PP38 Immersion in water during childbirth: A survey to the Spanish National Health System

Eva Reviriego-Rodrigo (ereviriego@bioef.eus), Nora Ibargoyen-Roteta, Soledad Carreguí-Vilar, Luis Mediavilla-Serrano, Sonia Uceira-Rey, Susana Iglesias-Casás, Ana María Martín-Casado, Ana Toledo-Chávarri, Gonzalo Ares-Mateos, Sonia Montero-Carcaboso, Belén Castelló-Zamora, Natalia Burgos-Alonso, Anai Moreno-Rodríguez, Naiara Hernández-Tejada, Carmen Koetsenruyter and Iñaki Gutiérrez-Ibarluzea

Introduction: Certain doubts about immersion in water during birth mainly regarding the safety of the infant, warrant analysis of the data to determine whether immersion in water during childbirth is safe and effective. The aim is to describe the situation regarding the use of water immersion during childbirth in hospitals of the Spanish National Health System across Spanish Autonomous Regions and Cities.
Methods: A questionnaire was developed to assess the use of water immersion on maternity wards of National Health System hospitals. The survey was reviewed by several categories of health professionals and stakeholders. The online questionnaire was distributed via email. A database was created using the Microsoft Excel 365® computer program. Quantitative results were described through percentages and frequency distributions. In the case of free responses, a content analysis was performed, coding the responses into different categories.
Results: Regarding the status of water birth in Spain, the availability of the option of water birth varies across hospitals of the National Health System. Forty-six hospitals in 13 autonomous regions indicated that they had birthing pools on their delivery wards. Among these hospitals, 20 percent reported having more than 10 years of experience in water births, 45 percent between five and 10 years and 35 percent less than five years. Of the 46 responses received, 78 percent of the hospitals indicated that there was a demand for information on waterbirth by pregnant women. Regarding the existence of criteria for the adequate selection of pregnant women who could opt for immersion in water during childbirth, 89 percent of the hospitals indicated that these did exist, while 11 percent indicated that they did not have agreed criteria for the selection of candidates for water birth.
Conclusions: The availability of the option of water birth varies in hospitals across the Spanish National System. All the hospitals that have birthing pools offer them in the first stage of labor (dilation), while 32 percent also use them in the pushing stage and 15 percent during delivery of the placenta. It would be advisable to have standardized protocols and training to ensure the possibility that all pregnant women, regardless of their place of residence, can safely opt for water immersion during childbirth with satisfactory results.

PP38 Designing A Training And Capacity Building Pathway In Patient Involvement

Yolanda Triñanes (yolanda.trinanes.pego@sergas.es), María J. Faraldo-Vallés, Patricia Gómez, Paula Cantero-Muñoz, María J. Vicente-Edo, Eva Reviriego-Rodrigo, Blanca Novella and Ana Toledo-Chávarri

Introduction: The Patient Involvement (PI) Interest Group of the Spanish Network of Health Technology Assessment Agencies (RedETS) was set up in 2017 by a group of health technology assessment (HTA) researchers interested in PI. Since its inception, training and capacity-building to support PI and patient-based evidence in HTA processes has been one of its main aims. The objective of this work was to identify the needs and priorities related to training and capacity building activities to be developed within the framework of the PI Interest Group.
Methods: The PI Interest Group met on November 14, 2022, for its Annual Meeting. The group discussed the needs, priorities and possibilities on training, and carried out a prioritization exercise. For this purpose, a self-reported and anonymous questionnaire was used, which included 16 training activities. Every item was scored with a Likert-type scale ranging from 0 to 10.
Results: The questionnaire was answered by twenty participants. The most highly rated training activities (mean less than or equal to 8) were: qualitative evidence synthesis (8.75); PI case studies (basic (8.65) and advanced (8.56) level); quality assessment tools for qualitative evidence (8.37); and qualitative research (8.11). Other proposals scoring above 7 points were: ethical aspects related to PI, evaluation of patient participation and impact, identification and recruitment procedures, and discrete choice experiments. The group agreed to organize bi-monthly webinars and three structured training activities for the whole RedETS network on: Qualitative Evidence Synthesis, Qualitative Research and PI Case Studies.
Conclusions: The prioritization of training activities according to PI Interest Group members allowed planning a tailored capacity-building program adapted to the needs of RedETS.

PP40 Structuring Unstructured Medical Device Reimbursement In India

Ashwin Goel, Arif Fahim (arif.fahim@abbott.com), Monika Pusha and Kirti Kataria

Introduction: As India makes rapid strides towards universal health coverage, focusing on medical device reimbursement is key to

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ensuring patient access to device-based technologies. The nascent medical device reimbursement process offers a promising opportunity for interventions driven by a diverse group of stakeholders. We conducted policy research to capture these diverse perspectives and highlight key elements to develop a structured framework for reimbursement.

