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ISMP An ECRI Affiliate

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Safety committees need to proactively address the risk of accidental cerebral injection of IV drugs

Problem: Inadvertent intraventricular administration of medications or contrast media is a rare but serious event caused in large part by the ubiquitous Luer connector that permits misconnections between parenteral syringes/tubing and intraventricular access devices. New neuraxial connectors—NRFit—meeting the International Organization for Standardization (ISO) design changes are beginning to emerge, and medical devices which connect to the neuraxial route will eventually change to the new ISO standard design that will prevent misconnections.[1] However, intraventricular drains and tubing are NOT presently included in the NRFit initiative, enabling conditions prone to inadvertent misconnections, particularly by healthcare practitioners unfamiliar with intraventricular drains. ISMP recently received such a report involving a postcraniotomy patient who received radiopaque contrast media via an external ventricular drain (EVD) instead of via an appropriate intravenous (IV) route during a magnetic resonance imaging (MRI) study.

External Ventricular Drain (EVD)

An EVD is a flexible plastic catheter placed in the brain that uses gravity to drain cerebrospinal fluid (CSF) out of the ventricles to an external chamber or bag, which relieves elevated intracranial pressure (ICP) and, when connected to a transducer, allows ICP monitoring. EVDs are typically used to manage: acute symptomatic hydrocephalus caused by a brain tumor, subarachnoid hemorrhage, intracerebral hemorrhage with ventricular extension, and cerebellar stroke; ICP monitoring in traumatic brain injury; and other targeted therapeutic interventions.[2,3] After an EVD catheter is placed in the brain, the distal end, which protrudes from the scalp, is connected to a collection system with tubing, at least one three-way stopcock or manifold, a flushless transducer for ICP monitoring and CSF drainage, and at least one access port (for the occasional administration of antibiotics such as vancomycin directly into the brain). The CSF collection system is mounted on an IV pole.

Epidural tubing is yellow-striped, without access ports, and may have a NRFit connector to prevent tubing or syringe misconnections, whereas the typical EVD collection system has clear rigid tubing (possibly with a thin blue line through the tubing), an access port, and is not available with a NRFit connector. Thus, EVD tubing is similar in appearance to IV tubing and vulnerable to tubing misconnections and wrong route drug administration errors. Also, the three-way stopcock/manifold and port connected to the EVD tubing is often white and the same shape and size as stopcocks/manifolds and ports on common IV tubing.

Recent Event

Prior to surgery, a neurosurgeon placed an EVD in a patient with a brain mass and hydrocephalus. A contrast-enhanced MRI was later ordered for preoperative planning. A nurse from the neurosurgical intensive care unit (ICU) transported the patient to the radiology suite and provided a verbal handoff to a radiology nurse and an MRI technologist. However, the radiology nurse had to leave the MRI suite for an emergent computed tomography (CT) scan for another patient. The MRI technologist who received the verbal handoff report was not certified to administer IV contrast,

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SAFETY briefs

HIGH-ALERT

Inadvertent intra-arterial promethazine injury. Many healthcare professionals know that promethazine injection is a vesicant, highly caustic to the intima of blood vessels and surrounding tissue. Parenteral administration can result in severe tissue damage, regardless of the route of administration. However, inadvertent intra-arterial injection associated with intravenous (IV) use has resulted in more significant complications, including burning pain, erythema, swelling, severe spasm of vessels, thrombophlebitis, venous thrombosis, phlebitis, nerve damage, paralysis, abscess, tissue necrosis, and

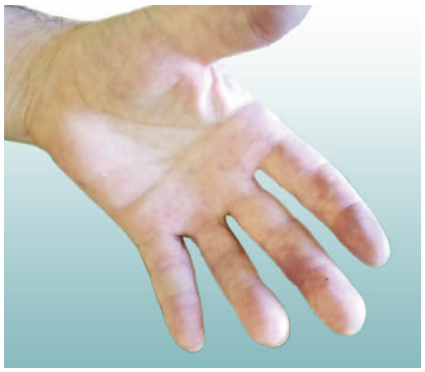

Figure 1. Darkened areas on the patient's fingers and thumb, soon after intra-arterial injection.

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Message in our Mailbox

In a featured article in our last newsletter (*Screening for dihydropyrimidine dehydrogenase [DPD] deficiency in fluorouracil patients: Why not?* July 15, 2021, www.ismp.org/node/25779), we reviewed the literature surrounding the hesitancy to adopt universal dihydropyrimidine dehydrogenase (DPD) deficiency screening in patients prior to the use of fluoropyrimidines (fluorouracil and capecitabine). We mentioned that the National Comprehensive Cancer Network (NCCN) has not recommended universal pretreatment

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so another MRI technologist came to assist. An incomplete handoff report occurred between the first and second MRI technologists. The ICU nurse remained in the MRI suite but did not repeat the verbal handoff to the second MRI technologist.

