IELLS IN MIDDLE INCOME COUNTRIES: METHODOLOGICAL QUESTIONS

Background: To provide valid efficiency-related data in support of economic analyses, studies should address generalizability of results, accuracy of DEX2 coding and co-morbidity.

METHODS: 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-defined tasks associated with a process in order to measure task durations to estimate total process time. As part of a T&M-study that investigates time for a new route of administration (subcutaneous), key design parameters that drive robustness as well as process elements that are crucial 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 T&M-study that investigates time for a new route of administration (subcutaneous) as an alternative to intravenous, it is important to discuss with staff the applicability of task descriptions, with local CPE 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 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 to create a scientifically robust design and operational feasibility, with the ultimate aim to produce valid efficiency-related data in support of economic analyses.

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

Al-Badriera 1, Mohamed H 1, Al-Mahbub Y 2

Qatar University, Doha, Doha, Qatar, 1Hamad Medical Corporation, Doha, Doha, Qatar

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 test the robustness of the study conclusions. RESULTS: Thirty-four innovative drugs were identified that met the CET criteria (2008, 2009, 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 drug expenditure reduction. This was equivalent to QAR124,829,630 to 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 application is believed with the implementation of a formal CET. For formulary drug selection, HMC decision makers should consider the cost-effectiveness in drugs, in addition to their effectiveness and safety.