QUERI Implementation Guide

Section II VA QUERI Research

II-1 VA QUERI Quality Improvement Demonstrations: Lessons Learned

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Section II Part 2: VA QUERI Quality Improvement Demonstrations: Lessons Learned

This Section outlines a number of lessons learned by individual QUERI groups as they conducted projects designed to integrate research findings into practice to improve the quality of care in VA health care facilities.

Examples are organized into issues related to:

- Evidence – the evidence base for the practice change,
- Context – the organizational context for the change, and
- Facilitation – the methods used for facilitating the change.

This typology is borrowed from the framework for implementation of evidence-based practice developed by Kitson and colleagues.[1,2] An "Other" category is used for lessons that do not readily fall into one of the above categories. The QUERI group that offers each example is identified as follows: Chronic Heart Failure QUERI – CHF, Colorectal Cancer QUERI – CRC, Diabetes Mellitus QUERI – DM, Human Immunodeficiency Virus/AIDS QUERI – HIV, Ischemic Heart Disease QUERI – IHD, Mental Health QUERI – MH, Spinal Cord Injury QUERI – SCI, and Substance Use Disorder QUERI – SUD. [At the time this section was written, these eight QUERI groups had been in operation, while the Stroke QUERI had not yet been funded.]

Evidence: Lessons Learned About the Evidence-Base for Practice Change

- *A strong evidence base for recommended practice is critical: Account for clinical exceptions to guidelines and discuss conflicting guidelines.*

MH: While there is strong evidence and guideline support for the use of moderate antipsychotic doses and limiting the use of high doses, there are still clinically appropriate instances indicating the use of antipsychotics above the recommended range. We needed to be open about these instances and tried not to "penalize" programs for the appropriate use of antipsychotics outside the recommended range. Therefore, we performed medical chart reviews of patients whose doses were above the recommended range to look for justification/circumstances for using high doses. Further, we had one instance where slightly conflicting dose recommendations for some antipsychotics were issued by another VA group (not the VA National Practice Guideline Council). This prompted an open discussion about the differences in the recommendations and why we were following the formal VA Psychosis Guidelines' recommendations for the project.

SUD: We had an experience similar to MH in that there is strong support for using higher methadone doses (> 60 mg), but there are clinically appropriate reasons that a patient may be maintained on a low dose. Not wanting to penalize appropriate use of low doses, we developed a

dose review process in which teams reviewed each low-dose patient and were able to make a determination as to whether the dose was clinically appropriate or needed adjustment.

DM: For a project focused on improving care for hyperlipidemia, we planned to develop a pocket card. Development was hampered by limited evidence on specific details of treatment. While the need for treatment of hyperlipidemia is well established, the details of when to initiate treatment and the medications and doses to use were less clearly evidence-based. We had hoped that offering details on initial statin doses for patients with and without coronary artery disease would assist providers. However, we were unable to come to agreement with project sites about recommendations to be included on the pocket cards so this planned component of the project was never implemented.

IHD: We used a goal level for low-density lipoprotein (LDL) treatment that conformed to both the VA/DoD guideline and a nationally recognized guideline. During the period of our intervention studies, the VA/DoD guideline goal for LDL was revised upward from 100 to 120, while the national guideline remained at the same level. Clinicians were both confused and unhappy about the change. As a VA (QUERI) group, we were bound to follow the VA/DoD guideline, which was actually somewhat better supported by the evidence. However, clinicians felt that the national guideline conformed better to their knowledge and experience.

SCI: While there was clear evidence supporting the administration of respiratory vaccines to persons with SCI, we also had strong evidence for each of the four interventions we chose to implement at our target sites: patient reminder letters and educational materials, provider education, computerized clinical reminders, and nurse standing orders. This evidence was generated in the context of improving preventive care practice in a wide variety of settings and was generalizable to the SCI care settings.

- *Clear targets/benchmarks for performance are helpful in changing clinical behavior.*

MH: Our program goals were to improve the use of antipsychotic doses within recommended ranges and increase the use of novel antipsychotics. Lack of specific performance goals for the percentage of patients receiving antipsychotic doses within the recommended range and the percentage of patients on novel antipsychotics was a barrier. Clinical presentations that indicate the use of antipsychotics outside of the recommended ranges as well as the continued use of older antipsychotic agents do exist. However, the appropriate percentage of patients that fall into these categories is unclear. While we were able to show reductions in high antipsychotic doses at most translation facilities because most agreed that their baseline rates regarding these practices could be improved, the lack of specific performance goals/benchmarks remained a barrier. Therefore, whenever possible use an evidence-based goal or benchmark to lead a behavior change intervention.

Context: Lessons learned About the Organizational Context for the Change

- *Understand organizational factors that influence the project and identify and utilize local key leaders, experts, and others.*

SCI: We learned about local variations in service delivery while conducting semi-structured and open-ended interviews about interventions (formative evaluation), particularly when we let local staff describe their situation. In some cases, the intervention, as we presented it, did not fit very well with local conditions, but staff had figured out other ways to achieve the same result.
DM: The selection of local champions could probably have been improved by our having better knowledge of the organization. In some cases, we used persons that might not have been viewed as the best experts or clinical leaders within their organizations. In informal talks with persons from sites after the completion of projects, it was recommended that we do more up-front discussion with a variety of people about our plans and how they fit into the organization. Two objectives can be met by increasing input from local staff: 1) improving the interventionists' knowledge about the organization, and 2) better involving those who are in the organization in the planning of the intervention. People want to be asked for their input and advice.
MH: While performing pre-implementation site visits to better understand the organization of care, processes of care and patient flow, attitudes about guidelines and the performance measures in the study, information technology needs, etc., we learned that we had not gathered enough information about the organizational and cultural factors that influence provider behavior. To name a few, issues of organizational and professional culture, incentives, financial concerns, perception of research, and leadership were not fully understood, and thus were not addressed or monitored adequately in our project. In our new project, we plan for more time to completely assess and address these factors within the intervention.
IHD: One of our QUERI project teams had significant exposure to, and interactions with, clinical leadership and staff from most of the sites in the intervention facilities prior to starting interventions. One of the activities had been site visits to all facilities in the VISN to assess implementation of primary care and managed care principles. The information and contacts gained from this experience were critical in our ability to launch and test interventions. However, we learned that even with a good deal of prior contact with leadership and knowledge of the organizations, we did not know as much as we needed to know about how to influence behavior change. For example, the relationships between front-line providers (the people doing the intervention, generally) and their managers, who needed to give them time to work on interventions, were sometimes portrayed as very positive. However, over time it became increasingly clear that the relationships were not as positive. Also, we found that the perception that VHA is doing well in lipid management limited interest in making changes.

- *Use existing organizational structures, communication, and work patterns for the opportunities they offer.*

SCI: The existing organizational relationships, such as those between the SCI Strategic Healthcare Group (SHG) and the specialized SCI Centers, facilitate the exchange of information and attach authority to communications. For example, it was not necessary to re-establish legitimacy of

knowledge and hierarchy-based authority at each contact. We think this was due to the established legitimate authority of SCI SHG.
Also, we found an advantage to working with centers that had well-established multidisciplinary teams. Personnel were accustomed to delivering care via teams. Persons of various professional training volunteered to attend calls pertaining to the influenza vaccine delivery initiative.

- *While organizational stability is not under your control, expect and be ready to respond to change.*

MH: Over the 12 months of our intervention implementation, mental health chiefs in three of four intervention sites changed. These changes in leadership complicated the involvement of the sites in our project. While the project continued in each of these sites, the level of support from the new chiefs varied. We recommend that project staff expect changes in leadership and staff (we also had changes in clinical staff), and be ready to engage new personnel quickly and personally. Try to have opinion leaders at intervention sites quickly provide information and support to new personnel regarding the project and the project's goals. In our initial depression project (TIDES-WAVES), the project survived the departure of a VISN Director. One key element to making the successful transition was the close relationships with multiple VISN leaders that the study was able to generate. The relationships helped insure continued support for the project during a potentially volatile time. A strong network of support in a VISN (or facility) can help to buffer the potential negative impacts of leadership turnover.

- *Participating in demonstration projects can evolve into routine practice.*

HIV: The extra work involved with participation in the Institute for Healthcare Improvement-style collaboratives soon became routine at the sites. Although there was extra work involved in the beginning of participating in this type of activity, the extra work eventually became part of the normal work routine; that is, old practices and structures that may not have worked well were displaced with new approaches, and even decreased the time needed for addressing some aspects of work (e.g., missed appointments).

- *When planning information technology interventions, know the national and local procedures for their implementation and expect delays.*

MH: In the depression project (TIDES-WAVES), the development of a proposed software system for collaborative care managers went relatively smoothly. Working through the Information Technology process to get the web-based software up and running on the Intranet took more time than anticipated and slowed the progress of the project. Even when the correct approval processes are followed to introduce a new web-site/software package, plan for delays as sites begin to implement the new technology tools. Unforeseen technical and system support problems often arise. MH QUERI investigators are pursing a Service-Directed project to improve the process of informatics development for translation work. The project will seek new ways to improve

cooperation and collaboration between voices from the field (e.g., researchers and clinicians) and VA technical support/developers.

Facilitation: Lessons learned About the Methods Used to Facilitate Change

- *Emphasize improving care rather than the "research" aspects of an intervention.*

SCI: We offered our interventions to improve vaccine rates to staff at SCI centers as ways to improve particular aspects of care for veterans with SCI, not as research. We have not hidden the research component, but we have not emphasized it, thus we have been able to work more as consultants and respond to the varied circumstances at the SCI centers.
CHF: We found that research is perceived as separate from and not quite part of day-to-day clinical practice, which affected the CHF QUERI Coordinated Care Program. Care providers may prefer to see this as a clinical activity rather than research, which would result in more thorough integration into day-to-day practice. Additionally, applying tools of Continuous Quality Improvement (CQI) could systematically improve the way questions are asked, the way answers are determined, and how problems are solved.

- *Tailor the intensity of facilitation to the needs of each site.*

SCI: Facilitation 'intensity' is not easily measured. We found that some centers have required very little assistance from the facilitators to carry out the interventions. Other centers have required a lot of assistance, while some could have used us more. We emphasize keeping the goal of each intervention in mind and having flexibility in ways to reach each goal at the individual centers. From our experiences, a tool was developed to quantify the degree of implementation of each strategy at each center (over a year), so that we would understand how the sites varied regarding the extent of the implementation. The Intervention Strategy Intensity Scores (ISIS) provide a summary measure of implementation.

- *Create networking opportunities to enhance opinion leader interaction.*

MH: The training session for opinion leaders at the beginning of the MH project, "Antipsychotic Treatment Improvement Program to Reduce Excessive Antipsychotic Doses," allowed for a good deal of interaction, both (social and project-related. Representatives from each intervention site discussed implementation strategies as well as potential barriers and facilitators. However, while we had a number of group conference calls during the intervention, we felt that we did not have the opinion leaders interact enough during the implementation.

- *Respond quickly to questions and concerns from stakeholders.*

MH: Concerns were raised during our project when an alternative set of "recommendations" was issued that did not completely agree with the antipsychotic dose ranges that we were disseminating/implementing. We quickly needed to explain that the VA Psychosis Guidelines (the basis of our project) had not changed, and that the dose recommendations in the tools we disseminated were still evidence-based and endorsed by the VA Guidelines Council. Regularly scheduled weekly conference calls with our identified opinion leaders allowed us to respond quickly and thoroughly to this concern. We learned that when there is a problem, question, or concern, it is beneficial to quickly evaluate the situation and to work on solving the problem as soon as possible. Rapid response is important.

- *Different types of users present different barriers.*

HIV: We implemented 10 guideline-based reminders on Computerized Patient Record System (CPRS) screens at eight sites that advised providers at the time of their patient's visit that current HIV care had failed to meet established standards. We found that some users, such as attending physicians, rarely use the CPRS system and have limited experience with reminders in general.

- *Involve all relevant stakeholders in behavior change interventions.*

MH: The main targets of our intervention were psychiatrists—often the only prescribers of antipsychotics in healthcare systems. While we were, for the most part, pleased with the intervention tools directed at this group, we realized over time that others in the process of delivering care (i.e., nurses, pharmacists, administrators) could also be very influential regarding the use of antipsychotics. The inclusion of these stakeholders in the intervention could improve performance. In our upcoming extension of the project, which will also include performance measures regarding monitoring for side effects and greater use of clozapine, we will test a translation strategy targeting multiple stakeholders in the process of care using a multidisciplinary team-based approach.

- *Participants in implementation efforts may derive benefits from participation.*

HIV: Provider participation in a group-based social support effort to improve quality of care (e.g., IHI Collaboratives) increased work satisfaction. Participants felt that their efforts made a difference in quality of care, and thus helped their clinic become more effective in its work through a greater understanding of how to implement change. Participants learned how to navigate the bureaucracy at their clinics and, in doing so, became familiar faces to those who facilitate organizational change.

- *Customize the intervention to local conditions.*

SUD: The quality improvement objectives may differ depending on site characteristics, such as baseline compliance with best practices and readiness to change. This may require greater focus

on certain program elements at each site. One objective of the SUD project was to improve compliance with dosing recommendations for opioid agonist therapy. At baseline, study clinics ranged from poor compliance with dosing recommendations to full compliance. Among the poor compliance clinics, some were more ready than others to improve compliance with higher dosing of methadone. For those ready to change, education could be tailored more to how to change (what doses should be used), and how to track changes with the provision of frequent feedback. For those less ready to change dosing, educational efforts and frequent feedback were required to demonstrate the relationship between adequate dosing and the desired outcomes of substance use reduction. Clinics with full compliance on dosing recommendations focused quality improvement efforts on other recommendations (e.g., implementing contingency management interventions).
CHF: Based on the preliminary outcomes from the CHF translation project, we recognize the importance of applying different strategies depending on the type of facility (small vs. large), types of caregivers (MD - cardiologist, PA or RN), and the facility's ability to identify at-risk CHF patients. Consider these kinds of variables in developing strategies.

- *Tailor data collection and feedback to varying QI goals at each site, rather than providing the same for all.*

SUD: Monthly data collection and feedback on methadone dosing was important for those clinics working to change dosing strategies, since it provided rapid documentation of progress (or lack thereof) toward goals. For clinics that were already in compliance with dosing benchmarks, periodic feedback on dosing was adequate to assure that they maintained compliance. For clinics whose QI goals were focused on changes in program orientation (moving towards a maintenance orientation) or other longer-term goals, quarterly assessments were sufficient to track changes. More frequent feedback on longer-term goals can be discouraging as the clinic may feel that they are not making progress. We learned that when goals are different at each site or change during the project, the type and frequency of data collection and feedback should be varied based on the QI objectives and the short or long term nature of the change of interest.

- *Using peer (VA) norms rather than national norms was helpful.*

SUD: Using peer feedback from other VA organizations was more powerful than outside or community benchmarks. It avoided arguments such as,… "but VA is different because… so we cannot be expected to be the same as those standards."

- *Use a flexible approach to meet local needs and differences.*

SCI: In order for a center to adopt one of our interventions other steps were required that had not been anticipated. By paying attention to these unanticipated barriers, we learned a great deal about changing the system at levels that are more likely to last. For example, after recommending that everyone use the computerized reminders for respiratory vaccines it was discovered that the programming in the reminders did not identify the target patients. Thus it may not be possible to

start with a completely mapped out process to meet your goal, but progress toward the intended goal will inform your future work.

- *Organizational and design issues impact intervention effectiveness.*

HIV: For our projects using clinical reminders, we found that many providers, particularly physicians, were not comfortable resolving reminders because they found them to be awkward (i.e., not intuitive) and time consuming. False alarming tended to intensify the latter complaint. A full report of a human factors assessment of clinical reminder use can be accessed at http://www.va.gov/queri-hiv/.

