THEORY AND PRACTICE

Monitoring and Evaluating Scale-Up of

Health System Innovations

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Table of Contents

Introduction

"Many interventions found to be effective in health services research fail to translate into meaningful outcomes in multiple contexts."

Damschorder et al, 2009

Hundreds of pilot studies of health innovations have been conducted around the world. Evaluations of many of them have revealed positive results on intended health outcomes. Yet few of these successfully-piloted innovations have been taken to scale, with fewer still scaled up sustainably. This is at least partially due to our lack of understanding of the scale-up process and to gaps in our knowledge of how to monitor and evaluate this process. Whether the innovation involves introducing new methods of contraception, decreasing HIV transmission from mother to child, or improving post-abortion care, taking 'what works' to scale is neither linear nor quick (Patton, 2011). The experience of the Institute for Reproductive Health, Georgetown University (IRH) scaling up Standard Days Method® (SDM) in five countries suggests that monitoring and evaluation (M&E) practices geared specifically toward the scale-up phase can increase the probability of achieving sustainable, large-scale implementation by providing real-time feedback designed to meet stakeholder needs.

The research-to-practice continuum can be conceptualized in three phases: pilot, scaling up, and large scale implementation. The particular M&E approaches and tools most appropriate and effective for each stage vary considerably. During the pilot phase, the M&E priority is to accurately measure the effect of an innovation, the complete package of interventions to be scaled up. During the scale-up period, the emphasis shifts to measuring processes to ensure the innovation is implemented with fidelity, at an acceptable pace, and achieves desired coverage, while maintaining the fidelity of the innovation. Once an innovation is operating at scale, that is, has become a routine part of services, efforts continue to measure fidelity, but may also include determination of population-level impact. M&E processes, indicators, benchmarks, and data collection methods need to reflect these evolving priorities.

The M&E process, as well as the information it generates, can support the scale-up process by helping stakeholders clearly define the innovation, maintain fidelity as the reach of the program expands, identify the need for adaptations, and ensure that the adapted innovation continues to produce the desired effect. A collaborative process of benchmarking, process documentation, and continuous feedback will engage stakeholders and involve new partners as services expand. This process can also help these stakeholders remain attentive and make midcourse adjustments as needed, to ensure that scale-up remains on track in a changing environment. M&E data can also verify that the evolving innovation maintains its effectiveness, and it can provide opportunities to advocate for investment and partnerships, while fostering discussions which reinforce the core values of the innovation.

Indeed, the systematic sharing of information generated through M&E can help multiple stakeholders, often based in different organizations and operating at different health system

levels, to manage and track the scale-up process. This includes monitoring the rate of program expansion, identifying the need for adaptations in the innovation, and ensuring the innovation maintains its fidelity and continues to produce the desired effect as the reach of the program expands in a changing environment. Involving stakeholders in M&E processes and sharing results also creates opportunities for diverse stakeholders to provide evidence in a variety of forums to advocate for continued scale-up investment and partnerships.

IRH recently completed a 5-year prospective case study of scaling up SDM in the Democratic Republic of the Congo, Guatemala, India (Jharkhand), Mali, and Rwanda. These studies, guided by the systems-oriented ExpandNet framework, have yielded a set of evidence-informed practices, methods, and tools to support M&E during the scaling up phase. These practices and tools have facilitated IRH's efforts to bridge the 'science–to-service' gap in scale-up and have been adapted and presented here for the benefit of other organizations. As a companion to the guidance and tools, this introduction presents relevant implementation and scale-up theory and conveys the critical importance of integrating and balancing process monitoring and outcome evaluation into each element of the scale-up process, starting from the early planning stages.

Scale-up Theory

> "Without theory it is hard to talk about practice and without practice, theory has no meaning."
>
> Moll, 1990

Theories that shed light on the scale-up process range from descriptive (how diffusion occurs) to dissemination-focused (how systematic and widespread sharing of information or policies or products will lead to scale-up) to active (ensuring end users begin using the innovation). The literature suggests that active approaches are more likely to result in the scale-up of innovations that retain essential elements (Simmons et al., 2007). Active approaches involve a specific plan for how, and with what supports, an innovation is to be scaled up. With a plan that includes benchmarks and clearly-defined actions designed to achieve these benchmarks, it is a roadmap of what needs to be monitored and evaluated.

