

Immunization Focus

A quarterly publication of the Global Alliance for Vaccines and Immunization

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GAVI

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A vaccine for Africa

NEWS

AFRICA'S much-feared epidemics of meningitis could be consigned to history within a decade with the help of an ambitious project that aims to develop and introduce more effective vaccines tailored to the needs of the continent.

The leaders of the project, the World Health Organization and the Program for Appropriate Technology in Health (PATH) are in discussion with vaccine manufacturers now and hope to see the first vaccines licensed between 2003 and 2006. The partnership has been given financial muscle with a grant of US\$70 million from the Bill & Melinda Gates Foundation, announced on 30 May.

If the project succeeds, it could be a template for the development and introduction of vaccines against other diseases that primarily affect the world's poorest peoples. As well as bringing candidate meningitis vaccines out of the laboratory and through field trials, the partnership aims to overcome problems of licensing products, financing their purchase through global mechanisms, and ensuring an adequate supply to meet needs. "I hope this project could become a model for other vaccines for developing countries," says Luis Jodar at WHO.

Meningococcal meningitis attacks a swathe of 18 countries across Africa (see Map), with irregular and unpredictable epidemics that wreak havoc on fragile health systems. The disease is feared more than HIV or malaria, even though it kills fewer people. In the worst recent season, in 1996, about 200,000 cases and 20,000 deaths were reported, though actual

numbers were probably higher. In the past year alone, some 4000 died, and thousands more were left with permanent disabilities.

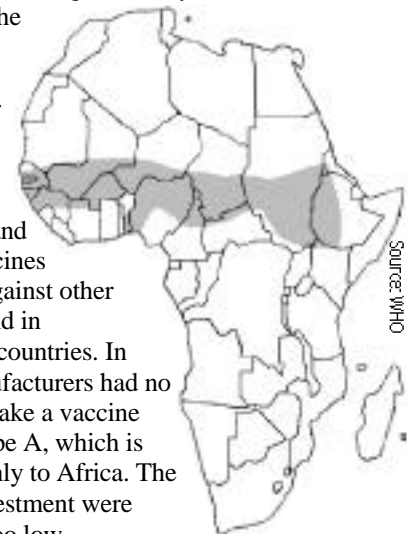
Of five strains, or serotypes, of meningococcal meningitis found worldwide, serotypes A and C are the two most likely to cause epidemics. An A/C polysaccharide vaccine exists, but it does not prevent the spread of infection between carriers and so cannot protect whole populations. Also, its protection may be shortlived. As a result, mass vaccination campaigns must be organized every time an epidemic occurs. The Meningitis Vaccine Project aims to develop A/C conjugate vaccines which would provide lasting immunity and interrupt the spread of infection. The technology for making these vaccines has been available for a decade, and conjugate vaccines are licensed against other serotypes found in industrialized countries. In contrast, manufacturers had no incentive to make a vaccine against serotype A, which is restricted mainly to Africa. The returns on investment were perceived as too low.

Officials from health ministries in at least eight African countries told WHO what they needed in a vaccine. "This is a tailor-made vaccine for Africa, designed by Africans," says Dr Jodar. ■

Further reading

www.VaccineAlliance.org/newsletter/jun2001/news_further_reading.html

Swathe of destruction: Africa's meningitis belt



Inside this issue

Global market – global vaccines? Supply and pricing of vaccines for developing countries	2
Taking care of tomorrow: planning sustainable finance for immunization	5
Good management means good measurement: the Data Quality Audit explained	9
New resources for immunization professionals	10

Global market – global vaccines?

Vaccines for developing and industrialized regions have been diverging, but today's global market is changing rapidly. Phyllida Brown asks manufacturers and others what the future holds

IT hasn't happened overnight, but gradually over a decade. Vaccines for certain diseases now come in different versions: those bought mostly by the industrialized countries, and those bought mostly for use in developing countries.

There are several reasons for the split, including different patterns of disease and judgments of need. But one key factor is the industrialized countries' increasing desire to avoid any adverse effects – however small or uncommon – from vaccines against diseases which are now relatively rare. In contrast, for most developing countries where these diseases are still widespread, the benefits of the traditional vaccines still heavily outweigh their risks, while the newer vaccines are currently too expensive to be a practical option.

Among the changes in industrialized countries, for example:

- Acellular pertussis (aP) has largely replaced whole-cell pertussis (wP) in the traditional “triple” vaccine for diphtheria, tetanus and pertussis (DTP);
- Inactivated polio vaccine has largely replaced the oral vaccine;

- Measles vaccine is usually combined with mumps and rubella, instead of being given alone; and
- Vaccines are packaged as single doses, without preservative, whereas in developing countries the norm remains multidose vials and some contain the preservative thiomersal.

Now, a team from WHO, the World Bank and the company Aventis Pasteur have investigated whether this trend towards two separate “tracks” is affecting the supply or price of vaccines needed for developing and industrialized countries⁽¹⁾. The answer is that, while today's picture is still uncertain, current trends could lead to supply difficulties and higher prices in the foreseeable future. Supplies of some traditional vaccines, once well in excess of demand, have now fallen to the point where they only narrowly exceed demand (see Box 1). “A batch failure now could precipitate a shortage,” says Julie Milstien at WHO, one of the study's authors. And, in some cases, prices that had remained stable for years are creeping up.

