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Start using a checklist, PRONTO: Recommendation for a standard review process for chemotherapy orders

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Abstract

Chemotherapy order review by pharmacists requires careful attention to many details, and serious consequences can occur if errors are made. Other high-risk industries have long used checklists to improve accuracy and reduce the risk of errors. Despite the recent expansion of checklist use in other areas of medicine, there is currently no published evidence that checklists are being widely used by pharmacists in the evaluation of chemotherapy orders. This article explains a flexible checklist called PRONTO (Patient, Regimen, Organ Function, Numbers, Toxicity, Order Verification) that has been successfully used by pharmacists in variety of practice settings in two academic centers in North Carolina. Proposed benefits of using a checklist in order review include standardization of review for better communication between collaborating pharmacists, a training tool for new or cross-training pharmacists, and an educational tool for students.

Keywords

Checklist, chemotherapy orders, order evaluation, standardized process

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Introduction

Employers in high-risk industries rely on checklists to reduce the risk of errors.[1,2] For example, the aviation industry has used checklists since the 1930s when a group of test pilots created one to reverse the poor safety record of the B-17 bomber.[2] In a similar way, the process of chemotherapy verification by pharmacists requires expertise and attention to detail to avoid errors with potentially dangerous consequences. Even with recent advances in computerized-physician order entry (CPOE), the process of reviewing chemotherapy orders requires attention to detail and a complex sequence with multiple levels of evaluation. While CPOE reduces the risk of medication errors overall, it can create a false sense of security that leads to new types of errors.[3] Since the 1990s, oncology pharmacy leaders have articulated the need for checklists covering operational pharmacy processes; however, there is no published evidence that checklists are currently being widely used by pharmacists in the evaluation of chemotherapy orders.[4]

The American Society of Health-System Pharmacists (ASHP) has referred to order evaluation as "checkpoint 2" in a process of nine safety checks covering the chemotherapy use process.[5] ASHP and other groups of experts have published recommendations of items that pharmacists should review at this checkpoint to reduce the risk of medication errors and have suggested that a systematic process or checklist be utilized.[4,6,7] The American Society of Clinical Oncology and Oncology Nursing Society (ASCO/ONS) guidelines provide safety standards for

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chemotherapy orders but do not provide specifics about pharmacist order evaluation.[8]

Interest in the use of checklists in medicine has continued to increase and reported outcomes have been universally positive.[9] In one example, a Surgical Safety Checklist developed by the World Health Organization cut the rate of death to almost half (1.5% to 0.8% after the checklist).[10] Within oncology, checklists have been developed to improve safety in the dispensing and administration of chemotherapy.[11,12] Checklists have been published for use by pharmacists in checking compounded chemotherapy products.[4,13] However, few publications exist that address pharmacists using a systematic method to evaluate chemotherapy orders.

The use of checklists in paper-based chemotherapy orders has been alluded to, but only one systematic approach resembling a checklist has been published.[6,14] This approach, called anDROIDs, guides review and documentation of paper-based chemotherapy orders. The anDROIDs tool provides a step-wise approach with additional detail on patient data and labs that are important for a pharmacist to review.[14] However, it did not include a checklist and suggests documentation that may no longer be applicable to those using electronic medical records (EMRs).

PRONTO: A checklist

In the sections that follow, we describe a six-step checklist using the acronym of Patient, Regimen, Organ Function, Numbers, Toxicity, Order Verification (PRONTO) that was developed to assist in the review of chemotherapy orders (Figure 1). Each step was intended to flow in a logical sequential order and be checked off when completed. Currently, the PRONTO system is used and taught by oncology pharmacists at two academic medical centers in North Carolina. Initially used to check paper inpatient chemotherapy orders, the PRONTO system has since been proven useful for electronic chemotherapy orders in both the inpatient and outpatient setting. Since 2005, the PRONTO system has also been used as a clinical education tool for pharmacy students, oncology residents, and new cross-covering pharmacists. It has also been incorporated into a pharmacy school lecture on preventing medication errors in oncology.

