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RESEARCH ARTICLE

Recommendations by the Spanish Society of Hospital Pharmacy, the Spanish Society of Oncology Nursing and the Spanish Society of Medical Oncology for the safe management of antineoplastic medication in cancer patients

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Abstract

Aim To define recommendations that permit safe management of antineoplastic medication, minimise medication errors and improve the safety of cancer patients undergoing treatment.

Methods By reviewing the literature and consulting the websites of various health organisations and agencies, an expert committee from the Spanish Society of Hospital Pharmacy and the Spanish Society of Medical Oncology defined a set of safe practices covering all stages of providing cancer therapy to patients. The Spanish Society of Oncology Nursing revised and endorsed the final list.

Results In total, 68 recommendations arranged in five sections were defined. They include issues concerning the training of health professionals, the technological resources needed, treatment planning, informing the patient and his/her family, the processes of prescribing, preparing, dispensing and administering cancer therapy (orally, parenterally or intrathecally), assessing patient adherence and treatment toxicity.

Conclusions It is essential for healthcare establishments to implement specific measures designed to prevent medication errors, in order to ensure the safety of cancer patients treated with antineoplastic medication.

Keywords Medication errors · Prevention and control · Safety management organisation and administration · Patient safety · Antineoplastic agents

Introduction

The rising incidence and prevalence of cancer, and the rapid development of new treatment strategies, have resulted in greater diversity and complexity of cancer therapies in recent years. Because of improved survival and quality-of-life outcomes in many cancers, together with greater use of the oral route and better tolerability of many new drugs, increasing numbers of patients are receiving cancer therapy in oncology departments. This situation poses new challenges for achieving safe management of cancer drugs by the health professionals involved.

For decades, cancer therapy (particularly chemotherapy) has been the prime example of high-risk medication. The risk of fatality or serious complications entailed in chemotherapy [1], including cases with major social repercussions such as intrathecal delivery errors [2], has led the scientific community to introduce hitherto unheard-of multidisciplinary practices for validating and double-checking treatment, in order to improve cancer patient safety [3, 4]. With the aim of preventing various types of errors and risks of adverse effects in patients, a wide range of recommendations have been published in recent years [5, 6]. They include standardisation of treatment orders [7], safe labelling [8–10], checklists [11] or, more recently, computer order entry systems integrated with electronic health records and machine-readable coding during administration [12–15]. All these measures have contributed greatly to improving safety [16], but do not

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entirely guarantee it [17]. Those recommendations were subsequently incorporated into national and international standards and guidelines [5, 18–23] by the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) [24–26], the American Society of Health-System Pharmacists (ASHP) [27] and the Institute for Safe Medication Practices (ISMP), among others [28, 29]. Complying with certain standards is a mandatory requirement in current cancer care quality systems [30].

However, in the context of growing patient safety demands and rapid introduction of new treatments, establishing safe basic procedures may not be enough. In particular, the advent of oral drugs for non-hospital use has not been accompanied by the same safety requirements now in place for intravenous chemotherapy in the oncology hospital setting [31]. That has generated new risks and challenges in cancer patient care, such as monitoring adherence and educating patients about their treatment [32, 33], resulting in new recommendations specifically for oral therapy [34, 35], now included in the latest versions of international publications [24, 25, 27].

In Spain, no consensus document is yet available in which a full set of multidisciplinary measures is defined for the safe treatment of cancer patients with antineoplastic drugs. Some advisable practices are contained in other reports, such as the recent Strategic Plan for Pharmaceutical Care in Oncology/Haematology Patients by the Spanish Group for the Development of Oncology Pharmacy (GEDEFO) [36] or the document on oncology day hospitals produced by the Spanish Society of Medical Oncology (SEOM) [37, 38].

The aim of this work has been to define a set of multidisciplinary safety recommendations for managing antineoplastic medications, to help prevent medication errors and improve the safety of cancer patients in Spain.

Methods

These consensus recommendations are based on a review of the available evidence about safe practices in cancer therapy, and the professional opinions of the Spanish Society of Medical Oncology (SEOM), the Spanish Society of Hospital Pharmacy (SEFH) and Spanish Society of Oncology Nursing (SEEO) experts.

