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CONSEQUENCES OF THE DISCONTINUATION OF GAVI SUPPORT FOR COUNTRIES' IMMUNIZATION SYSTEMS

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1. Acronyms

AFR	African Region (WHO)
AMR	American Region (WHO)
DTP	Diptheria, pertussis, tetanus vaccine
EUR	European Region (WHO)
Gavi JA	Gavi Joint Appraisal
GNI p.c.	Gross National Income per capita
HepB	Hepatits B vaccine
HIB	Haemophilus influenzae type B vaccine
HPV	Human papillomavirus vaccine
IPV	Inactivated polio vaccine
JEV	Japanese encephalitis vaccine
LIC	Low Income Country
MIC	Middle Income Country
MR	Measles/Rubella vaccine
NCDC	National Center of Disease Control
NITAG	National Immunization Technical Advisory Group
NIP	National Immunization Programme
OCV	Oral cholera vaccine
PCV	Pneumococcal conjugate vaccine
Penta	Pentavalent vaccine
Rotac	Rotavirus vaccine
SEAR	South-East Asian Region (WHO)
TCV	Typhoid conjugate vaccine
UNICEF SD	UNICEF Supply Division
WHO	World Health Organization
WPR	Western Pacific Region (WHO)
YFV	Yellow fever vaccine

2. Executive Summary

As part of Gavi's transition policy, which has been active in its' revised form since 2015, countries enter a 5-year transition period, once they reach a specific economic development threshold and are no longer classified as LICs but rather as MICs. During this period, they are expected to gradually adopt more co-financing responsibilities, until they no longer receive support at the end of the fifth year. This policy, similar to those applied by other Global Health actors, has been criticized for not being flexible enough to capture the needs of different countries. Also, it is becoming increasingly apparent, that the majority of vaccine preventable deaths are in MICs, rather than LICs. This study, therefore, analyzed how changes in countries' vaccine coverage correlate with the end of Gavi support for said vaccines (Penta, PCV, YFV, Rotac). It found that, while differences in coverage between different vaccines can be relativized when accounting for contextual information, there is a noticeable discrepancy in how well different regions seem to be prepared to be self-financed. While countries of the WHO EUR region generally were able to sustain or improve vaccine coverage after no longer receiving Gavi support, particularly countries of the WHO AFR region were not able to sustain coverage. The findings of the study further suggest that this could be due to a lack of overall financial capacity, as well as political commitment and sub-optimal decision-making processes. Therefore, this study recommends Gavi to revise its' transition policy and offer more flexible solutions that take into account more than just the economic development of countries.

3. Introduction

Since being founded in 2000, Gavi, the Vaccine Alliance, has been one of the leading Global Health actors, focusing primarily on providing countries with vaccines and technical support to improve immunization coverage worldwide. While a co-financing policy has been at the heart of Gavi's catalytic funding model since 2008 (Low-Income-Countries (LICs) co-pay US$ 0,20 per dose), in an effort to encourage countries to establish sustainable financing systems, the public-private partnership introduced its' eligibility and transition policy (and therefore replaced the eligibility and graduation policy that had been approved in 2008) in July of 2015(1).

As part of this policy, countries that reach a certain threshold (Gross National Income per capita (GNI p.c.) of US$ 1580 in 2018), are no longer eligible for Gavi support and will begin a 5-year transition period, during which they are expected to periodically increase their domestic

financial contributions for vaccines, until Gavi support comes to a halt at the end of the period (though countries might still be able to purchase vaccines at Gavi negotiated prices)(1).

The idea at the heart of Gavi's transition policy – helping countries to establish sustainable immunization financing systems – is common practice and is used similarly by other international organizations. However, it has become increasingly more apparent that the group of countries not eligible for support are being left behind. This issue is possibly best summarized by the following quote from the World Health Organization's (WHO)' "Middle-Income Strategy" report:

"Over the past decade, access to vaccines in middle-income countries (MICs) has been much debated. This focus on MICs has been fuelled by the realization that the majority of poor people and vaccine-preventable deaths are now in MICs and by a concern that this group of countries may be missing out on opportunities to introduce new vaccines, with donors focused on low-income countries (LICs)" (2)

This highlights one of the limitations of Gavi's transition policy: The GNI is a poor measure of economic equity (as the World Bank points out itself (3)) within a country and says little about how much of its' economic growth actually reaches the poorest people living within it. Also, it tells us little about a given countries' financial capacity to support immunization systems that previously had been supported by Gavi.

There is an increasing amount of literature that addresses this development. Multiple studies focusing primarily on health outcomes in these countries have shown that both the biggest burden of disease in general but also the biggest burden of vaccine-preventable deaths is now in MICs rather than in LICs (4)(5). This issue is enhanced because more and more countries are projected to be categorized as MICs and will, therefore, lose Gavi support. One study suggests, that of a total of 69 countries eligible for Gavi support in 2015, only 27 will remain eligible in 2040(6).

Although not all current MICs are "graduates" from Gavi support (some of them never were eligible) it is important to monitor this group of countries to ensure they do not fall behind global achievements related to vaccine coverage.

Despite these concerns about MICs, literature about the consequences of the discontinuation of Gavi support is scarce. While some scholarly attention has been focused on the transition period, assessment and plans (7)(8), as of January 2019, little has been written about how discontinuation of Gavi support for specific vaccines correlates with national coverage of those vaccines. This study will attempt to fill some of the void within this space, by analyzing the behavior of immunization systems in countries that have already at least partly graduated.

