

Tailoring an Intervention to the Context and System Redesign Related to the Intervention:  
Case Study of Implementing Shared Medical Appointments for Diabetes

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Abstract (350 word limit)

Incorporating shared medical appointments (group visits) into clinical practice to improve care and increase has become a popular intervention, but the processes to implement and sustain them have not been well described. Understanding these processes is critical because shared medical appointments more than most other types of interventions necessitate system redesign that intersects all levels of the system (micro- to supramacro system levels). Our own shared medical appointments for diabetes have resulted in improved intermediate clinical outcomes. The purpose of this study is to describe the process of implementation over time of shared medical appointments in the local context (a primary care clinic), including describing the adaptations and the factors that impeded or facilitated system redesign to implement and sustain successful diabetic shared medical appointments. We use systematic approaches to describe and analyze: 1) the pre-SMA local context/setting and the initial decisions/tailoring of the intervention (starting point); 2) implementation and evolution of the SMAs and context; and 3) the current local context/setting (post-SMA) and sustainability. We describe the processes by which an improvement intervention and the local context co-adapted and evolved during implementation, and continue to evolve to ensure sustainability.

## Background:

Successful implementation is a function of the relation between the nature of the evidence, the context in which the proposed change is to be implemented, and the methods by which the change is facilitated.(1;2) However, operationalizing improvement within a specific context based on the literature is challenging related in part to the limitations of the literature describing improvement efforts.(3) For example, often, the rationale for the choice of an improvement intervention is not given except in the most general terms. Similarly, specific barriers, especially factors other than those related to the individual professional, e.g. factors related to the patient, the health care team, the health care organization and the health care system when addressed, also tend to be presented in general terms.(4-14) The lack of specificity inherently recognizes the need for decisions to tailor the general concept to the specific location, but at the same time there is rarely guidance provided for thinking about local challenges and opportunities and for making those decisions. This phenomenon of context-dependence has led to calls for tailoring interventions. (6;15-20) Yet a systematic review of tailored strategies for behavior change in health care professionals revealed mixed results.(20) Moreover, much of the work describing tailoring of interventions has focused on individuals (end users) such as adaptation to patients' cultural background or adaptation of practice guidelines for healthcare professionals.(21-24) Thus, the process by which an organization-level practice change intervention can be individualized and implemented has not been well described. We suggest that part of the problem is conceptualizing the process as simply that of tailoring interventions to the context and not recognizing and adjusting the unique local context to optimize success of that intervention. In fact, there have been relatively few studies of adaptation at the multiple organizational levels from the individual (both patient and healthcare professional) to clinical microsystem, mesosystem and macrosystem and even supramacrosystem. and even fewer that describe the adaptation process itself, i.e., the basis for the choices made in determining the makeup of the intervention, and the evolution of the intervention over time. We will describe in detail the implementation of a specific intervention – shared medical appointments/group visits--in a specific context in order to elucidate these many issues.

Shared medical appointments (SMAs) constitute a promising improvement strategy to help address the complexities and demands of managing chronic health conditions and there is evidence in support of this approach including our own experience. (Kirsh et al. Quality and

Safety in Healthcare, 2007; in press) While not all evaluations of outcomes associated with SMAs are as encouraging, the format remains appealing in an environment of growing demands and limited resources. And, in fact, lack of success may be attributed to implementation challenges and issues that have not been adequately examined. While the general structure and processes for conducting SMAs have been established that recognize inter-related decisions, there is a lack of specificity to guide and ensure success. In addition, perhaps more than other interventions, SMAs necessitate system redesign that intersects a wide range of levels of a system (micro- to supramacro) for successful implementation and sustainability: SMAs require reconfiguring various levels of an organization's model of primary care. Accordingly, we describe the implementation and evolution of SMAs within a particular local context, a process that involved more than tailoring the intervention to the context; it also involved altering the context for intervention success. Successful implementation required expansion of the clinical microsystem by creating an inter-meso structure within the constraints of the existing microsystem (one-on-one doctor-patient relationship) and mesosystem (primary care clinic) that is nested within a macrosystem (medical center) which in turn is nested within a supramacrosystem (healthcare system of the Veterans Healthcare Administration). Our goal in this case study is to provide an in-depth look with the potential to identify themes and issues that will inform others interested in conducting or refining SMAs, in particular, and organization practice change, in general.

### Methods and Conceptual Framework

We used an in-depth case analysis approach focusing on the context and methods of implementation to describe the conceptual issues related to system redesign to achieve developing and implementing an SMA for patients with diabetes.(1;2;25-30) Such an approach best achieved our goals related to capturing the processes and key elements impacting on the processes and implications for health promotion practices.(31-34) We organize the case study of the process of tailoring an intervention and system redesign into the following sections where we describe and analyze: 1) the pre-SMA local context/setting and the initial decisions/tailoring of the intervention (starting point); 2) implementation and evolution of the SMAs and context; and 3) the current local context/setting (post-SMA) and sustainability.

We used a systems framework to help organize and summarize implementation and sustainability issues. Figure 1 provides a visual representation and framework for understanding the system redesign associated with successfully tailoring the intervention and the local context. Specifically, the left side of Figure 1 depicts the initial conceptual model of our health care system. It includes the care system components based on Batalden and colleagues that help to appreciate the complexity and levels of health care decisions and delivery.<sup>(35)</sup> The clinical microsystem is the small, frontline unit that is the primary clinical care unit (primary care provider and patient) which is nested within a mesosystem, nested within a macrosystem. The microsystem links to the mesosystem in that patients are referred, as needed, to nursing and other services. The macrosystem level refers to the local organization. The local organization is also linked to the national organization (supramacro level). We represented the supramacro system as a perpendicular layer to emphasize the role as a foundation and the distant though defining influence of the supramacro system on the local context.