Literature review

To identify safe practices regarding antineoplastic drug management, a structured literature search was performed in the PubMed database for publications on cancer therapy recommendations and safety and quality standards. The search was confined to articles published in English or Spanish between 1 May 2007 and 31 April 2017. The search syntax employed included the combination of MeSH descriptors and keywords or text words shown in Table 1. This search identified 85 publications, from which 23 in total were finally selected by reading the abstracts [1, 2, 4, 6, 7, 9, 11–13, 16–19, 24, 25, 27, 28, 30–33, 35, 39].

The literature search was supplemented by a manual search for secondary references cited in the articles initially selected [3, 5, 8, 15, 34]. A manual search for documents about standards or recommendations for safe practices with cytostatics was also performed on the websites of the following health organisations and agencies:

Table 1 Search strategy in PubMed

#1	"antineoplastic agents"[Pharmacological Action] OR "antineoplastic agents/Therapeutic use"[MAJR] OR "Neoplasms/drug therapy"[MAJR] OR ("antineoplastic"[All Fields] AND "agents"[All Fields]) OR "antineoplastic agents"[All Fields] OR "anticancer drugs"[All Fields] OR "Antineoplastic drugs"[All Fields]
#2	"medication errors/prevention and control"[MAJR] OR ("medication errors"[MeSH Terms] AND "prevention and control"[Subheading]) OR (("prevention"[All Fields] AND "control"[All Fields]) OR "prevention and control"[All Fields] OR "prevention"[All Fields] OR "preventing"[All Fields] AND ("medication"[All Fields] AND "errors"[All Fields]) OR "medication errors"[All Fields])
#3	#1 AND #2
#4	"chemotherapy administration safety standards"[All Fields] AND ("neoplasms"[MeSH Terms] OR "neoplasms"[All Fields] OR "cancer"[All Fields])
#5	#3 OR #4
#6	"recommendation"[All Fields] OR "Recommendations"[All Fields] OR "guides"[All Fields] OR "practical guides"[All Fields] OR "consensus"[All Fields] OR "guideline"[Publication Type] OR "Practice Guideline"[Publication type] OR "guidelines as topic"[MeSH Terms] OR "guidelines"[All Fields] OR "update"[All Fields] OR "review"[Publication Type] OR "review literature as topic"[MeSH Terms] OR "review"[All Fields] OR "systematic review"[All Fields]
#7	#5 AND #6
#8	"2007/01/01"[PDAT] : "2017/12/31"[PDAT]
#9	Spanish[lang] OR English[lang]
#10	#7 AND #8 AND #9

- Institute for Safe Medication Practices, Canada [29];
- Cancer Care Ontario, Canada [5, 10, 13, 20–22];
- Health Care Improvement, Scotland [23];
- National Health Service: North Wales Cancer Network, United Kingdom [40];
- Spanish Agency of Medicines and Medical Devices;
- GEDEFO [36];
- SEOM [37, 38].

Initial selection of safe practices by an expert committee

For the production of this document, SEOM and SEFH set up a committee of experts in cancer therapy and drug safety, composed of four specialists from each society.

The first stage involved the experts analysing the publications selected during the literature search, in order to identify and compile safe practices covering all stages of cancer therapy provision. The expected benefits were taken into account, as was the feasibility of incorporation into Spanish healthcare practice. This stage identified 74 safe practices, which were discussed and screened at a meeting attended in person by the expert committee members. Several rounds of revision then took place between the committee members, working remotely. At the end of this process, 68 practices were selected in total.

Revision of selected practices by independent professionals, and production of the consensus statement

The expert committee drafted a set of recommendations for the safe management of cancer medication, containing the 68 selected practices. This draft was e-mailed to various health professionals belonging to SEFH and SEOM, who had been chosen in advance for their knowledge of this field. They were asked for comments and suggestions about the practices included, in terms of content and wording. They were also given the opportunity to suggest the inclusion of new practices.

All the comments and suggested amendments to the contents and form of the document, sent by the health professionals consulted, were analysed and discussed by the expert committee until an agreed draft list of safe practices was achieved.

