



Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses

ISPOR 14th Annual International Meeting
May 18, 2009
Orlando, FL, USA

Drug Cost Standards Task Force
4/27/2009

DEVELOPING STANDARDS FOR DRUG COSTS IN PHARMACOECONOMIC STUDIES

- The mission of this Task Force is to develop good research practices for using drug costs in pharmacoeconomic studies.
- The specific tasks were to develop and publish:
 - A review of current drug cost practices in pharmacoeconomics studies undertaken in the US and five major European markets. Questions to be addressed in this review are: (a) are drug costing methods adequately reported in published studies? (b) Does current practice vary greatly? (c) Are these variations important for study results?
 - A review of the conceptual and methodologic literature on drug prices and their relation to social opportunity costs, including commentaries on the recent literature on drug patent protection
 - A best practices for using drug costs in pharmacoeconomic studies document

Some of the Issues

- Drug costs are important parameters in PEC Studies - yet there is relatively little study of how drug costs are estimated, and whether the methods are consistent across studies in the same jurisdiction and whether the methods used are theoretically correct.
- The costs of the drug regimen involve not only the estimation of the drug price, but the impact of any wholesale discounts, pharmacy add on-costs and assumptions about wastage (owing to package or vial size).
- Market prices for drugs may not be good approximations for the social opportunity cost
- Issues of importing price controls, parallel trade and the globalization of the pharmaceutical market make these pricing issues even more relevant to best practice guidelines for pharmacoeconomics.

Leadership and Group Perspectives

- **Task Force Co-Chairs**
 - Joel W Hay PhD, Professor, Pharmaceutical Economics & Policy, University of Southern California, Los Angeles, CA, USA
 - Jim Smeeding RPh, MBA, President, JostaRx Group, Dallas, Texas, USA
- **European Subgroup**
 - Michael Drummond PhD, Professor of Health Economics, University of York, Heslington, York, UK
 - Anita Burrell MBA, Sr. Director, Global Health Outcomes, Sanofi-Aventis, Bridgewater, NJ, USA
- **Industry Subgroup**
 - Jack Mycka, Global President and CEO, MME LLC, Montclair, NJ, USA
- **International Subgroup**
 - Lizheng Shi PhD, MS, Assistant Professor, Tulane University, New Orleans, LA, USA
- **Managed Care Subgroup**
 - Ed Mansley PhD, Health Economist, Merck & Co., Whitehouse Station, NJ, USA
- **Medicaid Subgroup**
 - Brian Seal PhD, RPh, MBA, Senior-Director Health Outcomes Research, Sanofi-Aventis Pharmaceuticals, Bridgewater, NJ, USA
- **Medicare Subgroup**
 - C. Daniel Mullins PhD, Professor & Chair, Pharma Health Research Services, University of Maryland, School of Pharmacy, Baltimore, MD, USA
- **Patient/Societal Subgroup**
 - Leslie Wilson PhD, Associate Adjunct Professor, University of California, San Francisco, CA, USA
 - Lou Garrison PhD, Professor, University of Washington, Seattle, WA, USA



Managed Care Subgroup

- **Members:**
 - Edward C. Mansley PhD (Chair), Merck & Co., Inc.
 - Norman V. Carroll RPh, PhD, Virginia Commonwealth University
 - Kristina S. Chen MS, PharmD, Ovation Research Group
 - Nilay Shah PhD, Mayo Clinic
 - Catherine Tak Piech MBA, Ortho Biotech Products, L.P.



