

The difference in event count was used to test national changes and a P-value of ≤ 0.05 was used to test significance. **Results:** There were 140,035 heart failure admissions in the observational period, 64,770 during the pandemic and 75,265 prior to the pandemic, all data were analysed. There were reductions in admissions (69,555 vs 80,715, $P < 0.0000000000$), bed days (586,430 vs 753,985, $P = 0.0000000000$) and inpatient deaths (7,650 vs 8,305, $P = 0.0000002154$) during the pandemic. **Conclusions:** There were significantly fewer admissions, bed days and inpatient deaths for patients admitted with heart failure during the coronavirus pandemic. Interpretation of this change is challenging as this may reflect unmet health needs as patients 'put off' seeking care. Further research is required to analyse the change in out of hospital healthcare utilisation, deaths in other settings and to explore potential for excess and latent morbidity and mortality that may result from reduced access to hospital services during the pandemic.

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TELEHEALTH ACCESS AND USE BY THE U.S. MEDICARE POPULATION DURING THE PANDEMIC

Swenson T

Des Moines University, Des Moines, IA, USA

Objectives: Telehealth access and reimbursement varied by payer and regionally prior to COVID-19, and its limited availability expanded in response to the pandemic. The health behavioral response by older adults to COVID-19 has varied over time with the geographic spread of the pandemic and affected access and utilization of medical services. The purpose of this paper is to examine changes in access to telemedicine in 2020 in response to the pandemic for the U.S. Medicare population. **Methods:** The first two waves in June and October 2020 of the rapid response survey fielded by the Centers for Medicare and Medicaid Services (CMS) to track and monitor the effects of the pandemic within the U.S. Medicare population. With a panel sample size of 9686 Medicare beneficiaries, the calculated statistics use replicate weights to adjust for the complex survey sample design and balanced repeated replication using Fay's adjustment of 0.3 for variance estimation. **Results:** Nearly 45 percent of the Medicare population reported use of a telehealth appointment between June and October of 2020. The likelihood of using telemedicine increased for those with chronic conditions, such as depression, and for those with higher incomes and education. Medical practices were more likely to encourage telehealth visits for Medicare patients between March and June with 57 percent of the Medicare population reporting that their usual provider offered a telemedicine appointment to replace a regular office visit during the spring and 48 percent reporting the suggested telemedicine replacement from July through October 2020. Overall access to telehealth increased from 60% to 64% but varied by race/ethnicity, gender, Census regions, and rural status. **Conclusions:** Access to telemedicine services expanded for the U.S. Medicare population during the pandemic but usage varied by chronic disease status, socioeconomic and demographic factors, and geography.



Impact of the COVID-19 Pandemic: Investigations in Populations of Interest

P25

IMPACT OF COVID-19 ON THE HEALTH-RELATED QUALITY-OF-LIFE OF PREGNANT AND POSTPARTUM PERSONS

Regan A,¹ Aytha Swathi P,² Nosek M,¹ Gu NY³

¹University of San Francisco, Sacramento, CA, USA, ²University of San Francisco, Signal Hill, CA, USA, ³NYG Technologies, Santa Clarita, CA, USA

Objectives: To assess the impact of COVID-19 on health-related quality-of-life (HRQoL) of those who were pregnant or recently pregnant during the pandemic. **Methods:** Individuals who were pregnant any time since January 2020, the beginning of the pandemic, were invited to participate in an online, national US survey (EuroQol grant: 260-2020RA). Respondents were asked to self-report their experiences with COVID-19, to complete the EQ-5D-5L, and other measurements of HRQoL. To estimate the association between COVID-19 infection with the EQ-5D-5L outcomes, we used median regression for the EQ-5D utility and EQ-VAS scores, and ordinal logistic regressions for the EQ-5D-5L health items. Post-stratification weights were used to ensure representation by age, race and US census region. **Results:** Among pregnant or postpartum persons, the median EQ-5D-5L utility score was 0.87 and EQ-VAS was 0.80. The median EQ-5D-5L utility score increased by 0.0058 (95% CI 0.0026, 0.009) for each additional year of age of the respondent. We observed no change in EQ-5D-5L utility measures by maternal age ($\beta = 0.00$; 95% CI -0.09, 0.09). On average, comparing Black pregnant persons to White, EQ-5D-5L utility values were 0.44 points lower, and EQ-5D-VAS scores were 0.31 points lower. Although median EQ-5D-5L utility values were similar for those with and without a diagnosis of COVID-19 (0.87 and 0.88), utility values declined by 0.022 (95% CI -0.040, -0.010) for each unit increase in perceived COVID-19 severity. Similar results were observed for the EQ-5D-VAS scores. When we evaluated EQ-5D-5L items individually, respondents diagnosed with COVID-19 reported more problems related to anxiety/depression compared with those who did not (OR 2.43; 95% CI 1.35, 4.40). No other items were significantly associated with COVID-19. **Conclusions:** We observed lower HRQoL measures associated with severe COVID-19 infection during pregnancy. In particular, problems with anxiety and depression contributed most strongly to lowered HRQoL during pregnancy.



