Epidemiology/Education and public health

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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.

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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.

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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.

*Partially supported by a grant of the Servicio Galego de Saude.

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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