

Abstracts

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anticipated in this study. Of the respondents 55% were females, 69% worked in a chain pharmacy, with an average 11 years of work experience. 65% of the respondents were aware of the labeling changes introduced by the FDA. Attitude of pharmacists towards all the specific labeling changes introduced for acetaminophen and NSAIDs were positive. Pharmacists strongly and significantly agreed ($p < 0.001$) that labeling changes like highlighting ingredient name or mentioning it in bold print (3.84 ± 1.08), appearance of "See New Warnings" statement on the principal display panel for one year (3.96 ± 1.06), age specific warnings for adults and for children below 12 years of age (4.12 ± 1.19), mentioning the maximum daily dosage units of acetaminophen under liver warnings (4.31 ± 1.06), will be useful for patients. **CONCLUSIONS:** The results indicate that majority of pharmacists agreed with FDA's labeling changes for OTC IAAA drug products. More information regarding these changes should be provided to pharmacists and consumers to increase appropriate use of these products.

HEALTH CARE USE & POLICY STUDIES – Health Technology Assessment Programs

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QUALITY ASSURANCE OF FOURTH HURDLE WITHIN THE SLOVAK REPUBLIC

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OBJECTIVES: Experience indicated that the quality of economic evaluations submitted in reimbursement dossiers and critical appraisals are heterogeneous. The objective of this study was to analyse the quality of submitted economic studies and related critical appraisal processes and to develop a policy-relevant, publicly available Slovak critical appraisal checklist for improving the quality of economic evaluation and budget impact analyses for reimbursement submission of dossiers concerning to drugs and medical devices. **METHODS:** We created a working group to review previously submitted economic evaluations and related critical appraisals in order to identify potential technical and methodological problems. The working group consisted of independent academic experts who scrutinized previous submissions and critical appraisals and developed a new checklist. Overall 50 economic evaluations submitted for reimbursement of drugs and medical devices in 2007–2009 were scrutinized. **RESULTS:** Evidence suggests that Slovak pharmaceutical expenditures do not result in the most cost-effective outcomes. Several potentially not cost-effective pharmaceuticals have been reimbursed in Slovakia. Economic evaluations of drugs and medical devices are mandatory but the quality of evaluations and critical appraisals are rather poor. Therefore in addition to the available Slovak health economic evaluation guidelines a detailed checklist for appraisal processes have to be prepared. Our analysis shows that the simplified questionnaire, which is currently used for the critical appraisal process within Slovakia should be replaced by a new Slovak critical appraisal checklist, which will be detailed enough to address the most common problems in the local economic evaluations and budget impact analyses for decision making process. **CONCLUSIONS:** The transparent method of technology assessment can improve the consistency of reimbursement decisions making related to drugs and medical devices in Slovakia. The current checklist for critical appraisal is not sufficient enough and there is significant room for improvement in this field.

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OUTCOMES OF BEDSIDE-BARCODE TECHNOLOGY INTERVENTION ON MEDICATION ADMINISTRATION TIME IN AN INTENSIVE CARE UNIT

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OBJECTIVES: The objective of this study was to evaluate outcomes of a bedside barcode technology intervention on medication administration time in an intensive care unit (ICU). **METHODS:** A prospective observational time-and-motion experimental study was conducted by considering two medication administration processes (a paper based approach vs. the bedside barcode system) in a large 500+ bed hospital setting. Medication administration by the nurse was operationalized as activities such as direct or indirect patient care, administration, and miscellaneous. Time devoted to complete these medication administration activities were measured separately by means of two pre-calibrated stop watches. Complexity factors of medication administration (age, sex, body-weight, comorbidities, number of drugs administered, and length of ICU stay) were included in linear regression model to predict time required for each of those medication administration activities. **RESULTS:** One hundred and fifty-one electronically documented medication administrations with the bedside barcode system were evaluated. Mean times of direct patient care activity (182.32 ± 131.68 seconds) and administration activity (59.83 ± 74.53 seconds) during bedside barcode medication administration improved significantly in comparison with paper based approach. In the bedside barcode system, significant ($p < 0.05$) predictors of time associated with direct patient care activity was number of drugs administered, for indirect patient care activity was comorbidities, and for administration activity was length of ICU stay. **CONCLUSIONS:** Variables that predict medication administration time in the bedside barcode system were different across the categorized

activities. To develop and implement efficient systems, such variables should be monitored and controlled as high cost technology is adopted by hospitals.