But what is less obvious – and more important in the long term – is how far these trends will continue, or whether different patterns will emerge. ▀

1: Endangered species: how and why supplies have been falling

For years, the availability of traditional vaccines supplied to UNICEF for the Expanded Programme on Immunization exceeded demand, usually by many millions of doses. But in the past three or four years, supplies of some vaccines have declined so that they only narrowly exceed demand. These include BCG, DTwP, tetanus toxoid and measles (see Figure 1). For example, in 1998, UNICEF was offered 600 million doses of DTwP. In 2000, the agency received a response to their tender of just 150 million doses. Prices of these vaccines have remained static for long periods but several, including measles and DTwP, appear to be rising slightly now^(1,2).

Part of the reason for the fall in supplies is that the traditional vaccines, typically priced at a few cents per dose for UNICEF, fail to compete with newer vaccines such as *Haemophilus influenzae* type b (Hib), whose profit margins are much higher, for manufacturers' limited capacities for production, filling and packaging. “We buy the ‘penny’ vaccines and compete for filling-line space with multidollar vaccines,” André Roberfroind of UNICEF told delegates at last year's GAVI Partner's Meeting in Noordwijk, the Netherlands⁽²⁾. And, as the number of routine children's vaccines available in industrialized countries has roughly doubled

in 30 years, the competition for capacity is increasing.

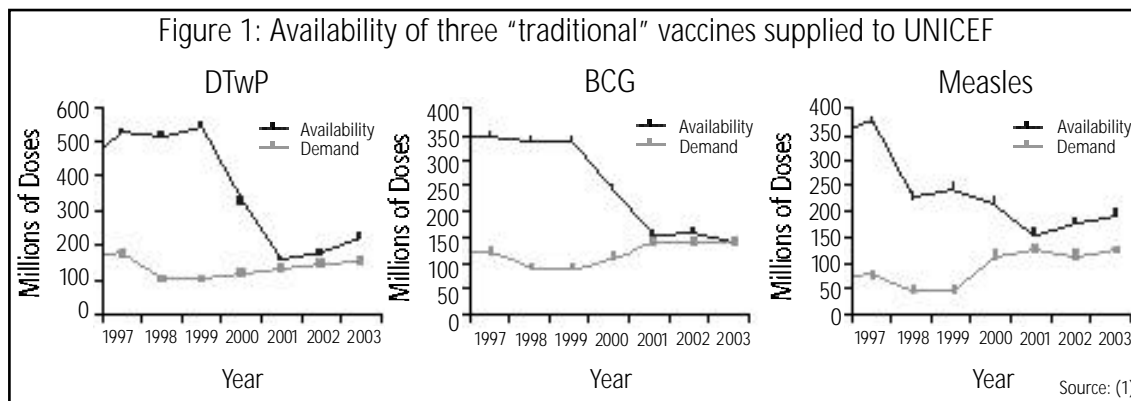
This situation particularly affects vaccines with extremely low profit margins, such as BCG and meningitis A/C polysaccharide. For example, Glaxo SmithKline (GSK) has said that it cannot commit itself to producing as much meningitis A/C vaccine for next year as it did for this year, partly because its freeze-drying capacity has been allocated to the manufacture of Hib vaccine. “It's true that both [vaccines] need to be freeze-dried and you have to allocate capacity,” says Tony Lakavage at GSK. He adds, however, that ensuring a match between demand and supply is always difficult with meningitis A/C vaccine, because epidemics are irregular and unpredictable.

The low prices offered by producers in developing countries have also reduced the incentive for manufacturers in high-income countries to make traditional products, says Walter Vandersmissen at GSK, citing “gigantic offers from [suppliers in] developing countries to UNICEF” as one reason for the fall in DTwP supplies from the industrialized countries. However, there are other technical reasons for the reduced availability of DTwP, he says, including changes in production methods and the increased demand for both diphtheria and

tetanus toxoids for use as components of the new conjugate vaccines.

Some manufacturers in North America have actually stopped making products such as DTwP. But European-based manufacturers have traditionally served a more global market and say they will continue to do so. For example, says Michel Greco of Aventis Pasteur in France, 70% of the vaccine doses made by the company are destined for developing countries, although these represent a fraction of overall revenue. Whole-cell DTP, for example, will continue to be made, not least because the supply of acellular pertussis is likely to be limited. “You can manufacture 10 doses of whole-cell pertussis for every 1 dose of acellular pertussis in the same facility,” says Mr Greco.

Indeed, in Mr Greco's view, there is no reason why developing countries should not continue to use different products from their industrialized counterparts, provided quality is assured. “Even if philosophically the dual-track concept is not a pleasant one, in practice it may be preferable,” he argues, given that many countries cannot afford the higher-priced vaccines. Products should be chosen case by case, he says, based on a country's disease burden, its resources, and the vaccine's efficacy and safety.



The global vaccine market is evolving rapidly for at least two reasons: first, the rise of new entrants into the market, in the form of manufacturers in developing countries whose products are increasingly important for global supply; and second, new buying power and mechanisms, through GAVI and the Fund, for the low-income countries. These changes are also happening against a background in which the requirements of regulatory bodies are becoming increasingly stringent. So in some respects, today's "divergence" of products along two tracks for developing and industrialized countries reflects the conditions of the past decade, and events over the next five years may be different. "This marketplace has changed dramatically," says Tony Lakavage, senior director of external affairs at Glaxo SmithKline in Rixensart, Belgium.

