(drug, patient weight range, concentration) to be used in end-of-life home care settings was drawn up and the main results regarding its implementation were analysed.

Results Five patient weight ranges (<6 kg, 6<11 kg, 11<20 kg, 20<30 kg, ≥30 kg) were established. According to these, solutions with standardised drug concentrations were defined as follows: diluted morphine 0.1, 0.2, 0.4, 0.8, 1.2 mg/ml, concentrated morphine (alone or combined) 0.4, 0.8, 1.6, 2.4, 4.0 mg/ml and haloperidol 0.02, 0.04, 0.08, 0.12, 0.2 mg/ml, respectively. Fentanyl and midazolam cassettes were set to contain 0.02, 0.04, 0.05 mg/ml and 1, 2.5, 5 mg/ml for weight ranges corresponding to <6 kg, 6<11 kg and ≥11 kg. The shelf-life of all reservoirs was defined to be 14 days. A minimum infusion rate of 0.1 ml/h was established, except when using subcutaneous reservoir catheters (0.5 ml/h), and an unlimited maximum rate, except for subcutaneous route (5 ml/h).

During the first 10 months, six patients were included: mean age 7.1 years (4 months – 19 years), weights 6 kg – 40 kg. Twenty-two solutions were elaborated (54% morphine, 21% morphine-haloperidol, 25% midazolam), of which 12 were necessary. The rest were discarded due to previous death (two) or satisfactory symptom management by oral route (eight). No medication error or incident related to the infusion was recorded.

Conclusions The standardisation of drug solutions containing morphine, haloperidol, midazolam or fentanyl permits the establishment of a rational programme to ensure safe and quality end-of-life home care in paediatric palliative patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-013

IMPLEMENTING THE EUROPEAN STATEMENTS OF HOSPITAL PHARMACY IN ITALY: RESULTS OF A WORKING GROUP

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Background The European Statements of Hospital Pharmacy express commonly agreed objectives which every European health system should aim for in the delivery of hospital pharmacy services to improve clinical outcomes and patient safety; 44 Statements are divided into six sections: (S1: Introductory Statements and Governance; S2: Selection, Procurement and Distribution; S3: Production and Compounding; S4: Clinical Pharmacy Services; S5: Patient Safety and Quality Assurance; S6: Education and Research). To obtain full achievement of the European Statements of Hospital Pharmacy, the European Association of Hospital Pharmacists (EAHP) has developed a project to implement the Statements within its member countries. The self-assessment tool (SAT), which allows hospital pharmacists to assess the level of implementation of the Statements within their hospitals, provides the means for hospital pharmacists to address the areas needing improvement with a tailor-made action plan and evidence-based resources, and to show progress over time, as it can be updated any time. The tool also helps hospital pharmacists to assess their status

within their own countries and compare this to others. In order to implement the project in Italy, a working group was formed including Italian Society of Hospital Pharmacists (SIFO) representatives: the EAHP Delegate, the EAHP Ambassador, university professors, hospital pharmacists and local healthcare unit pharmacists from all over Italy (SIFO-EAHP-WG).

Purpose The objective of the work was to analyse the level of implementation of the Statements within the SIFO-EAHP-WG healthcare services.

Materials and methods The link to access the SAT question set was sent via email to 30 SIFO-EAHP-WG participants associated with 23 healthcare settings (14 hospitals – two private and 12 public; 8 Local Health Units; 1 university). All data obtained from the SAT was collected and analysed in an Excel file.

Results Twenty participants (67%) belonging to 61% of the healthcare services answered the survey: 10 hospitals (H) of which one private and nine public, and four Local Healthcare Units (ASL). The level of implementation was: S1 61.3% (H: 67.7% [95% CI : 59.6–75.9]; ASL: 45.4% [29.1–61.6]); S2: 72.6% (H: 80% [74.2–85.8]; ASL: 53.9% [26.1–81.8]); S3: 83.9% (H: 89% [83.5–94.5]; ASL: 71.3% [34.7–107.8]); S4: 52.6% (H: 61.1% [48.9–73.3]; ASL: 31.3% [18.6–44.0]); S5: 73.7% (H: 82.6% [74.1–91.1]; ASL: 51.4% [38.9–64.0]); S6: 70.8% (H: 76.7% [63.4–89.9]; ASL: 56% [38.7–73.3]), confirming the high variability mainly for S1 and S4.

Conclusion The results have shown how the level of implementation of the Statements in the analysed sample is high. However, the variability between the single Statements highlights the need to obtain a complete picture of the Italian setting. Such data is fundamental for SIFO-EAHP-WG to be able to define an effective action plan to support a harmonised implementation of the Statements in Italy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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NP-014

DEVELOPMENT OF NEW PRODUCTION WHEN NEITHER PACKAGING NOR SOME OF THE RAW MATERIALS CONFORM TO EUROPEAN STANDARDS

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What was done? A new MR-scanning technology, hyperpolarisation, for the quantification of metabolic processes with an extremely high sensitivity enables physicians early detection of treatment effects in e.g. cancer and diabetes. A so-called Pharmacy Kit is used in the hyperpolarisation process and consists of a specially designed packaging with tubes, vessels and filters containing the contrast agent and buffer solutions. The objective for the hospital pharmacy¹ was to manufacture Pharmacy Kits complying with Good Manufacturing Practice (GMP), though neither packaging nor two of the raw materials conformed to European standards.

Why was it done? A research team at the MR Centre (MRC²) wished to set up a production of Pharmacy Kits, but had no prior experience with, or licence to, manufacture drugs). Thus, the hospital pharmacy was asked to participate in the development of such a production.

How was it done? The MRC research team presented the hospital pharmacy with the desired combination of compounds and the packaging required for Pharmacy Kit production. The task for the hospital pharmacy was then to set up a manufacturing process that met these requirements and complied with the guidelines for GMP. A production complying with GMP was developed in close collaboration with the MRC and an ongoing contact with the Danish Medicines Agency. During the process the hospital pharmacy executed its own microbiology test in order to determine if, and for how long, the non-CE-marked packaging could store the contrast agent and buffer solutions. Risk assessment of the raw materials not found in the European Pharmacopeia were conducted. The method investigated by the MRC already takes place in a few other places in and outside Europe. Experiences from these production sites were implemented and expanded with process

optimisation and a specially designed equipment for the production.

What has been achieved? Due to a strong inter-professional collaboration between the MRC and the hospital pharmacy and due to qualified risk assessments, it was possible to set up a production of Pharmacy Kits according to GMP.

What next? When researchers contact hospital pharmacies with new ideas, we have to be willing to work with GMP in a different way by applying knowhow and risk assessments in order to ensure developments within the healthcare system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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