

Long-Term Care Advise *ERR*TM

Educating the Healthcare Community About Safe Medication Practices

Independent double checks: **Undervalued and misused** *Selective use of this strategy can play an important role in medication safety*

High-alert medications are drugs that bear a heightened risk of causing significant harm to patients or residents when they are used in error. A manual independent double check of high-alert medications is a strategy that has been widely promoted in healthcare to help detect potentially harmful errors before they reach patients or residents.¹⁻³ On the other hand, independent double checks used as a risk-reduction strategy have long been disputed as well as misused in healthcare. Its use has been a source of stress for busy nurses, pharmacists, and prescribers who are short on time. Its impact on safety has been questioned by those who rarely find mistakes during the checking process. Inconsistent use and variability in how the task is carried out renders it less capable of detecting many errors. Its overuse as a risk-reduction strategy for high-alert medications has been challenged given its status as a weak error-reduction strategy, particularly if it is the only safeguard in place. Its frequent misuse as a quick fix for an ailing medication use system has been the bane of managers who have investigated serious errors that have reached residents due to failed double-check processes.

Despite these challenges, ISMP believes that the selective and proper use of independent double checks can play an important role in medication safety. As documented in **Table 1**, on page 2, numerous studies have demonstrated the ability of independent double checks to detect up to 95% of errors.⁴⁻¹⁰ Based on this, an error rate of 5% (1 in 20) can be reduced to 0.25% (1 in 400) by introducing an independent double-check process. While automated double checks such as barcode scanning may yield even better results, there is enough evidence today to suggest that carrying out a manual independent double check is worth the time and effort, particularly if technology is not available, and if this strategy is planned and carried out as follows.

Conduct double checks independently

First, to be most effective, the double check must be conducted independently by a second person.^{5,7-10} This reduces the risk of bias that occurs when the same person prepares and checks the medication, as that person is likely to see what they expect to see, even if an error has occurred. An independent double check requires two people to *separately* check each component of the work process. For example, a nurse calculates the amount of medication needed from a multiple-dose bottle of liquid medication, prepares an oral syringe of medication, and compares the product to the order; then, another nurse *independently* checks the order, calculates the dose, and compares the results with the product for verification. Two people are unlikely to make the same mistake if they work independently. If they work together or influence the checking process by suggesting what the checker should find, both could follow the same path to an error. Holding up an oral syringe and a bottle and saying, "This is 30 mg of **ROXANOL**, can you check it?" is not effective. The person asking for the double check must not influence the individual checking the product in any way.

In the absence of an independent double check, Grasha et al.⁷ found that delayed self-verification of work conducted hours or days after initial completion of the task

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SAFETYwires

⚡ Yet another expiration date issue. Add yet another problem with the way expiration dates appear on drug products. The **NITRO-DUR** (nitroglycerin) patch from Key Pharmaceuticals (**Figure 1**) embosses the lot number and expiration date over a corrugated area that seals the protective paper outerwrap. Unfortunately, this makes the date nearly impossible to read and the numbers 3 and 5 difficult to distinguish. An illegible expiration date on a nitroglycerin patch can result in negative outcomes for residents.



Figure 1. Embossed print is nearly impossible to decipher.

Previously, we received a report in which a nurse used a lactulose product, by Pharmaceutical Associates, that was past its expiration date because the lot number "2D15" looked more like 2015 next to the actual expiration date of "04/14" (04/14 2D15) (**Figure 2**, on page 2). Manufacturers have also used dates such as 15MAR14, which could be understood as March 14, 2015, or March 15, 2014, or the companies have abbreviated a month such as JN or MA, which could be January or June, or May or March, respectively.

ISMP has asked the US Food and Drug Administration (FDA) and the US Pharmacopeial Convention (USP) to ensure that manufacturers use specific expiration date formats that express dates in a uniform se-

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has detected errors at rates comparable to those reported with independent double checks; however, Grasha’s work clearly shows that healthcare professionals are better at detecting the errors of others than their own errors. Grasha concluded that double checks work best when they are performed independently.

