VALUE IN HEALTH REGIONAL ISSUES 1 (2012) 248–253

Available online at www.sciencedirect.com

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CONCEPTUAL ARTICLES

Performing Country-led Economic Evaluations to Inform Immunization Policy: ProVac Experiences in Latin America and the Caribbean

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ABSTRACT

New vaccines have been demonstrated to be effective in reducing morbidity and mortality, particularly in children, but come at increased costs to societies, governments, and their national immunization programs compared with other traditional childhood vaccines. Rational allocation of available resources requires systematic collection of the evidence base to decide whether to introduce a new vaccine, an important component of which is cost-effectiveness analysis. In this article, we develop in-depth case studies to examine the country experience of conducting cost-effectiveness analysis with the support of Pan American Health Organization ProVac Initiative and the implications of its process for decision making on new vaccine introduction in Latin America and the Caribbean. Key lessons regarding how cost-effectiveness analysis may be effectively used to inform evidence-based immunization policy are highlighted, drawing from the experience of Nicaragua and Paraguay. Based on the lessons identified, the vision going forward will focus on promoting the sustainability of multi-disciplinary country teams while continuing to prioritize capacity development as an overarching guiding principle for preparing countries to face future new vaccine policy decisions.

Keywords: cost-effectiveness analysis, economic evaluations, evidence–based policy, national immunization programs.

Introduction

New vaccines hold the extraordinary potential of saving lives and preventing disability but come at increased costs to governments and their national immunization programs. Considering the large investment new vaccines represent for many programs, the decision to introduce a new vaccine into a universal immunization schedule is a highly complex task [1,2]. Efficient allocation of available resources requires systematic review of the local evidence base to decide whether to invest public funds in a new vaccine. One component of the evidence base is economic analysis, including, among others, cost-effectiveness analysis [3]. Increasingly, national immunization programs in low- and middle-income countries are seeking ways to estimate the economic and financial burden as well as potential health gains of new vaccine introduction to ensure financial sustainability and efficient resource allocation in the long term [4]. As low- and middle-income countries assume greater financial responsibility for their national immunization program budgets, questions around financial sustainability and competition of resources among different health priorities become more relevant [5].

Ensuring sustainable vaccine introductions as well as efficient and equitable allocation of resources for health means that national public health decision makers must invest the time to collect the evidence base necessary to inform the decision-making process [1]. The Pan American Health Organization (PAHO), the regional office of the World Health Organization (WHO) for the Americas, provides technical assistance to

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

Authors' contributions: J.K.A. is the Deputy Director of PAHO and Principal Investigator of ProVac. He conceived and designed the initiative. B.J. is the Project Manager of the initiative, and C.B.J. is a technical officer for the initiative. J.K.A., B.J., C.B.J., and C.T. execute and coordinate the initiative's operations. A.D.C., B.M.B., S.R., and A.S. serve as technical consultants. A.D.C. developed the TRIVAC model. C.B.J., B.J., A.S., and A.D.C. drafted the manuscript. B.M.B., S.R., and C.T. made substantial contributions to the manuscript. J.K.A. revised the intellectual content of the manuscript. All authors participated in drafting and reviewing the article and approved the final manuscript.

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2212-1099 – see front matter

Published by Elsevier Inc.

http://dx.doi.org/10.1016/j.vhri.2012.10.003

countries in Latin America and the Caribbean (LAC) to facilitate and promote this process. Specifically, PAHO's ProVac Initiative has extended support to countries to build local evidence bases to inform decisions regarding the introduction of new vaccines [6]. The rationale and structure of the ProVac Initiative have been previously described [1,2,6]. In this article, we develop in-depth case studies to describe the country experience of conducting cost-effectiveness analyses (CEA) and developing local evidence bases to inform decision-making processes in LAC countries. The case studies reveal several lessons regarding the use of CEA to inform evidence-based immunization policy.

Supporting Country-Led Economic Analyses: ProVac's Approach to Strengthening Evidence-Based Immunization Policy

With support from the Bill and Melinda Gates Foundation, PAHO's ProVac Initiative was established to strengthen national capacity to perform economic analyses on new vaccines and to use the evidence to guide the decision-making process. While the ProVac Initiative promotes the development of a comprehensive evidence base to inform the decision on whether to introduce a new vaccine or not, drawing from technical, operational, and social criteria, its primary focus to date has been to respond to country requests to strengthen their capacity to conduct and to use economic analyses as one component of the evidence required for the introduction of new vaccines in the region [1,2,6].