Unfortunately, the technologist administering the IV contrast media, gadobutrol (**GADAVIST**), did not adequately confirm with the neurosurgical ICU nurse which specific line and access port to use to administer the gadobutrol. The technologist was unaware that the patient had an EVD in addition to an upper extremity midline IV access. The technologist mistakenly injected the contrast media into the EVD access port, which he mistook as the IV access port. Although he was an experienced certified radiology technologist, he omitted essential safety steps prior to injecting the contrast media, including tracing the line to the insertion point and aspiration of what the technologist thought was the midline IV access to ensure a blood return.

After the MRI, the patient's mental status deteriorated, and a stat cranial CT scan was performed. The CT scan revealed the presence of radiopaque contrast media in the intraventricular and cisternal system, and it became evident that the gadobutrol had been inadvertently injected into the EVD during the MRI. High doses of gadobutrol intended for cranial MRI contrast can cause severe neurotoxicity.[4] The patient was treated with a **PENT**obarbital infusion to induce a coma and serial EVD lavage with sterile saline. He slowly improved with treatment and supportive care.

Similar Events in the Literature

Similar events associated with inadvertent intraventricular administration have been published in the literature.[4-8] For example, in 2011, McConnell et al. reported a case of accidental intraventricular administration of phenytoin through an EVD.[5] The patient had been hospitalized with septic shock and a temporal lobe abscess with hydrocephalus. In the neurosurgical ICU, he was started on mechanical ventilation, and an emergency craniotomy was performed with placement of an EVD for CSF drainage. The patient developed acute renal failure requiring renal replacement therapy and transfer to a general ICU. An experienced ICU nurse injected 250 mg (25 mL) of phenytoin into the EVD port instead of the venous catheter. In this hospital, although EVDs were relatively common in neurosurgical ICUs, they were rarely seen in general ICUs; thus, unfamiliarity with the EVD was a contributing factor in this event. The error was immediately detected, and the EVD was drained and lavaged. The patient experienced tachycardia, hypertension, and seizure activity. A propofol infusion was used for sedation for 24 hours. After resolution of the renal failure, the patient was returned to the neurosurgical ICU. He recovered slowly and had no adverse effects due to the error.

In 2013, Nayak et al. presented two cases of postoperative inadvertent administration of gadobutrol into an EVD port that was mistaken for IV tubing.[4] In the first case, a patient underwent resection of a meningioma and placement of an EVD for drainage. Several days later, a contrast-enhanced MRI was performed to assess residual tumor mass, which demonstrated profound hyposensitivity throughout the ventricular system and subarachnoid spaces as well as susceptibility artifact along the margins of the ventricles. Shortly after the MRI, the patient became agitated and hypertensive. The following day, he developed aphasia, dysarthria, depressed mentation, right facial drooping, and increased urinary output suggestive of diabetes insipidus. A cranial CT suggested the inadvertent administration of MRI contrast via the EVD. The EVD tubing was mistaken as IV tubing, as it had been hidden underneath the patient's hospital gown, exiting a sleeve on the same side as the patient's antecubital IV line. The contrast media was found in the EVD collection bag, confirming the error. The patient required long-term ventilatory support and medical management of newly developed nonconvulsive status epilepticus.

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gangrene. Despite this well known problem, ISMP occasionally receives reports of promethazine injection tissue injuries with catastrophic consequences, including a report received a few weeks ago.

An emergency department (ED) patient with acute pancreatitis received promethazine 25 mg that was intended for IV administration but was inadvertently administered intra-arterially. The patient immediately experienced excruciating pain and redness from his fingertips to his shoulder. Then his fingers and arm turned dusky and blackish. See **Figure 1** (page 1) for a photo taken by the patient not long after the injection; note the red-purplish color of the fingers and thumb. After 48 hours, swelling appeared, and the patient was still experiencing severe pain. More recent photos show the development of gangrene (**Figure 2**). The patient told us recently that he is now facing possible amputation of the affected digits, at least to the first knuckle and possibly beyond.

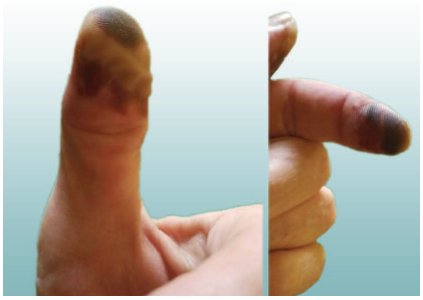

Figure 2. Worsening of the affected areas, now becoming gangrenous.

