

Patient Safety Tip of the Week

April 19, 2016

Independent Double Checks and Oral Chemotherapy

Our May 5, 2015 Patient Safety Tip of the Week “[Errors with Oral Oncology Drugs](#)” pointed out that, with the recent proliferation of oral chemotherapy agents, we are beginning to see more and more patient safety issues arising from their use. One facet we only briefly touched upon in that column was the use of independent double checks.

One of our most frequently accessed columns is our October 16, 2012 Patient Safety Tip of the Week “[What is the Evidence on Double Checks?](#)”. Usually when we are talking about independent double checks we are referring to such checks being done at the same stage of the medication continuum (eg. during ordering or during preparation). But medication safety also includes another type of independent double check at several levels. For example, in a hospital medications ordered by a physician or other prescriber are typically checked by a pharmacist and nurse at different times. In our November 3, 2015 Patient Safety Tip of the Week “[Medication Errors in the OR – Part 2](#)” we noted one of the reasons for more medication errors in the OR is that the anesthetist is often the one choosing a medication, preparing it, and administering it, thereby lacking those independent checks that might occur elsewhere.

While we’ve pointed out the limitations of double checks in several columns, we still recommend independent double checks for high alert drugs. In the hospital, chemotherapy agents are high alert drugs that get such attention. But what happens outside the hospital? Particularly as more and more oral chemotherapy agents are being developed and used, do they get the same degree of scrutiny that is typically done for IV chemotherapy agents? A new study ([Griffin 2015](#)) suggests no. Griffin and colleagues in Canada compared the performance of independent double checks for oral vs. intravenous chemotherapy and found striking differences. Using direct observation by two human factors experts and semi-structured interviews they found 57 systematic checks for IV chemotherapy compared to only 6 for oral chemotherapy. Systematic checks required the check be done clearly as a part of a qualified healthcare provider’s (HCP) role, be done consistently, and be done with all the information necessary to inform such a check. They defined “partial” checks if one of those elements was missing. Even when they included “partial” checks, the results were 64 checks for IV chemotherapy vs. only 17 for oral chemotherapy.

For IV chemotherapy there were checks at multiple levels (planning, ordering, and dispensing). So for IV chemotherapy there were several opportunities for a qualified HCP

to identify and mitigate an unintentional error before it reached the patient. Not so for oral chemotherapy. Often the only qualified HCP with an opportunity to intercept an error was the community pharmacist and these were in the ordering and dispensing phases only. And those community pharmacists were often lacking critical information. They often did not even have access to critical information such as the type of cancer the patient had.

Though this was a Canadian study, the authors cite studies from the US ([Weingart 2007](#)) that showed few of the safeguards routinely used for infusion chemotherapy have been adopted for oral chemotherapy at US cancer centers and lack of consensus at these centers about safe medication practices for oral chemotherapy.

In our May 5, 2015 Patient Safety Tip of the Week “[Errors with Oral Oncology Drugs](#)” we discussed an analysis of incidents involving oral chemotherapy agents in Canada ([ISMP Canada 2015](#)). They analyzed 516 incidents over a 12 year period and while patient harm or death occurred in only a small minority of cases there were multiple lessons learned. They were able to identify **3 major themes**: (1) lack of specialized knowledge by care providers (2) medication name mix-ups and (3) lack of safe medication handling processes. Under the first theme ISMP Canada noted that chemotherapy regimens can be very complex and that community pharmacists may not have a good understanding of chemotherapy cycles, side-effect profiles, etc. The same applies to many other non-oncologist healthcare professionals. As a result, patient education on these complex issues may be insufficient. The example they provide is a patient who was on a protocol-defined capecitabine cyclical dosing regimen who was mistakenly given capecitabine daily when admitted as an inpatient and then the prescription given the patient at discharge also erroneously called for daily capecitabine. You may recognize this problem of prescribing a drug daily rather than on a different regimen because we’ve written about very similar problems with methotrexate in the past (see our What’s New in the Patient Safety World columns for July 2010 “[Methotrexate Overdose Due to Prescribing Error](#)” and July 2011 “[More Problems with Methotrexate](#)” and February 2016 “[Avoiding Methotrexate Errors](#)”).

