BACKGROUND

In 2008, the Center for Information Technology leadership estimated that PHRs can save as much as 11 billion dollars annually for payer-administered systems, like the VA(1). PHRs would do so through improved efficiency, patient activation and self-management of illness, and averted adverse treatment reactions. This optimism was based several assumptions, such as the belief that secure messaging would pre-empt in-person visits and facilitate timely identification of medical problems before more serious exacerbations. Another assumption was that PHRs would improve accurate health information exchange between providers from different health systems, thereby improving medication reconciliation and reducing duplicative services. As stated above, it was believed that PHRs could benefit both quality and cost while activating informed and motivated patients.

PHRs are a new technology and there is a small but growing evidence base indicating that support for these assumptions are mixed. In a secondary analysis of administrative data, Zhou et al. (8) found that diabetic patients at Kaiser Permanente who used their PHRs better managed their HBA1c levels and had overall superior HEDIS outcomes when compared to those who did not use a PHR. Though it is possible that patient factors, such as health literacy or activation, may have accounted for both initiation of a PHR and improved diabetes outcomes, the investigators did find a linear association between PHR use and improved outcomes. A more recent study from Kaiser Permanente comparing utilization before and after initiation of a PHR, found a small but clinically significant increase in office visits, telephone encounters, after-hours clinic visits, emergency department encounters, and hospitalizations in PHR users (6). As this was a large retrospective chart review, the authors could not comment on the need for the additional care or its impact on health outcomes. Grant et al. (5) conducted a randomized controlled trial of providing PHR access to 244 patients with diabetes mellitus. The PHR treatment arm did not show improvement in glycemic control relative to usual care, though they were more likely to have a medication initiation or dose adjustment at their next medical visit. Frisse et al. (4, 9) examined the clinical and financial impact of health information exchange on emergency department outcomes and found a decrease in hospitalization when doctors had access to the presenting patients complete health record. Tenford et al. (7) conducted a MEDLINE review of all research on the use of PHRs in promoting chronic disease management and concluded that “the evidence remains sparse to support the value of PHRs in chronic disease management.”

PHRs are a relatively new technology and most were made available without formal instruction to patients in how to use the website or how to integrate the technology into self-management of chronic illness. The secondary analyses of administrative data suffer two important limitations. PHR use is not random and likely to be related to health literacy and patient activation, which are associated with better health as well as greater utilization. More importantly, most analyses of administrative data have no information on how patients are actually using their personal health record. Therefore, the question remains about whether meaningful use of a PHR would yield greater health and lower cost.

SIGNIFICANCE

PHRs and Care-Coordination

One of the greatest potentials of PHRs is to improve care coordination (11). In a study conducted by Schoen et al. (12), adults with chronic illness who had seen a physician in the previous 2 years reported that 1) either test results or medical records were not available at the time of a scheduled visit or 2) the doctor ordered a duplicate test 22% of the time for patients with just one physician and 43% of the time for patients with four or more physicians. Such poor coordination is consistent across studies examining care coordination between primary care and specialists, inpatient and outpatient doctors, and between physicians and patients and their families (13). Though the VA is a leader in implementing a nation-wide EHR, it has yet to fully apply its strength in health information technology to improving care coordination with providers outside the VA system.

Co-managed or dual use care refers to when veterans receive care from both VA providers and from providers practicing outside the VA system. There is growing evidence of high rates of co-managed care within the VA. The 1999 Large Health Survey of VHA Enrollees indicated that 72.6 % of VHA enrollees had alternative health care coverage. In the 12 months prior to the survey, 36% used both VA and non-VA systems (14). A recent study of rural veterans found that 90.5% received care outside of the VA system, primarily because of an already established relationship with a non-VA provider or distance to the nearest VA facility (15). The impact of dual use on health outcomes is just starting to be explored, but it is likely it contributes to poorer outcomes

when care coordination is compromised. Wolinsky et al. (16, 17) found a 98% increased mortality risk for veterans with dual use based on both inpatient and outpatient services after adjusting for key covariates.