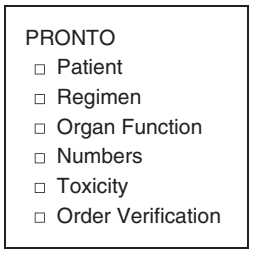

Figure 1. Summary of the checklist for the PRONTO system.

Patient

The first step in PRONTO is to gain an overview of the patient, their malignancy, and treatment goals. This information provides context for all of the steps that follow and confirms that the orders at hand are for the right patient. Once the cancer type is identified, the pharmacist should look for signs that the right patient is being treated. Do the patient's progress notes list the current treatment in the plan? Is this a returning patient with a history of the same treatment plan? Does the selected treatment plan make sense for the malignancy? If applicable, has an "ok to treat" order been released for the patient? Depending on the setting, these questions can be evaluated by review of the EMR and/or an interview with the patient. Additionally, a pharmacist can evaluate treatment intent or the patient's current performance status. These factors, along with age and laboratory data, are helpful in later steps to verify the dose.

Regimen

The second step in PRONTO verifies that the chemotherapy regimen prescribed matches a published regimen, and that, as published, the regimen applies to the specific patient. A pharmacist's familiarity with a regimen affects the amount of time that will be spent on this step. Oncology pharmacy experts recommend that "if the regimen is unfamiliar, the pharmacist should verify the dose by reviewing at least two independent literature sources." [4] See Table 1 for a list of questions that can be applied to the prescribed regimen.

If there is no exact reference for the prescribed treatment regimen, the pharmacist's primary responsibility is to determine whether a regimen is safe. Is there a reference supporting the regimen's use in a related or different cancer? Has that drug or combination of drugs been studied before at similar doses? Is there an

Table 1. Evaluating chemotherapy regimen details.

1. Do you have a reference that supports the patient's regimen?
2. Is the patient due for chemotherapy based on their cycle and day?
3. Are any chemotherapy drugs being held in the regimen?
4. Do the patient's current doses match the reference?
5. Have doses been reduced for toxicity or titrated upward?
6. Is the sequencing of the chemotherapy appropriate? [15]

abstract or study protocol that supports the regimen dosing? Increased screening for biomarkers has also led to the addition of targeted drugs, such as trastuzumab, to traditional regimens for biomarker positive patients. Ideally such additions would be done in the context of a clinical trial, but pharmacists may have to evaluate whether such extrapolations are safe for an individual patient. If a pharmacist decides to validate a regimen without an exact reference, it is prudent to prescreen insurance and then document in the EMR the rationale behind the regimen, any discussions with the oncology team, and any references from which the regimen is extrapolated.

Organ function and labs

Once the patient's regimen has been validated, the next step is to evaluate whether the patient's organ function and labs warrant full dose treatment. Additionally, blood counts myelosuppressed by chemotherapy in returning patients must show adequate recovery from the last cycle of treatment to proceed with another. Hold criteria or treatment conditions included as part of chemotherapy orders serve as a starting point for evaluation of labs. If these are not available, or questions persist for individual drugs, tertiary references, or package inserts, can be a good first source for recommended dosage adjustments and monitoring. These recommendations still require clinical judgment, as many are developed retrospectively based on a small number of patients who may not have received modern supportive care.[16] Prescribing information also often contains recommendations on when to withhold chemotherapy and how to adjust chemotherapy dosing based on organ dysfunction or labs parameters.