ProVac helps countries to establish multidisciplinary teams and then supports these multidisciplinary teams to gather evidence for economic analyses on new vaccines, conduct the analyses, contextualize results with other evidence criteria related to the introduction of new vaccines, and message results to relevant authorities, either ministries of health or National Immunization Technical Advisory Groups (NITAGs). Central to the ProVac approach has been ensuring that multidisciplinary national teams include collaborators from several government agencies and disciplines—health economists, immunization program managers and staff, clinicians from health care organizations, and experts in related disciplines from academia. ProVac promotes local stakeholder ownership over the data collection and analysis process to bolster national capacity to conduct future studies and to establish a strong, sustainable foundation for evidence-based immunization policy.

Efforts have resulted in a number of country-led economic analyses, including 17 CEAs to inform national decision making around the introduction of new vaccines. Nine studies have been performed on the pneumococcal conjugate vaccines in Argentina, Bolivia, Guatemala, Costa Rica, Ecuador, El Salvador, Paraguay, Peru, and Nicaragua, two studies on the rotavirus vaccines in Argentina and Guatemala, and six studies on human papillomavirus vaccine in Argentina, Bolivia, Ecuador, Jamaica, Paraguay, and Uruguay (Table 1). Case studies from Nicaragua and Paraguay illustrate how the locally derived quantitative results are critical for new vaccine policymaking at the national level, but also how the process renders many other important inputs for the decision-making process. Evaluating these case studies reveals key opportunities for the ProVac Initiative to continue bolstering national capacity around evidence-based immunization policymaking.

Table 1 – ProVac supported country-led economic evaluations conducted in LAC.

Country-led economic evaluations	Countries
Cost-effectiveness analysis of pneumococcal conjugate vaccines	Argentina, Bolivia, Costa Rica, Ecuador, El Salvador, Guatemala, Nicaragua, Paraguay, Peru
Cost-effectiveness analysis of rotavirus vaccines	Argentina, Guatemala
Cost-effectiveness analysis of HPV vaccines	Argentina, Bolivia, Ecuador, Jamaica, Paraguay, Uruguay
Costing of HPV delivery strategies	Barbados
Costing of EPI	Bolivia

EPI, Expanded Program for Immunization; HPV, human papillomavirus. LAC, Latin America and the Caribbean.

Case Studies on the Use of Decision Support Models for New Vaccine Policymaking

In the Americas, nearly 12% of all-cause mortality among children younger than 5 years is attributed to pneumonia. Of the estimated 284,248 all-cause deaths among children younger than 5 years in LAC countries that occurred in 2008, 4366 deaths were caused by meningitis and 33,798 deaths were caused by pneumonia [7]. Pneumococcal infection is an important pathogenic cause of these deaths and other serious diseases in children, including meningitis and sepsis. With the licensure of two efficacious vaccines to prevent pneumococcal infection in children, many countries in the Americas have sought to evaluate the cost-effectiveness of introducing either the 10-valent pneumococcal conjugate vaccine (PCV-10) or the 13-valent pneumococcal conjugate vaccine (PCV-13) as one component of the necessary evidence base to inform the decision-making process.

In collaboration with the London School of Hygiene and Tropical Medicine, PAHO's ProVac Initiative has developed an integrated childhood vaccination cost-effectiveness model (TRIVAC) for countries to use and to apply in their local decision-making process. A user-friendly, Excel-based cohort model, TRIVAC evaluates the costs, health benefits, and cost-effectiveness of introducing Hib, rotavirus, or pneumococcal conjugate vaccines. TRIVAC has preloaded data available from international sources for demography, vaccine coverage, disease burden, health service utilization, and costs, but national ProVac teams are encouraged to challenge and improve these estimates with local estimates where quality data are available. The model allows users to evaluate a series of possible scenarios favorable and unfavorable to the vaccine by varying parameters such as community herd immunity, vaccine serotype replacement, and waning protection. Because there may be a great deal of uncertainty around these parameters in the initial years of new vaccine introduction, ProVac generally encourages countries to consider these factors in alternative scenarios to the base-case scenario. By modeling these alternative scenarios, the TRIVAC model assesses the effect of such uncertain parameters on primary model outcomes. In addition, the TRIVAC model features options to conduct sensitivity analyses. Further description of TRIVAC model's methods are presented in the forthcoming article by Clark et al [8].