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THE PRACTICE OF FACE MASKING AMONG YOUNG ADULTS IN SOUTH INDIA: AN ONLINE CROSS-SECTIONAL SURVEY DURING SECOND WAVE OF COVID-19

Kochuparambil J, Issac A

Mary Queen's Mission Hospital, Kanjirappally, India

Objectives: COVID-19 pandemic urges the need for respiratory protective equipment like face masks as a public health measure to control the spread of infection. This study aimed to investigate the trends followed in the practice of mask-wearing by the South Indian population amid the second wave of COVID-19 outbreak in 2021. **Methods:** A web-based, online cross-sectional survey was conducted among the young adult population in India in late April 2021. An eight-item questionnaire was designed to assess the social perceptions and attitudes regarding wearing a face mask as a part of universal safety precautions. The social perceptions towards wearing masks were categorized as excellent, good average and poor on a scale (Social Perception Scale -SPS) scored out of 8. The details collected using a pre-designed google form are statistically analyzed using the Chi-square test with a p-value of < 0.05 is considered statistically significant. **Results:** Among the 1283 participants who completed the questionnaire, 57% wore cloth masks followed by 26% wearing N95 masks and 12% wearing surgical masks. Even though the age of the study population varied from 19 – 76 years and with a male preponderance of 56.3% (n = 723), students and recent graduates participated largely in the study (71.8%, n = 922). A mean SPS score of 5.67 ± 1.07 (out of 8) indicates that the social perception of the study population is good. A statistically significant association is observed between the SPS score and the age ($p = 0.003$), type of mask used ($p < 0.001$), and economic background of the study population ($p < 0.001$). Breathing difficulty, communication problems, additional cost incurred and dermatologic issues were commonly reported barriers against mask-wearing. **Conclusions:** Adjunctive public health measures such as mask-wearing are crucial in curbing the COVID-19 transmission. By shaping an appropriate public attitude, policymakers can ensure compliance towards mask-wearing.



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VACCINATION COVERAGE TRENDS FOR HEPATITIS B IN INFANTS FROM THE BRAZILIAN AND COLOMBIAN EXPANDED IMMUNIZATION PROGRAM: A REAL-WORLD ANALYSIS OF COVID-19 PANDEMIC IMPACT

Lima P,¹ Abreu A,² Hernández F,³ Martins J,² Kano B,¹ Kashiura D,² Julian G²

¹IQVIA Real World Insights, São Paulo, SP, Brazil, ²IQVIA Brasil, São Paulo, SP, Brazil, ³IQVIA Colombia, Bogotá, Colombia

