Opioid Prescribing Estimates Workgroup

Observations presented to the National Center for Injury Prevention and Control's Board of Scientific Counselors

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SUMMARY

The BSC Workgroup on Opioid Prescribing Estimates held four meetings addressing clinical situations in which opioids are prescribed: post-surgical pain, chronic pain, acute non-surgical pain, and cancer-related and palliative care pain. The charge of the Workgroup was to:

- Identify key recommendations from evidence-based guidelines for prescribing opioids for acute and chronic pain conditions, on which to develop estimates and goals
- Identify key diagnoses and procedures for which opioids might be prescribed to manage acute and chronic pain
- Identify key clinical and epidemiological studies that provide information for estimating opioid need for specific diagnoses and procedures
- Provide expert input on methods for generating opioid prescribing estimates and reference points
- Identify guidelines and recommendations for acute pain that could be further communicated by CDC through translational materials
- Identify other activities needed for the development, interpretation, dissemination, and implementation of opioid prescribing guidelines, recommendations, and reference points

The CDC conducted the literature search, identifying the diagnoses to be included based on availability of data and guidelines, the guidelines upon which to base opioid prescribing estimates, and developing proposed benchmarks for opioid prescribing. The Workgroup reviewed the work done by the CDC and provided additional recommendations.

Workgroup members gave several suggestions for improving the selection of benchmarks and conducting the analysis. Ideas included to adjust for comorbidities and concomitant medications (e.g. renal insufficiency, history of gastrointestinal hemorrhage, anti-coagulants, lithium, sedatives, etc.); to distinguish the needs of opioid-naïve from opioid-experienced patients due to the variation in opioid requirements; considering inpatient opioid requirement if the dataset would allow; to focus on duration of opioid therapy for acute pain rather than dose; to consider analyses focused on specific regions or even facilities to address the wide variation in patient population nationally; and to clearly define categories such as chronic pain, acute pain, cancer pain, and palliative care.

Members also suggested standards for when and how to pair a prescription with a diagnosis, including challenges in doing so, particularly for chronic pain. Members were mixed on the inclusion of pediatrics and of sickle cell disease, however there was greater consensus on the need to carefully select diagnoses and, often, to break down broad categories into more targeted diagnoses for which benchmarks could be more clearly defined. Some members suggested limiting the number of diagnoses for which benchmarks would be developed, while others recommended including more diagnoses. It was suggested by some that the CDC consider limiting the analysis to a descriptive review for some or all diagnoses, rather than set benchmarks where data are too limited or conditions too varied in presentation.

The Workgroup felt that the task planned by the CDC was challenged by several issues. First, several Workgroup members felt that the dataset selected for the work – Optum claims database – was problematic as it does not include Medicaid populations, which may make it difficult to identify pediatric data and data on conditions such as sickle cell, and may bias results away from ill and under-resourced patients. This database also cannot capture the uninsured and only represents a single payor through United Health rather than multiple payors, limiting the ability to draw conclusions on regional variation and generalizability. In addition, the dataset does not include medical record data and thus may lack sufficient information to adjust benchmarks for important clinical characteristics, such as co-morbidities, utilization of nonopioid pain management approaches or medications, inpatient or surgical case characteristics, etc. Second, pediatric, pregnant, and geriatric populations were felt both to be important to include in the analysis and to have insufficient data to be included in the analysis. Third, the selection of conditions was felt to be complicated by several factors, including absence of data, non-specificity (e.g. abdominal pain, low back pain), and limited data for many conditions. Fourth, concern was voiced from many Workgroup members that the CDC may not be able to prevent conclusions from this research (i.e. the benchmarks, developed from limited data) from being used by payors or clinical care systems to constrain clinical care or as pay-forperformance standards – i.e. interpreted as "guidelines". This issue was raised by several members on each of the four calls, raising the possibility that providers or clinical systems could thus be incentivized against caring for patients requiring above average amounts of opioid medication.

RECURRENT THEMES

There were several recurrent themes throughout the sessions.

Risk for misuse of the analysis. Several members expressed concerns that this analysis could be interpreted as guidance by regulators, health plans, or clinical care systems. Even though the CDC does not plan to issue this as a guideline, but instead as research, payors and clinical care systems searching for ways to reign in opioid prescribing may utilize CDC "benchmarks" to establish pay-for-performance or other means to limit opioid prescribing. Such uses of this work could have the unintended effect of incentivizing providers against caring for patients reliant upon opioids, including patients receiving treatment for opioid use disorder.

