# VACCINE DELIVERY RESEARCH DIGEST

UNIVERSITY OF WASHINGTON STRATEGIC ANALYSIS, RESEARCH & TRAINING (START) CENTER

REPORT TO THE BILL & MELINDA GATES FOUNDATION

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# **Details of Articles**

## 1. Effect of ten-valent pneumococcal conjugate vaccine on invasive pneumococcal disease and nasopharyngeal carriage in Kenya: a longitudinal surveillance study

Hammitt LL, Etyang AO, Morpeth SC, Ojal J, Mutuku A, Mturi N, et al. *Lancet.* 2019 Apr 15. [Epub ahead of print] PubMed ID: 31000194

## ABSTRACT

#### BACKGROUND:

Ten-valent pneumococcal conjugate vaccine (PCV10), delivered at 6, 10, and 14 weeks of age was introduced in Kenya in January, 2011, accompanied by a catch-up campaign in Kilifi County for children aged younger than 5 years. Coverage with at least two PCV10 doses in children aged 2-11 months was 80% in 2011 and 84% in 2016; coverage with at least one dose in children aged 12-59 months was 66% in 2011 and 87% in 2016. We aimed to assess PCV10 effect against nasopharyngeal carriage and invasive pneumococcal disease (IPD) in children and adults in Kilifi County.

#### METHODS:

This study was done at the KEMRI-Wellcome Trust Research Programme among residents of the Kilifi Health and Demographic Surveillance System, a rural community on the Kenyan coast covering an area of 891 km2. We linked clinical and microbiological surveillance for IPD among admissions of all ages at Kilifi County Hospital, Kenya, which serves the community, to the Kilifi Health and Demographic Surveillance System from 1999 to 2016. We calculated the incidence rate ratio (IRR) comparing the prevaccine (Jan 1, 1999-Dec 31, 2010) and postvaccine (Jan 1, 2012-Dec 31, 2016) eras, adjusted for confounding, and reported percentage reduction in IPD as 1 minus IRR. Annual cross-sectional surveys of nasopharyngeal carriage were done from 2009 to 2016. FINDINGS:

Surveillance identified 667 cases of IPD in 3 211 403 person-years of observation. Yearly IPD incidence in children younger than 5 years reduced sharply in 2011 following vaccine introduction and remained low (PCV10-type IPD: 60.8 cases per 100 000 in the prevaccine era vs 3.2 per 100 000 in the postvaccine era [adjusted IRR 0.08, 95% CI 0.03-0.22]; IPD caused by any serotype: 81.6 per 100 000 vs 15.3 per 100 000 [0.32, 0.17-0.60]). PCV10-type IPD also declined in the post-

vaccination era in unvaccinated age groups (<2 months [no cases in the postvaccine era], 5-14 years [adjusted IRR 0.26, 95% CI 0.11-0.59], and  $\geq$ 15 years [0.19, 0.07-0.51]). Incidence of non-PCV10-type IPD did not differ between eras. In children younger than 5 years, PCV10-type carriage declined between eras (age-standardised adjusted prevalence ratio 0.26, 95% CI 0.19-0.35) and non-PCV10-type carriage increased (1.71, 1.47-1.99).

#### INTERPRETATION:

Introduction of PCV10 in Kenya, accompanied by a catch-up campaign, resulted in a substantial reduction in PCV10-type IPD in children and adults without significant replacement disease. Although the catch-up campaign is likely to have brought forward the benefits by several years, the study suggests that routine infant PCV10 immunisation programmes will provide substantial direct and indirect protection in low-income settings in tropical Africa.

