National Experience of Clinical Audit:

The Norwegian Experience

Ingrid Bjørseth Heikkilä

DSA

Direktoratet for strålevern og atomsikkerhet

Norwegian Radiation and Nuclear Safety Authority

Contributors:

I do not have any conflict of interest to disclose

QA-group at DSA:
Dag Clement Johannessen
Eric Sundqvist
Gunilla Frykholm
Ingrid Bjørseth Heikkilä
Sverre Levernes
Taran Paulsen Hellebust

The Norwegian breast cancer group (NBCG):

Bjørn Naume	OUH
Erik Wist	OUH
Reino Heikkilä	OUH

Auditors:

Annette Andersen	OUH, Helse Sørøst
Arve Kylling	AAH, Helse Midt-Norge
Bernt Rekstad	OUH, Helse Sørøst
Christer Jensen	AAH, Helse Midt-Norge
Gun Anker	HUH, Helse Vest
Ingvil Mjaaland	SUH, Helse Vest
Jomar Frengen	SOH, Helse Midt-Norge
Kari Anne Haugen	OUH, Helse Sørøst
Kirsten Marienhagen	UNN, Helse Nord
Kristin Iversen	SUH, Helse Vest
René van Helvoirt	SHHF, Helse Sørøst
Tatiana Abramova	AAS, Helse Midt-Norge
Turi Danielsen	OUH, Helse Sørøst

Nine RT departments from all four Norway Regional Health Trusts participated in the audits

HELSE NORD HELSE MIDT-NORGE HELSE VEST HELSE SØR-ØST

DSA

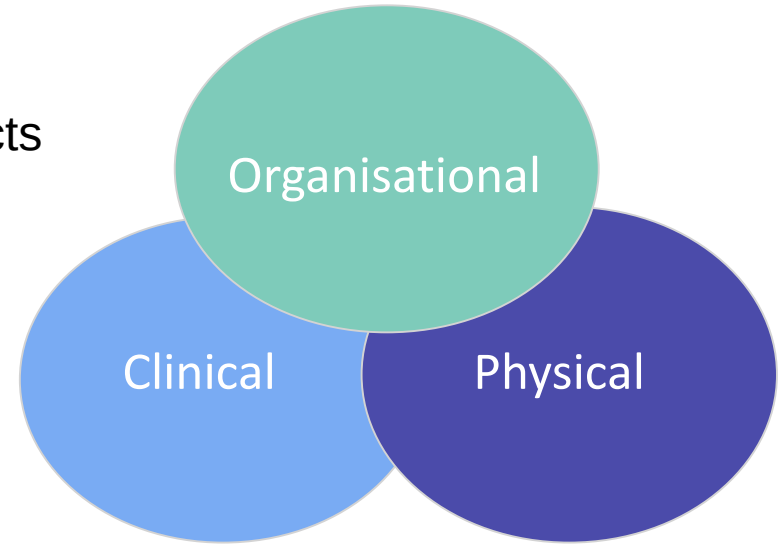
DSA Norwegian Radiation and Nuclear Safety Authority

Quality assurance in radiotherapy in Norway

A QA-program in radiotherapy (KVIST) was established at the Norwegian Radiation Protection and Nuclear Safety Authority (DSA) in 2000:

- Background - the planned expiation in radiotherapy capacity in Norway at that time

- The program was funded through the national budget
- The program encompasses organisational, clinical and physical aspects of radiotherapy, and is carried out in national projects.
- All QA-projects:
  - are multidisciplinary (oncologists, medical physicists, RTTs)
  - result in national consensus-based guidelines
- One QA-project was to establish a national system for external peer review clinical audits in radiotherapy



Hellebust et al. J Radiother Pract. 2014 Mar;13(1):35-44.

Clinical audits

Principles for Best Practice in Clinical Audit (NICE 2002):

«Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of patient care against explicit criteria and the implementation of change».

