Clinical research nurses and non-licensed study coordinators observed variation in procedures for reconciliation and disposal of oral investigational medications across the institution. An academic medical center implemented a quality improvement project to standardize the process of reconciliation and disposal of oral investigational medications. An interprofessional collaborative workgroup was formed, which led to multiple interventions to standardize practice, including revision of three policies and procedures, redesign of specific work areas to establish drug-counting rooms, review of personal protective equipment requirements, revision of educational training, and regular cleaning of potentially contaminated workstations.

AT A GLANCE

- Global use of oral investigational agents has grown exponentially during the past two decades.
- Clinical research programs that provide oversight for medication administration require rigorous processes for reconciliation and safe handling of oral agents to protect staff.
- Educational initiatives and systematic internal policy updates support a culture of quality and safety in cancer care research settings.

KEYWORDS
clinical research nurses; oral investigational medications; safe handling; policies

DIGITAL OBJECT IDENTIFIER
10.1188/21.CJON.587-590

Reconciliation and Disposal of Oral Medication

Creating a safe process for clinical research personnel

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Clinical research staff members who manage clinical trials are responsible for ensuring patient compliance to administered oral investigational medications. Nearly eight million healthcare professionals are at risk for hazardous drug (HD) exposure during the preparation and administration of anticancer drugs (Celano et al., 2019). Real and potential adverse health effects have been associated with HD exposure (National Institute for Occupational Safety and Health [NIOSH], 2018). Safe practices for handling and administering investigational drugs are not universally standardized, and several areas of the medication-use process may pose safety risks to research nurses and nonlicensed clinical study coordinators (Brown et al., 2017).

The University of Texas MD Anderson Cancer Center (MDACC) in Houston boasts a robust clinical trial research community. There are approximately 250 research nurses and 450 nonlicensed study coordinators within the hospital. In May 2021, the MDACC clinical trial portfolio consisted of 6,449 total clinical trials, which included 1,968 treatment trials. From September 2019 to August 2020, a total of 23,959 individual outpatient oral investigational medication prescriptions were filled at MDACC pharmacy (S. Amin, personal communication, May 21, 2021).

Background

HDs used in cancer medicine include chemotherapy, antivirals, hormones, bioengineered medicine, and other miscellaneous agents (NIOSH, 2016). According to the Occupational Safety and Health Administration (2016), a safe level of occupational exposure to HD is unknown (Olsen et al. 2019). Toxicologic data may be incomplete or unavailable for investigational drugs used in clinical research, and they have the potential to be hazardous (NIOSH, 2018, 2020). NIOSH (2020) suggests that healthcare professionals consider these drugs hazardous until validated information becomes available. The U.S. Department of Health and Human Services advises the use of personal protective equipment (PPE) as a standard precaution against the exposure of HD for healthcare workers (Phan et al., 2019).

Clinical research nurses at MDACC observed variation across the inpatient and outpatient settings related to the safe handling of oral investigational medications. It was common practice for clinical research staff to keep patient-returned oral investigational medications at their office workspace until time permitted for the proper reconciliation and disposal, which created potential exposure. An interprofessional workgroup conducted a review of institutional practices, policies, and industry standards for minimizing