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INTERNATIONAL COMPARISON OF PHARMACEUTICAL EXPENDITURE IN MIDDLE INCOME COUNTRIES: METHODOLOGICAL QUESTIONS

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OBJECTIVES: Scarcity of public resources in middle-income countries, especially in challenging economic times, draws attention to potential reduction of pharmaceutical expenditure. Per capita pharmaceutical spending in purchasing power parity (PPP) exchange rates, proportion of pharmaceutical spending compared to GDP and total health care spending are frequently used indicators to justify potential savings. Our objective was to explore the influencing factors of pharmaceutical spending in European middle-income countries. **METHODS:** We conducted a literature review to set up hypotheses for differences in pharmaceutical spending between middle-income (below 30'000 USD GDP/capita) and high income countries (above 30,000 USD GDP/capita). Cross sectional survey based on OECD Health Data 2010 and cluster analysis was conducted to test those hypotheses by applying Mann-Whitney-Wilcoxon test. **RESULTS:** Payers calculate international price references in currency exchange rates, no adjustment is made to local purchasing power. Due to manufacturers' response to international price referencing and parallel trade middle-income countries have to pay almost the same global price for innovative drugs as high income countries. Therefore adjustment of pharmaceutical expenditure to GDP PPP may not be justifiable, application of currency exchange rates is more appropriate for comparison of pharmaceutical spending. Our cluster analysis indicates that expenditure is proportionally higher in middle-income countries compared to high income countries (1.89 vs. 1.41% of GDP%, $p=0.039$; 23.58% vs. 14.14% of total health expenditure, $p<0.001$), as prices of pharmaceuticals are not adjusted to local price levels, whilst costs of other health care services are lower mainly due to lower salaries of health care professionals. **CONCLUSIONS:** It can be misleading to compare the pharmaceutical expenditure of middle-income countries to the average of OECD countries. Cluster analyses of countries with similar economic status and comparison of absolute spending based on currency exchange rate provide appropriate benchmarks to substantiate policy initiatives.

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BURDEN OF ILLNESS OF CHRONIC CONDITIONS (CC) AMONG HOSPITALIZED PATIENTS: THE ARGENTINE-HEALTH CARE COST AND UTILIZATION PROJECT (A-HCUP)

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OBJECTIVES: Non-Communicable Diseases (NCDs), are difficult to measure, so we used a Chronic Conditions (CC) table in a discharge registry to obtain them. **METHODS:** In a 1 year output of 3 hospitals, a CC (MCRR, 2006; 63: 327 - 346) table was used. A Pareto rank of first 10 CCS with CC (+) in primary diagnosis (Dx1) and secondary diagnosis (Dx2) among ≥19 yrs old, costs, Clinical Classification Software-CCS single level-SL groupers (2009) (#CCS [descriptive term]), average length of stay (ALOS), total costs (CT$) mean and median per discharge cost ($), (25P-75P-percentiles), in international dollars PPP, (1Arg$ = 1.608 I$ PPP, 2008) were obtained. CT$ of all CC burden is reported. **RESULTS:** Among ≥ 19 years, 17169 Dx1 with CC (+) (37,76%), had CT$: I$ 243 893 494 (39,36% of hospital cost) and ($): I$ 14 473,04. 15 102 discharges had 1 or more CC(+) in Dx2 (32,97%), with a CT:I$ PPP 216 158 768, (1,86% of discharges not costed). The top 10 CCS with CC where 7489 discharges, a 16,35% of total discharges ≥19 years old, CT$: I$ 109 896 918. The first 10 CCS of the pareto ranking, mean age 42 years (SD 30,45 yrs), an ALOS was 3,54 (SD 5,07) days, with a ($): I$ 10 560,92 (SD I$ 18 101,73), a median cost of I$ 4057,56 (25-75 percentiles I$ 1022,97-8250,84). The CCS #45 [Maintenance chemotherapy; radiotherapy] of which 100% was CC (+) was ranked #1, followed by CCS #149 [Biliary tract disease], of which 19,34% was CC(+). In hospital mortality of CC (+) in Dx1 was 817 deaths (4,75%). **CONCLUSIONS:** CC table obtained the Burden of CC in discharges at 38% of total costs. Behavior of CC in CCS are compatible with each condition. Future studies should address generalizability of results, accuracy of Dx2 coding and co-morbidity.

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DESIGN AND OPERATIONAL CHALLENGES WITH TIME AND MOTION (T&M) STUDIES RUN ALONGSIDE CLINICAL TRIALS

