PMD11
CAN BLOOD UNITS COMING FROM WHOLE BLOOD AUTOMATION DELIVER A CLINICALLY MEANINGFUL DIFFERENCE TO ANEMIC PATIENTS VERSUS ALTERNATIVE BLOOD COLLECTION TYPES?

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Objectives: With COVID-19 voluntary blood donations strongly reduced, clinicians are investigating which whole blood types or red blood cells concentrates (RBC) deliver most clinical value at the lowest volume possible. Hence the objective of this research was to investigate if the type of whole blood process could drive clinically meaningful differences for severely anemic patients. ***Methods:*** By means of literature review we investigated the main drivers of clinical outcomes in severe anemia (i.e. circulating blood volume and hemoglobin level (Hb)). Next we created different patient scenarios in severity of anemia and hence the need for blood transfusion. After this we compared the characteristics of blood units (volume and hemoglobin concentration) coming from whole blood automation (WBA) versus those coming from manual or semi-automated whole blood processes (mBC). Next we evaluated how these characteristics may deliver value to patients and their professional caregivers. ***Results:*** We found that between 5% and 35% of blood loss, as many WBA-derived RBC and mBC-derived units would need to be transfused to patients to overcome the anemia. Between 35% and 75% blood loss WBA-derived RBC requires on average 33% less blood units to restore normal volume and Hb concentration levels than mBC-derived RBC. ***Conclusions:*** In times of blood shortage, patients suffering from severe, acute bleeding and reduced Hb levels are likely to benefit faster from WBA-derived RBC transfusion blood units to improve oxygen delivery to cells than from mBC-derived RBC.

PMD12
BUDGET IMPACT ANALYSIS: FIRST PASS EFFECT IN MECHANICAL THROMBECTOMY FROM THE PERSPECTIVE OF A COMPREHENSIVE STROKE CENTER IN ENGLAND

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Objectives: Mechanical thrombectomy (MT) is indicated for the treatment of acute ischemic stroke caused by large vessel occlusion. The first pass effect (FPE) is achieved when recanalization of the vessel is achieved after first pass. FPE has been associated with improved functional outcomes and we investigate the impact to the cost of care within English comprehensive stroke centers (CSCs). ***Methods:*** A budget impact model was created from the perspective of CSCs, covering one year and considering resource utilization during hospital stay and the hospital length of stay. Clinical outcomes and resource data were obtained from a post-hoc analysis of a large clinical multi-country study. To avoid selection bias, we only considered successfully recanalized patients, defined by a modified treatment in cerebral ischemia score (mTICI) of 2c-3. Current and future FPE rates were obtained from public literature. Cost data was also obtained from the literature and not from the National Health Service unit costs. ***Results:*** Patients benefiting from FPE were associated with mean reductions of 29.2 minutes in Angio suite time, 0.39 thrombectomy devices per procedure and 3.4 days shorter hospital stay compared to patients recanalized with more passes. Estimated mean cost of an FPE patient was £5,393 compared to £7,476 for the others. In the current scenario of 80 MT procedures with an FPE rate of 23%, 18 patients benefit from FPE. If in the future FPE could be raised to 40%, 32 patients would benefit, and the CSC could potentially safe £29.162. ***Conclusions:*** Increasing the proportion of patients benefitting from FPE was associated with meaningful reductions in resource utilization and costs. Limiting the analysis to successfully recanalized patients was a conservative approach since patients who are not successfully recanalized present worse outcomes and higher cost.

Medical Devices - Epidemiology & Public Health

PMD13
A HEALTH ECONOMIC EVALUATION OF THE IMPACT OF PATHOGEN REDUCTION TECHNOLOGY ON EMERGING PATHOGENS WITHIN THE PLATELET COLLECTION AND TRANSFUSION SPACE

