



Cancer Care Ontario

# Best Practice Recommendations for Regimen Development and Maintenance

*For Systemic Treatment Computerized Prescriber Order Entry Systems and Pre-Printed Orders*

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## Acknowledgment

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## Best Practice Recommendations for Regimen Development and Maintenance

Systems-based safeguards are essential to prevent medication errors in prescribing. This is especially important with chemotherapy, where small prescribing errors can have a significant effect on patient outcomes. Commonly used safeguards include systemic treatment computerized prescriber order entry (ST CPOE) systems and pre-printed orders (PPO), as handwritten prescriptions are more prone to error and often do not provide essential supporting information.<sup>1</sup> Aside from their benefits towards patient safety, standardized orders also help to promote evidence-based prescribing and allow for data to be captured for research and quality improvement initiatives.<sup>2</sup> However, for CPOE systems and pre-printed orders to be effective, careful consideration must be given to both design and revision of standardized regimens.

### Evidence Review

While the essential components of CPOE systems and PPOs are clearly documented in the literature, best practice processes for regimen development and maintenance are not nearly as well-described. No oncology-specific best practice guidelines regarding the processes of development and maintenance were found in the literature. Although, two “case reports” of electronic chemotherapy order development were found where the authors acknowledged that standardized processes (e.g. frequency for formal review of regimens) are not yet established.<sup>7,8</sup> James Nolin, the editor-in-chief of Elsevier’s InOrder, an electronic order management system, has published several articles on order set management.<sup>3-5</sup> Nolin describes the process of building a central order set committee, chaired by a physician lead and consisting of representatives from clinical informatics, nursing, pharmacy and senior management.

In regards to order set maintenance, Nolin states that “while the majority of healthcare organizations review all order sets every one to three years, there will be a need to re-evaluate order sets in response to changes in medical knowledge, regulations or guidelines.”<sup>3</sup> For example, it would be prudent to review and update filgrastim/pegfilgrastim (Neupogen/Neulasta) standard order sets to integrate new recommendations from the July 2015 ASCO granulocyte-colony stimulating factor (G-CSF) guideline update.<sup>6</sup>

