from an academic public hospital using an average of 18 months (2016–2017) for the department costs.

RESULTS:

The real average cost was USD 128,923. Most significant resource costs was medical staff, particularly for the three survivor patients, and the ECMO equipment presented the second highest cost. ECMO activities were separated into: before implantation of ECMO, period using ECMO, intensive care post-ECMO and rehabilitation, being the period where ECMO is the most expensive, particularly in nurse and physician costs. The SUS average was USD 31,437, which shows a difference of USD 97,485 between the real ECMO cost and the public reimbursement in Brazil.

CONCLUSIONS:

A critical element of the propagation of ECMO in Brazil and its reimbursement by public health system is the high cost and out-of-date standard payments by the Ministry of Health. Effort to implement a trustworthy method to guide decisions of SUS for the adoption and financing new technologies is essential to contribute to the optimization of public health policies in a country with a universal health system and limited resources dedicated to health sectors.

PP51 Updating Canadian Pharmaceutical Budget Impact Analysis Guidelines

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INTRODUCTION:

The Canadian BIA guideline was published by the Patented Medicine Prices Review Board (PMPRB) in 2007. Our initial systematic literature review of national and international BIA guidelines showed that a number of new recommendations relating to BIA model structure, input data and reporting format have been adopted in other jurisdictions such as UK, Australia, Poland, Ireland, Belgium, France and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). The main objective of the present study was to conduct a comparative review of national, international and Canadian Federal, provincial and territorial BIA guidelines and provide a list of new recommendations related to the BIA key elements which have not been discussed or included in the Canadian PMPRB BIA guidelines.

METHODS:

BIAs guidelines were searched in databases such as MEDLINE, EMBASE, Cochrane, and the gray literature including regulatory agency websites. An Excel-based data abstraction form was designed in order to highlight differences between recommendations related to the BIA key elements provided by PMPRB, provincial, and other national and international BIA guidelines.

RESULTS:

Twelve guidelines were reviewed in detail. Sixty percent of the recommendations were new or were different from recommendations in the Canadian PMPRB BIA guidelines. They related to BIA key elements such as perspective, target population, costing, presenting results, data sources and handling the uncertainty.

CONCLUSIONS:

The present literature review is the initial step towards updating the Canadian BIA guidelines. This study presents a comparative review of key elements in BIA among different guidelines and provides a list of relevant practical recommendations for the improvement of the Canadian BIA guidelines. The new methodologic advancements and recommendations that were identified are being presented to Canadian stakeholders for their opinion and feedback prior to the development of a proposed new set of Canadian guidelines.

PP53 New Medical Device Law: Germany's Experience With Refund Restrictions

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INTRODUCTION:

Since 2005, new hospital examination and treatment methods (NUB) were reimbursed by hospital individual supplementary fees as long as they were not sufficiently covered by a DRG. In 2016, the NUB procedure was decisively changed by legal norm §137 h SGB.V to

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evaluate medical devices (MD) of high risk classes, particularly invasive, or new theoretical-scientific concepts versus treatment alternatives by the Federal Joint Committee (G-BA). Hospitals and manufacturers have to submit detailed information on the application of the MD and the scientific evidence to G-BA along with a NUB application. This assessment may lead to exclusion of the method from reimbursement by the statutory health insurance (SHI).

METHODS:

The published MD consultation submissions, assessments and G-BA resolutions (to date) were analyzed regarding evaluation criteria, treatment potential and study obligation.

RESULTS:

In 2017, nineteen procedures were reviewed by G-BA with respect to §137 h. Two ultra-controlled high-intensity focused ultrasound (HIFU) indications were regarded as having potential benefit but not sufficient evidence yet, thus respective studies have to be initiated. Three procedures were regarded as eligible according to §137 h but not yet evaluated. Six procedures (ultra-controlled HIFU in five indications, targeted lung denervation in chronic obstructive pulmonary disease) were rated as having no potential benefit, while eight procedures were regarded as not eligible according to §137 h.

CONCLUSIONS:

Initially put into place for high risk class and primarily invasive devices, consultations and assessments under §137 h show that there is some uncertainty around applicability criteria. The majority of those procedures which fell under the assessment law failed to be granted potential benefit as treatment alternative. Currently consultations are ongoing which could possibly lead to the exclusion of these methods from the performance spectrum of the SHI. Manufacturers should revise their study concepts in order to fulfill the specific demand for robust evidence.

PP54 Effectiveness And Costs Analysis Of Smartphone Apps in Health Care

AUTHORS:

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INTRODUCTION:

Smartphones have been one of the success stories of the last decade. Recently apps have been used to promote, manage, and provide medical and healthcare education. Since smartphones are used to support healthcare and public health interventions, they can also provide a useful and easy method for collecting data for healthcare research. In addition, smartphone apps have been successfully used to support telemedicine and remote healthcare in developing nations. This study aimed to assess the effectiveness and analyze costs before and after the inclusion of type 2 diabetic patients in a smartphone app healthcare program.

METHODS:

The smartphone app healthcare program is available for Android and IOS systems, and is used to manage behavior changes and to improve patient adherence to pharmacotherapy. Patient follow up is done through a specialized telephone monitoring center made up of a physician, nurses, nutritionists, and psychologists who provide constant monitoring and guidance to patients. A retrospective study was conducted of twenty-nine patients before (year 2016) and 12 months after they were included in the smartphone app healthcare program. Data on physician visits, hospitalizations, and medical and laboratory exams were collected from medical records. The cost analysis was conducted from the private healthcare group perspective and was performed using the micro-costing method.

RESULTS:

Ninety-eight percent of patients had reduction or maintenance of glycosylated hemoglobin levels, reaching the therapeutic goal (glycosylated hemoglobin of less than 7%). The cost analysis showed a twenty-five percent total cost saving due to a twenty-three percent reduction in the number of physician visits, a thirty-three percent decrease in hospitalizations, and a thirty-five percent cutback in medical and laboratory exams.

CONCLUSIONS:

The smartphone app healthcare program can facilitate and improve diabetes care, especially with respect to controlling and managing the use of health resources.

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