Existing challenges with respect to the transposition of the BSS regarding generic justification

Case study : France

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Article 55. 2.a

“ new types of practices involving medical exposure are justified in advance before being generally adopted”

CONTENT

1. Tomosynthesis
2. Intraoperative radiotherapy
3. New techniques in radiation therapy

Tomosynthesis


RAPPORT

IRSN
INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE

Faire avancer la sûreté nucléaire

La tomosynthèse

Rapport d'étude bibliographique
PRP-HOM n°2015-00008

Pôle radioprotection, environnement, déchets et crise
Service d'études et d'expertise en radioprotection
Unité d'expertise en radioprotection médicale

In February 2016, IRSN published a report on tomosynthesis in France with several recommendations and warnings

http://www.irsn.fr/FR/expertise/rapports_expertise/radioprotection-homme/Pages/Rapport-IRSN-PRP-HOM-2015-00008-Tomosynthese.aspx

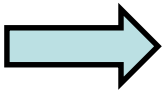
Tomosynthesis

Extracts of the IRSN report

Extract 1:

“Although its place and clinical indication are not still clearly defined, tomosynthesis is already used in France.

The introduction of this technique within the national breast cancer screening program seems to be foreseen by the Authorities in the coming years.”



It seems to be already (generally) adopted with no justification in advance

Tomosynthesis

Extracts of the IRSN report

Extract 2 :

“Most of the clinical trials validating the use of tomosynthesis were realized on systems of a single manufacturer. However, manufacturers’ strategies of design are heterogeneous. There is no unique technique of tomosynthesis but several, of which equivalence in terms of technical and clinical performances is not demonstrated. Due to the heterogeneity of the different models available on the French market, IRSN recommends not to extrapolate the results of clinical studies obtained on a specific system but to consolidate them for all the available systems.”

Several techniques to be considered

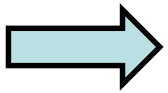
Tomosynthesis

Extracts of the IRSN report

Extract 3:

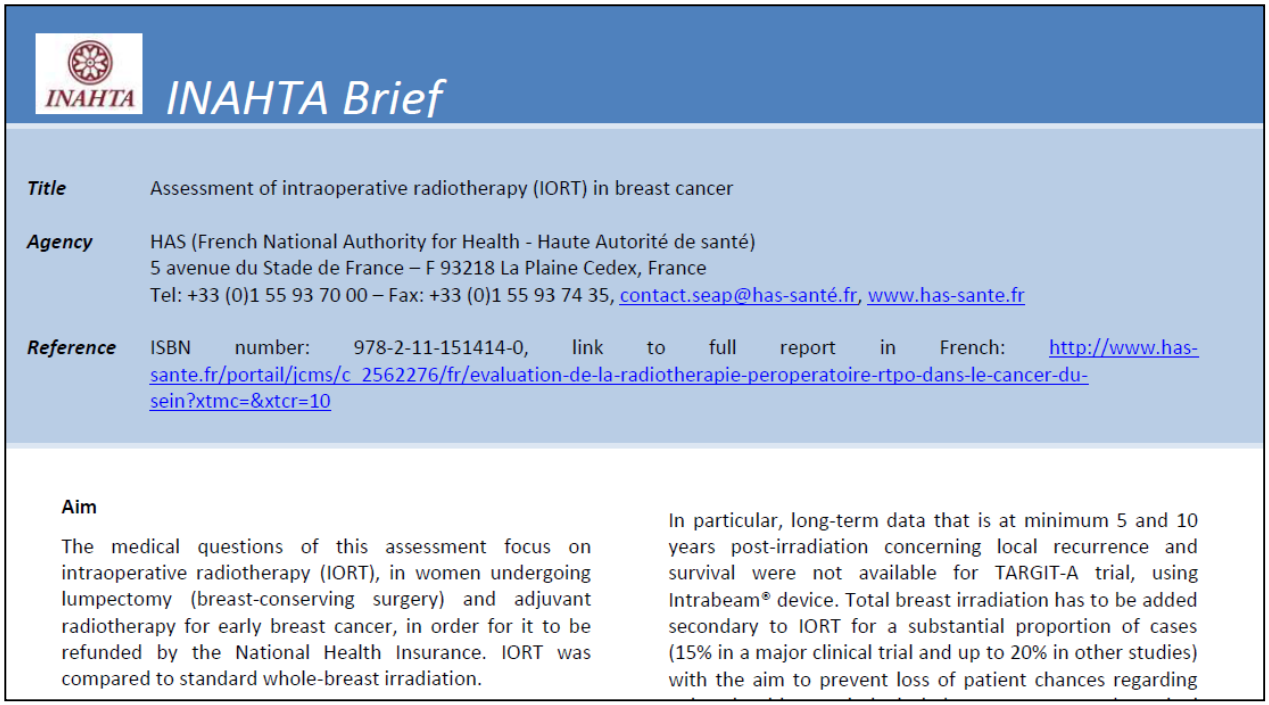
“In many imaging departments, tomosynthesis is already implemented in addition or in substitution of 2D mammography without any regulatory quality control and periodic technical checks. […] To be able to monitor the development of this technique, IRSN recommends to initiate as soon as possible works at national level on the quality control of tomosynthesis systems.

