Epidemiology/Education and public health

873 POSTER

A comparison of cancer drug approval between European and the United States ADN between cancer drugs and anti-HIV drug approval in Europe

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Purpose: Regulatory agencies have a responsibility to make innovative cancer drugs which are safe and effective available as speedily as possible so that cancer patients can benefit from their therapeutic effects. The purpose of this survey was to evaluate the time it takes the European Medicines Evaluation Agency (EMEA) to approve cancer drugs through its centralised procedure in comparison to the U.S. Food and Drugs Administration (FDA). A comparison of the time it takes EMEA to approve anti-HIV and cancer drugs was also undertaken.

Methods: Data on approval times for cancer and anti-HIV drugs between January 1995 and March 2001 was gathered from EMEA's and FDA's web-sites and analysed using descriptive statistics.

Results: The median time it takes EMEA to approve cancer drugs (n=21) is 471 days (range 301-812). In contrast, FDA has a median time to approval for new drugs (all classes) of 12 months and in Europe the median time for approval of anti-HIV drugs (n=19) is only 342 days (range 197-701). EMEA rarely uses a fast track approval procedure for cancer drugs with a high anticipated therapeutic benefit, whereas FDA has a priority drug review process where drugs deemed to have the greatest potential for medical benefit are approved on average within 6 months. In 1999, 5 out of 28 of FDA's priority drug applications were for cancer drugs. EMEA can approve drugs under exceptional circumstances, however since 1995 only 2 cancer drugs have been approved using this provision. Over the same period, EMEA approved 8 anti-HIV drugs under exceptional circumstances and FDA gave approval for 6 cancer drugs using its accelerated development and approval procedure (FDA equivalent of exceptional circumstances procedure. In addition, a number of cancer drugs approved by FDA since 1995 have not been approved by EMEA.

Conclusions: EMEA is slower than FDA in approving cancer drugs. Furthermore, EMEA approves anti-HIV drugs faster than cancer drugs and is more likely to approve anti-HIV drugs under exceptional circumstances. This means that European cancer patients are deprived of potentially effective treatments which are available for use in other parts of the world.

874 POSTER

Attitude toward genetic testing in Turkish society

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Background: Genetic testing may identify individuals with susceptibility to develop cancer later in life. It is not precisely known how people of various cultural backgrounds would respond if cancer risk information was available to them. Objectives:To survey several subsets of the Turkish society in order to identify attitudes toward genetic testing. To evaluate the effect that this information might have on decisions regarding issues such as pregnancy, abortion, and prophylactic surgery.Methods: One-hundred seventy nine individuals were chosen arbitrarily from four different subsets of Turkish Society(students, nurses, patients without the diagnosis of cancer, and caregivers of cancer patients) were asked to participate in a confidential 23 question survey.Results: Eighty five percent of the survey participants were familiar with the concept of genetic testing, 84,7% expressed interest in genetic testing in order to determine cancer risk, 56,9% would not change their marriage decision if they knew their future spouse had increased cancer risk, 62,6% would change their decision regarding pregnancy if they knew they were at inreased risk, 83,9% would have their fetus tested for such cancer risk, 65,1% would terminate their pregnancy if testing revealed an increased risk of cancer, 92,2% would have their children tested if they were determined to have an increased cancer risk, 67,6% would agree to undergo prophylactic mastectomy or prostatectomy if an increased cancer risk was detected, and 71,9% would agree to undergo prophylactic oopherectomy or orchiectomy if an increased cancer risk to these organs was detected. Subgroup analysis showed that women would prefer not to become pregnant if they knew that they carried an increased risk for cancer while men would not have changed their child-bearing decisions based upon this information(p=0,013). Women would want an abortion if their fetus was known to carry an increased cancer risk while men would not(p=0,000). Responses were not affected by marital status, education level or smoking habits except for general knowledge about genetic testing which was positively correlated with education level(p=0,000).Conclusions: It appears that at least the sampled segment of Turkish society is knowledgeable about and willing to undergo genetic testing to determine if they are at increased risk for cancer. They also appear prepared for prophylactic surgery or pregnancy termination if an increased cancer risk existed.

875 POSTER

Hospital tumour registry as source to generate indicators of quality of cancer care

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Research for appropriate methods of obtaining reliable data to assess Quality of Cancer Care is a priority task.

Objective: Hospital Tumour Registry might serve as source to generate indicators to assess the quality of cancer care in a hospital with no specific oncologic services.

