

# Rotavirus Vaccine: Supply & Demand Update

UNICEF Supply Division

July 2014

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## Rotavirus Vaccine (RV): Supply & Demand Update July 2014

**This update provides new information on countries and their scheduled RV introductions, forecasted demand and supply.**

**A more recent note covering XXXX exists. Please visit [http://www.unicef.org/supply/index\\_54214.html](http://www.unicef.org/supply/index_54214.html)**

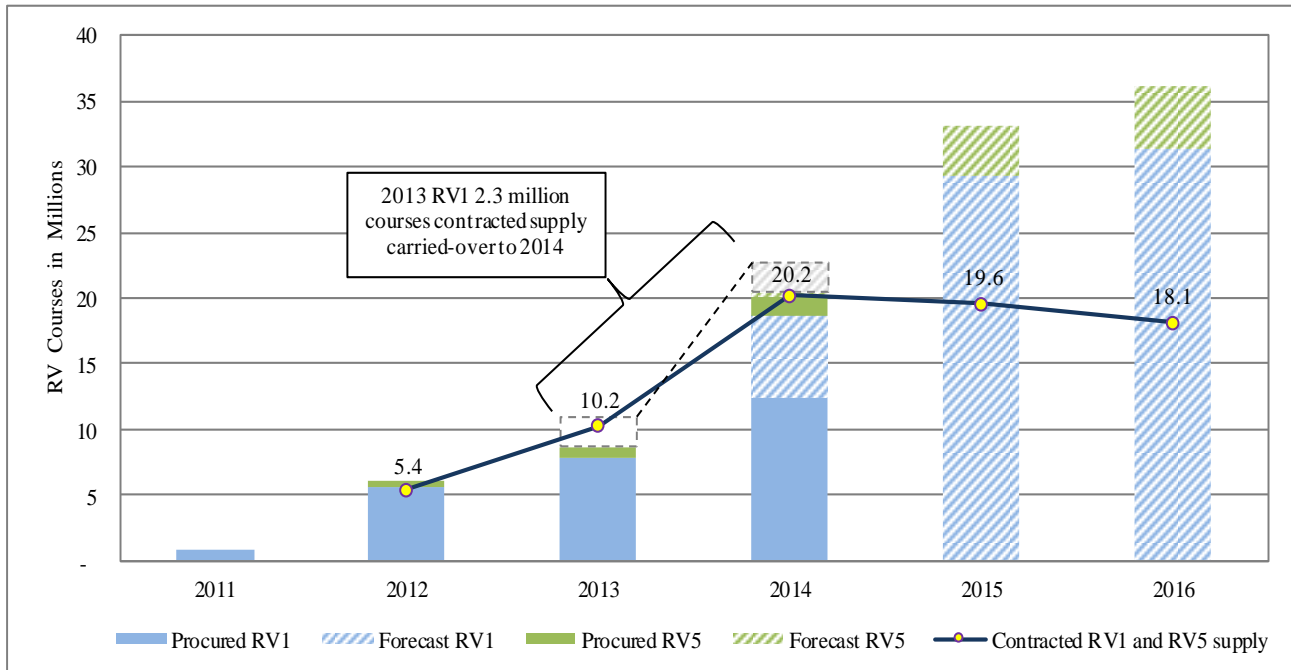
### 1. Summary

- UNICEF's previous [August 2013](#) Supply and Demand Update highlighted RV1 demand exceeding manufacturer production capacity. However, as of July, 2014, the supply situation for RV1 has improved due to increased manufacturing capacity. Increased capacity from RV manufacturers has facilitated an increase in the number of scheduled country vaccine introductions during 2014.
- 15 countries procuring through UNICEF are expected to introduce RV during 2014, of which 10 countries have already introduced the vaccine during 2014 year-to-date (end-June). An additional 5 countries anticipate RV introduction during 2015.
- UNICEF procured 8.7 million RV courses during 2013, which was 21% less than initially anticipated. Whereas 6 countries (~4.7 million surviving infants annually) introduced RV during 2013, 3 countries postponed vaccine introductions to 2014 due to supply availability materialising only during 4Q 2013. Unused supply in 2013 was carried-over to 2014.
- 2014 RV contracted supply is 20.2 million courses. Actual availability is expected to reach 22.8 million courses, as it includes 2.3 million additional courses of RV1 carried-over from 2013, as well as the additional availability of 250,000 RV1 courses. Current 2014 country-specific demand is 19.8 million courses, although by the end of the year, UNICEF expects to have procured the full availability, as additional demand should materialise and in preparation for anticipated large country introductions in 2015. While RV availability can meet current demand, the high concentration (93%) with one supplier due to country product preference (RV1) incurs sustained risk, despite ample RV5 availability.
- During 2015 and 2016, demand is anticipated to reach 33.1 million and 36 million courses, respectively. Additional awards will be required to increase supply to meet anticipated country demand. The need for new awards is currently being reviewed based on a review of 2015 projections and beyond against 2014 country applications.

