THE JOURNEY TO SCALE

Moving together past digital health pilots
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**BBC MEDIA ACTION**

BBC Media Action is the BBC’s international development charity which uses media and communication to reduce poverty, improve health, and support people in understanding their rights. In Bihar, India, it partnered with the Bill & Melinda Gates Foundation and the government to improve reproductive, maternal, newborn, and child health (RMNCH) through use of mobile services for frontline health workers (FHWs) and families.

**DIGITAL HEALTH INTERVENTION**

The use of information and communication technology (ICT) as a tool to improve health systems and services. This definition deliberately includes concepts of both mobile health (mHealth) and electronic health (eHealth).

**DISTRICT HEALTH INFORMATION SOFTWARE (DHIS 2)**

The District Health Information Software (DHIS) is widely-adopted software used to strengthen public health systems by improving the collection and use of health indicators.

**DIGITAL HEALTH COMMUNITY**

Includes all global health community actors including countries, donors, international nongovernmental organizations (INGOs), private- and public-sector developers, and multilaterals.

**INSTITUTIONALIZATION**

Embedding in policies, practices, workflows, and daily life.

**INTEROPERABILITY**

Defined by the Healthcare Information and Management Systems Society as: “Interoperability describes the extent to which systems and devices can exchange data, and interpret that shared data. For two systems to be interoperable, they must be able to exchange data and subsequently present that data such that it can be understood by a user.”

**LEVERS OF SCALE**

Key enabling factors whose absence may hinder an intervention reaching scale, and whose presence may accelerate it.

**MOBILE ALLIANCE FOR MATERNAL ACTION (MAMA)**

The MAMA partnership delivers vital health messages to new and expectant mothers in developing countries via their mobile phones. MAMA started with a three-year, $10 million investment to create and strengthen programs in Bangladesh, South Africa, and India. MAMA’s efforts align with the UN Secretary-General’s Every Woman Every Child campaign and efforts to achieve Millennium Development Goals (MDGs) 4 and 5.

**PRINCIPLES FOR DIGITAL DEVELOPMENT**

Principles for design that capture the most important lessons learned by the development community in the implementation of information and communication technology for development (ICT4D) projects. These principles were inspired by the Greentree Principles of 2010, the United Nations Children’s Fund (UNICEF) Innovation Principles of 2009, and the UK Design Principles, among others.

**STANDARDS**

Norms or requirements that must be met.

**VACCINE VIAL MONITOR (VVM)**

A label placed on vaccine vials that measures cumulative heat exposure.
This paper was commissioned by the Bill & Melinda Gates Foundation to motivate the digital health community to consider new approaches to scaling digital health interventions.

The Bill & Melinda Gates Foundation asked PATH to consider why scale remains a continuing challenge for digital health interventions in the developing world and to examine if there were key factors in which further investment is needed to reach scale. Because scale is a much-studied concept in business and global health generally, we built upon this rich foundation to understand which existing frameworks for scaling products might apply to digital health, linking and applying these concepts in a new way and verifying them against current digital health case studies.

Our hypotheses and findings, based on review of more than 121 books and articles and 40 expert interviews, are intended to spark an ongoing dialogue in 2015 and to develop some specific reference examples. This paper is not intended to be a peer-reviewed or academically-rigorous publication that provides final answers to the challenges faced. Rather, we have focused on suggesting frameworks and provocative questions to stimulate community debate and new forms of collaboration to reach scale.

The opinions contained in this paper are solely those of the authors and may or may not be shared by those that contributed to this piece.
The digital health community is on a journey to deliver health impact.

We have achieved considerable success in the past decade, demonstrating that information and communication technology (ICT) can improve health services delivery in the developing world.

Although our achievements implementing pilots should be celebrated, we must also acknowledge that digital health interventions are not yet routinely used as part of all global health service delivery and have not yet been proven to demonstrate large scale health impact.

We propose that digital health interventions will impact health outcomes significantly only when routinely used, or institutionalized, as a common practice in service delivery. When institutionalized, digital health interventions will provide frontline health workers with real-time, operational data affecting every conceivable part of the primary care continuum from ensuring adequate stock to checking lab reports to workforce training, thus addressing current capacity issues and improving quality of care. In this way, greater institutionalization will achieve the health impact for which we all strive. This paper is intended to stimulate debate on what targeting institutionalization implies for our investment and collaboration strategies.

The path to institutionalization begins when a common challenge and possible solution emerge and create a case for action. This need and opportunity convince multiple leaders in the value chain to contribute by providing initial seed funding; developing effective products; supporting standards; driving clear value propositions; and ultimately embedding the change through policies, program management, and champions. When the products or services persist beyond catalytic funding and are so embedded in the daily practices at each level of the health system that alternative options no longer seem viable, successful institutionalization has occurred. Examples from some business and global health practices illustrate a common pattern of levers that lead to institutionalization, as shown in Figure 1.
Lacking a shared goal of achieving institutionalization has fragmented how the digital health community funds and applies these levers, limiting digital health’s potential to become sustainable and dramatically improve health outcomes in developing world markets. To achieve institutionalization, all stakeholders should adjust current approaches. Figure 2 illustrates our vision for digital health investments.

The community can take several steps to accelerate institutionalization. First, we should develop a collective blueprint of existing digital health investments and meaningful measurements of institutionalization. This discussion will help align key actors on milestones indicating progress. Second, a few examples of comprehensive, national digital health implementations should be catalyzed and tested. Third, we recommend aligning and deepening cross-matrix investments in the seven levers so that they can be broadly shared across countries.

The digital health community contains creative, persistent, and passionate innovators. Our current approaches are not working, however, and we are seeking a more holistic approach to digital health as a component of health systems. If defining “institutionalization” as our goal resonates, we propose that the community call for ongoing dialogues in 2015 to refine what institutionalization means, what enables it, how we measure it, and determine what investments we can make together to scale digital health interventions.
THE JOURNEY TO SCALE SO FAR: Why is a new approach required?

*If you do not change direction, you may end up where you are heading.*

– Lao Tzu

Photo: PATH/Richard Anderson
This paper describes a journey toward successful scale in digital health interventions. Along the journey, use of digital tools for health will shift from being a disruptive innovation to being institutionalized as common practice.

Our vision is a world where we no longer refer to mHealth or eHealth services, but rather take as a given that digital tools are incorporated seamlessly throughout health systems, enabling greater health impact.

To achieve this vision, we believe the digital health community should deliberately and clearly define that we are working towards a common goal of institutionalization and develop an investment strategy to achieve it. This paper is intended to stimulate debate on the following questions:

- What does the goal of institutionalization mean for scale?
- What levers enable institutionalization?
- How can we work together to reach institutionalization?

Like most long and arduous journeys, reaching our destination will require time, investment, and collaboration. We recognize that our collective effort to deliver meaningful health impact using digital interventions could be transformational to the communities we serve.

**WHY NOW?**

Over the past few decades, the number of digital innovations has exploded, fundamentally changing the way people engage with information and with one another. At 7.2 billion, there are more mobile connections than people on the planet. 30 percent of the world’s population has access to and uses the Internet. Asia accounts for half of all mobile-phone subscriptions, and use of digital technology in Africa is growing rapidly, with roughly 170 million Internet users. An estimated one billion users in Africa will access the Internet through low-cost mobile phones by 2050. These consumer trends, coupled with declining hardware and communications costs globally, offer a huge opportunity to use ICT as a tool to address long-standing issues in health services delivery.

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1 Sources: International Telecommunication Union, GSM Association.
Although many small-scale digital health interventions have been introduced to tackle global health challenges, the use of digital devices for health services has not achieved the promise suggested by the high levels of market penetration by ICTs. As Figure 3 shows, there is no shortage of digital health service product launches in developing markets.

Yet these efforts tend to be fragmented and slow to build on the achievements and lessons of others. Even those who use their devices daily to manage everything from their communications, banking, and entertainment needs, have not embraced digital health interventions to the same degree.

Much work remains before connected devices are as essential to a health worker as a stethoscope, or patients monitor their health status as frequently as they monitor trending tweets. The presence of the phone and point-of-service applications are powerful catalysts, but they are not sufficient for adding value to health service delivery. Scale still eludes us, and other barriers—such as the lack of national eHealth infrastructure, the structure of development financing, weak economic models, insufficient leadership, and the deployment and program management capacity—must be tackled if we are to reach it.

Yet the majority of interviewees, when asked to identify digitally enabled health services that have successfully scaled, cannot name more than 1 or 2 examples, if that.

Note: Figures based only on mobile-enabled products and services in developing world tracked by GSMA (including those merged/closed). Excludes services in pipeline with an impending launch.
No one has a problem with the first mile of a journey. Even an infant could do fine for a while. But it isn’t the start that matters. It’s the finish line.

–Julien Smith

IN THIS SECTION WE WILL CONSIDER:

• What are the current definitions of scale for digital health interventions?
• How will aligning on the goal of institutionalization help?
An agreed goal for scale has yet to emerge within the digital health community.