Promethazine labeling acknowledges that the drug can cause severe chemical irritation and damage to tissue, regardless of the route of administration. Although the labeling states the intramuscular (IM) route is preferred, the drug is available in a 25 mg/mL strength intended for deep IM or IV use, while a 50 mg/mL strength is intended for deep IM use only, which is confusing. The labeling mentions that, due to the proximity of arteries and veins in the areas used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or accidental intra-arterial injection. However, as the present case indicates, it may not always be possible to prevent intra-arterial injection. No proven management of unintentional intra-arterial injection or perivascular extravasation exists.

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Upon retrospective review of MRI images, a second case was discovered, which occurred 2 years previously.[4] A craniotomy patient with an EVD had a postoperative contrast-enhanced MRI that showed an identical pattern of profound hyposensitivity throughout the ventricular system and subarachnoid spaces and susceptibility artifact along the margins of the ventricles. After the MRI, the patient's mental status was altered and she suffered severe headaches. Unlike the patient described previously, this patient did not develop status epilepticus, nor did she require long-term ventilatory support. Her neurological status returned to baseline several days after the MRI.

In 2016, Singh et al. reported a case of inadvertent administration of gadolinium contrast through an EVD during an MRI in a patient after resection of a meningioma.[6] After the MRI, the patient became hypertensive and complained of nausea and anxiety. By the next morning, the patient developed rapidly progressing aphasia, right facial droop, and delirium. The MRI from the previous day demonstrated extensive cerebral edema, which led to the investigation and discovery of the inadvertent intraventricular administration of contrast media via the EVD. This was later confirmed by the presence of gadolinium in the EVD collection bag. The patient had to be mechanically ventilated, a lumbar drain was placed, and IV dexamethasone, hypertonic saline, norepinephrine, and antiseizure medications were started. The patient developed nonconvulsive status epilepticus and continued to deteriorate. He was discharged to a skilled nursing facility with long-term, irreversible disability still present after 2 years.

Other published errors occurred more than a decade ago. In one close call, an EVD tunneled to exit just below a child's clavicle was mistaken for a central venous line, and the child almost received intraventricular propofol and rocuronium during induction of anesthesia.[7] In another case, an adult patient received intraventricular etomidate and rocuronium through a ventriculostomy catheter during rapid sequence intubation in an ICU.[8]

Safe Practice Recommendations: The issue of medical tubing misconnections has become a global imperative for patient safety with the new ISO medical device connector standards. However, to our knowledge, inadvertent EVD misconnections have yet to be considered within the ISO standards development process. Nevertheless, these strategies can prove effective in reducing the risk of an error, although many rely on individual practice and vigilance.

EVD Safety Management

Avoid tunneling near the clavicle or neck. When placing an EVD, if the catheter exits from any location other than the scalp, avoid subcutaneous tunneling of the EVD to common central venous access sites, including just below the clavicle or near the jugular vein in the neck.[7]

Affix bright warning labels. To distinguish EVD tubing from other medical tubing (including IV lines), affix a prominent and colorful label near the distal end of the EVD tubing set-up to communicate that it is a ventricular drain (e.g., CSF drain). Also consider labeling the EVD stopcock or manifold.

Cap the ports. McConnell et al. recommend placing caps or some type of covering on every access port that is not intended for IV administration, including EVD ports.[5] The removal of the cap or covering for any injection requires an independent double check of the medication or solution, including the route of administration. Some hospitals also require an independent double check prior to any injection through a stopcock, and others have a policy to never use a stopcock for injecting medications.

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The ISMP 2020-2021 ***Targeted Medication Safety Best Practices for Hospitals*** recommend the removal of injectable promethazine from all areas of the organization, including the pharmacy, classifying it as a non-stocked, non-formulary medication. Further, the *Best Practices* call for an automatic therapeutic substitution policy to convert all injectable promethazine orders to another antiemetic, and removal of injectable promethazine from all drug order screens, order sets, and protocols. Although the product labeling notes the IM preferred route, the *Best Practices* recommend avoiding IM promethazine because it can also cause tissue damage or be accidentally injected intra-arterially. Product labeling notes that aspiration of dark blood does not preclude intra-arterial needle placement because blood is discolored upon contact with promethazine. Also, using a syringe with a rigid plunger or a small-bore needle might obscure typical arterial backflow. Subcutaneous injection is contraindicated in the labeling.

