PC13285

A risk based choice of syringes and associated equipment for compounding and intravitreal administration of drugs for wet age-related macular degeneration

E. GLEDITSCH, D. FOSSUM
HOSPITAL PHARMACIES ENTERPRICE, SOUTH EASTERN NORWAY - OSLO HOSPITAL PHARMACY, OSLO, NORWAY.
Contact: espen.gleditsch@sykehusapotekene.no

What was done?:

A risk assessment to decide syringes and associated equipment for compounding and administration.

Why was it done?:

There are no available syringes with CE approval for intravitreal administration. The choice of syringe and associated equipment have to be based on a risk assessment. The aim of this work was to find the syringes, associated equipment and compounding process that present least risk to the patients.

How was it done?:

The risks associated with each syringe, needle and compounding process were assessed with a Failure Mode Effects Analysis Method.

Concequence		Probability				
Failure (Effect of failure)	Criticality	May occur in some exceptional circumstances	Could occur some time	Might occur occasionally	Will probably occur in most circumstances	Expected to occur in most circumstances
Sterility (infection)	Critical (Death or non reversibel serious injury)					
Particles (inflammation)	Major (Seriois, but reversibel injury)					
Silicone oil (floaters in the vision)	Moderate (Moderate discomfort or not serious injury)					
Injection volume (ocular pressure) Technical performance (leakage and compatibility with needle)	Minor (Measurable discomfort)					
	Negligible (No dicomfort or injury)					

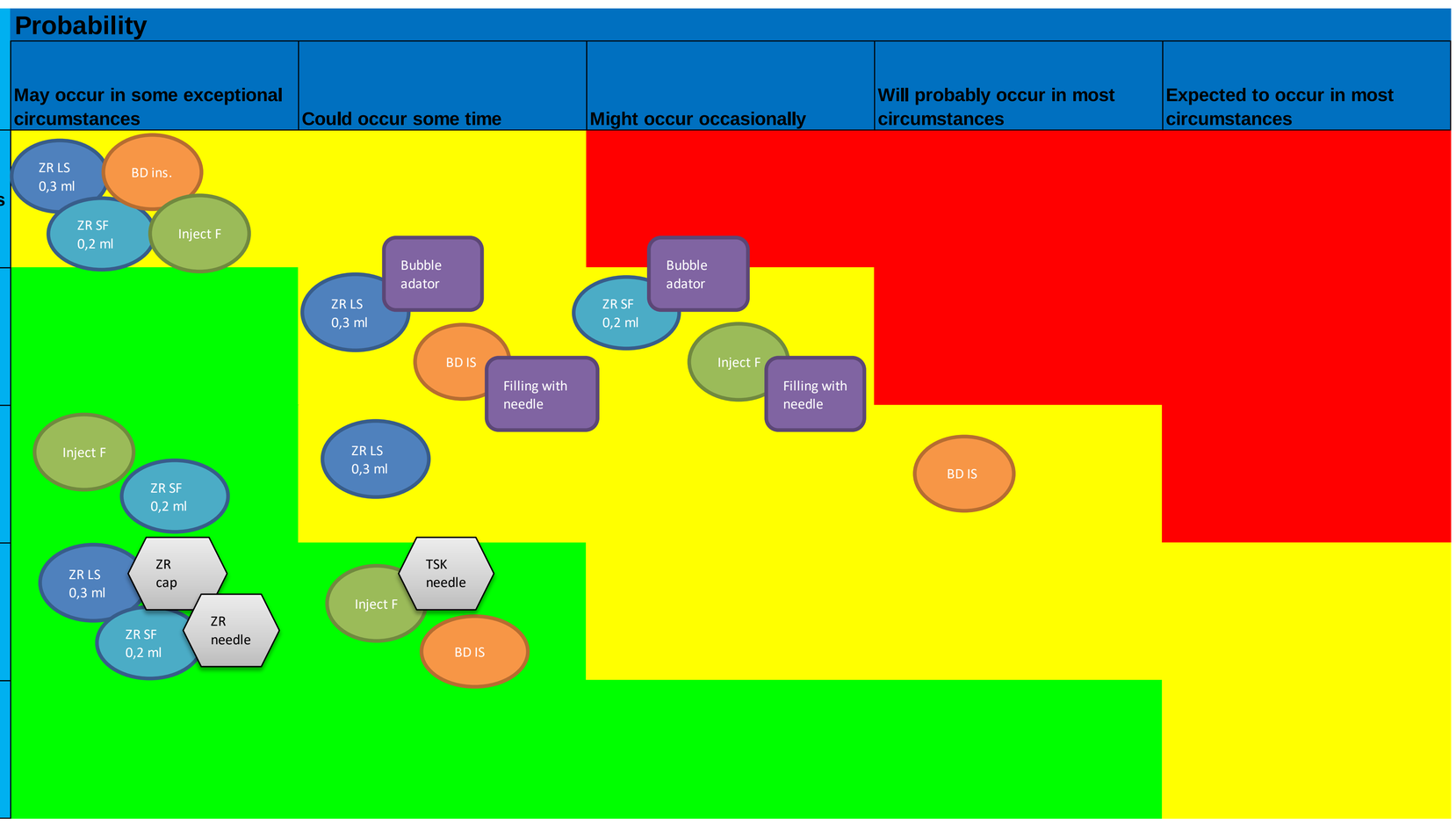

Figure 1:

Syringes: Insulin syringes with prefixed needles (BD)●, Inject F (BBraun) ● and Zero Residual (SJJ Solutions, Low Silicone 0,3 ml ● and Silicone free 0,2 ml ●) . Needles/cap⬟: TSK Low Dead Space , Zero Residual (SJJ) and cap (SJJ). Compounding methods■: needle or Zero Residual bubble adaptor. All ready to use syringes are compounded in isolators with grade A in the working chamber, and packed in sterile bags.

What has been achieved?:

The risk assessment shows that the risk to the patients are lowest when administrating drugs with Zero Residual syringes and needles, filling the syringes with bubble adaptor and deliver with cap.

What next?:

This work is relevant for other pharmacists and prescribing practitioners when assuring that syringes and associated equipment are of appropriate quality and suitable for intended use.

SYKEHUSAPOTEKENE