Formative Report: Evaluation of the Massachusetts Department of Industrial Accidents' Opioid Alternative Pathway Program

Occupational Health Surveillance Program Massachusetts Department of Public Health

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The recommendations expressed in this report are those of the authors and do not necessarily reflect the official policy or position of the Massachusetts Department of Public Health or the Centers for Disease Control and Prevention.

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Summary

This report explores issues related to the Massachusetts Department of Industrial Accidents' (DIA) Opioid Alternative Treatment Pathway program that was initiated in 2017 to help reduce injured workers' dependence on opioid pain medications. Senior Judge Omar Hernandez convened a stakeholder process to design and support a mediation process that included Care Coordination for injured workers with settled claims who were taking high-dose long-term opioids. Approximately 24 workers have entered the program.

In order to gain insights into the current functioning of the program and opportunities for further evaluation, an associate from the Center for the Promotion of Health in the New England Workplace was supported by the Massachusetts Department of Public Health to conduct a formative assessment of the program. Twenty-four key informants with experience of the program in a variety of capacities including legal, medical, administrative and as participants, were interviewed about the program goals and their experiences of the program. Additionally, members of the DIA's Healthcare Services Board gave input during one of their meetings.

The interviewees spoke about the goals for the program, incentives for participation by injured workers, measures of success, the process and administration of the program, Care Coordination, medical care for participants, financial issues, education and awareness, and barriers to success. Despite the diversity of the interview participants, they were united in support of the program and their hopes for its expansion. They shared their experiences and perceptions of barriers to participation and optimal functioning, and gave many concrete recommendations for improvement, including educational programs, clinical guidelines for tapering, opening participation to those without settled claims, and more administrative support for program operations.

The goal of the formative evaluation was to identify potential process and outcome evaluation strategies to assess program implementation and impact. This report contains recommendations for a stakeholder survey of potential program enhancements, program participant survey pilot study, document review and case study development, and further interviews of stakeholders.

Introduction

Background and Project Goals

This project grew out of a previous one sponsored by the Massachusetts Department of Public Health (DPH) Occupational Health Surveillance Program to document issues related to workers and the opioid crisis. The purpose of that report was to help guide opioid hazard awareness educational interventions for working people. The full report can be accessed here. The report also discussed medical and legal issues related to opioids for injured workers who file claims through the Commonwealth's Department of Industrial Accidents (DIA), the workers' compensation system for Massachusetts. Senior Judge Omar Hernandez has led an effort to introduce reforms at the DIA to assist injured workers overcome obstacles to reducing their dependence on opioids. That work coalesced in the Opioid Alternative Treatment Pathway Program (OATP) which began as a pilot in 2016 and which became a full-fledged program at the DIA in 2018. At the time of his interview for the prior report mentioned above, Judge Hernandez expressed an interest in assistance in evaluating and improving the OATP.

In 2019, the evaluation of the OATP was submitted as proposed component of the Commonwealth's Opioid Assistance for States proposal to the CDC and was funded as a cooperative agreement, *Overdose Data to Action (OD2A)*. The rationale for this work as part of the Commonwealth's response to the opioid crisis includes that this program represents a cutting edge state-sponsored initiative to prevent opioid overdose by intervening to reduce opioid dependence in a high risk population: injured workers.

This report is the result of the first year (actually six months) of the three-year project and fulfills the first goal of the project which is to conduct qualitative formative research to inform potential strategies for further evaluation of the program. This formative assessment **provides recommendations for potential feasible and effective evaluation of the program**, and **addresses issues related to human subjects** participation/ ethics. Additionally, the appendix to this report includes potential assessment areas and instruments and questions that might be utilized.

Summary of the Opioid Alternative Treatment Pathway Program

The OATP was initiated by the DIA in June 2017 to provide an expedited process for injured workers to reduce or eliminate their opioid use and improve their pain management. The program is overseen by Judge Hernandez and does not have dedicated staff. The program is viewed as an integrated "pathway" in the processes and operations of the DIA. DIA staff reported that there are 24 current program participants and 70 who are "in process." It was not clear how many have begun and either dropped out or "finished."

Only injured workers with settled indemnity claims can participate in the program. These workers have received a lump sum settlement, but receive on-going medical treatment with opioids. Very often these workers are under the care of their primary care physician and are not receiving any additional treatments or clinical care from pain specialists. Workers whose cases are not yet settled, or who receive weekly income support from the DIA are not eligible to participate. The rationale for including only settled lump sum cases is to avoid the contentiousness of disability-related income support issues in the process of coming to agreement on medical care. Unfortunately, a worker may fear that their income support would be threatened if they became less opioid dependent, while still being uncertain about their ability to support themselves.

Eligible workers may volunteer to participate at any time, however, in most cases, a worker is encouraged to participate after the insurance company has filed a form to discontinue payment for opioid medications. At that point, the injured workers' attorney may recommend the mediation process, or the Judge may suggest it at the hearing on the matter. If the worker and the insurer agree to participate in the OATP, a mediating judge, who is not the judge who adjudicated the original case, supervises a "19A Medical Mediation" where the injured worker agrees to work with a Care Coordinator to reduce or eliminate their use of opioids, and the insurer agrees to pay for treatment (including opioids, pain management physician, primary care, and alternative treatments), the Care Coordinator fees, and a fee for the claimant's attorney.

The 19A form is not prescriptive – it is essentially a blank document for the parties to record their commitments and agreements. The 19A form agreement can be updated or renegotiated and is specific to the particulars of each situation. There are no time limits or guidelines for program participation. Each case's timeframe is determined on an individual basis, however expectations are that some progress will be made within 6 months and that at a year, progress would be reviewed.

When the injured worker and the insurance company agree to participate, they will first come to agreement on who the Care Coordinator will be. The supervising judge requests regular reports from the Care Coordinator to make sure that progress is being made and hearings may be held to check in with all parties. The goal is a non-adversarial process where the insurer's adjustor is open to approving the recommendations of the care coordinator. Because the process is generally to wean the injured worker, rather than eliminate opioids through a rapid detox, the insurer will continue to pay for opioids as well as pain management and other treatments. The injured worker or the insurance company can end the 19a agreement and revert to "traditional" litigation at any time. The Care Coordinator may report that a point of success has been achieved and the 19a agreement will be amended to sustain alternative treatments. It may also be the case that the Care Coordinator determines that further progress is unlikely and may suggest that the process be ended by the Judge.

The DIA has asked healthcare professionals (principally nurse case managers) to provide an application and credentials to be listed on the DIA site as a potential Care Coordinator. The goal is a geographically and otherwise diverse roster of professionals who can guide the patient through an opioid tapering process and help promote improved pain management through new therapies. Additionally, the Care Coordinator plays a critical support role for the injured worker, and liaison role for the other parties to communicate progress and challenges. Basic qualifications are reviewed, but specific experience with tapering injured workers is not required nor publicized. Many Care Coordinators work for insurers or companies that contract with them.