First to agree would be the manufacturers in developing countries, who were once labelled as "local" producers but who now play a much bigger role. "Manufacturers such as Bio Farma have actually changed the global supply picture radically," says Thamrin Poeloengan, president director of this Indonesian supplier to UNICEF, based in Bandung.

Immunization Focus sought the views of a range of producers in developing countries on the direction that vaccine production is taking. Their responses demonstrate that they are all highly committed to meeting the health needs of developing countries, with vaccines against diseases that primarily affect poorer populations. However, the actual products they make to meet these needs may change fast. And the prices they charge may change too. Some of the developing-country vaccine producers, particularly those who are public-sector institutions, insist that they will be able to continue making vaccines at today's very low prices, taking advantage of economies of scale. But others say that their prices may have to rise.

Until now, most developing-country producers have concentrated on making traditional vaccines such as DTwP and measles and also, recently, monovalent hepatitis B vaccine. For most low-income countries, the high prevalence of childhood disease and a lack of resources make the traditional vaccines the most appropriate response, they argue. Take, for example,

DTwP – an order of magnitude less costly than DTaP. In Brazil, says Isaias Raw, president of the Sao-Paulo based producer Instituto Butantan, "Adopting aP would represent going from cents to many dollars [per dose], and would result in a decrease in vaccination."

But it would be a serious misjudgment to think that the developing-country manufacturers are restricting themselves to the "old" vaccines. Some, such as Bharat Biotech and Shantha Biotechnics, both of Hyderabad, India, are already developing combination vaccines such as DTP-HepB, for which the emergence of GAVI and the Fund has sharply increased demand. In some cases, says Susan McKinney at WHO, combinations are being achieved by different developing-country producers collaborating and "marrying" components. "These producers are on a fairly fast track to providing a DTP-HepB combination," says Ms McKinney.

Another mistake would be to assume that the developing-country producers will make products only for developing countries. As well as these, says Krishna Ella of Bharat Biotech, "We also see ourselves as contract manufacturers for vaccines and other biologicals for the industrialized countries." Indeed, a few manufacturers in developing countries are considering developing vaccines that may appeal to industrialized and developing countries equally – such as meningitis conjugates or rotavirus.

Equally, it would be simplistic to assume that developing countries will never want the products that have replaced traditional vaccines in most of the industrialized countries. Varaprasad Reddy, managing director of Shantha, is just one of the producers who believes that populations in at least some emerging and middle-income countries will gradually shift their demand as income increases and disease burden changes. Dr Ella at Bharat Biotech agrees.

In the short term, however, a more pressing issue is whether the developing-country producers' prices will rise. Traditionally, these manufacturers have offered their products to UNICEF at very low prices – even lower than the concessionary prices charged on sales to UNICEF by the industrialized-country manufacturers. But this situation may not be sustainable. As developing-country manufacturers

"This marketplace has changed dramatically"

improve their production facilities to meet the increasingly stringent regulatory requirements for international sales, their production costs are rising. Whoever makes the traditional vaccines, it seems that they cannot remain as cheap as they have been.

Modern vaccine production requires massive capital investment, but once the plant is up and running the number of personnel needed is small. So the savings on labour costs that can be made in developing countries by other industries, such as clothing or software production, do not apply to vaccine producers. Producers that have traditionally charged very low prices may have to raise them if they are going to invest in modernizing equipment.

Companies in the industrialized countries, meanwhile, have historically been prepared to sell vaccines for use in developing countries at reduced prices because they make more money on sales of the same products in the industrialized countries. But, obviously, if few in the industrialized countries want to buy these same products, the options for offering them at these “tiered” prices in the developing-country markets may diminish. For David Salisbury, head of the immunization and infectious diseases group in the UK government’s Department of Health (see Box 2), this is a major problem for the world as a whole. It is implausible, he believes, that the major manufacturers will continue to offer vaccines at reduced prices for developing countries if they can no longer get the higher prices they need from the industrialized country markets to make their products profitable.

Expensive kit: vaccine production is capital-intensive



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Companies such as Aventis Pasteur and GSK have said they will keep tiered pricing – for now. “We are committed to tiered pricing as long as we have protected pricing in Europe and the United States,” says Lakavage. “That is our stated public position. But what happens in the developed world does have an impact on what happens in the developing world.”

In circumstances as uncertain as today’s market, then, what can anyone do to ensure that high-quality, appropriately priced vaccines keep flowing to meet the needs of developing countries? In the end, says Dr Milstien at WHO, it’s vital that manufacturers from both the industrialized and the developing countries stay in the market to assure a range of

2: Not every industrialized country wants to ditch the “old” vaccines

For David Salisbury, head of the immunization and infectious diseases group in the UK government’s Department of Health, the falling supply of certain “traditional” vaccines is a major problem. In his view, it has become a seller’s market. “We find it difficult because you cannot say to a manufacturer, ‘This is which vaccine we want’ – and we are the customer.”

In the UK, children are still immunized with DTwP because, Dr Salisbury says, trials have shown that the whole-cell vaccine protected 85% to 90% of children, whereas acellular products’ efficacy ranged from 70% to 85%. Despite other vaccine safety “scares”, British parents today generally find DTwP acceptable, says Dr Salisbury, and immunization rates with the vaccine remain high. “Why would we change to a less efficacious vaccine at higher cost?” he asks. Yet, because of supply problems with whole-cell vaccine, Britain recently had to use the acellular product for a period.

