A How-To Guide for the AMCP P&T Competition

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This guide is based off of the 2020 Ohio Northern University submission that was awarded Honorable Mention. An example of the work can be found at: https://digitalcommons.onu.edu/honors_student/1/

1. Introduction

Each year, the Academy of Managed Care Pharmacy (AMCP) holds a student Pharmacy & Therapeutics (P&T) competition.

In practice, P&T committees help decide which drugs are covered on insurance plans. Each committee is composed of numerous healthcare professionals, but always includes a pharmacist. The committee works together to decide which drugs will be included on the formulary (a list of covered medications) through evidence-based literature.

In the competition, teams of four students collaborate to evaluate a recently approved drug. The drug is released in the fall by AMCP. Teams must then create a monograph and PowerPoint presentation. Extensive research is required for the monograph portion. Clinical and pharmacoeconomic evidence is required to evaluate the drug. Current treatment options and a disease background are also assessed to help decide if the given drug should be covered by the insurance company or institution. Students must gather and analyze numerous articles and studies to determine if and where the drug should fall onto the formulary. This task requires both time and dedication. The competition is very competitive, and each school is only allowed one submission to the national level. If more than one team participates for each school, a local competition may be held to determine which group will submit nationally. The top 8 submissions are selected as national qualifiers. They will then present at AMCP Annual in the spring. All travel expenses are paid for by AMCP. It is a great networking opportunity, and allows an expansion of public speaking and presenting skills.

2. Why Participate?

Participating is a fantastic way to get more involved in AMCP, learn about how and which drugs are chosen to be covered, and improve professional writing and drug information skills. There is even a two-credit hour elective course if the team completes the monograph and PowerPoint. The competition is also a great way to network with professionals, not to mention an excellent CV. Having an ONU team advance also gives our college national recognition.

Partaking can give students a glimpse of what pharmacists can do with their degree. Pharmacists have numerous career paths available to them that may not be widely known. We are not restricted to a drugstore or hospital as some may think. Encouraging involvement in this competition is one of the many ways that we can encourage students to look at all of the career options they have, both upon graduation and later in life.

3. Where to Begin?

Teams are generally composed of four people, but it can be done with three. Once you have a team, the first thing you should do is divide up the sections. Decide which pieces of the monograph are similar, and split up the work based on that.

A four-person team may decide to split up the sections as follows:

One member on all clinical trial areas
One member on all other primary and secondary research
One member on all economic parts
One member on all background information

A three-person team may want to divide sections like this:

One member on all clinical data
One member on all economic data
One member on all background information

Some large sections may also be shared, such as in the Executive Summary or Evidence Gaps segment, since all team members may be of use in these areas. There are no rules to who can contribute to which section. Some teams may even decide to split up articles, and then complete the corresponding sections. It all depends on what the team is most comfortable with doing.

The next tip would be to not worry about starting at the beginning. Feel free to work on any part at any time. Starting at the end or working backwards might even be what works for your team best.

The third suggestion is to start this over Christmas break. You will be so relieved if you can get the majority of it done while you're not also balancing schoolwork. The submission to nationals is due towards the last week of January, so getting as much done in December will save you the headache later on.

4. Tips for the P&T Chair

One way that the P&T chair can solicit interest in the competition is by holding different educational sessions. After an initial informational meeting, the P&T chair should begin to gather names and groups who are interested in participating. From there, the chair can hold workshops that go over things helpful to creating the monograph. These could include going over the dossier, economics, overall strategies, and a review of the disease state.

5. Dossier

The dossier is a resource full of information about the drug that comes directly from the manufacturer. Variability between dossiers may occur since there are different manufacturers for the selected drug. At times, it may even seem like only the good things about the drug, and less

about the inferior or typical aspects of the medication that can be found in all drugs of its class. It is one of the most significant resources required for the monograph, but it is also important to find studies that have no connection to the pharmaceutical company or bias.

6. Monograph

The monograph has multiple sections, which are then divided into subsections. Each year AMCP will release a monograph template for groups to use. The bolded terms listed below are sections found in the monograph in order. The text in red is a suggestion on what to include within that specific section.

Patients First Health Plan Formulary Drug Monograph

Therapeutic Alternatives

Agents in the Same Pharmacologic Class

Preferred/Formulary

Nonpreferred/Nonformulary

Agents in a Different Pharmacologic Class

Preferred/Formulary

Nonpreferred/Nonformulary

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Abbreviations

If any abbreviations are used in the monograph, they may go in this table. You do not have to explain what they are in the body of the monograph if they are included in the table.

Executive Summary

This section should include anything the team feels the P&T Committee members should know in order to reach the conclusion of the recommendation. Each subsection should summarize the key points in a brief paragraph. The team members must also rate the strength of evidence as high, medium, or low, and provide a reason for the evidence grade.

Efficacy in Clinical Trials

How did this compare to placebo? Did it actually work in real patients?

Safety in Clinical Trials

Were there any major adverse reactions to this medication?

Real World Comparative Effectiveness

Because this is a new drug, there may not be any published evidence at the time of submission. It is permissible to not have any information stated here.

Value Proposition

Does this drug offer any savings for the patient or health plan? Could PCP office visits be avoided while on this medication? Does it need to be administered by a HCP?

Target Patient Subgroups

Who could this medication be most cost-effective for?

Evidence Gaps

This helps the P&T Committee to understand if there are any limitations of the evidence.

Population

Do the subjects in the clinical trials correspond to the member demographics of the Patients First Health Plan?

Intervention

How is the medication administered? Is it practical outside of the study setting?

Comparator

Are there any studies that compare the drug to alternatives already available? Do the studies correlate to the Patients First Health Plan?