Objectives: COVID-19 pandemic has posed major challenges for healthcare systems and societies worldwide. Mitigation measures and the fear of exposure to COVID-19 might have negatively impacted local health policies, such as pediatric immunization programs strategies. This observational study aims to analyze the vaccination coverage (VC) for hepatitis B in infants in Brazil and Colombia between 2015 to 2020. **Methods:** This is a descriptive analysis using real-world data from the Expanded Immunization Program System from Brazil (SI-PNI) and the Epidemiological Surveillance System from Colombia (SIVIGILA). We calculated the annual variation of VC for hepatitis B in infants from 2015 to 2020 for both countries. **Results:** Overall, Brazilian VC had an average annual decline of 3.6% in the pre-COVID-19 period (2015-2019), reaching the lowest coverage in 2019 (78.57%), while the Colombian VC had an increasing pattern for the same period (0.4% annually), reaching the highest coverage in 2017 (89.3%). In 2020, VC decreased by 19.8% in Brazil, compared with 2019. In Colombia, VC decrease was notably lower (1.0%). **Conclusions:** In Colombia, VC increase might be explained by the implementation of the national plan for hepatitis B elimination in infants during this period. In Brazil, VC coverages for several other infectious diseases have also faced a decrease during the last years, but no formal mitigation activity or plan was yet established. Although both countries showed a reduction of the VC coverage in 2020, the impact was considerably higher in Brazil. These trends could be explained by the distinct health strategies linked to the Expanded Immunization Programs for each country in preparation for the COVID-19 pandemic.



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IMPACT OF COVID-19 ON MENTAL HEALTH IN YOUNG ADULTS IN THE UNITED STATES

Intermill T,¹ Gong CL,² Gu NY³

¹University of San Francisco, Sacramento, CA, USA, ²Children's Hospital Los Angeles, Los Angeles, CA, USA, ³NYG Technologies, Santa Clarita, CA, USA

Objectives: To assess the impact of COVID-19 pandemic on mental health in young adults in the US. **Methods:** Three waves of online surveys were designed to capture mental health status in the US (EuroQol grant: 84-2020RA): Wave1 (Apr 1st – May 6th, 2020 (n=2,734)), Wave2 (July 4th – Sept 4th, 2020 (n=2,454)), and Wave3 (Jan 10th – Mar 15th, 2021 (n=2,252)) using the EQ-5D-5L to evaluate respondent's health-related quality-of-life (HRQoL) and the Patient Health Questionnaire (PHQ-4) to assess anxiety and depression. The EQ-5D-5L utility, VAS scores and 5 domains were stratified by age, gender, and race/ethnicity. Binary Logistic regressions were used to estimate the associations between anxiety/depression and various covariates. Chi-square tests were conducted for significant differences in mental health outcomes between age groups. **Results:** Most participants were white (68.7%) non-Hispanic



(89%). On average, participants were 42 (± 13) years old, 47% being female. In all 3 waves, self-reported anxiety and depression were significantly higher in young adults (18-34) compared with older adults (35+) ($p < 0.01$). Anxiety scores were 42%, 53%, and 33% in waves 1-3 respectively for young adults, whereas 33%, 40%, and 22% were reported by adults 35-64 and 19%, 20%, and 12% were reported by adults 65+. Similar trends were observed for depression, with younger adults reporting 39%, 54% and 35%, compared with 27%, 38% and 22% for those aged 35-64 years and 14.5%, 16% and 14.85% for 65+. EQ-5D-5L utility in waves 1-3 were 0.82, 0.75, and 0.82 ($P < 0.01$) and 74.7, 78.7, and 76.4 for EQ-VAS ($P < 0.01$). Age and employment status were significant predictors for anxiety and depression outcomes. **Conclusions:** Mental health deterioration during COVID-19 was pronounced among young adults for all waves, especially in wave 2. Findings suggest although people adapt over time, the US was ill-prepared for a mental health crisis, especially among young adults.

Informing the Decision-Making Process in Real Time

P29

REIMBURSEMENT OUTCOMES FOR COMBINATION THERAPIES VS MONOTHERAPIES IN LUNG CANCER AND MULTIPLE MYELOMA IN THE TOP FIVE EUROPEAN MARKETS

Izmirlieva MA,¹ Reinaud F,² Taiyeb M,³ Ando G¹

¹IHS Markit, London, UK, ²IHS Markit, Paris, France, ³IHS Markit, Bangalore, India

