



## Sentinel Event Alert

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### Preventing vincristine administration errors

Despite repeated warnings over the years and extensive labeling requirements and standards, tragic errors related to the inadvertent administration of vincristine intrathecally (into the subarachnoid space), rather than intravenously, continue to occur. And, while such events occur infrequently, such "wrong route" errors are very preventable.

There is little reported data in the United States regarding intrathecal administration of vincristine. One case has been reported to the Joint Commission Sentinel Event Database and three cases to the United States Pharmacopeia (USP) MEDMARX database for medication errors. In each of the reported MEDMARX cases, the error was intercepted before reaching the patient; in the Joint Commission case, the error resulted in permanent paralysis. The USP-ISMP (Institute for Safe Medication Practices) Medication Errors Reporting (MER) Program has eight cases which resulted in five deaths, two injuries (one quadriplegia) and one unknown result. In 2001, England's National Patient Safety Agency (NPSA) reported 14 cases of intrathecally administered vincristine since 1975. (1) However, numerous cases have been reported by the U.S. media in recent years, suggesting that health care organizations are choosing not to voluntarily report these fatal errors to the Joint Commission or USP, possibly due to concerns over legal discoverability of the related information. An independent literature search on vincristine administration errors identified 37 cases since 1968. (2)

"This tragedy is so preventable—yet there have been many cases reported in the media of patients being injected with vincristine intrathecally," says Michael R. Cohen, R.Ph., M.S., Sc.D., president, ISMP. "These cases are especially tragic because the patient experiences paralysis and a slow and extremely painful deterioration, which in nearly all cases results in death."

### Identifying problem areas

Although USP has a dispensing standard and requirements for specific labeling of vincristine, some health care workers may not be aware of the labeling and dispensing requirements. USP requires that a label stating "FATAL IF GIVEN INTRATHECALLY. FOR IV USE ONLY. DO NOT REMOVE COVERING UNTIL MOMENT OF INJECTION" be applied to each syringe by the person doing the dispensing. Each syringe should also be placed in an overwrap carrying the same label warning.

The risk of error is also increased if health care personnel remove the vincristine from its overwrap in advance of the IV injection. Though the drug may be correctly labeled and packaged, if it is prematurely removed from the overwrap, the physician – whose attention is focused on performing the procedure – may overlook the labeling and pick up the vincristine syringe instead of the medication intended for intrathecal injection. Other reported reasons for error include failure to check the physician's orders, and unfamiliarity with cancer drugs and protocols that result in physicians mistaking vincristine for an intended intrathecal drug or assuming vincristine is an additional drug to be injected. Simply put, the intrathecal injection of vincristine can be the end-result of either a single error or a series of system errors. There is a potential for eliminating these errors through implementation and enforcement of appropriate protocols.

### Practitioner insights

At the Dana Farber Cancer Institute, a protocol addressing the proper handling and dispensing of vincristine was developed as part of the organization's safety program. According to Sharon Lane, RN, MSN, AOCN, director, Clinical Trials Operation, and Sylvia Bartel, R.Ph., MHP, director, Pharmacy, the protocol for preparing and dispensing vincristine has many built-in safeguards that involve specific and clear labeling; overwrap packaging; preparing the medication at the time it is to be administered; attaching a unique filter; dispensing the vincristine separately from all other medications and then only to the individual who is administering the drug; and administering the drug in a room separated from other rooms where medication is administered. These steps, in conjunction with appropriate training and education, and ensuring that all practitioners are credentialed and have demonstrated competency, are part of the organization's safety practices for avoiding accidental intrathecal injections of vincristine.

Another proposed method for eliminating the risk of inadvertent intrathecal vincristine administration is the preparation of vincristine in minibags. (3) According to a report in the July 2001 issue of *Hospital Pharmacy* (4), the use of vincristine sulfate doses diluted in 0.9% sodium chloride for injection and packaged in minibags or in 30 mL syringes showed no evidence of physical or chemical instability. Though this practice may require extra preparation and administration time, the risk of accidental intrathecal administration is eliminated.

### Joint Commission recommendations

Efforts to increase awareness of the significant potential for this usually fatal error and to develop effective solutions are ongoing through the work of numerous individuals and industry professional organizations, including ISMP and the Food and Drug Administration (FDA). The Joint Commission recommends the following steps for eliminating the risk of accidental intrathecal administration of vincristine:

#### **Vincristine must only be administered intravenously!**

Recommendations for preparing, dispensing, and administering intravenous vincristine (and other vinca alkaloids):

1. Dilute intravenous vincristine in a volume—ideally for IV infusion in a minibag—that precludes administration via the intrathecal route.

2. If vincristine is to be administered via syringe, clearly label each vincristine syringe: "FATAL IF GIVEN INTRATHECALLY. FOR IV USE ONLY. DO NOT REMOVE COVERING UNTIL MOMENT OF INJECTION." Each syringe also must be placed in an overwrap carrying the same label warning.
3. Do not dispense intravenous vincristine (or any IV medication) in a manner that would permit it to be administered at a time and location where intrathecal medications are administered. If a dedicated location for intrathecal administration is not possible, the pharmacy should not dispense IV vincristine to a location where intrathecal medications are administered until it receives confirmation that intrathecal drug administration is not imminent or has been completed.
4. Conduct a "time out" with at least two qualified health care professionals to independently verify and document the drug, dose and route at the time of pharmacy preparation of intravenous vincristine and before each administration of intravenous vincristine.

Recommendations for drugs that are intended for intrathecal administration:

1. Prepare intrathecal medications in the pharmacy as close as possible to the time of administration, label them with an appropriate short expiration time (e.g., eight hours), and then deliver them to and administer them in a designated (ideally separate) location, at a regular, specified time of the day or week.
2. Establish a list of drugs that can be administered intrathecally, designate specific locations where intrathecal administration may be done, and ban all other injectable drugs from those physical locations during times when intrathecal injections are administered.
3. Conduct a "time out" with at least two qualified health care professionals to independently verify and document the drug, dose and route at the time of pharmacy preparation of drugs for intrathecal administration and before each intrathecal administration of such drugs.
4. Wrap intrathecal drugs within a sterile bag, which is then wrapped again in a sterile towel or another bag labeled: "FOR INTRATHECAL USE ONLY." Wraps or packages must be removed immediately prior to injection only by the person administering the medication.

## References

1. National Patient Safety Agency
2. Andrew Seger, PharmD, senior research pharmacist at Partners HealthCare Systems and the Division of General Medicine & Primary Care at Brigham & Women's Hospital, aseger@partners.org
3. Stefanou A., Dooley M. "Simple Method to Eliminate the Risk of Inadvertent Intrathecal Vincristine Administration," J. Clin Onc 21, 2003; 2044
4. Trissel A.L., Zhang Y., Cohen M.R. "The Stability of Diluted Vincristine Sulfate Used as a Deterrent to Inadvertent Intrathecal Injection," Hospital Pharmacy, 2001;36: 740-745
5. Cohen M.R. "Patients Still At Risk Of Accidental Intrathecal Vincristine Injection," Hospital Pharmacy, 2000;35: 808-11

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