Blue Button and Care Coordination

Though many functions within My Health*e*Vet can be harnessed for care coordination, the Blue Button feature is uniquely suited to this purpose. Veterans can compile a complete health summary including both CPRS and self-entered information into one document or PDF. (See Appendix 1). This document can be provided to informal caregivers such as family members or health care providers and provide a convenient summary of most medications, recent laboratory results, wellness reminders, appointments, and providers. Evaluation of the Blue Button feature and its impact on health is a high priority to the VA as well as other federal providers of health insurance, such as TRICARE and Medicare. The Blue Button feature is also being launched in the private insurance industry including Kaiser Permanente and United Healthcare (18).

Between its inception and October 2012, there have been 655,850 unique users of the Blue Button feature with 71,850 unique users in the past month. In that same time period, there have been 2,631,297 downloads of the Blue Button file with 165,399 occurring in the past month (19). Though there is clear interest in the Blue Button among veterans, how they are using it and its impact on health outcomes remains unclear. Preliminary surveys of MHV users indicate that a minority use it to improve communication with or between their providers. Therefore, the My Health*e*Vet Program Office has collaborated with the eHealth QUERI in conducting a Blue Button Evaluation lead by Dr. Turvey (RRP 11-407). Given Dr. Turvey's interest in dual use, this evaluation focused on how veterans may or may not be using the Blue Button in care coordination.

PRELIMINARY STUDIES

In collaboration with the My Health*e*Vet Program Office Performance and Evaluation Workgroup, Dr. Turvey designed an online survey to be administered to veterans while they were using My Health*e*Vet. The American Consumer Satisfaction Index is an industry standard survey method to evaluate satisfaction and usability of websites (20). Veterans using My Health*e*Vet are sampled randomly using a 4% sampling rate and asked to complete a brief survey of their experience of the website.

Design of survey questions were informed by the Unified Theory of Acceptance and Use of Technology (21) and the Theory of Planned Behavior (22). The aim was to determine whether the low use of the Blue Button feature was because veterans didn't know about the feature (low knowledge), they knew about it but did not value it (perceived value/attitude toward behavior), they perceived that it was too complicated to use (perceived complexity/perceived behavioral control), or that they had other ways to organize and share their health information (relative value).

The response rate to the survey was 17%, yielding 22,756 online survey responses. Of these, 13,820 (60.7%) had never used the Blue Button feature (non-users), 8020 (35.2%) currently used the Blue Button (current users), and 916 (4.0%) had used it in the past, but no longer use it (past users). Blue Button use was slightly related to age ($p<0.001$) with 71% of the non-users being aged 60 or older, as compared with 69% of the past users and 71% of the current users. Blue Button current users were also slightly more likely to be men than women (35.5% vs. 32.4%; $p<0.007$), and less likely to characterize themselves as a beginner in using the internet (current users 2.9%, non-users 5.8%, past users, 5.5%; $p<0.0001$).

Reasons for not using the Blue Button: When veterans who never used the Blue Button were asked why, 59.6% reported that they were not aware of it. Of those who were aware of the Blue Button, 35.0% said they did not use the Blue Button because they did not know how to use it. Only 9.0% said they did not think the Blue Button was useful and 11.3% said they preferred to use other methods to keep track of their health care. Veterans who tried the Blue Button, but did not return, stated that the main reason they did not return was because they could not find the information they were looking for (n=916; 38.4%). When asked what types of information they wanted, 32% wanted their record from the military, 56% wanted their lab results, and 44% wanted to view their appointments –all three items recently or soon to be released and available in the Blue Button print out.

Care Coordination: Forty-four percent (n=10,038) of survey respondents reported having a non-VA provider. This rate was comparable between user groups. When asked how the VA and non-VA providers communicated, users, non-users, and past users all indicated that they were the one responsible for sharing the information between providers (50%), while only 17% indicated the providers exchanged information via phone, mail, or fax.

Current Users and Care Coordination: The majority of current users of the Blue Button indicated that they read it (62%) or saved it for their records (47.7%). Far fewer shared it with their VA provider (6.3%) or their non-VA provider (10.1%). Of the 3451 current users who have non-VA providers, 22% shared their Blue Button print out with this provider and 87.7% of these endorsed that the non-VA provider found it somewhat or very helpful.

