Montana Workers' Compensation Drug Formulary: Recommendation, Reasoning, and Other Considerations

Introduction

Implementation of a drug formulary for workers' compensation in Montana seeks to accomplish two goals: (1) reduce the number of potentially dangerous drug prescriptions and (2) improve worker outcomes by reducing disability duration and increasing return to work rates. It is with these goals in mind that the Montana Department of Labor & Industry has reviewed three formulary options: ODG (Work Loss Data Institute), ACOEM (ReedGroup), and the Washington L&I Outpatient Formulary (State of Washington).

All three formularies present their own strengths and weaknesses. Based on the information provided by representatives, the current and available literature, as well as internal research and discussion, the Department proposes that the ODG formulary would *best* meet the needs of Montana. The following is intended to outline the reasons for the Department's recommendation, as well as address other key areas of concern.

Evidence Based Medicine and Transparency

Statute requires that adoption of a formulary is contingent on the formulary being evidence based. A transparent process is also necessary to understand how decisions are made and by whom. ODG utilizes an evidence based process that includes both internal and external experts to review the most up-to-date medical literature and rank studies by both study type and quality. A full description of their methodology is publically available online. Additionally, ODG has been very forthcoming and open in answering all our questions regarding their process and their staff. Finally, while both ODG and ACOEM offer an external process for stakeholder input, ODG has also offered to include a Montana clinician on the ODG Advisory Board to allow for internal feedback as well.

If Montana were to choose the ODG formulary, stakeholders should know that ReedGroup has and will likely continue to publicly dispute that choice and declare that ODG does not characterize evidence based medicine. In our conversations with ReedGroup, they have shared that they adhere to criteria set by the National Guidelines Clearinghouse (NGC), a "publicly available database of evidence-based clinical practice guidelines", for their definition of "evidence based". In 2016, the NGC updated their inclusion criteria, and the ODG guidelines were removed from their website. The primary reason was due to ODG's lack of evidence tables. ODG has been very clear in explaining the situation from their perspective, specifically, that all the information contained within an evidence table is available within their guidelines but not in the format required by NGC. For ODG to produce the evidence tables would have required them to completely reformat their product, which they did not find necessary given their proven track record. Although the NGC standards are rigorous, we do not find their standards to be the "end-all" definition of what qualifies as evidence based medicine. Please see below ("Description and Assessment of Evidence Based Methods in ODG") for further explanation on why we believe ODG to be evidence based.

Use with the Montana Utilization and Treatment Guidelines

One issue that has come up is how a formulary created by a separate party and process will mesh with the current Montana Utilization and Treatment Guidelines and how conflicting recommendations between the formulary and the guidelines will be dealt with.

It is important to consider that, regardless of which formulary is selected, as long as the formulary and the guidelines are developed separately, *there will always be a risk of discrepancy between the two*. While full integration of commercial guidelines and formulary is an option, it is our understanding that this option is not desirable to stakeholders at this time, but that adoption of new guidelines may be a future consideration. Therefore, the Department has begun the process of reviewing the Montana guidelines for any recommendations of medications and comparing those to the ODG formulary to get a better understanding of how much effort would be needed to reformat each chapter of the guidelines in order to minimize potential confusion or disputes. Thus far, after reviewing the Low Back chapter and comparing the medication recommendations against the ODG formulary, we found there to be no contradictions or areas of concern.

Accessibility and Simplicity

The formulary should be accessible to stakeholders at low or no cost and simple to understand to prevent access to care issues and disputes. ODG would provide their formulary list to be posted to the DLI website allowing for easy access for all stakeholders at no charge. In addition to the list, ODG will make their "NDC Advisor" tool available to stakeholders to utilize also at no charge. ACOEM and Washington also have a no-cost option available to stakeholders[1], but at a much higher cost for administration as either formularies would require reformatting. Stakeholders who would prefer to purchase the ODG guidelines for access to the evidence underlying the formulary recommendations could do so at their discretion.

The "yes/no" formulary structure may seem *oversimplified* or that it does not take into consideration the specific condition being treated. However, the ODG formulary is an extension of the ODG guidelines, which are based on condition. In addition, a "no", "non-preferred", or "not recommended" status does not preclude an injured worker from obtaining medication. Rather, the status alerts the provider, the PBM, and the adjustor when a drug requires that medical necessity, *based on diagnosis or condition*, be substantiated. If the treating physician is operating within the Montana guidelines, then the ODG formulary is sufficient in allowing providers the flexibility to treat their patients on a case-by-case basis.