Figure 1 also depicts the conceptual model that evolved with the successful implementation of SMAs for patients with diabetes (right side of the figure). The system redesign that resulted from implementing SMAs included continuous tailoring of the intervention to and continuous adjusting of the local context. This interplay of co-evolving components added a new clinical venue to which referral of patients was possible. To conceptualize SMAs as another clinical microsystem was not consistent with expanding and integrating other services and resources of the primary care clinics in a unique way that was contrary to traditional thinking about care (clinical microsystem). Accordingly, SMAs are identified as an intra-mesosystem component to recognize the linkages among and between other meso components (intra-meso) beyond the microsystem and to emphasize the system redesign. This is in contrast to the initial starting system design where there was only the closed microsystem with the components within (intra-micro) the inner clinical microsystem.

System redesign is also reflected in the arrangement of the SMAs: the circles represent participants on equal footing by recognizing the role of each discipline's expertise, including the patients who also bring expertise to the exchange. In addition, the graphic representation of the flow of communication underscores the mutual contributions and simultaneous, not sequential nature of the interactions for patients and providers. Finally, the clinical microsystem and the intra-meso system (SMAs) are overlapping to reflect that SMAs did not eliminate the traditional

clinical microsystem but rather offers another opportunity for care, with both approaches co-evolving. This point is particularly important to recognize, as one concern providers often expressed was the potential undermining impact SMAs might have on the individual provider-patient relationship.

#### Pre-SMA Local Context/Setting, General Dimensions of SMA Innovation and Initial Decisions (Starting Point) ~ Accommodating the Innovation into the Local Context:

The primary care clinic into which this intervention was initiated, is an urban academic medical center of the Veterans Health Administration (VHA). This clinic's primary care providers (5 NPs, 1PA, 8 part-time attending physicians, and 60 resident physicians) care for 10,000 patients, of whom 25% have diabetes. The local context prior to initiating SMAs for patients with diabetes is outlined in Table 1. Again, the Care System components are based on Batalden and others. Specifically, Table 1 defines the local context in January 2005 related to care for patients with diabetes and lists key elements related to diabetes care-based practices before introducing SMAs.

The microsystem component prior to SMAs consisted of the patient care visit (primary care providers and patients). The visits consisted solely of one-on-one encounters with patients and differing providers (primary care provider, nurse, pharmacist, psychologist). The mesosystem was the whole primary care clinic where patients were seen. High-risk patients (part of the clinical microsystem) not meeting physiologic or process measure goals for diabetes were referred to any number of support staff for further education and treatment (mesosystem). A link back to the primary care provider existed via the electronic medical record. Additionally, differing disciplines were not supervised by one director, but by leaders in their own discipline who did not work within the mesosystem. Changes in processes of care were difficult to achieve without multiple discussions with multiple discipline-specific supervisors. At the macro-system level, the Cleveland VAMC was engaged in demonstrating quality measures for diabetes based on the supra-macro system level of VHA Central Office. At both supra and macro levels, there was increasing awareness of SMAs as a means to improve waiting times while meeting quality imperatives in an efficient manner. The organizational context at the level of the macro- and supramacro-systems had a greater influence; there were mandates to conduct SMAs issued by VHA, primarily to address issues related to waiting times and clinic access. Mandates from outside the local medical center aside, local leadership in general and in the primary care clinic

in particular were strongly supportive of improvement efforts and open to the use of novel methods of care delivery. Moreover, the local facility has had a long history of support for and success in the implementation of clinical improvement allowing reliance on internal rather than external facilitation. (Stetler et al).

After the decision to begin SMAs, it was necessary to take general guidelines about SMAs and translate those into the local context, with its resources and needs. Implementation fidelity is often presented as critical to achieving the levels of efficacy demonstrated in clinical trials. However, it became apparent that descriptions of SMA interventions provided insufficient detail to guide implementation into differing clinical settings. While the decisions that needed to be made and the potential options were sometimes discussed, guidance on translating and mapping out to the local context was not provided. Table 2 outlines the initial dimensions of the SMA innovation we found (first column). The second column delineates our initial decisions or translation of the intervention to the needs of the local context. In order to maximize success and meet demanding clinical care needs, we began with diabetes as a focus because of the existing core team and its openness to change, some collaboration between key disciplines was loosely in place, the volume of patients with diabetes, the cost to the organization, and the high-demand of resources required to manage patients with diabetes. However, as is true with most decisions, there were aspects of many decisions that included promoting factors but also came with hindering factors. Therefore, Table 2 also outlines the promoting and hindering factors associated with each of the initial decisions.

It is worth highlighted key promoting factors for the innovation that relate to the system levels because ultimate system redesign requires successful alignment and interplay between all levels. While the organizational structure is very hierarchical (Figure 1), there is openness to novelty and in fact, there was the supramacro system level mandate to start SMAs with considerable latitude given to how those mandates were achieved. Descriptions of the transformation of the Veterans Health Administration describe these seemingly contradictory strains.(36) Thus, at the supramacro system level promoting factors included the mandate for action to address performance deficiencies, the so-called ‘burning platform’ and the simultaneous freedom and flexibility to pilot test to secure buy-in. (Kizer) At the macrosystem level, there was similar support for innovation. At the mesosystem level, a strong core care team was essential that reflected multi-disciplinary members from the various services that needed to be linked. This

team was open to new care models and expanding roles with a leader who had the ability to make changes at the microsystem level.

