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bodies’ decisions varies across countries). Regarding integrated healthcare, it is worth to remark Colombia’s recent health reforms, which are shifting the paradigm toward Value-Based Healthcare (VBHC). Health data heterogeneously collected across countries due to fragmented healthcare systems (especially in Argentina and Mexico), Brazil and Colombia have the strongest health information systems in the region; however, outcome data availability is scarce in all countries. No formal stakeholder training in VBHC was found in any of the countries. Financial, capitation payments seem to be the mainstream in the region, although payers in all countries report outcome-based and bundled payment initiatives. Nationwide P4P and bundled payment policies were only found in Chile. Conclusions: By successfully implementing Value-Based Healthcare, countries can achieve better evidence-based outcomes, improve outcomes, better patient experience and improve the experience of providing care. This review shows that although no country has achieved a complete and successful transition to VBHC, advancements can be seen in individual domains across all countries.

PNS32
SOCIOECONOMIC INEQUALITIES IN SUBJECTIVE WELL-BEING IN HUNGARY
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Objectives: A robust understanding of well-being inequalities is recognized as a critical problem in public health science and decreasing disparities in well-being outcomes. This study aims to analyse the socioeconomic inequalities in subjective well-being (SWB) and to explore determinants of well-being inequality among the Hungarian adult general population. Methods: The data originated from a large cross-sectional study that represented broadly representative survey in Hungary conducted in 2020. A total of 2001 respondents were enrolled to the study (men 46.5%; age range: 18-87). We applied validated multi-item instruments for measuring subjective well-being, namely Satisfaction with Life Scale (SWLS) and the 5-item World Health Organization Well-Being Index (WHO-5). Raw scores on these two measures were transformed to a 0-1 scale. ANOVA was used to examine the differences between subgroups. The concentration index (CI) was used to measure the degree of income-related inequality in well-being. Results: The means ± SD of SWLS and WHO-5 scores were 0.51 ± 0.21 and 0.51 ± 0.23, respectively. Using both SWB measures, having a higher income level, a higher educational level, or living with a spouse/partner tended to increase well-being (p<0.05). Respondents living in neighborhoods with higher mean ± SD WHO-5 (0.54 ± 0.21) compared to those living in other towns (0.50 ± 0.21), or villages (0.50 ± 0.21) (p<0.05). The CI of WHO-5 scores was lower than that of SWLS scores both in the total sample (0.0371 vs. 0.0707) and in subgroups by sex (male: 0.0469 vs. 0.0889, female: 0.0237 vs.0.0582). The positive concentration index values implied a slight pro-rich inequality in this population. Conclusions: To protect against the subsequent adverse effect of lower socioeconomic status on subjective well-being, we recommend the potential interdisciplinary discourses regarding socioeconomic inequalities and well-being to support the development and evaluation of relevant policies.

PNS33
RECOMMENDATIONS FOR THE DESIGN AND IMPLEMENTATION OF AN EARLY FEASIBILITY STUDIES PROGRAM IN ITALY
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Objectives: Early Feasibility Studies (EFS) are limited exploratory clinical investigations taking place early in the development of devices, in small number of patients, typically before the device design has been finalized, when further non-clinical testing is not possible or meaningful. An EFS program was introduced by the US Food and Drug Administration (FDA) in 2013 to accelerate access of American patients to medical technologies and recoup a leading role in the pre-market research. The aim of this study was to explore perceptions of relevant stakeholders about the desirability and feasibility of an EFS program in Italy and of critical factors favoring or hampering its implementation. Methods: Qualitative research methods (i.e., exploratory and confirmatory focus groups) involving an expert panel of clinicians, biomedical engineers, members of ethics committees, academics, and industry representatives were used to collect opinions on the appropriateness and feasibility of an EFS Italian program. Results: The expert panel agreed that an EFS program would maximize the efficiency of evidence generation process, strengthen competitiveness at a European level, and investments in the biotechnological area. Potential challenges relate to the need for a clear legal framework and high level of technical competencies to evaluate studies. A particular attention must be given to ethical aspects, safety and risk analysis. Any device could be eligible, but potential benefits should offset the cost of the device on hard-to-treat patients. It is of paramount importance to engage all stakeholders in the design of these studies. Conclusions: Italian EFS program is highly desirable, however it requires trust and open dialogue between stakeholders, strong investments in capacity building, and patient protection measures to be successful. If successful, it could be scalable to the European context.

