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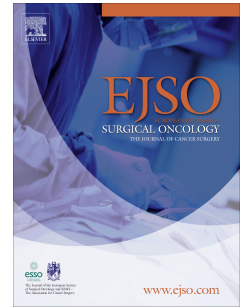


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Enhancing Patient Safety and Quality of Surgical Cancer Care: The French National Cancer Plans

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Abstract

Two National Cancer Plans (2003 – 2007 and 2009 – 2013) have been launched in France to organise the healthcare offer in order to enhance quality and safety. The current Cancer Plan[1] defines regulatory frameworks across the three major areas of cancer therapy: surgery, chemotherapy and radiotherapy. These regulatory frameworks are based on three pillars: transversal requirements for the quality of care; establishment of minimal thresholds for institutions and technical criteria that are required for each type of cancer surgery. Based on adherence to these requirements and following a process of continuous assessment, institutional accreditations (currently being allocated in 2010) will be given for a period of 5 years.

Introduction

The French healthcare system is a plural system. Patients have the choice of being treated in private hospitals, in public non-teaching hospitals, in teaching hospitals or in private hospitals also participating in the public sector. Some structures can be small and quite isolated or, at the opposite end, can be secondary or tertiary referral centres. Specifically for oncology, a special type of hospital exists with the Comprehensive Cancer Centres (CLCC) which are private but also operate in the public sector and which are also teaching Hospitals (20 in France). Given this range in types of institutions, the French Government felt it necessary to ensure minimum standards of care across all institutions offering care to cancer patients, by defining a National Cancer Plan on which institutional accreditations are based.

Prior to the introduction of the first Cancer Plan in 2003, patients with cancer were very dependent on the first practitioner they met in terms of his/her speciality, for example surgeon, medical oncologist, organ specialist or radiotherapist, for the type of care they would receive. The therapeutic proposal was completely up to the practitioner to choose without any obligation to refer to evidence-based medicine, to any medical thesaurus and without any discussion with the other specialists potentially involved in the treatment of the cancer.

Since 2003, two National Cancer Plans (2003 – 2007 and 2009 – 2013) have been launched to organise the healthcare offer in order to enhance quality and safety, covering three types of cancer treatment: chemotherapy, radiotherapy and surgery. The first plan established the fundamental bases for cancer care in France. The objective of the second plan is to sustain and further the progress achieved by the first plan with a special focus on coordination for post-hospital care, equal access to treatment and innovation. In this paper, we will present the legal requirements surrounding the practice of surgical oncology as determined by these National Cancer plans. It should be noted that oncology is the first medical domain to be discussed and defined as such at a political level which has forced medical professionals to increase the quality of their practices. As an interface between politicians and medical professionals, an Institute was created in 2004, the National Institute for Cancer (INCa) which introduced a new paradigm of medical management in France. As a result of cancer being decreed to be a 'national concern', medical professionals have had to accept limitations on their freedom and to abide by sometimes restrictive rules. INCa has the mission to implement this national policy as the interface between healthcare professionals and the population.

This process sets the minimum, system-wide, expectations for medical personnel, facilities and services that are required to deliver a consistently high level of care. Accreditation for delivering cancer care services, given for a period of five years, is granted to healthcare institutions (public hospitals, private sector, cancer care centres, etc) and not to individuals, on the condition that they meet and maintain compliance with a number of safety and quality requirements. Healthcare institutions must obtain their accreditation from “regional hospitalisation agencies” (ARH) to be authorised to treat cancer patients. The accreditation allocation process began in November 2008 and has continued throughout 2009 and 2010. The complete regulatory framework will be fully implemented by the end of 2010. The regulatory framework applicable to all three modalities of cancer treatment including surgery is based on three pillars which will be covered below: transversal requirements, minimum volume thresholds and technical criteria.

TRANSVERSAL REQUIREMENTS

All accredited cancer care providers have to satisfy the following requirements.

1. Apply the diagnosis “announcement” procedure.

This procedure has been established to announce “bad news” to the patient and his/her family including not only the diagnosis of cancer but also recurrences, aggravation or the necessity of mutilating surgery. Not only is the surgeon implicated but also nurses, psychologists, etc.

