HEALTH CARE USE & POLICY STUDIES—\hfill PHP58
Quality of Care

EVALUATING THE PERFORMANCE OF AN INNOVATIVE PUBLIC HEALTH INSURANCE: THE CASE OF A DECENTRALIZED PROVINCE IN ARGENTINA

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In Argentina, the public health system is deeply decentralized and organized mainly at the provincial level. In this context, differences regarding income distribution and access to health services require the creation of regulatory devices and state intervention, the public health system is deeply decentralized and organized mainly at the provincial level. In this context, differences regarding income distribution and access to health services require the creation of regulatory devices and state intervention. One of the answers provided by the Buenos Aires Health Ministry was the creation of a Provincial Public Health Insurance, aimed at guaranteeing access to quality health services to population without formal health coverage and economic resources to afford one. This program included an innovative mechanism of human resources payment for the public sector—a capitated system with the possibility to generate a plus over the fixed salary and aimed to reach the coverage of 2.4 million citizens.

OBJECTIVES: To analyze the performance of the strategy in terms of focalization and development of preventive tasks associated with higher quality at the primary health care level.

METHODS: A database of 1.7 million consultations in 59 municipalities during the period 2004 to 2006 was analyzed, considering the evolution of preventive and curative consultations. Logistic regression models were implemented to determine the variables conditioning those tendencies (patient age and sex, physicians’ expertise, poverty, population density and health expenditure by municipality, among others).

RESULTS: The program was appropriated focalized in poor municipalities. Preventive consultations increased 107% during the three year period, and curative consultations decreased by 56%. Preventive consultations were significantly associated with young and female patients, as well as younger physicians. Also, poor and populated municipalities showed high associations with preventive consultations. Differences between municipalities were relevant, showing significant associations on both sides.

CONCLUSIONS: The insurance’s hiring and payment mechanisms, results were innovative and successful in the public health subsector, causing the professionals to increase their efforts towards higher quality preventive care. The strategy might be seen as one of the instruments with the potential to enhance care, quality and performance. Nevertheless, municipalities show particular characteristics regarding their management and administrative structures that affect the success of the program.

HEALTH CARE USE & POLICY STUDIES—\hfill PHP59
Regulation of Health Care Sector

LABEL CLAIMS BASED ON PATIENT REPORTED OUTCOMES IN EMEA AND FDA APPROVALS SINCE 2000

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OBJECTIVES: To document patterns in EMEA and FDA approved product label claims based on patient self-report data before and after publication of the 2005 EMEA Reflection Paper on Health-related Quality of Life (HRQL) and FDA’s draft guidance on Patient Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.

METHODS: PRO claims for products approved between January 2000 and June 2008 were identified from review of the PROQOLID database. Analyses compared FDA and EMEA claims for the same product to document patterns in the number and types of claims approved, and to determine whether the nature of claims reflect recent FDA and EMEA guidance on review of PRO and HRQL data.

RESULTS: More PRO-based claims were approved by FDA than EMEA (147 vs. 77) during the 9 year period. Of these, only 27 were for the same product reviewed and approved by both agency. PRO-based claims usually involved symptoms (FDA = 127, 86%; EMEA = 53, 69%). EMEA approved more claims for improvement in HRQL than did FDA (EMEA = 31; FDA = 11). Nine of 31 (29%) of EMEA approved HRQL claims were granted since the publication of the EMEA Reflection paper; compared with 45% (5 of 11) of FDA-approved HRQL claims granted since the draft FDA PRO guidance was issued.

CONCLUSIONS: Despite concerns that PRO and HRQL claims would be less common after issuance of these guidance documents, approvals to date suggest that PRO continue to be critical for symptom claims and HRQL claims continue to be granted by both agencies. Clinician-reported symptom assessments may explain some differences in symptom claims.