Material and Methods: In our hospital, 834 patients were included in the 1999 database. 125 cases were in situ tumours or skin cancers. We define some parameters previously reported as quality indicators and look for completeness of the recorded data: Staging, Dates of biopsy and surgery, Pathologic confirmation, Early stage in breast cancer (I-IIA), Number of nodes examined in breast cancer, Conservative surgery in breast cancer, Hormone receptors determination, Assessment by a medical oncologist, Inclusion in a clinical trial.

Results: In 150 (21%) patients we could find any statement of the stage. In 691 out of 691(100%) the dates of biopsy were recorded. In 439 out 468 (94%) patients with surgery we registered the date. 739 (89.6%) had any pathologic confirmation.

86 breast cancers were diagnosed: 42/77 (54%) were diagnosed at an early stage. Median of dissected nodes was 14 (3-32). Conservative surgery was done in 23 out 42 at early stage. 71% had determination of hormonal status.145/709 (20%) were assessed by a medical oncologist. 18 patients were included in a clinical trial (2.5%).

Conclusions: 1. Data obtained from a registry are limited by intrinsic characteristics of the medical chart, and registry procedures.

2. By using data from Hospital Tumour Registry we could calculate quality measures that were valid assessments in hospital cancer process.

3. In our data staging and oncologic assessment are clearly under standards of quality.

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876 POSTER

Use of quality indicators to improve medical oncology practice

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Purpose: In both the USA and the UK a number of documents (Ensuring Quality Cancer Care, Crossing the Quality Chasm, National Cancer Plan, Manual of Cancer Services Standards) and initiatives (NCI's identification of disease-specific core process measures; UK's National Study of Cancer Services) highlight the need to ensure, and document, the delivery of quality cancer services to patients. The recent IOM report stated that information technologies must be more widely used to improve access to clinical information and to support clinical decision-making. We demonstrate how practice-based information technologies can be used to provide data on indicators of the quality of cancer care services delivered and how these data can be used to inform and guide the cancer care delivery change process.

Methods: The data from 2 cancer sites in the US that use the optx clinical information system were reviewed to identify possible indicators of quality medical oncology practice. Quality indicators were created for breast and lung cancer. Overall performance at the 2 sites for these indicators was compared as was oncologists' performance on the indicators within the sites.

Results: 5 indicators were selected for breast cancer and 4 for lung cancer. Performance varied widely within the indicators; for example, performance on the breast cancer indicators ranged from 27.7% to 88.1%. In

addition, there was significant performance variability within oncologists at a site. For example, recording of stage ranged from 17.6% to 91.4% among oncologists at one site. Additional analyses revealed the patterns of data entry on other clinical variables also varied significantly.

Conclusion: The variability in performance in quality indicators for breast and lung cancer suggests there are many opportunities for improvement in cancer care delivery within the selected oncology practices. Use of information technologies allows collection and feedback of data on a near real-time basis. However, for the feedback of performance data to have a meaningful impact on practices, and physicians within a practice, it must be done in a manner consistent with recent research findings on physician profiling.

Cancer prevention

877 POSTER

Colorectal cancer (CRC): program for early diagnosis in the disctrict Alba-Bra (ASl18), Piedmont - Italy

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Purpose: in Italy, CRC is the second leading cause of death from cancer, with an annual incidence of 28.000 new cases. The diagnosis in early stage of disease is associated with more than 80% of 5-years survival; endoscopic removal of adenomas can decrease the CRC incidence of 40-60%; the fecal occult-blood test (FOBT), performed every 1-2 years, can lead to a reduction of 15-30% in mortality.

Methods: since April '97, in the district of Alba-Bra (ASL18), a program for early diagnosis of CRC is in progress to evaluate utility, acceptability and impact on population (150.000 inhabitants). The participation in the program is spontaneous and free. The visit consists of careful clinical history taking, abdominal and digital rectal examination, immunochemical FOBT (on 3 samples), indication to diet and behavior modification. Subjects with symptoms, high risk factors and/or FOBT positivity are invited to undergo colonoscopy.

Results: in 4 years of activity, 419 visits (250 first visit and 169 follow-up) were performed. The mean ages were respectively 52 years for the first visit (range 20 - 78) and 51 for the follow-up (range 35-77). The residence of the patients was urban in 105 cases (42%) and rural in 145 cases (58%). Patients information was obtained: 96 cases by local mass media, 81 by leaflets, 41 by relatives/acquaintances, 19 by health operators, 7 by family doctor and 6 by other. In 79 cases there was familiar occurrence for intestinal adenomas and/or CRC and in 13 cases adenomas were removed from the large bowel before entering the program. FOBT were positive in 24 cases: 8 related to adenomas and 16 to other conditions (hemorrhoids, diverticulosis, anal fissures). The 8 detected adenomas (3 cases transverse colon, 2 sigma, 2 rectum, 1 ascending colon) were removed endoscopically.