PNS34
ANALYSIS OF STRUCTURE OF E-PRESCRIPTIONS IN PROGRAM “AFFORDABLE MEDICINES”
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Objectives: The Government program “Affordable Medicines” is implemented in Ukraine to provide outpatient treatment to patients with chronic diseases with the essential medicines from April 2017. The e-prescriptions have implemented under the administration of the National Health Service of Ukraine (NHSU) since April 2019. The Study Aim: was to analyze the dynamics of the regional distribution of e-prescriptions in the program for 2019-2020 according to criteria such as: prescribed and released e-prescriptions, gender and age of patients. Methods: Analysis of the NHSU database, statistical data of e-prescriptions, comparative analysis. Results: According to statistics data of NHSU, 24605999 e-prescriptions were prescribed during the selected period, of which 21020988 were delivered. The increase e-prescriptions in 2020, and the highest rates were in the Southern (+ 25.3%) and Western regions of Ukraine (+ 23.2%). Accordingly, the growth in e-prescriptions is + 20.5% with the highest rate in the Southern (+ 26.3%) and Western regions (+22.8%). The highest increase in e-prescriptions for patients depending on gender was found in the Southern region (women + 24.8%, men + 26.8%). By age distribution: 65+ patients had the highest increase in the Western region (+ 23.4%); 40-64 (+ 26.5%), 18-39 (+ 30.1%), 6-17 (+ 30%) in the Southern region; 0-5 (+ 16.2%) in the Central region. Conclusions: After analyzing the sample of e-prescriptions in the program “Affordable Medicines” for the selected period, we found a positive trend in the number of patients from different categories of the population who receive quality treatment with medicines from the program.

PNS35
THE IMPACT OF SOCIAL DETERMINANTS OF HEALTH ON CANCER CARE: A SURVEY OF COMMUNITY ONCOLOGISTS
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Objectives: Social determinants of health (SDOH) have consistently been shown to correlate with health outcomes, with greater SDOH burden contributing to disparities in access to care, adherence to treatment, and follow-up in patients with cancer. In addition to poor outcomes, high SDOH burden is also associated with higher utilization of acute healthcare, adding to burgeoning costs of care. In this study, we surveyed oncologists regarding their perceptions of the impact of SDOH on their patients, and their opinions on how these effects could be remediated. Methods: Between February and April 2020, community oncologists/hematologists from across the United States (US) completed web-based surveys about how SDOH affected their patients, which factors represented the most significant barriers, and how the impact of SDOH could be mitigated through assistance programs. Results: Of the 165 physicians who completed the survey, 93% agreed that SDOH had a significant impact on their patients’ health outcomes. Financial/safety/lack of insurance and access to transportation were identified most often as the greatest barriers for their patients (83% and 58%, respectively). Eighty-one percent of physicians indicated that they had limited time to spend assisting patients with social needs, and 76% reported that assistance programs were not readily accessible. Government organizations, hospitals, non-profit organizations and commercial payers were selected by 50% or more of oncologists surveyed as who should be responsible for delivering assistance programs to patients with SDOH needs; 42% indicated that pharmaceutical manufacturers should also be responsible. Conclusions: In this cross-sectional survey of practicing US oncologists, nearly all respondents agreed that SDOH, especially financial issues, had a significant impact on their patients’ health. Most physicians indicated that they lacked adequate time to support patients’ social needs, and identified a need for greater involvement in addressing these barriers (government, non-profit and commercial entities) in addressing SDOH to improve health outcomes.