Drug Cost Standards Task Force
4/27/2009

Managed Care Issues and Perspective

- **Focus:**
 - Estimate cost to a US Managed Care Organization (MCO)
- **Primary Issues:**
 - Lack of transparency due to confidential pricing agreements
 - Published prices overstate cost to MCOs
 - Evolving pricing environment
 - e.g., AWP being discontinued & AMP to be made public

Estimation for Single Source Products

- Pharmacy reimbursement = AWP - % discount + dispensing fee
 - Typically AWP – 17% + \$1.73 at retail and AWP – 23% + \$0.00 for mail
- Deduct patient copay
 - Based on formulary tier
 - Typically \$24 to \$42 depending on tier
- Deduct manufacturer rebate
 - Proprietary information
 - Depends on formulary tier and competition

Estimation for Multi-Source Products

- Pharmacy reimbursement
 - Retail = MAC + dispensing fee
 - Mail order = AWP - %
- Deduct patient copay
 - Usually first tier copay
 - Typically \$10 for retail
- Usually no manufacturer rebate
- Lower of contract price or usual and customary
 - \$4 Wal-Mart generics

Estimation for Physician Administered Drugs

- Usually injected or infused products
- Medicare pays ASP + 6%
- Many managed care payers still base reimbursement on AWP - %
- Estimate of 68% to 85% of AWP may be reasonable for reimbursement rate

Managed Care Recommendations

- Make assumptions explicit:
 - Type of drug (Single or multi-source)
 - Acquisition method (Retail, Mail-order, Physician-Admin)
 - Formulary status & Patient co-pay
 - Pharmacy discount off of AWP & dispensing fee;
 - Rebate %
- Calculate MCO cost:
 - Negotiated Pharmacy Reimbursement
 - e.g., AWP-15% + \$2 dispensing fee for branded drug sold via retail
 - Less patient co-pay implied by formulary status & acq. method
 - e.g., -\$25 for a branded drug on 2nd tier purchased via retail
 - Less rebate amount going to MCO
 - e.g., -15% of catalog price for a 2nd tier drug with moderate competition

Managed Care Recommendations

- Keep current about which price (AWP, WAC, ASP, MAC) provides best basis for estimating MCO drug cost
- Estimates should include drug ingredient cost, dispensing fees, patient copays, rebates, and other price concessions
- Estimates should consider proportion of drug distributed at retail, through mail order, and by physician administration
- Sensitivity analyses should be used, especially for rebates
- Drugs that are, or will soon be, off-patent should include generic pricing in base case or sensitivity analyses
- ISPOR should maintain a website with updated recommendations for drug cost estimation for MCOs



Drug Cost Standards Task Force: Societal Perspective Subgroup Report

Report for Annual Meeting
May 18, 2009

Contributors/Acknowledgements

- Subgroup Members:
 - Louis P. Garrison PhD
 - Edward C. Mansley PhD
 - Thomas A. Abbott, III, PhD, MBA
 - Brian Bresnahan PhD
 - Joel W. Hay PhD
 - James Smeeding RPh, MBA
- Received comments from other Task Force members and ISPOR membership.

What is the “Societal Perspective”?

- It's a term that seems to have originated in pharmacoeconomics.
 - Related to economic concept of “social costs”
- U.S. Public Health Service “reference case” specifies three conditions:
 - 1) the inclusion of time costs
 - 2) the use of opportunity costs
 - 3) the use of community preferences

Current Practice

- In practice, very few, if any, cost-effectiveness analyses (CEAs) published since then have met all of these conditions, though many claim to have taken a societal perspective.
 - This usually means some attempt has been made to account for indirect costs related to productivity losses.
 - Few studies have attempted to estimate true opportunity costs of resources, using instead market prices for drugs as well as other inputs.
- Branded drug costs, in particular, have used actual acquisition rather than the much lower social opportunity costs that would reflect only short-run manufacturing, marketing, and distribution costs.

Limitations of Current Practice

- This approach focuses on **static** rather than **dynamic efficiency**
 - How to handle sunk costs of R&C—“first-copy” costs?
 - Patent-related monopoly power of branded drugs implies, by economic theory, that price will be higher and use lower than a competitive market.
 - The rationale for accepting this trade-off is that it will elicit a higher rate of innovation.
- National vs. Global Societal Perspective.
 - In general, information—including knowledge about how drugs work in the body—is a global public good. All citizens of the world can potentially benefit from pharmaceutical innovation.
 - This argues for consideration of “differential” pricing across countries.

