emergency and outpatient departments over a three-year period. Market share in each year, device costs and the number of nurses in each department were based on the survey data from a hospital. Frequencies and costs of NSIs, time of blood collection and other related costs were collected from literature and Chinese government websites. ***Results:*** Compared with the conventional blood collection needles, the total cost savings of implementing safety needles were estimated to be 53,308 CNY, 133,269 CNY and 266,539 CNY, with a corresponding percentage reduction of 7.52%, 18.80% and 37.61%, respectively. The key driver of lower costs on the departments is the frequency of NSIs, where the implementation of safety needles avoided NSIs 94 times, 235 times and 470 times from year 1 to year 3 respectively. The expenditure of associated NSIs costs was decreased by 92,908 CNY, 232,269CNY and 464,539 CNY when implementing safety needles. ***Conclusions:*** The present budget impact results suggest that safety needles for venous blood collection achieved greater clinical and economic benefits, where it can significantly reduce the incidence of NSIs among healthcare workers as well as saving the expenditure for the emergency and outpatient departments. Safety needles for blood collection is therefore recommended as a beneficial option for the key clinical departments.

PMD4
ANALYSIS OF COSTS, LENGTH OF HOSPITAL STAY (LOS), READMISSION AND QUALITY OF LIFE IN PATIENTS UNDERGOING PRIMARY TOTAL KNEE ARTHROPLASTY (TKA) FROM CHINA ATTUNE® STUDY

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Objectives: This study describes the cost during hospitalization, LOS, readmission and quality of life (QoL) among Chinese patients received the ATTUNE® Knee system in primary TKA in China ATTUNE® study (ClinicalTrials.gov Identifier: NCT03542045). ***Methods:*** China ATTUNE® study is a prospective, single arm, non-randomized, 4-center observational study on primary TKA. The eligible patients were involved for the analysis after TKA until December 25th, 2019. Descriptive analysis was performed to understand the total cost of hospitalization in RMB, LOS in days, readmission rate and readmission cost. Sign test or Wilcoxon Signed Rank Test was performed to compare repeated measurements of EQ5D-5L at baseline and follow-up period. ***Results:*** At cutoff date, a total of 119 patients were enrolled. 115 eligible patients (16.5% male; age: 63.3 +/- 6.77 years) were included in this analysis with average 7.07 (1.11-17.48) month follow-up period. The total cost of hospitalization was ¥83 645.9 +/- 28 151.05. The average cost of medicine, procedure service, implant, disposables, examination and other medical cost was ¥5447.6+/-2 872, ¥7180.4 +/- 1 754.1, ¥72750.4 +/- 82 844.2, ¥2680.1 +/- 1516.8, ¥5360.0 +/-1977.1, ¥3433.6 +/- 2180.8 respectively. The intra-operative complication rate was 2.6% (3/115). The average LOS was 9.3 (± 2.98) days. All patients were discharged to home/caregivers. During the follow-up period, no readmission was observed. Provisional results showed that compared to pre-op baseline (0.50 +/- 0.18), significant improvement was observed in EQ5D-5L index at 6 week (0.60 +/- 0.13), 6 month (0.70 +/- 0.12) and 1 year (0.80 +/- 0.17) ($p < 0.001$), as well as the improvement in self-rated health status measured by EQ-VAS ($P<0.0001$). ***Conclusions:*** Compared with existing clinical pathway of China ministry of health on average LOS of TKA (14-20 days), ATTUNE® Knee system showed shorter LOS and could reduce related hospitalization cost while maintaining quality care and improve long-term QoL of patients.

PMD5
EVALUATION OF COST ANALYSIS OF THE MIDLINE CATHETER VERSUS PERIPHERALLY INSERTED CENTRAL CATHETER IN KOREA IN THE INPATIENT SETTING

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Objectives: Unlike traditional Peripherally Inserted Central Catheters (PICCs), which are placed in central venous system for ≥30 days, analysis aimed to compare both clinical and economic outcomes between MC and PICC in inpatient setting in Korea. ***Methods:*** A cost model which evaluated the annual clinical and economic outcomes between MC and PICC (calculated per year) was developed. Model inputs included patient population, catheter characteristics, and device, complication and labor cost. Patient population was assumed based on assessment Service (HIRA) claims data: 100,000 patients were assumed to have PICC insertion, and of those. Based on published literature, per 1000-catheters was 0.2 and 5.49 for MC while 2.3 and 5.49 for PICC respectively. Time per insertion was 9.5 minutes for MC and 30 for PICCs. Published complication, device and labor costs were used. ***Results:*** By switching 50% of 100,000 patients from PICCs to MC, an estimated annual cost savings of $3.8M may be observed. When only PICCs are used the total annual device cost was $14.8M, total annual treatment cost for complications such as CRBSI and occlusion was $2.2M and total annual labor cost was $3.2M, while these costs were $13.3M, $1.1M and $2.0M with a 50% switch to MC. ***Conclusions:*** Introduction of MC now offers patients to a new vascular access option with possibility of the full length of stay infusion therapy, lower complication rates, less time per insertion which is also a cost-saving option. The appropriate use of MCs can now relieve the burden of using unnecessary PICCs by providing both clinical and economic benefits to patients.

