

Afterword: Perspectives on future new vaccine introductions in Ethiopia

Yayehyirad Kitaw¹

I. The Decade of Vaccines: “IMMUNISATION FOR ALL: NO CHILD LEFT BEHIND”:

The pace of development of new vaccines is accelerating more than ever before. In the next few years, we should expect at least a doubling of the 20-odd vaccines available to date with forays in the hitherto uncharted fields of parasite and fungal vaccines (1). In 2005, WHO registered 22 vaccines available for routine immunization programs and foresaw 20 new or improved vaccines by 2015 (2).

There is considerable pressure to adopt new and under-utilized vaccines (NUVI) as early as possible since in particular the 61st World Health Assembly decision in May 2008 (3). However, there are several challenges because decision-making is a relatively little understood process, new vaccines tend to be more expensive, some ‘hidden’ but important problems may lack public/political attractiveness (4) and most introductions are made under conditions for which low-income countries (LIC) have little experience in proactive planning (5). As the papers in this special issue show (6, 7, 8), there have been recent attempts to understand better the decision-making processes and impacts of the introductions of new vaccines and approaches. This afterword tries to assemble the lessons learnt and prospects in adoption of NUVI in the Ethiopian context. A hard look at the facts and paving the way for a proactive planning is important as, in spite of ups and downs (5), there is an unprecedented pledged funding by the GAVI Alliance (9). Ethiopia has been in a very favourable position as the country where GAVI has invested the highest amount overall in Africa since 2001. In addition, a previous evaluation showed that the specific GAVI contribution to health systems strengthening was “greater than what would have been allowed under the HSS normal allocation formula i.e. \$5 per newborn.” (10).

Immunization in Ethiopia has a long history but gained an institutional anchor with the introduction of EPI 1980 (11). Since then a number of new vaccines have been introduced and the Health Sector Development Program (HSDP) IV (2010-2015) plans to introduce 10 further vaccines by 2015 (14) of which PCV 10, October 2011 (8) and Rota, November 2013 have already been introduced (12).

II Opportunities and Threats:

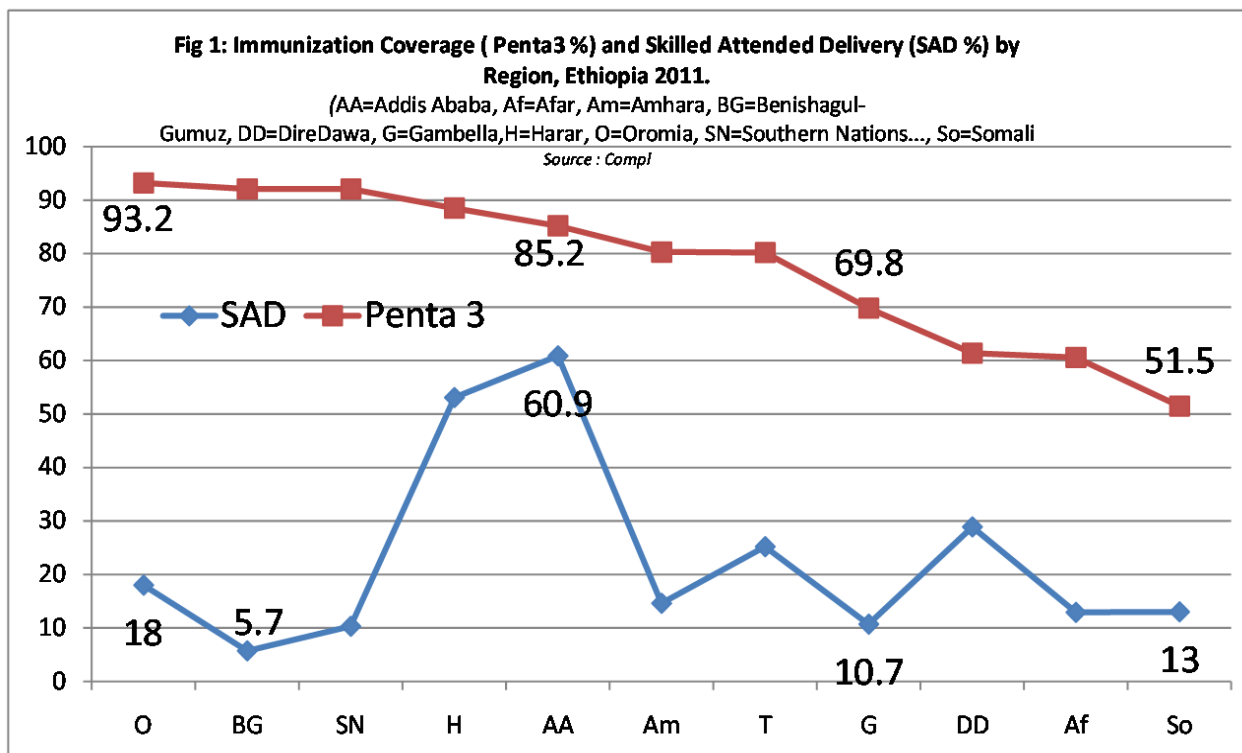
Future introductions of NUVI in Ethiopia present undeniable promises of better health outcomes but also challenges. There is a proactive and committed leadership promoting an ‘integrated health system