2. Organise multidisciplinary meetings.

Every patient’s file has to be discussed by a multidisciplinary team consisting of different specialists like surgeons, organ specialists or medical oncologists, radiotherapists, radiologists, pathologists, etc. Three different specialties are required to be constituent of a multidisciplinary staff meeting. For certain types of difficult surgeries, the physical presence of the surgeon who will do the procedure is mandatory.

3. Establish an individualized care plan

At the end of the consultation, a document summarising the different steps of the care must be given to the patient.

4. Implement best practice guidelines

The decision of the multidisciplinary staff meeting must be implemented in reference to good medical practice thesaurus. Two types of thesaurus are available. For chemotherapy, each drug is allowed in specific cases depending on the disease, its stage and the number of therapeutic lines. Secondly, therapeutic algorithms for patient treatment depending on the

stage and the nature of the disease are proposed as standards, options or recommendations due to the level of evidence-based medicine observed.

5. Ensure access to supportive care

Every surgical department must participate in a supportive care network.

6. Enhance access to innovative treatments and clinical trials

The goal for each oncology department is set at including 10% of patients in clinical research programmes. At the same time, all patients asking to participate in a clinical trial should have the possibility to do so. Offers of clinical research programmes are published on different national or regional websites.

MINIMUM VOLUME THRESHOLDS

The second pillar requires that health care institutions meet fixed minimum volume thresholds which are specified for cancer surgery, radiotherapy and chemotherapy. For radiotherapy, the minimum activity threshold for a radiotherapy centre with at least two accelerators is set at 600 patients treated per year. For chemotherapy, each health institution has to treat over 80 patients per year including 50 out-patients. For cancer surgery, the annual minimum activity threshold is fixed at 30 surgical interventions per year for breast cancer, digestive system, urological and thoracic cancers, and at 20 surgical interventions per year for gynaecological, Ear, Nose and Throat (ENT) and maxillofacial cancers.

Despite the fact that all thresholds are fixed at a low level, some healthcare structures will not be accredited for delivering cancer care on the basis that they don't treat enough patients. However, these healthcare structures treat only a small part of cancer patients, around 5% of the total number of patients.

TECHNICAL CRITERIA

In addition to compliance with these requirements and participation in a regional cancer network, healthcare institutions must also meet certain technical criteria defined by INCa and adopted by its Executive Board in December 2007. The technical standards came into effect at their publication on INCa's official website (www.e-cancer.fr) in June 2008. This detailed set of standards for cancer surgery, radiotherapy and chemotherapy provides comprehensive coverage of critical issues related to the improvement of quality and safety of cancer care.

Each set of standards has been developed and approved by expert working groups after a comprehensive review of international literature on quality assessment techniques. A consultation took place with key cancer care stakeholders during the drafting of these criteria.

Among these technical standards, some are considered as “fundamental”. They consist of specific standards for the implementation of:

- Multidisciplinary approach
- Qualification of health professionals (including continuing professional education)
- Specific safety rules
- Use of self-assessment quality indicators (as defined by INCa)

Each discipline; chemotherapy, radiotherapy and surgery, also has specific standards. For surgery, the following technical criteria have been set:

- Surgeons must be qualified in their speciality and justify of sufficient activity in their department even if minimal thresholds are for the centres and not for the surgeon.
- At least one of the surgeons who will participate in the surgery must be present in person or by teleconference at the multidisciplinary meeting.
- Patient files must include at least the report of the multidisciplinary staff meeting, pathologists' reports and an operative report (as defined by INCa).
- Frozen sections of surgical specimen during operations are possible.
- Preservation of pathological specimens in the biobank is organised when needed and following national conventions.
- A training plan is established in the institution for all health professionals involved in surgery.
- Morbidity and mortality survey staff meetings are organised on a regular basis in the institution as part of the quality assurance.
- A self-evaluation of each surgeon's activity is organised yearly. Anonymous data are sent to INCa for national summaries.

