that a positive correlation exists in hospitals between service specialization and the level of clinical quality; furthermore, one also exists between clinical quality and financial performance. Finally, service specialization has a positive effect on financial performance, which is fully mediated by clinical quality.

CONCLUSIONS: Based on a complete set of national data, this study demonstrates that hospital specialization has positive effects. Specialist hospital organizations provide superior quality of care and enhanced financial performance. Consequently, more specialization may prove to be a beneficial policy for the NHS.

HEALTH CARE USE & POLICY STUDIES – Regulation of Health Care Sector

PHP136
PRE-MARKETING AUTHORIZATION OF NEW MEDICAL DEVICES IN THE EUROPEAN UNION AND THE UNITED STATES
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OBJECTIVES: The European Union (EU) and the United States (US) have different regulatory systems for pre-marketing approval of medical devices (MDs) that result in differences in the MDs market authorizations and dates of market entry. This study analyzed differences between the MD regulatory systems in the US and the EU and evaluated the effect of those differences in pre-marketing authorization of new MDs in the period January 2000 to September 2012.

METHODS: The study included a comparison of the regulation of MDs in the EU and the US and an analysis of MDs pre-marketing authorization dates in both systems in the period January 2000 to October 2012. Data were collected from the US Food and Drug Administration (FDA), companies’ webpages and a review of the literature. Descriptive statistics were used to compare differences in approval dates. Regression analysis was used to assess trends in differences in approval dates over the study period. RESULTS: There were important differences in the pre-marketing authorization systems of MDs between the US and the EU. More clinical information was required for approval of MDs in the US than in the EU. The FDA listed 514 new MDs approved in the study period. FDA pre-marketing authorization and EU pre-marketing authorization (i.e. CE mark) dates were available for 201 MDs. Approval of MDs occurred on average 2.57±3.79 years earlier in the EU than in the US (median=2.42 years; 95%CI=1.86-3.39 years). Overall, 171 MDs (85.1%) were authorized first in the EU. The differences in approval dates grew over the study period at a rate of approximately 2.5 months per year. CONCLUSIONS: The EU and the US have different safety and efficacy regulatory requirements for MDs pre-marketing authorization. New MDs patients have early access to new devices, whereas US patients have more MD-related information available for reimbursement and clinical decisions.

PHP137
THE EFFECT OF MASSACHUSETTS HEALTH CARE REFORM ON INPATIENT AND EMERGENCY DEPARTMENT USE
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OBJECTIVES: The Commonwealth of Massachusetts implemented the first phase of a first wave of health care reform on January 1, 2006 through the Massachusetts (MA) reform has increased insurance coverage and improved access to care. How the ACA will affect the hospital sector is undefined. The objective of this study was to examine the effects of health care reform on inpatient services and emergency department visits in MA. METHODS: We used data from AHQR’s Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID) and the State Emergency Department Databases (SEDD). We implemented a difference-in-difference model which compared the legislation and examined the changes between 2005 and 2009 in both MA and in control hospitals for a limited number of high-level indicators: discharges (overall and in selected categories), length of stay, cost per discharge, and emergency department (ED) visits and charges. We also estimated regression models that controlled for the hospital’s competitive environment for both the inpatient and ED variables. There were 64 MA hospitals with nonmissing values for all of the variables used in this study (62 with EDs). The control populations for all of the variables used in this study (62 with EDs). The control populations for all of the variables used in this study (62 with EDs). The control populations for all of the variables used in this study (62 with EDs).

RESULTS: We used data for 64 MA hospitals with nonmissing values for all of the variables used in this study (62 with EDs). The control populations for all of the variables used in this study (62 with EDs). The control populations for all of the variables used in this study (62 with EDs). The control populations for all of the variables used in this study (62 with EDs). The control populations for all of the variables used in this study (62 with EDs).

METHODS: The study included a comparison of the regulation of MDs in the EU and the US and an analysis of MDs pre-marketing authorization dates in both systems in the period January 2000 to October 2012. Data were collected from the US Food and Drug Administration (FDA), companies’ webpages and a review of the literature. Descriptive statistics were used to compare differences in approval dates. Regression analysis was used to assess trends in differences in approval dates over the study period. RESULTS: There were important differences in the pre-marketing authorization systems of MDs between the US and the EU. More clinical information was required for approval of MDs in the US than in the EU. The FDA listed 514 new MDs approved in the study period. FDA pre-marketing authorization and EU pre-marketing authorization (i.e. CE mark) dates were available for 201 MDs. Approval of MDs occurred on average 2.57±3.79 years earlier in the EU than in the US (median=2.42 years; 95%CI=1.86-3.39 years). Overall, 171 MDs (85.1%) were authorized first in the EU. The differences in approval dates grew over the study period at a rate of approximately 2.5 months per year. CONCLUSIONS: The EU and the US have different safety and efficacy regulatory requirements for MDs pre-marketing authorization. New MDs patients have early access to new devices, whereas US patients have more MD-related information available for reimbursement and clinical decisions.