British children are also given oral polio vaccine when many other industrialized countries have shifted to inactivated vaccine to avoid the risk of vaccine-associated outbreaks. The country’s historical links with the Indian subcontinent and some West African states, where polio remains endemic, mean that there is constant and large-scale traffic between Britain and these regions, and this raises the risks of wild-type virus entering the country. “We constantly review and review this policy,” says Dr Salisbury. When polio transmission stops in these regions, the balance of risk and benefit will change, and the switch to IPV will be made, says Dr Salisbury.

products and continued investment in R&D. And that means keeping the incentives for both to stay.

In the medium term, the emergence of GAVI and the Fund may be improving the incentives to manufacturers – at least for some vaccines. Companies’ decisions about whether or not to develop products for developing countries are based, says Lakavage at GSK, on “an assessment of what the purchasing entities can and will buy”. With GAVI and the Fund catalysing changes in the market, he says, “there are more resources for purchase, and improvements in the infrastructure to deliver the vaccines”. Demand for vaccines is also becoming easier to foresee with work done by the GAVI Financing Task Force’s subgroups on forecasting and procurement, together with the new purchasing arrangements that UNICEF is now adopting for new and under-used vaccines paid for by the Fund. And in the longer term, as tougher regulatory demands drive costs up, both producers and buyers in a global market will need to be willing to invest more in products whose value the world has taken too much for granted. The next few years will be critical. ■

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Taking care of tomorrow

Developing countries – and other GAVI partners – are starting to plan how immunization services should be financed beyond 2005. Along the way, they may even be triggering a rethink of the relationships between countries and donors, as Phyllida Brown reports

NOT so long ago, Zimbabwe's immunization programme experienced some of the worst effects of an unsustainable financing scheme. Through a financial loophole in the then-closed economy, international corporations in Zimbabwe could donate money to a non-governmental organization, which increased the proportion of their profits that they could repatriate. For its part, the organization used the donations to buy hepatitis B vaccine for introduction into the national immunization programme. Vaccination began, but, soon after, the law changed and the scheme finished. Vaccine supplies stopped, babies could no longer be immunized against the virus, and many parents mistakenly assumed there was something wrong with the vaccine itself.

Paulinus Sikosana: education and long-term planning are essential

That was in 1994. Since 1999, Zimbabwe has successfully re-introduced hepatitis B vaccination as part of a properly planned, government-funded programme – helped by a major education campaign. But no one under-estimates the damage

done seven years ago.

Paulinus Sikosana, Secretary for Health and Child Welfare in Zimbabwe's health ministry, told the GAVI partners this cautionary tale earlier this month at a meeting in Geneva⁽¹⁾ in which developing countries started to plan how they should pay for their immunization programmes from 2005 onwards (see Box 1). Although the circumstances of the incident are clearly different from the way GAVI works, the message was clear: once immunization starts, it must be sustained. Governments must take responsibility for ensuring their immunization programmes are stable, but donors and other partners must also act responsibly.

No one should be more aware of this responsibility than GAVI and the Fund. Their awards to countries are intended as catalysts. The awards last for five years, and the money can be spread over seven if a country chooses. But when the awards run out, countries will need different, sustainable sources of funds. If the GAVI partners – the countries themselves, plus donors, development banks and the international agencies – do not plan sustainable financing for the second half of this decade and beyond, those countries will be no better off – and possibly worse off – than before the awards were made. "If we fail, we will create a vacuum, by starting things and not

1: Steps to sustainability: how countries are preparing plans

Next year, the first countries will be asked to submit plans to GAVI showing how they will phase in money from other sources and how they will sustain their programmes after their five-year awards end. This month's meeting was one of the first steps in preparing for those plans. The GAVI Financing Task Force (FTF) and others worked with teams from four countries – Bangladesh, Benin, Ukraine and Zimbabwe – to seek their views about what a sustainability plan should contain, and how sustainability should be measured. Unusually for a health meeting, officials from the finance ministries of several of the countries participated. Using the four teams' input, the FTF will report to the GAVI Board and then develop guidelines by this winter for all countries to use in preparing their plans. Some of the countries' suggestions for the content of a sustainability plan are shown in Box 4.

following on in the longer term," says Steve Landry, from the US Agency for International Development (USAID) and co-chair of the GAVI Financing Task Force.

A widening gulf

Some developing countries are increasing their investment in health despite difficult economic conditions and severely limited resources (see Box 2). Immunization remains one of the most cost-effective health interventions, and accounts for no more than 5% of the health budget in those countries studied so far, and often much less. As a percentage of those countries' gross national product, immunization accounts for no more than 0.1%⁽²⁾. But the costs – as well as the benefits – of immunization must be expected to grow as under-used vaccines and essential improvements, such as