- *Plan for process evaluation and tracking of the degree of implementation.*

SCI: We have qualitative data from semi-structured and open-ended interviews, conference calls, e-mail messages and reports on our activities to implement and facilitate interventions from the beginning of our first translation project. This data has been useful not only for facilitation of the interventions and assessing their status, but also for evaluation purposes. Some of this data has been useful in ways we never expected. We intend to fully incorporate qualitative methods of data collection and analysis into our next project.
IHD: Qualitative interviews with key clinical participants in the interventions demonstrated that: 1) We did not know exactly what interventions were carried out in each facility, and facilities we had classified as "controls" actually did carry out interventions; 2) Intervention doses were low in all participating facilities; and 3) Organizational barriers were difficult to surmount because of inadequate planning and preparation by intervention participants.
DM: In a number of demonstration projects, we lacked information about some details of implementation. For example, in a project that offered education and feedback, we had limited information about: the extent to which the education and feedback materials sent to each site were distributed, whether they were used, or whether other information would have been preferred by the users. For a case management project, additional information on opinions of the providers about ways the case management activities were helpful or how they might have been improved or modified would have been useful in further understanding the results and in planning future projects. If funds or resources had been available, additional formative and process evaluation would have been helpful.

- *Keeping up momentum is important. Continue contacts, monitor, and respond quickly when the process stalls.*

CHF: It is important to keep up momentum and foster sustainability through communication and devoting attention to increasing understanding about the long-term program goals. It is important to maintain close collaboration with care providers, hospitals, VISN leaders, and others.
MH: Through close monitoring of performance measures (quantitatively) and the project's implementation (qualitatively), we were able to tell when momentum stalled. At these times, we

tried different strategies to re-engage the opinion leaders and other stakeholders at the sites. For example, we tried scheduling conference calls with opinion leaders across sites to stimulate discussion, seeking ideas from opinion leaders about alterations/additions to the intervention, conference calls with mental health chiefs to discuss the project to stimulate activity at the sites, and implementing new intervention tools. One such new intervention tool was a feedback system whereby patient identifiers of specific patients with very high-dose profiles of antipsychotics were delivered to opinion leaders at the intervention sites each month. The opinion leaders were able to approach the clinical teams responsible for these patients in order to explore their antipsychotic management. The feedback system was introduced toward the end of the project, but it produced new performance gains. As well, the opinion leaders were very satisfied with this addition to the intervention.

SUD: Ongoing contact and enthusiasm with the project staff makes a difference. Persons involved in day-to-day activities often have issues that are more pressing than a QI project. We learned that contact with the QUERI translation team was helpful in keeping the projects going. Also, "substantial outsider prompting to create/sustain momentum" was required to keep the project going.

DM: Over time some of the site clinical champions may have lost interest and may have not passed on information or resources sent to the sites. For other projects it was not always clear who was to deal with and problem solve certain issues (research staff or site contact). Questions that should be addressed during the planning of the intervention include:

- What are the roles of the site contacts and how are the roles communicated and agreed upon?
- What kinds of regular communication with site contacts will be part of the project?
- To what extent will site contacts be relied on to problem-solve at their location? How are site contacts perceived at their site?
- What are the best ways to orient the site liaison and keep them involved with the projects?
- What can be done when these persons/roles are not functioning well?

Consider establishing a climate of joint problem solving and distinguishing who is responsible for different kinds of issues.

- *Foster patient contact and facilitation. Find ways to reach patients, enhance patient empowerment, and account for patient differences.*

CHF: It is important to find ways to reach all patients. Possible communication vehicles include community outreach, group visits, making information available on the Internet, and enhancing our understanding of patient preferences. Collaborative efforts of translation and quality enhancement researchers and quality managers may be required to accomplish this. It is critical to empower and motivate patients by encouraging patients' responsibility for their own health, increasing sense of worth, providing knowledge and self-management support, as well as

assessing barriers, problem solving, and goal setting. In the CHF Coordinated Care Program, customization of the intervention for patients included taking into account the severity of illness, and their ability and willingness to implement rigorous follow-up (patient's adherence to the prescribed intervention).

- *Identify and use models and resources that are available.*

SCI: The descriptive model of facilitation by Kitson, Harvey and McCormack was very helpful.[1] It describes three components of facilitation – purposes, activities and skills/attributes of facilitators – on continua. For example, purposes of facilitation range from 'tasks' to 'holistic' roles (activities), which range from 'doing for others' to 'enabling others.'

Other Research Issues

- *The activity of facilitation can create tension in a team of "traditional" health services researchers.*

SCI: Tensions arose over which team members were to have contact with centers and what data was to be noted. This derived from a lack of shared understanding of qualitative and quantitative procedures. These issues can be reduced by regular team discussions about roles. Acknowledging the wide range of skills necessary for an implementation research project and broadening team knowledge about these skills can also help.

- *Select measures carefully, look at differing sources of information (e.g., qualitative and quantitative), and look further if things don't seem to add up.*

SUD: At first it was believed that identifying the number of patients working on a detoxification goal would be a good indicator of the treatment orientation of a clinic; that is, the clinic is either oriented toward detoxification/abstinence vs. indefinite maintenance on methadone (the more desirable treatment orientation), or not. This was not necessarily the case because clinics universally reported that 90 to 100% of their patients were not currently working on a methadone taper goal. However, other indicators of a "detox" orientation, including lower-dose methadone and more punitive responses to continued substance use, were identified through policy reviews with clinic leadership. So, rather than using the proportion of patients with a maintenance goal as demonstration of clinic change, SUD used a more direct measure of program orientation, the Abstinence Orientation Scale[32] as the measure for achievement of a maintenance orientation in the clinic.

- *Be aware of benefits and problems of different staffing mechanisms and the impact of the immediate environment.*

DM: One research staff person, who was part time on the project and who spent time in clinical areas, began spending more time on non-project activities than allocated, probably because of her ongoing relationships within the organization and being drawn into high priority activities taking place in the immediate environment. We were not aware of this until it had gone on for sometime. This may have affected the outcome because the staff person had less time available for patient and provider contact and follow-up. However, spending some time on non-project activities builds a sense of participation and being part of the team. For another of our projects, one of the nurses was new to the organization. As research staff, she was hired and paid for by the project and was a temporary employee. Because she was not a known entity, she was an outsider, and her tenure was seen as temporary. This appeared to limit her ability to engage with the providers in working with them to suggest and make changes for the organization. On the other hand, another nurse who had worked at the institution and then took on the project tasks was already well known to the clinicians, and this was beneficial to the project functioning.
In yet another DM case management project, research project staff were treated differently (e.g.,promotion opportunities) and negatively because they were temporary employees. At one DM site, project staff was perceived as being a group apart who did not attempt to "fit in" with the rest of the clinic staff. This then created tensions between the two groups – clinic staff and research staff.

- *Evaluate time and cost burden.*

HIV: We estimated that the average cost of implementing10 HIV-related clinical reminders per site was moderate at about $30,000 for the 12-month study period.
The average cost of implementing a group-based social support, Institute for Healthcare Improvement-style collaborative intervention per site was estimated – by site personnel – to be minimal at $6,000 for the 12-month study period. This intervention provided mentored application of a model for rapid quality improvement, adapted from the Institute for Healthcare Improvement's Breakthrough Series, offered to two key HIV care providers from each of eight facilities.[43] See the Institute for Healthcare Improvement website for further information about breakthrough collaboratives at
http://www.ihi.org/IHI/Results/WhitePapers/TheBreakthroughSeriesIHIsCollaborativeModelforAchieving%20BreakthroughImprovement.htm

*****This section was collated and written by Mary Hogan, PhD, Implementation Research Coordinator(IRC) for DMQUERI and Hildi Hagedorn, PhD, IRC forSUD QUERI, with substantial input from other IRCs: Barbara Kimmel, PhD (CHF); Laura Kochevar,PhD (CRC); Candy Bowman,PhD (HIV); Anne Sales,PhD (IHD); Geoff Curran,PhD (MH); and Marcia Legro,PhD (SCI), and theAdministrative Coordinatorfor CHF QUERI, Donna Espadas, MPH.

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Section II Part 2: Tools and Toolkits

This section of the Guide is devoted to the tools and toolkits developed and/or used by the QUERI groups in their translation projects.

QUERI-Developed Tools

As QUERI groups have conducted projects focusing on translating evidence-based practices into routine care, many groups developed their own tools to assist in the implementation of these projects. In this section of the Guide, we present brief descriptions of the tools and provide links to the tools themselves, which may be useful for future translation/implementation projects – either as tools to be adopted or to serve as models for new product development. It should be noted that most of these tools are still in a developmental stage. Also, given space constraints, only sample pictures (e.g., screen captures) of some tools (e.g., computerized clinical reminders) that have been developed could be provided. If you have an interest in using any of these reminders, which are not already nationally available, please contact the Implementation Research Coordinator (IRCs) from the relevant QUERI group for more information regarding implementation, evaluation, and the extent of reliability/validity data available, etc.

Other Tools Used in QUERI Projects

Many QUERI groups also have used tools developed by others in their projects, which are not yet at a point ready for distribution. We recommend contacting the IRC for the disease state of interest to see if there are additional tools available.

Structure of this Section

Common categories of tools in QUERI projects include:

- Provider education materials,
- Patient education materials, and
- Clinical practice support tools (e.g., guideline pocket cards or clinical reminders).

Some groups have their tools pre-bundled into electronic toolkits, while other groups have their tools available individually. Below are links to bundles of tools, as well as individual tools. The tools are organized around the disease-specific QUERI groups.

Diabetes Mellitus QUERI

Clinician Education Materials

DM QUERI developed educational briefs for the Diabetes Care Project – an education, profiling and

feedback initiative in VISN 11. The briefs target aspects of the goals of the project: better blood pressure control, glycemic control, and lipid management. Each brief summarizes recent research evidence on the topic and offers suggestions for patient care. The briefs were designed to be distributed to clinicians, either as a follow-up to an educational session, or as a stand-alone item. Because evidence in these areas continues to be developed, such briefs should be updated before use. These are offered as examples only. For more information, please contact Mary.Hogan@med.va.gov, Implementation Research Coordinator for DM QUERI.

- Summary – Blood Pressure Control
- Summary – Diabetes and Glucose
- Summary – Diabetes and Lipids

Ischemic Heart Disease QUERI

Assessment of Organizational Readiness for Evidence-Based Care for IHD

This survey was designed by IHD QUERI to assist in the planning stages of a translation/quality improvement project in IHD. The survey elicits information on beliefs about the strength of the evidence base in IHD management and the context of care provision. A few of the domains covered in the survey include: organizational leadership, process, culture, and resources. Please contact Anne Sales, PhD, IHD QUERI Implementation Research Coordinator, (ann.sales@va.gov) for more information on the survey.

- IHD Pilot Organization tool

Facilitator Packet for IHD QUERI Quality Improvement

This packet was developed specifically for IHD QUERI's translation project concerning monitoring lipid levels in patients with ischemic heart disease. The packet outlines strategies for developing an intervention to improve lipid monitoring and provides tools to help in the implementation. The packet is designed to assist small group facilitators in a kick-off meeting to help participants plan and carry out an intervention in their facilities.

- IHD Facilitator Packet

IHD Tracking Database

This database was developed in Microsoft Access to assist in conducting process evaluations concurrently with implementation of interventions to improve lipid measurement and management. It has been adapted for use in other process evaluations. Adaptation requires some knowledge of MS Access and, for advanced adaptation, the ability to program in Visual Basic.

- IHD Tracking Database

IHD National Lipid Clinical Reminders

These two reminders were developed by IHD QUERI in collaboration with Systems Design and Development, an office of the VA national Office of Information. The first reminder is triggered to appear in the reminders folder of a patient's CPRS record if the patient has ischemic heart disease, is being seen in primary care or selected other clinics, and does not have a low-density lipoprotein (LDL) cholesterol value recorded within the last 24 months. The second reminder is triggered if the patient has a current LDL value recorded, and the value is above 130 mg/dL.

- For information about National Lipid Reminders, contact Anne Sales, PhD, IHD QUERI's Implementation Research Coordinator at **Ann.Sales@va.gov**

Mental Health QUERI

Schizophrenia Project (ATIP)

Fact Sheet on VHA Schizophrenia Guidelines

This one page fact sheet provides succinct information on VHA guideline recommendations for the use of antipsychotic medications (e.g., dosing, switching from conventional to novel antipsychotics).

- Schizophrenia Guidelines Fact Sheet

Fact Sheet on Cost-Effectiveness of Novel Antipsychotic Medications

This one page fact sheet briefly summarized the literature on the cost-effectiveness of novel antipsychotic medications.

- Cost-effectiveness of Novel Antipsychotics Fact Sheet

Pocket Card on Antipsychotic Treatment for Schizophrenia

This pocket card presents information from the VHA guidelines on the appropriate use of novel antipsychotic medication.

- Pocket Card on Antipsychotic Treatment

VHA Psychosis Guidelines Help File

This help file/program can be loaded onto any computer. It is organized around the modules in the VHA Psychosis Guidelines. Diagrams and flowcharts visually depict the psychosis treatment algorithms. Users of the help file can use their cursor and mouse to highlight and view annotations on the nodes of the algorithms.

- Psychosis Guidelines Help File (To download this file, place your cursor on the link, right click, and save to your desktop.)

Pharmacy Order-Entry "Reminder" on Dose Recommendations for Antipsychotics

This tool is a dose "reminder" tag that appears on the pharmacy order entry screen in CPRS when a physician orders an antipsychotic medication. When this is installed on CPRS, every time an antipsychotic medication is ordered, the VHA guideline-recommended dose range appears in the order entry screen. See an example pharmacy order entry screen below. Contact the Mental Health QUERI Implementation Research Co-Coordinator (Jeffrey.Smith6@va.gov) for more information on how to use this tool.

- Pharmacy Order-Entry "Reminder"

Clinical Reminder on Olanzapine and Diabetes/high lipids

This clinical reminder notifies physicians that a patient is being treated with olanzapine and has also been identified as having diabetes mellitus and/or high lipids. Olanzapine has been associated with elevations in both blood sugar and lipids. The reminder offers responses or potential clinical adjustments to physicians. See the sample reminder depiction below. Contact the Mental Health QUERI Implementation Research Co-Coordinator (Jeffrey.Smith6@va.gov) for more information on how to install this reminder in your facility.

- Clinical Reminder on Olanzapine and Diabetes

Feedback Performance Report on Use of Antipsychotics

This report was designed specifically for Mental Health QUERI's initial translation project in the area of antipsychotic prescribing. Mental Health QUERI provided monthly feedback to intervention sites on several performance measures related to the use of antipsychotic medications, such as dosing, switching to novel medications, use of medications to treat side effects of antipsychotics, etc. MHQ can provide the programming code and associated steps necessary to produce these reports at any VA facility. Contact the MHQ Implementation Research Co-Coordinator (Jeffrey.Smith6@va.gov) for more information on how to use this tool.

- Feedback Performance Report

Flyer on Newer Antipsychotic Medications for Patients/Families

This flyer briefly presents information on novel antipsychotics and provides other treatment recommendations for schizophrenia. It was developed for patients and their families. The flyer was developed in collaboration with the South Central Mental Illness Research, Clinical, and Education Center.

- Flyer on Newer Antipsychotics

Wall poster: "Ask your Doctor If Newer Antipsychotics are Right for You"

This poster was designed for display in waiting rooms and clinics. It is designed also to hold the flyers listed above in a pocket on the poster. The poster was developed in collaboration with the South Central Mental Illness Research, Clinical, and Education Center.

- Wall Poster

Depression in Primary Care Project (TIDES-WAVES)

Education Program for Primary Care Providers on Collaborative Care for Depression

Materials for this program include:

  - Three PowerPoint educational presentations for providers (recognizing depression, medication management, and interviewing patients):

- Depression care dissemination notebook with education materials (contact the Mental Health QUERI Implementation Research Co-Coordinator (Jeffrey.Smith6@va.gov) for more information), and
- Depression care pocket guide.

These materials were developed to use in clinics that are adopting a collaborative care model for treating depression in primary care. Please see the project description in the "Translation Studies" section of the Guide for more information on collaborative care for depression.

