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Publication Alert: Qualitative risk assessment FSH injectable products

Abstract | Case report/series | Retrospective study | Controlled study | Randomized, placebo-controlled study | Review article| Commentary | Meta-analysis | Real world study analysis | **Qualitative study**

Title: Qualitative risk assessment of follicle stimulating hormone injectable products

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SUMMARY

This was a user experience study and qualitative risk assessment performed to evaluate different FSH injection product types for risks to patients when preparing and administering injections.
Nine women all formally trained in risk assessment, naïve to FSH injection therapy and of child-bearing age each prepared and administered injections of six product types: single- and multidose vials of menotropin for reconstitution (Merional® and Menopur®), FSH reusable pen injectors with separate cartridges (Puregon®), and with pre filled cartridges (Gonal-f®), and single-use, multi-dose FSH pre-filled pens (Bemfola®).
Risk assessments based on user feedback were made with reference to EU regulations for implementing practices for safe use of injectable products and in a second stage a very experienced, expert interdisciplinary panel assessed overall risks including possibility of dosing errors.
Products requiring reconstitution with diluent in glass ampoules were associated with medium risk for sharps injury and a lower level of user confidence. Pen injectors were considered easy-to-use, with a low risk of sharps injury. Single-use, multi-dose pens were associated with the lowest risk of dosing errors.

Key Communication Support

- Both single- and multidose vials of menotropin for reconstitution raise concerns of risks of sharps injuries particularly when alternative FSH pen options exist.
- Although over time multiuse pens could be improved, this qualitative assessment suggests that the simplicity of single use, multi dose pens will fundamentally continue to provide advantages over multiuse pens particularly with regard to reduction of risks of dosing errors.
- Multi-use products present particular challenges to avoid dosing errors, with the requirement for patients to keep a treatment diary in order to record the amount remaining for subsequent doses.
- Practical considerations can influence users' confidence with the products. When using the Gonal-f® pen, user judgment is required to determine whether priming is required: if no fluid is observed to appear from the needle tip, then manual priming is required to avoid an air bubble. In contrast, the Bemfola® pen enforces priming by design. Ease of use is likely to contribute to patients' confidence in self-administering injections and might be expected to be a factor in reducing hazards associated with administration as well as other risks such as handling/dosing errors.
- In view of the impact of Covid-19 on ART practice, with ESHRE recommendations to limit the number of persons simultaneously present in the IVF center, easier-to-use FSH administration options may be preferable to shorten the time required for training
- Potential increased plastic waste associated with single use FSH pens was not considered an issue, as this was felt to be insignificant with respect to the overall waste during an IVF cycle, which is principally driven by plastic waste in the IVF laboratory.
- Healthcare professionals have a responsibility to ensure the safe use of treatments that present a potential hazard to the patient. This paper presents both the approach to risk assessment and the rationale underlying the conclusions, enabling readers to conduct risk assessments to inform their own practice. Consideration of these risks should inform the choice of FSH treatment to minimize the risk of harm to patients and reduce the risk of dosing errors.

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