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An EMR-Based Tool to Support Collaborative Planning for Medication Use among Adults with Diabetes: Design of a Multi-Site Randomized Control Trial

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Abstract

Patients with type II diabetes often struggle with self-care, including adhering to complex medication regimens and managing their blood glucose levels. Medication nonadherence in this population reflects many factors, including a gap between the demands of taking medication and the limited literacy and cognitive resources that many patients bring to this task. This gap is exacerbated by a lack of health system support, such as inadequate patient-provider collaboration. The goal of our project is to improve self-management of medications and related health outcomes by providing system support. The MedtableTM is an Electronic Medical Record (EMR)-integrated tool designed to support patient-provider collaboration needed for medication management. It helps providers and patients work together to create effective medication schedules that are easy to implement. We describe the development and initial evaluation of the tool, as well as the process of integrating it with an EMR system in general internal medicine clinics. A planned evaluation study will investigate whether an intervention centered on the MedtableTM improves medication knowledge, adherence, and health outcomes relative to a usual care control condition among type II diabetic patients struggling to manage multiple medications.

Keywords

medication adherence; illness self-management; patient/provider collaboration; health literacy; cognition; Electronic Medical Record

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Introduction

Type II diabetes is a prevalent chronic illness in the US that tends to increase with age [1]. Along with managing blood glucose levels, medication is central to treating and managing diabetes in ambulatory care. Nonadherence is a common barrier to effective treatment --as many as half of patients do not take their medications as prescribed [2, 3]. The problem is linked to many patient, medication-, and system-related factors [4]. One important reason for nonadherence involves a gap between the demands of adherence and the limited resources that patients bring to this complex task. This gap is exacerbated by inadequate support from the health care system. Adherence demands depend on factors such as medication regimen complexity. Complex regimens require patients to create plans for taking multiple medications that meet many constraints, such as medication interactions and auxiliary instructions. Nonadherence increases with complexity [5], in part because of inadequate planning [6]. Planning requires health literacy skills [6, 7, 8] and broader cognitive resources such as processing capacity (e.g., working memory) and health knowledge [9]. Adherence especially challenges older adults, who are more likely to have a chronic illness requiring complex regimens, yet experience declines in literacy and cognitive resources needed for self-care [4, 5].

Patient-provider collaboration and other system support are crucial for adherence [10, 11]. For example, patient education can increase knowledge and literacy skills, and simplifying regimens and coordinating treatment across providers reduces demands on adherence. Unfortunately, system support is often inadequate, especially for adults with lower health literacy [2]. Collaboration requires partners to work together to ensure information is mutually understood [12]. However, providers do not always collaborate with patients effectively. For example, they may not present key information [13], use patient-centered language [14], or check patients' comprehension of information [15] [16]. More generally, system support for medication management in primary care is inadequate for supporting adequate adherence. Medication review is sporadic and fragmented [17] and reconciliation, the process of ensuring comprehensive and current patient medication lists, is lacking [2].

The consequences of inadequate system support are especially acute for adults with low health literacy because, although they may be most likely to benefit from it, they are also less likely to develop shared adherence plans with their providers, leading to nonadherence [2, 18, 19]. Adults with diabetes and lower health literacy report worse communication with providers [20] and have worse health outcomes than do patients with adequate literacy [21, 22].

Poor patient-provider collaboration reflects system barriers such as limited patient contact time, inadequate communication training, and lack of support for consistent use of patient-centered strategies [2]. Health information technology (IT) can provide system support for patient-centered communication [23, 24]. For example, comprehensive medication lists printed on cards are recommended for medication review and reconciliation with patients, but studies evaluating such cards in pharmacy [25], hospital discharge [26], and specialized clinic [18] environments produce inconsistent evidence. This may reflect the fact that the cards were not designed to support patient-provider collaboration nor linked with health IT and thus not integrated with clinical practice. There is need for robust support for collaborative medication management [2]. This paper details the development of a tool to support the patient/provider collaboration that is important to medication use among older adults with diabetes, and describes a study that will evaluate the impact of the tool on patient outcomes.

Design and Method

Study overview

We are evaluating the effects of an IT-based intervention designed to improve patient-provider collaboration in primary care clinics on medication use and health-related outcomes among patients with type II diabetes. The intervention involves nurses using the interactive, EMR-integrated tool (the Medtable™) to support patients' medication planning. Nurses were chosen to deliver the intervention because their education and training focuses on patient-centered care, they indicate a need for strategies to address barriers to patient education [27], and nurse-delivered interventions have been found to significantly improve patient outcomes for other diseases [28, 29]. We hypothesized that, compared to a usual care control condition, patients randomized to this intervention would have greater medication knowledge, adherence, and better health outcomes (as measured by HbA1c levels). A secondary hypothesis was that intervention benefits would be greater for patients with lower health literacy than for those with adequate literacy, because the intervention was designed to address literacy-related barriers.

Medtable™ Intervention

Development of the Medtable™ was guided by distributed cognition theory, which assumes cognitive activity can be effectively distributed across individuals (such as nurses and patients) and external artifacts (tools such as computers or paper) [30, 31]. Additionally, health care tools more effectively mesh with clinicians' abilities and goals when they are accurate, easily updated, reliable, relevant, clear, and malleable [32, 33]. Therefore, the Medtable™ was designed to accomplish three goals: 1) promote patient knowledge by clearly conveying accurate and relevant medication information; 2) support collaborative planning by organizing this information so that simple medication schedules can be created; 3) embed the tool into clinical practice by integrating it with EMR systems so that it is easily updated, efficient, and reliable.