As Figure 4 shows, digital health thought leaders describe scale quite differently. Some organizations maintain a more traditional definition of coverage of a target population of patients or providers within a geography (i.e., scaling up) or across geographies (i.e., scaling out). Relevant scale also differs dramatically by the type of digital product or service (e.g., medication adherence or national health management information systems [HMIS]), making it difficult to align on a meaningful goal for the entire suite of digital interventions.

Another perspective is to shift from viewing mHealth innovations as a direct way to achieve a health outcome, toward viewing them as “a strategy to overcome obstinate barriers to the delivery of known efficacious interventions.” In this framing, success is when, “...integrated mHealth strategies... together address multiple gaps in the pathway to universal health coverage, improving performance in the quality, cost, and coverage necessary to provide care to all in need.”

A more holistic health systems viewpoint on scale is emerging. The Groupe Speciale Mobile Association (GSMA), reflecting mobile operator perspectives, has shifted its definition of scale from achieving a certain level of subscriber volumes and average revenue per user targets, to a more strategic view of the potential long-term value of offering sustainable mHealth services in partnerships across multiple markets. Donors such as the German Federal Ministry for Economic Cooperation and Development (BMZ) and Norwegian Agency for Development Cooperation (NORAD) similarly have taken a longer-term view of their eHealth investments given that their priorities are more focused on overall health systems strengthening. Their investments have focused both on developing long-term capacity and extensible software platforms.

Although these various definitions of scale are not mutually exclusive, the slight differences in the end goal can deter community alignment on steps toward achieving scale. We propose that regardless of your definition, a digital product or service, no matter how robust or how many people use it, only successfully scales when it is embedded or institutionalized into the workflow of health system service delivery or a recipient’s daily habits.

WHY INSTITUTIONALIZATION

Institutionalization is all around us. Sending an email or text message has become so entrenched in daily life that the prior practices of sending a fax or a letter became virtually obsolete. In business, the journey to standardize shipping containers and barcodes (Appendix 1 and 2) followed this pattern. In global health, standard practices as diverse as microscopy and placing vaccine vial monitors (VVMs)

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vii Interview with GSMA, October 7, 2014.
Agreeing on institutionalization as our end point has two benefits. First, it helps the digital health community align objectives while honoring the differences among stakeholders’ perspectives and motivations. Although focusing on institutionalization may appear to suggest that the primary optic is of a national government and public health system, the concept of it as the end-point of scale can be realized by any of the key actors (Figure 5).

A second benefit is it recognizes the significant differences across various types of digital health interventions—from simple short message service (SMS)-based demand-generation tools to integrated national-level reporting infrastructure. Different technologies achieve scale by different means and according to different time frames.

A direct-to-consumer service such as delivery of Mobile Alliance for Maternal Action (MAMA) messages to expectant and new mothers (Appendix 4) is designed, deployed, and adopted differently and on a shorter timeline than the cross-cutting infrastructure investment associated with a national rollout of DHIS 2 (Appendix 5). Although both may be institutionalized in a country, the associated approaches, investment levels, and timescales required to achieve it are quite different.

### WE LACK A SHARED DEFINITION OF SCALE FOR DIGITAL HEALTH INTERVENTIONS

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<tbody>
<tr>
<td><strong>DIGITAL HEALTH NGO</strong></td>
<td>‘We consider a service to be at scale if a vast majority of the intended users are using it. For example, if 80 percent or 85 percent of community health workers in a country are using a tool, we consider that scale.’</td>
</tr>
<tr>
<td><strong>DIGITAL HEALTH CONSULTANT</strong></td>
<td>‘We’ve defined scale as 1 million users for a consumer-focused service, and 1,000 users for a health provider service.’</td>
</tr>
<tr>
<td><strong>MOBILE OPERATOR</strong></td>
<td>‘A product or service is scalable if we can quickly adapt it for use across markets. Scale also depends on return; if I can earn a large margin on a service for a small number of customers, that’s as valuable as earning a minimal margin on a large-volume service.’</td>
</tr>
<tr>
<td><strong>MEDICAL DEVICE MANUFACTURER</strong></td>
<td>‘For commercial direct-to-consumer products, successful scale is in the millions using a product or service each month, rather than cumulatively. But you also need a denominator, e.g., cost/user or time/user.’</td>
</tr>
<tr>
<td><strong>TECHNOLOGY PROVIDER</strong></td>
<td>‘Scale is when there’s an ecosystem, or many groups working together so users have heterogeneity of support without relying on a sole source. Scale also is when people who benefit from an intervention pay for it.’</td>
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</table>

*Source: PATH interviews. Quotes are lightly edited for clarity.*
The lens of institutionalization helps to define successful scale-up for both of these very different interventions. Programs using MAMA are at scale when their routine use as part of an integrated approach to awareness and service demand generation is embedded into national maternal and child health strategies and practice, and when mothers incorporate the tool into their personal approach to childbearing. DHIS 2 is at scale when a government, from the ministry of health to the front-line health worker, routinely accesses its reporting data to manage health service delivery and health system performance across multiple health areas.

Alignment on the end goal of institutionalizing digital health services is a necessary step toward enabling large-scale health impact. Once an agreed destination on the journey is in place, the next step is to consider the pathway to get there.
The best teachers have showed me that things have to be done bit by bit. Nothing that means anything happens quickly—we only think it does. The motion of drawing back a bow and sending an arrow straight into a target takes only a split second, but it is a skill many years in the making.

–Joseph Bruchac

IN THIS SECTION WE WILL CONSIDER:

- What levers enable scale across industries?
- Which apply to achieving institutionalization in digital health?
Having proposed a destination—institutionalization of digital health interventions—the next step is to identify the pattern and levers that can accelerate our progress.

Lessons from promising examples in the digital health sector, as well as from successful scale-up in other sectors, point to factors that enable institutionalization.\textsuperscript{viii}

A common first step in successful scale up is the emergence of a strong case for action. Sometimes, an urgent need, such as demand for an Ebola vaccine, triggers action. In other cases, new evidence prompts action, as when The Lancet series on nutrition and the Copenhagen Consensus made a call to action for greater global investment in nutrition.\textsuperscript{vix}

THE RIGHT LEADERS
The next lever results from an individual recognizing the case for action, understanding how to address the problem at hand, and mobilizing others. One example of this pattern was the standardization of shipping containers, conceived by a single innovator who mobilized an industry-wide transformation (see text box on page 16). Another example has been Rwandan President Paul Kagame’s vision to implement e-Government.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure6.png}
\caption{WHAT DOES IT TAKE TO INSTITUTIONALIZE A PRODUCT OR SERVICE?}
\end{figure}


This explicit sponsorship has encouraged every ministry to automate service delivery from immigration forms to patient records.\(^1\)

Case studies and interviews also indicate, that a single, catalytic innovator is not sufficient for institutionalization. Leaders from other disciplines who share the catalytic leader’s vision and values, need to join forces, contribute key inputs (e.g., money, technology, political will), and work together to reach institutionalized scale. Figure 7 describes six distinct leadership roles for digital health interventions that emerged from our research.

Rwanda’s ongoing development of its eHealth infrastructure provides a good leadership model at multiple stages of institutionalization. Strong political leadership at the presidential level encouraged Ministry of Health leadership to develop the eHealth architecture, standardize the approach, and commit to ongoing national rollout of multiple systems (e.g., Rapid SMS, DHIS 2, iHRIS). Technology partners emerged (e.g., IntraHealth, Management Sciences for Health, Partners in Health, Regenstrief Institute), working under the Ministry’s leadership to implement the service, and various funders (e.g., Global Fund, U.S. President’s Emergency Plan for AIDS Relief [PEPFAR]) have supported financially and advocated the benefits of the program nationally and internationally. Together, leaders across diverse stakeholder groups are supporting existing use cases and working to resolve daily challenges.

THE RIGHT SOLUTION

Leaders must make important investment choices early in the journey to institutionalization. Two early and key solution levers are

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\(^1\) Interview with Management Sciences for Health on October 6, 2014.

LEADERSHIP ROLES

**INNOVATE**
- Spark design of a technology
- Spark design of a service or program using digital tools in a new way and/or new setting

**FUND**
- Sufficiently long funding commitment to allow services to breathe
- Engaged donor with appetite to advocate and engage beyond funding

**DECIDE**
- Well-informed, data-driven decision-making
- Willingness to support publicly

**CONVENE**
- Foster effective partnerships and engagement with all key stakeholders

**IMPLEMENT**
- Committed leaders from implementing organizations that inspire others to deliver

**ADOPT**
- Early adopters willing to test innovations and forge the path for other providers, patients, etc.

Identifying an effective, scalable product and a viable economic model that addresses key stakeholder needs. Key principles underlying development of effective digital health products have now been codified in the Principles for Digital Development.\(^{xii}\) Existing products—such as DHIS 2, OpenMRS,\(^{xiii}\) OpenLMIS,\(^{xiv}\) and others—already follow these principles, with more emerging each day. Effective products that become institutionalized (e.g., mobile phones, ATM machines) generally offer users easy alternatives to existing processes, with benefits that encourage the average user to follow early adopters.\(^{xv}\) The lesson for digital health interventions is that one must invest upfront to re-imagine the workflows instead of simply automating the paper processes. This is a critical step in modifying, testing, and simplifying products before deploying nationally, particularly since many end users, such as FHWs or pregnant women, may be relatively new to using technology and will need to immediately see the benefits of the new way of working to adopt it. Further, all tools must be measured by their ability to deliver savings (e.g., time, effort) for the end users to sustain its use.