Conclusion: achieved the objective of generating useful insight in patients for modification in diet and in lifestyle, the program is now directed to improve compliance to the endoscopic procedure, diagnostic and therapeutic examination, at present, indispensable for prevention of CRC.

878 POSTER

Cisplatin/epinephrine injectable gel for the intralesional treatment of melanoma metastases: Results of a multi-institutional trial

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Intratumoral treatment of melanoma patients with metastases to skin, soft tissue and/or lymph nodes that are not recectable by conventional surgery and/or radiotherapy appears to be promising.

A novel product for intralesional chemotherapy (cisplatin/epinephrine (CDDP/epi) injectable gel; Matrix Pharmaceutical, Inc., Fremont, CA) was tested in 28 heavily pretreated melanoma patients in two identical multicenter Phase II trials. A total of 25 pts with 244 lesions were evaluable for efficacy. Tumors were injected with 0.5 mL gel/cm^3 (2 mg CDDP; 0.05 mg epi in a sterile bovine collagen gel). Patients received up to 6 weekly treatments in an 8-week period. The objective, response rate for target tumors (each patient's single most symptomatic, largest, or most threatening tumor) was 44% (5 CR, 6 PR). The median response duration was 63 days (30–632 days) for patients without additional treatment. In addition, the response rate in all lesions (1–72/patient) was 53% (duration: 30–783 days; median: 347 days). Systemic toxicity was negligible, local adverse reactions such as erythema, necrosis, or pain occurred frequently, but were easily managed in most cases.

In conclusion, CDDP/epi injectable gel provides a new therapeutic approach for local control of metastatic melanoma confined to skin, soft tissue, and lymph nodes.

879 POSTER

Model screening for oral cavity and pharyngeal cancer in Hungary

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Between 1990 and 1999, deaths due to tumours of the oral cavity and the pharynx increased among men in Hungary by 44%, especially among 40-60 year-olds, where the increase was 76% on the average making cancer of the oral cavity and the pharynx the second most common cause of death after lung cancer in this age group. These tumours are clearly linked to alcohol consumption and smoking; the majority is discovered at an advanced stage due to lack of awareness of health-related issues and of cooperation in this segment of the population.

Compared to the other former socialist countries the mortality rate due to cancer of the oral cavity and the pharynx is 2.8-4.1 times higher in Hungary.

The number of alcoholics and smokers on file under the age of 55 increased by 12.6% and 13,8% respectively.

Earlier attempts to screen for tumours in the oral cavity and the pharynx in other countries were unsuccessful due to poor access to the endangered population, which includes appr. 866000 individuals in Hungary.

Our institute initiated a unique method for screening of the highest-risk population of drinkers and smokers.

The objective of the screening is primary and secondary prevention, i.e., teaching people about the dangers of their habits and making those affected aware of the early signs of the disease that allows early diagnosis.

Results: Based on the files of 17 family physicians (covering a population of 42500 people) only the recorded smokers and alcoholics (5,1%) were invited for the screening, and 39% of them appeared. First they were asked about social parameters, their habits, knowledge of the early signs of oral and pharyngeal cancer by a simple questionnaire afterwards they were examined.

The screened population belonged socially to lower classes (76,4%), were heavy smokers (64,2%) and regular drinkers (68,8%). The scores of their answers about oral cancer proved almost complete lack of knowledge in this respect. The examination revealed pathological changes in 48% in the head and neck region, although no proven malignancy has been found. At the end each person was informed about important facts of the disease and its prevention.

Conclusion: The screening of high-risk patients selected by their GP-s who know them personally, might be an effective first step toward reaching and educating the most likely candidates for oral and pharyngeal cancer.

Communication–information

880 POSTER

Variability in estimating late normal tissue toxicity for patients receiving radiotherapy. Does experience influence what we are telling our patients?

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Aim: Patients frequently request estimates of the risk of late complications before a proposed course of radiotherapy. Most readily available data is in the form of tolerance doses (eg TD 5/5s). However dose delivered to normal tissues often differs from reported tolerance doses. Thus it is possible that risk estimates (REs) provided by radiation oncologists (ROs) for different clinical scenarios vary widely, and are based more on personal experience than on published evidence. To quantify variability and determine factors affecting estimates, a survey of ROs was undertaken requesting REs of late toxicity given a number of clinical scenarios.