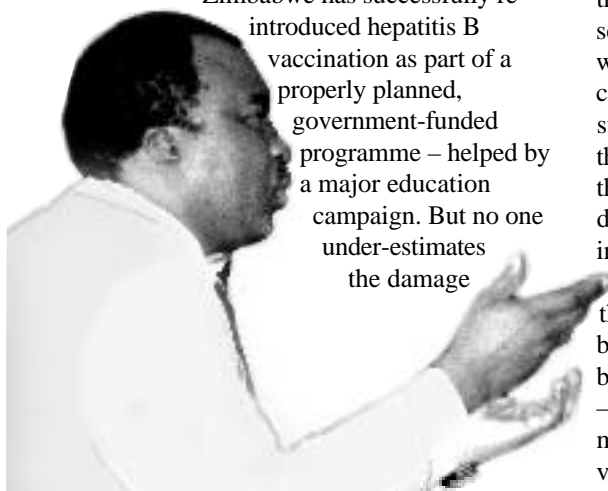
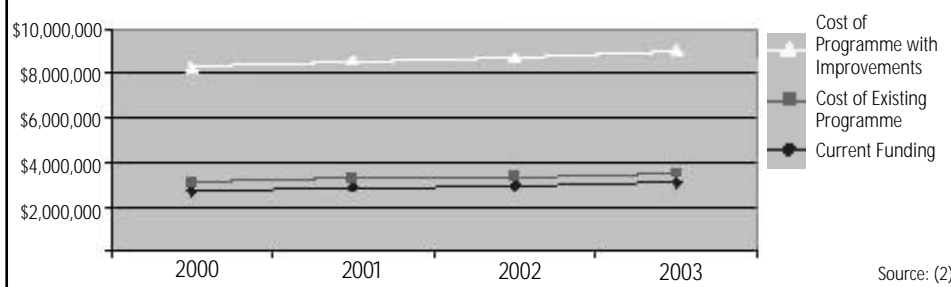


Figure 1: Closing the gap: the costs of running Côte d'Ivoire's immunization programme



higher coverage, a better cold chain and the introduction of auto-disable syringes, are built into national programmes. The gap between what many governments pay for immunization now and what they will need to pay is large – and growing.

In Côte d'Ivoire, for example, a recent study suggested that, by 2003, improvements to the existing national programme and the addition of hepatitis B vaccine would more than double the annual cost of the programme, from under US \$4 million to about \$9 million⁽²⁾ (see Figure 1).

Given the many competing demands on the health purse, the idea that cash-strapped governments in the poorest countries will be able to finance such services entirely by

themselves in the foreseeable future looks increasingly unrealistic. Indeed, the experience of the 1990s had already shown, says Tore Godal, executive secretary of GAVI, that some programmes from which donor support was withdrawn were not sustained. Despite this, some donors and analysts have continued to argue the philosophy that developing countries should move swiftly to achieve self-sufficiency because dependency on donors is undesirable.

In the near term, sustainability need not mean self-sufficiency

Now, however, fresh thinking has produced proposals for a more realistic way forward. In an analysis⁽³⁾ commissioned by the GAVI Financing Task Force, Ruth

Levine, a health economist at the World Bank, and others, call for a new definition of financial sustainability for developing countries' immunization programmes. No longer, they argue, need sustainability be considered to be synonymous with self-sufficiency. In current conditions, after all, progress towards self-sufficiency would mean, in effect, a growing "health gap" between rich and poor nations. At this month's GAVI meeting in Geneva, the participants discussed and endorsed the ideas put forward by Dr Levine and her colleagues. The participants proposed that: "Although self sufficiency is the ultimate goal, in the nearer term sustainable financing is the ability of a country to mobilize and

2: A tale of two countries

Benin: political commitment and practical schemes to guarantee funds

Jacques Hassan, director of research and development in Benin's health ministry, is hopeful. Although income per head is just \$325 a year, the country's immunization budget has increased by an amount exceptional for any country – almost 30-fold – since 1996. Back in 1982, just 12% of children were routinely immunized; today, the reported figure is 85% and Benin has received an international award for its programme's success. Immunization has high-level political support; the president immunizes children himself on polio days. Equally important, the health budget contains a line item for immunization so that the programme is always allocated a minimum sum.

But there are acute strains. Many health threats compete for resources. As in other developing countries, trained personnel are scarce and the international brain drain keeps taking them away. Staff are overstretched, and there is a risk that coverage will fall. Benin has applied to GAVI and the Fund for awards to introduce additional vaccines and to improve its existing services.

Already, the government has taken steps to mobilize new and sustainable resources at home. It has set up an EPI Foundation,



Jacques Hassan

to collect private donations and use them to help purchase vaccines. It is also developing health insurance schemes that will give people incentives to prevent ill health in their families, and creating income within communities to pay for some costs of the immunization programme, such as fuel and vehicle maintenance. Nonetheless, Dr Hassan is under no illusions about the gap between what the government

can raise and what it needs. "We must be realistic," he says. "With the best will in the world, the government cannot do everything alone. We need help from external contributors and from the private sector."

Bangladesh: popular demand for immunization will ensure the future of the service

For the government of Bangladesh, there's no question that immunization must be assured for the long term, says Siddiqur Rahman Choudhury, a senior official in Bangladesh's finance ministry who attended the Geneva meeting. A key step, he says, is to educate and inform people, and especially girls, so that demand for immunization grows and remains high. Mothers who have received education are more likely to protect their infants' health than those who are uneducated. "Once you popularize immunization, the government cannot stop providing it," he says. "That's the way to build financial sustainability."

Bangladesh's overall health budget has increased from 4.7% of the total government budget in the mid-1980s to 7.5% of the total today. Within the immunization programme, a World Bank loan pays much of the cost of vaccines, and only 22% of the programme is currently funded by the government's own direct resources. Before applying to GAVI and the Fund for support, Bangladesh committed itself to sustaining the programme after the awards run out. "We will have to, not because GAVI has asked for it, but because there is a need for it, a demand for it," says Mr Choudhury. "A good programme is useless unless we sustain it." And, because that cannot be done by Bangladesh alone at present, it is up to the government, donors and lenders to work together, he says. "Sustainability should be a joint responsibility of national governments and donors."