As described above, the OATP program differs from the "traditional" process in that it is a voluntary mediated agreement where all parties sit down together and agree to a plan, rather than an adversarial process resulting in a judge's order. In the "traditional" process, an injured worker continues the medical program agreed to at settlement of their case until either they or the insurance company requests a change. Because of the high cost, high risk of overdose, as well as the evolving literature documenting limited efficacy, insurance companies are generally challenging claimants' continued long-term opioid treatment. Insurers file Form 108-A - Insurer's Request for Post-Lump Sum Medical Mediation in order to initiate proceedings to get a court-ordered change in treatment. They may also directly deny claims and the injured worker may find that the pharmacy will not fill their prescription.

Because insurers are well aware of the risks of abruptly cutting off opioids, they generally file the form to initiate the legal process to reduce or eliminate opioids. However, if they do deny claims, an employee can file Form 110-A - Employee's Claim for Post-Lump Sum Medical Mediation which could also initiate the OATP.

If the OATP process does not begin at that point, either because the injured worker or the insurer do not agree to it, the injured worker may challenge the insurers' request and a mediating judge will make a determination. Most likely that determination will be appealed by one side or the other and in the appeal process, the judge will ask for an independent medical evaluation of the case. These independent reviews are charged with determining if the pain is related to the injury and if opioids are appropriate treatment. Taking into account the independent review, the insurers' arguments, and the patient and their lawyers' concerns, the judge will mostly, out of caution, order continuation of the prescription. As with most DIA proceedings, this process is adversarial, contentious, lengthy, and expensive. It does not provide assistance to the worker to reduce their opioid dependence. The "traditional" process may take over a year.

Stated OATP Program Goals

In Judge Hernandez' words¹, the objectives of the OATP are:

- Dramatically improve quality of care for those suffering with chronic pain conditions.
- Reduce time required to resolve clinical disputes.
- Reduce pain, suffering and side effects associated with inappropriate opiate prescribing.
- Provide attorneys, judges and injured workers with better tools for appropriate decisionmaking.

From the clinical perspective, the goal of the program is to help injured workers learn to manage their pain with less reliance on opioid medication, which in turn reduces the injured worker's risk for an adverse event, such as overdose.

Embedded in these objectives are the goals to reduce the contentiousness of the process, to avoid Judges making medical decisions, and to provide assistance to a willing injured worker to reduce their opioid dependence. Judge Hernandez suggested the following metrics to evaluate the program:

- How many employees discontinue the use of opioids
- How many cases enter the program
- How many parties opt out and return to the normal litigation process
- Reductions in prescription amounts and corresponding alternative care changes
- Average length of time to resolve cases
- Average cost to insurers (the average cost of continued opioid use compared to the average cost of treatment)

Judge Hernandez and others have described this program as a life-saving mission, recognizing that reducing opioid dependence among injured workers with chronic pain is a critical intervention to save workers' lives and can improve their pain management and overall health.

¹ From slides prepared for presentation to the Harvard ERC 2/28/20

Methods

The methods for this formative assessment were very simple: identify key informants who were stakeholders or had first-hand knowledge of the program and interview them over the phone using a few basic questions. Key informants were identified from two sources. Several of the participants, including Judge Hernandez himself, participated in the prior project described above to identify issues related to opioids and injured workers. The second source were the participants themselves who were asked to identify others with experience of the program. Interviews generally lasted an hour and notes were taken on the conversation. For each call, I described the objectives of the formative study and I asked the interviewees to respond to the following questions:

- 1. What are the goals of the program? What would success look like from your perspective?
- 2. What is your experience of the program?
- 3. What data or documents do you know of that could help inform an evaluation of the program?
- 4. Who else should I speak with?

I also would prompt them to identify goals that would be "representative" of their particular stakeholder perspective, e.g. "what is important to injured workers' attorneys?". As common themes and recommendations began to emerge (need for education, treatment guidelines, administrative coordination, eligibility of participants), I would ask the interviewees to reflect on these potential recommendations. I also asked them about their attitudes toward the use of patient records for program evaluation and any other documents or data sources.

The proposed work was reviewed by the University of Massachusetts Lowell Institutional Review Board and determined to be exempt from review on the basis of it being "public health surveillance" and program evaluation, rather than research. The funding source also specified that research, per se, not be conducted. The MA DPH Institutional Review Board also reviewed the project and exempted it from review. In line with the goal of characterizing the human subjects/research ethics issues related to this study, I discussed the project and potential future evaluation activities with Emily Sousa, Manager of the Office of Research Integrity, University of Massachusetts Lowell and Kevin Foster, of the MA DPH Institutional Review Board.

In addition to the interviews, I led a discussion on the program and its evaluation at the May 2020 meeting of the DIA's Healthcare Services Board Meeting.

The interview participants and their roles are listed here:

<u>Legal</u>

Judge Omar Hernandez (Senior Judge)

Deb Kohl, Attorney (representing injured workers)

Judge Dennis Maher, Department of Industrial Accidents, Worcester

Nicolle Allen, Esq., Commonwealth Workers' Compensation Attorney (insurance/employer)

Shannen Pelligrini, Esq., Attorney (representing employers)

Russ Gilfus, Esq., Lead Attorney, Director, Commonwealth Workers Compensation Insurance (employer)

Amy Mercier, Esq., Attorney (injured workers), representing enrolled patient

² Letters were prepared for Judge Hernandez to invite participation by participants and by Care Coordinators, however they were not sent, most likely due to the chaos of the pandemic which evolved during this project.

Medical

Dr. Dean Hashimoto, Occupational Health Physician, chair, Healthcare Services Board

Dr. Jonathan Burress, Occupational Health Physician, ACOEM

Mike Pringle, RN, Windham Group, Care Coordinator

Dr. Michael Erdil, Occupational Health Physician

Dr. Roberto Feliz, Reviewing and Treating Physician (Pain Management and Tapering)

Carol Dennehy, RN, Care Coordinator

Lisa Aspinwall, RN, Nurse case manager for Commonwealth Workers Compensation Insurance

Administrative

Bill Taupier, Deputy Director of Administration, DIA Diane Neelon, RN, Esq. DIA Director, Office of Health Policy Program Coordinator, HCSB

<u>Insurance</u>

Laurie Parsons, Adjuster, MIA Mutual Insurance Michael Shor, RN, AIM Mutual Insurance Co/Best Doctors (retired) Michael Kelley, Senior Executive, AIM Insurance

Other

Vennela Thumula, PhD., Senior Researcher, Workers Compensation Research Institute D.K., injured worker, enrolled participant Len Young, PhD., Director, Massachusetts Department of Public Health, Prescription Monitoring Program

HealthCare Services Board Meeting 5/16/20

Health Care Services Board Members: D. Hashimoto, Chair; H. DiCarlo, Vice Chair Members: John Burress, David Deitz, Ron Kulich, Nancy Lessin, Tiger Li, Janet Pearl, Elise Pechter, Marco Volpe

HCSB Staff: Diane Neelon, HCSB Executive Director; David Michels, Counsel

Other Attendees: Sheri Bowles, JD, Director of Operations and Interim Director, DIA; Omar Hernandez, JD, Senior Judge, DIA; William Taupier, Deputy Director of Administration, DIA; Nathan Jones, MD, The Harvard T.H. Chan School of Public Health/Occupational Medicine Residency Program; Rob Filler, MD, The Harvard T.H. Chan School of Public Health/Occupational Medicine Residency Program, Hussam Kurdi, MD, The Harvard T.H. Chan School of Public Health/Occupational Medicine Residency Program; Cora Roelofs, ScD, Center for the Promotion of Health in the New England Workplace, University of MA Lowell; Kathleen Grattan, MPH, Epidemiologist, Occupational Health Surveillance Program, DPH; Emily Sparer-Fine, Director of the Occupational Health Surveillance Program, DPH; Michael Shor, MPH, Consultant and former Managing Director of Best Doctors Occupational Health Institute.