4. Objectives

The overall objective of this study is to determine to what extent the discontinuation of monetary Gavi support for vaccines correlates with national coverage of those vaccines. This will be done by analyzing changes in the performance of immunization systems while and after receiving vaccine support

5. Methodology

This paper employed a mixed methods approach, consisting of both a quantitative and qualitative analysis, to reach the objective outlined above.

For the quantitative analysis, vaccines that are supported by Gavi were selected. In a next step, countries that had received support for those vaccines in the past and have since transitioned from Gavi were identified. To determine if and how vaccine coverage changed after no longer receiving support, vaccine coverage data for said countries were collected, covering the last year of support and consecutive years without.

For the qualitative analysis, five countries were selected from the above-mentioned cohort. For them, additional information was compiled. This information was then used to triangulate possible reasons for changes in coverage, besides the end of Gavi support.

These steps will be explained in more detail below.

5.1 Quantitative Analysis

Gavi's website mentions 13 vaccines (Pentavalent vaccine (Penta), Pneumococcal conjugate vaccine (PCV), Inactivated polio vaccine (IPV), Yellow fever vaccine (YFV), Rotavirus vaccine (Rotac), Human papillomavirus vaccine (HPV), Measles/Rubella vaccine (MR), Meningitis A vaccine, Japanese encephalitis vaccine (JEV), Typhoid conjugate vaccine (TCV) and Oral cholera vaccine (OCV)) that countries can apply for under the vaccine support programme (see Table1; Hepatitis B (HepB) mono vaccine and Haemophilus influenzae type B (Hib) mono vaccine are not listed here, since they are now included in the Penta vaccine) (9).

Table 1: Total number of Gavi disbursements per vaccine

Vaccine	Penta	PCV	IPV	YFV	Rotac	HPV	MR	Meningitis A	JEV	TCV	OCV
Number of disbursements	722	363	254	232	228	74	68	22	9	4	/

Initially, the following criteria to select from those vaccines were established:

1. Price: Expensive vaccines (e.g. HPV) will be excluded because countries may choose to focus their limited resources on cheaper vaccines, that cover a broader range of the countries burden of disease. Therefore, changes in the coverage of those vaccines could not be captured by the qualitative part of this paper explained below.

2. Inclusion in vaccines: Some vaccines (e.g. HepB mono, Hib mono) are included in other vaccines (Pentavalent), that will already be analyzed.

3. Routine use: Not all vaccines are disbursed regularly but rather in emergency/epidemic settings (e.g. OCV) and will therefore not be analyzed.

However, an analysis of Gavi's country disbursement list (10) showed that there was a significant difference in the number of disbursements between the 5 vaccines disbursed most often (Penta, PCV, IPV, YPV, and Rotac) on the one hand and the rest of the vaccines on the other. Therefore, to ensure a large enough sample size, the initial criteria were not used. Instead, four of the five most frequently disbursed vaccines (Penta, PCV, YFV, and Rotac) were selected for the analysis. The inactivated polio vaccine was excluded for two reasons: Firstly, because of the global focus on polio eradication, countries may choose to prioritize IPV to comply with international norms. Secondly, countries may have had access to other procurement and funding options specifically designed for polio eradication efforts. This can lead to higher IPV coverage percentages which will then skew the analysis.

In a second step, a statistics software (Stata) was used to identify countries for the analysis from Gavi's disbursement list based on the two following criteria:

1. Countries needed to have received disbursements for one or more of the four selected vaccines for a period of at least three consecutive years (between Gavi inception and 2017). It was assumed that countries that had received support for less than 3 consecutive years already had relatively well-functioning immunization systems in place, hence why the inclusion of those countries could skew the analysis.

2. The last disbursement had to be made before 2017. Since vaccine coverage data is only available until 2017, changes in vaccine coverage after no longer receiving support could not be analyzed, if countries had not stopped receiving support before or in 2016.

The application of the criteria outlined resulted in the selection of 17 countries (see Table 3). For those countries, immunization coverage during and after receiving support was analyzed. Variation in coverage was measured and expressed in percentages to determine whether there was an increase or decrease after the end of Gavi support. An increase or decrease was initially defined as a change in coverage by at least three percentage points. However, due to the limited sample size, this was changed to one percentage point.

Vaccine coverage data was retrieved from the WHO immunization database (11). This database includes both country-reported data, as well as WHO/UNICEF estimates. After an initial analysis showed, that the WHO/UNICEF estimates included fewer overall values than the country reported data, the country reported dataset was used going forward. Data from this resource was used based on the following criteria (see Table 2):

Table 2: Vaccines/dosages used to capture coverage

Gavi disbursement list	Penta			Pneumo	Rotavirus	Yellow Fever
WHO coverage dataset	DTP, 3rd dose	HepB, 3rd dose	Hib, 3rd dose	PCV, 3rd dose	Rotac, 2nd or 3rd dose depending on schedule	YFV

1. Penta is not listed in the WHO reports, therefore DTP-3, HepB3 and Hib 3 was used to capture coverage and will in all 3 cases relate to the administration of the third dose.
2. Coverage of the pneumococcal vaccine will relate only to the coverage of the 3rd dose, as the administration of the 1st and 2nd dose is implicit.
3. Coverage of the rotavirus vaccine relates only to the coverage of the last dose (2nd or 3rd), as the administration of the 1st dose is implicit.

Going forward, this study uses the term “case” to describe the situation in which the outlined criteria apply to a country. Those cases are represented visually in Table 3 (each non-grey cell representing one case).