- http://www.va.gov/tides_waves/docs/RecognizingDepression.ppt
- http://www.va.gov/tides_waves/docs/medicmanag.ppt
- http://www.va.gov/tides_waves/docs/InterviePatients.ppt

- MHQ Pocket Card

Educational Programs for VISN Leaders on Collaborative Care for Depression

This program contains a PowerPoint presentation and a dissemination notebook with educational materials for VISN leaders (contact the Mental Health QUERI Implementation Research Co-Coordinator (Jeffrey.Smith6@va.gov) for more information on the notebook). The project that developed this program worked in three VISNs to promote VISN-wide adoption of collaborative care for depression in primary care. VISN leadership was integral to the success of the project, and this program facilitated VISN leader buy-in and activity in support of the project (e.g., redistribution of resources).

- http://www.va.gov/tides_waves/docs/tidesorientation.ppt

Depression Care Website

This website contains information about the TIDES-WAVES intervention. The study's procedures and outcomes are documented here, and you have access from the site to many of the tools (education materials, etc.) used in the intervention.

- http://www.va.gov/tides_waves

CPRS Progress Note Templates for Collaborative Care for Depression

These are progress note templates for use in the VA computerized medical record. See the following website for more details and examples.

- http://www.va.gov/tides_waves/docs/templateexplanationreview.htm

Substance Use Disorders QUERI

All materials described below are part of the Opioid Agonist Therapy Monitoring System, a complete toolkit to support implementation of evidence-based practices in opioid agonist therapy (OAT) clinics. For a copy of the complete toolkit, please contact Hildi Hagedorn, PhD, Substance Use Disorders (SUD) QUERI Implementation Coordinator .

Evidence Summary for Methadone Dosing

This fact sheet summarizes recent evidence regarding best practices in methadone dosing and the relationship of adequate dosing to treatment outcomes.

- Methadone Dosing Summary

Methadone Dosing Consensus Statement

This is a one-page consensus statement developed by a panel of experts in OAT that contains dosing recommendations for physicians prescribing methadone.

- Dosing Consensus Statement

Methadone Dosing Algorithm

This is an algorithm designed to assist physicians in establishing an effective methadone dose for new OAT patients.

- Methadone Dosing Algorithm

Methadone Dosing Review Form

This is a tool designed to assist OAT teams in evaluating their compliance with methadone dosing best-practice recommendations.

- Methadone Dosing Review Form

Evidence Summary for Counseling Services in Opioid Agonist Therapy Treatment

This fact sheet summarizes recent evidence regarding standards for counseling services in OAT and the relationship of adequate counseling services to treatment outcomes.

- OAT Counseling Summary

Evidence Summary for Maintenance Orientation in OAT

This fact sheet summarizes recent evidence regarding the relationship between a long-term maintenance orientation to OAT and improved patient outcomes.

- Orientation Summary

Abstinence Orientation Scale

This is a 14-item questionnaire developed by John Caplehorn that can be used to evaluate staff's acceptance of a maintenance-orientated approach to OAT treatment.

- Abstinence Orientation Scale

Evidence Summary for Contingency Management in OAT

This fact sheet summarizes the principles of effective contingency management interventions, as well as recent evidence regarding the relationship of contingency management interventions to improved treatment outcomes.

- Contingency Management Summary

Contingency Management Implementation Tools

This document contains several tools designed to assist OAT teams in implementing effective contingency management interventions. Tools include a detailed example of a contingency management intervention, a worksheet for staff to complete as a team to assist them in determining what type of contingency management intervention would fit into their clinic structure, and a sample case manager/patient contingency management contract.

- Contingency Management Implementation Tools

The Opioid Agonist Therapy Monitoring System

This CD ROM contains a Microsoft Excel program that OAT clinics can use to enter data on key patient treatment and outcome variables (e.g., dose, frequency of counseling visits, number of take-home doses, frequency of urine screens, and percentage of urine screens positive for opioids). The program allows clinics to quickly and easily view summary statistics and create feedback graphs by case manager, or for the clinic as a whole. The CD also contains a PowerPoint tutorial that walks users through the process of data entry and feedback production. For a copy of this CD please contact the SUD QUERI Implementation Research Coordinator (**Hildi.Hagedorn@va.gov**).

Developing a Contingency Management Plan for Take-Home Privileges

This is a tool for assisting clinics in developing a contingency management plan for take-home privileges that will be feasible and acceptable for clinic staff. First, an example of a contingency management plan will be presented. Second, a series of questions for discussion are presented which will assist clinic staff in modifying the example plan for practical implementation in their clinic. This sample is consistent with current federal regulations regarding patient access to methadone take-home doses.

An Example Contingency Management Plan

The staff at OAT Clinic 1 has decided that they want to implement a contingency management (CM) plan for take-home privileges that is as consistent with the evidence for effective CM plans as possible given the constraints placed on them by federal regulations.

Take-home number one: 

Clinic 1 is open Monday through Saturday. Therefore, all clients immediately receive one take-home dose per week on entry into the clinic.

Take-home number two: 

Based on federal regulations, in the first three months of treatment, Clinic 1 can award one discretionary take-home dose every week beyond the dose they give out to every patient for Sunday. The staff decides that it is going to use this one take-home dose to try to reduce the rate of urine screens that are positive for opiates, cocaine, amphetamines, and benzodiazepines.

It is highly recommended that clinics focus their first three to four discretionary take-homes on abstinence. However, this combination of targeted drugs is only one option. Clinics will differ in the prevalence of positive urine screens for particular drugs. Some clinics may choose to target opiates only. Some may choose opiates and cocaine as the target drugs. Others may have a large problem with benzodiazepines use but little amphetamine use and may therefore choose to target opiates, cocaine, and benzodiazepines but not amphetamines.

The staff at this clinic has decided not to focus the CM protocol on marijuana and alcohol use until patients are able to demonstrate abstinence from other drugs.

It is recommended that alcohol and marijuana use be "higher level" targets in a CM protocol (i.e., not used as a behavioral goal until patients are able to demonstrate abstinence from other substances). This is not to imply that abstinence from these substances is not encouraged or addressed in other ways. Counseling visits and recommendations for additional treatment, or AA/NA involvement, particularly for patients with serious dependency issues, can also be helpful.

Based on their research into contingency management, they know it is important to set an objective behavioral goal, and that it is important to reward achievement of that goal as immediately as possible. They decide that they will reward their patients with the one discretionary dose after submission of two drug-free urine samples. This particular clinic tests urine once a week for every patient, therefore when a client submits two drug-free urine screens in a row, she receives an extra take-home dose starting the following week.

Note: It is ideal for implementation of a CM plan to test urine weekly. Clinics that test less often (e.g., once per month), may want to consider ways to increase their testing schedule. If this is not feasible, then a patient's take-home schedule could be set for a month following a drug-free urine test.

The patient's take-home privilege is reevaluated every week based on her most recent urine test. As long as the tests continue to be negative, the patient retains her discretionary take-home. If a patient submits a positive urine, the privilege is revoked until the patient is again able to submit two negative urine screens. Clinic 1 staff decides that this first discretionary take-home will always be awarded on Saturdays. This eliminates any negotiation with patients or confusion about when they will receive their take-home dose.

Take-home number three: 

Once a patient has been enrolled with a clinic for three months, federal regulations allow for a third take-home dose. Clinic 1 staff decides that this discretionary take-home should also be rewarded for urine tests free of the four target drugs.

Clinic 1 has decided to continue to target the same drugs for take-home three as for take-home two. This does not have to be the case. For example, a clinic may choose to target opiates only with the first take-home, then target opiates and cocaine for the second take-home, and then target all four drugs for the third take-home.

Clinic 1 also decides that the third take-home will always be given on Thursdays. Again, this eliminates negotiation with patients. In addition, the staff chose Thursday (as opposed to Friday or Monday) to decrease the number of take-home doses that a patient would have in her possession at one time. To earn her third take-home, a patient must submit four consecutive weeks worth of drug-free urines. Take-home privileges continue to be reevaluated every week. Once a patient has earned three take-homes,

she continues to receive these take-homes as long as drug-free urine samples are provided. If a patient submits one positive urine, her third take-home is revoked. The patient must then submit two consecutive drug-free urines to regain her third take-home. If a patient submits a second positive urine while on a two take-home schedule, she then also loses her second take-home. She then must submit two consecutive drug-free urines to regain her second take-home and two additional consecutive drug-free urines to regain her third take-home.

Take-home number four: 

Once a patient has been enrolled with a clinic for six months, federal regulations allow for a fourth take-home dose. Clinic 1 staff decides to continue to focus take-home privileges on urine tests free of the target drugs. The staff decides that the fourth take-home dose will be given on Tuesdays. Again, this decreases the number of take-home doses that a patient would have in her possession at one time. To earn her fourth take-home, a patient must submit six consecutive weeks worth of drug-free urines. Once a patient has earned her fourth take-home dose, she continues to receive four take-homes as long as drug-free urine samples are provided. If a patient submits a positive urine, her fourth take-home is immediately revoked. The patient must then submit two drug-free urines to regain her fourth take-home. If a patient submits a second positive urine while on a three take-home schedule, her third take-home is revoked as well. She would then have to submit two consecutive negative urines to regain her third take-home and two additional consecutive urines to regain her fourth take-home. If a patient submits another positive urine while on a two take-home schedule, her second take-home would also be revoked. She would have to submit two consecutive negative urines to regain her second take-home, two additional consecutive urines to regain her third take-home, and two additional consecutive urines to regain her fourth take home.

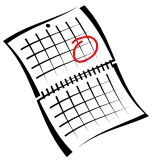
Take-home number five: 

Once a patient has been enrolled with a clinic for nine months, federal regulations allow up to six take-homes. This means Clinic 1 has two more discretionary take-homes to work with. The clinic staff decides to use the fifth take-home to continue to reinforce abstinence from the targeted drugs. In order for a patient to receive a fifth take-home dose, she must have submitted at least eight consecutive negative urine screens. Once a patient has earned her fifth take-home dose, she continues to receive five take-homes as long as drug-free urine samples are provided. If a patient submits a positive urine, her fifth take-home is immediately revoked. The patient must then submit two consecutive drug-free urines to regain her fifth take-home. For each positive urine submitted, the patient loses take-homes in a step-wise fashion. She can regain take-homes in a step-wise fashion as well, regaining one take-home for every two consecutive negative urines submitted. All patients in the clinic who earn a fifth take-home dose receive it on Wednesdays. This limits the take-home supply to three consecutive days rather than four.

Take-home number six: 

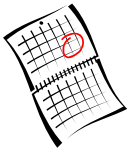
The Clinic 1 staff decides that the privilege of having to attend the clinic for dosing only once per week should be tied to higher level goals. In order to earn this privilege, a patient must have submitted at least ten consecutive negative urine screens for the targeted drugs; she must continue to submit urine screens that are negative for all illicit substances, including marijuana, and she must be able to document some productive daily activity such as employment or school attendance for at least 20 hours per week. As long as a patient can maintain these requirements, she can receive six take-homes per week. If a patient can no longer document productive activity, she loses her sixth take-home until she can again document achievement of this goal. If a patient tests positive for any illicit drug including marijuana, her sixth take-home is immediately revoked. The patient must then submit two consecutive drug-free urines to regain her sixth take-home. For each positive submitted, the patient loses take-homes in a step-wise fashion. She can regain take-homes in a step-wise fashion as well, regaining one take-home for every two consecutive negative urines submitted. For all patients in Clinic 1, the sixth take-home is awarded on Friday. This way all once per week patients are seen on Mondays providing more of an opportunity to assess them for drug use directly following the weekend.

Clinic 1 chose to continue to set a target behavior that is required of all patients to receive additional take-homes. A clinic may also choose to use a patient's treatment plan goals as a guide for setting individualized requirements for higher levels of take-outs. Several possible behaviors could be targeted. For example, a patient who continues to abuse alcohol could have his sixth take-home dose tied to submitting urine that is negative for all substances including alcohol. A patient who has no productive daily activity could have his sixth take-home tied to having a productive daily activity, such as full-time employment or student status. In this case, a patient would receive an additional take-home dose as long as he could verify employment or student status. For patients with serious psychiatric or medical problems, additional take-home doses could be tied to proof of medication compliance, or regular attendance of scheduled appointments or therapy sessions.

13-day take-outs: 

Once a patient has been enrolled in a clinic for a full year, federal regulations allow for up to 13 take-homes. Clinic 1 decides that for a patient to earn the privilege of only reporting to the clinic once every two weeks, the patient should have been on weekly dosing with no positive urines, including marijuana, for a minimum of three months. If a patient submits a positive urine screen, he returns to a six take-home schedule. He must remain on weekly dosing with no positive urines, including marijuana, for a

minimum of three months. If a patient continues to submit positive urine screens for targeted drugs other than marijuana, the patient loses take-homes in a step-wise fashion for every positive urine. He can regain take-homes in a step-wise fashion as well, regaining one take-home for every two consecutive negative urines submitted. Any patient who can no longer document 20 hours per week of constructive activity will be reduced to a five take-home schedule until he can again document achievement of this goal at which time he can return to the highest take-home status previously achieved.

27-day take-outs: 

Once a patient has been enrolled in a clinic for two years, federal regulations allow for up to 27 take-homes. Clinic 1 decides that for a patient to earn the privilege of only reporting to the clinic once every month, the patient should have been on a 13-day take-out schedule with no positive urines, including marijuana, for a minimum of one year. If a patient submits a positive urine screen, he returns to a 13-day take-home schedule until he can submit six months of negative urine screens. If a patient continues to submit positive urine screens, the patient loses take-homes in a step-wise fashion for every positive urine. He can regain take-homes in a stepwise fashion as well. Any patient who can no longer document 20 hours per week of constructive activity will be reduced to a five take-home schedule until he can again document achievement of this goal, at which time he can return to the highest take-home status previously achieved.

Starting a Contingency Management Protocol with Patients Who are Not New to the Clinic

The CM plan described above can be applied to all patients in a new clinic or to all new patients in an established clinic. However, in most cases, an established clinic will want to put such a protocol in place and apply it to all of their patients. The main modification for patients already attending a clinic for some time is that such patients can earn take-home doses more quickly. This is because the number of take-home doses allowed by federal regulation would not be as restrictive as for a new patient. For example, a patient who has been dosing at a clinic for a year is eligible for up to two weeks of take-home doses. Therefore, if such a patient has submitted negative urines for several months, but is currently not involved in any regular constructive activity, he could be moved up to dosing two times per week and the privilege of only having to dose once per week could be tied to documenting involvement in a constructive activity. In another case, a patient who has been with a clinic for a year may still be submitting positive urines. In this case, he would have to meet the same requirements for each take-home as a new patient, however he would be able to move up to dosing only twice a week much more quickly (i.e., after submitting eight consecutive drug-free urine screens).

Designing Your Clinic's Contingency Management Protocol

As described in the above protocol, several decisions must be made in order to establish a CM protocol. Clinics must decide the maximum number of take-homes they are willing to provide and to what behavioral goal each one of those take-home privileges will be tied. Decisions must be made about what days particular take-home doses will be provided on, how frequently urine screens will be required, how often take-home dose schedules will be reviewed, etc. The above protocol is a template; however individual clinics may want to modify this protocol due to unique conditions at their clinic (e.g., number of days the clinic is open, how quickly urine screen results are available, or whether adequate resources are available to do weekly urine screens). The attached questionnaire is meant to be used for generating discussion within a team about the most feasible and acceptable form of CM protocol for that particular clinic. Where there is a strong recommendation for a particular decision, the recommendation will be noted beneath the question. A sample worksheet based on the Clinic 1 protocol example is attached for reference. Table 1 (page 53) describes the levels of take-homes available in Clinic 1, the requirements for achieving each level, and the consequences of violations of level requirements.

Contingency Management Staff Worksheet

1. Maximum number of take-home doses allowed by this clinic:

☐ 1/week	☐ 2/week
☐ 3/week	☐ 4/week
☐ 5/week	☐ 6/week
☐ 13 days	☐ 27 days

2. Frequency of urine testing at this clinic:
   - ☐ More than 1/week
   - ☐ 1/week
   - ☐ 1/month
   - ☐ Less than 1/month

   → If your clinic tests less than 1/week, are there any strategies you could implement to increase testing (e.g., on-site test cups)?

Once per week is recommended, once per month is feasible, less than once a month is <u>not</u> recommended.

