# P & T Competition: "How to" Session

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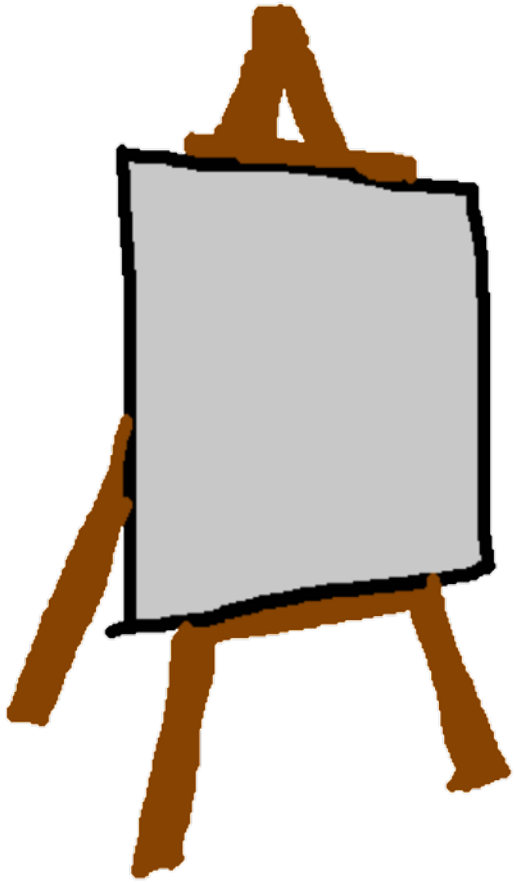
AMCP Academy of Managed Care Pharmacy®

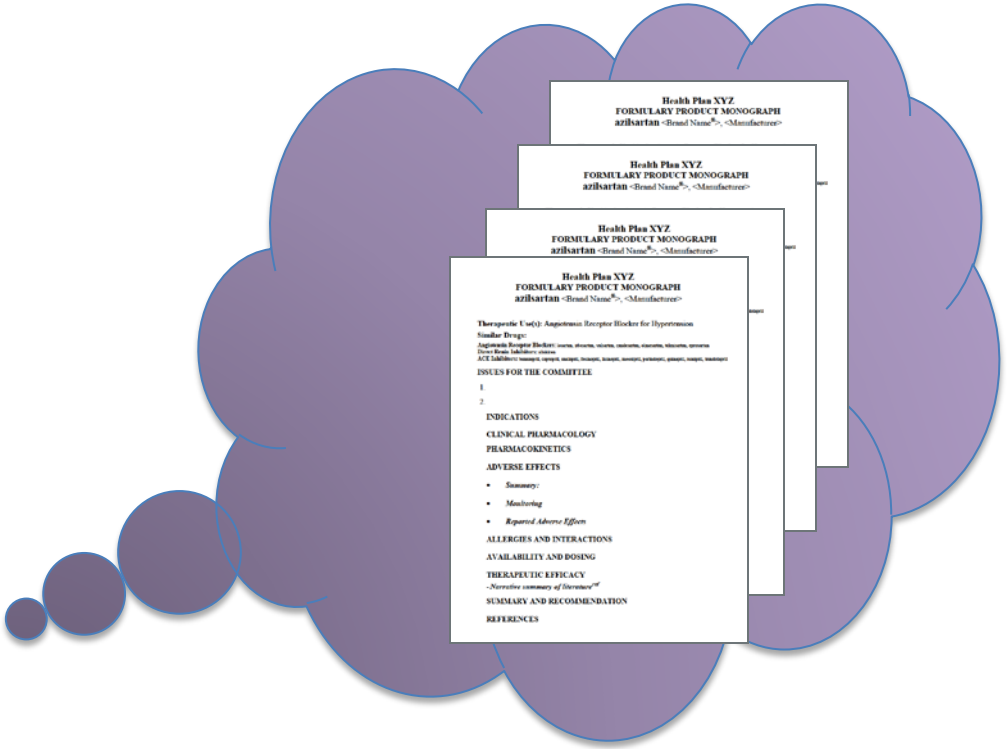
# Objectives: Developing Your Drug Monograph

- Additional insight in drug evaluation process
- Tips for monograph creation/best practice
- Key areas for emphasis
- Enhancement opportunities