#### WEB: 10.1016/S0140-6736(18)33005-8

IMPACT FACTOR: 53.25 CITED HALF-LIFE: 9.20

### START COMMENTARY

Using 18 years of clinical, laboratory, and demographic surveillance data through the KEMRI-Wellcome Trust Research Programme, Hammitt et al. conducted an evaluation of the impact of the ten-valent pneumococcal conjugate vaccine (PCV10) on the incidence of invasive pneumococcal disease (IPD) and pneumococcal nasopharyngeal carriage among children and adults in Kilifi, Kenya. The authors considered the following potential confounders: time, annual incidence of admissions, malaria admissions, moderate or severe malnutrition admissions, and compliance with recommendations for investigation by blood culture. They also used a Bonferroni correction to adjust for the multiple serotype-specific tests. The authors found a significant reduction in IPD and carriage of vaccine serotypes among those vaccinated, as well as those unvaccinated, indicating herd immunity. There are several strengths to this study: the use of a robust surveillance system, multiple years of data, exclusion of data collected and person-time during hospital strike periods and sensitivity analyses to tackle uncertainty around parameters. An interesting observation is the lack of reduction in 6A and 19A IPD; authors suggested that the vaccination schedule with a booster may elicit a stronger protection against these serotypes, but that further study is needed. A limitation to this study is in the before-after study design. Authors noted that several indicators suggest improvement in health over time, thus improvement in IPD may be due to other factors beyond the vaccine. Despite these limitations, this study has many strengths and contributes to the understanding of PCV10 impact in a low-income setting.

## 2. <u>Sustaining pneumococcal vaccination after</u> <u>transitioning from Gavi support: a modelling</u> <u>and cost-effectiveness study in Kenya</u>

Ojal J, Griffiths U, Hammitt LL, Adetifa I, Akech D, Tabu C, et al. *Lancet Glob Health*. 2019 May;7(5):e644-e654. PubMed ID: 31000132

### ABSTRACT

#### BACKGROUND:

In 2009, Gavi, the World Bank, and donors launched the pneumococcal Advance Market Commitment, which helped countries access more affordable pneumococcal vaccines. As many lowincome countries begin to reach the threshold at which countries transition from Gavi support to selffinancing (3-year average gross national income per capita of US\$1580), they will need to consider whether to continue pneumococcal conjugate vaccine (PCV) use at full cost or to discontinue PCV in their childhood immunisation programmes. Using Kenya as a case study, we assessed the incremental cost-effectiveness of continuing PCV use.

METHODS:

In this modelling and cost-effectiveness study, we fitted a dynamic compartmental model of pneumococcal carriage to annual carriage prevalence surveys and invasive pneumococcal disease (IPD) incidence in Kilifi, Kenya. We predicted disease incidence and related mortality for either continuing PCV use beyond 2022, the start of Kenya's transition from Gavi support, or its discontinuation. We calculated the costs per disability-adjusted life-year (DALY) averted and associated 95% prediction intervals (PI).

FINDINGS:

We predicted that if PCV use is discontinued in Kenya in 2022, overall IPD incidence will increase from 8.5 per 100 000 in 2022, to 16.2 per 100 000 per year in 2032. Continuing vaccination would prevent 14 329 (95% PI 6130-25 256) deaths and 101 513 (4386-196 674) disease cases during that time. Continuing PCV after 2022 will require an estimated additional US\$15.8 million annually compared with discontinuing vaccination. We predicted that the incremental cost per DALY averted of continuing PCV would be \$153 (95% PI 70-411) in 2032.

#### INTERPRETATION:

Continuing PCV use is essential to sustain its health gains. Based on the Kenyan GDP per capita of \$1445, and in comparison to other vaccines, continued PCV use at full costs is cost-effective (on the basis of the assumption that any reduction in disease will translate to a reduction in mortality). Although affordability is likely to be a concern, our findings support an expansion of the vaccine budget in Kenya.

WEB: <u>10.1016/S2214-109X(18)30562-X</u> IMPACT FACTOR: 18.71 CITED HALF-LIFE: 1.00

### START COMMENTARY

Ojal et al. conducted an analysis to compare the 10-year impact and cost-effectiveness of continuing pneumococcal conjugate vaccine (PCV) after 2022 versus discontinuing PCV. The dynamic compartmental, age-structured model accounts for serotype replacement disease. Authors analyzed cost-effectiveness from a societal perspective and included medical costs, opportunity cost of caretaker time, and household out-of-pocket costs. The validity of the study is dependent on how well the authors estimated the impact of PCV in mortality, morbidity, and DALYs averted and estimated the cost of assigned to each outcome. In Figures 1 and 2, the authors showed relatively good agreement between observed and their fitted model to IPD prevalence and incidence, perhaps, with the exception of IPD incidence in children <1 year. The authors also cited a number of parameters which may be overestimated or underestimated, including the proportion of cases getting hospital treatment or the proportion of non-hospitalized cases treated as outpatients; however, these estimates would overestimate the ICER providing a conservative estimate. Authors also highlighted other unknown scenarios that might impact the validity of their study such as estimates around non-vaccine serotype disease. Additional analyses examining the impact and uncertainty of these parameters would be beneficial. Overall, Ojal et al. provide a valuable examination of the impact of discontinuation of PCV in a LMIC setting.

