SDR 14-392
Pilot Study to Improve Care Coordination
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SPECIFIC AIMS:

Recent studies reveal that a large portion of veterans receiving care from the Department of Veterans Affairs (VA) also seek services outside the VA health care system. Though estimates are highly variable, ranging from 28-75%,(1-9) they reveal that dual use is more the rule than the exception for veterans receiving VA health care. Moreover, dual use is likely to rise in light of the Patient Protection and Affordable Care Act because veterans can also enroll in insurance plans offered through the new health insurance exchanges, and they may become eligible for Medicaid plans in states implementing Medicaid expansion.

Though common, dual use is a concern because a small but growing literature indicates that dual use veterans have poorer outcomes than VA-only patients(10-12). One of the main reasons for poor outcomes in dual users is poor coordination of care which increases the risk for medical errors. Interventions designed to improve coordination of care, most often using staff designated specifically as care coordinators, show promise but have mixed results(13). The VA has implemented several services that either directly or indirectly aim to improve coordination of care such as Care Coordination and Home Telehealth (CCHT) or Patient Aligned Care Teams (PACT). Moreover, the VA does support fee-based care outside the VA when deemed appropriate. Though successful in their own right, the impact of these programs on coordination with providers and systems outside the VA is unclear. Results from studies comparing outcomes between dual user and VA-only veterans suggest the need for a more concerted effort targeting this population specifically.

The Iowa City VA Health Care System (ICVAHCS) is home to the VA Center for Access and Delivery Research and Evaluation (CADRE), the VA Office of Rural Health - Rural Health Resource Center—Central Region (VRHRC-CR), the VISN 23 PACT Demonstration Laboratory, a Women's Health core with a focus on OIF/OEF women veterans, and investigators from the *e*Health QUERI. As a primary and tertiary care center in a largely rural state, issues of dual use are common. Investigators in each of these cores have conducted mixed methods studies of dual use in rural veterans which have explored 1) the *scope and quality of information exchanged,2) the level of patient care coordination, 3) health benefit coordination between VA and Medicare, and 4) satisfaction between VA and non-VA health care teams*. The results of this work, described herein, indicate major impediments to effective management for dual use veterans.

Investigators at the ICVAHCS have started to develop interventions to address the gaps in care identified in these studies. Dr. Carolyn Turvey is currently developing and implementing ways to improve health information sharing through the Blue Button feature of My Health*e*Vet. Dr. Mary Charlton has developed and disseminated a Co-management Toolkit which contains materials to help inform non-VA providers when a patient also gets care at the VA, and specific information about VA pharmacy benefits. The PACT Demonstration Laboratory has conducted extensive analyses of patterns of dual use for veterans who are also enrolled in Medicare.

Pilot funding is sought to integrate both the descriptive background studies and the pilot interventions to begin developing best practices for care of dual use veterans in rural settings. Many of the ICVAHCS studies described focused on informing non-VA providers about VA healthcare and benefits. We aim to pilot an intervention that combines our prior tools with strategies to help VA providers become more aware of non-VA care for dual use veterans. As this intervention is in its early stages, most of the strategies will rely on veteran education and training. However, in conducting this pilot, we will explore the acceptability and feasibility of care coordination protocols for providers. This proposed pilot aims to do so through the following Specific Aims:

1) To conduct a pilot randomized controlled trial comparing usual care to an intervention which aims to improve care coordination for dual use rural veterans by educating them about the use of information technology to share health information and informing their providers about the extent and nature of care from other health care systems.
2) To determine the impact of this intervention on patient perceptions of integrated care coordination, provider perception of relational coordination, and the impact of health information sharing as indicated by concordance of medication lists, and lower levels medical duplication when compared with usual care.
3) To integrate the results from prior background research and ongoing interventional studies conducted at ICVAHCS into a White Paper that makes recommendations for best practices to improve care in rural settings for veterans who are dual users.
4) Exploratory Aim: To explore the acceptability and feasibility of Co-Management Care Coordination Agreements between VA and non-VA providers.

Overview of Pilot Intervention:

The basic structure of the pilot and its evaluation is very similar to that of Dr. Turvey's HSR&D study and her multi-site ORH study. Dual use veterans will be identified through mailed recruitment and screening, they will be trained to use My HealtheVet to improve CC, and their next provider visits will be evaluated for impact of added information, satisfaction, and evidence of medical duplication. Evaluation will be conducted through brief post-visit surveys and patient and provider interviews. Dr. Turvey's experience in her current studies demonstrates the feasibility of these methods including provider completion of the brief evaluation forms.