Experience from Nicaragua

In 2009, Nicaragua began weighing the option to introduce one of the two available WHO prequalified vaccines to prevent pneumococcal pneumonia and other invasive disease. Alongside plans to implement sentinel surveillance sites for bacterial pneumonia and meningitis, the Ministry of Health requested support to undertake special studies to inform the decision-making process. One such request was for support from PAHO's ProVac Initiative to evaluate the cost-effectiveness of introducing a pneumococcal conjugate vaccine into the routine vaccination schedule.

The Ministry of Health established a national team to perform the study, including participation from the national Expanded

Program for Immunization (EPI) manager, a public health clinician dedicated full time to coordinate the study, and the PAHO immunization focal point, a trained infectious disease epidemiologist. The country team drafted a data collection plan around the TRIVAC model parameters: demography, disease burden, vaccine efficacy, serotype coverage, immunization coverage, incremental program costs, health service utilization, and treatment costs. In the following months, the country team coordinator organized meetings for interviews and data extraction with relevant actors in the Ministry of Health and local hospitals.

The national team agreed on a series of assumptions that would form the base-case scenario for evaluating the introduction of each vaccine (Table 2). For both PCV-10 and PCV-13, the base-case scenario assumed the implementation of a three dose primary schedule without a booster (3+0) for children beginning in 2011. The base-case scenario evaluated 20 successive cohorts of children younger than 5 years. Because treatment costs saved by families were considered important to the national government, the study was conducted from the societal perspective, including costs borne by the government and by households, such as transportation costs, fees to access private services, and foregone earnings by caretakers. The team also received training to perform scenario analysis to evaluate a series of scenarios favorable and unfavorable to the vaccines.

For each model parameter, the country team reviewed government databases, hospital registries, and billing reports for procedure and treatment costs associated with managing invasive pneumococcal disease cases. After an extensive review, the team concluded that existing national data on the incidence and severity of pneumococcal disease in children younger than 5 years were either sparsely documented or of poor quality. Abstracting estimates from a systematic review of regional data on the burden of pneumococcal disease in children younger than 5 years in LAC countries, Nicaragua populated the model with

Table 2 – Qualitative description of assumptions, processes, and outcomes of ProVac country-owned cost-effectiveness analyses in Nicaragua and Paraguay.

Assumptions, processes, and outcomes	Nicaragua	Paraguay
Vaccines evaluated	PCV-10 and PCV-13	PCV-10 and PCV-13
Base-case assumptions	• 3+0 schedule • Evaluation period 2011–2030 • Societal perspective • 3% discounting for costs and health benefits	• 2+1 schedule • Evaluation period 2011–2020 • Societal perspective • 3% discounting for costs and health benefits
Local vs. international data sources		
Demography	• National Census (2005) and national demographic projections	• National Census (2002) and national demographic projections
Disease burden	• Regional disease burden studies and outpatient registries	• Local and international disease burden studies
Vaccine efficacy	• Clinical trials and Cochrane review	• Clinical trials and Cochrane review
Immunization coverage	• Historical DPT3 coverage	• Historical DPT3 coverage
Incremental EPI costs	• Local costing exercise for nonvaccine costs	• Local costing exercise for nonvaccine costs
Health service utilization	• Ministry of Health study (2004) and National household surveys (2005)	• National household survey (2006)
Treatment costs	• Local costing study in three subsectors (2010)	• Local costing study in three subsectors (2009)
Duration of study	7 mo	4 mo
Country team composition	• EPI manager • Public health clinician* • PAHO country immunization advisor	• EPI manager • Health economist* • Pediatrician • PAHO country immunization advisor Lab and surveillance officers
Flow of CEA results	Final results presented to Ministry of Health authorities	Final results presented to NITAG
Process outcomes	• Decision to introduce PCV-13 with PPP support • Government report exploring financial sustainability of PCV-13 in the absence of PPP support	• NITAG endorsed recommendation to introduce PCV-10 • Government final report to support consultations with parliament and Ministry of Finance to request budget increase
Uncertainty analyses?	Scenario analysis	Scenario analysis One-way sensitivity analysis

CEA, cost-effectiveness analysis; DPT3, third dose of diphtheria-tetanus-pertussis vaccine; EPI, Expanded Program for Immunization; PPP, private-public partnership; NITAG, National Immunization Technical Advisory Group; PAHO, Pan American Health Organization; PCV-10, 10-valent pneumococcal conjugate vaccine; PCV-13, 13-valent pneumococcal conjugate vaccine.