## 3. Introduction of new vaccines for immunization in pregnancy - Programmatic, regulatory, safety and ethical considerations

Kochhar S, Edwards KM, Ropero Alverez AM, Moro PL, Ortiz JR. Vaccine. 2019 May 31;37(25):3267-3277. Epub 2019 May 6. PubMed ID: 31072733

## ABSTRACT

Immunizing pregnant women is a promising strategy to reduce infectious disease-related morbidity and mortality in pregnant women and their infants. Important pre-requisites for the successful introduction of new vaccines for immunization in pregnancy include political commitment and adequate financial resources: trained, committed and sufficient numbers of healthcare workers to deliver the vaccines; close integration of immunization programs with antenatal care and Maternal and Child Health services; adequate access to antenatal care by pregnant women in the country (especially in low and middle-income countries (LMIC)); and a high proportion of births occurring in health facilities (to ensure maternal and neonatal follow-up can be done). The framework needed to advance a vaccine program from product licensure to successful country-level implementation includes establishing and organizing evidence for anticipated vaccine program impact, developing supportive policies, and translating policies into local action. International and national coordination efforts, proactive planning from conception to implementation of the programs (including countrylevel policy making, planning, and implementation, regulatory guidance, pharmacovigilance) and country-specific and cultural factors must be taken into account during the vaccines introduction.

WEB: 10.1016/j.vaccine.2019.04.075

IMPACT FACTOR: 3.29 CITED HALF-LIFE: 5.50

## START COMMENTARY

Kochhar et al. summarized important factors to consider for new vaccines for pregnant women in Table 2, highlighting the important needs, gaps, and considerations to vaccinating this population. The authors also commented on the alignment of ANC visits and vaccination programs, improving guidance and standardization of definitions and protocols to avoid confusion and misinformation for healthcare workers, the need to include pregnant women in clinical trials, and use other sources of data if systems are not in place for surveillance or monitoring of adverse events. Kochhar et al. also highlighted the role of vaccine hesitancy with maternal immunization. Table 4 provides factors that

might lead to vaccine hesitancy among pregnant women. Authors also noted the importance of including pregnant women in vaccine clinical trials in order to include the clear language around the indication on the vaccine label and avoid confusion among healthcare workers who rely on the labels to provide vaccination guidance. Of note, authors also touched on the ethical considerations of giving women autonomy to make decisions about receiving vaccines and inclusion of women in decision-making bodies around immunizations in pregnancy programs.

## 4. <u>Pregnant women & vaccines against emerging</u> <u>epidemic threats: Ethics guidance for</u> <u>preparedness, research, and response</u>

Krubiner CB, Faden RR, Karron RA, Little MO, Lyerly AD, Abramson JS, et al. *Vaccine.* 2019 May 3. [Epub ahead of print] PubMed ID: 31060949

### ABSTRACT

Zika virus, influenza, and Ebola have called attention to the ways in which infectious disease outbreaks can severely - and at times uniquely - affect the health interests of pregnant women and their offspring. These examples also highlight the critical need to proactively consider pregnant women and their offspring in vaccine research and response efforts to combat emerging and reemerging infectious diseases. Historically, pregnant women and their offspring have been largely excluded from research agendas and investment strategies for vaccines against epidemic threats, which in turn can lead to exclusion from future vaccine campaigns amidst outbreaks. This state of affairs is profoundly unjust to pregnant women and their offspring, and deeply problematic from the standpoint of public health. To ensure that the needs of pregnant women and their offspring are fairly addressed, new approaches to public health preparedness, vaccine research and development, and vaccine delivery are required. This Guidance offers 22 concrete recommendations that provide a roadmap for the ethically responsible, socially just, and respectful inclusion of the interests of pregnant women in the development and deployment of vaccines against emerging pathogens. The Guidance was developed by the Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies (PREVENT) Working Group - a multidisciplinary, international team of 17 experts specializing in bioethics, maternal immunization, maternal-fetal medicine, obstetrics, pediatrics, philosophy, public health, and vaccine research and policy - in consultation with a variety of external experts and stakeholders.

