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Providing oncology pharmacy services during the coronavirus pandemic: French Society for Oncology Pharmacy (Société Francaise de Pharmacie Oncologique-SFPO) guidelines.

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Abstract

Introduction: Cancer patients are at a higher risk of the COVID-19 infection and more likely to be subjects of a higher morbidity and mortality. This is a big challenge for oncology teams that have to treat patient avoiding contamination by SARS-Cov-2. The aim of the current work is to present oncology pharmacy practice guidelines during the COVID-19 pandemic to secure pharmaceutical care of the cancer patients.

Methods: The bureau of the French Society for Oncology Pharmacy proposed these recommendations according to the French High Authority of Health regarding the guidelines for Good Practice, slightly modified according to pandemic crisis situation. These guidelines were elaborated by a working group of 7 experts in oncology pharmacy practice. Furthermore, the guidelines were assessed by 31 independent reviewers.

Results: One hundred percent of reviewers approved the guidelines and 90% of them suggested some improvements. The final version incorporates the best compromises and consists of 26 recommendations organized in 8 different sections.

Conclusion: These guidelines allow to secure the pharmaceutical management of cancer patients during the COVID-19 pandemic.

***Introduction*.**

The outbreak of coronavirus disease 2019 (COVID-19) first appeared in China but rapidly spread throughout the world, and the World Health Organization (WHO) declared it a pandemic. Europe is severely hit by the pandemic with more than 50% of world's confirmed cases and around 55% of reported world's deaths in only 4 European countries (*e.g.* Italy, Spain, France and United Kingdom) [1]

It is clear that cancer patients are at a higher risk of COVID-19 infection and more likely to have a higher morbidity and mortality [2-5]. This situation presents challenges for oncology teams to maintain a favorable benefit-risk ratio to their patients, suggesting a treatment when it is possible and avoiding contamination by SARS-Cov-2 [6].

Facing the challenge, many professional guidelines from oncology learned medical societies, both at the national and international levels, were published in order to address this specific issue [7-25]. These guidelines were further expanded by national and international institutions guidelines as well as by specific national legislations [26-39].

However, with respect to pharmaceutical field, few guidelines were published. They focused mainly on COVID-19 patients' pharmaceutical care in both hospital [40-45] and community pharmacies [45-51]. No specific guidelines were elaborated concerning the specific field of oncology pharmacy in the view of the COVID-19 pandemic crisis.

The French Society for Oncology Pharmacy (SFPO) is a member of the European Society for Oncology Pharmacy (ESOP). It is a reference learned society in France and Europe for Oncology Pharmacy. It has a long successful experience in elaboration of the professional guidelines [52-54]. In this work, SFPO offers comprehensive professional Oncology Pharmacy guidelines to improve the pharmaceutical care of cancer patients during COVID-19 pandemic.

Methods.

These guidelines were drafted in accordance with the recommendations of the French High Authority of Health (HAS) regarding the guidelines for Good Practice, but slightly modified according to pandemic crisis situation [55]. Briefly, method is based on a 4 phase's procedure (systematic review and synthesis of the literature, drafting of the initial version of the guidelines, reading and finalization).

A working group of 7 professional's expert in oncology pharmacy practice was gathered (all of them members of SFPO board). The working group met once to write the initial version of the guidelines and to validate bibliographic references. Initial version was submitted to a peer review group of 31 reviewers.

Guideline draft was sent to reviewers. A binary assessment of guideline manuscript (approved/not approved) was requested to each reviewer as well as comments to improve it. Pertinent comments were taken into account in final version. Modified version with analysis of comments was sent to working group for final validation.

Results.

Guidelines building and reviewers' agreement

Twenty-six recommendations were issued, organized in 8 different sections. One hundred percent of reviewers approved guidelines. Nineteen percent of reviewers suggested guideline improvements. Based on reviewers' comments, modifications proposed to working group were accepted and validated unreservedly.

Guidelines

PATIENT HYGIENE AND SAFETY

Given that cancer patients are more at risk of rapidly developing severe and fatal forms of COVID-19, oncology departments must be protected. The wearing of surgical masks is recommended for caregivers working in these at-risk departments [26, 28].

Recommendation No. 1: The SFPO recommends that pharmaceutical staff in these at-risk departments wear surgical masks.

Pharmaceutical staff will only go to cancer departments when necessary.
The relevant staff must take protective measures (see recommendation 3).
When the production unit is located within the cancer department, the same rules apply.

Recommendation No. 2: Bio-cleaning in Controlled Atmosphere Zones (CAZ) is enforced.

