

Reduced price on rotavirus vaccines: enough to facilitate access where most needed?

Lizell B Madsen,^a Marte Ustrup,^a Thea K Fischer,^a Ib C Bygbjerg^a & Flemming Konradsen^a

Introduction

Rotavirus infections, the most common cause of severe childhood diarrhoea, result in approximately 527 000 child deaths every year. The majority of these deaths occur in low-income countries, particularly in Africa and Asia.¹ Rotavirus-associated diarrhoea can be prevented by new live attenuated human rotavirus vaccines. These vaccines have proved safe and efficacious in large-scale clinical trials and post-licensure studies have confirmed their effectiveness in middle- and high-income countries.^{2,3} However, they have only been partially implemented in national immunization programmes in low-income countries, even though these countries have higher rates of death from rotavirus infection.⁴

The pharmaceutical companies behind the two internationally licensed rotavirus vaccines, Rotarix[®] (GlaxoSmithKline Biologicals, Rixensart, Belgium) and RotaTeq[®] (Merck & Co. Inc., Whitehouse Station, United States of America), have recently pledged to the United Nations Children's Fund and the international donor community to provide their vaccines to low-income countries at greatly reduced prices.^{4,5} In spite of these reductions, rotavirus vaccines continue to be more expensive than most traditional childhood vaccines included in the Expanded Programme on Immunization (EPI). This rekindles the traditional debate surrounding access to new childhood vaccines in low-income countries.

In this paper, we examine whether the newly-proposed vaccine prices are low enough to make rotavirus vaccines universally accessible to the millions of children in need of protection against rotavirus infection, a major threat to child health. Furthermore, we discuss the steps that need to be taken in the future to facilitate the introduction of rotavirus vaccines and ensure their

sustained financing in low-income countries.

Rotavirus vaccine introduction

At least 43% of the 527 000 child deaths and 51% of the 27 million annual medical visits that take place in low- and middle-income countries on account of rotavirus-associated diarrhoea could be prevented if universal rotavirus vaccination were achieved. The savings in treatment and societal costs would be enormous.⁶ As a result, the World Health Organization (WHO) has recommended including the rotavirus vaccine in national immunization programmes worldwide. So far, however, rotavirus vaccines are only being routinely used in 14 countries in Latin America and one African country. Notably, only four of the world's 56 poorest countries are routinely using the vaccine.⁴ Several factors account for this delay in implementing vaccination against rotavirus in low-income countries. Clinical trials are seldom conducted in these settings, and few data are available on the disease burden and treatment costs that could be averted by vaccination. Furthermore, rotavirus vaccines must compete for scarce resources with other new childhood vaccines, such as the pneumococcal conjugate vaccine and the meningococcal A conjugate vaccine. The high cost of these vaccines is another major barrier to their introduction.¹ In general, new vaccines are becoming more expensive and immunization expenditures have risen over the past decades. In 2000, the annual expenditure on vaccination in low-income countries averaged 6.00 United States dollars (US\$) per live birth, but by 2015, it will exceed US\$ 30.00 per live birth.¹ Consequently, the governments of low-income countries wishing to sustain existing immuniza-

tion programmes and to add to them newly developed vaccines face a serious financial challenge.

Financial challenges

New requirements for the development, production and licensure of new vaccine candidates have caused a marked rise in manufacturers' investment costs.¹ To pay off these investments in research and development and generate profits while the manufacturer monopolizes the market, new vaccines are generally marketed at higher prices than the traditional childhood vaccines included in the EPI.¹ Rotavirus vaccines are no different. The two rotavirus vaccines have undergone the largest safety and efficacy trials in history because intussusception was a suspected complication of the first rotavirus vaccine, RotaShield[®].¹ When the two vaccines were licensed in 2006, Rotarix[®] was approximately 132 times more expensive per dose than the cheapest traditional EPI vaccine, while RotaTeq[®] was 90 times more expensive (Fig. 1).^{4,5,7}

GlaxoSmithKline has offered to provide its vaccine at US\$ 2.50 per dose, which constitutes a 67% reduction over the lowest public price currently available.⁴ Merck & Co. Inc. has offered to provide its vaccine at US\$ 3.5 per dose once the purchase volume reaches 30 million doses.⁵ However, as seen in Fig. 1, even at these prices rotavirus vaccines would continue to be more expensive than most traditional EPI vaccines. Since vaccine procurement has been estimated to account for 60% of the total costs of introducing new vaccines into national immunization programmes in low-income countries, the proposed prices will still represent a serious strain on national health budgets.¹