Improving patient knowledge

The Medtable™ is a multi-media tool that combines mutually reinforcing text and graphic formats to help patients learn how to take their medication (Figure 1). Successful learning depends on developing a situation model, a mental representation that reflects a deep understanding of the presented information so that it can be acted on appropriately [34]. The tool may especially improve learning by older patients with inadequate health literacy. First, it reduces demands of learning on age-vulnerable cognitive abilities such as speed of mental processing. Graphic formats such as pictures may especially benefit patients with limited literacy by reducing the need for verbal processes such as recognizing and integrating word concepts [35]. Second, multi-media formats may support and build on patients' knowledge (e.g., about illness), which tends to increase with age [36].

Direct and explicit language is used in the Medtable™ to convey medication information because such language helps readers develop concrete situation models, which may especially benefit older adults [37]. Direct language improves comprehension of instructions by older adults with low health literacy [38] and is included in recommendations for improving medication label instructions [8].

Graphic formats in the Medtable™ support the text in several ways. First, a timeline is used to reinforce and more explicitly convey when to take the medications (Figure 1). Timelines embedded in medication instructions improve older adults' comprehension of dose and time information [39]. Second, familiar icons representing key daily events (e.g., meals, bedtime) are included on the timeline to help patients map medication times onto their daily routine.

Familiar icons may also encourage use of knowledge to scaffold comprehension. Similar graphic formats have been recommended for improving medication label instructions [8]. For example, “take twice daily” can be made more explicit (take two pills at 10:00 am and at 2:00 pm) when the information is mapped onto the table that is anchored to the timeline that summarizes the patient’s daily routine. Finally, graphic formats help people create schedules that satisfy constraints related to medications (e.g., drug interactions) and patients’ daily routines (e.g., which medications can be taken with meals). They are more computationally efficient than text, reducing the need to search for and integrate information [40]. For example, a table that represents relationships between medication and daily routine constraints reduces the need to keep these constraints in working memory in order to create a schedule [41]. Table formats may also help patients create optimal schedules because simpler schedules (consolidated around fewer medication times with equal spacing between doses) look simpler in the table. Table-based tools may especially help older adults who take many medications because, without help, these patients tend to create overly complex schedules [6]. Moreover, anchoring schedules to a specific daily routine may encourage patients to think concretely about how to take their medications, which engenders implementation intentions that have been shown to improve memory for actually doing tasks [42].

Supporting patient-provider collaboration

The Medtable™ may support collaboration by providing a shared workspace that helps patients and providers build a shared understanding of the task [12]. For example, patients and nurses may find it easier to share critical information via the Medtable™ because they can simply point to information on the tool rather than having to describe it, which helps to coordinate joint attention to the information [43, 44]. Additionally, they can point to the daily event icons and to previously scheduled medications when discussing when to take new medications. Because the Medtable™ helps nurses see how patients plan to take their medications, it may also support strategies that have been shown to support patient comprehension. These include teachback and teach-to-goal strategies, in which patients demonstrate (verbally or nonverbally) their understanding of critical information, enabling nurses to check comprehension so that the information is grounded as mutually understood [23].

We first evaluated a paper Medtable™ prototype in the laboratory using a simulated patient-provider collaborative medication planning task [45]. Older adults were randomly assigned to serve as provider and patient, with the provider receiving information about several medications (e.g., number of times to take; whether to take with food) and the patient receiving information about their daily routine (e.g., when they wake, eat meals, work). The pair then scheduled the medications, using either the paper-based Medtable™, an unstructured tool (blank paper), or no tool (talk only). Participants created more accurate schedules when using the Medtable™, presumably because it explicitly represented the task constraints and reduced the cognitive demands of creating the schedules. Analysis of participants’ conversation suggested the Medtable™ was more effective because it supported collaborative processes-- conversation was more structured and interactive (less information needed to be verbally presented and there was more explicit confirmation of presented information), and review of proposed schedules was more frequent in the Medtable™ than the other condition (Kannampallil, Morrow, Fu, Raquel, and Schriver, unpublished data, 2011). The paper Medtable™ was also evaluated in a clinical context with providers (physician, nurse, or pharmacist) using the tool to work with patients who had complex regimens and diverse skills (40% had inadequate health literacy as measured by the REALM). All patients were able to organize their regimens around their daily routine using the tool. They were then asked whether the tool was helpful and easy to use, because these

attitudes predict intention to use technology [46]. Ninety percent thought it was very helpful for organizing their medications and 80% thought it easy to use [47]. An early version of the Medtable™ was also included in a pharmacy-based patient education intervention that improved adherence among older adults with heart failure [48].

Integrating into practice: Developing an EMR-integrated Medtable™

We next developed an electronic version of the Medtable™ to provide more flexibility for creating schedules tailored to patients with differing routines and medication regimens, and for updating schedules as patients' regimens change (see Figure 1) [49]. We replicated key features of the paper Medtable™ (e.g., table format representing medication and patient routine constraints; schedule icons, large font). Perceptual-motor demands of using the computer-based tool were minimized to address variable perceptual motor abilities (for example, large clickable buttons that did not require precise movements of the cursor), which can pose a barrier to technology use [50]. At this stage of development, our simulated collaborative planning task was again used to compare the computer-based and paper Medtables to a less structured tool: a card that presented medication information in a list rather than a table format, similar to medication reconciliation cards used in many health care organizations. Although participants created accurate schedules regardless of which tool they used, the two structured tools were easier to use—participants rated their workload as lower and tool usability as higher when using these tools. Most important, the medication schedules created using the structured tools were more optimal, with medications taken at fewer daily times and with more evenly spaced doses [51]. These simpler schedules should also be easy to follow because they are anchored to daily routines, a strategy previously shown to improve adherence [52]. Finally, the computer- and paper-based Medtable™ were equally effective, suggesting that older participants did not have additional difficulty using the computer tool. One implication of this finding is that older adults could use the tool to support self-care at home, although in our intervention study, nurses rather than patients interact with the tool when collaboratively developing schedules with patients.