The notes of these interviews were reviewed and characterized by theme and according to the objectives of the formative assessment using QRS Nivo 12 Pro.³ Participants were given the opportunity to review and comment on these interpretations. Of the 24 participants, comments on the draft report were received from eight. These comments were incorporated into the final report.

Findings: Interviewees' Assessments and Recommendations

Despite the diversity of the interview participants and the interests that they represent, there was remarkable consensus regarding the importance of the OATP and the challenges that it faces. This speaks to the stakeholder process that was led by Judge Hernandez to build consensus and support for the program. The interviewees spoke positively about the program in general and, in particular, about the benefits of the OATP in reducing contentiousness so that progress could be made in engaging "legacy cases" in reducing harmful opioid dependence. They were united that an alternative process was necessary to build trust and that the goals were to reduce opioid dependence while improving pain management and function for injured workers. They offered consistent suggestions for improving the program including expanding outreach and the program itself, addressing operational barriers and reducing stigma, and providing on-going administrative support to the program.

A summary of interviewee's comments is summarized by theme below.

Rationale and Goals for the OATP

Interviewees representing diverse perspectives generally agreed that the purpose of the OATP was to:

- Reduce contentiousness of the process in order to help injured workers on high-dose long-term opioids reduce their opioid dependence while improving their pain management and function.
- Reduce the amount of time required for a legal process to address disputes around opioid medications.
- Move medical decision-making out of the legal realm.
- Improve medical care for injured workers.
- Prevent opioid overdoses, misuse, and substance use disorder among the injured worker population.
- Reduce post-lump sum medical costs.

Several interviewees spoke of the damaging impacts of the contentiousness and breaches of trust in the workers' compensation litigation process. They spoke of ill will and anger generated by insurance claim denials. One injured worker expressed that he thought that the insurance company was trying to kill him by cycles of approval and denials forcing him into withdrawal over and over. An attorney reported getting a call from her client:

All of a sudden the insurance company would say 'you can't have them anymore.' She would go to the pharmacy and find out that payment was denied. It was traumatic, constantly in tears, "I didn't do anything wrong. They just give me them because it

³ QSR Nivo is a qualitative data management tool that allows researchers to manually code data using themes they supply. QSR Nivo does not automatically code data, but it does assist the researcher in organizing the data for analysis and summary of findings.

helps and I don't know what to do." On the insurance side, they are saying 'we don't want to be responsible for her overdosing.'

Measures that were taken to "re-set" this trust included new attorneys to represent the employer/insurance company. Additionally, the Judge on the original case is not the Judge for the mediated process. The attorney for the injured worker plays a key role in re-building trust in the process. They have to reduce the stigma around getting help when the injured worker may feel like everyone is treating them as an "addict."

In some cases, the injured worker feels lost and abandoned by everyone including their lawyer and their primary care physician. As explained below, the Care Coordinator plays a key role in "finding" them and starting over. One Care Coordinator explained that her patient felt that "nobody cares about me. I'm just a number...they don't want to pay for this just want me off opioids...they never wanted to help me in the past, why now?" The Care Coordinator attempted to convince her that the Care Coordinator's involvement was a product of the system becoming more caring. In the Care Coordinator's words: "healing starts with healing."

Many interviewees felt that the OATP mediation was a dramatic change from the litigious status quo and that it facilitated a conversation based on compassion. However, I did not interview participants who dropped out or never volunteered to participate. One lawyer who I spoke with described a case where the insurance company would not agree to participate, most likely because they did not want to accept the liability for continuing opioid prescriptions even if they were being tapered. Some in the insurance world expressed doubt about the potential for success among "the tough cases," i.e., injured workers with long-term high dose opioid use, co-morbidities, and lack of social support. In short, the OATP can work for those committed to the goals, but it will not work when either the insurance company or the injured worker do not trust the process and do not see their interested represented. However, due to the agreement with these goals, interviewees did not offer suggestions for changing them.

Incentives for Participation

Insurance companies' attorneys filing forms to discontinue opioid treatment was mentioned as the most common "incentive" for injured workers to volunteer to participate in the program rather than go the traditional litigation route. Prior to filing these forms, some mentioned that an insurance company might approach the injured worker or their attorney to suggest participation. Closely related to this is the case where injured worker filing claims after their prescriptions were denied opting for participation in order to continue their prescriptions. While the OATP is a voluntary program, it is clear that these scenarios have something of a coercive element to them.

Other routes to participation include an injured worker's attorney encouraging participation, a Judge encouraging participation, or family and friends encouraging participation. One attorney described her efforts as follows:

You have to have tough conversations that most workers comp attorneys aren't prepared to have with their clients – about the psychological impact of being on the medications along with the physical dependence. These are hard conversations about addictions, that it isn't a moral failing, that they didn't do anything wrong, that we didn't understand the medication when it was prescribed like candy. Then, you have

to reassure them along the way – 'You need to be there for your family...you want to hold your grandchildren...you are important...we need to get your medication down.'

Such encouragement might result in agreement to participate if the conditions are right such as the injured worker reaches a point of being "ready to change," recognizing harms of opioids physically, emotionally/psychologically, and socially. Finally, there are "scare tactics" such as their doctor prescribes Narcan (overdose reversing rescue medication) and the injured worker sees it as a "wake up call" that the level of opioids is dangerous.

Once an injured worker agrees to participate, they may need more encouragement to continue. Such encouragement usually comes from motivational interviewing by a skilled Care Coordinator and/or pain management specialist. One physician suggested an approach that combined dire warnings of negative consequences of continuing on high dose opioids, such as a "brain on fire," and straightforward efforts to strengthen the patient's belief that they will be successful ("If you want to do this we can, I've done it a million times."). Encouragement to stick with it also comes from successes achieved through alternative pain management in conjunction with dose lowering. As discussed below, tapering must address opioid induced hyperalgesia where the opioids increase sensitization to pain. Additionally, withdrawal symptoms may include a greater perception of pain. Thus, the patient must be thoroughly committed and aware in order to withstand increased perception of pain while reducing opioid medications.

Suggestions were made by interviewees regarding enhancing incentives for participation, including:

- More robust advertising and marketing of the program. Such marketing would include a clear
 description of the process, successes, and participants discussing how they feel better with less
 opioids. As one interviewee put it "We need bigger voice that this program does work."
- Given the potential influence by injured workers' attorneys, one suggestion was to compensate attorneys to discuss the program with their clients.
- Direct outreach to prescribing/treating physicians was also recommended.
- One physician suggested that injured workers be financially compensated to reduce their opioids.⁴
- Expanding the program beyond settled lump sum cases would remove a barrier to participation among others who are motivated to participate.