This draft list of safe practices was then submitted for review and endorsement to the SEEO, which suggested additional comments and amendments to clarify some practices. These amendments were discussed by the expert committee and were included in the final document.

Results

Table 2 contains the full list of safe practices for the management of cancer therapy agreed by this expert committee. This list includes 68 practices divided into five sections, following a scheme like the one used in the ASCO/ONS chemotherapy administration safety standards [24]. "Introduction" contains 17 general measures intended for healthcare establishments, about the training of health professionals involved in cancer patient treatment, the human and technological resources needed, the standard operating procedures that should exist, and procedures for continuity of care and risk management. "Methods" supplements the above with nine practices related to cancer therapy planning, informed consent, and informing the patient and his/her family or carers about medication.

Section 3 of Table 2 contains 33 practices addressing the stages of prescribing, preparing, dispensing and administering oral and parenteral cancer therapy, including specific measures for intrathecally delivered medication. This section is supplemented by "Discussion", which contains five practices on treatment monitoring, including the assessment of patient adherence and cancer treatment toxicity. Lastly, the four practices in Sect. 5 briefly highlight the importance of ensuring the safety of health professionals who prepare and administer antineoplastic medication. It was decided that in-depth consideration of this issue was beyond the scope of this document, because it did not form part of the initial aim of these recommendations.

Discussion

Medication safety management is a critical aspect of cancer patient care. Because antineoplastic drugs have a narrow therapeutic range, medication errors that can arise for various reasons during the course of treatment carry a high risk of causing patients serious adverse effects or compromising the clinical benefit of therapy. Safe practices to minimise them and prevent unnecessary harm to patients must, therefore, be implemented. Aware of this need, SEFH and SEOM have worked closely together to produce a multidisciplinary document that brings together a set of fundamental practices to ensure the safety of cancer patient care. Starting from a literature review, an expert committee produced a set of recommendations tailored to Spain. These were revised by a group of independent professionals from both societies and endorsed by the SEEO.

The recommendations are intended for healthcare establishments and professionals who provide parenteral and oral cancer therapy, either with commercially available medications or with clinical research products. The

Table 2 SEFH//SEEO/SEOM antineoplastic drugs safety recommendations

1. General measures for healthcare centres: training, resources, procedures, continuity of care and risk management
   1.1. The hospital has a procedure for ensuring that all health professionals involved in treating cancer patients have the necessary knowledge and skills and are competent to perform their functions. For this purpose, the following have been established:
      1.1.1. The educational requirements and competencies of newly joined professionals
      1.1.2. The continuing professional development requirements demanded of staff, which should be updated at least once a year
      1.1.3. The criteria for accreditation by authorised independent organisations, and how this accreditation is documented
      1.1.4. The criteria for assessing the competence of professionals
      1.1.5. A full training programme that ensures compliance with the established requirements for initial and continuing training for all categories of staff who prescribe, dispense, prepare and administer cancer therapies
   1.2. The hospital has sufficient staff to ensure that individuals assigned to each healthcare process are suited to the volume of work, so that established safe practices are is followed and high-risk behaviour encouraged by high pressure on care staff is avoided
   1.3. At least one specialist in medical oncology and one oncology nurse trained in basic life support are at the hospital and are available immediately when the antineoplastic therapy is administered
   1.4. The hospital has an information and communication technology-based integrated information system for the management of cancer patients (inpatients, outpatients and external patients). It is integrated into the single medical record and the hospital's information systems, so that full information about the cancer patients and their medication is available to all health professionals who provide them with care, including emergency care
   1.5. The hospital has in place standard operating procedures designed to prevent errors, containing clear definitions of the processes for medical prescribing, pharmaceutical reviewing, preparing, dispensing, administering and monitoring antineoplastic therapy, and staff responsibilities in each process
   1.6. The hospital has up-to-date, evidence-based treatment protocols, clearly and unambiguously written, and accessible to all health professionals involved in cancer patient care. Those protocols specify at least the following aspects of each treatment regimen:
      1.6.1. Name of the protocol/regimen
      1.6.2. Tumour and stage for which it is intended
      1.6.3. The full antineoplastic therapy, including drugs to be administered orally or by other routes, and the order of administration of each drug
      1.6.4. Administration route of all drugs
      1.6.5. Dose of all drugs and calculation method
      1.6.6. Drug diluent and volume, if applicable. Specific filters and tubing, when needed
      1.6.7. Rate and duration of administration
      1.6.8. Administration frequency and time intervals
      1.6.9. Laboratory tests required to monitor toxicity
      1.6.10. Dose adjustments for each agent, according to laboratory test results and/or adverse effects
      1.6.11. Expected adverse reactions and their treatment
      1.6.12. Supportive therapy (hydration, antiemetics, etc.)
   1.7. Before the first cycle of a new treatment regimen is administered, essential information about the patient and the therapy is entered in the medical records, including:
      1.7.1. Histopathological confirmation or verification of the initial diagnosis
      1.7.2. Initial cancer stage and current status
      1.7.3. Full medical history (including comorbidities) and physical examination
      1.7.4. Weight and height
      1.7.5. Full list of the patient's concomitant medication (see 1.12)
      1.7.6. History of allergy or hypersensitivity reactions
      1.7.7. Initial psychosocial assessment and actions taken when indicated
      1.7.8. Antineoplastic treatment plan, including at least the patient's diagnosis, drugs, doses, duration of therapy and goals of therapy
      1.7.9. Expected frequency of follow-up visits and patient monitoring appropriate for the individual antineoplastic agents
   1.8. At each clinical consultation or on each day of treatment, healthcare staff carries out an assessment of the patient and documents it in the medical records. This should include:
      1.8.1. Performance status

