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Radiotherapy : Treatment efficacy and risk control

Public hearing of 15 november 2007
Organised by Mr Claude Birraux, Deputy, Haute-Savoie,
First Vice-President of OPECST

Radiotherapy has become a major and ever more effective cancer treatment mode.
However, recent accidents have caused concern and mistrust.
This hearing was aimed at:

- *Providing an overview of radiotherapy: its place in cancer treatment and its new technologies;*
- *Presenting the radiation protection procedures set in place by professionals to guarantee patient safety and better quality care.*

Radiotherapy : a major cancer treatment

Radiotherapy in 2007

• *An ever more effective treatment*

Radiotherapy, invented in France at the Institut Curie, consists in using ionising radiations to destroy cancerous cells by blocking their capacity to multiply, while sparing the surrounding healthy tissues. 60 to 70% of cancer patients are treated by radiotherapy, most often in conjunction with surgery and/or chemotherapy.

Nearly 200,000 persons are concerned every year in France. This considerable figure is constantly rising owing to ever earlier cancer diagnosis, the ageing of the population and various epidemiological factors. The treatments are ever more effective. 45% of patients are currently cured of cancer. The most effective treatment is surgery (22% of patients), followed by radiotherapy alone or in conjunction with other treatments (19% of patients).

Therefore the very considerable increase in the incidence of prostate and breast cancers is not matched by a comparable rise in mortality. This means that the treatments of these cancers are ever more active and, as one of these treatments, radiotherapy plays a key role.

Radiotherapy treatments have gained in efficacy and also in quality. For instance, out of the 6,000 breast cancers diagnosed for one million screened women, 3,000 are managed by organ conserving treatments.

• *The stock of equipment : complete modernisation achieved with the Plan Cancer*

The Plan Cancer, launched in 2003 and run by the Institut National du Cancer, (INCA – National cancer institute) has rapidly made up for the French backwardness as regards radiotherapy equipment. For instance, cobalt machines have disappeared, replaced by linear accelerators.

Linear accelerator (RX)

One in four pieces of equipment has been renewed over the past five years. Today, throughout the French territory there are 180 radiotherapy centres grouping 400 pieces of equipment; 47% of these centres are public and 53% private. 55% of the machines have been set up in the public sector and 45% in the private sector.

The map of radiotherapy centres shows territorial inequalities. The density of facilities and above all their size do not always tally with the population to be treated.

• *Radiotherapy professionals : worrisome demography*

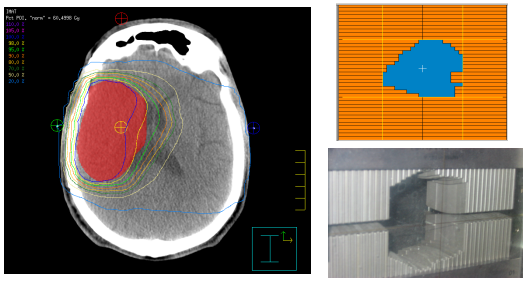
The demography of radiotherapy professionals is closely akin to that of doctors, with a very noticeable inflection in numbers from 2005-2010. As for radiotherapists, of which there are 663, the rise in radiotherapy housemen has rewarded the efforts accomplished to make this sector attractive, but will be insufficient to cover health needs. Turning to the 300 medical

physicians, their number is notoriously insufficient. This fact has been observed by the: Caisse nationale d'assurance maladie des travailleurs salariés (CNAMTS – National salaried workers' health insurance fund), which pointed out a risk of a lack of safety in treatments in half the centres owing to the lack of radiophysicians; Institut de radioprotection et de sûreté nucléaire (IRSN – Nuclear safety and radiation protection institute) during many field inquiries; and lastly the Autorité de sûreté nucléaire (ASN – Nuclear safety authority) which considers that one in three centres does not have a physician during all the length of treatments. The doubling of personnel has been announced for the next five years but the number of students choosing this sector every year will not lead to such a rise.

An activity undergoing massive technological change

• ***Constantly evolving techniques and equipment***

Since the past ten years or so radiotherapy has been undergoing a genuine technological revolution, especially owing to progress in imaging and data processing. The advances always head in



3D conformational radiotherapy

the direction of greater precision and could be summarised by the remark by Claude Huriet defining the 'radiotherapist's grail' as follows: *'irradiate the tumour, all the tumour and nothing but the tumour'*. Apart from the replacement of cobalt devices by linear accelerators generating very high energy X-rays, the main technological evolution is the switch to far more 'conformational' radiotherapy, in other words which manages to 'hug' the shape of the tumour in order to decrease the dose to healthy tissues and, possibly, increase the dose targeted at the cancerous tumour itself.