Measures of Success

Participants were asked what would indicate that the program was successful. These metrics and benchmarks can be used for on-going and periodic program evaluation.

- Reduced morphine equivalent dose (MED) of opioid medication; everyone below 50 MED
- Improved function as attested by the patient and assessed in functional scales/patient survey, and through medical record notes
- Injured workers' personal goals achieved
- Improved health behaviors including weight loss and preventive medical care
- Return to work, full or part-time

⁴ Investigators have found that "<u>contingency management</u>" programs based on rewards for abstinence shown by urine drug tests are effective in helping those with substance use disorder maintain drug-free status.

- Improved quality of life, reported by patient (e.g. better sleep, social relationships)
- Better coping, emotional and psychological functioning
- Improved sense of control over pain and medical care; shared decision-making
- Enhanced "self-efficacy" confidence in ability to manage pain without high dose opioids
- Number of program participants enrolled, retained, and completed
- Greater percentage of eligible patients participating
- Number of stakeholders aware of the program and educated about how it works
- Stakeholders with improved understanding of how opioids impact the body and mind, including addiction/dependence, opioid hyperalgesia, disability, side effects, etc.
- Stakeholders with improved understanding of opioid tapering process and alternative pain treatments and pain management
- Better understanding of pain "expectations" including potential for co-existing pain and function improvement and transient increased pain
- Increased patient capacity for pain self-management and coping strategies
- Prevention of cases where the injured worker, "cut off" from insurance payment for opioids, "goes to the street"
- Decreased fatal and non-fatal opioid overdoses, misuse, addiction, and opioid use disorder. Reduced emergency visits by injured workers related to opioids.
- Improved trust in and greater satisfaction with the legal process; fewer phone calls to lawyers
- Fewer litigated cases and more mediated ones
- Improved trust in and greater satisfaction with medical care
- Easier access to pain management and alternative treatments
- Fewer denials of recommended treatment by utilization review
- Reduced costs of care
- More reliance on evidence-based treatments

Several interviewees were clear that pain scales were not useful and "pain" as a metric would fail to capture positive changes in injured workers' lives. Many who had reduced their opioids felt better even if they still reported living in pain. They reported that patients perceive less "pain interference" in their lives and thoughts and that they are able to do more things, which, in turn, helps to "break the pain cycle" of feeling too bad to do anything. A couple of interviewees mentioned that substance use disorder diagnoses and treatment might be beneficial in some cases, but no one mentioned "more people in SUD treatment" as a goal. Some mentioned a process metric whereby a person is transformed by the realization that they are overly dependent on a medication that is not helping them and that is causing problems. Significant reduction in MEDs were regarded as a more realistic goal than complete elimination of use of opioid medications.

OATP Process and Program Administration

As mentioned above, the program was established in order to create a less contentious process of resolving disputes regarding opioid medications. In traditional litigation, Judges were in a position to rule on the medical issue of whether opioids should be continued. Interviewees provided more in-depth perspectives on the functioning of the OATP and how it could be improved. In general, they described the process as somewhat informal framework, open-ended and individual. 19A agreements have no clear required content or timeline. While there are advantages to this, several felt that greater program

oversight and devoted program administration would enhance the program as long as the treatment approach and timeframe could be tailored to the individual.

Several interviewees observed that there may not be clear understanding of the steps and stages of the OATP for the involved parties including DIA conciliators and judges. Those who participated generally agreed that the OATP "took it down a notch" so that parties could sit together, have a conversation, and negotiate a 19A agreement, however the Judges continue to have purview over reporting requirements, in person hearings, required progress, and timelines. They rely heavily on the Care Coordinator, determines what "care coordination" means and how it proceeds, and when it ends.

While the first step is to find the "right" nurse case manager to serve as the Care Coordinator, some interviewees noted that it is not easy to find that person. It is not clear how Care Coordinators are screened for inclusion on the DIA website or if they have qualifications and experience in assisting opioid-dependent injured workers. Some interviewees felt that it was difficult to find appropriate Care Coordinators in the Western part of the Commonwealth.

It is not uncommon for treatments recommended by the Care Coordinator or Pain Management Specialist to be challenged by the insurers' utilization review as either not reasonable or not related to the injury, and, therefore, denied. The adjustor can usually override denials by utilization review departments, however it can cause delays and breach trust. While the patient could utilize private/noncomp insurance for some aspects of the process, it is not clear how to coordinate the process/payments between insurances.

The absence of a program administrator means that there is no one who can "troubleshoot" OATP process issues other than the lawyers, care coordinators and the Judge. There are no standard report forms or reporting schedule to the DIA from Care Coordinators or Judges. There are apparently no formal records of the OATP other than 19A forms. For those program participants who withdrew from the program, or where progress is stalled, there is no information on why.

Many attorneys and others refer to the program as the "opiate diversion program" which most likely references their association with "drug court" sentencing alternatives in criminal litigation. It may be stigmatizing to associate the program with criminal litigation and does not reflect the actual OATP process.

Injured workers' attorneys need to negotiate their fee in the process. These attorneys generally felt that they were not appropriately compensated for their time and it would be better to have a fixed fee.

Many of the interviewees' recommendations for improved OATP administration are included in other sections below, however it is worth highlighting one of those:

• Establish a DIA program administrator staff position to manage the program, be a liaison, keep records, write reports, promote the program, educate participants and stakeholders, monitor participants' progress, troubleshoot, conduct periodic evaluations, and facilitate progress towards overcoming challenges faced by the OATP.

Care Coordination

As mentioned above, care coordination, which is the heart of the OATP process, is not defined beyond the goal of working with the patient, their primary care provider (treating physician) and specialists to

reduce opioid MED and increase patient's pain management and function. This involves communication with the injured worker, the insurer (who pays for their services on an hourly basis), the Judge and clinicians. The roles includes avoiding communication breakdowns among stakeholders and coordinating inter-disciplinary care. The 19A form includes the agreement as to who the care coordinator will be. One Care Coordinator interviewed for this report said that she gave a guideline for her estimated number of hours, but the insurance company did not restrict her hours, which for the first three months were 10 hours a month to work with one participant.

Care Coordinators were described as very special individuals with unique skills in motivational interviewing, trouble shooting, counseling, education, and managing the overall interdisciplinary clinical care, including tapering processes. Professional qualities included knowledge of addictions counseling, social work, as well as strong listening skills and patience. It is not clear how these qualifications and qualities are assessed up-front, as mentioned above.

In many cases, the Care Coordinator steps in when the primary care/treating physician has given up doing anything more than writing the opioid prescription. In many cases, the provider doesn't know what to do and is grateful for the assistance. In other cases, the provider may object to the "interference." Negotiating the injured workers' care with this treating physician can be easy or extremely difficult depending on the attitude of the physician. Additionally, the injured worker usually has a long-standing relationship with their provider whom they trust. The Care Coordinator must gently "massage" this trust if the provider is an obstacle to alternative approaches and improved care. One Care Coordinator went to appointments with her client and the primary care physician to "get him on board while saving face." The patient had been with the primary care physician for 30 years and trusted him, so the Care Coordinator need to provide a way to show him trying to help, even though he was providing suboptimal medical care.

