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Background: Consumers often lack adequate understanding of their prescription medications, which can lead to medication errors, adverse drug events or sub-optimal treatment benefits. While several reviews have targeted problems with aspects of prescription labeling and information sources, these often vary widely in scope and focus. Thus, variable recommendations to industry and health systems have been set forth by state and government agencies. There has also been increasing consideration for the value of patient involvement in the design of health materials, yet whether and how patient perspectives are addressed and incorporated into these materials has not been systematically examined.

Objectives: Our objective is to 1) provide an updated, comprehensive review of best practices regarding the presentation of safety information accompanying prescribed medications and 2) assess the role of the patient in the development of these materials.

Methods: Articles were selected from three online databases and eligible if they were 1) in English-language, 2) of a randomized design, and 3) provided evidence on how to improve prescription drug labeling practices.

Results: Seventy six trials were included for review. Article analysis revealed themes related to 1) readability and the use of plain language, 2) formatting and organization, 3) representation of empirical results, 4) use of pictograms and illustrations, 5) information content, and 6) dissemination mode. The use of plain language principles and enhanced formatting for written medication information and pharmacy-generated container labeling were most supported in the literature. Design principles for multimedia tools, supplementary instructions, and promotional materials were less cohesive. Common outcomes included preference, comprehension, and recall. Outcomes related to actual use of prescribed medications and clinical endpoints were less prevalent. The majority of studies were of fair methodological quality. Less than half of studies directly engaged patients' perspectives in the design of these educational materials. Most studies provided only minimal detail on how patient involvement was operationalized or failed to report on this information.

Conclusions: This review provides advisement to regulatory bodies and industry sponsors regarding best practices for the development of patient-directed education materials for prescribed medications, as well as identifies important gaps in the existing literature to direct future research.

250. Quality of Life of People Living with HIV/AIDS Initiating Antiretroviral Therapy in the Single Tablet Regimen Era

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Background: Antiretroviral therapy (ART) has increased life expectancy of people living with HIV/AIDS (PLHA). Single tablet regimens (STR) contributed to increase patient's adherence to ART, but its influence in the quality of life (QoL) is still unknown.

Objectives: To outline the profile and assess the QoL and associated factors of patients initiating ART in a reference hospital in Belo Horizonte, Brazil.

Methods: Baseline evaluation of a cohort of 184 patients initiating ART between Sep/2015 and Aug/2016. We obtained sociodemographic, clinical and behavioral data through face-to-face interviews and used EuroQoL5D-3L (EQ5D) and WHOQoLHIV-bref instruments to assess QoL. We used non-parametric tests to compare QoL within groups using SPSS v21.

Results: Patients were mainly men (79%), mean age of 35.9 ± 11.6 years old, unmarried (75%), non-browns (51%), had 9+ years of schooling (71%), were employed (81%) and with family income between 205 and 773 dollars (70%). In addition, 47% had children and 21% had health insurance. The majority was religious (78%) and had experienced in their lives alcohol (82%), tobacco (53%) or illicit drugs (46%). Median time of diagnosis and treatment was five and two months, respectively. Signs and symptoms of anxiety occurred in 37% of patients and of depression in 27%. About 84% used STR, 46% were adherent to ART and 75% reported at least one adverse reaction. Patients showed a good QoL in both instruments: EQ5D index (0.842 ± 0.146) and VAS ($73.62 \pm$

21.3%). Average values of WHOQoLHIV-bref domains were 15.1 ± 3.2 (physical), 14.7 ± 2.8 (psychological), 14.7 ± 2.9 (independence), 14.7 ± 3.1 (social), 13.9 ± 2.5 (environment) and 14.5 ± 3.7 (spirituality). Patients in STR had higher QoL in EQ5D index ($p = 0.02$), VAS ($p = 0.03$) and in the WHOQoLHIV-bref independence domain ($p < 0.01$). Other factors influenced at least one domain: sex, age, marital status, schooling, health insurance, family income, religiousness, use of tobacco, signs and symptoms of anxiety and depression, time of treatment and of diagnosis, adverse reaction and adherence.

Conclusions: QoL is influenced by the type of ART regimen and other sociodemographic, clinical and behavioral characteristics. This knowledge is useful to guide interventions to improve QoL of PLHA initiating ART.

251. Self-Management Research of Asthma and Good Drug Use (SMARAGD Study): A Pilot Trial

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Background: Pharmacists have a role in supporting optimal use of inhaled corticosteroids (ICS).

Objectives: To assess the effectiveness of pharmacists' monitoring on asthma disease control in ICS-users.

Methods: Asthma patients (18–60 years) using ICS from two intervention (IG) and two control (CG) pharmacies were invited. Participating patients completed questionnaires at study start and after six months, including the Control of Allergic Rhinitis and Asthma Test (CARAT) questionnaire. IG patients completed the CARAT every fortnight and received counselling on managing their asthma disease, ICS adherence, inhalation technique and self-management by pharmacists when scores were suboptimal, deteriorated or missing. For Turbuhaler® users, additional electronic monitoring of inhalation medication (EMI) was

available, with daily alerting for ICS intake. As primary outcome, CARAT scores at six months were compared between IG and CG in a linear regression model. As secondary outcomes, adherent patients according to refill-adherence and MARS-5 scores were compared with logistic regression. Finally, patients with EMI were compared to non-EMI users.

Results: From March to July 2015, 39 IG and 41 CG-patients were enrolled. At follow-up, CARAT-scores did not differ between IG and CG (-0.19 , 95% CI -2.57 – 2.20), neither did patient numbers with ICS adherence $>80\%$ (0.82 , 95% CI 0.28 – 2.37) or MARS-5 scores >20 (0.55 , 95% CI 0.15 – 2.05). In EMI users, ICS adherence $>80\%$ was 4.52 times increased (95% CI 1.56 – 13.1) compared to non-users of EMI, but no differences were seen for the other measures.

Conclusions: Pharmacist monitoring did not impact on primary outcomes, but EMI-use showed improved ICS refill-adherence.

252. Patient Reported Symptoms as an Inducement for Medication Optimization

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Background: Healthcare professionals mainly focus on potentially serious symptoms and tend to ignore common ones. From a patient perspective, however, these symptoms may be highly relevant. As a suitable instrument to collect information on patient reported symptoms was lacking, an instrument was developed to collect patient-reported side effects, PROMISE.

Objectives: To determine whether the PROMISE instrument was useful to assist patients in reporting symptoms and side effects in clinical medication reviews (CMR) and to facilitate pharmacists in reducing drug related symptoms.