It has been nearly 15 years since ISMP first recommended that the US Food and Drug Administration (FDA) reexamine promethazine product labeling to consider eliminating the IV route of administration. In the same August 10, 2006 newsletter, we also called for hospitals to consider removing promethazine injection from hospital formularies (www.ismp.org/node/934). We repeat these recommendations today. The drug has been available since the 1950s. Would the drug meet current standards for safety and efficacy? In looking at the approved indications for parenteral promethazine (www.ismp.org/ext/734), there are safer alternatives for each, including for the prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery. So, we question why this drug continues to be labeled for IV use, why it needs to be on a hospital formulary or available in ambulatory procedural settings, and perhaps, why it needs to be available at all? Please take action now to prevent these harmful events.

Manufacture of legacy feeding tubes ended. The Global Enteral Device Supplier Association (GEDSA) announced last week that its member manufacturers ended

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Placement on different sides. Equipment for EVDs and pumps for venous lines should be placed on separate IV poles and, when possible, maintained on opposite sides of the patient's bed.

Avoid threading through a gown. Never thread EVD CSF collection tubing through the sleeve of a patient's gown, which is often done with a central venous line.

Staff education. Annual skills review to reinforce safe use of EVDs is required for those who typically manage the drains. Staff who infrequently encounter EVDs increases the risk of a misconnection error. While just identifying the risk is not enough to prevent a potential misconnection, all professional staff should be informed about EVDs, if used in the hospital, to raise awareness. Whenever possible, staff familiar with EVDs should stay with patients during procedures and be involved in the checking process to reduce the risk of wrong route drug administration.

Recognize inadvertent intraventricular administration. Educate providers and staff to recognize the signs and symptoms of accidental intraventricular administration (e.g., hypertension, anxiety, depressed mentation, aphasia, dysarthria, facial drooping) so they can manage the event promptly. When reading a cranial contrast-enhanced MRI, Lele et al. suggest that profound hyposensitivity throughout the ventricular system and subarachnoid spaces as well as susceptibility artifact along the margins of the ventricles should be a signal that inadvertent intraventricular contrast administration has occurred.[2] Evaluation of the EVD collection bag can confirm the presence of contrast media.

Intrahospital Transport/Transfer of Patients with an EVD

Transport/transfer policy and procedure. Establish a policy and procedure for intrahospital transport/transfer of patients with an EVD. At a minimum, include guidance describing the transport of patients with an open or closed CSF collection system (if closed, ensure clamping at both the proximal port on the EVD and distal port on the CSF collection system); head-of-bed status during transport and leveling of the EVD at the external auditory meatus (ear); using a dedicated, clearly labeled, IV pole for the EVD mount; required patient monitoring during transport; trouble-shooting for typical problems like kinked tubing; and the management of intracranial hypertension, including the medications needed to treat this crisis.[2,3] A pretransport screening checklist might be helpful.

Accompany patients. A patient with an EVD requires monitoring during transport by a trained professional (nurse, physician) familiar with EVDs and the management of intracranial hypertension. Monitoring might include capnography and arterial, intracranial, and cerebral infusion pressure readings. The transporting practitioner also must confirm the availability of medications needed to treat intracranial hypertension should the need arise during transport.

Provide a verbal handoff report. The trained professional who accompanies the patient during transport should, at a minimum, provide a verbal handoff to the receiving practitioner. The receiving practitioner's scope of practice and familiarity with EVDs should be considered, and enough guidance should be provided to ensure the patient's safety. For example, the trained professional accompanying a patient to the radiology suite for an invasive procedure or contrast-enhanced MRI should speak directly with the technologist or radiology practitioner(s) conducting the study, point out the EVD and the need to avoid all tubing connections and injections into any EVD access port, and identify which specific IV line and port to use if an IV injection is or might be required. A standardized handoff tool, such as a checklist, should be considered to guide the process.

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production of legacy feeding tubes and cross-application connectors on July 1, 2021, as scheduled, to support the transition to safer ENFit enteral feeding devices (www.ismp.org/ext/733). On January 1, 2022, GEDSA members will end production of transition sets and adaptors sold separately from other devices. Individual GEDSA members will continue to provide legacy devices until their supplies run out. GEDSA recommends that all US hospitals convert to ENFit by the end of the year.

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DPD deficiency screening, and that it is not currently the standard of care in the US. However, we concluded that the risk of patient harm and potential fatality seems clear when administering fluoropyrimidines to patients with a DPD deficiency, while the hurdles to implement widespread testing seem to be manageable. So, ISMP has joined others who have asked the question, "Why not test?"

