July, 2012

News Letter

Vol. XVI No. 6 Price: 50 Paisa

Rajiv Gandhi Cancer Institute and Research Centre

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Registered under "Societies Registration Act 1860"

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EDITORIAL
GENERIC vs BRANDED DRUGS

A **generic drug** is defined as "a drug product that is comparable to brand/reference listed drug in dosage, form, strength, route of administration, quality, performance characteristics, and intended use." It has also been defined as a term referring to any drug marketed under its chemical name without advertising.

A generic drug must contain the same active ingredients as the original formulation. According to the U.S. Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetic and pharmacodynamic properties. In most cases, generic products are available once the patent protections afforded to the original developer have expired. When generic products become available, the market competition often leads to substantially lower prices for both the original brand name product and the generic forms. The time it takes a generic drug to appear in the market varies. In the US, drug patents give 20 years of protection, but they are applied for before clinical trials begin, so the "effective" life of a drug patent tends to be between seven and 12 years.

For as long as a drug patent lasts, a brand name company enjoys a period of "market exclusivity" or monopoly, in which the company is able to set the price of the drug at a level which maximizes profitability. The profit often greatly exceeds the development and production costs of the drug. The advantage of generic drugs to consumers comes with the introduction of competition, which prevents any single company from dictating the overall market price of the drug. Competition is also seen between generic and name-brand drugs (or Branded Generics) with similar therapeutic uses when physicians start prescribing generic drugs. With multiple firms producing the generic version of a drug, the profit-maximizing price generally falls to the ongoing cost of producing the drug, which is usually much lower than the monopoly price.

Prescriptions may be issued for drugs specifying only the chemical name, rather than a manufacturer's name; such a prescription can be filled with a drug of any brand meeting the specification. Generic drugs are usually sold for significantly lower prices than their branded equivalents. Cost of generics may be as low as 20% of the cost of branded versions. One reason for the relatively low price of generic medicines is that competition increases among producers when drugs no longer are protected by patents. Companies incur fewer costs in creating generic drugs (only the cost to manufacture, rather than the entire cost of development and testing) and are therefore able to maintain profitability at a lower price.

If your doctor has prescribed a medicine by its brand name, your pharmacist must dispense that brand. However, if a medicine has been prescribed by its generic name, your pharmacist can dispense whatever version of the medicine they have available, because each version will have the same therapeutic effect.

Why do people still take branded or brand - named drugs?

Basically, it's marketing. If the drug company can convince the average patient that the generic is the "cheap" version and that they deserve the best, many patients accept it. Also, if a patient is finally on a drug that works, he might be less likely to switch to the generic version for fear of losing the effect of the branded drug. Generic may look and taste different, making people wonder if the cheaper drug has left something out.

We are also biased by our belief systems, and they exist in practically every area of our lives. Medication is no exception. Your Pharma company representative may tilt your bias in favor of one particular brand-name drug.

Last year USA restricted drug-industry gifts to doctors with the slogan, "Better Ethics, Cheaper Drugs," They contended that marketing inflates the cost of medicine. All the favors that drug companies do for doctors raise overall health costs in two ways. First, the marketing cost gets added on to each prescription a patient buys. Secondly, the industry's goal in influencing doctors is often to get them to prescribe a new, higher –priced medication when a generic of cheaper version is just as effective.

Problem in India is compounded by hundreds of branded generics for one drug. Medical fraternity is not confident of quality of products and is biased by Pharma representative's tall claims. Drug regulatory authorities should allow only limited branded generics (or named brands) of one particular compound and ensure good quality.

Let us instill confidence in public that generics are better value for money than branded drugs.

