

amounting to 15.63 billion euros to be invested in the health-care sector, most of which are dedicated to revolutionising our SSN and ensuring its greater efficiency and effectiveness in the territory.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

1ISG-012

BALANCING CLINICAL BENEFITS AND COST SAVINGS: COMPASSIONATE DRUG USE AT AN ITALIAN UNIVERSITY HOSPITAL – EVIDENCE AND INSIGHTS

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10.1136/ejhp-2024-eahp.24

Background and Importance Compassionate use of drugs (CU) allows patients with serious diseases and no further treatment options to access treatments not yet approved. Specialist referral centres provide a reference point for access to these medicines, with significant benefits both for patient health and for avoided costs to the healthcare system.¹

Aim and Objectives The aim of this study is to describe the impact, in terms of clinical outcomes and saved costs, of CU at a University Hospital.

Material and Methods An 18-month retrospective analysis of approved CU at the Azienda Ospedale-Università Padova (AOUP) was conducted. A monitoring activity was implemented by the AOUP's Clinical Research Unit through creation of follow-up forms submitted to corporate Operational Units' physicians, which made it possible to track the number of patients involved in CU programmes, their clinical outcomes and duration of therapy. The economic impact was assessed by calculating cost-therapy for each patient based on drug dosage, duration of treatment, and ex-factory price published in the Official Gazette of Italian Republic, for drugs available on the market.

Results In the analysed period, a CU regimen was approved for 84 patients mainly in the haematology (17 patients) and paediatric (24) settings. Of the total, five patients did not start therapy due to death, clinical deterioration, or personal reasons. The remaining 79 underwent treatment. In 81% of cases, this resulted in a partial or complete improvement in the clinical status or, when degenerative diseases occurred, a stabilisation of the disease. On the economic side, avoided costs amounted to €7,130,668, 62% of which resulted from CU of burosumab in patients with X-linked hypophosphatemic osteomalacia.

Conclusion and Relevance CU in a University Hospital brings both clinical benefits and potentially significant economic savings. Early access to experimental therapies both enhances patients' life expectancy and quality and facilitates the gathering of valuable clinical data on promising investigational drugs. Cost savings generated from this approach can be reinvested to expand, enhance, and make the national healthcare system more sustainable. Collaboration between teaching hospitals, pharmaceutical companies and

regulatory authorities is essential to optimise CU programmes and ensure equitable access to potentially lifesaving treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

1ISG-013

REAL-LIFE DATA OF CDK4/6 INHIBITORS PALBOCICLIB, RIBOCICLIB AND ABEMACICLIB IN LOCALLY ADVANCED OR METASTATIC BREAST CANCER: EFFECTIVENESS EVALUATION

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10.1136/ejhp-2024-eahp.25

Background and Importance Breast cancer is the world's most prevalent cancer. There are approximately 55000 new diagnosed cases per year in Italy. CDK4/6 inhibitors are targeted orally available cancer drugs. These are highly selective inhibitors of CDK4 and CDK6, serine-threonine kinases that regulate the cell cycle progression. CDK4/6 inhibitors are indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, in combination with an aromatase inhibitor or with fulvestrant in women who have received prior endocrine therapy.

Aim and Objectives To provide real-world evidence of CDK4/6 inhibitors, to analyse drug effectiveness in our hospital.

Material and Methods We included all patients diagnosed with locally advanced or metastatic breast cancer who received CDK4/6 inhibitors (palbociclib, ribociclib and abemaciclib) from national marketing authorisation to 15 September 2023. Patients were stratified by drug, age, line of therapy, Eastern Cooperative Oncology Group (ECOG) performance status (PS) and cancer staging. We assessed progression-free survival (PFS) with the Kaplan-Meier method.

Results Sixty-three patients received CDK4/6 inhibitors. 63% were treated with palbociclib, 24% with ribociclib and 13% with abemaciclib. The mean age was 65. Median PFS was 22.4 months. There was no statistically significant difference between cases treated with palbociclib and ribociclib. Median PFS in the abemaciclib group was not reached. Age older than 65 was a significant predictor for PFS benefit (median PFS 27 months). 51% were first-line treatments (median PFS 22.4 months). Beyond first-line therapy median PFS was 27 months. 49% had baseline PS of 0. PS was identified as an important prognostic factor for PFS: PS0 median PFS 22.4 months versus PS1 median PFS 15.9 months. Locally advanced breast cancer cases had worse prognosis (median PFS 13 months). We recorded 10 cases of dose reduction due to toxicity, but only one patient discontinued therapy due to treatment-limiting toxicity.