strengthening approach’ (10, 13, 14). Extensive coverage has been achieved through the Health Extension Program (HEP) with a health post for less than 5000 people and health extension workers (HEW) for about 2000 (10, 14). “With the expansion of the HEP, some services like vaccination and delivery services are coming closer to the community” (10) enhanced by house to house efforts by HEW and the Development Army (15). The number of health centers (HC) and rural hospitals has also grown rapidly, thus ensuring a better accessible infrastructure for immunization. Total annual per capita expenditure for health has increased, for example from US\$4 in 1995/6 to US\$16 in 2007/8 (16). Accelerated training programs, the ‘Flooding Strategy’, have markedly increased the health workforce at the low and mid-levels in particular (17).

Improved and more equitable immunization coverage has been achieved with over 80% in most woredas/districts (11). With growing numbers of universities and research capacity, the possibilities for more informed/evidence-based introductions of new vaccines and technologies promise to greatly improve (18). The potential and temptation of using immunization services as vehicle for other interventions, maternal, neonatal and child health (MNCH) initiatives in particular, is great (24). Immunisation services seem to be a logical place to begin (19), being relatively better endowed, well-functioning and more equitably distributed. However, EPI also faces a number of threats.

Limited participation of NGOs and civil society (10); poor, even though rapidly improving, infrastructure; poverty; political instability; migration (20); complex disasters – ‘the constants of Ethiopian history’ (21) - continue to pose major challenges. Poor quality of health services has meant underutilization, with outpatient visits (OPD) per capita stagnating at around 0.3 for the last 50 years. In spite of better and more equitable coverage (compared to skilled attended delivery, for example), the immunization service is very weak in some administrative areas (Fig 1), in particular the ‘emerging regions’ with significant under-coverage and ‘silent’ [no/low reporting, low coverage] districts (11). The national regulatory authority, the cornerstone of vaccine quality, is nascent and, as in many developing countries, considerable attention is needed to improve injection safety in Ethiopia (22). Overall, strengthening the routine immunization system, which in some regions could be highly deficient (23), remains a priority (24, 25).

¹Independent consultant, Ethiopia, Email: yayehyiradk@yahoo.com.



In spite of very rapid increase, the health workforce (HWF) density in Ethiopia, 0.7/1000 including HEWs, remains very low, one of the lowest in the world. Consequently, shortages and low skill levels of staff are major concerns of health services providers and the community at large (21, 26). Thus the laudable initiatives to use the relatively successful immunization platform as vehicle for other interventions should be handled cautiously. Overburdening the already under-resourced system should be avoided as most interventions require more time than immunization (Table 1) and there are, as Ryman et al (26) put it, “Concerns related to integration including being labor-intensive, inadequate staff to implement, inadequately trained staff, in addition to a number of more broad health system issues (e.g. stock outs, wait times)” (27).