3. How quickly are urine screen results available to clinic staff?
   ☐ Immediately ☐ After 1 day ☐ 2 Days ☐ 3 Days ☐ 4 Days
   ☐ 5 Days

   ☐ 6 Days ☐ One week ☐ Longer than one week

4. Patients' take-home schedules will be reevaluated:
   ☐ Every week ☐ Every month

5. Please indicate the length of time patient must attend the clinic, what goal is targeted, and how the attainment would be demonstrated for each take-home dose. *If clinic is closed one day each week, please check "clinic closed" at dose number one.*

DOSE #	**WHEN ELIGIBLE**	**GOAL:**	**HOW DEMONSTRATED: (please describe)**
DOSE 1	☐ Clinic closed ☐ **Immediately** ☐ **30 days** ☐ 60 days ☐ Other:_____	**Abstinence from: (check all that apply)** ☐ Opiates ☐ Cocaine ☐ Amphetamines ☐ Benzodiazepines ☐ Other:_____	_____ _____ _____ _____ _____

DOSE 2	☐ Clinic closed ☐ **Immediately** ☐ **30 days** ☐ 60 days ☐Other:_____	**Abstinence from: (check all that apply)** ☐Opiates ☐Cocaine ☐Amphetamines ☐ Benzodiazepines ☐ Other:_____	_____ _____ _____ _____ _____
DOSE #	**WHEN ELIGIBLE**	**GOAL:**	**HOW DEMONSTRATED: (please describe)**
DOSE 3	☐ 90 days ☐ 6 months ☐ 9 months ☐ Other:_____	**Abstinence from: (check all that apply)** ☐Opiates ☐Cocaine ☐Amphetamines ☐ Benzodiazepines ☐ Other:_____	_____ _____ _____ _____ _____
DOSE 4	☐ 6 months ☐ 9 months ☐ 1 year ☐ Other: _____	**Abstinence from: (check all that apply)** ☐Opiates ☐Cocaine ☐Amphetamines ☐ Benzodiazepines ☐ Other:_____	_____ _____ _____ _____ _____
DOSE 5	☐ 9 months ☐ 1 year ☐ 2 years ☐ Others:_____	**Abstinence from: (check all that apply)** ☐Opiates ☐Cocaine ☐Amphetamines ☐ Benzodiazepines ☐ Other :_____	_____ _____ _____ _____ _____ _____
DOSE 6	☐ 9 months ☐ 1 year ☐ 2 years ☐ Others:_____	Abstinence from: ☐ Marijuana or ☐ Alcohol ☐ 20 hours/week constructive activity ☐ Goal defined by pt's treatment plan ☐ Other:_____	_____ _____ _____ _____ _____
13-DAY TAKE-HOME	☐ 1 year ☐ 2 years ☐ 3 years ☐ Other:_____	Abstinence from: ☐ Marijuana or ☐ Alcohol ☐ 20 hours/week constructive activity ☐ Goal defined by pt's treatment plan ☐ Other:_____	_____ _____ _____ _____ _____
27-DAY TAKE-HOME	☐ 2 years ☐ 3 years ☐ Other:_____	Abstinence from: ☐ Marijuana or ☐ Alcohol ☐ 20 hours/week constructive activity ☐ Goal defined by pt's treatment plan ☐ Other:_____	_____ _____ _____ _____ _____

6. Please indicate on which day each take-home will be awarded.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Dose # _____	Dose # _____	Dose # _____	Dose # _____	Dose # _____	Dose # _____	Dose # _____

It is recommended that take-homes are spaced evenly over the week as much as possible to limit the number of doses that a patient is carrying home at one time.

7. For each take-home dose, please specify under what conditions the dose can be revoked.

Dose:	**Can be revoked for the following reason:**
1	
2	
3	
4	
5	
6	
13	
27	

We strongly recommend a client/case manager contract so that both the client and the case manager are aware of exactly what is required from the client to earn take-home doses. The following page is a sample of such a contract based on the CM plan described for Clinic 1.

Sample Take-Home Earning Contract

This is a contract between (client) and (case manager) that specifies how take-home privileges can be earned.

A “drug-free urine” is defined as a urine sample free of opiates, cocaine, amphetamines, and benzodiazepines. All clients must submit a urine sample when requested. Urine samples will be requested *at least* once per week.

This clinic is open Monday through Saturday. All clients automatically receive one take-home dose for Sunday when they enroll in the clinic.

Clients are eligible for a second take-home day (Saturday) when they enroll in the clinic. The second take-home day will be earned after two consecutive drug-free urine samples are submitted.

Clients are eligible for a third take-home day (Thursday) when they have attended the clinic for three months. The third take-home day will be earned after at least four consecutive drug-free urines have been submitted.

Clients are eligible for a fourth take-home day (Tuesday) when they have attended the clinic for six months. The fourth take-home day will be earned after at least six consecutive drug-free urines have been submitted.

Clients are eligible for a fifth take-home day (Wednesday) when they have attended the clinic for nine months. The fifth take-home day will be earned after at least eight consecutive drug-free urines have been submitted.

Clients are eligible for a sixth take-home day (Friday) when they have attended the clinic for nine months. The sixth take-home day will be earned after at least ten consecutive drug-free urines have been submitted. To earn the sixth take-home day clients must also test negative for marijuana and document involvement in some structured activity (e.g., employment, school, volunteer work) at least 20 hours per week.

Clients are eligible to receive 13 take-home doses when they have attended the clinic for one year. A client is eligible to receive 13 take-home doses when they have been on a six take-home schedule for a minimum of three months with negative urine screens for all drugs including marijuana. Clients must also continue to document involvement in some structured activity at least 20 hours per week.

Clients are eligible to receive 27 take-home doses when they have attended the clinic for two years. A client is eligible to receive to receive 27 take-home doses when they have been on a 13-day take-home schedule for a minimum of one year with negative urine screens for all drugs including marijuana. Clients must also continue to document involvement in some structured activity at least 20 hours per week.

Loss of Take-Home Privileges:

Two through Five Take-Homes:
Any client submitting a positive urine for opiates, cocaine, amphetamines, or benzodiazepines, will immediately have her take-home privileges reduced by one. Additional positive urine tests will result in additional decreases in take-homes. Clients can regain one take-home for every two consecutive urine screens that are submitted.

Six Take-Homes:
Any client submitting a urine test positive for any illicit drug including marijuana will immediately have her take-home privileges reduced to five per week. To regain a six-day take-home schedule, she must submit two consecutive urine screens negative for all illicit substances including marijuana. In addition, any client who can no longer document a minimum of 20 hours per week of constructive activity (e.g., employment, school attendance, volunteer work), will have her take-home privileges reduced to five per week until she can again document achievement of this goal.

Thirteen Take-Homes:
Any client submitting a urine test positive for any illicit drug including marijuana will immediately have her take-home privileges reduced to six per week. To regain a 13 take-home schedule, she must submit three months of urine screens negative for all illicit substances including marijuana. In addition, any client who can no longer document a minimum of 20 hours per week of constructive activity will have her take-home privileges reduced to five per week until she can again document achievement of this goal.

Twenty-seven Take-Homes:
Any client submitting a urine test positive for any illicit drug including marijuana will immediately have her take-home privileges reduced to 13. To regain a 27 take-home schedule, she must submit six months of urine screens negative for all illicit substances including marijuana. In addition, any client who can no longer document a minimum of 20 hours per week of constructive activity will have her take-home privileges reduced to five per week until she can again document achievement of this goal.

I have read or have had read to me all of the above and agree to the terms of this contract.

_____ _____
Client's Signature Date

_____ _____
Case Manager's Signature Date

Sample (Table 1)
Methadone Take-Home Dose Requirements for Clinic 1

Number of Take-Home Doses	Time in Treatment	Requirements	To Regain Status
2 per week	N/A	2 consecutive negative urine screens *	2 consecutive negative urine screens *
3 per week	3 months	4 consecutive negative urine screens *	2 consecutive negative urine screens *
4 per week	6 months	6 consecutive negative urine screens *	2 consecutive negative urine screens *
5 per week	9 months	8 consecutive negative urine screens *	2 consecutive negative urine screens *
6 per week	9 months	1) 10 consecutive negative urine screens * 2) Most recent urine screen also negative for marijuana 3) 20 hours/week of documented constructive activity	1) 2 consecutive urine screens negative for all illicit substances including marijuana 2) 20 hours/week of documented constructive activity
13 per 2 weeks	1 year	1) Three months of negative urine screens for all drugs including marijuana. 2) 20 hours/week of documented constructive activity.	1) Three months of negative urine screens for all drugs including marijuana. 2) 20 hours/week of documented constructive activity.
27 per 4 weeks	2 years	1) One year of negative urine screens for all drugs including marijuana. 2) 20 hours/week of documented constructive activity.	1) Six months of negative urine screens for all drugs including marijuana. 2) 20 hours/week of documented constructive activity.

* Urine screen negative for heroin, cocaine, benzodiazepines, and amphetamines.

Practice 4: Contingency Management

Contingency management is the fourth evidence-based practice area. Its implementation requires individual patient-based planning and an awareness of the evidence-based practices discussed in the three previous sections: dosing, counseling frequency, and program orientation. This last section contains a contingency management evidence summary, a step-by-step guide with ideas for developing and implementing a contingency management policy in your clinic, and some examples of the approaches that OpiATE Initiative clinics took to develop and implement contingency management.

"The use of Contingency Management. We're real quick to take take-homes away if the patients are dirty; that was in place before. However, the counseling staff are more alert to getting patients into a take-home schedule once they qualify. This is my sense any way." —clinical coordinator

Contingency management (CM) is the term used to describe substance abuse treatment that structures the client's environment in such a way as to encourage change. This is accomplished by setting specific, objective behavioral goals and specific, objective consequences for meeting or not meeting those goals. Numerous, well controlled laboratory and outpatient studies have provided unambiguous evidence that drug use behaviors can be modified by environmental consequences (Kidorf & Stitzer, 1999). As used in opioid agonist therapy (OAT) programs, CM techniques have been successfully used to promote the reduction or elimination of illicit drug use (Stitzer, Bigelow & Liebson, 1980). Within OAT programs, CM techniques that make clinic privileges contingent on evidence of abstinence are one of the only specific interventions for continued poly-drug abuse to have been systematically evaluated for efficacy (Stitzer, Iguchi, & Felch, 1992). At little additional cost, CM programs clarify expectations of clients and provide objective, standard consequences for their behavior.

Both positive incentives for clean urines (e.g., monetary reinforcement, dose increases, take-home privileges) and negative incentives for drug positive urines (e.g., dose decreases, discharge from treatment) are effective in reducing drug use on average for those left in the group. However, positive reinforcers have the advantage of retaining clients in treatment for longer periods (Stitzer et al., 1992). Contingent treatment availability obviously reduces clients' treatment period if they are unable to comply with

the goals of the contingency program. Methadone dose decreases for drug positive urines also reduce treatment periods because of increased dropouts. Stitzer and colleagues compared a positive incentive CM program, which provided dose increases for clean urines, to a negative incentive CM program, which decreased dose for drug-positive urine (Stitzer, Bickel, Bigelow & Liebson, 1986). While they found that approximately half of the patients in both groups showed marked improvement in their percentage of drug-positive urines, they also found that the patients in the negative incentive condition were more likely to leave treatment early. Nolimal and Crowley (1990) also evaluated the effectiveness of decreases in contingent methadone dosing and came to the same conclusion that drug use was clearly reduced, but that 36% of the patients chose to detoxify and leave treatment rather than stop illicit drug use. Nolimal and Crowley concluded that the risk of discharge outweighed the benefits of the contingent dose intervention. This is an extremely important consideration given that retention in an OAT program reduces criminality, HIV infection rates, and mortality.

Contingent take-home doses provide a simple and low cost positive incentive that has been consistently rated by patients as the most desirable incentive (Chutuape, Silverman, & Stitzer, 1998). Take-home doses have also been shown to be the most powerful incentive available in OAT clinics, and therefore are the most highly recommended (Chutuape, Silverman, & Stitzer, 2001). The evidence for the success of take-home incentive programs is extensive. Stitzer and colleagues (1992) implemented a program in which two weeks of clean urines were required to earn one take-home day. Clients could earn a maximum of three take-home days. Any positive urine test during a two-week period resulted in a loss of one take-home day. Thirty-two percent of the clients on the contingency program qualified as “improved” compared to only 8% of clients who received their take-home doses randomly. In addition, 28% of control clients improved when crossed over from the control to the contingent condition. Across multiple studies and multiple target drugs (e.g., opiates, cocaine, benzodiazepine), the percentage of patients improving with contingent take-home programs is surprisingly consistent at 30-50% (Iguchi, Stitzer, Bigelow & Liebson, 1988; Kidorf & Stitzer, 1999; Magura, Casriel, Goldsmith, Strug, & Lipton, 1988; Milby, Garrett, English, Fritschi, & Clarke, 1978).

Most OAT clinics provide take-home privileges at some point during treatment but do not use take-home privileges in a flexible and responsive CM program that provides immediate rewards for changed behavior (Stitzer et al., 1992). One major problem with many current take-home policies is that the time between the goal and the consequence is too long. Often clients are required to submit three months worth of clean urines before they are rewarded with a take-home dose. As described above, for maximum effectiveness, incentives should be awarded as proximally to the goal behavior as possible (Kidorf & Stitzer, 1999). Therefore, take-home CM programs generally require as little as two weeks of clean urines before awarding a take-home dose. While research protocols allow take-home privileges sooner than do federal standards for patients who have entered treatment, OAT programs can still work within Federal guidelines of take-home dosage and apply the principles of CM. For example, when a client has been in a program for 90 days and is eligible for a second take-home dose,

receiving this privilege can be based on the client's urine test results for the past two weeks, and maintaining this privilege can then be contingent on the client's continued submission of clean urine samples. Implementing a take-home contingency program is a matter of formalizing policies about when take-home privileges will be granted, and when those privileges will be revoked.

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QUERI-DM

Quality Enhancement Research Initiative Diabetes Mellitus

The Need for Tight Blood Pressure Control in Patients with Diabetes!

Inadequate treatment of hypertension in people with type 2 diabetes results in many cases of preventable stroke, myocardial infarction, end-stage renal disease, visual impairment/blindness, and premature death. Most veterans with diabetes also have hypertension and meticulous control of their blood pressure is probably the single most important medical intervention in improving their health and prolonging their life. The VA guidelines committee and the Quality Enhancement Research Initiative for Diabetes (QUERI-DM) have made improved blood pressure control one of the priorities for quality improvement in VHA. Here is an excellent opportunity for us to provide the highest quality of care to our patients, allowing them to live longer, healthier lives.

Benefits of Tight Blood Pressure Control in Diabetic Patients

Important studies conducted over the past two years have demonstrated that:

1. Patients with diabetes get at least twice the benefit out of blood pressure control than do non-diabetics.[1]
2. Blood pressure has at least as much impact on eye and kidney disease in diabetes as does blood sugar control.[2]
3. Patients with diabetes require much more rigorous blood pressure control than most patients without diabetes.[2,3]

Just how tightly blood pressure must be controlled is not precisely known, but for diabetics 140/90 is not sufficient. The HOT Trial[3] and the UKPDS[2] have shown conclusively that lowering diastolic blood pressure to at least less than 85 mg Hg results in substantial improvements in cardiovascular risk. The ADA recommends 130/85. The VA guidelines, which use an evidence-based approach, recommend a target of at least <140/85 but also recognize that even lower blood pressures may be beneficial.