PNS36
VALUE BASED PROCUREMENT: A TOOL TO MAKE BETTER PURCHASING DECISIONS AFTER COVID-19
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Objectives: The G20 proclaimed that Value-Based Healthcare (VBHC) offers the best approach to support and improve healthcare services after the pandemic. Value-based procurement implementation (VPB) is a model of VBHC considering total cost of care and health outcomes to support better purchasing decisions. This poster advocates for a broader adoption of VPB in Latin America (LA). Methods: We conducted semi-structured interviews with six experts from academia, government, industry and multilateral organizations. A standardized questionnaire was used to identify case studies, key success factors and hurdles for implementation of VPB in LA. Experts provided supporting literature that was further expanded using the snowball technique. Results: We identified three examples: (1) Integrated Renal Care Services (Colombia), where the High Cost Account defines and record clinical
outcomes financially rewarding those outperformers; (2) Vaccines virus-based recommendation (Argentina, Brazil, Colombia), where a National Vaccine Advisory Committee selects the vaccine to be procured informed by a cost-effectiveness analysis; and (3) Diabetes Type 1 care model (Brazil), in a public-private collaboration defines and gathers outcomes to support a value-based tender for 2022. Common key success factors include multi-stakeholder alignment on value attributes; monitoring and reporting performance indicators and the training of stakeholders. Studies identified included lack of 

Field safety corrective actions (FSCA), communicated through

Field safety notices (FSN), are actions taken by manufacturers to reduce risk of death or serious

Positive decisions lacked C-RJ without a claim to clause 107.4 (D). In every
do not included but not verifiable due to re-
ductions, and lack of C-RJ with (C) and without (D) a claim to clause 107.4 of law on administrative conduct. This clause allows for abandoning any justification when decision fulfills all the applicant requested but excluding cases when competitive interests are involved. Number and percentage of decisions in each category was calculated separately for positive and negative decisions. 

The study included 122 decisions of which 118 were positive and 4 negative. 100% (118/118) positive decisions lacked C-RJ without a claim to clause 107.4 (D). In every

have insurance coverage, with mostly private insurance and

Conclusions: The study employed secondary data analysis of the 2016 Ethiopian demographic and health survey (DHS) dataset for women aged between 15 and 49 years old. The analysis involved a total of 15,083 women. Univariate and multivariate logistic regression analysis, Odds ratios (OR) and 95% confidence intervals (CI) were calculated for the relevant variables. All p-values less than 0.05 were considered statistically significant. Results: More than half (10084; 64.3%) of the respondents reported facing at least one barrier to access health care services meaning only 36.7% of the women had easy access to health services. Being married/living together (OR = 1.339; 95% CI = 1.204-1.489), having some form of formal education (OR = 1.194; 95% CI = 1.088-1.310), and being in the richest quintile in terms of wealth status (OR = 1.647; 95% CI = 1.312-2.427) were independent predictors of better access to health care services. In contrast, being older than 19 years of age (OR = 0.841; 95% CI = 0.753-0.940) and living in rural areas (OR = 0.7; 95% CI = 0.613-0.8) independently predicted lesser access to health care. Moreover, women who had insurance coverage were about 1.6 times (95%CI = 1.336-1.880, p < 0.001) more likely to have access to health care than their uninsured counterparts. Conclusions: Based on these findings, targeting of vulnerable individuals in health policy implementation and expansion of health insurance are recommended.

