and might also lead to the identification of candidate genes for single nucleotide polymorphism (SNP) association studies. So far, most of the SNP association studies reported have been limited by the inclusion of a small number of investigated genes and low numbers of patients with different kinds of normal tissue toxicity. Future genetic association studies will be equally impeded by the difficulties in identifying relevant candidate genes, characterising well-defined clinical and biological phenotypes, and handling of the many confounding factors. International collaborations to assemble appropriate cohorts and technological developments (like the ESTRO GENEPI project) will hopefully lead to the identification of potential markers and assays, and validation of genetic markers through the use of candidate gene approaches and whole genome association studies.

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After cancer therapy, prevention and promotion

64 INVITED

Optimal approaches to post treatment recovery: multidisciplinary team working

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Most survivors of adult cancers will not experience serious long term effects of cancer treatment but even with the best modern surgery, radiotherapy, hormone and biological treatments, it is not possible to cure cancer without the risk of damage to normal tissues.

In the UK alone it is estimated that there are currently 500,000 people experiencing a long term effect with an adverse effect on health and well being.

Some problems start during treatment and resolve within a few weeks or months, others begin during treatment and persist, still others may not appear until months or years later. This long time frame offers challenges to characterizing populations with particular needs, describing and populating care pathways and developing the teams with the competency to respond to different levels of need. There are challenges in supporting and educating primary care, both to detect and manage new chronic survivorship conditions and to recognize the increased incidence and severity of common chronic conditions (e.g. cardiovascular disease, diabetes and osteoporosis). Establishing and testing specialist multidisciplinary services for those with the most severe complex multi organ effects is particularly difficult in the current financial climate. Testing through the UK NCRI consequences of cancer treatment workstream has suggested some early learning.

65 INVITED

Exercise for disease prevention and health promotion in cancer survivors

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Background: The transition from primary cancer treatment to survivorship can be a challenging one marked by chronic and late effects such as functional limitations, fatigue, psychosocial distress, poor quality of life (QoL), weight gain, disease recurrence, and increased risk of other chronic diseases. These challenges have generated interest in behavioral strategies that might improve QoL, reduce the risk of disease recurrence, and extend survival in cancer survivors. One lifestyle factor that has received significant research attention is exercise or physical activity (PA). The purpose of this presentation is to provide an overview of research examining the effects of PA on supportive care and disease endpoints in cancer survivors that have completed primary treatments.

Materials and Methods: An overview of the literature of previous exercise intervention trials and observational studies conducted during the survivorship phase.

Results: Several recent meta-analysis have summarized the research on PA and supportive care endpoints in cancer survivors. These systematic reviews have reported favorable effects of PA interventions on physical fitness, quality of life, fatigue, and psychosocial outcomes. Interestingly, these reviews have observed that the effects of PA interventions on supportive care endpoints may be larger during the survivorship phase compared with the adjuvant treatment phase. This finding is important given that 50% of cancer survivors indicate that they would prefer to start a PA program after they have completed their primary treatments. Most studies to date have focused on breast cancer survivors, however, several recent observational studies using cross-sectional designs have reported positive associations between PA and QoL in understudied cancer survivor groups such as multiple myeloma, brain, ovarian, endometrial, bladder, colorectal, lung, and non-Hodgkin lymphoma but few randomized trials have been conducted in these groups. Within the last five years, researchers have begun to examine the association between postdiagnosis PA and disease endpoints in cancer survivors. Several recent large epidemiologic studies have shown that higher levels of PA are associated with a lower risk of disease recurrence, cancer-specific mortality, and longer survival in breast and colon cancer survivors. Nevertheless, all of the studies to date are based on observational data.

Conclusions: Overall, research indicates that PA interventions are safe and feasible for several cancer survivor groups and result in favorable improvements in physical fitness, QoL, fatigue, and psychosocial outcomes. More recently, prospective observational studies have provided evidence for an association between PA and disease endpoints but the causal role of PA on disease outcomes has not been established. In Canada and Australia, we have launched the Colon Health and Life-Long Exercise Change (CHALLENGE) trial, which is a multinational, multicenter randomized controlled trial designed to determine the effects of a 3 year structured PA intervention on disease-free survival in stage II and III colon cancer survivors who have completed adjuvant therapy within the previous 2−6 months. If this research confirms that PA improves disease-free survival in colon cancer survivors, there will be a strong case for implementing PA programs in the cancer setting to improve both QoL and disease outcomes.

66 INVITED

Assessment of young adult survivors needs: building an evidence-based late effects service

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There is now strong evidence from late mortality and morbidity studies to support the establishment of late effects services for childhood, adolescent and young adult cancer survivors. The requirements of the service are more difficult to determine. Cancer survivor's needs change over time. This is influenced by at least two factors. Firstly cancer determined factors like the patients age at diagnosis, the treatment received, the interval from end of treatment, and the natural history of late sequelae. Secondly the age of the survivor at follow-up, whether still a child, adolescence or adult and their expectations.

The aim of a late effects service is to enable the survivor to reach their maximum potential in all aspects of a multidimensional quality of life. To enable this to occur, input is important from multidisciplinary teams, survivors, their families and the community. From a medical perspective the aims of follow-up are to detect late effects early and treat as necessary. To educate survivors regarding self management to help decrease the effects of treatment. The degree of input from health care professionals varies enormously from minimal follow-up to hospital based multispecialist clinics depending on the risk and type of late sequelae. The provision of care needs to be flexible and individualised for each survivor.

Assessment of needs must involve survivors. Reports from focus group work with survivors have all highlighted the need for comprehensible information regarding late effects of treatment from knowledgeable health care professionals with good communication skills. They often state that they wish to be in control of their follow-up care but are aware that their involvement with professionals will vary. They want the ability to make contact with a key worker in the late effects service as required and for many it is important to move on in their lives and leave their medical history behind.

The evidence for the need of a late effects service is present but to date there are no studies on the cost benefits of such a service. More research is needed to assess different models of care and to determine the effects of new treatments.

67 INVITED

Managing late effects following haematological malignancy and BMT

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Background: More than 40,000 haematopoietic stem cell transplants (HSCTs) are performed worldwide each year and with improvement in technology and care more patients now survive. However there are late complications that can cause substantial morbidity. Furthermore HSCT poses significant challenges to the surviving patient's longer-term adjustment due to the frequent, ongoing presence of treatment late effects and vulnerabilities. Late effects include chronic Graft versus Host Disease (cGvHD), immune deficiency, lung, liver, cardiac, endocrine, dental and ocular effects, sexual dysfunction, osteoporosis, hypercholesteraemia, secondary malignancies and late graft failure. Functionally, patients experience significant fatigue and weakness and consequent difficulties with resuming work, family and leisure activities. Psychologically, recovering from the 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.

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Head and neck cancer treatment − how aggressive should we be ?

70 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 compromizing 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 24891trials). The larynx could be preserved in nearly 60% of the cases without compromizing 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 substancial 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 int he 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.

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Quality assurance and audit in colorectal cancer in Europe

73 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, in1986−88, 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.