FECS Presidential Session: FECS/EJC Award

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Using clinical competencies to underpin cancer and palliative care education for nurses

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Background: Developing clinical assessment tools for nursing education has been agonised over for many years without producing a tool that delivers rigor, objectivity and reliability. This problem becomes even more acute when applied to nurses undergoing post-registration training. An eighteen-month clinical rotation programme was developed in South East London that aimed to give nurses experience caring for patients across the spectrum of cancer and palliative care. A tool was required that could both direct nurses to seek exposure to all aspects of the patient's journey, and could demonstrate clinical knowledge and skill, that together can be seen to make up "competence". This paper will provide an overview of the process of development of clinical competencies and the domains which they were comprised. Examples of evidence produced by the students will be presented.

Development: Initial work was undertaken in developing competencies by using focus groups of clinical nurses from settings across the region. A smaller sub group then developed the competencies using regular consultation with clinical experts. Guiding principles for developing the competencies were that they should:

Reflect skills of good basic registered practitioners working in cancer and palliative care settings.

Be skills-based rather than aiming to directly measure knowledge

Be fulfilled by collecting evidence to demonstrate those skills.

Reflect all the specific phases of the cancer trajectory

Reflect role development of a qualified nurse

Outcomes: The competencies have been trialed by the first cohort of rotation nurses. Producing evidence and completion of the competencies has been time consuming, with some being difficult to meet. Much of the written evidence has been reflective and insightful and can be seen to illustrate high quality care.

Conclusions: As a tool to demonstrate consistent, competent clinical performance, proof remains elusive. However, the competencies have met their objective of directing learning across the patient's journey and helped nurses join the different facets of care together, helping them to support patients and families through their illness.

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A randomized trial with 1485 patients evaluating the importance of accelerated versus conventional fractionated radiotherapy in squamous cell carcinoma of the head and neck. Final results of the DAHANCA 6&7 study.

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Aim: The trial was initiated to examine whether reduction of the overall treatment time by increasing the number of weekly radiotherapy fractions from 5 to 6 (and maintaining same total dose and fraction number) did improve the tumor response, and were acceptable with regard to early and late morbidity.

Patients and methods: Pts. eligible for primary radiotherapy alone were randomized between 5 or 6 weekly fractions of radiotherapy (66-68 Gy in 33 to 34 fx). All patients, except those with glottic cancers, were also treated with the hypoxic radiosensitizer Nimorazole. Patients were recruited from all Danish institutions and from the Norwegian Radium Hospital in Oslo. Between January 1992 and December 1999, 1485 patients were randomized and 1476 eligible patients were included in the analysis. More than 97% received the planned total dose. The median treatment times were 46 and 39 days in the 5 and 6 fx/wk arm, respectively.

Results: Overall, the results showed a benefit in 5-year loco-regional control (58% vs 67% (p=0.001) for the 5 vs 6 fx/wk arm, respectively. The effect of overall treatment time appears especially to occur in the T-site (62% vs 73% for 5 vs 6 fx/wk respectively, p=0.0001), whereas the response in the neck nodes was not significant different. The benefit in T-control was also reflected in an improved conservation of larynx and voice in 908 patients with laryngeal cancer (68% vs 80% for 5 vs 6 fx/wk, p = 0.007) The benefit in tumor control resulted in a significant better overall disease-specific survival (66% vs 73% for 5 vs 6 fx/wk respectively. p=0.01), whereas there was no significant difference in overall survival. Acute morbidity in the form of severe mucositis was significantly more frequent in the 6 fx/wk group, but there were no difference in late radiation side effects.

Conclusion: The accelerated schedule was considered superior to conventional fractionation, and has now become a new standard baseline treatment for larynx and pharynx carcinoma in Denmark.

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Adjuvant chemotherapy in colorectal cancer: Joint analyses of randomised trials by the Nordic Gastrointestinal Tumour Adjuvant Therapy Group

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Background: The US NCI consensus conference recommended in 1990 adjuvant therapy for colon cancer stage III and rectal cancer stages II + III. The recommendations were not immediately accepted in the Nordic countries. Separate trials with a surgery alone group were initiated, first in western Denmark and Stockholm, Sweden and subsequently in the rest of Sweden and Norway. The aim of a joint analysis was to gain further insight into the benefits of adjuvant chemotherapy when used as in routine care at many hospitals in colon and rectal cancer stages II and III.

