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Evidence-Based Series 12-11 Version 2

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Patient Safety Issues: Key Components of Intravenous Systemic Cancer Therapy Labelling

M. Trudeau, E. Green, R. Cosby, F. Charbonneau, T. Easty,
Y. Ko, P. Marchand, D.U, N. Berger, and S. Hertz

April 14, 2023

Evidence-based Series 12-11 was reviewed in 2023 and ENDORSED by the Expert Panel on Key Components of Intravenous Systemic Cancer Therapy Labelling (See Section 4: Document Assessment and Review for details)

EBS 12-11 Version 2 is comprised of 4 sections. You can access the summary and full report here:
https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/1191

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or contact the PEBC office at:
Phone: 905-527-4322 ext. 42822 Fax: 905-526-6775 E-mail: ccopgi@mcmaster.ca

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Guideline Report History

GUIDELINE VERSION	SYSTEMATIC REVIEW		PUBLICATIONS	NOTES AND KEY CHANGES
	Search Dates	Data		
Original version August 2009	1950 - 2009	Full Report	Web publication Journal publication	NA
Version 2 April 2023	2009-2022	New data found in Section 4: Document Assessment and Review	Updated Web publication	2009 recommendations are **ENDORSED**

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Evidence-Based Series 12-11: Section 1

Patient Safety Issues: Key Components of Intravenous Systemic Cancer Therapy Labelling: Guideline Recommendations

M. Trudeau, E. Green, R. Cosby, F. Charbonneau, T. Easty, Y. Ko, P. Marchand, D.U, N. Berger, and S. Hertz

A Quality Initiative of the Chemotherapy Labelling Panel
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Report Date: August 6, 2009

The 2009 guideline recommendations have been ENDORSED, which means that the recommendations are still current and relevant for decision making. Please see Section 4: Document Assessment and Review for a summary of updated evidence published between 2009and 2022, and for details on how this guideline was ENDORSED.

QUESTION

What are the necessary components and formatting of a chemotherapy label to maximize safe delivery and minimize errors? Chemotherapy labels associated with the delivery of a dose of intravenous chemotherapy are of particular interest.

INTENDED USERS

The intended users of this guidance document are any health care professionals who prescribe, prepare, or administer intravenous chemotherapy, including medical oncologists, pharmacists, pharmacy technicians, and oncology nurses, as well as designers of prescription label software, patient safety directors in organizations, administrators of hospitals, and community access care organizations.

RECOMMENDATIONS

The following recommendations are based on the expert opinion of the Chemotherapy Labelling Panel but informed by the currently available evidence (see Section 2). The evidentiary base is composed of three guidelines developed by expert groups, one systematic review, and 13 studies of varying design and sample size. These recommendations apply to the production of intravenous chemotherapy labels in a cancer setting. Although the production of labels for investigational cancer drugs was not specifically examined, the same

principles apply for all intravenous chemotherapy labels. Examples of labels using these recommendations are included at the end of this section.

1. General Components for Medication Labels

The following are general components of an optimal drug label for injectable dosage forms.

(a) Identifying Information

- Patient's name (first name, middle name or initial, and last name **OR** last name, first name, and middle name or initial such that it is consistent with the rest of the patient record) and unique identifier
- Drug name
- Amount of drug per container
- In those circumstances in which overfill is required, the overfill volume (in mL) should be printed on the label separately from the dose information
- If a product contains two or more active ingredients, they should all appear in the generic name field

(b) Drug Information

- Route of administration
- Amount of drug per dose (when the container holds more than one dose, e.g., multiple doses administered intermittently over a 24-hour time period)

(c) Administration Information

- Volume of fluid to be administered
- Duration of infusion
- Rate of administration expressed in mL/hour or as a duration in minutes in the case of medications given by IV push. There is a need to standardize pump technology within an institution or at least to use pumps with a common format. The use of pumps programmed in mL/hour is strongly recommended over the use of pumps programmed in mL/24 hour.
- Supplemental administration instructions (e.g., starting and completion dates/times, prohibitions about when medications are to be administered with respect to other medications, warnings about route of administration, handling and storage conditions)
- Numbering of the medication containers, when the drug is to be administered sequentially (e.g., bag 1 of 3)
- Relevant auxiliary information should be included on auxiliary labels. Examples of auxiliary labels include "AVOID EXTRAVASATION" and "FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES"