These lessons are highlighted in A Quiet Revolution: Strengthening the Routine Health Information System in Bangladesh recently published by Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) which notes that “a simple tool makes a world of difference.” A key factor behind the selection of DHIS 2 by the Government of Bangladesh was that the product had been well-tested, is stable, and has consistent backing from the University of Oslo and NORAD.\(^{xvi}\) In addition, prior to rollout of the system, all parties partnered with the Government of Bangladesh to re-imagine how the work could be done and modified the features accordingly.

This is not to suggest there is no room for new product innovation; there is great promise in piloting exciting new intersections of technology and health. However, to achieve sustained impact, it is critical to strike a balance between excitement over the “next new thing” and the need to build on current investments and institutionalize a few, simple, much-needed tools. For example, MAMA offers standardized

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\(^{xii}\) Principles for Digital Development website. Available at: http://ict4dprinciples.org/.

\(^{xiii}\) OpenMRS is an open-source enterprise electronic medical record system platform.

\(^{xiv}\) OpenLMIS is an open-source electronic logistics management information system.


\(^{xvi}\) GIZ. A Quiet Revolution: Strengthening the Routine Health Information System in Bangladesh. 2014. Interview with Kelvin Hui, October 24, 2014.
FIGURE 8

ANALYSIS OF THE ECONOMIC VALUE BY STAKEHOLDER TYPE

Value proposition: how mHealth helps stakeholders achieve their mission and goals vs. the next best alternative (including doing nothing)

<table>
<thead>
<tr>
<th>STAKEHOLDER</th>
<th>PUBLIC</th>
<th>NON-PROFIT</th>
<th>FOR-PROFIT</th>
<th>HEALTH WORKER</th>
<th>INDIVIDUALS &amp; HH</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMPARATIVE NET UTILITY</td>
<td>• Improved health outcomes (e.g., longer life, higher quality of life)</td>
<td>• Improved health outcomes</td>
<td>• Increased sales/revenues</td>
<td>• Improved health outcomes</td>
<td>• Improved health outcomes</td>
</tr>
<tr>
<td></td>
<td>• Efficiency gains and cost savings in achieving mission</td>
<td>• Efficiency gains and cost savings in delivering products and services</td>
<td>• Efficiency gains and cost savings for health delivery</td>
<td>• Reputational benefits (i.e., standing in community)</td>
<td>• Efficiency gains and cost savings in seeking health care</td>
</tr>
<tr>
<td></td>
<td>• Increased donations/sales/revenues</td>
<td>• Improved health outcomes</td>
<td>• Note: Improved branding/PR is not a driver for long-term participation</td>
<td>• Improved health outcomes</td>
<td>• Reputational benefits (i.e., standing in community)</td>
</tr>
<tr>
<td></td>
<td>• Higher productivity levels for the overall economy</td>
<td></td>
<td></td>
<td></td>
<td>• Higher productivity levels for household</td>
</tr>
</tbody>
</table>

content, as well as lessons and tools for adapting this content for local communities. Rather than reinventing this content and tools, partnerships are building on MAMA’s work to create and deliver locally relevant content.\textsuperscript{xvii}

Determining what makes a viable economic model for all stakeholders and why it is such a crucial lever to achieve institutionalization is complex. We define a viable economic model as one that provides incentives and willingness to pay for all participants along the value chain. For example, although private health services are common in many developing countries, the bulk of the investment to improve services—including investments in health information systems and health worker training—depends on initial, catalytic government or donor funding, rather than consumer investment. Governments, particularly ministries of health, must balance the need to deliver care with their interest in developing their digital health infrastructure. Similarly, donors need a rationale for their investments and want to invest in tools that ultimately generate cost savings or better, faster health outcomes. Figure 8 shows a helpful way of framing the value proposition for digital health interventions for various stakeholders.\textsuperscript{xviii}

\textsuperscript{xvii} Interview with MAMA representative and MAMA website.

\textsuperscript{xviii} The mHealth Alliance and Vital Wave Consulting. Sustainable Financing for Mobile Health (mHealth): Options and opportunities for mHealth financial models in low- and middle-income countries. Washington, DC: The mHealth Alliance and Vital Wave Consulting; February 2013.
A sustainable economic model requires that all key stakeholders derive sufficient value from their investments and are willing to put their own resources into the system. For example, mobile operators and other industry participants may initially invest in digital health interventions for corporate social responsibility reasons, but they will require more substantial commercial incentives over time. The economic model has to consider demand; even if an end user (e.g., government policymaker, FHW) does not initially pay for the service, he or she must invest time to learn and adopt it. Also, the governments must demonstrate an early commitment to co-investing in a digital health intervention for it to reach true institutionalization. Digital health interventions are more likely to scale if value propositions for each of these stakeholders are clearly articulated as the services are being defined even if the benefits for all are only realized over time.

THE RIGHT APPROACH

Even the best-designed, most economically viable products will not realize their potential if they cannot get to market. The need for supportive policy, regulation, and standards for digital health interventions to reach institutionalization is fairly clear: few innovations have become standard practice within a health system without inclusion in global and/or national guidelines and in government budgets and plans. One example is the case of VVMs (Appendix 3), which became institutionalized across markets only after WHO and the UNICEF began to advocate their use and then updated global cold chain guidelines requiring usage on all packaging. More than five billion VVMs have now shipped globally. Similarly, adoption of barcodes (Appendix 2) and shipping containers (Appendix 1) ramped up dramatically once international standards were agreed upon, becoming a global norm.

Global health informatics standards are critical to building robust national health information system platforms, and a few key actors are emerging. The OpenHIE community, for example, has led a broad-based effort to institutionalize product approaches to patient and facility registries. The Health Information Systems Programme (HISP), a member of the OpenHIE community, is enabling institutionalization of DHIS 2 in part by building on global programming standards such as HTML 5 and SDMX-HD to make it interoperable with Android applications, web portals, and other information systems. Incorporating global standards and employing open application programming interfaces to all digital health interventions is critical to enabling countries and consumers to harmonize multiple information systems. Resources such as Connecting Health Information Systems for Better Health: Leveraging Interoperability Standards to Link Patient, Provider, Payor, and Policymaker Data and a pending WHO publication on selecting standards and interoperability provide guidance and tools to help national informatics leaders select and embed standards into national information technology (IT) architectures.

In addition to effective products, strong economic models, and standards-based approaches, thoughtful, program management is a key lever for institutionalization. For example, BBC Media Action’s approach (Appendix 6) to scaling its suite of mobile services for maternal and child health demand-generation tools, first in Bihar and then at the national level in India, illustrates some of the key principles characterizing effective program management. Engaging the right stakeholders from the beginning is key; in Bihar, state government agencies were partners from the very beginning, increasing the likelihood they would incorporate future investments in their annual budgets. Likewise, a structured, disciplined approach and ongoing delivery of project management and

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*The Open Health Information Exchange (OpenHIE) community works to help underserved environments better leverage their electronic health information through standardization.


PATH supports multiple peer learning forums around the world. In discussion with eHealth leads in both Asia and Africa, a consistent topic has been which standards matter and how do we convince policymakers that standards matter.
communications—both in Bihar and again at the national level—have been critical to helping the state and national governments to move toward institutionalization. Iterative approaches to technology design, as well as to program design, have been crucial to the services’ success thus far: BBC Media Action developed its Mobile Kunji, Mobile Academy, and Kilkari services via an iterative user-centered design process. It has subsequently localized the content for other states to take into account differences not only in language, but in communicable diseases, government incentive programs, and the availability of health products in each state. Within Bihar, the team modified its rollout approach as it scaled to improve buy-in and sustainability by leveraging existing government health worker training staff to promote education and adoption of the tools by frontline workers.\textsuperscript{xxii}

The team also had people on the ground who drove the day-to-day implementation, promoting delivery of a robust project plan. As one sector expert has estimated, digital health intervention success is 20 percent about the intervention itself and 80 percent about making it happen.\textsuperscript{xxiii}

**THE RIGHT CAPACITY**

In the end, a good strategy and approach are gated by the ability to do long-term execution. Delivering health services using digital health interventions requires greater levels of **national human capacity** to champion, choose, design, use, and maintain these tools. Digital health community leaders have highlighted that human capacity and national technology prowess are both our greatest opportunity and biggest challenge.\textsuperscript{xxiv} Although capacity-building efforts have improved since 2010 with the support of efforts such as Knowledge for Health, training programs, and the emergence of peer-learning networks such as the Asia eHealth Informatics Network and the Joint Learning Network for Universal Health Coverage, the low levels of embedded ICT experience in most ministries of health and lack of familiarity with the complexities of ICT rollouts at each level of the health system continue to be a challenge.