Data source. There were numerous concerns raised with regard to the Optum dataset. The lack of Medicaid data was felt to be a major concern for many diagnoses, because (a) some patient groups are more likely to rely upon Medicaid and thus would not be represented; (b) the more morbid manifestations of some diseases, such as sickle cell, might result in lower income and more reliance upon Medicaid; and (c) patients on Medicaid might have less access to social support and non-opioid pain management ranging from non-opioid medications to physical therapy, acupuncture, massage, or psychological services.

It was also noted that, in order to obtain sufficient granularity to establish the need for, dosage, and duration of opioid therapy, it would be necessary to have much more extensive electronic medical record data. In addition, pain and functional outcomes are absent from claims data, but were felt to be important when considering risk and benefit of opioids.

The absence of sufficient data for many diagnoses led some members to suggest that the CDC consider a descriptive analysis, rather than defining benchmarks. This was also noted to potentially address the risk that the work be interpreted as a "guideline." If benchmarks are used, it was suggested that a range be applied in circumstances where data are not solid.

Some members suggested looking at one-year safety data from pharmaceutical trials to establish how long and at what dosage people take opioids.

Timing of prescription. Members discussed how to best tie the prescription to the diagnosis and the many resultant challenges. For emergency department diagnoses, it was assumed that most opioid prescriptions would be filled in 1-2 days, unless the diagnosis results in hospitalization. For post-operative patients, an opioid prescription up to 30 days prior may be for that event. In the primary care setting, linking a prescription to a diagnosis could be extremely challenging, particularly with regard to chronic pain disorders which may result in a first opioid prescription being filled months to years after the diagnosis is made. Some members suggested an *Annals of Emergency Medicine* study looking at ankle sprains as guidance. Another member noted that newer Optum data ties prescriptions to de-identified provider data – the link of a diagnosis to a prescriber was felt to be a stronger way than chronology to link a specific chronic pain diagnosis with an opioid prescription.

Opioid experience. Prior opioid use was felt to be an important factor in determining the needed amount and duration of opioids for many indications. This applied to chronic pain as well as to acute post-operative and non-surgical pain conditions. Opioid experience also referred to chronic use prior to the development of a condition or procedure, as well as opioid use during hospitalization for a condition or following a procedure. Patients on buprenorphine or methadone were also felt to be important to consider, and a population that may not be identifiable given the barriers to accessing data on addiction medications (e.g. different payors and legal constraints).

Pediatrics. There was a mix of feelings regarding inclusion of pediatrics in the analysis. It was felt by some members to be extremely important to include pediatrics, whereas it was also felt that the Optum dataset was insufficient to capture the appropriate population which relies heavily upon Medicaid. Leaving out pediatrics led to concern that the adult-based analysis would by inappropriately applied to children and/or support the belief that opioids are never appropriate in children. It was noted that even a descriptive look at prescribing patterns would be helpful in this arena.

Members suggested reviewing existing literature, demarcating challenges for different age groups of children (e.g. note age ranges that may have a higher risk of use disorder), state that the analysis does not include a representative sample, and explicitly state conditions and populations for which benchmarks could not be developed, so as to ensure the results are not applied to those conditions or populations. Another approach considered was to use weight rather than age, with the exceptions of chronic pain and hernia treatment which are managed differently in children than adults. Also, if reliable benchmarks cannot be established, it was suggested to offer alternative benchmarks.

Some specific differences in pain management between children and adults were discussed. Members noted that non-cancer chronic pain is generally not treated with opioids in children, including conditions such as lower back pain, fibromyalgia, and headache. Post-operative hernia repair, in contrast, was considered appropriate for opioid therapy in children. Children with sarcoma and solid tumor malignancies were noted to be the most likely to experience pain that may require opioid therapy, with the highest prevalence of these conditions among adolescents.

Sickle cell disease. There was some disagreement as to the inclusion of sickle cell disease, as well as its categorization as acute versus chronic pain. Some felt it was important as the results might be extrapolated if the disease state were not included. However, the Optum dataset was felt to be not representative of the population of patients suffering from the disease. Furthermore, those with sickle cell disease who remain employed and thus not relying upon Medicaid may be more likely to have less morbid disease and a lower reliance upon opioid therapy. It was also noted that patients with sickle cell disease may metabolize opioids differently from others. Some members noted that opioids are often required to manage chronic pain in sickle cell patients, rather than just acute pain crises.

Members repeatedly inquired as to the possibility of using Medicaid data for this population.