PHP138
PREDICTORS OF STATE ADOPTION OF FEDERAL HEALTH INSURANCE EXCHANGES
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OBJECTIVES: Health insurance exchanges (HIX) are regulated, standardized online marketplaces that allow consumers to compare and purchase health insurance coverage. The U.S. Patient Protection and Affordable Care Act (2010) required all states and the District of Columbia to choose between establishing state-controlled HIX, either independently or through a state-federal partnership, or else defer to federally-controlled programs. Following a December 2012 state federation strategy deadline, states and the District of Columbia opted to establish state-based programs, 7 states opted for partnership programs, and 25 states deferred to federally-controlled programs. The objective of this study was to examine the factors associated with the adoption of state-controlled HIX versus state-controlled and partnership HIX. METHODS: This descriptive, cross-sectional study used publicly available state-level data (n=51) from 2009 to 2012. Information was obtained from sources such as the Kaiser Family Foundation and the Centers for Medicare and Medicaid Services. Chi-square analyses were performed on categorical variables in relation to federal versus state-controlled and partnership HIX. Kendall’s rank correlation was used to examine the association of continuous variables, including political, economic, and population health measures, were included in this analysis. Of these, political party of the governorship (p<0.001), 2012 federal deficit crisis result (p<0.001), and political variables (p<0.001), unemployment rate (6.78% for federally-controlled HIX vs. 7.79% for state, p<0.05), and Medicaid enrollment in the <200% of Federal Poverty Guideline population (37.1% for federally-controlled HIX vs. 44.5% for state, p<0.05) were found to be significantly associated with default to federally-controlled HIX. CONCLUSIONS: States that opted for, or defaulted to, federally-controlled programs have shared political, economic, and population characteristics. The findings may impact state policy, implementation, and administrative decision-making. Further state-level data may yield further significant findings.

PHP139
REVIEW OF FRANCE’S TRANSPARENCY COMMITTEE’S 2011-2012 ASSESSMENTS
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OBJECTIVES: In France assessments by the Transparency Committee (TC) plays a significant role in pricing and market access of new products. TC evaluates clinical efficacy and safety data of new interventions, and compares it to current standard of care. TC’s assessments are made using ASMR ratings ranging from I to V (major innovation to no improvement). The objective of this study was to understand trends in TC’s assessments for new products approved by the EMA between 2011-2012. METHODS: TC’s assessments for 514 new MDs approved by the EMA between 2011-2012 were analyzed for their ASMR ratings. Analysis was conducted to identify new trends and compare them for products based on their indications, comparators, regulatory type, date of approval, and the year of analysis. RESULTS: Analysis of 2011-2012 assessments by TC shows that 27% of the products received an ASMR rating of III and IV. A new trend in TC’s assessment is the assignment of two ASMR ratings for one product for different subgroups or patient line of treatment. During last one year out of 11 products received two ASMR ratings. None of the products received ASMR rating of I and II. The products that received ASMR rating of V (no improvement) were indicated for cardiovascular, epilepsy, and bone metastases. All assessments included analysis of intervention’s data versus one or more comparators. CONCLUSIONS: France’s TC’s assessment trends show a need for robust comparison of effectiveness data to obtain better health ratings, which affects both pricing and market access of new products. Future products would need subgroup analysis to obtain high ASMR ratings for all patient populations.

PHP140
CHARACTERISTICS OF COMMUNITY PHARMACIES IN CAIRO, EGYPT: RESULTS FROM THE FIRST WAVE OF A CROSS-SECTIONAL SURVEY
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OBJECTIVES: In the pursuit of performance enhancement in the health care system in Egypt, particularly in the pharmaceutical sector, researchers face severe lack of relevant data. This limits our understanding of the health care system and the ability to detect policy-relevant problems. This is especially true for community pharmacies, which make the most easily accessible health care avenues for Egyptian households. We, therefore, sought to explore the characteristics of pharmacies in the Cairo area. METHODS: A cross-sectional survey conducted in 28 community pharmacies in the Cairo area. We collected data through personal interviewing of the pharmacist on duty in the surveyed pharmacies. RESULTS: One hundred-and-nine community pharmacies participated in the study (response rate 68%). Independent pharmacies accounted for 88% of respondents. Only 35% of the pharmacies had a full time pharmacist, while 20% suffered recent layoffs of pharmacists. Virtually all pharmacies offered disease and medication counseling, 58% offered compounding services, 56% offered drug information services, and 40% carried durable medical equipments. Respondent pharmacists were on average 31.6 years old, 62% were male; the majority (94%) had only the pharmacy school diploma. Work 56.3 hours a week and received 0.65 Egyptian Pounds (EGP) (~ $1) per hour in compensation. Male pharmacists worked more working hours (58.8 vs. 52.4, p<0.02) but the average hourly earnings did not statistically differ from females (6.12 vs. 5.94 EGP, p=0.2).

