### General and risk management, patient safety

**Conclusions** Lenalidomide's haematological toxicity is doserelated and often made worse by the basal bone marrow damage due to the haematological disease. Despite this certainty, hardly half of the patients with platelet or neutrophil damage had their dose or schedule adjusted. At this point, the patients could benefit from hospital pharmaceutical care. Important limitations of our study were lack of data about support measures and the small number of cases.

No conflict of interest.

#### GRP-110 LINEZOLID ADVERSE REACTIONS. A ONE YEAR OVERVIEW

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**Background** Linezolid is an antimicrobial approved for the treatment of hospital or community-acquired pneumonia and complicated skin and soft tissue infections due to Gram positive bacteria. Its use, though effective, is not free from possible harm.

**Purpose** To describe the incidence and nature of the adverse reactions related to linezolid, taking place before and after the 28-day limit given in the label information.

**Materials and Methods** All the linezolid treatments over one year (September 2011–September 2012) were recorded. Data sources were the electronic chart as well as the electronic prescription programme.

**Results** 280 cases were recorded, the median treatment duration being 8 days (1 to 73 days). 4 treatments were interrupted early due to potential interactions with antidepressants. A total of 27 patients developed adverse reactions.

Among the 255 patients treated for less than 28 days, 19 developed adverse reactions. 14 presented suppression of at least one myeloid cell line, 7 of them requiring transfusions (one with adverse skin reaction as well). Among the others, two had diarrhoea, one a skin reaction, one vomiting and the remaining patient, asthenia. Median treatment duration in patients with adverse reactions treated for less than 28 days was 12 days (3 to 27 days)

25 patients exceeded 28 days of treatment, 8 of whom had adverse reactions. Seven presented suppression of at least one myeloid cell line, 5 of whom required transfusion. The other patient suffered from asthenia. Median treatment duration in these patients was 37 days (32 to 56 days).

**Conclusions** Attention should be paid to blood cell counts from the beginning of the treatment, since, as seen, hematologic adverse reactions are not limited to treatments lasting more than 28 days. The same is applicable to other less frequent reactions such as skin reactions, vomiting and asthenia.

No conflict of interest.

## GRP-111 MANAGEMENT OF METHOTREXATE-INDUCED RENAL FAILURE WITHOUT GLUCARPIDASE

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**Background** Glucarpidase (Voraxaze) is effective in the treatment of methotrexate (MTX)-induced renal dysfunction but many cases this can be handled with standard treatment.

**Purpose** To describe the progress of a patient with MTX-induced renal failure in whose management glucarpidase was not used.

**Materials and Methods** A 13 year-old girl with acute lymphoblastic leukaemia treated with high-dose MTX. Baseline laboratory tests were normal, except for elevated transaminases and GGT.

Results The patient received her first consolidation cycle with  $500 \text{ mg/m}^2$  of MTX in 30 minutes, followed by  $4500 \text{ mg/m}^2$  in 23.5 hours, oral mercaptopurine 30 mg/m<sup>2</sup>/day and triple intrathecal therapy. Simultaneously, she received hyperhydration/ alkalinisation (3000 ml/m²/day). There was no pharmacological interaction to MTX. 24 hours after the MTX infusion stared, the serum creatinine level (Cr) had tripled (see the table below). The following measures were taken: hyperhydration/alkalinisation (4500 ml/m<sup>2</sup>/day), colestyramine (3 g/6 h) and folinic acid rescue at 500 mg/m<sup>2</sup>/6 h 31 hours after the start of the MTX infusion. Although the protocol provides for the possibility of administering glucarpidase, it was decided not to do this because the methotrexate level was <250µM and glucarpidase administration can be delayed until 96 hours after the start of MTX infusion. Difficulty in the subsequent monitoring, the absence of effect in renal function improvement and high cost were the reasons for delaying the treatment until at least having levels at 36 and 48 hours. Although Cr values were still high, elimination kinetics of the drug were seen as adequate. Without the use of glucarpidase, methotrexate levels were undetectable at day nine. The patient recovered her baseline renal function and did not have mucositis or liver toxicity.

**Conclusions** An early intervention with supportive treatment based on folinic acid, hyperhydration and urine alkalinisation was effective in the management of MTX-induced renal toxicity.

#### Abstract GRP-111 Table 1

Time since MTX		
infusion started (h)	Cr (mg/dL)	MTX levels (µM)
0	0.35	0
24	1.12	190
36	1.41	24
48	1.32	5.9

No conflict of interest.

# GRP-112 MEDICAL DEVICES IN MOROCCO: WHAT GUARANTEES OF QUALITY AND SAFETY?

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**Background** Nowadays, all over the world, many medical devices, initially considered as non-risk or low risk, have been proved to be extremely dangerous to human health, as evidenced by the latest scandal of PIP implants.

**Purpose** To report the experience of Mohammed V Military Teaching Hospital of Rabat in evaluating the quality and safety of medical devices and to analyse elements that can compromise the quality of these products in our country.

**Materials and Methods** 30-month prospective study (January 2010–June 2012). We collected claims relating to the quality of medical devices at our hospital, in normal conditions of acquisition, dispensing and use. We also analysed the processes of placing on the market medical devices, the systems governing their use in hospitals and the main Moroccan rules regulating them.

**Results** 30 claims were collected. They concerned: catheters (40%), surgical drapes (20%), gloves (17%) and other medical devices (23%).