Guidelines: The following additional guidelines were proposed:

- Washington State AMDG guidelines/Bree collaborative. The guidelines were updated in 2015 and during the summer of 2018. [Note: It was mentioned that while the guidelines have been applied, it is unclear whether they have been effective (Von Korff illustrated they did not affect overdose).]
- o ASCO policy statement and management of chronic pain among survivors of adult cancer.
- o ACTION guidelines. [Note: This was said to potentially be helpful with classification.]

Translational materials. Members mentioned several translational materials/topics, including low back pain and abdominal pain, fibromyalgia, cancer surgery, differential management of different age groups, management of patients with opioid use disorder and on agonist treatment, post-operative tapers and tapers in general.

Risk vs benefits and best practices: Some members felt that definitions of terms like "best" practices and "risks" and "adverse harms" were unclear. Some felt that the framework focused on benefits outweighing risks, rather than risks outweighing the benefits. Some also felt that risks should include other non-fatal concerns, such as diversion.

Tapering: Concerns about benchmarks and the implications for tapering were voiced. If tapering occurs, guidance was felt to be needed regarding how, when, in whom tapering should occur. This issue was felt to be particularly challenging for patients on chronic opioids (i.e. "legacy" patients). In addition, the importance of measuring risk and benefit of tapering was noted.

POST-SURGICAL PAIN

Members were asked the following questions:

- To identify guidelines and research studies that could be helpful to the CDC
- To help determine factors that could serve as markers in the analysis to determine with benefits of opioids may outweigh risks
- To comment on how well the CDC mapped data to benchmarks and ways in which that could be improved, as well as how to account for shared decision-making in clinical care
- To provide suggestions for translational efforts

General comments. Some Workgroup members noted that most patients prescribed opioids do not experience adverse events, including use disorder. Many suggested that further discussion of opioids with patients prior to surgery was important, with an emphasis on expectations and duration of treatment. A member suggested that take-back programs would be more effective than prescribing restrictions, given that diversion is a primary concern.

It was suggested that the CDC develop a list of markers of risk when prescribing opioids, such as renal failure and sleep apnea, as well as medications such as sedatives. It was also suggested that the CDC develop a list of factors which may indicate a benefit of opioids. It was also noted that surgeons often consider opioids to be the safest post-operative pain management option and that some non-opioid medications might be more harmful (e.g., bleeding or the possibility of poor bone healing with NSAIDs). Members noted that NSAIDS can be the more risky option in some cases (e.g. Solomon DH, Rassen JA, Glynn RJ, Lee J, Levin R, Schneeweiss S. The Comparative Safety of Analgesics in Older Adults With Arthritis. Arch Intern Med. 2010;170(22):1968-1978. doi:10.1001/archinternmed.2010.391).

Some Workgroup members suggested that the CDC focus on non-opioid modalities for pain management. This was in the context of a discussion about the multi-modal nature of pain management and the benefits of regional anesthesia, although many of these modalities were noted to not be available in many clinical care settings.

Developing the benchmarks and analysis plan.

Data source. Concerns were raised with regard to the data source of Optum claims may underrepresent special populations such as pediatrics, minorities, and under-resourced individuals, with a suggestion to include Medicaid data. This was also felt to affect the generalizability of results in different U.S. regions, which have different rates of reliance upon public insurance due to differences in both income and relevant co-morbidities, as well as different rates of penetrance of United Health as the payor. Furthermore, not having access to electronic medical record data was seen as problematic in differentiating patient groups based on several factors discussed by the Workgroup.

Patient-level factors. Members noted that opioid-experienced patients should be considered differently from opioid-inexperienced patients, due to tolerance; this concern applied also to

patients with opioid use disorder. Members suggested that psychological aspects also be taken into account, such as anxiety.

Members noted that some key contraindications to NSAIDs should be incorporated into the analysis, including renal failure, a history of gastrointestinal hemorrhage, use of lithium, anti-platelet agents, or anti-coagulants. Furthermore, it was noted that some patients may not be satisfied with the analgesia provided by alternative agents, which would not be possible to detect through claims data.

Pediatrics. Data for pediatric populations was felt to be extremely limited and the nature of listed procedures may vary for these two populations (e.g. indirect vs direct hernias). As noted, it was also felt that the Optum dataset was not optimal for pediatric populations, given the high reliance on Medicaid for this population. At the same time, members felt it would be suboptimal to leave pediatric populations out of the analysis entirely.