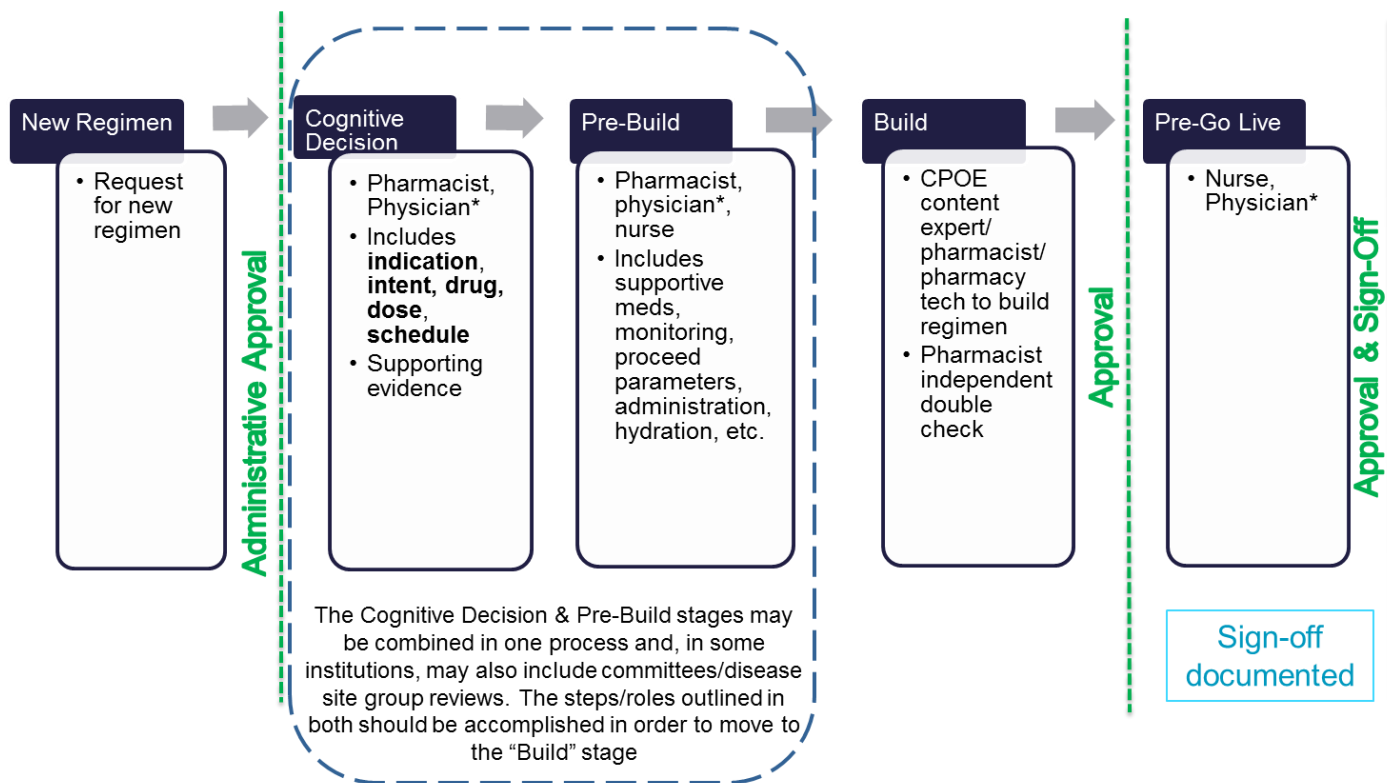
### Recommendations

Ontario is at the forefront of CPOE and PPO development in Canada and although it is challenging to create guidelines without substantial support from the literature, careful analysis and application of the expertise and experiences of cancer care professionals will allow for the advancement of standardized chemotherapy prescribing. A group of experts from varying disciplines (pharmacists, medical oncologist, administration/nursing) and using different CPOE systems/PPOs were recruited to develop consensus-based recommendations on the development and maintenance of oncology regimens. Both intravenous and oral cancer medications are considered in scope, as well as clinical trial regimens for cancer.

### New Regimens

Requests for new regimens should follow a detailed process with the involvement of the multidisciplinary team (medical oncologist/hematologist, pharmacist, nursing). The following steps outline the minimum recommended steps and roles involved. Figure 1 provides a graphical representation of this process. Note that while the terminology may be more relevant to ST CPOE systems, they are applicable to PPOs as well.

**Figure 1: New Regimen Development Process**



\*For the purposes of the graphic, physician refers to either a medical oncologist/hematologist

### New Regimen

The process is initiated with a request for a new regimen. Before the request can proceed, there is an administrative check that should occur to ensure that this regimen can be added from an operational perspective. For example, if the new regimen calls for an 8-hour infusion, this could require extended clinic hours. An authority with administrative decision-making abilities should 'approve' this regimen to proceed into the development process before the next phase is entered.

### Cognitive Decision + Pre-Build

The order of the next steps may vary depending on processes and resource structure at individual facilities. It is important that the listed members of the multidisciplinary team are involved and that the steps are achieved before proceeding to the Build phase. However, the order in which each happens is at the discretion of the facility.

The Cognitive Decision is reached when a pharmacist and medical oncologist/hematologist (at minimum) review the indication, intent (disease site and whether adjuvant/curative or palliative), drugs and doses of the drugs as

well as schedule and frequency of the regimen, with the supporting evidence and agree that the regimen should proceed. The level of evidence (i.e. phase 3 studies) is at the discretion of the clinical team. However, if the regimen is different than the source of information provided, a rationale for that variation should be provided and documented. Provincial resources (ex. CCO Drug Formulary) can be used as references.

The Pre-Build phase will provide additional details about the regimen. Any supportive medications, monitoring requirements and proceed parameters, diluents, rates, administration instructions including programming of infusion pumps, hydration, guidance for dose modifications and other preparation instructions will be included for review. In addition to the pharmacist and medical oncologist/hematologist, a nurse should also review this information prior to proceeding to Build. A clinical trials coordinator should also review regimens used as part of a study.