These results suggest that low adoption of the Blue Button and its use in care coordination is due to low knowledge and low perceived behavioral control, not low perceived value. A large portion see non-VA providers, yet a minority actually use the Blue Button in care coordination in spite of the fact that veterans see themselves as primarily responsible for facilitating communication between VA and non-VA providers. However, of the current users who did share their Blue Button print out with provider, 87% indicated that the provider found it helpful. Blue Button non-users were asked about what types of things would lead them to try using the Blue Button and 64% endorsed that they would "definitely use the Blue Button" if a VA staff member or an easy-to-use booklet showed them how to use it.

One limitation of the ACSI survey is its low response rate. However, this rate is actually higher than that of many online surveys used to evaluate governmental websites and the descriptive characteristics of the respondents are comparable to that of MHV users in general. However, given that the respondents are already MHV users and have opted to complete an online survey, it is likely their rates of Blue Button use in care coordination are higher than the average MHV user and certainly the average veteran. To gain a broader understanding, the Blue Button Evaluation also included qualitative interviews of veterans not recruited by an online survey through My Healthe*V*et and VA and non-VA providers.

Interviews with Veterans and Providers: The Blue Button evaluation included qualitative interviews of 33 veterans, 10 VA providers and 8 non-VA providers about their experiences in care coordination and their opinion about the strengths and weaknesses of the Blue Button print out. Comparable to the veterans completing the online survey, veteran interviewees were not aware of the Blue Button, yet saw great value in it. One stated "If I did have an outside provider, I would definitely, uh, print and take that in. It's almost like my, ya know, health records for them." In general, non-VA providers expressed more dissatisfaction with care coordination than VA providers. When asked about contact with VA providers, one non-VA provider stated "I will say, in truth, that is one of the difficulties, sometimes working with vets, because they'll also go to the VA and see their primary care team there as well. It's almost like they're duplicating the care they get, and then they get medication there . . . and so we don't always get that information". Most VA providers felt that the Blue Button print out provided redundant information because they already have access to CPRS. Veteran self-entered information was more valued. Non-VA providers saw great value in the Blue Button print out though many were concerned with its length. When asked about the most important information to include in the Blue Button, they endorsed a medication list, most recent laboratories, and wellness reminders.

Based on this evaluation, a short usability study was developed to determine any difficulties with using My Healthe*V*et and specifically, the Blue Button feature in order to develop training materials to facilitate use. Eight male veterans with upgraded MHV accounts, who had never used the Blue Button feature, completed a series of tasks using My Healthe*V*et, including making a Blue Button print out (Appendix 2). All 8 participants had difficulty generating the Blue Button report on the first try and many needed guidance from the research assistant. Though discouraging, the nature of their difficulties informed both the online video and the training booklet developed for the study.

Both paper (Appendix 3) and online video training materials have been developed. The initial version of the video can be found at the URL posted below. Consistent with the preliminary findings regarding the Unified Theory of Acceptance and Use of Technology and the Theory of Planned Behavior, the training aims to address low knowledge and veteran perceived behavioral control to promote use of the Blue Button. Both start with a rationale for using the Blue Button. For those with non-VA medications, the training also includes how to

self-enter medications to form a complete medication list. Kim Nazi, Management Analyst for the Veterans and Consumers Health Informatics Office, and head of the My Health*e*Vet Performance Evaluation Workgroup, will communicate upcoming changes in My Health*e*Vet and the Blue Button feature so training materials will be modified as needed to remain current with future MHV changes.

USE: http://www.public-health.uiowa.edu/herce/Blue%20Button%20output/story.swf
OR: http://www.public-health.uiowa.edu/herce/Blue%20Button%20output/story.html

RESEARCH DESIGN

This is a pilot of a two-arm randomized controlled trial where veterans will receive either 1) an onlinetraining video and companion printed materials on the Blue Button; or 2) training on how to evaluate the validity of health information on the internet. The intervention arm will also include phone support for training and a telephone call one week before a visit with a non-VA provider to remind the veteran to bring the print out to their non-VA provider. The comparison arm will receive comparable contacts regarding the health information training. We are focusing on use of the Blue Button with non-VA providers, rather than VA providers, because it lends itself most to providing valued information in this aspect of care coordination. In the previous qualitative interviews, both veterans and VA providers valued far less the use of the print out for care coordination with VA providers because it provides information primarily taken from the VA medical record to which VA providers already have access.

