HEALTH CARE USE & POLICY STUDIES - Quality Of Care

PHP180

MULTIPLE CORRESPONDENCE ANALYSIS TO UNDERSTAND THE ROLE OF MULTIPROFESSIONAL TEAM FOR SHARED DECISION MAKING TO IMPLEMENTATION IN CLINICAL PRACTICE

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OBJECTIVES: Several studies have shown that traditional statistical measures of association and agreement are not able to capture relevant appreciation of physician-patient relationship. Literature has shown evidence of miscommunication between: a) members of multidisciplinary team; b) teams and specialized care; and c) health care and user. The aim of study was to evaluate the properties of correspondence analysis technique, describing the viewpoint of health professionals on multidisciplinary teamwork and interaction with specialty assistance, and its contribution for shared decision-making process. **METHODS:** Cross sectional, descriptive study using a questionnaire, was applied in a face-to-face interview. A pilot questionnaire seeking improvement for sample calculation was conducted. We used descriptive analysis to map the results. Multiple correspondence analyses were performed to explore the outcomes and assumptions established. **RESULTS:** We interviewed 78 health professionals, 50% Caucasian, 82.5% female, mean age was 36.97 yrs (min. 22; max. 70, SD: 9.98). Participants were physicians (12.82%); nurses (14.1%); nurse technicians (25.64%); dentist (12.82%), dentist technicians (8.97%) and health assistance technicians (8.97%). Correspondence analysis plot illustrated that a multiprofessional team can improve patient's knowledge about their diseases and treatments and it can be a strategy for shared decision-making approach. However, for multiprofessional team maintenance, professional roles and responsibilities must be well defined. Regarding primary and specialty care communication, the plots showed that primary care usually refers patients to a specialist more than is needed, because they have low abilities to manage complex diseases. The willingness for shared decision-making approach is low due to high number of patients which they have to assist on primary care. **CONCLUSIONS:** Correspondence analysis suggested that multiprofessional team was involved on the process of health decision-making, which can improve the patient participation. However, roles and responsibilities must be clearly defined. These points can derive assumptions for shared decision-making approach and for strategies to its implementation on clinical practice.

HEALTH CARE USE & POLICY STUDIES - Regulation Of Health Care Sector

PHP181

COSTS/QALY THRESHOLD IN NEW LEGISLATION AND ITS IMPACT ON ACCESS TO INNOVATIVE MEDICINES IN SLOVAKIA

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OBJECTIVES: There were several pricing and reimbursement policy (P&R) restrictions introduced in Slovakia during last 5 years, including new reimbursement law valid from 1 December 2011. The objective of the review is to evaluate the impact of policy restrictions and assess their future impact on the access to new medicines. **METHODS:** Based on the legal framework, development of P&R policy and its impact on the drug expenditures and consumption was evaluated. The level of reimbursement by Health Insurance companies and consumption of medicines were taken from official database sources. Officially published MoH reimbursement decisions were analysed, particularly in relation to the assessment of pharmacoeconomic submissions. **RESULTS:** During the last five years several cost containment measures were implemented in P&R policy (reference pricing, flat price decrease, VAT change, digressive margin, health economic evaluation guidance). As a result Slovakia reached sustainable drug expenditures during last three years. Despite of restrictions, the availability of innovative treatments is still comparable to other CEE countries. The new reimbursement law defines new requirements for setting of P&R. Some of them will have serious impact on reimbursement of new drugs and access to them (second lowest price within EU, price set in at least five EU countries, cost/QALY threshold, reimbursement level measured by defined clinical advantages, etc.). During the last evaluation in June 2012, new drugs for metastatic melanoma, metastatic prostate cancer and metastatic breast cancer were refused as well as 4 new indications, due to non-compliance with the law requirements. **CONCLUSIONS:** The P&R policy in Slovakia has gone through several changes in last five years. The new legislation can dramatically influence the P&R approval of new, particularly high priced medicines. This will challenge payers, health care providers, industry and patients to find new ways to maintain the availability of innovative treatment in Slovakia.