WEB: 10.1016/j.vaccine.2019.01.011

IMPACT FACTOR: 3.29 CITED HALF-LIFE: 5.50

### START COMMENTARY

Krubiner et al. provided 22 recommendations to move vaccine research, delivery, and accessibility forward for pregnant women, drawing from a moral argument. An executive summary is provided

that summarizes the comprehensive report. Of note, Table A provides a summary of considerations for assessing risk and benefits of including pregnant women in research and delivery of vaccines.

## 5. <u>"It depends how one understands it:" a</u> <u>qualitative study on differential uptake of oral</u> <u>cholera vaccine in three compounds in</u> Lusaka, Zambia

Heyerdahl LW, Pugliese-Garcia M, Nkwemu S, Tembo T, Mwamba C, Demolis R, et al. *BMC Infect Dis.* 2019 May 14;19(1):421. PubMed ID: 31088376

## ABSTRACT

#### BACKGROUND:

The Zambian Ministry of Health implemented a reactive one-dose Oral Cholera Vaccine (OCV) campaign in April 2016 in three Lusaka compounds, followed by a pre-emptive second-round in December. Understanding uptake of this first-ever two-dose OCV campaign is critical to design effective OCV campaigns and for delivery of oral vaccines in the country and the region. METHODS:

We conducted 12 Focus Group Discussions (FGDs) with men and women who self-reported taking no OCV doses and six with those self-reporting taking both doses. Simple descriptive analysis was conducted on socio-demographic and cholera-related data collected using a short questionnaire. We analyzed transcribed FGDs using the framework of dose, gender and geographic location. RESULTS:

No differences were found by gender and location. All participants thought cholera to be severe and the reactive OCV campaign as relevant if efficacious. Most reported not receiving information on OCV side-effects and duration of protection. Those who took both doses listed more risk factors (including 'wind') and felt personally susceptible to cholera and protected by OCV. Some described OCV side-effects, mostly diarrhoea, vomiting and dizziness, as the expulsion of causative agents. Those who did not take OCV felt protected by their good personal hygiene practices or, thought of themselves and OCV as powerless against the multiple causes of cholera including poor living conditions, water, wind, and curse. Most of those who did not take OCV feared side-effects reported by others. Some interpreted side-effects as 'western' malevolence. Though > 80% discussants reported not knowing duration of protection, some who did not vaccinate, suggested that rather than rely on OCV which could lose potency, collective action should be taken to change the physical and economic environment to prevent cholera.

#### CONCLUSIONS:

Due to incomplete information, individual decision-making was complex, rooted in theories of disease causation, perceived susceptibility, circulating narratives, colonial past, and observable

outcomes of vaccination. To increase coverage, future OCV campaigns may benefit from better communication on eligibility and susceptibility, expected side effects, mechanism of action, and duration of protection. Governmental improvements in the physical and economic environment may increase confidence in OCV and other public health interventions among residents in Lusaka compounds.

#### WEB: 10.1186/s12879-019-4072-6

IMPACT FACTOR: 2.62 (2016) CITED HALF-LIFE: 3.80

### START COMMENTARY

Heyerdahl et al. conducted 12 Focus Group Discussions (FGDs) of 171 participants to understand perceptions and beliefs around cholera and the oral cholera vaccine (OCV). Several themes were identified in the FGDs that highlighted the need for better education around the cholera and OCV as misconceptions around how cholera is spread and the effectiveness of OCV were identified. A strength of the study was that the study was conducted among those who refused both doses of the vaccine and those who received both doses of the vaccine to provide a range of perspectives. Authors noted that they excluded those who received partial dose (one dose) from the current study, but results from those individuals will be included in another study, which will provide the full spectrum of vaccination behavior. Authors also identified participant opinions of how to improve the vaccination campaigns, including mobile units for vaccine administration, more education, outreach on weekends, improve the taste of OCV and increase of the size of the vial. Limitations of the study include relying on self-report of vaccination status, inability to identify individuals who recently moved from rural areas (a group that may be rooted in traditional beliefs), and the lack of generalizability to other settings.

