

Vaccine to prevent diarrhoea

A vaccine to prevent rotavirus associated diarrhoea has been launched recently in Bangladesh

Dr TAREQ SALAHUDDIN

Throughout the world, rotaviruses are the single most causative agents of severe diarrhoea in infants and young children. As a result of the associated mortality and morbidity, rotaviral gastroenteritis represents a major public health burden. Within the first five years of life, virtually every child becomes infected with this diarrhoeal pathogen, irrespective of race or socio-economic status.

Globally, it is estimated that rotaviruses are responsible for more than 111 million cases of infantile gastroenteritis leading to approximately 600,000 deaths per year. 82 percent of these deaths occur in the developing countries like ours. Children of developing nations die more frequently, because of poorer access to treatment and a greater prevalence of malnutrition.

ICDDR,B estimated that between 5,756 and 13,430 children died each year in Bangladesh between 2001 and 2004 from severe rotavirus gastroenteritis.

The similar incidence of rotavirus in both developed and developing countries suggests that the disease will not be controlled by merely improving

water quality, sanitation of hygiene.

Administration of oral rehydration therapy (ORT) and Zinc in the treatment of severe rotavirus gastroenteritis have helped to decrease the number of severe and fatal infections, the mortality rate remains unacceptably high, particularly in our part of the world.

These findings, together with the high level of morbidity and associated costs emphasise the dire need for the introduction of a new and effective public health intervention like vaccine, which is strategic to prevent rotavirus-attributable disease.

Understanding the natural history of rotavirus-attributable disease, its pathogenesis, immunologic response of human body to the pathogen have helped to develop a live-attenuated vaccine against the virus. The use of an attenuated rotavirus strain as a vaccine is designed to provide broad protection, mimicking natural infection without causing the disease.

It is anticipated that this vaccine will have a substantial impact in reducing rotavirus-related mortality and morbidity, and their associated costs.

The global clinical development programme has proven



Speakers at the launching ceremony of Rotarix™ vaccine: From left Dr S A R Chowdhury, Prof Dr M A Mannan, Prof Dr Selim Sakur, Prof Dr T A Chowdhury, National Prof Dr M R Khan, Prof Dr Phua Kong Boo, Dr K Zaman and Dr Sanjay K Datta



A mother is giving oral rehydration therapy at ICDDR,B to her child who is severely dehydrated due to diarrhoea. Rotavirus is the main cause of severe acute gastroenteritis among children under 5 years of age.

that Rotarix™ protects against the most common circulating strains (G1 and non-G1 rotavirus strains) including the globally emerging G9 strain.

GlaxoSmithKline, which is pioneer in vaccine manufacturing in the world has recently launched their novel vaccine against rotavirus, Rotarix™, a live-attenuated based on human rotavirus strain in Bangladesh. It has been investigated in an extensive, and still ongoing, worldwide clinical development programme including Bangladesh.

Earlier it has been approved in over 63 countries in the world.

Rotarix™ is a lyophilised oral vaccine and is administered in two doses within the first six months of life. The first oral dose can be administered from as early as six weeks of age with a minimum interval of four weeks prior to the second oral dose. The vaccination course must be completed by 24 weeks.

It can be co-administered with all infant vaccines within the routine infant vaccination schedules.

Although some protection is already conferred after the first dose, as expected from the experience of natural infection, effective protection is achieved after two doses.

A vaccination course of only two doses (compared with a three-dose schedule required for another vaccine in development) provides protection earlier in life, enhances compliance and reduces physician visits and costs.

The vaccine is likely to be available in the local market from the very beginning of next year. Sources of GlaxoSmithKline Bangladesh Ltd. informed that the price would be at an affordable range of the common people of the country.

Many countries in the world have included a vaccine against rotavirus in their routine childhood immunisation programme.

Data from Asia Pacific support rationale for a rotavirus vaccine to be made available through government's paediatric immunisation programmes. Both the World Health Organisation (WHO) and Global Alliance for Vaccines and Immunisation (GAVI) have declared rotavirus vaccination a public health priority.

Whereas, Bangladesh is a GAVI eligible country, it should thing about the introduction of these sort of vaccine in the Expanded Programme on Immunisation (EPI).