Clinical trials of *e*Health interventions vary in whether or not usual care is the comparator. Although, it would be reasonable to compare this intervention to usual care, we want to collect data from all non-VA medical visits in order to understand how the Blue Button can impact a visit. Collecting this information in the comparison arm, without providing any health related intervention, may raise issues of credibility or reduce motivation for veterans to complete the latter assessments of the study. The comparison arm is similar enough to the intervention to make it credible, yet different enough that it will not necessarily yield the outcomes targeted in this study, such as printing out and sharing information available in the Blue Button with a non-VA provider.

As with all pilot studies, the main aim is to estimate the effect of the intervention relative to a reasonable comparison condition. However, this pilot is also needed to address three other methodological issues to establish feasibility for a larger trial. First, we are exploring innovative ways to measure what occurs during the medical visit with the non-VA provider. This pilot will establish feasibility and allow us to make any necessary changes before a full trial. Second, we will develop the methods and exact metrics to quantify redundant services. Our center, the Center for Comprehensive Access & Delivery Research and Evaluation (CADRE), has several investigators interested in characterizing redundant services in dual use situations that are collaborating on this proposal; however, most of this prior work was conducted through secondary data analysis. The pilot will allow us to test the methods for comparing treatment from two providers to determine duplication in the context of a clinical trial. Finally, this study includes qualitative interviews, assessments in the comparison condition, and additional support and coaching around the training that would not necessarily be scalable or desired in a large-scale trial of this training. However, at this stage of intervention development and evaluation, they are necessary to fully inform the final design of both the training program and an eventual large randomized controlled trial.

METHODS:

Sample: Fifty veterans who have not used the Blue Button feature and have a non-VA provider will be recruited from the Iowa City VA Health Care System. Based on earlier research that identified criteria for patients at risk for a medication-related problem (23), participants must be taking five or more medications as determined by medical record review. Eligible veterans will be sent a recruitment letter with a postage paid return postcard asking them to indicate whether they have a non-VA provider or have ever used the Blue Button feature. When contacted, the research assistant will confirm inclusion criteria and request the date of the next scheduled non-VA provider appointment. Only those with a visit upcoming in the next 3 months will be contacted by phone and will be included. In the qualitative evaluation, we were able to use comparable methods to find veterans who had non-VA providers and we expect similar success in this study. To complete the study procedures, participants will be required to have access to a computer with internet, phone, and

printer. Potential recruits will be told that this is a study that will examine how training on how to use the internet for health information can influence how patients communicate with their providers. This rationale is consistent with both treatment arms, yet does not reveal the main hypotheses of the study. At the time of enrollment, veterans will also be asked to complete a release of information so we may communicate with their non-VA provider and obtain a copy of their recent visit note, problem list, and medication list.

To best approximate the target population for this training, we will include veterans regardless of whether they are currently registered for My HealtheVet, though we will aim to recruit a balanced number of each in both study arms. If a veteran is not registered, we will facilitate enrollment prior to conducting the Blue Button training. The ACSI survey did not indicate large gender or age differences in Blue Button adoption. Nonetheless, we will aim to recruit at least 5 to 8 women in each treatment arm and an equal balance of veterans older and younger than 60 years-of-age. If we do not initially recruit a representative number of veterans who are minorities, we will conduct targeted recruitment to ensure inclusion of 5 or more in each intervention arm. Although a multi-site study would improve representativeness of this sample, at this point we will focus the limited resources of this funding mechanism on thorough validation of complex study methods.

The study statistician will develop a computer program to implement randomization grouped in blocks to ensure equal distribution in study arms by age, gender, and race. The study coordinator will maintain randomization assignments in sealed envelopes to ensure that randomization and recruitment of specific patients is not influenced by future assignments.

Intervention Group Training: If randomized to the training group, the veteran will receive written instructions and an e-mail with a link to the online training video. They will be instructed to review the materials and create a Blue Button print out. A postage paid addressed envelope will be provided with the request to send one completed copy of their Blue Button print out to the research team. This will serve as a check on whether the veteran completed the training and generated a print out. A research assistant will contact the participant by phone to determine if they are having difficulties with the program and to provide any further assistance needed to bring success. A log of who needed additional assistance to complete a print out will be maintained.