Patients and methods: Between 10/91 and 12/97, 2 225 patients with a curatively resected colorectal adenocarcinomas stage II and III below 76 years of age were randomised between surgery alone or chemotherapy. The chemotherapy varied between the trial, either the original Moertel scheme (n=445) for 12 months, a modified Mayo Clinic schedule alone (n=164) or with levamisole (n=95) for four months (4 courses) or the Nordic FLv schedule, alone (n=246) or with levamisole (n=152) for 4 and a half months (10 courses). Early randomisation and treatment initiation were emphasised but different time limits were set (4 to 10 weeks). Minimum follow-up was 4 years.

Results: Between 5 7% of patients randomised to surgery alone received adjuvant chemotherapy and a similar proportion randomised to chemotherapy did not receive any treatment. Treatment started after median 50 days (range 34 58 days in the separate trials). Between 46 and 73% of the patients received the treatment as intended in the various trials. In all randomised patients, there was no statistically significant survival benefit (p=0.1) according to an intent-to-treat analysis. Neither was there a statistically significant benefit in colon cancer stage III (n=760) with 5 year overall survival of 49% in the surgery alone group and 56% (p=0.2) in the chemotherapy group. There was no interaction between chemotherapy arms.

Conclusions: When several Nordic pragmatic trials totally including 2 225 patients were analysed together, no statistically significant overall survival benefit from adjuvant chemotherapy was detected, neither in the entire material nor in colon cancer stage III. The results for colon stage III in these trials do, however, not differ statistically from those in other trials

revealing significant differences. The gains of adjuvant chemotherapy in colon cancer stage III are well established in the literature, but the benefits are comparably limited and may be even less if treatment is not provided as in the trials (early start after chemotherapy, 6 or more months of treatment, adequate compliance at least 60%).

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Analysis of the EORTC Melanoma Group 18952 randomized trial on 2 intermediate dose schedules of IFN-alpha2b compared with observation in 1388 patients with high risk melanoma stages IIB-III

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Introduction: EORTC 18952 is the largest adjuvant IFN trial ever conducted in melanoma. The efficacy of intermediate doses of IFN-α 2b (10 MU qd, 5d/wk,sc,4 wks followed by either (arm A) 10MU, sc, tiw, for ONE YEAR, or by (arm B) 5MU, tiw, sc for TWO YEARS, was compared to observation (arm C). in 1388 patients with high risk melanomas (T4N0M0, anyTN1-2M0). The intent-to-treat analysis has been used.

Results: A total of 740 pts developed distant metastases and 648 died; the median follow up was 4.2 yrs. The differences between the 3 arms were not statistically different neither in terms of distant metastasis free interval (DMFI) (p=0.22) not in terms of survival (p=0.40).

Endpoint		Control	1-year IFN-α 2b	2-year IFN-α 2b
Distant Metastasis-	4-year rate (SE)	44.4% (3.1%)	44.6% (2.2%)	48.7% (2.2%)
Free Interval	HR (95% CI)	1	0.95 (0.79-1.16)	0.85 (0.70-1.04)
	P2-value		0.62	0.11
Survival	4-year rate (SE)	51.8% (3.1%)	53.0% (2.2%)	55.1% (2.2%)
	HR (95% CI)	1	0.99 (0.80-1.21)	0.89 (0.72-1.10)
	P2-value		0.88	0.27

HR: Hazard ratio

Treatment regimens were relatively well tolerated with an overall reporting of grade 3-4 toxicities in about 10% of the patients in the treatment arms A and B. In contrast to a very low rate of haematologic and hepatotoxic events the constitutional symptoms such as fatigue, anorexia and mood changes including severe depression were the most frequent causes for reductions, interruptions and for going of treatment early.

Conclusions: One year treatment with highintermediate dose (10 MU) IFN-α 2b showed no effect at all whereas 2-year treatment with the lower dose with 5 MU had a marginal effect that failed to reach significance. Duration may therefore well be of more importance than dose.

