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Assessing the Readiness to Implement USP<800> within the Investigational Drug Service of a Pediatric Hospital

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Short Communication

DESCRIPTION

United States Pharmacopeia (USP) General Chapter 800 requires the development of policy and procedures for the receipt, handling, and storage of hazardous drugs [1]. These regulations also expand the definition of hazardous drugs and require an annual risk assessment of medications listed on the NIOSH (The National Institute of Occupational Safety and Health) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings [2]. The limited amount of clinical trials in pediatric patients results in the lack of pediatric-specific information. Therefore, it is essential to carry out research in pediatric population to ensure that better therapies become available. Children are identified as uniquely vulnerable clinical research subjects. All efforts should be made to minimize the risks while carrying out research in children [3]. Pediatric Investigational Drug Services (IDS) have an additional barrier to USP 800 implementation given the frequent use of novel agents and the enhanced risk of pediatric trials.

This study was designed to assess safe handling of hazardous drugs of IDS in pediatric hospitals in the United States related to USP <800> compliance. A 13-item electronic survey was developed to assess the readiness of USP 800 implementation and its barriers, specific to pediatric IDS pharmacies. Surveys were sent to 47 IDS pharmacists at 28 pediatric hospitals. Pharmacists were identified by those enrolled in the Children's Oncology Group IDS Pharmacist listserv. Participants were given a week to complete the survey. One email reminder was sent during this timeframe. Qualtrics, an online survey program, was utilized to distribute the questionnaire in July 2017. Highlighted areas of concern were the development of hazardous risk assessments for investigational agents, strategies for attaining compliance, and overall integration into current policies.

A total of 15 responses from 10 pediatric hospitals were received throughout the country. The majority were aware of the upcoming USP 800 implementation date, but had not received any information from their institution. Sixty percent of participants reported that the implementation will be a combined effort by both IDS pharmacists and pharmacy administrators at their practice sites. Nearly half of the respondents have already conducted a risk assessment for handling investigational drugs. Investigator Brochure (36.59%) and Study Sponsors (29.27%) are the leading sources for HD requirements and information. If toxicity profiles are not available majority of respondents utilize Cleaning/Handling information (24%) and Recommended PPE (26%) as indicators of HD status. Only 13.33% of those surveyed were meeting all requirements in the chapter, with the lack of written policies and procedures being the most common barrier.

USP 800 will have a positive influence on the health care professionals' safety and awareness for handling hazardous drugs. Implementation is dependent on institutional interpretation of the guidelines. Compliance with all aspects of the chapter are necessary but not a simple endeavor. A collaborative effort amongst pediatric institutions may be beneficial when performing risk assessments for novel agents and drafting the policy and procedures necessary to achieve compliance. Additional surveys should be performed prior to implementation to assess USP 800 knowledge, changes to institutional practice, and overall guideline consensus.

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