Commentary

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Dearth of Benzodiazepines: A Problem that must be Fixed and Reoccurs

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Description

Benzodiazepines have been widely used, including in the field of toxicology, ever since the Food and Drug Administration (FDA) of the United States granted approval to chlordiazepoxide in 1960. Some of the toxicological conditions that are treated with benzodiazepines include alcohol and sedative-hypnotic withdrawal, agitation associated with sympathomimetic and anticholinergic toxidromes, serotonin syndrome, neuroleptic malignant syndrome, and drug-induced seizures. Toxicologists and other healthcare professionals caring for poisoned patients face difficulties as a result of a lack of benzodiazepines because of their significant role in the toxicology formulary perhaps unmatched by other medication classes in terms of frequency and scope of use.

Benzodiazepine shortages have unfortunately become more frequent and prolonged in recent years. 35 shortages of benzodiazepines have occurred since the University of Utah Drug Information Service (UUDIS) began keeping track of them in 2001. “A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent” is how the UUDIS defines a drug shortage. UUDIS keeps track of a shortage at the national level, but it doesn't keep track of trends in the region, so it can't always tell the difference between a lack of drugs and a limited supply. There were 11 shortages in the first decade of the 21st century, with a median duration of 230 days; however, in the second decade, there were 20 shortages, with a median duration of 244 days, and four of these shortages are still ongoing; the longest is the shortage of parenteral lorazepam, which began in February 2016. Four more shortages have occurred since 2020; parenteral diazepam and midazolam are two of the three that will continue into 2022. Parenteral formulations of diazepam, lorazepam, and midazolam, which are frequently used in the treatment of critically ill patients, are particularly troubling because of their increasing frequency and duration. Since 2001, fifteen shortages of parenteral benzodiazepine have occurred. The median duration of parenteral benzodiazepine shortages is 576 days, whereas oral formulation shortages last for 216 days.

Multiple Simultaneous Shortages

Agent substitution becomes more difficult when there are multiple simultaneous shortages. Differences in agent characteristics may have a negative impact on patient care when substitution does occur, particularly when healthcare providers use medications with which they are less familiar or that are not ideal agents for a particular patient or scenario. In the event of a drug-induced seizure in a patient who does not have access to intravenous fluids, for instance, diazepam, which has erratic and slow intramuscular absorption, may be administered in place of intramuscular midazolam, which consistently exhibits rapid intramuscular absorption and has a decreased antiepileptic effect. Non-benzodiazepine alternatives such as phenobarbital, ketamine, or antipsychotics, which each have their own distinct risk profiles, may also need to be substituted by healthcare providers. These alternative agents might make use of more resources; For instance, when phenobarbital is used to treat alcohol withdrawal, some hospital guidelines call for the patient to be admitted to the Intensive Care Unit (ICU). Pharmacotherapy is further complicated by prolonged and recurrent physostigmine shortages in the particular case of the prevalent anticholinergic toxidrome, for which benzodiazepines are the primary treatment option. During a benzodiazepine shortage, patients may experience inadequate treatment of their disease process even if substitution occurs, resulting in increased morbidity and mortality. Utilizing medication vials multiple times may unintentionally compromise sterility in an effort to reduce drug waste. A provider's lack of familiarity with a substitute agent or the stocking of a different concentration than usual may even result in outright medication errors like dose errors. In addition to causing direct harm to patients, benzodiazepine shortages may impose significant labor costs on healthcare facilities, which is especially concerning given the current staffing shortage in hospitals. Healthcare facilities, the pharmaceutical industry, and policymakers have all struggled to come up with effective solutions despite the fact that drug shortages in general and benzodiazepine shortages pose safety concerns. The majority of benzodiazepines used to treat toxicologic conditions are generic, parenteral medications with a single or few suppliers, which accounts for shortages.

The majority of shortages of sterile injectable medications are the result of manufacturing or quality issues that can take a long time to fix. Additionally, suppliers have difficulty compensating by increasing production at a different location due to the absence of mandated manufacturing redundancy. Seven of the 15 shortages of parenteral benzodiazepine products that have occurred since 2001 involve products that are "single-source," which means that there is only one supplier. Even if a product is not "single-source," one company typically holds the majority of the market share, and if it experiences a shortage, other suppliers may not be able to increase production enough to make up the difference.

Drug Shortage

To address the intractable issue of benzodiazepine shortages, a multifaceted strategy involving a variety of stakeholders, including toxicologists and other healthcare providers, is required. Toxicologists, who possess a distinct clinical and pharmacologic skill set, ought to be included as members of pharmacy and therapeutics and drug shortage committees at the institutional level in order to assist in providing guidance regarding the preservation of the limited supply of drugs and the most suitable therapeutic alternatives. Though toxicologists must be aware of the risks of contamination and dose miscalculation, compounding of scarce drugs can be considered. A quality rating system for manufacturers should be implemented and the identity and location of drug manufacturers should be disclosed to healthcare institutions to facilitate transparency in purchasing. Healthcare systems should, whenever possible, make purchases from suppliers who have a track record of high quality and availability. In the event of unanticipated manufacturing issues, manufacturers of benzodiazepine products are required to develop plans for business continuity. Tax credits, rebates for factory upkeep, temporary market exclusivity, accelerated approval of another product, and the removal of Medicare generic injectable price caps could be considered as incentives for new manufacturers to enter the market. It is necessary to pass legislation that imposes appropriate financial penalties on suppliers who fail to report shortages. Even though many of these solutions fall outside the traditional scope of toxicology practice, some toxicologists may take on leadership, regulatory, or legislative roles during their careers that give them the chance to put them into practice. Toxicologists can also push for these changes through their professional associations and elected officials. Lastly, although outcome data from shortages is limited, it is essential to enacting legislative change because without it, suppliers primarily motivated by financial incentives will not implement the necessary changes to prevent shortages in the future. Utilizing a database like the ToxIC Registry or MedWatch, we recommend documenting patient harm and potential patient harm caused by shortages as well as patient-and institution-specific solutions. Toxicologists should be advocates for reporting within their institutions, stressing the significance of documenting these findings, which must be diligently communicated to the public, the scientific community, and legislative and regulatory bodies.

It is difficult to find a solution to the issue of benzodiazepine shortages; however, it is essential that all stakeholders work together in concert to achieve this goal by implementing the aforementioned strategies. Although regulatory and legislative action on transparency and quality metrics can facilitate this process, suppliers ultimately bear responsibility for manufacturing issues. Toxicologists can make a difference in a variety of ways, such as at the bedside, in an institution, as reporters of outcomes and advocates for change. We need to take advantage of these opportunities because the consequences of ongoing shortages for patients and those who provide their care cannot be tolerated.