Although one goal is for the training materials to teach veterans how to use the Blue Button, it is also of interest if the veteran can meaningfully use the print out to improve care coordination. At enrollment, the date of the participant's next non-VA appointment will be collected. One week prior to that appointment, a research assistant will call the veteran to remind him or her to bring the Blue Button print out to that appointment. Though this adds a level of support and motivation beyond what is found in most promotional campaigns, it is appropriate at this stage of development in order to understand and estimate the impact of sharing the Blue Button print out on veteran and provider behavior. Therefore, we want to do all we can to insure the patient will bring the print out to their non-VA provider visit. In addition, we will mail to the veteran study materials to give to their provider to inform him/her of the study.

Comparison Group Training: The comparison group will be provided some written materials describing how to determine the validity of health information found on the internet using the PILOT criteria (Appendix 4). Upon enrollment in the study, the research assistant will present the training materials to the veteran and ask him or her to review them in the next two weeks. Comparable to the intervention arm, the associate will contact the veteran at two weeks to see if there are any questions about using these criteria and searching for health information. This will be repeated one week prior to the visit with the non-VA provider. The multiple contacts ensure comparability in exposure to the intervention arm and promotes credibility and motivation to provide the additional data collected about the actual visit.

Non-VA provider visit: Veteran participants will provide contact information for their non-VA provider. A letter informing the provider of the study with the provider appointment questionnaire (Appendix 5) and consent to obtain information for the veteran will be sent one week prior to the scheduled visit. The veteran will also be provided this letter and called approximately one week prior to their non-VA appointment as a reminder. He/she will be asked to present the information to their provider during the office visit. To facilitate participation, a waiver of signature of consent will be obtained from the IRB for providers. The provider appointment questionnaire contains a brief checklist about what occurred during the visit and includes a specific indicator for sharing of the Blue Button. If the provider indicates that the Blue Button was shared, some questions about its impact on provider behavior and satisfaction follow. The questionnaire will also

include a section where the physician can indicate if he or she would be willing to complete a 15 minute audio recorded qualitative interview about the medical visit. Although the proposed methods make some immediate demands on non-VA providers, we were able to recruit non-VA providers to participate in the Blue Button evaluation. It seems that this cooperation stems, in part, from their wish to discuss some of their frustrations in care coordination. There will also be a financial incentive to participate.

Provider and Veteran Interviews: Providers and veterans who agree will be interviewed briefly by phone about their experience during the medical visit with a focus on care coordination. (Appendix 6) Willing veterans will be interviewed regardless of whether their provider does an interview. We will plan to conduct these interviews within one week of the scheduled appointment. For visits where the Blue Button was shared, the interview will contain open ended questions about how the Blue Button print out had an impact on the visit and the strengths and weaknesses of information received. If the non-VA provider agrees to complete a qualitative interview, a separate consent letter will be provided at that time prior to data collection detailing the information to be obtained. Again, a waiver of signature of consent will be utilized with clear instructions that by completing the audio recorded interview that he/she is providing consent to participate.

Qualitative Data Analysis: Dr. Sarah Ono will lead the qualitative analysis for this study. Transcripts will be reviewed for accuracy, and imported into MAXQDA, a qualitative data management and analysis software package. (24) The qualitative lead and a research assistant trained in qualitative analysis will conduct a thematic content analysis to inductively characterize issues emerging from patient and physician interviews. Together with deductive themes based on the research objectives including specific themes relevant to the UTAUT or Theory of Planned Behavior, an initial codebook with overarching themes and their description will be developed and tested using 3 patient and 3 physician transcripts from each treatment arm. Coded segments of text will be tested for inter-rater reliability, and disagreements between coders will be compared and discussed until consensus is achieved. All transcripts will be independently coded by both team members, assigning text segments to corresponding codes. Inter-rater reliability will be checked periodically, and codes with poor reliability (percent agreement <0.90) will be reviewed until consensus is achieved. The codebook will be iteratively revised as new themes emerge; an audit trail will be recorded to track these changes. Results may inform minor changes in training or study design.

