SP2: P&T 101: A Basic Understanding of a P&T Committee & Competition

2011 Educational Conference

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OBJECTIVES:

1. Review pharmacoeconomics and outcomes and how to interpret the relevance to managed care decision-making
2. Cite strcategies to have a successful local P&T competition at the chapter level
3. Discuss benefit design and strategies for appropriate placement of therapy

DESCRIPTION:

The P&T Competition is a challenging, exciting and fundamental part of occupational development for many student pharmacists. Participation helps to hone hands-on skills and knowledge-sets that may otherwise not present themselves until much later on in their career path, if at all. However, many students are unaware of or do not possess the necessary skill sets and tools to be successful in this endeavor. In this student session, faculty will discuss key components of the Pharmacy and Therapeutics (P&T) Committee. There will be five roundtables to choose from that will review benefit design, clinical literature evaluation, dossier review, pharmacoeconomics and specific logistics on how to run a local P&T competition. Participants will be able to choose which areas they desire most to participate in during each 20 minute presentation.

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Pharmacoeconomic Overview

Vinson C. Lee, PharmD, MS

Basics of Pharmcoeconomics and Economic Models

- Studies and models can focus on either costs, outcomes, or both
- Four kinds of costs:
  - Direct medical costs, such as drug costs and hospital visits
  - Direct non-medical costs, such as patient transportation
  - Indirect costs, such as absenteeism
  - Intangible costs, which are hard to quantify, and related to quality of life
- Three types of outcomes:
  - Surrogate outcomes, which act as markers of progression
  - Mortality, which acts as a direct life of death outcome
  - Quality of life, which can be calculated in a variety of ways
- Models are designed to predict events and outcomes in the absence of experimental data, estimate economic data if they were not captured during a clinical trial, or extrapolate data beyond the trial to final endpoints, such as long-term survival
- Models may also be helpful when examining the impact of a drug or intervention in a clinical trial setting compared with what would be found in a 'real-world' setting

Types of Models

- To evaluate the economic impact of the disease and healthcare interventions, there are several different types of analyses:
  - Budget impact
  - Cost-effectiveness
  - Cost of illness, also known as burden of illness
  - Cost-benefit
  - Cost-utility
  - Cost-consequence
  - Cost-minimization analysis
- Of these types of analyses, only budget impact and cost of illness focus solely on cost outcomes

- ***Budget Impact Models (BIMs)***
  - Budget impact models are useful for estimating system-wide (e.g., pharmacy and medical) budget impacts and estimate drug costs, healthcare cost offsets, adverse event costs, and the expected utilization in the healthcare system, to derive projected per member per month (PMPM) costs
  - Budget impact models demonstrate the likely impact of adding a new drug to formulary and determine affordability
- ***Cost-effectiveness Models (CE Models)***
  - Cost-effectiveness models are useful for assessing the overall clinical risk-benefit and economic value of a drug in relation to drugs in its class and other healthcare interventions in general
  - Cost-effectiveness models compare therapies to determine whether the additional cost of one therapy is worth paying and determine value for money
  - Cost-effectiveness analysis is a technique for comparing the relative value of competing clinical alternatives by calculating a CE ratio or incremental cost effectiveness ratio (ICER) which can be thought of as 'price' of the additional outcome of the new therapy

    $$\text{CE Ratio} = (\text{Cost}_{\text{new therapy}} - \text{Cost}_{\text{existing therapy}})/(\text{Effect}_{\text{new therapy}} - \text{Effect}_{\text{existing therapy}})$$
  - Cost Effectiveness Outcomes
    - Typically, cost per life year gained (LYG) or cost per quality-adjusted life year gained (QALY) are used as the main outcome

        - QALYs are a way to measure the disease burden, but it includes both quantity and quality of life
    - Interpreting ICERs
        - Threshold for which therapies are considered cost effective
            - In the US, the cost per QALY threshold is $50,000-$75,000
            - In the US, the cost per LYG threshold is $50,000-$100,000
    - Cost-effective ≠ cost saving
        - Remember ICER is the price for that outcome, not how much you save