However, there are several new components to the proposed intervention. Once dual use veterans are identified, they will complete a comprehensive interview determining their full care team and veterans' perceptions of the role each provider plays in their care (Appendix C). Then, all identified non-VA providers will receive a letter indicating that the veteran receives care at the VA and a copy of the Co-management Toolkit. Veterans will be trained to use My Health*e*Vet to generate a CCD, but they will also be trained to use My Health*e*Vet secure messaging to provide their VA providers information about their non-VA care. They will be requested to exchange a complete medication list, problem list, most recent laboratory values and visit note from their non-VA providers. If veterans' non-VA provider has a patient portal with CCD functions, we will assist the patient in learning that system if requested. Veterans will be followed to their next two visits – their first post training non-VA provider visit and their first VA provider visit. Both of these visits will be evaluated to determine the impact of additional information provided by the veteran. At these visits, veterans will be asked to share their perceptions of the roles providers play in their healthcare to receive feedback from their providers.

This study focuses on the role the veteran can play in CC. However, we believe that both VA and non-VA providers must also be active partners in the CC process. The proposed intervention is seen as the start of a broader conceptualization of how patients and providers can negotiate co-management. Veteran report of the nature of their discussion with their providers about role sharing and provider input will be integrated to develop further interventions targeting improvements in provider behavior regarding CC. Development of provider-based interventions will be done in consultation with both local and national PACT leadership representatives in the Executive Committee and will be tested in later studies. Moreover, we acknowledge that information technology is a necessary but not sufficient requirement for the cultivation of actual collaborative relationships(14). This study aims to develop and test the information technology, but also start the process of helping to improve collaborative relationships, with the veteran being at the center of that discussion.

In addition to the above considerations, this intervention targets the role of patient facing technologies in health information sharing. The availability of both patient and provider-facing technologies to improve health information exchange is rapidly evolving. The My Health*e*Vet Program Office anticipates that veterans will be able to send their CCD electronically directly from the MyHeltheVet website as of Fall/Winter 2014. In addition, Dr. Turvey is working with local and national initiatives to promote provider-to-provider and state-based health information exchanges where the patient is not the intermediary. Though exciting, these technical developments are not currently available so they could not be incorporated into the design of this study. However, if they do become available during the study, the team and the Executive Committee will explore whether or not it would make sense to revise study methods to include them. The main focus of the assessments within the study is not whether a specific technology is used, but whether there is accurate and timely communication. At this level of analysis, we may be able to change the specific technology used, yet still determine the impact of health information sharing on the quality and efficiency of care provided.

Sample: Sixty dual use veterans who have a non-VA provider and who are not already using My Health*e*Vet for health information sharing will be recruited from the Iowa City VA Health Care System. Based on earlier research that identified criteria for optimal impact of CC(15-17), participants must have at least one of the following chronic illnesses or ambulatory care sensitive conditions: diabetes, chronic obstructive pulmonary disease, hypertension, congestive heart failure, angina, asthma, coronary artery disease, arthritis, gynecologic conditions, or cancer -as determined by medical record review. We will oversample women veterans so that the final sample contains at least 20 women veterans -30% of the total sample. 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 My Health*e*Vet for sharing health information with providers. When contacted, the research assistant will confirm inclusion criteria and request the date of the next scheduled VA-provider and

non-VA provider appointment. Only those with upcoming visits with both providers in the next 6 months will be recruited. In our current work, 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. 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.

This pilot will be a randomized controlled trial comparing the CC intervention to usual care. This will allow for more conclusive determination of the impact of the intervention. In addition, results from this pilot can be compared to Dr.Turvey's pilot study examining unidirectional sharing of health information from the VA to non-VA providers only, to determine whether there was any additional benefit to bi-directional information sharing, the inclusion of the Co-Management Toolkit, and discussion of provider roles.

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. Veterans and providers in the usual care condition will complete all the same assessments, but will otherwise receive no aspects of the intervention.

