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AMCP One-Day P&T Competition Kit

Table of Contents

Introduction

The One-Day Pharmacy & Therapeutics (P&T) Competition was developed by the AMCP Student Chapter at the University of Houston College of Pharmacy in 2018. The competition was then presented at the 2019 Chapter Leadership Academy (CLA) in San Diego, California. Since its inaugural year, the competition has been adopted by chapters across the nation to provide additional support to local P&T competitions. The purpose of this competition is to expose students to aspects of P&T and formulary management and provide students a basic understanding of the P&T Competition. It is intended as a preparatory tool, not a replacement for local or national P&T Competition.

The National Student Pharmacist P&T Competition is organized annually by the AMCP Foundation (learn more: www.amcpfoundation.org/PT). The P&T Competition allows students to apply their clinical knowledge, test their ability to evaluate literature, practice presentation skills, and more. The One-Day P&T Competition is designed to give students a way to use the same skill set required for the full P&T Competition within a condensed time span. It serves as a small representation of the local competition by highlighting the same clinical and economic knowledge required. This competition will also require strong critical thinking and decision making in a short time period because of the time constraint of research and evaluation, which will be considered by the judges in presentation judging.

The One-Day P&T Competition was designed to serve as a teaching tool and help bridge some of the learning gaps that may exist with the local P&T competition. The competition is meant to encourage students to participate in their respective local competitions and further develop the skills necessary for the national P&T competition. This competition is not meant to replace the local competition, nor should it serve as a deciding factor in determining a winning entry for the national competition. The competition is simply meant to help expose students to the necessary pharmacoeconomic and clinical knowledge needed for the local competition.

When reading through this document, keep in mind that it is meant to serve as a tool to help guide the development of the One-Day P&T Competition at your respective student chapter. The structure and format of the competition can be altered to fit the needs of your school and the experience you would like your members to gain.

The One-Day P&T Competition Structure

Students will work in pairs to make a formulary recommendation based on a presented case study. They will have 60 minutes to research, evaluate, and formulate their recommendation. One of their resources will be a curated document about the drug that will simulate the eDossier/drug monograph. The information in the document should be sourced from Lexicomp, Micromedex, package inserts, and/or other sources available to practicing pharmacists. They will also be provided additional resources, such as clinical trial articles, to assist them in their formulary recommendation within the allotted time. They are not, however, limited to the resources provided. Once their formulary recommendation is completed, they will have 5 minutes to present their recommendation to judges. Afterward, they will have 5 minutes to answer any questions pertaining to their presentation.

Competition Overview

- Teams should consist of 2 members. Students can sign up as individuals or as a team. Individual sign-ups are paired once the sign-up closes. Individuals are then notified who their partner will be.
- Once the number of teams is finalized, teams may sign up for designated time slots for their presentation. Their research period starts 65 minutes before that time.
    - 60 minutes are allotted for research
    - 5 minutes are allotted for teams to transition to the presentation room
    - *Note: The research time was extended from 40 minutes to 60 minutes since the 2018 CLA presentation and saw better results among contestants.*
- Team members are asked to bring their laptop(s) in order to access online resources. Teams may use any outside resource accessible through the internet such as Clinical Pharmacology, Micromedex, Lexicomp or PubMed during the research phase.
- Additional source materials, such as print-outs of lecture notes, textbooks, etc., are not allowed. Students may not contact any persons or organizations during the research time or ask questions about the actual case study.
- The case study, drug monograph, and provided resources should be released to the team a few minutes before their research time begins.
    - This may be performed by an auto-send feature available on email applications prior to each team's research time.
    - See appendix for Sample Case Study and Sample Drug Monograph
- Teams can research in a single room but they must be spread apart from each other.
- An optional electronic worksheet may be provided for the team to fill out on their laptops. The worksheet is meant to assist teams in outlining their formulary recommendation and rationale for judges.
    - See appendix for Sample Recommendation & Rationale Worksheet
- At the end of the research period, this worksheet may be printed out and used by the judges.
- Once their submission is completed, the team should be escorted to a second room where the judges will evaluate their presentation using a prepared rubric.
    - See appendix for Sample Judging Rubric

Competition Logistics

Event Promotion

The One-Day P&T Competition should be open to all students in your school of pharmacy. Holding the event towards the beginning of the school year will help promote AMCP to new students. Advertising the event as an opportunity to gain exposure in unique topics not typically discussed in the pharmacy school curriculum may help further student interest. Utilizing different platforms such as social media, emails, and flyers also helps maximize exposure (see appendix for Sample Promotional Flyer).