CONCLUSIONS: This study illustrates an ongoing effort to document
the characteristics of community pharmacies in Egypt. The current study and future ones would significantly improve the ability to probe practice-related issues and economic challenges community pharmacies and pharmacists face in Egypt.

**PHP141**

**BRIDGING HTA AGENCIES ACROSS EUROPE: A SYSTEMATIC APPROACH TO CATEGORIZE EVOLVING AGENCIES**

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**OBJECTIVES:** HTA agencies are mushrooming in Europe. Industry faces the challenge to meet their diverse requirements and comply with decision criteria. Our aim was to investigate similarities and distinguishing characteristics of HTA agencies. Anchor institutes take different approaches regarding the HTA and serve as a reference for others, and to assign other countries to one of the anchor institutes.

**METHODS:** We identified the primary institutions in European countries where HTA plays a role in decision making. We developed a template for the unified assessment of the input needs of the agencies, and a set of criteria an anchor country should meet. Agencies were assessed based on a literature review, and assigned to one of the anchor countries, which was validated by MSD subsidiaries across Europe. Future trends in anchor countries were investigated.

**RESULTS:** We identified three anchor institutes in Europe using different value assessment concepts. IQWIG in Germany primarily assesses HTA submissions on the basis of patient-related outcomes requiring hard endpoints. HAS in France sees the medical benefit of technologies in innovativeness rating them from no innovation to breakthrough innovation. NICE in the UK uses evidence of the cost-effectiveness and efficacy of the technologies. This project identified major patterns and differences among the European HTA agencies. We found that other European countries tend to primarily follow one of these concepts. Analysing future trends, one can see converges in the fields of HTA requirements, between regulatory and HTA, in coordination and problem solving, and in the field of HTA. Health technology assessment (HTA) is an input to the design of clinical trials, and can support the development of industrial HTA strategies. Using a single snapshot cannot substitute the deep knowledge of local requirements and needs regular update to follow-up future trends.

**CONCLUSIONS:** European HTA agencies can be systemized based on their requirements. This review can serve as a depository of individual country needs in HTA, an input to the design of clinical trials, and can support the development of industrial HTA strategies. Such a snapshot however cannot substitute the deep knowledge of local requirements and needs regular update to follow-up future trends.

**PHP142**

**CHANGES IN THE NUMBER OF ENROLLEES IN THE HUNGARIAN MANAGED CARE PROGRAMME**

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**OBJECTIVES:** A pilot care managing programme was introduced in Hungary in 1999. The conceptual foundations of the Hungarian implementation of managed care is closer to what was called the GP fundholding in the UK than HMOs in the USA. The purpose of the study is to analyse the changes in the number of enrollees in the care managing programme.

**METHODS:** The data derived from the financial database of the Hungarian National Health Insurance Fund Administration (NHIFA) covering the period 1999-2007. We identified the average annual number of persons enrolled to Care Managing Organizations. The Hungarian care managing programme increased from 158,984 (1.5 % of the Hungarian population) to 601,915 persons (5.9 %) in 2007. The proportion of enrollees decreased to 15% (25/165) of all NCDs, and “health education and behavior” (p=0.0195; 1999-2012), now representing 7% (11/165) of all NCDs, and “health education and behavior” increased from 7% in 2000 to 67% in 2012 (p<0.0001; CA test, 1999-2012). The proportion of occasions CMS cited, a “lack of relevant health outcomes” increased from 14% in 2000 to 67% in 2012 (p<0.0001; CA test, 1999-2012). The proportion of occasions CMS cited a “lack of studies including Medicare beneficiaries” increased from 7% in 2000 to 67% in 2012 (p=0.0003; 1999-2012). CMS has increasingly relied on coverage with evidence development (CED) policies (p=0.0292; 2009-2012). Since 2009, 10 NCDS (29% of NCDS in this period) resulted in CED policies, more than half of all CEDs (n=19) implemented since 2003. In recent years, NCDS have increasingly pertained to primary and secondary prevention level interventions (p=0.05971; 1999-2012), and now represent 28% (46/165) of all NCDS. The type of intervention evaluated also changed, with more NCDS pertaining to “diagnostic imaging technology” (p=0.0971; 1999-2012), now representing 15% (25/165) of all NCDS, and “health education and behavior” (p=0.0971; 1999-2012) reduced to 10% (16/165) of all NCDS.

**CONCLUSIONS:** CMS’s NCD process is evolving in important ways. CMS increasingly notes that technologies considered lack relevant outcomes. The agency increasingly uses CED, clinical trials, and HTA, as a medical technology, while collecting evidence for future use. It increasingly uses NCDS to evaluate preventive services and diagnostic technologies.