* Study coordinator.

annual incidence estimates as follows: 1174 episodes of all-cause radiologically confirmed pneumonia per 100,000, 11 episodes of pneumococcal meningitis per 100,000, and 32 episodes of other severe invasive pneumococcal disease per 100,000 [9]. Selected parameters such as vaccine efficacy data were drawn from published clinical trials. The national team decided that the local data available for the remaining model parameters, including vaccine coverage, program costs, and health service utilization and disease management costs, were of good quality. With the exception of disease burden data, Nicaragua's cost-effectiveness study of pneumococcal conjugate vaccine introduction primarily considered local data.

At the request of the Ministry of Health, the national team presented findings from the cost-effectiveness analysis in early 2011. Base-case analysis results indicated that both the PCV-10 and the PCV-13 vaccines would be cost-effective if introduced universally with a 3+0 schedule at a price per dose of $14.85 (Revolving Fund price) and of $0.36 (private-public partnership (PPP) co-financing price), respectively. Cost-effectiveness thresholds used were those defined by the WHO, in which an intervention is considered cost-effective if the cost per disability-adjusted life-year is less than three times the gross domestic product per capita and highly cost-effective if less than one time the gross domestic product per capita [10]. The data collected for the cost-effectiveness study, in particular regional estimates on disease burden and local data on circulating pneumococcal serotypes and treatment costs, had alerted the national authorities to the urgency with which the country should introduce a vaccine to avert the substantial epidemiological and economic burden of pneumococcal disease in the country. By late 2010, Nicaragua decided to introduce PCV-13 because it was the only pneumococcal conjugate vaccine approved for co-financing support from PPP at an initial price to the country of $0.36 per dose and guaranteed for a 5-year period.

In addition to the base-case results, Nicaragua presented a series of alternative scenarios to communicate uncertainty around future PPP co-financing and possible vaccine prices in the absence of PPP support. The evaluation of the alternative pricing scenarios, determined by actual prices offered through PAHO's Revolving Fund, decreasing PPP co-financing support, and an assumed market price of US $20 per dose for both vaccines, indicated that the introduction of either vaccine would be cost-effective for the price ranges considered. However, the conclusions that the vaccine was cost-effective did not imply that the country would be able to afford the long-term investments required to achieve a high-coverage vaccination program. Nonetheless, the process of conducting a cost-effectiveness analysis allowed for the country to begin answering questions to inform a sustainable introduction. The Ministry of Health expressed that the process of reviewing data on the impact of future financing strategies was useful to evidence the need for resource mobilization to ensure access to pneumococcal conjugate vaccination in future years.

Experience from Paraguay

In late 2010, Paraguay requested technical support from PAHO to conduct a cost-effectiveness analysis of the pneumococcal conjugate vaccines. Considered a high-level priority from the outset, the Vice Minister of Health endorsed a ministerial decree (Ministry of Health Resolution S.G. No. 552) to establish a working group responsible for collecting evidence to assess the need and impact of vaccination against pneumococcal disease in the younger than 5 years population. The ministerial decree officially chartered and empowered a national team to undertake a ProVac supported cost-effectiveness analysis and a financial feasibility study on the potential adoption of a pneumococcal conjugate vaccine. The national team included the EPI manager, the PAHO immunization country focal point, a health economist from the Ministry of Finance, and a pediatrician. Additional support was provided by the Ministry of Health laboratory and surveillance staff.