By order of sophistication and equipment cost, these techniques are: two-dimensional radiotherapy, three-dimensional conformational radiotherapy, intensity-modulated radiotherapy, image-guided radiotherapy, radiosurgery, tomotherapy and the cyberknife and, lastly, protontherapy which uses protons having the capacity to cross tissues without damaging them and applying all their energy at a given depth. Today, the very great majority of patients in France are treated either by so-called 'basic' radiotherapy, in other words two-dimensional, or by so-called 'three-dimensional conformational radiotherapy', based on scanner imaging. Advanced techniques concern only a few patients for the moment: the technique applied to the greatest number of patients is protontherapy, practised at Orsay and in Nice on more than 4,000 patients and used to treat eye or brain tumours with remarkable results.

Apart from their greater therapeutic efficacy, these recent techniques allow the secondary effects of radiotherapy treatments to be lessened. For instance, for patients treated for prostate cancer, it is observed that, with an identical tumour control rate, 3D radiotherapy compared with 2D radiotherapy, helps decrease the complications rate most significantly.

• ***Recent innovation : the 15 pilot centres and the 'Etoile' project***

The Institut National du Cancer funds the development of innovative technologies in fifteen pilot centres: nine centres house latest generation accelerators, three tomotherapy and three the first radiotherapy robot, the cyberknife. Tomotherapy, a technique that has arrived from the United States where it is enjoying exponential development, allows intensity-modulated radiotherapy to be practised. This new machine produces modulated volumes of irradiation that vary with the patient's movement. For prostate tumours, the results are remarkable. The cyberknife, for its part, is not a radiotherapy device but a genuine robot capable of following in real time tumour movement due to patient breathing.

Cyberknife

Lastly, the construction in Lyon of the first French carbon ion radiotherapy centre is scheduled for 2013. The 'Etoile' project, dimensioned to treat 1,000 patients a year, is to

allow the validation of hadrontherapy which is a treatment already practised in Japan and Germany. Heavy-ion beams have the advantage of destroying deep tumours with great precision without irradiating healthy or radiosensitive tissues.

Risk control : real awareness of the issue by the public authorities and health professionals

Mobilisation of the competent health authorities

• ***The new pivotal role of the Autorité de sûreté nucléaire (ASN)***

The Nuclear Safety Authority (ASN) is an independent administrative authority created by Act no. 2006-686 of 13 June 2006. On behalf of the State, it monitors nuclear safety and radiation protection to protect workers, the public, patients and the environment from the risks related to the use of nuclear and radiological facilities and sources, and contributes to citizen information, with the IRSN's technical support and expertise.

The authority is therefore tasked with health security against ionising radiations, whether it be a matter of the safety of facilities or the radiation protection of people. After the transposition of Euratom directives 96/29 and 97/43, the ASN set up an operational structure by setting in place radiation protection inspection. It visited the 180 radiotherapy centres between April and December 2007, to assess services from the viewpoint of organisational and human factors.

The ASN's ambition is to make French radiotherapy exemplary. In this respect, the ASN **has set in place major measures**: declaration of events on the basis of the scale drawn up by the ASN and the Société française de radiothérapie oncologique (French oncological radiotherapy society) (ASN-SFRO) classifying the gravity of events; improvement of the safety of medical devices in liaison with the AFSSAPS and improvement of the safety of treatments; elaboration of a quality assurance reference framework applicable in centres and of a tumour radiotherapy guide drafted by oncologists-radiotherapists.

The aim is to permanently instill a **safety culture** in radiotherapy centres and in attitudes. While the ASN is showing great determination, it rightly feels that a minimum five to ten year period will be necessary before full effectiveness of the strengthening of regulatory requirements and of the workforce as well as of the application of the new recommendations for good professional practices.

• ***Persistent shortcomings :***

➡ **A surveillance and warning system lacking clarity**

The surveillance and warning system is complex, both from the regulatory and institutional viewpoints. Field operators do not always know what they must declare nor to whom.