Tomosynthesis seems to deliver more dose than 2D mammography. The diversity in design of these systems leads to an expected variability of their behavior in terms of image quality and dose with breast thickness.”



New technique already in use with no QC framework and possible delivery of more dose than 2D

Intraoperative radiotherapy



INAHTA Brief

Title Assessment of intraoperative radiotherapy (IORT) in breast cancer

Agency HAS (French National Authority for Health - Haute Autorité de santé)
5 avenue du Stade de France – F 93218 La Plaine Cedex, France
Tel: +33 (0)1 55 93 70 00 – Fax: +33 (0)1 55 93 74 35, contact.seap@has-santé.fr, www.has-sante.fr

Reference ISBN number: 978-2-11-151414-0, link to full report in French: http://www.has-sante.fr/portail/jcms/c_2562276/fr/evaluation-de-la-radiotherapie-peroperatoire-rtpo-dans-le-cancer-du-sein?xtmc=&xtcr=10

Aim

The medical questions of this assessment focus on intraoperative radiotherapy (IORT), in women undergoing lumpectomy (breast-conserving surgery) and adjuvant radiotherapy for early breast cancer, in order for it to be refunded by the National Health Insurance. IORT was compared to standard whole-breast irradiation.

In particular, long-term data that is at minimum 5 and 10 years post-irradiation concerning local recurrence and survival were not available for TARGIT-A trial, using Intrabeam® device. Total breast irradiation has to be added secondary to IORT for a substantial proportion of cases (15% in a major clinical trial and up to 20% in other studies) with the aim to prevent loss of patient chances regarding

In April 2016, HAS published a report on intraoperative radiotherapy (IORT) in breast cancer : assessment in order to be refunded by the National Health Insurance

http://www.has-sante.fr/portail/upload/docs/application/pdf/2016-08/inahta_brief_iort.pdf

Intraoperative radiotherapy

Conclusion of the assessment:

"In conclusion, the available data are not mature enough to demonstrate that IORT is useful in adjuvant conservative breast cancer treatment in comparison with standard external whole breast irradiation.
As a consequence, at this stage, the elements are not gathered to support IORT payment by National Health Insurance.
Long-term data from clinical and medico-economic studies are needed to prove clinical utility of the IORT in early breast cancer. »

