by The Federal Regulatory Agency for Private Health Insurance and Plans (ANS) in supplementary health sector. **METHODS:** A comparative analysis between the LP 7169/2014 and the NR 343/2013 (normative resolution that defines mediation rules in ANS currently) was made focusing on their similarities and differences. **RESULTS:** According to the LP, mediation is an alternative way to solve controversies in public administration. In supplementary health sector, the only way to have conflicts solved by ANS is through mediation. It's not an option, but the first step to every patient complaint about its health plan. Another difference is about the mediation closing. The LP provides the autonomy of the parties while in ANS, the mediation is just closed when there's no irregularities or when the problem is really solved by the health plan. The comparison allowed the identification of some common principles like equality, good faith, the search for consensus and neutrality of the mediator. **CONCLUSIONS:** The conflicts' mediation in supplementary health sector is a successful experience developed by the ANS. It has some rules defined by the NR. The LP brings some other rules to the mediation of conflicts in the public administration. So, it's possible to note that the mediation carried out by ANS nowadays is not fully suited to the Law Project. Maybe, the deeper knowledge of successful experiences in other countries, where the tool is more widespread, could guide the discussion about the improvement of the current LP and also point the best way to adapt the existing experiences in Brazil to the new legal provision.

PHP304

CONFLICTS' MEDIATION BETWEEN CONSUMERS AND HEALTH PLANS: THE USAGE PROFILE OF THE AVAILABLE CHANNELS FOR COMPLAINTS

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OBJECTIVES: To identify the most used way to make complaints about health plans to The Federal Regulatory Agency for Private Health Insurance and Plans (ANS) in Brazil. **METHODS:** A retrospective analysis of data was done to identify the most used channel of the three currently available: the personal, the call center and the electronic. Two different periods were considered to the study: the second semester of 2013 (the last one that still used an institutional email to the electronic complaints) and the second semester of 2014 (after the creation of a specific form for complaints available on ANS website). **RESULTS:** According to the data, the way most consumers choose to make a complaint is the call center (68,5% -2013 and 71,7%-2014). The second one is the electronic way. Comparing the two periods of the study it's possible to note a decrease of 5% in the use of electronic complaints after the form implementation (26% to 21%). The less used way is the personal one (6, 7% -2013 5,4%-2014). The study doesn't point a clear relationship between the themes of the complaints and the kind of service used. **CONCLUSIONS:** The study showed the call center is the primary service used. The personal service is less used then the others, probably because it's offered only in the biggest Brazilian cities. The implementation of the electronic form, through which the consumer can register and track their complaints, didn't increase the use of this channel. It's possible that form design, with required fields and limited number of characters, is acting like a complicating factor. As is known, the excessive work of the call center can compromise its quality and efficiency. So, it would be interesting to verify the key points to improve the electronic form to spread its use aiming to reduce costs through a future staff downsizing.

PHP305

EFFECT OF THE REORGANIZATION OF THE INTENSIVE CARE UNITS SYSTEM IN HUNGARY

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OBJECTIVES: In 2012 the Hungarian intensive care units system was restructured. The multidiscipline intensive care units were separated from the postoperative intensive units and the one specialty intensive units. The effect of it was analyzed. **METHODS:** Data were got from the National Health Insurance Fund Administration of the intensive care units for 10 years. There were investigated the organizational and the patient care related data. **RESULTS:** In 2012 the number of the multidiscipline intensive care units decreased 20% and the number of beds decreased 10%. Due to reorganization both the CMI and days of mechanical ventilation increased significantly in the multidiscipline intensive care units. In 2000 the 12% of the patients were discharged from the intensive care units to home, but by 2014 this rate decreased to 3%. It showed the use of the intensive care units were partially unnecessary before the reorganization. If we take the optimal bed-usage for the intensive care units to be 85%, in the new situation the actually available reimbursement approached to the theoretical value. The average bed-usage was 55% in the both period, but the statistical variance between the separated intensive care units decreased in the last years. **CONCLUSIONS:** The results shows that the reorganization was effective. Level of the intensive care have got higher, the use of the beds and the reimbursement increased. It is suggested to do similar reorganizations in the other specialties.

HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

PHP306

THE RELATION BETWEEN REAL COSTS OF DRUGS TEMPORARILY REIMBURSED IN MODE OF COVERAGE WITH EVIDENCE DEVELOPMENT AND BUDGET IMPACT ANALYSIS SUBMITTED AS A MANDATORY REQUIREMENT OF THE APPLICATION

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OBJECTIVES: The coverage with evidence development (CED) is a mode of reimbursement intended for highly innovative drugs (HID) in the P&R system in the Czech Republic. Cost-effectiveness analysis and budget impact analysis (BIA) are mandatory requirements for setting the reimbursement. The objective of the present study was to assess whether the drug costs stated in BIA matches to real costs. **METHODS:** Twelve HID obtained CED in 2013. The drug costs were identified in BIA of eleven HID. Real costs of General Health Insurance Company (VZP) were found out for each HID in the first year of therapy. As VZP holds 60% of the health insurance market, the data were extrapolated to the whole population. The differences between estimated and real drug costs were analysed and a correlation between this differences and drug characteristics justifying their HID status were investigated. **RESULTS:** The estimated costs were exceeded in five cases (overrun between 31-332%). In six cases real costs did not achieve the estimation (12-91% of estimated costs). Concerning effectiveness and safety characteristics of investigated drugs, within seven drugs granted as HID because of absence of an alternative drug, four exceeded the estimation. One of two drugs granted as HID because of adverse effects reduction compared with current treatment exceeded the estimation. Remaining two drugs did not achieve the estimation, one was granted HID because of mortality reduction, another because of higher effectiveness compared with current treatment. **CONCLUSIONS:** However HID costs estimated in BIA are submitted in order to predict costs of public health insurance, the analysis did not prove their validity and contribution to a reasonable decision making. Despite the fact that BIA is a mandatory requirement and it is cost and time consuming, its role is formal only and its premises have neither practical impact nor they are subject of further review.

PHP307

REVIEW OF POLICIES AND PERSPECTIVES ON REAL-WORLD DATA FOR DRUG DEVELOPMENT AND ASSESSMENT (IMI-GETREAL DELIVERABLE)

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OBJECTIVES: To conduct a review of different stakeholders' policies and perspectives on using Real-World Data (RWD) for early drug development and clinical effectiveness assessment in order to shed light on the possibilities for the incorporation of RWD and Real-World Evidence (RWE) in both aspects. **METHODS:** A qualitative methodology was selected that combines semi-structured interviews with a literature review. 19 stakeholders from 8 different stakeholder groups were interviewed. Meanwhile, a review of academic and grey literature was performed. Transcripts of interviews and data from review articles were subjected to coding analysis. Analysis focused on: definitions for RWD provided, current policies on RWD, context (actual & perceived) for RWD use, advantages and disadvantages of RWD, practical obstacles to using RWD, and political and procedural implications for RWD incorporation. **RESULTS:** Consensus regarding the definition of RWD and types of RWD was lacking among stakeholders. A current gap in policies addressing RWD also exists. Despite this, RWD is currently used for reimbursement, regulatory and drug development processes. RWD has high external validity & generalisability and can provide valuable data on long-term outcomes. Yet biases in data, poor data quality (completeness, comprehensiveness) and lack of standardisation entice scepticism for its use. Ambiguity still remains on governance of RWD/RWE as well as a cultural barrier among stakeholders against the use of RWD/RWE. **CONCLUSIONS:** Increased stakeholder collaboration is needed to harmonise definitions and evidence needs of RWD, reach consensus on the relevance of RWD for addressing specific questions, and to standardise RWD data collection and analysis methods.

PHP308

EFFICACY-EFFECTIVENESS-GAP – EXTENT, CAUSES AND IMPLICATIONS

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OBJECTIVES: The term efficacy-effectiveness-gap refers to the difference between the outcomes received within randomized controlled trials and those observed in real-word clinical practice. The phenomenon is often described in literature whereas papers generally remain unassertive or unspecific. The objective of our paper is to give a summary of the literature regarding extent, causes and implications of the gap. **METHODS:** A systematic review was undertaken. We searched PubMed, the Cochrane Library and Scopus for relevant articles. Papers assessing extent, causes and/or implications were included. Only full-papers in English or German language were eligible. Scanning reference lists, internet search and targeted contact with experts complemented our search. Two authors independently reviewed titles, assessed articles' eligibility for inclusion and extracted relevant data. **RESULTS:** In total 650 studies were identified. 27 of them met the inclusion criteria. We found that causes were most often analyzed in literature. The causes most often mentioned include patient-related causes such as lack of adherence, but also health-system related, service-provider-related as well as disease- or drug-related causes. 18 studies derived implications. Implications found predominantly focus on possibilities on how to bridge the gap. Only 5 articles address the extent of the gap whereof not a single one actually tried to quantify it. Instead, statements remain unassertive ("quite large", "huge", etc.) and results diverge regarding size as well as direction. **CONCLUSIONS:** While the causes of the gap seem to be relatively well understood, there is a lack of studies trying to analyze the actual extent of the gap. Authors encourage further research especially on approaches to quantify the extent of the gap.

PHP309

CHALLENGES ALONG THE ROAD TO UNIVERSAL HEALTH COVERAGE IN EGYPT, AN HIO PERSPECTIVE

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INTRODUCTION: In Egypt, health insurance organization (HIO) was established since 1964 as the governmental health insurer for public servants. Since then, it has significantly grown both in coverage and services as it currently covers 58% of