Although Care Coordinators are contracted by the insurance company, and usually have experience working for insurance companies, they are perceived to be "neutral." The relationship between the Care Coordinator and the program participant is of paramount importance. Additionally, the Care Coordinator is responsible for reporting honestly on the participants' progress to the Judge. The Care Coordinator is also responsible for identifying appropriate alternative treatments and pain management, which can be challenging because of barriers described below.

Interviewees' recommendations for improved Care Coordination included:

- DIA to hire Care Coordinators directly, similarly to the Rehabilitation Specialists that work through the DIA's Office of Educational and Vocational Rehabilitation.
- Provide a Clinical Guideline for Care Coordination/Opioid Tapering/Alternative Pain Management.
- If Care Coordinators are to be contracted, provide clearer screening and qualifications, which include experience with tapering and addictions counseling.
- Facilitate "Rounds" or other meetings among Care Coordinators to build a "Community of Practice."

Medical Care for OATP Participants

The OATP exists because some injured workers continue to receive high-dose opioids for chronic pain. The Centers for Disease Control and Prevention, many clinical studies, and the American College of

Occupational and Environmental Medicine are in agreement that opioid medications are generally not supported for chronic pain because of their lack of efficacy and their significant harms, including addiction, overdose and death. Many interviewees noted that program participants and non-participants were just being maintained on opioids with no other medical care and that the primary care physicians who were writing these scripts didn't know what to do. The patients continue to report pain and are resistant to reducing or eliminating opioids, and so the prescriptions continue and are increased. Prescribers often do not provide evidence-based monitoring for compliance, quantified assessment of pain and function, screening for misuse and risk of addiction, psychological assessment and support, nor evidence- based rehabilitation. The provider may be aware that their patient is opioid dependent, addicted, and even potential misusing through hording, etc., however, they fear the consequences of stopping the medications and are unclear about how to reduce them.

In other cases, the patient has essentially been abandoned by the provider. One Care Coordinator noted that her patient was experiencing many side effects of the opioid medication including sleeplessness and constipation that had never been addressed by the primary care physician. Her goal was to help her patient feel a bit better in order to enable her to begin a tapering program.

All treatments, including the tapering schedule, are individual to the patient. However, there are some common approaches mentioned by the clinical interviewees. First is a slow, well-monitoring tapering schedule that is complimented by other pain management strategies -- some interventional such as steroid injections and some non-interventional such as massage, movement therapy, pain self-management, and coping skills. Functional improvement and "getting them moving" is an extremely important component of the process, according to several interviewees in order to "break the pain cycle." As one physician said

In a good tapering program, they feel better. They still have pain, but they feel better. The person is more functional and more active. They have more energy and they are interacting with loved ones. They don't feel zombie-like.

There are a number of evidence-based and less well documented approaches to pain management. As one Care Coordinator explained, "you wouldn't ride a bicycle with one spoke. You have to be able to try different approaches." Insurers have been open to considering a wide variety of alternative treatments, however there is no guideline for evidence-based approaches to alternative treatments, nor for opioid tapering schedules. Pain management is an interdisciplinary practice involving functional restoration programs, self-training, counseling, and pharmacology. Some of these modalities, especially psychotherapy, have traditionally been resisted by insurers because of their fears of "endless, openended" claims that go way beyond treatment for the injury. For this reason, Care Coordinators related that they themselves integrate psychosocial counseling into their work with patients. Functional restoration often requires patients to go to a gym, however one clinician said that his patients sometimes fear being videotaped by the insurance company if they visited a gym.

The standard approach to opioid dependence where there is no longer a legal source of opioids is a "detox program," followed by Medication Assisted Treatment: opioid-based medications that do not cause euphoria and reduce withdrawal symptoms, such as Buprenorphine or methadone maintenance. However, while insurers and other interviewees initially thought that substance use disorder treatment would play a major part in treatment in the OATP, it has not. Clinicians instead have opted for a tapering

process that is complimented by pain management strategies. One clinician described the tapering process as

a slow purposeful taper, to allow the patient to adapt to the reduction, with 4-6 weeks between dose reductions of 15 mg at a time with a window of tapering of 2 or 3 months. This is to avoid "rebound <u>opioid hyperalgesia</u>," which they experience as bump in pain. I have to prepare them, if their pain gets up there, don't be surprised.

The US Department of Health and Human Services has offered a <u>guideline</u> for tapering. Some physicians recommend weaning protocols of dose reductions around 10% at a time every 1-2 weeks, followed by 5% at a time towards the end of the tapering period. Because opioid tapering or weaning is not generally practiced or understood by the provider community, program participants need to be able to come under the care of a pain management specialist. However, interviewees reported challenges finding pain specialists that would take on program participants. One reason was low reimbursement, and another is that due to the opioid epidemic and liability concerns, very few pain management specialists would take over an opioid prescription while the tapering is occurring. Thus, it is often necessary for the primary care provider to continue to write the opioid prescriptions.

Recommendations for improved medical care for OATP participants included:

- The DIA's Healthcare Services Board, with input from healthcare professionals involved in the program, should create an Opioid Tapering and Pain Management Clinical Guideline covering tapering procedures, withdrawal management, opioid side effects, non-opioid pain management including interventional and non-interventional treatments, polypharmacy, functional restoration, primary care, substance use disorder treatment, health coaching, self-help, and psychological modalities.
- Advance negotiation with insurance adjustors regarding permissible alternative treatments, timeframes, and budgets.
- Cultivation of tailored pain management multidisciplinary programs for injured workers including psychosocial support groups and self-help skills development
- Develop a list of professionals in the medical and psychosocial fields who have particular skills and capacities to work with injured workers with long term opioid use, including experience with weaning
- Educational programs for primary care physicians on opioid weaning and pain management
- Creation of a decision-guide for injured workers with regard to their choices for pain management and reducing opioid use and dependence

Finances and Cost

As noted above, an explicit goal of the program is lower the cost of care for injured workers while improving their medical care and their health outcomes. Many if not all of the cases that have entered OATP were initiated by insurance companies that did not want to continue to pay for opioids, in part because of the expense associated with medical treatment that was not recommended, and in part because the liability associated with unsafe prescribing.

Many interviewees framed the cost issues as a greater investment up front (so to speak), with a goal of reducing costs. The OATP process does involve considerable investment by the insurance company. They are paying for their own and the client's attorneys, the hourly rate of the Care Coordinator, primary care

fees, fees from pain management practices, and interventions such as spinal cord stimulators, while continuing to pay for opioids as they are decreased. Some insurers interviewed were neutral about the costs as they felt that their interest was in "getting the patient to a better place." An attorney reported that one insurance company refused to participate because "opioids were cheaper." Other interviewees felt that many insurers were too focused on short term costs and would balk at further investment in these cases. Insurance companies are unlikely to share their cost data with evaluators, so it will remain to be seen if the industry perceives the costs as a barrier to participation in OATP cases or expansion of the program.