There was concern that the default opioid amount for most pediatric populations of "0" as provided by the CDC was too low. Futhermore, recent changes in hospital practices involve early discharge after surgery for children, and it is important to consider that post-surgical pain previously treated as during inpatient care is now being managed as an outpatient, which might contribute to the conversion of acute to chronic pain. It was also felt that adolescents were at higher potential risk of non-medical use of opioids following procedures. Finally, certain pediatric conditions involving acute and chronic pain (e.g. sickle cell, malignancy, or various congenital conditions) warrant additional consideration for opioid therapy.

Procedure-related care. Members also noted that patient factors may drive opioid need more than characteristics of a procedure. Thus there may be a need to determine the opioids needed to control the surgical pain during and immediately after the procedure (this was felt to be the best predictor of opioid need), in order to determine how much opioids were required for outpatient prescription – data which would not be available in the Optum dataset. It was suggested that analyses of refill rates could shed some light on this issue.

Members noted that prescriptions, including opioids, are often issued prior to a procedure (e.g. 2 or 4 weeks prior, at least for elective procedures among opioid-naïve patients), thus complicating the planned analysis. However, it was also noted that the development of e-prescribing for controlled substances in some settings alleviates this issue and could allow providers to safely issue shorter courses of opioid medications.

Members also noted that patients are often discharged while still unable to sense pain (e.g. dental procedures) and thus it can be challenging to determine the amount of analgesia required by a given patient.

Procedures. Members noted that elective versus trauma procedures are very different and pain management needs could vary substantially. Furthermore, inpatient versus outpatient procedures should be considered differently in the analysis.

Some members suggested selecting the most common procedures, while others suggested limiting the analysis to procedures with clear evidence in favor or against post-operative opioid prescribing. Some members raised the idea of adding the top 10 orthopedic procedures, vaginal delivery, cesarean section, vaginal hysterectomy, and craniotomy to the list of conditions, given high rates of likely unnecessary opioid prescribing.

Dose and duration. Due to the paucity of quality data for most diagnoses, it was suggested that the CDC consider using a range, and that the range always include some value above "0". It was also suggested that the threshold could be set at a point including the amount used by 75-80% of patients undergoing a particular procedure or with a particular diagnosis.

Guidelines and translational efforts. Some members suggested evaluating practice in developed countries that are not experiencing an opioid crisis. The CDC was encouraged to look at the Minnesota protocol of using non-opioid options. The CDC was encouraged to work with Epic and other EMRs to incorporate pop-ups and to expand provider education.

Members suggested the CDC work on development of post-operative opioid taper plans, utilize the benchmark development process to make such benchmarks available to providers, develop simple tools that convert pills to MMEs, and allow products to be flexible given the rapidly changing field of pain management.

CHRONIC PAIN

The Workgroup session on chronic pain was attended by:

Members were asked the following questions:

- To identify guidelines and research studies that could be helpful to the CDC
- To help determine factors that could serve as markers in the analysis to determine with benefits of opioids may outweigh risks
- To comment on how well the CDC mapped data to benchmarks and ways in which that could be improved, as well as how to account for shared decision-making in clinical care
- To provide suggestions for translational efforts

General comments. Members were concerned about how chronic pain was defined, given that many pain conditions are recurrent although not chronic, some conditions never get better, and some chronic pain conditions are related to procedures. The CDC clarified that they were referring to pain lasting longer than 3 months, that headaches were considered acute, and that other acute non-surgical pain conditions were considered separately.

It was noted that anything coming out of the CDC might be considered as guidelines and that this misinterpretation can be difficult to counter. There was extensive discussion of the 50 and 90 MME levels included in the CDC Guidelines. It was recommended that the CDC look into the adverse effects of opioid tapering and discontinuation, such as illicit opioid use, acute care utilization, dropping out of care, and suicide. It was also noted that there are major gaps in guidelines for legacy patients, patients with multiple diagnoses, pediatric and geriatric patients, and patients transitioning to lower doses.

Some members felt that evidence may be weighted in favor of opioid therapy for chronic pain. Some members wished to ensure it be noted that opioids alone are generally not the optimal therapy for chronic pain.

Developing the benchmarks and analysis plan.

Data source. Concerns were raised with regard to the data source of Optum claims may underrepresent special populations such as pediatrics, minorities, and under-resourced individuals, with a suggestion to include Medicaid data. Specific populations noted were pediatrics and sickle cell disease. It was also noted that this claims database would not identify other costs related to chronic pain, such as time off work, OTC medications, and psychological interventions. An alternative data collection method was suggested:

www.nejm.org/doi/10.1056/NEJM200103013440906

There were concerns that insufficient clinical data will be available from the dataset to appropriately consider the individual-level factors that weigh into determination of opioid therapy. The data would also fail to account for the shared decision-making process involved in opioid prescribing for chronic pain conditions, which may be dependent on primary care providers as well as ancillary care providers (e.g. physical therapists, psychologists, etc).