At the same time, there were several key innovation hindering factors associated with the general decision/mandate to conduct SMAs and the specific decisions to translate the mandated innovation into the local context: limited resources (such as space); potential to alter longstanding patient-provider relationships; organizational silos with core team members reporting to different supervisors; difficulties in documenting workload for credit; and finally, the flexibility itself and absence of specific guidelines for meeting the mandates resulted in a certain inefficiency and delay in the process. Implementation in a space-constrained facility that was in the middle of major construction/renovation meant that the choice of a location resulted in displaced providers who used the room and limited access to computers available in the conference room. There was concern that group visits with different providers would disrupt established provider-patient relationship and inhibit those providers from referring patients. The different lines of authority for each of the core team members necessitated negotiations with four different supervisors, some of whom were more open to SMAs than others. In this organization, there is a strongly perceived need (varying among different clinical and administrative departments) for meticulous accounting of one's workload. It was not intuitively obvious how to account for SMA work within current accounting systems.

#### Implementation and Evolution:

SMAs require complex changes that impact on care routines, collaborations, and various levels of the organization. As such, implementing the initial decisions involved more than putting decisions into place. As noted by others, implementers and champions of innovation are critical. This is particularly true the more complex the change and the need for system redesign. Those who conduct and carry out the implementation obviously play a key role in helping to initiate and sustain the intervention. Implementers for our SMA intervention included a physician who was the Medical Director of the clinic and an Endocrine Nurse Practitioner. The physician was an established leader of the Primary Care Clinic for two years prior to initiating the intervention and had some training in Quality Improvement. The physician felt ownership of the improvement processes overall and had the authority to solicit and get approval for staff in other disciplines to participate in the SMA. The Endocrine Nurse Practitioner was not a member of

the Primary Care Clinic but was considered to be a content expert and opinion leader at our institution. She had worked with high-risk patients with diabetes for 20 years prior to the intervention and was willing to share her expertise with patients as well as other less knowledgeable provider team members. All members of the core team were strongly committed to working together and reflected key stakeholders at the mesosystem level. The substrate with which the implementers worked was the context for implementation and the characteristics of the innovation.

Although the initial analysis and translation of the innovation (Table 1) provided a starting point and the implementers provided additional local motivation, further analysis of the SMA beyond the promoting and hindering factors associated with the decision was necessary for guidance to tailor the innovation to the local context and to adjust the local context. Grohl et al. identified a series of characteristics of innovations that might promote or hinder implementation processes.(27) The relationship between these factors and the local context is outlined in Table 3. While the relative advantage/utility was appreciated by the initiators early on, three other innovation characteristics factors also appeared to be critical to successful implementation: compatibility, involvement and collective action. This innovation was very compatible with the norms and values of the institution in promoting improvement in chronic disease quality measures. The involvement of the core team who would be implementing the SMA was very high. Individuals met to collectively decide the specific details of the clinical experience for patients and providers. However, hindering factors included: low compatibility with the traditional one-on-one visit with a primary care provider, high complexity in that the innovation was difficult to explain, and low collective action from the primary care providers who did not have input into the SMAs into which their patients would be recruited.

The initial decisions and implementation endeavors began the process of practice change but iterations of tailoring the intervention and negotiating system redesign were necessary. While not surprising that there would be issues on the road from start-up to sustainability, little attention has been given to identifying and categorizing them. Within our local context the SMA process for patients with diabetes has changed over the last 2 years. These changes have occurred at the level of the clinical microsystem, mesosystem, and macrosystem. Within the “micro” system, many changes have involved team structure, the patient population and clinic flow. In Table 3

we have used the Grol et al. framework to list the key changes related to the evolution of influence over time and strategies for promoting implementation and sustainability.(27)

#### Local Context and SMAs 2 Years Later and Sustainability

The current local context and care-based practices related to diabetes is summarized in Figure 2. Changes or differences are denoted in italics, with items directly impacting on diabetes care aligned on the right side of the last column. The current state of the SMAs for patients with diabetes is summarized in the pull-out box that reflects the intra-meso system redesign level. This table and Figure 1 help to identify the major changes and shifts in local context as well as the issues related to tailoring the intervention and adjusting the context.

It is worth highlighting some issues at each level of the care system. At the supramacro level, while continued improvement in information technology helps further support the SMA as configured at the local level, the mandates and priorities have changed. While this is to be expected, it does alert innovators and implementers to appreciating windows of opportunity. If the innovation hasn't taken off and achieved a force of its own (including demonstrating some levels or areas of success consistent with the organizational goals), changing priorities (new mandates), and the lack of success will create increasingly difficult challenges.

Given the demonstrated successes, leaders at the macrosystem system want the SMAs to be expanded to other conditions and possibly other care sites, e.g., the community based outpatient clinics linked to the main facility. Some new or adjusted practices beyond the actual SMA venue at the mesosystem level have also come about because of SMAs (e.g., monthly clinic meetings to discuss resource allocation and group meetings among discipline representatives) and some will help to further propel SMAs forward (e.g., registry and protocol development to identify high risk patients).

At the microsystem level, primary care providers are experiencing more pressure to meet performance measures of quality and productivity (and at the supramacro system level, the current context is also for more prescriptive approaches about how to get to goals). The objectives of the diabetes SMA map out to the increased pressures experienced by providers. Seeing the successes of the SMA, providers began to send patients with A1c's very close to goal. This was not necessarily all positive as we were unable to accommodate those identified in the registry with A1c > 9. While the magnitude of the increase in referrals to SMAs created some

unanticipated adjustments, we have worked and continue to work and negotiate with providers to prioritize resources. Their clear desire to refer more patients to SMAs underscores the growing foundation for sustainability.

