ABSTRACT

OBJECTIVE: To describe research methods and key issues in the HTA process in Europe.

METHODS: Representative from HTA bodies globally were recruited by members of the ISPOR HTA SIG Methods and Principles Working Group to complete a 45-minute on-line survey consisting of 48 items within 4 topics related to (1) organizational information and process, (2) primary HTA methodologies and importance of attributes, (3) HTA application and dissemination, and (4) quality of HTA including key issues. Data were reported for Europe.

RESULTS: The survey was completed by 11 European countries including Austria, Denmark, France, Germany, Hungary, Italy, Netherlands, Portugal, Spain, Sweden, and Switzerland. Top issues in HTAs were evaluated included impact on patient outcomes, potential cost, and prevalence of the condition. The most common methodologies used were economic analyses, systematic reviews & meta-analyses, clinical trials, modeling, and comparative analysis. The most important attributes (in order) were effectiveness, efficacy, safety, cost-effectiveness, and budget impact. While quality of life was assessed by European respondents, it was not listed as an attribute of high importance. Only 24% repeated the assessment at regular intervals. For 50%, a different organization makes the final decision on coverage, only partially relying on the report. The most common educational background for decision-makers were physicians, specialists. Stakeholders are allowed to review the report and are involved in assessments >50% of the time and in the final decisions ~35% of the time. Key issues/trends included early assessment of technologies with mechanisms for conditional coverage, increasing regional interest in HTA, reassessment/horizon scanning, and link between theory and practice in HTA.

CONCLUSION: This survey of representatives within HTA and reimbursement bodies provides current insight into the state of HTA research methods in Europe. Future research could update the results to specifically address Eastern European countries, Asia, and other emerging markets.

INTRODUCTION

- The research methods/principles Working Group of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)/Health Technology Assessment (HTA) Special Interest Group (SIG) conducted a survey of international HTA and reimbursement bodies to:
  - Assess methodologies used in HTA and health care reimbursement policies, and
  - Identify important aspects of current research methods used in current research methods.

- Our objective was to highlight the findings from 11 European countries (out of 16 countries total) that responded to the survey.

RESULTS

- An on-line survey was developed consisting of 48 items within 4 topics related to:
  1. organizational information and process,
  2. primary HTA methodologies and importance of attributes,
  3. HTA application and dissemination, and
  4. quality of HTA including key issues.

- For research methodology questions, responses were organized by country (Albania, Armenia, Austria, Belarus, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Russia, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, Uruguay, and Uzbekistan) as well as the country and the method/issue.

- The full survey can be reviewed online at http://www.ispor.org/HTA/EDU/HTA_SURVEY.html.

- Seventeen HTA and/or reimbursement bodies from 27 countries responded.

- Respondents from targeted countries were recruited from HTA contact lists residing at ISPOR as well as contacts available through working group members in various countries.

- Efforts were made to invite key individuals within the organizations who would be knowledgeable and senior enough to provide insight to the survey questions. Respondents were not paid.

- Table 1 shows the European countries and organizations that responded.

METHODS

<table>
<thead>
<tr>
<th>Table 1. European Survey Respondents</th>
</tr>
</thead>
</table>

- Respondents were asked whether international (as opposed to country-specific) data was available or used in the assessment. 42% of respondents indicated that country-specific data were accepted by more than 90% of respondents. However, reasons for utilization and cost data is more likely required to be country-specific.

- Table 2 provides an overview of the use of international versus country-specific data for survey respondents who answered the question.

RESULTS (CON’T)

- The most common attributes assessed in HTA processes are effectiveness, safety, costs, and cost-effectiveness across technologies and evolutionary stages. Figure 2 presents the frequency and relative importance of the attributes assessed, and shows that the attributes are valued equally.

- Figure 3 features the application and use of HTA.

- Figure 4 shows the characteristics of HTA organization and process.

- Figure 5 illustrates the key methodology trends and issues facing HTA bodies.

- Figure 6 shows the generalizability and transferability of international data to economic analyses.

- Table 3 provides an overview of the use of international versus country-specific data for survey respondents who answered the question.

- Table 4 provides an overview of the use of international versus country-specific data for survey respondents who answered the question.

CONCLUSIONS

- These results within European HTA and reimbursement bodies provide current insight into the state of HTA research methods and applications in Europe.

- The results suggest that HTA, using evidence-based medicines, will continue to be rapidly evolving area and in need of standardization research methods and principles to guide assessment and decision-making among drug companies, medical decision, and emerging technologies.

- Future research could expand the results to specifically address Eastern European countries, Asia, and other emerging markets.

ACKNOWLEDGEMENTS

- The authors would like to thank the ISPOR HTA SIG Research Methods and Principles Working Group.

- The working group would like to thank

- Jennifer Stephens, PharmD, Bonnie Handke, RN, MBA, and Jalpa Doshi, PhD on behalf of the ISPOR HTA SIG Research Methods & Principles Working Group.

- Pharmmer International, Bethesda, MD, USA; Medtronic, Inc, Minneapolis, MN, USA; University of Pennsylvania, Philadelphia, PA, USA.

Presented at the 13th Annual ISPOR European Congress, Nov 6-9, 2010, Prague, Czech Republic. #PHP102