Subgroup Recommendations to Task Force (1)

1. Raise awareness that few published CEAs produce a “reference case” with a truly societal perspective, particularly due to an overestimate of drug cost.
2. Consider proposing that the reference case embrace a new concept of a “restricted” or “limited” societal perspective, defined as meeting two of three conditions required for this perspective, viz., including indirect costs and using community preferences.
 - Or it may be easier and clearer to re-define this as a “health system perspective”, in contrast to the payer perspective or a true societal perspective.
3. Insist that analysts not claim that they are taking a true societal perspective when they are not.
4. Suggest that analysts *note* that using some fraction (e.g., 40%-60%) of net acquisition drug cost (i.e., cost net of discounts and rebates) would be an appropriate proxy for opportunity cost for a societal CEA for marketed products, but that limited societal or health systems perspective is more relevant and useful for current decision-makers.

Subgroup Recommendations to Task Force (2)

5. Distinguish between positive (or “behavioral”) CEAs—that explain or predict behavior—vs. normative CEAs—that prescribe decisions that would support an specified objective.
6. Emphasize that the payer perspective is a valid normative approach: i.e., advising payers on what they should do.
7. Encourage greater discussion within ISPOR of the role of pricing and reimbursement and the incentives for R&D.
8. Highlight the issue of static vs. dynamic efficiency.
9. Emphasize that drug prices for patented products are, in effect, rewards and incentives for innovation.
10. Begin discussion and design of value-based reimbursement systems.



Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: A Report of the ISPOR Drug Cost Task Force – Part IV: Medicare, Medicaid and Other US Government Payers Perspectives

C. Daniel Mullins PhD, Subgroup Chair
 Brian Seal PhD, Subgroup Chair
 Enrique Seoane-Vazquez PhD
 Jayashri Sankaranarayanan PhD
 Carl V. Asche PhD
 Ravishankar Jayadevappa PhD
 Won Chan Lee PhD
 Dorothy K. Romanus MSc
 Junling Wang PhD

Recommendation – Drug Cost

- We recommend the use of:
 - Actual acquisition cost (AAC) paid by each public program
 - incorporating any rebates or discounts, if feasible
 - when several programs are evaluated, weighted average of AAC
 - Average Sales Price (ASP) for studies of Medicare Part B drugs
 - Average Manufacturer Price (AMP) for studies of Medicaid fee-for-service outpatient drugs
 - If program-specific costs are not available, the economic evaluation of 340B programs should use Medicaid outpatient fee-for-service price net of pharmacy discounts and federal rebates to estimate the drug product cost.

Recommendation – Perspective

- Patient:
 - Out-of-pocket cost
 - Premiums
 - co-payments
 - Deductible
 - donut hole and/or above the catastrophic threshold
 - Dependent upon the type of plan of enrollee
- Private insurer administering the benefit:
 - AAC plus dispensing and administrative fees less estimated patient cost sharing
- Government:
 - All drug payments, regardless of source

Recommendation – Other

- Transparency
- Where drug is covered (medical v pharmacy)
- Limitations of Medicare Part D data in “early years”
- Oncology and other high cost drugs
- Inflation adjustment for NPV (CPI)
- Drug costs for BIA guidance is needed
- Sensitivity analysis is critical



Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: An Industry Perspective

Drug Cost Standards Task Force
4/27/2009

Thank You from the Authors

- To the ISPOR Board of Directors, the Drug Cost Good Research Practices Task Force, all of the participating reviewers and other interested parties from:
 - Jack M. Mycka - MME LLC, Montclair, NJ
 - Renato Dellamano PhD - ValueVector S.r.l., Milan, Italy
 - E.M. “Mick” Kolassa MBA, PhD - MME LLC, Montclair, NJ, USA
 - Michael Wonder BSc (Hons), Bpharm - Novartis Pharmaceuticals Australia, North Ryde, NSW, Australia
 - Sabyasachi Ghosh PhD, - The University of Oklahoma Health Sciences Center, Oklahoma City, OK
 - Joel W. Hay PhD - Department of Clinical Pharmacy, Pharmaceutical Economics & Policy, University of Southern California, Los Angeles, CA
 - James Smeeding RPH, MBA - JestaRx Group, Dallas, Texas

Report Objectives

- From an industry perspective, the drugs value matters more than its acquisition cost
 - Drug costs should be framed by actual and relevant prices
 - The goal of research should be to help decision-makers make informed judgments about "real world" use of medicines
- This report provides guidance and recommendations on how manufacturers should approach the use of "drug costs", since the term has different meanings
 - A medicine's **PRICE** is the monetary exchange component of a business transaction.
 - A medicine's **COST** includes its acquisition price, the price of ancillary and associated products and procedures, and the humanistic and societal costs that may be incurred with the use of the medicine.
 - A medicine's **VALUE** is the net of the clinical, economic, and humanistic effects of the use of the medicine.

Industry should always strive for:

1. A focus on drug value and not just cost
2. Credibility - i.e. correct and consistent prices
3. Transparency - by disclosing the prices and ensuring that they reflect the actual cost of the drug whenever possible
4. Providing actionable results that help customers comprehend the value offered by a drug therapy and to use products more efficiently and effectively

Report Conclusions

- In the best interests of all parties to understand and account for all costs and consequences of a bio/pharmaceutical's use
 - Benefits prescribers, consumers, payers / reimbursers, sellers, and manufacturers
- Concept is especially important because the use of models and other decision support mechanisms is growing in acceptance, and these models must be fully populated
- To help with appropriate decision making all parties share the goals of:
 - Transparency;
 - Consistency; and
 - Clear communication of costs and value



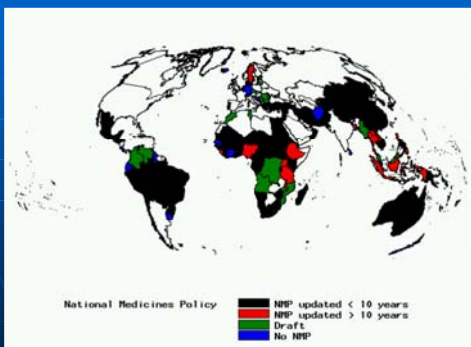
DCTF: An International Perspective: A Report of the ISPOR Drug Cost Task Force – Part VI

Lizheng Shi, PhD, MS,¹ Meredith Hodges, MPH,² Michael Drummond, PhD,³ Jeonghoon Ahn, PhD,⁴ Shu Chuen Li, PhD,⁵ Shanlian Hu, MD,⁶ Federico Augustovski, MD,⁷ Joel W. Hay, PhD,⁴ and Jim Smeeding, RPh, MBA⁸

- ¹ School of Public Health and Tropical Medicine, Tulane University, New Orleans, LA, USA
² School of Pharmacy, The University of Texas at Austin, Austin, TX, USA
³ University of York, Heslington, York, UK
⁴ School of Pharmacy, University of Southern California, Los Angeles, CA, USA
⁵ School of Biomedical Sciences, University of Newcastle, Callaghan, NSW 2308, Australia.
⁶ School of Public Health, Fudan University, Shanghai, China
⁷ Institute for Clinical Effectiveness and Health Policy (ICEHS), Argentina
⁸ JestaRx Group, Dallas, TX, USA