Conclusion and Relevance All CDK4/6 inhibitors are beneficial in terms of PFS: we found no significant differences among the three drugs. Toxicities were managed by dose reductions. CDK4/6 inhibitors confer PFS benefit in elderly patients with metastatic disease. We can confirm that these drugs have radically changed the treatment for metastatic breast cancer with increased rates of treatment response and PFS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

11SG-014 SUSTAINABLE HEALTHCARE: AN EXAMPLE OF PHARMACEUTICAL INTERVENTION

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10.1136/ejhp-harm-2024-eahp.26

Background and Importance Our health facility conducts approximately 400 annual carpal tunnel (CT) surgeries using three distinct ambulatory methods: (1) ultrasound-guided in the operating room (OR), (2) ultrasound-guided office surgery in the consultation room, and (3) endoscopy-assisted in the OR.

Aim and Objectives The study's objective was to assess the environmental footprint of each care pathway and to eco-design the care pathway with the lowest possible impact.

Material and Methods A mixed multidisciplinary team (pharmacist, surgeon, sustainable development engineer) was established. The pharmacist was defined as the pilot of the study. Three life cycle assessments (LCA) were conducted using SimaPro software. The functional unit was 'Performing an outpatient CT surgery, from planning to post-op care'. Ten impact categories were considered including for example global warming (kg CO₂e), terrestrial; freshwater and marine ecotoxicity (kg 1.4-DCB), assuming equal patient-to-health-facility distance and surgical efficiency.

Results Care pathway (2) has a 20 kg CO₂e carbon footprint, which is half of (1) at 43 kg CO₂e, and a third of (3) at 75 kg CO₂e. The most significant impacts are patient transport and electricity: for (2) 74% from patient transport and 1% from electricity; for (1) 26% from patient transport and 54% from electricity; for (3) 40% from patient transport and 36% from electricity. Healthcare products (HP) represent an average of 25% of the total impact. The stages with the highest HP impacts were: draping and sterile dressing (0.28kg CO₂e (2), 2.7kg CO₂e (1) and 6.7kg CO₂e (3)); skin preparation of the operating area (0.5kg CO₂e (2), 0.9kg CO₂e (1) and (3)); and anaesthesia (0.3kg CO₂e (1) and (2), 1kg CO₂e (3)). In anaesthesia, drugs (acetaminophen, lidocaine, mepivacaine) had minimal impact (10%), whereas for skin preparation, drugs (alcoholic betadine) had a greater impact (70% to 100%) than sterile medical devices. Modelling the implementation of teleconsultation showed a potential savings of 6kg CO₂e for (1) and (2) and 12kg CO₂e for (3).

Conclusion and Relevance Office surgery, with its minimal impact and equivalent clinical effectiveness, should be promoted. Further reducing its environmental footprint requires essential steps, such as promoting teleconsultation. Pharmacists can also make a significant impact by optimising HP utilisation (e.g., right-sized drapes, no reinforced gowns for non-invasive procedures, controlled betadine use, efficient neurostimulation needle cable recycling).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

11SG-015 ASSESSMENT OF PREPARATORY STAFF'S KNOWLEDGE OF CARCINOGENIC, MUTAGENIC AND REPROTOXIC (CMR) RISKS

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10.1136/ejhp-harm-2024-eahp.27

Background and Importance Context: The preparation of pharmaceutical products is governed by Good Preparation Practices (GPP). Guideline 2: 'Preparation of medicinal products containing substances that may present a risk to health and the environment' states that personnel must be trained and informed.

Aim and Objectives

Objectives To assess the initial knowledge of the preparation team on carcinogenic, mutagenic and reprotoxic (CMR) risks and to establish appropriate training.

Material and Methods

Method A SPHINX[®] questionnaire was developed based on bibliographical data with methodological support from COMEDIMS, risk preventionists and occupational medicine. The 12-question questionnaire covered not only basic knowledge of the risk, but also the practical application of CMR risk management in the unit. It was submitted to all staff over a 1-month period. The analysis of the results led to the implementation of a training programme adapted to all staff.

Results

Results 28 people completed the questionnaire with a mean score of 12.5/20 [5.8–17.9]. Staff seniority seemed to contribute to a better knowledge of risk (Student, $p = 0.06$), with a mean of 14.7 for those working in our department for more than 5 years compared to 12.1 for new staff. In terms of knowledge, the basic concepts of CMRs and personal protective equipment were acquired (64% and 79% of workers answered these questions correctly). On the other hand, collective protection equipment, guidelines and what to do in case of exposure were less well understood (39%, 7% and 11% respectively).

Conclusion and Relevance

Discussion Based on the results of the questionnaire, CMR risk concepts are not fully understood by all staff, although seniority in the department seems to increase their knowledge. The responses have enabled us to identify the gaps in the team's knowledge and to propose a targeted training course for all, combined with situational exercises. The effectiveness of the training is then evaluated using a questionnaire combined with a satisfaction survey.

Conclusion This assessment enables us to meet the initial training requirements of Guideline 2. The training and assessment materials will form the basis for maintaining skills as part of the unit's ongoing training.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.