# Getting Started

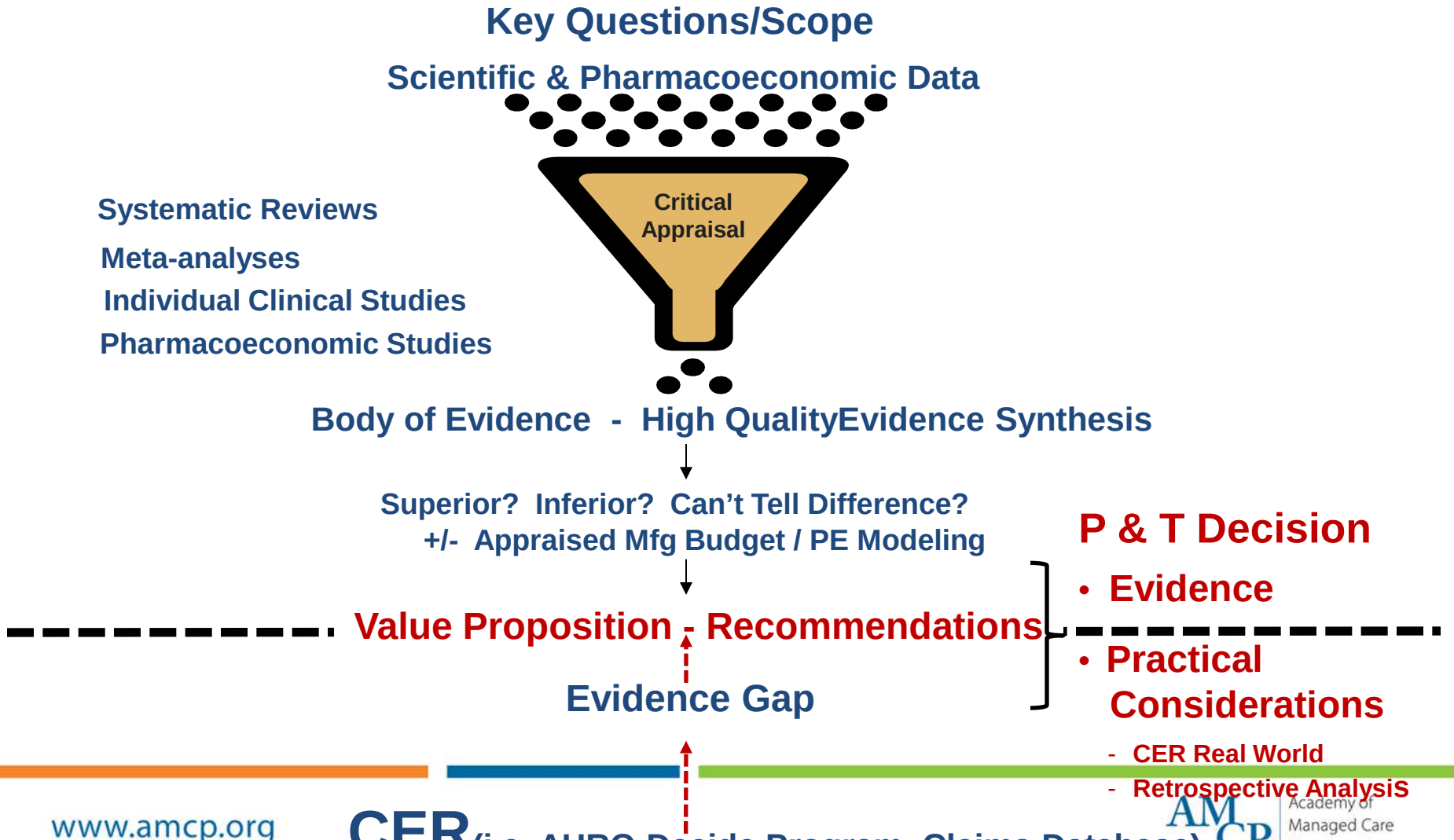


# Drug Monograph- Where to begin…



# Drug Monograph Development

- EBM Process: Ask, Acquire, Assess, Apply



# Drug Monograph – Areas of Emphasis

- Background Information
- Executive Summary
- Literature Search Method
- Critical Appraisal/Evaluation
- Evidence Synthesis
- Clinical/Cost Effectiveness (Model?)
- Recommendations
- References

# Background Information

- Disease Characteristics & Treatment Options
  - Incidence
  - Severity
  - Disease characteristics
  - Treatment options and goals
  - Need for improved treatment options
  - Economic impact

"Grounding your reader"

# Executive Summary

- **Scope**
- **Key Questions**
- Responses to Key Questions
- Value Proposition
- Recommendations
- Formulary/Non-formulary
- Applicable Utilization Management Criteria
  - Prior Authorization
  - Quantity Limits

# Scope/Key Questions

- Scope
  - Focus on what is important
  - Narrow vs broad
  - Defines what your research covers
- Key Questions
  - Population
  - Intervention
  - Comparator (How much better ?)
  - Outcome  (Short vs Long term)