In addition, specific requirements exist according to the type of cancer involved in the surgery.

Breast carcinoma

- The practice of oncoplastic surgery and all techniques associated with plastic procedures are possible on the operative platform. The sentinel lymph node detection technique is also available.
- An X-ray of the removed specimen must be done on the operative platform.
- Techniques for the tagging of preoperative lesions are available as is access to a nuclear medicine department.

Digestive surgical oncology

- For carcinomas of the oesophagus, the liver, the pancreas, the mid and low rectum, the following rules must be observed at the multidisciplinary staff meeting:
 - The patient's file must be discussed and not only recorded.
 - The operative strategy must be validated.
 - The surgeon who will perform the surgery must be present and be part of the final treatment decision.
 - The adequacy of the surgical strategy to the specificities of the technical platform and post-operative follow-up possibilities must be verified.
- Per-operative endoscopy must be available as a technique of interventional radiology.

Urology surgical oncology

- Access to urological interventional radiology is organised and available.

Thoracic surgical oncology

- The institution allows access to:
 - tracheo-bronchial endoscopy techniques,
 - thoracoscopy techniques,
 - RMN and PET scans.

Gynaecological surgical oncology

- For ovary carcinoma, requirements of the multidisciplinary staff meeting are as follows:
 - The patient's file must be discussed and not only recorded.
 - The operative strategy must be validated.
 - The surgeon who will perform the surgery is present.

- The adequacy of the surgical strategy to the specificities of the technical platform and post-operative follow-up possibilities must be verified.
- Access to coelioscopy is available in the institution

ENT surgical oncology

- Techniques of endoscopy must be available and collaboration with a maxillo-facial prosthetics laboratory is organised.

Practical implications of the Cancer Plan

A map of the different institutions gaining accreditation for oncological care across the country was published on the INCa website in March 2010 (www.e-cancer.fr). These accreditations will be confirmed after a period of no longer than 18 months. This period can be used by the institutions to verify the conformity of their health care offers to the rules and standards of oncological practice. An accreditation visit will be performed by the Regional Health Agency to finalise the process of certification. After this, the certification is valid for 5 years.

Nationally, 868 health care institutions over 914 geographical sites have received accreditation for at least one therapy: surgery, chemotherapy or radiotherapy[2]. This amounts to a total of 1391 accreditations (more than one per institution). Overall, by far the largest amounts of institutions have been accredited to perform surgery in cancer treatment: 328 institutions are accredited to perform surgery only, 335 to perform surgery and chemotherapy and 90 to perform surgery, chemotherapy and radiotherapy. Twenty four percent (284) of the 1152 hospitals offering such services in 2008 did not meet the criteria for accreditation in 2009. Specifically for surgery, only 754 hospitals of 998 were attributed the label (75%) in 2009. As a consequence, some activities have to be redistributed regionally to institutions that have acquired the authenticating label, particularly for surgery which has the highest rate of redeployment required at 7.8% overall. Percentages of surgical activities to be redeployed per surgery type are shown in Table 1.

Conclusions

The National Cancer Plan implemented in France serves to continually improve the quality of cancer care offered to patients. Since January 1st 2010 one last measure to improve oncological surgical safety has been implemented in every French operating theatre. The practice of the surgical check-list[3] is now mandatory before launching a surgical procedure. To ensure the sustainability of this regulatory framework, evaluation measures will be required in the coming years to check for full adherence to the system from all healthcare professionals involved.

Table 1: Surgical activities process, accredited institutions and activities requiring redeployment over 2008-2009 according to National Cancer Plan accreditations.

Type of surgery	Number of hospitalisations	Number of health care institutions	Activities to be redeployed to authorised institutions
Breast	73 735	523	3 671 (5%)
Digestive	58 919	646	3 595 (5.7%)
Thoracic	18 151	150	2 099 (11.6%)
Urology	48 338	462	2 604 (5.3%)
Gynaecology	17 697	390	3 306 (14.7%)
ENT	23 668	322	3 489 (14.7%)
Total	240 508	743	18 528 (7.8%)

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