Diffusion of innovation theory (Rogers, 1995) focuses on understanding **how ideas and innovations spread naturally across time and space**. This theory was developed through observations of how innovations are adopted and the qualities of innovations that may lead to greater uptake. Through the lens of this theory, an innovation is adopted throughout a system without organized support for its dissemination and spread. Individuals or organizations within a system can be categorized in terms of the time at which they adopt the

> "The diffusion literature takes us up to the point of deciding to adopt an innovation and says nothing about what to do next to implement that innovation with fidelity."
>
> *Rogers 1983*

innovation (Lanham et al., in press; Rogers, 1995). This theory has been primarily used as a descriptive tool, leaving implementation and scale-up to be conceptualized as more passive processes. This is a starting point for thinking about how innovations diffuse through systems, but is insufficient for guiding a planned scale-up process and thus cannot substantially inform scale-up M&E practice.

Building on diffusion theory, *dissemination theory* goes one step further, with **structured methods for spreading the innovation**, such as wide-scale provider training, mass communication, and social marketing. Here the innovation may be less static, and changes in characteristics of the innovation itself (i.e., complexity, observability, etc.) can facilitate dissemination. While dissemination is still a fairly passive method of implementation, it involves efforts to actively spread information about the innovation. However, relying solely on dissemination methods, such as publishing scientific papers and guidelines, delivering materials to clinics, or giving one-time workshops to local health workers, will be ineffective in implementing and sustaining an innovation in new regions (Fixsen, Blase, Metz, & Van Dyke, in press).

Implementation theory and practice support a more **active approach to successful scale-up**. Implementation theory arose from "…the recognition that even when information, ideas, or policies *do reach* practitioners or other intended users, and even if they profess that they accept and intend to use them, the effective application tends to wane, deviate from the intended use, or take on new forms" (p.152, Green, Ottoson, Garcia, & Hiatt, 2009).

While diffusion of innovation and dissemination theory offer insight into how to design an innovation so it will have a greater chance of being expanded, and how to create awareness about the innovation, implementation theory works with, and then moves beyond, the innovation to define the supports necessary to effectively and successfully implement and sustain the innovation. M&E is one of those supports.

Based on a synthesis of the implementation literature, active implementation has been defined as "a specified set of activities designed to put into practice an activity or program of known dimensions" (p. 5, Fixsen et al., 2005). The "specified set of activities" (i.e., implementation supports) to implement an innovation can originate from local leadership, be developed by resource teams, and be used to support provider competency and organizational change, in order to sustain the innovation (Fixsen et al., 2005). For example, national resource teams may work to leverage funding streams for district workers to implement an innovation in a community. This capacity may then support the training, supervision, and periodic monitoring of community-health workers actually implementing the innovation.

As discussed above, scale-up requires active processes to achieve sustainable success. Active implementation requires that resource teams work within existing systems to gain buy-in for an innovation and adapt non-essential components of the innovation to fit within existing context and climate (Yamey, 2012), monitor implementation, and adjust the course of implementation during scale-up. Accurate, timely information provided in a format that facilitates decision-making supports active implementation, helping the resource team make sure that essential elements of the innovation do not shift over time and informing

real-time adjustments. A variety of M&E tools which collect data across many points in time and at different system levels will be most useful to this process.