Section 4.0 (AMCP Dossier Format 3.0) – Economic Value and Modeling Report

- How well does the economic data and model support the manufacturer's value statement?
- Is there any information that is excluded from the report?
- Analyze the model that was provided based on the following:
    - **Structure**
        - Is it a disease-progression model with an appropriate time horizon?
        - Are the treatment pathways relevant to the decision?
        - Does it model usual and appropriate clinical practice?
        - Are the mathematics of the model accurate and available for inspection?
    - **Data**
        - Are the sources of evidence valid?
        - Have the data been interpreted and incorporated accurately?
        - Have uncertainties in the data been addressed?
        - Are linkages between intermediate and long-term outcomes:
            - Valid and based on appropriate (trial or retrospective) evidence?
    - **Presentation**
        - Are outcomes relevant to decision-making in the health plan?
        - Was incremental analyses performed on both health effects and costs?
        - Are outcomes verifiable, i.e. traceable back to the inputs and model structure?
        - Is uncertainty in the data tested in a reasonable fashion?
        - Is the sensitivity analysis displayed via tornado diagram?
        - Are results and uncertainty presented in a fashion that facilitates incorporation into formulary monographs and decision-making?

Literature Evaluation –Medical Literature Checklist

Diana Toe, PharmD.

OVERVIEW

- Is the journal peer-reviewed?
- Is the title or abstract misleading or biased?
- Were the investigators qualified to undertake this study?
- Was the location of the study adequate or appropriate?
- Was the article referenced with key up-to-date articles?

INTRODUCTION

- Was there a brief review of previous work and background on why the study was done?
- Was the hypothesis or objective of the trial clearly defined?

OVERALL STUDY DESIGN

- Was the study design appropriate to the hypothesis?

METHODOLOGY

- Were the inclusion and exclusion criteria appropriate for the purposes of the study? Were they adequate for extrapolation to the appropriate population?
- In addition to inclusion/exclusion criteria, was adequate pertinent patient information provided? (eg. disease severity, demographics, pervious treatment used/failed, etc.)
- Was the number of subjects enrolled adequate?
- Were appropriate controls used?
- Were study drug and control allocated randomly?
- Were drug doses, schedules, and duration of drug treatment appropriate? (eg. within known therapeutic ranges, safe, proper interval, equally effective doses when active drugs are compared, treatment duration adequate for assessing effect?)
- Were washouts used? Were they of sufficient duration?
- Was concurrent therapy allowed? Was concurrent therapy use discussed?
- Was the study blinded? If yes, was the blinding technique appropriate?
- Were observers identified? Were they qualified? Were they blinded?
- Were the outcome measures or endpoints used indicative of therapeutic efficacy? Are they validated or accepted practice?
- Did the outcome or endpoint measurements use subjective or objective assessment?
- What is the test measurement's sensitivity, specificity and reliability? Could a more reliable test measure have been used?
- How long were subjects followed? Was it long enough?

RESULTS

- Were the results clearly, accurately, and adequately presented?
- Were all the results presented?
- Were dropouts adequately accounted for?
- Were appropriate statistical methods used?
- If there is a statistical difference between groups, is this clinically significant?

DISCUSSION AND CONCLUSION

- Were valid conclusions based upon the results presented?
- Were valid conclusions based upon the objective or hypothesis of the study?
- Does the discussion place the results of this study into the perspective of previous clinical trials comparing and contrasting results? Does the discussion honestly outline the clinical trials shortcomings?

REFERENCES

- Did the article provide an appropriate reference list to verify footnoted citations?
- Were references cited only those of the investigators own work or work/findings from others?

Benefit Design

Mitzi Wasik, PharmD

Review basic formulary benefit designs

- Tiering-- A pharmacy benefit design that financially rewards patients for using generic and preferred drugs by requiring the patient to pay progressively higher copayments for preferred brand-name and non-preferred brand-name drugs. For example, in a three-tiered benefit structure, copayments may be $5.00 for a generic, $10.00 for a preferred brand product, and $25.00 for a non-preferred brand product.

- Coinsurance- The percentage of the costs of medical services paid by the patient. This is a characteristic of indemnity insurance and preferred provider organization (PPO) plans. The coinsurance usually is about 20% of the cost of medical services or pharmacy prescription after the deductible is paid.
- Copayment: A fee charged to an insured member to offset costs of paperwork and administration for each office visit or pharmacy prescription filled. A cost-sharing arrangement in which a covered person pays a specified charge for a specific service, such as a fixed dollar amount for each prescription received; 10.00 Tier 1, 25.00 Tier 2, 45.00 Tier 3.
- Specialty Benefit (ex: Tier 3/4)- Medications generally prescribed for people with complex or ongoing medical conditions such as multiple sclerosis, hemophilia, hepatitis, and rheumatoid arthritis. These medications also typically have one or more of the following characteristics: injected or infused, but some may be taken by mouth; unique storage or shipment requirements; additional education and support required from a health care professional; usually not stocked at retail pharmacies.