Table 1: Observed time for selected services delivery (minutes), Ethiopia

Intervention	Median	Range
Infant vaccination	4:0	2:16, 4:49
Family planning (recurrent methods)	3:03	1:34, 5:43
Growth monitoring	5:05	4:19, 7:58
Antenatal care visit	2:59	1:48, 5:20
Treatment of sick infant	9:24	7:50, 10:20
HIV counselling & testing	12:07	3:20, 20:53
Family planning (IUD)	8:08	4:20, 1:02

Source: 24

Risk of overburdening the system could also result from unfinished immunization-related agendas, elimination projects in particular. Ethiopia is, among others, involved in Polio Eradication Initiative (PEI), Maternal and Neonatal Tetanus Elimination (MNTE) and Measles elimination. Following the African Union (AU) decision in 2007, Ethiopia is committed to move from control to elimination of malaria (28, 29). In spite of laudable progress – no wild polio transmission for a

number of years; elimination MNT except in insecurity-challenged Somali Region (30); tangible progress in measles elimination (6) – major uncertainties remain as most of the ‘silent districts’ are in the remote areas bordering with countries (Somalia, [South] Sudan) with vulnerable programs (11, 21) and high cross-border movements (31).

New vaccines & technologies: Globally, there have been major developments in vaccines and related technologies with more and better advances expected in the near future (32). The RTS,S/AS01 Phase 3 malaria vaccine trial has been completed and WHO is poised to make evidence-based recommendations in 2015 (33). Work on an HIV vaccine is progressing with possibilities that some would be available, as are a large number of other vaccines (see above) now in the pipeline, in a not too distant future (1, 2). In vaccine technology, the meningococcal A conjugate vaccine (Men Afri Vac®) can now be kept in a controlled temperature chain at up to 40°C for up to four days with major potential for access to hard-to-reach areas (34). Information Technology promises to revolutionize the management of immunization programs with, for example, E-learning course on Vaccine Safety (35). For instance, Lumidigm Fingerprint Sensors could potentially completely change the way we trace immunization coverage (36).

Other researchers have urged caution in generalizing about different vaccines and varied epidemiological settings. The use of evidence including cost-effectiveness of new vaccines has been shown as a key tool for rational decision-making in this area (37). However, a number of concerns should be addressed. First of all, affordable and potentially life-saving technologies are not [yet] reaching those who need them most” (19), in Ethiopia and in Sub Saharan Africa

more generally (see also 38). On the other hand, hasty introduction of new vaccines might impact negatively on existing immunization and other health services (4, 5). Potential conflict between individual and collective interests should be addressed (39). Availability, predictability and consistency of financing should be thought-through as GAVI could face pledge reduction as in 2010 (5). Ultimately, as highlighted by UNICEF, “Sustainability is the key for the next phase of the drive towards full immunization” (40).

In Ethiopia, the pressure to introduce new vaccines, whether sequential or multiple, when funding is available (GAVI, WHO) will continue to be irresistible (5, 41) as would also be the pressure to add functions to an effective and relatively equitable program. It can also be argued that Ethiopia is much better prepared than ever before to adopt some vaccines.

Hepatitis B, Hib, PCV10 and, more recently, Rotavirus vaccines (12, 42) have been introduced successfully. An innovative method of pharmaco-vigilance of observing potential risk adapted to the situation in the country was carried out for PCV10 vaccine (43). There is better preparedness for malaria vaccine introduction, as an economic study has been conducted recently (33) and a “Future Decision Making Framework” has been prepared (44). A meningococcal ACW135 vaccine safety study has been conducted (45) and Ethiopia has been declared vaccine safety E-Learning champion (46), one of the highest users in the world; and the first in Africa (35). There is a plan to start, as of next year, vaccine production in the country (47). All these are promising developments from which future introductions could profit. However, major programmatic concerns will have to be addressed.

The decision making process to date has been centralised (7) and care should be taken, as much as possible, to involve all stakeholders in future adoption processes. The role of the public not only in communication campaigns but in dialogue and trust building should be enhanced (48) as experience from other countries (49) shows that the positive disposition of Ethiopians to immunization could easily be eroded unless perceptively nurtured; grandstanding against vaccinations are not only historic phenomena (41). The local evidence base for decision-making should be further strengthened and whatever data is available should be used appropriately. The health care system in general and even the relatively stronger immunization system is rather fragile (50), the human resource base in particular is inadequate, of low quality and poorly motivated and while “periodic shocks and recovery” might be salutary (5), care should be taken not to overburden it. The health system in general and immunization in particular are highly donor dependent (11, 21). Measures should, therefore, be designed to withstand a possible crisis in donor (e.g. GAVI) funding or as Ethiopia might have to face problems

related to ‘graduating countries’ (5, 51) as early as 2020 if, as predicted, it moves to middle income country status (52).