Many are the legal and regulatory obligations. Four types of signalling obligations can relate to a radiotherapy incident:

- The obligation for any health care player to declare serious undesirable events;
- The obligation imposed on operators of nuclear facilities to declare incidents to the ASN;
- The obligation for State representatives to inform the InVs of signallings of threats to the population's health ;
- The obligation for manufacturers and users of radiotherapy devices to signal to the Agence française de sécurité sanitaire des produits de santé (AFSSAPS – French agency for health product safety) incidents or risks of incidents having led to or likely to lead to the death of or serious damage to the health of a patient, a user or a third party.

In addition, the administrative landscape lacks clarity: five administrations or agencies are competent at national level in the radiation protection field. The ASN, Institut de veille sanitaire (InVS – Health surveillance institute), AFSSAPS, IRSN and Direction générale de la santé (General Health Directorate) must therefore make a major coordination effort every day.

➡ **Notorious insuffiency of clinical and epidemiological data on the follow-up to radiotherapy**

In France there is no register of the rate of late complications of radiotherapy treatments. Epidemiological studies are not therefore readily available. Such a situation can be largely explained by the insufficient follow-up of patients. To say the least, the clinical follow-up protocols of patients vary greatly between centres. In the case of the Epinal centre, the lack of follow-up is believed to have been a decisive cause of the non-detection of dysfunctionings that led over long periods to serious damage to patients.

Whereas the funds allocated to cancerology research are high and have led to

major progress, no significant financial support programme is devoted to research on radiotherapy complications. Yet France has an internationally recognised network of players specialised in the medical management of accidental irradiations, which is formed by Percy military hospital, the armies blood transfusion centre, Saint-Antoine hospital and the IRSN. This network therefore proposed to the Epinal patients an innovative cell therapy treatment by mesenchymal stem cells. This type of treatment must be supported within the framework of genuine research programmes, especially to improve the treatment of pain following radiant burns.

➡ **Unsatisfactory checking of equipment before start-up**

Radiotherapy equipment is increasingly complex, featuring highly sophisticated automatic ballistic adjustment mechanisms of ionising radiations, run by integrated software. However, most of these pieces of equipment do not allow the radiotherapist to check on the spot, during sessions, the dose indeed delivered or its spatial geometry. The IRSN feels that the checking of this equipment, which intrinsically bears considerable radiological risks, should be strengthened, so that its methods are brought closer to the checks carried out at nuclear facilities, by using in particular the 'defence in depth' principle.

Radiation protection and quality assurance : professionals on the front line

● **Professionals increasingly aware of risks**

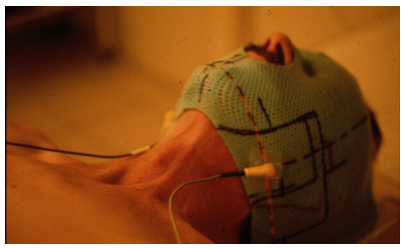
In radiotherapy there are two types of risks: **risks of complications** and risks of accidents. The former are an integral part of the therapeutic plan, are partially known and above all, thanks to new technologies, have greatly decreased. In effect, all the recent radiotherapy progress has led to better ballistic precision allowing the tumour to be better targeted and therefore sparing as much as possible the surrounding healthy tissues. The second type of risk is, by definition, not planned and unacceptable. The **risk of an accident** can be controlled only by faultless quality assurance throughout the patient's journey. This quality assurance approach naturally existed before the 'electric shock' caused by the dramatic accidents at Epinal and Toulouse. The initial training of professionals includes learning security behaviours and the teams involved are made aware of the risks of accidents. However, the serious recent accidents have opened professionals' eyes to the vulnerability of radiotherapy practices with regard to the safety principle.

● ***Essential additional means for the rapid roll-out of a safety culture***

Quality assurance must firstly be based on coherence between the radiotherapy teams grouping three professions around the patient: radiotherapists, medical physicians and radiographers. It must be based on the signalling of the slightest 'precursory events' with a systematic feedback of experience, as is the case at nuclear power plants or in the air industry.

Risk control therefore entails the optimisation of procedures and traceability of practices. The involvement of services in such a quality assurance approach cannot be achieved with constant means.

The workforce must be rapidly strengthened and most considerably, especially regarding medical physicians. The continuing education of personnel must be generalised and regularly updated given the constant evolution of technologies, so as to guarantee the application of new recommendations: tumours radiotherapy guide drafted by the Société française de radiothérapie oncologique and quality assurance reference guidelines; approval criteria decided by the INCA within the framework of the authorisation of cancerology care activities, among which appears the major criterion of *in vivo* dosimetry security.



Detectors on the patient of the dose really received

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