New York University Post-Graduate Medical School

IMPROVING CHRONIC PAIN MANAGEMENT *(ICPM)*

Prepared for:

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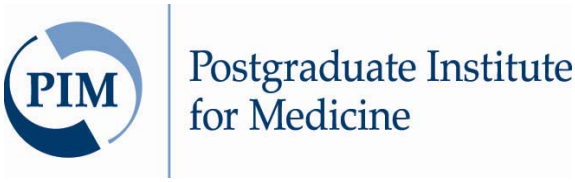

Presented by:

Joann M. Carpana
Accreditation Manager
NYU Post-Graduate Medical School

Dean Beals
President & CEO
DKBmed

Michael R. Lemon
President
Postgraduate Institute for Medicine

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C. Main Section of Proposal

1. *Overall Aim and Objectives*

Introduction: Chronic pain is a growing scourge in America. It afflicts more than 100 million people — more than diabetes, coronary artery disease, stroke, and cancer combined.[1]

According to a 2010 national US survey of clinicians treating pain, primary care physicians (PCPs) treat approximately 52% of patients who present with chronic pain — yet PCPs are the least likely of the groups surveyed (pain physicians, chiropractors, and acupuncturists) to feel confident in their ability to treat chronic pain.[2]

Despite their admitted lack of confidence, PCPs report that more than one-third of their adult patient visits are for chronic pain. At the same time, they report inadequate training in pain and a low satisfaction in delivering pain treatment.[3]

Lack of training and low satisfaction go hand in hand. Indeed, the Institute of Medicine (IOM) notes "multiple and significant" barriers to pain care and management for primary care physicians; the IOM stresses the need for continuing education that addresses gaps and competencies related to pain assessment and management among clinicians. Additional barriers include a lack of understanding about the magnitude of the chronic pain problem, negative provider attitudes toward patients with pain, insurance coverage for chronic pain management, patients' cultural issues, and geographic and regulatory constraints.[1] Combined, these issues point to the imperative for intensive and thorough continuing medical education about this important issue.

Objectives: This initiative will assess the impact of a medical education-based program consisting of series of multimodal interventions designed to improve the clinical outcomes of patients with nociceptive pain, fibromyalgia, and centralized neuropathic-like pain that are being treated by primary care physicians at the New York University Langone Medical Center. The primary objectives are to:

- Assess key practice gaps, knowledge deficits, and system deficiencies that result in suboptimal treatment of patients with chronic pain, which results in protracted disability, severely diminished quality of life, frustration and discouragement in patients and providers alike, and ever-increasing costs to an already overburdened health care system.
- Increase providers' awareness and use of established pain management tools through an interactive educational curriculum and by integrating pain assessment tools into the Epic electronic medical record system (EMR) at New York University School of Medicine.
- Lay the foundation for making these tools and teaching strategies widely available to primary care providers throughout the country, with the ultimate goal of removing many of the barriers that currently stand in the way of effective, lasting relief for patients with chronic pain.

2. Technical Approach

The goal of this program is to achieve effective pain relief for the patients treated by clinicians enrolled in this initiative. This will be measured through 1) the adoption of pain measurement tools and 2) documented improvements in patient quality of life scores as measured by the NYU EMR system.

Partner Roles: This effort is a collaboration between New York University School of Medicine (NYU), DKBmed, RealCME, and The Postgraduate Institute for Medicine (PIM). NYU will be responsible for program certification and overall management of the initiative as the accredited provider. NYU's EPIC Integration Department will incorporate the pain scales and other requirements into the EMR system and provide the mobile EMR interface. DKBmed will work with the NYU office of CME and NYU expert faculty to design and develop the curriculum, including the production of all course materials, videos, online learning, and a *patient website* that will track pain/adherence to therapy over time. RealCME will provide the online learning platform. DKBmed will also create the patient website in concert with NYU's Epic Integration Department. PIM will provide outcomes measurement including the review and analysis of EMR data and patient QOL scores.

a) Current Assessment of Need in Target Area

i) Quantitative Baseline Data Summary

A group of approximately 200 PCPs within the NYU Langone Faculty Group Practice Physician Network will take part in this study. A cohort of 100 PCPs will be selected from the larger study group to participate in the intervention. The second group of 100 nonparticipating PCPs will be selected to serve as a control. For each PCP in both groups, we will audit 20 patient charts (a total of 4000 patient records) to evaluate whether those PCPs are currently 1) assessing nociceptive pain, fibromyalgia, and centralized neuropathic-like pain using standardized scales; and 2) measuring patient satisfaction and QOL with respect to pain. We will not require that clinicians use specific measurement approaches in this audit, just that they assess pain using standardized scales and use some methodology to gauge patient satisfaction and QOL. The NYU Institutional Review Board (IRB) will approve the study design, and the methodology and baseline metrics will be recorded.