As one interviewee noted, “Because health officials are not cognizant of all the factors involved in ICT development and deployment and users may not know the full potential of the solutions, fully informed decisions on how ICTs could be used, designed, or optimized to improve data collection or service delivery may not always be manifested.”

HISP has been a key champion of capacity-building, and their approach offers useful lessons. Part of the University of Oslo, HISP builds capacity by combining educational degree programs with practical, on-the-ground experience. Informatics students build, manage, and improve the DHIS with the guidance of HISP staff.

Participation in DHIS development helps strengthen commitment and skills among graduate students; many students from the developing world who have worked on its development remain involved after their return to their home country. HISP’s DHIS 2 Academies similarly foster a global community of users and experts and build national and regional capacity to design, implement, and suggest new features to the core platform.

Elements of these seven levers are often discussed by stakeholders. But, if so many levers for institutionalization are widely known, why has scale-up for digital health interventions been so difficult to achieve? Our hypothesis is that institutionalization cannot occur because global investments are fragmented across the levers so they cannot be systematically combined and applied in specific geographies. This raises the question “Is there a way to align our community’s collective efforts to reach the institutionalization that VVMs, barcodes, and container ships enjoy today?”

\textsuperscript{xxii} Interviews with representatives of the Bill & Melinda Gates Foundation, BBC Media Action, and Grameen Foundation.
\textsuperscript{xxiii} Interview with Vital Wave Consulting.
REACHING INSTITUTIONALIZATION: What are some strategies to accelerate our journey?

If you want to go fast, go alone. If you want to go far, go together.

–African proverb

We must never be afraid to go too far, for success lies just beyond.

–Marcel Proust

IN THIS SECTION WE WILL CONSIDER:

• How can our community develop a roadmap collaboratively in 2015?
• What investments should we make “together” to accelerate reaching scale
Consensus is emerging among donors (e.g., Global Fund, Gavi, and NORAD) that digital investments are key tools for strengthening health systems.

Many governments (e.g., Philippines, Rwanda, Nigeria, Ghana) are strengthening their governance mechanisms, driving their eHealth planning and implementation, and participating in nascent regional and national informatics peer learning and training efforts (e.g., Asia eHealth Informatics Network, University of Stellenbosch).

Developers and implementers (e.g., Abt Associates, Dimagi, Grameen Foundation, John Snow Inc., PATH), have struggled with scaling products beyond a district, and are increasingly interested in fostering long-term national ownership of effective products based on viable business models and integrated into standards-based, back-end infrastructure.

Reaching institutionalization and thus achieving significant health impact requires combining all of these elements into a more holistic and deliberate approach. For the levers explained in the last section to be effective, the stakeholders in the digital health ecosystem need to (1) align on the long-term vision for digital health; (2) prioritize a few, focused geographic investments; and (3) invest in and leverage some common, reusable assets that span geographies. The coming year can be a very deliberate time to catalyze this next phase of our journey, creating this alignment and setting the stage for the next decade in which digital health interventions are institutionalized across the developing world.

Our detours have taught us all about what does and does not work, and we are crystallizing these lessons into tangible strategies. If we can join forces discussing, developing, and implementing the proposed steps outlined below, we can accelerate our journey to scaling successful digital health interventions that embody the attributes in Figure 9.

**FIGURE 9**

**WHAT IF EVERY DIGITAL HEALTH INVESTMENT WERE...**

- Triggered and selected according to the needs of the health system?
- Mandated and driven by the Ministry of Health?
- Enabled by committed, long-term funding and robust program management so solutions have time and support to iterate, evolve, and embed into existing systems and practices?
- Built around realistic, long-term funding models?
- Integrated into existing national platforms?
- Selected and designed to conform to agreed standards?
- Designed and implemented with the participation of the end users and long-term implementers?
STEP 1: AGREE ON THE DESTINATION AND DEVELOP A ROADMAP

Developing agreement on a shared goal of institutionalization as our end-point and required investments are crucial first steps. We propose that the community call for a series of dialogues in which a diverse, cross-sector group of committed leaders convene over the course of a year to develop a five-year blueprint of the investments required to institutionalize digital health interventions. This new call would emphasize our commitment to collaborating on implementing the Principles of Digital Development and developing a global action plan to: (a) country-led national institutionalization efforts; and (b) cross-market investments in core levers for institutionalization.

-step 2: catalyze national digital health investments

Step 2 would entail adopting a more collective, coherent approach to planning and implementing national digital health strategies, taking into account the levers that enable institutionalization. Building on lessons from other sectors, such as national HIV/AIDS or malaria control strategies, these approaches should start with assessment and gap analyses of infrastructure design, and lead to joint roadmaps, pooled funding streams, investment prioritization conversations, and eventually coordinated implementation and monitoring planning in a few identified markets.

A number of national-level institutionalization efforts in digital health are emerging: Nigeria’s government-led digital health coordination mechanism under the ICT4SOML, India’s approach to national-scale digital tools for health care workers, South Africa’s approach to harmonizing messaging to mothers, and multiple countries’ experiences embedding DHIS 2 into health systems.

As the community embarks upon this step, we will benefit from examining how these countries are designing and evolving their coordinated strategies,

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**FIGURE 10**

**POTENTIAL COUNTRY INVESTMENTS**

<table>
<thead>
<tr>
<th>CASE FOR ACTION</th>
<th>NEAR-TERM INVESTMENTS</th>
<th>LONGER-TERM INVESTMENTS</th>
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<tbody>
<tr>
<td></td>
<td>Develop rigorous total cost of ownership (TCO) models and collect consistent health impact data on each implementation</td>
<td>Sponsor national advocacy and education efforts on the impact seen from digital health investments</td>
</tr>
<tr>
<td>LEADERSHIP</td>
<td>Require government and donor coordination before allocating investments</td>
<td>Invest in design and implementation of country-led strategies</td>
</tr>
<tr>
<td>EFFECTIVE PRODUCT</td>
<td>Direct investments toward making products inter-operable with existing infrastructure</td>
<td>Evaluate more rigorously each project against agreed performance levels and health outcomes</td>
</tr>
<tr>
<td>VIABLE ECONOMIC MODEL</td>
<td>Identify the “gives” and “gets” for each product before rollout by stakeholder</td>
<td>Require that each rollout identifies a viable long-term business model after catalytic financing ends</td>
</tr>
<tr>
<td>SUPPORTIVE POLICY, REGULATION AND STANDARDS</td>
<td>Support national development of eHealth architecture and implementation plans</td>
<td>Provide incentives to adopt agreed standards and policy frameworks to national governments</td>
</tr>
<tr>
<td>EFFECTIVE PROGRAM MANAGEMENT</td>
<td>Require new investments to have dedicated program management staff through national rollout</td>
<td>Capture and share best program management practices within a country</td>
</tr>
<tr>
<td>HUMAN CAPACITY</td>
<td>Sponsor greater local university and entrepreneurs’ participation from the outset</td>
<td>Embed national informatics capacity in projects versus using overseas staff</td>
</tr>
</tbody>
</table>
including how they are addressing the individual levers for institutionalization.

The community should then make a few specific, national-level demonstration investments channeling deliberate attention and funding by lever. Figure 10 illustrates some of the near- and long-term investments that may be required in a given market. With sufficient, targeted investment in each lever, participation by key actors in each market, robust leadership by government, and patience, these efforts could demonstrate if this holistic investment approach achieves health impact, and if these models can serve as enduring demonstration examples for other countries.

These collaborative, country-level efforts will be more successful if undertaken in parallel with efforts to strengthen levers for institutionalization across markets.

**STEP 3: INVEST IN CROSS-MARKET LEVERS FOR INSTITUTIONALIZATION**

Step 3 will require harmonizing and deepening existing investments in specific, cross-market levers for institutionalizing country-level digital health strategies (e.g., human capacity-building, effective products). While country-level examples are critical to demonstrating the potential impact of institutionalized digital health interventions, cross-market lessons, tools, and mechanisms provide core building blocks and offer economic synergies for country-level efforts.

A number of near- and long-term cross-market investments and approaches logically arise from the levers, as illustrated in Figure 11.

Some of these efforts already are underway but are generally fragmented, competing for resources and attention, and struggling to achieve sustained activity or impact across or within geographies. To break this cycle, the digital health community should focus on a set of fewer, yet better-resourced investments with more robust partnerships and longer time horizons, and consider how we can leverage aggregated demand from many countries to negotiate improved financing terms with operators and licensing agreements with standards providers.