Outcomes Assessment and Statistical Analysis for the Primary Hypotheses: The primary outcome is whether or not the veteran brings the Blue Button to their visit with the non-VA provider. This will be determined by a form the provider is asked to complete during the visit where assessment of sharing of the Blue Button is embedded in a checklist of possible visit activities. If the provider does not return the form, we will contact veterans in both study arms and ask them if they gave their provider a copy of the Blue Button print out. Hypotheses #2 and #3 will address whether or not the print out improves medication reconciliation and reduces therapeutic duplication or unnecessary laboratories and will be based on comparison of VA and non-VA medical records as well as data collected from the patient and provider for the non-VA provider visit. These metrics will be calculated as described below. In addition to the main outcomes, we will ask veterans at study entry to complete a brief assessment packet that assesses 1) demographics, 2) veteran experience and comfort with using the computer and using My HealtheVet; and 3) a measure of patient activation (25). The relation of these constructs to study outcomes and intervention effectiveness will also be explored.

Hypothesis #1: Veterans in the Blue Button intervention arm will be more likely than those in the comparison group to share their Blue Button print out with their non-VA provider.

Outcome Assessment: We will determine whether or not the veteran shared their Blue Button print out based on the questionnaires returned after the non-VA provider visit. If the provider does not complete the form, we will gather this information from the veteran. The following analysis will be conducted 1) using only veterans where the provider completed the form and 2) using both provider and veteran report on whether or not the Blue Button was shared to determine if there is a large difference in effect size between the two methods.

Statistical Analysis: The primary statistical goal of this pilot application is to estimate intervention effect relative to an attention control, which may vary by a number of factors. The proposed study does not have adequate sample size to guarantee sufficient power to test hypotheses concerning efficacy. However, we can estimate intervention-comparator differences and variances needed to plan for a larger trial (26). Results of this study

will be compared with accepted standards of clinical significance to inform sample size calculation for a future study.

The outcome measure is simple dichotomous “Yes” or “No” variable and groups will be compared using a Pearson chi-square test. With 25 participants per group, and using a one-tailed p-value of 0.05, and aiming for 70% power, if the proportion that shared their Blue Button print out is between 20%-50% in the comparison group, a difference of at least 35 percentage points will be detected between groups. We do expect a large difference as the intervention arm will receive explicit instructions to present the Blue Button print out with a reminder one week before the actual visit. This pilot study will also provide a possible range of the expected effect size as measured by the 95% confidence interval of the odds ratio for sharing Blue Button print out.

Hypothesis #2: Veterans in the Blue Button intervention arm will have better medication reconciliation than those in the comparison group.

Medication reconciliation will be calculated by making two lists, one of the VA medication list current at the time of the non-VA provider visit. This will be taken from CPRS. The second list will be the medications documented in the non-VA provider’s medical record. We will obtain both the visit note and the medication list from the non-VA provider’s visit to make this second medication list. If the note does not indicate any medication change and there is none indicated on the form we ask the provider to complete, the non-VA provider’s medication list will simply be the final medications documented for that visit. If there is an indication of a specific medication change, either in the note, or in the form we request providers to complete, the discrepancy between the provider’s and the VA prescription for the changed medication will not be counted as an “unreconciled” medication.

Our metric for medication reconciliation will be based on reviewing both the VA and non-VA medication lists and determining the total number of distinct medications. A distinct medication is defined by 1) the type of medication and 2) the daily dose. Therefore, if both medication lists include citalopram 20mg qd, that will count as one distinct medication. If one medication list includes citalopram 20mg qd and the other includes citalopram 20mg bid, that would count as two distinct medications. As stated earlier, medication changes or additions made by the non-VA provider will not be counted as unreconciled medications and will not be included in the calculation of this metric. The final calculation of appropriate medication reconciliation will be calculated as the total number of distinct medications included on both lists divided by the total number of distinct medications. This way, the possible range is from 0 to 100 with 100 indicating perfect medication reconciliation.