Evaluate tools available to implement cost containment strategies

- Prior authorizations (PA)
    - Requires clinical pharmacist review for proper utilization
- Step therapy (ST)
    - can be set up with PBM (prescription benefit management company) to have system "look" for required drugs to use prior to coverage of requested agents
- Quantity limits (QL)
    - Allows a limit to be placed on medications to ensure proper usage of dosage forms and can implement management of maximum daily dosages

Identify differences between pharmacy and medical benefits

- Difference in coverage
- New legislation that are blurring the lines of coverage design
    - Ex: chemo parity drug act: requires health plans to offer both IV and oral agents at the same level of out of pocket cost and coordinate between medical and pharmacy benefits

Discuss key factors when developing a copay/co-insurance payment structure

- Trend
- Competing with retail cash programs (4.00 lists)
- Delta in copay needed to drive utilization to lower tiers
- Generic placement (not always tier 1)

Questions to ask when reviewing a drug for formulary placement:

- What other drugs are available generically?
- Is this a novel agent?
- Where does the drug fit in evidence based guidelines?
- What is the delta of copay to drive utilization to first line agents?
- Is the drug orally administered or injectable?
    - If injectable, is this administered in the physicians office or self administered by the patient?
- What cost containment strategies can be used? Ie: PA, QL or ST?
- Are any labs/tests/pharmacogenomic testing required prior to treatment?
    - If yes, will need to implement PA to capture appropriate population utilization

Understanding the Dossier and Monograph write up

Debora Sternaman, PharmD

AMCP Product Dossier

- What a dossier should contain, how it should be set up, etc
- Differences between 2.1 and 3.0 formats
  - 3.0 took effect with any new Dossier's created after January 1st, 2010
  - Information was reorganized in version 3.0
    - Section 1.0 Executive Summary – Clinical and Economic Value of the Product replaced version 2.1's Section 4 which was the AMCP Format for Formulary Submissions.
- Key terminology and definitions
  - Found in Section 6.0 of *The AMCP Format for Formulary Submissions, Version 3.0*
  - Should review this section so you fully understand the analyses within the Dossier as well as supplemental studies which you review.

Key sections within the Dossier

- Executive Summary - Clinical and Economic Value of the Product
  - This section is where the manufacturer has the opportunity to briefly summarize the value of its product. This is great for getting an overview of the key points. This section should help to guide you in key points, however some information may not be included here which is crucial (and possibly does not portray the product in the best light so keep this in mind).
  - Clinical Benefit section summarizes (in 1-2 paragraphs)
    - FDA-approved indication for the drug
    - Short overview of the efficacy and safety information found within the prescribing information and the clinical trials.
  - Economic Benefits section summarizes (in 1 page or less)
    - The economic benefit of the proposed therapy. Including the:
      - Cost per unit
      - Context of the proposed cost taking into consideration clinical and economic benefits
      - Shortcomings of other therapies.
    - Briefly reviews observational data, economic data, comparative effectiveness data and other published information on cost or economics.
  - Conclusions (no more than ½ page)
    - Summarize the value of the proposed therapy
    - Review major advantages (both clinical and economic) and any unique attributes of the therapy.
    - A summary statement about the impact of the product in therapy against other treatment options (not just other drugs).
- Product Information and Disease Description
  - Product description section review (max 20 pages)
    - Detailed information about the product, including comparisons with other available therapies
    - This section includes much of the package insert information as well as additional information only available via an unsolicited request for the monograph.
      - Including a comparison of the products package insert with those of the competitor products in a table.
  - Place in therapy section review
    - This should be provided for each indication (if there are multiple). Information should not duplicate that in other sections.
    - Three sections
      - Disease description (1-2 pages per indication/disease)