ii) Primary Audience

The primary audience who will use and benefit from this educational intervention includes the approximately 100 identified PCPs within the NYU Langone Medical Center Faculty Group Practice Physician network. The Faculty Group Practice is a group of more than 1050 physicians in 100 medical practices and ambulatory sites owned and operated as part of the NYU Langone Medical Center and the NYU School of Medicine. Faculty Group Practice physicians treat patients throughout the New York metropolitan area. These PCPs and their patients will benefit from improved communication facilitated by the interactive features of this effort, with the goal of better patient care and enhanced patient and clinician satisfaction.

We will monitor and measure the study groups' participation and engagement in all aspects of the learning; this includes attendance at the small group lectures and academic detailing, as well as participation in the online RealCME cases.

We will also use an internal recruitment campaign (emails, text messages, and other internal communications) to ensure a statistically significant number of participants complete the program.

b) ***Intervention Design and Methods***

After completing initial measurements and baseline assessments, we will develop tools for our participants and the educational components to accompany them.

Incorporation of Pain Scales - EMR/Mobile/Tablet Interface: After the baseline assessments, we will incorporate standardized clinician and patient pain scale algorithms (e.g. Brief Pain Inventory, McGill Pain Questionnaire, or Dolorimeter Pain Index) directly into the NYU EMR system. We will also develop a mobile/bedside data entry interface using smartphones and tablets.

Relevant Experience: The mobile/tablet Interface will be similar to a highly effective program DKBmed developed for managing depression. That program, *Optimizing Depression Management* (ODM), used standardized depression measurement scales to track the degree of depression across multiple office visits. In much the same manner, ***ICPM*** will enable clinicians and patients to calculate a pain score by entering data directly into the patient record (either on their computer or via mobile technology) within the NYU EMR system. The information will be available for subsequent visits so clinicians can quickly and accurately gauge treatment efficacy.

Unique Patient Interface: For tracking pain and adherence to pain medications between clinician visits, we will also develop an integrated patient website that delivers daily text messages to patients' mobile devices, enabling them to track their pain and reminding them to take their pain meds.

Relevant Experience: The patient web interface will be similar to *My Daily PACE* (www.MyDailyPACE.org), part of a DKBmed CME program for ulcerative colitis. A simple sign-in and encrypted password ensures the site's confidentiality. The website will feature an easy-to-use interface that lets patients determine the time they receive a daily text reminder; texts ask whether they took their meds and the severity of their pain based on standardized scales. The website tracks their entries so patients can review their progress to see if 1) their pain is being consistently and successfully managed, and 2) whether they adhered to their medication regimen. With patient permission, information can be shared with their physicians and uploaded directly to the NYU EMR, to provide more consistent monitoring of pain between visits.

Educational Components: The Center for the Study and Treatment of Pain (CSTP) at NYU's Langone Medical Center will work with DKBmed to develop a series of educational interventions. This initiative will include a multimodal educational curriculum consisting of small group lectures, online case materials, simulated patient case studies,

and academic detailing. The impact/success of the curriculum will be measured through 1) the adoption of pain measurement tools and 2) documented improvements in patient quality of life scores as measured by the NYU EMR system. The curriculum will encompass three separate formats:

