Trypan blue staining to determine vaginal exposure in two types of plastic vaginal applicators containing two different microbicide formulations

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Abstract:

Dye staining of applicators has been shown to be a reliable and objective method to test vaginal insertion in clinical microbicide trials, but different plastics, dyes, and product formulations may impact the accuracy of this method. Reportedly used applicators returned from 3 clinical trials were stained with 1% trypan blue. In a phase 1 study (VivaGel), using gel-filled HTI polypropylene applicators, 1271 (97%) of applicators stained positive. In a phase 1 and a phase 2a study (LACTIN-V) using linear low-density polyethylene applicators to deliver a dry powder formulation, 57 (95%) and 135 (86%) tested positive, respectively. Dye staining of vaginal applicators is an objective low-cost measure suitable for low-resource settings.