(d) General Formatting

- Allow for text wrap and continuation of information on another label. This is intended to allow for long names and enough space to ensure readability as well as eliminating the need to add in additional hand-written information.
- Use white labels: better visualization of text and bar codes (if used). Use black for bar codes.
- If a different colour label is required to draw attention to a specific class of high-alert drug, use yellow labels.

2. General Principles for Label Preparation

The following are general formatting principles to be considered when preparing a chemotherapy drug label for injectable dosage forms.

(a) Drug Name

The following practices are recommended:

- Use the complete generic drug name rather than an abbreviated version.
  - cisplatin not CDDP
- Use lower case or mixed case lettering for generic drug names as appropriate
  - Use TALL man lettering to differentiate between look alike/sound alike drug names (examples can be found at http://www.ismp.org/tools/tallmanletters.pdf)
    - CISplatin to differentiate it from CARBOplatin
- List the brand name using uppercase letters.
  - HERCEPTIN

(b) Abbreviations and Dose Designations

- The recommended practice is to follow Institute for Safe Medication Practices (ISMP) guidelines for abbreviations and dose expressions (examples are provided in Section 2, Table 6) and United States Pharmacopeia (USP) standards for dosage units and standard units for weight and measures (examples are provided in Section 2, Table 7). Alternative abbreviations and dose expressions should be avoided.

(c) Font, Font Size, and Formatting

It is recommended that:

- Patient name, generic drug name and patient specific dose are bolded.
- 12-point Arial, Verdana or an equivalent proportionally spaced font is used for all text and numbers.
  - **Jane A. Smith** not Jane A. Smith
- When drug name, strength, dosage form, and dosage units appear together, provide a space between them
  - propranolol 20 mg ***not*** propranolol20 mg
- Laser printers that support all label formatting expectations be used.

(d) Order of Information

- It is recommended that label information should be presented in the following order: generic name, brand name, patient dose, dosage units, and route of administration.
  - **ondansetron** (ZOFRAN) **4** mg IV Push
    Dose = 4 mg = 2 mL
    (2mg per mL)*

    *include this information only if needed by practitioners (e.g., to program infusion pump)
- The order of information on the label should match the user's workflow; that is the order in which information is programmed into the pump. This will vary depending on the type of pump used in an institution.

(e) Technology

- While more evidence is required, the use of bar coding may be considered for use.
- The use of computerized physician order entry (CPOE) is recommended.

