

acute phase and adjusting to long-term effects often impacts on mood, identity, body image and sexuality, social roles and family function; cognitive deficits have also been noted. This service development project aim was therefore to develop a new model of care to optimize outcomes through prevention and screening. This challenged the clinical teams to develop the necessary multidisciplinary working skills and bio-psychosocial models of care to respond adequately to the needs of patients and their families.

**Methods:** The multidisciplinary team developed the Standard Operating Procedure (SOP) to include guidelines on screening investigations. Service level agreements were arranged with expert clinicians. A locally developed patient questionnaire was designed to include screening questions on the full range of bio-psychosocial late effects.

**Results:** Physical late effects were frequently encountered, for example, cGVHD was evident in 44% patients (n=50); bone loss was evident in 38% of patients with 8% requiring bisphosphonate and calcium therapy for osteoporosis; 16% of patients reported shortness of breath or persistent cough and these patients were referred to the specialist chest physician. All patients were referred for vaccination. The evidence gathered in our clinical practice suggests that patients rank psychosocial concerns highly. For instance, cognitive (identified as a problem by 55% of patients), emotional (40%) and sexual (35%) problems were ranked just below fatigue (75%), and above hormonal (15%), lung (20%) and GVHD (25%) problems. Twenty per cent of patients were referred to specialist in endocrine and sexual function. Further analysis demonstrated that around 30% of patients experience persistent low mood, anxiety, and body image concerns, though as a group patients also reported high levels of self-efficacy and a coherent understanding of their condition.

**Conclusion:** This model of care demonstrates late effects are being identified and pro-actively managed with the aim of optimizing outcomes. The evolving service model using evidence from our clinical practice seeks to address these issues and we conclude with recommendations for future research and clinical development.

## Scientific Symposium (Mon, 21 Sep, 16:15–18:15) Head and neck cancer treatment – how aggressive should we be ?

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INVITED

### New developments in larynx preservation

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Over the past 3 decades an intensive clinical research has been carried out with the goal of preserving the larynx function by the means of non surgical alternatives to total laryngectomy. The challenge was and remains to propose an alternative to mutilating surgery that provides at least similar chances of cure and survival, that does not generate side effects compromising the laryngeal function and that has an acceptable overall toxicity.

The 1st generation of larynx preservation (LP) trials compared surgery to induction chemotherapy (ICT) with cisplatin and 5FU (PF) followed by radiotherapy (RT) in good responders (VA and EORTC 24891 trials). The larynx could be preserved in nearly 60% of the cases without compromising either the survival or the disease control.

The 2nd generation of LP trials compared PF-based ICT strategy versus concurrent chemo-RT with cisplatin (CRT). The LP rate was higher in the CRT arm (84%) but with a substantial toxicity (RTOG 91–11). In the same frame, PF-based ICT strategy was compared to alternating chemo-RT (ART). There was no difference in LP but the acute toxicity was lower in the ART arm (EORTC 24954).

The appearance of molecular targeted therapies and of taxanes provided new data for this research. Cetuximab added to RT provided in a phase III trial better overall (OS) and progression-free (PFS) survivals than RT alone (Bonner J). Docetaxel added to PF (TPF) provided in 2 phase III trials (TAX 323, TAX 324) better OS and PFS than PF as ICT regimens before RT. A French LP trial (GORTEC 2000–01) compared TPF vs PF followed in both arms by RT in good responders found a higher LP (72%) in the TPF arm but as in the previous LP trials the survival was unchanged. The TAX 324 trial showed that sequential chemo-radiotherapy (SRT i.e. ICT followed by CRT) was feasible and in a subset of larynx-hypopharynx cases LP appeared also higher in the TPF arm.

The tolerance of the overall SRT treatment could be a concern. With this in mind, another French (GORTEC-GETTEC) randomized phase II LP trial (TREMPLIN) compared in good responders after 3 cycles of TPF in one arm CRT with in the other arm RT with cetuximab (RTE). The LP rate 3 months after the end of treatment was similar in both arms but the overall toxicity profile was more favourable in the RTE arm.

In a 3rd generation of LP trials, 3 approaches could be now challenged: CRT versus TPF and RT versus TPF and RTE, such a trial is under discussion.

## Scientific Symposium (Mon, 21 Sep, 16:15–18:15) Quality assurance and audit in colorectal cancer in Europe

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INVITED

### The Norwegian programme

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**Background:** The Norwegian Rectal Cancer Project was launched in 1993. Prior to the project the prognosis of rectal cancer was very poor in Norway. The aim of the Norwegian programme was to improve the quality of rectal cancer treatment.

**Material and Methods:** The Norwegian Rectal Cancer Registry is a separate part of the Norwegian Cancer Registry, thus securing enrollment of every case of rectal cancer into the database. Since 2007 colon cancer has been included. A national teaching programme has included gastrointestinal surgeons, radiologists, oncologists and pathologists. It was recommended that the surgery should be performed by certified gastrointestinal surgeons specifically trained in total mesorectal excision after attending courses with live demonstrations of this technique. Radiologists have been trained in CT and MRI scanning, and pathologists have been taught modern principles of detailed examination of the specimen and standardised reporting. Every department that treats colorectal cancer receives regular feedback of their performance. These reports include their own results and the national means for comparison. During the first six years, the project was funded by The Norwegian Cancer Society, a non-profit organization. Since 2000 the project has been funded by the Ministry of Health.

**Results:** Prior to the project, in 1986–88, a national audit reported that for rectal cancer patients younger than 75 years treated for cure the 5-year survival was 55%. During the first six years of the project (1993–99) (n=3388), the 5-year survival for this group was 71%. The 5-year local recurrence was 28% before the project, 18% in 1994 and 9% in 1999. At the same time, the rate of anastomotic leakage was reduced from 17% in 1994 to 8% in 1999. During the project, the use of chemoradiotherapy increased from 4% in 1993–1997 to 15% in 2002–2004.

These results were national means, but a considerable variation was observed between single hospitals (2–35% local recurrence), and also for single hospitals from one period to another. Haugesund Central Hospital had 31% local recurrence in the period 1993–1998, 11% in 1999–2001, and 6% in 2002–2004. Since 2005 there have been no local recurrences in patients treated at this hospital. Several steps were taken in order to improve standards of care at this hospital: only specially trained gastrointestinal surgeons were allowed to perform rectal cancer surgery, and a gastrointestinal oncologist, as well as an MRI radiologist and a pathologist were recruited, thus establishing a multidisciplinary team of dedicated experts deciding treatment for every patient at weekly meetings. These steps had been recommended by opinion leaders at the national courses. During the project, the number of hospitals treating rectal cancer in Norway was reduced from 55 to 25. Due to increased survival, 2500 lives were saved in the period 1993–2007. For this period, the cost of the project was 1.5 million Euros, and the cost of each saved life was 600 Euros.

**Conclusions:** Nationwide quality assurance is a continuous process best performed within audits. For rectal cancer treatment, improved standards of care may be explained by healthcare structures and processes of care. Thus, surgeon skill and competence are not sufficient. For complex procedures, the skills of other clinicians and the hospitals organizational skills are equally important.