them to have visibility on the market, prices and products in the pipeline.

For the next vaccine we plan to introduce, the hexavalent, UNICEF allows us to have a good visibility on the price evolution, the new producers who may appear, and also helps us with planning the introduction. UNICEF's **support with technical data**, such as the economic benefits of the vaccination in terms of public health, is also important. It allows us to properly put together our advocacy case file.

Finally, the **role of communication** in promoting vaccines is also key. The post-covid effect is still present and implies a small decline in demand for vaccination. In this area, a technical framework would be useful."

"UNICEF can **support countries technically**, with the preparation and communication plans, the post-introduction evaluation of the vaccine and cold chain equipment.

It can also **support countries financially** with the acquisition of additional cold chain equipment. Indeed, the three vaccines that we are planning to introduce are single-dose vaccines that will require most of the cold chain equipment that exists in Tunisia."

QUESTIONS & ANSWERS



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What are the key points to achieve financial sustainability? What mechanisms have you implemented to ensure it? "We have been planning with many companies to start producing new vaccines in Egypt. This project is curated by the agency responsible for procurement and by the government.

We believe it will take few years for production to start and new vaccines to be manufactured. In the meantime, we will procure vaccines from external sources so we can cover the first 2 or 3 years until we have our own products.

But we cannot start purchasing vaccines with the support of the Ministry of Finance for 1 or 2 years and then stop or reduce them. We are looking for sustainable options to vaccinate our children. So, we will rely on signing a contract until we start manufacturing our vaccines. And only then, we will introduce these new vaccines."

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In terms of advocacy, what can UNICEF do to make countries more sustainable? How do we make immunisation sustainable and help countries with prioritising among other health concerns? "An **investment case** is a good first step. Looking at the cost effectiveness, cost per death averted, can be very theoretical. Countries need to **gather practical information** about how to introduce vaccines and how to get them in the budget.

The most important data for governments is **budget impact analyses**, as they realistically show what the vaccines are going to cost. The cost per death averted is nice but it does not affect the budget directly. As we can hear from our panellists, the key issue is the procurement cost. So, countries need a very clear understanding of the budget impact, and it should be as realistic as possible.

Finally, countries need to try and **identify how the budget could be** increased."

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"The National Immunisation Programme allows the vaccination of more than 97% of the Moroccan population free of charge.

Our current project is to **involve insurance companies** and medical insurance plans **in the co-financing of vaccines**, as vaccines allow them to save money, by reducing the health problems. So, they should financially contribute to this primary prevention measure.

We have started negotiating with them and would like them to directly contribute to the vaccine budget. This will provide us with a significant financial windfall which will improve our immunisation programme.

Alongside this project, we are also talking about manufacturing vaccines locally."

B How do you ensure the financial sustainability of the vaccines you already introduced?

"Ensuring sustainability goes without saying in Tunisia. We never had a vaccine that was introduced and then withdrawn. The Tunisian Health Minister cannot decide to withdraw a vaccine after its introduction.

A vaccine introduction takes time for the advocacy case file to be put together and to convince the Health and Finance Ministers. But as soon as the vaccine is introduced, it is sustainable."



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