Judges

It is recommended to have at least two judges for the One-Day P&T Competition. Options for potential judges are similar to judges you may have for a local P&T competition. Options to consider could be school faculty or pharmacist contacts with experience in pharmacoeconomics or formulary management.

Room Set-Up

The One-Day P&T Competition requires two rooms (room 1 & room 2).

Room 1 will be used for team preparation and research. Room 1 should be spacious enough to allow a reasonable distance between teams such that they cannot hear each other. A projector is also recommended to display competition rules for contestants (see appendix for Sample Rules PowerPoint Display).

Room 2 will be used for team presentations. Room 2 requires a table for judges to write and an area for teams to present.

Virtual Hosting

The One Day P&T can be hosted virtually if necessary. Consider utilizing breakout rooms in zoom in lieu of Room 1 and 2 from above. Additionally, personalized zoom links for each team may help to facilitate event coordination. A virtual environment does allow for more participation from judges from across the country. Make sure to reach out to a wide network of judges to optimize event success.

Information Resources

Outside resources may be used to obtain information to create a mock drug monograph for the competition. Suggested resources are outlined below:

- AMCP.org
- Lexicomp
- Micromedex
- Red Book
- PubMed
- ClinicalTrials.gov
- UpToDate

Timeline for Planning

MONTH	TASKS

Two months before event or earlier	• Contact guest judges
	• Confirm date and reserve venue
	• Create the curated items for competition (see appendix for examples):
	  ○ Case Study
	  ○ Mock Drug Monograph
	  ○ Recommendation & Rationale Worksheet
	  ○ Judging Rubric

One month before event	• Advertise/promote event through emails, Facebook, and class announcements up until the event • Open signup to entire student body • Shortly after signup closes, send a sign-up for teams to select their sign-ups or create a schedule for and assign each team a time slot
One week before event	• Send reminder emails about the event and sign up for time slots • Get prize(s) for winning team and thank you items for judges • Send judges case study and rubric
The day of event	• Have coordinators ensure the event is running smoothly and on time • Print judging rubrics, schedule, and other necessary resources for judges • Documentation of event through pictures • Thank student pharmacist and judges
Within week after the event	• Meet with officers to discuss pros and cons of the event and how to improve the event for next year

Appendix 1: Example Case Study

2018 One Day P&T Competition Case Study

Synjardy® (empagliflozin and metformin)
for Vantage Health Plan P&T Committee

Permissions and Disclaimer

This material was created and curated for the specific purpose of the 2018 One Day P&T Competition.

Organizations and individuals are prohibited from reusing material contained herein. This includes any quantity redistribution of the material or storage of the material on electronic systems for any purpose other than personal use in the Competition.

While this team exercise involves the use of an actual product dossier and model, the exercise is not meant to illustrate either effective or ineffective handling of the formulary management issues within a managed care organization.

Vantage Health Plan

Vantage Health Plan provides coverage to 2.90 million people in Texas and pays for more than $689 million of outpatient ("retail") prescription drugs each year.

Vantage has its own P&T Committee that meets quarterly. Vantage Pharmacy and Therapeutics Committee, includes both internal and external physicians, pharmacists, and pharmacoeconomic experts, that meets regularly to provide clinical reviews of all medications. They also determine coverage and tier status for all medications.

At its next meeting, the Vantage P&T Committee will review the formulary status of Synjardy® (empagliflozin/metformin). Synjardy® is an FDA approved prescription medicine adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin is appropriate. Note: Empagliflozin is also

indicated for risk reduction of cardiovascular mortality in adults with type 2 diabetes mellitus and established cardiovascular disease.

Vantage Health Plan uses a single formulary for all of its prescription programs.