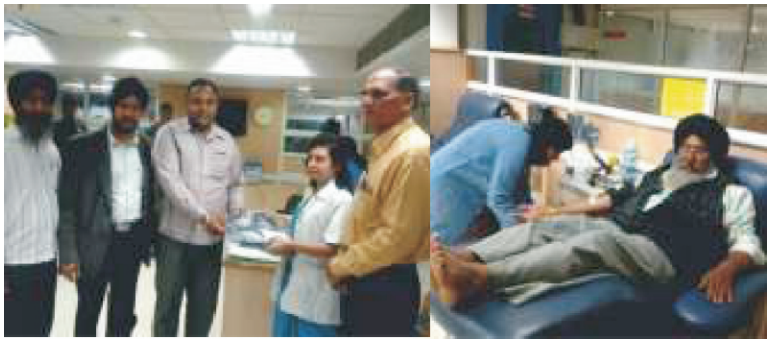
Let us adhere to the principle of "**Better Ethics and Cheaper Drugs**".

Dr. Dewan A K

COMMUNITY PARTICIPATION IN CANCER PREVENTION (VILLAGE TALLEWAL, PUNJAB)

Department of Preventive Oncology and Marketing team of RGCI&RC under the banner of Cancer Jagrukta Abhiyan organized a Cancer awareness and screening program at Village Tallewal on 2.4.11. The area is known for large number of Cancer cases in Malwa area of Punjab and the area is famous for Cancer Train from Bhatinda to Bikaner and this train mostly carries cancer patients and their attendants. Awareness talk and screening camp was sponsored by SAHAITA, an NGO of that area which have large number of volunteers. Marketing Team organized the camp. Awareness talk was given by Dr. J.G. Sharma, ENT specialist of Department of Preventive Oncology. Around 200 people were screened by Dr. J.G. Sharma & Dr. Rajni Mutneja (for Breast & Cervix).

Blood Donation Camp at RGCI & RC



Cancer Jagrukta Abhiyan at Tallewal, Moga (Punjab)

Another camp was organized in the village of Tallewal with more vigor. Dr. J.G. Sharma, Dr. Indu Aggarwal, Dr. Sabina and Dr. Upasna attended the camp. Awareness talk was delivered by Dr. Indu Aggarwal, Dr. J.G. Sharma and 256 people were screened. Females in the age group of 10 – 26 were given vaccine for prevention of cervical Cancer to more than 250 females.

Blood Donors from Tallewal came to RGCI and donated more than 100 units of blood. It was a nice and passionate gesture.

This is an excellent example of community participation in creating awareness for prevention & awareness of Cancer.

Dr. J G Sharma
Coordinator Preventive Oncology

PAP'S TEST IN CERVICAL CANCER – HOW, WHY, WHEN?

CERVICAL CANCER PREVENTABLE, TREATABLE BUT STILL A MAJOR KILLER IN INDIA

In developing countries, cancer cervix is the most common genital malignancy. It is No 1 cause of cancer related death amongst women in India and is even more common than breast cancer. Everyday around 200 women in India die due to cervical cancer. Sadly every 4th women dying of cervical cancer in the world is an Indian.

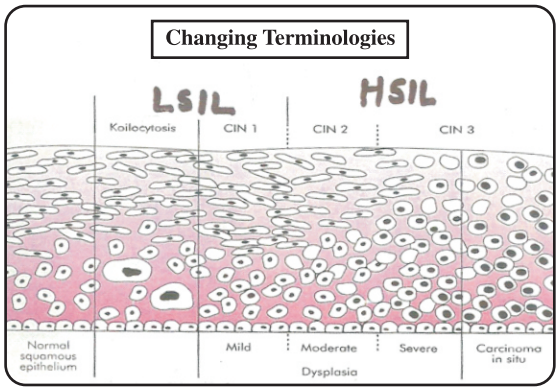
Cervical cancer screening policies follow a triage system for detection, treatment, and follow – up. The principal screening test for cervical cancer in developed countries is the Pap smear, in which a cellular specimen from the cervix is fixed and stained on a slide for visual interpretation. Morphologic changes of precancerous cells, cervical intraepithelial neoplasia (CIN), are identified. Patients with abnormal findings on Pap smears are referred for colposcopy, in which 3% to 5% acetic acid is applied to the cervix and examined under magnification with a bright light to enhance lesions for biopsy. Women are then recalled for results and treatment. In some clinics a "see and treat" approach is taken, in which patients with an abnormal Pap smear are evaluated and treatment is determined by colposcopy in the same visit. The see and treat method is advantageous in low resource areas or when patient compliance is of concern. The overall cost of treatment should be less, but the possibility of overtreatment is disadvantageous.