5.2 Qualitative analysis

After applying the outlined criteria, five countries were selected for the qualitative analysis (Angola, Armenia, Congo, Georgia, Moldova). These countries were selected based on the following criteria:

1. Countries were only selected if they showed cases for at least two different vaccines. For this, the combination of DTP, HepB, and Hib was counted as one vaccine (Penta).
2. Countries were only selected if they showed a case for Penta since it is the most frequently disbursed and arguably the most impactful vaccine.

Although Kiribati also fit those criteria, it was not included, because there have not been any updates to its’ Gavi Joint Appraisal (JA) since 2015. With the JA’s being an important source of information, it was necessary for them to be as recent as possible. For the other countries, JA’s had been updated as recently as 2017.

For the selected countries, additional information was compiled, with the goal of being able to triangulate potential reasons for changes in coverage after transitioning from Gavi support. Areas for additional information were chosen following the four key areas (if information on the key area was accessible) identified in the MIC Strategy report(2), which include the following:

1. *Decision-making*

Do countries have National Immunization Technical Advisory Groups (NITAGs) in place? As identified in the MIC Strategy document, NITAGs are useful tools for countries that no longer receive Gavi support for one or more vaccines. These structures can help communicate the need for the funding of different vaccines to the decision-making levels by providing necessary, local data without having to rely on international recommendations(12).

2. *Political and financial commitment*

Since comprehensive data on the financial commitment of countries towards immunization systems is not easily accessible, information on this aspect was retrieved from Gavi's Joint Appraisals (JAs). Additionally, countries should adopt new National Immunization Programmes (NIPs) covering the period after their transition, that can account for the loss of Gavi support and ensure political commitment to immunization systems.

3. Equitable delivery of vaccines

To ensure the equitable delivery of vaccines to all of its' population, it is important that countries have reliable evidence about the needs of said population(13). Therefore, this area will include information about the effectiveness of the surveillance system within the country and other bottlenecks that can be identified by using Gavi JAs, as well as the WHO Immunization Repository.

4. Timely and affordable access

In order to guarantee access to life-saving vaccines, certain infrastructural aspects (e.g. cold chain) need to be in place.

There will also be some general information about these countries, including the exact changes in vaccine coverage and what the countries' GNI p.c. was during the year it stopped receiving support.

Finally, for each of the countries, local experts with expertise in the area of vaccination were contacted and asked to be interviewed. In these interviews, experts were asked to identify barriers/bottlenecks to increasing vaccine coverage or effective interventions that lead to increased coverage, whether they noticed any changes in the availability of vaccines after Gavi support had halted and how well they believe the national, aggregated data used in the quantitative part is reflective of the situation within the country.

Multiple channels were used to identify potential experts. Initially, experts were contacted by E-Mail using the ISGlobal network. Additionally, E-Mails were sent out to multiple catholic church missions working in the countries of interest and to authors of articles with similar objectives. Finally, experts were also contacted through the social network LinkedIn and a forum post was created on the TechNet-21 platform.

Experts were eligible as interviewees if they were currently working in an immunization-related position and had worked in such a position during the respective countries' transition from Gavi support. Experts were not eligible, to avoid potentially conflicting interests when answering the questions if they were employed by Gavi or the respective countries' government. Interviewees were given the broad topic of the interview beforehand (immunization system performance of the respective country) but were not shown the specific questions.

A total of 17 experts were directly contacted by E-Mail. Unfortunately, only three of them (one for each Angola, Mongolia, and Georgia) agreed to an interview. Interviews were conducted via online telecommunication applications (Skype, WhatsApp) and lasted between 15-25 minutes. The interviews were not recorded since they included potentially confidential information. Instead, notes were taken by the interviewer.

The information gathered was used to compliment and prioritize information compiled throughout this study and to triangulate possible explanations for changes in immunization system performance.

6. Results

6.1 General results

Seventeen countries were selected that had shown one or more cases, adding up to a total of 55 cases (see Table 3; each colored cell represents one case). Looking at overall trends, coverage immediately increased in 14 (25,45%) of the cases, while it decreased in 16 (29,09%) of them.

Vaccine coverage stagnated in 18 (~32,73%) cases. While no change in coverage might not seem like a "win" initially, it should be noted that coverage for most of these vaccines often was already above 80% (and in some cases coverage was already above 90% or even at 99%), therefore maintaining those levels of coverage is quite an achievement in itself.

Six of the cases were defined as special. In these cases, the vaccine coverage dropped the year immediately after the end of support, only to recover and reach the level of the last year of support or improve upon that in year 2 without support. While maintenance of coverage percentages of years with Gavi support should be seen as a positive, it does suggest that

these countries (namely, Congo and Guyana) might not have been ready to be fully self-financing.

Table 3: Changes of coverage by vaccine and country

Country	Status DTP	Status HepB	Status Hib	Status YFV	Status PCV	Status Rotac
Albania						
Angola						
Armenia						
Azerbaijan						
Bhutan						
Bolivia (Plurinational State of)						
Congo (the)						
Georgia						
Guyana						
Honduras						
India						
Kiribati						
Mongolia						
Nigeria						
Republic of Moldova (the)						
Sri Lanka						
Uzbekistan						

Color code:

Country received support until 2018 or coverage data not available	Vaccine coverage stagnated	Vaccine coverage increased	Vaccine coverage decreased	Vaccine coverage dropped in the first year, then increased again the year after

Some interesting patterns can also be observed by looking at the behavior of coverage of some of the vaccines. The yellow fever vaccine will be disregarded here since there were only 2 observed cases which are too few to detect any meaningful patterns. The best performing vaccine by far within this cohort was the rotavirus vaccine. There were 6 cases identified, all of which showed an increase. This result will be discussed in a later chapter. However, other vaccines, like the pneumococcal conjugate vaccine, did not show similar results. A total of 8 cases were observed within the PCV column, only one of which showed an increase, one showed no change and 4 showed a decrease in coverage. Also, 2 special cases were identified.