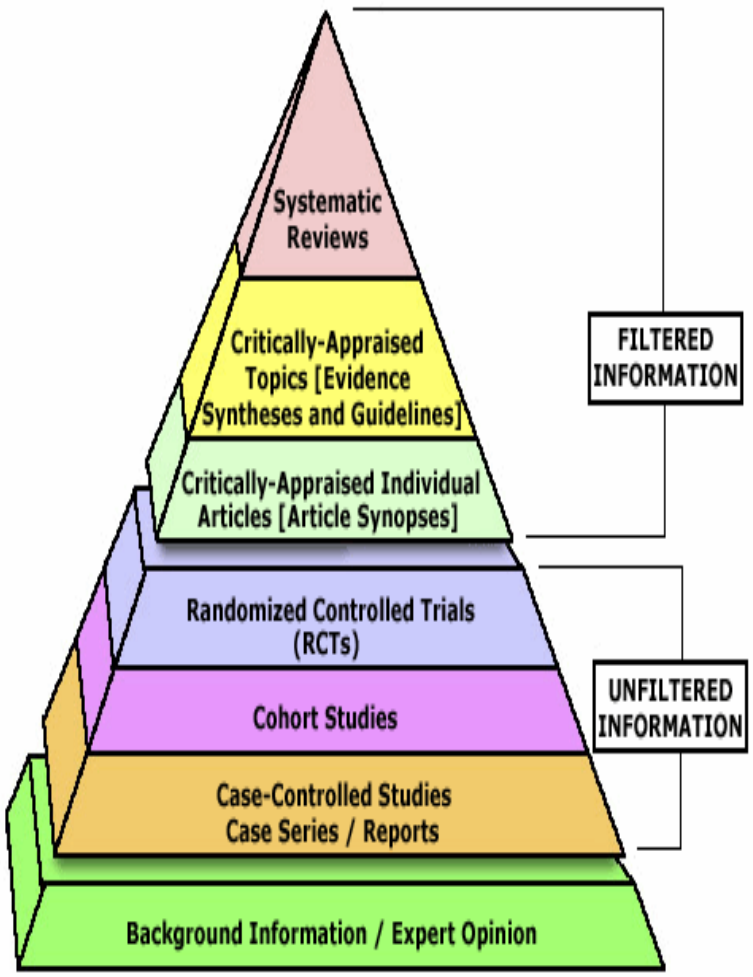
# Literature Search Method - Results

- Assure reproducibility
- Include trials in your evidence tables
- Document in your references
- Make sure your numbers add up

# Literature Search Method - Considerations

- Source (Database, Manual)
- Search Method
  - Published Data
  - UnPublished Data
- Search terms
- Date span covered
- Date conducted
- Exclusion Criteria / Limitations
- Search Results

# Literature Search Method – Evidence Hierarchy




## Filtered (Published)

**Examples of Trusted Sources***

- **Cochrane Database of Systematic Reviews**
- **Agency for Healthcare Research & Quality**
- **Drug Effectiveness Review Project (DERP)**
- **Centre for Reviews and Dissemination**
- **Database of Abstracts of Reviews of Effects**
- **Canadian Agency for Drugs & Technologies in Health**

**"Trusted Sources" are generally known for:**

- Rigorous, systematic methodology
- Transparency
- Auditing/critical appraisal of included research to base conclusions
- Systematic reviews that hold up to critical appraisal by external users.

## Unfiltered (Published & Unpublished)

**Sources**

- **PubMed**
- **Professional Organizations & Societies**
- **Manufacturer Dossier**

# Literature Search Method

## Formulary Review

**10 ACE Inhibitors, 8 Angiotensin Renin Blockers, 1 Direct Renin Blocker**

***New product – azilsartan***

Total # of Medications: 19 drugs

Search Strategy: ACEI's, ARB's, Direct Renin Blockers

- ✓ PubMed / Medline
  - Type: RCT's, Systematic Reviews, Meta-analyses
  - Timeframe: 1990 – March 2011
  - Conditions: Hypertension, Heart disease, Kidney disease
- ✓ Systematic Reviews "Trusted Sources" (i.e. Cochrane, AHRQ, DERP)
- ✓ Manufacturer Dossier (eDossier)

Search Results: 3000+ RCT's & Review Citations

# Literature Search – Example

## Formulary Review

ACE Inhibitors, Angiotensin Renin Blockers, Direct Renin Blockers

*New product – azilsartan*

**Search Results: Over 3000+ RCTs & Review Citations**

**Step 1: Identify Pertinent High Quality CER Systematic Reviews**

**1 AHRQ CER Review**
**Hypertension**

**May '96 – May '06**
**1185** citations
- **Excluded 1116**
- **Included 69**

+

**1 AHRQ CER Review**
**Ischemic Heart Disease**

**May '96 – Feb '09**
**1342** citations
- **Excluded 1287**
- **Included 57**

+

**1 DERP/AHRQ CER Review**
**Hypertension, CHD, Left ventricular dysfunction, diabetic nephropathy, non-diabetic kidney disease**

**1950 – June '09**
**1328** citations
- **Excluded 1205**
- **Included 123**

+

**2997+ Citations to review**

**"Systematically Screens & Appraises" Large Body of Literature**

# Literature Search - Example

## Formulary Review

**ACE Inhibitors, Angiotensin Renin Blockers, Direct Renin Blockers**

***New product – azilsartan***

**2997+ Citations left**

**1 AHRQ CER**
**Hypertension**

**May '96 – May '06**
**69 studies**

+

**1 AHRQ CER**
**Ischemic Heart Disease**

**May '96 – Feb '09**
**57 studies**

+

**1 DERP/AHRQ CER**
**Hypertension, CHD, Left ventricular dysfunction, diabetic nephropathy, non-diabetic kidney disease**

