



## TED Challenge: Tracking & Tracing Vaccines in the GAVI Alliance Supply Chain

15 February 2013

*Vaccines are a powerful but sensitive technology. They have to be stored at a certain temperature, or they become unviable. We work hard to make sure these vaccines get to the people who need them, but we need a better system to keep track of them and we need your help. Is there a way to put a 2D barcode on every vial of vaccine so that countries can track every dose as it is shipped, delivered and administered? Or on the box? Will this standard be around for long enough to invest in the technology, or is there something new and better coming down the track? What about RFID tags? Although managing the supply chain has always been an important goal, it didn't have such urgency when vaccines cost pennies a dose; next year we will be spending more than \$2B a year on powerful new vaccines and so improving our systems is critical. It means the difference between life and death for children living in the poorest countries in the world. Our goal is to save the lives of 4 million children by 2015 by administering 250 million additional doses of vaccine - a goal worthy of the TED community.*

### **Background to the GAVI Alliance**

The GAVI Alliance is a public-private partnership whose mission is to save children's lives and protect people's health by increasing access to immunisation in poor countries.<sup>1</sup> We fund immunisation and health systems in the 73 poorest countries in the world, where 77 million children are born each year, representing about 60% of the global birth cohort. Since GAVI was founded in 2000, we have helped to immunise an additional 370 million children, preventing more than five and a half million deaths.

Most high-income countries rapidly make new vaccines part of their national routine immunisation programmes, but it can take an average of 10 – 15 years or longer for a vaccine to reach a low-income country. GAVI aims to increase immunisation coverage in these countries, whilst rapidly expanding the number of vaccines that these children receive. This ensures that powerful new vaccines, for example vaccines against the most serious forms of the two biggest killers of children, pneumonia and diarrhoea, are available to children regardless of where they live.

### **Background on the challenge**

GAVI has created a market where none existed for new vaccines in developing countries, and has created tiered prices so that vaccines are provided to developing countries at much, much lower prices than those for high-income countries. However, even though the prices of new vaccines for GAVI countries are falling, they still cost dollars a dose, rather than the pennies a dose that older vaccines cost. The success of immunization systems in the world over the past decades has depended upon vaccine

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<sup>1</sup> [www.gavialliance.org](http://www.gavialliance.org)

supply chains that were appropriate to a world where there were only a few, relatively cheap, vaccines.

In recent years, the growing numbers of new vaccines, delivery strategies and technological advances have created opportunities and pressure for country supply systems to adapt, innovate and scale-up. Supply systems are becoming a bottleneck to introducing new vaccines, to reaching our ever more ambitious coverage goals, and to maximising the impact of our donors' and developing country governments' dollars.



Tanzania, August 2011 – A nurse at a health centre in Dar-es-Salaam shows how temperatures for the vaccine storage refrigerators are recorded twice a day (Credit: GAVI/Doune Porter/PATH/2011)

For most GAVI-eligible countries, UNICEF supply division procures the vaccines and ships them to an airport in the implementing country. The government is then responsible for ensuring that vaccines reach immunisation points – clinics or mobile teams – in the country. Most vaccine supply chains in GAVI countries have the following characteristics:

- Supply chain levels tend to follow administrative boundaries, with many countries having four or five levels;
- Most data is recorded on paper. There is some use of computers at the central level, but the data that is recorded centrally is drawn from paper records. Sometimes there are even stock-outs of paper record forms/books;
- There is a lack of comprehensive birth/death registers and uncertainty about the size of birth cohorts;
- There is a lack of dedicated staff managing the supply chain – the responsibility tends to fall to medical professionals;
- Cold chains suffer from intermittent electricity supply, and unreliable equipment.

Supply chains are a constraint to increasing coverage as stock-outs at clinics means that vaccines are not available when a child arrives at the facility. In addition, there is significant wastage of vaccines, estimated to be between 5% and 50% depending on the number of doses per vial (however we do not have reliable data on this).

## Solutions

GAVI is developing an end-to-end supply chain strategy with its partners, which will involve considering the adoption of new technology. New technologies can improve data quality, quantity, reliability and timeliness, contributing to:

- Better stock management leading to fewer stock-outs and reduced wastage;
- Improved patient safety by facilitating the linking of specific products with adverse event reporting;
- Improved data on coverage through links of vaccine delivery data with birth registries (to the extent that these exist).