Many institutions have committees (Pharmacy and Therapeutics, Systemic Therapy, Quality, etc.), or established Disease Site groups. Although it is not within the scope of this paper to define the level and type of committee, it is recommended that facilities institute a review via a multidisciplinary committee, where possible.

### **Build**

Once appropriate details have been determined in the Cognitive Decision and Pre-Build phase, that information needs to be entered into the institution-specific format (ST CPOE system or PPO). The technical build may be done by a CPOE/PPO content expert, pharmacist or pharmacy technician. Following the build, an independent double check should be performed by a pharmacist (or pharmacy technician provided a pharmacist was involved in the build).

It is necessary to obtain **Approval and Sign-Off** at the end of the Pre-Go Live section or before activation/implementation. At minimum, the approval should include a medical oncologist/hematologist, but preference is for a multidisciplinary approach with the committees listed above. The approval may occur prior to the Build phase (ex. in the cognitive decision phase), as long as it is obtained prior to completing the Pre-Go live. The specific approval process is at the discretion of the individual facilities.

### **Pre-Go Live**

A final quality assurance (QA) step is required before the regimen is activated in the ST CPOE system, or finalized as a PPO. This step is to ensure that everything that was agreed upon in the Cognitive Decision and Pre-Build phase has been entered without error. A medical oncologist/hematologist and nurse (at minimum) are involved in this QA measure. The pharmacists have performed this QA activity through the independent double-check in the Build section.