**1950 – June '09**
**123 studies**

**Step 2:**

**Exclude: 1950 – May 2009**

**Include:**
**June 2009 – Mar 2011**

**242 Citations Left**

- **Exclude 224 studies**
- **Include 18 studies**
  - 7 (azilsartan)
  - 6 (aliskirin)
  - 5 (older ACEI's, ARB's)

**Appraise & Inclusion in Formulary Review**

**Final Results = 3 CER Reviews + 18 Clinical Studies**

# Literature Search: Documentation

| Search Parameters | Total Results | Met Inclusion Criteria |
|---|---|---|
| **Database (Date searched)**<br>• **drug AND disease, etc.**<br>• **Only placebo/active comparator studies**<br>• **Only studies with certain endpoints?**<br>• **Limits: Humans, English. RCT?**<br>• **Excluded: PK trials? Post hoc?**<br>• **Date span for Body of literature** | # trials | **RCTs: # trials**<br>**Systematic Reviews: # trials**<br>**Meta-analysis: # trials** |
| **Database (Date searched)**<br>• **drug AND disease, etc.**<br>• **Only placebo/active comparator studies**<br>• **Only studies with certain endpoints?**<br>• **Limits: Humans, English. RCT?**<br>• **Excluded: PK trials? Post hoc?**<br>• **Date span for Body of literature** | # trials | **RCTs: # trials**<br>**Systematic Reviews: # trials**<br>**Meta-analysis: # trials** |
| **Other manual search for published/unpublished data. List source and criteria used (i.e. dossier, National Organizations, FDA Docket)**<br>• **Inclusion Criteria**<br>• **Exclusion Criteria** | # trials | **RCTs: # trials**<br>**Systematic Reviews: # trials**<br>**Meta-analysis: # trials** |
| **Overall Total (Unique)** | **# Unique Trials** | **RCTS: # total Unique**<br>**Systematic Review: # Total Unique**<br>**Meta-analysis: # Total Unique** |

# Literature Search - Documentation

## Systematic methodology used to identify data for evidence synthesis

### INCLUSION CRITERIA

| Study Type | N |
|---|---|
| Randomized controlled trials (RCT) ? | |
| Meta-analyses of RCTs ? | |
| Systematic reviews ? | |
| Randomized pragmatic Trials ? | |
| Prospective cohort studies ? | |
| Retrospective cohort or case-control studies ? | |
| Economic modeling studies ? | |
| Case Series ? | |
| RCT abstracts, not peer-reviewed ? | |
| Other abstracts, posters, etc., not peer-reviewed ? | |

### EXCLUSION CRITERIA

| Study Type | N |
|---|---|
| Randomized controlled trials (RCT) ? | |
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| Retrospective cohort or case-control studies ? | |
| Economic modeling studies ? | |
| Case Series ? | |
| RCT abstracts, not peer-reviewed ? | |
| Other abstracts, posters, etc., not peer-reviewed ? | |

### Final Results for Critical Appraisal and Evidence Synthesis

| Study Type | N |
|---|---|
| Randomized controlled trials (RCT) | |
| Meta-analyses of RCTs | |
| Systematic reviews | |
| Randomized pragmatic Trials | |
| Prospective cohort studies | |
| Retrospective cohort or case-control studies | |
| Economic modeling studies | |
| Case Series | |
| RCT abstracts, not peer-reviewed | |
| Other abstracts, posters, etc., not peer-reviewed | |

- Demonstrate transparency
- Include in evidence tables
- Document in references
- Make sure numbers add up

# Critical Appraisal Evaluation Tools

## - Individual Clinical Trials/Systematic Reviews, Meta-analyses
## - Individual Pharmacoeconomic Studies

# Critical Appraisal Evaluation

## Evidence Tables – Populating your Evidence Tables

- Reporting study element
- Identifying study strengths/weaknesses
- Critically appraising trials
- Methods for study grades / documenting rationale
  - ICER (High certainty, Moderate certainty, Low certainty)
  - U.S. Preventive Task Force (Good, Fair, Poor)
  - AHRQ (Good, Fair, Poor)
  - Delfini (Useful, Possibly Useful, Uncertain Usefulness, Poor)

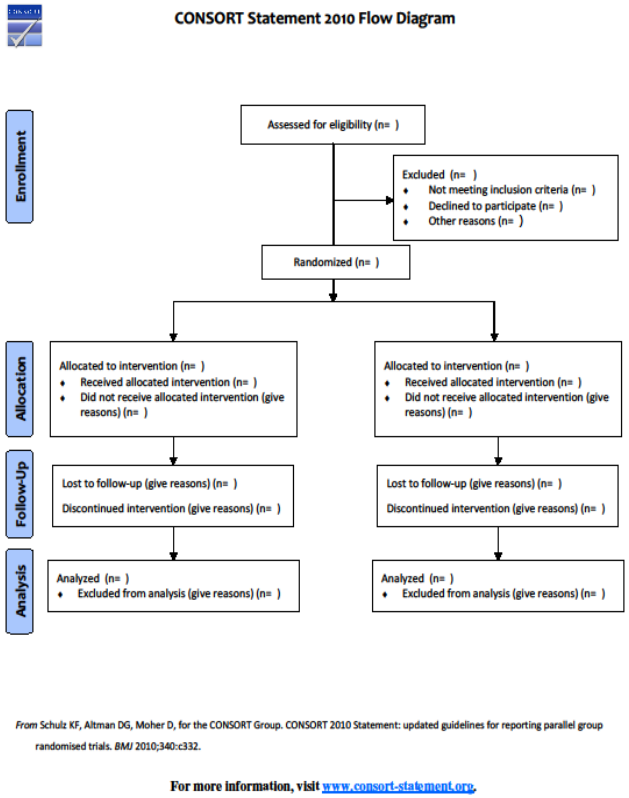
# Critical Appraisal: Evidence Table-Reporting Elements