Some of these vaccines are limited by manufacturing capacity, so a more careful management of supply may also mean improved vaccine availability for additional children.

Part of this exercise will be to accelerate the introduction of standards for technology that will help with tracking and tracing vaccines, and this will be the focus of the discussion at TED.

At present, vaccine vials that are used in developing countries are labelled with batch numbers and expiry dates. There is most often no barcode on the packaging, or on the vaccine vial. Vaccine vials do however have a vaccine vial monitor<sup>2</sup> which is a label that contains heat sensitive material that registers cumulative heat exposure. The monitor tells a health worker whether a vaccine has been heat damaged or not. There is no equivalent monitor for freezing on the vials – many vaccines are as sensitive to freezing as they are to heat – and there is evidence of damage to vaccines from freezing.

Tracking and tracing is a manual (often paper-based) exercise. There are pilots underway to test new systems, but unless these are commonly applied and integrated into a user friendly, cost-effective application (for a resource-constrained environment) they will not impact the market and help us reduce wastage, and increase coverage. In the vaccine sector, these applications need to support temperature monitoring, whilst providing information on location and stock-levels. Some of the existing opportunities for tracking are available in the solutions described below.



Rwanda, July 2010 – At a rural health centre in Rwanda, the temperatures of the vaccine storage fridges are monitored and recorded by hand (Credit: GAVI/Doune Porter/PATH/2010)

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<sup>2</sup>Further information on the VVM can be found here:

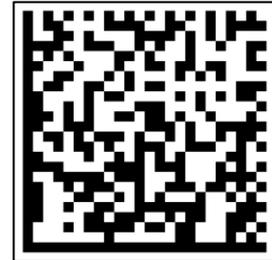
[http://www.who.int/immunization\\_standards/vaccine\\_quality/What%20is%20VVM%20and%20how%20does%20it%20work.pdf](http://www.who.int/immunization_standards/vaccine_quality/What%20is%20VVM%20and%20how%20does%20it%20work.pdf).

### (a) Barcodes

A linear (or one-dimensional, 1D) barcode represents data in the widths and spacing of the parallel lines and typically holds less than 85 characters.



A two dimensional (2D) barcode, also known as a data matrix, has patterns of dots, squares and other geometric patterns. It holds up to 100 times more data per unit size than a linear barcode, at multiple levels e.g. lot numbers, date of manufacture, expiration date, manufacturer location and distribution channel, component details, and unique serial numbers. This is important as 'real estate' on a vaccine vial label is limited: because of their data density, 2D barcodes can be easily added to existing labels. Furthermore, they can be scanned from any angle (including in reverse through a clear material), whilst 1D barcodes can only be scanned from certain angles; and 2D barcodes can often be read when damaged, unlike 1D barcodes which can provide false data if damaged.



GS1 is a non-profit entity leading the design and development of global standards for supply and demand chains. Their standard product numbering schema, called the Global Trade Item Number®, identifies the manufacturer and product. A standard is emerging in the US, Canada and the EU that would use a GS1 data matrix which includes vaccine lot numbers and expiry dates. Using a global standard identification barcode allows different countries and entities to link the product to a record in a product database containing all the information they need and ensures that the identification number will be unique.

Standards are important to everyone across the supply chain as it limits costs and potential incompatibilities and maximises the visibility of product through the entire supply chain. GAVI and the members of the Alliance – UNICEF, WHO, PATH and others – are working to see the GS1 standard adopted for GAVI countries as soon as possible.

Adopting the standard is necessary but not sufficient to see the barcode reading technology and systems introduced in GAVI countries, and much further work will be required on implementation.

### (b) Radio-frequency Identification (RFID)

RFID is a semi-conductor in the label of a tag that stores information. Data is then written or read to the tag when it is exposed to radio waves of the correct frequency. Unlike a bar code, it can be read without line of sight of the reader/scanner and thus may be embedded in the tracked object. RFID scanners can be battery operated or use a local power source; more sophisticated RFID tags have their own power source.

The advantage of the RFID is that it can read through layers of packaging (and hence individual products do not require scanning). It can also capture the date and time a

product reaches a point in the supply chain. The main concern however is the cost as the track and trace solution used should be appropriate for all vaccines, even low cost ones.