Paraguay chose to evaluate the costs and health benefits of universal vaccination with a two-dose primary series and booster dose (2+1) schedule in 10 successive cohorts of children younger than 5 years of age beginning in 2011. Like the experience of Nicaragua, Paraguay underwent an extensive data collection process, consulting several local sources. By December 2010, the national team had collected sufficient information to populate all model parameters. As was the case in Nicaragua, estimates for disease burden were obtained from regional sources.

After concluding the study and performing scenario analysis, the national team presented the findings to Paraguay's NITAG. The NITAG serves to review the available evidence base to make recommendations to the Ministry of Health and inform national immunization policy. During the January 2011 NITAG meeting, the EPI manager presented the study findings, highlighting that both PCV-10 and PCV-13 would be considered cost-effective interventions in the Paraguayan context. However, PCV-10 was slightly more cost-effective than PCV-13 due to the vaccine's greater protective effect against acute otitis media. By preventing a greater number of acute otitis media cases, PCV-10 would avert frequent health service costs associated with treating the infection in children borne by families. The EPI manager underscored other important considerations. The study outcomes forecasted a doubling of the EPI budget in the second year of introduction, as assumed coverage efforts would undergo a rapid scale up. The study findings also served to communicate data gaps identified in the existing health information system, such as poor and disparate local disease burden data. NITAG members made a call to improve surveillance systems in order to have better quality data to inform decisions.

The primary outcome of the NITAG meeting was a formal recommendation to the Ministry of Health to introduce PCV-10. In part, the country's decision to introduce PCV-10 was influenced by the availability of only one pneumococcal conjugate vaccine in PAHO's Revolving Fund, a pooled procurement mechanism. The NITAG recommended using the Revolving Fund's transparent procurement mechanism to guarantee an uninterrupted supply of WHO prequalified vaccines at the best available price. With the results in hand, the EPI manager began informal consultations with members of parliament to seek the necessary budgetary increases to support universal introduction of PCV-10 in the near term. In addition, the Minister of Health used the study findings to lobby for a substantial expansion to the immunization program budget with the Ministry of Finance.

Discussion

The experience of Nicaragua and Paraguay signals the capacity of public health professionals to incorporate cost-effectiveness analysis into the decision-making process for new vaccine introduction when country teams have access to adequate tools and training for their use. Through reviewing how country teams applied decision-support tools and methods in the new vaccine introduction decision-making process, five key lessons were identified.

CEA Results Are Not Generalizable

Because several countries in the Americas have conducted CEA on the pneumococcal conjugate vaccines, the remaining countries that have not conducted studies may consider applying study results and neighboring country recommendations in their

own countries. But the experience of Nicaragua and Paraguay demonstrates that cost-effectiveness results are influenced by several country-specific factors and processes (Table 2). The two case studies highlight that despite grounding decisions in evidence, even similar cost-effectiveness results can lead to different new vaccine introduction decisions. Both vaccines represented "value for money" in Nicaragua and Paraguay, but the countries chose to introduce different vaccines. There are several reasons for this. First, the process of conducting cost-effectiveness analysis can shed light on other important considerations such as budgetary implications, which can be different from one country to another. Second, countries have unique characteristics such as PPP eligibility, which is an important factor for estimating long-term incremental costs to the vaccination program. And third, countries can prioritize different criteria for introduction, such as whether a certain vaccine can be procured through a more reliable and efficient mechanism. Therefore, the results of country-level CEA cannot be extrapolated to neighboring countries, and much less to make a recommendation for which vaccine to introduce.

A Framework for Building Up Timely Evidence Bases Is Critical

Model-based economic analyses are data-intensive, requiring the synthesis of information from disparate sources. These analyses provide a framework to begin collecting and analyzing the multiple layers of evidence relevant in the decision-making process. The iterative data collection and analysis process of disparate sources required for model-based economic analyses helps countries build up the evidence base around new vaccine introduction even before final results are obtained. For example, Nicaragua's final cost-effectiveness results came after the decision had already been made on the basis of an offer of a greatly subsidized price per dose for PCV-13, but the need to introduce the vaccine was evidenced in the early stages of data collection and analysis. Authorities knew that price subsidies for the pneumococcal conjugate vaccines were time bound and would not last forever, and the study exposed the substantial burden of pneumococcal disease in the country. The process of collecting and analyzing data necessary for the cost-effectiveness analysis signaled authorities early-on of the need to introduce the vaccine.