recommendations address all stages involved in the process of providing cancer drug treatment, from prescribing to patient monitoring. Additionally, they cover other measures considered essential for improving cancer patient safety, some of which entail profound change in an organisation's culture. Examples include continuing professional development and assessment of competence, standardisation of all working procedures and healthcare protocols, and setting

Table 2 (continued)

1.8.2. Vital signs

1.8.3. Weight

1.8.4. Hypersensitivity reactions and other adverse events that occurred during treatment administration

1.8.5. Adverse reactions experienced with the treatment

1.8.6. Pain assessment

1.9. At each visit, the patient's treatment is reviewed and updated if required by the oncologist and validated by the pharmacist

1.10. Oral antineoplastic therapy is subject to the same documentation, prescribing, checking and dispensing procedures as parenteral therapy

1.11. Antineoplastic treatments given in clinical trials should follow the same safe practices described in this document as for commercially available treatment, in order to prevent medication errors

1.12. At the first consultation, before each treatment cycle begins, a structured procedure is used to obtain a full list of medication being taken by the patient, including prescription and non-prescription drugs, vitamins, herbal medicines and substance abuse, and that list is compared and reconciled with drugs prescribed during the consultation and upon any subsequent transition of care. At the following consultations, a procedure will be used to learn of subsequent changes in treatment, and they will be reviewed by the pharmacist

1.13. The hospital has in place a standard procedure for reconciling treatment at discharge, which ensures appropriate education of patients or carers and good communication with professionals who care for the patient, to ensure suitable treatment monitoring

1.14. The hospital has a full-time emergency department for dealing with treatment-related adverse reactions and emergencies in cancer patients. If required, an oncologist can be consulted, and there is the option of transferring the patient to a site with specialist oncology services

1.15. The hospital has rules in place for recording and reporting adverse drug reactions

1.16. The hospital has an interdisciplinary patient safety or risk management committee, which has set up a reporting system enabling health professionals to report adverse events, potential events and medication incidents that occur at the site. The committee analyses these incidents in order to introduce measures designed to prevent their recurrence. It also reviews external errors and published information about new safe practices and develops and implements effective practices for improving the safety of cancer therapy

1.17. The hospital has a general or specific quality management system for oncology procedures, which is accredited or certified by an external body

2. Treatment planning, patient consent and information

2.1. The hospital has a standard procedure for obtaining informed consent from patients and documenting it before they receive cancer therapy

2.2. Before each treatment regimen begins, the existence of informed consent to treatment is verified

2.3. Patients are provided with verbal and written information (supported by applications or websites) before the first treatment administration, and at subsequent visits if required or if changes occur. The information consists of at least:

2.3.1. The patient's diagnosis and treatment objectives, i.e. curing disease, prolonging life or reducing symptoms

2.3.2. Expected treatment duration and dosing schedule

2.3.3. Names of antineoplastic drugs and supportive medication, and possible interactions with drugs or food

2.3.4. Expected adverse effects of treatment and specific measures for minimising them. Patients of reproductive age must be informed about the risks of sterility and resources for preserving fertility

2.3.5. Procedures for handling drugs, excreta and waste at home

2.3.6. Monitoring plans and hospital contact details

2.3.7. Warning symptoms that may require urgent medical attention

2.4. Information is provided to family or carers, depending on the patient's decision and ability to take responsibility for treatment management. Information materials should be suited to the understanding of the patient or carer. Provision of information should include feedback from the patient or carer, that shows understanding and commitment to follow instructions appropriately

2.5. When the hospital pharmacy department dispenses drugs intended for cancer therapy to patients, specifically trained pharmacists provide the patients or carers with verbal and written information about the following issues concerning their medication:

2.5.1. Safe handling of the medication and additional precautions (treatment of excreta and waste)

2.5.2. Storage conditions

2.5.3. Administration instructions

2.5.4. Dosage and advisability of adhering to treatment

2.5.5. What to do in the event of forgotten doses or vomiting

2.5.6. Dose adjustments, as prescribed by the oncologist, when applicable

2.5.7. Additional information about adverse effects and how to manage them, especially dose-limiting effects

2.5.8. Potential interactions with other drugs, food or alternative therapies

Table 2 (continued)

- 2.5.9. Contact details for contacting the site if necessary
- 2.5.10. Returning unused medication to the pharmacy

2.6. When home treatment dosage is intermittent or changed because of toxicity, proper understanding by the patient or carer must be ensured

2.7. It is important to define and coordinate in each hospital, both for parenteral and oral treatments, the complementary roles of the various health professionals (medical oncologists, pharmacists and oncology nurses), and their responsibility for the patient's health education and follow-up, reinforcing key information while avoiding redundancy and inefficiency

2.8. The hospital has comprehensive, up-to-date resources and information sources. Verbal and written information provided must be comprehensible and updated regularly. A translation system must be available, if necessary, to enable the patient to understand the treatment plan. The use of patient diaries is recommended, to assist with adherence and to record incidents or adverse effects

2.9. The hospital encourages the development of new technologies designed for good patient education, which facilitate better access to information about medication and the patient's active involvement in his/her cancer therapy

3. Prescribing, preparing, dispensing and administering treatment

3.1. Medical prescriptions for antineoplastic therapies are signed by hand or electronically

3.2. The hospital has a specific policy for prescriptions for antineoplastic therapies, which ensures that:

- 3.2.1. Verbal orders are not permitted, except to discontinue or cancel the administration of antineoplastic drugs
- 3.2.2. Any change or new treatment is documented in the medical records, as are any dose adjustments to oral treatments communicated directly to the patient

3.3. The hospital has a computer physician order entry system integrated into the medical records, equipped with clinical decision support systems that minimise prescribing errors (dose calculation alert systems based on body measurements or biomarkers, adjustments according to clinical situations, allergies, maximum doses and disease-specific decision trees)

3.4. The hospital uses standard, pre-printed or electronic forms for each cancer therapy regimen

3.5. Medical prescriptions for antineoplastic therapies state at least the following elements:

- 3.5.1. Patient's full name
- 3.5.2. A second unambiguous patient identifier (medical record number or date of birth)
- 3.5.3. Weight, height and body surface area
- 3.5.4. Prescription issue date
- 3.5.5. Diagnosis and name of the regimen or protocol
- 3.5.6. Cycle number and day, when applicable
- 3.5.7. Full generic drug names (including trade name in the case of biosimilars)
- 3.5.8. Drug dose according to the protocol: theoretical dose according to the regimen and resultant dose for the patient, dose adjusted according to pharmacokinetic or laboratory parameters, and correction factor used for any dose increase or reduction
- 3.5.9. Administration date
- 3.5.10. Route of administration
- 3.5.11. Vehicle used and final volume of solution prepared
- 3.5.12. Allergies
- 3.5.13. Supportive care treatments appropriate for the treatment regimen: pre-medication, hydration, growth factors, drugs to prevent hypersensitivity reactions, and antiemetic therapy when applicable
- 3.5.14. Sequencing of drug administration, when applicable
- 3.5.15. Administration rate, when applicable.
- 3.5.16. Prescriber's ID, including his/her signature or corresponding electronic ID