Several interviewees mentioned the low medical reimbursement rates offered by the DIA were a barrier to accessing more quality pain management services for OATP participants. Additionally, it was felt that the injured workers' attorney fees were insufficient. As mentioned, some interviewees found that utilization review was inhibiting or slowing approval of alternative pain therapies, while others thought that insurers were generally cooperative with the recommendations of the Care Coordinators.

Some recommendations from the cost/financial side included:

- Establish budgets or "capitation" for pain management to create predictable costs and incentives for pain management providers to provide the best care at the lowest cost
- Establish fixed rather than negotiated fees for injured workers' attorneys
- Relax utilization review ("reasonable and related to the injury") while a patient is participating in OATP under Care Coordination
- Shift some costs of the OATP to within the DIA budget through directly hiring an administrator and Care Coordinators

Education/Awareness

Several interviewees saw potential avenues for education as necessary for the functioning and expansion of the OATP, such as:

- "Rounds" or seminars for clinicians on tapering and pain management
- Informational sessions or materials for injured workers on alternatives to opioids, skills for pain management, and the OATP
- Opioid awareness: risks of addiction and overdose, clinical guidelines, side effects, opioid tolerance/hyperalgesia, functional and pain improvements with weaning
- Seminars for attorneys on working with clients who are eligible for the OATP
- Develop role-specific guidance about the OATP, e.g. for Judges, Conciliators, and Attorneys.

Barriers to Success

Interviewees discussed what they perceived as challenges facing the OATP – many of which they felt could be overcome. Some were commonly mentioned, such as the lack of participants. Several felt that the program should be expanded to all injured workers with claims, regardless of settlement status. The reasons for restricting the participants to those with lump sum settlements was to avoid challenges to income support while the participant is enrolled in the OATP. One interviewee suggested that this obstacle could be overcome by putting a moratorium on such challenges while progress is being made in the OATP.

Other barriers to success mentioned by interviewees were:

- Low provider reimbursement
- Lack of access to quality pain management
- Difficulty identifying skilled Care Coordinators
- Lack of providers in Western part of the Commonwealth
- Limited provider experience with tapering and functional restoration
- Lack of evidence-based guidelines and effective practices
- Cost concerns
- Disruption caused by review of medical claims
- Resistance to psychological therapies
- Lack of quality providers with experience with opioid weaning and opioid use disorder
- Lack of appreciation of the time required for success
- Injured workers' resistance to opioid reductions and alternative therapies
- Lack of incentives for attorneys to encourage client participation
- Lack of skills in "tough conversations"
- Stigma in discussing opioid addiction
- Acceptance of "legal addiction"
- Residual distrust in the medical and legal system
- Excessive trust in prescribing physician
- Lack of understanding of physical and psychological changes caused by opioids
- Lack of understanding of pain and pain management including expectations to be "pain-free"
- Lack of awareness of the OATP
- Limited eligibility for participation

Human Subjects Participation and Ethical Concerns

This formative assessment and subsequent activities towards the goal of program evaluation of the DIA's OATP were reviewed by the UML Institutional Review Board and the MA DPH Institutional Review Board and determined to be exempt from review. This is because the work is not considered research and the participants are not human subjects/research participants. This work is considered "public health surveillance" and "program evaluation," which are exempt from review. While it is expected that the results of this work would not be published as research findings, they could be published as a public health report on surveillance activities in a peer-reviewed journal.

Additionally, the CDC specified in its funding documents that the funds were not to be used for "research." Research is defined as investigatory activities to generate generalizable knowledge. There are no activities that are characterized as research versus other, thus interviews, surveys, document review, observation, etc., can all be undertaken in pursuit of program evaluation and are not considered research. Any and all documents that the DIA wishes to make available to the program evaluator, including personal health records and legal records, can be used by the evaluator to conduct the program evaluation, without consent of the subject.

Thus, while this determination grants tremendous latitude to the program to release documents to the evaluator, there are also ethical concerns, confidentiality and privacy, agency rules, and program

objectives that might be compromised by the evaluation if they are not considered. In particular, because the legal and medical documents include the personal identifiers of individuals considered to have problematic opioid use, issues of privacy and confidentiality are significant. Some felt that the program itself could be undermined if confidentiality of the participants was perceived to have been compromised. Others felt that participants were aware that many people, including attorneys, judges, medical professionals, and administrators, had access to this information through their contact with the OATP, and they were not concerned.

Interviewees were asked about their concerns regarding the evaluator having access to and reviewing the medical and legal records of injured workers who had not given consent for inclusion of their cases in program evaluation. There was not consensus among the interviewees on this point. One DIA administrator felt strongly that either these records should not be included, or permission should be sought from each worker for inclusion of their documents. Members of the HCSB felt strongly that these records were of vital importance to the goals of reducing opioid dependence among injured workers and should be included without seeking permission.

Some felt that if records were made available, the participant's name and identifying factors should be redacted first. Others thought that this was unnecessary and the evaluator could "mask" the identity of the participants as necessary in the program evaluation findings. One DIA administrator with access to records expressed that when the documents were requested, the agency would discuss it to make a determination themselves about what would be provided and if they would be redacted. He also expressed that he thought that the records would be provided with names redacted. Judge Hernandez was asked if the Form 19A could be amended to include a check box for participants to opt-in or opt-out of having their records included in program administration and he agreed that this was possible and desirable.

Given the complexity of these issues, the following approach is recommended:

- 1. Following internal discussion, the DIA makes OATP records available to the evaluator, including names and contact information of program participants and their attorneys. These records should include at a minimum, all 19A forms with the participants' name redacted, if necessary.
- 2. For records that include identifying information, no names nor identifying characteristics, such as exact job title and geographic location, will be used in any public report without permission of the program participant.
- 3. 19A forms should be modified so that future OATP participants may opt-in or out of having their records included.
- 4. Interview and survey respondents (not program participants) will be requested to not use the name or other identifying information of program participants.
- 5. While not required, solicitation of program participants in future surveys or case studies should include an informed consent process which includes description of how their identities will be protected and their responses kept confidential.
- 6. The program evaluator will not share information about individual OATP program participants with other people, including those who are involved with the OATP, in ways that would compromise privacy and confidentiality of that information.

- 7. Before program evaluation activities are undertaken, the proposed protocols and instruments will be again submitted to the UML and MA DPH IRBs to confirm their compliance with requirements and their previous determination of exempt activities.
- 8. The DIA should consult with their advisory board to gain more input on this issue as necessary.
- 9. Manuscripts and reports may be reviewed both by MA DPH and DIA. Timelines for this review will be at least 30 days. Final content of these documents will reflect the concerns expressed by the agencies with regard to the protection of the participants and the integrity of the program.