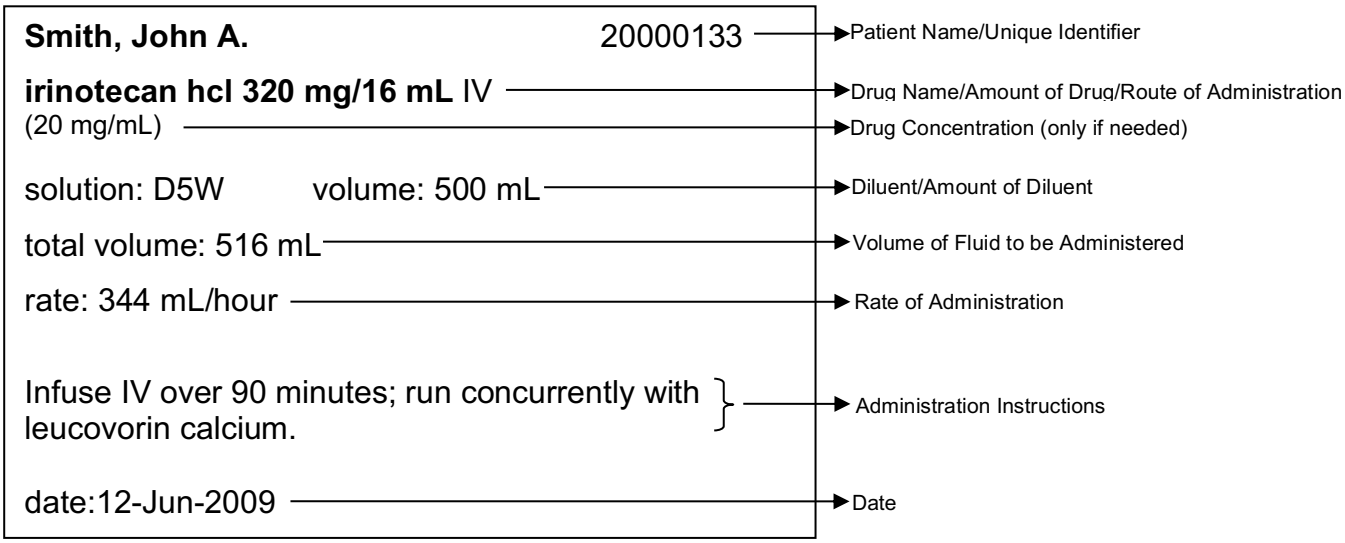
KEY EVIDENCE

- Guideline documents (1-3) provided a framework to identify domains that ought to be considered in an optimal label.
- Label generation should be guided by the overarching rule that medication labels not contain any unnecessary information (4).
- Communication of orders for infusions should be standardized such that "mL per hour" is used rather than "mL per 24 hour" (4).
- ISMP Canada (5) and ISMP United States [US] (6) provide sets of abbreviations, symbols and dose designations that should not be used, which the authors of this document endorse. Please see Tables 6 and 7 in Section 2 for examples.
- TALL man lettering has consistently been shown to reduce drug name identification errors (7-10).
- Larger font size and font weight results in fewer reading errors (11) and better knowledge acquisition (12).
- Proportionally spaced fonts result in better reading speed and accuracy (11).
- There are beginning studies on bar coding indicating that medication administration errors may be reduced with the use of this technology (13, 14). More research is needed before a recommendation regarding this technology can be made.
- CPOE has been demonstrated to reduce medication errors (15-19).
- There is limited evidence that laser printers are preferred over dot-matrix printers (20).

Examples of Labels using the Recommendations in this Guidance Document

The following examples are for illustrative purposes and do not account for overfill volumes which may require consideration.

Example 1 – Intravenous Infusion



Example 2 – Intravenous Infusion

Smith, John A. 20000133

leucovorin calcium 360 mg/36 mL IV
(10 mg/mL)

solution: D5W volume: 250 mL

total volume: 286 mL

rate: 191 mL/hour

Infuse IV over 90 minutes; run concurrently with irinotecan.

date:12-Jun-2009

Example 3 – Continuous Intravenous Infusion

Smith, John A. 20000133

fluorouracil 4350 mg/87 mL CIV
(50 mg/mL)

