

eHealth Partnered Evaluation Initiative - Evaluation of the Initial Deployment of VA's Annie Texting System (Annie Eval)

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## **Objective**

We describe the first evaluation of the VA's automated texting system (aTS). Consistent with an implementation-effectiveness hybrid 2 study design, our aims were to: (1) qualitatively and quantitatively assess implementation outcomes for the aTS; and (2) assess impact of the aTS on HCV clinical outcomes in a real-world setting.

## **Methods**

Our evaluation was guided by the Practical, Robust, Implementation and Sustainability Model (PRISM), which defines a set of factors for consideration when designing, implementing, sustaining and evaluating interventions.<sup>i</sup> PRISM posits that the extent to which an intervention achieves results can be linked to the four PRISM domains, namely the intervention's characteristics (via patient and organizational perspectives), the intervention recipients (via patient and organizational perspectives), the external environment, and the implementation and sustainability infrastructure.

## **Design**

This was a multi-site, mixed-methods, randomized, two-group hybrid type 2 study design comparing the effectiveness of usual implementation (UI) and augmented implementation (AI).<sup>ii</sup> Matched comparison (i.e., no intervention) sites helped to determine effectiveness of the aTS in aiding HCV treatment. The study was reviewed by the Institutional Review Board (IRB) at the Edith Nourse Rogers Memorial Veterans Hospital in Bedford, Massachusetts and determined to be a quality improvement study (VA Handbook 1058.05).<sup>iii</sup> The project was conducted from February 2017 through February 2018.

## **Setting & Participants**

The group of clinics selected reflects a purposive sample based on several criteria, including clinic size and complexity, and geography. HCV clinics were recruited via a national HCV provider email listserv and monthly HCV provider phone call. The seven HCV clinics selected were randomly assigned to either UI or AI, using set randomization, which, with small sample sizes, helps to achieve balance on a set of relevant characteristics – in this case, urban/suburban setting and on HCV patient volume.<sup>iv</sup> Two additional comparison clinics were selected purposively because they had similar patient volume, clinic complexity, and geographic locale to the other participating clinics.<sup>v</sup> Thus in total, data were collected from nine VA clinics: four AI clinics, three UI clinics, and two comparison clinics. Care teams within the HCV clinics had different compositions and involved pharmacists, nurse practitioners, registered nurses, and social worker to varying degrees.

## **Intervention: Text Messaging for HCV treatment**

At the time of implementation, usual care for HCV included starting a patient on daily oral medication for 8-16 weeks, and follow-up in-person visits, blood lab work, and medication refills at 2- or 4-week intervals. The aTS for HCV was intended to improve processes and outcomes of care, and satisfaction with care. The HCV texting protocol included reminder text messages about medication taking, appointment keeping, and laboratory completion, and motivational text messages to encourage continued engagement in treatment. To be consistent with the standard treatment processes, each of the seven clinics worked collaboratively with study team members (VY, KM, and national aTS program office) to tailor the HCV texting protocol to align with their clinic's workflow (e.g., adjusting messaging logic from 2 to 4 weeks for different treatment intervals). Motivational messages were supportive in nature and intended to promote self-management and increase feelings of connection to the treatment team.

Message content could be tailored for content (e.g., adding clinic name and phone number) and timing (e.g., adjusting time of day that medication reminder is sent) through patient and provider discussion at the time of aTS enrollment, or later to reflect patient preferences. Veterans who did not use the aTS received otherwise standard HCV care.

### ***Usual Implementation Facilitation and Augmented Implementation Facilitation***

Facilitation was employed to support adoption of the aTS at participating clinics, with facilitation delivered by a primary (VY) and a secondary (KM) external facilitator. During the four-month *pre-implementation* phase, the functions of the external facilitators included engaging local, regional and national stakeholders to garner support for the aTS. The *implementation* phase took place over six months and differed between usual implementation (UI) and augmented implementation (AI), as detailed below. The *post-implementation* (evaluation) phase took place over three months.

**UI clinics:** UI clinics received the start-up experience that VA designed for all new clinics instituting the aTS. This involved a live virtual demonstration of the aTS, and access to an aTS resource website that included promotional materials and training guides. UI clinics could receive troubleshooting assistance from the external facilitators by phone or email, but only if and when they reached out to the them.

**AI clinics:** In addition to the start-up experience for UI sites described above, AI clinics received an implementation toolkit, support for local champion development, and proactive outreach by the primary external facilitator. The toolkit was developed by our team based on a formative evaluation that involved visits to 5 VA medical centers around the country to conduct interviews with patients and clinical staff who were using a pilot version of the aTS for conditions other than HCV. The toolkit contained sections on evidence of texting in healthcare, gaining leadership and clinic support for technology like the aTS, use of champions to support aTS adoption, tips and tools on how to use the aTS, and aTS promotional materials to encourage clinic and patient participation. Each AI clinic received one in-person visit from the primary external facilitator early in their implementation efforts. Additionally, the primary external facilitator-initiated check-ins with AI clinic champions throughout implementation.