Utilizing benchmarks from other countries was generally discouraged in this session, as there was concern that formulations and doses would vary widely and that there would be a bias as only countries in which it is legal to prescribe opioids for chronic pain would be included. It was felt that Canada and the United Kingdom might be acceptable sites for such data. In addition, it was noted that in countries with universal health care, access to non-pharmacologic treatment may bias opioid prescribing estimates.

Patient-level factors. Members noted that opioid-experienced patients should be considered differently from opioid-experienced patients, due to tolerance and the difficulty of reducing dose (compared to not increasing dose in the first place). One option raised in this context was to exclude patients on high doses of opioids, as those individuals would be qualitatively different from others. A variant of this concern was about management of "legacy" patients who are inherited on high doses of opioids. Members voiced concerns that results of this work could cause harm to patients currently reliant upon opioids prescribed by their providers. Members noted that the current CDC guidelines have been used by insurance companies and some clinical care systems in ways that were not intended by the CDC, resulting in cases of and the perception of patient abandonment.

It was suggested that patient factors should be considered including a history of opioid use disorder, which might result in higher opioid requirements, and comorbidities or coadministered medications limiting utilization of NSAIDS (e.g. renal failure, gastrointestinal hemorrhage, lithium, anti-platelet or anti-coagulant therapy). It was also recommended that prior history of opioid and non-opioid treatment be considered in weighing benchmark for patient sub-populations. Further, it was suggested to consider prior non-opioid therapies to determine if opioids were appropriately preceded by non-opioid treatment options, although it was also noted that a person who does not benefit from non-opioid therapy might also not be appropriate for opioid therapy.

Some members suggested that functional improvement and patient-reported outcomes be considered as ways to determine risk/benefit ratio; these might be accessible through linking to other data sources or proxy variables such as employment/disability status. Others suggested weighing diversion, storage and takeback programs, and not underestimating risk.

Members suggested that provider-level differences also factor into opioid prescribing, and that adjusting for such factors may improve the analysis.

Pediatrics. Data for pediatric populations was felt to be extremely limited and further consultation with pediatric specialists was recommended.

Diagnoses. Some members suggested limiting the analyses to the top 5-10 conditions and to categorize each condition by severity. Expert opinion was suggested for additional conditions that do not have relevant data, although it was suggested that the CDC consider restricting the analysis to populations and conditions for which there exist high-quality data.

Some members felt that the type of lower back pain should be selected rather than looking at the disease as a uniform diagnosis (e.g. lumbar radiculopathy versus axial low back pain, rheumatologic versus musculoskeletal pain, and non-radicular or non-post-operative pain).

Guidelines and translational efforts. Several members suggested that guidance in weaning / tapering patients on opioid therapy would be well-received by providers. In addition, guidance for managing legacy patients was felt to be useful. Guidance for older patients was also requested.

Members suggested that the CDC focus on translational efforts for the most common diagnoses (e.g. lower back pain and osteoarthritis). Another suggestion was guidance for patients who are opioid experienced. Tools that integrate into EMRs were felt to be useful.

ACUTE NON-SURGICAL PAIN

The Workgroup session on acute non-surgical pain was attended by:

Members were asked the following questions:

- To identify guidelines and research studies that could be helpful to the CDC
- To help determine factors that could serve as markers in the analysis to determine with benefits of opioids may outweigh risks
- To comment on how well the CDC mapped data to benchmarks and ways in which that could be improved, as well as how to account for shared decision-making in clinical care
- To provide suggestions for translational efforts

General comments. A member suggested that the CDC consider not establishing benchmarks, but focusing on current prescribing practices. The rationale for this was the limited data from which to set benchmarks and the lack of a comprehensive view of how opioids are currently utilized for the many diagnoses evaluated.

There was some disagreement as to whether to look at pain as the type of pain versus the disease state driving the pain.

Developing the benchmarks and analysis plan.

Data source. It was noted that clinical pain management involves first trying non-opioid analgesics, a factor not captured in claims data. Members noted that prescription of opioids may not reflect actual use. Members also noted limitations in claims data with regard to the ability to differentiate acute from chronic pain. Claims data were also felt to be lacking due to the absence of inpatient opioid treatment data, which can serve as a good predictor of outpatient opioid needs.