Siddiqur Choudhury



efficiently use domestic and supplementary external resources on a reliable basis to achieve target levels of immunization performance*.”

This definition emphasizes a government’s skills in planning and securing stable funding for immunization, and making good use of its resources, rather than its ability to pay for everything itself. Under this definition, the spectre of “donor dependency” becomes less threatening, because the national government is taking responsibility, and negotiating with its partners on what it needs to achieve its goals.

The definition also means that a government is responsible for using its resources as efficiently as possible, while at the same time meeting standards for quality and safety, and reaching increasing numbers of hard-to-reach children. Programme costs can be kept in check, for example, by using the best value vaccines and the most cost-effective means to immunize children. For the new approach to sustainability to work, it’s essential that the government should have a strong commitment to immunization, and evidence at

its fingertips – such as

estimates of the cost-effectiveness of vaccines – to argue its case with external and private domestic investors. “The challenge is fundamentally a political one,” says Dr Levine. For, despite the growing costs of wider immunization, the absolute amounts of money involved are small relative to other health interventions. “The resources are there,” says Dr Levine, “both in countries and in the international community. Compared with many other health interventions, arguing the case for immunization is really easy – even when you add the new vaccines such as hepatitis B and Hib this is not actually a lot of money.” Dr Levine points to countries such as Honduras, and Bolivia (Box 3), whose political commitment to immunization can only be envied by most industrialized countries.

New thinking for donors, too

The new definition also challenges donors to update their roles. In a global economy, the benefits of immunization cross borders. So, out of self-interest as well as a concern for people’s welfare, it makes sense for richer countries to invest in the health of poorer ones. Evidence is mounting that better health is a key step to reducing poverty in the poorest economies. To ensure sustainable support, donors could be asked to commit themselves in writing to a certain number of years. If there is to be a genuine collaboration, donors who are used to setting targets for the countries they support could even agree to meet certain targets themselves so that responsibility is evenly shared.

But definitions are just definitions. What difference will a new definition make? Potentially, a lot. After delegates at the Geneva meeting supported the broader definition of sustainability, it is now being put to the GAVI Board. If GAVI policy is built round the new definition, it could give

Practical ways to move towards sustainable financing

For governments:

Use existing resources more efficiently

- Identify main inefficiencies, including wastage, and correct
- Reduce barriers to children’s access to immunization through new approaches to service delivery
- Educate people to increase demand for immunization, and keep demand high
- Buy vaccines efficiently (through international or national mechanisms)

Mobilize resources

- Get a mandate for baseline funding such as
 - a budget line item (this is already in place in many countries)
 - a law to protect a minimum budget for immunization (Ukraine, for example, has this)
 - a memorandum of understanding between the government and the Interagency Coordinating Committee (Bolivia, for example, has this).
- Push for the allocation of resources to immunization on the grounds that it is cost-effective and benefits society at large, not just individuals
- Commission and disseminate cost-effectiveness studies
- Earmark funds and establish performance targets for regions
- Engage development partners in an informed discussion of resource needs, and seek structured commitments to fill key funding gaps

For donors/development partners:

- Engage in a collaborative way, as true partners in a shared challenge
- Within the health sector, promote the use of resources for cost-effective interventions such as immunization
- Move towards multi-year commitments
- Structure grants and loans to promote sustainability (for example, using performance-based criteria)
- Consider developing new funding instruments that are buffered from the impact of the donor countries’ domestic political changes.

Source: adapted from Levine *et al*(3)

Ruth Levine:
“The challenge is fundamentally a political one”



3: Sweet victory: how Bolivia put performance into its programme

In 1999, faced with falling vaccination coverage, Bolivia set about revamping its immunization programme, with the World Bank and the Pan American Health Organization as partners and co-financers of the initiative. As well as improving the service by adding new antigens, implementing safe injection practices, and improving surveillance, the initiative strengthened the political and financial stability of the programme. Among other actions, the government:

- More than doubled its own spending between 1999 and 2001, from US\$1.15 M to an estimated US\$3.5 M;
- Committed itself to increasing its support to the programme by \$500,000 a year progressively as external agencies reduce theirs;
- Introduced a line item for immunization into the budget;
- Imposed a tax on the national Social Security Agency with the proceeds earmarked for vaccine purchase;
- Introduced performance-based contracts with local governments to encourage competition between areas for the highest coverage rates;
- Signed a memorandum of understanding with the Interagency Coordinating Committee for the next phase of the initiative, up to 2005.

By 2000, coverage for three doses of diphtheria, tetanus and pertussis (DTP) was up from 75% in 1997 to 89%. Combination vaccine including DTP, Hep B and Hib now reaches 75% of the population. And the number of municipalities with low coverage has dropped by two-thirds.

Source: (4)

definition, it could give governments in developing countries more flexibility about how to approach their plans for sustainable financing – and it could also mean that donors become more engaged in those plans. If all parties use the planning process as a real opportunity, rather than a bureaucratic exercise, says Dr Levine, real progress can be made.