Facilitation was delivered via email, phone, and in-person. In the pre-implementation period, to establish rapport and trust, there was more emphasis on phone calls and in-person meetings, whereas during implementation, those modes were used less while use of emails increased. Facilitation calls lasted from 5 minutes to 90 minutes (40-minute average) and site visits by the external facilitator lasted two to four hours. The most common facilitation strategies employed were local technical assistance, assessing for readiness, site visits, identifying and preparing champions, developing and distributing educational materials, building a coalition, and tailoring implementation to context.<sup>vi,vii</sup> The template for intervention description and replication (TIDieR) checklist was used to guide intervention description (Additional File 1).<sup>viii</sup>

### ***Measures and Data Collection***

PRISM domains (implementation and sustainability infrastructure, intervention characteristics, recipients via both patient and organizational perspectives, external environment) guided the measures and data collection and are denoted in parentheses.

**Implementation Processes: Facilitation (Implementation and Sustainability Infrastructure).** The external facilitator (VY) logged facilitation events on a tracking sheet, including facilitation date, length of time, mode of delivery (i.e., email, phone call, or in-person visit), purpose, notes, and other observations. From the perspective of the primary facilitator, if multiple facilitation events occurred in one day, only one event per person, per day was counted.

**Implementation Outcomes: Texting Use (Intervention).** Providers logged the number of patients who were offered the aTS and noted whether patients enrolled or declined, including the reason for declining. The content of patient text message replies was extracted from the aTS portal. To be eligible for the texting protocol, patients had to be starting HCV medication treatment. There were four steps to initiate a patient on the aTS: (1) providers verbally offered patients the aTS, (2) providers registered interested patients in the aTS portal and assigned them the HCV protocol, and (3) once a patient was registered, the aTS would send an automated text message requesting the patient authenticate themselves by replying to this initial text message thus prompting the assigned HCV protocol to begin, and (4) patients actively text with the aTS.

**Clinical Effectiveness Outcomes.** Medication adherence was measured via patient text response rate, operationalized as the number of days of text-confirmed medication taking divided by the number of days

receiving medication reminder texts. Consistent with other adherence standards, an affirmative text response rate of  $\geq 80\%$  was considered high adherence.<sup>ix</sup> Clinical data, including HCV treatment regimen and duration, and lab dates and results, were extracted from VA's National HCV Dashboard with data from VA's Corporate Data Warehouse.<sup>x</sup> The goal of treatment is to achieve cure, or sustained virologic response (SVR), where there is an undetectable HCV lab result 12 weeks after completion of treatment.

*Questionnaires (Recipients, intervention, implementation).* Patients at each clinic completed baseline and follow-up (after 8-12 weeks of using the aTS) questionnaires. The comparison clinics followed the same schedule, though without any use of texting. Patient questionnaires covered the topics of self-rated health status, adherence, illness perception, health engagement and activation, technology use, experiences with the aTS (usability, usefulness, working alliance), and demographics.<sup>xi,xii,xiii,xiv,xv,xvi</sup> Provider questionnaires followed the same schedule and covered topics of technology experience, quality improvement culture, climate and readiness for implementation, satisfaction with current local HCV care processes, experiences with the aTS (usability and usefulness), and demographics.<sup>xvii,xviii,xix,xx</sup> Questionnaires were pre-tested for clarity, redundancy, and relevancy by two patients and four providers and implementation scientists independent of the study team.

For effectiveness outcomes measures, we combined patients who were using the aTS regardless of whether they were in UI or AI clinics. These were referred to as “texters”. In contrast, “non-texters” could come from UI or AI clinics (patients who agreed to participate in the project but never completed the last step of authenticating themselves with the aTS, and thus never received any text messages), as well as from the two comparison clinics that did not implement the aTS.

*Semi-structured interviews (all PRISM domains).* Qualitative semi-structured telephone interviews were conducted with patients and providers who used or were invited to use the aTS. Interviews were conducted in the follow-up period during September and October 2017. The interview guides were informed by PRISM domains (denoted in parentheses) and explored issues regarding barriers to and facilitators to aTS uptake and use (intervention; implementation and sustainability), usability and usefulness of the aTS (intervention), and how the aTS was experienced by patients and providers (recipients) in the course of treatment and daily practice (external environment). Interviews were conducted by members of the study team not involved in facilitation (BP, CG) and lasted about 30 minutes.

For each questionnaire or qualitative interview completed, patients received a \$10 store gift card to compensate them for their time.