Cost	Tier	What's covered	Helpful hints	Copay ($) or Coinsurance (%)
Lowest cost	1	Medications that provide the highest overall value. Mostly generic drugs. Some brand-name drugs may also be included.	Use Tier 1 drugs for the lowest out-of-pocket costs.	$10
Mid-range	2	Medications that provide good overall value. A mix of brand-name and generic	Use Tier 2 drugs, instead of Tier 3, to help reduce your out-of-pocket costs.	$30
Higher cost	3	Medications that provide the lowest overall value. Mostly brand-name drugs, as well as some generics.	Ask your doctor if a Tier 1 or Tier 2 option could work for you.	$80

Vantage Plan Demographics

Covered lives	2,900,000
Gender distribution	56.4% female
	43.6% male
Age distribution	<18 years: 12.1%
	18-64 years: 61.2%
	≥65 years: 26.7%

Instructions: Fill out the Recommendation/Rationale document to the best of your knowledge. Below is helpful information you can use to formulate your recommendation

1) Synjardy® Drug Monograph: https://drive.google.com/file/d/1siC49NRRw6f5e9qUv_0KUDCs0t_xLg5U/view?usp=drive_open

2) Clinical Trials Overview (only section 14): https://drive.google.com/file/d/1CDl_Ue4j2LxrZfvaNTcSC0HZpODEqtYE/view?usp=drive_open

Full articles of selected clinical trials are linked for your convenience but may not be required

a) *Empagliflozin Add-On Combination Therapy with Metformin:* https://drive.google.com/file/d/1WMY8bl5en0RaicncTEaWI_uGxMp90N6d/view

b) *Empagliflozin Initial Combination Therapy with Metformin:* https://drive.google.com/file/d/1wXIOHQ9EIbG3a2ZC_5KEzgJ3RhN_1i1l/view?usp=drive_open
c) *Empagliflozin Cardiovascular Outcome Study in Patients with Type 2 Diabetes Mellitus and Atherosclerotic Cardiovascular Disease:* https://drive.google.com/file/d/1Cn_To-CbEMTepqkzbFARDSryaJYarLL/view

Appendix 2: Example Drug Monograph

2018 One Day P&T Competition

Pharmacy & Therapeutics Committee Drug Monograph

Empagliflozin/ Metformin (Synjardy® - Boehringer Ingelheim and Eli Lilly and Company)

Contents

I. Pharmacology

A. Empagliflozin is utilized for the treatment of type II diabetes and is part of the gliflozin class. These agents inhibit the sodium-glucose cotransporter 2 (SGLT2) that is located in the proximal renal tubules. As a result of this inhibition, urinary glucose excretion is increased.

B. Metformin is also utilized for the treatment of type II diabetes and is part of the biguanide class. This agent exhibits a major effect in the liver by decreasing glucose production and has minor effects in the muscle by increasing peripheral glucose uptake. In addition to this, it improves insulin sensitivity.

II. Pharmacokinetics

A. Empagliflozin

- Protein binding: 86.2%
  a) t1/2: 12. 4 hours
  b) Time to peak: 1.5 hours
- Volume of distribution (Vd): 72.8 L
- Metabolism: glucuronidation by UGT2B7; minor metabolites via UGT1A3, UGT1A8, and UGT1A9
- Excreted:
  a) Urine (54.4%; 50% unmetabolized)
  b) Feces (41.2 %; majority unmetabolized)

B. Metformin
   - Bioavailability: 50-60% when fasting
     a) Protein binding: negligible
     b) t1/2: 4-9 hours (plasma), 17.6 hours (blood)
     c) Time to peak: 2-3 hours (IR), 7 hours (ER) with a range of 4-8 hours
     d) Onset of action: days; takes up to 2 weeks for max effects
   - Volume of distribution (Vd): 654 ± 385 L
   - Metabolism: not metabolized
   - Excretion: urine (90% unmetabolized)

III. Clinical Efficacy

See Additional Documents for more detailed information

A. The additional indication for Synjardy® was based on a Phase III, double-blind, randomized, active-controlled study that evaluated the efficacy and safety of empagliflozin in combination with metformin as initial therapy compared with treatment with either empagliflozin or metformin alone. At 24 weeks, combination treatment displayed significant reductions in hemoglobin A1c as compared to treatment with either component alone.