In the final development phase, the computer-based Medtable™ was embedded into an EMR environment, allowing providers to efficiently access patient medication lists in order to populate the tool and provide further flexibility for working with diverse patients. The Medtable™ tool is invoked within the EMR by leveraging the EMR's default internet browser functionality. The EMR passes a patient and encounter identifier to the Medtable™ application. The Medtable™ uses a "GetMeds" web service to make a call back to the EMR to render the patients' medication list within the tool. The Medtable™ translates the medication's Generic Product Identifier into a list of medication purposes and associated information (stored in an external database), which allows the nurse to create more complete and patient-friendly directions for each medication on the Medtable™. This system could be extended to other EMRs that can pass a patient and encounter identifier (composite key) and that have a "Get Meds" web service. The Medtable™ translation of the EMR medication list into a more complete and patient-friendly form would need to utilize a standard such as RxNorm that is extended across EMRs. Challenges to implementing the tool included system barriers to medication reconciliation at the research sites, such as variable language for documenting medication prescriptions in the EMR. Such barriers represented broad challenges to improving medication reconciliation, review, and education for patients and had to be addressed by our tool.

Consistent with practice-based models of chronic illness management [11] and of technology implementation [46], we developed a protocol for providers to use the Medtable™ in a clinic context to support collaborative medication planning. The protocol has three steps: set up, reconciliation, and scheduling (Figure 2). During the set up stage, before the patient visit, the nurse loads the patient's medication list from the EMR system

into the tool and reviews the information, making changes to the technical information in the EMR using simple, customized language appropriate for patients with low health literacy. The second stage of the protocol involves patient-initiated medication reconciliation. Specifically, when the patient arrives, they review a form with their medication list from the EMR system, adding or deleting medications as needed to update their list. The nurse then reviews the form with the patient in order to address any concerns and to update the medication list in the EMR if necessary. This step ensures that a complete and current medication list is available for creating the medication schedule.

The final stage is medication scheduling, where the patient and nurse jointly create the medication schedule using the Medtable™ tool. During this step, the patient describes their daily routine so that the nurse can set up the tool around the routine. In this way, the patient's routine is displayed by icons and the corresponding highlighted columns so that provider and patient can refer to it while developing the schedule. Next, the nurse and patient schedule each medication that is prescribed to be taken daily by clicking on the cell corresponding to the medicine (row) and time slot (column) corresponding to the chosen time ("take as needed" medications are listed below the table that summarizes the patient's plan for taking their daily medications). Because the schedule is easy to see as it is built, the tool encourages optimal scheduling (e.g., all medications to be taken with food are presented together on the tool and may be scheduled at the same daily time), as well as teach-back and teach-to-goal strategies that improve comprehension among patients with low health literacy. Clinical decision support is available, both before prescribing within the EMR to avoid potential drug-drug interactions, but also with the nurse guiding the Medtable™ activities to ensure patients find the most efficient and safe schedule for taking their regimen. Finally, the patient is given a printed copy of the completed schedule to take home and use as a support when taking their medications.

Before launching the study, the intervention nurses were educated in using the Medtable™ as part of patient-centered care, using it to support collaborative goals that are often inconsistently attained in practice: (a) present medication information that patients need to know; (b) check patient comprehension, and (c) explore patients' concerns and seek their perspective (e.g., [15, 53]). This approach addresses a recognized need to train practitioners in patient-centered communication as part of their medical education, with a focus on how to collaborate with low literacy patients [2]. However, our goal is to provide a structured tool that is integrated into the clinic EMR to help organize collaborative patient/provider medication review and education. Our approach to nurse education was consistent with current medication education and reconciliation practices at the research sites, and involved a multimedia manual with a project overview and rationale for the intervention, overview of the tool and how it is used, and more specific information about Medtable™ procedures. During the education sessions, the nurses interacted with the tool as patient as well as provider so they would understand how the tool is used and perceived by both groups, with a focus on teach-back and teach-to-goal strategies to ensure patients understand how to take their medications. In a series of simulated patient encounters, the nurses set up the tool and worked with patients to develop schedules for medication regimens of varying complexity. To ensure integrity of the intervention, the nurses were also observed while working with several actual patients at both research sites. Feedback was provided to the nurses to reinforce initial training and ensure consistent delivery of the intervention across sites.

Setting

The efficacy of the EMR-based Medtable™ is currently being evaluated in a randomized clinical trial comparing the intervention to a usual care condition to determine its impact on patients' medication knowledge, satisfaction with provider communication, adherence, and health outcomes. The study takes place at general internal medicine clinics at the

Northwestern Medical Foundation in Chicago and the OSF Medical Group at Peoria, IL. Both sites serve large numbers of adult patients from diverse backgrounds who have been diagnosed with type II diabetes and other chronic conditions. Both also use the Epic EMR system (Epic Systems Corp., Verona, WI) to support clinic practices, including medication management.

Study sample

We focus on type II diabetes because it is a chronic illness common in the middle and later years that threatens quality of life [1]. The illness makes considerable demands on self-management: in addition to taking multiple medications, patients must monitor and optimally control blood glucose levels on a daily basis, which involves medication adherence, exercise, healthy eating habits, and regular follow up with healthcare professionals. Moreover, health literacy is associated with differences in self-care knowledge [54] and health outcomes [22] among adults with type 2 diabetes.

We are recruiting 750 (375 per site) patients. The sample size for this study was based on a comparison between the two groups around the primary outcome of improved medication use at 6 months. We expect based on prior investigations that baseline understanding of one's multi-drug regimen will be approximately 45% in the usual care arm. Estimating approximately 80% retention at six months ($n=600$, 300 per arm), we will have sufficient power (82%) to detect a difference of 12% between study arms assuming a 5% Type I error rate.