- Minimum recommendations for reporting RCTs
- Standard way of reporting clinical trial findings
- Complete/transparent reporting
- Aid in critical appraisal and interpretation

# Evidence Tables – Populating

## Individual Clinical Studies – Identifying Strengths/Weaknesses

### CONSORT Flowchart




*From* Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c332.

**For more information, visit www.consort-statement.org.**

Helps track all participants through the trial

# Evidence Tables – Populating

## Individual Clinical Studies – Identifying Strengths/Weaknesses

### CONSORT Checklist

| PAPER SECTION And topic | Item | Description | Reported on Page # |
|---|---|---|---|
| *TITLE & ABSTRACT* | 1 | How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned"). | |
| *INTRODUCTION* Background | 2 | Scientific background and explanation of rationale. | |
| *METHODS* Participants | 3 | Eligibility criteria for participants and the settings and locations where the data were collected. | |
| Interventions | 4 | Precise details of the interventions intended for each group and how and when they were actually administered. | |
| Objectives | 5 | Specific objectives and hypotheses. | |
| Outcomes | 6 | Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors). | |
| Sample size | 7 | How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules. | |
| Randomization -- Sequence generation | 8 | Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification) | |
| Randomization -- Allocation concealment | 9 | Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned. | |
| Randomization -- Implementation | 10 | Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups. | |
| Blinding (masking) | 11 | Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated. | |
| Statistical methods | 12 | Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses. | |
| RESULTS Participant flow | 13 | Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons. | |
| Recruitment | 14 | Dates defining the periods of recruitment and follow-up. | |
| Baseline data | 15 | Baseline demographic and clinical characteristics of each group. | |
| Numbers analyzed | 16 | Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%). | |
| Outcomes and estimation | 17 | For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval). | |
| Ancillary analyses | 18 | Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory. | |
| Adverse events | 19 | All important adverse events or side effects in each intervention group. | |
| DISCUSSION Interpretation | 20 | Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes. | |
| Generalizability | 21 | Generalizability (external validity) of the trial findings. | |
| Overall evidence | 22 | General interpretation of the results in the context of current evidence. | |

- **Randomization**
- **Inclusion/Exclusion Criteria**
- **Controls**
- **Washout**
- **Treatment arms**
- **Blinding**
- **Allocation Concealment**
- **Power**
- **Intent-to-treat**
- **Results (primary & secondary endpoints)**
- **P-values**
- **Confidence intervals**

→ **Critical Appraisal**
- **Study Strengths**
- **Study Weaknesses**



Reference: www.consort-statement.org/Downloads/Checklist.doc

# Evidence Tables – Populating

## Critical Appraisal – Common Findings

- Missing details (blinding, randomization, concealment)
- Small studies
- Lack of an intent to treat analysis.
  - Number randomized ≠ Number reported
  - What happened to missing subjects
- Large drop-out
- Endpoints
  - *A priori*
  - Unvalidated
  - Uncertain clinical relevance or benefit.



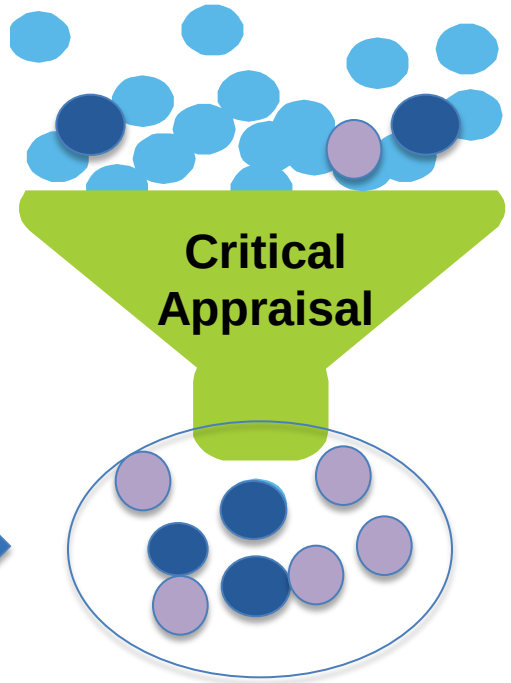
Delfini White Paper. Missing Data Considerations. Available at www.delfini.org. Accessed October 27,2009.