IV. Adverse Effects/Precautions/Contraindications

A. Empagliflozin Adverse Effects
   - Black Box Warning: Rarely, metformin may cause an acid health problem in the blood (lactic acidosis). The risk of lactic acidosis is higher in people with kidney problems and in people who take certain other drugs like topiramate. The risk is also higher in people with liver problems or heart failure, in older people (65 or older), or with alcohol use. The risk is also higher in people who are having an exam or test with contrast, surgery, or other procedures. If lactic acidosis happens, it can lead to other health problems and can be deadly. Lab tests to check the kidneys may be done while taking this drug.
   - Urinary tract infections (>10%)
     a) females: 18%, males: 4%
   - Dyslipidemia (4%)
   - Increased thirst & nausea (2%)
   - Increased hematocrit (3-4%)

B. Metformin Adverse Effects
   - Diarrhea (IR: 12-53%, ER: 10-17%)
   - Nausea and vomiting (IR: 26%, ER: 7%)
   - Flatulence (4-12%)

C. Precautions

- Cardiovascular: Intravascular volume contraction and symptomatic hypotension may occur, especially in elderly patients or those with renal impairment, low systolic blood pressure, or taking diuretics; correct volume status before initiating and monitoring recommended.
- Concomitant use: Excessive alcohol use should be avoided
- Endocrine and metabolic: Ketoacidosis, including fatalities, has been reported with empagliflozin and may result in hospitalization; monitoring is recommended and discontinue if suspected.
- Endocrine and metabolic: Increased risk of hypoglycemia when used with insulin or insulin secretagogues; dosage adjustment may be necessary
- Endocrine and metabolic: Reversible decreases in serum vitamin B12 levels, which are rarely associated with anemia or neurologic symptoms, have been reported with metformin; monitoring recommended.
- Endocrine and metabolic: Increases in LDL-C may occur with empagliflozin; monitoring recommended
- Geriatric: Increased risk of volume depletion-related adverse events and urinary tract infections in patients 75 years or older
- Hepatic: Avoid use in patients with hepatic impairment due to increased risk of lactic acidosis.
- Immunologic: Hypersensitivity reactions (including angioedema) have been reported; discontinuation required
- Radiologic studies with contrast media: Acute decrease in renal function and lactic acidosis may occur; discontinuation may be necessary and monitoring recommended.
- Renal: Acute kidney injury, sometimes requiring dialysis and hospitalization, has been reported. Increased risk in patients with hypovolemia, chronic renal insufficiency, congestive heart failure, and concomitant use of medications (eg, diuretics, ACE inhibitors, angiotensin II receptor blockers, and NSAIDs); monitoring recommended and discontinuation may be required
- Renal: New or worsening renal impairment may occur, especially in elderly patients; monitoring recommended and discontinuation may be necessary
- Renal: Urinary tract infections resulting in life-threatening urosepsis and pyelonephritis have been reported; monitoring recommended
- Reproductive: Rare, serious cases of Fournier gangrene have been reported with sodium-glucose cotransporter-2 (SGLT2) inhibitors; if suspected, institute antibiotics and surgical debridement if appropriate; discontinue use of the SGLT2 inhibitor and provide alternative therapy for glycemic control.
- Reproductive: Genital mycotic infections may occur, especially in patients with history of chronic or recurrent genital mycotic infections; monitoring recommended.
- Respiratory: Hypoxic states (e.g., acute congestive heart failure, cardiovascular collapse or shock, acute myocardial infarction, sepsis) may lead to lactic acidosis; discontinue use.

- Special populations: Elderly patients are at increased risk of lactic acidosis; monitoring recommended
- Surgery: Discontinue use temporarily for surgical procedures requiring restricted food or fluid intake.