Members suggested some factors that might be considered in the analysis:

- Prescriber and facility level variables
- Variation by small geographic areas
- Historic levels of prescribing (although in the early 1990s pain treatment may have been inadequate)
- Internal v external validity (i.e. consider fewer treatments with better data).

Patient-level factors. Members felt that opioid naïve versus experienced patients might be considered separately, as opioid requirements among those experienced – or those on opioids for opioid use disorder treatment – could vary widely. These differences might be important regionally based on opioid use disorder prevalence, for example, and such data may not be available through claims.

Alternative ways to benchmark when data are insufficient. There was a diversity of opinion regarding utilizing other sources for benchmarks. Some felt utilizing similar diagnoses was problematic, although certain cases might be okay, such as back to neck pain. It was also felt that international sources led to complexities, although others suggested that such

comparisons might help the U.S. to understand the differential opioid use that occurs domestically. Relying upon expert opinion was felt to be an option, but introduced additional methodologies that might be undesirable. Selecting just the upper or lower limit was also felt to be incorrect. Guidelines were also noted to be often based on consensus, which may be incorrect. Certain study designs were suggested, such as those used in antibiotic stewardship or the RAND appropriateness method. It was suggested to consider benchmarking by region or even facility to account for anticipated variations.

Dose and duration. Some members felt that duration was the most important factor, rather than dose, because duration is what leads to use disorder concerns.

Specific diseases: A member suggested that the analysis be limited to lower back pain, migraines, and other diseases in which opioids are substantially over utilized.

Major fractures. Members inquired as to the type of fractures that would be included (e.g. long bone, rib) and the mechanism of injury (e.g. motor vehicle collision), as those factors may contribute to level of pain and appropriateness of opioid therapy. Members noted that opioid prescribing for long bone fractures is a quality of care measure – with absence of an opioid prescription considered an indicator of low quality care – and thus benchmarking would be challenged by quality of care guidelines. Members noted that it may be necessary to restrict the analysis to "initial" visits for this diagnosis, as subsequent visits may be contending with subacute or chronic pain / sequelae of the fracture. Members also noted that ideally failure of non-opioid analgesia would be measured, but this is likely not possible in the analysis. Furthermore, claims data would not allow for differentiation of major from minor fracture. Members suggested to evaluate claims for fractures requiring overnight hospitalization, as these would be more serious and more likely to warrant opioid prescribing. Some members suggested utilizing more specific diagnoses, such as ankle sprain, for which opioids are not generally provided (that diagnosis was also noted to have wide variability with regard to the proportion of patients receiving an opioid prescription [www.ncbi.nlm.nih.gov/pubmed/30054152]).

<u>Herpes zoster</u>. Decisions to utilize opioids are based on level of pain and, again, failure to respond to non-opioid analgesics.

<u>Abdominal pain</u>. Members consistently considered abdominal pain to be too broad of a category for analysis, as the appropriateness of opioid therapy would vary widely based on the source of the pain (e.g. pancreatitis versus dyspepsia, surgical conditions versus non-surgical). Members suggested limited the analysis to more specific diagnoses.

<u>Low back pain</u>. Members advised against combining all low back pain states, as compression fractures, disc herniations, and radiculopathies might be quite different than pain that often lacks an anatomically-identified source.

<u>Renal colic</u>. There was some disagreement regarding use of opioids for renal colic. Overall opioids were felt to be indicated due to the absence of other medical treatments for the resultant pain, in constrast to migraines which have many other options. It was also noted that NSAIDS have a mechanistic rationale for treatment of renal colic.

<u>Headache</u>. It was noted that migraines are not the only headache and that other headaches may have differential management. Nonetheless, opioids are discouraged for most headaches.

<u>Sickle cell</u>. Some members felt that a benchmark may not be possible, given the wide variability in opioid needs for patients with sickle cell disease. Genotype was also not felt to be sufficient to determine analgesic need. It was suggested that other treatments should be optimized in order to minimize vasoocclusive crises. Members felt that Optum is flawed for this disease state, due to the large percentage of patients with sickle cell who rely upon Medicaid or Medicare. One option suggested was to look at the trend of opioid use over time to evaluate for significant increases. There was also concern voiced that opioid prescribing "limits" could lead to worsening bias toward patients with sickle cell disease.

Guidelines and translational efforts. Members noted that opioid prescriptions are still connected to the CMS pain scale which providers are instructed to rely upon and respond to with pain management offers; it was suggested that the CDC work with CMS to remove this reliance.