        - Overall review of the disease and characteristics of patients who need treatment, as well as any subpopulation data.
        - Brief literature summary should be provided for each.
    - Approaches to Treatment (1-2 pages per disease)
        - How the disease is currently treated, how the product fits into existing therapy.
        - Any post-marketing obligations (i.e. Risk Evaluation Mitigation Strategies (REMS), patient registries, etc)
    - Relevent Treatment Guidelines and Consensus Statements from National or International Bodies.
        - Any treatment guidelines or tools available regarding therapy.
        - Discussion on differences in guidelines
- Evidence for Pharmaogenomic tests and drugs
    - Review of if this is indicated for this product as well as any markers which should be used for monitoring effectiveness of therapy.
- Supporting Clinical Evidence (2 pages max)
- Economic Value and Modeling Report (20 pages max)
- Other supporting evidence (2 pages max per study
    - Summary of other evidence – including unpublished studies as well as support of off-label indications.
    - Evidence table spreadsheets

Best practices of write up

- Technical tips
    - Ensure you comply with criteria for font type and size, margins, spacing, page numbers, headers/footers, etc.
    - Reference all materials used and use appropriate referencing style criteria – including references throughout the document and not just at the end.
    - Check grammar, organization
    - Do not be redundant but ensure you have a consistent opinion throughout
        - Make sure to stick to this opinion throughout the document AND in your presentation
            - You may start doubting your opinion based on questions but be prepared to back up your answers
            - Know your information from the write up to help.
- Detail
    - What level of detail should you go out to
    - What consists of a thorough write up
        - Key points you should hit
            - Be able to defend your points
    - Tips on writing
        - Writing style
        - Don't contradict yourself – ensure you follow the same rationale throughout and defend yourself.
    - Basic guidelines on the write up
        - Evaluation of the Dossier
            - Demonstrate within your write up a thorough understanding of the format and rationale for the sections.
                - Be able to summarize how well the manufacturer followed the AMCP Format for Formulary Submissions guidelines.
                - Do not focus only on section length but also on key components as outlined in the guidelines
                    - Did they include too litte OR too much information.
                    - Did they show only biased information.
                    - In what ways did they not follow the guidelines?

        - What was missing?
        - What was good?
    - Analysis of the value proposition
        - Evaluate if you have enough information to come to the same conclusions as the dossier.
            - Are outcomes available, if so do they support the conclusions.
        - Grade the evidence utilizing a recognized grading system, such as Delfini
        - Was there Bias in the evidence?
        - Discuss the budget impact section of the dossier
    - P&T Monograph
        - Reference other monographs out there for examples (many posted on the internet and monograph services)
        - Should include a therapy class review
        - Should be SOLID on the recommendations for formulary status including at minimum all the following
            - Should it be added to the formulary? If so what should the formulary status be (preferred, non preferred, tier placement)?
            - How would you classify the product (medical benefit specialty, pharmacy benefit specialty, pharmacy benefit non specialty, etc)?
            - Ensure you have a solid rationale for your decision and STICK to your rationale throughout.

Reference/Resources

- Comparative Effectiveness Research Glossary of Terms. Found at http://www.amcp.org/cerglossaryofterms/
- Value of Pharmaceuticals and Managed Pharmaceutical Care. Found at http://www.amcp.org/FmcpCategory.aspx?id=9173
- Primer on Cost-Effectiveness Analysis. Found at http://www.acponline.org/clinical_information/journals_publications/ecp/sepoct00/primer.htm
- International Society for Pharmaceconomics and Outcomes Research. Found at www.ispor.org
- Motheral BR, et al. Pharmacoeconomics and Outcomes Research: Evaluating the Studies. *JMCP.* 2000; 6:S1-16.
- Delfini Group, LLC. Evidence and Value-based Solutions for Health Care. www.delfini.org
- Agency for Healthcare Research and Quality. www.ahrq.gov
- Oregon State Drug Formulary Reviews – Oregon Health Services University. http://www.ohsu.edu/drugeffectiveness/index.htm
- Cochrane Library. www.cochrane.org
- www.amcp.org: Managed care terminology
    - Review terminology prior to presenting any formulary review to make sure you can "talk the talk" with your audience.
- www.jmcp.org The AMCP Format for Formulary Submissions Version 3.0. Published January 2010 in the Supplement
    - Review criteria for each section and key components of the section
    - Review terminology
- Delfini Group, LLC. Evidence and Value-based Solutions for Health Care. www.delfini.org
    - Assistance in Grading the evidence

- http://depts.washington.edu/expharmd/FormularyReviewHowTo.pdf Evaluating Drugs for Formulary Inclusion: Evidence-Based Decision Making
  - Assistance in formulary decision making.
  - Tips for monographs
- www.amcp.org/WorkArea/DownloadAsset.aspx?id=9156 Appendix C: Sample P&T Committee Monograph