In practice, what is most important is that we are willing to use at least three to four blood pressure medications in pursuit of tight blood pressure control, and that it is a goal important enough to search for the optimal 3-4 medication regimen. However, we must also realize that it will not always be possible to reach the desired blood pressure goal (especially the systolic blood pressure goal, which is particularly difficult to achieve) and we must balance patient side effects while attempting to achieve these tight levels of control. In doing so, the level of blood pressure achieved appears to be much more important than which anti-hypertensive agent is used to achieve it.[4]

This being said, current evidence tends to support ACE-inhibitors as the best first choice agent for most patients with diabetes (with ARBs being an excellent choice for those who cannot take ACE-inhibitors). Calcium channel blockers are not appropriate first line treatments for hypertension for those with diabetes and are best used as a third or fourth choice agent. Not only are calcium channel blockers more expensive than most other agents, but two studies have suggested that when used as a single first choice agent, they are less effective in preventing important cardiovascular outcomes.[3,5,6]. This should not keep us from using calcium channel blockers if needed to decrease blood pressure, but given the higher cost and the possibility of being inferior to other agents in preventing adverse outcomes, they should generally be reserved for instances in which other agents are insufficient or contra-indicated. Also, low dose hydrochlorothiazide (HCTZ) and beta-blockers can be extremely effective in improving blood pressure and decreasing adverse outcomes in people with diabetes. Indeed, in the UKPDS, beta-blockers appeared to be at least as effective in preventing adverse outcomes in type 2 diabetics when compared to ACE-inhibitors.[4] Low dose HCTZ (often starting at 12.5 mg/day) is an inexpensive and highly effective anti-hypertensive especially for elderly and African-American patients with hypertension and diabetes.[1]

Although it may seem preferable to use home readings to treat and monitor blood pressure, only office blood pressures have been used in studies showing adverse outcomes with elevated blood pressures. Thus, office blood pressures are an important monitor of the quality of care. Moreover, monitoring and implementing optimal therapy for our diabetic patients with hypertension must be a key priority. This may not be easy given busy practices and the many important treatments and problems of patients with diabetes. However, tight blood

pressure control is substantially more important than many other conditions that might occupy our time and our attention[7] and we must become more vigilant in addressing this important clinical issue. In particular, evidence suggests that physicians often do not treat systolic hypertension aggressively, even though there is now compelling evidence that aggressive treatment of systolic hypertension is beneficial.[1-3]

Recommendation

- Be willing to use 3-4 anti-hypertensive medications with a goal of blood pressure <130-135/80-85.
- In, general, blood pressure control is more important than which agent is used, but ACE-inhibitors are the preferred first-choice agents for most patients with diabetes.
- Low doses of HCTZ and beta blockers are effective, inexpensive, and safe
- Calcium channel blockers are sometimes very useful, but should generally be relegated to a third or fourth choice agent

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QUERI-DM

Quality Enhancement Research Initiative Diabetes Mellitus

Glycemic Control and Self-Monitoring of Blood Glucose

Self-monitoring of blood glucose (SMBG) is an important part of the care and management of people with diabetes. Nevertheless, how often patients need to perform SMBG can vary substantially between patients, and whether routine monitoring is necessary for all diabetics, especially those not treated with insulin, remains controversial.

Benefits of self-monitoring of blood glucose (SMBG)
For type 1 diabetes, frequent SMBG is considered standard of care.[1] Most often it is recommended that such patients check their sugar about 3-4 times a day but frequency may vary depending on the individual patient's characteristics and treatment goals. Routine SMBG is also generally considered important for patients with type 2 diabetes who are on insulin. This is particularly true for those who are having their insulin doses adjusted regularly, but it is also considered important in minimizing insulin reactions. Unfortunately there is not good evidence from the literature to guide us in the benefits of different intensities of SMBG for type 2 diabetics on insulin.

For those patients not on insulin, the majority of studies have failed to produce evidence of benefit for routine SMBG. Of six randomized controlled trials of SMBG for individuals with diabetes not on insulin, only one showed any sign of improved glycemic control.[2]

Costs of SMBG
It is important to use SMBG effectively and efficiently since it is a relatively expensive intervention and patients often find it both onerous and painful. In VISN 11, the average cost of monitoring is roughly $75 per patient per year with a total cost of over $1.5 million per year. In addition, the costs for SMBG for patients not on insulin vary widely across facilities without any evidence that more aggressive SMBG results in better glycemic control. Responsible use of SMBG supplies can help the VA use it's resources more effectively and reserve the resources for other important diabetes care pharmaceuticals (such as anti-hypertensive and lipid lowering medications).

Recommendation
Self monitoring of blood glucose (SMBG) is an important part of diabetes care and management. All patients should be educated in SMBG. In addition, all patients should know the signs and symptoms of hyperglycemia and hypoglycemia and should be instructed to check their blood sugar if such symptoms occur.

The VA guidelines recommend that the frequency of SMBG be tailored to meet the needs of each individual patient. Occasional routine SMBG (once to 3 times a week), and more frequent monitoring before visits, should suffice for type 2 diabetic patients who are:

- At low risk for hypoglycemia
- Not making regular adjustments to their medications (especially those not on insulin)

Factors that should increase the frequency of routine SMBG include:

- Being on insulin therapy, especially when striving for tight glycemic control
- History of serious hypoglycemia
- Patient preferences and goals
- Lability and fluctuations of patient's glycemic control
- Recently diagnosed diabetes or actively undergoing medication adjustments
- Illness or treatments that put the patient at risk for worsening control (e.g., infection, prednisone, etc.) or hypoglycemia (e.g., poor oral intake of calories and fluids, renal insufficiency, etc.)

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QUERI-DM

Quality Enhancement Research Initiative Diabetes Mellitus

The Importance of Eliminating Poor Lipid Control in Patients with Type 2 Diabetes

Although treatment of blood sugar can help prevent devastating eye, kidney, and nerve complications, we must never forget that the most common causes of death and morbidity in type 2 diabetes are related to cardiovascular disease. Therefore, we must aggressively treat modifiable cardiovascular risk factors and substantial elevations of LDL must be one of our highest treatment priorities.[1]

The optimal LDL-cholesterol level in patients with type 2 diabetes is uncertain. Some evidence suggests that there may be benefit in pushing levels below 100 mg/dL (as recommended by the ADA).[2-4] However, it is likely that the majority of the excess mortality risk occurs at LDL levels above 130 mg/dL. Even for those with known coronary artery disease (CAD) extreme lowering of LDL values has mainly been associated with fewer non-fatal events, not with improved survival. Recent studies suggest that patients with diabetes with known CAD may achieve more benefit than the general population when those with LDLs greater than 130 mg/dL are treated with statins.[1,4] Elimination of substantially elevated LDL levels in individuals with type 2 diabetes is likely to be highly cost-effective and must be one of the highest priorities for VA diabetes care. In addition, since diabetics have a high annual incidence of cardiovascular events, it is critical to get LDL-C below this high-risk level within 4-6 months whenever possible.

Just when and how aggressively triglycerides and low HDL syndrome should be treated in type 2 diabetes remains controversial. It is well established that low HDL, particularly in combination with elevated triglycerides, is an independent risk factor for CAD in patients with type 2 diabetes.[3,5-8-] However, there is no clear evidence that treatment of this syndrome is beneficial in patients with type 2 diabetes.[8] Recently, a study of patients with low HDL and low LDL syndrome demonstrated substantial improvement in cardiovascular events with gemfibrozil treatment.[9]

Recommendation

- Lipid profiles should be obtained on patients with diabetes annually or as indicated to guide therapy
- Treatment with aggressive lipid lowering therapy should be instituted as needed to achieve an LDL value < 130 mg/d.
- Get LDL-C under-control within 4-6 months whenever possible (by dosing statins so as to meet goals quickly and arranging 1-2 month follow-up until the minimum LDL-C goal (< 130mg/dl) is achieved

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Facilitator's Packet

Group Facilitation Outline

Problem: Monitoring lipid levels in-patients with IHD.
Goal: Reduce LDL levels to below 100mg/dl in patients with IHD

Force Field Analysis:

I. Driving forces vs. Restraining forces (overhead)
   A. Patient influences
   B. Personal influences
   C. Educational influences
   D. Economic influences
   E. Administrative factors
   F. Other factors (not included above)
   G. Questions to add if group is lost:
      1. What about your VA facility makes it easy for clinicians to comply with this intervention?
      2. Why might clinicians NOT wish to participate with this intervention?

II. If you get stuck on one issue…
   A. Use affinity grouping (like groups organize to present items)
   B. Multivoting to identify the most likely items to present the most significant barriers/driving forces to implementation

III. Support Strategies
   A. Give specific examples of strategies
      1. Buy in from Chief of Medicine (Staff)
      2. Verbal support by COM for PR purposes
      3. Clinician education
   B. Alternative courses of action
   C. Prioritize strategies
   D. Get feedback as to what strategies can be used for each facility

IV. Brief presentation from each group summarizing the general key implementation problems and general key support strategies identified by each facility.

V. Review the intervention step-by-step (overhead)
   A. How could the process of care breakdown or fail to follow the recommended guideline (failure mode effects analysis table)
      1. Brainstorm about reasons this may occur
      2. The severity of each failure (scale of 1 to 5)
      3. Likelihood of failure occurring (scale 1 to 5)
      4. Impact (S X L)

B. What would support the implementation of the guidelines and address the potential problems cited above.

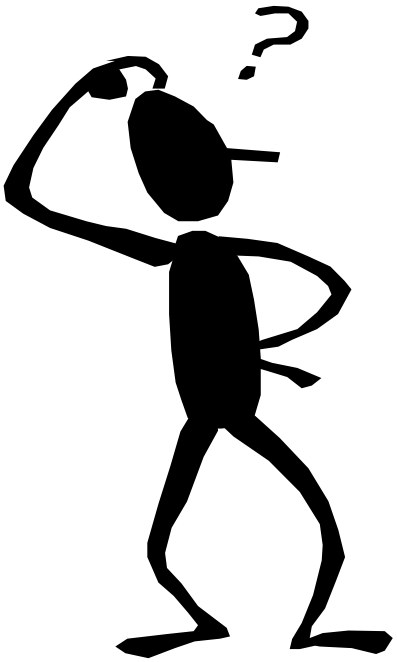
VI. Prepare brief presentation for summarizing the key implementation problems and key support factors identified by each facility specific for the intervention.

VII. Design a Measurement System
- A. Input measures (patients being managed with the intervention)
  1. Lipid Measurement and Management System should correctly identify these patients
  2. Validation can occur at the facility
- B. Process measures (key elements of the intervention being followed)
  1. Are patients being contacted to have their lipids checked?
  2. Educational materials up-to-date and accessible?
  3. Proportion of patients participating (where applicable)
  4. Proportion of providers participating (where applicable)
- C. Outcome measures (intervention achieving its key goals)
  1. Feedback from LMMS—changes in LDL levels
  2. Other key outcomes include: hospital admissions, cardiac procedures, death, etc

VIII. Data Collection Questions/Technique
- A. What forms should be used to collect the data?
- B. Who will collect the data?
- C. How often will the data be collected?
- D. Who will be responsible for maintaining the measure?
- E. What is the unit of analysis?
- F. How will the data be fed back to Seattle?

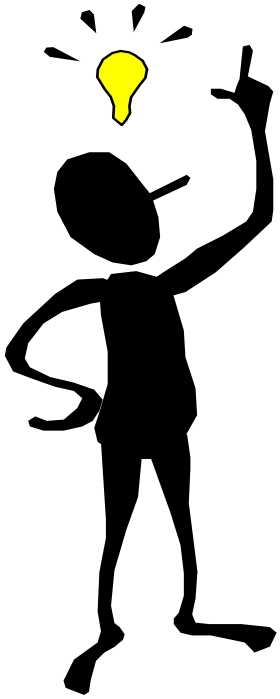
IX. Logistics
- A. Assess environment/technical issues
- B. Leader/director needs to be chosen
- C. Assign responsibilities
  1. When will activities be done?
  2. How much time each activity will take?
- D. Do any additional people need to be recruited?
- E. Brain-storm alternatives

X. Groups should prepare a brief presentation to summarize what their measurement system will look like.



I'm hoping a lot less of you are looking like this…

…and a lot more are looking like this.



Driving Forces	Restraining Forces
1. Patient Influences	**1. Patient Influences**
2. Personal Influences	**2. Personal Influences**
3. Education Influences	**3. Education Influences**
4. Economic Influences	**4. Economic Influences**
5. Administrative Factors	**5. Administrative Factors**
6. Other factors	**6. Other factors**

Questions to clarify points:

1. **What about your VA facility makes it easy for clinicians to comply with this intervention?**
2. **Why might clinicians NOT wish to participate?**

Comment:
This page can be used on an overhead projector as a transparency.

Support Strategies

♦ Examples should be given to help participants brainstorm

Support from the Chief of Medicine (Staff) is important :

(a) Logistically he has to know what research projects are taking place in the institution
(b) He is an opinion leader and is respected by other clinicians
(c) Other clinicians will accept the intervention more readily if the COM verbally supports it.

Clinician Education

(a) Clinical champion should do short educational sessions
(b) Review IHD Module 8 Guidelines

♦ Alternative Courses of Action

Specify if certain strategy does not work what is the alternative?

♦ Prioritize Strategies

Numerically list them in order of priority to get a clear picture of the importance of each

Comment/Suggestions:
Simultaneously write strategies on the flip chart or white board while participants make suggestions with an alternatives column.

Presentations from each facility describing general intervention implementation problems and support strategies

Step-by-Step Review of the Intervention
(Failure Mode Effects Analysis Table)

Intervention Step	Reasons for Breakdown	Severity (1 to 5)	Likelihood (1 to 5)	Impact (S X L)	Support factors
1. Personnel: Physician Director Lipid Nurse Specialist Pharmacist	1. No $ to hire new employees 2. No incentive for new employees to take on more responsibility 3. No qualified personnel	5	3	15	No $ needed present clinical champions willing to take on responsibilities and are qualified

Comment/Suggestion:
You can use this as a transparency and add steps specific to your intervention so have the steps ready in mind to jot down. The other columns can be filled in by the participants. Example given was for the case management intervention.

Each Group prepares a brief presentation summarizing the key implementation problems and key support factors identified for the intervention

Measurement System

❖ Input Measures

Patients managed with the intervention

Lipid Measurement and Management System database should correctly identify patients
Validation can occur at the facility level

❖ Process Measures

Specific to the intervention: key elements of the intervention that need to be followed

Examples:

1) Are patients being contacted to have their lipids checked?
2) Are educational materials up-to-date and accessible?
3) What is the proportion of patients participating?
4) What is the proportion of providers participating?

❖ Outcome Measures

Is the intervention achieving its goals?

Lipid Measurement and Management System will be gathering this data.

Comment/Suggestion:
Stress to participants that Process Measures will be their key goals. We will have the data for each facility but if the data does not change we need to track process measures goals that are not being achieved.

Data Collection Questions

Measure	What forms/database should be used to collect the data?	How Often?	Who is responsible for maintaining the measure?	Who will collect the data?	Feedback method and frequency

Comment/Suggestion: Since LMMS will be able to track outcomes, the emphasis on data collection should be to track process measures ideally with a local database.

Logistical Questions

- Environment/Technical Questions

Is there physical space for the intervention to take place?
Is there access to computers/software to keep track of data and patients?

- Personnel Issues

Let's start naming names:

Leader/Director needs to be chosen
Who will serve what function?
When will activities be done?
How much time will each activity take?

- Do additional people need to be recruited?

- Brainstorm alternative plans

Facility Groups should meet to summarize what their measurement system will look like

Assessment of Organizational Readiness for Evidence-Based Health Care Interventions

Name of Station: _____

I. Evidence Assessment

Finding: Patients with Ischemic Heart Disease should have a current LDL-c measurement at or below 100 mg/dL.

Based on your assessment of the evidence basis for this statement, please rate the strength of the evidence in your opinion, on a scale of 1 to 5 where 1 is very weak evidence and 5 is very strong evidence:

very weak	weak	neither weak nor strong	strong	very strong
1	2	3	4	5

Now, please rate the strength of the evidence basis for this statement based on how you think respected clinical experts in your institution feel about the strength of the evidence, on a 1 to 5 scale similar to the one above:

very weak	weak	neither weak nor strong	strong	very strong
1	2	3	4	5

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree)

(Research) The proposed practice changes or guideline implementation:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) are(is) supported by RCTs or other scientific evidence from the VA	1	2	3	4	5
b) are(is) supported by RCTs or other scientific evidence from other health care systems	1	2	3	4	5
c) should be effective, based on current scientific knowledge	1	2	3	4	5
d) are(is) experimental, but may improve patient outcomes	1	2	3	4	5
e) likely won't make much difference in patient outcomes	1	2	3	4	5

(Clinical Experience) The proposed practice changes or guideline implementation:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) are supported by clinical experience with VA patients	1	2	3	4	5
b) are supported by clinical experience with patients in other health care systems	1	2	3	4	5
c) conform to the opinions of clinical experts in this setting	1	2	3	4	5
d) have not been attempted in this clinical setting	1	2	3	4	5

(Patient Preferences) The proposed practice changes or guideline implementation:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) have been well-accepted by VA patients in a pilot study	1	2	3	4	5
b) are consistent with clinical practices that have been accepted by VA patients	1	2	3	4	5
c) take into consideration the needs and preferences of VA patients	1	2	3	4	5
d) appear to have more advantages than disadvantages for VA patients	1	2	3	4	5

II. Context Assessment

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree).