It is well accepted that the Pap test has decreased the incidence of cervical cancer. However, controversy exists as to the frequency with which the test should be performed, how to implement human papillomavirus (HPV) DNA testing into screening procedures, and the lack of applicability for Third world countries.

Observational data suggest the effectiveness of screening increases when Pap tests are performed more frequently. Although a single Pap test may have a relatively low sensitivity, the cumulative sensitivity of several yearly tests should be high. Current

recommendations favor initiation of screening by the age of 21 years or within 3 years of first sexual intercourse, whichever comes first. Up to the age of 30 years, screening is advised at 1- to 3- year intervals. Intervals may be extended to 3- year intervals if the patient meets specific low-risk criteria. Most recommendations stop screening by 65 or 70 years of age or after hysterectomy. Those women who test negative by cytology and HPV do not require retesting for 3 years. Women who have received HPV vaccination should continue cervical cancer screening according to the guidelines.

Cervical cytologic specimens can be collected with a variety of devices. The use of an ectocervical spatula and endocervical brush or swab together appears to be the best method for obtaining cervical cells for conventional specimens. Liquid – based and conventional exfoliate cytology Pap tests are acceptable for screening.



The Bethesda System used for reporting uniform cervical cytology results was initially developed in 1988. More than 90% of laboratories in the United States use the Bethesda System. Bethesda (2001) added a new category for atypical cells at higher risk of association with precancer, "atypical squamous cells – cannot exclude a high – grade lesion" or "ASC-H." This category highlights the 5% to 10% of atypical squamous cells of undetermined significance (ASCUS) that are more likely to contain high-grade squamous intraepithelial lesions.

Overall, cervical cytology screening programs for the detection of CIN 3 or cancer have reported a range of sensitivities (50% to 75%) and specificities (69% to 94%). The sensitivity of cytology is limited by sampling error, in which the abnormal cells do not get collected and reading error, in which a few abnormal cells are not identified among the normal cells or obscured by blood or debris. Cytology also has problems with specificity. The screening program is overburdened by borderline smears of uncertain malignant potential, which are costly to follow and cause anxiety to the women involved.

The clinical utility of HPV-based screening for cervical disease results from its negative predictive value. A positive HPV result can indicate infection only rather than a high probability of cervical disease. Most HPV infections are transient, persisting for only 12 to 18 months. However, women who develop a persistent infection with an oncogenic HPV have a much higher risk of developing neoplasia compared with uninfected patients. Given the importance of HPV in the development of cervical cancer, clinical detection of HPV has become an important diagnostic tool for identifying patients at risk for cervical cancer.

HPV testing can be used as an alternative approach for the follow-up of ASCUS in order to determine who is referred for further colposcopy. The ultimate benefits, risks, and cost of HPV testing compared with cytology screening depend on the subsequent triage procedure, HPV typing assay, and primary testing frequency. It is unclear whether HPV testing will become more or less important in a population of women vaccinated against HPV 16 and 18.

Widespread cytology screening programs that function well in industrialized regions are simply not feasible in the developing world. They are far too expensive and do not attain adequate coverage. Moreover, poor countries often lack the manpower, technical support, and expertise to guarantee accurate results. In low-resource settings, direct visual inspection has been evaluated as a screening test alone or with cytology. The cervix is visualized with either the naked eye or a low-power magnification device after the application of 3% to 5% acetic acid. There is considerable variation in the mean sensitivity and specificity (80% and 80%) reported for direct visual inspection, probably because of the variation in the training and performance of the test and failure to adjust for verification bias.