D. Contraindications

- Acute or chronic metabolic acidosis, including diabetic ketoacidosis
- History of serious hypersensitivity to empagliflozin, metformin hydrochloride, or any component of the product
- Moderate to severe renal impairment (estimated eGFR < 45 mL/min/1.73 m^2), ESRD, or dialysis

V. Drug Interactions

This medicine may also interact with the following medications:

- acetazolamide
- alcohol
- amiloride
- certain medicines for blood pressure like amlodipine, felodipine, nifedipine
- cimetidine
- dichlorphenamide
- digoxin
- diuretics
- female hormones, like estrogens or progestins and birth control pills
- gatifloxacin
- isoniazid
- medicines for blood pressure, heart disease, irregular heartbeat
- morphine
- nicotinic acid
- phenothiazines like chlorpromazine, mesoridazine, prochlorperazine, thioridazine
- phenytoin
- procainamide
- quinidine
- quinine
- ranitidine
- steroid medicines like prednisone or cortisone
- thyroid medicines
- topiramate
- triamterene
- trimethoprim
- vancomycin
- zonisamide
- certain contrast medicines given before X-rays, CT scans, MRI, or other procedures

VI. Dosage and Administration

A. Initialization requires individualization based on the patient's current regimen. For patients on metformin, empagliflozin can be added at 10 mg/day with a similar daily dose of metformin. The regimen can be administered in 2 divided
doses with the immediate release formulation or once daily with breakfast with the extended-release formulation.

B. For patients currently on empagliflozin, metformin 1,000 mg/day with a similar dose of empagliflozin can be administered. The regimen can be administered in 2 divided doses with the immediate release formulation or once daily with breakfast with the extended-release formulation. ER formulation should not be split, crushed, chewed, or dissolved.

C. Maximum dosage: Empagliflozin 25 mg/metformin 2,000 mg/day

VII. Cost

A. Tablet, 24-hour (Synjardy XR® Oral)
- 5-1000 mg (per each): $9.30
- 10-1000 mg (per each): $18.60
- 12.5-1000 mg (per each): $9.30
- 25-1000 mg (per each): $18.60

B. Tablets (Synjardy® Oral)
- 5-500 mg (per each): $9.30
- 5-1000 mg (per each): $9.30
- 12.5-500 mg (per each): $9.30
- 12.5-1000 mg (per each): $9.30

VIII. References

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3. Metformin. Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: .https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/7260
4. Synjardy(R) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; 2017
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Appendix 3: Example Recommendation & Rationale Worksheet

One-Day P&T Competition

Answer the two questions in their entirety to the best of your knowledge. This page will be given to the judges during your presentation. You may use more than the allotted space, if needed. At the end of your preparation session, print **2 copies** of the document to the Pharmacy Black and White printer with the ID () and one of the moderators will print it for you.

Recommendation:
Be specific about your formulary recommendation. Possible things to mention, if applicable to your recommendation, are: patient criteria, dosage, monitoring, reimbursement.

Criteria for Formulary Placement (if any)

Rationale:
Be specific and use citable facts that lead to your formulary recommendation. Key considerations can be, but are not limited to: effectiveness, safety, clinical, economic, comparative medications.

Appendix 4: Example Judging Rubric

One-Day P&T Competition Judging Rubric

Team Members:

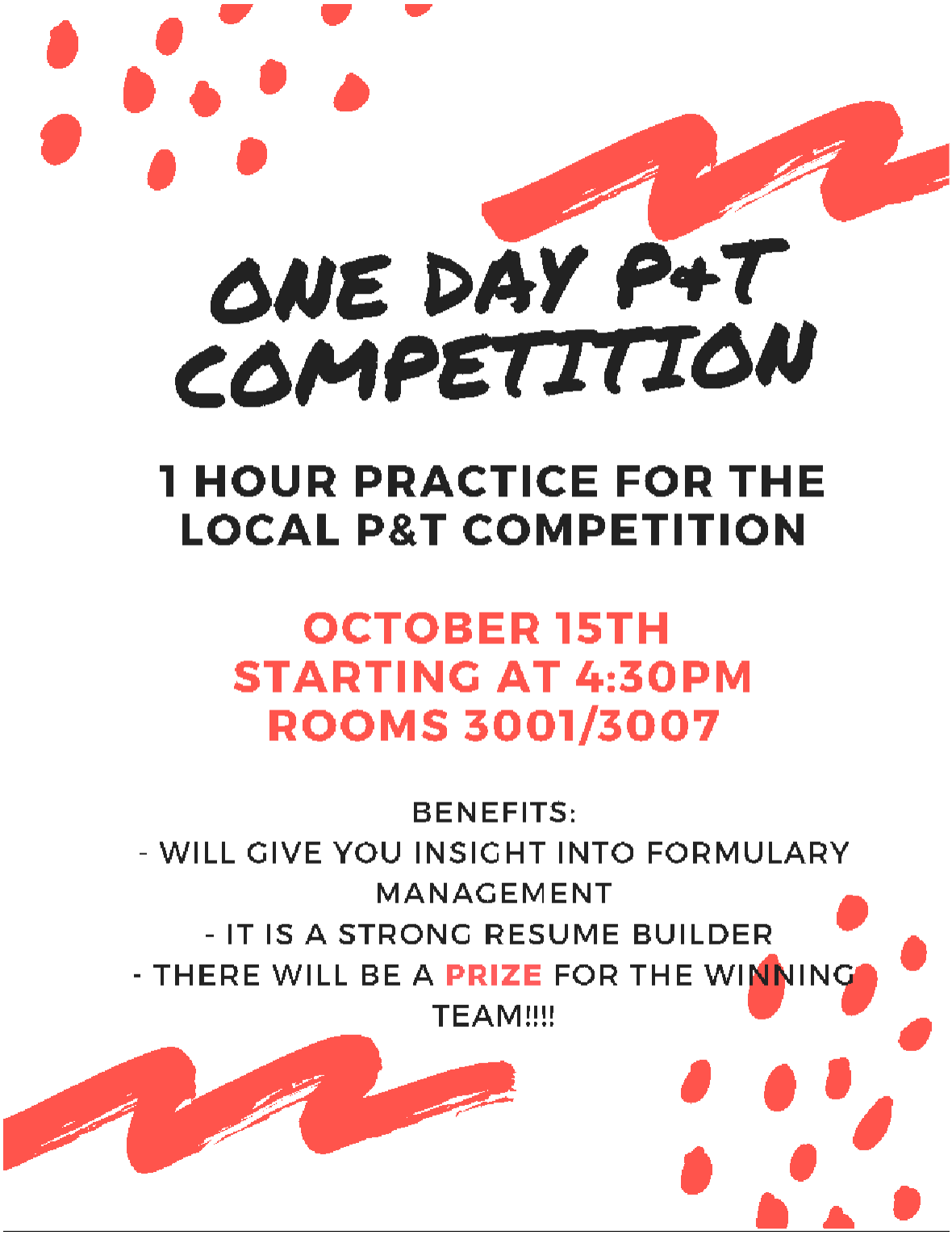
Component	Scoring Considerations	Score
Written Recommendation	• Clear recommendation • Recommendations are consistent with presented evidence • May consider, but not limited to: efficacy, safety, cost-effectiveness, care guidelines, follow up of recommendation • May deduct up to 5 points for poor grammar and/or spelling errors	**0 to 15 points**
Oral Presentation	• Content of presentation: accurate, clear, knowledgeable, organization of structure and coherence • Verbal skills: clear voice, enunciation, correct pronunciations • Non-verbal skills: body language, eye contact • Consistency of team members in knowledge and contribution	**0 to 10 points**
Question & Answer Session	• Ability to answer questions • Clinical knowledge • Clarity of responses - ramble or fail to address question • Consistency of team members in knowledge and contribution	**0 to 5 points**
Total		

Judge Comments:
Please be as clear and detailed as possible. These comments will be shared with the competitors to help improve their presentations skills as well as guiding their thinking when approaching P&T decisions.

Appendix 5: Example Competition Schedule

Research Time	Team Member #1	Team Member #2	10-minute warning	5-minute warning	Presentation Start
3:45 - 4:45	Name	Name	4:35	4:40	4:50
4:00 - 5:00	Name	Name	4:50	4:55	5:05
4:15 - 5:15	Name	Name	5:05	5:10	5:10
4:30 - 5:30	Name	Name	5:20	5:25	5:35
4:45 - 5:45	Name	Name	5:35	5:40	5:50

Appendix 6: Example Promotional Flyer



Appendix 7: Example Rules PowerPoint Display

This PowerPoint slide is an example of how to display rules and guidelines in the preparation/research room (Room 1) on the day of competition.