# Evidence Tables - Populating

- Systematic Reviews* - Identifying Strengths/Weaknesses

| Elements | Critical Appraisal for Strengths/Weaknesses |
|---|---|
| **Search Strategy** | Limited, omitted, outdated time frame |
| **Study Selection** | No description of study selection. Critical appraisal performed on included trials. |
| **Quality of Studies Included** | Authors base conclusions (such as comparative efficacy statements, hazard ratios, relative risk, etc) on poor quality trials. |
| **Patient Population Assessment** | Subjects studied may not be representative of population overall. |
| **Homo-/heterogeneity** | If results of the studies were combined, (i.e. meta-analyses), did authors apply tests of homogeneity/heterogeneity to assure that the variation between studies is due to chance? |
| **Data Collection** | Did more than one author extract and combine data? |
| **Weighting** | If weighting was employed, was a reasonable approach taken (e.g., larger or higher quality studies)? |
| **Transparency** | Could this review be replicated? |
| **Other Issues** | Potential conflict of interest. Lack of disclosure. |
| **Safety Analysis** | Was safety analyzed? How was it pooled? |

# Evidence Synthesis



# Evidence Synthesis – Choose a Grading Methodology

- Collating body of evidence after critical appraisal
- Evidence Synthesis Methodologies (Examples)
  - Integrated Evidence Rating (ICER)
  - Agency for Healthcare Research and Quality (AHRQ)
  - U.S. Preventive Services Task Force (USPSTF)
  - Delfini
- Apply based on evidence that you critically appraised for strengths/weaknesses
  - High Quality evidence – Conclusions are acceptable for use
  - Low Quality evidence – Conclusions are generally uncertain
- Demonstrate application, consistency, transparency
  - Evidence Grade
  - Strength of Evidence

# Institute for Clinical & Economic Review (ICER)*

| | Negative Health Benefit | Comparable Health Benefit | Incremental Health Benefit | Substantial Health Benefit |
|---|---|---|---|---|
| **High Certainty** | **D**<br>Inferior or Poor value<br>High certainty of inferior health benefit | **C**<br>Comparable or No added Benefit<br>High certainty of comparable health benefit | **B**<br>Incremental or Modest Benefit<br>High certainty of small health benefit | **A**<br>Superior or Great Benefit<br>High certainty of moderate-large net health benefit |
| **Moderate Certainty** | **I**<br>Insufficient | | **U/P**<br>Unproven with Potential / Moderate certainty of small or moderate-large net health benefit | |
| **Low Certainty** | **I**<br>**Insufficient**<br>The evidence does not provide high certainty that the net health benefit of the medication is at least comparable to that provided by comparators (or placebo/best supportive care, if no other treatment is available.) | | **I** | |

*Institute for Clinical and Economic Review: http://www.icer-review.org/index.php/medcare-icer-evidence-rating-682010.html.

# U.S. Preventative Task Force*

| Level of Certainty | Description of Available Evidence |
|---|---|
| High Certainty | - Consistent results based on well-designed, well-conducted studies in applicable populations.<br>- Able to assess effects on health outcome and quantify the net benefit.<br>- Conclusions are unlikely to be strongly affected by results from future studies. |
| Moderate Certainty | - Sufficient to determine effects on health outcomes; however, confidence in the estimate is limited by factors such as:<br>  - Number, size or quality of individual studies<br>  - Inconsistency of findings across studies<br>  - Limited generalizability<br>  - Lack of coherence in the chain of evidence<br>- As more information evolves, the magnitude or direction of observed effect could change. Change could be large enough to alter the conclusion. |
| Low Certainty | - Insufficient to assess effects on health outcomes because of:<br>  - Limited # or size of studies<br>  - Important flaws in study design or methods<br>  - Inconsistency across individual studies<br>  - Gaps in chain of evidence<br>  - Findings not generalizable to applicable population<br>  - Lack of information on important health outcomes<br>- More information may allow an estimation of effects on health outcomes |

* US Preventive Services Task Force: http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm

# Agency for Healthcare Research and Quality*

| Grades for Body of Evidence | Definition |
|---|---|
| **High** | **High Confidence** that evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of benefit |
| **Moderate** | **Moderate Confidence** that evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate. |
| **Low** | **Low confidence** that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate |
| **Insufficient** | Evidence either is unavailable or does not permit a conclusion |

*AHRQ: http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=328.

# Evidence Tables – Grading of the Evidence

## *Delfini*™ Validity & Usability Grading Scale

**Grade A: Useful**
The evidence is strong and appears sufficient to use in making health care decisions; it is both valid & useful.

**Grade "High to Low B": Possibly Useful**
The evidence is potentially strong and might be sufficient to use in making health care decisions.

- **High B:** Evidence is strong enough to conclude that results are probably valid & useful; however, results from multiple studies are inconsistent, or studies may have some (but not lethal) threats to validity.
- **Low B:** Evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that evidence cannot fully reach a high Grade B and uncertainty is not great enough to fully warrant a Grade U.

