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, an industry standard for defining a standard set of nomenclature, processes, configurations and metrics for different manufacturing 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 and selecting for use.

**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 and conditions and follows best practices for security and privacy.

**Configuration:** Ensuring 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

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#### References

1. Mansur E. Shomali, 1, 2, Janice MacLeod1, and Malinda M. Peeples1
2. WellDoc, Inc. Columbia, MD and 3MedStar Health, Columbia, MD

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**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 straightforward. 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. For BlueStar, we are already working to rapidly introduce digital health tools into their program workflow, support adoption and ensure ongoing engagement for outcome achievement.

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**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.

**Health Care Provider**
- **Practice objectives:**
  - Clinical care
  - Specialty care
- **Behavioral Population characteristics**
- **Technology literacy**
- **FDA indications for use**
- **Point-of-care engagement**
- **Digital champion**
- **Medication setup**
- **Medication setup**
- **Face-to-face Provider and staff utilizing user data**

**Diabetes Educator (US & Canada)**
- **Service objectives:**
- **Clinical care**
- **Behavioral Population characteristics**
- **Technology literacy**
- **FDA indications for use**
- **Point-of-care and virtual engagement**
- **Telehealth**
- **Diabetes educator**
- **Medication setup**
- **Medication setup**
- **Face-to-face Educator and patient utilizing user data**

**Health Plan**
- **Program objectives:**
- **Clinical care**
- **Behavioral Population characteristics**
- **Technology literacy**
- **FDA indications for use**
- **Email campaign**
- **Self-activation**
- **Medication setup**
- **Medication setup**
- **Face-to-face Non-Patient/Provider utilizing user data**

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**Results**

- **Health Care Provider**
- **Diabetes Educator (US & Canada)**
- **Health Plan**

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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 plans 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.