The Expanding Use of Health Outcomes and Economic Evaluations in Clinical Publications: An Example From Cardiovascular Disease Literature

Shelley Reich,[a] Bagi Ravishankar,[b] Nes Elipenahli,[b] Sheelah Smith[c]

[a]PAREXEL MedCom, Hackensack, NJ, USA; [b]PAREXEL MMS, a PAREXEL company, Hackensack, NJ, USA; [c]PAREXEL MMS, a PAREXEL company, Worthing, UK

ABSTRACT

OBJECTIVES: Multiple forces drive the inclusion of health outcomes and economic evaluations (HOEE) in research to demonstrate the value of health technology. Research in chronic diseases, including cardiovascular disease (CVD), uses a host of HOEE terminologies. To gain an insight into the usage of HOEE in clinical publications pertaining to the treatment and risk factor prevention of CVD, the present study focused on hypertension (HTN), a major risk factor for CVD. The purpose of this research was to evaluate literature published from January 1, 1999-December 31, 2009 that utilized HOEE terminology in clinical studies relating to HTN treatment in CVD versus CVD risk factor prevention in adults, and identify the changing trends in the utilization of HOEE terminology in selected studies. **RESEARCH DESIGN AND METHODS:** The search strategy consisted of a PubMed database search, using search terms for HTN treatment in CVD and primary prevention of CVD risk factors. **RESULTS:** Review of published literature over an 11-year period showed only 26% of the published articles had health outcomes specific terminology relating to HTN treatment of which less than 10% had data relating to HOEE terminology. Notably, utilization of health outcomes terminology was greater in clinical publications relating to HTN treatment compared with CVD risk factor prevention (26% vs 19%, respectively). **CONCLUSIONS:** Although there is a trend toward increased utilization of health outcomes terminology in core clinical journals pertaining to the treatment and risk factor prevention of chronic disease conditions such as CVD, the low occurrence of HOEE terminologies suggest that there is a greater need for consistent usage of terminologies in the measure of health outcomes and economic evaluations.

Background

- Multiple forces have driven the inclusion of health outcomes and economic evaluations (HOEE) in clinical research to demonstrate the value of health technology. These include:
  - — Increased regulatory and payer demand for health outcomes and cost-effectiveness analyses to determine the value of care
  - — Escalating resource utilization and drug costs
  - — Increased patient demand for improved quality and access to care
- To evaluate the usage of HOEE terminology in clinical literature, we chose cardiovascular disease (CVD) and hypertension (HTN) as examples:
  - — CVD is a major health problem in the United States and worldwide, and HTN is an important risk factor
  - — Chronic disease-state research, including CVD, uses a host of HOEE terminologies[1]
  - — Significant health care resources are used in HTN treatment and CVD risk factor prevention[2]
- HOEE terminology varies by stakeholder perspective.

Burden of CVD[3]

- Affects 1 in 3 adults in the US
- Leading cause of death in the US
- Imposes great strain on health care spending
  - — 2010 cost of care to exceed $324 billion
    - Additional $137 billion in lost productivity due to premature death, work absences, and disability

Objectives

- To evaluate the clinical literature published from January 1, 1999 to December 31, 2009 that utilized HOEE terminology in studies relating to HTN treatment in CVD versus CVD risk factor prevention in adults.
- To identify the changing trends in the utilization of HOEE terminology in selected studies.
- To identify and compare HOEE terminologies used across selected studies.

Research Design and Methods

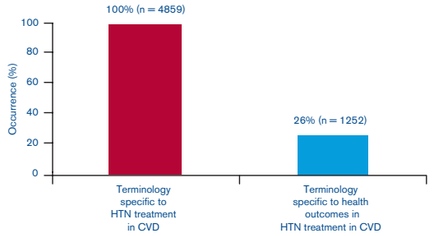
- The search strategy consisted of a PubMed (Medline and Central) database search using a combination of free text and MeSH (Medical Subject Heading).[4,5]
- First-level search terms for HTN treatment in CVD were: *cardiovascular disease*, *hypertension*, *treatment*.
- Second-level search terms for health outcomes in studies associated with HTN treatment in CVD were: *outcomes research*, *economic evaluation*.
  - — Search terms associated with economic evaluations in HTN treatment in CVD were: *cost-effectiveness*, *cost benefit*, *direct and indirect costs*, *quality of life*, *quality-adjusted life years (QALY)*, *United States*
- First-level search terms for primary prevention of CVD risk factors were: *cardiovascular disease*, *risk factors*, *primary prevention*.
- Second-level and HOEE search terms for primary prevention of CVD risk factors were as described above for HTN treatment.
- Search was refined by including the following limitations: *Years (01-1-1999 to 12-31-2009)*, *core clinical journals*, *humans*, *English language*, *adults aged > 19 years*.