Medical Devices - Health Policy & Regulatory

PMD6
HOW TO PROMOTE THE APPLICATION OF REGULATORY SCIENCE IN COMBINATION PRODUCTS

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Objectives: Combination products (CPs), combining two or more drug, device and/or biologic, have the potentials to enhance therapeutic advantages. While CPs are becoming increasingly complex, the challenges faced by the drug regulatory authorities (DRAs) in ensuring their quality, safety and effectiveness are immense. To better address the regulatory issues, DRAs have developed and adopted regulatory science (RS). However, little is known about how RS is driving the advancement in CPs regulation. This research aimed to analyze the experiences of RS development in CPs based on a cross-country comparison. ***Methods:*** DRAs in China (National Medical Products Administration, NMPA), the United States (Food and Drug Administration, FDA) and the European Union (European Medicines Agency, EMA) were the study targets as they had officially launched initiatives in RS. Documentary analysis of government documents were conducted for data collection. ***Results:*** DRAs have seen a steady increase in CP applications in recent years. The definition, classification and regulatory requirements of CP are different across DRAs. Product classification and the corresponding review process are determined based on the primary mode of action at the discretion of the assigned department in charged of drug, medical device or biologics. With the adoption of RS, FDA mainly focused on post-marketing adverse-event reporting, good manufacturing practices and developing adaptive equivalence standards; EMA created an integrated evaluation pathway for product assessment and developed network-led partnerships with academia to facilitate integration of science and technology in product development and evaluation; NMPA clearly indicated CP was among the one of the 9 prioirty of actions and had developed a guidance on CP classification and a database of CP regulatory requirements and decision-making algorithm. ***Conclusions:*** Consideing the globalization of pharmaceutical products nowadays, RS should be adopted by DRAs in a collaborative manner to help achieve standardization of regulatory requirements.

PMD7
ANALYSIS OF MEDICAL DEVICE RECALL REPORTS IN CHINA FROM A REGULATORY SCIENCE PERSPECTIVE: IMPLICATIONS FOR POST-MARKETING SURVEILLANCE

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Objectives: In China, medical device is an essential part of healthcare service and represents a fasting growing healthcare market. To safeguard patient safety and improve regulatory decision-making, the National Medical Products Administration (NMPA) has set to advance the post-marketing surveillance system and adopt regulatory science (RS) for capacity enhancement. However, little is known about the most recent concerns of medical devices in the sizeable marketplace. This research aimed to analyze the official medical device recall reports and to explore priority actions for advancing RS in medical device. ***Methods:*** The risk class of the device ranges from I (lowest) to III (highest), and the recall classification was categoried based on potential harm: Type I (highest); Type II (medium); and Type III (lowest). We collected data from the NMPA to study medical device recalls from 2015 to 2019, and analyzed the number, reasons, risks of medical device recall, origins and indications of the products. ***Results:*** From 2015 to 2019, there were 1,781 medical device recalls, increased from only 184 in 2015 to 505 in 2019; all recalls were initiated by the manufacturers. In 2019, medical device recall cases involved local products (34.85%) and imported products (65.15%); most recalls were for low-medium risk class medical devices (Class II, 35.64%; Class III, 55.64%); 4.55% recalls might result in serious public hazard (Type I). The commonly recalled medical devices were those used in clinical testing equipment and surgical instruments, most of which were high-medium technology products; the main reasons for product recall were process problem (37.62%), component problem (18.81%) and labeling problem (17.23%). ***Conclusions:*** The medical device surveillance in China relied primarily on spontaneous reporting and recall system. By adoption RS, NMPA should focus on developing a proactive, robust, integrative, and predictive post-marketing surveillance system to facilitate the regulatory decision-making process and technology advancement.

Medical Devices - Health Technology Assessment

PMD8
MORTALITY AFTER USE OF PACLITAXEL-BASED DEVICES IN PERIPHERAL ARTERIES : A REAL-WORLD ANALYSIS

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Objectives: Drug technology for the treatment of peripheral arterial disease (PAD) have been an emerging concept for many years thanks to improve the freedom from target lesion revascularization (TLR). However, recent meta-analysis published in 2018 caused a cataclysm in the vascular field reporting higher mortality in the