The vaccine with the most cases by far was the Pentavalent vaccine. Of the 39 cases that were observed in total, 8 showed an increased and 17 showed no change. Table 4 shows that, again, some of the countries were already at 99% coverage, which limits the possibility of improvement. There were also 11 decreases and 3 special cases. These results will be discussed further in a later chapter.

Another way of looking at this data is by comparing countries, rather than vaccines. Of the 17 analyzed countries, Armenia's, Moldova's and Georgia's immunization system seemed to perform the best. Armenia and Moldova were both able to maintain or increase coverage of the Penta vaccine and even though Georgia's coverage of DTP and HepB decreased, it did so only slightly (3 percentage points) and in 2017 was still at 91%. Also, Georgia's coverage of PCV increased from 75% in 2016 to 80% in 2017. All three of the countries were able to increase their Rotac coverage. India also performed relatively well, with coverage of the Penta vaccine components either stagnating or improving. Interestingly, while 4 more countries (Albania, Mongolia, Sri Lanka, and Uzbekistan) did not experience a drop of coverage of any of the vaccines, 10 of the analyzed countries (Angola, Azerbaijan, Bhutan, Bolivia, Congo, Georgia, Guyana, Honduras, Kiribati, Nigeria) showed an immediate decrease in coverage for at least one of the previously supported vaccines.

Table 4: Coverage of vaccines (in %) during and after Gavi support. Bold numbers indicate last year of support, cursive numbers indicate years without support

Country	Vaccine	2017	2016	2015	2014
Albania	Penta	*99*	*99*	*99*	**99**
Angola	Penta	*77*	*80*	**80**	80
	PCV	*74*	**74**	73	61
Armenia	Penta	*94*	*94*	**94**	93
	Rotac	*94*	*94*	**93**	91
Azerbaijan	Penta	*95*	*97*	**96**	94

Bhutan	Penta	*98*	*98*	**99**	99	
Bolivia	PCV	*83*	**87**	86	56	
	Rotac	*84*	*87*	*89*	*85*	Support ended in 2013 at 77%
Congo (the)	Penta	*80*	*73*	**80**	90	
	PCV	*80*	*73*	**80**	85	
	Rotac	*80*	**66**	80	60	
	YFV	*80*	*69*	**80**	80	
Georgia	DTP3/HepB	*91*	*92*	**94**	91	
	Hib3	*91*	*92*	**87**	91	
	PCV	*80*	**75**	16		
	Rotac	*76*	*75*	**72**	69	
Guyana	PCV	*97*	*92*	**94**	97	
Honduras	PCV	*90*	*99*	**99**	85	
	Rotac	*91*	*99*	*99*	*85*	Support ended in 2013 at 83%
India	DTP3/HepB	*88*	**88**	87		
	Hib3	*88*	**80**	45		
Kiribati	Penta	*90*	*81*	**87**	75	
	PCV	*91*	*79*	**94**	57	
Mongolia	Penta	*99*	**99**	99	99	
Nigeria	YFV	39	41	41	71	Support ended in 2013 at 64%
Moldova	DTP3	*89*	*91*	**88**	92	
	HepB	*89*	*91*	**88**	92	
	Hib3	*88*	*89*	**87**	89	
	Rotac	*65*	*71*	**62**	69	
Sri Lanka	Penta	*99*	*99*	**99**	99	
Uzbekistan	Penta	*99*	*99*	**99**	99	

Finally, patterns within this dataset can also be found by grouping countries into their WHO regions. Of the 5 WHO regions (AFR, AMR, EUR, SEAR, WPR) that can be found in this cohort, the EUR region was not only the one with the most countries (Albania, Armenia, Azerbaijan, Georgia, Moldova, and Uzbekistan), it was also the one with the best overall performance. As can be seen in Figure 1, the majority of cases within this region (17), showed either an increase or maintenance of vaccine coverage, while there were only 6 negative results. Both the WPR (Kiribati and Mongolia) and the SEAR regions (Bhutan, India, Sri Lanka) behaved similarly, with most of the cases positive results. The AMR region (Bolivia, Guyana,

Honduras) only had 4 cases in total and while the results were split evenly between increases and decreases, this sample size was too small to make any definitive statements.

The most negative results came from the AFR region (Angola, Congo, Nigeria). Of 10 total cases, only 1 showed a positive result, while 4 decreases and 5 special cases were observed. This pattern will be discussed further in the next chapter.