Clinical audits is about the patient, the clinical guidelines, the clinical practice and the willingness to change that practice when indicated

The Norwegian method

- Decided on external, peer review, site-visit audits
- Established a multidisciplinary task group with professionals with broad experience in RT
  - Identified national guidelines relevant for the audit topic (audit standard)
  - Defined a set of audit parameters (audit criteria)
  - Established a pool of 20 auditors for the nine planned audits

- Sent invitation to hospitals with RT departments
  - Described the purpose of the audit
  - Scope of the audit
  - Organisational preparation needed for the audit team
  - Access to PJ, RT journals, workspace

- Set a time and date suitable for RT department and auditors

The Norwegian method

On-site, during audits:

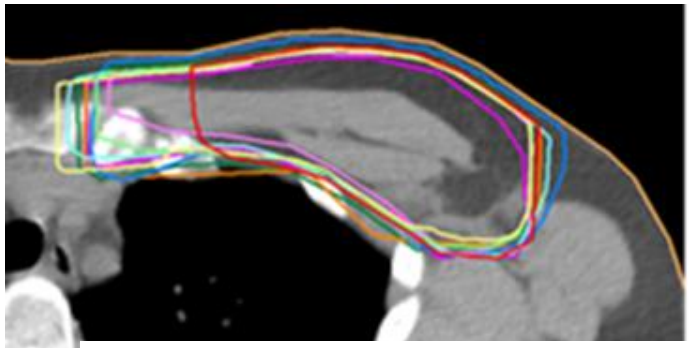
- Declarations of confidentiality were signed by auditors before the audit could start
- Opening meeting (hospital staff and management)
- Audits:
  - Oncologists evaluated clinical criteria against audit standard
  - MP and RTTs evaluated physical criteria against audit standard
- Closing meeting
  - Presented audit results
  - Discussion – RT challenges and possible solutions

Audit report to the hospital – sent from the audit team (not from the DSA)

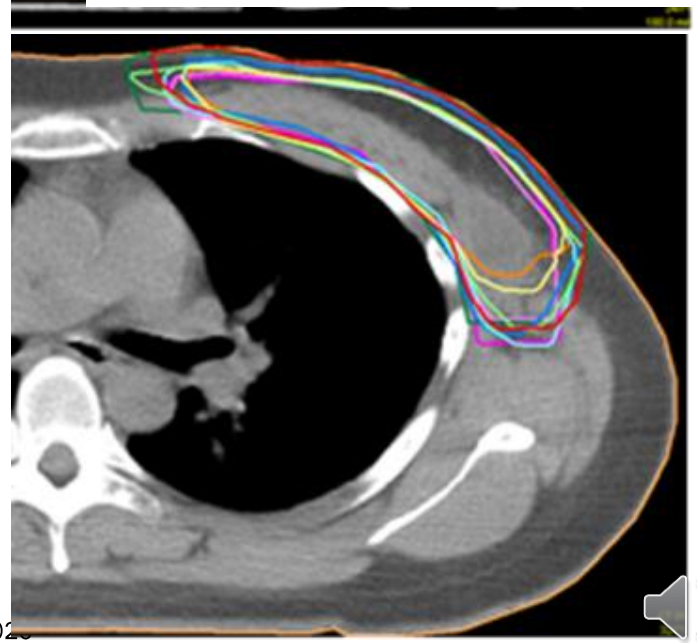
Final national report presenting (anonymous) audit results, analyses and recommendations.

Audit Topic – RT-breast cancer

- RT for breast cancer was chosen to be our audit topic.
- Results from a national workshop on RT for breast cancer in 2008, suggested some deviance between the national guidelines criteria for RT for breast cancer and clinical practice in the RT departments. Each coloured line in the pictures to the right, represent the delineation from each individual hospital.
- Audit standard was the guidelines for the diagnostics, treatment and follow up for breast cancer, approved by the Norwegian Directorate of Health
- Audit criteria were clinical indication to treat, prescription, delineation and dose distribution to the treatment volumes and the OARs.



Each coloured line represent the delineation of treatment volumes for one hospital



Materials and methods

- In each hospital, we selected 20 consecutive patient files from the1st of January 2009. That made a total of 180 patient files and about 10% of all patients treated with RT for breast cancer in Norway that year.

