

PP17 Comprehensive Evaluation Of A Technology With Expanding Indications

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INTRODUCTION:

The use of transcatheter aortic valve implantation (TAVI) is evolving. Our Cardiovascular Evaluation Unit is implementing a comprehensive approach to inform decision-makers on optimal use of TAVI, including the development of quality standards. We are implementing a multifaceted evaluation framework in collaboration with clinical stakeholders.

METHODS:

Our unit has carried out a continuous field evaluation in collaboration with the clinical teams at all six TAVI centers in Québec for the past four years (1 April 2013–31 March 2017), with regular feedback to the teams and sharing of results with each individual center. Hospital documentation was reviewed according to established national quality indicator definitions. Field evaluation data were combined with the results of systematic literature review to establish provincial standards for practice, through a deliberation process by an interdisciplinary committee of clinical experts from each center. Systematic surveillance of the literature is ongoing.

RESULTS:

In the period 2013–2017, use of TAVI in Québec was limited to very elderly patients with significant comorbidities at high risk of operative mortality. We observed improvements in both processes of care (e.g. documentation of risk scores) and clinical outcomes (e.g. 30-day and 1-year mortality) over time. Our consensus standards recognize the potential value of TAVI for patients at moderate operative risk, identify uncertainties and recommend best practices for patient evaluation and clinical decision-making about choice of treatment.

CONCLUSIONS:

A comprehensive, long-term evaluation process of TAVI with feedback to centers is associated with improvements in processes of care and outcomes. In the present context of expanding clinical indications, we

will continue to evaluate patient selection, processes and outcomes according to the newly-established provincial quality standards. This iterative approach facilitates continued evidence generation and decision-making for optimal use of an evolving intervention. We acknowledge the contribution of the members of the expert clinical committee.

PP18 An Access Evidence IT Solution Within A Pharmaceutical Company

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INTRODUCTION:

During 2014, Roche tested whether the EUnetHTA HTA Core Model© was a useful, exhaustive and relevant value framework to promote efficiencies in scoping, storing and sharing health technology assessment (HTA) evidence within a pharmaceutical company. The conclusion was positive and Roche decided to build a cloud based information technology (IT) platform to store all relevant HTA evidence to support global and regional market access activities, tagged with metadata according to the HTA Core Model©. The platform should be user-friendly and promote efficiencies and knowledge sharing across the organization. Eventually this platform may also be used by external stakeholders to access relevant HTA evidence.

METHODS:

In order to better equip global functions, regions and affiliates in a major pharmaceutical company with user-friendly and fast access to product-relevant HTA and payer evidence as well as access evidence plans, an easy-to-use IT-based platform was needed. The platform, internally called #TAg, is a central repository of information to support market access activities and promote collaboration between Affiliate, Region and Global teams. The platform uses metadata to label all types of evidence and uses the HTA Core Model© domains to categorize the evidence.

RESULTS:

The platform #TAg was developed throughout 2016/2017 and officially launched on 1 October 2017. Within

the first 30 days, the platform has been readily accepted by affiliates, regions and global functions through significant use uptake as measured by user registration and download activities. In addition, #TAg was used successfully in a pilot project for a submission to an external HTA body.

CONCLUSIONS:

A complete knowledge management system for HTA evidence is important for driving efficiency in scoping, storing and disseminating access evidence information within a pharmaceutical company. #TAg has so far proved a good start on such a system with further development expected in the coming years.

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PP19 Opioid Poisoning Deaths: A National Picture

AUTHORS:

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INTRODUCTION:

The factors associated with opioid poisoning death are poorly understood. We performed a retrospective autopsy study of decedents (a term used for people who are deceased) of opioid poisoning in Wales in 2015. Using anonymized linked data, we describe demographic characteristics, patterns of emergency service utilization, and clinical presentation prior to death.

METHODS:

Decedents of opioid poisoning in Wales in 2015 were identified from the Office of National Statistics (ONS) mortality dataset. Records were linked with the Emergency Department Dataset (EDDS) by the National Welsh Informatics Service (NWIS); and held in the Secure Anonymized Information Linkage (SAIL) databank. The data were accessed and analyzed in the SAIL gateway.

RESULTS:

Age at death ranged from eighteen to seventy-eight years, with a mean age of forty-two years. Average male age was forty-one years and average female age was forty-four and a half years. Seventy-three percent of decedents were men (n = 228/312). Eight-seven percent of decedents (n = 281/312) attended the emergency department in the three years prior to death. In total

2081 attendances were made, forty-one percent of which involved conveyance by ambulance. Attendances per individual ranged from one to 114, with over half of decedents attending more than three times. Diagnostic codes were mostly missing or non-specific, with only seven and a half percent of attendances representing eighty-two decedents, coded as drug related. Treatment codes were also mostly missing or non-specific, with sixteen percent of attendances representing 148 attendees attributed a treatment code. Thirty-nine percent of attendances (n = 822) ended in treatment and discharge, whilst twenty-seven percent (n = 562) led to hospital admission.

CONCLUSIONS:

Matching previously published data, we found that fatal opioid poisoning is preceded by a period of high emergency health service utilization. On average decedents were in their fifth decade and more likely to be male than female. Attendances varied widely, with men less likely to attend than women.

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PP20 Assessment Of The First Software Combined With Telemonitoring Support

AUTHORS:

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INTRODUCTION:

More and more software programs, including those with medical device status, are coming into the market that aim to facilitate management of diabetic patients. In France, their coverage requires a positive opinion from the French National Health Agency (HAS) dedicated committee. To understand the utility of these products for patients, real-life experiments are in progress. Since the evaluation principles are similar for all medical devices, it was important to find out with this first connected software if specific methods or evaluation criteria are necessary.

METHODS:

After obtaining CE marking, the manufacturer submitted a dossier to HAS outlining the clinical data and technical performance of the software. HAS