**Grade U: Uncertain**
There is sufficient uncertainty so that caution is urged regarding the use of the information in making health care decisions.

- Grade UV: Uncertain Validity – perceived methodological weaknesses
- Grade UU: Uncertain Usefulness - methodology appropriate but applicability of results uncertain
- Grade UVU: Uncertain Validity and Usefulness – combination of the above
- Grade UA: Uncertainty of Author – author uncertain about findings

**Grade X: Not Useful**
Studies are so poorly done and are so potentially misleading that the strongest caution is urged about their quality.

# Delfini – Overall Level of Evidence

| Classification | Definition |
|---|---|
| High | Evidence is conclusive that…. |
| Moderate | There is sufficient evidence to conclude… |
| Borderline | There is uncertainty due to low quality data that…. |
| Inconclusive | There is insufficient evidence to conclude that…. |

Reference: www.delfini.org. Accessed October 27,2009.

# Clinical / Cost Effectiveness

# Clinical / Cost Effectiveness

- Quantifying the Benefit Observed
- Clinically relevant magnitude of effect?
  - Based on reliable evidence
  - Quantify the benefit
- Value relative to other options or no treatment
  - Number needed to treat (NNT)
  - Number needed to harm (NNH)
- Generalizability of evidence

# Clinical/Cost Effectiveness & Safety Considerations/Limitations

- Rarely have gold standard
  - Double blind randomized controlled trial?
  - Specific harms defined in advance?
  - Was trial powered to detect harms?
  - P-values reported between drug and placebo?
- How many subjects were studied?
- How long were the trials?

# Good Models - Checklist

## Structure

- Is it a disease-progression model with appropriate time horizon?
- Are the treatment pathways relevant to the decision?
- Does it model usual 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?
  - Based on appropriate (trial or retrospective) evidence?

## Analysis/Summary

- 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?

# Pharmacoeconomic/Budget Models

| Elements | Critical Appraisal |
|---|---|
| Drugs compared & doses | Strengths and Weaknesses |
| Form of economic analysis | |
| Model Structure (if relevant) | |
| Time-horizon | |
| Perspective of the analysis | |
| Source for Efficacy & Safety data | |
| Sources for Utility weights (if relevant) | |
| Cost-Effectiveness Results | |
| Sensitivity Analysis | |