Contamination by skin or inanimate surfaces remaining a disputed topic [56], as a precautionary measure special attention must be paid to the bio-cleaning of premises of production.
Usual bio-cleaning procedures may be applied more frequently.

STAFF HYGIENE AND SAFETY

Recommendation No. 3: Protective measures are applied in the professional context.

Reminder of protective measures [37]:

- Wash your hands very regularly (see recommendation 7)
- Cough or sneeze into your elbow
- Greet others without shaking hands, hugging or kissing
- Use disposable tissues

In addition, social distancing rules are applied as much as possible.

These recommendations may be signposted appropriately within the ward.

Recommendation No. 4: In case social distancing [37] is not necessarily achievable in professional spaces, which are sometimes cramped, the staff in the production units must wear surgical masks in and outside of the production area.

CAZs are at-risk areas.

Surgical masks, worn by all staff, including outside the production area, are sufficient [38].
A surgical mask is used in the recommended way [45,57]

Recommendation No. 5: Particular attention must be paid to staff with specific comorbidities [27-28,45,58]. Their dismissal from the professional framework may be decided by a physician.

Recommendation no. 6: If a positive COVID-19 case is confirmed among department staff, close contacts (those who have been within one meter of the sick person without protection) are tested after receiving medical advice. Staff who are close contacts are excluded from the production area pending the result of their test with respect to the SARS-Cov-2 infection.

The concerned staff members must be sent to the occupational health service for evaluation and/or follow the recommendations defined by the healthcare center [28].
Staff exhibiting signs of the infection are also directed to the occupational health service and temporarily excluded from the production area pending their results.
Staff suffering from COVID-19 are temporarily excluded from their professional activities on the basis of a medical decision. Reintegration within the pharmaceutical team is carried out on the basis of a medical decision and in accordance with the internal rules of the healthcare center.

HOSPITAL HYGIENE

Recommendation no. 7: Aqueous-Alcoholic Solution (AAS) that meets NF EN 14476 standards, preferably in pump bottles and wall-mounted dispensers or, failing this, in any other packaging, is made available to pharmaceutical teams.

Staff members should wash their hands regularly with soap and/or Aqueous-Alcoholic Friction (AAF). The recommendations of the WHO are applied [59].

Recommendation no. 8: Wearing the same gloves continuously throughout the day, regardless of the activity carried out, is not recommended.

Regular glove changes should be carried out in the production area and when handling cytotoxic vials or any other material potentially contaminated with cytotoxics.

The wearing of gloves must follow professional recommendations. They must be used as protection against chemical hazards, in accordance with the usual procedures [60]:
- Avoid vinyl gloves.
- Change gloves at least every 30 minutes (preferably every 15-20 min).
- Change gloves when they have been torn or when a tear is suspected.
- Be especially careful when handling low-molecular-weight lipophilic molecules.

Wearing gloves to perform administrative tasks or tasks without identified chemical hazards is prohibited.

Recommendation no. 9: Regular and repetitive decontamination during the day of certain critical surfaces (door handles, switches, computer mouses, keyboards, etc.) and sanitary facilities is carried out with products meeting NF EN 14476 standards.

Contamination by skin or inanimate surfaces remaining a disputed topic [56], as a precautionary measure special attention must be paid to the bio-cleaning of the production premises.
The bio-cleaning of materials allowing for the delivery of chemotherapy, and passing daily between the departments and the production unit, must also be enforced. The wearing of gloves and protective glasses for the bio-cleaning of these materials is to be considered, especially if cases of COVID-19 have been identified in the cancer departments where these materials are used.
These actions are logged, where possible.

ADAPTATION AND SANCTUARIZATION OF HUMAN RESOURCES

The production of chemotherapy is very specific and a limited number of pharmaceutical staff is trained to carry out this activity.
In addition, the production units' activity may be modified due to medical recommendations (injectable anticancer medication prescribed less often in favor of Oral Therapies (OTs), spacing out or cancellation of cycles, etc.).

Recommendation no. 10: Depending on staff availability (risks of staff reduction due to the contraction of COVID-19 or dismissal on medical grounds) and necessity [52], it is recommended to set up an operational reserve of trained staff [25,44-45].