Ease to Implement and Maintain

The ODG formulary provides the easiest means of implementation with zero maintenance necessary and minimal administrative cost. As stated above, the formulary list could be posted to the DLI website. From there, the formulary is maintained and updated monthly[2] by Work Loss Data Institute. In comparison, both the ACOEM and Washington formularies would require additional administrative work in order to format the formulary for Montana. ACOEM's formulary would require we develop a P&T Committee to develop a list, similar to what California has developed, from the MD Guidelines and Formulary. Furthermore, ODG has offered to travel the state at no cost to assist with stakeholder education and training.

Consistent and Well Established Track Record

The ODG formulary has a proven track record for success in other states including Texas (2011), Oklahoma (2014), Arizona (2014), and Tennessee (2016). Texas, required by state law to track the impacts, reported a decrease in the total cost of "N" drugs of almost 80%, from $1.42 million to

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[1] ReedGroup allowed for a no-cost option only as of late August. Prior to this option becoming available, all stakeholders would have been required to purchase a license.

[2] Or as needed.

$290,000, between 2013 and 2014. Many other states and organizations utilize the ODG guidelines as well[3]. In comparison, the ACOEM formulary has been adopted in Nevada (2015) and is currently pending adoption in California. However, Nevada's formulary is not mandatory, making the impact of the formulary in terms of dollars or injured worker outcomes difficult to track. California went through the process of adapting the ACOEM formulary tool into a publically available list, which received initial criticism for its restrictiveness[4]. Montana would need to develop a similar list in order to make the ACOEM formulary work.

Jurisdiction Dependent Decisions

Certain decisions are beyond the scope of the formulary selection process. Prior authorization, first fill, dispute resolution (standard and expedited), and legacy claims are all areas of concern that will need to be addressed and procedures that will need to be written in rule. However, none of the proposed formularies have an advantage over the other with these types of decisions. Since the handling of legacy claims are of particular trepidation, it should be noted that the adoption of any formulary does *not* imply workers' will simply be cut off from their medications. A provider would only need to substantiate that a drug is medically necessary.

ODG and ACOEM have both offered to assist with the rulemaking process. Given ODG's adoption in several other states, the Department would have many sources of information to discuss what has and hasn't worked with regards to these issues. This is one of the next crucial steps within the internal Formulary Working Group.

Provider Perspective: Comments from Dr. John Shumpert, MD

The Department's Medical Director, Dr. John Shumpert, has also shown support for the ODG formulary moving forward. Dr. Shumpert has expressed concerns with regards to access to care for injured workers' and has stressed that ease of use was *essential* from a provider's perspective. He agrees providers are not likely to embrace a new formulary if they are also required to purchase new guidelines.

Conclusion

Based on review of the relevant information and the above criteria, the Formulary Working Group proposes that the ODG formulary will best meet the needs of Montana. To summarize, the ODG formulary:

- Utilizes an evidence-based process
- Is easy to implement, easy to read, and easy understand for all parties
- Does not require stakeholders to purchase access to the guidelines
- Allows for stakeholder input
- Will allow for assistance with rulemaking and stakeholder training
- Is well established in many other states

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[3] See http://www.worklossdata.com/uploads/2/4/1/6/24166932/odg_state_adoptions_08-23-2017.pdf

[4] See http://www.businessinsurance.com/article/00010101/NEWS08/912313324/Major-comp-stakeholders-call-for-California-drug-formulary-start-delay

Description and Assessment of Evidence Based Methods in ODG

The ODG methodology of rating study type and quality in selecting evidence are supported in outside, widely-accepted sources, and are based on fundamental study design issues in epidemiology. The following provides a brief explanation of (1) how ODG rates various types of studies and (2) how ODG rates the quality of those studies based off their own methodology description[5], as well as our response to their legitimacy.