Inclusion criteria are (a) age 40 and older because older adults are more likely to experience type II diabetes and often must manage complex medication regimes [1]; (b) native speaker of English; (c) no physical or cognitive impairments that could limit participation (e.g., stroke in the last 3 years, current cancer treatment involving radiation or chemotherapy); (d) score of 4 or higher on the short screen for dementia [55]; (e) no severe visual impairment ($<20/50$ corrected vision) that would limit participation; (f) diagnosis of type II diabetes; (g) taking at least 5 prescribed medications; (h) HbA1c level of 7.0 or higher. Therefore, we target patients who have not yet achieved tight glycemic control and therefore would be more likely to benefit from the intervention (also see [7]). The inclusion criteria related to language proficiency, physical, sensory, and cognitive impairment help to minimize factors that might reduce response to the intervention and complicate interpretation of the findings.

Patient eligibility is determined from review of patient records and telephone screening. Potential participants are chosen from patient records by age, HbA1c, and number of medications. Potential participants are contacted by mail and telephone, provided detailed study information, and encouraged to complete a screening questionnaire that includes questions about native language, stroke, cancer, type of diabetes, number of medications, medication responsibility, any hospital stays and cognitive and function status.

Design

The study is a multi-site longitudinal randomized controlled trial, and is registered on clinicaltrials.gov. A simple 1:1 random assignment is made at each site, placing patients in either the Medtable™ intervention study arm (see Section III) or to a usual care condition. Patients in the usual care condition at both research sites receive the medication counseling and communication that is standard of care at these sites. This includes a medication reconciliation process supported by patient cards that give providers opportunity to review medications. Although this process is similar to creating the medication list for the Medtable™, our tool also encourages patients and providers to collaborate in order to organize this list in terms of the patient's routine to create a patient-specific, concrete plan

for taking the medications. Therefore, patients assigned to the intervention condition received the Medtable™ and the collaborative processes it entails in addition to standard of care.

Participants are seen for three visits. During the first visit, baseline data collection is immediately followed by the first Medtable™-based interaction (for those patients randomly assigned to the intervention), followed by immediate post-intervention data collection (control patients are re-tested at similar times). Data collection also occurs at 3 and 6 months after the intervention is introduced (usual care participants are seen at the same times), with HbA1c levels collected from patient records at each visit, as well as at 9 and 12 months. This plan for data collection should be feasible because quarterly visits with A1c measurement is the standard of care for diabetic patients at both research sites.

Procedure

For their first study appointment, patients schedule a time to come in within a week after their next regularly scheduled appointment. A research assistant administers the baseline individual differences battery, the medication knowledge, and adherence measures (about 45 min). Then patients in the intervention condition work with intervention nurses using the Medtable™. Immediately following the intervention with the nurse, patients meet with a research assistant during which medication knowledge and satisfaction with provider communication are measured. Patients continue using the Medtable™ during their visits for the six months after first using the tool with providers. Office visits at three and six months post-intervention initiation are scheduled to coincide with patients' regularly scheduled office visits in order to collect the measures described above.

Measures

Demographic, health literacy, and sensory/cognitive variables are measured because of their importance to models of patient self-care [5] and to examine their impact on intervention response (see Table 1). Patient variables such as health status and regimen complexity may influence need for the intervention (support for self-care), while health literacy, cognitive, and knowledge variables may influence efficacy of self-care (influencing response to intervention).

Demographic and health variables

Patient age, gender, race, education, income, and marital status are measured by a modified version of the OARS instrument [56]. General health status is measured by the Medical Outcomes Survey-short form (SF-36) [57], and the Charlson Comorbidity index [58]. Medication regimen complexity, which may influence the need for and response to the intervention, is measured by patient interview. To measure diabetes self-care demands in addition to medication use, a questionnaire about self-care behaviors such as monitoring blood glucose levels and healthy diet choices was included [59]. Patients' knowledge of diabetes is also measured [60].

Health literacy

The REALM [61], a health word recognition test that involves pronouncing 66 medical terms, is used to measure health literacy. Performance on this commonly used measure [62] is associated with patient age, comprehension, and recall of medication information (e.g., [63]), as well as adherence and health outcomes [7].

Cognitive and sensory function

In addition to general cognitive status as measured via the 6-item cognitive screener [55], specific cognitive abilities relevant to patients' comprehension of health information and capacity for self-care planning are measured. We focus on fluid mental ability, which is most vulnerable to aging [64], and is associated with differences in health literacy [9] and adherence [54, 65], via assessments of speed of mental processing. Visual function is measured by the Rosenbaum card for near vision (with corrected vision).

Outcomes

Outcome measures (for both intervention and usual care participants) include satisfaction with provider communication (baseline, immediate, 3 and 6 months), medication knowledge (baseline, immediate, 3 and 6 months), adherence (baseline, 3 and 6 months), and HbA1c levels (from patient records at baseline, 3, 6, 9 and 12 months; standard care for diabetic patients at both sites include quarterly visits with HbA1c measured). Process measures include addressing suboptimal patient schedules during intervention versus usual care office visits (an important metric of electronic-based patient quality information). Three and 6 month data collection for intervention patients includes questions about Medtable™ use, such as whether they kept a copy at home, and how they used it (e.g., how often they referred to it; how easy it was to use), and whether they brought it to office visits to be updated. Patients in the usual care control condition are screened in the same way, and the same measures collected at comparable times relative to when they are recruited.

Specifically, patient satisfaction with provider communication related to medication is measured by the Satisfaction with Information about Medicines Scales (SIMS; [66]). Patient knowledge of their medication regimen is measured by a revised version developed by Michael Wolf of the Pills Taken/Pills Prescribed measure [67]. Patients are asked about their daily schedule for each medication prescribed as well as the dosage, the number of pills they are supposed to take, and the total number of pills they take each day. Patients are given a 24-hour time grid and asked to mark the number of pills they take and at which time they take it. This assessment is done to capture the patients' pill-taking habits and to provide a baseline schedule of their medication regimen that allows analysis of the extent to which the intervention optimizes participants' schedules. This measure is completed for each medication.