### FIGURE 11

**POSSIBLE CROSS-MARKET INVESTMENTS FOR SCALING DIGITAL HEALTH INTERVENTIONS**

<table>
<thead>
<tr>
<th>NEAR-TERM INVESTMENTS</th>
<th>LONGER-TERM INVESTMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CASE FOR ACTION</strong></td>
<td>Create better advocacy toolkits to educate national leaders and donors</td>
</tr>
<tr>
<td><strong>LEADERSHIP</strong></td>
<td>Call for a global action plan for digital health investments</td>
</tr>
<tr>
<td><strong>EFFECTIVE PRODUCT</strong></td>
<td>Direct investment toward a smaller pipeline of best-in-class cross-cutting platform</td>
</tr>
<tr>
<td><strong>VIABLE ECONOMIC MODEL</strong></td>
<td>Develop financial forecasting tools that any country can use to consider TCO and return on investment of new digital health tools.</td>
</tr>
<tr>
<td><strong>SUPPORTIVE POLICY, REGULATION AND STANDARDS</strong></td>
<td>Continue more inclusive development of shared standards and best practice frameworks</td>
</tr>
<tr>
<td><strong>EFFECTIVE PROGRAM MANAGEMENT</strong></td>
<td>Capture and sharing of best practices in more digestible, practical forms</td>
</tr>
<tr>
<td><strong>HUMAN CAPACITY</strong></td>
<td>Sponsor regional peer networks and specialized capacity programs targeted towards practitioners</td>
</tr>
<tr>
<td></td>
<td>Develop the next cadre of eHealth leaders through university-level health informatics programs in emerging markets</td>
</tr>
</tbody>
</table>
CONCLUSION

While the journey to scaled digital health interventions continues, a willingness to share the journey has emerged.

The digital health community consists of creative, persistent, and passionate innovators who recognize that “it is not about us, it is not about technology, it is not about money, it’s about impact.”

We see, however, that our current approaches are not working, and we are seeking answers to enable us to increase this impact. The call for a deliberate, inclusive dialogue and a coordinated investment strategy is the first step. Now is the time for the digital health community to pause in our individual journeys, assess the current landscape, and align on a more common path forward. Recognizing that lasting change will take time, we can focus on both near- and long-term efforts to develop the digital health products, practices, and polices required to support high-performance health care systems.

While much work lies ahead, we look forward to collaborating in 2015 to define a roadmap and invest together. Discussing what institutionalization means for successful scale and how to move the levers required to get there will enable us to capitalize on digital health’s potential to drive innovation to save lives.

ACKNOWLEDGMENTS

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PATH would like to point readers to the list of excellent work already conducted in this area that informed this paper. These papers have developed rigorous methodologies and contributed extensively to the conclusions discussed in this paper and the field generally.

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100. Taylor PR. An approach to designing viable and sustainable telehealth services Health Informatics: Digital Health Service Delivery – The Future is Now! *Studies in Health Technology and Informatics*. 2013;188.


## APPENDIX 1:
### STANDARDIZING SHIPPING CONTAINERS ANALOGUE

<table>
<thead>
<tr>
<th>TITLE</th>
<th>Standardizing shipping container dimensions</th>
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<tbody>
<tr>
<td>INDUSTRY</td>
<td>Shipping</td>
</tr>
<tr>
<td>CONTEXT</td>
<td>Malcom McLean (a highly influential person in the trucking industry, head of Sea-Land), frustrated with the time it took to load products in ports, realized it would be much more efficient if a container of goods could be lifted directly from a truck to a ship, and vice versa, without having to unload and re-load its contents (intermodalism). The first container ship sailed in 1956, and demonstrated the significant cost and time savings. Time spent in port was reduced from days or weeks to hours. Container shipping grew rapidly due to increasing demand (domestic and global, as well as demand from the US government for shipping supplies for the Vietnam War). In 1961, the International Organization for Standardization (ISO) set standard sizes for all shipping containers so that they could be stacked on all modes of transportation (ships, cranes, trucks, trains) in the safest and most efficient way. Standardization of shipping container sizes facilitated the expansion of the shipping industry to ports around the world, opening access to new markets at significantly reduced costs.</td>
</tr>
<tr>
<td>SCALE ACHieved</td>
<td>“In 1966, in the decade after the container first came into international use, the volume of international trade in manufactured goods grew more than twice as fast as the volume of global manufacturing production, and two-and-a-half times as fast as global economic output.” Today, hundreds of millions of containers are shipped around the world each year.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>A significant challenge to switching to containerization was posed by port labor unions, whose workers stood to lose jobs due to the increased efficiency.</td>
</tr>
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xvi According to the World Shipping Council, “Intermodalism is a system that is based on the theory that efficiency will be vastly improved when the same container, with the same cargo, can be transported with minimum interruption via different transport modes from an initial place of receipt to a final delivery point many kilometers or miles away. That means the containers would move seamlessly between ships, trucks and trains.”

xvii The ISO was founded in 1946 by delegates from 25 countries which felt there was a need for an international organization to facilitate the development of global industrial standards. Today, 165 countries make up its membership.


xx Levinson page 12.

APPENDIX 2:
BARCODES CASE STUDY

A clear value proposition for both retailers and manufacturers brought executives together to set an industry-wide standard that rapidly scaled and institutionalized barcodes, now used by millions of companies in over 150 countries.

BACKGROUND

For all actors involved in creating and distributing a product—from manufacturer to distributor to retailer to consumer—the ability to keep track of how much of your inventory you have, where it is, and when you will need to buy more is very important.

Before barcodes, managing inventory was difficult, and the mistakes were costly. Better insight into data around inventory and demand can reduce waste, prevent stockouts, and improve efficiency and profitability.

Before the 1960s, punch-card technology existed but was bulky and expensive. Norman Woodland and Bernard Silver recognized this need for technology to automatically read product information and began to explore solutions. They filed the first patent for a barcode, named bull’s-eye code due to its resemblance, in 1949.

In the 1960s, grocery trade associations in the United States began to seriously pursue barcode innovation as a potential solution for automated data capture and improved inventory management. They worked with RCA to develop barcodes for groceries in the 1960s, and developed guidelines and standards based on key principles: easily readable from any angle, affordable, and easy to reproduce. The result of years of research and meetings was the Universal Product Code (now commonly referred to as simply the U.P.C. barcode). By 1974 saw the first live scan of a barcode in a grocery store, on a pack of Wrigley’s gum that can now be found in the Smithsonian Institute. By 1981, more than 60 percent of grocery stores nationwide were equipped with scanners. Though it took over 20 years to reach national adoption, barcodes are now ubiquitous, and are arguably one of the most significant productivity improvement innovations in the supply chain.

DEFINING SCALE

Barcodes achieved scale once all products sold in grocery stores contained barcodes on their packaging, and all stores contained barcode readers. The grocer executives leading the industry associations recognized the chicken-and-egg situation facing them: manufacturers would not produce and apply barcodes if grocers did not invest in scanners, and vice versa. Recognizing their power in numbers, six grocery associations established a committee in 1970 to develop a standard, inter-industry code (UPC) to identify products using a machine-readable symbol. They needed a standard to avoid having different manufacturers use different codes readable by multiple, incompatible machines. As more grocers and manufacturers invested in barcodes, the numbers grew exponentially. By 1997, 177,000 manufacturer-specific UPC codes had been created. About five billion products’ barcodes are scanned per day.

Today, barcodes and barcode standards have reached global scale, used by millions of companies in over 150 countries.

xxxviii Ibid.
The broad cooperation between trade associations with the leadership of top executives and the establishment of standards-writing bodies enabled support for uniform barcodes to reach critical mass. Leaders recognized the network effect—the value of the new technology for a potential adopter was dependent on how many others were using it. A grocer had no use for a scanner if manufacturers were not applying barcodes to their products; and vice versa.

The clear, underlying value of the potential benefits of barcodes (faster checkout process, reducing labor required; ability to collect and process information about stock and demand, and use it to reduce market risk) made it appealing across industries. The ease of use for the end user was paramount. Clerks were not familiar with technology and needed to intuitively understand upon first use to reach scale.

Inflation and rising food prices reduced profitability of food retail and motivated companies to push for ways to improve efficiency and reduce costs in the grocery industry. Advancements in capabilities and decline in the cost of computer hardware and software to process and communicate information encoded in barcodes made barcoding affordable.

Policies, regulations, and standards enabled barcodes to scale exponentially across industries. Trade associations established standards early on so different manufacturers, producers, and sellers could readily adopt barcodes. With standards in place, retailers avoided having to buy multiple scanning systems to read different barcodes used by manufacturers. Without such standards, barcodes would have complicated the retail process and likely would not have scaled. Additionally, states passed laws mandating price stickers be kept on to quell consumer fears about barcodes replacing price stickers.

**TIMELINE**

1949: Norman Woodland and Bernard Silver filed first patent for “bull’s eye code.”

1952: Patent issued for bull’s eye code. Philco purchased the patent, then sold it to RCA.

1959: First commercial use of linear barcodes to track rail cars, called KartTrak. The first scanner was installed by Sylvania/GTE on the Boston and Maine railroad.