The ultimate goal in scaling up a health innovation is to create significant outcomes that address a significant problem at large scale. Having a **well-defined, effective, and scalable innovation** is not sufficient to achieve these outcomes. It is only when the innovation is coupled with **effective implementation supports, including M&E of both the scale-up process and the innovation** (Fixsen et al., 2005; Fixsen et al., in press; Paina & Peters, 2012), and **sufficient demand** for the innovation in communities where it will be implemented (Westley & Antadze, 2010), that socially significant outcomes can be observed and sustained over time. In other words, scale-up of a well-defined and effective innovation involves creating awareness and demand for the innovation (Yamey, 2012), as well as assessing implementation supports for an innovation to determine those that are in place and those that need to be developed. Accordingly, the M&E plan must include the establishment of benchmarks and regular assessments of scale-up components starting with the early planning stages, along with a collaborative process that engages stakeholders and involves new partners as services expand.

Active implementation recognizes that implementation does not occur in a vacuum, and that the process is embedded within many highly dynamic and interacting complex systems (Fixsen, Blase, Horner, & Sugai, 2009), including political, economic, and social systems, to name a few. These systems are characterized by varying rates of evolution, non-linearity, interdependencies, and often paradoxical behavior and unintended outcomes (Lanham et al., in press; Paina & Peters, 2012; Patton, 2011; Westley & Antadze, 2010). For example, the political and policy climate may differ across regions where an innovation is implemented and this climate is likely to shift over time (Paina & Peters, 2012; Simmons et al., 2007). Unanticipated consequences must be expected and examined. For example, an innovation such as performance-based financing that intends to reward clinics that provide certain services may result in their offering only the rewarded services, thus reducing options for their clients. The adoption of a flexible, but intentional, scale-up strategy can help anticipate and navigate system changes and ensure scaling up implementation is not blocked. Similarly, the complex and evolving nature of the systems in which innovations are implemented requires a M&E approach which addresses multiple levels, employing flexible, qualitative approaches to capture a holistic view of the scale-up process. Suggestions for meeting these challenges are discussed in the final section of this paper.

In conclusion, what does theory tells us about M&E of scale-up? M&E efforts must view systems, rather than individual outcomes, as the focus of change. M&E approaches which seek to understand and take into account the ways systems are organized and evolve over time will be more effective at guiding scale-up than typical mechanistic evaluation models. Newer evaluation methods derived from developmental evaluation and systems thinking provide more nuanced understanding of the emergent, dynamic nature of scale-up than formative and summative evaluation, which are most useful with established innovations. Complexity-informed M&E processes will facilitate adaptation of the innovation and the implementation process based on empirical evidence.

M&E of Scale-up

> "Linear approaches replicating implementation arrangements, costs, and impacts produced on a small scale in controlled situations commonly do not fit the dynamic and unpredictable ways health systems can expand and be sustainable."
>
> Paina and Peters, 2012

Poor definition of the innovation that is being scaled up, an unclear scale-up process, and inadequate information about what is happening on the ground, can all stand in the way of successful scale-up. Periodic snapshots of progress can contribute invaluable support to scale-up efforts (DeJong, 2001) and discussion of M&E results can keep stakeholders and implementers focused and engaged while facilitating mid-course corrections to the scale-up process. A lack of consensus on best practices and few tested tools for M&E of scale-up, though, limits the potential of M&E to support the scale-up process (Lemaire, 2011).

Interpreting change in health systems through the Complex Adaptive System lens

Increasingly, scale-up practitioners are turning to complexity-informed evaluation methods. These approaches take into account the dynamic environment in which health service innovations are expanded, and are therefore well-suited to providing information to guide adaptation and scale-up. Within complex systems, unexpected events and their effect on the scale-up process or health outcomes may go unnoticed without frequent monitoring that pays careful attention to evolving systems.

M&E tools are needed to examine the extent to which essential elements of an innovation are implemented during scale-up (innovation fidelity), as well as to monitor the scale-up process itself, while accounting for adaptation in evolving environments. Information in these two crucial areas is needed to know whether an innovation, as it was intended, was scaled up. Without regular data informing the scale-up process, an innovation may 'fail' in a new environment, and the resource team may never know why or understand what went wrong. Additionally, actual monitoring of the scale-up process allows for 'kinks' to be worked out during implementation.

Complex adaptive system analysis…

✓ Is non-linear

✓ Looks at emergent characteristics

✓ Explores unintended consequences that can undermine scale-up

✓ Pays attention to local context, incentives and institutions

✓ Uses tools of network analysis, systems thinking, path analysis, tipping points and more!