3.6. Prescriptions for oral antineoplastic drugs state the following:

- 3.6.1. Patient's full name
- 3.6.2. A second unambiguous patient identifier (medical record number or date of birth)
- 3.6.3. Weight, height and body surface area.
- 3.6.4. Prescription issue date
- 3.6.5. Diagnosis and name of the regimen or protocol

Table 2 (continued)

3.6.6. Full generic drug name

3.6.7. Drug dose according to the protocol: theoretical dose according to the regimen and resultant dose for the patient, dose adjusted according to pharmacokinetic or laboratory parameters, and correction factor used for any dose increase or reduction

3.6.8. Route of administration and special instructions, if any

3.6.9. Amount of drug to be dispensed

3.6.10. Dosing schedule

3.6.11. Duration of treatment, when applicable

3.6.12. If appropriate, the instructions should state how drugs should be taken as regards food intake, and whether certain food types can affect the efficacy or toxicity of the medication

3.6.13. Prescriber's ID, including his/her signature or corresponding electronic ID

3.7. All prescription orders for cancer therapies, including oral medication, must be validated by a hospital pharmacist specifically dedicated to cancer therapy

3.7.1. Validation is mandatory as an independent preliminary step in treatment preparation

3.7.2. In order to validate the treatment order, the pharmacist checks the patient's previous treatment (paying attention to cumulative maximum doses), and verify all drugs and administration routes, scheduling, if all doses are correct according to patient weight, BSA and renal and liver function, potential interactions, the patient's allergies, dose adjustments related to previous adverse effects, compliance with site protocols, and whether patient blood counts and other laboratory results allow the treatment to be administered

3.7.3. If any discrepancies are found in the validation process, they must be resolved with the prescribing physician before the preparation process continues

3.8. The hospital has a system for ensuring that preparation is safe and traceable, covering all stages from the prescribing to the administration of antineoplastic drugs

3.8.1. Antineoplastic therapies must be prepared under the control and supervision of the hospital pharmacy department

3.8.2. When antineoplastic therapies administered on-site are prepared off-site, the external site must satisfy all the general requirements for quality, safety and traceability

3.9. It must be ensured that antineoplastic therapies are prepared by specifically trained staff

3.9.1. Antineoplastic therapy must be prepared by health professionals trained to prepare such treatments, and under the direction of a specifically dedicated hospital pharmacist

3.9.2. Health professionals (nurses, technicians) involved in preparing antineoplastics must know the rules of cytotoxic drug management and receive specific training before they start work and regularly thereafter

3.10. The material resources available must allow antineoplastic medication to be prepared under conditions of safety for both patient and healthcare staff, according to legislation and good manufacturing practice

3.10.1. Cancer drugs should be prepared in clean rooms, under negative pressure and using aseptic technique

3.10.2. Specific Class II Type B2 biosafety cabinets are used for preparing cytostatics, and personal protective equipment is worn, in accordance with current regulations

3.10.3. Only authorised staff is allowed in the preparation area

3.10.4. Each site should assess whether it is cost-effective to use robots for preparing cytostatics. These devices improve the accuracy of preparation and provide additional elements of safety

3.11. There should be a safety policy for selecting and storing antineoplastic drugs, aimed at preventing errors with drugs that have similar names or packaging, and to avoid the coexistence at the hospital of presentations of different strengths. If the usual presentations are changed, staff must be informed, and the computer program updated

3.12. The pharmacy department has standard guidelines or protocols specifying the composition, reconstitution, dilution, stability, labelling, etc. of each drug used in cancer therapies at the site

3.13. Antineoplastic therapy is prepared in the cabinet for one patient at a time, and each drug is prepared individually