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Objectives: Given the recent COVID-19 outbreak our objective was to assess the role a European installed base of pathogen reduction technology (PRT) could have on controlling the potential devastating impact of future bloodborne emerging pathogens. In specific we wanted to assess its impact within the platelets collection and transfusion environment. ***Methods:*** Based on literature review, the characteristics of common bloodborne pathogens (e.g. the basic reproduction number, mortality and morbidity), current blood testing (BT) capabilities (e.g. blood test availability and sensitivity), pathogen reduction levels (e.g. log kill rate) as well as cost information in case of infection, were identified and modelled to assess the potential scenarios from a direct and indirect costs point of view. The assessment was performed for platelets collected within the current EU countries. ***Results:*** Assuming 2 million platelet collections and in case a new pathogen emerges for which no sensitive BT is immediately available. PRT could, within the first wave of infections, prevent 3696 infections through blood transfusion and avoid 2634 infections from transfused patients to others. Avoiding these infections would reduce health care expenditures by 97 million euro and save 25.000 days of hospitalization. Up to 1500 lives would be saved which would have an immediate positive economic impact of 74 million euro. Indirectly PRT would save 46189 days of productivity and reduce overall indirect morbidity costs by 19,6 million euro. ***Conclusions:*** In case of an emerging pathogen for which no highly sensitive DT is directly available, PRT and its known ability to avoid transfusion transmitted infections in platelets, may facilitate substantial economic and societal savings. As we only investigated for platelets, future research that considers plasma collections or red blood cell collections may be relevant. Country differences as well as differences based on the procedure to collect platelets may occur.

Medical Devices - Health Policy & Regulatory

PMD14
THE EVOLUTION OF REGULATORY FRAMEWORKS OF DIGITAL THERAPEUTICS (DTX) AND IMPLICATIONS FOR MARKET ACCESS

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Objectives: As technological development and uptake of consumer devices increase, the relevance of Digital Therapeutics (DTx) becomes increasingly relevant and viable. The objective is to identify how regulatory frameworks have developed to assess benefit and value of DTx and how this impacts of innovation, market access and ultimately patient care in the US and UK. ***Methods:*** The research methodology included a literature review, based on peer-reviewed materials but also grey literature to make up for the academic material paucity. Thematic analysis identified common perspectives on regulatory framework development and status. Policy analysis review identified working regulatory requirements, definitions, and potential future developments. Case studies were used to map regulatory pathways and market access strategies and to elucidate how these frameworks are realised in the real-world. Qualitative interviews were conducted to contextualise the findings and further inform the research with a focus on hurdles to the further development of value frameworks for DTx and foreseeable trends ***Results:*** US and UK frameworks define DTx as medical devices. There is a lack of clarity over when Digital Health apps require regulatory oversight. US policy has been borne out of a risk-based approach encouraging innovation, market expansion and access. Recent FDA Pre-Certification pathway has shifted the assessment of DTx to Quality Assurance of the developer. UK policy requires a 'declaration of conformity' outlining how the product design conforms to EU's Medical Device Directive which prioritises safety and performance data, through the CE marking requirement, with a lower burden of clinical efficacy evidence. ***Conclusions:*** DTx require demonstrations of clinical effectiveness. The US shows greater regulatory maturity, flexibility and nimbleness in DTx appraisal than the UK. The postponement of EU Medical Device Regulation and subsequent impact of Brexit provides an opportunity for the UK to their approach to DTx to better capture value and efficacy outcomes.

PMD15
MEDICAL DEVICES MANAGED ENTRY AGREEMENTS IN FRANCE

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Objectives: In France, the price of medical devices is regulated by the CEPS (Healthcare Products Pricing Committee) when products are registered under the LPPR. During negotiations, a contract is signed between the company and the CEPS and may include various terms and conditions of agreements (MEA). The objective of this study is to present the main types of agreements that exist and to determine trends according to the type of product. ***Method:*** All medical devices seen by the CEPS between 2018 and 2019 were included in the analysis. Contracts with manufacturers were analyzed individually. Univariate analyses were carried out to determine correlations between the type of MEA and the main characteristics of the products. ***Results:*** 307 products were analyzed in this study. Among these medical devices, 33.6% (103) have at least one MEA present in the agreement between the CEPS and the manufacturer. The most frequent MEA is a discount based on sales volumes (80%), followed by a simple discount (16%) and finally the performance clause (10.6%) and the review clause (6.7%).The univariate analysis shows a correlation between the type of discount and the level of clinical improvement (ASA), the size of the target population, the dispensing area, the therapeutic area and the budgetary impact. ***Conclusion:*** The different MEAs represent an important part of the CEPS tariff regulation methods. Not all MEAs are necessarily activated every year (especially if the volume thresholds are not exceeded).