Intervention Arm:

Veteran Intake Interview: In the intake interview, conducted by phone, veterans will be asked to confirm their medical conditions and list all their providers, including pharmacies, provide provider contact information, and to specify what roles and responsibilities are held by these providers (initial draft of form can be found in Appendix C). Veterans will also provide the dates of upcoming VA and non-VA provider visits. The results of the interview will be summarized. Veterans will also complete the Patient Perceptions of Integrated Care Survey(18, 19) with instructions to rate their experience in the past year. This initial assessment will serve as the baseline measure for patients' perceptions of CC.

The Patient Perception of Integrated Care Survey (Appendix D) is a 33-item measure assessing perceived coordination within the care team, across care teams, between care teams and community resources, continuity, patient centeredness and shared responsibility. It has demonstrated internal consistency, discriminant validity, and goodness-of-fit.

Upon completion of the intake interview, study staff will send the veteran the training materials and link to online training videos that teach the veteran to use My Health*e*Vet to generate a CCD, share with their non-VA provider, and to compile information from non-VA providers that can be shared with VA providers through secure messaging. If the non-VA provider supports an online patient portal (e.g. Epic's My Chart), the staff will assist the veteran in using that tool if the veteran is amenable. 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. In-person training and assistance will be offered when needed. In Dr. Turvey's current study, veterans have rarely needed assistance beyond the training materials provided. It appears that once veterans are made aware of the Blue Button Feature, the value of the feature in CC, and receive some guidance about how to go about generating a CCD, they can be fairly independent progressing through the whole process. More of a challenge has been finding veterans with scheduled visits within the next 6 months, though the original study did not target veterans with specific chronic or ambulatory care sensitive conditions. We expect that these patients will have more regular visits to manage their illness.

Within My Health*e*Vet, a veteran can attach a file to their secure message and send that file to their VA health care team. If deemed clinically relevant, the VA health care team can then save that secure message in CPRS as a note and also save the file attachment In VistA Imaging. Phase 1 of this functionality was released in March 2014 and Phase 2 is scheduled for the12.9 release of My Health*e*Vet in June 2014. Phase 2 will allow for a total of 4 file attachments per message with a maximum cumulative size of 6MB. The content included in the materials sent to the VA through secure messaging will be determined during the initial intake interview and will be shaped by perceived functions of health care team members. However, in general, patients will be asked to include a copy of their medication list, problem list, and most recent labs and most recent visit note.

We will instruct veterans to secure message non-VA health information to their PACT nurse care manager. The nurse care manager will then save the relevant information in CPRS and also notify other VA treatment team members, such as specialty care providers, of receipt of this information. We have discussed this process with ICVAHCS PACT leadership and they agree to promote this workflow.

Provider Visit: Veterans in both conditions will be followed in the study until they have had one VA and one non-VA provider visit. Those in the intervention arm will receive a reminder call one week prior to these visits

instructing them to bring hard copies of their list of providers and either their CCD from the VA, and informational aspects of the co-management toolkit (for non-VA providers) or most recent information from their non-VA care (for VA providers). Veterans will be asked to share this information with their providers and discuss whether or not the provider was aware of the other care and whether or not the provider concurs with the attributed roles. If discrepancies in expectations exist, the veteran will notify the PACT nurse care manager and work with the relevant stakeholders to start to clarify roles. Data about such discrepancies will be described in detail as part of the qualitative study of clarification of roles.

Veterans in both study conditions will also be provided a postage paid envelope and brief evaluation forms to be completed by their providers and by the veteran. The patient post-visit questionnaire will include the Patient Perceptions of Integrated Care Survey. The provider forms include confirmation of receipt of information, its impact on care, provider satisfaction (Appendix E), and Gittell's Seven Item Measure of Relational Coordination designed for providers(20). (Appendix F) Gittell's 7-item measure of Relational Coordination assesses providers' perceptions of the frequency, timeliness, accuracy and problem-solving nature of communication, as well as relationships of shared goals, knowledge, and mutual respect. To facilitate participation, a waiver of signature of consent will be obtained from the IRB for providers.

The provider post-visit questionnaire will be comparable to the one currently used in the HSR&D study but additional questions will be added pertaining to the designation of provider roles, knowledge of and acceptability of CC agreements, and the usefulness of the Co-management Toolkit for non-VA provider questionnaires. 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, response rate for the brief evaluation forms was high and 5 out of 21 providers agreed to be interviewed. Non-VA providers will also receive a small financial incentive for participation.