Use double checks judiciously

With workload issues looming heavily over practitioners, independent double checks should only be used for very selective high-risk tasks or high-alert medications (not all) that most warrant their use. Selected tasks and medications should not be based simply on those which have historically always been double checked, but on a careful assessment of scenarios with the greatest risk. As such, ISMP does not recommend use of an independent double check for all high-alert medications or all high-risk tasks. Lack of time to carry out the checking process properly was a strong, recurring theme in studies of failed double checks and staff resistance to this strategy.¹⁰⁻¹¹ Studies of nurses suggest that it may add up to 20 minutes to each medication pass to carry out an independent double check for most medications.^{12,13} Fewer double checks strategically placed at the most vulnerable points of the medication use process will be much more effective than an overabundance of double checks.

Table 1. Studies on the Impact of Double-Check Systems

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Study	Description	Error Rate (ER) or Error Detection Rate (EDR)	Comments
Kruse H, et al. ⁴ 1992	Compared use of 1 nurse to the use of 2 nurses to administer medications; second nurse double checked work of first nurse	ER per 1,000 doses: 1 nurse: 2.98 2 nurses: 2.12	Use of 2 nurses led to a statistically significant 29% reduction in errors reaching patients
Campbell GM, et al. ⁵ 1998	Use of process control charts to monitor dispensing errors and errors detected with an independent double check	EDR: 95%	An independent double check detected 95% of errors, leading to a reduction in error rate from 5% to 0.25%
Ross L, et al. ⁶ 2000	Compared dispensing error rate with and without a double check	ER per year: Without check: 9.8 With check: 6	Double check led to a 39% reduction of dispensing errors
Grasha T, et al. ⁷ 2001	Studied errors pharmacists found when they randomly checked completed prescriptions awaiting pick-up	ER per 5,700 prescriptions: 4.2%	Use of double check identified 4.2% of errors otherwise not detected prior to dispensing; of these, 2.1% were potentially clinically significant
Grasha T, et al. ⁷ 2001	Introduced artificial errors into medication carts and sample pharmacy orders, and measured detection rate with an independent double check	EDR: 95%	The ability to detect and correct 95% of errors was not affected by workload or time on shift
Jensen LS, et al. ⁸ 2004	Reviewed drug errors detected during anesthesia with second person double check and prevention strategies	EDR: 58%	Double check was the single most effective measure in the study
Gosbee LL. ⁹ 2006	Usability testing to compare use of flow sheet and verbal read-back method of double checks to detect PCA infusion pump errors	EDR: 88% with no differences in methods	Use of either flow sheet or read-back led to detection of 88% of infusion pump errors; all undetected errors were drug concentration errors
White RE, et al. ¹⁰ 2010	Simulation to test ability of second nurse to detect wrong patient errors using new checklist with prompt to verify patient identifiers versus old checklist without prompt	EDR with checklist: No prompt: 15% With prompt: 80%	Use of checklist with prompts when conducting double check led to significantly higher (433% increase) detection of wrong patient errors

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quence to clearly communicate the date in a consistent and unambiguous manner. Manufacturers should also avoid packaging features that might interfere with the legibility (e.g., printing on shiny foil, corrugated areas, end seals on shrink-wrap).

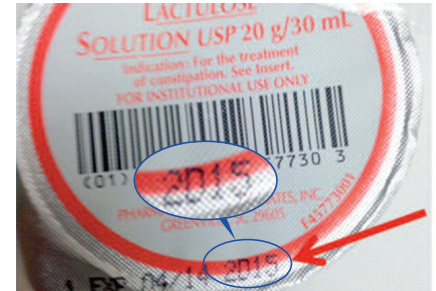


Figure 2. “2D15” is the Lot number, not the expiration year.

Florinef vs. Floranex. A nurse took a verbal order for lactobacillus tablets but did not know how to enter the order into the electronic ordering system, so she called the pharmacy. A pharmacist told her to enter the probiotic supplement **FLORANEX** (lactobacillus). However, she thought she heard a familiar drug name, **FLORINEF** (fludrocortisone), a systemic corticosteroid and endocrine-metabolic agent, so she entered that. Fortunately, a pharmacist recognized the error while reviewing the order.