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CONCORDANCE OF PRO LABELING CLAIMS BETWEEN THE FDA AND EMA

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OBJECTIVES: Recent reviews have examined differences in PRO label claims comparing U.S Food and Drug Administration (FDA) decisions to those in the European Medicines Agency (EMA). Limited research has been conducted to identify where there is concordance between agency decisions in PRO labeling. This analysis sought to discover instances where similar PRO labels were granted by each agency to determine if there are precipitating factors that would increase the likelihood of claims being granted by both. **METHODS:** AA listing of drug approvals granted by both the FDA and EMA was generated, identifying a total of 75 products (2006-2010). PRO claims found in US Drug Approval Packages and European Public Assessment Reports packages were compared to detect any similarities or differences in claims made for the same product by the same company. For analysis purposes, PRO claim type was categorized as symptoms, functioning, HRQOL, patient global rating (PGR), or other. **RESULTS:** A total of 75 products were approved by both agencies. Of these, a total of 35 (47%) were granted at least one PRO claim by the EMA as compared to 14 (19%) by the FDA. Of the 14 products with PRO claims granted by both agencies, only a small number (n=4, 11%) had the same claim types granted, without deviation. Despite these discrepancies, upon dissection of the labels, commonalities were identified. Symptom claims were granted in 12 of 14 products by both agencies as were 5 functioning and 3 PGR claims. **CONCLUSIONS:** While PRO label claims do not demonstrate perfect agreement between agencies, upon close examination there appears to be greater concordance then previously recognized. Precipitating factors such as therapeutic area, PRO measure or order of regulatory submission may influence the agreement between agencies. Further investigation is warranted to better support effective PRO strategies.

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THE ROCKY ROAD TO MARKET EQUILIBRIUM – PRICE REGULATION AND ENTRY LIBERALIZATION IN PORTUGUESE RETAIL PHARMACY

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OBJECTIVES: In the last years, several measures in the Portuguese pharmaceutical sector were adopted aimed at decreasing pharmaceutical prices and profit margins of pharmacies. Since both prices and profit margins are regulated, pharmacies are not able to react to these changes by changing prices. The political and economic case for these measures was made based on economic models od the pharmaceutical distribution, based on econometric estimations cost functions and their implications for market equilibria. The policy advocacy was made first in 2005, using information from 2002. Today, the sector faces a different reality. Results based on 2002 data potentially are outdated. **METHODS:** This paper estimates the cost function for the Portuguese pharmacies and its implications towards the policy-measures taken in the last years. We use individual information from 1 346 pharmacies for the year 2010, enlarging considerably previous studies in terms of observations and updating to more recent data. We also study the effect of price and entry liberalization policies, using simulations from a theoretical model with spatial competition. **RESULTS:** Our results show that the cost structure for Portuguese pharmacies changed drastically from 2002 to 2010. Indeed, while the marginal cost decreased by 6.6%, the fixed cost increased by 91.3%, resulting in an increase in the economies of scale. Therefore, pharmacies need higher profits margins in order to be able to have nonnegative profits. Our simulations show that price liberalization (with regulated entry) would result in negative profits, contrary to what would happen in 2002. **CONCLUSIONS:** Price policies that focus only in the marginal cost, as has been happening so far, may not be adequate to ensure the sustainability of the retail pharmaceutical sector, as they do not account for fixed costs. New policies should reflect the relation between the price and the average cost, rather than the marginal, whenever prices are administratively decreased.

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CHANGING MARGINS IN PHARMACEUTICAL DISTRIBUTION: WHO BENEFITS FROM THE NEW SLICING OF THE PIE?

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OBJECTIVES: In May 2011, the Portuguese government signed a Memorandum of Understanding with the EC, ECB and IMF as part of a financial rescue program. Part of the program involved a reduction of € 50M in the public expenditure with pharmaceuticals. One specific measure introduced a new margin scheme to pharmacies (and distributors), consisted of an increasing fixed fee and a regressive margin as a percentage of the ex-factory price, making prices lower in general. Prior to this margin scheme, a linear system was in place. This measure will clearly affect the pharmaceutical retail sectors, with a decrease in the pharmacies' profits. In this study we assess the impact of the several measures aimed at decreasing pharmaceutical expenditure on the profitability of the Portuguese pharmacies, namely administrative and voluntary price reductions and if pharmacies can support the change in the margin scheme. **METHODS:** We use a sample of 383 pharmacies, with data from the sales of each different transaction. The time span considers the period from January to May in both 2011 and 2012. **RESULTS:** Using transaction-level data, the analysis allows for the simulation of new and old margins, keeping consumption constant. Estimates regarding savings for patients and for payers (mainly the National Health Service), and impact on retail and wholesale distributors can be traced. In particular, we address issues such as whether small pharmacies are harder hit than large ones, and whether particular groups of patients (eg. Old pensioneers) benefit more or less than the majority of the population. Due to the new margins design, patients benefit, though payers (especially the National Health Service) also benefit. **CONCLUSIONS:** The new remuneration system is likely to produce the expected savings. Special attention should be given to harder-hit pharmacies and patient access to medicines and pharmacy services.