(Culture) Senior leadership/clinical management in your organization:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) reward clinical innovation and creativity to improve patient care	1	2	3	4	5
b) solicit opinions of clinical staff regarding decisions about patient care	1	2	3	4	5
c) seek ways to improve patient education and increase patient participation in treatment	1	2	3	4	5

(Culture) Staff members in your organization:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) have a sense of personal responsibility for improving patient care and outcomes	1	2	3	4	5
b) cooperate to maintain and improve effectiveness of patient care	1	2	3	4	5
c) are willing to innovate and/or experiment to improve clinical procedures	1	2	3	4	5
d) are receptive to change in clinical processes	1	2	3	4	5

(Leadership) Senior leadership/Clinical management in your organization:

	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) provide effective management for continuous improvement of patient care	1	2	3	4	5
b) clearly define areas of responsibility and authority for clinical managers and staff	1	2	3	4	5
c) promote team building to solve clinical care problems	1	2	3	4	5
d) promote communication among clinical services and units	1	2	3	4	5

(Measurement) Senior Leadership/clinical management in your organization:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) provide staff with information on VA performance measures and guidelines	1	2	3	4	5
b) establish clear goals for patient care processes and outcomes	1	2	3	4	5
c) provide staff members with feedback/data on effects of clinical decisions	1	2	3	4	5
d) hold staff members accountable for achieving results	1	2	3	4	5

(Readiness for change) Opinion leaders in your organization:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) believe that the current practice patterns can be improved	1	2	3	4	5
b) encourage and support changes in practice patterns to improve patient care	1	2	3	4	5
c) are willing to try new clinical protocols	1	2	3	4	5
d) work cooperatively with senior leadership/clinical management to make appropriate changes	1	2	3	4	5

(Resources) In general in my organization, when there is agreement that change needs to happen:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) we have the necessary support in terms of budget or financial resources	1	2	3	4	5
b) we have the necessary support in terms of training	1	2	3	4	5
c) we have the necessary support in terms of facilities	1	2	3	4	5
d) we have the necessary support in terms of staffing	1	2	3	4	5

III. Facilitation Assessment:

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree):

(Characteristics) Senior leadership/clinical management will:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) propose a project that is appropriate and feasible	1	2	3	4	5
b) provide clear goals for improvement in patient care	1	2	3	4	5
c) establish a project schedule and deliverables	1	2	3	4	5
d) designate a clinical champion(s) for the project	1	2	3	4	5

(Characteristics) The Project Clinical Champion:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) accepts responsibility for the success of this project	1	2	3	4	5
b) has the authority to carry out the implementation	1	2	3	4	5
c) is considered a clinical opinion leader	1	2	3	4	5
d) works well with the intervention team and providers	1	2	3	4	5

(Role) Senior Leadership/Clinical management/staff opinion leaders:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) agree on the goals for this intervention	1	2	3	4	5
b) will be informed and involved in the intervention	1	2	3	4	5
c) agree on adequate resources to accomplish the intervention	1	2	3	4	5
d) set a high priority on the success of the intervention	1	2	3	4	5

(Role) The implementation team members:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) share responsibility for the success of this project	1	2	3	4	5
b) have clearly defined roles and responsibilities	1	2	3	4	5
c) have release time or can accomplish intervention tasks within their regular work load	1	2	3	4	5
d) have staff support and other resources required for the project	1	2	3	4	5

(Style) The implementation plan for this intervention:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) identifies specific roles and responsibilities	1	2	3	4	5
b) clearly describes tasks and timelines	1	2	3	4	5
c) includes appropriate provider/patient education	1	2	3	4	5
d) acknowledges staff input and opinions	1	2	3	4	5

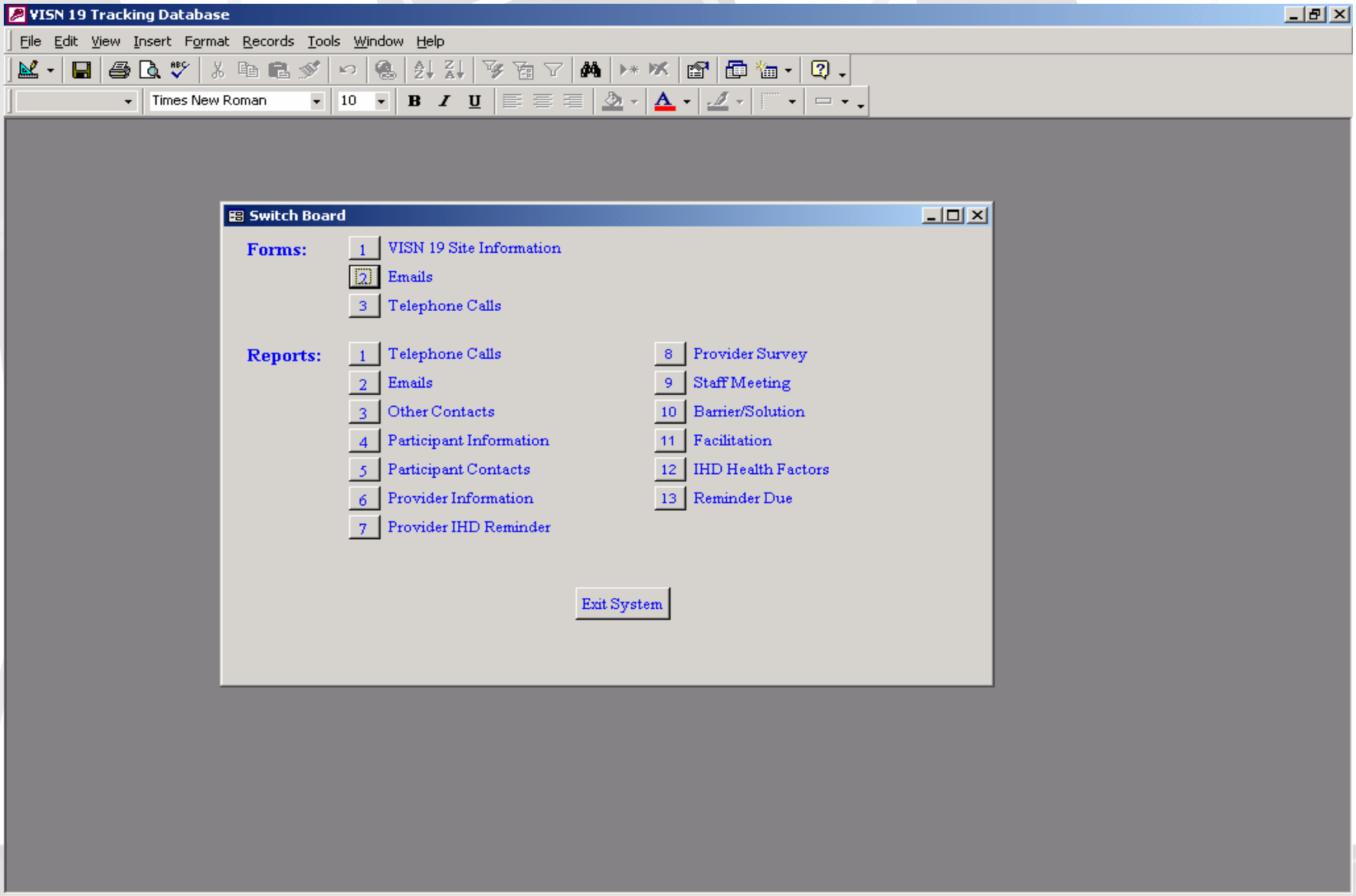
(Style) Communication will be maintained through:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) regular project meetings with the project champion and team members	1	2	3	4	5
b) involvement of quality management staff in project planning and implementation	1	2	3	4	5
c) regular feedback to clinical management on progress of project activities and resource needs	1	2	3	4	5
d) regular feedback to clinicians on effects of practice changes on patient care/outcomes	1	2	3	4	5

(Style) Progress of the project will be measured by:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) collecting feedback from patients regarding proposed/implemented changes	1	2	3	4	5
b) collecting feedback from staff regarding proposed/implemented changes	1	2	3	4	5
c) developing and distributing regular performance measures to clinical staff	1	2	3	4	5
d) providing a forum for presentation/discussion of results and implications for continued improvements	1	2	3	4	5

(Resources) The following are available to make the selected plan work:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) staff incentives	1	2	3	4	5
b) equipment and materials	1	2	3	4	5
c) patient awareness/need	1	2	3	4	5
d) provider buy-in	1	2	3	4	5
e) intervention team	1	2	3	4	5
f) evaluation protocol	1	2	3	4	5

(Evaluation) Plans for evaluation and improvement of this intervention include:	strongly disagree	disagree	neither agree nor disagree	agree	strongly agree
a) periodic outcome measurement	1	2	3	4	5
b) staff participation/satisfaction survey	1	2	3	4	5
c) patient satisfaction survey	1	2	3	4	5
d) dissemination plan for performance measures	1	2	3	4	5
e) review of results by clinical leadership	1	2	3	4	5

IHD TRACKING DATABASE



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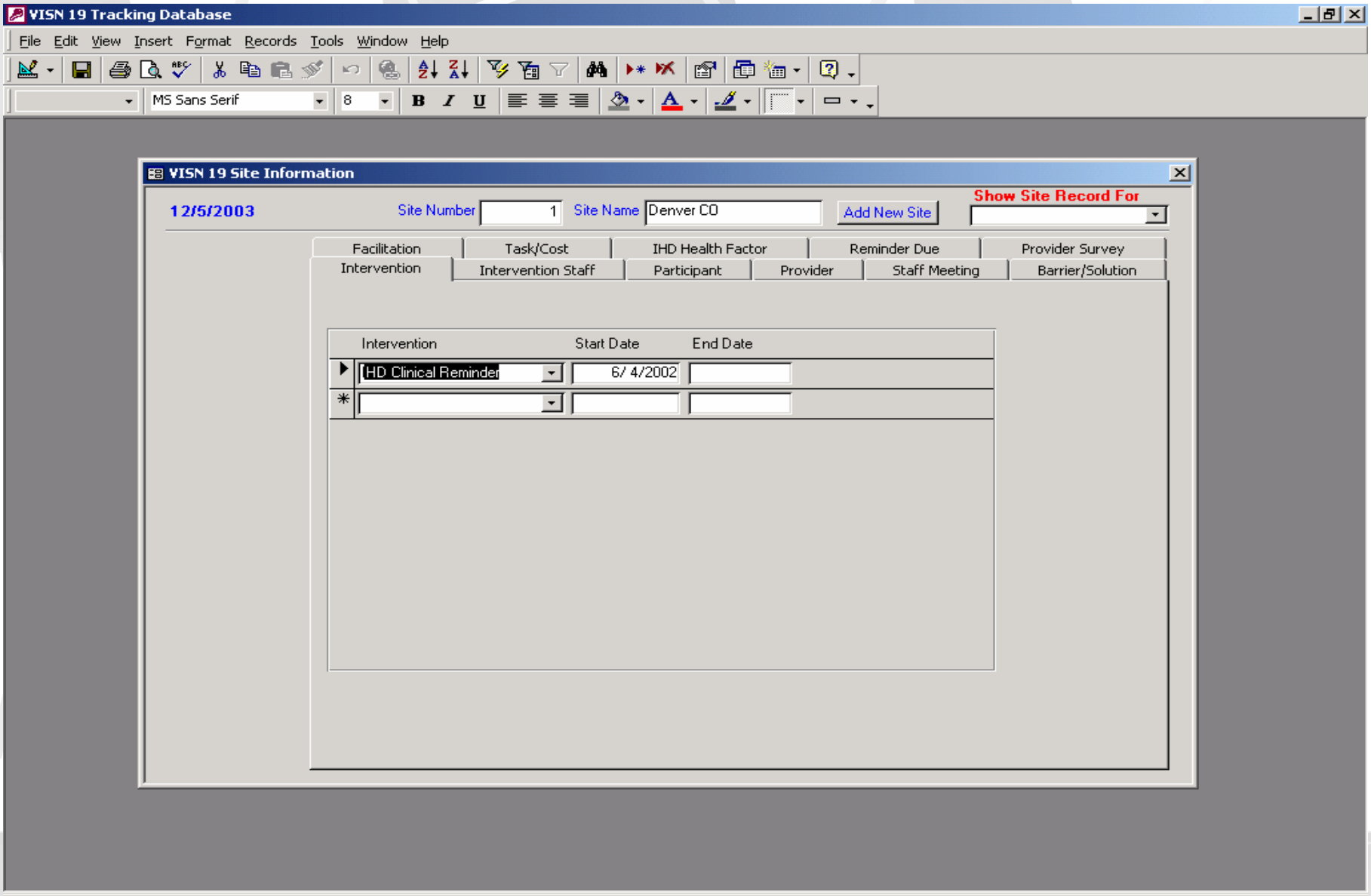


Novel Antipsychotics and Cost-Effectiveness

From a Review of Current Peer-Reviewed Literature on Cost Studies

Are Novel Antipsychotic Medications Cost Effective?

To answer this question, researchers from Mental Health QUERI examined current studies that evaluated cost differentials between second generation (or "novel") antipsychotic medications and traditional antipsychotic medications. These studies were published in peer-reviewed publications over the past seven years.

Taken as a whole, these studies strongly support cost savings associated with novel antipsychotic medications. Twelve of the 20 studies revealed that novel antipsychotics were associated with cost savings. Of the eight remaining studies, six found no difference in cost, one found a significant increase in total costs, and one simulation of treatment of "high utilization" patients (with two relapses and/or hospitalizations within one year) reported a cost advantage for traditional depot antipsychotic medications over novel agents.

In studies indicating cost advantages, the most important factor associated with these savings was *reduced inpatient days for patients on novel agents*. Cost advantages for patients in acute stages of schizophrenia appeared within two months of starting the novel agent. Longer term cost comparisons of novel and traditional medications have not been conducted in clinical studies. However, simulation models suggest that cost advantages may continue over several years or more in certain patient populations.

Researchers at Mental Health QUERI are continually reviewing the literature for new studies directly related to cost effectiveness. The abstract of this literature review and a table that summarizes its findings are available upon request.

