it cannot be ruled out that the differences were due to differences in the profile of the patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

Section 6: Education and Research

6ER-001 PCSK9 INHIBITORS: VARIATION IN THE LIPID PROFILE IN A REAL WORLD SETTING

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Background and importance The proprotein convertase subtilisin kexin type 9 inhibitors (PCSK9i), evolocumab and alirocumab, approved by the European Medicines Agency in 2015, are a new approach in obtaining a large reduction in serum low density lipoprotein cholesterol (LDL-C), which is traditionally linked to cardiovascular events.
Aim and objectives This study was conducted to shed light on the variation in lipid profile of patients treated with PCSK9i, in a setting that differed from clinical trials.
Material and methods An observational retrospective study was conducted of all patients treated with a PCSK9i in our hospital (September 2016 to February 2019). The following data were obtained from the electronic clinical record: demographic variables, diagnosis, drug, posology, previous treatments, prescription for primary or secondary prevention and adverse events. Before (1 determination) and after (1–3 determinations) PCSK9i, total cholesterol (TC), LDL-C, high density lipoprotein cholesterol (HDL-C) and triglyceride (TG) concentrations were obtained and statistically analysed using R statistical software.
Results Fifty-three patients were included, 33 men, with a median age of 64 years (range 35–83). Diagnoses were heterozygous familial hypercholesterolaemia (64%), homozygous familial hypercholesterolaemia (2%) and dyslipidaemia (34%): 70% received evolocumab (140 mg/14 days, except for 1 patient who received 420 mg/month) and 30% received alirocumab (75 mg/14 days except for 2 patients who received 150 mg/14 days). Regarding previous treatments, 83% had been treated with ezetimibe and 73% with a statin. Eight patients suffered adverse effects of whom four discontinued treatment. Analytical data were obtained from 51 patients (table 1).

Abstract 6ER-001 Table 1

	Before iPCSK9 (mg/dL) (mean ±SD)	After iPCSK9 (mg/dL) (mean ±SD)	% change	Mean differences (mg/dL)	95% CL (mg/dL)	P value
TC	268±84	163±75	40	107	90 to124	<0.001
LDL-C	188±79	85±68	55	105	90 to 121	<0.001
HDL-C	49±16	52±17	4	−3	−6 to −1	0.011
TG	161±95	149±103	7	19	−7 to 44	0.156

Conclusion and relevance A large decrease in TC and LDL-C, which is agreement with commercialisation trials, was observed. A slight increase in HDL-C levels can be assumed, although clinical trials referred to a higher increase. Moreover, no statistically significant reduction in TG was observed in this study in contrast with the clinical trials. These findings reveal the importance of real world data studies, in a context where all the variables are not controlled, unlike in clinical trials, to disclose the real efficacy of new drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

6ER-002 A COMPARATIVE REVIEW OF THE IMPACT OF THE INTRODUCTION OF ON-SITE MOLECULAR TESTING ON THE MANAGEMENT OF ADULT PATIENTS HOSPITALISED WITH SUSPECTED INFLUENZA VIRUS INFECTION

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Background and importance Hospitalised influenza positive patients should be isolated and prescribed antiviral treatment. During the flu season of 2017–2018, influenza screens were processed off-site. On-site molecular flu testing was introduced prior to the 2018–2019 season. This study investigated its impact on the clinical management of hospitalised adult patients with a high suspicion of influenza virus infection.
Aim and objectives This retrospective cohort study investigated the impact of on-site influenza testing on adult inpatients by comparing key clinical parameters over the flu seasons before and after its introduction.
Material and methods Data from influenza peaks in January 2018 and January 2019 were used to compare: (i) uptake of influenza testing, using laboratory records; (ii) turnaround times (TATs), recorded using iLab; (iii) infection control isolation data; and (iv) oseltamivir use, as prescribed in inpatient drug kardexes.
Results Number of flu tests performed: 2018=47; 2019=73 (55% increase).

Median TAT (days): 2018=7.2 (range 4–11); 2019=0.5 (range 0–3).

Appropriate isolation of flu positive patients: 2018=36% (8/22); 2019=78.3% (18/23).

Flu exposure (bed nights): 2018=48 (48/98, 49%); 2019=12 (12/110, 10%).

Flu exposure in coronary care (no isolation facilities) (bed nights): 2018=7 (2 patients); 2019=10 (4 patients).

Inappropriate isolation of flu negative patients (bed nights): 2018=41 (results unavailable during treatment);

2019=0.

Appropriate oseltamivir use in flu positive patients: 2018=63.6% (14/22); 2019=95.7% (22/23).

Oseltamivir use in flu negative patients: 2018=60% (15/25) and median duration=5 days (range 2–7); 2019=28% (14/50) and median duration=1 day (range 1–3 days).

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Appropriate isolation and oseltamivir use in flu positive patients: 2018=27% (6/22); 2019=74% (17/23).