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WHEN AND HOW ARE EVIDENCE REVIEWS ON PERSONALIZED MEDICINE USED FOR HEALTH PLAN POLICY DECISIONS?

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OBJECTIVES: A goal of evidence review is to inform policy decisions such as for insurance. This study examines whether and how U.S. payers use evidence reviews in policy decisions for personalized medicine. **METHODS:** We used literature review, focused interviews and a Roundtable meeting. Literature review was used to review and compare seven evaluation frameworks available to guide payer decisions: Blue Cross Blue Shield Technology Evaluation Center (BCBS TEC); ECRI Institute, Evaluation of Genomic Applications in Practice and Prevention, Institute for Clinical and Economic Review, Hayes, Inc., Up-To-Date and United States Preventive Services Task Force. Seventeen interviews of health plan executives were used to identify whether and how these frameworks were used in policy decisions made by individual plans. A meeting that included interviewees and other thought leaders was used to discuss similarities and differences across payers in whether and how formal evaluations informed policy. The study focused on personalized medicine, the use of genetics or genomics to guide health care decisions. **RESULTS:** We found that frameworks vary in: purpose, questions of interest, range of evidence included, availability, and capacity. All frameworks were used by at least one payer to inform policy decisions with one framework (BCBS TEC) used by all but one interviewed payer. All payers reported using multiple frameworks. Payers reported key gaps in frameworks including: lack of evidence on health care system factors, lack of timeliness and lack of breadth. Across payers the range of evidence used to inform decisions was believed to result in policy variation. In particular, when clinical evidence is uncertain but decisions needed, payers reported using nonclinical evidence to help guide decisions. **CONCLUSIONS:** Payers use evidence reviews to inform policy decisions but no single framework is sufficient. Key ways to improve reviews for insurance policy decisions might focus on balancing the tension between comprehensiveness and timeliness.

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DEVELOPING GLOBAL ROAD MAPS FOR REIMBURSEMENT PROCESSES USED IN HEALTH TECHNOLOGY ASSESSMENT: PHARMACEUTICALS, MEDICAL DEVICES, AND DIAGNOSTICS

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OBJECTIVES: Health technology assessment (HTA) is used to evaluate health care technologies (e.g., pharmaceuticals, medical devices, and diagnostics) with respect to cost and their projected impact on patient outcomes and society. Currently, there is an ongoing initiative by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) to develop *Road Maps* that describe the utilization of HTA in health care. The purpose of this study was to develop models for HTA decision-making structures along with reimbursement road maps for several countries. **METHODS:** Members of the ISPOR Special Interest Group (SIG) for HTA contacted key individuals in several countries, including: Austria, Denmark, Hungary, Ireland, France, Germany, Denmark, UK, Sweden, Australia, Canada, Taiwan, United States, and others. Once decision models and corresponding reimbursement road maps were developed within designated HTA subgroups, the information was disseminated to all HTA committee members for review. After review, the decision models were sent to key stakeholders in each selected country for review and validation. **RESULTS:** Decision-making structures and review processes for reimbursement were developed for the selected countries. Key decision makers and/or third-party payers (e.g., person or organization) were identified and defined in accordance with their role in the reimbursement process. Evaluators were defined as individuals or organizations that provide input into the decision-making process regarding HTA development, but may not be responsible for final coverage and payment decisions. **CONCLUSIONS:** Decision structures for reimbursement (e.g., coverage, coding, and payment) vary according to the type of product (e.g., pharmaceutical, medical device, and diagnostic), the individual country and in some instances, by regions within the country. The HTA-SIG will continue to identify and validate HTA decision pathways for reimbursement within each country to provide guidance to manufacturers and policy makers in a way that optimizes efficiencies and supports the ongoing societal needs for access to emerging technologies.

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DECISION CRITERIA FOR TECHNOLOGY ACQUISITION IN RADIOONCOLOGY—WHAT REALLY MATTERS?

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OBJECTIVES: The assessment of medical technologies in hospitals is often an unstructured not transparent process, only involving a small group of decision makers. To overcome barriers while discussing or implementing decisions, a clear communication