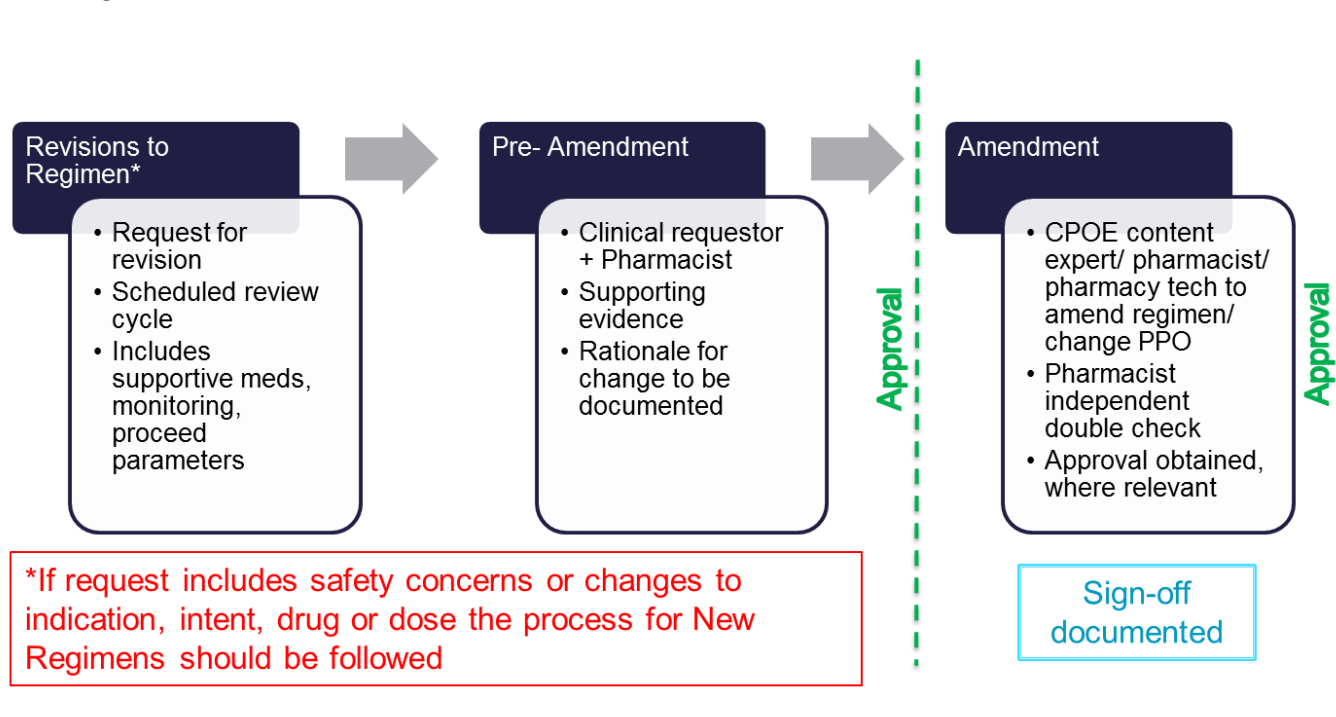
### **Documentation**

The process of documentation can be at the discretion of the facility, as it could take the form of Committee minutes, email sign-off, or hard-copy sign-off. It is most important to have the process in place to be able to attach accountability as it relates to individual roles in the safe delivery of chemotherapy and to have a historical record of the process and decision-making that occurred for any regimen. To ensure the records are complete, the date of documentation should also be included.

## Regimen Modifications

Changes to regimens can occur because of new clinical evidence, funding decisions or other reasons. This can be ad hoc from any requestor, or as the result of a regimen review. Figure 2 provides a graphical representation of this process. Note that while the terminology may be more relevant to ST CPOE systems, they are applicable to PPOs as well.

**Figure 2:** Regimen Modification Process



### Revisions to Regimen

Before proceeding with the Regimen Modification process, if the request includes a change to the intent, chemotherapy medication drug or dose in the regimen or significant change to the indication, then it should follow the same process as that for New Regimens (Figure 1).

### Pre-Amendment

The individual who requested the change (requestor) and at minimum a pharmacist should be involved in the pre-amendment review. If the modification relates to nursing administration, a nursing representative should approve the change. If an amendment is requested by a pharmacist, a second pharmacist should be consulted regarding the change. The rationale for why a change is warranted should be documented with the supporting evidence.

## Amendment

Since these regimens are already live, the QA process will need to occur at the Amendment phase. An independent double check by pharmacy should occur at this step. The double check must have at least one pharmacist involved and the second check could be by a pharmacy technician or CPOE/PPO Content Expert. If the requestor was not a pharmacist, the requestor would be involved in the QA process, where appropriate. All changes should be appropriately communicated to all those who use the regimen.

**Approval** should be obtained before proceeding with the change in the Amendment section, where appropriate and at the discretion of the requestor and/or builder. At minimum, the requestor should approve the change for Pre-Printed Orders. The specific details of the approval process (ex. verbal, written, etc.) are at the discretion of the institution.

## Regimen Maintenance & Review

As discussed in the Evidence Review section, there is no available literature on a recommended timeframe for frequency of regimen reviews for oncology. The expert members recommend that *at most* three years is acceptable in between reviews. This time period aligns with the literature of other order sets. It is felt that while there is a fairly rapid change in clinical practice in oncology, the three year time frame would align with the pace. This may be a new practice in some facilities and it will be a noted increase in workload. This is to say that any one regimen should not go beyond three years without a review. Some facilities may find it more manageable to stagger the review process by drugs or disease site so that the fulsome review is not as onerous.

At the time of the review, regimens should be checked for intent, schedule, dose and drugs against historical evidence via clinical documentation as well as against new evidence if applicable. Consideration should also be given to frequency of use. Any regimens that are found to be clinically inappropriate or pose safety concerns because of low use should be removed from use. It should be clear that the regimen is no longer available for use on any patient (ex. inactivated).

## Summary

In summary, it is important that a multidisciplinary team be involved throughout both the regimen development and maintenance process. This will help ensure that the regimens are built as intended by the full clinical team. While many facilities struggle with time and resource management, a high-quality process at the outset will help prevent safety events and potential errors in the future. There are provincial tools available that can be leveraged through the regimen development and maintenance process. These include: Cancer Care Ontario's [Drug Formulary](#), [Systemic Treatment QBP](#), and the [Systemic Treatment CPOE Best Practice Guidelines](#).

## References

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