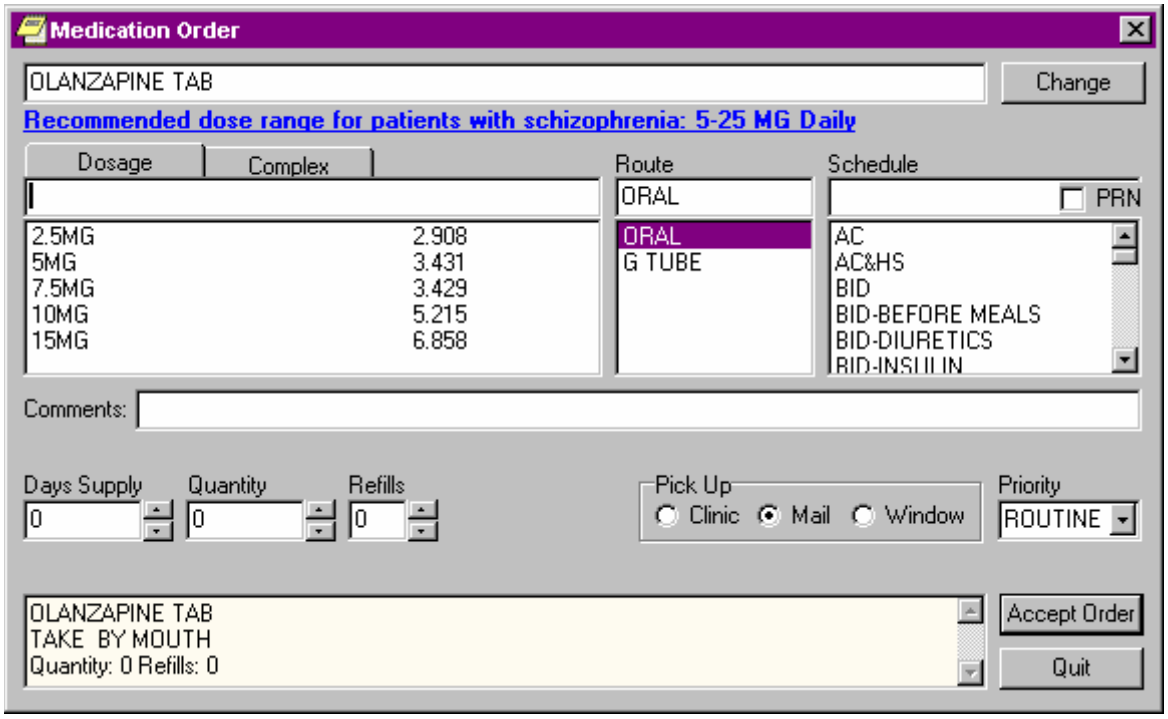
Studies had to focus on cost evaluation and be peer-reviewed to be included in this literature review. Details of this review can be found in *Economic Evaluations of Novel Antipsychotic Medications: A Literature Review*, by researchers at the Department of Psychiatry at the University of Arkansas for Medical Sciences and the VA HSR&D Center for Mental Healthcare and Outcomes Research in Little Rock, AR.

For additional information about cost-effectiveness of novel antipsychotics or this review, contact: Dale Chadwick, MBA, 2200 Fort Roots Drive, 152/NLR, North Little Rock, AR 72114; Phone: 501-257-1068; Fax: 501-257-1707; E-mail: rousmanieredalec@uams.edu.

MENTAL HEALTH QUERI
Quality Enhancement Research Initiative

May 2001

PHARMACY ORDER ENTRY



Olanzapine Reminder

Purpose of Reminder

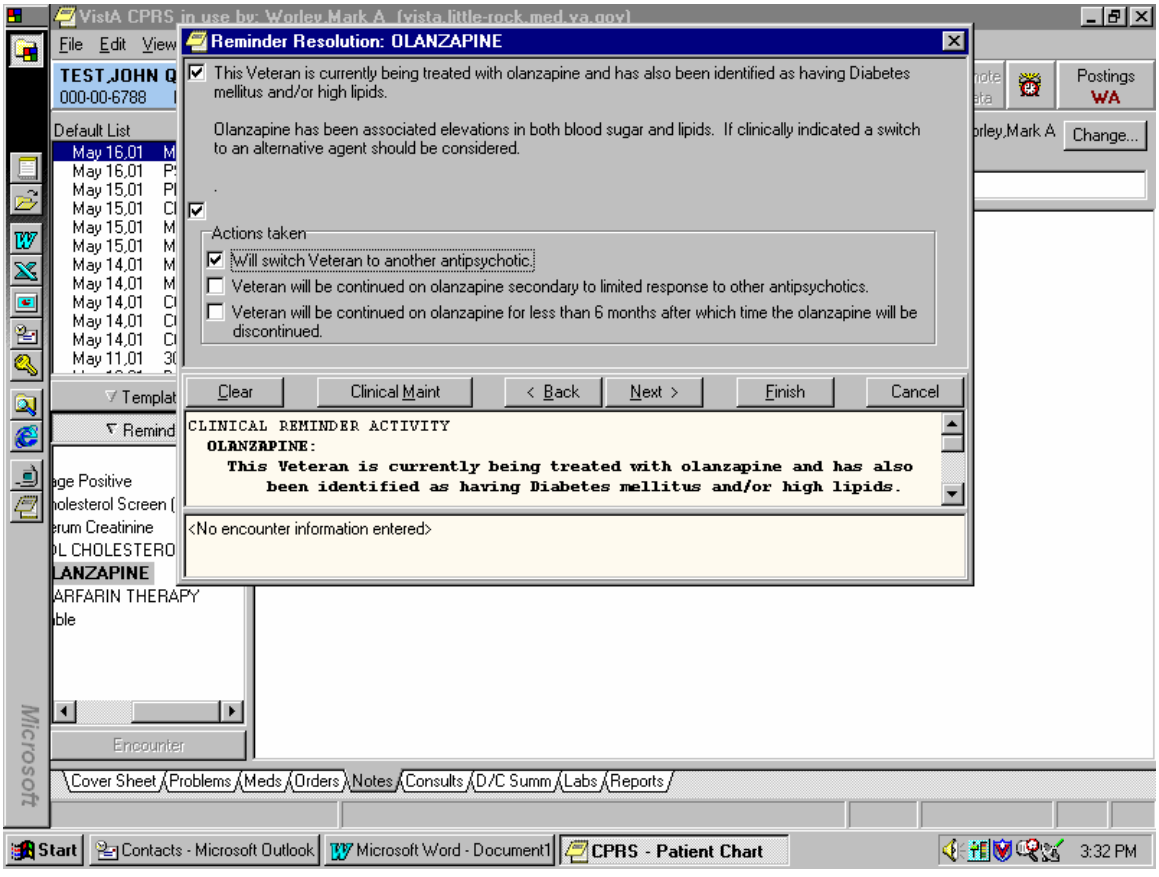
This reminder was developed to help clinicians identify medical conditions that may be worsened when olanzapine is used. Olanzapine has been identified in published reports to cause a worsening control of diabetes mellitus and hypertriglyceridemia. The reminder gives the provider information and allows the provider to select several options

Non-technical Explanation of Olanzapine Reminder

1. Cohort logic - Patients are identified in this reminder on the basis of taking olanzapine and also having previously been diagnosed with Diabetes mellitus or hyperlipidemia.

   (SEX)&(AGE)&(FI(OLANZAPINE 10MG TAB)!FI(OLANZAPINE 2.5MG TAB)! FI(OLANZAPINE 5MG TAB)!FI(OLANZAPINE 7.5MG TAB))&(FI(VA-DIABETES)! FI(Hyperlipidemia))

2. Resolution logic - Processing of the olanzapine clinical reminder, will satisfy the reminder for 6 months. If the patient remains on olanzapine beyond 6 months the reminder will re-prompt the provider for possible reconsideration of the use of olanzapine



Olanzapine Reminder Definition

OLANZAPINE No. 598019

Print Name: OLANZAPINE

Related VA-* Reminder:

Reminder Dialog: Olanzapine Reminder

Priority:

Reminder Description:
For all patients on olanzapine, who also have diabetes mellitus and/or hyperlipidemia. This reminder will alert the provider and remind of the above conditions may be worsened by olanzapine and recommend consideration of switch to a different antipsychotic.

Technical Description:

Baseline Frequency:

Do In Advance Time Frame: **Do if DUE within 10 days**
Sex Specific:
Ignore on N/A:
Frequency for Age Range: **6 months for all ages**
Match Text:
No Match Text:

Findings:

Finding Item: **VA-DIABETES (FI(2)=TX(28))**
Finding Type: **REMINDER TAXONOMY**
Match Frequency/Age: **6 months for all ages**
Found Text: **Patient carries the diagnosis of diabetes mellitus.**
Not Found Text:
Rank Frequency:
Use in Resolution Logic:
Use in Patient Cohort Logic: **AND**
Effective Period:
Use Inactive Problems: **N**
Within Category Rank:
Condition:
MH Scale:

Finding Item: **OLANZAPINE 10MG TAB (FI(3)=DR(7448))**
Finding Type: **DRUG**
Match Frequency/Age:
Found Text:
Not Found Text:
Rank Frequency:

Use in Resolution Logic:
Use in Patient Cohort Logic: **OR**
Effective Period:
Use Inactive Problems:
Within Category Rank:
Condition:
MH Scale:

Finding Item: **OLANZAPINE 2.5MG TAB (FI(4)=DR(7766))**
Finding Type: **DRUG**
Match Frequency/Age:
Found Text:
Not Found Text:
Rank Frequency:
Use in Resolution Logic:
Use in Patient Cohort Logic: **OR**
Effective Period:
Use Inactive Problems:
Within Category Rank:
Condition:
MH Scale:

Finding Item: **OLANZAPINE 5MG TAB (FI(5)=DR(7436))**
Finding Type: **DRUG**
Match Frequency/Age:
Found Text:
Not Found Text:
Rank Frequency:
Use in Resolution Logic:
Use in Patient Cohort Logic: **OR**
Effective Period:
Use Inactive Problems:
Within Category Rank:
Condition:
MH Scale:

Finding Item: **OLANZAPINE 7.5MG TAB (FI(6)=DR(7446))**
Finding Type: **DRUG**
Match Frequency/Age:
Found Text:
Not Found Text:
Rank Frequency:
Use in Resolution Logic:
Use in Patient Cohort Logic: **OR**
Effective Period:
Use Inactive Problems:
Within Category Rank:
Condition:
MH Scale:

Finding Item: **Hyperlipidemia (FI(7)=TX(598021))**
Finding Type: **REMINDER TAXONOMY**
Match Frequency/Age:
Found Text:
Not Found Text:
Rank Frequency:
Use in Resolution Logic:
Use in Patient Cohort Logic: **OR**
Effective Period:
Use Inactive Problems:
Within Category Rank:
Condition:

MH Scale:

General Patient Cohort Found Text:

General Patient Cohort Not Found Text:

General Resolution Found Text:

General Resolution Not Found Text:

Customized PATIENT COHORT LOGIC to see if the Reminder applies to a patient:
(SEX)&(AGE)&(FI(3)!FI(4)!FI(5)!FI(6))&(FI(2)!FI(7))

Expanded Patient Cohort Logic:
(SEX)&(AGE)&(FI(OLANZAPINE 10MG TAB)!FI(OLANZAPINE 2.5MG TAB)!FI(OLANZAPINE 5MG TAB)!FI(OLANZAPINE 7.5MG TAB))&(FI(VA-DIABETES)!FI(Hyperlipidemia))

Default RESOLUTION LOGIC defines findings which can resolve the Reminder:

Expanded Resolution Logic:

Abstinence Orientation Scale

Used with permission of J.R.M. Capelhorn

The *Abstinence Orientation Scale* is used as an indicator of a clinic's approach to Opioid Agonist Therapy. The 14-item scale asks questions about treatment goals and approaches. Each of these items is rated by the respondent on a 1-5 point scale, with lower scores reflecting a maintenance orientation, and higher scores indicating an abstinence orientation. A maintenance orientation is reflected by therapy that supports long-term opioid agonist therapy (OAT), whereas abstinence orientation supports an ultimate goal of detoxification from all opioid agonists. Abstinence orientation has been linked to lower retention rates, more restrictive dosing and take-home privileges and more punitive responses to illicit drug use. Counselors that endorse abstinence are also more likely to score lower on a test of knowledge of OAT risks and benefits. A score higher than three would suggest that at least some staff hold fairly strong abstinence orientation beliefs. If your clinic has scored close to 3 or higher, you may want to consider interventions for increasing your staff members' knowledge about the benefits of long-term OAT and the risks associated with detoxification. Suggestions include inviting guest speakers on this topic or developing a journal club for staff to read and discuss key articles related to this issue. Key references are listed in the orientation evidence summary.

Scoring the Orientation Scale:

The items are scored on a five point Likert scale with strongly disagree having a score of 1; disagree = 2; uncertain=3; agree = 4; and strongly agree =5. On questions 3, 5, 12, and 14, the score was reversed, with strongly disagree = 5, disagree = 4, uncertain = 3, etc. Scores are calculated by dividing the total for the scale by the number of questions answered, with a range of 1-5. If you are using the Excel *Case Management Log*, you do not need to reverse score questions 3, 5, 12, and 14. The computer program will automatically reverse score them for you.

Abstinence Orientation Scale

Used with permission of J.R.M. Capelhorn

Please indicate your level of agreement with each of the following statements, using the scale provided. Please select only one answer for each statement.

1. Methadone maintenance patients who continue to use illicit opiates should have their doses of methadone reduced.

⬭Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

2. Maintenance patients who ignore repeated warnings to stop using illicit opiates should be gradually withdrawn off methadone.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

3. No limits should be set on the duration of methadone maintenance.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

4. Methadone should be gradually withdrawn once a maintenance patient has ceased using illicit opiates.

⬭Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

5. Methadone services should be expanded so that all narcotic addicts who want methadone maintenance can receive it.

⬭Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

6. Methadone maintenance patients who continue to abuse non-opioid drugs (e.g., benzodiazepines) should have their dose of methadone reduced.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

7. Abstinence from all opioids (including methadone) should be the principal goal of methadone maintenance.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

8. Left to themselves, most methadone patients would stay on methadone for life.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

9. Maintenance patients should only be given enough methadone to prevent the onset of withdrawals.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

10. It is unethical to maintain addicts on methadone indefinitely.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

11. The clinician's principal role is to prepare methadone maintenance patients for drug-free living.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

12. It is unethical to deny a narcotic addict methadone maintenance.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

13. Confrontation is necessary in the treatment if drug addicts.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

14. The clinician should encourage patients to remain in methadone maintenance for at least three to four years.

⬭ Strongly Disagree ⬭ Disagree ⬭ Uncertain ⬭ Agree ⬭ Strongly Agree

Thank you for your help

Practice 1: Dose

"I got a fact sheet from [Translation Facilitator] about our dosing. We've experienced a 15% increase in patients that are receiving doses of 60mg or more. That was one of the things we used for the JCAHO survey, it was very helpful." –clinic coordinator

Appropriate methadone dosing is a critical component of effective opioid agonist therapy (OAT). If a patient's methadone dose is inadequate, she cannot benefit fully from improvements made in the three other practice areas, which are counseling frequency, program orientation, and contingency management. Therefore, it is recommended that your clinic focus first on current dosing practices and how they might be improved to better meet the needs of your patients. The following section contains a *Dosing Evidence Summary* with references, an *Expert Panel Consensus Statement*, a *Dosing Algorithm*, a *Dose Review Form*, a *LAAM-Methadone Conversion Chart*, and some examples of dosing policy changes made by OpiATE Initiative clinics.

Methadone has been used for the treatment of opiate addiction for more than 30 years. However, programs using methadone maintenance treatment vary greatly in their daily dosages. Several studies suggest that higher doses of methadone are more effective in treating narcotic addiction. Two areas of study focusing on dosage that have received much attention are dosage and its effects on program retention, as well as its effects on illicit opiate use.

Caplehorn and Bell (1991) looked at retention and dosing rates of patients on methadone and found that the maximum daily dose of methadone dispensed during the study period was a highly significant predictor of retention ($p<0.00001$). This study stratified the maximum daily dosage into three levels: <60mg, 60-79mg, and 80+mg; and looked at retention rates of patients during a 450-day period. Using the lowest dose group as a baseline, they found the relative risk of leaving treatment was reduced by nearly half (0.47) for those in the middle dose group (60-79mg maximum daily dose). The relative risk was halved again for those in the highest dose group (0.21). A retrospective, longitudinal study by Magura, Nwakeze, & Demsky (1998) also found that higher methadone dosage was one variable significantly associated with longer retention ($p\leq 0.01$). Rhoades, Creson, Elk, Schmitz, & Grabowski (1998) similarly reported that higher doses of methadone (80mg vs. 50mg) resulted in lower dropout rates. In a large observational study looking at treatment retention of heroin users in Italy, methadone dosage was found to be one of the most important factors affecting retention of the 721 patients in a methadone maintenance program (D'Ippoliti, Davioli, Perucci, Pasqualini & Baragagli, 1998). Patients receiving at least 60mg were 70% more likely to stay in treatment when compared to those at a dosage of 30mg or less. This same study found that treatment retention over one year was 54% for patients with

an average daily dose of 60mg or more. Patients with psychiatric comorbidity or cocaine dependency may require even higher doses (Maremmani et al., 2000; and Magura, Nwakeze, & Demsky, 1998).