Outcome

Is the outcome appropriate, accurate, and clinically meaningful? Is it better than an existing or lower cost alternative?

Time Frame

Is the duration of follow up in the clinical trials long enough to assess the outcomes? This could vary depending on the disease state. Chronic conditions may require a longer time frame than acute conditions.

Important Questions that Remain Unanswered

Is there anything that would improve the recommendation if clarified? Has the drug been studied in other age groups than what is FDA approved? Could it be as efficacious if the duration is shortened? Could safety profiles be improved if the frequency was decreased? Are there any studies that compare effectiveness of the drug to another in its class? Is there a concern for withdrawal?

Value and Operational Matrix

This is a chart that looks into economic evidence. Will the treatment be superior to the current standard of care? Will it be valued by society? Are there any budget considerations? Is prior authorization or step therapy recommended?

Recommendations to the Committee

This section calls for one to two paragraphs that include the key points of the drug. How can the team justify the recommendation? Expressing personal opinions in this section is acceptable.

Coverage Criteria

FDA Approved Indication

Criteria for Prior Authorization

Is there an age requirement for this drug? Are there specific requirements in the diagnosis to be considered for this medication? Have they tried any other agents before this medication? Are you requiring step therapy? Clinical guidelines can be helpful at determining other agents that should have been attempted and failed before initiating this medication.

Length of Approval

Is the prior authorization good for 3 months? 6 months? 1 year?

Reauthorization Criteria

Do they have to show that the medication is helping their condition? Are they reporting less symptoms? Are they demonstrating adherence? Will you require an adherence percentage?

Exclusions

Is this medication contraindicated in any patient population?

Clinical Evidence Evaluation

Efficacy

What do the trials show in terms of efficacy? Are there changes from baseline? How does the drug compare to placebo?

Real World Comparative Effectiveness

Are there any comparative trials released for this drug? Since it is newer, there may not be any. Post-marketing surveillance could help with this section.

Safety

Analyze the safety data here, don't just state prescribing information. This may not be widely published yet either. Were there adverse effects that made participants withdrawal from the trial? Any drug interactions? How is it tolerated?

Patient Subgroups

In which groups would this drug be most beneficial and cost-effective? How will this group be determined? Are there any biomarkers?

Economic Evidence Evaluation

Value Proposition

Summary of Product Value

Does this product have multiple indications? Could it be useful in helping other disease states? Is it a better value than competitors? Is administration more desirable when compared to alternatives?

Incremental Cost-effectiveness

Does this drug reduce adverse outcomes, or decrease hospitalizations? Does it improve quality of life? Is it worth it for the cost?

Summary of Incremental cost-effectiveness ratios found by studies

Were and cost-utility studies reviewed?

Budget Impact

How does this drug impact the market compared to alternatives? Is there an ICER report that used a model with a specific timeframe?

Clinical Evidence Tables

This information can be directly pulled from the trials and placed into the tables.

Cost-Effectiveness Evidence Summary

Is there a budget impact model or ICER report that can be entered here?

Background

Disease Background

In this section you may use secondary sources and meta-analysis articles to describe the disease state. Does it target certain populations? Try to include US data in this area more so than global information.

Disease Burden

What is the social or economic impact in the US? How much does the US spend annually on this disease? How many Americans have the condition? Are symptoms controllable? Does the disease lead to missed days of work or lost productivity? What are the social impacts in children?

Pathophysiology

How does this disease state occur? What triggers it in the body? Are receptors activated? Is there any sort of cascade that may occur? What is the final outcome?

Treatment Alternatives

When explaining current treatment options, it may be best to use the published treatment guidelines, if available. Are there multiple dosage forms of medications that are used to treat this disease? Are any more advantageous over the other? What nonpharmacological treatment is there?

Preferred Existing Therapy

What is the gold-standard, if applicable? What is most common?

Other Therapeutic Alternatives

What supportive care is available? Are there any non-allopathic treatments that are commonly used?

Product Background

Pharmacology

What is the drug's mechanism of action? How does it work in the body?

Pharmacokinetics

What happens to the drug once inside the body? What is the route of administration? Is there bioavailability or half-life data? Time to peak? How is it eliminated?

Methodology

What search strategies were used? Did you use a specific time frame to filter results?

Databases Searched

Secondary Sources

Search Strategy

What terms were used when searching for articles?

Inclusion Criteria

Did you look for RCTs? Meta-analysis?

Search Results

What study types did you find? Which did you use in the monograph?

Articles Excluded from Evidence Synthesis

Why were they excluded from the monograph?

References

Cited in AMA formatting

7. PowerPoint

AMCP releases a template of slides that groups can follow. You can pick what you feel are the most important pieces of information that should be shared. It may be easiest to focus on finishing the monograph first, and then simply copying the exact same information into the slides. Once submitted to nationals, this cannot be changed.

8. Discussion Questions

One to two discussion questions are also required for a complete submission. They are given by AMCP and vary each year. They may be related to the drug or disease state that corresponds to the drug's indication. These may be answered similarly to how your group determined to include or not include the drug on the Patient's First Health Plan formulary.

9. Conclusion

While this may seem like a lot, it is very much doable. Having a group to complete this with makes all the difference. While it may not seem like it at first, completing the P&T competition offers so many benefits, both in school and for later in life. I cannot encourage your participation in this enough. If you've made it this far, thank you for reading. This guide was created to help you and your group feel less intimidated by the P&T competition, and with the ultimate goal that you attempt writing the monograph. There are few greater feelings than hitting the final submit button on this extensive project, and I hope that when you complete it, you will be glad that you decided to take on such a large task when it wasn't required of you.

Wishing you the best,
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