In another case involving a probiotic supplement, a physician gave a verbal order for **FLORASTOR** (*Saccharomyces boulardii*) to a healthcare professional who entered “flor” into the computer and accidentally selected Florinef. The person entering the order thought Florastor and Florinef were the same product and ordered the default dose built into the order entry system. Luckily, a pharmacist also caught this error.

If you use Floranex or Florastor at your facility and also list Florinef in your system, be alert to the risk of a mix-up. These names sound almost identical when spoken and can also be confused in print or when handwritten. According to the US Food and Drug Administration (FDA), the brand Florinef has been discontinued, so work with your pharmacy and IT staff to remove the brand name product from your computer system to prevent errors, and to use the generic name. Lactobacillus should be listed in computer systems and prescribed by its generic name.

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Also, do not use double checks as a means of fixing problems when a more fundamental system redesign is needed.¹⁴ Independent double checks do not prevent errors, they simply catch them. Independent double checks are a poor substitute for system improvements that will actually help prevent errors. Strategies with higher leverage (such as the use of barriers, improving access to information, standardization, and automation) should be considered. Any errors uncovered during the double-check process should also be used for learning and system improvement.

Avoid sole reliance on double checks

Double checks will sometimes fail for a variety of reasons, not the least of which is that the process essentially depends on one fallible person assessing another fallible person's work. Human performance limits foretell inevitable slips, lapses, and mistakes that will result in an occasional failed check system.

The origin of the error can also predict a certain amount of failure with even the most robust independent double-checking process. For example, an endogenous (or internal) error can arise solely within an individual from a random and unpredictable cognitive event like miscalculating a dose.¹⁵ Another person performing the same function will rarely make the same exact mistake. Therefore, endogenous

Table 2. Possible questions or steps to include in the independent double check.

Comparison to prescriber's order:
▶ Is this the prescribed drug?
▶ Is this the prescribed dose/strength/rate of infusion?
▶ Is this the prescribed route of administration?
▶ Is this the right resident?
▶ Is this the prescribed frequency/time for drug administration?
Additional cognitive checks:
▶ Does the drug's indication match the resident's diagnosis or condition?
▶ Is the drug appropriate given the resident's other diagnoses or conditions?
▶ Is this the right formulation of the drug?
▶ Are dose calculations correct?
▶ Is the dosing formula used to derive the dose correct (mg/kg)?
▶ Is the prescribed dose appropriate for <u>this</u> resident?
▶ Is the dosing frequency/timing appropriate for <u>this</u> resident?
▶ Is the route of administration safe and proper for <u>this</u> resident?
▶ Are pump settings correct (if applicable)?
▶ Is the correct infusion running through the correct pump channel?
▶ Is the infusion line attached to the correct port (if applicable)?
▶ Have appropriate monitoring tests been ordered?
▶ Are the test results upon which a dose has been based verified as belonging to this resident?

errors are likely to be detected if a double check is performed independently by another person. An exogenous (or external) error arises from conditions in the work environment, such as poor design of drug packages and labels, complex task characteristics, or unclear presentation of information.¹⁵ Double checks are often less successful in detecting exogenous errors, even when the check is performed independently. Similar external factors that initially led to the error are often still present, and people in the same environment could easily make the same mistake during the double check.

Because double-check systems will sometimes fail, the intended improvement in system reliability will be illusory if you rely on these alone to catch all errors. Independent double checks should be bundled with other risk-reduction strategies and system changes to reduce the frequency of errors.