## 6. <u>Herd protection of unvaccinated adults by oral</u> <u>cholera vaccines in rural Bangladesh</u>

Ali M, Kim P, Zaman K, Clemens J. *Int Health*. 2019 May 1;11(3):229-234. PubMed ID: 30496408

## ABSTRACT

#### BACKGROUND:

Past research has suggested that the most cost-effective approach to using oral cholera vaccines (OCVs) to control endemic cholera may be to target only children <15 y of age. However, the assumption that vaccination of children with OCVs protects unvaccinated adults has never been tested.

METHODS:

We reanalyzed the data of an OCV trial in Bangladesh in which children 2-15 y of age and women >15 y of age were allocated to OCV or placebo and assessed herd protection by relating the risk of cholera in each nonvaccinated adult (>15 y) to OCV coverage (OCVC) of residents residing in virtual clusters within 500 m of the residence of that unvaccinated adult.

RESULTS:

The risk of cholera in unvaccinated adults decreased by 14% with each 10% increase of OCVC of all targeted age groups (95% 7 to 21%, p=0.0004). Also, the risk of cholera in unvaccinated adults decreased by 13% with each 10% increase in OCVC of children 2-15 y of age (95% CI 6 to 20%, p=0.0007). A high correlation between levels of OCVC of children and adult females precluded an assessment of the herd protection of unvaccinated adults by vaccinating children <16 y of age, independent of concomitant vaccination of adult women.

CONCLUSIONS:

Unvaccinated adults benefitted from herd protection conferred by OCVs in this trial. Vaccination of children may be sufficient to confer this protection, but this possibility needs to be evaluated in further studies.

WEB: <u>10.1093/inthealth/ihy085</u> IMPACT FACTOR: 1.80 CITED HALF-LIFE: n/a

### START COMMENTARY

Ali et al. conducted an analysis to determine whether the oral cholera vaccine (OCV) conferred herd protection among unvaccinated adults by analyzing data from a trial conducted in 1985. The authors

commented on a few limitations to their study including assuming that the risk estimate of cholera was the same between the Matlab trial and the study period. Authors also commented on the lack of generalizability of results to cholera-naïve settings and that while the original study design was randomized, vaccination coverage was not randomized and thus unmeasured confounders may be an issue. Despite these limitations, Ali et al. report on a valuable study of herd protection with interesting observations of protection between women and men.

## 7. Building health workforce capacity for planning and monitoring through the Strengthening Technical Assistance for routine immunization training (START) approach in Uganda

Ward K, Stewart S, Wardle M, Sodha SV, Tanifum P, Ayebazibwe N, et al. *Vaccine*. 2019 May 9;37(21):2821-2930. Epub 2019 Apr 15. PubMed ID: 31000410

### ABSTRACT

#### INTRODUCTION:

The Global Vaccine Action Plan identifies workforce capacity building as a key strategy to achieve strong immunization programs. The Strengthening Technical Assistance for Routine Immunization Training (START) approach aimed to utilize practical training methods to build capacity of district and health center staff to implement routine immunization (RI) planning and monitoring activities, as well as build supportive supervision skills of district staff.

#### METHODS:

First implemented in Uganda, the START approach was executed by trained external consultants who used existing tools, resources, and experiences to mentor district-level counterparts and, with them, conducted on-the-job training and mentorship of health center staff over several site visits. Implementation was routinely monitored using daily activity reports, pre and post surveys of resources and systems at districts and health centers and interviews with START consultants. RESULTS:

From July 2013 through December 2014 three START teams of four consultants per team, worked 6 months each across 50 districts in Uganda including the five divisions of Kampala district (45% of all districts). They conducted on-the-job training in 444 selected under-performing health centers, with a median of two visits to each (range 1-7, IQR: 1-3). More than half of these visits were conducted in collaboration with the district immunization officer, providing the opportunity for mentorship of district immunization officers. Changes in staff motivation and awareness of challenges; availability and completion of RI planning and monitoring tools and systems were observed. However, the START consultants felt that potential durability of these changes may be limited by contextual factors, including external accountability, availability of resources, and individual staff attitude.

CONCLUSIONS:

Mentoring and on-the-job training offer promising alternatives to traditional classroom training and audit-focused supervision for building health workforce capacity. Further evidence regarding comparative effectiveness of these strategies and durability of observed positive change is needed.