Many factors contribute to implementation and sustainability of the SMA within the mesosystem (intra-mesosystem component) and with regard to its relationship to the clinical microsystems. Most importantly is how the SMA is valued. The increased number of referrals is evidence of the value placed on SMAs by the mesosystem providers. SMAs are valued by the professionals on the team based on their experiences with patients and on their feelings of a high degree of teamness.<sup>(37)</sup> Team members meet after each SMA where various members take turns working a little extra to support the SMA during non-clinical time with things like: making extra phone calls, generating letters to be sent out to new patients, tracking patient satisfaction data, meeting to change flow if needed. In addition, the flexibility of the individual team members is manifest during the SMA sessions; all different staff members pitch in as needed and do clerical duties, recheck blood pressures and download glucometers. A weekly meeting after each SMA continues to occur to discuss patients and process to assure that all team members have an open forum to voice concerns and make group changes, thus maintaining the high degree of shared governance. In addition, beyond improved clinical outcomes, patient satisfaction has helped confirm the added value to providers and to administration (macro- and supramacrosystems). Comments from patients have include: “I learned a lot”, “this clinic really takes such good care of patients” and “I wish this kind of clinic existed 20 years ago.”

Although the SMA was not originally envisioned as a form of system redesign that would alter the context in which it was implemented, it became clear that tailoring the intervention alone would not ensure sustainability without adjustments to the system. The innovation necessitated reconfiguring some aspects of the mesosystem (the primary care clinic and other services from which the patients and the team were derived) and relationships with the microsystems. Though not specifically anticipated, evolution of the former was associated with evolution of the latter: As the patients from the primary care providers were seen in the SMA and then transitioned back to them there was transfer (spread) of management knowledge in patients with diabetes, particularly among the nurse practitioner providers. We have noted anecdotally that many more PCPs initiate insulin appropriately at a lower threshold. Additionally, the use of patient check-out sheets that had been modified for the SMA to include lab results, targets, and self-

management goals have been adopted by PCPs. When they saw these sheets, they wanted that information on the check-out sheets for all clinic patients, not just patients seen in the groups.

Other sustainability ingredients observed at the mesosystem level include a high level of interest and volunteers to help staff additional SMAs for hypertension and hyperlipidemia. This will provide the cadre of individuals necessary for sustainability. At the macro-system level, the implementation of a SMA for diabetes and its success has come to the attention of the Chief of Staff and Medical Center Director. They have committed resources (i.e., financial resources) to maintain our clinical registry which serves as part of the critical infrastructure supporting SMAs. There has also been some redesign of clinic space to better accommodate the needs of SMAs. A construction project is planned to create a new room within the clinic designed specifically for group visits.

The fact that implementation could be accomplished without requiring the hiring of additional personnel facilitated gaining administrative support (macrosystem), but this required a compromise – using a less cost-effective approach to visit documentation. The organizational mandate and sponsorship of the clinic leader allowed time to be freed up for the staff. Different policies had to be developed for scheduling for the new clinic. Over time, this innovation became “accepted practice” and SMAs for other conditions have been established and the mesosystem redesign factors and processes directly and indirectly related to SMAs for patients with diabetes is ongoing.

### Summary and Conclusions

Our study describes in detail the processes by which an improvement intervention and the local context co-adapted and evolved during implementation, and continue to evolve to ensure sustainability. In theory, high implementation fidelity is necessary to achieve the levels of efficacy demonstrated in clinical trials. (reference) However, it is also clear that interventions must be tailored to meet the needs of the sites in which they are implemented. Unfortunately, guidance on specifics of that tailoring to the practice environment is lacking. We have described initial key characteristics of the intervention (SMA) that required adaptation and those perceived important to maintain without change if successful implementation was to occur. By identifying innovation characteristics (Grol et al.) as they pertain to our innovation (SMA) we illustrate the iterative processes involved in implementation.(27) Although specific factors of the intervention

and the context appeared to be critical in this particular circumstance, it is most noteworthy that both the intervention and the context (at multiple levels) had to change. By illustrating key portions we found that the more the intervention necessitated organizational and structural changes the more difficult it was to translate successfully. A strong core team, clinical improvements and an organization that supports innovation were paramount in overcoming the inertia inherent in clinic structure re-design, a necessary step to sustain the innovation. This system redesign needed to happen and could not have occurred devoid of appreciating and co-adapting the context and the intervention.

Our study is limited to one local context and one intervention. At the same time, the issues faced, both the challenges and opportunities, are not unique. While predicting change and its course are challenging, understanding case studies of the process of individualizing or tailoring interventions to the existing and evolving environment provides important lessons, as others have noted.(38) Our adaptations did not sacrifice the improved clinical outcomes, and in fact may have enhanced clinical outcomes. Thus, our study provides insights into a successful implementation process for shared medical appointments by describing how we addressed initial contextual decisions and why those decisions were made, by identifying factors and considerations that necessitated adjusting initial decisions and actions regarding issues ranging from clinic set-up to provider roles and tasks, by sharing strategies to sustain this clinic as an adjunct to the primary care clinic, and by providing information on how and what we chose to evaluate.

#### Authors' contributions

The authors shared equally in the conception of the study, design, coordination and drafting the manuscript. All authors read and approved the final manuscript.