Methods: This research was a two-part process, including secondary research with expert interviews followed by policy research using focus group discussions (FGDs) through an online workshop with key stakeholders. We developed a white paper proposing changes to the reimbursement pathway, based on a benchmarking study of global markets and interviews with experts in the field. As a next step, key changes proposed in the white paper were deliberated upon by three focus groups (six to eight participants). Group participants were selected by quota sampling and represented key stakeholders in the reimbursement process. A discussion guide was used to capture participants' opinions and an addendum to the white paper was released highlighting small, actionable, and impactful changes to the reimbursement process.

Results: FGDs with key stakeholders highlighted the need to establish a more structured, inclusive, and transparent process. Accordingly, we proposed key recommendations to the medical device reimbursement process in India. A first change is the creation of an online submission portal allowing different healthcare stakeholders to submit new technologies for consideration through a streamlined pathway. Secondly, we proposed enhancing evaluation transparency by improving availability of publicly shared information on the evaluation process, metrics, and assessment timelines. We also suggested adoption of adaptive health technology assessments to leverage existing evidence for faster, efficient decision-making.

Conclusions: Through this process, we created a pragmatic and concrete call for a stronger voice from care-providers and patient groups in the evaluation process. Consecutively, the proposed innovative framework introducing value-based incentives for implantable medical devices will be instrumental in enabling access to quality health care for poor patients. These strategies follow the principles of value-based care and will go a long way in achieving better health outcomes for the population. The scientific initiative has been made possible with the support of St. Jude Medical India Pvt Ltd (now Abbott).

PP41 Using Medicare Claims Data To Support Reimbursement Of A Novel Leadless Pacing System For The Management Of Bradycardia

Koji Makino (kmakino@thema.net), Mia Mudge, Chelsea Zaunmayr and Dom Tilden

Introduction: The Micra Transcatheter Pacing System (Micra TPS) is a single-chamber transcatheter leadless pacemaker (LPM). LPMs do not require leads or a subcutaneous pocket, which represent the primary sources of device-related complications with conventional transvenous pacemakers (TVPMs). Complications such as infections and lead dislodgements cause significant patient burden, which have significant economic consequences. Running a randomized controlled trial (RCT) to estimate risk differences of infrequent events requires large sample sizes and long follow-up periods. Real-world observational data, while informative, requires an appropriate study design and statistical adjustments to control for potential biases.

Methods: The Micra Coverage with Evidence Development (CED) study was a cohort study of LPM versus TVPM based on US Medicare claims data of 16,431 patients with 2-year follow up (LPM: n=6,219; TVPM: n=10,212). Propensity score matching (PSM) was applied to account for differences in baseline characteristics. As no RCT was identified in the literature, this study was presented to the Australian payer as the primary source of clinical evidence, upon which a cost-utility analysis was conducted.

Results: After PSM, the CED study demonstrated significantly more complications with TVPM versus LPM with adjusted rates of 6.5 percent and 4.6 percent ($p<0.001$). Significant differences favoring LPM ($p<0.01$) were observed in device breakdown (1.4% vs 2.0%), dislodgment (0.4% vs 1.2%) and infection (<0.1% vs 0.6%). Based on these findings, a claim of superior safety was accepted by Medical Services Advisory Committee (MSAC) to support reimbursement. In making this decision, MSAC considered that the large sample size and propensity weighting overcame some of the potential biases and the magnitude of the benefit supported cost-effectiveness relative to TVPM.

Conclusions: The lack of a sufficiently powered RCT with an extended follow-up period can mean the impact and benefits of new technologies that reduce clinically important adverse events of relative infrequency are not formally incorporated into payer decision making, particularly where RCTs are a requirement. A well-designed observational study can provide valuable, real-world evidence to support a HTA for reimbursement decisions.

PP42 Insights Of Health Technology Assessment In Brazilian Health Unified System: Areas Of Interests In Health

Wolney Pires, Stefani Borges (stefani.borges@saude.gov.br), Fernanda Rodrigues, Nathalia da Costa, Priscila Louly, Clementina Prado and Vania Santos

Introduction: The National Committee for Health Technology Incorporation of the Brazilian Public Health System' s (Conitec) principle is to advise the Ministry of Health (MS) in the tasks related to incorporation, exclusion or modification of any health technologies into the Unified Health System (SUS). Moreover, this also involves alteration of clinical protocols or therapeutic guidelines.

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