this study was to analyze how the KA model could be institutionalized within the HTA framework. **METHODS:** We conducted a systematic search on "KA" theoretical approaches and empirical evidence. Based on a comparative analysis of relevant articles, and over a series of discussion meetings with different stakeholders, we generated an adjusted KA model fitting the purposes of HTA. Then, we identified the key institutional questions that would be relevant for the institutionalization of the adjusted KA model in the context of HTA. **RESULTS:** The evidence on the KA model focuses on solving real problems, the use of evidence from different sources, and the need of including preferences of evidence users in real life, all elements included in the adjusted version. The institutionalization of KA within the HTA framework is challenged by, at least, the following questions: (i) which is the right way of choosing representative evidence users (e.g. healthcare team), stakeholders (health policy makers), and those affected by evidence use (patients); (ii) how to monitor the adaptation of guidelines to local contexts, (iii) which are the sets of rules that model the stakeholder´s behaviour, (iv) and which are the implied outcomes that are expected from these rules. **CONCLUSIONS:** The KA model adds important elements to HTA, which can be useful for the institutionalization processes in many countries of the world. This piece of research identified the main components/questions that need to be addressed to undertake this institutional process.

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EXTENSION OF INDICATION WITH MATURE PRODUCTS: TOWARD MORE INCENTIVES REWARDING INNOVATION?

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BACKGROUND: Mature products (MPs - marketed for 10 years or more) are widely used off label (from 15 to 35% according to studies) despite little evidence on benefit risk ratio. This exposes patients to risks or lack of efficacy and healthcare providers to liability. However manufacturers are rarely investing in R&D development for MPs. Indeed MPs face price cuts in Europe, whether due to generic competition, price negotiations or inclusion in reference price groups. Moreover new indications, even if demonstrating a higher value of the drug, often lead to price reductions in Europe due to a combination of price/volume agreements and external reference pricing. Products are included in reference price groups even for a new indication. While reference price groups only include off-patent drugs in France and Italy, these groups may include patented drugs in Spain (if older than 10 years) and Germany.There are significant disincentives for manufacturers to invest in R&D for MPs, preferring instead to develop new molecular entities rather than unlocking the full therapeutic potential of MPs. This is especially the case for small populations (rare and ultra-rare diseases) where there is high unmet medical need and MPs could offer cost-effective solutions with known safety profiles. **DISCUSSION:** The development of new indications for MPs can be a win-win solution for patients and payers. It offers an alternative to off label or lengthy and expensive development of new therapies, as well as more equity in patients' access to treatment. As safety accounts for approximately 30% of drug failures in clinical trials, mature products can also offer a quicker and less expensive access to therapy, especially in areas of high unmet need. **CONCLUSION:** Incentives for orphan drugs or pediatric indications have proven to be effective in promoting R&D. New incentives should be developed to promote R&D in MPs.

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REFORMING DRUG PRICING AND PATIENT ACCESS SYSTEMS TO SUPPORT UNIVERSAL COVERAGE IN DEVELOPING COUNTRIES

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Developing countries moving to universal coverage seek to increase medicine access. They face the problem of determining which medicines to reimburse and how to set price and access for them. Medicine price and access are set by many organisations in developing countries - ministry of health, hospitals, national/regional payers and procurement bodies - with limited or no data on prices and utilisation. This leads to a fragmented system with widely varying price and access levels within the same country. Ad hoc solutions such as median pricing, international price referencing (IRP), HTA or arbitrary price cuts, with no overarching framework or logic, exacerbate the problems leading to supply shortages, poor quality, irrational use and continuing large differences in price and access. There is no consistent mechanism for setting price and access for innovative medicines. In the few countries performing cost-effectiveness assessments, these medicines are almost never found to be cost effective at local thresholds. In this paper, we lay out a structured Pricing and Patient Access (PPA) framework that empowers countries with effective approaches and tools to price medicines. These include competitive pricing for generics and setting price/access based on benefit assessment for patented medicines. Specific tools such as IRP, therapeutic referencing and price-volume/risk-share negotiations and managed entry agreements can then be used within this overall framework to improve access to priority medicines. While many of these tools exist in developed countries, we develop specific adaptations for developing countries. Further, building of such systems faces obstacles such as a cognitive disconnect between what stakeholders think they know and what they really know about PPA, institutional fragmentation, stakeholder buy-in and limited local capabilities (number of staff, skills, IT systems to track price and utilisation). To address these we also lay out a pathway to reform that addresses each of these issues.