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TABLE 1: Defining the local context prior to introducing shared medical appointments

<i>Care System Components</i>	<i>Defined via Local DM Care Context</i>	<i>Existing DM Care-Based Practices Pre-SMA (January 2005)</i>
<i>Supramacro</i>	VHA Central Office	Initiatives on outpatient quality figure out how locally
		ACA mandate to reduce waiting times; increase efficiency
		Chronic Disease Index emerging as a priority
		EMR tracking performance measures & providing feedback
<i>Macro</i>	Cleveland VAMC	Pursue current mandate: ACA
		Meetings about intermediate DM care goals
		Wanted updates about how going to meet goals
		Firms have medical training focus not quality care focus
		Longer-term major construction creating space constraints
<i>Mesosystems</i>	Primary care clinics	Monthly reports about meeting DM care goals
		Monthly clinic meetings review & allocate resources
		No formal process to identify and refer high risk pts
		Individual meetings with silo representatives
		Go to macro level for change if needed
	Other services	PCP is additional signer on notes for pts
	Clinical pharmacy	Individual referral to education (meds and adherence)
		Medication algorithms (augment/adjust; problems)
	Nursing	Nurse manager meeting & viewed separately
	Clerks	Make appointments for follow-up/referrals

<i>Microsystems</i>	Individual Units	One-on-one meetings with patient
Intra-micro Patient	~ 1,500 w/ A1c > 9 High Risk	Attend individual visits (3 months recommended)
		Follow-up with referrals to other services including:
		Pick-up new medications now and then see:
		Clinical pharmacist to change medications (1 month)
		Lab work prior to next visit
Nurse	4 RN	Take vitals, updates from patient, etc.
	2 LPN	Provide case management/education as referred
Provider	PCPs w/ DM pts:	Expected to meet performance measures but limited support
	8 Part-time attendings 5 NPs 1 PA Preceptors (5 new) Residents (60/year)	Worked individually with patient
		Goals A1c < 9; LDL < 100; SBP < 130
		Receive scores regarding % of patients meeting goals
		If patient not meeting measures, then educate patient via: Referrals for Consults to one or more (variable): Nurse; Clinical pharmacist; Nutritionist; Endocrine DM Self-management classes as a referral option  <i>*Primary focus: medications to get to goal</i>

TABLE 2: Analysis of Shared Medical Appointments Innovation: Translating SMA into Local Context (February 2005)

Dimension of SMA Innovation – Basic guidelines that needed to be translated	Starting Point: Initial Decisions	Promoting Factor	Hindering Factor
Shared Medical Appointment Initiation	Core team with strengths related to DM were open to change and working together	Mandate from Central Office; Training provided; No specific guidelines; local facility has long history of supporting novel methods of care delivery	No specific guidelines; limited resources
Focus: disease-specific or non-specific	DM (reduce cardiovascular risk)	Provided focus consistent with strong core team	
Drop-in or Schedule Patients	Scheduled	Able to call and remind; able to plan	Limits number and requires more planning
Multi-disciplinary Professional Team	Collaboration with key disciplines present	Strong, committed core team, including one member representing key leadership within primary care clinic	Difficulty coordinating, and finding and freeing up time to participate
1 or more with prescribing authority	MD (Medical Director of Clinic); Endocrine NP; PharmD		Team members had different supervisors; Workload credit and credit for SMAs participate in
1 or more variety of disciplines	Psychologist; RN		Different supervisors; Workload credit
Group of patients (8-20)	4-8 patients (8 invited)	Flexibility to pilot test with small numbers of patients	Questions raised about inefficiency

Target population	Local registry to identify pts	Sufficient numbers who would benefit	
PCP pool (pull from one or more)	All PCPs' pts eligible	Able to include all high risk patients	Threatened provider-patient relationship
Patient pool	A1c>9; SBP>130; LDL>100		Getting several patients there; Viewed as difficult and non-compliant; concern about no-show rates
Time and Frequency: Meet for 90-120 minutes and variable regarding frequency	90 minutes and to meet weekly (Friday afternoons)		
Techniques and Processes for conducting SMA	Modification of chronic care model as a guide		
Didactics	Keep at a minimum		Many team members use to 'teaching' not discussing
Information display and sharing	Large board with pt lab values and other outcomes (e.g., A1c, SBP, LDL); prepared by PharmD		
Group discussion	Peer support Motivational interviewing		
Clinical component	Group chart display		
Forms: General information	ABC, foot care, etc.		
Forms: Patient-specific	Pt completed form with Current #s (copied from board), goals, med changes, plan of care outlined		
Space	Remote training rooms not available and negotiated clinic space	Able to secure some space	Limited options especially given construction
Location	Firm Clinic Conference Room	Familiar	Displaced providers who use the room and limited access to computers

			available in the conference room
Size and arrangement	Small conference room with computers and crowded		Limited in size and mobility; configuration not ideal
Mechanics			
Documentation (suggest identify individual take responsibility)	Developed a template note in electronic record system	User friendly, consistent with usual methods of documenting	

TABLE 3: Key implementation and evolution factors using Grol and Wensing’s *Characteristics of Innovations Framework*(27)

Characteristic of Innovation ~ Degree to which innovation provides or is:	Promoting Factor for SMA Implementation	Hindering Factor for SMA Implementation	Addressing the Issues to Facilitate Implementation and Sustainability
Relative advantage or utility over existing or other methods	Advantage of seeing several experts at same time, especially for behavioral barriers	No clear evidence; questioned value and whether patient would accept it	Proved not to be a major issue.
Compatibility with existing norms and values	Consistent with norm and values of achieving process measures	Inconsistent with norm and value of sacred PCP-pt relationship; Different roles of health care professionals filling in-difficult switching from traditional to multidisciplinary team approach	Had a few team building and motivational interviewing learning sessions-lecture vs facilitation of patient info
Complexity of explaining, understanding and using		Too vague and many unknowns; not easy to explain	Explain and sell it and take advantage of a trial period with small numbers of patients to highlight success
Costs relative to benefits and level of investment		Efficacy questioned regarding clinical physiological outcomes and uncertain level of investment for various stakeholders	1.Reorganizing flow allowed up to 18 patients to be seen in one SMA 2. Change in way patient data distributed in order to reduce prep time of pharmD and overall cost 3. introduced use of templated notes
Risks related to uncertainty regarding results and consequences		High risk – no conceptual model for designing or plan for diffusion	The organizational culture supported risk taking.