This section staff remains in quarantine for a fixed period, getting ready to take charge of the activity in the event of a reduction in the number of professionals authorized to carry out the production activity due to contamination followed by professional dismissal.
Pharmaceutical staff may participate in this operational reserve. However, a physical pharmaceutical presence remains legally obligatory and the activity of remote prescription validation cannot replace the presence of a pharmacist.
Remote prescription validation is possible but must comply with the regulations, emphasized by the National Council of the Order of Pharmacists (CNOP) [61-62], namely:

- In Hospital Pharmacies (HPs) where the pharmacist is alone, this practice (remote prescription validation) is not possible. Pharmaceutical assistants carry out remote prescription validation under the management and effective monitoring of the pharmacist, therefore in their presence, and an HP can only function when the pharmacist or their replacement is present (article R. 5126-16 of the CSP). This text requires the presence of the pharmacist on the premises of the HP.
- During the COVID-19 health crisis period, in HPs where several pharmacists work on the same site, it is possible to set up remote validation of certain prescriptions (to be determined by the pharmacist managing the HP depending on each establishment) on the condition that the pharmaceutical acts performed within the HP (supply, delivery, preparation, etc.) are carried out under the effective monitoring and technical authority of one or more pharmacists.

Recommendation no. 11: Pharmacy students will continue their internship in hospitals. In light of the current situation, they will be mobilized and reassigned with priority given to under-staffed pharmaceutical sectors [39].

PATIENTS: PHARMACEUTICAL CONSULTATIONS, TUMOR BOARD MEETINGS (TBM), CLINICAL TRIALS, PHARMACEUTICAL ANALYSIS OF PRESCRIPTIONS

Recommendation no. 12: Oncological clinical pharmacy activities are maintained [40,42-43,53].

These activities make it possible to optimize the therapeutic care of the cancer patient.
In the context of medication reconciliations, the direct, face-to-face collection of information from patients is suspended wherever possible. The use of telephone interviews and electronic sources (medical records, prescriptions online, etc.) must be prioritized.

Recommendation no. 13: Teleconsultations are prioritized [40-43].

Pharmaceutical consultations (PC) contribute to the optimal management of the cancer patient [53].
Reducing contact with at-risk patients such as cancer patients requires telephone consultations or teleconsultations [2,20,26,28].
Increased attention will be paid to the initiation of treatment.
The use of computer and/or smartphone applications for monitoring treatment remotely is recommended [13].

Recommendation no. 14: Pharmacists continue to participate in Tumor Board Meetings (TBMs), but in a secure, digital manner as recommended by the National Institute for Cancer (INCa) [29] and medical associations.

Any change in treatment due to the pandemic must be recorded in the TBM: stoppage of transitional treatment, substitution by an OT, etc.

Recommendation no. 15: Pharmacists support medical decisions relating to the modification of therapeutic care aimed at reducing the presence of patients in the hospital (use of OT, change of the administration schedule, foregoing treatment) [42].

Their advice is based on the recommendations of medical associations [7-25] and data from the literature.
For example, the following will be promoted:

- the use of flat-dose immunotherapy at the widest possible administration intervals based on available scientific data and at least on a local consensus [2,14,17,20,26].
- the wider use of portable medical devices (diffusers or cassettes) in order to facilitate the quick discharge of patients [2,13,19-20,26].
- the use of OTs where possible to replace injectable anticancer medication [2,11-13,19-20,26].

Recommendation no. 16: Specific protocols are created in the prescription software to respond to medical recommendations.

Particular attention must be paid to the wording of these new protocols in order to clearly identify them.
The abolition of these protocols (especially those which are off-label) and the re-inclusion in the previous protocols will be evaluated at the end of the health crisis.

Recommendation no. 17: Particular attention is paid to the new treatment sequences induced by changes in doses or the administration frequency.

Special attention is paid to:

- treatment history, in particular the spacing out of for dose and intervals adjustment potentially at risk of toxicities, for example when oral treatments have replaced injectable regimens.
- treatment history in the event of recourse to Home Care (HC)
- decreases in the dosage of certain cytotoxics or a change in treatment in order to reduce the risk of neutropenia or avoid the use of G-CSF [11].
- follow-ups of temporary treatment stoppages.

This information must appear in the patient file to make a link with the production unit and the handover service and be validated in TBMs.

Recommendation no. 18: Activity related to clinical trials is minimized [33-35,45]

The relevance of beginning new trials must be evaluated, priority being given to trials relating to the management of patients infected with SARS-CoV-2 [33].
Early phase clinical trials, including medication for which the benefit to the patient has not yet been demonstrated, should not begin [7].
Continued inclusion may be considered in situations of unmet medical need and subject to the potential risks associated with the risk of concomitant infection by SARS-CoV-2 [33].