Figure 1 represents an example from IRH's work of scaling up SDM with a range of activities to monitor scale-up within a health system. The Y axis represents institutionalization – integration of the innovation into systems and norms. The X axis shows a series of activities which were monitored related to the expansion of services, such as training of providers, demand for the innovation and actual uptake of SDM.
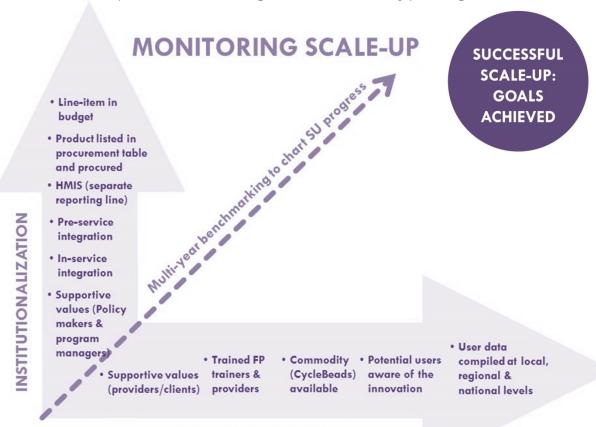
Figure 1 Monitoring institutionalization and expansion:
Example of wide-scale integration of a new family planning method

While a variety of indicators to measure institutionalization and expansion must of course be identified from the outset, there is another crucial set of questions:

- How will the innovation and scale-up process be monitored?
- What will be appropriate benchmarks?
- Who will do the monitoring? How often will it occur?
- What methods and tools are appropriate given the unique local context?

Scale-up theory suggests that the scale-up process almost always takes place in complex systems with emerging characteristics. In such settings the outputs and outcomes that seem prudent to measure initially may turn out to be less useful over time. While traditional formative (process) and summative (outcome) evaluation is useful once an innovation has been established and scaled up, M&E during scale-up calls for different evaluation approaches. One

such approach, developmental evaluation, offers a fresh and dynamic perspective on evaluation and explicitly takes complexity and use of M&E information into account. A main tenet of developmental evaluation is that it seeks to gain an understanding of the emergent dynamics and interactions that occur during implementation (Patton, 2011). Developmental evaluators themselves are not usually external to the innovation and implementation process but are part of the scale-up process. This not only gives the evaluator intimate knowledge of the innovation and context for implementation but also access to stakeholders who are engaged in the process. It also allows for the learning that takes place through evaluation to be immediately applied. The evaluator's primary function is to elucidate team discussions with evaluative data and logic, and to facilitate data-based decision-making during the expansion process. Developmental evaluation intersects well with the ExpandNet framework. Patton (2011) suggests that those who monitor implementation be a part of a team much like the resource team described by ExpandNet (see below) and others. Additionally, from a developmental evaluation standpoint, systems – rather than the particular innovation – are viewed as the focus of change rather than the discrete intervention itself. This perspective is reflected in the ExpandNet focus on building system capacity during scale-up. Lastly, both Patton (2011) and ExpandNet emphasize the importance of taking local context into account. Scale-up will likely be unsuccessful without consideration for contextual changes.

Linking Scale-Up Practice and M&E Practice

Within international health, similar but differing definitions of scale-up have been suggested (Billings, Crane, Benson, Solo, & Fetters, 2007; Binswanger, 2000; Bloom & Ainsworth, 2010; Nyonator, Awoonor-Williams, Phillips, Jones, & Miller, 2005; Picciotto, 2004; Yamey, 2012) along with various conceptual models illustrating how scaling up occurs (DeJong, 2001; Hardee et al., 2012; Paina & Peters, 2012). While there is no unifying model guiding the scale-up of health services across innovations, IRH has found ExpandNet's framework for scaling up instrumental in supporting a process which will lead to sustained large-scale implementation (Paina & Peters, 2012; Simmons, Fajans, & Ghiron, 2007). This model provides a simple heuristic framework and language to help scale-up practitioners organize scale-up planning, implementation and M&E.

