

HEALTH CARE USE & POLICY STUDIES – Patient Registries & Post-Marketing Studies

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REGISTRY OF PATIENT REGISTRIES (ROPR): PURPOSE, DESIGN AND EARLY EXPERIENCE

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OBJECTIVES: Patient registries are important tools for health care research. The goal of this project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), is to design and implement the Registry of Patient Registries (RoPR), the first searchable, public database designed specifically to provide information about registries. The RoPR is integrated with ClinicalTrials.gov, supports research collaboration, reduces redundancy, and improves transparency in observational clinical research. **METHODS:** The RoPR consists of a registration system and a public search Web site. The registration system collects over forty data elements which define a registry profile. The search site serves as a central listing of registries and includes options to filter for relevant profiles. RoPR registration is integrated with ClinicalTrials.gov: users registering a study on ClinicalTrials.gov who designate it as a patient registry are presented with a pop-up window displaying the RoPR registration system. Users complete and submit the requested data elements, creating a registry profile in the RoPR that is linked to the ClinicalTrials.gov listing through a unique identifier, the NCT ID. **RESULTS:** The RoPR was launched on December 1, 2012. As of January 11, 2013, 54 new patient registries are registered on ClinicalTrials.gov. Twelve of these have been fully published in the RoPR, representing 21 different condition areas. Most are classified as disease/disorder/condition (67%), drug (33%), and/or procedure (33%) registries. Reported registry purposes include effectiveness (50%), safety or harm (42%), natural history of disease (42%) and clinical practice assessment (33%). A total of 67% of registry sponsors are open to being contacted for collaboration, data access, investigator or patient participation, or for information requests. **CONCLUSIONS:** The RoPR is a searchable Web site used by registry sponsors to publish information about registries and by members of the public to search for information about existing registries. Integration with ClinicalTrials.gov presents a user-friendly interface to encourage registration.

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POST-MARKETING REQUIREMENTS: AN OVERVIEW OF THE THERAPEUTIC AREAS TARGETED BY THE EMA AND THE FDA

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OBJECTIVES: Post-marketing requirements (PMRs) include studies and clinical trials that sponsors are required to conduct under one or more statutes or regulations. The objective of this research is to identify which therapeutic areas, and within these areas, which therapeutic indications have been subjected to the highest number of PMRs from the Food and Drug Administration (FDA, USA) and the European Medicines Agency (EMA, EU). **METHODS:** The Post-Marketing Requirements Database was used to explore requirements for post-approval studies published on the websites of the FDA and the EMA since 2005. The search was performed on January 2, 2013. **RESULTS:** The therapeutic area for which the EMA required the highest number of studies was “factors influencing health status and contact with health services” (n=36) for the indication “prophylaxis of influenza in a pandemic situation” (n=36). Within this indication, ten different products were concerned with Pandemrix and Cepalvan being the products with the highest number of studies requested (n=6 for each product). In comparison, the FDA had requested only 27 studies for the same therapeutic area, and neither Pandemrix nor Cepalvan were approved in the USA. The area for which the FDA requested the highest number of studies was “endocrine, nutritional and metabolic diseases” (n=80), and within this area, the more populated indication was “diabetes mellitus”(n=41). Within this indication, Onglyza, Byetta and Victoza were the products with the highest number of studies requested (n=4, 5, and 6 respectively). In comparison, the EMA had requested only 14 studies for the same area. Onglyza, Byetta and Victoza were approved in Europe but not subjected to PMRs. **CONCLUSIONS:** This brief review showed discrepancies in PMRs between the FDA and the EMA. More research is needed to explain these differences.

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CHALLENGES IN DEVELOPING AN OUTCOME MEASURES FRAMEWORK FOR PATIENT REGISTRIES

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OBJECTIVES: Patient registries are important tools for health care research, but variations in definitions of outcome measures and their data elements make it difficult to compare or link data from different registries. Standardizing outcome measures would help identify registries capturing similar information and promote collaboration, reduce redundancy, and improve efficiencies of new registries using standardized data elements. The goal of this project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), is to develop a prototype of an Outcome Measures Framework (OMF) for use within the Registry of Patient Registries (RoPR) to collate and characterize the outcome measures currently used in patient registries. The long-term objective of the OMF is to