Post Medical Visit 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 CC. 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. 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. The interview will address two main issues: the impact of the information exchange on the visit, and the acceptability and optimal design of a co-management care coordination agreement.

Outcome Assessments and Quantitative Analysis: The main outcomes of this study and when they will be collected are presented in Table 2. Though ordered in the table, we will not dictate what order the VA and non-VA provider appointments must occur – though this order will be noted in data collection. As this is a pilot study, we are conducting analyses to determine an estimate of effect size and expected variability to be used in a later power calculation for a larger experimental or quasi-experimental study.

Table 2: Study Assessments

Outcome			
Patient Perceptions of Integrated Care	Baseline	Post VA Visit	Post Non-VA Visit
Provider Relational Coordination Survey		Post VA Visit	Post Non-VA Visit
Medication Concordance- From Chart		Post VA Visit	Non-VA Visit
Medical Duplication- From Chart		Post VA Visit	Post Non-VA Visit

Hypothesis 1: Patients in the intervention arm will have greater increase in the Perceptions of Integrated Care Survey score from baseline to the two provider visits when compared with usual care. This hypothesis will involve three dependent sample t-tests, assuming that Patient Perceptions of Integrated Care are distributed normally (if not normally distributed, analyses will use a Wilcoxon rank sum test). Specifically, we will examine differences between intervention and usual care patients with respect to the within-patient change between baseline perceptions and 1) perceptions after the first subsequent visit with a VA provider, 2) perceptions after the first subsequent visit with a non-VA provider, and 3) perceptions after subsequent VA and

non-VA provider visits averaged. Sub-analyses looking for differences between demographic groups based on age and gender will also be conducted.

Hypothesis 2: Providers in the interventional arm will have higher scores on the Relational Coordination Survey as compared to that of providers in usual care. The Relational Coordination survey will be completed by providers at each patient's first VA visit and first non-VA visit subsequent to baseline. Assuming coordination perceptions are normally distributed, analysis will use independent sample t-tests to evaluate differences in relational coordination perceptions between providers caring for patients in the treatment and usual care groups (alternatively, the Wilcoxon test may be used for non-normal measures). Differences in perceptions between usual care and treatment groups will be evaluated separately for VA providers and non-VA providers. These analyses assume that no two patient participants share a provider. If this assumption is not met, analyses will be adjusted to account for clustering within physician.

Hypothesis 3: Medication concordance will be higher for patients in the intervention arm than usual care. Medication concordance for each of the two medical visits will be calculated by making two lists, the current VA medication list and the current non-VA medication list. The former will be taken from CPRS while the latter will be taken from the non-VA provider visit most proximal temporally to the VA visit. We will obtain both the visit note and the medication list from the providers' visits. If the note does not indicate any medication change and there is none indicated on the form we ask the provider to complete, the provider's medication list will be designated the final medication list 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 pertaining to this change will not be counted as an "unreconciled" medication.

Our metric for concordance of medication lists 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. The final calculation of appropriate medication concordance 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 1 with 1 indicating perfect concordance of medication lists. The metric will range from 0 to 1, 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(10, 21). We will first examine the distribution of medication concordance to determine the appropriate statistical test. If the distribution is highly skewed, we may categorize the variable into two or more categories (e.g., <10%, 50%, or >=80% agreement) and evaluate differences between patients in the intervention and usual care groups using a Chi-square test. Alternatively, medication concordance may be treated as a continuous variable and evaluated using the t-test or Wilcoxon rank sum.

Hypothesis 4: Medical duplication will be lower for patients in the intervention arm than usual care. Prior research has quantified therapeutic and laboratory duplication, yet these are clearly difficult constructs to operationalize(10, 21-23). 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. (24) and more recently adapted by Chrischilles et al.(10). 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. Matt Witry, a clinical pharmacist, and Dr. Stacey Klutts, head of the ICVAHCS pathology department. Both are current collaborators on Dr. Turvey's HSR&D and ORH study. Drs. Witry and Klutts will be blind to whether or not the visit met criteria for treatment or diagnostic 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. Each patient will be assigned a dichotomous indicator for whether they received either therapeutic or laboratory duplication during their non-VA provider visit. Differences in the occurrence of medical duplication between usual care and intervention groups will be examined using the Chi-square test.

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