Flexibility, adaptability to situation/needs of local context/target group	Vagueness provided options for adapting to local context and needs	Key non-flexible components not consistent with micro-system and mesosystem silo design	1. Recognition of additional patient needs prompted addition of a nutritionist to the team
Involvement of target group in development	High involvement of the core team only	Existing structure impeding involvement	1. Unanticipated impact on staff not involved feeling left out addressed by creating opportunities for these staff
Divisibility so able to try out parts separately		Low divisibility of shared appointments	Unable to address; we have kept the basic model of SMAs.
Trialability, reversibility without risk if doesn't work	High and approached as a trial period		Because of early successes, this proved not to be a major issue
Visibility, observability of results by other people	High – part of local culture is feedback	High – part of local culture is feedback	1. Patient successes led to increased referral of patients close to performance measure goals overloading the clinic and prompting the redirection of resources
Centrality of impact on daily working routine		High	Impact of patients' stories has contributed to team's finding meaning in their work, negating the effects of the changes in work routine.
Pervasiveness, scope, impact on total work, people involved, time it takes and relationships		High: fear more work and would jeopardize primary care provider-patient relationships	Proved not to be a major issue.
Magnitude, disruptiveness, radicalness		High	The core team was made up of individuals willing to take risk and were unafraid of the potential disruption.

Duration for when innovation/change must take place	Not a pressing factor		
Form, physical properties of innovation: material or social; technical or administrative; etc.)		High: material change, space requirements, schedule changes, administrative and technical adjustments	Continues to provide challenges
Collective action related to decisions	Low collective action	Strong core team (3-5 members)	Unanticipated impact on staff not involved feeling left out. Some of these staff were recruited to participate in other types of SMAs where they were involved in the decision-making.
<i>Nature of Presentation:</i> length, clarity, attractiveness	High attractiveness	Low clarity	Proved not to be a major issue

Figure legends.

Figure 1. Conceptual Framework of the System Redesign.

Figure 2. Framework of Care System Components Defined by the Local Diabetes Care Context and Their Evolution. Changes or differences are denoted in italics, with items directly impacting on diabetes care aligned on the right side of the last column.

## Reference List

- (1) Rycroft-Malone J, Kitson A, Harvey G et al. Ingredients for change: revisiting a conceptual framework. *Qual Saf Health Care* 2002; 112(174):180.
- (2) Rycroft-Malone J. The PARIHS framework-a framework for guiding the implementation of evidence-based practice. *J Nurs Care Qual* 2004; 19(4):297-304.
- (3) Davidoff F, Batalden P. Toward stronger evidence on quality improvement. *Qual Saf Health Care* 2005; 14(5):319-325.
- (4) Brown J, Harris S, Webster-Bogaert S, Wetmore S, et al. The role of patient, physician and systemic factors in the management of type 2 diabetes mellitus. *Family Practice* 2002; 19(4):344-349.
- (5) Fixson D, Naoom S, Blase K, Friedman R, Wallace F. *Implementation Research : A Synthesis of the Literature*. Tampa: National Implementation Research Network, 2005.
- (6) Grimshaw J, Thomas R, MacLennan G, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technology Assessment* 2004; 8:iii-72.
- (7) Helfrich C, Savitz L, Swiger K, Weiner B. Adoption and implementation of mandated diabetes registries by community health centers. *Am J Prev Med* 2007; 33(Suppl 1):S50-S65.
- (8) Hulscher M, Wensing M, Grol R, van der Weijden T, van Weel C. Interventions to Improve the Delivery of Preventive Services in Primary Care. *American Journal of Public Health* 1999; 89(5):737-746.
- (9) Hysong S, Best R, Pugh J. Clinical Practice Guideline Implementation Strategy Patterns in Veterans Affairs Primary Care Clinics. *HSR: Health Services Research* 2007; 42(1):84-103.
- (10) Li R, Siomn J, Bodenheimer T, et al. Organizational factors affecting the adoption of diabetes care management processes in physician organizations. *Diabetes Care* 2004; 27:2312-2316.
- (11) Macfarlane R, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q* 2004; 82(4):581-629.
- (12) Renders C, Vak G, et al. Interventions to improve the management of diabetes in primary care, outpatient, and community settings: a systematic review. *Diabetes Care* 2001; 24:1821-1833.
- (13) Savitz L, Kaluzny A. Assessing the implementation of clinical process innovations: a cross-case comparison. *J Healthc Manag* 2000; 45(366):379.