- **Small Group Lectures** — A series of four 45-minute unique seminars will be developed by NYU faculty and DKBmed to provide a comprehensive overview of pain and its management. Groups will be limited to 25 participants and held once a week for four weeks. Participants will select the best seminar based on their schedule. Live and archived webcasts will be provided if physicians cannot attend in person. The curriculum will feature four seminars: 1) an introduction to pain, including taxonomy, epidemiology, pathophysiology, and sequelae of poorly controlled pain; 2) pain assessment history-taking (medical, pain psychosocial, vocational, and functional); physical exam (neurologic and musculoskeletal); behavioral evaluation; and a discussion of disability and malingering; 3) treating pain, including patient communication (establishing realistic expectations and goals of care) and a multidisciplinary discussion of medications, psychotherapy, physical therapy, interventions, and complementary therapies. Participants will learn how to monitor treatment response, manage adverse effects, and optimize outcomes. Risk management, documentation and special patient populations will also be discussed. 4) The last section will include an introduction to the patient cases and a review of the academic detailing.
- **Online Interactive Education** — In collaboration with the NYU faculty and RealCME, we will develop a unique learning experience that captures the real life, day-to-day encounters of a medical practice treating patients with pain. Featuring a series of realistic cases, this online learning experience will be introduced during the last class and will connect lecture-based learning with patient cases. These simulated “patients” will begin with a short video featuring trained actors who portray believable patients suffering from chronic pain. The participants will go through the steps of establishing a diagnosis, quantifying the degree of pain using standardized scales, determining a treatment approach, and modifying that approach as the patient re-presents over several visits. These cases will reinforce the information and content learned in the small-group presentations. Brief refresher videos on taking a pain history and using the assessment tools within the EMR will also be embedded into the online component. All elements can be accessed online through an intuitive, user-friendly interface, and will be available 24/7. Email reminders will be sent to participants to remind them to complete the case programs. DKBmed and RealCME have created similar programs in cystic fibrosis, HIV, and rheumatoid arthritis.
- **Academic detailing** — At the completion of the small group lectures and online learning, participants will have 20-minute, one-on-one sessions with an experienced academic detailer to ensure they are fully familiar and comfortable

with the pain tools and measurements that have been integrated into the NYU EMR system.

- **Central Hub** — A central web-based hub with all program elements will be available 24/7 to the study cohort. Class schedules, online case studies, academic detailing appointments, archived seminars, and other program information will be available here.

Uniqueness and Effectiveness of this Approach: This combination of measurement (EMR and patient QOL measures), education (small group, online cases, patient simulation, and physician detailing), and technology-enabled tools (EMR, Mobile EMR, web-based patient symptom tracking) is unique in pain management. To our knowledge, this will be the first such clinician education and measurement system in chronic pain management. However, the training methods and assessment tools we will employ are all effective and time-tested. DKBmed has used many of the approaches described here in other CME programs.

This program is designed to easily expand to other clinicians within NYU and later to clinicians at other institutions by incorporating the courseware and modular technology into their EMR systems. Because the Epic system is among the most widely used EMR platforms, the tools can be disseminated widely and rapidly to other institutions throughout the country with minimal programming adjustments. With "cloud computing," the educational materials can be readily accessible to anyone from any-where at any time.

c) ***Evaluation Design***

Baseline Data: A target group of 100 primary care physicians will be recruited from within the NYU Langone Faculty Group Practice Physician network of over 1000 clinicians. An additional cohort of 100 PCPs from within the same network will be selected as a control. For each PCP in both groups, we will audit 20 EMR records of patients being treated for nociceptive pain, fibromyalgia, and centralized neuropathic-like pain (a total of 4000 patient records) in a HIPAA-compliant manner. We will extract information on whether those PCPs are currently 1) assessing pain using standardized scales and 2) using tools to measure patient QOL with respect to pain. Again, we will not require that clinicians use specific measurement approaches, just that they assess pain using standardized scales and use some methodology to gauge patient QOL. The baseline metrics derived from the Epic EMR review will be recorded for latter use in analysis. The NYU IRB will review and approve the study design and methodology.

Post Analysis: Twelve weeks after completing the educational interventions described, we will once again audit 20 EMR records for each participant in each cohort. Their use of pain scales and QOL measures will be analyzed for the aggregate of the 2000 patient records in each cohort at baseline and final measurement, as we recognize the samples will not be identical. Appropriate statistical methods will be chosen to assess change in frequency of use of these measures for each cohort, as well as any relationship to type of pain/disease state. Alpha for all statistical measures will be set at 0.05.

Surveys: In addition, we will survey the target group to see whether there were any barriers to implementation. We will also survey the control group to see whether they

participated in any continuing medical education (journal reading, grand rounds, and other educational forums) related to pain during the duration of this initiative. Finally, we will survey patients to assess their current QOL as well as their QOL before our educational intervention.

For all surveys an incentive will be considered to increase participation, but any incentive would be limited to no more than $20 in value and would be approved by NYU to be compliant with Stark 1 and 2 requirements.