CANCER-RELATED AND PALLIATIVE CARE PAIN

This session also covered further discussion of several major issues raised in prior sessions, which is covered in the **Recurrent Themes** section.

General comments. Some members noted that "active cancer pain" is not sufficiently descriptive and suggested a term such as "in active cancer treatment" to differentiate patients who may be experiencing significant pain, although this term was also felt to have limitations. It was generally felt that those who have successfully completed cancer treatment and continue to suffer from pain be considered in the "chronic pain" category. This could apply also to patients with chemotherapy-induced peripheral neuropathy, which is felt to be similar to the neuropathy resulting from diabetes. Some members felt that the 90MME threshold should apply in this category of patients. Others noted that the CDC guidelines have been misinterpreted to create a limit to the dose of opioids that can be provided to people at all stages of cancer and its treatment. It was also noted that the cancer field is rapidly evolving, with immunotherapy, CAR-T, and other novel treatments that affect response rates and limit our ability to rely upon historical data in establishing opioid prescribing benchmarks.

Developing the benchmarks and analysis plan.

Patient-level factors.

There was concern that claims data would not be able to identify all of the conditions responsible for pain in a patient with a history of cancer (e.g. people who survive cancer but with severe residual pain). Further, it was noted that certain complications of cancer and cancer treatment – such as graft versus host disease – may require the least restrictive long-term therapy with opioids.

The definition of palliative care was also complicated and it was suggested that this include patients with life-limiting conditions. Overall, it was felt that in patients who may not have long to live, and/or for whom returning to work is not a possibility, higher doses of opioids may be warranted. It was also suggested that sickle cell disease be included among palliative care diagnoses.

APPENDIX: RECOMMENDED GUIDELINES, RESEARCH STUDIES, and TOOL KITS

Post-Operative Pain

An Evidence-Based Approach to the Prescription Opioid Epidemic in Orthopedic Surgery
Trends and predictors of opioid use after total knee and total hip arthroplasty.

American Academy of Orthopaedic Surgeons (AAOS) Pain Relief Toolkit
Opioid-Prescribing Guidelines for Common Surgical Procedures: An Expert Panel Consensus

CORR Insights®: The 2018 Chitranjan S. Ranawat, MD Award Developing and Implementing a

Novel Institutional Guideline Strategy Reduced Postoperative Opioid Prescribing After

TKA and THA

Opioid Prescribing Recommendations for Surgery

Good practice in postoperative and procedural pain management, 2nd edition

MN Health Collaborative Call to Action: Adult Opioid Postoperative Prescribing, V2 July 2018 BASH Management Guidelines

<u>Pediatric visits to the emergency department for postoperative pain</u> [Abstract]

Analgesic prescribing patterns after outpatient inguinal hernia repair in children [Abstract]

Adolescents' home pain management after laparoscopic appendectomy [Abstract]

Monitoring home pain management after laparoscopic appendectomy [Abstract]

Home management of children's pain after laparoscopic appendectomy: unexpected findings [Abstract]

Hill et al. Guideline for Discharge Opioid Prescriptions after Inpatient General Surgical Procedures. JACS 2018

American Dental Association Statement on the Use of Opioids in the Treatment of Dental Pain, 2016

Michigan Opioid Prescribing Engagement Network (Michigan OPEN): Opioid Prescribing Recommendations for Surgery

<u>Washington State Bree - Supplemental Postoperative Pain Guidelines</u> (Adopted July 2018) <u>Washington State Agency Medical Directors' Group (AMDG) – Interagency Guideline on</u> <u>Prescribing Opioids for Pain</u>

Chronic Pain





Opioid Tapering



Acute Non-Surgical Pain

<u>Current management of migraine in US emergency departments: An analysis of the National</u> Hospital Ambulatory Medical Care Survey

Excessive acute migraine medication use and migraine progression

Migraine Treatment in the Emergency Department: Alternatives to Opioids and their Effectiveness in Relieving Migraines and Reducing Treatment Times

Management of Adults With Acute Migraine in the Emergency Department: The American Headache Society Evidence Assessment of Parenteral Pharmacotherapies

The acute treatment of migraine in adults: the American headache society evidence assessment of migraine pharmacotherapies.

