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USE OF NEEDLEFREE CLOSED SYSTEM DEVICES IN THE RADIOLABELLED WHITE BLOOD CELLS (WBC) PROCEDURE

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BACKGROUND-AIM

Scintigraphy with labelled WBC is the gold standard in nuclear medicine techniques to detect sites of acute and chronic infection/inflammation.
However, such extemporaneous preparation has a high microbiological risk and requires an aseptic environment and specific operators' skills.
Since there isn't a specific monograph in the Pharmacopoeia, the procedure's reference are the EAMN Guidelines 2010 and AIMN Guidelines 2011.
Radiolabelled WBC preparation was introduced in S.Croce and Carle Hospital in April 1983 and, over the years, the original method have been changed, with the aim of improving the product's quality and safety.
In the past year the implementation of needlefree closed system devices (CSD) has been evaluated and validated.

METHODS

We conducted a risk analysis in the current preparation's method, step by step focusing on the easily improvable weak points without great changes in the procedure.
In the preparatory phase, the most relevant aspect proved to be the massive waste of raw materials (anticoagulant and sedimentation agent), currently available in a much larger volume than necessary, and until now removed daily at the end of the procedure.
Using a closed system transfer device, tested by the producer about the maintenance of sterility and pyrogenicity over time, we tried to extend the validity of these raw materials up to seven days after opening, without damaging their chemical and microbiological features.
Concerning the blood sample taking phase, we found critical the possibility that the blood sample could be contaminated during its introduction in the syringe and the following sedimentation. The insertion of a needlefree CSD on the syringe appeared as a valid solution both to avoid an accidental exposure during nurses' operations and to maintain the sterility during the following 45 min of sedimentation.
To introduce the use of CDS we performed a microbiological validation

RESULTS

The microbiological tests conducted on raw materials seven days after the opening showed the sterility's maintenance.
Using CSD on sampling syringe proved to be advantageous in terms of safety and easy handling of blood during sample taking and sedimentation (therefore executable also in a non-class A environment), with no impact on the following blood components' separation and labelling.
The cost-benefit analysis performed on a 12 months period (sample of 500 preparations) showed that, adopting the two CSD, we save more than 1000 € on the total production cost, compared with the previous method, with a significant improvement of product's quality and safety.
Both devices subjected to validation have been accepted to be used in routine.

CONCLUSION

Knowing the CSD available on the market and studying their applicability to radiopharmacy open a new perspective in the production of radiopharmaceuticals according with NBP-MN and a significant reduction of the procedure's weak points.
It seems pursuable to extend the use of CDS to the production and administration of radiopharmaceuticals kits, largely replacing the use of needles and multiple vial piercing, reducing needlestick injuries and contamination of working areas and safeguarding the microbiological integrity of preparations over time.