II. Conclusions:

The Ethiopian government, like its peers in all LICs, will face irresistible pressures and tough decisions to introduce new vaccines as soon as they are available; “a privilege and responsibility” (53). It will also be faced with the challenges of adding functions to a relatively effective and equitable immunization program. “Deciding to adopt a new vaccine is not simply a technical, evidence-informed decision but rather an example of the craft of policy-making” (54).

Ethiopia is much better prepared than ever before to adopt some vaccines, e.g. malaria, meningococcal, but care should be taken to involve all stakeholders in the adoption process; base decision on local evidence base; not over-burden the system given the meagre human resources for health in particular; and to ensure sustainability. The challenge is to take bold steps in order to make up for lost time, with an eye on the evidence base and programmatic strengthening without undermining the policy momentum because as Meessen et al 2012 (55) say “Our own experience has taught us that most schemes anywhere fail because of poor design, insufficient funding, weak governance and muddled implementation” is truer for countries such as Ethiopia (17, 21).

References

1. Moxon ER and CA Siegrist. The next decade of vaccines: societal and scientific challenges. *Lancet* 2011; 378: 348–59
2. World Health Organization (WHO). Global Immunization Vision and Strategy 2006-2015. Geneva, 2005 [cited 2014]; Available at: URL: http://www.who.int/vaccines-documents/DocsPDF05/GIVS_Final_EN.pdf.
3. World Health Organization (WHO). *Resolution of the 61st World Health Assembly*. Geneva, World Health Organization, 2008.
4. Burchett HED, Mounier-Jack S, Griffiths U, Biellik R, Ongolo-Zogo P, Chavez E, Sarma H, Uddin J, Konate M, Kitaw Y, Molla M, Wakasiaka S, et al. National Decision Making on Adopting New vaccines: A Systematic Review. *Health Policy and Planning* 2012; 27: ii62-ii76.
5. Gordon WS, Jones A, Wecker J. Introducing Multiple Vaccines in Low-and Middle-Income Countries: Issues, Opportunities and Challenges. *Health Policy and Planning* 2012; 27: ii17-ii26.
6. Molla M, Torres-Rueda S, Mounier-Jack S, Kitaw Y. Impacts of accelerated measles elimination activities on immunization services and the health system in Ethiopia. *Ethiop J Health Dev* 2015; Special Issue I:23-30.