Medication adherence is measured by a revised version of the Patient Medication Adherence Questionnaire (PMAQ), designed for ease of use by low literacy patients and to reduce memory demands associated with self-report measures [68]. Revisions of the original instrument included items that were simplified to be more easily understood by less literate patients. The PMAQ requires patients to report on a missed dose in the past four days for each medication in their regimen. Four questions are asked regarding whether the patient had missed taking a dose yesterday, the day before yesterday, three days ago, and over the past weekend. Those participants acknowledging one or more missed doses are considered non-adherent, while those who self-report no missed doses are deemed adherent. Validity of this measure is suggested by the finding that patients with more accurate self-reported adherence also had a lower associated HbA1c measurement [69]. Blood glucose levels (HbA1c) are identified from patients' medical records. HbA1c is measured routinely during clinic visits at both sites.

Planned analyses

The primary analyses evaluate whether the Medtable™ intervention improves patient outcomes relative to the usual care group by using multivariable generalized linear models that include patient education, medication regimen complexity, patient health status (time

since diabetes diagnosis, number of co-morbid conditions), self-reported frequency of diabetes self-care activities, and provider experience as co-variables. Group (Intervention vs. Control), Time and Group x Time interaction terms, will be included, with time of measurement a repeated measure. The Group x Time term allows us to explore whether any intervention-related benefits vary with the amount of time using the collaborative tool (e.g., patients may need time to learn to use the tool to structure medication-taking strategies at home and to communicate with providers during office visits). Levels of the Time variable depend on the outcome measure: For medication knowledge, Time is defined by the immediate, 3, and 6 month testing points; for adherence, Time is defined by baseline, 3, and 6 months. Finally, intervention effects on health outcomes will be assessed by a similar multivariable regression that analyzes HbA1c levels controlling for patient and provider variables, and including Group and Time (baseline, 3, 6, 9, and 12 months). Research site will be included in all analyses. We will also explore whether intervention effects on adherence and HbA1c are mediated by medication knowledge, using hierarchical regressions. Regression analyses will also evaluate whether any intervention effects are moderated by level of patient health literacy, and whether these effects reflect differences in broader cognition.

Discussion

Patients with type II diabetes often struggle with self-care, especially the ability to take complex medication regimens as prescribed. Medication nonadherence in this population relates to many factors, including a gap between the demands of taking medication, limited literacy, and cognitive resources that patients bring to this task, which is exacerbated by inadequate patient-provider collaboration and other aspects of the health care system. The Medtable™ intervention is designed to support patient-provider collaboration needed for effective medication management. We target patients most in need of support—patients struggling with complex medication regimens, as reflected in poor glycemic control. The intervention supports medication reconciliation, similar to other tools introduced in the health care system (e.g., medication cards designed to ensure an accurate and current medication list for patients; [2]). However, the Medtable™ also encourages patients and providers to collaborate in order to organize this list in terms of the patient's routine to create a patient-specific, concrete plan for taking the medications. The tool is integrated into clinic EMR systems to facilitate flexible use with diverse patients and to address barriers to integrating with clinic practice. A randomized controlled trial at two sites is under way to evaluate whether the intervention improves patient medication knowledge, adherence, and health outcomes.

A potential limitation of this study is that intervention effects on the A1c outcome measure may be less likely to be detected than effects on the other outcome measures because the study was powered to the patient medication knowledge measure. In addition, participants in the study with A1c levels between 7.0 and 8.0 may already be at their target levels. Nonetheless, the study should determine whether a tool that supports nurse/patient collaboration related to self-care care has an impact on patient knowledge and self-care behaviors among a vulnerable group of older adults with high need for self-managing chronic illness.

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References

1. American Diabetes Association. Standards of Medical Care in Diabetes. *Diabetes Care*. 2009; 32(1):S13–S61. [PubMed: 19118286]
2. Aspden, P.; Wolcott, JA.; Bootman, JL.; Croenwett, LR. Preventing medication errors. Washington, DC: The National Academies Press; 2007.
3. Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med*. 2005; 35:487–497. [PubMed: 16079372]
4. Morrow, DG.; Wilson, EAH. Medication adherence among older adults: A systems perspective. In: Cavanaugh, JC.; Cavanaugh, CK., editors. *Aging in America: Psychological, Physical, and Social Issues*. Vol. 2. Westport CT: Greenwood; 2010.
5. Park, DC.; Jones, TR. Medication adherence and aging. In: Fisk, AD.; Rogers, WA., editors. *Handbook of human factors and the older adult*. San Diego: Academic Press; 1997. p. 257–288.
6. Wolf MS, Curtis LM, Waite K, Bailey SC, Hedlund LA, Davis TC, et al. Helping patients simplify and safely use complex medication regimens. *Arch Intern Med*. 2011; 171(4):300–5. [PubMed: 21357804]
7. DeWalt DA, Malone RM, Bryant ME, Kosnar MC, Corr KE, Rothman R, et al. A heart failure self-management program for patients of all literacy levels: a randomized, controlled trial. *BMC Health Serv Res*. 2006; 02:6–30.
8. Wolf MS, Wilson EAH, Rapp DN, Waite KR, Bocchini MV, Davis TC, et al. Literacy and Learning in Health Care. *Pediatrics*. 2009; 124(3):S275–S281. [PubMed: 19861481]
9. Chin J, Morrow D, Stine-Morrow EAL, Conner-Garcia T, Graumlich JF, Murray MD. The process-knowledge model of health literacy: Evidence from a componential analysis of two commonly used measures. *J Health Commun*. 2011; 16:222–241. [PubMed: 21951254]
10. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic illness in primary care. *JAMA*. 2002; 288:2469–2475. [PubMed: 12435261]
11. Wagner EH, Bennett SM, Austin BT, Greene SM, Schaefer JK, Vonkorff M. Finding common ground: patient-centeredness and evidence-based chronic illness care. *J Alt & Comp Med*. 2005; 11:S7–S15.
12. Clark, HH. *Using Language*. Cambridge: CUP; 1996.
13. Tarn DM, Heritage J, Paterniti DA, Hays RD, Kravitz RL, Wenger NS. Physician communication when prescribing new medications. *Arch Intern Med*. 2006; 166:1855–62. [PubMed: 17000942]
14. Stewart M. Effective physician-patient communication and health outcomes: A review. *Journal of the Canadian Medical Association*. 1995; 152:1423–1433.
15. Schillinger D, Piette J, Grumbach K, Wang F, Wilson C, Daher C, et al. Closing the loop: Physician communication with diabetic patients who have low health literacy. *Arch Intern Med*. 2003; 163:83–90. [PubMed: 12523921]
16. Schwartzberg JG, Cowett A, VanGeest J, Wolf MS. Communication Techniques for Patients With Low Health Literacy: A Survey of Physicians, Nurses, and Pharmacists. *Am J Health Behav*. 2007; 31:S96–S104. [PubMed: 17931143]
17. Tarn DM, Paterniti DA, Kravitz RL, Fein S, Wenger NS. How Do Physicians Conduct Medication Reviews? *J Gen Intern Med*. 2009; 24(12):1296–1302. [PubMed: 19813063]
18. Machtinger E, Wang F, Chen L, Rodríguez M, Wu S, Schillinger D. A visual medication schedule to improve anticoagulant care: a randomized controlled trial. *Jt Comm J Qual Patient Saf*. 2007; 33(10):625–35. [PubMed: 18030865]
19. Persell S, Osborn CY, Richard R, Skripkauskas S, Wolf MS. Limited Health Literacy is a Barrier to Medication Reconciliation in Ambulatory Care. *J Gen Intern Med*. 2007; 21:1523–1526. [PubMed: 17786521]
20. Schillinger D, Wang F, Rodriguez M, Bindman A, Machtinger EL. The importance of establishing regimen concordance in preventing medication errors in anticoagulant care. *J Health Commun*. 2006; 11:555–67. [PubMed: 16950728]
21. Heisler M, Vijan S, Anderson RM, Ubel PA, Bernstein SJ, Hofer TP. Do Patients and Their Physicians Agree on Diabetes Treatment Goals and Strategies, and What Difference Does It Make? *J Gen Intern Med*. 2003; 18:893–902. [PubMed: 14687274]

22. Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. *JAMA*. 2002; 288:475–482. [PubMed: 12132978]
23. Paasche-Orlow MK, Schillinger D, Greene SM, Wagner EH. How Health Care Systems Can Begin to Address the Challenge of Limited Literacy. *J Gen Intern Med*. 2006; 21:884–887. [PubMed: 16881952]
24. Parker R, Wolf MS, Kirsch I. Preparing for an Epidemic of Limited Health Literacy: Weathering the perfect storm. *J Gen Intern Med*. 2008; 231:1273–1276. [PubMed: 18452047]
25. Kripalani S, Robertson R, Love-Ghaffari MH, Henderson LE, Praska J, Strawder A, et al. Development of an illustrated medication schedule as a low-literacy patient education tool. *Patient Educ Couns*. 2007; 66(3):368–377. [PubMed: 17344015]
26. Cordasco KM, Asch SM, Bell DS, Guterman JJ, Gross-Schulman S, Ramer L, et al. A low-literacy medication education tool for safety-net hospital patients. *Am J Prev Med*. 2009; 37(6 suppl 1):S209–S216. [PubMed: 19896021]
27. Page AEK. Transforming nurses' work environments to improve patient safety: The Institute of Medicine Recommendations. Policy, Politics, & Nursing Practice. 2004; 5:250–258.
28. DeBusk RF, Houston MN, West JA. Diabetes case management. *Ann Intern Med*. 1999; 130(10): 863. [PubMed: 10366383]
29. Smith PM, Kraemer HC, Miller NH, et al. In-hospital smoking cessation programs: who responds, who doesn't? *J Consult Clin Psych*. 1999; 67(1):19–27.
30. Hazlehurst B, Gorman PN, et al. Distributed cognition: an alternative model of cognition for medical informatics. *Int J Med Inform*. 2008; 77:226–234.
31. Hutchins E. How a cockpit remembers its speeds. *Cognitive Sci*. 1995; 19(3):265–288.
32. Nemeth CP, Cook RI, O'Connor MF, Klock PA. Using cognitive artifacts to understand distributed cognition. *IEEE Trans Syst, Man, Cybern A, Syst, Humans*. 2004; 34:726–735.
33. Wears RL, Perry SJ, Wilson S, Galliers J, Fone J. Emergency department status boards: User-evolved artefacts for inter- and intra-group coordination. *Cognition, Technology and Work*. 2007; 9(3):163–170.
34. Mayer, RE. *The Cambridge Handbook of Multimedia Learning*. New York, NY: Cambridge University Press; 2005.
35. Houts PS, Doak CC, Doak LG, Loscalzo MJ. The role of pictures in improving health communication: A review of research on attention, comprehension, recall, and adherence. *Patient Educ Couns*. 2006; 61:173–90. [PubMed: 16122896]
36. Beier ME, Ackerman PL. Age, ability and the role of prior knowledge on the acquisition of new domain knowledge. *Psychol Aging*. 2005; 20:341–355. [PubMed: 16029097]
37. Radvansky GA, Dijkstra K. Aging and situation model processing. *Psychon Bull & Revi*. 2007; 14:1027–1042.
38. Davis TC, Federman AD, Bass PF, Jackson RH, Middlebrooks M, Parker RM, et al. Improving patient understanding of prescription drug instructions. *J Intern Med*. 2009; 24:57–62.
39. Morrow DG, Hier C, Menard WE, Leirer VO. Icons improve older and younger adult comprehension of medication information. *J Gerontol B Psychol Sci Soc Sci*. 1998; 53B:240–254.
40. Larkin JH, Simon HA. Why a diagram is (sometimes) worth ten thousand words. *Cognitive Sci*. 1987; 11(1):65–100.
41. Day, RS. Alternative representations. In: Bower, GH., editor. *The psychology of learning and motivation*. New York: Academic Press; 1988. p. 261-305.
42. Liu LL, Park DC. Aging and medical adherence: the use of automatic processes to achieve effortful things. *Psychol aging*. 2004; 19:318–25. [PubMed: 15222825]
43. Gergle, D.; Kraut, RE.; Fussell, SR. *Preceedings of Computer Supported Cooperative Work*. New York: ACM Press; Action as Language in a Shared Visual Space; p. 487-496.
44. Monk, AF. Common ground in electronically mediated conversation. In: Carroll, JM., editor. *Synthesis lectures on human-centered informatics #1*. Morgan & Claypool; 2009. p. 1-45.
45. Morrow DG, Raquel LM, Schriver AT, Redenbo S, Rozovski D, Weiss G. External support for collaborative problem solving in a simulated provider/patient medication scheduling task. *J Exp Psychol-Appl*. 2008; 14:228–297.