Estimating Administrative Costs Linked to Medical Devices Recalls from the Perspective of the Healthcare Provider

Conclusions: The study assessed the quality of content-related justifications (C-RJ) which Minister of Health is legally obliged to provide in these decisions. Methods: All decisions on increasing a price of reimbursed drugs requested and received under Polish FOIA by the Foundation for Transparency and Predictability of Administrative Decisions in 2017-2020 were identified. Every decision was assessed and classified as (A) C-RJ included and verifiable, (B) C-RJ probably included but not verifiable due to redactions, and lack of C-RJ with (C) and without (D) a claim to clause 107.4 of law on administrative conduct. This clause allows for abandoning any justification when decision fulfills all the applicant requested but excluding cases when competitive interests are involved. Number and percentage of decisions in each category was calculated separately for positive and negative decisions. Results: The study included 75 decisions of which 42 were positive and 33 negative. 100% (42/42) positive decisions lacked C-RJ without a claim to clause 107.4 (C). 100% (33/33) negative decisions were extensively redacted in contrast to positive decisions with usually only personal applicant data redacted. Based on the length of justification by far exceeding that in positive decisions they were all classified as (B). Conclusions: Directive 85/105/EEC requires EU countries to establish objective and verifiable criteria of decisions to increase a drug's price. Poland accessed EU in 2004 but established the criteria seven years later in 2011 within the new law on drug reimbursement. Even the most objective and verifiable criteria will not ensure fair competition for public funds if their fulfillment is not fully referred in content-related justifications.

PNS40 SOCIOECONOMIC FACTORS AND INSURANCE COVERAGE AS PREDICTORS OF ACCESS TO HEALTHCARE AMONG WOMEN IN ETHIOPIA

Conclusions: Although we focused in 3 cases involving public funding, traditional procurement approaches undermine value realization from healthcare investments. Although we focused in 3 cases involving public funding, traditional procurement approaches undermine value realization from healthcare investments.

PNS39 POSITIVE DECISIONS BY MINISTER OF HEALTH ON INCREASE OF EX-FACTORY OFFICIAL PRICE OF PUBLICLY FUNDED DRUGS IN POLAND LACK CONTENT-RELATED JUSTIFICATIONS - AN ANALYSIS OF QUALITY OF JUSTIFICATIONS OF DECISIONS ON INCREASING PRICES OF REIMBURSED DRUGS

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Objectives: Decisions to reimburse highly priced innovative drugs are crucial for Decisions to reimburse highly priced innovative drugs are crucial for policy decisions. The United States (US) and Europe vary in their adoption of real-world policy decisions. The United States (US) and Europe vary in their adoption of real-world evidence (RWE) as evidence (RWE) as an integral component of the decision-making process for new drugs.

PNS38 CAN REAL-WORLD EVIDENCE DRIVE POLICY DECISIONS: A COMPARISON OF THE UNITED STATES AND EUROPE

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Background: The passage of the 21st Century Cures Act in 2016, the European Medicines Agency (EMA) has been conservative in its approach, fearing biases in data that might impact the quality and credibility of evidence generation. Objectives: The objectives of this paper are to evaluate the current role of RWE in US and European stakeholder decision-making and to provide recommendations for RWE harmonization. Methods: We evaluated research papers as well as review articles from 2015 onwards to ensure relevance to policy decision making. Articles that referred to the use of RWE for regulatory, payer, market access, and policy decisions were selected. Results: Most-alone and colleagues indicate that while US payers are interested in RWE, they perceive several practical challenges to utilizing RWE while making policy decisions. These include the lack of relevant endpoints, the timeliness of the research conducted, and the transparency of the methodology used to conduct the research. Faced with these challenges, associations with data harmonization across Europe often caused by legal, political, economic, and digital barriers. While France, Sweden, and Norway maintain robust electronic medical and governmental records with unique patient identifiers, they lack data on prescription drug use. Conversely, Italy and Portugal track utilization of prescriptions, but using bespoke registries and outcomes-based managed entry agreements. In the UK, the National Institute of Clinical Excellence is working to incorporate comparative individual patient data earlier into the technology appraisal process to better estimate treatment effectiveness. Conclusions: We recommend the development of a North Atlantic Healthcare Data Alliance to serve as the starting point towards harmonizing RWE protocols and data generation to provide rich and timely insights for policy decisions.