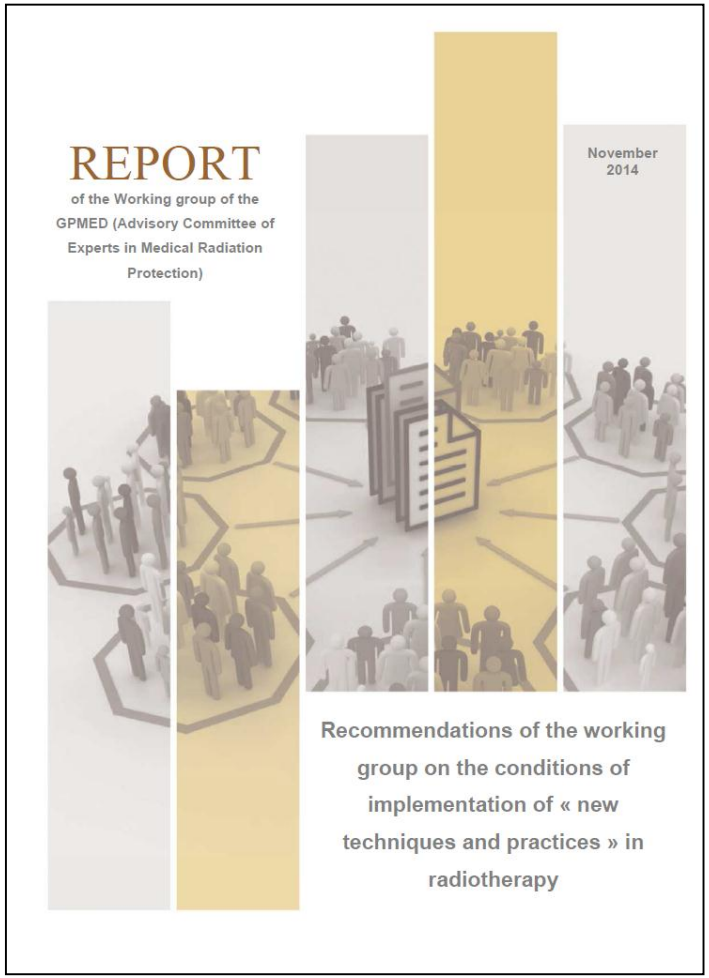
However, several hospitals (10 centers in 2014) propose this treatment to patients : what about generic justification?

Recommendations from HAS:

« HAS recommends eventually that IORT is performed exclusively in the context of clinical research in breast cancer »

How (by who/when) is defined the transition between clinical research and generic justification?

Conditions of implementation of new techniques and practices in radiotherapy



In June 2015, ASN published the report of its group of experts on the « conditions of implementation of new techniques and practices in radiotherapy »

http://www.french-nuclear-safety.fr/Media/Files/Recommendations-of-the-working-group-on-the-conditions-of-implementation-of-new-techniques-and-practices-in-radiotherapy

Conditions of implementation of new techniques and practices in radiotherapy

What is a new technique/practice in this report?

"A new radiotherapy technique and/or practice is defined as being a significant change that can concern treatment planning, the software, the performing/delivery of the treatment and the related quality controls. This notion of significant change corresponds to the processes which are not yet implemented in clinical practice at national level or in the centre concerned"

Conditions of implementation of new techniques and practices in radiotherapy

Observations from the WG

"In the course of the various hearings held during its work, the WG observed that the new techniques in radiotherapy are developing with insufficient recommendations and with no specific supervision in the current radiotherapy licensing systems"

⇨ *It seems to be generally adopted with no proper framework (regulatory, QC etc…)*

Conditions of implementation of new techniques and practices in radiotherapy

This report gives 12 recommendations. Among others :

R1: Creation of an Advisory Committee of Experts comprising professionals proposed by the learned societies, in relation with representatives of the Health and RP authorities concerned.
This committee would be tasked with:

- determining which device or technique requires new provisions,
- defining the prerequisites before implementing a new technique,
- detailing what new measures must be developed (training, quality control, informing patients, etc.)

R2: Organise clinical audits by peers

R7: Improve the testing of the technical and dosimetric performance (acceptance and quality control)

R9: Develop the prospective collection and analysis of data concerning the radiotherapy patients *-> see plenary session 5*

Conditions of implementation of new techniques and practices in radiotherapy

These recommandations have been brought at national level to the National Institute for Cancer (INCa) and have been studied during its annual national follow-up committee of radiotherapy measures (Sept 2016),

Some recommandations have been considered during the transposition of the BSS into the French regulation

The group of experts will be set up by ASN