Outcomes - Overall: The results of the analyses noted above will provide information on whether 1) use of pain scales increased in the target cohort as a result of the educational interventions and access in EMR, as compared to the control cohort; 2) whether patient perception of QOL improved for patients treated by the target cohort; 3) there was congruity between the physician recorded changes in the EMR related to pain and QOL, and the patients' perception of changes in QOL; 4) participation on the ***ICPM*** patient website made a difference in either physician or patient results. Barriers to practice change for physicians treating pain will also be identified. A summative report of findings from the initiative will be developed.

Outcomes - Small Group Lectures: In addition to the overall long-term evaluation of practice change, we will assess changes in knowledge and competence (Moore Levels 3a and 4) as a result of participation in the four 45-minute live seminars on pain for those in the target cohort. Clinical Assertion methodology, including a pre- and post-survey of learners, will be used for this portion of the evaluation plan. The results will be summarized initially in one report on the assessment of these four CME interventions and will be considered in the summative report findings at the conclusion of the initiative.

Outcomes - Online Interactive Education: The online case study activities measure outcomes based on Moore's Expanded Level 1-5 CME Framework. This part of the curriculum is supported by a robust analytic platform that measures the impact of each activity on knowledge, competence, confidence, and practice change. Detailed breakdowns of participation patterns include pre- and post-activity, as well as a 45-day follow-up survey, and Level 5 outcomes (subjective and objective) data demonstrating changes in practice resulting from this initiative. This component also electronically tags each learner's response to one or more learning objectives and subject-matter codes, allowing objective assessment of the level to which learning objectives have been achieved.

This methodology enables objective and quantitative measurement of the effectiveness of the curriculum and its impact on learners' clinical practice. Assessment includes the RealIndex®, a multidimensional situation-based question that evaluates learners' performance of evidence-based best practices, as well as paired-question sets related to specific learning domains. Participants are presented a real-life clinical scenario, followed by a series of statements to be assessed as either consistent with or inconsistent with evidence-based best practice and with actions they would take in their own practice. The RealIndex is administered before the first activity of the curriculum (baseline), after each activity is completed, and finally in a post-curriculum follow-up

assessment. Each activity in the RealMeasure platform contains a variety of question types that focus on specific learner domain.

Question Type	Point of Administration	Question Format	Assessment
Knowledge	Pre-Test, Post-Test, and PCA	Multiple choice or True/False	Scored
Competence	Pre-Test, Post-Test, and PCA	Multiple choice or True/False (case-based)	Scored
Confidence	Pre-Test, Post-Test, and PCA	Multiple choice (Likert scale)	Self-report (non-scored)
Practice	Pre-Test, Post-Test, and PCA	Multiple choice (Likert scale)	Self-report (non-scored)
RealIndex®	Presented prior to initial curriculum activity, after each activity, and PCA	Clinical vignette, multiple statement, drag-and-drop categorization	Scored

The results will be summarized initially in one report on the assessment of these case-based CME interventions, and will be considered in the summative report findings at the conclusion of the initiative.

2. *Detailed Workplan and Deliverables Schedule*

Improving Chronic Pain Management will be developed and delivered in five stages over the course of a 12-month period. Stage one (Spring 2013) will consist of project planning, participant recruitment, and the development of a chart abstraction tool. We will assess the patient records of our target and control groups during stage two (late Spring 2013). Stage three (Summer 2013) will be devoted to developing our educational interventions. The educational interventions will be deployed to the target group in succession in stage four (Fall 2013). Finally, we will conclude the program with outcomes assessments in stage five (Winter 2013-2014).

The schedule of deliverables is:

Deliverables	Date of Completion
Program Planning and Design	MAR – APR 2013
Central Hub Website Build and Design	MAR – APR 2013
Program Recruitment	MAR – APR 2013
Initial Assessment - Epic EMR System Data Abstraction	MAY 2013
Content Development for All Educational Components	JUN – AUG 2013
Pain Scales and Tools Development Within EMR System	JUN – AUG 2013

Development and Deployment of EMR Mobile Interface and Patient Interface	JUN – AUG 2013
Educational Interventions	SEP – NOV 2013
Outcomes Assessments	DEC 2013 – FEB 2014
Report to Pfizer	APR 2014

References

[1] Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* Washington, DC: Institute of Medicine. 2011.

[2] Breuer B, Cruciani R, Portenoy RK: Pain management by primary care physicians, pain physicians, chiropractors, and acupuncturists: A national survey. *South Med J*. 2010 Aug;103(8):738-747.

[3] Upshur CC, Luckmann RS, Savageau JA, et al. Primary care provider concerns about management of chronic pain in community clinic populations. *J Gen Intern Med.* 2006;21:652-655.