Models of scale-up do not typically include detailed discussion of M&E. Here, we present the conceptual framework for scaling up developed by ExpandNet (Figure 2), and discuss ways to more explicitly include M&E into the framework.

As defined by ExpandNet, scale-up involves:

> Deliberate efforts to increase the impact of health service innovations successfully tested in pilot or experimental projects so as to benefit more people and to foster policy and program development on a lasting basis.
>
> Simmons et al., 2007

From this definition, it is clear that scale-up focuses not only on having a larger presence, but also on expanding and sustaining the impact of successful innovations (Bloom & Ainsworth, 2010).
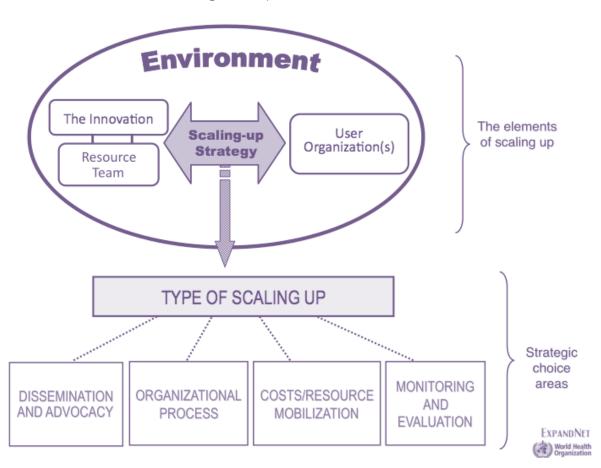
Figure 2 ExpandNet framework

ExpandNet's scale-up framework includes five elements of scaling up, as well as various strategic choice areas that must be considered in developing a scaling up strategy. M&E can be viewed as an integral part of the elements of scaling up and the strategic choice areas that comprise the scaling up strategy.

Elements of scaling up and M&E

First, an innovation must be well-defined during the pilot and then maintained throughout the scale-up process. While changes to the innovation may be made from pilot to scale-up, the essential elements must remain constant, as they are key to the innovation's effectiveness. A well-defined innovation allows for practitioners to monitor innovation fidelity (whether the innovation is being implemented as planned, including the values inherent in the innovation) and implementation fidelity (whether key implementation supports, such as staff training for the innovation and administrative support, are being addressed). As the innovation is adapted for

large-scale implementation in new settings, evaluation research may be needed to determine whether the new, usually simplified, version of the innovation is still efficacious.

> *SDM Scale-up Experience:* In the case of IRH's scale-up case study, the innovation was SDM. Country teams worked with stakeholders to carefully define the innovation 'package' which included not only CycleBeads, the tool that helps users keep track of their fertile days and user instructions, but also provider training, a specific counseling protocol which addresses couple and partner issues, and availability of barrier methods and values such as informed choice and gender equity. The actual family-planning method remained unchanged from pilot studies through the scale-up process. However, as the SDM innovation was adapted for large-scale implementation and integrated into existing service systems, changes were made to further simplify client and provider materials as well as training curricula and counseling procedures.

Second, in an active implementation context, the *resource team* refers to those who facilitate the scale-up of the innovation – they take the active steps to move the scale-up process along. The team may be composed of researchers, representatives of user organizations, decision-makers, or service providers, among others. The importance of a resource team to facilitate implementation has been emphasized across disciplines (Fixsen, 2012; Lemaire, 2011; Simmons et al., 2007).

> *SDM scale-up experience*: The resource team to scale up SDM into FP programs began small in each country, consisting of one or two IRH staff and a few individuals who had been involved in pilot activities. In subsequent expansion phases the resource team grew and changed over time to include representatives from additional organizations and new stakeholders that gained expertise in SDM as they became involved in scale-up efforts.