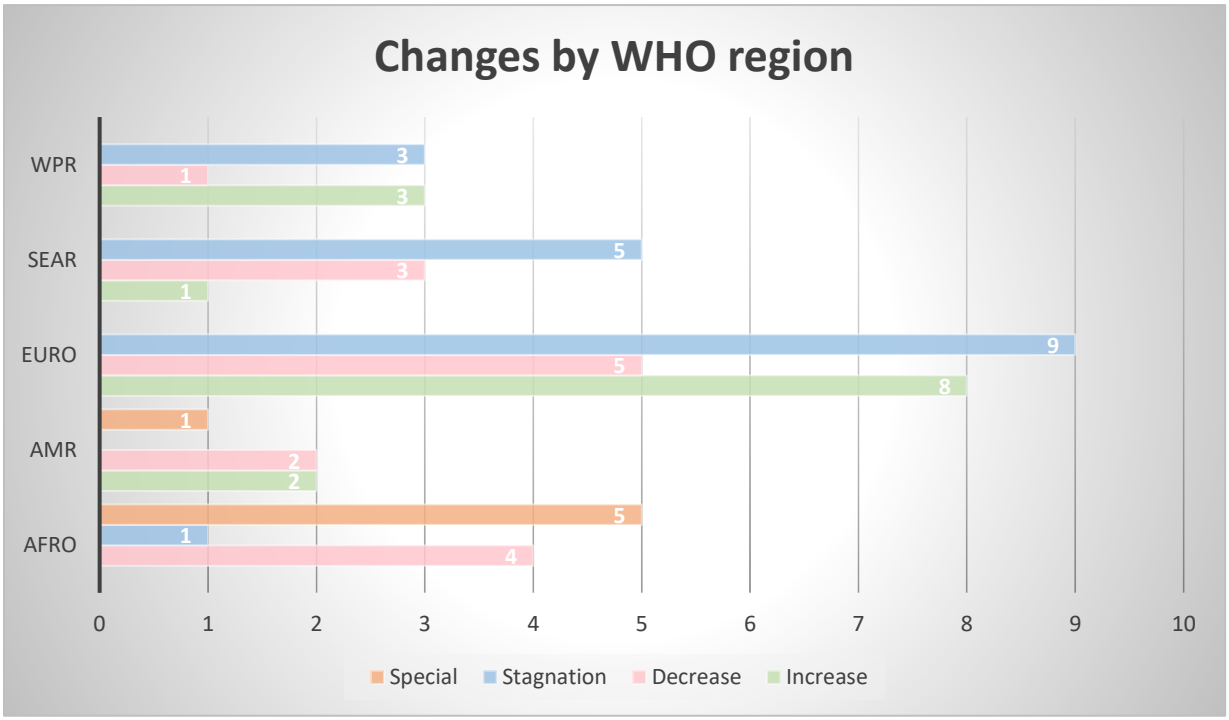

Figure 1: Changes in vaccine coverage by WHO region; white numbers indicate the number of cases per category

6.2 Country-specific results

The quantitative analysis showed, that there were some noticeable differences in how countries' immunization systems perform in the absence of Gavi support. However, many factors can lead to increases or decreases in coverage. With the aim of understanding better the differences in performance of these countries, for this second part of the study more in-depth information about some of the above-mentioned countries was compiled and will be analyzed by creating short country profiles.

Table 3: Results of country-specific analysis

Country	General Information		Decision-making	Political and Financial Commitment		Equitable delivery		Timely and affordable access
	Vaccine coverage change	GNI p.c. at time of no support	Establishment of NITAGs	Financial situation	National Immunization Programme in place	Effective Surveillance	Other Bottlenecks	Sufficient Cold Chain
Angola	Penta decreased (80% to 77%), PCV stagnated (74%)	(2016) 3,770 US$	Yes	Main source of income is oil, prices continuously decreasing. Budget for vaccine procurement too low	No NIP in place	No	Insufficient human resources at all levels (both in terms of quantity and quality) and mobile immunization activities and stock-outs of vaccines at local level	Yes
Armenia	Penta stagnated (94%), Rotac increased (93% to 94%)	(2015) 4030 US$	No	7% decrease in health budget in 2016 but only slight decrease in immunization budget	New NIP after Gavi transition ranging from 2016-2020	Yes	Vaccine hesitancy, cold chain could be improved upon	Yes
Congo, The	Penta , YFV, PCV special cases (Penta and PCV 80% to 73% to 80%, YFV 80% to 69% to 80%) , Rotac increased (66% to 80%)	(2015) 2350 US$	No	JA not in English	No information	Yes	JA not in English	Yes

Georgia	DTP3 and HepB decreased (94% to 91%), HIB, PCV and Rotac increased (Hib 87% to 91%, PCV 75% to 80%, Rotac 72% to 76%)	(2015) 4110 US$	Yes	There are no funding issues, budget for immunization systems increased after no longer receiving Gavi support	New NIP after Gavi transition ranging from 2016-2020	Yes	Privatization of the majority of health service providers makes quality control difficult. PHC providers could tailor their activities to specific population needs more	Yes
Moldova	Penta, Rotac increased (DTP & HepB 88% to 89%, Hib 87% to 88%, Rotac 62% to 65%)	(2015) 2140 US$	Yes	Although the Ministry of Finance can and does cut budget targets submitted by the Ministry of Health, historically immunization was never under-funded	New NIP after Gavi transition ranging from 2016-2020	Yes	Brain drain, vaccine hesitancy, lack of knowledge about the benefits of vaccines	Yes

Angola

Of the 5 countries that were chosen for this analysis, Angola's immunization system had the most negative performance. The quantitative analysis shows, that coverage of all Penta components decreased by 3%, from an already relatively low 80% in 2016 to 77 in 2017 and even though PCV coverage did not seem to be impacted, the overall coverage of 77% for this vaccine ranks at the lower end of countries in this cohort. While there are no reported issues with the cold chain, there are some concerns about the effectiveness of Angola's surveillance systems(14). This is also reflected when contrasting country reported data on vaccine coverage with WHO/UNICEF estimates, which are about 20 percentage points lower.

There are also issues regarding the financial situation. Because of the drop in current oil prices, Angola, whose main source of income is the export of oil, is in the midst of a financial crisis. This has resulted in a lack of allocated funds for vaccine procurement (15).