# Executive Summary - Completion

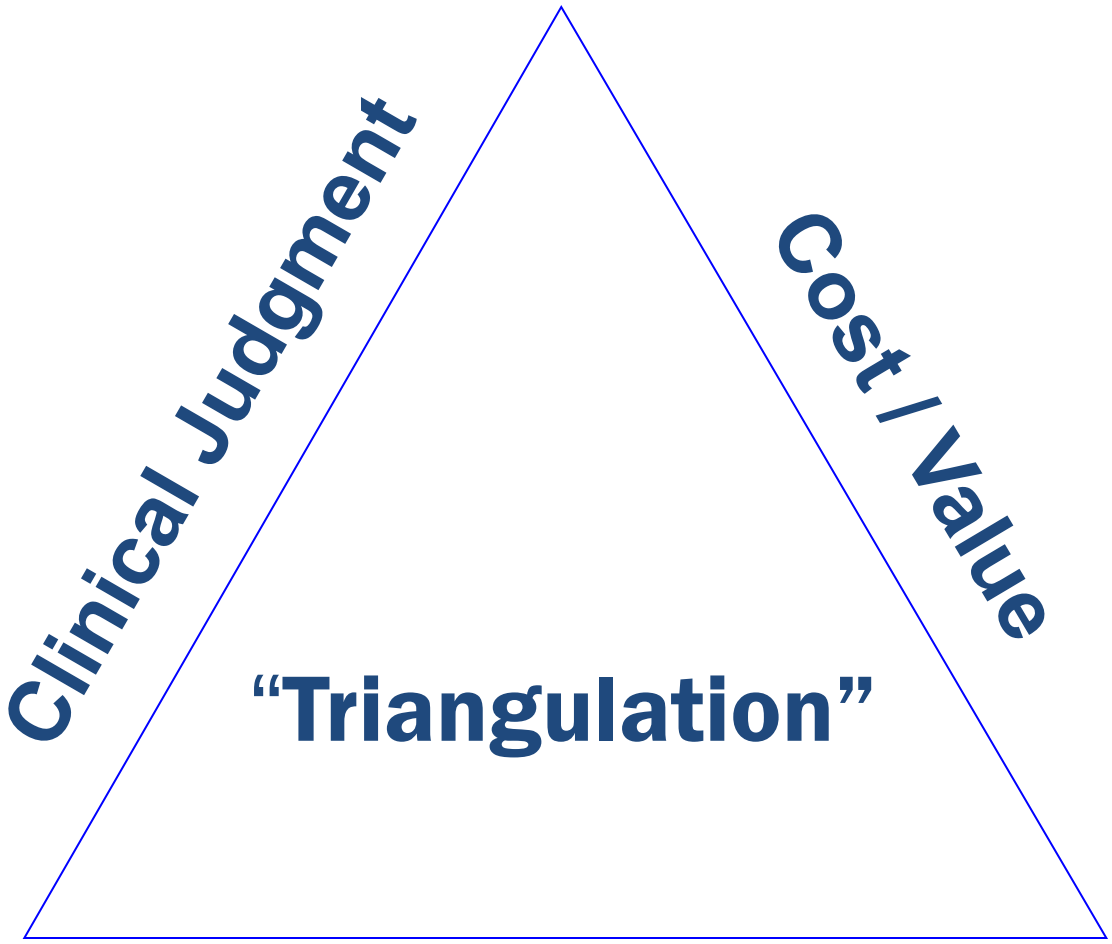
- Scope Defined
- Key Questions

- **Responses to Key Questions**
- **Value Proposition**
- **Recommendations**
- **Applicable Utilization Management Criteria**
  - **Prior Authorization**
  - **Quantity Limits**

# Executive Summary

- Key Questions Response
  - Answer the Question
  - Include statement describing overall quality for body of evidence
  - State/identify where there is evidence gap

# Value Proposition




## Evidence

# Value Proposition - Considerations

| Consideration | Description | Definitions |
|---|---|---|
| **Other Options** | **Established treatment options/ Track Record** | - FDA approved for an indication<br>- Standard of practice treatment guidelines, compendia or expert opinion (professional position statements) |
| **Safety** **(safer)** ↑ ↓ **(less safe)** | **Proven Safety Advantages** | Profound, proven safety advantages over established treatment<br>- Reliable, comparative safety data (safety= primary endpoint)<br>- "All or none" observational data demonstrating relative absence of serious or troublesome adverse effects. |
| | **Track record** | Post-marketing data:<br>- A minimum one year for acute, serious diseases<br>- Three years or more for chronic, preventative therapy<br>No serious, unusual safety concerns relative to other options |
| | **Safety concerns are manageable** | - Significant adverse effects are known, but identifiable/manageable<br>- Because of the nature of the treatment, patients will be monitored closely so potentially under recognized adverse effects may be able to be identified. |
| | **Safety concerns are significant and may outweigh benefit** | - Black Box Warnings<br>- Safety signals that risk of harms could potentially outweigh benefits;<br>- Safety concerns require significantly more monitoring than other available treatment options or may not be readily recognizable even with earnest monitoring. |
| **Cost** | **Costs Prior to Mfr Contracting** | Average estimated "amount allowed" (actual dollars paid to a pharmacy) for an average prescription. |
| | **Lowest Overall Total Cost** | Overall actual costs to the plan and members are considered after mfg discounts are applied to the medication in question or across a portfolio of drugs. |
| **Disease Characteristics** | **Multiple treatment options are needed** | Complex conditions that are known to often require multiple treatment options based on clinical experience (standard of practice), inter-patient variability, recognized quality standards, resistance-patterns, or pharmacogenomics. |
| | **Observable clinical benefit** | The impact of therapy is readily observable ("all or none response") and attributable to the medication. |
| **Standard of Care** | **"Standard of Care"** | There is not significant controversy regarding the effectiveness of the treatment. |
| **Impact on Clinical Burden** | **Remove or reduce clinical barriers to treatment** | The therapy must be recognized to remove or significantly reduce known barriers to care. |

# Recommendations

- Formulary vs Non-Formulary
- Prior Authorization
- Quantity Level Limits
- Timing for next review

# References

# Summary

| Area of Emphasis | Considerations |
|---|---|
| Introduction/Background | • Disease state.<br>• Pharmacotherapy<br>• What do we need to be aware of |
| Executive Summary | • Key questions and reason for review<br>• Scope clearly defined<br>• Responses include quality of evidence assesses<br>• Recommendations consistent with assessment; Practical |
| Evidence Tables | • Reporting of important elements<br>• Identify key trial strengths/weaknesses<br>• Critical appraisal and grading with supportive rationale |
| Clinical/Cost Effectiveness | • Tables populated<br>• Critical appraisal grades/Evidence Synthesis<br>• Rationale |
| Search Methodology | • Documented of complete search strategy<br>• Aligns with # of clinical trials assessed & references |
| Recommendations | • Consistent evidence synthesis & overall value proposition.<br>• Utilization management<br>• Practical application and rationale for prior authorization; quantity limits |

# Final Checklist

- Demonstrating Knowledge
- Tone/Objectivity
- Clear, Concise
- Reproducibility
- Grading of evidence (arbitrary or consistent)
- Quality of Evidence
- Practical / Clear responses & recommendations
- References – do citations add up

# Enhancement Opportunities

## Developing Your Drug Monograph

- Pipeline information
  - Medications in the category going generic?
  - New brand medications soon to be approved?
- European data
- Perspectives on real world data
- Utilization management, outside of PA
- Creation of own PE models?

# Resources

- Institute for Clinical and Economic Review: http://www.icer-review.org/index.php/medcare-icer-evidence-rating-682010.html
- AHRQ: http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=328.
- US Preventive Services Task Force: http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm
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