Evaluating renal function. To prevent drug overexposure and increased risk of renal toxicity, it is important for pharmacists to monitor estimated glomerular filtration rate (GFR) during treatment. Monitoring serum creatinine alone is unreliable in cancer patients as it does not factor in age and decreased muscle mass.[17] GFR is most commonly estimated for medications using the Cockcroft–Gault formula. However, formulas relying on serum creatinine levels may not accurately predict GFR in patients with advanced age, obesity, edema, cachexia, low body mass index, or severe renal dysfunction.[18,19] A 24-h urine collection may be warranted in these situations. The practice of rounding serum creatinine to a minimum of 0.8 or 1, to avoid overestimating a patient's clearance, has been found to yield inaccurate estimates of GFR.[20]

If a patient's creatinine clearance is worsening over time, a pharmacist must first determine if adjusting or holding the chemotherapy dose is warranted. Second, a pharmacist should review the patient's profile for alternate causes of the renal dysfunction and medications that are cleared renally. Supportive medications such as NSAID analgesics, antibiotics, diuretics, calcineurin inhibitors, and bisphosphonates can contribute to nephrotoxicity.[19,21] Finally, an evaluation of potential reversibility of the worsening creatinine clearance is helpful in developing a plan. The patient may have multiple risk factors for nephrotoxicity besides chemotherapy, such as age, dehydration, metabolic disturbances, tumor-lysis syndrome, comorbid conditions, and the cancer itself.[19,22]

Evaluating liver function. Patients with liver dysfunction also present challenges with respect to drug dosing and choice. Unlike renal function, there is no accepted formula for estimating hepatic function. A rise in liver function tests (LFTs) can have many causes (e.g. hemolysis, infection, alcohol use, bone disease, Gilbert's syndrome) and may only reveal past damage to the liver as opposed to intrinsic function. LFT trends may be more useful to monitor potential toxicity. Additionally, if a patient's liver has tumor involvement; providers may opt to go against traditional dosing recommendations on the theory that treatment may improve liver function data.

Pharmacogenomics (PGx) can assist with prediction of liver clearance and toxicity of certain chemotherapeutic agents with validated testing options available. Examples of genes that predict metabolism of chemotherapy include UGT1A1 (irinotecan), dihydropyrimidine dehydrogenase (DPD—capecitabine/5-flurouracil), and TPMT (6-mercaptopurine).[23–25] Increasingly, the Food and Drug Administration (FDA) also approves PGx companion tests to help determine who would benefit from molecular targeted drugs such as KRAS tests approved for use with cetuximab and panitumumab.[26] In other cases, more data are needed to resolve conflicting data on how to interpret the presence of polymorphisms that effect drug metabolism (e.g. CYP2D6 and tamoxifen).[27] Currently, the use of PGx is limited by cost, limited laboratories performing the tests, and studies to validate the results on clinical decision-making.[28]

Pharmacists must also rule out concomitant medications that can cause hepatotoxicity. The mechanism of renal and hepatic toxicity with anti-cancer agents is beyond the scope of this article, but several reviews cover this topic in depth.[18,28–33]

Additional organ and lab monitoring. While renal and hepatic functioning are most broadly assessed, depending on the patient and regimen pharmacists may need to evaluate additional organ systems and labs prior to approving treatment. This may include examining

cardiac (e.g. anthracyclines, trastuzumab, carfilzomib), lung (e.g. bleomycin, methotrexate), or cerebellar (e.g. high-dose cytarabine) functioning. Additionally, lab results are helpful to identify signs of electrolyte wasting and for any urinalysis results that may be required (e.g. proteinuria with VEGF agents, high-dose methotrexate, etc.). Finally, an evaluation of fluid status may be necessary for certain chemotherapies that have the potential to ''third space'' to areas of fluid collection such as effusions (e.g. high-dose methotrexate).

The most common treatment conditions on chemotherapy orders involve minimum values for platelets and neutrophils. A complete blood count with differential reveals whether bone marrow recovery is adequate for retreatment where applicable. The pharmacist must pay attention to the timing of any labs used in the evaluation. A retrospective trial suggested that labs within seven days of treatment are accurate in the majority of cases.[29] If labs are outside the stated treatment conditions or recent labs are not available, the provider should be contacted. While we have provided some highlights of laboratory monitoring, the interested reader can find a more thorough treatment of the topic in a previously published review.[30]

Numbers

Dose calculations. Once it has been established that the orders are for the right patient, they are being treated with the right regimen, and they meet treatment conditions, it is the time to verify the math behind a chemotherapy order. The advent of electronic prescribing lessens the need for manual calculations, but does not eliminate it. If an EMR is being utilized, doses, body surface areas (BSAs), creatinine clearances, and even carboplatin dosages may be calculated automatically. However, before relying on these numbers, pharmacists need to understand what formulas their system uses and where to find additional detail about a calculated dose if questions arise.