The Journal of Headache and Pain

Opioid-Induced "Likeability" and "Feeling Good" Are Not Associated With Return Visits to an ED
Among Migraine Patients Administered IV Hydromorphone

EFNS guideline on the drug treatment of migraine – revised report of an EFNS task force
Randomized study of IV prochlorperazine plus diphenhydramine vs IV hydromorphone for
migraine Potential

A review of current European treatment guidelines for migraine

American Academy of Emergency Medicine (AAEM) Clinical Practice Statement: Emergency

Department Opioid Prescribing Guidelines for the Treatment of Non-Cancer Related

Pain, 2013

Osteoporotic vertebral fractures: current concepts of conservative care Procedure Specific Postoperative Pain Management (PROSPECT)

Orthopaedic Trauma Association has clinical practice guidelines that are in the process of being finalized and then published.

Washington State Opioid Guidelines

American Society of Hematology (In Progress. Potentially on Sickle Cell)

2014 National Heart and Lung Blood Institute (NHLBI) Guidelines on Sickle Cell [Potential Site: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816 0.pdf]



Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-Term Use

Annals of Emergency Medicine paper on ED opioid-naïve patients with ankle sprains: National Variation in Opioid Prescribing for Ankle Sprains (Delgado et. Al)

Association between Electronic medical Record Implementation of Default Opioid Prescription Quantities and Prescribing Behavior in Two Emergency Departments https://ldi.upenn.edu/brief/association-between-electronic-medical-recordimplementation-default-opioid-prescription

American College of Obstetricians and Gynecologists (ACOG) Committee Opinion on Postpartum Pain Management. There may be some references to include

Widely used ALTO clinical protocols (Potential site:

https://smhs.gwu.edu/urgentmatters/sites/urgentmatters/files/ALTO%20program%20E D%20protocols%2C%20Innovation%20Award 0.docx)



ALTO protocols.pdf

American Dental Association Statement on the Use of Opioids in the Treatment of Dental Pain. 2016. Available at: http://www.ada.org/en/about-the-ada/adapositions-policies-and-statements/statement-on-opioidsdental-pain

Benefits and harms associated with analgesic medications used in the management of acute dental pain:
An overview of systematic reviews. The Journal of the American Dental Association, Volume
149, Issue 4, April 2018, Pages 256-265.e3, Paul A. Moore, Kathleen M. Ziegler, Ruth D. Lipman,
Anita Aminoshariae, Angelo Mariotti

American College of Occupational and Environmental Medicine (ACOEM) Guidelines

American College of Occupational and Environmental Medicine (ACOEM) Lower Back Disorder

Guideline

<u>American College of Occupational and Environmental Medicine (ACOEM) Knee Disorders</u>
<u>Guideline</u>

American College of Occupational and Environmental Medicine (ACOEM) Hip Disorder Guideline

American College of Occupational and Environmental Medicine (ACOEM) Shoulder Disorder

<u>Guidelines</u>

<u>American College of Occupational and Environmental Medicine (ACOEM) Cervical/Thoracic</u>
Disorders Guidelines

American College of Occupational and Environmental Medicine (ACOEM) Ankle/Foot Disorder
Guidelines

<u>American College of Occupational and Environmental Medicine (ACOEM) Elbow Disorder</u>
<u>Guidelines</u>

<u>American College of Occupational and Environmental Medicine (ACOEM) Hand/Wrist/Forearm</u>
<u>Disorder Guidelines</u>

American Society of Hematology (In Progress. Potentially on Sickle Cell)

2014 National Heart and Lung Blood Institute (NHLBI) Guidelines on Sickle Cell [Potential Site: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-

report%20020816 0.pdf

Cancer-Related and Palliative Care Pain

American Society of Clinical Oncology (ASCO) Guidelines

Antiphospholipid Syndrome Alliance for Clinical Trials and International Networking (APS ACTION) Guidelines

<u>Miscellaneous</u>

Nurses' Role in Preventing Prescription Opioid Diversion

Recognition and Management of latrogenically Induced Opioid Dependence and Withdrawal in Children

American College of Occupational and Environmental Medicine's Opioid Guideline, 2017 (Potential site:

http://www.acoem.org/uploadedFiles/Public Affairs/Policies And Position Statements /Guidelines/Library and Reference Material/OPIOID%20TREATMENT%20-%20Reed%20Group%20Guidelines.pdf)

<u>American College of Occupational and Environmental Medicine (ACOEM) Practice guidelines:</u>
Opioids for Treatment of Acute, <u>Subacute</u>, <u>Chronic</u>, <u>and Postoperative Pain</u>

American Academy of Pediatrics Guidelines (In Progress)

American College of Physicians (ACP) Low Back Guideline (Potential site:

http://annals.org/aim/fullarticle/2603228/noninvasive-treatments-acute-subacute-chronic-low-back-pain-clinical-practice)