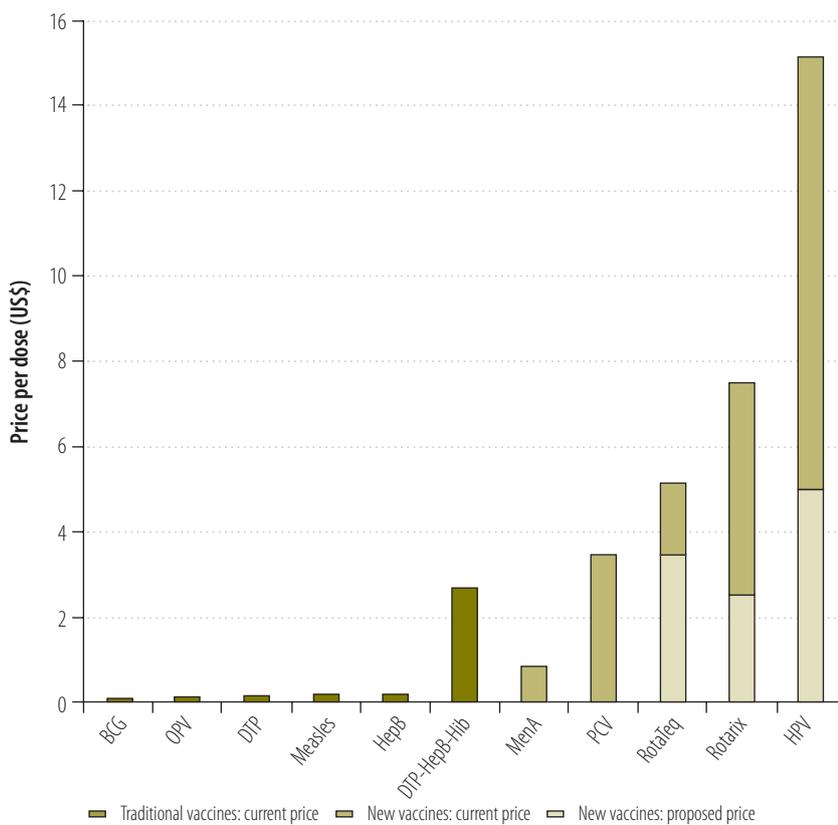
The GAVI Alliance (GAVI) has pledged to financially support the world's poorest countries in the procure-

^a Department of International Health, Immunology and Microbiology, University of Copenhagen, Oester Farimagsgade 5, bd. 9, PO Box 2099, Copenhagen 1014, Denmark.

Correspondence to Lizell B Madsen (e-mail: lizell@sund.ku.dk).

(Submitted: 13 August 2011 – Revised version received: 12 January 2012 – Accepted: 18 January 2012)

Fig. 1. **Prices of childhood vaccines**



BCG, bacille Calmette-Guérin vaccine; DTP, diphtheria-tetanus-pertussis vaccine; DTP-hepB-Hib, combination vaccine against diphtheria-tetanus-pertussis, hepatitis B and *Haemophilus influenzae* type b; Hep B, hepatitis B vaccine; HPV, human papillomavirus vaccine; MenA, meningococcal A conjugate vaccine; OPV, oral polio vaccine; PCV, pneumococcal conjugate vaccine; US\$, United States dollars. The data were obtained from GlaxoSmithKline, Merck & Co. Inc. and the United Nations Children's Fund 2011.

ment of rotavirus vaccines.¹ Thus, for the governments of GAVI-eligible countries, vaccine prices may not pose a major problem in the introductory phase. However, these countries still need to secure the financial sustainability of vaccination programmes after GAVI support ends. In addition, lower-middle-income countries that are not eligible for GAVI support will face increasing difficulty in financing the introduction of new vaccines.¹ Thus, to what extent the proposed price reductions will influence the decision to introduce rotavirus vaccines in these countries remains to be seen.

Finally, the impact of the proposed price reductions needs to be reviewed in light of the overall costs associated with introducing new vaccines. Vaccine implementation brings high system expenditures because of the costs of training health personnel, expanding surveillance and increasing advocacy activities and outreach visits.¹ Furthermore, rotavirus vaccines occupy a lot of

space in cold storage and consequently put an unprecedented strain on the cold chain system, which may need to be expanded in many low-income countries.¹

Future steps

Identification of new sustainable financing opportunities and mechanisms is urgently needed. In particular, ways for lower-middle-income countries to receive financial support for vaccine procurement need to be found. This issue is of global importance and political commitment is a precondition for the successful introduction and sustainability of immunization programmes. International health and development organizations need to initiate effective dialogue with concerned governments in low-income countries on the introduction of rotavirus vaccines.

On the supply side, product development partnerships and technology transfers could stimulate vaccine

research and development and allow low-income countries to manufacture rotavirus vaccines locally. This would create more market competition.¹ Furthermore, if vaccine manufacturers agreed to tiered pricing, the profits made from selling the vaccine to high-income countries at a higher price would make the price affordable in low-income countries.¹

Immunization is an integral part of the health system. Thus, combined delivery of vaccination with other health interventions would lead to several health system benefits: increased coverage, a pooling of human and financial resources, shared storage and distribution systems, improved management and integrated surveillance.¹ However, successful integration is only possible in settings where a well-functioning health system can serve as a platform for delivering interventions.

Conclusion

The two major pharmaceutical companies that manufacture rotavirus vaccines have recently offered to sell these vaccines to the world's poorest countries at greatly reduced prices. This is eloquent proof of the industry's commitment to facilitating access to life-saving vaccines. However, even at these lowered prices rotavirus vaccines would still be substantially more expensive than traditional childhood vaccines and the introduction and sustainment of a rotavirus vaccination programme would still be unaffordable for low-income countries. Thus, vaccine manufacturers need to be pressured to further reduce the price of their vaccines, and new sustainable financing opportunities for immunization programmes in low-income countries need to be identified. These pursuits should rank high on the agendas of international health and development organizations.

By reducing deaths from rotavirus-associated diarrhoea, universal access to rotavirus vaccines could greatly contribute to the attainment of the United Nations' Millennium Development Goal of reducing child mortality. The international public health community should make every effort to ensure universal access to rotavirus vaccines. ■

Competing interests: None declared.

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