So what do the donors themselves think about the new thinking on sustainability? *Immunization Focus* approached officials in several donor agencies. Those who responded were generally positive. Norway, which last year committed \$125 million to GAVI, has long believed in long-term investment in countries. Its programmes with countries typically last at least 10-15 years, says Rune Lea, health adviser in the Norwegian Agency for Development Cooperation. The aim is to invest in human capital, through health and education, as a way to build each country's capacity towards eventual self-sufficiency. Dr Lea warns that a truly sustainable immunization programme will need to be planned within the overall health

system's framework, but is broadly supportive of the arguments put forward by Dr Levine and her colleagues.

For the US, too, there is increasing recognition that the long-haul approach makes sense, although no one imagines it will

"All partners are sharing some responsibility for the function of the programme now"

be easy to achieve. "We acknowledge that this is the way it is going to have to be, because there are no reasonable alternatives in the short term," says Steve Landry at USAID. It

will mean that donor agencies' staff at country level, who serve on Interagency Coordinating Committees, will engage more actively than before as real partners with the government. "The whole concept of the ICC is that now all the partners are sharing some responsibility for the function of the programme, in explicit terms, and they have to engage on a routine basis in working with the government to take this on." In other words, the future of immunization is everyone's responsibility. ■

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*NOTE: "Immunization performance" is defined in terms of current and future goals for access, utilization, quality, safety and equity.

4: What should be in a sustainability plan?

Suggestions from Bangladesh, Benin, Ukraine and Zimbabwe for the content of governments' plans include:

- An assessment of current conditions affecting the service
- Projected resource needs for first 1-2 years after the Fund awards end
- A plan for implementing the service in those first years
- Statements of 5- to 7- year commitments from (a) government and (b) partners
- An identification of potential problems ahead (such as devaluation)
- Plans for different scenarios, based on different financial commitments by government and partners
- Strategies for mobilizing funds from (a) external (b) domestic and (c) private sources
- Measures for cost savings
- Plans for staff training and capacity building at national and district levels
- Endorsement by (or Memorandum of Understanding with) the Interagency Coordinating Committee

Good management means good measurement

All countries need to be able to measure the performance of their national immunization services accurately. The World Health Organization and the Bill and Melinda Gates Children's Vaccine Program at PATH have developed a new tool called the Data Quality Audit (DQA) to help countries check whether their information systems are working well. Specifically, the DQA will assess whether nationally reported data accurately reflect the number of children being immunized and recorded at district level. As auditors begin training this month in the use of the DQA in Kenya, Uganda and Pakistan, **John Lloyd** explains why it matters and how it works

Why do we need the DQA?

There are three good reasons why the Data Quality Audit (DQA) is needed to audit the system that reports on the performance of immunization services in each country.

First, managers of immunization services need correct and timely information to detect improvement or decline in performance. Second, the partners of the GAVI Alliance working at all levels need reliable information to judge the impact of new efforts and new resources on performance. Third, GAVI and the Fund award money to countries to improve their immunization services according to a system of "shares", one share being earned by the country for each additional child reported to have been immunized relative to the previous year. The Fund can only reward governments on the basis of children who have been correctly recorded and reported as immunized. So, the DQA aims to:

- Assess the quality, accuracy and completeness of administrative immunization reporting systems; and
- Provide practical feedback to health staff on how to improve the quality of reported data.

Where did the idea come from?

The DQA was born last summer, at the start of the Fund application process, when it

became clear that progress in reaching more children with vaccines should be verified annually.

How will the audit ensure independence and transparency?

The DQA is external and independent both of the national management and the local staff of the GAVI partners. The procedure is carried out by a team of international experts in private- and public-sector auditing and in the field of public health. The procedure, which lasts two to three weeks, may be carried out in any country receiving assistance from GAVI and the Fund. But in practice, it is probable that it will be applied to a selection of

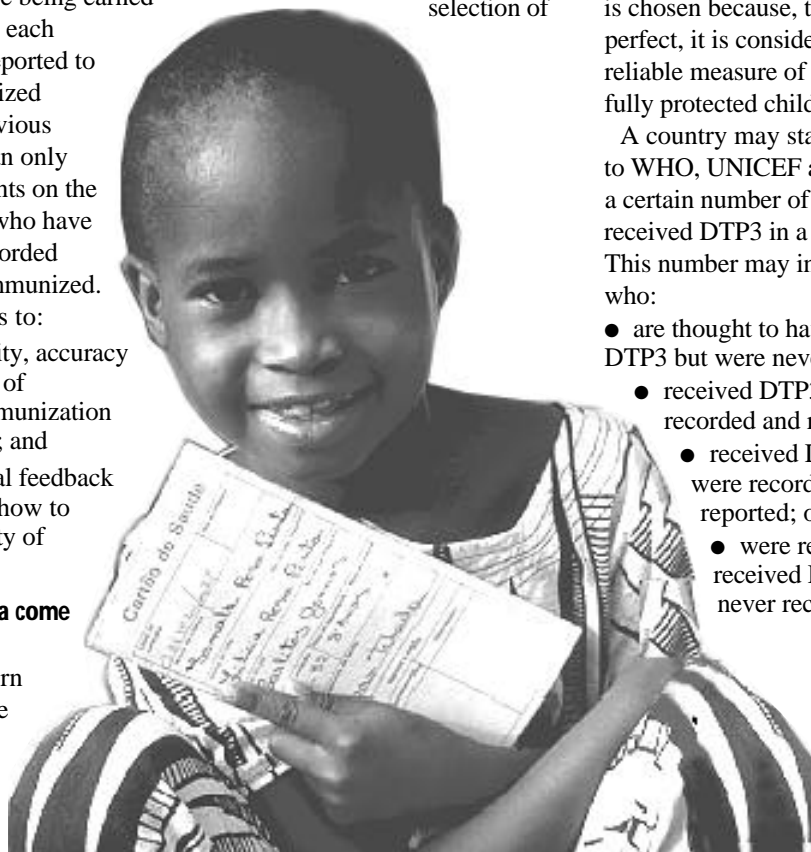
countries, depending on evidence of the quality of reporting systems and the size of the Fund grant.