### 2. General Brief and Background

UNICEF's previous RV Supply and Demand Update ([August 2013](#)) provides general market background and actions taken to manage the constrained supply situation for one of the vaccine presentations (RV1) and country introduction schedules. Increased RV1 manufacturer production capacity, in addition to the carry-over from 2013, have doubled supply from 10.2 million courses during 2013 to 22.8 million courses during 2014. Supply includes an offer from GSK of an additional 250,000 courses (500,000 doses) above quantities already awarded (Figure 1). UNICEF procured 8.7 million courses in 2013. 2.3 million courses for RV1 under UNICEF contract were carried-over to 2014 as most of the supply was only made available during the last quarter of 2013. As a result, some countries chose to postpone introductions into 2014.

**Figure 1 UNICEF RV Supply and Demand Forecast through 2016**



Source: UNICEF Supply Division.

### 3. Current Market Situation

#### 3.1. Demand

58 countries<sup>1</sup> are currently eligible for support from GAVI through UNICEF with a combined surviving infant population of 69.5 million children. 9 graduating countries can also self-fund<sup>2</sup> RV procurement with access to GAVI RV prices through UNICEF.<sup>3</sup>

As of 30 June, 34 countries have been approved for GAVI support to introduce RV with procurement through UNICEF. This includes 5 new countries that applied in the last GAVI New Vaccines Support round and were recently approved for RV introduction in 2014. In total, 24 countries procuring RV through UNICEF have already introduced the vaccine into their national expanded programme on immunization (EPI). The remaining 10 countries are anticipated to introduce RV over the next year.

23 countries remain eligible to apply to GAVI for RV introduction. Following is an overview of the approved and applicant countries at different stages of introduction through UNICEF (Table 1).

<sup>1</sup> 52 GAVI-eligible countries + 6 graduating countries procuring through UNICEF.

<sup>2</sup> The 9 self-funding countries are Azerbaijan, Bhutan, Indonesia, Kiribati, Mongolia, Papua New Guinea, Sri Lanka, Timor-Leste, and Ukraine.

<sup>3</sup> Data excludes the 6 Latin American and Caribbean countries (Bolivia, Cuba, Guyana, Haiti, Honduras and Nicaragua) which procure vaccines through the Pan American Health Organisation (PAHO) Revolving Fund, of which five are graduating. Five of the six have introduced RV into their national immunization programmes. The other remaining country (Cuba) has not applied. As it is no longer eligible, it would have to self-fund.

Table 1 Rotavirus Vaccine UNICEF Procuring Country Introduction Status as of end-June 2014

2011	2012	2013	2014	2015 onwards	Others	
Sudan	Armenia*	Burkina Faso	Angola*	Guinea-Bissau	Afghanistan	Lao, PDR
	Ghana	Burundi	Cameroon	Liberia	Azerbaijan*	Lesotho
	Malawi	Ethiopia	Congo*	Mozambique	Bangladesh	Mongolia*
	Moldova*	Gambia	Djibouti	Tajikistan	Benin	Myanmar
	Rwanda	Georgia*	Madagascar	CAR	Bhutan*	Nepal
	Tanzania	Zambia	Mali		Cambodia	Nigeria
	Yemen		Sierra Leone		Chad	Pakistan
			Togo		Comoros	Papua New Guinea*
			Uzbekistan*		Congo DR	Sao Tome and Principe
			Zimbabwe		Côte d'Ivoire	Solomon Islands
			Eritrea		Guinea	Somalia
			Kenya		India	Sri Lanka*
			Mauritania		Indonesia*	Sudan, The
			Niger		Kiribati*	Timor-Leste*
			Senegal		Korea, DPR	Uganda
					Kyrgyzstan	Ukraine*
						Viet Nam

	Approved and Introduced
	Approved pending introduction
	Applied pending approval
	Countries not yet applied

Source: UNICEF Supply Division.

Even though RV1 availability increased during 4Q 2013 and 1Q 2014, a number of countries postponed vaccine introductions due to a number of factors including limited human resources to manage competing priorities, lack of training and cold chain readiness, as well as political changes. Shipments covering a total of 3.7 million doses were postponed as a result of delayed introductions. All countries currently approved for 2014 introduction with a combined surviving infant population of 7.7 million children, will receive vaccine delivery according to the planned scheduled introduction timing below (Table 2).

