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Bioequivalence global requirements harmonization, importance and applicability

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Since majority of drug regulation deals with registration of generic drug products and the fact that bioequivalence studies are essential part of the registration dossier. This presentation aims to discuss importance of bioequivalence global requirements harmonization with respect to different parts of bioequivalence study namely; study protocol and documentation, clinical part, bioanalytical methods and statistical methods. In addition, shortcoming and impact of not having harmonized bioequivalence requirements on pharmaceutical industry will be discussed. The presentation will be concluded by discussing applicability of the bioequivalence global requirements harmonization on the regional level as well as the global level.

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Replacing nebulizers by MDI-spacers for bronchodilators and inhaled corticosteroids administration: Impact on the utilization of hospital resources

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Metered-dose inhalers plus spacers (MDI-spacer) are as effective as, or better than, nebulizers in aerosol delivery. The selection of aerosol delivery system for hospitalized children can have a significant impact on the utilization of healthcare resources. This was investigated in a quality improvement project in a tertiary pediatric ward from April to May 2013. Our project was conducted over a 6-week period. In the first two weeks, data were gathered from all hospitalized children receiving BDs and/or ICSs by nebulizers. This was followed by a two-week washout period. In the last two weeks, data were gathered after conversion to MDI-spacer. The primary outcome was the mean time of medication preparation and delivery. Secondary outcomes included: Need for respiratory therapy assistance, estimated cost of treatment sessions, and patient/caregiver satisfaction. Five hundred seventy-five treatment sessions were enrolled. The nebulizer group had more male predominance and were slightly older compared to the MDI-spacer group. The duration of treatment preparation and delivery was significantly lower in the MDI-spacer group (2 min reduction in preparation time and 5 min reduction in delivery time; $p < 0.01$). Caregivers mastered MDI-spacer use after an average of two observed sessions. Medication cost analysis showed savings in favor of MDI-spacer (cost reduction per 100 doses: 50% for albuterol, 30% for ipratropium bromide, and 87% for ICSs). The patient satisfaction survey showed "very good" to "excellent" levels in both groups. Conversion to MDI-spacer for BDs and ICSs administration in hospitalized children improve hospital resource utilization.

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