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

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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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