1969–1970: Computer Identics developed the first black-and-white barcode and computer processing and reporting to expand to other industries. Six grocery associations established a committee to work with IBM to develop an inter-industry UPC to identify products using a machine-readable symbol.

1971: Control Module developed the first portable barcode scanner. Computer Identics installed its first two systems at General Motors and General Trading Company.


1974: The first scan of barcode on a pack of Wrigley’s gum. Europe adopted a standard code compatible with UPC.

1977: Scanners were used in about 200 grocery stores; evidence of the return on investment was growing.

1980: Thousands of grocery stores were adopting barcodes each year.

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APPENDIX 3: VACCINE VIAL MONITOR CASE STUDY

The leadership exhibited by committed product champions throughout the product-development process, the policy decision to promote vaccine vial monitors (VVMs), as well as a procurement and financing mechanism unique to immunization which served as a demand aggregator helped to institutionalize VVMs on most vaccines supplied in the public sector in low-income countries.

BACKGROUND

Vaccines require constant refrigeration from the point of manufacturer to point of use. International protocols require health workers discard any vaccines exposed to heat.

Too often, vaccine potency is compromised due to weaknesses in the cold chain in resource-poor settings, and vaccine wastage is a significant cost to immunization programs.

For decades, health workers had no way of verifying heat exposure, and guidelines erred on the side of caution, instructing frontline workers to throw out any vaccines they suspected of being too long outside the cold chain. This likely resulted in the wastage of significant quantities of good vaccines.

Staff in the World Health Organization (WHO)’s Expanded Programme on Immunization (EPI) had an idea: what if each vial of vaccine could be fitted with a sensor that monitors exposure to heat, indicating to health workers when the vaccines actually need to be discarded? Such monitors were affixed to cartons of vaccines, and WHO hoped a similar product could be developed for use at lower levels of the health system. The search for a suitable product began in 1979, with VVMs finally achieving scale on all United Nations Children’s Fund (UNICEF)-procured vaccines in 2006.

The VVM is a label that indicates cumulative heat exposure, changing color as a vial of vaccine has been exposed to temperatures above normal refrigerated storage conditions. While the VVM does not measure the actual potency of the vaccine, it indicates when excessive heat exposure has occurred, and health workers are instructed to discard the vials accordingly. VVMs have been effective in reducing unnecessary vaccine wastage, and assuring the potency of vaccines even in hard-to-reach areas. They also enable health workers to more effectively manage vaccine stocks by using vaccines that have some heat exposure (but have not reached their discard point) before others. VVMs have also strengthened the implementation of WHO’s multi-dose vial policy, allowing health workers to use open vials for more than one day if the heat exposure end point has not been reached, further contributing to reduction in vaccine wastage. In 1995, the VVM was introduced on vials of oral polio vaccine (OPV), and over the course of the following decade, became a requirement for all UNICEF-procured vaccines.

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xliii Frost L, Reich M. How to good health technologies get to poor people in poor countries? Available at: http://www.accessbook.org/index.htm.
DEFINING SCALE
The time required to develop and eventually scale a device like the VVM was a lengthy process, in this case requiring 26 years from WHO’s initial call for the development of a heat exposure indicator in 1979 to inclusion on most UNICEF-procured vaccines in 2006. Once a suitable product had been identified, efforts to scale the VVM were accelerated by a convergence of factors, notably the actions of UNICEF and GAVI as demand aggregators and a changing vaccine market. VVMs did not take off until the timing and context were favorable.

The development and eventual scale up of VVMs benefitted greatly from being embedded within the ‘global immunization machine’, a sphere in which an unusual degree of global coordination exists and where influential gatekeeper organizations can make the decision to promote the scale up of such a technology. This is not the case for most innovations, which instead work across health systems, requiring buy-in and acceptance from multiple stakeholders and gatekeepers.

<table>
<thead>
<tr>
<th>CONDITION OF SUCCESS</th>
<th>APPROACH</th>
</tr>
</thead>
</table>
| CASE FOR ACTION      | Efforts to scale up VVMs benefitted significantly from evidence demonstrating a contribution to reduced wastage rates. In Turkey, vaccine wastage rates were found to decline by 77 percent. A study of health worker knowledge, attitudes, and practices in Bhutan found that health workers found the VVM easy to interpret. This evidence contributed to an ‘enormous and growing evidence base’, and promoted adoption among the global policy bodies and vaccine manufacturers, because ‘they couldn’t come up with excuses’.

LEADERSHIP
The role of product champions at many stages of the process was critical to the success of VVMs. From the outset, WHO was instrumental in setting the agenda, calling for the development of a heat-exposure indicator in 1979, and promoting the concept from that point forward. After a successful product had been identified, WHO exercised its influence as a decision-maker, revising international cold chain protocols to include VVM. When stakeholders raised concerns about the VVM technology, WHO acted as a convener, bringing together product developers, vaccine manufacturers, and international organizations (including UNICEF) to discuss and address concerns.

PATH also provided essential leadership as an innovator, responding to WHO’s call and initiating the search for prospective technologies. When a promising candidate was identified, PATH worked with the developer (Temptime) to modify the technology for use on vaccine vials, providing leadership in the implementation of VVM technology on vaccines.

VVMs illustrates the importance of determined leadership throughout the process, from international organizations like WHO, UNICEF, and GAVI, and also from organizations like PATH, steering the development and implementation of innovations. Further, the willingness of the product developer, Temptime, to continually iterate on the technology in response to stakeholder feedback was essential to bringing vaccine manufacturers on board.

EFFECTIVE PRODUCT
The VVM is a simple indicator that changes color if a vaccine has been too long outside of the cold chain. Because VVMs are affixed directly to vaccine vials at the point of manufacture, they do not drastically alter the workflow of FHWs. Expanded Programme on Immunization (EPI) staff reported that the labels were easy to interpret, alleviating the need to make subjective judgments about whether or not to discard vials of vaccine.

Advocates were able to actually quantify the cost savings attributable to VVMs by reducing vaccine wastage, a significant cost to immunization programs. This is an important advantage over products that claim generally to ‘improve quality...lots of things can improve quality’.

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xlvIII Interviews on September 29, October 9, and October 17, 2014 with people involved in the development and scaling of VVMs.
xlv Interview with PATH representative on September 29, 2014.
xlvII Frost and Reich 2008.
xlv Frost and Reich 2008.
xlvIII Interview with PATH representative, October 9, 2014.
The expense of adding VVMs is largely borne by vaccine manufacturers. Though they were initially skeptical, a couple of factors succeeded in convincing them to include the VVM. First was the role of UNICEF Supply Division (SD) and GAVI as demand aggregators. UNICEF SD is the procurer of vaccines for most low-income countries, and GAVI is the financier.\textsuperscript{a ix} When both bodies included VVMs in the minimum set of requirements for tender, vaccine manufacturers were forced to consider inclusion.

Attempts to scale VVMs further benefitted from a changing vaccine market. Because competition among manufacturers was on the rise, they were more responsive to UNICEF’s request to include VVMs.\textsuperscript{1} Further, the cost of adding VVMs was probably less for new manufacturers than for those that had traditionally produced vaccines.

For VVMs to achieve global scale, supportive policies were required at the global level. In 1999, WHO and UNICEF issued a joint statement advocating the inclusion of VVMs on vaccines.\textsuperscript{li} UNICEF included VVMs as a minimum requirement in its 2002-2003 bid for global tender for new vaccines. UNICEF’s action was further strengthened by GAVI including VVMs as a minimum requirement in its first request for proposals to introduce underutilized vaccines.

Temptime’s willingness and ability to iterate, making ongoing adaptations and improvements in response to stakeholder feedback and the needs of specific vaccine manufacturers, was critical. Different vaccines and vaccine manufacturers had unique labelling systems, and manufacturers were unhappy about the requirement to introduce a new labelling system for VVMs into their vaccine production. In response, Timplite agreed to work with each manufacturer to develop a labelling system that suited their needs.

PATH played a critical project management role, driving the VVM through the early product-development process. This included identifying and testing product candidates, bringing partners to the table, and persuading the VVM producer, Timplite, to stay involved, when the company feared the product was not viable. PATH even provided Timplite a loan in 1993 to purchase special labelling equipment so that they could print VVMs directly on the manufacturers’ labels. PATH’s work was made possible due to funding through US Agency for International Development’s (USAID’s) HealthTech program and other sources.