However, these are not even the biggest bottlenecks to an improvement in vaccine coverage for Angola. A WHO expert that was interviewed for this study reports a lack of human resources, both in terms of quantity and quality, as the biggest issue, a concern which is echoed by Gavi's JA(15). Both sources note, that there is a lack of trained professionals at all levels, which leads to nurses having to perform vaccinations themselves and even though the country is not lacking in the number of health facilities, about 40% of them do not offer immunization services at all. The outreach activities, like mobile immunization services, that provide vaccinations to people outside of the coverage areas of those health facilities, have been reduced in frequency due to the budgetary constraints and prioritization of other public health issues (e.g. yellow fever outbreak in late 2015).

In summary, Angola is an example of a country that despite being well above the GNI threshold faces many challenges in achieving vaccine coverage similar to that of other countries of similar economic status.

Armenia

Armenia is one of the best-performing countries in this cohort. Vaccine coverage rates are at 94% for both Penta and Rotac. While Penta coverage has stayed constant after no longer receiving support, Rotac coverage has increased, though only by one percentage point, from 93% in 2015 to 94% in both 2016 and 2017. There are no issues related to cold chain or

surveillance reported within the country(16) and a new NIP has been put in place in 2016, which covers a 4-year period until 2020. Armenia has establishment NITAGs, as per the recommendation made by the Global Vaccine Action Plan(17).

Although GNI growth has somewhat plateaued and the health budget was cut by 7% in 2016, the immunization budget was only slightly decreased (0,5%)(18) and procurement of vaccines has not been an issue.

The one area that could pose a threat to Armenia's immunization system is the vaccine hesitancy movement that is currently affecting Eastern European countries in particular. Healthcare-workers, as well as politicians, need to be trained and educated on how to clearly communicate the benefits of vaccinations, which will help combat this movement(18). Also, with the help of other European countries facing similar issues, effective policies (like compulsory vaccination) need to be developed.

It should be noted as well, that with a GNI p.c. of 4030 US$, Armenia has almost doubled the transition-threshold and is the country with the second highest GNI of the ones analyzed here. Intuitively, one would suspect countries' health systems, in general, to perform better, the higher its' economic capacity.

Republic of the Congo

The Republic of the Congo is an interesting case for this analysis. While coverage of the Rotavirus vaccine immediately increased, as it did in all analyzed cases for this vaccine, Penta, PCV, and YFV coverage all dropped quite significantly (7 percentage points in Penta and PCV, as much as 11 percentage points in YFV) in the year following the last year of support. While coverage of the above-mentioned vaccines did recover in 2017 and reached the level it was at before, this drop in coverage suggests an issue in the overall readiness of the country to be fully self-financing.

Unfortunately, there was not much other information available for this specific country. Gavi's JAs for Congo, which were main sources of information for this project, were written in French and could therefore not be included in this analysis. Also, no local expert could be found to provide further insight.

While effective surveillance does not seem to be an issue and a sufficient cold chain exists, the country has not yet established NITAGs to help with the decision-making process(19). This could help explain the decrease in coverage of most of the vaccines. However, without further information about other bottlenecks within the country, no definitive assessment can be made.

The Republic of the Congo is the country with the second lowest GNI p.c. analyzed in this cohort.

Moldova

The example of Moldova further suggests that the GNI p.c. is not an index well suited to predicting how countries' immunization systems will perform in the absence of Gavi support. While Angola performed the worst of all countries, with a relatively high GNI, Moldova was one of the better performing countries, while having the second lowest GNI per capita.

Most of the areas that were analyzed in the qualitative part do not seem to be an issue in Moldova. The country has established NITAGs and has a NIP in place through 2020. While the financing structure overall is not optimal and health budgets have experienced cuts in recent years, the immunization budget was only marginally impacted and has historically been sufficient (20). No issues were reported regarding effective surveillance or sufficiency of the cold chain(21). However, in an interview with a UNICEF employee, some concerns about the overall quality of coverage data were raised. The countries' non-electronic surveillance system is not linked to primary health care services and the issue of falsification of vaccine certificates was mentioned. This is a challenge that should be monitored in order to ensure the maintenance of the positive trajectory of the countries' vaccine coverage.

Also, the state of Transnistria is an area of concern. It is not internationally recognized to be an independent state and thought to be a part of Moldova. However, it is not covered by the Moldovan health system and there is no available data on vaccine coverage, though there was an immunization programme review conducted by the WHO as recent as 2014 (22). Unfortunately, this report could not be accessed.

One potential pitfall to the immunization system in Moldova, as it is for most other eastern European countries, is the vaccine hesitancy movement. This concern is mentioned in Gavi's JA and was reinforced by the Interviewee. It was further mentioned, that there is an overall distrust in the Moldovan government, as well as vaccine producers, which complicates already poor communication efforts by healthcare providers.

Georgia

Georgia, like its two eastern European neighbors in this study, did not seem to be impacted by the end of Gavi support too heavily. Albeit the coverage of both DTP and HepB dropping

slightly (from 94% in 2015 to 91% in 2017), Hib, as well as PCV and Rotac improved by up to 5 percentage points.

Similar to the case of Moldova, Georgia has implemented NITAGs to strengthen decision-making processes(23) and has a NIP in place that will cover the years between 2016-2020. The health budget has increased significantly since Gavi support has halted and with the country still purchasing vaccines through the UNICEF Supply Division (SD), availability of vaccines is not an issue. Both the surveillance and the cold chain are functioning well and should not be a bottleneck for further increases in vaccine coverage(23).