3.14. Antineoplastic therapy is prepared in such a way that no further preparation is required by the health professional responsible for administering the treatment. Priming of intravenous tubing and syringes is performed inside the safety cabinet

3.15. A standardised labelling method is available for ensuring easy identification of patient, medication, route and dose. Labels are printed (not handwritten). Mixtures are labelled as soon as they are prepared. The label is checked against the physician order and the worksheet. Labelling for injections includes:

3.15.1. Patient's full name

Table 2 (continued)

3.15.2. A second unambiguous patient identifier (medical record number or date of birth). Location if applicable

3.15.3. Generic drug name

3.15.4. Drug dose expressed in terms of total content (total dose/total volume)

3.15.5. Diluent

3.15.6. Route of administration

3.15.7. Administration rate and duration of infusion

3.15.8. Preparation date and administration date

3.15.9. Expiry date and storage conditions

3.15.10. Instructions for administration (e.g. needs a filter), if applicable

3.15.11. dditional warning label about handling cytotoxics

3.16. Cancer drugs dispensed at hospital for external patients can be labelled individually per patient or provided in their commercial packs

3.16.1. When medication is dispensed individually labelled for a patient, the labelling includes:

3.16.1.1. The patient's name and unambiguous identifier

3.16.1.2. Generic drug name

3.16.1.3. Pharmaceutical form and dose

3.16.1.4. Route of administration

3.16.1.5. Batch number, expiry date and storage conditions

3.16.2. When medication is provided in its commercial forms of presentation, the labelling includes items 3.16.1.2 to 3.16.1.5

3.16.3. The pharmacy department uses bar codes or other systems to verify all medication dispensed to patients or carers for cancer therapies

3.17. In the case of cancer medication pertaining to a clinical trial, as well as the above-mentioned points, the guidance for the trial protocol is followed. The clinical trial protocol and the time of preparation are stated on the labelling

3.18. The components of intravenous mixtures of cancer drugs are verified using bar codes or a similar system. Additionally, a gravimetric method is used to verify correct preparation of the mixture. If this is not possible, the filled syringes and vials are independently double-checked by staff other than the person who prepared them, before they are added to the final solution. The check performed is recorded in writing

3.19. After the prepared mixture has been verified, the antineoplastic drug is inserted into a plastic bag with a leak-proof closure. Transparent bags facilitate identification by nursing staff, with no need for unpacking. Bags are transported in an easily washed, rigid container, identified with the cytotoxic hazard symbol, containing an absorbent plastic pad at the bottom

3.20. Until they are transported, prepared mixtures are stored, in accordance with the storage conditions, in a properly identified, purpose-designed area, bearing in mind the stability data for the mixture

3.21. Prepared mixtures are transported by properly trained healthcare staff. The use of mechanical transport systems such as pneumatic tubes is not recommended

3.22. Antineoplastic therapy is administered by a qualified member of nursing staff

3.23. Before antineoplastic therapy is first administered, an expert nurse must check for the presence of risk factors for extravasation. If several factors are present, prior insertion of a central line should be evaluated

3.24. Before each administration of antineoplastic therapy, patient ID is verified by an expert nurse in the presence of the patient, using at least two identifiers: full name, and a second unambiguous identifier (medical record number, date of birth, or verification by national ID card when administration takes place outside the hospital)

3.25. Before the start of each administration cycle, an expert nurse confirms the treatment with the patient: drug name, infusion time, route of administration, and infusion-related symptoms that must be reported, stipulating which symptoms must be reported urgently by the patient

3.26. Before each administration of cancer therapy, the following are verified and documented by an expert nurse:

3.26.1. Drug name

3.26.2. Dose

3.26.3. Route of administration

3.26.4. Volume to be infused

3.26.5. Administration rate

3.26.6. Expiry date and time

Table 2 (continued)