Conclusion and relevance Increased flu screening in 2019 despite a national fall in hospitalised flu cases compared with 2018 suggests that clinicians were more likely to consider influenza when rapid diagnostics were available on-site. On-site testing significantly reduced TAT, having a measurable impact on the appropriateness of isolation and oseltamivir use. The absence of isolation facilities in the coronary care unit represented a significant clinical risk of influenza exposure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-003 EFFECTIVENESS OF NEOADJUVANT TREATMENT IN LOCALLY ADVANCED BREAST CANCER

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Background and importance Neoadjuvant chemotherapy has become the standard treatment for patients with inoperable locally advanced tumours, and it is also optional for operable stages. The literature reports rates of 20–30% and 56–66% for pathological complete response (pCR) in patients treated with combinations of anthracyclines and taxanes, and dual blockade of human epidermal growth factor receptor 2 (HER2), respectively.

Aim and objectives To assess the effectiveness of neoadjuvant chemotherapy in stage II/III breast cancer according to expression of HER2 and hormonal receptors (HR) based on pCR.

Material and methods A retrospective observational study was carried out between January 2016 and December 2018 in a second level hospital. Through the Farmatools software, patients were identified. Clinical histories were obtained through Selene software to compile demographic (sex and age) and clinical (stage, HR and HER2, lymph nodes, treatment regimen and pCR results) data.

Results Within the study period, 35 patients received neoadjuvant chemotherapy regimens for breast cancer. Median age of the women was 50 years (IQR 18 years), 54.3% were diagnosed with stage II neoplasia and 62.9% had lymph nodes involved: 40% reached pCR. Patients were classified according to HER2 expression:

45.7% showed positive HER2 expression (HER+), 50% of whom reached pCR after neoadjuvant treatment. In 81.25%, treatment was a docetaxel–carboplatin–trastuzumab regimen plus pertuzumab, obtaining pCR in 53.85%, and 18.75% received chemotherapy regimens based on anthracyclines+taxane+trastuzumab+ pertuzumab, reaching a pCR of 33.33%.

In the 54.3% of HER2 negative (HER2−) patients, 31.58% reached pCR: 94.74% received combinations of anthracyclines+taxanes, obtaining a pCR of 33.33%. Only one patient was treated with docetaxel–cyclofosfamide (TC), not achieving pCR. Within the HER2− group, 57.89% did not overexpress any receptor, qualifying as triple negative (TN). All of these patients received regimens based on anthracyclines and reached a pCR of 45.45%.

Conclusion and relevance pCR rates obtained in our centre were correlated with the results described in the literature, and slightly lower in HER2+ patients. In the case of the TN subgroup, a pCR rate greater than in reported data was found, despite being the subgroup with the worst prognosis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-004 PRELIMINARY CLINICAL RESPONSE OF RIBOCICLIB AS A SINGLE AGENT IN ADVANCED BREAST CANCER: IN SEARCH OF NEW THERAPEUTIC INDICATIONS

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Background and importance Ribociclib, an orally bioavailable CDK4/6 inhibitor, is currently approved in combination with anaromatase inhibitor for the treatment of pre/perimenopausal women with HR positive, HER2 negative advanced breast cancer. Alterations in the CDK4/6-Rb-E2F pathway, which promotes cell proliferation, usually occur in human tumours. Thus ribociclib remains as an attractive therapeutic strategy for the treatment of other neoplasms in which this pathway is significantly dysregulated.

Aim and objectives To evaluate the preliminary clinical response of ribociclib as a single agent, in terms of best overall response (BOR) and progression free survival (PFS) in patients with Rb+ advanced solid tumours (AST) and lymphomas.

Material and methods A literature review was carried out of studies published during 2016–2019 in the electronic databases Medline, Embase and Cochrane Library. No restrictions in terms of language or publication year were applied. Search strategy terms were: 'Ribociclib', 'clinical response', 'single agent' and 'advanced cancer'. Boolean operators were used to connect specific search keywords for each database and other free text terms.

Results Five clinical trials were found. A phase I study of single agent ribociclib in 132 patients from Europe and USA with Rb+ AST and lymphomas showed preliminary signs of clinical activity (NCT01237236): 3 patients achieved a partial response (PR), 43 a BOR of stable disease (SD) and 8 had PFS for >6 months. In another phase I trial in 17 Japanese patients with advanced oesophageal, breast, peritoneum and soft tissue tumours (NCT01898845), ribociclib exhibited a limited response, as no patient achieved a complete response (CR) or PR, and 4 achieved BOR on SD. In a phase I study in 32 paediatric patients with neuroblastoma and malignant rhabdoid tumours treated with single agent ribociclib (NCT01747876), BOR was SD in 9 patients and 5 achieved SD for more than 6, 6, 8, 12 and 13 cycles, respectively. The results of phase 0 and phase Ib studies that assessed the clinical response of ribociclib as monotherapy in glioblastoma (NCT02933736, NCT02345824), showed limited clinical efficacy and ineffectiveness, respectively. Both studies mentioned the presence of a significant increase in cells mTOR/PI3K signalling pathway activity.

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