Unlike in Moldova, vaccine hesitancy is not a big issue yet, though the movement is gaining momentum within the country. This was mentioned by an employee of an NGO that is involved in health policy consultancy, who also mentioned some concerns about the preparedness of the country, should this movement gain more momentum.

Both the Gavi JA (24) and the interviewee mentioned the structure of the health system as one of the biggest challenges. Since most health services are being provided by private entities, free access to these facilities for purposes of quality control cannot always be guaranteed for members of the public sector. It was also mentioned, that these providers could tailor their services more to the need of individuals within the population, to reach the relatively small number of unvaccinated people. Data quality was reported to be improved and is not an area of concern.

It should be mentioned as well, that the country's Ministry of Health has approved a budgetary request from the National Center of Disease Control (NCDC) for the introduction of the hexavalent vaccine, which should help improve vaccine coverage.

Georgia was the country with the highest GNI p.c. analyzed in this part of the study.

7. Limitations

Before moving on to the discussion of the data analyzed above, some noteworthy limitations of this research project should be discussed. Since the most recent vaccine coverage data (as of spring 2019) only goes as far as 2017, the sample size becomes relatively small. This means that finding patterns in the way vaccine coverage across different countries or across different vaccines behaves is difficult and should be interpreted cautiously. Also, expert interviews could only be conducted for 3 of the 5 countries that were part of the country case analysis, and only

one expert per each of the 3 countries, which is suboptimal. Expert input was still considered to triangulate with other sources of information.

Additionally, due to the limited sample size, increases or decreases in coverage were defined as a change of coverage by one percentage point. A change that small can occur due to errors in measurement and might not be statistically significant. Therefore, interpretations of the results of the quantitative analysis need to consider this limitation.

Another limitation regarding data lies in the cohesiveness of how data is presented by different entities. To give an example, the WHO immunization coverage data does not include Penta, resulting in the decision this study undertook to use DTP3, HepB and Hib coverage data. This is sub-optimal because the 3 individual components of the Pentavalent vaccine can - and in some cases do - behave differently.

Also, there is no real analytical framework that can be applied to a study like this. The MIC strategy report was used here and does provide some utility; however, it was created specifically with non-Gavi countries in mind. The lack of the framework, as well as the overall scarcity of literature on this topic, is influenced by the fact that many countries will only recently have fully transitioned or will do so in the near future. With the cohort of fully transitioned countries growing, so should the literature on the topic.

One final limitation is that most of the countries analyzed here are still receiving Gavi support for one or more of the four analyzed vaccines. This can create a spill-over dynamic, where even though one of the vaccines no longer is supported, its' coverage is enhanced by support for one or more of the other vaccines.

8. Discussion

Because of the relatively small sample size and some of the other limitations mentioned above, it is difficult to give a conclusive result about the performance of countries' immunization systems in the absence of Gavi support. In reality, there are big differences in the performance of systems analyzed here and both positive and negative results will always be the sum of many different factors. However, there are some lessons to be learned, when interpreting the compiled data with the help of the additional information.

One of the interesting findings of the quantitative analysis was the fact that all Rotac cases showed an increase in coverage (minimum of 1 percentage point in Armenia, maximum of 14

percentage points in Congo), a result that set this vaccine apart from the other ones. There are multiple factors that will have contributed to this:

1. In contrast to many of the other analyzed vaccines, the rotavirus vaccine is often already effective after two doses. One study conducted in Malawi showed no statistically significant increase in protection between doses 2 and 3(25). Therefore, WHO coverage data for Rotac includes both second and third doses, depending on the schedule, while coverage data for the other vaccines always relates to the administration of the third dose. It can be assumed, that fewer people will receive three doses and therefore count as "covered" in the dataset used here.

2. In addition to requiring fewer doses, the two most commonly used rotavirus vaccines are administered orally. This necessitates less training for the provider and makes reception of the vaccine more accessible.

3. A final driver for the increase in coverage of the rotavirus vaccine is the baseline percentages countries showed in the final year of Gavi support. Of the 6 countries that showed cases in the Rotac column, only one had coverages of above 90% at the end of Gavi support, while the other 5 ranged somewhere between 62% and 87%. This means, that there was more potential for improvement of coverage for the Rotac vaccine compared to i.e. the PCV vaccine (7 countries with cases, coverage ranging between 74% and 97%, 3 countries above or at 90%).

There certainly are other factors that contribute to the positive result of the rotavirus vaccine cases, e.g. high associated burden of disease or high cost-effectiveness and while these cannot be adequately analyzed in this study, it could be an interesting approach for further research.

Data on Penta vaccine coverage also allows for some interesting discussion. This vaccine was disbursed more than twice as often as the next closest one and therefore had the most cases. Of the 17 analyzed countries, 14 showed cases for Penta and of those 14, 4 were able to maintain a coverage of 99% even without Gavi support, while almost all of the other countries showed coverage ranging between 88% and 98% regardless of whether the coverage had increased or decreased after the end of Gavi support. The only two countries which were significantly below this range were Angola (77%) and Congo (80%).

Since this vaccine protects against a total of 5 major infections (diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type b) and therefore is fundamentally important, especially in LICs and MICs, such high coverage percentages and the maintenance of it in the absence of Gavi support is a positive sign.