Third, the *user organization* represents those who are expected to implement the innovation on a large scale. The user organization could be a ministry of health, multiple community-based organizations, or a network of institutions. Taken together, members of the resource team and user organizations represent the stakeholders who must be involved in designing the M&E plan (defining indicators, selecting methods, etc.), interpreting results and taking action based on the data. Full participation in the M&E process will enhance their evaluation capacity and their ability to think systemically, critical skills for expanding and sustaining effective health innovations at scale.

> *SDM scale-up experience*: Many user organizations – those integrating or expanding SDM services – were involved in scale-up discussions and activities from the beginning, starting with the process of defining the innovation package and scope of scale-up and establishing benchmarks and operationalizing indicators. As user organizations became more closely immersed in scale-up activities, many transformed into resource organizations and actively contributed as experts to the scale-up process.

Fourth, the *environment* refers to conditions or institutions outside of the user organization that can influence the scale-up process. Taking the time to understand the unique context in which the innovation is being implemented allows implementers to make modifications to the

innovation, or to the scale-up strategy. Flexible, qualitative methods, such as process tracking, focus groups and in-depth interviews, and environmental scans / key event tracking can shed light on the changing environment.

> *SDM scale-up experience.* In the case of IRH's scale-up work, many tools were used to scan the constantly evolving environment and adapt scale-up implementation to changing conditions. Baseline key informant interviews to gauge stakeholder perceptions of the environment in each country allowed the resource team to identify political and resource obstacles on the road to successful scale-up and design approaches to overcome them. Annual discussions were also held with resource team members to shed light on changes in the environment that would influence scale-up processes. A key events time line, in which significant elements of the environment were charted, along with scale-up benchmark accomplishments, provided a visual tool to help track changes in the environment (Figure 3).
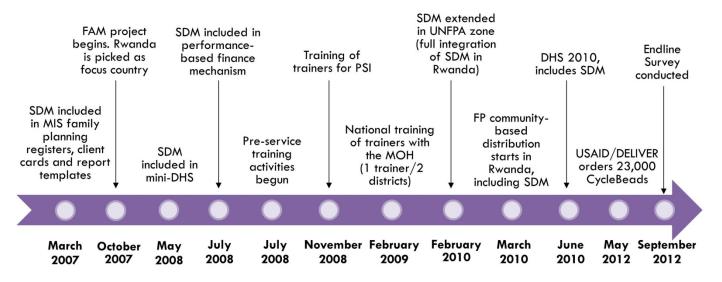
Figure 3 Rwanda Events timeline

Strategic choice areas and M&E

Fifth, a *scaling up strategy* must be developed based on the analysis of the above four elements. The strategy includes plans for how to implement the innovation at multiple levels (policy, program, and service delivery), considerations for how to advocate for the innovation, the organizational processes involved in implementation and the costs and resources needed. There are three types of guided scale-up featured in the ExpandNet framework. Horizontal scaling up focuses on replicating and expanding the impact of innovations to more people; diversification involves adding components to existing innovations; and vertical scaling up focuses on creating sustainability of the innovation through political or legal action (Simmons et al., 2007). Developing and implementing a robust, comprehensive M&E plan will help practitioners operationalize their scale-up strategy. The M&E plan allows for well-defined benchmarks to be set and progress towards established goals to be tracked that include both

the expansion of services (horizontal scale-up) as well as integration of the innovation into systems to achieve sustainability (vertical scale-up).

Using collected M&E data, rapid feedback cycles allow the research and user teams to make systematic changes to the innovation and scale-up process. Gathered over successive points in time, data is fed back to the resource team and shared with stakeholders at all levels. Data may lead to discussions about how to improve, adapt or simplify aspects of the innovation, when to modify necessary implementation supports, or how to garner more demand for the innovation. Decisions may then influence non-essential components of the innovation, scale-up process, or a variety of implementation supports.