Contact must be established with the investigator and the sponsor in order to optimize the care of patients by limiting their hospital stay as much as possible.

Recommendation no. 19: Pharmaceutical analysis of prescriptions for anticancer medication, especially OT, takes into account the patient's undercurrent treatments [42].

Special attention will be paid to:

- non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids [8,31].
- the risks of drug interactions in patients receiving treatment with anticancer medication, in particular Kinase Inhibitors (KI), and receiving, moreover, on an experimental basis or otherwise, an anti-COVID-19 treatment [30-32,63].
- Self-medication supposed to prevent COVID-19, in particular the use of Complementary Therapies [54,64].

Recommendation no. 20: The activity of dispensation, in particular in Unit-Dose Daily Distribution System (UDDDS) and including within pharmaceutical branches in the hospital sector, is maintained along with the implementation of adapted health and safety measures [44-45].

This activity constitutes additional support for departments under strain during the health crisis.
The number of pharmaceutical staff dedicated to this activity (pharmacists, assistants, students) must be limited in order to limit the risk of contamination.
It is essential to identify all areas and activities at risk. As an example, it is necessary to develop procedures for decontaminating medication dispensing carts and in particular in the contact area (decontamination of medication dispensing carts, contact areas for pill dispensers).
The return of unadministered medication and medical devices (MD) are subject to quarantine (24 to 72 hours) [56] before being put back into circulation.

STOCK MANAGEMENT AND SUPPLY

Recommendation no. 21: The monitoring of medication and MD stocks is reinforced due to drug shortages and strain in the usual supply circuits, some of which may come from pandemic areas [40-41,44-45,65].

Information monitoring, in particular originating from drugs agency and pharmaceutical laboratories, is essential.
Repeated inventories may be required.
An emergency alert procedure in the event of a supply shortage must be set up with the pharmacists in charge of supplies (order, market, etc.)
Alternative protocols must be anticipated, developed, and approved in the event of strain or shortage (midazolam for palliative situations in oncology [66], for example).
The same vigilance is also applied to the MD and solute supplies.
Special attention will be paid to the supply of gloves and, if necessary, masks.
The same attention is paid to the supply of consumables necessary for the operation of production and control facilities.
A regular call to suppliers is essential.

MATERIALS

Recommendation no. 22: The IT departments set up a remote connection so as to allow, if necessary, the carrying out of certain activities (orders, prescription validations, pharmaceutical teleconsultations) by operational staff in quarantine.

This remote access must be secure.
The exchange of information with health professionals and colleagues working in the health center or in community pharmacies must be done via secure messaging channels.

Recommendation no. 23: Contact with companies that can repair any faulty facilities is maintained.

The facilities concerned include:

- production systems (isolators, Biological Safety Cabinets (BSC), production robots, etc.)
- control equipment (video control, spectrophotometers, chromatography devices, etc.)
- delivery systems (wire-guided trolleys, tires, etc.)
- IT tools (prescription software, preparation and administration of chemotherapy, etc.)

The companies concerned may be asked for information relating to their Business Continuity Plan (BCP) (opening hours, contacts, telephone numbers, staggered procedures, etc.).

Recommendation no. 24: Staggered procedures are planned and applicable, in this context, in the event that the facilities cannot be repaired.

CRISIS MANAGEMENT AND EXPERIENCE FEEDBACK

RECOMMENDATION No. 25: The pharmacist specialized in cancer care is associated with crisis meetings within the health center or, at least, informed of the decisions taken in this body if the number of participants is limited.

Due to the fragility of the patients for whom they provide therapeutic care, participation in these meetings, or daily feedback is imperative.
Team management and information meetings on the health crisis are organized, within the pharmacy, in compliance with the rules of social distancing and/or digitally.

Recommendation no. 26: The organization of a specific Experience Feedback Committee (EFC) with the goal of analyzing the dysfunctions caused by the pandemic and drawing corrective measures from it retrospectively is essential.

Conclusion

The COVID-19 pandemic, disturbing both hospital organizations and therapeutic strategies, strongly impacts cancer patients' care. These guidelines, specifically focused on the oncology pharmacy field, to the best of our knowledge, are the only ones available in Europe and even in the whole world. They represent a professional consensus and follow the most efficient pharmaceutical practices in the French hospitals. Moreover, these recommendations constitute a solid basis to share for a further adaptation to the existing oncology pharmacy practices in many hospitals during the COVID-19 pandemic. Ultimately, these guidelines will be facing feedbacks from numerous practicing pharmacists around the world to add putative improvements.

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