The IMPLEMENTATION STRATEGY for a Digital Health Tool Influences User Engagement

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Introduction

Digital health tools should not only be effective in clinical trials, but should be implemented and integrated into the healthcare ecosystem without adding undue burden for patients and the care team. In fact, the implementation process is critical for activating users and promoting appropriate engagement with the system, thus leading to desired outcomes.

BlueStar®, the first FDA-cleared digital therapeutic for type 2 diabetes (WellDoc, Inc., Columbia, MD) is comprised of a highly sophisticated platform that coaches patients based on their providers' specific treatment plan and sends clinical decision support back to the providers using the user-generated health data. Based on several programs using various care models, we wanted to generalize an implementation framework and view how the implementation strategy has the potential to influence user engagement and outcomes.

Methods

For the purpose of this analysis, four implementations of BlueStar were examined in three models: a health care provider model, a diabetes educator model (two different implementations – United States & Canada), and a health plan model. In the first model, BlueStar from their healthcare providers and a practice-based "digital champion" assisted patients with activation and configuration of BlueStar. In the second model, certified diabetes educators provided the digital tool to the patients. In the third model, the digital tool was distributed via a direct-to-patient email from a large, national health plan for Medicare enrollees. The user data was collected electronically and de-identified according to WellDoc data policies.

Results

As we worked with the different models, a series of steps evolved that included business processes, the best clinical and software practices, people skill development, and performance metrics or outcomes. The organization of these steps was informed by the *Supply Chain Operations Reference (SCOR) model*[1], an industry standard for defining a standard set of nomenclature, processes, configurations and metrics for different manufacturing supply chains.

Identification: The practice or program determines the objectives for implementing the digital therapeutic based on organizational goals for both business and health improvements. This results in criteria for identifying end users.
Enrollment: The method of outreach to potential users may include electronic, telephonic, paper, and point-of care activities that are HIPAA-compliant. An organization may select single or multiple approaches.
Activation: The app download and user registration process that includes terms & conditions and follows best practices for security and privacy.
Configuration: Entering profile information specific to the user's treatment plan and self-management goals supports individualized, contextualized mobile messaging feedback, tailored education, sharing of patient generated data that supports focused conversations between users and their care team.
Support: This includes automated and people strategies to engage users in starting and continuing to use the product to achieve outcomes
Outcomes Continuum: Initial Engagement (Activation) ➔ Ongoing Engagement (Persistence) ➔ Clinical & Cost Outcomes [2,3]

Model	Implementation Steps					Insights
	Identification	Enrollment	Activation	Configuration	Support	Outcomes
Health Care Provider	**Practice objectives** • *clinical* • *behavioral* **Population characteristics** • *demographics* • *technology literacy* • *disease specific self-management capabilities* **FDA indications for use**	**Point-of-care** *Users at primary and specialty care practices enrolled at point-of-care (POC)*	**Digital champion** *A practice-based digital champion supported the integration of BS into visit workflow and directed the use of the user-generated data report to care team members for treatment optimization and focused conversations*	**Medication setup** • *Metabolic meds* • *Reminders* **Health information & standards of care** • *ABCs* • *Exams* **Set up plan for sharing data with care team** • *Office visit* • *Med management*	**Face-to-face** *Provider and staff utilizing user data* **Virtual on-demand** *BlueStar Customer Care and care team* **Virtual programmed** *BlueStar Customer Care*	3141 Users with 24 engagements/week Engagement was higher with age and complexity of treatment regimen. Significant improvement seen in both laboratory measures (A1C) as well as patient generated data (BG values, fewer hypoglycemia entries). Engagement with food feature was highest, followed by blood glucose. 70.3% of users configured the system to their diabetes medications.
Diabetes Educator **(US & Canada)**	**Service objectives** • *clinical* • *behavioral* **Population characteristics** • *demographics* • *technology literacy* • *disease specific self-management capabilities* **FDA indications for use**	**Point-of-care and virtual** *Users enrolled at POC as part of routine visit workflow or through remote email or telephonic outreach*	**Clinician activation** *Diabetes educator introduced the app and worked with individuals and population health services*	**Medication setup** • *Metabolic meds* • *Other meds* • *Reminders* **Health information & standards of care** • *ABCs* • *Exams* **Self-management plan** • *BlueStar Goals* **Set up plan for sharing data with care team** • *Provider outreach*	**Face-to-face** *Educator and patient utilizing user data together* **Virtual on-demand** *BlueStar Customer Care and care team* **Virtual programmed** *Local staff*	In one program driven by CDEs, there were 144 active users, average age 55 with equal engagement by men and women. Users with at least 2 A1C values had a mean 1.1 point reduction. In another CDE-driven program, users were divided into high engagers (>2.5x per week, n=96) and low engagers (<1x per week, n=76). High engaged users had an A1C drop of 1.6%.
Health Plan	**Program objectives** • *clinical* • *behavioral* **Population characteristics** • *demographics* • *technology literacy* **FDA indications for use**	**Email campaign** *The health plan invited identified members to participate via opt-in approach*	**Member self-activation** *User followed link in email invitation*	**Medication setup** • *Metabolic meds* • *Reminders* **Health information** • *ABCs* • *Exams*	**Face-to-face** *None* **Virtual on-demand** *BlueStar Customer Care* **Virtual programmed** *None*	Email without promotion resulted in lower engagement with BlueStar. Users average age 72 in this Medicare population. 67% of these users engaged with BlueStar via the web, versus mobile. Engagement averaged 21 times/week per user.

Conclusions

In the provider and the educator models, individuals were provided BlueStar mostly during face-to-face visits and in some cases by telephone. Enrollment and activation was straight forward. The support of the patients' own care teams fostered adoption. A minority of users did not enter their medications into the system, a critical aspect of configuration since the BlueStar interventions are specific to each user's treatment plan.

In the health plan driven model, without a marketing campaign or incentive program, only a small proportion of email recipients activated their accounts. Though virtual enrollment has a greater capacity to scale, it has the disadvantages of lower activation and a greater reliance on user self-configuration without the support of their care team.

The SCOR model provides a useful framework for the implementation of a digital health tool like BlueStar. This framework, along with the insights gained from various implementation models can be used to guide the effective integration of promising digital tools into clinical practice and health programs.

Based on our learnings, efforts to optimize and automate implementation support are in progress to address enrollment challenges and enable scalability across all implementation models. These implementation tools will enable organizations to rapidly introduce digital health tools into their program workflow, support adoption and ensure ongoing engagement for outcome achievement.

References

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American Diabetes Association.

78th Scientific Sessions · Orlando, FL · June 22 – 26, 2018

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