Another pattern to be further discussed emerged when countries were grouped geographically. There are significant differences between the different WHO regions and especially when comparing the best performing region, EUR, against the worst performing region, AFR. The EUR region had the highest number of countries in this cohort. Three of those countries, Armenia, Georgia, and Moldova were the three best-performing countries and the country-specific analysis shows, that one of the biggest challenges to these immunization systems is the vaccine hesitancy movement, which is something they have in common with many, fully developed, western systems. The three eastern European countries generally had effective decision-making processes in place and immunization seemed a high financing priority for its' governments. While the sample size is small, this suggests that countries within the EUR region are generally better developed in terms of their financial capacities and have stable-enough governments so that the sustainability of vaccine coverage can be expected.

The same cannot be said for the AFR region. While this study only included 3 countries from this region, Angola and Congo were the two countries with the worst immunization system performance and the only case observed for Nigeria was a decrease in coverage of the Yellow Fever Vaccine from 64% during the year it last received support for it (2013) to 39% in 2017, which is well below herd immunity level. Since September 2017, Nigeria is suffering from a Yellow Fever outbreak with over 3500 suspected cases in all 35 Nigerian states (26). In general, this study focused more on health system performance and not so much on health outcomes and therefore it did not attempt to analyze how changes in immunization coverage corresponded to changes in the burden of disease these countries face. However, this type of analysis could be interesting, especially for the special cases, most of which were observed in the AFR region.

The two African countries included in the country-specific analysis, Angola and Congo, showed similar issues in terms of immunization financing, political commitment, and decision-making processes (according to the limited data available). Even though both countries are well above the transition threshold, they do not seem to be ready to fill the void left by the end of Gavi support. This begs the question, what would happen to other African countries, who are at a similar or even worse economic position. It does not seem unthinkable, that those countries could perform even worse when they start transitioning out of Gavi support.

One final interesting piece of information that was gathered during this project should be mentioned, for purposes of comprehensiveness. In all 3 of the interviews that were conducted, interviewees were asked specifically, whether, in their professional opinion, there was an overall lack of availability of vaccines noticeable in the countries they worked in after those countries had transitioned from Gavi support. All 3 experts reported, that no such lack was noticed and that Gavi had been very supportive and resourceful during the transition period. While this suggests that other factors might be more important to changes in vaccine coverage, than the transition from Gavi support, the sample size is far from representative and conclusions should, therefore, be made cautiously.

9. Conclusion

This studies' objective was to find out to what extent the discontinuation of monetary Gavi support for vaccine correlates with national coverage of those vaccines. Its' findings suggest, that there is a correlation between the end of Gavi support and changes in countries' vaccine coverage, even though those changes seem to differ, depending on the vaccine or geographical region analyzed. It further suggests that the eligibility criteria used by Gavi do not always appropriately reflect a countries' preparedness to enter the transition period.

In general, it seems that countries belonging to the EUR region can maintain or even improve upon vaccine coverage levels after no longer receiving Gavi support. Immunization systems of countries belonging to the AFR region, however, seem to perform worse. This could be explained by a lack of financial prioritization of vaccines and issues regarding political commitment to NIPs. The findings of the study further suggest, that GNI p.c. is not correlated with immunization system performance (higher GNI did not always correlate with higher vaccine coverage).

The study further suggests, that vaccines only necessitating two doses, instead of three, and those that can be administered orally, instead of through injections, remain at higher coverage percentages after Gavi support.

10. Recommendations

It is not difficult to argue in favor of transition policies in general. As country's economies grow and become more capable, the availability of resources for health systems, and therefore immunization systems, increase. As such, they should be able to adopt more financing responsibilities and rely less on international development aid.

An argument has also been made, that without such transition policies, country governments might be less incentivized to increase domestic spending on health(27). Therefore, this study does not attempt to argue against the usefulness of such policies.

However, the eligibility criteria established by Gavi seem arbitrary. There are certainly arguments to be made in favor of using GNI p.c. as an eligibility criterion: It is simple, regularly updated, transparent and allows for comparison across countries(28).

Despite those advantages, this study suggests, that GNI p.c. might not be flexible enough to assess the readiness of countries to transition. It has been shown, that for some countries, particularly those of the EUR region, the GNI seems to be well suited to use as a threshold. For other countries, like those of the AFR region, though, the same cannot be said. Hence, this study recommends a re-thinking of Gavi's eligibility criteria. The Gini-coefficient could be used to maintain some of the advantages of the GNI while being able to account for income distribution within countries. Also, the approach taken by the Global Fund, using a combination of the GNI per capita and data on disease burden within a country, could lead to less variation in coverage percentages after countries have transitioned.

Another possibility for Gavi could be to try to apply a combination of the GNI per capita and vaccine coverage thresholds. In other words, according to this recommendation, a country would only start the transition process once it has reached both the GNI threshold but also a baseline coverage of vaccines. While this could still result in decreased coverages after the transition, this solution could try to account for that decrease by setting the threshold high enough, that coverage is still at an acceptable level and can reach, for example, herd immunity (e.g. threshold of coverage is 85%, therefore even with a 5 percentage point decrease, coverage still remains at an acceptable 80%).

Finally, with all the information Gavi collects during the transition process (transition assessments/plans), it should be possible to develop a case-by-case strategy that takes into account known bottlenecks to immunization coverage (e.g. those identified in the MIC strategy report). This would allow a maximum of flexibility to decide whether a country is prepared to start transitioning or not. While this solution would certainly require more resources than the one currently used, one can assume that it would lead to fewer countries experiencing significant decreases in coverage.

There is no doubt that Gavi has made and is making a great contribution to the field of global health. However, to ensure the sustainability of their achievements, it seems as though specifically African countries are in need of more support, especially in the areas of decision-making and financial sustainability.

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