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OBJECTIVES: T&M studies are designed to collect observational data to quantify efficiency-related outcomes, mainly staff-time and consumables associated with medical interventions. Our aim is to describe scientific and operational challenges that were observed when implementation a T&M study alongside a clinical trial. **METHODS:** T&M-method involves repeated observations of pre-identified tasks associated with a process in order to measure task durations to estimate total process time. As part of a multi-centre T&M study run as a sub-study to a clinical trial, we identified key design parameters that drive robustness as well as process elements that are critical factors to successful operational conduct. **RESULTS:** T&M-endpoints are to be carefully selected to align with their final use as inputs in e.g. economic models. As part of a trial that investigates time for a new route of administration (subcutaneous as alternative to intravenous), it is important to discuss with staff the applicability of task descriptions, with local CRF adjustment justifiable if providing more accurate time measurements. Trial protocol determines number and timing of observations, leading to sample size restriction and potentially extended study period. In the absence of clear guidelines on T&M study classification, regulatory processes are to be well understood, and absence of patient interaction clearly stated. Initiation of T&M-sub-study together with First-Patient-In is crucial to avoid losing valuable observations. Sites prefer to be given options for selecting observers, but ideally observers are external to the care unit (within or outside the hospital) and are competent and available during study period. As sites are inexperienced with T&M-method, streamlined communication and focused training proved crucial. **CONCLUSIONS:** T&M-methodology is associated with important design and operational challenges that must be identified early on to guarantee a scientifically robust design and operational feasibility, with the ultimate aim to produce valid efficiency-related data in support of economic analyses.

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THE ECONOMIC IMPACT OF A COST-EFFECTIVENESS THRESHOLD ON THE INNOVATIVE DRUG EXPENDITURE IN QATAR

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OBJECTIVES: Hamad Medical Corporation (HMC), the main health provider in Qatar, does not implement a cost-effectiveness threshold (CET) of acceptable cost-per-effect for the innovative drugs when considered for formulary inclusion, i.e. drug selection is based on the drugs' safety and effectiveness with no regard to cost. This study sought to estimate the economic impact of implementing a CET on the expenditure of innovative drugs in HMC. **METHODS:** This is a retrospective study, in which we analyzed the HMC drug utilization data for the period 2008-2010. From the Qatari perspective, a CET was calculated and used to screen innovative drugs for formulary inclusion. This was based on cost-per-quality adjusted life years (QALYs) values of innovative drugs, as analyzed from literature. Drugs that had estimated negative costs (savings) and equal/more QALYs compared with standard treatment were not taken into the analyses. Threshold and scenario one-way sensitivity analyses, and an uncertainty (Monte Carlo simulation) analysis were performed to assess the robustness of the study conclusions. **RESULTS:** Thirty-four innovative drugs were identified (12 in 2008, 11 in 2009, and 11 in 2010) and included in the analysis. Based on an underestimation of the CET effect, a potential 22.2-68.0% reduction in innovative drug expenditure was demonstrated. Based on the uncertainty analysis, there is a 70% chance that a CET will result in the 68.0% innovative drugs expenditure reduction. This was equivalent to QAR16,429,260 and to a 2.1% reduction in the overall HMC drug expenditure. Drugs were ranked as per their influence on the CET effect, where the drug 'Sitagliptin' had the highest influence. According to sensitivity analyses, study results were robust against uncertainties with inputs. **CONCLUSIONS:** Reduction in HMC innovative drug expenditure maybe achieved with the application of a formal CET. For formulary drug selection, HMC decision makers should consider the cost-effectiveness of drugs, in addition to their effectiveness and safety.

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REFERENCE PRICINIG PROPOSAL BASED ON GROSS DOMESTIC PRODUCT PER CAPITA

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OBJECTIVES: Even though the lowest of the prices amongst reference countries are taken into account during reference piricing, these price are still relativley high according to our country's purchasing power. The price of a certain medication is considered normal in a developed country whereas that price for the same product presents itself higher than the purchasing power of developing country.Development of a new reference pricing system estimated in accordance with Turkey's GDPC is proposed. **METHODS:** The most essential requirement for reference pricing is to reach a new reference price based on the molecule significance coefficient-(MSC) - obtained through an assessment and GDPC no higher than the lowest reference country price. A committe of 5 academicians convened from different universities has evaluated bevacizumab, erlotinib and rituximab, using the assessment form prepared on grounds of 5 questions for the calculation of the coefficient. New public pricesof the products were calculated by the use of the MSC. The pharmaceutical product pricing calculation is suggested as below: Product Price = Σ (Country GDPC/Ref. Country GDPC × Ref. Country Price) × Molecule Significance Coefficient; Mol. Sig. Coeff. = Average Score/Total Score × 3. **RESULTS:** The MSC values for bevacizumab, erlotinib and rituximab were 1.09, 1.21 and 1.29, respectively. The probable the new calculated public prices depending the formulas were decreased from the public price, 37%, 40% and 21%, respectively. **CONCLUSIONS:** GDPC-based reference pricing sample may provide a new perspective in pharmaeutical pricing control in countries like Turkey. On the other hand, this can also provide an opinion for countries with insufficient facilities for approaching MSC and HTA, during reimbursement decision making. For instance, an MSC value under 1 is not included in reimbursement whereas one falling in between 2 and 3 is suggested for reimbursement.This can be similarly used for determining the MSC reimbursement levels independent from reference pricing.

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THE HEALTH AND ECONOMICS BULLETIN – AN ANALYSIS OF THREE YEARS OF PUBLICATION

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OBJECTIVES: The Health and Economics Bulletin is an electronic periodic of The Brazilian Health Surveillance Agency (ANVISA). It aims to provide information to health care decision makers and patients when there is more than one pharmaceutical option to treat the same disease and there is no scientific evidence of