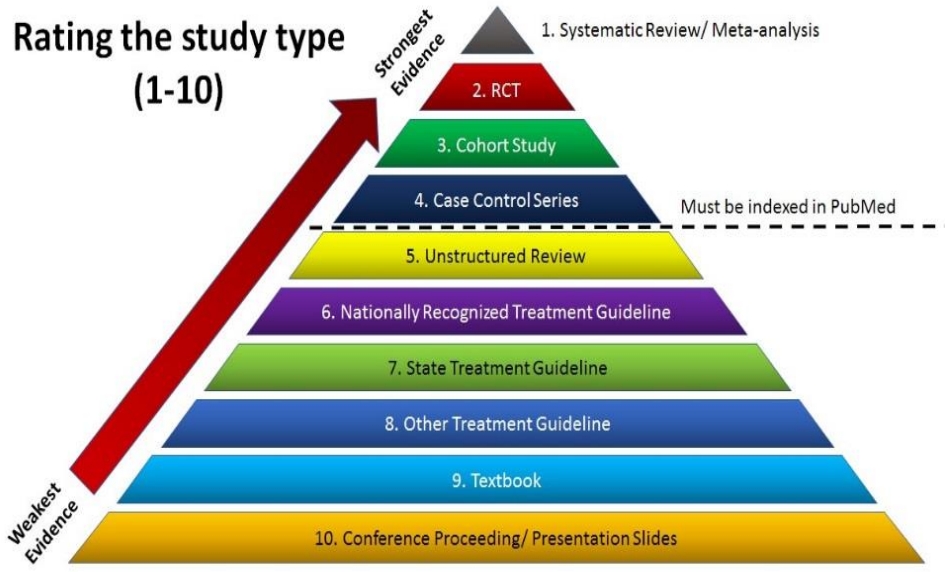
1. How ODG Rates *Types* of Study:

From ODG Methodology Description (Appendix B):

As indicated in Exhibit C, ODG Medical Literature Ratings, preference is given to evidence that meets the following criteria: The article is written in the English language, and the article had any of the following attributes: (1) It is a systematic review of the relevant medical literature, or (2) The article reports a randomized controlled trial, or (3) The article reports a cohort study, whether prospective or retrospective, or (4) The article reports a case control series involving at least 25 subjects, in which the assessment of outcome is determined by a person or entity independent from the persons or institution that performs the intervention the outcome of which is being assessed.
Especially when articles on a specific topic that meet the above criteria are limited in number and quality, ODG also reviews lower quality evidence, but all evidence is ranked alphanumerically using the methodology in Exhibit C (and found in second chapter of ODG) so that the quality is clearly and consistently weighted. The ranking used is alphanumeric ranging from 1a to 10c-

Ranking by Type of Evidence:
STUDIES
1. Systematic Review/Meta-Analysis
2. Controlled Trial – Randomized (RCT) or Controlled
3. Cohort Study - Prospective or Retrospective
4. Case Series
5. Unstructured Review

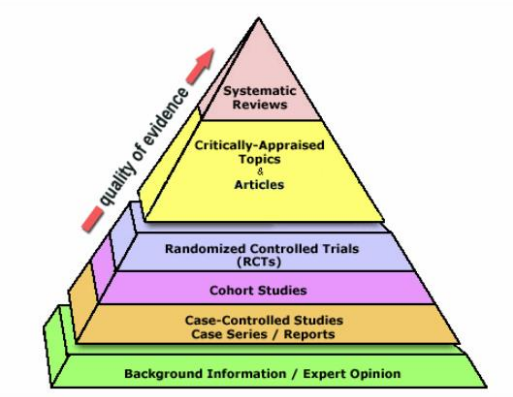
OTHER:
6. Nationally Recognized Treatment Guideline (from guidelines.gov)
7. State Treatment Guideline
8. Other Treatment Guideline
9. Textbook
10. Conference Proceedings/Presentation Slides
11. Case Reports and Descriptions



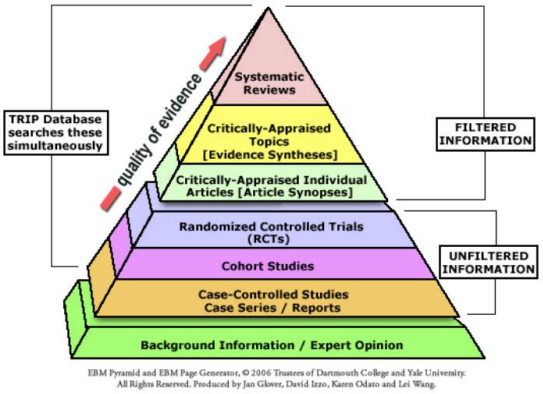
[5] See: http://www.worklossdata.com/uploads/2/4/1/6/24166932/odg_agree_2017.pdf

Our Comments:

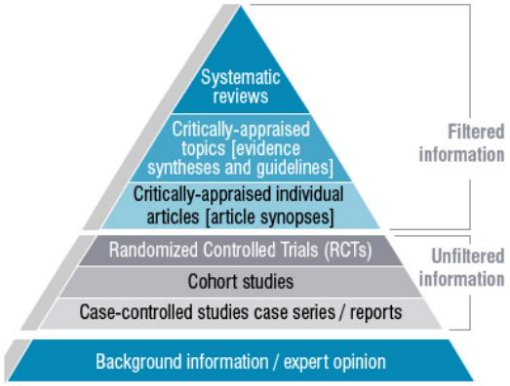
The hierarchy of evidence is an important principal to guide the adoption of any evidence-based practice. Study types are ranked based on strength and precision of research methods. Experts may disagree on exact ranks within the hierarchy depending on the research question, but here are widely-accepted examples of evidence rankings:



Source: The Research Medical Library at MD Anderson Cancer Center



Source: University of Chicago Library



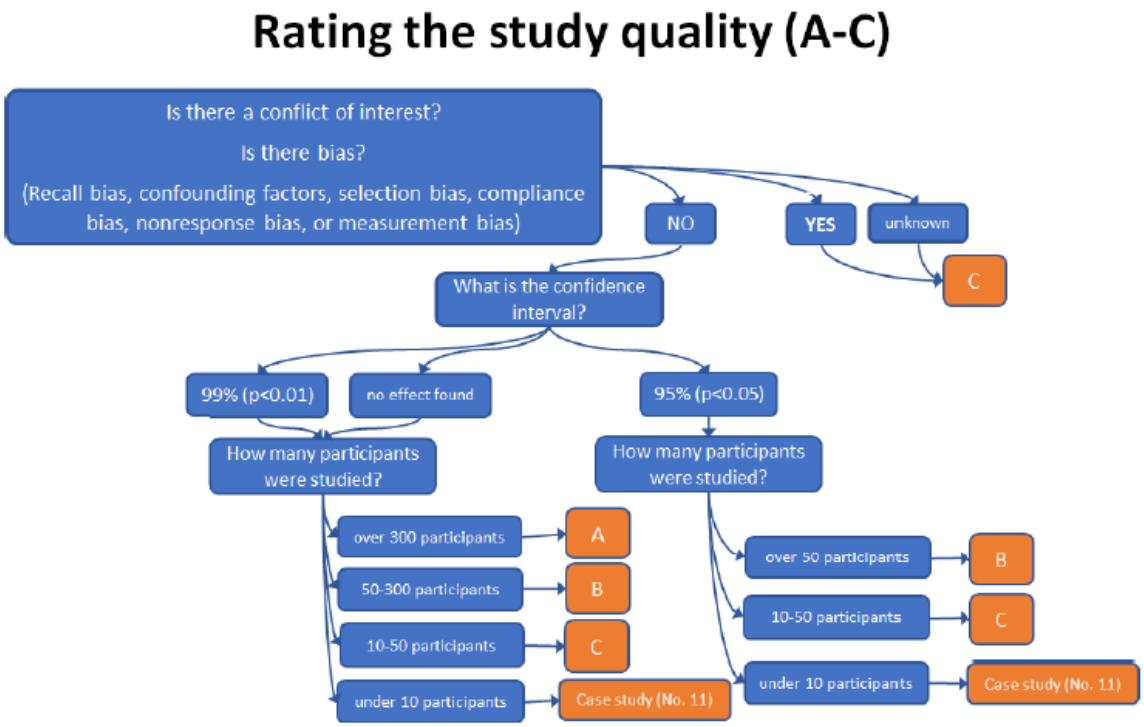
Source: National Health and Medical Research Council, University of Canberra

Our Statement on ODG Regarding Study Ranking: The ranking system that ODG uses to select evidence is highly supported by independent and outside sources, and follows the accepted standard of ranking evidence used in medical research and epidemiology.

2. How ODG Ranks Study *Quality*:

From ODG Methodology Description (Appendix B):

Ranking by Quality within Type of Evidence:
A. High Quality
B. Medium Quality
C. Low Quality



Our Comments:

ODG uses standard epidemiologic methods to guide the rating of study quality.

Critical issues relating to study quality are assessed: various types of bias, presence of confounding factors, conflicts of interest, precision of the study results (confidence intervals), strength of results (p-value), and number of study participant (sample size). Larger sample sizes provide more reliably study results, so ODG is correct to select larger studies as being of better quality than smaller studies.

Source: Modern Epidemiology, 3rd edition, Rothman, Greenland, and Lash (authors)

Our Statement on ODG Regarding Study Quality:

The rating system that ODG uses to determine study quality is highly supported by independent and outside sources, and takes into consideration key epidemiologic study design issues (bias, confounding, sample size, precision, etc).