Recommendations for Evaluation Strategies

This formative assessment has brought out a rich understanding of the OATP program, including its strengths and how it could be improved. A great deal was learned about the OATP process, but much less about its outcomes, due to the fact that few have participated and very little data is currently available to assess outcomes. Given these realities, four potential evaluation strategies are proposed below for consideration as the project moves into its second year. The process outcome strategy builds upon what was learned in the formative assessment and advances stakeholder support for program enhancement through a stakeholder survey of program enhancement priorities. It also solicits assistance with those program enhancements. The outcomes evaluation proposed is a pilot to generate primary data through a participant survey. The document review is an evaluation strategy made possible with access to program documents, as well as for the case study proposal. Finally, another qualitative interview round is proposed as a way of reaching more stakeholders who were not represented in the formative assessment and as a follow-up following program enhancements. While all these strategies may be pursued, the purpose of this report is to present options for prioritization by both MA DPH and MA DIA in line with grant and agency objectives.

1. Survey of Potential Program Enhancements

The purpose of this proposed survey is to gauge support for and perspectives on the feasibility of potential program enhancements. The method would be a survey of OATP stakeholders (clinicians, lawyers, injured workers, DIA administrators and staff including Judges and conciliators) via web and paper surveys distributed through networks. The survey content would be drawn from formative assessment. Content areas would include incentives to participate, education/training, administration, costs and finances, care coordination, and clinical care. Additionally, the survey could further explore why there are not more participants, expansion to pre-settlement patients, and also include other topics drawn from the "barriers" section above. Participants could rank importance of proposed change, assess feasibility, and provide additional comments on potential program enhancements, e.g. ways to promote participation, expansion of program eligibility, or seminars on alternative pain management. The survey could also assess program satisfaction and reach. The findings of this survey could be used to support budget requests and programmatic directions. Additionally, the survey could be used to solicit volunteers to assist with proposed enhancements such as developing a clinical guideline or giving a seminar on talking with clients about opioid use.

2. Program Participant Survey Pilot

In order to assess program outcomes, it is recommended that a survey of current and "completed" program participants be undertaken to generate pilot level data and instrument testing. The potential domains of this survey are included in the Appendix following this report. The domains come from both the formative assessment and also from the many standardized surveys relevant to this work. The pilot

would be used to assess participation strategies, validity of domains, and to generate preliminary outcomes data focusing on improved function and reduced MED of opioid medication. The pilot data and experience can be used to support both on-going evaluation and also potentially a broader evaluation once there are more participants. This is dependent upon release of participant names and contact information.

The Workers Compensation Research Institute (WCRI) has periodically conducted a survey of outcomes for workers' compensation system participants. In 2017, they published their findings comparing Massachusetts' to 14 other states. The key outcomes assessed through interviews with claimants (over 400 in Massachusetts) were 1) recovery of physical health and functioning, 2) return to work, 3) earnings recovery, 4) access to medical care, and 5) satisfaction with medical care. These outcomes strongly overlap with those that would be included in a survey of outcomes and process related to the OATP. The results provide a baseline response on these measures and a potential comparison between Massachusetts and other states that do not have an OATP. The survey instruments, methodology and findings, are available in the WCRI report: Comparing Outcomes for Injured Workers, 2017 Interviews. (2018). Future collaboration with WCRI could be explored as part of this pilot survey work.

3. Document Review and Case Studies

Very few OATP documents were available to the evaluator during this formative assessment. The COVID crisis prevented the evaluator from meeting in person with DIA administrators and visiting the DIA offices where these documents, such as 19A Agreements, could be reviewed. While the formative assessment included a review of the legal and ethical issues related to document review, the DIA has yet to discuss its preferences and policies regarding the protection of participant data balanced against a desire for program evaluation. It is recommended that the next phase of evaluation, DIA administration convene a discussion of which documents they wish to make available for the purposes of program evaluation and what level of redaction will be necessary. Upon review of these documents, the evaluator can both abstract data and potentially develop case studies that illustrate the experience of the OATP. Case studies generally have common categories of analysis, such as those themes discussed above – why they participated, what their medical care and care coordination looked like, costs, etc. Case studies are a form of qualitative evaluation that can present a picture and tell a story of the program without large numbers and in a way that protects the identity of the individual.

4. Survey and Interview of Stakeholders

The final proposed strategy is a repeat of the formative assessment qualitative interview complemented by a survey with content drawn from the first assessment. Ideally, this would be conducted as a follow-up following program enhancements, passage of time and greater numbers of enrolled participants. While the first formative assessment was very open-ended, this one would be more focused and specific to prioritized evaluative domains.

Conclusion

This formative assessment interviewed diverse stakeholders and found significant support for the program and abundant suggestions as to how it could be enhanced. While the program has emerged from pilot status, it does not have enough participants nor data generated internally to provide a valid assessment of outcomes. A process evaluation strategy that blends evaluation and program enhancement is proposed along with a strategy to generate data for outcomes assessment through a

participant survey. The data from the outcomes pilot survey could be used to support a broader impact evaluation and clinical assessment that would build the evidence base for the OATP as an intervention to reduce opioid dependence and overdose. The importance of this project should not be underestimated. The toll of the opioid epidemic on injured workers has been significant and the OATP program evaluation represents a tremendous opportunity to elucidate opportunities and barriers to reversing its course.

Appendix: Draft Questionnaire, Domains, and Source Instruments for a Questionnaire for OAPT participants and non-participant patients, including former OAPT participants

1. Demographics and Characteristics

- a. Program participation status
- b. Date entered program
 - i. Why they entered program (their own words and administrative process, e.g. Judge ordered it)
 - ii. If left, date left
 - iii. Reason for withdrawal
- c. Gender
- d. Age
- e. Marital status
- f. Working Status (full, part-time, homemaker, work-disabled, retired)
 - i. Industry/occupation
 - ii. Earnings change
 - iii. Disabled because of pain, retired because of pain
 - iv. Job security change
 - v. Job satisfaction change
- g. Work History
- h. Description of Injury
- i. Date of injury
- i. Diagnos(es)
- k. Medical Treatment History including Surgery(s)
 - i. Medical treatment Coordinated by OATP Care Coordinator
 - ii. Other Medical Treatment
 - iii. Timeline/prescription record
 - iv. Self-reported current dose
 - 1. Report of changes initiated by patient
- I. Prescribing Provider Name
- m. Prescribing Provider Discipline
- n. Other providers
- o. Other major health issues (co-morbidities)
 - i. Prior or subsequent to injury?

2. Pain and Functional Assessment

- a. Modified Brief Pain Inventory Assessment Tool
 - i. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain during the last week?
 - ii. In the last week, how much relief have pain treatments or medications provided? (Percentage in 10% increments, 0 = no relief, 100% = complete relief)
 - iii. Circle the one number (0 no interference; 10 complete interference) that describes how much, during the past week pain has interfered with your:
 - 1. General Activity:
 - 2. Mood:
 - 3. Walking Ability:

- 4. Normal Work: (includes both work outside the home and housework)
- 5. Relations with other people:
- 6. Sleep:
- 7. Enjoyment of life
- b. Body part-specific functional inventories: NDI and ODI for spine, quick DASH for upper extremity and LEFS for lower extremity
- c. NHIS Chronic Pain Questions 339-351
 - i. In the past three months, how often did you have pain? Would you say never, some days, most days, or every day?
 - ii. Thinking about the last time you had pain, how much pain did you have? Would you say a little, a lot, or somewhere in between?
 - iii. Over the past three months, did you use any of the following to manage your pain?
 - 1. Over-the-counter medications such as aspirin, Tylenol, Advil, or Aleve
 - 2. A pain reliever prescribed by a doctor, dentist, or other health professional
 - a. Name
 - 3. Marijuana
 - 4. Physical therapy, rehabilitative therapy, or occupational therapy
 - 5. Spinal manipulation or other forms of chiropractic care
 - 6. Talk therapies such as cognitive-behavioral therapy (CBT)
 - 7. Yoga, Tai Chi, or Qi Gong (chee-GONG)
 - 8. Other forms of exercise, such as walking, swimming, bike riding, stretching, or strength training
 - 9. Massage
 - 10. Meditation, guided imagery, or other relaxation techniques
 - 11. Over the past three months, did you use any other approaches to manage your pain
 - a. Describe
 - iv. In the past year, would you say that your pain has worsened, improved, stayed the same? (CR made this up)
 - v. Measure of Opioid-induced hyperalgesia?
- d. PHQ-9 Assessment Tool (Mental Health)
- e. General/Physical Health (2020 National Health Interview Survey)
 - i. Would you say your health in general is excellent, very good, good, fair, or poor?
 - ii. During the past 12 months, how many times have you had to visit an emergency room or urgent care center?
 - 1. Reason (0)
 - 2. Related to Injury?
 - iii. During the past 12 months, how often did you receive physical therapy, speech therapy, rehabilitative therapy, or occupational therapy? (From NHIS)
 - iv. About how long has it been since you last saw a doctor or other health professional for a wellness visit, physical, or general purpose check-up? (NHIS) (w/in past yr, 2 yr, etc.)
 - v. During the past 12 months, how often did you receive counseling or therapy from a mental health professional such as a psychiatrist, psychologist, psychiatric nurse, or clinical social worker? (from NHIS)
- f. Other Biopsychosocial measures
 - i. Maladaptive health behaviors
 - 1. Exercise

- 2. Diet/Weight gain
- 3. Substances
- 4. Sleep schedule
- 5. Missing medical appts/no medical appointments
- 6. Opioid "budgeting" save for when they need it
- ii. Disability assessment? Pain Disability Assessment Scale (PDAS)
- iii. Side effects related to medication? (from DIA list)
 - 1. Confusion
 - 2. Poor judgment
 - 3. Nausea/Vomiting
 - 4. Stomach ache
 - 5. Constipation (hard stools that may be painful to push out).
 - 6. Sleepy or drowsy feeling
 - 7. Poor coordination and balance (such as feeling unsteady, tripping, and falling)
 - 8. Slow reaction time
 - 9. Slow breathing or I can stop breathing which could cause me to die
 - 10. More depression (such as feeling sad, hopeless, or unable to do anything)
 - 11. Dry mouth
 - 12. Increased feeling of pain (hyperalgesia)
 - 13. Addiction (it may be very hard to stop taking the pain medicine when I'm ready to quit)
 - 14. For men: the pain medicine may lead to less interest in sex and poor sexual performance
 - 15. For pregnant women, the pain medicine may hurt my unborn child and may cause my child to be born addicted to the pain medicine
- iv. My list of side effects
 - 1. Constipation
 - 2. Spaciness/lack of focus
 - 3. Sleepiness
 - 4. Low energy
 - 5. Weight gain
 - 6. Weight loss
 - 7. Irritability/moodiness
- g. Substance use
 - i. Opioid Use (NHIS)
 - 1. During the past 3 months, have you taken any opioid pain relievers prescribed by a doctor, dentist, or other health professional?
 - a. to treat short-term or acute pain, such as pain due to a broken bone or muscle sprain, pain from dental work, or pain following surgery?
 - b. to treat long-term or chronic pain, such as low back pain or neck pain, frequent headaches or migraines, or joint pain or arthritis?
 - c. Other
 - 2. During the past 3 months, how often did you take a prescription opioid? Would you say some days, most days, or every day?
 - a. Medication/dose now
 - b. Medication/Dose 1 year ago

- ii. How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons? (AHRQ question)
 - 1. Which drug(s)
- iii. Measures of Opioid Misuse: Current Opioid Misuse Measure (COMM)
- iv. <u>Attitudes toward opioids</u> among long-term chronic pain sufferers: Opioid Beliefs and Behaviors Questionnaire (OBBQ)
- v. How many times in the past month have you consumed more than 5 drinks in a two hour period? (CR made this up based on NHIS which asks about # drinks in one occasion which is defined as 2 hrs with 5 being the men's binge number)
- 3. OAPT Program Satisfaction and Quality Assessment
 - a. Healthcare Effectiveness Data and Information Set <u>HEDIS</u>? Or other standard HC quality measures (NOTE: HEDIS is for health insurance plans to measure effectiveness)
 - i. AHRQ/IOM has following domains of HC quality: [I like these as basis of questions]
 - 1. Safe: Avoiding harm to patients from the care that is intended to help them.
 - 2. Effective: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively).
 - 3. Patient-centered: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
 - 4. Timely: Reducing waits and sometimes harmful delays for both those who receive and those who give care.
 - 5. Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy.
 - 6. Equitable: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.
 - b. Potential quality questions/domains
 - i. Care coordination
 - 1. Conversations/coaching
 - 2. Assistance with obtaining care
 - ii. Experience with primary care/treating physician
 - iii. Satisfaction with care (right track, etc.)
 - iv. What has helped the most?
 - v. What has helped the least?
 - vi. Communication
 - vii. Got the care you need/costs covered
 - viii. How many times called your attorney related to your case?
 - ix. Time spent related to administrative issues/conflict with payor
 - c. Interviews of those who dropped the program or didn't enroll
- 4. Subjective Experience
 - a. Understanding of the program (self, dr, attny, family)
 - b. Locus of Control (pain, dr, self)
 - i. Multidimensional Health Locus of Control Scale (MHLC) developed by Wallston
 - 1. 18-item questionnaire that is perfect and validated for pain
 - c. Knowledge of pain and pain management
 - d. Self-efficacy: Pain Self-Efficacy Questionnaire (PSEQ)

- i. 10 questions asked about activities despite the pain (overlaps with the interference questions above)
- e. Catastrophizing/fear avoidance/pessimism/negative affect?
 - <u>Fear Avoidance Model</u> "interrelationships between catastrophizing, fear, depression, and pain-related disability, and the role of fear as a common barrier to recovery"
 - ii. ACTTION-APS Pain Taxonomy (AAPT)
 - 1. Based on biopsychosocial model of pain
 - iii. Resilience/Coping Factors: social support, acceptance, active coping, self-efficacy
- f. Quality of life
 - i. Satisfaction with family life, financial, social life, living environment
- g. Feel better/worse than 1 year ago
- h. Perception of control over pain (opioids vs. other methods)
- i. Shame/stigma around taking opioids
 - i. "Has a doctor ever expressed concern about your use of opioids?"
 - ii. Family member or friend?
 - iii. Your own
- j. Concern
 - i. Won't work over time
 - ii. Need higher doses
 - iii. Physician/insurance won't continue to prescribe them
 - iv. Addiction/dependence
 - v. Side effects
 - vi. Fatal and non-fatal overdose