7. Molla M, Torres-Rueda S, Mounier-Jack S, Kitaw Y. New Vaccine Adoption and Decision Making in Ethiopia: Qualitative Study of National Decision-Making Processes for the introduction of PCV 10. *Ethiop J Health Dev* 2015; Special Issue I:17-22.
8. Sergio Torres Rueda, Yayehyirad Kitaw, Mitike Molla, Sandra Mounier-Jack. Introduction of PCV-10 in Ethiopia: Effects on the Health System. *Ethiop. J Health Dev* 2015; Special Issue I:8-16.
9. Rees H and SA Madhi. Will the Decade of Vaccines mean business as usual? *Lancet* 2011; 378: 382-384.
10. Abebe Alebachew and C Ortendahl. GAVI Health System Strengthening Support Evaluation: Ethiopia Case Study. RFP-0006-08. Final Version - August 2009.
11. Habtamu Belete, Teklaye Kidane, Filimona Bisrat, Mitike Molla, S Mounier-Jack, Yayehyirad Kitaw. Routine Immunization in Ethiopia. *Ethiop J Health Dev* 2015; Special Issue I:2-7.
12. Program for Appropriate Technology in Health (PATH). Rotavirus disease and vaccines in Ethiopia. October 2013.
13. Ministry of Health (MOH). HIV/AIDS and the Health-related Millennium Development Goals: The Experience in Ethiopia. Federal Democratic Republic of Ethiopia, Ministry of Health, September, 2010.
14. Ministry of Health (MOH). Health Sector Development Program (HSDP) IV: 2010/11-2014/15. 2010, Addis Ababa.
15. HEPCAPS1 Project Team. 2012. *Ethiopia's Health Extension Platform: A background paper prepared for the HEPCAPS1 project*. Ethiopia HEPCAPS1 Series Paper #1. Boston, Massachusetts and New Haven, Connecticut: Harvard School of Public Health and Yale Global Health Leadership Institute.
16. USAID. Health Care Financing Reform in Ethiopia: Improving Quality and Equity. 2012.
17. Yayehyirad Kitaw, GebreEmanuel Teka, Hailu Meche. Evolution of Human Resources for Health in Ethiopia: 1941-2010. EPHA, Addis Ababa, 2014.
18. Ethiopian Academy of Sciences (EAS). Report on Mapping the Health Research Landscape in Ethiopia. Ethiopian Academy of Sciences, Addis Ababa, 2013.
19. Naimoli JF, Challa S, Schneidman M, Kostermans K. Toward a grounded theory of why some immunization programs in sub-Saharan Africa are more successful than others: a descriptive and exploratory assessment in six countries. *Health Policy and Planning* 2008; 23: 379-389.
20. Kiros GE and MJ White. Migration, community context, and child immunization in Ethiopia. *Social Science & Medicine* 2004; 59: 2603-2616.
21. Yayehyirad Kitaw, Hailu Meche, GebreEmanuel Teka, Damne Hailemariam, Mesganaw Fantahun. Evolution of Public Health in Ethiopia: 1941-2010. 2nd Revised Edition, EPHA, Addis Ababa, 2012.
22. Dicko M, AQO Oni, S Ganivet, S Kone, L Pierre, B Jaquet. Safety of immunization injections in Africa: not simply a problem of logistics. *Bulletin of the World Health Organization* 2000;78 (2): 163-169.
23. Asres M and M Fantahun. Health facility preparedness for routine immunization services in Gambella Region, Ethiopia. *Ethiop Med J* 2013; 51(S1): 67-69.
24. World Health Organization (WHO AFRO). In-depth Evaluation of Reaching Every District Approach, 2007.
25. LaFond, A.K., & Sequeira, J.M. *Drivers of Routine Immunization System Performance at the District Level: Ethiopia Case Study, ARISE Research Brief No. 2*. Arlington, VA: JSI Research & Training Institute, Inc., ARISE Project for the Bill & Melinda Gates Foundation, 2012.
26. Ryman TK, Wallace A, Mihigo R, Richards P, Schalanger K, Cappelier K et al. Community and health worker perceptions and preferences regarding integration of other health services with routine vaccinations: Four case studies. *The Journal of Infectious Diseases* 2012; 205:S49-55.
27. Wallace A, Ryman T, Mihigo R, Ndoutabe M, Tounkara B, Grant G et al. Strengthening Evidence-Based Planning of Integrated Health Service Delivery Through Local Measures of Health Intervention Delivery Times. *The Journal of Infectious Diseases* 2012; 205: S40-8.
28. African Union (AU). African Union Launch of the Africa Malaria Elimination Campaign during the 3rd Session of the AU Conference of Ministers of Health Johannesburg, South Africa April 9th-13th, 2007.
29. Teodros Adhanom. Leadership Interview: Success on malaria requires strong political commitment and a partnership approach. Roll Back Malaria Partnership Secretariat, January 2009.
30. Yusuf N. Maternal & neonatal tetanus elimination in the African region – *what does it take to reach the 2015 goal?* Nasir Yusuf – UNICEF/ESARO Annual Regional Conference on Immunization (ARCI). UNICEF and WHO, 10 – 12 DEC 2012, Dar es Salaam, Tanzania.
31. Filimona B, Legesse K, Kibrom A, Muluken A, Bezunesh D, Conlob F. et al. Cross-Border Wild Polio Virus Transmission in CORE Group Polio Project. *Ethiop Med J* 2013; 51(S1): 31-39.
32. Rappuoli R, S Black, PH Lambert. Vaccine discovery and translation of new vaccine technology. *Lancet* 2011; 378: 360-68.
33. Cropper ML, Haile M, Lampietti J, Poulos C, Whittington D. The demand for a malaria vaccine: evidence from Ethiopia. *Journal of Development Economics* 2004; 75: 303-318.
34. World Health Organization (WHO). Global Immunization News. November 2012.
35. World Health Organization (WHO). Routine vaccination reaching four in five children but 22 million still miss out. Global Immunization News November, 2012.
36. Lumidigm Fingerprint Sensors Help Track Vaccination Histories of Children in Developing
Ethiop. J. Health Dev. 2015;29(Special Issue)1