CEA Alone Cannot Answer All New Vaccine Policy Questions

Considering the current economic climate and constrained health budgets in the PAHO region, countries need answers to several questions to ensure efficient and equitable resource allocation for health. An important component of the evidence base for immunization policy, CEA can determine the relative value of introducing a new vaccine versus status quo; however, subsequent analyses are required to answer more complex policy questions around affordability and financial sustainability amid competing health priorities. In the example of Paraguay, a financial feasibility study was conducted to understand how the introduction of a pneumococcal vaccine would affect the program's current budget and spending trends. In addition to supplemental analyses, countries should seek to contextualize cost-effectiveness results with other technical, operational, and social criteria. Standardized decision cases, or short, concise policy documents targeting high-level public health decision makers, could include the evaluation of other evidence criteria to complement cost-effectiveness findings.

Country-Led Economic Evaluations Are a Useful Tool for Price Negotiation

Cost-effectiveness results can be an effective tool for negotiating prices, allowing governments to save more lives with their limited resources. The threshold from cost-effective to highly cost-effective or another national-level threshold can be used as negotiating power to access a lower price for the vaccine. In Nicaragua, estimating the cost-effectiveness of PCV-13 at different prices per dose as well as the resulting budgetary impacts gave the country a potentially powerful tool to mediate discussions with PPP about future co-financing support. At the same time, the secondary analysis allowed for decision makers to reflect on the resource needs to sustain vaccination against pneumococcal disease in the long term if PPP co-financing support were no longer available after the initial 5-year agreement. Even though favorable cost-effectiveness results for a new vaccine do not signal affordability for immunization programs, cost-effectiveness evidence can make it easier for decision makers to justify the national investment.

Effectively Channeling Cost-Effectiveness Results and Educating Decision Makers Is Key

While CEA has the potential to guide resource allocation and improve rational decision making, findings need to be channeled through key policy actors to have a tangible impact on the immunization policy. ProVac attempts to build infrastructure to improve communication between actors to increase the potential for informed, evidence based decision making. Paraguay's experience suggests that evidence reaches the decision maker more effectively when the relevant actors in the immunization policy arena are involved from the beginning. Early buy-in from the Vice-Minister of Health in Paraguay empowered the EPI manager and the national team to defend study results in front of a wide audience of policymakers, including parliamentarians. Another crucial factor for ensuring CEA considered in the decision-making process is the need to educate NITAG members and high-level authorities in the Ministry of Health on what types of information may be useful for prioritizing public health investments. Cost-effectiveness results can only be useful insomuch as the policymakers are aware of the advantages and limitations of economic analyses. For example, Nicaragua's experience illustrated how a relatively complex concept, such as uncertainty analysis, can be an effective tool for decision makers when simultaneous education and proper communication about its use is provided. Using the lower and upper limits of a few key parameters, such as vaccine efficacy, disease burden, and vaccine price per dose, showed national authorities that the vaccine was still considered cost-effective in a scenario unfavorable to the vaccine.

Conclusions

Policy questions and needs for technical support in the national decision-making process for new vaccine introduction continue to evolve in LAC. Implementation of PAHO's ProVac Initiative in LAC countries demonstrates how country-led economic analyses can help build capacity and infrastructure to make more informed, evidence-based decisions. Multidisciplinary country teams that gather the evidence base for public health policy are an essential component of this process. Government-sustained multidisciplinary country teams that generate, synthesize, and present evidence to decision makers are an effective instrument for promoting evidence-based immunization policy. The vision going forward for the ProVac Initiative will focus on promoting the sustainability of multidisciplinary country teams while continuing to prioritize capacity development as an overarching guiding principle for preparing countries to face future new vaccine policy decisions. In addition, the lessons learned from the initial experiences in LAC countries with country-led economic analyses to inform immunization policy will help inform the application of the ProVac approach for country support in other regions of the world. As PAHO's ProVac Initiative continues to support evidence-based decision making for new vaccine introduction in the Americas, it

will be important to share lessons and experiences gained in the Americas with other regions.

Acknowledgments

The authors gratefully acknowledge the ProVac country teams in Paraguay and Nicaragua. The ProVac Initiative is funded by the Bill and Melinda Gates Foundation, with additional in-kind support from the Pan-American Health Organization.

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