46. Karsh, B.; Holden, RJ. New technology implementation in health care. In: Carayon, P., editor. *Handbook of Human Factors and Ergonomics in Health Care and Patient Safety*. Mahwah, New Jersey: Lawrence Erlbaum Associates; 2007. p. 393-410.
47. Conner-Garcia T, Morrow DG, Graumlich JF, Ellison J, Wang H. Outpatient Perceptions of the Medtable: A medication scheduling tool. *J Pharm Technol*. In press.
48. Murray MD, Young J, Hoke S, Tu W, Weiner M, Morrow DG, et al. Pharmacist intervention to improve medication adherence in heart failure: A randomized trial. *Ann Intern Med*. 2007; 146:714–725. [PubMed: 17502632]
49. Waicekauskas, KT. The e-medtable: development and testing of an electronic collaborative tool to support medication scheduling (master's thesis). Urbana, Illinois: University of Illinois at Urbana-Champaign; 2010.
50. Mead, S.; Lamson, N.; Rogers, WA. Human factors guidelines for web site usability: Health-oriented websites for older adults. In: Morrell, RW., editor. *Older Adults, health information, and the world wide web*. Hillsdale, NJ: Erlbaum; 2002. p. 89-107.
51. Kannampallil T, Waicekauskas K, Morrow D, Kopren K, Fu W-T. Collaborative tools for a simulated patient-provider medication scheduling task. *Cognition, Technology, and Work*. In press.
52. Maylor EA. Age and prospective memory. *Q J Expl Psychol- A*. 1990; 142:471–493.
53. Makoul G. Essential elements of communication teaching in medical encounters: the Kalamazoo consensus statement. *Acad Med*. 2001; 76:390–393. [PubMed: 11299158]
54. Gazmararian JA, Williams MV, Peel J, Baker DW. Health literacy and knowledge of chronic illness. *Patient Educ and Couns*. 2003; 51:267–275.
55. Callahan CM, Unverzagt FW, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Med Care*. 2002; 40:771–781. [PubMed: 12218768]
56. Fillenbaum, GG. *Multidimensional functional assessment of older adults*. Hillsdale, NJ: Erlbaum; 1988.
57. Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36®): conceptual framework and item selection. *Med Care*. 1992; 30:473–83. [PubMed: 1593914]
58. Charlson ME, Pompei P, Alex KL, MacKensie CR. A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. *J Chron Dis*. 1987; 40:373–383. [PubMed: 3558716]
59. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure. *Diabetes Care*. 2000; 23:943–950. [PubMed: 10895844]
60. Garcia, Kousekanani; Villagomez, Hanis; Brown, S. *Diabetes Care*. 2001; 24:16–21. [PubMed: 11194219]
61. Davis TC, Long SW, Jackson RH, Mayeaux EJ, George RB, et al. Rapid estimate of adult literacy in medicine: a shortened screening instrument. *Fam Med*. 1993; 25:391–5. [PubMed: 8349060]
62. Paasche-Orlow MK, Parker RM, Gazmararian JA, Nielsen-Bohlman LT, Rudd RR. The prevalence of limited health literacy. *J Gen Intern Med*. 2005; 20:1–10. [PubMed: 15693920]
63. Davis TC, Wolf MS, Bass PF, Middlebrooks M, Kennen E, Baker DW, et al. Low literacy impairs comprehension of prescription drug warning labels. *JGIM*. 2006; 21:847–851. [PubMed: 16881945]
64. Baltes PB, Staudinger UM, Lindenberger U. Lifespan psychology: Theory and application to intellectual functioning. *Annu Rev Psychol*. 1999; 50:471–507. [PubMed: 15012462]
65. Insel KC, Morrow DG, Brewer BB. Cognitive function and medication adherence. *J Gerontol B Psychol Sci Soc Sci*. 2006; 60B:P102–P107. [PubMed: 16497953]
66. Horne R, Hankins M, Jenkins R. The Satisfaction with Information about Medicines Scale (SIMS): a new measurement tool for audit and research. *Qual Saf Health Care*. 2001; 10:135–140.
67. Jerant A, DiMatteo R, Arnsten J, Moore-Hill M, Franks P. Self-Report Adherence Measure in Chronic Illness: Retest Reliability and Predictive Validity. *Med Care*. 2008; 46(11):1134–1139. [PubMed: 18953223]

68. Wolf MS, Davis TC, Osborne CY, Skripkauskas S, Bennett CL, Makoul G. Literacy, self-efficacy, and HIV medication adherence. *Patient Educ Couns*. 2007; 65:253–260. [PubMed: 17118617]
69. Krapek K, King K, Warren SS, George KG, Caputo DA, Mihelich K, et al. Medication Adherence and Associated Hemoglobin A1C in Type 2 Diabetes. *Ann Pharmacother*. 2004; 38:1357–1362. [PubMed: 15238621]