Results

HTN Treatment in CVD

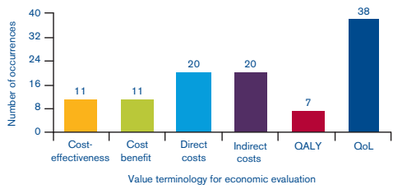
- Disease-specific terminology associated with HTN treatment in CVD:
  - — A first-level search for HTN treatment in CVD identified 4859 articles during the study period (Figure 1)
- Health outcomes-specific terminology in studies associated with HTN treatment in CVD:
  - — A second-level screening of the initial search results identified 1252 (26%) articles that included health outcomes terminology (Figure 1)

Figure 1: Use of HOEE terminology in publications relating to HTN treatment in CVD, January 1, 1999 to December 31, 2009



  - — HOEE-specific terminology associated with HTN treatment in CVD:
    - Screening of second-level search data identified 120 (9.6%) articles that included HOEE terminology
    - Of the 120 articles, 12 (10%) originated in the United States
    - Commonly encountered HOEE terminology in the above search results were: *cost-effectiveness*, *cost benefit*, *quality of life (QoL)*, *quality-adjusted life years (QALY)*, *direct costs*, *indirect costs* (Figure 2)

Figure 2: Health outcome value terminologies used in clinical publications relating to HTN treatment in CVD

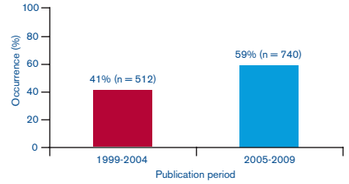


- The low occurrence of these value terminologies suggests that a large proportion of the studies may not have included economic evaluation, or may have used inconsistent terminologies

Trend Toward Increasing Use of Health Outcomes Terminology in Clinical Publications

- 59% of the articles that included health outcomes terminology relating to HTN treatment in CVD were published in the last 5 years (Figure 3).

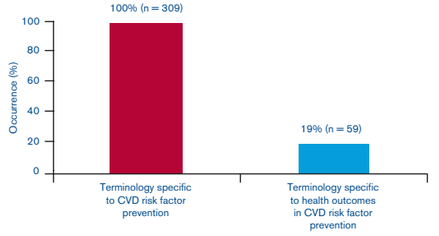
Figure 3: Increasing utilization of health outcomes terminology in studies relating to HTN treatment in CVD



CVD Risk Factor Prevention

- A first-level search for *CVD*, *risk factors*, and *primary prevention* identified 309 articles during the study period (Figure 4).
- A second-level screening of the initial results identified 59 articles (19%) that included health outcomes terminology.
  - — Screening of second-level search data identified 12 articles (20%) that included HOEE terminology

Figure 4: Use of HOEE terminology in publications relating to CVD risk factor prevention, January 1, 1999 to December 31, 2009



Comparison of HOEE Terminology: HTN Treatment in CVD Versus CVD Risk Factor Prevention

- Utilization of health outcomes terminology was greater in clinical publications relating to HTN treatment in CVD compared with CVD risk factor prevention (26% vs 19%, respectively).
  - — Among those studies that utilized health outcomes, usage of terminology specific to economic evaluations was greater in studies relating to CVD risk factor prevention compared with HTN treatment (20% vs 9.6%, respectively)

Gaps in evaluation of literature

- There is a paucity of data examining the impact of CVD risk factor prevention on future health care spending
- To help decision-makers assess the economic impact of CVD risk factor prevention, future studies should employ standardized methods to produce meaningful metrics[6]

Limitation

- The search strategy employed may have affected the quantity and type of articles identified.

CONCLUSIONS

- Use of health outcomes terminology in core clinical journals is on the rise; however, only 26% of the journal articles relating to HTN treatment in CVD over an 11-year period included terminology relating to health outcomes and less than 10% of those included HOEE, suggesting that many of the studies published in core clinical journals may have used inconsistent terminology to measure health outcomes and perform economic evaluations.
- Use of health outcomes terminology was more prevalent in HTN treatment in CVD versus CVD risk factor prevention, suggesting that health outcomes in treatment studies may have included clinical and humanistic outcomes in addition to economic outcomes.
  - – Given that CVD risk factor prevention is not limited to HTN treatment but also encompasses other areas of disease management interventions, greater usage of economic evaluation terminology in health outcomes in CVD risk factor prevention would be expected

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