Conduct a cognitive review

Analysis of failed double-check processes and interviews with staff suggest that double checking often becomes a superficial routine task. People may lose sight of its importance. These failed checking processes can often be traced to common themes: auto-processing in which the person checking the work of another does so in a habitual manner with little real appraisal; a deference to authority in which the

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It's doubtful that the dietary supplement manufacturer would be motivated to change the name of its Floranex product, especially since Florinef is no longer on the market. However, pharmacy may consider purchasing a different brand of lactobacillus (e.g., **CULTURELLE**) to prevent mix-ups. The issue of drug names being confused with dietary supplements is one that bears consideration by FDA's Center for Food Safety and Applied Nutrition (CFSAN), which regulates food supplements so situations like this can be avoided.

Clotrimazole Topical Solution. We received a report that clotrimazole 1% topical solution was administered into a patient's eye in error.



Figure 1. Bottle of clotrimazole 1% topical solution mistaken as an eye drops bottle.

Clotrimazole is available as a cream and topical solution for the topical treatment of candidiasis due to *Candida Albicans* and tinea versicolor due to *Malassezia furfur*. The topical solution is available in what looks like a typical ophthalmic dropper squeeze bottle (**Figure 1**). The outer carton and immediate container labels contain warnings that the product is for topical use only. However, in this case, these warnings were missed, or "topical" may have been misunderstood as including the eye. We have communicated with the US Food and Drug Administration (FDA) about the packaging. The use of special auxiliary warning labels on the product bottle and warnings in the medication administration record (MAR) indicating the proper route of administration of these types of products can help avoid such errors.

Updated list of confused drug names. An updated list of confused drug names was recently added to the ISMP website at: www.ismp.org/sc?id=515. **FARXIGA** (dapagliflozin) and **FETZIMA** (levomilnacipran), discussed in last month's issue, are on this list. You may purchase a full color wallchart from our online store at: www.ismp.org/sc?id=544. Our hope is that you will review this list and consider which drugs require special safeguards at your practice site.

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person checking the work of someone who outranks them may not ask questions; a reduction of responsibility or overreliance on double checking in which staff believe someone else will catch any mistakes; social interactions that can lead to unrelated conversations that interfere with the checking process; and lack of time.¹¹

What is often missing in the double-check process is a “sterile cockpit” environment without extraneous conversation, which would lead to a more cognitive review of all components of the medication, beyond verification of the “5 rights,” that requires purposeful thought. Is the drug and dose appropriate for this resident? Does the drug’s indication match the resident’s diagnosis or condition? Is the route of administration correct? These questions and more need to be answered independently by the initial clinician preparing the selected medication and the second clinician who is independently double checking the medication. See **Table 2**, on page 3, for other items to consider when conducting an independent double check. Without a cognitive review of the prescribed medication during a double-check process, errors—particularly prescribing errors that may be overlooked if simply matching the drug order with the product—may not be detected and corrected before reaching the resident.

Standardize the process and tools

To reduce process inconsistencies, establish a standard process for carrying out an independent double check, and educate staff about its importance and how to carry it out properly—as an independent cognitive task and not a superficial routine task. Make it easy for practitioners to follow the independent double-check process without relying on vigilance and memory.¹⁶ For example, add a checklist as a reminder of the components of the process or medication that should be checked and when it should be checked. The questions in **Table 2**, on page 3, can be used as a broad template to start an intuitive checklist. However, checklists that include very specific items associated with critical information, rather than more general topics, significantly improve their effectiveness.¹⁰ For example, a checklist that instructs users to check the medication label against the original order is not as effective as a checklist that specifies the exact elements to check on the label and the drug order.¹⁰ However, design the checklist with care so that the detail does not replace the need for the practitioner to think critically about each aspect of the double-check process. As appropriate, redesign order forms to facilitate crosschecking of information, and make sure the sequence of information on checklists uses the same terminology and follows the logical progression of typical workflow.

Conclusion

In most organizations, a review of the most recent medication errors will likely uncover some aspect of an ineffective double-check process. Take the time to evaluate the procedures for which you require a double check, educate staff how to carry it out properly, monitor compliance, assess how often the checks are conducted as designed, and then make the necessary revisions to promote effectiveness. When employed judiciously, conducted properly, and bundled with other strategies, manual independent double checks can be part of a valuable defense to prevent potentially harmful errors from reaching residents.

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