- Countries: Biometric vaccine records are now in place for tens of thousands of adults and children in Kenya, Uganda, Benin and Zambia. November 12, 2013.
37. Kou UK. More vaccines? Using economic analysis to decide. *Bulletin of the World Health Organization* 2002; 80 (4): 263.
 38. Editorial. A shot in the arm for MDG 4 in Africa. *Lancet* 2011; 377: 632.
 39. Massad E, da Rocha AF, Burattini MN, Struchiner CJ. Modeling decision making considering collective versus individual interests in public health [cited 2014]; Available at: URL:<http://ssrn.com/abstract=2335633>.
 40. UNICEF. Expanding immunization coverage. Geneva, 2010 [cited 2014]; Available at: URL:www.unicef.org/immunization/index_coverage.html.
 41. Bloom DE, Canning d, Weston M. The Value of Vaccination. *WORLD ECONOMICS* 2005; 6(3): 15-39.
 42. Ministry of Health (MOH). Millions of Ethiopian children to be protected each year against leading cause of severe diarrhoea. Press Release Nov 7, 2013, Addis Ababa.
 43. Addis Continental Institute of Public Health (ACIPH). A multi-site observational epidemiology study to assess the potential risks that may be associated with misuse of a two-dose vial of 10-valent Pneumococcal Conjugate Vaccine (Synflorix) in Ethiopia: The Ethiopian PCV-10 Study [Eth-PCV]), Final Report. Addis Continental Institute of Public Health and The study Team, 2013.
 44. Program for Appropriate Technology in Health (PATH) and WHO. Ethiopia: Future Decision Making on the Introduction of Malaria Vaccines, Meeting Report 2007.
 45. Aseffa A, Bedru A, Yamuah L, Arga D, Worku A, Chandramohan D et al., Safety of a trivalent meningococcal ACW135 vaccine among young children in Ethiopia, *Vaccine* (2007), doi:10.1016/j.vaccine.2007.04.046
 46. World Health Organization (WHO). Ethiopia becomes vaccine safety e-learning champion in Africa. *Global Immunization News* November 2012.
 47. Ethiopian Health and Nutrition Research Institute (EHNRI). A Five Year, Balanced Score Card Based Strategic Plan (2010-2015 GC). Addis Ababa, 2010.
 48. Paterson P and HJ Larson. The role of publics in the introduction of new vaccines. *Health Policy and Planning* 2012; 27: ii77-ii79.
 49. Larson HJ, Cooper LZ, Eskola j, Katz SL, Ratzan s. Addressing the vaccine confidence gap. *Lancet* 2011; 378: 526–35.
 50. World Bank (WB). *Ethiopia: National Immunization Program Costing and Financing Assessment*. January 2002.
 51. Makinen M, Kaddar M, Molldrem V, Wilso L. New vaccine Adoption in Lower-Middle-Income Countries. *Health Policy and Planning* 2012; 27: ii62-ii76. *Health Policy and Planning*. 2012; 27: ii39-ii49.
 52. World Bank (WB). Ethiopia Economic Update II: Laying the Foundation for Achieving Middle Income Status. World Bank, June 2013.
 53. Mantel C and SA Wang. The Privilege and Responsibility of Having Choices: Decision-Making for New Vaccines in Developing Countries. *Health Policy and Planning*. 2012; 27: ii62-ii76. *Health Policy and Planning* 2012; 27: ii1-ii4.
 54. Burchett HED, Mounier-Jack S, Griffiths U, Mills AJ. New Vaccine Adoption: Qualitative Study of National Decision Making Processes in Seven Low- and Middle-Income Countries. *Health Policy and Planning* 2012; 27: ii5-ii16.
 55. Meessen B, van Heteren G, Soeters R, van Damne W. Time for innovative dialogue on health systems research. *Bull World Health Organ* 2012;90(10): 715.