In response to that article, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Panel for Colon/Rectal/Anal Cancers sent the following letter to ISMP:

The authors raise some important issues about screening for dihydropyrimidine dehydrogenase (DPD) deficiency; it is a complicated topic regarding a complex metabolic pathway. Our panel has discussed this issue extensively and we will continue to monitor any new developments in the literature.

There are a few comments we would like to make regarding DPD deficiency and pre-treatment testing. The incidence of true total enzyme deficiency is probably less than 1% depending on the population while some level of deficient DPD activity occurs in about 5-10% of the population overall.[1] Deficient DPD activity is due to natural variations in the DPYD gene that make the patient less efficient in metabolizing the drug and its metabolites due to decreased activity of the patient's particular enzymes in the pathway.

In promoting pre-treatment testing for DPYD variants, the authors cite studies which looked at a few specific variants and

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Safety Steps Prior to Injection

Perform a universal "time out." Perform a "time out" with all procedural staff in the room to identify the patient, the procedure being done, the access port for IV injections, and other IV lines or drains also attached to the patient.

Trace the lines. All these cases highlight the importance of confirming the route of administration by tracing all access lines and injection ports to their origin (insertion site into the patient) prior to administration. Label all lines placed during a procedure.

Aspirate blood. If appropriate, use a syringe to aspirate blood prior to injection to verify intravascular placement of a line being used for IV administration. If the syringe has been accidentally attached to an EVD port, the aspirate (CSF) would most likely be a clear yellow color (xanthochromic), tea colored, or pink, but not frank blood.[2,3]

ISO and EVD Manufacturer Recommendations

ISO standards and design changes. It is our hope that these rare but serious events will lead to the use of the ISO medical device standard for neuraxial connectors, NRFit. These are unique and cannot be attached to other medical connectors, including Luer lock syringes/tubing. In our opinion, NRFit compatibility of EVDs, CSF collection system tubing, and any associated stopcocks or ports should be accomplished as soon as possible. We have made this suggestion to the Global Enteral Device Supplier Association (GEDSA), which represents companies implementing ENFit, also an ISO standard. ENFit prevents misconnections between gastrointestinal tubes and catheters and Luer connectors. We also strongly encourage EVD collection system manufacturers to design their products so the tubing does not resemble IV tubing.

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Editors: Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Kelley Shultz, MD. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.

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did show the benefits of pretesting in terms of diminishing the incidence of very severe fluorouracil associated toxicities. However, these studies provide no survival data to inform whether reducing the dose of fluorouracil by 50% at the start of treatment impacts efficacy, which is especially important when fluorouracil or capecitabine are being used in the adjuvant setting for patients with potentially curable cancer. If we had more precise dosing recommendations based on specific variations and survival data—if in fact dosing would be totally dependent on that particular enzyme variant—it would be a reasonable test to run. In fairness, these are small select studies, but we still need to know if we diminish the chance of a cure.

As for capecitabine, which is an oral prodrug, there are so many other variables regarding toxicities in individual patients, including age-related decreases in creatinine clearance, actual kidney disease and dysfunction, diet, and emerging data on the microbiome, that we would have no idea how to incorporate DPD findings into the dosing of that drug.

In summary, because of the integral role fluoropyrimidines play in the treatment of colon cancer, and the uncertainty regarding the impact of different DPYD variants on fluoropyrimidine metabolism and how dosing should be adjusted, the National Comprehensive Cancer Network (NCCN) panel does not support universal pretreatment DPYD genotyping at this time.

Al B. Benson III, MD, FACP, FASCO, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chair of the NCCN Guidelines Panel for Colon/Rectal/Anal Cancers

Alan Venook, MD, UCSF Helen Diller Family Comprehensive Cancer Center, Vice-Chair of the NCCN Guidelines Panel for Colon/Rectal/Anal Cancers

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SUMMER 2021

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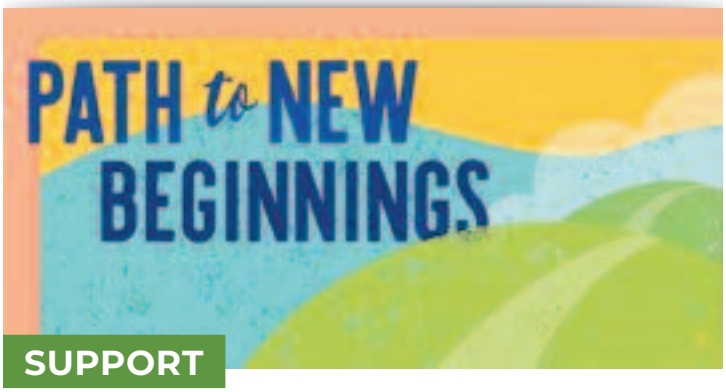

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