- Each patient file was evaluated by using about 100 audit criteria

Example clinical audit criteria

3.2.2	**Definition of CTV**
3.2.2.1	CTVbreast/chestwall adequat in depth (to m. resp costae)
3.2.2.2	CTVbreast/chestwall caudal border
3.2.2.3	CTVbreast/chest wall cran border (axillary tail included?)
3.2.2.4	CTVbreast/chest wall med border
3.2.2.5	CTVbreast/chest wall lateral / posterior border
3.2.2.12	Margins from CTV to PTV
3.2.2.13	**Conclusion: Definition of CTV**

Example physical audit criteria

3.2.3	**Dose to CTV breast/chest wall** , DVH (50Gy to CTV)
3.2.3.1	Mean dose (Gy)
3.2.3.3	Max dose to CTV (Gy)
3.2.3.4	Min dose to CTV (Gy)
3.2.5	**Dose to the heart and lung**
3.2.5.5	The heart, V25Gy (%)
3.2.5.8	Left lung V20Gy (%)

Audit results

Audit criteria against audit standard	1: Achieved		2: Small deviations		Sum 1+2	
	n	(%)	n	(%)	n	(%)
Clinical indication	173	(99,5)	1	(0,5)	174	(100)
Prescription	170	(98)	4	(2)	174	(100)
CT for dose planning	172	(99)	2	(1)	174	(100)
Delineation CTV	87	(50)	77	(44)	164	(94)
Delineation heart	88	(51)	75	(43)	163	(94)
Dose prescription	174	(100)	0	(0)	174	(100)
Dose distribution clinical evaluation	152	(89)	19	(11)	171	(100)
Dose to heart	161	(94)	9	(5)	170	(100)
Dose to ipsilateral lung	167	(98)	4	(2)	171	(100)
All clinical audit criteria					***150***	***(87)***
Mean dose CTV	*171*	*(100)*	*0*	*(0)*	*171*	*(100)*
Max/min CTV	*145*	*(65)*	*52*	*(30)*	*163*	*(95)*
Dose constraints heart	*155*	*(91)*	*10*	*(5)*	*165*	*(96)*
Dose constrains lung	*152*	*(89)*	*13*	*(7)*	*165*	*(96)*
All physical audit criteria					***131***	***(77)***

Audit standards were achieved for:

- the indication for RT (justification)
- the dose levels and treatment technique

Audit standards were not completely achieved in three areas:

- the delineation of CTV and heart
- the dose distribution to CTV
- the dose constraints to the heart

Clinical audit criteria were achieved completely or with small deviance to the national guideline principles for 87 % of the patients.

Dose planning audit criteria were achieved completely or with small deviance to national guideline principles for 77 % of the patients.

Conclusion

- Audit standards were achieved for a majority of the audit criteria

- The clinical evaluation of the audit criteria regarding dose distribution was less rigid than the dose planning evaluation (87% vs 77%):
  - This may suggest that the auditors evaluated the clinical significance of low or high dose spots within the treatment volume to be of minor importance??
  - This emphasize the importance of both qualitative and quantitative evaluation of patient files as well as multidisciplinary clinical discussions during the audits.

Follow up; recommendations

The auditors, RT professionals and the guideline group at the Norwegian Directorate of Health agreed that there was a need to improve guideline specifications for:

- delineation of CTV and OAR
- criteria for balancing dose to CTV towards dose to OARs
- improved techniques to reduce dose to the heart (this was before gating was implemented as routine treatment in all RT departments in Norway)

They also agreed that repeated clinical audits with the same topic was welcomed:

- using the same audit criteria, and adding
- waiting times between surgery and RT
- patient positioning through the treatment course

Experience

The clinical audits were welcomed in the RT community.

External audits are expensive, and we were fortunate to get funding through the National budget.

Clinical audits must be anchored in the hospital management and by the professionals:

- There must be a will prioritize and give the necessary time to the audits.
- There must be a will to change clinical practice if necessary
- There must be an opportunity to propose changes to national clinical guidelines if necessary.

Clinical audits do not necessarily have to be external:

- Several hospitals have performed internal clinical audits using new and updated national guidelines as the audit standard.