\textbf{TIMELINE}

\begin{itemize}
\item \textbf{1979:} Staff at WHO’s EPI called for a heat-exposure indicator for use at the lowest levels of the cold chain.
\item \textbf{1991:} Suitable product identified and ready for introduction on all UNICEF-supplied OPV vaccines.
\item \textbf{1994:} UNICEF includes VVMs in tender for OPV.
\item \textbf{1996:} All OPV producers complied with UNICEF request to include VVMs.
\item \textbf{1999:} WHO/UNICEF policy on the use of VVMs in immunization services.
\item \textbf{2000:} UNICEF includes VVMs in tender for all vaccines.
\item \textbf{2006:} 45/71 prequalified vaccines include VVMs.
\end{itemize}

\textsuperscript{a ix} Interview with PATH representative, September 29, 2014.
\textsuperscript{1} Frost and Reich 2008; Interview with PATH representative, October 9, 2014.
APPENDIX 4: MOBILE ALLIANCE FOR MATERNAL ACTION ANALOGUE

<table>
<thead>
<tr>
<th>TITLE</th>
<th>Mobile Alliance for Maternal Action (MAMA)(^{ii})</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDUSTRY</td>
<td>mHealth</td>
</tr>
<tr>
<td>CONTEXT</td>
<td>The MAMA partnership (USAID, Johnson &amp; Johnson, the mHealth Alliance, the United Nations Foundation and BabyCenter(^{®})) delivers health messages to new and expectant mothers in Bangladesh, India, and South Africa via their mobile phones. MAMA started in 2011 with a three-year, $10 million investment. MAMA also creates tools and resources for mHealth programs serving mothers in a variety of languages. The goal is that these messages can increase knowledge and change behaviors to improve maternal and child health.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>Managing cross-sector partners and their expectations, requirements, and agendas. Governance structure of MAMA itself. Launched without a solid structure in place. Cost of messages themselves.</td>
</tr>
<tr>
<td>LESSONS</td>
<td>Funding: Substantial up-front investment allowed MAMA to be strategic and flexible, and build a brand and partnerships that enabled its success. Collaboration: Engagement, collaboration with, and buy-in from stakeholders from the start, especially governments, was essential to MAMA's success.</td>
</tr>
</tbody>
</table>

\(^{ii}\) This information was gathered from the MAMA website and from an interview with a representative on October 2, 2014.
APPENDIX 5:
DISTRICT HEALTH INFORMATION SOFTWARE (DHIS 2) CASE STUDY

By adopting open standards and an inclusive, iterative design approach, DHIS 2 has been institutionalized within 12 countries, and is a key element of digital health strategies of an additional 34 countries.

BACKGROUND
The District Health Information Software (DHIS) is widely adopted and used to strengthen public health systems by improving the collection and use of health indicators. The Health Information Systems Programme (HISP), a global research and implementation network with major bases in South Africa and Norway’s University of Oslo’s Department of Informatics, developed and maintains the DHIS with key funding from the Norwegian Agency for Development Cooperation (NORAD).

HISP’s approach is participatory in nature, grounded in a belief in “empowering workers who were affected by or threatened by new technology, by exploring ways in which their influence over technological solutions could be ensured.”

DHIS has been designed in three release. The first version of DHIS was developed for one district in South Africa in 1996 after the fall of apartheid, and was based on the Microsoft Access platform. DHIS 2, the newest version launched in 2008, is a free, web-based, open-source information system developed in Java that can run on any hardware. DHIS 2 can be used for health data collection, validation, analysis, and presentation.

DEFINING SCALE
DHIS was designed for institutionalization in a given market and for smooth customization in order to replicate fairly easily across markets. According to HISP, DHIS is at scale when it becomes the national health management information system. Bangladesh, Burkina Faso, the Gambia, Ghana, India, Kenya, Liberia, Rwanda, Sierra Leone, Tanzania, Uganda, Zambia, and Zimbabwe are all using DHIS as their national health information system. DHIS is being used for programs and pilots in many other countries, bringing its global network of users to include 46 countries in Africa and Asia.

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Page on What is DHIS2. DHIS 2 website. Available at: https://www.dhis2.org/doc/snapshot/en/user/html/ch01.html#mod1_1.

Page on HISP. HISP website. Available at: http://www.mn.uio.no/ifi/english/research/networks/hisp/.
LEVERS FOR INSTITUTIONALIZATION

CASE FOR ACTION

DHIS was designed to meet post-apartheid South Africa’s needs: an inexpensive health management information system that could collect data at the facility level and be integrated into a decentralized health system. With 12 national-scale use cases, DHIS has demonstrated effectiveness in enabling more transparent, timely, and accurate data.

LEADERSHIP

HISP has championed DHIS from the early days of its innovation and design, through coordinating a global network of developers, advocating adoption by ministries of health and helping to implement throughout national systems. NORAD took the lead as a funder, enabling sustained resources to build a strong and flexible platform.

EFFECTIVE PRODUCT

DHIS 2 is designed to empower users with better access to and control over data at all levels of the health system. The flexible platform has customizable options for inclusion, developed by a global team working on the ground with its users. Being open-source, further customizations are always possible. The interface can be translated into eight languages and users can switch between languages easily. Data-validation rules help ensure data quality and accountability at the source.

VIABLE ECONOMIC MODEL

Committed, core funding from NORAD and PEPFAR and ties to the University of Oslo’s Department of Informatics enables HISP to refine the software platform over time.

SUPPORTIVE POLICY, REGULATIONS, STANDARDS

DHIS 2 is a free, web-based, open-source information system developed in Java that can run on any hardware. By adhering to existing global standards (e.g., HTML 5 and SDMX-HD), DHIS 2 is easy to learn and adapt, and is highly interoperable with third-party clients like Android apps, web portals, and other information systems.

EFFECTIVE PROGRAM MANAGEMENT

HISP’s philosophy led it to adopt a highly participatory and iterative development approach, involving rapid prototyping in the context of use with the participation of the users themselves.

HUMAN CAPACITY

HISP’s DHIS 2 Academies create a global community of users and experts, building national and regional capacity to design, implement, and maintain DHIS software. Participation in DHIS development helped foster commitment and skills in a broad set of graduate students.

TIMELINE

1997: HISP developed DHIS 1, a free, database application based on Microsoft Access, selected mainly because it was already common amongst potential users in South Africa.

1999: South Africa rolls out DHIS as national health information systems.

2001: DHIS 1 implemented in all provinces and districts in South Africa.

2003: HISP South Africa established.

2004: DHIS 1.4 developed and implemented with users in Cape Town, Botswana, and Zanzibar.

2006: The first implementation of DHIS 2 in Kerala, India.

2008: After improvements, DHIS 2 was implemented in more than 20 Indian states.

2011: First DHIS 2 Academy held in Dar es Salaam, Tanzania.

2014: DHIS is at national scale in 12 countries, and has implementations in 46 countries, and has held 14 DHIS 2 Academies.

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APPENDIX 6:
BBC MEDIA ACTION CASE STUDY

The emerging Indian national government approach to using mobile services for FHWs and families to improve maternal and child health offers helpful lessons in scaling up digital services. A committed set of champions in government and beyond designed and demonstrated the value of an iterative, structured approach to meeting key FHW and family needs with simple tools that integrate into existing health systems.

BACKGROUND

In 2010, the government of the Indian state of Bihar entered into a partnership called Ananya with the Bill & Melinda Gates Foundation to improve reproductive, maternal, newborn, and child health (RMNCH) services across the state, which has a population of nearly 104 million people, including 27 million women of child-bearing age.

One of several elements of the integrated Ananya program is a suite of mobile-enabled services designed and developed by BBC Media Action in order to communicate lifesaving information and help to shape healthy behaviors that tackle the main causes of RMNCH-related deaths. These services include:

- **Mobile Academy**, launched in May 2012, features a fee-based, interactive voice response (IVR)-based training course to refresh FHW knowledge of nine maternal and child health behaviors and to enhance their interpersonal communication skills with families in their communities.

- **Kilkari**, launched in September 2013, is a fee-based IVR subscription service for families, providing audio information on maternal and child health issues at appropriate times in the pregnancy and childhood lifecycle.

BBC Media Action developed these services using the Grameen Foundation’s modular, open source software, Mobile Technology for Community Health (MOTECH) as the back-end rules engine, database and reporting system. Thoughtworks was contracted to implement the system in India. OnMobile Global Ltd, one of India’s largest mobile technology solution providers, also played a critical role by providing the front-end, commercial-grade IVR software platform, which integrates the services with multiple mobile operator networks and billing systems.

Thus far, the results in Bihar are promising. As of June 2014, 38,512 FHWs, or 96 percent of the FHWs in the eight program districts in Bihar, were exposed to Mobile Academy and Mobile Kunji. Since September 2013, when Kilkari was launched in the eight priority districts in Bihar, more than 82,000 subscription requests have been received. Encouragingly, nearly 70 percent of families are listening to all the content they receive, and loyalty to the service is high. The Government of Bihar has agreed to scale up the services state-wide, and, with the support of BBC Media Action and the Gates Foundation, has now added 12 districts to the original eight.