solution: D5W volume: 146 mL

total volume: 233 mL

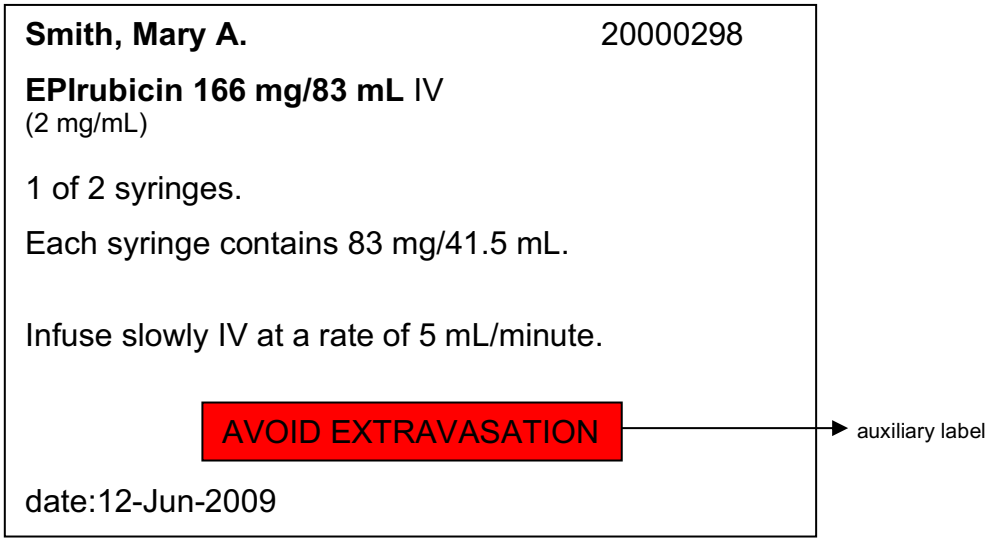
rate: 5 mL/hour

IV continuous infusion over 46 hours.

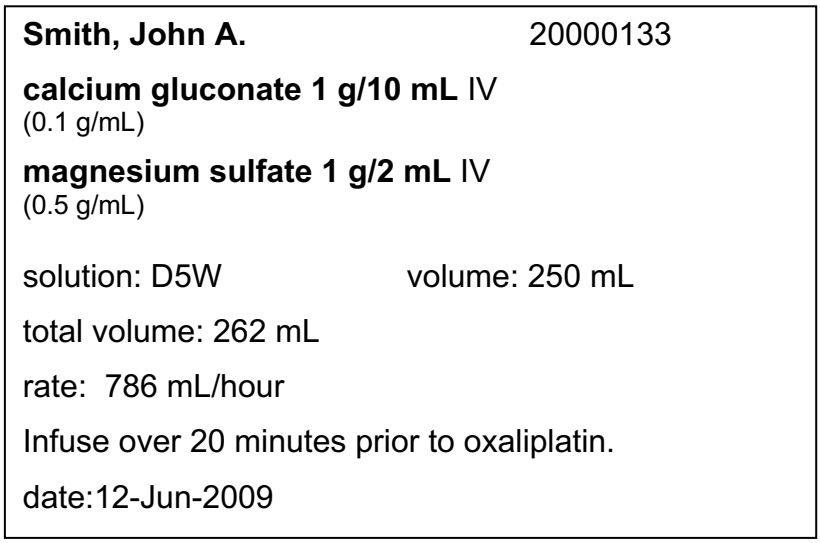
*** INSERT INFUSOR REFERENCE NUMBER ***

date:12-Jun-2009

Example 4 – Intravenous Push with Multiple Syringe and use of TALL man Lettering



Example 5 – Multiple Additives



FUTURE RESEARCH

More research is needed on the use and effectiveness of strategies to reduce medication administration errors. Specifically, more studies evaluating the effectiveness of bar coding to reduce medication errors and adverse events are needed. In addition, studies are needed to evaluate the best method(s) for patient identification to enhance the safe administration of chemotherapy. There are now a few institutions that generate two labels: one for pharmacy staff who fill the prescriptions and one for the nurses who administer the chemotherapy. Research is needed to determine if a system that makes use of two labels results in fewer medication errors than a system in which one label is used. The safe administration of chemotherapy is a complex process in which good labels are necessary but not a sole or sufficient strategy.

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Contact Information

For further information about this report, please contact:
Dr. Maureen Trudeau, Cancer Care Ontario, 620 University Avenue, Toronto, ON, M5G 2L7
Phone: 416-480-5145 Fax: 416-481-6002 E-mail: Maureen.trudeau@sunnybrook.ca
or
Esther Green, Cancer Care Ontario, 620 University Avenue, Toronto, ON, M5G 2L7
Phone: 416-971-9800 x1278 E-mail: esther.green@cancercare.on.ca

For information about the PEBC and the most current version of all reports,
please visit the CCO website at http://www.cancercare.on.ca/
or contact the PEBC office at:
Phone: 905-527-4322 ext. 42822 Fax: 905-526-6775 E-mail: ccopgi@mcmaster.ca

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