The metric will range from 0 to 100, but we expect agreement between the two medication lists to yield estimates ranging between 0.50 and 0.90 based on prior research in medication appropriateness (27). A sample size of 50 allows for detection of only large effect sizes which may not be obtained for this outcome. This pilot study will be able to provide information on the distribution of number of distinct medications and the distribution of reconciled medications for the comparison group and the intervention group that will be needed to evaluate effect size and sample size for a larger study.

Hypothesis #3: Veterans in the Blue Button intervention arm will have few redundant or duplicative services than those in the comparison arm.

Prior research has quantified therapeutic and laboratory duplication, yet these are clearly difficult constructs to operationalize (27-30). Dr. Mary Charlton is currently a principal investigator for an HSR&D funded IIR entitled “Dual Use of VA and non-VA Healthcare Services in Veterans Younger than Age 65.” In this project, Dr. Charlton is examining dual use by combining VA administrative data with Blue-Cross/Blue Shield claims data in Iowa and Maine. She has agreed to collaborate and share the findings from her research to illuminate the best way to quantify therapeutic duplication and has provided initial guidance as described below.

Therapeutic duplication will be defined as concurrent use of more than one medication from the same therapeutic class, based on modified VA classes, according to the method published by Fitzgerald et al. (28) and more recently adapted by Chrischilles et al. (27). For laboratory duplication, we will identify all orders for labs occurring within the 6 months prior to the non-VA provider visit. For sensitivity analysis, we will compare

different intervals, e.g., 14 days, 30 days, 60 days. Since there are multiple indications for laboratory referrals, we will collect temporally associated diagnoses. Each patient will be assigned a dichotomous indicator for whether they received therapeutic duplication and/or laboratory duplication during their non-VA provider visit.

To validate these metrics, all instances of identified duplication plus a random sample of visits where no apparent duplication occurred will be reviewed by Dr. Peter Cram and Dr. Bonnie Wakefield. They will be blind to whether or not the visit met criteria for treatment redundancy and they will also be blind to the treatment arm of the patient whose visit is being reviewed. Their clinical assessment of presence of duplication will be used to validate the metric. If agreement is poor between these two raters and the criteria described above (Kappa < 0.80), the investigative team will meet to determine the source of the discrepancy and how to remedy it. This will include Dr. Charlton's input on how these discrepancies relate to her current work on dual use using a much larger sample size in administrative data. Through this process we aim to arrive at a validated quantifiable measure of duplication that can be scaled to a larger clinical trial.

Each patient will be assigned a dichotomous indicator for whether they received either therapeutic or laboratory duplication during their non-VA provider visit. Therefore, the analysis will be comparable to that for Hypothesis #1. Given this small sample size, it is possible that redundancy will not be common and if so, statistical tests based on alternate distributions may be explored.

Additional Measures: Upon entry into the study, veterans will be asked to complete an assessment packet that includes demographic variables, a brief assessment of experience and comfort with computer use (31) and use of My HealtheVet when applicable, and a measure of patient activation (25, 32) . Exploratory correlational and associational analyses will also be conducted to examine whether these patient factors influence retention in the study and response to the intervention.

DISSEMINATION PLAN

The first step in disseminating this intervention would be to conduct a large randomized controlled trial. However, eventual broader dissemination was considered in every step of developing this intervention. The online video can be placed on the My HealtheVet website or other VA websites at little to no cost. However, as many potential users of the Blue Button have limited computer skills, the paper based training is also available and can be distributed via mail or at VA clinics. Of course, a PDF of this paper manual can also be available on the web. For the purposes of the pilot study, there will be some phone support and a reminder to bring the Blue Button print out to the non-VA provider visit. However, we will be recording how many veterans were able to complete the training successfully without the phone support so, by the end of this study, we will have some idea about how much additional support would be needed in disseminating this intervention. For veterans who would need more support, the training would be brief and could be conducted as part of the PACT program. In addition, each VA medical center has a designated My HealtheVet Coordinator who could also conduct group or individual training sessions.

PROJECT MANAGEMENT PLAN

Project start up should be quick as the training is already developed and would need, at the most, some updates related to any recent changes in My HealtheVet. Most of the necessary study personnel are already available at our center. We aim to recruit 10 veterans in Months 0 to 3, and 20 veterans in Months 4 to 6 and Months 7 to 9. We will be interviewing veterans and providers at the time of the non-VA provider visit and expect this aspect of data collection to continue into Month 10. We will be reviewing medical records and provider data concurrently with data collection so that this aspect of data collection can be completed and fully analyzed after the final patient has completed the study in Month 10.

