product name and its formulation) reported as shortages between 2015 and 2018.

**Results** The classification work identified two major categories of causes of drug shortages: causes related to the manufacturing process and those related to the drug distribution system. Causes related to manufacturing dysfunction were divided into five subclasses: 83 types of causes allowed the building of a systematic classification related to the manufacturing circuit. Material issues use ranked first (31%), followed by manufacturing issues, pharmaceutical market and regulatory issues, and inventory and stockage practice (30.4%, 23.5% and 9.89%, respectively). The number of reported pharmaceutical market causes of shortages showed a 3.5-fold increase between 2015 and 2018. In 78% of reported shortages, only one dysfunction caused the shortage. The number of multiple causes of shortages increased by 2.4 during the study period.

**Conclusion and relevance** To our knowledge, there are no studies with the same results. Drug shortages are increasingly reported in this country. Precise knowledge of the causes of the shortages can identify short term solutions to reduce their severity and long term solutions to reduce their numbers.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

The authors thank the drug shortages team and the pharmacosurveillance division. They also thank the professor team of Strasbourg Faculty of Pharmacy.

No conflict of interest.

**1ISG-013 SMARTPHONE APPLICATIONS FOR PATIENTS DIAGNOSED WITH GENITOURINARY TUMOURS: ANALYSIS OF THE QUALITY USING THE MOBILE APPLICATION RATING SCALE**


10.1136/ejhpharm-2020-eahpconf.13

**Background and importance** The large number of health apps for genitourinary cancers means a transparent and objective evaluation by app experts and healthcare professionals is needed.

**Aim and objectives** To analyse the quality of apps for patients diagnosed with genitourinary cancers, using the mobile application rating scale (MARS) methodology.

**Material and methods** This was an observational, cross sectional descriptive study. Inclusion criteria were apps available in the ‘App Store’ and the ‘Play Store’ for genitourinary cancers intended for patients and/or careers. Inclusion period was February 2019.

Platform (Android/iOS), cost, date of the last update, type of cancer, purpose and participation of health professionals on their development were recorded. A multivariate analysis was conducted.

The quality of the apps was assessed using MARS. This evaluation includes 23 evaluation criteria clustered in five domains (engagement, functionality, aesthetics, information and subjective quality). Each evaluation criterion is rated from 1 to 5 according to its conformity (1=inadequate, 2=poor, 3=acceptable, 4=good, 5=excellent). The total mean score of MARS, which describes the overall quality of the app, was obtained by the mean score of every domain.

**Results** Forty-six apps were downloaded (31 Android, 6 iOS, 9 both platforms); 89.1% were free and 60.9% were updated in the last year. The most frequent cancers in the apps were prostate (30.4%), cervical (17.4%), testicular (13.0%) and ovarian (13.0%). The main purpose was informative (63.1%), preventive (23.9%) and diagnostic (13.0%). Seven apps (15.2%) were developed by healthcare organisations.

The average MARS score was 2.98 (SD=0.77), with a maximum of 4.63 and a minimum of 1.95. Functionality scores were similar among all the apps. The greatest differences were found in engagement and aesthetics criteria which showed acceptable scores only in a third of the apps. Multivariate analysis showed statistically significant differences according to the platform and participation of health professionals in the development (p<0.001 and p=0.01, respectively).

**Conclusion and relevance** Very few apps for patients with genitourinary cancers were focused on how to handle the disease after diagnosis, correct administration of treatment or adequate monitoring of symptoms. The participation of health professionals in the development was low but was correlated with quality. MARS is a helpful methodology to analyse app quality and make better recommendations to patients.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

**1ISG-014 COST EFFECTIVENESS ANALYSIS OF PATIENT SELF-ADMINISTRATION OF MEDICATION DURING HOSPITALISATION IN A CARDIOLOGY UNIT**

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10.1136/ejhpharm-2020-eahpconf.14

**Background and importance** Patient involvement is increasingly becoming part of clinical practice, including self-administration of medication (SAM) during hospitalisation. Previously, we have investigated the effectiveness of SAM in a randomised controlled trial (RCT). The proportion of ward level dispensing errors was considered the best way to explore safety differences between workflows. We saw that SAM was effective, and also user friendly. However, due to the scarcity of healthcare resources, a health economic evaluation is important when choosing the best, safest and most economically advantageous way to manage medication in hospital.

**Aim and objectives** To evaluate the cost effectiveness of SAM during hospitalisation compared with nurse-led medication dispensing and administration.

**Material and methods** A cost analysis (microcosting level) was performed from a hospital perspective with a short term incremental costing approach, including the costs of medication, materials and nursing time spent on dispensing, administration, SAM start and discharge preparation.

The RCT was performed in a cardiology unit and included patients ≥18 years that were capable of SAM. In the intervention group, patients were instructed about the medication and

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self-administered their own medication. In the control group, medication was dispensed by nurses in the ward.

The proportion of ward level dispensing errors was collected through disguised observation of patients in the patient room and nurses in the medicine room.

A dispensing error was defined as a deviation between the prescription and the dispensed medication (eg, incorrect dose). Opportunity for errors (OEs) was defined as any medication dispensed and any medication prescribed but not dispensed. Dispensing error proportion=(dispensing errors/OEs)×100%.

Results A total of 250 patients were recruited; 11 were withdrawn as they were discharged prior to observation. The proportion of men was 66% and mean age was 64.2 years (SD 12.2). Total cost per patient in the intervention group was 49.9€ (95% CI 46.7; 53.1€) compared with 52.6€ (95% CI 47.1; 58.1€) in the control group (p=0.09). Sensitivity analysis consistently showed total costs favouring the intervention. The dispensing error proportion was 9.7% (95% CI 7.9 to 11.6%) (100 errors/1033 OEs) in the intervention group compared with 12.8% (95% CI 10.9 to 15.6) (132 errors/1028 OEs) in the control group (p=0.02).

Conclusion and relevance SAM seem to cost less but the results were not statistically significant. As SAM patients made fewer dispensing errors compared with nurse-led medication dispensing, the results are suggested to be cost effective.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

ENVIROMENT SUSTAINABILITY IN PERSONALISED MEDICINE: FONDO AIFA 5% AND THE ITALIAN EXAMPLE

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Background and importance Sustainability in the era of personalised medicine represents one the major problems because of the possible limited access to innovative therapies. Since 2003, the Agenzia Italiana del Farmaco (AIFA), along with pharma industries, has established an innovative and unique programme, ‘Fondo 5%’,1 to deliver innovative and highly expensive therapies to patients with rare diseases after their approval by the EMA. Once AIFA authorisation and reimbursement for the specific indication. A joint evaluation by physicians and clinical pharmacists, based on the scientific literature, clinical reports, treatment plan and cost estimate analysis, produces a patient specific request for a peculiar drug not otherwise available through conventional channels. AIFA is responsible for the scientific evaluation, and final authorisation or rejection. The treatment plan has received AIFA official approval, the clinician is authorised to administer the therapy whose cost will be subsequently refunded by the AIFA.2

Aim and objectives To describe the Italian method in order to improve the availability of the best innovative therapies, considering sustainability of the national health system.

Material and methods Collection and processing of drug requests for Fondo 5% and analysis of the clinical and economic impact.

Results From August 2018 to September 2019, 24 treatments were authorised by AIFA: 20 (83%) in the adult and paediatric haematological area (venetoclax for acute myeloid leukaemia/mantle cell lymphoma, eltrombopag for pure red cell