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Dose-response models of infection: A novel approach in assessment of the microbiological safety of the pharmaceutical formulae

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Water activity is very critical aspect in assessing the risk of microbial contamination of medicinal products. Multi-dose pharmaceutical preparations are prone to spoilage due to growth and proliferation of microorganisms, if they were not well preserved either physically or chemically. There have been several reports about infections due to consumption of contaminated drugs by the patients observed worldwide. Due to this challenge, an approach for assessing the microbiological risk hazard of infection from the contaminated multi-dose medicinal products was established based on the dose-response models of infections using an appropriate indicator microbe per route of administration. This new method of evaluation for pharmaceutical formulae has broader view and scope than the conventional Preservative Efficacy Test (PET). Moreover, it takes into consideration the misuse of the product by the customer at short intervals of use rather than the long intervals of the standard Antimicrobial Efficacy Test (AET). The risk evaluation takes into consideration not only the preservation power of the formula, but also the dose size, dose frequency, physical geometry with the integrity of the primary package, the indicator microbe chosen, the characteristic nature of the probability of infection, number of infecting particles and the route of administration. This new methodology may provide a promising method for the assessment of the newly designed and established pharmaceutical formulae in a quantitative manner using the probability risk of the infection. The value of this method can be extended to cover other multi-dose products such as cosmetics and other items that may impact human health.

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## Awareness and knowledge of oral contraceptive among women living in Riyadh, Saudi Arabia

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**Background & Purpose:** The main purpose of this study is to measure women's awareness and knowledge of oral contraceptive use in Riyadh region.

**Methods:** An online questionnaire data was conducted in Saudi Arabia, in Riyadh region, from August to November 2015. Women now living in Riyadh were eligible for this study.

Results: The study analyzed 1445 of oral contraceptive pill users who used it for different purposes. The knowledge of the correct way on OCP side effects was associated with age and length of usage. For every one-year increase in use, the odds ratio of awareness that OCP may cause depression was 61% higher and therefore duration of OCP usage was a significance predictor for knowledge even after adjusting for covariate (adjusted OR=1.523; 95% CI=1.053 to 2.203, p=0.009). At the baseline characteristics of 1,303 (90.03%) of the total women participated who thought that they have a little or enough information, univariate analysis showed that 1157 (80.07%) of women in total demanded for having more knowledge towards OCP. The research noticed that there is an enormous gap between participant's manner of practice and the correct method in all aspects. Consequently, the majority of participants were not able to deal with missing pill, diarrhea and vomiting. Reading OCP pamphlet were statistically significant with participant's age, marital status and whether they had OCP by prescription or not, p=0.003, p=0.001, & p=0.001, respectively.

**Conclusion:** There is little information and knowledge that was noticed for OCP practice. Participants in this study were asked for more OCP's information and instructions.

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