> *SDM scale-up experience.* Early in the scale-up planning process, the resource team in each country decided on performance targets over the five year scale-up period (e.g., quality SDM services available in 90% of public and private health facilities nationwide) and measurable annual performance benchmarks were then developed. Indicators included horizontal scale-up components (e.g., proportion of facilities incorporating the innovation in their activities, estimated number of individuals trained to counsel clients in SDM use, number of local organizations with the capacity to undertake SDM-related activities without technical support), as well as vertical scale-up (e.g., number of key FP policies, norms, and guidelines that include SDM, number of pre-service education institutions including SDM in FP curricula, number of donors including SDM in procurement lists, integration of SDM into FP HMIS and more). Once the benchmarks were established, specific, measurable indicators were identified to measure progress toward achieving the benchmarks. A database was designed in Microsoft Access to facilitate the collection of data to monitor progress toward achieving the benchmarks. Traditional outcome or impact evaluation tools were also used to measure scale-up success, including a facility assessment, provider and community health worker surveys and household surveys. Together, these results created a snapshot of the status of SDM scale-up at baseline and midline to guide planning and adjustments in scale-up strategies.

A strong M&E system for scale-up encourages a planned, deliberate, and active process, which is more likely to achieve success in implementing and sustaining the innovation over time. Following this approach, implementers and stakeholders work together to identify what is needed to expand and sustain the innovation, collectively setting and then monitoring benchmarks along the way; as well as collecting data to determine whether the innovation is implemented with fidelity and is having the expected impact at scale.

Tips for M&E of Scale-up

> "We are faced with the paradox of non-evidence-based implementation of evidence-based programs."
>
> Drake, Gorman & Torrey, 2002

Throughout this introduction the importance of a planned, but flexible scale-up process, accompanied by strong M&E has been underscored in many ways. Periodic data collection translates into guideposts along the scale-up process that can keep the essential innovation components moving along the road to effective scale-up.

1. **Define the innovation AND the implementation and scale-up process**
   Implementation theory suggests that a clear picture of key innovation components and the scale-up process (including well-defined benchmarks) will improve outcomes for large populations. It is important to develop consensus with stakeholders about the essential components of the innovation and the supports necessary to improve the organizational and systems environment for implementation. Have a clear process for scaling up along with a clear picture of essential innovation components in order to improve outcomes for large populations. Setting measurable benchmarks and indicators along with routine progress data is essential.

2. **Measure program fidelity AND scale-up process**
   Don't lose sight of *what* is being scaled up. Process monitoring is generally well-implemented, but monitoring program fidelity is less common. Monitoring data may accurately capture essential program elements only if there is a clearly defined innovation. Fidelity monitoring allows timely adjustments to improve adherence.

3. **Be flexible**
   The flexibility of process tracking allows for the adaptation of methods to adjust to emergent outcomes of interconnected, evolving systems. If new health districts emerge during a scale-up period, outcome indicators may need to be adjusted. Expect the unexpected and once discovered incorporate it into your M&E process.

4. **Use information from existing M&E structures and set up additional processes to maximize information utilization over the course of scale-up**
   Remember that scale-up will be a multi-year process with multiple, changing stakeholders and plan for the long-term. Be on the lookout for secondary data to use in monitoring, (e.g, monthly health service statistics and larger scale studies conducted by other organizations such as SPAs and mini-DHS). These data can inform the status of scale-up and signal issues and problem areas. Small studies may be needed to complement existing data.

5. **Context is key**
   A scale-up goal may be meaningful to stakeholders in one setting, but not another. Diverse contexts, values and beliefs require unique goals, benchmarks and M&E approaches. Moreover, it is essential to understand the context to inform future implementation.

6. **Think long-term and consider multiple levels**
   Collect data frequently from multiple levels over longer periods of time. These data will reveal the effect of scale-up, allow for implementation efforts to be focused on specific systems, and help the team make midcourse changes while keeping an eye on integration and sustainability.

7. **Make M&E a central function of active implementation**
   Employ and measure active implementation supports to build the capacity of systems to sustain the innovation, to train practitioners to implement the innovation, and to incorporate the innovation into key policies at multiple levels. Without active implementation, an innovation is unlikely to be sustained over time. M&E supports active implementation through feedback cycles that bring together stakeholders to examine data and determine where adaptations are needed.

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