Whilst both 2D barcodes and RFIDs have initial start-up costs for software and scanning equipment, a large expense with the RFID is the tag (which can be more or less expensive, depending upon whether it can be scanned at close range or at a distance) and readers; whereas 2D marginal costs are low as it is incorporated into the printing of the label or carton. It is preferable to have an identifier available on the primary packaging level and barcodes remain the most practical option at this time. It is, however, quite conceivable to consider a mixed RFID/barcode approach with RFIDs for tertiary packaging and barcodes on lower levels of packaging. GSM enabled devices could also play a role in parts of the supply chain. Alternatively, barcode technology may advance to the extent of an RFID in terms of its capacity and readability of data. Data standards as well as frequency and radio standards are also relevant to enabling widespread use of RFID technologies.

### The Challenge

An integrated track and trace system will need to leverage multiple hardware and (interoperable) software solutions along the value chain, whilst being easily integrated into a resource (including human resource) constrained healthcare environment. A Standardized Numerical Identifier (SNI) will need to be generated, applied and recorded by the manufacturer, and then scanned, recorded and authenticated along the supply chain, including at distributors and health care facilities. Technology requirements may thus include serialization software, data carrier technology (e.g. RFIDs, 2D barcodes), tag scanners, traceability and authentication software and database software, as well as training. The model would most likely entail some type of public-private partnership which can be replicated simply in developing countries, and it would in all likelihood be de- or semi-centralized, whilst needing to ensure security of data and facilitate feedback mechanisms (e.g. in order to report adverse effects following immunization).



Malawi, November 2011 – Health workers transport vaccines in vaccine carriers to keep them cool, on their way to an immunisation outreach session at a remote village in eastern Malawi (Credit: GAVI/Doune Porter/PATH/2011)

With this in mind, our challenge could be broken down into three broad categories:

1. Standardization globally (countries, regulators, producers) - making people understand why this is important and making it happen.
2. Systemic/infrastructure/behaviour constraints to rapid and appropriate use - how to ensure the technology is accepted and used appropriately and reliably.
3. How to drive further technological innovation that respects cost sensitivities.

We need you to consider: what this model will look like? How can we track each step of a vaccine from the manufacturer, to a rural health care facility? What systems and technologies exist, or do we need to develop and invest in, in order to better manage limited supply? How can we drive down the cost of appropriate technology and encourage scale up and use? We want you to help us reach our target of immunizing an additional 250 million children by 2015!

### **A note on ‘The Other Challenge’**

Although not within the scope of this discussion, our other challenge is knowing how many children are fully immunized and that the vaccines are effective and preventing the diseases they are targeted against. Ultimately, an integrated digital data system should both manage supply but also coverage and disease reporting. GAVI’s aim is that all districts in GAVI-supported countries should reach at least 80% coverage, however in 2010 it was estimated that only one third of countries worldwide reached this target. We need to know which children we are reaching, in order to help us reach those that may be missing out.

*GAVI would like to thank PATH, an international non-profit that transforms global health through innovation, for their contributions to this TED Challenge. PATH president and CEO, Steve Davis, will attend our second discussion on Tuesday, February 26.*

### **Background facts**

- GAVI currently supports 8<sup>3</sup> vaccines, with 14<sup>4</sup> different presentations (e.g. 10 dose vial, two dose vial) administering 12 antigens.
- In GAVI eligible countries, the costs of vaccine to fully vaccinate a child (excluding HPV) can be as little as \$22.
- Last year GAVI funded in excess of 300m doses of vaccines. With new launches over the next few years, this will exceed 450m<sup>5</sup> doses in 2015.
- UNICEF Supply Division on behalf of GAVI managed in excess of 400 shipments across all vaccines, an average of 6.5 shipments per country.
- Vaccines need to be kept within a temperature range to maintain their viability – a range of 2-8 degrees centigrade is typical – and thus most vaccines need to stay in the cold chain until they are administered.
- GAVI vaccines are bundled with autodisable (AD) syringes which add volume to the shipments but of course are not temperature sensitive nor of high cost (average cost of an AD syringe is \$0.047 plus shipping which can be a 2% – 23% of the cost of the vaccine).

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<sup>3</sup> Pentavalent, Yellow Fever, Measles, Measles-Rubella, Pneumococcal Conjugate, Rotavirus, Meningitis A Conjugate, Human Papilloma Virus

<sup>4</sup> 3x Penta, 2x Rota, 2x Pneumo, 1x Measles, 1x MeningitisA, 2x HPV, 2 x Yellow Fever, 1x Measles-Rubella

<sup>5</sup> Source: GAVI Alliance, Supply & Demand Forecast v6