Table 2 Approved GAVI-Supported Country Vaccine Introduction Plans 2014

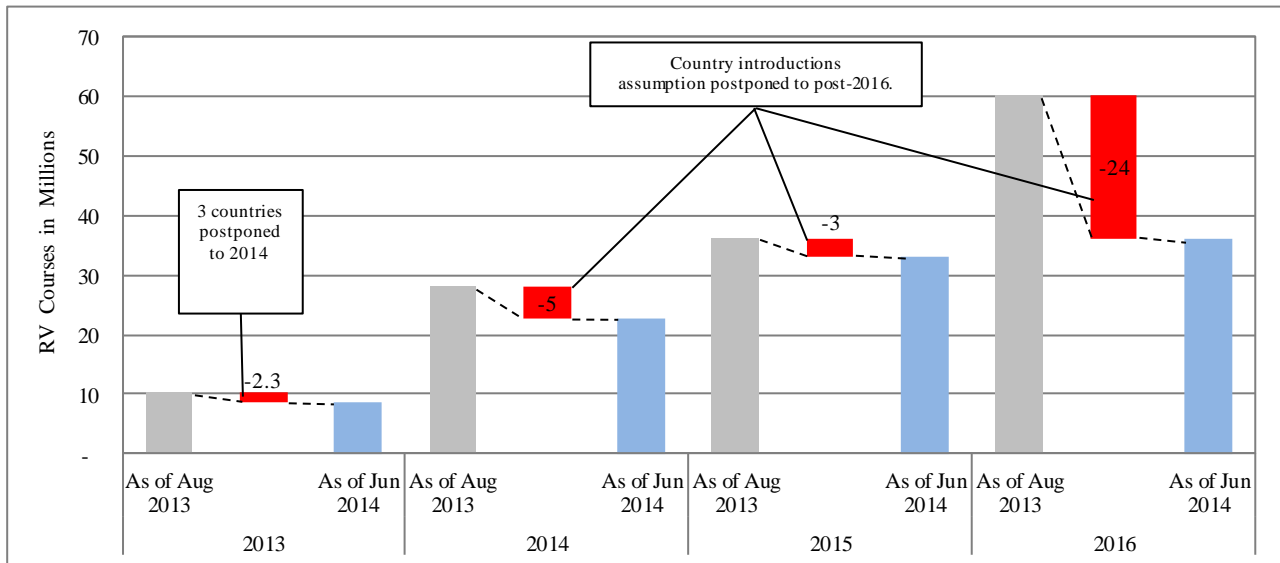
2014							
Q1	Q2		Q3		Q4		
<b>RV1</b>							
Cameroon	759,000	Angola	844,000	Eritrea	220,000	Mauritania	121,000
Sierra Leone	196,000	Congo	154,000	Kenya	1,455,000	Senegal	498,000
		Djibouti	23,000	Niger	812,000		
		Madagascar	751,000	Uzbekistan	595,000		
		Togo	229,000				
		Zimbabwe	422,000				
<b>Total birth cohort (surviving)</b>	<b>955,000</b>	<b>Total birth cohort (surviving)</b>	<b>2,423,000</b>	<b>Total birth cohort (surviving)</b>	<b>3,082,000</b>	<b>Total birth cohort (surviving)</b>	<b>619,000</b>
<b>RV5</b>							
Mali	643,000						
<b>Total birth cohort (surviving)</b>	<b>643,000</b>	<b>Total birth cohort (surviving)</b>	<b>-</b>	<b>Total birth cohort (surviving)</b>	<b>-</b>	<b>Total birth cohort (surviving)</b>	<b>-</b>

Source: UNICEF Supply Division.

\* Note: Graduating country and not eligible to apply for GAVI support for RV introduction.

Changes in the forecast assumptions of RV introduction timing in large countries (e.g. Bangladesh, Pakistan) have generated a substantial demand forecast revision compared to UNICEF's previous RV Supply and Demand Update ([August 2013](#)). An aggregate of 32 million courses is now not expected to materialise until the post-2016 period (Figure 2).

**Figure 2 Current RV Demand Forecast Assumptions versus Previous (August 2013)**



Source: UNICEF Supply Division.

Previous global supply constraints (which are being resolved by increased production capacity), as well as competing vaccine introductions and RV1 training readiness, have been the main challenges faced by countries in vaccine introduction and cause for country introduction postponements since the launch of RV introductions.

### 3.2. Supply

UNICEF anticipates procuring 22.8 million RV courses (47 million doses)<sup>5</sup> during 2014. In order to meet both planned and un-forecasted needs, UNICEF increased 2014 allocations during 2013 from 33 million to 37.2 million RV1 doses (to increase the number of courses on contract from 16.5 million to 18.6 million). UNICEF has long term arrangements (LTA) with two manufacturers for 73.5 million courses (152.5 million doses) from 2012 through 2016 (Table 3).