In terms of impact on health-related behaviors, as-yet unpublished Ananya mid-line evaluation in Bihar suggests a strong positive correlation between the rollout of Mobile Kunji and changes in specific health behaviors, suggesting it is an effective complement to other job aids and tools used by FHWs. The study, which will be supplemented by a forthcoming evaluation specific to the BBC Media suite of services in Bihar, finds that 40 percent of the women who received a home visit from an FHW in the previous six months had been exposed to Mobile Academy and Mobile Kunji. Monthly, 48,000 people use Mobile Kunji, playing nearly 11 million minutes of content, and 28,000 FHWs have graduated from the Mobile Academy course, playing more than 7.6 million minutes of content. Since September 2013, when Kilkari was launched in the eight priority districts in Bihar, more than 82,000 subscription requests have been received. Encouragingly, nearly 70 percent of families are listening to all the content they receive, and loyalty to the service is high. The Government of Bihar has agreed to scale up the services state-wide, and, with the support of BBC Media Action and the Gates Foundation, has now added 12 districts to the original eight.

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exposed to Mobile Kunji, there was a 28 percentage point increase in the number who took recommended steps to prepare for birth (e.g., arranged transport, identified a hospital in case of emergency, saved critical phone numbers, saved money) than those who had not been exposed. Mothers exposed to Mobile Kunji had a 13.5 percentage point increase in the practice of complementary feeding for children aged 6-11 months. Early analysis concludes that exposure to Mobile Kunji adds substantial value in predicting behavior; is strongly correlated with delivery preparation and complimentary feeding; and serves as a good complement to other job aids and tools used by frontline workers.\(^{11}\)

Sustained take up and usage of the services in Bihar, historically one of the more challenging states in terms of health outcomes and ease of operations, led others to replicate the model. In 2013, the state governments of Odisha and Uttar Pradesh elected to adopt versions of this suite of RMNCH mobile tools. BBC Media Action launched Mobile Kunji and Academy in Odisha with support from the United Kingdom’s Department for International Development and from the state government in February 2014, and has just launched the services in Uttar Pradesh with support from the state government and the Gates Foundation.

Meanwhile, with the election of a new national government in April 2014, the national Ministry of Health received renewed support and impetus to encourage rollout of Mobile Academy, Mobile Kunji and Kilkari across all 35 Indian states and territories. In August 2014, the Indian government’s Ministry of Health and Family Welfare (MoHFW) approved the pan-India rollout of the three services. The Gates Foundation and BBC Media Action, in partnership with the Grameen Foundation and Dimagi, will develop a national toll-free platform for the services. BBC Media Action and the Gates Foundation also are working very closely with the ministries to develop and support the rollout strategy.

**DEFINING SCALE**

India’s sheer size often has others trying to define the concept of scale. BBC Media Action’s mobile program in Bihar arguably was a pilot, as it tested a suite of interventions in eight of Bihar’s districts before scaling up to the remaining 30 districts or replicating in other states. However, with nearly 40,000 FHWs in these eight districts, this program covered an objectively large population.

But perhaps more importantly, the Indian example demonstrates the value of defining scale as institutionalization. In Bihar, the overarching Ananya program, which featured BBC Media Action’s services, was only possible due to the committed partnership of the state government, including the Chief Minister of Bihar and the Secretary of Health and Executive Director of the State Health Society. Decisions by the states of Odisha and Uttar Pradesh, and subsequently by the national Ministry of Health, to fund and implement the services demonstrates significant commitment and investment in the services.

The table below offers some of the key lessons learned from the Bihar and pan-India projects, across each of the levers for institutionalization.

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<table>
<thead>
<tr>
<th>LEVERS FOR INSTITUTIONALIZATION</th>
<th>APPROACH</th>
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<tbody>
<tr>
<td><strong>CASE FOR ACTION</strong></td>
<td>The evidence that a large-scale mobile program for FHWs and mothers could succeed in a challenging operating environment such as that of Bihar was a critical factor convincing Odisha and Uttar Pradesh decision makers to include the program in their annual budget and program implementation plans. It is very unlikely the national government would have adopted the suite of services without the evidence of sustained uptake and usage by FHWs at scale in Bihar, as well as requests for funding by five additional states, to support its decisions.</td>
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<tr>
<td><strong>LEADERSHIP</strong></td>
<td>Senior-level government commitment and leadership, including the serving Chief Minister of Bihar and the Secretary of Health and Executive Director of the State Health Society, have been crucial to institutionalization in Bihar. Government leadership enabled replication in Odisha and Uttar Pradesh, and the leadership of the MoHFW led to the decision to introduce the services across India. BBC Media Action’s Head of ICT in India and National Creative Director India and their teams have played a recognized role as dogged champions with government, industry, and other stakeholders, providing structure for the effort and delivering the painstaking lobbying and negotiations required to seal the commitment of government, mobile operator, and other stakeholders. The Gates Foundation has played a recognized role in offering a sustained funding commitment, as well as in convening government and other stakeholders to ensure ongoing commitment across the partners. Senior, local champions from both BBC Media Action and the Gates Foundation played a key role in advocating and provide strategic support to the Ministry on a sustained basis for months.</td>
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<tr>
<td><strong>EFFECTIVE PRODUCT</strong></td>
<td>BBC Media Action undertook six rounds of user testing research across diverse districts to ensure the services and training approaches were appropriate for the local populations. For example, research indicated the importance of local languages and dialects, so the IVR scripts and voices were adapted to be appealing to the diverse populations in the program footprint. A key design feature in Bihar is simplicity; in particular, the IVR approach was adopted in recognition of the generally low level of literacy amongst the target population. The suite of products is likely to become ever simpler from the user perspective, featuring a single long code for use with any mobile operator network.</td>
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<tr>
<td><strong>VIABLE ECONOMIC MODEL</strong></td>
<td>In Bihar, BBC Media Action worked with partners to develop a rigorous business case, which was a critical success factor for encouraging mobile operator participation. All major operators in Bihar participated, and while they agreed to a significant reduction in the cost of a standard commercial IVR call, they participated because they recognized the value the services added to their commercial offerings. The economics of the national rollout have been tailored to reflect more of a public health financing approach to offering the service. The national government plans to pay the airtime costs for the services, reflecting a public sector financing—rather than consumer-based—approach to funding the services. But again, it’s been critical to demonstrate to the central government that the services can be cost-effectively managed at scale, with relatively manageable operational challenges.</td>
</tr>
<tr>
<td><strong>SUPPORTIVE POLICY, REGULATIONS, STANDARDS</strong></td>
<td>A national ministry of health mandate to adopt the services provides a green light to incorporate the services.</td>
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</table>
### EFFECTIVE PROGRAM MANAGEMENT

The India experience demonstrates the power of a strong approach to implementation, which those involved cite as a key success factor. Highlights include:

- Designing for scale from the outset, using tried and tested IVR technology that was already ubiquitous pan-India and leverages the handsets that health workers and families already own.
- Employing strong commercial skills, a robust business case was developed for each mobile operator to support negotiations to reduce tariffs. Detailed capital and operating expenses at scale were calculated and shared with the central government to support its decision-making.
- An iterative approach, both for the services themselves, as well as the program-delivery approach, such as learning over time to work more closely with early adopters in the communities and to leverage existing government FHW trainers to promote adoption.
- Supporting the national government with strong project management tools, practices, and capacity in order to define roles and responsibilities during the crucial start-up phase.
- Adopting a sequenced approach to rollout nationally, to enable lessons learned to inform subsequent deployments.
- Adopting an integrated approach in terms of building on existing, large-scale management information systems.
- Designing a centralized technology platform for delivering services across states, but tailoring content to meet the local needs in each state.

### HUMAN CAPACITY

In Bihar, BBC Media Action initially introduced Mobile Academy to 40,000 FHWs via a 15-minute teaser. Subsequently, they added a 15-minute training program at the health sub-center level. This latter approach, which involved working with existing government health supervisors, helped build both their capacity and buy-in for the long-run. They also learned that showcasing and rewarding success (rather than highlighting gaps) helped to encourage FHW adoption of tools.

The rollout approach features sustained monitoring and supervisory support to health workers on the ground, to encourage long-term and effective usage of the services.

### TIMELINE:

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2010</td>
<td>Project Ananya, including the BBC Media Action suite of mobile services for demand generation, begins in Bihar.</td>
</tr>
<tr>
<td>2011</td>
<td>Primary market research carried out, prototypes developed, user-testing conducted.</td>
</tr>
<tr>
<td>May 2012</td>
<td>Mobile Kunji is launched in eight districts in Bihar.</td>
</tr>
<tr>
<td>May 2012</td>
<td>Mobile Academy launched in eight districts in Bihar.</td>
</tr>
<tr>
<td>Sep 2013</td>
<td>Kilkari launched is launched in Bihar.</td>
</tr>
<tr>
<td>2013</td>
<td>State governments of Odisha and Uttar Pradesh agree to replicate Mobile Kunji and Academy.</td>
</tr>
<tr>
<td>2014</td>
<td>Mobile Kunji and Academy launch in Odisha and Uttar Pradesh.</td>
</tr>
<tr>
<td>April 2014</td>
<td>National Ministry of Health begins discussion of national-level services.</td>
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<tr>
<td>October 2014</td>
<td>National Ministry of Health announces plan to support national rollout of the RMNCH mobile suite.</td>
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</tbody>
</table>