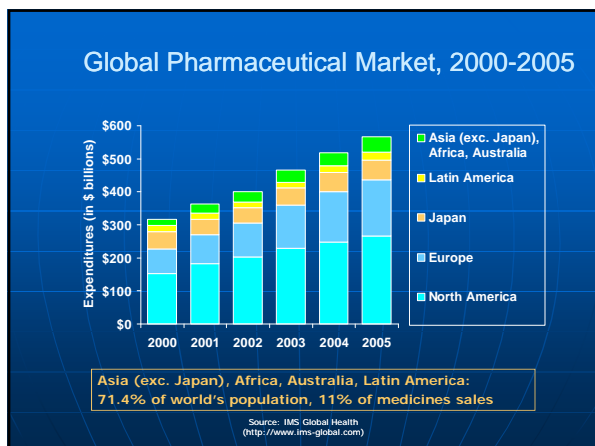
Drug Cost Standards Task Force
4/27/2009

Why International?



Objective

- We aim to review pharmaceutical price and cost issues from our subgroups' designated perspective (i.e., ex-US perspective).
- Two questions:
 - (1) How are drug prices set in your respective country?
 - (2) What are the sources of drug cost estimates used in pharmacoeconomic studies in your respective country and what are the key issues?



Panel of Experts

- Pharmaceutical prices in emerging markets
 - J Ahn (S Korea)
 - F Augustvoski (Argentinian/LA)
 - S Hu (China)
 - S Li (Australia)

Recommendations

- Drug units should be standardized in terms of volume of active ingredient, regardless of package and dosing strength variations across countries
- Drug costs should be measured in local currency per unit of active ingredient and should be converted to other currencies using sensitivity analyses of PPP and exchange rate, whichever is more appropriate
- When using drug prices from different years, the consumer price index for the local currency should be applied before the PPP and/or exchange rate conversion

Recommendations (Cont.)

- A modified social perspective should be employed where drug costs should reflect the best pricing available to the government or other large third-party payers in the country
- Drug costs should be kept as transparent as possible
- The type of drug pricing (value-based, reference pricing, market pricing, Maximum Allowable Cost, etc.) should be clearly identified in the pharmacoeconomic application
- ISPOR should maintain a website indicating how drug prices are determined in each country and region, to be updated periodically by the DCTF



ISPOR Drug Cost Task Force: Overview and Summary

Joel W. Hay PhD
Professor, Pharmaceutical Economics & Policy
University of Southern California

Orlando, FL
May 18, 2009

Drug Cost Measurement

- The assignment of prices or costs to pharmaceuticals is crucial to results derived from pharmacoeconomic cost effectiveness analyses (CEAs).
- Pharmacoeconomic guidelines are available in the literature and have been promulgated in many countries,
- Guidelines are either vague or silent about how drug costs should be established or measured.

Drug Cost Measurement

- Particularly problematic in pharmacoeconomic studies done from the "societal" perspective.
- The "cost" of a brand name drug is not a true economic cost but also transfer payments from some members of society (patients and third party payers) to other members of society (pharmaceutical manufacturer stockholders) in large part as a reward for biomedical innovation.

Results

- Drug cost measurements should be fully transparent and reflect the net payment value most relevant to the user.
- For brand name drugs from a societal perspective either i) CEA analysts use a cost that more accurately reflects true societal drug costs (e.g., 20%-60% of average sales price), or if that is too unrealistic, ii) refer to their analyses as from a "modified societal perspective".

Results

- CEAs done from a payer perspective should use drug prices actually paid by the relevant payer net of all rebates, co-pays or other adjustments.
- When such price adjustments are confidential, the analyst should apply a typical or average discount that preserves this confidentiality.
- CEAs should account for inflation and currency exchange using appropriate indices

Conclusions

- Drug transactions prices not only ration current use of medication but also ration future biomedical R&D.
- CEA researchers should tailor the appropriate measure of drug costs to the analytic perspective, maintain clarity and transparency on drug cost measurement and report the sensitivity of CEA results to reasonable drug cost measurement alternatives.



Thanks!
Questions?