Evidence-based Health Policies for Medical Devices and Diagnostics in Asia

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Outline of Presentation
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- Why Evidence-based Health Policy?
- Evidence-based Economic Evaluation in Health Technology Assessment
- Methods of Health Economic Evaluation
- Evaluation of Health Technologies: Critical Guidelines
- Some Issues in Evidence-based Policies for Health Technology Assessment
- Conclusions

Introduction: Why Evidence-based Health Policy-making?
Rising health care costs ➔ focus on doctors, hospitals, medical technology and drugs
Health care financing and cost-containment ➔ payment and reimbursement systems
Managed care ➔ gatekeeping, clinical guidelines, utilization reviews, disease management (drugs)
Pharmacoeconomics ➔ rational drug use, drug reference pricing, pharmacoeconomic evaluation
Outcomes research ➔ evidence-based medicine, quality assurance, health technology assessment

Evolution of Evidence-based Health Technology Assessment
Generally covers Health Technologies, including Pharmaceuticals, Diagnostics & Medical Devices:
- Technical Quality
- Efficacy
- Safety
- Quality of life
- Cost-benefit
- Cost-effectiveness

Development of Major Health Technology Assessment Agencies
Leading Western Countries
- 1972 OTA USA
- 1982 CEDIT France
- 1984 CMT Sweden
- 1987 TNO Holland
- 1991 CAHTA Spain
- 1992 TA-SWISS Switz
- 1996 NCCHTA UK
- 1997 DACEHTA Denmark
- 1998 SMMNCHTA Norway
- 1999 NICE UK
- 2000 DAHTA Germany
- 2006 EUnetHTA EU

Leading Asian Economies
- 1985 ISTAHC
- 1990's ISTAHC/DC Thailand
- 1995 HTA Unit Malaysia
- 1999 BHDT Phil
- 2000 HSA Spore
- 2004 PMDA Japan
- 2006 HITAP Thailand
- 2007 NHATAC Korea
- 2007 CDE-HTA Taiwan
- 2008 HTA&CPGC Malaysia

Policy Issues in the Utilization of New Health Technologies
- Clinical evidence of efficacy and effectiveness
- Management/administrative issues regarding production, distribution, quality control and service development
- Economic aspects including pricing & financing, cost-efficiency and cost-effectiveness
- Ethical, legal & social issues of new technology – access, costs and quality
Economic Issues in Evidence-based Health Technology Assessment

- Does it work? Is it safe? (efficacy and safety)
- Does it pay off? (cost versus benefit)
- What is most effective and at least cost? (cost versus effectiveness)
- What impact on the quality of life (utility) and at what cost? (cost versus utility)

Easier said than done?

- How do we conduct economic evaluation?
- How do we cost health technologies?
- How do we judge their effectiveness?
- There are several approaches:
  1. Close your eyes and hope for the best
  2. Plan and manage on the basis of evidence

1. Close your eyes and hope for the best …..

- Blissful ignorance, strong traditions and powerful support can go a long way …..
  but not always.
- How to know whether the best outcome has been achieved, or a different strategy might not be better?

2. Plan and manage programs on the basis of evidence

- What desired objectives and means to be achieved?
- What best practices that can be adopted?
- What available data and information as proof?

Hierarchies of Evidence

- meta-analyses
- systematic reviews
- randomised trials
- uncontrolled trials
- quasi-experiments
- simulation models
- case-studies

Evidence-based Evaluation in Health Care – Economic Criteria

- Efficiency
  - Allocative (doing the right things)
  - Technical (doing the right things right)
- Cost-effectiveness
  What outcomes at what cost?
- Equity (distribution)
  Who benefits? Who pays?
Objectives of Economic Evaluation in Health Care Assessment

- To choose the most optimum alternatives for resource use (allocative efficiency)
- To maximise service outputs with minimum resource inputs (technical efficiency)
- To maximise benefit or effectiveness in outcomes with minimum costs (cost-effectiveness)

Are uses of health technologies efficient and cost-effective?

