Aim and objectives Our objective was to assess the value of FCM versus FS for anaemia in patients undergoing benign gynaecologic surgery in our country. We followed a multicriteria decision analysis (MCDA) by using the EVIDEM framework that allows the incorporation of multiple stakeholders, including patients.

Material and methods The framework was adapted considering evidence retrieved with a PICO-S-T search strategy and grey literature. Criteria/subcriteria were weighted by relevance and an evidence-based decision-making exercise was developed to assign a score from −5 (in favour of FS) to +5 (FCM) to each alternative for each criterion. Weights and scores were multiplied to obtain the value of intervention relative to each criterion/subcriterion. Values were added to calculate the Modulated Relative Benefit–Risk Balance (MRBBB) on a −1 (FS) to +1 (FCM) scale. Ten stakeholders (gynaecology/obstetrics, haematology, anaesthesiology, midwifery, hospital pharmacy, hospital management, and patients and patients’ representatives) participated to collect different perspectives.

Results Weights were different among profiles: Compared Effectiveness (28% on average, 26.7% for hospital pharmacists (HP)) was the most relevant criterion. Compared Safety/Tolerability (18%, 24%) showed the greatest difference among all participants and HP. In general, participants were in favour of FCM in all criteria, as were HP, except for Economic Consequences (+1, −2.82). Lastly, the value of each criterion was calculated. The criterion with the highest impact was Compared Effectiveness (+0.178, +0.15). All profiles were in favour of FCM except Hospital Management. General MRBBB was +0.48; for HP, MRBBB was +0.34.

Conclusion and relevance From global and HP perspectives, FCM was the preferred alternative for treating anaemia in patients undergoing benign gynaecological surgery. MCDA can be a useful tool to incorporate diverse voices in the decision-making process, including professionals as well as patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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6ER-005 REDUCING INVASIVE DEVICE-RELATED BLOODSTREAM INFECTIONS: A CHALLENGE FOR THE PREVENTION OF HEALTHCARE-ASSOCIATED INFECTIONS
University Hospital of Poitiers, Hygiene, Poitiers, France
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Background and importance An infection is healthcare-associated (HCA) if it occurs during the care of a patient. Nosocomial infections (NI) are infections acquired in a healthcare setting. Bloodstream infections are the fourth most common NI in France and half the cases are associated with a vascular catheter. Reducing invasive device-related bloodstream infections is a major priority of the national programme: prevention of HCA infections.

Aim and objectives In our hospital we noticed an increase in healthcare-associated bloodstream infections (HCA-BSI) including those related to invasive devices. The objective of the study was to describe HCA-BSI acquired in our establishment in order to reduce the number of infections related to invasive devices by promoting their correct use.

Material and methods We applied the methodology of the French network SPIADI to compare our results with those of the other hospitals monitored. Each positive blood culture corresponding to a HCA infection was analysed to define the portal-of-entry of the infection. For HCA-BSI related to invasive devices, data on vascular and urinary catheters were collected. The study was carried out between January and April 2020. The intensive care, paediatrics, nephrology, haemodialysis and surgery services were excluded (no electronic medical records).

Results We included 156 patients with HCA-BSI: 60% were aged over 65 years and 66% were immunosuppressed. HCA-BSIs (n=164) were most frequently identified in oncology (21%) and in haematology (17%). Urinary infection (44/164; 27%) and presence of a catheter (40/164; 24%) were mainly associated with HCA-BSI. Enterobacteriaceae were mostly responsible for HCA-BSI with a urinary portal-of-entry and staphylococci for central line-associated bloodstream infections (CLABSI). Implantable port catheters (IPC) were the most frequent cause of CLABSI (25/40; 62.5%). The incidence of HCA-BSI was comparable to that of other institutions, except for oncology, where it was higher (8.37 vs 3.65 per 1000 hospital days), and this was particularly the case for IPC (2.87 vs 0.96 per 1000 hospital days).

Conclusion and relevance In the light of these results, we implemented a strategy involving the reporting of surveillance data, the updating of protocols with professionals, practice observations, and the training of professionals in charge of handling invasive devices. The impact of all these measures will be assessed through the results of future monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

6ER-007 REAL-WORLD EFFECTIVENESS OF GENE THERAPY ONASEMNOCENE ABEPARVOVEC (ZOLGENSMA) FOR SPINAL MUSCULAR ATROPHY: A REVIEW
1AC Martins De Figueiredo*, 2RP Pinheiro Gonçalves Marques, 1AF Cosme Silva, 1AP Mecheiro De Almeida Martins Silvestre Coreia, 1Faculdade de Farmácia da Universidade de Lisboa, Lisbon, Portugal; 2Centro Hospitalar Universitário de Lisboa Norte – Hospital de Santa Maria, Lisbon, Portugal
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Background and importance Spinal muscular atrophy (SMA) is an autosomal recessive neurodegenerative disorder. SMA I infants have a lifespan of <2 years if not treated. Zolgensma is an innovative drug of gene therapy strategy for SMA patients. Notwithstanding, there remains considerable uncertainty about the long-term sustainability of the Zolgensma clinical effect due to the narrow durability and limited sample size of clinical trials. Therefore, it is essential to measure its effectiveness to increase confidence in the technology use and its market access.

Aim and objectives Our study aimed to provide a critical review of the literature regarding the clinical outcomes in SMA infants in the real-world setting after the one-time Zolgensma dosing.

Material and methods A review of the literature was constructed, comprising five phases: (a) identifying the research question; (b) searching for relevant studies; (c) selecting
Background and importance Zolgensma is an innovative gene therapy for spinal muscular atrophy (SMA) infants. Nevertheless, the life-long clinical follow-up needed for understanding the long-term effectiveness of Zolgensma in combination with the exceptional large single payment represents scientific and financial challenges for the pharmaceutical industry, regulators and payers. The so-called Performance-Based Risk-Sharing Arrangements-Performance Linked Reimbursement (PBRSA-PLR) are financial models that have been developed for reducing uncertainty through greater investment in evidence collection, while a technology is used within a healthcare system.

Aim and objectives The scope of this investigation comprised the development of a hypothetical PBRSA-PLR for Zolgensma Gene Replacement Therapy (GRT).

Material and methods A review of the literature was constructed, comprising five phases: (a) identifying the research question; (b) searching for relevant studies; (c) selecting studies; (d) analysing data and (e) presenting the results. A comprehensive English-language literature search of the electronic databases PubMed and Science Direct was undertaken to identify published papers. Data were collected and analysed until May 2021.

Results We propose an outcome-based scheme based on Zolgensma performance in terms of sustainability of the clinical effect. The relevant outcomes should be the subsequent for a given SMA infant: (a) overall survival and (b) event-free survival. We further suggest an annuity-based payment scheme to reduce the consequences of the annual budget impact with a pay-over-time of 5 to 15 years to increase patient access. More favourable outcomes could be achieved if SMA infants started treatment earlier. Thus, we propose a maximum 50% refund for Zolgensma early dosing in SMA infants (until 3 months old), and a maximum 25% refund for Zolgensma late dosing in SMA patients (after 3 months until 9 months old), if Zolgensma fails to meet the agreed-upon outcomes and predefined timing of outcome assessments.

Conclusion and relevance We conclude that it would be possible to mitigate uncertainty around the incremental budgetary impact and cost-effectiveness of Zolgensma GRT. Nonetheless, it should be outlined that innovative payment schemes should only be applied in circumstances where there is scope for such mechanisms to effectively reduce decision uncertainty so that the probability of long-term cost-effectiveness can be improved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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