### **Data Analysis**

Descriptive and bivariate analyses of facilitation log data were conducted to compare facilitation dose, comparing UI and AI implementation groups. Descriptive and bivariate analyses were conducted on provider and patient questionnaires, text message frequencies, and clinical data to assess differences between implementation groups (UI and AI) in implementation outcomes. We then compared clinical effectiveness outcomes between texters and non-texters. We examined patient progression through the aTS initiation process, by calculating the percent retained from one step to the next, by UI and AI implementation group. Chi-square tests were used to assess differences between the two groups. All analyses were conducted in RStudio Version 1.0.153 and statistical significance was defined as  $p < 0.05$ .<sup>xxi</sup>

Qualitative interviews were audio recorded, transcribed verbatim, and then analyzed using NVivo 11 software.<sup>xxii</sup> Thematic analysis of all qualitative data (interview transcripts, meeting notes, text messages) was conducted.<sup>xxiii</sup> PRISM domains provided the deductive *a priori* codes and other codes emerged with inductive coding. The triangulation of quantitative and qualitative data served as a final step of analysis.

## References

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- <sup>i</sup> Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *The Joint Commission Journal on Quality and Patient Safety*. 2008 Apr 1;34(4):228-43.
- <sup>ii</sup> Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*. 2012 Mar;50(3):217.
- <sup>iii</sup> Department of Veterans Affairs. VA Handbook 1058.05, VA Operations Activities That May Constitute Research. 2011.
- <sup>iv</sup> Efirid J. Blocked randomization with randomly selected block sizes. *International journal of environmental research and public health*. 2010 Dec 23;8(1):15-20.
- <sup>v</sup> Veterans Health Administration. VHA Facility Complexity Model 2017. <http://opes.vssc.med.va.gov/FacilityComplexityLevels/Pages/default.aspx>. Accessed Nov 2018.
- <sup>vi</sup> Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, Proctor EK, Kirchner JE. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science*. 2015 Dec;10(1):21.
- <sup>vii</sup> Rogal SS, Yakovchenko V, Waltz TJ, Powell BJ, Kirchner JE, Proctor EK, Gonzalez R, Park A, Ross D, Morgan TR, Chartier M. The association between implementation strategy use and the uptake of hepatitis C treatment in a national sample. *Implementation Science*. 2017 Dec;12(1):60.
- <sup>viii</sup> Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, Macdonald H, Johnston M, Lamb SE. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *Bmj*. 2014 Mar 7;348:g1687.
- <sup>ix</sup> Haynes RB. A critical review of the “determinants” of patient compliance with therapeutic regimens. In: Sackett DL, Haynes RB, editors. *Compliance with therapeutic regimens*. Baltimore, MD: Johns Hopkins University Press; 1976. pp. 26–39.
- <sup>x</sup> Department of Veterans Affairs. HIT Dashboard Workgroup Hepatitis C Virus Analytics.
- <sup>xi</sup> Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. *The Annals of Family Medicine*. 2008 May 1;6(3):246-52.
- <sup>xii</sup> Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Quality of Life Research*. 2009 Sep 1;18(7):873-80.
- <sup>xiii</sup> Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Survey Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.
- <sup>xiv</sup> Mayberry LS, Gonzalez JS, Wallston KA, Kripalani S, Osborn CY. The ARMS-D out performs the SDSCA, but both are reliable, valid, and predict glycemic control. *Diabetes research and clinical practice*. 2013 Nov 1;102(2):96-104.
- <sup>xv</sup> Davis FD. User acceptance of information technology: system characteristics, user perceptions and behavioral impacts. *International journal of man-machine studies*. 1993 Mar 1;38(3):475-87.
- <sup>xvi</sup> Horvath AO, Greenberg LS. Development and validation of the Working Alliance Inventory. *Journal of counseling psychology*. 1989 Apr;36(2):223.
- <sup>xvii</sup> Hannon PA, Helfrich CD, Chan KG, Allen CL, Hammerback K, Kohn MJ, Parrish AT, Weiner BJ, Harris JR. Development and pilot test of the workplace readiness questionnaire, a theory-based instrument to measure small workplaces' readiness to implement wellness programs. *American Journal of Health Promotion*. 2017 Jan;31(1):67-75.
- <sup>xviii</sup> Jacobs SR, Weiner BJ, Bunger AC. Context matters: measuring implementation climate among individuals and groups. *Implementation Science*. 2014 Dec;9(1):46.
- <sup>xix</sup> Wen KY, Gustafson DH, Hawkins RP, Brennan PF, Dinauer S, Johnson PR, Siegler T. Developing and validating a model to predict the success of an IHCS implementation: the Readiness for Implementation Model. *Journal of the American Medical Informatics Association*. 2010 Nov 1;17(6):707-13.
- <sup>xx</sup> Brooke J. SUS-A quick and dirty usability scale. *Usability evaluation in industry*. 1996 Sep;189(194):4-7.
- <sup>xxi</sup> Team R. RStudio: integrated development for R. RStudio, Inc., Boston, MA URL <http://www.rstudio.com>. 2015 Jun;42:14.
- <sup>xxii</sup> Bazeley P, Jackson K, editors. *Qualitative data analysis with NVivo*. Sage Publications Limited; 2013 Apr 25.
- <sup>xxiii</sup> Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: A hybrid approach of inductive and deductive coding and theme development. *International journal of qualitative methods*. 2006 Mar;5(1):80-92.