

USE OF CLOSED SYSTEM TRANSFER DEVICES WITH INVESTIGATIONAL DRUG PRODUCTS

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Background and Importance

Investigational drug products (IDP) should be treated as hazardous drugs (HD) as it is not frequent to have hazard studies available or the information about safety is usually insufficient. This is a handicap for pharmacists, who must guarantee the safety of professionals during the handling, preparation and administration of IDP as well as drug quality.

Recommendations by NIOSH and USP include the use of closed system transfer devices (CSTDs) in the healthcare setting to reduce occupational exposure to HD.

Frequently there is a lack of information about the potential impact of using CSTDs on product quality. This may be a challenge when they are used with IDP, especially with monoclonal antibodies (mAb) and drug-conjugated mAb.

Aim and Objectives

To review the scientific evidence related to the use of CSTDs when compounding and administering IDPs, in order to determine the main challenges related to its use and to establish the use criteria in daily practice.

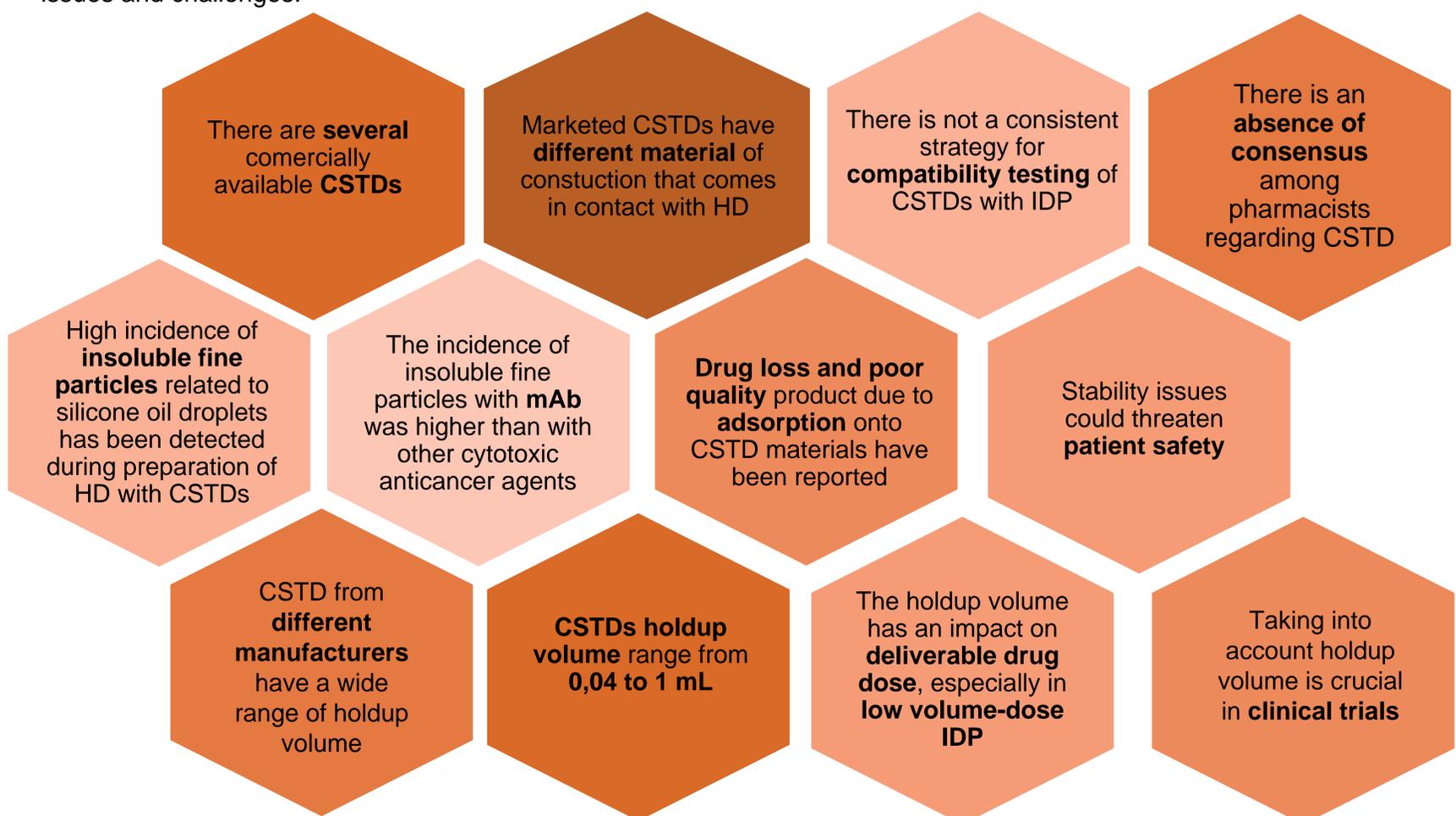
Materials and Methods

A comprehensive search in Medline (PubMed) database was performed. The search strategy was based on a combination of the following terms: closed system transfer devices, drug development and biological products (meSH term). We included studies evaluating CSTD, safe handling and drug quality.

CSTD was defined as a drug transfer device that prohibits the transfer of contaminants into the system and the escape of HD.

Results

We included 7 articles (one systematic review, four reviews and two prospective studies) that showed the following critical issues and challenges:



Conclusion and Relevance

- Variety of components in CSTDs can potentially lead to incompatibility issues, physical and chemical instabilities
- There is insufficient information to exclude safety concerns for IDP leading to broad use of CSTDs according to guidelines.
- There is an urgent need to increase knowledge about the hazard of new therapies and to assess CSTDs impact on product quality, clinical trial outcome and patient safety.