support efforts to standardize outcome measures. **METHODS:** Stakeholders from a broad range of organizations (e.g., clinicians, registry sponsors, researchers, government agencies) were identified and invited to participate in a series of meetings to gather and refine the design requirements for the OMF. Requirements were also refined through user acceptance testing. Over 110 individuals participated in OMF design activities. **RESULTS:** Stakeholders identified several challenges necessary to address in designing the OMF. They want a framework that 1) distinguishes between outcome measures collected on a patient level and those collected or calculated on a population level; 2) describes the frequency or timeframe in which a particular outcome measure is collected; 3) identifies outcome measures that are clinically equivalent to each other and clearly displays this information; and 4) minimizes user burden, since participation in the RoPR is currently voluntary. **CONCLUSIONS:** By using a design process that solicited the opinions of a wide variety of stakeholders, several challenges were identified. These challenges were addressed in the design of the OMF prototype, and will require further clarification if the OMF is developed and implemented into a system such as the RoPR.

HEALTH CARE USE & POLICY STUDIES – Population Health

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RELATIVE IMPACT OF MULTIMORBID CHRONIC CONDITIONS ON HEALTH-RELATED QUALITY OF LIFE MEASURED BY THE EQ-5D

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OBJECTIVES: Multimorbidity has a negative impact on health-related quality of life (HRQL). Previous studies included only a limited number of frequent conditions and their combinations. The aim of this study was to analyse the relative impact of a large number of chronic conditions on overall HRQL in multimorbid patients. **METHODS:** This analysis is based on the MultiCare Cohort study, a multicenter, prospective cohort study of 3189 multimorbid primary care patients aged 65 to 85. The impact of 45 conditions on HRQL was analysed. The severity of the conditions was rated between 0 (insignificant) and 4 (very severe). The EQ-5D, a questionnaire consisting of 5 items (dimensions) and a visual-analogue-scale (EQ VAS) was employed to measure HRQL. Data were analyzed using multiple ordinary least squares regression and multiple logistic regression. **RESULTS:** Multimorbidity measured by a weighted count score was significantly associated with lower overall HRQL (EQ VAS). Parkinson's disease had the most pronounced negative effect on overall HRQL (EQ VAS), followed by rheuma, depression, obesity and cardiac insufficiency. With regard to the individual EQ-5D dimensions, depression and obesity affected all five dimensions of the EQ-5D negatively except for the dimension anxiety/depression. Obesity had a positive effect on this dimension. Cardiac insufficiency was associated with three dimensions. The dimensions 'self-care' and 'usual activities' were most strongly affected by Parkinson's disease. **CONCLUSIONS:** The overall HRQL of multimorbid patients decreases with an increasing count and severity of conditions. Parkinson's disease, depression and obesity have the strongest impact on health-related quality of life.

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SELF-RATED HEALTH MEASURES WITH DIFFERENT REFERENCE POINTS AND MORTALITY

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OBJECTIVES: Self-rated health (SRH) has been shown to be a good predictor of mortality. However, there are mixed findings of the association between mortality and SRH measures with different reference points (i.e., with respect to either global or peer age group). This study assessed whether SRH measures with different reference frames influence the association of the SRH and mortality in old population. **METHODS:** We analyzed data from 2000-2005 Medical Expenditure Panel Survey (MEPS) respondents in Panel 5-7, aged 60 or over, linked to the National Death Index (NDI) through 2006. To test whether the SRH measures with different reference points were comparable measures to predict mortality, two SRH measures (global and age-comparative SRHs) were applied separately and concurrently. Cox proportional hazards model was conducted, adjusted for demographic and social characteristics. **RESULTS:** A total of 4787 respondents were included in the analysis. More respondents were likely to assess their health as excellent or very good on the age-comparative SRH measure than on the global SRH measure (excellent, 14.7% vs. 7.6%; very good, 28.6% vs. 25.8%, respectively). In the independent models, 'poor' SRH ratings were the strongest predictor of mortality. Poor global SRH ratings increased mortality risk by 5.06 times and poor age-comparative SRH rating increased mortality risk by 5.02 times compared to their respective excellent ratings. When two measures were concurrently analyzed in the relation to mortality risk, both measures significantly predicted mortality and poor global SRH ratings were the strongest predictor of mortality (Hazard ratio = 2.75; 95% CI = [1.694, 4.469]). **CONCLUSIONS:** In this study, both global and age-comparative SRH measures were associated with increased risk of mortality. However, we also found that the global SRH measure tended to have more predictive power than the age-comparative measure. Our findings imply that the different reference points may affect the association between SRH measures and mortality.