Pharmacists should verify that the patient height and weight used are recent and consistent with previous values. Is the correct weight being used for calculations? In obese patients, experts have recommended using actual body weights to avoid underdosing.[31]

Pharmacists should be familiar with institution rules about dose rounding. One drug-specific rule for dose rounding is with carboplatin, where the FDA has recommended that creatinine clearances should be capped at 125 ml/min to avoid overdosage in patients with artificially high clearances.[32] The Hematology/Oncology Pharmacy Association has also published a position statement supporting dose rounding protocols that allow rounding doses of biologic/cytotoxic anticancer agents within 5–10% of the prescribed dose.[33]

Dose Tracking. Chemotherapy dose trends reveal important details for the reviewing pharmacist. The patient's previous dose can serve as another check of the current dose. The overall trend of past treatments can indicate whether doses are being tolerated and how often delays in therapy have occurred. Any change in weight should be noted, as dramatic weight changes can occur during treatment, though many practitioners only recalculate chemotherapy dosages if a patient's actual body weight changes by more than 10% from baseline.[34]

Cumulative dose tracking is critical for anthracyclines, mitoxantrone, and bleomycin to minimize organ toxicity. Many EMRs now include cumulative dose tracking features. However, both electronic and paper systems struggle to account for chemotherapy doses given at outside facilities or before an EMR was implemented. Careful examination of a patient's past treatment history is critical to fill these gaps. Interviewing the patient or contacting the patient's previous treatment center may help establish an accurate history of the number of previous doses received.

Admixture and administration numbers. The ''N'' step also involves evaluating the compounded product and administration details. Drug concentrations should be verified for both stability reasons (e.g. etoposide) and to avoid affecting expiration times (e.g. daratumumab). Pharmacists should also review proposed rates of infusion and the route of administration to make sure they match supporting references. There are also administration details to consider. Are there any compatibility issues with either the proposed route of administration, base fluid, or mixing of ingredients? Is the choice of fluid appropriate for the drug and patient? Is the infusion time clear and does it make sense with the amount of fluid the patient is getting? If syringes are involved, does the dose require multiple syringes for either the route of administration or to prevent extravasation? Many institutions have standards for the maximum volume of an extravasant that can be placed in a syringe (e.g. 80% full). As treatment protocols become more advanced, the need to adjust fluids to achieve dosing concentration ranges should diminish. An increasing number of rules in EMR's are able to adjust the bag size and infusion time depending on the dose.

Beyond the math. Chemotherapy dosing appears black and white in tertiary references; however, certain elements of chemotherapy dosing remain an art. BSA dosing is imperfect.[17] Published doses may be less tolerated in different patient populations (e.g. cetuxmab in TN/NC,[35] more toxicity with capecitabine in the United States[36]). Dosages require reevaluation each cycle and a patient's tolerance, performance status,

Table 2. Examples of supportive therapies to counteract expected toxicities.

Antidiarrheals
Antiemetics[38,39]
Chemotherapy protectants[40]
Corticosteroids to prevent fluid retention[41,42]
Fluids to prevent nephrotoxicity
Growth factors[43]
GVHD prophylaxis
Infection prophylaxis[44–46]
Leucovorin rescue
MESNA
Premedications to prevent hypersensitivity reactions[47]
Tumor lysis prevention[48–50]
Urine alkalization with sodium bicarbonate (e.g. high-dose methotrexate)

and treatment goals must all be weighed. Because patient details have already been reviewed, the pharmacist will know whether this is a curable patient and what their performance status is. If the patient is incurable, dosing should reflect a more conservative approach aimed at palliative care and toxicity avoidance.