#### WEB: 10.1016/j.vaccine.2019.04.015

IMPACT FACTOR: 3.29 CITED HALF-LIFE: 5.50

### START COMMENTARY

In addition to on-the-job training and mentorship, repeat visits were also an important component of the START approach. Country nationals were hired as START consultants to facilitate sustainability. Table 3 shows general improvement in routine immunization planning and monitoring tools and systems from pre- to post-implementation of START. Authors mentioned that while the primary focus of the intervention was planning and monitoring, the START approach could be used to address other topics in routine immunization programs such as "procurement, management and delivery of vaccines and surveillance of adverse events following immunizations." Limitations of the study include potential Hawthorne effect, responder bias to self-reported data, and the inability to attribute intervention impact to longer term outcomes as is common with program evaluations.

## 8. <u>Awareness and Factors Associated with Health</u> <u>Care Worker's Knowledge on Rubella</u> <u>Infection: A Study after the Introduction of</u> <u>Rubella Vaccine in Tanzania</u>

Chotta NAS, Mgongo M, Uriyo JG, Msuya SE, Stray-Pedersen B, Stray-Pedersen A. *Int J Environ Res Public Health*. 2019 May 14;16(10). PubMed ID: 31091685

### ABSTRACT

Background Congenital rubella syndrome is a global health problem. The incidence is much higher in Africa and Southeast Asia than the rest of the world, especially in countries where universal rubella vaccination has not been implemented. Healthcare worker's knowledge on rubella infection and the rubella vaccine is of utmost importance in achieving and maintaining vaccination coverage targets. This study aimed to assess health care workers knowledge on rubella infection in Kilimanjaro Tanzania, after the introduction of a rubella vaccination. Methods This was a health facility-based cross sectional study. It was conducted in three districts of the Kilimanjaro region between August and October 2016. The study involved eligible health care workers in selected health facilities. An interview guide was used for collecting information by face-to-face interviews. Multivariate analysis was used to assess factors associated with rubella knowledge among healthcare workers. Results A total of 126 health care workers were interviewed. An acceptable level of knowledge was considered if all five questions about rubella were correctly answered. Only 26.4% (n = 31) answered all questions correctly. In multivariate analysis education level and working department were predictors of rubella knowledge; health care workers with an advanced diploma had an adjusted odds ratio (AOR) of 7.7 (95% Confidence interval; CI: 1.4, 41.0), those with a university degree (AOR: 10; 95% CI: 2.4; 42.5) and health care workers in the outpatient department (AOR: 0.06; 95% CI: 0.04; 0.29). Conclusions Our study confirmed that health care worker's knowledge on rubella infection was low in the areas where rubella vaccination had been introduced. We recommend continuous education and supportive supervision post vaccine introduction in order to increase healthcare worker's knowledge on rubella infection, congenital rubella syndrome and prevention through sustained high vaccination coverage.

WEB: <u>10.3390/ijerph16101676</u> IMPACT FACTOR: 2.15 CITED HALF-LIFE: 3.40

## START COMMENTARY

This study was conducted two years after the introduction of the rubella vaccine in Tanzania. A multistage sampling technique was used to select the health centers and hospitals from one urban and two rural districts of the Kilimanjaro region (Figure 1). Table 1 describes the proportion of health care workers who responded to each of the seven questions correctly, disaggregated by profession. While a pilot study was conducted to test the interview questionnaire, authors did not comment on the results of that study. More information about the validity of the interview questions and interviewers, and on variable selection for the adjusted model would have been helpful. Potentials areas of bias could be interviewee bias and measures of association could be subject to unmeasured confounding.

## 9. Incomplete childhood vaccination and associated factors among children aged 12-23 months in Gondar city administration, Northwest, Ethiopia 2018

Yismaw AE, Assimamaw NT, Bayu NH, Mekonen SS. BMC Res Notes. 2019 Apr 29;12(1):241. PubMed ID: 31036071

## ABSTRACT

**OBJECTIVE:** 

Despite the fact that immunization services are offered free of charge in Ethiopia but the coverage of complete vaccination is still low. The aim of the study is to determine incomplete vaccination and associated factors among children aged 12-23 months in Gondar city administration, Northwest Ethiopia, 2018.