Regular cervical cancer screening needs to be encouraged for all women, especially those likely to be exposed to HPV and human immunodeficiency virus infection. Special efforts are needed to reach those women less likely to be screened, like the elderly, poor, less educated and recent immigrants.

To maximize efficient use of limited resources, the program should focus on Pap screening on those who have not been tested for 5 years and then increase the screening interval to every 3 years.

Rajiv Gandhi Cancer Institute and Research Centre has a preventive oncology department primarily to focus on creating awareness among the general public, risk assessment & their reduction and early detection of common cancers. Screening Package for woman is provided at highly subsidized rate of Rs 200/- which includes clinical examination by an ENT specialist (for oral cancer) and, by a gynecologist. CBC and Pap smear are also carried out. RGCI conducts community based cancer detection camps in Gender Resource Centers (GRC) in collaborations with NCT of Delhi. Camps are also arranged regularly at schools, colleges, corporates, RWAs etc. to create awareness about regular screening & early detection of cancer.

Dr. Indu Aggarwal
Sr. Medical Officer
Department of Preventive Oncology

Posted at : Ashok Vihar Head Post Office, Delhi-110052
Registered with Registrar of Newspaper Under No. 68797/98
Postal Department Registration No. DL(N)/004/2012-14
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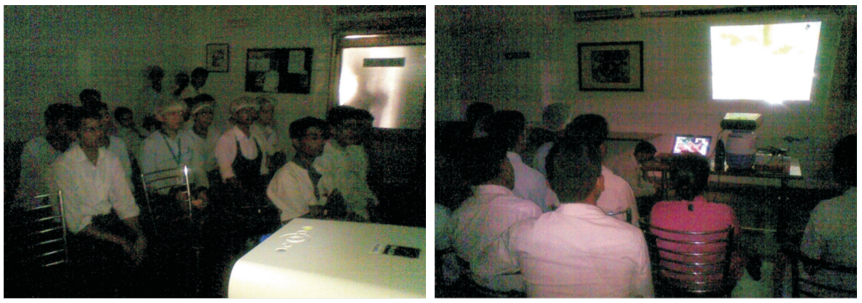
CME FOR NURSES ON 14th JUNE 2012

On 14th June Infection Control Team of RGCI & RC organized a unique event for nursing staff. Main aim of the event was to sensitize and re-enforce the idea of infection prevention and reduction in the hospital. A quiz ("KAUN BANEGA GYANPATI")followed by live skit was presented by employees of RGCI&RC. After that there were videos showing errors on handling sharps ,correct methods and policy regarding PEP . The session ended with poster competition (on infection prevention) and prize distribution.

CME OF KITCHEN WORKERS (29th -30th MAY 2012)

Two days CME was organized for kitchen workers on 29th and 30th may in RGCI & RC. Main focus was on good personal and hand hygiene practices through PPT ,videos & live demonstrations.



WASTE MANAGEMENT AND PEP (O.T. 30thJUNE 2012)

Waste management and handling of waste materials has seen dramatic changes over the past few decades.
A CME was organized by Infection Control Team of RGCI & RC for OT staff on bio-medical waste management. Main emphasis was on disposal of waste generated in a hospital and post exposure prophylaxis in case of needle stick injury.

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Printed & Published by Mr. K. K. Mehta on behalf of Indraprastha Cancer Society & Research Centre and Printed at Raju Art Printers, 18-A, Old Gobind Pura Extn., Street No. 2, Parwana Road, Delhi-51, Tel. : 9871006333, Published from RGCI&RC, Sector-V, Rohini, New Delhi-110085

Editor : Dr. A. K. DEWAN

shoot, concept & design: patch creative unit 9811023882