Objectives: Theoretically, combination therapies would face greater difficulty in demonstrating cost effectiveness because the backbone therapy is often priced close to the relevant country's cost-effectiveness threshold. Unless the backbone therapy's cost is reduced, the combination may not be cost-effective even if the add-on therapy is priced at zero. We set out to verify if this is true in practice by assessing reimbursement outcomes for combination therapies vs monotherapies in lung cancer and multiple myeloma. **Methods:** Reimbursement status and level of reimbursement for all drugs in lung cancer and multiple myeloma, which were first priced between 1 January 2011 and 31 December 2020, were assessed in France, Germany, Italy, Spain and the United Kingdom using data from the IHS Markit POLI database. The reimbursement status review was supplemented by Amélioration du Service Médical Rendu (ASMR) ratings in France, Federal Joint Committee (G-BA) ratings in Germany and NICE guidance in the UK to assess the likely pressure on prices for those combination therapies that gained reimbursement. **Results:** In lung cancer combination therapies were more likely to be rejected for reimbursement compared to monotherapies. Across the five countries, 20 out of the 56 combination therapy presentations (equivalent to 35.7%) were rejected for reimbursement compared to 11.4% (31 out of 271) for monotherapy presentations. In multiple myeloma, 5.3% of combination therapy presentations (7 out of 132) were rejected for reimbursement, while every single monotherapy was approved for reimbursement. Combination therapies also had less favourable ASMR and G-BA ratings. **Conclusions:** This review of reimbursement decisions and cost-effectiveness assessment outcomes for drugs approved over a 10-year period in the top five European markets confirms that combination therapies in lung cancer and multiple myeloma face greater difficulty in demonstrating cost-effectiveness compared to monotherapies. Even when approved for reimbursement, combination therapies are subject to greater pressure on prices.

P30

POTENTIAL IMPACTS OF THE NEW MHRA POLICY FOR BIOSIMILAR APPROVAL FOR THE INDUSTRY AND PATIENTS

Ribeiro A, Walker A, Walsh K

Lifescience Dynamics Ltd, London, UK

Objectives: To understand the potential impact of the new MHRA guidance for biosimilar licensing in the UK and other key markets, in terms of accelerating biosimilar development, time to market, prescribing limits (e.g. automatic substitution) and, patient access to biologics. **Methods:** We reviewed the MHRA guidance on biosimilar licensing, alongside that from the FDA/EMA, and country-specific guidance on biosimilar use. We also analysed FDA/EMA approvals for biosimilars approved without confirmatory efficacy trials. Finally, a virtual iAdBoard was organised with payers/KOLs from France, the UK and US to capture different perceptions on the new policy and downstream impacts on biosimilar access. **Results:** The MHRA has discontinued the requirement for biosimilars to undergo confirmatory efficacy trials as a licensing condition. Although the new policy was celebrated by the biosimilar industry, one must note the FDA and EMA do not explicitly state a Phase 3 trial requirement for biosimilar approval, and to date, two pegfilgrastim biosimilars have been approved without a Phase 3 trial (Udenyca, Nyvepria), given their robust chemical characterization and Phase 1 trials' Results: Additionally, the new MHRA guidance contemplates exceptions where comparative trials are required, leaving uncertainty around for how many biosimilars, particularly monoclonal antibodies, chemical characterization plus PK/PD trials will suffice. The virtual iAdboard revealed payer differences in opinion regarding impacts on biosimilar development timelines (vs agreement on economic viability), and in future policies encouraging biosimilar uptake, with EU payers more receptive to the change

than US counterparts, but concerned with backlash from HCPs. **Conclusions:** If the FDA/EMA endorse the MHRA decision, in the future, a strong CMC/Phase 1 package could replace Phase 3 studies for biosimilar licensing. However, it is yet unclear whether this abbreviated data package will result in faster times to market or if it will have negative impacts on prescribing freedom and patient access to biosimilars.