	Months 0 to 3	Months 4 to 6	Months 7 to 9	Months 10 to 12
Project Initiation (planning, data base management, IRB approval	x			
Identify and Recruit Subjects	x	x	x	
Conduct Training including Follow up Phone Calls	x	x	x	

Conduct Veteran and Provider Interviews	X	X	X	X
Calculation and validation of Metrics for Hypotheses 2 and 3		x	x	x
Final Expert Review and Discussion of Study Metrics.				x
Conduct Analyses of Final Outcomes and Group Differences				x
Prepare Manuscript				x

KEY PERSONNEL:

Carolyn Turvey, PhD (Principal Investigator;) is a Core Investigator in the Iowa City REAP and Associate Professor of Psychiatry at the University of Iowa. Dr. Turvey is a core member of the eHealth QUERI and since 2008 has worked with the My HealtheVet Performance Evaluation work group. As Principal Investigator, Dr. Turvey will assume responsibility for all aspects of implementation, management, and evaluation of the study, including development of the training materials and dissemination of findings. She will lead the investigative team, supervise study personnel, and oversee data collection and analysis. Dr. Turvey will devote 15% of her time to the project.

Bonnie Wakefield, PhD, RN is a former VA HSR&D Advanced Career Development awardee (2000-2005) and Core Investigator at the Center for Comprehensive Access & Delivery Research and Evaluation (CADRE) at the VA Iowa City Health Care System. She has been a registered nurse for over 35 years, with almost 30 of those within the VA. Her research interests focus on application of innovative telemedicine strategies to improve health care delivery for the elderly. Dr. Wakefield will collaborate with Dr. Turvey on all aspects of the development of the study. In particular, she will provide her expertise on the analysis and interpretation of data related to duplication of services. She will devote 5% of her time to the project

Mary Charlton, RN, PhD is a CADRE Core Investigator and Project Leader in the Veterans Rural Health Resource Center-Central Region and a Clinical Assistant Professor in the Department of Epidemiology at the University of Iowa. She has conducted studies related to assessing dual use and co-management of veterans, and was recently funded by VA HSR&D to study dual use of VA and Non VA services among veterans younger than 65. She also has extensive experience in the private sector working for Wellmark Blue Cross Blue Shield of Iowa and South Dakota as a health research analyst. She will provide expertise on dual use care in veterans and assist with the development and analysis of the measures to assess service duplication. She will devote 5% of her time to the project.

Peter Cram, MD, MBA is a CADRE Core Investigator and Professor of Medicine, and Director of the University of Iowa Department of Internal Medicine. His work has examined the epidemiology and consequences of missed test results and the design of feasible strategies to improve test follow-up. He has been funded by the NIH (*K23 and R01 awards*), and a prestigious Robert Wood Johnson Foundation Faculty Scholar Award. Dr. Cram will also assist in the analysis of measures to quantify service duplication. He will devote 5% of his time to the project.

Michael Jones, PhD is a CADRE Investigator and Professor of Biostatistics, at the University of Iowa. Dr. Jones is an expert in survival data methods, used in modeling time to event data such as time to death, adverse health outcomes and hospitalization, and in the use of hierarchical modeling for analyzing clustered data. Dr. Jones will oversee the development of protocols for data quality control, randomization, and analysis of the primary study hypotheses including calculating estimates of effect size. He will also collaborate in the consensus meetings about metrics for therapeutic duplication. He will devote 5% of his time to this project.

Sarah Ono, PhD is the Qualitative Core Director in CADRE, a group of experts in qualitative methodology with background training in public health, anthropology, sociology, and geography. Dr. Ono is a cultural anthropologist with extensive ethnographic and interview experience. Dr. Ono will work with Dr. Turvey to oversee qualitative research tasks and supervise the members of the Qualitative Core. She will contribute her expertise to the team through local supervision of the training and coding at CADRE. She will attend regularly scheduled meetings of the investigative team.