

(OSs) were included. Compared to cataract surgery alone, implantation of iStent® combined with cataract surgery was associated with a decrease in IOP at 12 months in RCTs (-1.37 mmHg; 95 percent Confidence Interval, CI: - 2.76 to .03 mmHg,  $p = .055$ ). Results from RCTs and OSs on the effect of iStent® combined or not with cataract surgery suggest also a 12-month positive effect on IOP (mean reduction: 1.5 to 9.5 mmHg) and on mean number of medications (reduction: .3 to 2.0) compared to baseline. Scattered results were found on the proportion of patients who no longer use glaucoma medications. Small sample size, short duration of follow-up, and potential conflicts of interest were among studies limitations. The most common adverse events reported were posterior capsular opacification, decrease in visual acuity, and stent obstruction or malposition.

### CONCLUSIONS:

Appraisal of the effectiveness and safety suggests that iStent® implantation combined to cataract surgery in mild-to-moderate OAG is an emerging practice. Uncertainties related to clinical benefits, safety and care organization need to be clarified before an introduction as a standard of medical practice.

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## PP032 Holistic Patient Access Processes Of Medical Devices In South Korea

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### INTRODUCTION:

Historically, patient access processes of new and innovative medical devices including *in-vitro* diagnostics are made in the sequence of regulatory approval, new Health Technology Assessment (nHTA) approval, reimbursement coverage and coding finally reaching the pricing approval stage in South Korea. Although the individual patient access process has its own distinct objective and perspective, there are still

opportunities for the authorities or agencies in charge to streamline their processes by working together to promote earlier patient access of new and innovative medical devices to patients without impacting their own decision making.

### METHODS:

This research examined and analyzed the current policies about: patient access processes with a holistic viewpoint, industry-wide survey about patient access practices; case studies of two innovative medical devices for patient access in South Korea and also proposed new or alternative programs which can contribute to patient access harmonization efforts with a holistic approach.

### RESULTS:

Historically, health authorities play defensive strategies by delaying the adoption of new and innovative medical devices and implementing certain periods (that is, 2 to 5 years) for a patient's out-of-pocket payment scheme. It is well illustrated with the statistic that only twenty-nine percent of new and innovative medical technologies which have successfully gone through the nHTA process were determined for reimbursement coverage in the past 7 years.

The survey by the medical device industry to determine the patient access lead-time of innovative medical devices with a holistic perspective indicated significantly delayed patient access even considerably exceeding the legally required decision-making lead time. The in-depth case studies with two innovative devices indicated the disadvantageous patient access processes to the innovator in terms of both final approval timing and the price level.

### CONCLUSIONS:

The concurrent review process for reimbursement coverage decision making for medical procedures, medical devices and reimbursement coverage payment guidelines committed within the Health Insurance Review and Assessment Service shall be created. New programs to deal with uncertainty in reimbursement coverage decision making shall be considered such as coverage with evidence development,

performance-based risk-sharing arrangement, multi-criteria decision analysis and economic evaluation.

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## PP033 Patient And Public Involvement In Health Technology Assessment: The Brazilian Experience

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### INTRODUCTION:

The National Committee for Health Technology Incorporation (CONITEC) (1) was created in 2011, when the participation of civil society in the Health Technology Assessment (HTA) process was formalized in Brazil. According to legislation, patient and public involvement (PPI) in HTA occurs through: public consultations (PC); representation of SUS (Brazilian Public Health System) users in the plenary of CONITEC and by public hearings in relevant cases. Due the incipient culture of social participation in Brazil, strategies involving better communication, direct participation and popular education were developed to broaden and qualify this participation.

### METHODS:

- Case study about PPI strategies developed in 5 years of CONITEC
- Analysis of documents and official records from the Brazilian Ministry of Health.

### RESULTS:

Since its creation, the innovations of CONITEC regarding PPI were: creation of specific PC form to reproduce or represent the perspectives of patients and caregivers; summarized versions of technical reports written in a simplified language to improve users involvement; surveys prior to elaborating clinical guidelines, a bi-weekly educational program transmitted by

streaming, and the recent launch of an HTA Users Guide and a mobile app.

After the implementation of these strategies (which started in 2014), there was an increase of annual contributions, from 2,584 in 2014 to 13,619 in 2015. Most participants were patients, family members or caregivers. Surveys concerning clinical guidelines received about 3,000 contributions. There were thirty-seven published society reports until December 2016. The publication of the HTA Users Guide and other related actions increased the number of accesses to the CONITEC website and its subsection for social participation. The educational program had more than 800 online accesses in five months.

### CONCLUSIONS:

These actions allowed expanding and qualifying PPI beyond what is legally defined, and it is possible to predict an increasingly favorable scenario regarding the patient and public participation in HTA in Brazil.

### REFERENCES:

1. National Committee for Health Technology Incorporation (CONITEC). Available in: [www.conitec.gov.br](http://www.conitec.gov.br).

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## PP037 Quality Criteria And Good Practices In The Health Technology Assessment Spanish Network

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### INTRODUCTION:

The Spanish Network of Agencies for Health Technology Assessment (REDETS) is a group of eight agencies, units and services, depending on National and Regional Governments that coordinate their work within a