In 1997 the National Institutes of Health Consensus Development Conference stated “A dose of 60mg given once daily may achieve the desired treatment goal: abstinence from opiates.” Several other studies had similar findings in this area. A 1998 study on retention, HIV risk and illicit drug use during treatment, found the opiate-positive results on urine screens were approximately 20% in the 80mg group (Rhoades, Creson, Elk, Schmitz, & Grabowski, 1998). This was compared to 45% at the 50mg group. Strain, Stitzer, Liebson & Bigelow (1993) conducted a study in which patients were divided into three different dosage groups: 0mg, 20mg and 50mg. By treatment week 20, only the 50mg group experienced a reduced rate of opiate-positive urine samples; however, the rate of positive urine samples was still 56.4% (vs. 67.6% and 73.6% at the 20mg and 0mg groups, respectively). In a later study, Strain and colleagues (1999) investigated moderate dose (40-50mg/day) vs. high dose (80-100mg/day) methadone maintenance patients, and found the patients in the high dose group reported using illicit opiates no more than once a week, whereas the moderate dose group reported using two to three times per week. Similarly, Hartel and colleagues (1995) looked at heroin use during methadone treatment with high doses of methadone. They concluded that patients on less than 70mg were twice as likely to use heroin as those receiving 70mg or more.

Determining dose for an individual patient is based on a clinical evaluation of the patient, taking relevant factors into consideration (Blaney and Craig, 1998). A flexible approach, along with patient participation in the dose decisions, helps find the optimum dose to stabilize patients’ lives (Maddux, Prihoda, & Vogtsberger, 1997).

In general, most studies of methadone maintenance treatment recommend that higher doses of methadone are more effective in retaining patients. In addition, several studies strongly support higher doses to promote abstinence from illicit opiates. Coexisting psychiatric and other drug dependence may indicate a need for a higher dose.

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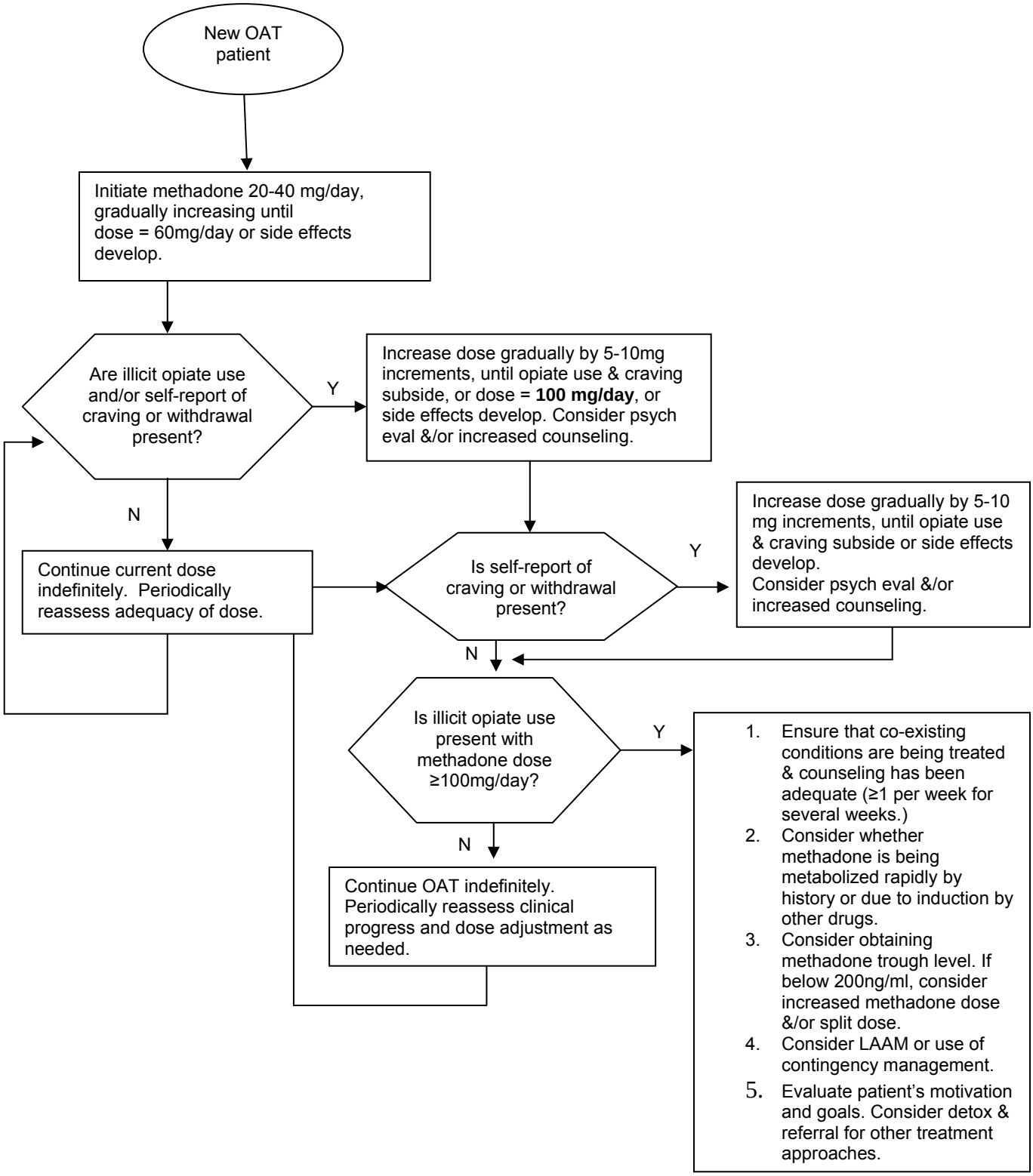
Opioid Agonist Dose Algorithm



Expert Panel* Consensus on Dosing Practices in Methadone Maintenance

Evidence Base

There is very strong evidence that methadone doses between 60-100mg daily are more effective than doses less than 60mg.

There is moderate evidence that within the recommended range of 60-100mg, higher doses are generally more effective than lower doses.

There is no evidence supporting an absolute upper limit on methadone dose.

Although clinically some patients require doses above 100mg, research on the efficacy of doses over 100mg is limited.

Consensus Statements

1) Dosage should be determined clinically, using clear outcome measurements (e.g., illicit opiate use, self-report of craving or withdrawal) to indicate effectiveness.
2) Clinical outcome is measured primarily by illicit opiate use by urine toxicology screen and self-report. Secondary measures include self-report of craving or withdrawal, other drug and alcohol use, and psychosocial function (e.g., employment or training, interpersonal functioning, illegal activities).
3) Most patients will require doses between 60-100mg to achieve stable outcomes. An estimated 10-20% of methadone patients has a good clinical outcome on stable daily doses of less than 60mg daily.
4) If illicit opioid use continues after methadone maintenance has been started, the dose should be increased gradually, until illicit opioid use stops, side effects develop, or the dose reaches 100mg daily.
5) If illicit opioid use continues at a methadone dose of 100mg daily, dose should be raised if the patient complains of withdrawal, craving, or “it’s not holding me.” There is no absolute upper limit on dose, nor is there convincing evidence that doses above 100mg are more effective for patients not complaining of withdrawal or craving.
6) If illicit opioid use continues at a dose of 100mg or more, and the patient is not complaining of withdrawal or craving, or if a patient receiving less than 100mg daily repeatedly refuses dose increases, consideration should be given to changing the treatment plan in other ways. Examples include:
    a) Increasing counseling frequency
    b) Implementing contingency management
    c) Evaluation for coexisting mental disorders
    d) Switching to LAAM
    e) Discontinuation of agonist treatment and referral to drug-free treatment and naltrexone therapy.

**Members: Eric Strain, MD; George Woody, MD; Thomas Kosten, MD; Joseph Liberto, MD.*

Instructions for use of *Dose Review Form*

The *Dose Review* forms can be used as part of baseline data collection to assist in determining the extent to which the clinic is meeting best-practice dosing recommendations. Dose reviews can be repeated at specified intervals to document continued compliance with dosing recommendations (e.g., yearly) or to monitor progress toward increasing clinic performance on dosing recommendations (e.g., quarterly).

1) Counselors complete the Dose Review Form for each client that is on a dose of less than 60mgs of methadone or methadone equivalent per day.

2) *Dose Review* forms are reviewed in team meetings.

3) *Dose Review* forms with an **ACTION** item checked should be retained by the team coordinator for follow-up in one month to ensure that appropriate action has been taken.

Dose Review Form

(for patients on doses less than 60mg/day of methadone or equivalent)

Patient ID:

Current Dose (mg/day):

Reason for Current Dose:

1. ☐ Patient refuses dose increase despite continued use of illicit opiates.
   a. ☐ **ACTION for patients concerned about risks of higher doses:**
   1) Counsel regarding risks/benefits of increased dose compared to continued illicit opiate use.
   2) Refer for a consultation with the medical director.
   b. ☐ **ACTION for patients intentionally keeping dose low so he/she can continue to feel the effects of using heroin (i.e., "chip" or "shoot over their dose"):** Patient may need to be asked to choose between following clinic recommendations and leaving the program.

2. ☐ Patient is abstinent from illicit opiates.
   ☐ **ACTION:** Monitor patient urine screen results for a minimum of six months to document stability.

3. ☐ Patient is currently on a voluntary taper from methadone/LAMM
   a. ☐ **ACTION for patients using illicit opiates:** Counsel patient regarding the need to cease taper and return to a blocking dose.
   b. ☐ **ACTION for patients abstinent from illicit opiates:** Monitor patient urine screens closely during taper. If illicit opiate use reoccurs, counsel patient regarding the need to cease taper and return to a blocking dose.

4. ☐ Patient is currently on an administrative taper from methadone/LAMM.

5. ☐ Patient cannot be on higher dose due to side effects or other medical concerns.

6. ☐ This is a new patient whose dose is still being titrated.

7. ☐ **NONE**: Patient does not fall into any of the above categories.
   ☐ **ACTION: Dose increase** followed by monitoring of illicit opiate use, reports of cravings/withdrawal symptoms, and side effects (see dosing algorithm).

Practice 2: Counseling Frequency

Once your clinic has implemented a quality improvement strategy for methadone dosing and a system for measuring improvement, it may be appropriate to begin reviewing your clinic's current policies regarding one of the other three target practice areas discussed in the following sections. Quality improvement can be made in more than one target practice area at a time.

"That was surprising [that our counseling frequency was low]. *It seems like we see patients all the time, but I guess it's just that we see so many of them.*
—clinic coordinator

Opioid Agonist therapy (OAT) clinics provide a wide array of services beyond simply dispensing methadone and LAAM. These services generally include drug abuse counseling, urine monitoring, and social work services, and may include medical and psychiatric care, employment and educational counseling, and family services. While the major goal of OAT is to reduce illicit opioid use, much more has come to be expected of OAT, including reduced use of other drugs and alcohol, reduced criminal behavior, increased productive activity, and increased psychological well-being and social functioning (Cacciola, Alterman, Rotherford, McKay & McLellan, 1998). Beyond adequate methadone dosing, controversy continues regarding which elements of methadone maintenance therapy can be considered "active ingredients." If methadone dosing alone were sufficient to prompt client change in the multiple outcomes that OAT clinics are expected to effect, unnecessary and expensive psychosocial services could be eliminated and more patients could be enrolled in OAT clinics. Logically, it seems unrealistic that dosing alone could have such a broad impact on so many areas of patients' lives. In fact, there is a strong clinical consensus that dosing alone does not meet appropriate standards of treatment for opiate addiction.

The clinical consensus that patient contact beyond dosing is a necessary ingredient in OAT is supported by a particularly well designed, randomized, controlled study comparing three levels of psychosocial services (McLellan, Arndt, Metzger, Woody, &O'Brien, 1993). Patients in all conditions received a minimum dose of 60mg of methadone. Minimal methadone services (MMS) consisted of virtually no counseling. Counselors saw patients for 15-minute appointments once per month. Standard methadone services (SMS) consisted of weekly counseling visits in the first month. After

the first month, if a patient showed improvement (e.g., decreased illicit opioid-positive urine screens and positive social change), counseling could be reduced to twice monthly. Patients who did not improve, or whose performance declined, were asked to attend sessions twice a week or more. Enhanced methadone services (EMS) consisted of counseling, as described for SMS, plus on-site medical and psychiatric, employment, and family therapy services. The results indicated that patients receiving MMS had significantly greater cocaine and illicit opioid use throughout the six-month treatment compared to the patients assigned to SMS or EMS. In addition, patients receiving SMS had significant changes in legal, family, and psychiatric problems that were not seen in the MMS group. Patients receiving EMS demonstrated significantly greater improvement than SMS patients in the same areas did. Most significantly, 69% of patients in MMS were protectively transferred to SMS because of eight consecutive illicit opioid or cocaine positive urine screens or three emergencies requiring immediate health care. Of the transferred patients, significant reductions in illicit opioid and cocaine use were evident within four weeks of the transfer with no change in methadone dose.

Kraft and her colleagues completed a cost-effectiveness study comparing the three conditions from the above study (Kraft, Rothbard, Hadley, McLellan, & Asch, 1997). They concluded that large amounts of support for methadone patients (EMS) improve outcomes as compared to moderate amounts of support (SMS), but only to a modest degree. On the other hand, moderate amounts of support improve outcomes as compared to minimum support (MMS) to a degree that offsets the additional expense of increased counseling. They concluded that SMS is the most cost-effective of the three treatment conditions, and that the findings of their analysis suggest a level below which supplementary support should not be allowed to fall.

In summary, it appears that “more is better” when considering services to offer as part of an OAT program. However, the incremental benefit of additional services may decline as more services are added. Given budget constraints that may effect many clinics, a *minimum* standard of weekly counseling visits in the first month of OAT involvement and monthly counseling visits during the next year is a reasonable standard. However, the design of the McLellen et al. (1993) study suggests that it is not simply time spent with a counselor but rather the responsiveness of the OAT program to patient behavior that affects patient outcomes. Several other studies have found that involvement of the patient with the program staff is an essential ingredient of effective OAT programs (Broome, Simpson, & Joe, 1999; Hser, Grella, Hsieh, Anglin & Brown, 1999; Joe, Simpson, & Broome, 1999; Magura, Nwakeze, & Demsky, 1998). Therefore, while monthly visits are set as a minimum standard for a stable patient, programs are encouraged to increase counseling frequency contingent on client behavior. For example, as in the McLellan study, patients who do not demonstrate a reduction in illicit opioid-positive urine tests in the first month of treatment should not have their counseling schedule reduced, and patients who enter a period of crisis (e.g., relapse, medical, interpersonal) should have their counseling schedule increased. Additional services such as medical and psychiatric care, employment counseling, and family services are encouraged.

If clinic leadership determines that increasing compliance with counseling frequency is an appropriate QI goal, there are several factors to consider. First, is it the clearly stated policy of the clinic that new patients (i.e., enrolled less than one month) and unstable patients (i.e., those testing positive for illicit substances) should be seen by their case manager a minimum of once per week, and that stable patients should be seen by their case manager a minimum of once per month? If not, the first step toward meeting best-practice recommendations is to make policy changes supportive of these recommendations and to clearly communicate these expectations to the clinic staff and patients.

If counseling frequency consistent with recommended levels is already clinic policy, the next step would be to assess clinic caseloads. In general, a caseload of no more than 50 clients is considered reasonable for a full-time case manager. However, this number assumes that case managers have a case mix that includes stable, long-term patients as well as new and unstable patients who require significantly greater time to manage. If a case manager has predominately new or unstable patients, a caseload of 35 to 40 may be more reasonable. If this is not possible, the clinic may have to limit the number of new intakes until the clinic census stabilizes at a level that can be adequately served by the existing staff.

If policies supporting counseling frequency recommendations are in place and clearly communicated to staff, and caseloads are assessed to be within a reasonable range, it may be a matter of educating staff about the importance of regular case management contact to client outcomes. The monthly *Case Management Forms* can be used by the clinic leadership to monitor an individual case manager's progress toward meeting counseling expectations.

Counseling frequency is a relatively simple practice to monitor, but implementing changes may be more challenging, depending on your clinic's current policies and available resources (e.g., staffing, program funding).

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