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DEVELOPMENT OF HOSPITAL-BASED HTA UNIT PROCESSES IN THE CZECH HOSPITAL ENVIRONMENT

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OBJECTIVES: The current trend in HTA is its application to local medical facilities (called hospital-based HTA or HB-HTA), where HTA methods can foster strategic decisions of the hospital management, especially in employing and/or procurement of new technology. The essence of HB-HTA utilization is to implement processes that allow assessment of the technology considering specific conditions of the hospital. Although there are multiple concepts of HTA implementation that can be tailored to the particular hospital´s needs, establishing a HTA unit seems the most practical in the case of big university hospitals. **METHODS:** The models must be tailored for the Czech healthcare system and specific conditions of the particular hospital. The processes accommodated for evaluating, making decisions about and incorporating technologies are described to supportthe Motol University Hospital'sBoard of Directors. The hospital comprises all medical specialties and shows rich technological equipment including necessary expertize, providing sufficient internal resources for HTA analyses focused on clinical practice. **RESULTS:** Based on a management needs survey, assessment requirements are divided into four categories according to their urgency: 1. Urgent, immediate risk of service (device operation) interruption. 2. Technology requires to be substituted due to impracticability of its recovery. 3. Technology requires to be expanded due to existing demand. 4. Incorporation of new innovative technology or planned replacement of obsolete technology. For each category, a flow chart was designed specifying the assessment process and assessment team composition. The processes have been tested in introducing advanced point of care testing methods into the clinical practice in the Motol University Hospital. CONCLUSION: The model will be used for establishing working procedures of the intended HTA Unit in the Motol University Hospital, and further tested and enhanced in line with practical experience. The process is supported by the hospital management, who have collaborated on model adjusting.

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THE IRISH COST-EFFECTIVENESS THRESHOLD: DOES IT SUPPORT RATIONAL RATIONING OR MIGHT IT LEAD TO UNINTENDED HARM OF IRELAND'S HEALTH SYSTEM?

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BACKGROUND: Ireland is one of few countries worldwide to have an explicit cost-effectiveness threshold. It was agreed in a 2012 agreement between government and the pharmaceutical industry. In conjunction with substantial cost-savings on existing medications the agreement established a threshold of €45,000/QALY. Prior to this there had been an unofficial threshold of €20,000/QALY. The agreement only applies to pharmaceuticals, so there remains no official threshold for non-drug interventions. According to the agreement, drugs with cost-effectiveness ratios within the threshold will be granted reimbursement, whereas those exceeding the threshold may still be approved following further negotiation. A number of drugs far exceeding the threshold have been approved recently. **ANALYSIS:** There are four reasons for concern regarding Ireland's threshold. Firstly, that it only applies to drugs creates potential inconsistencies and inefficiencies whereby relatively cost-effective non-drug interventions are not approved while expensive drugs are. Secondly, as a price floor rather than ceiling it offers only a weak constraint on the introduction of cost-ineffective interventions. Thirdly, it has no apparent empirical basis. Finally, a recent threshold estimate based on the cost-effectiveness of services forgone for the UK was approximately £13,000/QALY. Assuming Ireland's threshold should be broadly comparable, the current threshold is probably too high. **CONCLUSION:** An excessive threshold risks causing the Irish health system unintended harm, as newly adopted interventions may produce less health than alternative interventions foregone. The lack of an empirically-informed threshold means the policy recommendations of cost-effectiveness analysis cannot be considered fully evidence-based rational rationing. Finally, it also means that the current threshold does not accord with recent legislation on the pricing of medical goods, which defines cost-effectiveness in terms of the opportunity cost of other services foregone. Policy makers should consider these issues when choosing what threshold to apply once the current industry agreement expires at the end of 2015.

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DO CLINICAL GUIDELINES FOR HERNIA SURGERY REDUCE COSTS AND IMPROVE PATIENT OUTCOMES, AND DO SURGEONS FOLLOW THEM?

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OBJECTIVES: Hernia repair is one of the most commonly performed surgical procedures. Hernia societies encourage surgical decisions based on up-to-date evidence-based guidelines rather than surgical intuition. The objective was to identify whether surgical guidelines and protocols for hernia repair can reduce costs and improve patient outcomes, and whether they are followed. **METHODS:** Comprehensive literature search to identify publications on hernia repair guidelines and summarise their impact on cost and patient outcomes. **RESULTS:** A Dutch study that compared inguinal hernia repair outcomes before and after evidence-based guidelines were introduced showed a significant reduction in hernia recurrence when guidelines were followed. A Spanish study of emergency ventral hernia repairs found that the proportion of patients treated after introduction of a protocol was significantly lower for mortality following bowel resection and the incidence of severe complications was reduced (excluding femoral hernia) versus pre-protocol. Introduction of a protocol for inguinal hernia repair in a UK general hospital improved patient outcomes to a level comparable with a specialist hernia centre. The authors also reported potentially large cost savings by increasing the proportion of ambulatory patients and those that received local anaesthesia. The Royal College of Surgeons noted that ambulatory operations are recommended for 80% of groin hernia repairs but found that only 67% were ambulatory, ranging from 32–100% across UK healthcare providers. Another UK study looked at the uptake of NICE guidelines for several procedures, including laparoscopic repair of inguinal hernia, and reported that although Hospital Episode Statistics suggested 96% compliance, a detailed audit of healthcare trusts showed only 65% compli-