- 3.26.7. Appearance and physical integrity of the drugs
- 3.26.8. Integrity and suitability of chemotherapy delivery devices: medical devices and infusion pumps
- 3.27. The patient's clinical status is documented by nursing staff during treatment and after it ends
- 3.28. Whenever possible, technologies are introduced to improve patient safety, such as traceability by bar code, data matrix, radio-frequency identification (RFID) or other system, with data transfer to smart infusion pumps
- 3.29. Systems for recording administered medication are available, so that medication errors can be more easily prevented, and full details can be kept of treatment given
- 3.30. Extravasation management procedures are defined and antidotes with protocols for using them are available
- 3.31. Hospitals ensure that home administration of antineoplastic drugs meets the same requirements as at hospital
- 3.32. At hospitals where intrathecal medication is prepared and/or administered, specific procedures exist to prevent treatment-related errors. They include at least the following:
  - 3.32.1. Intrathecal chemotherapy is prepared separately from intravenous chemotherapy
  - 3.32.2. The labelling of medication for intrathecal use clearly states "for INTRATHECAL use only", written out in full, in bold capital letters
  - 3.32.3. Prepared mixtures are stored separately from intravenous chemotherapy
  - 3.32.4. Drugs for intravenous use and for intrathecal use are not dispensed together for the same patient
  - 3.32.5. Intrathecal chemotherapy is administered after having been independently double-checked by the physician and by the nursing staff involved in administering it
- 3.33. All vinca alkaloids are prepared in the pharmacy department in ready-to-administer minibags. The following warning is displayed: "For intravenous use only. Fatal if administered by other routes"

4. Follow-up after antineoplastic drug administration: adherence, toxicity and complications
   - 4.1. The hospital has specific procedures for monitoring treatment response, defining the appropriate timing for assessing the treatment regimen and the necessary functional tests
   - 4.2. The hospital has a defined policy for new treatments for patients, which considers:
     - 4.2.1. The availability of new treatments
     - 4.2.2. Monitoring procedures and care plan
   - 4.3. The hospital has a procedure for evaluating, at each visit by the patient, his/her treatment adherence as well as the toxicity associated and its treatment
   - 4.4. The hospital has a procedure for evaluating and documenting treatment-related adverse reactions and dose adjustments required, and for reporting them before subsequent administration
   - 4.5. For drugs associated with cumulative toxicity, the doses administered are monitored
5. Staff safety
   - 5.1. Health professionals are adequately trained in safety procedures and updated in hazardous drugs handling, and wear personal protective equipment suitable for preparing, dispensing and administering cancer drugs, and for handling the patient's body fluids
   - 5.2. The hospital employs standard operating procedures for preparation and administration, which ensure the safety of people handling cancer drugs, including the use of closed system transfer devices (CSTD) to reduce the risk of vapours and aerosols being released
   - 5.3. The hospital has a protocol to manage accidental exposures and a spill kit is available, with appropriate instructions for use, for those cases, which are registered
   - 5.4. The hospital has policies and procedures regarding cytotoxic waste management, in accordance with current legislation

up risk management systems. All of these are crucial for improving safety. These recommendations also incorporate the minimum technological and human resources that need to be available at healthcare centres in order to reduce variability of care provided, ensure fairness, and assure the safety of cancer therapy.

Today, cancer is regarded as a chronic disease, and oral antineoplastic therapies are increasingly used. Together, these two facts have required patient care strategies to change direction, towards a cooperative multidisciplinary model, in which it is particularly important to inform and talk to the patients and/or carers who will have to be actively involved in treatment. One whole section of recommendations is, therefore, devoted to this. The document contains other fundamental practices in these patients, such as monitoring adherence and reconciling treatments during transitions of care.

The practices listed in this consensus statement are not intended as safety standards for healthcare establishments, because the scientific societies that produced them do not provide certification. Nevertheless, these specific measures aimed at preventing medication errors should obviously be adapted and implemented by healthcare establishments, in order to improve the safety of the care they provide. This document is also intended to assist health professionals,

who can use the recommendations as a benchmark for their healthcare practice.

Lastly, it should be noted that SEFH, SEOM and SEEO intend to promote the development of initiatives to encourage the introduction of these recommendations, and to update them periodically, when new practices are developed that affect the safety of cancer therapy. The aim is for patients receiving antineoplastic therapy in Spain to do so with maximum assurances of quality and safety.

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Compliance with ethical standards

Conflict of interest The authors declare that they do not have any conflict of interest that may inappropriately influence this work.

Ethical approval This article is a review article of published literature and does not contain any original study with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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