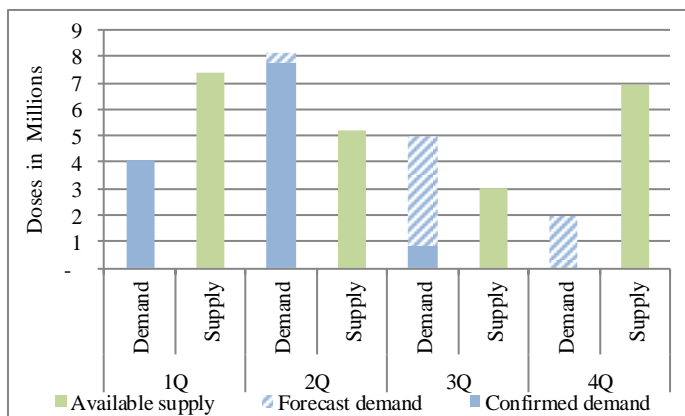
**Table 3 UNICEF Awards for 2012-2016**

Manufacturer	Vaccine	Duration	Presentation	Doses	Schedule	Courses
GlaxoSmithKline (Belgium)	RV1	4 years	1 dose	136,200,000	2 doses	68,100,000
Merck (USA)	RV5	4 years	1 dose	16,332,100	3 doses	5,444,033
<b>Total</b>				<b>152,532,100</b>		<b>73,544,033</b>

Source: UNICEF Supply Division.

<sup>5</sup> 22.7 million RV courses are made up of 41.9 million doses of RV1 (2 dose schedule) and 5.4 million doses RV5 (3 doses schedule).

**Figure 3 UNICEF Rota Supply and Timing versus Demand Forecast 2014**



Source: UNICEF Supply Division.

2014 RV availability has improved from 2013 on account of increased manufacturer capacity. RV availability is expected to reach 22.8 million courses, including the carry-over of 2.3 million courses from 2013 and an additional 250,000 courses offered by GSK. 64% of 2014 demand and 56% of 2014 supply is concentrated during 1Q and 2Q 2014. As currently planned, excess supply during 4Q (compared to demand) may lead to supply carry-over into 2015. (Figure 3).

UNICEF currently has 152.5 million doses (73.5 million courses) under contract through 2016 (Table 4). The need to increase manufacturer awards will be assessed during 2H 2014 against new country applications and 2015 SDF projections and beyond. Several other manufacturers anticipate WHO prequalified RV from 2017 at the earliest.

**Table 4 Current RV Doses Availability 2014-2016.**

RV Production	2012	2013	2014	2015	2016	Total
RV1 contracted supply	10,000,000	18,900,000	37,200,000	35,000,000	35,100,000	136,200,000
RV5 contracted supply	1,286,500	2,360,250	4,820,850	6,206,700	1,657,800	16,332,100

Source: UNICEF Supply Division.

#### 4. Issues and Challenges

- RV availability during 2014 has improved and is able to meet an increased number of country introductions. However, the increasing number of country introduction postponements is also delaying supply utilisation and reducing demand forecast for the near-term. Support for country preparations and planning for a realistic timeline for introduction is required to optimise supply utilization.
- From 2015, current contracted supply will not be sufficient to meet total requirements. The need for new awards is being reviewed based on a review of 2015 projections and beyond considering 2014 country applications.
- Product preference imbalance remains a challenge (93% of demand with one supplier), which contributes to the supply constrained situation for RV1 and risky over-reliance on one product. Several large countries have yet to apply for rotavirus vaccine, including Pakistan, Nigeria, Bangladesh and DRC. While countries that are already approved have been allocated the preferred presentation, the introduction plans and product preference of large countries will determine whether product preferences can be met from 2016 and beyond.

#### 5. Steps Forward

- UNICEF and other GAVI Alliance partners will continue to closely monitor the supply capacity and requirements through 2016 and beyond. Demand will be re-assessed upon the completion of

country applications to GAVI during 2014 for country RV introduction and against the strategic demand forecast (SDF) projections.

- UNICEF and other GAVI Alliance partners will continue to support country implementation and ensure readiness to launch.
- UNICEF will meet with manufacturers during 2H 2014 to discuss supply capacity and projected country requirements during 2015 and beyond.
- A new procurement strategy will be developed in consultation with partners and industry to secure vaccine availability and increased supply.

For further questions or additional information, please contact:

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Other UNICEF information notes can be found at [http://www.unicef.org/supply/index\\_54214.html](http://www.unicef.org/supply/index_54214.html).