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IMPACT OF COVID-19 ON HTA/PRMA OF MEDICINAL PRODUCTS IN EUROPE: A PAYER PERSPECTIVE

Mycka J,¹ Dellamano R,² Lobb W,¹ Dalal N,¹ Dellamano L,² Pereira E¹

¹Medical Marketing Economics LLC (MME), Montclair, NJ, USA, ²ValueVector, Milan, Italy

Objectives: Assess payer perceptions of COVID-19 pandemic's impact on health systems, focusing on HTA, pricing, reimbursement and market access (PRMA) of new, branded medicines in the EU4 and UK. **Methods:** In June 2021, MME Advisors conducted a virtual, national payer / advisor board with representatives from France (2), Germany (2), Italy (1), Spain (1), and the UK (2) - to discuss key topics within the pandemic's context, such as:

- Disruption to healthcare systems
- HTA impact: backlog, re-prioritization, framework
- PRMA impact: net price pressure, conditional pricing/RWE and time to market
- Differences and similarities within oncology, rare diseases, ATMPs and general medicines

Results: Unlike the significant disruptions seen during the height of the pandemic in 2020, payers saw impact ranging from moderate (Italy) to high (Spain) as of June 2021. Disruption by disease state varied: oncology was highly disrupted everywhere but Germany. Most payers did not anticipate shifts in long term priorities or budget cuts to healthcare post pandemic. HTA impact was minimal, with no need to re-prioritize by therapy area or alter plans to adjust frameworks. Likelihood of stricter HTA criteria varied with payers in Italy anticipating more scrutiny for oncology and in Germany for rare diseases/ATMPs. While time to market was expected to remain mostly stable, delays anticipated in Spain. Majority of payers anticipated increasing pressure on drugs' net prices; however, they were divided on increases in conditional pricing/RWE. **Conclusions:** Perceived COVID-19 impact varied by country based on infrastructure and adaptability. Germany less impacted, whereas in other markets (e.g., Spain) COVID-19 seemed to have accelerated changes, rather than drive PRMA policy. Given the importance of healthcare, overall budget cuts were not anticipated, although the need to deploy funds to diverse areas (e.g., healthcare worker salaries, hospital capacity) could complicate future scenarios, especially for high-cost therapies. Therefore, continued monitoring is warranted.

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PRICE ANALYSIS OF CANCER THERAPIES FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE HEPATOCELLULAR CARCINOMA

Williams A,¹ Anderson N,² Gwon YG,³ Wifler W²

¹Boston Scientific, Marlborough, MA, USA, ²Boston Scientific, Maple Grove, MN, USA, ³Boston Scientific, Kuala Lumpur, MN, Malaysia

Objectives: The price of cancer therapy for the treatment of adult US patients with hepatocellular carcinoma (HCC) remains unknown. This study estimated the price of systemic therapies (ST) compared to selective internal radiotherapy (SIRT) for the treatment of HCC from the payer and provider perspectives. **Methods:** The National Comprehensive Cancer Network (NCCN) Guidelines were used as a framework to model the treatment strategies for HCC. The associated drug prices as of May 2021 for ST and SIRT were obtained from the IBM Micromedex Redbook (Average Wholesale Price [AWP]), (Wholesale Acquisition Cost [WAC]), Medicare's Average Sale Price (ASP), and Decision Resources Group (DRG) ASP. Clinical parameters, such as treatment duration and FDA-recommended daily dose (DDD), were obtained from randomized controlled trials and FDA-approved labels. The total price/DDD was calculated for each treatment therapy and treatment duration over a short-term (<12 months) horizon. Sensitivity analysis was conducted to explore the impact of treatment duration uncertainty on model Results: Because drug rebates are unknown, these price estimates did not account for drug rebates or patient assistance programs negotiated directly with manufacturers by Pharmacy Benefit Managers. **Results:** 11 STs and 3 SIRTs were included in our analysis. The median price/DDD of ST varied by perspective: Medicare ASP: \$97,466 (IQR: \$341-\$205,393); Provider WAC: \$123,322 (IQR: \$18,475-\$305,615); Provider AWP: \$186,389 (IQR: \$22,170-\$366,738). The median price for SIRT was estimated; Medicare ASP: \$21,877 (IQR: \$21,877-\$22,269) and Provider ASP: \$21,873 (IQR: \$21,316-\$21,873). The price differences are greater than SIRT when considering patients who progress through first-line and second-line ST. **Conclusions:** The price of cancer therapy for HCC varies widely by payer-provider perspective. The availability of alternative cancer therapies, such as locoregional (non-surgical) approaches, may offer clinical meaningful benefit and reduce the total costs of HCC care from the payer-provider perspectives.