Toxicities

This step reconciles a prescribed supportive care regimen with the expected toxicities of a regimen. Oncology pharmacists can identify common toxicities of individual chemotherapy drugs. Therefore, it makes sense for pharmacists to work backwards from toxicities and to ensure the patient has medication(s) to prevent, support, or treat those common toxicities. See Table 2 for supportive therapies that should be considered in this step. For example, any regimens that carry a greater than 20% risk of febrile neutropenia should have colony-stimulating factors (CSFs) built into them according to ASCO guidelines (e.g. aggressive lymphoma patients over age 65).[37] The risk of tumor lysis syndrome should also be assessed for at-risk cancers. If tumor lysis risk is high, additional monitoring and additional prophylactic measures (e.g., fluids, allopurinol, rasburicase) should be considered.

Chemotherapy ordersets and standard ordersheets frequently include supportive care medications, but there are reasons to do an independent evaluation of accompanying orders. First, providers may opt to add or subtract medications from the standard supportive meds. Second, if the standard chemotherapy regimen has been modified, the associated supportive meds may no longer apply. Third, if a patient has experienced toxicity in a previous cycle, supportive care may need to intensified to the patient's needs. This could include adding a more aggressive antiemetic regimen or adding a CSF in a patient that was admitted for febrile neutropenia. Pharmacists should also use this toxicity step to assess the patient's profile for the patient allergies and risk of drug interactions with traditional, over-the-counter, and complementary or alternative medicines.

Order verification

Order verification consists of two final safety checks.

Independent double-check. Guidelines recommend that a chemotherapy order process includes as many ''independent'' checks as possible during and prior to administration.[4,5] However, the guidelines do not specify exactly how orders should be double-checked or whether all cycles must be double-checked. Many institutions have implemented double-checks on all first cycles, but allow single pharmacist checks on future cycles if no changes to the first cycle order have occurred. If using an EMR, ideally it should be set up to not allow label printing until an alert pops up reminding that the order may require an independent double check. The second pharmacist performing a double check should review the first five steps—''PRONT''—to verify dosing, labs, numbers, and dispensing details.

Chemotherapy labels and staff communication. The last step in the review of chemotherapy orders is to check the chemotherapy label dispensed with the product. Are any notes needed on the production or compounding labels to improve clarity for nursing or the IV room pharmacy staff? Should certain labels be prioritized for compounding to avoid delays to the patient? And, finally, once the label comes out, did it print as intended?

Discussion

The PRONTO system is an easy-to-remember acronym that provides basic framework for reviewing oncology orders. The mnemonic can apply to various settings (inpatient, outpatient, paper, EMR). In addition, the PRONTO system can serve as a teaching tool; both in practice, on rotation, or in the classroom. The system can serve as a ready lesson on a standardized process that an oncology pharmacist uses when evaluating an order. It gives students, residents, and cross-covering hospital pharmacists a place to start with validating chemotherapy orders.

While the PRONTO system provides a checklist to ensure steps are not skipped, the implementation of such a checklist into current pharmacy practice may face barriers. Pharmacists may need to be convinced that they need them. Oncology pharmacists are highly

trained individuals who grow increasingly familiar with many details about a large number of regimens. As such, a seasoned oncology pharmacist may believe that his/her knowledge and experience would not be enhanced by use of a checklist. When hospital pharmacists in Canada were surveyed about potential use of a checklist for medication order review, they felt that a checklist was most useful as a training tool that could be employed on an ''as needed'' basis if a pharmacist was unfamiliar with a medication.[51] A checklist's purpose is not to replace the need for the clinical experience of a pharmacist on any unique patient, but a standardized checklist helps ensure that all components of a necessary process are followed every time. Additionally, the very fact that many chemotherapy orders are routine and familiar sets up the potential for errors. A similar situation is at work in the aviation industry, where well-trained professionals who perform routine high-stakes tasks are aided by checklists to prevent a disastrous error. While it may be challenging to convince longtime oncology pharmacists to adopt the PRONTO system, it is our experience that it remains useful, as pharmacists who have been trained with it as students and residents continue to use it many years into their practice.