- (14) Weiner B, Helfrich C, Savitz L, Swiger K. Adoption and Implementation of Strategies for Diabetes Management in Primary Care Practices. *American Journal of Preventive Medicine* 2007; 33:S35-S49.
- (15) Bosch M, van der Weijden T, Wensing M, Grol R. Tailoring quality improvement interventions to identified barriers: a multiple case analysis. *Journal of Evaluation in Clinical Practice* 2007;161-168.
- (16) Davies B, Hodett E, Hannah M, et al. Fetal health surveillance: a community-wide approach versus a tailored intervention for the implementation of clinical practice guidelines. *Canadian Medical Association Journal* 2002; 167:469-474.
- (17) Flottorp S, Oxman A. Identifying barriers and tailoring interventions to improve the management of urinary tract infections and sore throat: a pragmatic study using qualitative methods. <http://www.biomedcentral.com/1472-6963/3/3/3> 3[3]. 2003.  
Ref Type: Electronic Citation
- (18) Goodwin M, Zyzanski S, Zronek S, et al. A clinical trial of tailored office systems for preventive service delivery. The study enhanced prevention by understanding practice (STEP-UP). *American Journal of Preventive Medicine* 2001; 21:20-28.
- (19) Jansen Y, deBont A, Foets M, Bruijnzeels M, Bal R. Tailoring intervention procedures to routine primary health care practice: an ethnographic process evaluation. <http://www.biomedcentral.com/1472-6963/7/125> . 2007.  
Ref Type: Electronic Citation
- (20) Shaw B, Cheater F, Baker R, Gillies C, et al. Tailored interventions to overcome identified barriers to change: effects on professional practice and health outcomes. *The Cochrane Database of Systematic Reviews* 2005;(3).
- (21) Castro F, Barrera M, Martinez C. The Cultural Adaptation of Prevention Interventions: Resolving Tensions Between Fidelity and Fit. *Prevention Science* 2004; 5(1):41-45.
- (22) Gonzales J, Ringeisen H, Chambers D. The Tangled and Thorny Path of Science to Practice: Tensions in Interpreting and Applying "Evidence". *Clinical Psychology: Science and Practice* 2002; 9(2):204-209.
- (23) Hill L, Maucione K. A Focused Approach to Assessing Program Fidelity. *Preventive Science* 2007; 8:25-34.
- (24) Rohrbach L, Grana R, Sussman S, Valente T. Type Translation Transporting Prevention Interventions From Research to Real-World Settings. *Evaluation & the Health Professions* 2006; 29(3):302-333.
- (25) Abelson J, Forest P, Eyles J, Casebeer A, Martin E, Mackean G. Examining the role of context in the implementation of a deliberative public participation experiment: Results from a Canadian comparative study. *Social Science & Medicine* 2007; 64:2115-2128.

- (26) Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *Milbank Q* 2004; 82(4):581-629.
- (27) Grol R, Bosch M, Hulscher M, Eccles M, Wensing M. Planning and studying improvement in patient care: the use of theoretical perspectives. *Milbank Q* 2007; 85(1):93-138.
- (28) kochevar L, Yano E. Understanding Health Care Organization Needs and Context: Beyond Performance Gaps. *J Gen Intern Med* 2006; 21:S25-S29.
- (29) May C, Mair F, Dowrick C, Finch T. Process evaluation for complex interventions in primary care: understanding trials using the normalization process model. <http://www.biomedcentral.com/1471-2296/8/42> . 2007.  
Ref Type: Electronic Citation
- (30) May C. A rational model for assessing and evaluating complex interventions in health care. <http://www.biomedcentral.com/1472-6963/6/86> . 2006.  
Ref Type: Electronic Citation
- (31) Anderson R, Crabtree B, Steele D, McDaniel R. Case Study Research: The View From Complexity Science. *Qualitative Health Research* 2005; 15(5):669-685.
- (32) Flyvbjerg B. Five Misunderstandings About Case-Study Research. *Qualitative Inquiry* 2007; 12(2):219-245.
- (33) Lenz M, Stecklberg A, Richter B, Mühlhauser I. Meta-analysis does not allow appraisal of complex interventions in diabetes and hypertension self-management: a methodological review. *Diabetologia* 2007; 50:1375-1383.
- (34) Yin RK. *Case Study Reseach*, 3rd ed. Thousand Oaks: Sage Publications, 2003.
- (35) Batalden P, Nelson E, Edwards W, Godfrey M, Mohr J. Microsystems in Health Care: Part 9. Developing Small Clinical Units to Attain Peak Performance. *Joint Commission Journal on Quality and Patient Safety* 2003; 29(11):575-585.
- (36) Oliver A. The Veterans Health Administration: An American Success Story? *Milbank Q* 2007; 85(1):5-35.
- (37) Lencioni P. *The Five Dysfunctions of a TEAM: A Leadership Fable*. San Francisco: Jossey-Bass, 2002.
- (38) Ruhe M, Weyer S, Zronck S, Wilkinson A, Wilkinson PS, Stange K. Facilitating practice change: lessons from the STEP-UP clinical trial. *Preventive Medicine* 2005; 40:729-734.