Medicines	6:30 AM	7:00 AM	7:30 AM	8:00 AM	8:30 AM	9:00 AM	9:30 AM	10:00 AM	10:30 AM	11:00 AM	11:30 AM	Noon	12:30 PM	1:00 PM	1:30 PM	2:00 PM	2:30 PM	3:00 PM	3:30 PM	4:00 PM	4:30 PM	5:00 PM	5:30 PM	6:00 PM	6:30 PM	7:00 PM	7:30 PM	8:00 PM	8:30 PM	9:00 PM	9:30 PM	10:00 PM	10:30 PM	11:00 PM	11:30 PM	Midnight	
INSULIN ISOPHANE HUMAN 100 UNIT/ML SUSP controls blood glucose			100																																		
GLYBURIDE 5 MG TABS lowers blood glucose			1																																		
OMEPRAZOLE 20 MG CPDR treats ulcers -treats Gastroesophageal Reflux Disease (GERD)		1																							1												
CYCLOBENZAPRINE HCL 10 MG TABS is a muscle relaxant -relieves pain				1																							1										
NAPROXEN 375 MG TBEC relieves pain, swelling and stiffness -treats osteoarthritis and rheumatoid arthritis				1																						1											
DICYCLOMINE HCL 10 MG CAPS treats irritable bowel syndrome				1																							1										
MELoxicam 7.5 MG TABS treats osteoarthritis and rheumatoid arthritis				1																																	
DULoxetine HCL 60 MG CPDR treats depression and anxiety				1																																	
FERRUS SULFATE 325 (65 FE) MG TABS				1																																	
AMITRIPTYLINE HCL 50 MG TABs treats depression				1																																	
RANITIDINE HCL 300 MG TABs treats ulcers and gastroesophageal reflux disease (GERD)																											1										

Figure 1. Medtable™ printed schedule

The schedule indicates the medication taking times that are jointly chosen by patient and nurse.

The screenshot shows the MedTable™ interface for patient Ztest, Penelope. The top header includes patient information: MRN 25852, DOB 5/13/1926, Age 85y/o, Sex F, Flag (None), Code (None), Allergies (12/0009), PCP, HM Alert, INS, and MyChart. The main section is titled 'Medication Lists' and is dated 12/22/2011. It contains three medication entries:

- Budesonide (PULMICORT) 1 MG/2ML SUSP**: SIG from EPIC: None Entered; SIG from Saved DB: Take 1 Tablet 1 x daily. Includes fields for 'Instruction for medication' and 'Treats'.
- CALCIUM + D HX**: SIG from EPIC: Correct Dosage to be Verified; SIG from Saved DB: Take 1 Tablet 1 x daily. Includes fields for 'Instruction for medication' and 'Treats'.
- Drospirenone Ethinyl Estradiol (YAZ) 3.0/0.02 MG TABS**: SIG from EPIC: None Entered; SIG from Saved DB: Take 1 Tablet 1 x daily. Includes fields for 'Instruction for medication' and 'Treats'.

At the bottom, there is a 'More Activities' link and a copyright notice: © 2012 Epic Systems Corporation. All rights reserved. The time 10:36 PM is displayed in the bottom right corner.

Figure 2. Medtable™ set-up screen

This screen allows the nurse to populate the tool with patient-specific medication information from the patient's record in the EMR system.

Set your daily routine

Wake: 06:30 AM | Breakfast: 08:00 AM | Lunch: 12:30 PM | dinner: 06:00 PM | Sleep: 10:00 PM

Time	Medication	Notes
12:00 AM		
12:30 AM		
01:00 AM		
01:30 AM		
02:00 AM		
02:30 AM		
03:00 AM		
03:30 AM		
04:00 AM		
04:30 AM		
05:00 AM		
05:30 AM		
06:00 AM		
06:30 AM		
07:00 AM		
07:30 AM		
08:00 AM		
08:30 AM		
09:00 AM		
09:30 AM		
10:00 AM		
10:30 AM		
11:00 AM		
11:30 AM		
Noon		
12:30 PM		
01:00 PM		
01:30 PM		
02:00 PM		

Medication: medicine

Notes: real reflux disease

Notes: Once daily, it is usually before bedtime. If you are or self-treatment of acid by mouth with a glass

Notes: th - TabgtyBURIDE 5 MG

Notes: phageal Reflux Disease

Figure 3. Medtable™ medication scheduling screen

The nurse uses this screen to tailor the tool to the patient routine so that the nurse and patient can jointly develop the patient's medication schedule.

Table 1

Individual Difference Measures

INSTRUMENT	SOURCE	REL*
<i>Health Literacy</i>		
Rapid Estimate of Adult Literacy in Medicine (REALM)	Davis et al., 1993	0.91
<i>Cognitive and Functional Status (screening)</i>		
Six-item screener	Calahan et al., 2002	
<i>Sensory Ability (screening)</i>		
Near vision	osenbaum	
<i>Processing Speed</i>		
Letter Comparison	Salthouse (1991)	0.73 – 0.84
Pattern Comparison	Salthouse (1991)	0.73 – 0.84
<i>Health Status</i>		
Summary of Diabetes Self-care Activities (SDSCA)	Toobert et al., 2000	0.47
SF-36	Ware & Sherebourne, 1992	0.85
Charlson Comorbidity Index		

Table 2

Summary of Data Collection

	Baseline	Research Visit				Chart extraction only		
		Immediate	Follow-Up	Month 3	Month 6	Month 9	Month 12	
Demographic	X							
Medical history: SF-36	X							
Literacy, cognitive, and sensory testing	X							
Satisfaction with Information about Medicines Scales (SIMS)		X		X	X			
Medication knowledge test (Pills Taken/Pills Prescribed)	X	X		X	X			
Patient Medication Adherence Questionnaire (PMAQ)	X			X	X			
Medtable™ utilization and satisfaction				X	X			
HbA1c	X			X	X	X		X