RESULT:

The proportion of incomplete vaccination among children aged 12-23 months in Gondar city adminstration was 24.3% (95% CI 19.3, 29.2). Knowledge about the benefits of vaccination (AOR = 6.1 (95% CI 1.3, 28.9), the age at which the child begins vaccination (AOR = 2.4 (95% CI 1.09, 8.4) time taken to reach nearby health facility and means of transportation to nearby health facility (AOR = 0.22 95% CI 0.06, 0.9) have statistically significant association with incomplete vaccination. In the current study the proportion of incomplete vaccination was found to be high. Increasing the awareness about vaccination for child care givers and further improve caregiver's knowledge towards the benefit of vaccination is important.

WEB: 10.1186/s13104-019-4276-2

IMPACT FACTOR: n/a CITED HALF-LIFE: n/a

## START COMMENTARY

Yismaw et al. used a simple random sampling method to select participants in this community-based cross-sectional study. The authors demonstrate 24.3% incomplete vaccination, finding pack of knowledge and other barriers associated with incomplete vaccination. Limitations to the study include recall bias and small sample size, which may impact the authors' ability to detect small differences. With this study, Yismaw et al. identified areas of potential intervention that public health officials could address to improve completeness of vaccination.

## 10. <u>Opportunities for improving access to</u> <u>vaccines in emerging countries through</u> <u>efficient and aligned registration procedures:</u> <u>An industry perspective</u>

Dellepiane N, Pagliusi S, Regulatory Experts Working Group. Vaccine. 2019 May 21;37(23):2982-2989. Epub 2019 Apr 23. PubMed ID: 31027928

## ABSTRACT

Vaccines play an essential role in preventing infectious diseases. Their registration in importing countries is often cumbersome and unpredictably lengthy, leading to delays in vaccine access for populations that need them most. This report builds on a previous publication identifying challenges for registration of vaccines in emerging countries. As a matter of social responsibility, it was judged necessary to address the challenges and offer a set of solutions for open dialogue. Based on regular exchange of information and experiences, a group of regulatory experts from the vaccine industry developed three sets of proposals for consideration by vaccine stakeholders, with a view to improving the situation, by fostering regulatory convergence, with viable options for streamlining registration procedures through reliance on other experienced regulators or international agencies. Further, it offers options for alignment of structure and contents of Common Technical Document modules and presents a harmonized template application form that could potentially be used by all countries.

WEB: <u>10.1016/j.vaccine.2019.03.025</u>

IMPACT FACTOR: 3.29 CITED HALF-LIFE: 5.50

### START COMMENTARY

The first proposal seeks to align registration procedures and requirements across countries and regions. The second proposal seeks to improve alignment of dossier structure and contents. The third proposal seeks a common application form. Results of the meeting led to pursue the third proposal, allowing for feasible improvements without requiring modification to regulations, but achieving streamlining and accelerating vaccine registration procedures.

# Appendix

The literature search for the June 2019 Vaccine Delivery Research Digest was conducted on May 26, 2019. We searched English language articles indexed by the US National Library of Medicine and published between April 15, 2019 and May 14, 2019. The search resulted in 221 items.

## **Search Terms**

(((((vaccine[tiab] OR vaccines[tiab] OR vaccination[tiab] OR immunization[tiab] OR immunisation[tiab] OR vaccine[mesh] OR immunization[mesh]) AND (logistics[tiab] OR supply[tiab] OR "supply chain"[tiab] OR implementation[tiab] OR expenditures[tiab] OR financing[tiab] OR economics[tiab] OR "Cost effectiveness"[tiab] OR coverage[tiab] OR attitudes[tiab] OR belief[tiab] OR beliefs[tiab] OR refusal[tiab] OR "Procurement"[tiab] OR timeliness[tiab] OR systems[tiab])) OR ("vaccine delivery"[tiab])) NOT ("in vitro"[tiab] OR "immune response"[tiab] OR gene[tiab] OR chemistry[tiab] OR genotox\*[tiab] OR sequencing[tiab] OR nanoparticle\*[tiab] OR bacteriophage[tiab] OR exome[tiab] OR exogenous[tiab] OR electropor\*[tiab] OR "systems biology"[tiab] OR "animal model"[tiab] OR cattle[tiab] OR sheep[tiab] OR goat[tiab] OR pig[tiab] OR mice[tiab] OR mouse[tiab] OR murine[tiab] OR porcine[tiab] OR ovine[tiab] OR