- May not be efficient and effective
- Even when efficient, may not be effective
- Even when effective, may not be cost-effective
- Most have not been evaluated for efficiency and cost-effectiveness

Economic Evaluation Methods for Health Technology Assessment

- Cost minimization analysis
- Cost-benefit analysis (CBA)
- Cost-effectiveness analysis (CEA)
- Cost-utility analysis (CUA)

Common Methods of Health Economic Evaluation

- Cost-Benefit Analysis
  - $ Benefits / $ Costs
- Cost-Effectiveness Analysis
  - Health Effects / $ Costs
- Cost-Utility Analysis
  - Effects in Quality Adjusted Life-Years / $ Costs

Evidence in Health Technologies – Measuring Costs and Benefits

- **Direct Costs**
  - Costs of Health Technologies
  - Operating Expenditure (Wages, Rents, Utilities, etc)
  - Others (Fees, Subsidies, Interest, Donations, etc)
- **Indirect Costs**
  - Productivity Losses (Work Absence, Labour Costs)
  - Time Costs (Travel, Waiting, etc)
  - Others (Storage, Packaging, Distribution, Wastage, etc)
- **Intangible Costs**
  - Pain/Suffering, Stigma, Loss of Freedom, Side-effects

Evidence in Health Technologies – Measuring Costs and Benefits

- **Direct Benefits**
  - Health (Physical/Psycho-Social) Functions
  - Behavioural Changes
  - Quality of Life
- **Indirect Benefits**
  - Savings in Expenditure (Medical, Social Care)
  - Productivity Gains (Labour Cost-savings)
- **Intangible Benefits**
  - Morale, Self-esteem, Independence, etc
Economic Evaluation of Health Technologies: Critical Guidelines

- Objectives
- Options – alternative strategies/treatment choices
- Costing data – valuation of all relevant costs
- Medical data – reliable epidemiological, demographic and clinical evidence
- Benefit measurement – valuation of all benefits
- Risk and uncertainty – sensitivity ranges, differential timing, distribution of cost & benefits
- Economic appraisal and decision-making

Health Economic Evaluation: Checklist for Assessment

- Was a well-defined question posed in answerable form?
- Was a comprehensive description of the competing alternatives given? (Can you tell who? Did what? To whom? Where? How often?)
- Was there evidence that program effectiveness has been established?
- Were all important and relevant costs and consequences measured accurately in appropriate physical units (eg. hours of nursing time, number of physician visits, lost days, gained life-years?)
- Were costs and consequences valued credibly?
- Were costs and consequences adjusted for differential timing?
- Was an incremental analysis of costs and consequences of alternatives performed?
- Was a sensitivity analysis performed?
- Did the presentation and discussion of study results include issues of concern to users?

(Source: Drummond et al)

Economic Evaluation Guidelines: Summary of Canadian guidelines

- Target audience
- Timing of studies
- Management of studies
- Incremental and total analysis
- Analytic technique
- Indications
- Treatment comparator
- Perspective
- Analytic horizon
- Efficacy versus effectiveness
- Health-related quality of life
- Outcomes for cost-utility analysis
- Outcomes for cost-benefit analysis
- Source of preferences
- Equity
- Discounting future outcomes
- Cost identification
- Cost measurement
- Cost valuation
- Standard costs
- Discounting future costs
- Dealing with uncertainty
- Reporting results
- Disclosure of relationships

Economic Evaluation Guidelines: Data for approval of new technology

Voluntary submission by industry in Japan
- Category (relative effectiveness & tolerability)
- Final outcome
- Intermediate outcome
- Type of analysis
- Target population
- Time horizon
- Alternatives included in analysis
- Results: cost calculation and comparison

(Source: Ministry of Health & Welfare, Japan)

Issues in Economic Evaluation of New Medical Technologies

- Lack of empirical scientific evidence in the literature due to newness and initial costs
- Although potentially beneficial, most are only suggestive in cost-effectiveness
- Many studies are flawed in terms of their assumptions, data and methodology
- This calls for more rigorous research in evaluation of healthcare technologies

Some Issues for Evidence-based Health Technology Assessment

- Study design
- Quality of data
- Causality
- Time-lag effects
- Outcomes measurement
- Ethical issues
Conclusions: Evidence-based health economic evaluation

- Economic and financing policy issues are increasingly recognised as important in medicine and healthcare
- Economic evaluation methods can be employed in medical care and health technology assessment
- Common methods include cost-benefit analysis, cost-effectiveness analysis and cost-utility analysis

Conclusions: Evaluation of health technologies

- Economic evaluation is necessary to clarify values and to allocate resources based on evidence
- Evaluation is an aid to health policy-making and management, given the scarcity of resources
- Efficiency and cost-effectiveness are desired objectives in health technology assessment, despite inherent problems of measurement

Conclusions: The Way Ahead for Asian Countries

- Need for more evidence-based policies for health technologies in Asia
- HTA not panacea but to provide guidance
- Towards an Asian HTA Network?
  Aims of regional collaboration in Asia:
  - Standardization of methods
  - Sharing of data and evidence
  - Develop common training/research
  - Comparative benchmarking
  - Adoption & adaptation of best practices
  - Ultimately to raise the standards of care and health of the population

Thank you for your attention