Additionally, any checklist that is widely adopted must not significantly increase the amount of review time for a pharmacist. In the Canadian study of pharmacists using a checklist for medication review, a focus group expressed concerns over the amount of additional time required.[51] The PRONTO system is a relatively short checklist, providing a logical framework for the process of evaluating an order, while remaining loose enough to allow for flexibility. In fact, the PRONTO system is easily expandable and customizable for those who want a more involved checklist (e.g. see Table 3). One pharmacist not involved in final verification of chemotherapy order labels customized the last step to ''outpatient follow-up'' to facilitate transitions of care and communication with clinic pharmacists.

The evaluation steps in PRONTO flow in a sequence that can match workflow well. Even if the chemotherapy orders are on paper, finding the details to check an order often require access to EMR. The linear nature of a checklist like PRONTO helps keep chemotherapy reviews consistent amongst multiple pharmacists. Additionally, there are ways the PRONTO system can save time without compromising quality. If interruptions occur, the pharmacist can come back to the next step with confidence what has already been completed. If a patient schedule is known in advance, the first evaluation steps of ''patient'' and ''regimen'' can be done the day ahead of treatment, preparing the pharmacist to review the order more quickly when

Table 3. Expanded PRONTO checklist.

Patient
Does the patient's diagnosis match the protocol treatment?
Yes □ No □
Does patient have a performance status of 2 or higher?
Yes □ No □
Is the treatment intent curative?
Yes □ No □

Regimen
Are one or more supporting references documented?
Yes □ No □
Is it too early for treatment based on frequency?
Yes □ No □
Confirm the following match reference(s):
□ Frequency and days of therapy
□ Dosing
□ Route
□ Chemotherapy sequence
Are any abbreviations or brand names used in the order?
Yes □ No □

Organ Function / Labs
Confirm the following are within normal treatment parameters?
□ liver / renal function
□ platelets, absolute neutrophil count
□ urinalysis or additional hold parameters
Does liver and renal function require any dosing adjustments?
Yes □ No □
Do other organ systems need evaluation to start (e.g. cardiac function)?
Yes □ No □
If deviations from hold criteria: Is a discussion with a physician documented?
Yes □ No □

Numbers
Confirm the following are correct:
□ Patient's weight is within 10% of dosing weight
□ Calculated dosages (e.g. Calvert equation)
□ Time and rate of administration
□ Drug concentration and fluids
Are IV compatibility issues present?
Yes □ No □

Toxicity Support
Rule out the following:
□ Drug interactions
□ Drug allergies
Does the patient's require prophylaxis for:
Acute and delayed nausea? Yes □ No □
Hypersensitivity reactions? Yes □ No □
≥20% risk of febrile neutropenia? Yes □ No □
Tumor lysis prophylaxis? Yes □ No □
Other common toxicities? Yes □ No □

Order Entry
Is an independent double-check required?
Yes □ No □
Are notes to nursing or pharmacy staff needed?
Yes □ No □

the patient arrives. If labs become available, organ function can be assessed before providers or nurses officially release the treatment orders.

The benefits of checklists in error prevention are well documented, and the chemotherapy review process is generally unstandardized. While use of the PRONTO system has been found feasible in our practice, additional studies are needed to conclusively validate the benefits of checklist use by oncology pharmacists in general, and the PRONTO tool in particular. Future studies could focus on whether the use of checklists impact turnaround times or error rates by new practitioners. However, it is our hope that a standardized chemotherapy order review checklist, like PRONTO, will someday be incorporated into EMR's. PRONTO is a comprehensive, flexible system. It is simple enough to teach to the pharmacist who is just beginning to learn chemotherapy review, and useful enough that seasoned oncology pharmacists continue to use it, adapted for their own practice settings, years into their careers.

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