How does it work?

The DQA country visit focuses on reporting practice in a sample of four districts and six health centres in each district – 24 health centres in all. The auditors check the accuracy of *recording* of the number of immunizations, the transcription and aggregation of these numbers and the *reporting* from level to level of the system. The audit focuses mainly on one key indicator of performance: the number of children who receive a third dose of diphtheria, tetanus and pertussis (DTP) vaccine. The third DTP dose, known as DTP3, is chosen because, though not perfect, it is considered the most reliable measure of the number of fully protected children.

A country may state in its reports to WHO, UNICEF and GAVI that a certain number of children received DTP3 in a given year. This number may include children who:

- are thought to have received DTP3 but were never recorded; or
- received DTP3 and were recorded and reported; or
- received DTP3 and were recorded but never reported; or
- were reported to have received DTP, but were never recorded. ▸



Hold onto it:
the immunization record card is vital for an effective system

Immunization Focus

The DQA does not substantiate the first group of children as having been immunized. But it does assess the ability of the administrative reporting system to count and report correctly those children that were recorded at the site of immunization. Since awards will be made on the basis of the additional number of children relative to the previous year who are recorded as having received DTP3, there is a strong incentive to reduce the first group of children – those who were immunized but never recorded – to zero.

What else does the DQA check, and how does it help countries?

In addition to re-counting and checking the data, the DQA judges the overall reliability and timeliness of the reporting system, using a set of standard indicators. For example, it looks at the proportion of records that get lost and the proportion of reports that arrive late. If the child's immunization cards are lost, the wrong vaccine dose may be given and recorded. Late reports result in incorrect aggregations and coverage calculations at higher levels. There are many pitfalls that can be avoided if the critical elements of quality are in place. This information enables the auditors to offer advice to the health workers, managers and national leaders of immunization. DQA is a powerful capacity building block for each nation's health management information system and is a good example of the way in which GAVI can strengthen the health system.

What next?

Dr Linda Archer, a WHO consultant based in Nairobi, has developed successive drafts and refinements of the DQA that have been tested in Kenya and Sri Lanka. Now, the latest revision of the DQA manual is ready⁽¹⁾. The GAVI partners decided to search for a suitable organization to implement the audit, and after a tendering procedure they chose a consortium headed by Liverpool Associates in Tropical Health, UK, a body associated with the Liverpool School of Tropical Medicine with a strong research knowledge base and global experience in health assessments and evaluations. The training of auditors begins this month in Kenya, Uganda and Pakistan and then six other countries will be visited by September 2001. Each year thereafter, a proportion of countries that receive assistance from GAVI and the Fund will be visited by DQA auditors. ■

(1) Copies may be requested by email from Lisa Jacobs at the GAVI Secretariat: ljacobs@unicef.org

John Lloyd is Resident Adviser at the European office of the Bill and Melinda Gates Children's Vaccine Program, implemented by PATH. Dr Lloyd took part in the creation of the DQA concept, the development of the methodology and has participated in the testing and the training of auditors.

New resources...New resources...New resources...New resources

Strengthening immunization programmes: Practical workshop guides for immunization professionals

The GAVI partners have created a set of six guides for workshop facilitators, focusing on strengthening immunization programmes and management systems. These practical guides can be adapted for workshops in different regions or countries. Key topics covered by the guides include the development of in-country coordinating mechanisms, immunization programme assessments, multi-year plans, and financing.

The guides were developed for a workshop held in Annecy, France, in April to update immunization professionals on "the GAVI approach" to strengthening immunization services. Participants were nominated by their regional working groups and came from Africa, Asia, the Newly Independent States and the Middle East. They represented national ministries of health, WHO, UNICEF, the World Bank, PATH and the Association Pour L'Aide à la Médecine Préventive (AMP). As a result of the Annecy workshop, participants from the regional working group in west Africa have already scheduled their own localized versions of the course to be held in Abidjan in August. The GAVI partners anticipate similar activities in other regions.

The workshop facilitator guides, supportive materials, and further information about the Annecy workshop are available at: www.VaccineAlliance.org/training/annecy/annecy.html or by mail or email from Molly Mort, PATH, 4 Nickerson Street, Seattle, Washington 98109, USA. mmort@path.org

Sustainable financing: Resources from the GAVI Financing Task Force

The GAVI Financing Task Force (FTF) has produced a set of briefing materials and analyses for use by national governments and other stakeholders. The resources are intended to support decision-makers in areas such as: identifying long-term financing options for immunization programmes; promoting the development of new vaccines for low-income and middle-income countries; forecasting vaccine demand; and capacity building in financial management. The analyses and briefings have been commissioned from a range of independent experts and include background and discussion papers and case studies on the financing of immunization services, and a model for forecasting vaccine demand. A vaccine finance policy "briefcase" is also being prepared. The first materials, together with details of the FTF and its scope of work, are available on the GAVI website at www.vaccinealliance.org/financing/intro.html; these will be updated and added to regularly.

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