As a subtheme of the “lack of specialized knowledge” they mention that failure to include some critical information on the prescriptions may contribute. Such information might include diagnosis, patient height and weight, duration of the chemotherapy cycle, etc.

We also cited a classic article on medication errors related to oral chemotherapy ([Weingart 2010](#)). Weingart and colleagues warned that the use of oral chemotherapy was expanding and that few of the safeguards that apply to prescribing, dispensing and administering IV chemotherapy have been applied to oral chemotherapy. They identified issues with oral chemotherapy from a variety of sources. They identified over 500 such errors, including 99 actual adverse drug events. While many of the remaining events were near-misses they did provide the opportunity for patient harm and thus were helpful in identifying potential vulnerabilities. Importantly, they identified that over half the errors (55.9%) were intercepted, preventing actual patient harm. Of those intercepted, this was most often by a pharmacist (69.5%), followed by patient or family (10.2%) or nurse

(6.9%). Wrong dose errors were most frequent but wrong drug and missed dose errors also occurred. But one particularly salient problem was **supplying the wrong number of days**. Whereas the majority of errors involving wrong dose, wrong drug, or missed dose resulted in near misses, 39.3% of errors involving wrong number of days supplied resulted in adverse drug events. We went on in that column to discuss several other instances of pharmacies supplying the wrong number of days or doses for oral chemotherapy.

So now that we've identified lack of double checks as a vulnerability for oral chemotherapy, how do we address it? One is to ensure that a pharmacist with access to all critical clinical information and a thorough understanding of both the particular cancer and the chemotherapy regimen is involved as a potential double checker. Unfortunately, this may mean that some community pharmacists and mail order pharmacies are not the most appropriate for patients on oral chemotherapy regimens. Anyone who has picked up a prescription at a community pharmacy will recognize how busy the pharmacist is, further increasing the vulnerability to errors. And very often there is only a single pharmacist working. So there is no opportunity for a double check. The only barrier left to intercept the error is the patient him/herself (or their family/caregiver). So one consideration would be to ensure that prescriptions for oral chemotherapy are only dispensed in certain pharmacies that meet all the safety requirements. Such pharmacies would most likely hospital- or clinic-based but some community pharmacies would be eligible if they met those criteria. That may also require various payors to ensure that such special pharmacies are included in their networks. Since the criteria should include not only ability to perform double checks but also have full access to relevant clinical information, knowledge about the various chemotherapy regimens, and ability to sit down with the patient to thoroughly go over the instructions, we doubt that mail order pharmacies would meet the criteria.

Secondly, recognizing that complex regimens and cycles are the most vulnerable to errors involving wrong number of day supplies, we need to look at how we prescribe. We are always balancing patient convenience against patient safety. In several of our previous columns on home infusion chemotherapy we noted no one seemed to be asking "what is the highest dose that a patient could tolerate in one day (or less) if there was inadvertent administration of the infusion?". A safety culture would design the protocol with sublethal dosages that would protect the patient in the event of "what can go wrong will go wrong". It also would not put the healthcare workers at the "sharp end" in a situation none of us would want to be in. The same question should apply to oral chemotherapy regimens and be "What would be the highest aggregate dose a patient could tolerate over a specified period?" and avoid prescribing more than that inadvertently. Yes, the patient might be inconvenienced by having to do another physician or clinic visit to get a prescription for the next cycle or the second part of a complex regimen. But isn't that preferable to receiving a chemotherapy overdose due to an avoidable error?

Our prior columns related to chemotherapy safety:

- September 11, 2007 “[Root Cause Analysis of Chemotherapy Overdose](#)”
- April 2010 “[Medication Incidents Related to Cancer Chemotherapy](#)”
- April 6, 2010 “[Cancer Chemotherapy Accidents](#)”
- July 2010 “[Methotrexate Overdose Due to Prescribing Error](#)”
- July 2011 “[More Problems with Methotrexate](#)”
- May 7, 2013 “[Drug Errors in the Home](#)”
- May 5, 2015 “[Errors with Oral Oncology Drugs](#)”
- September 15, 2015 “[Another Possible Good Use of a Checklist](#)”
- February 2016 “[Avoiding Methotrexate Errors](#)”

References:

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