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PRIORITIZATION OF DRUGS FOR REIMBURSEMENT IN THE MALTESE HEALTH SYSTEM.

Background

Governments often experience difficulties in striking an optimal balance between ensuring access to promising drugs while sustaining the healthcare system. We investigated how Malta prioritizes drugs for inclusion in the basic benefit package. Malta, an archipelago (i.e. group of small islands) in the Mediterranean Sea, is with its 475,000 inhabitants and 316km^2 the smallest of all EU countries. Malta's government, consisting of the President as head of the state, the Prime Minister with executive power and the Cabinet, is responsible for public healthcare services, which are financed through payroll contributions and which are free of charge at point of access. To achieve an optimal balance between access and sustainability, Malta implemented the Medicines Act in 2009 to regulate drug reimbursement.

Conclusion

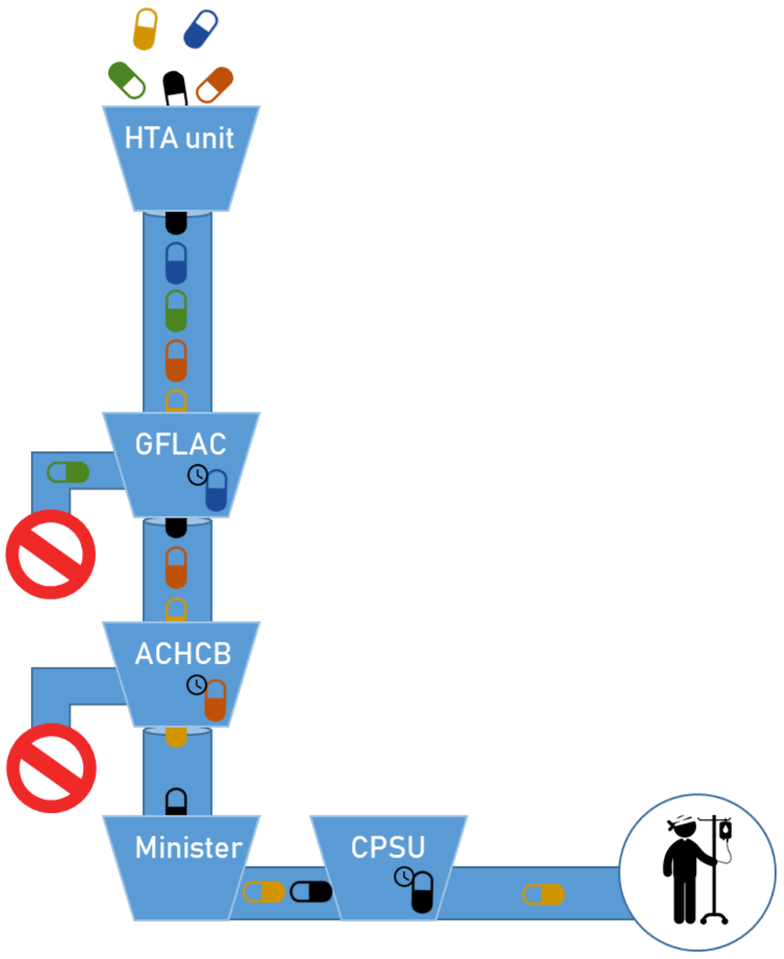
Decision-making at multiple levels complicates the prioritization of drugs in Malta. Pending decisions further impact the prioritization process. The main criteria for prioritisation at each level seems, however, to be budget impact and allocation of sufficient funding.

Methods

Our descriptive analysis of the Maltese reimbursement system was based on policy documents and semi-structured interviews guided by the Hutton Framework. We interviewed 32 key stakeholders including policymakers, committee members, clinicians, pharmacists, hospital managers and representatives of patients, the pharmaceutical industry, and the Ministry's procurement department.

Results

Prioritization of medicines for introduction on the Government Formulary List (GFL) and thus reimbursement by the government, is firstly determined by Schedule V of the Social Security Act. The Act stipulates that a person suffering from a health condition listed on Schedule V is entitled to free healthcare. Schedule V consists of 16 categories with mostly chronic diseases, such as malignant diseases, cardiovascular diseases, and respiratory diseases. Sub-categories further specialize these main categories. Drugs eligible for the introduction on the GFL need to target a condition listed on Schedule V. Once eligibility is confirmed, all drugs for reimbursement have to pass through the Health Technology Assessment (HTA) Unit at the Ministry for Health, for drawing up a drug assessment report, and two committees advising the Minister for Health, before the drug is purchased by the procurement unit (CPSU). The HTA unit assesses all drugs but gives priority to drugs targeted at disease areas with an earmarked budget. The first committee, the Government Formulary List Advisory Committee (GFLAC) then prioritizes the drugs based on health benefits and estimated costs compared to other drugs within a clinical pathway. GFLAC advises the second committee, the Advisory Committee on Health Care Benefits (ACHCB). The ACHCB further prioritizes the drug based on affordability (i.e. budget impact), sustainability and capacity of the system. Between 2014 and 2017, ACHCB recommended 73% of the appraised 89 drugs to the Minister for Health and rejected 12%. For 15% of the drugs, the decision is pending. The Minister for Health subsequently endorses the recommended drugs, usually without further prioritization. However, as final decision-maker, the Minister may prioritize disease areas at point of assessment. For example, in 2017 and 2018 specific annual budgets were allocated to oncology and diabetes. At procurement, CPSU may additionally prioritize which medicines to purchase first since procurement of approved drugs often exceeds CPSU's available budget.



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