The question whether IFN is a cytokine that requires long term maintenance treatment for a significant improvement of outcome is presently addressed in the EORTC18991 trial which investigates the impact of 5 years of treatment with PEG-Intron in comparison to observation in stage III melanoma.

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Breast cancer screening - status and perspectives

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Randomised controlled trial from Sweden have demonstrated that it is possible to reduce the mortality from breast cancer when mammography screening is offered to women aged 50-69 every second year. Based on these results, service mammography screening is now offered throughout Europe. Screening is, however, testing of healthy women, and screening therefore has both potential advantages and potential disadvantages. It is, furthermore, not a straightforward task to customize the trial results to routine health care, and quality assurance is therefore needed of all activities in the service screening programmes. The presentation will review the outcome of service screening. It will include available data on the effect of service screening on breast cancer incidence and stage distribution, the effect on treatment, the occurrence of false positive tests, the occurrence of false negative tests as measured by the proportionate interval cancer rate, and the effect on breast cancer mortality.

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Prostate cancer screening - status and perspectives

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Screening for prostate cancer remains controversial in spite of positive indirect evidence that screening may effect prostate cancer mortality. This evidence is mainly related to the decreasing prostate cancer mortality in the US and to the so-called "Innsbruck screening study" which shows a 32% prostate cancer mortality in a geographical comparison. In the meantime, major randomized studies are ongoing in the United States and in Europe which will eventually produce the answer to most of the open questions. These relate to mainly: Does prostate cancer screening decrease prostate cancer mortality? What are the appropriate age-groups to be screened? What are the appropriate time intervals? At what time should screening commence? Can risk groups be identified which warrant more aggressive diagnostic strategies? Many of these answers will remain pending until the outcome of the ongoing randomized studies is known. However, intermediate endpoint evaluation at least give some clue. The European Randomized Study of Screening for Prostate Cancer (ERSPC) allows estimates of stage migration, leadtime, overdiagnosis, screening interval evaluation and other important features. The design of more appropriate screening tests is also subject of these protocols. Facts will be presented.

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Cervical cancer screening - status and perspectives

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Cervical screening has been the most successful cancer prevention programme ever implemented. However the approach does have limitations in terms of the infrastructure and expertise required, and is now more that 50 years old.

Ongoing audit is essential if high quality screening is to be maintained. The current performance of the England screening program will be reviewed. Results of a pilot audit based on the screening histories or lack thereof in women who develop cancer will be presented. Such audits should become routine for all organized screening programmes.

The human papilloma virus is now established as the primary cause in over 95% of all cervix cancers worldwide. It is readily detectable in material collected in a smear, and is an obvious candidate for screening. There are three potential roles for the test:-

i) Improving management in women with borderline or mildly dyskaryotic smears.

ii) Post-treatment surveillance to detect incomplete excision on CIN

iii) As a part of primary screening to improve sensitivity

HPV has better sensitivity for CIN 2/3 than cytology, and thus argues for its use in the first two situations. Questions of specificity are crucial in assessing its appropriateness in primary screening and a potential algorithm will be presented.

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Screening for colorectal cancer

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Organised screening for familial colorectal cancer (CRC) is in place in the Nordic countries, based on countrywide registers. Screening for metachronous neoplasia after curative treatment of sporadic CRC, usually is done by colonoscopy with intervals of a few years, but the predictive value of microsattelite instability may cause a substantial reduction of the number of colonoscopies.

Also colonoscopic follow-up in adenoma patients may bee limited, based on predictive value of different histopathologic features. Effectiveness of colonoscopic screening with multiple biopsies in patients with IBD is very minor.

The major impact on mortality from CRC will come from screening of the average population above 50 years of age. So far, the efficiency has been demonstrated in RCT's with fecal occult blood tests (FOBT's), and within the next few years flexible 60 cm sigmoidoscopy may be demonstrated to have a place in combination with FOBT's.

The evidence for a reduced incidence of CRC because of removal of polyps still is limited, but promising. Initial colonoscopy in average risk