# System Redesign

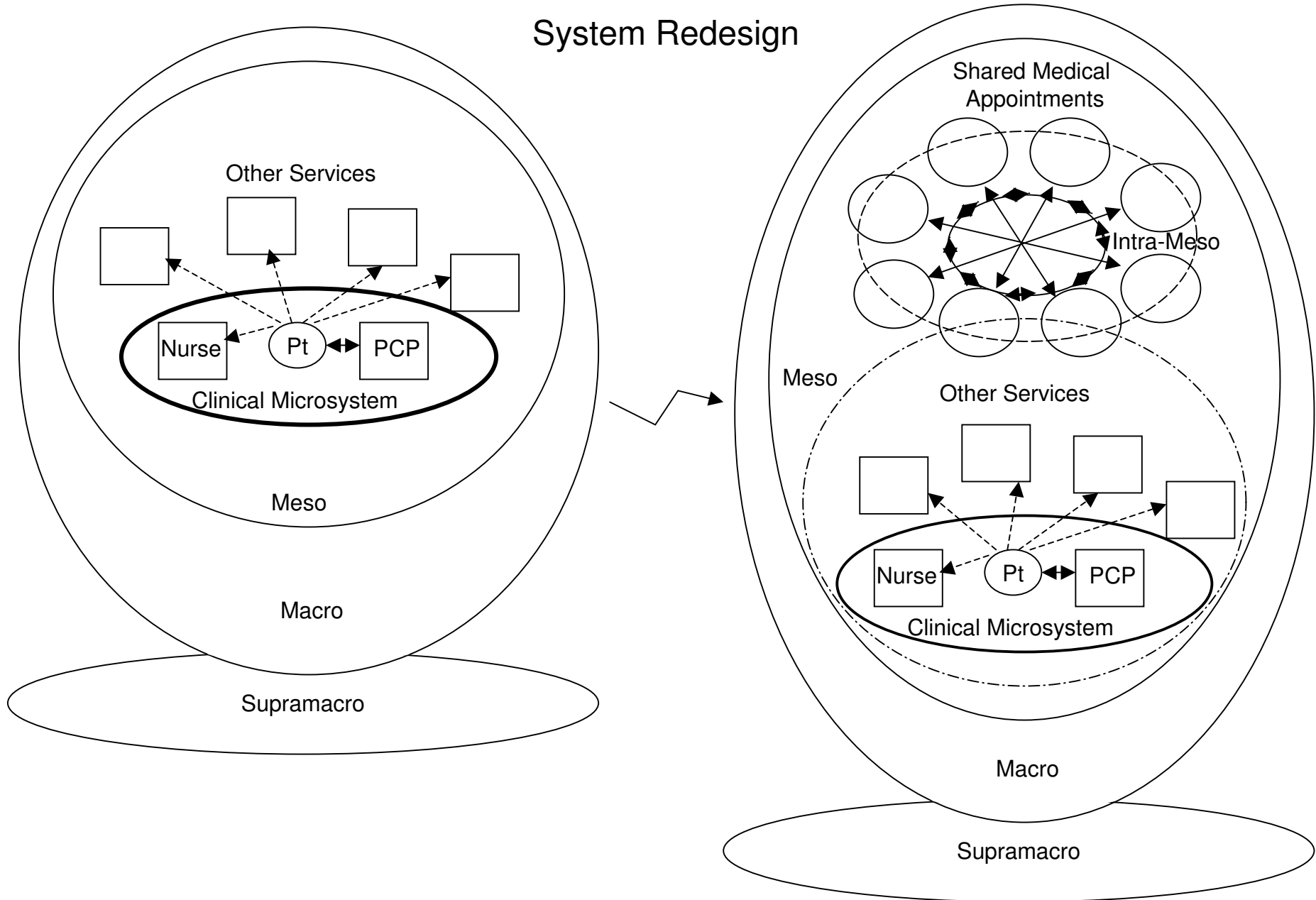


Figure 1

Figure 2

Care System Components	Defined via Local DM Care Context	Current DM Care-Based Practices (August 2007)	
Supramacro	VHA Central Office	Initiatives for veterans returning from Operation Iraqi Freedom/Operation Enduring Freedom	
		Inpatient Flow to reduce fee basis care	
		More prescriptive about how to get to goals	
		EMR and registry for patients	
Macro	Cleveland VAMC	Roll-out SMA as part of ACA	
		Meetings about intermediate goals and strategies	
		Resource negotiation along with updates; Targeted space for SMA	
		Pursue mandates: OIF/OEF	
		Equal focus on quality care	
Meso-systems	Primary care clinics	Monthly reports about meeting DM care goals	
		Monthly clinic meetings review & allocate resources	
		Registry & protocol to identify and move high risk pts	
		Individual & group meetings with discipline representatives	
		Go to macro level for change if needed but now less necessary	
	Other services	PCP is additional signer on notes for pts	
	Pharm	Individual referral to education (meds and adherence)	
		Medication algorithms (augment/adjust; problems)	
	Nursing	Nurse manager meeting overlap with MD meetings	
	Clerks	Make appointments for follow-up/referrals	
Intra-meso	Multi-disciplinary	SMA with interactions to create supportive setting	
Microsystems	Individual Units		
	Intra-micro	900 w/ A1c > 9	Attend individual visits (3 months recommended)
	Patient	High Risk	Follow-up with referrals to other services including:
			Pick-up new medications now and then see:
			Clinical pharmacist to change medications (1 month)
	Nurse		Lab work prior to next visit
		4 RN	Take vitals, updates from patient, etc.
		2 LPN	Provide case management/education as referred
			More lower level clinical reminders
	Provider	PCPs w/ DM pts:	More pressure to see more pts & meet goals
		8 Part-time attendings	Goals A1c < 9; LDL < 100; SBP < 130
		5 NPs	Scores regarding meeting goals
		1 PA	If pt not meeting measures, then Educate Pt via:
		Preceptors (5 new)	Referrals for Consults: Self-management classes
		Residents (60/year)	Nurse ; Clinical pharmacist; Nutritionist; Endocrine

Deference to expertise not hierarchy  
 Comprehensive care  
 Team equal supportive roles  
 MD  
 PhD  
 PharmD  
 RN  
 NP, CDE  
 Trainees  
 Patients (accommodate 15 or so)  
 Two PharmDs present when attending  
 physician is not  
 Weekly meeting  
 90 -120 minutes (group w/ each pt meeting  
 individually with a provider)  
 Motivational interviewing