DID YOU KNOW?

Obesity may hurt women's chances of conception

REUTERS, Chicago

Obesity decreases the chances that a woman will get pregnant, and the more obese she is, the worse her prospects of conception, Dutch researchers said.

Researchers at the Academic Medical Center in Amsterdam looked at how obesity affects women who are still ovulating but having trouble with conception.

The study, published in the journal Human Reproduction, included more than 3,000 couples between 2002 and 2004 in 24 hospitals in the Netherlands.

Dr. Jan Willem van der Steeg and colleagues looked at the relationship between fertility in these women and their body mass index, a ratio of weight to height. Women with a BMI of 30 or higher are considered obese.

The women had to be ovulating and have at least one working Fallopian tube, and the men had to have a normal semen analysis.

The researchers found that women with a BMI of 30 or higher had significantly lower probability of becoming pregnant naturally, compared with normal weight women who had BMIs of between 21 and 29.

"In the case of a woman with a BMI of 35, the probability of

spontaneous pregnancy was 26 percent lower, and in the case of a woman with a BMI of 40, it was 43 percent lower," van der Steeg said in a statement.

One reason for this may be the hormone leptin, which regulates appetite and energy expenditure and is secreted in fatty tissues.

"It is possible that obese women may have disturbed hormone levels, which decrease the chances of successful fertilisation and implantation," he said.

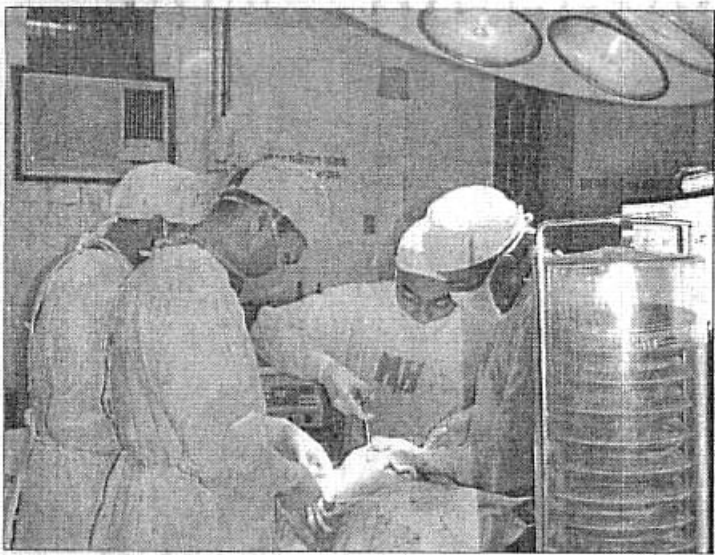
Obesity is already known to disrupt ovulation, and the Dutch study now suggests it can lower pregnancy rates, compared with women of normal weight.

However, the researchers did not track the timing and frequency of sexual intercourse, which may have affected the results. Some studies have shown that obesity is linked with less frequent sex and reduced sexual desire.

The researchers said the finding should be tested in further studies, especially given the rising rates of obesity.

"Owing to the fact that more women of child bearing age are becoming overweight and obese, this is a worrying finding," they wrote.

Surgery in the mainstay of cancer treatment



DR TAREQ SALAHUDDIN

Dr MD MIZANUR RAHMAN

More than two and half lacs of patients are diagnosed with cancer in Bangladesh. Everyday there is emergence of new problems in medical science. Surgery is the oldest form of cancer treatment. The branch of surgery which deals with cancer patients is called surgical oncology and surgeons are called oncosurgeons.

Surgery has also an important role in diagnosing and staging (finding the extent) of cancer. Advances in surgical techniques have allowed surgeons to successfully operate on a growing number of patients.

Today, less invasive operations offer removal of tumors saving as much normal tissue and function as possible. Surgery offers the greatest chance for cure of many types of cancer, especially those that have not spread to other parts of the body.

Surgery can be done for several reasons. The purposes are as follows:

Diagnostic surgery: This is to get a tissue sample to tell whether cancer is present or not and to describe the type of cancer. Usually

it is done by a biopsy (a procedure by removing a tissue sample for histological examination).

Staging surgery: Staging surgery is done to find out the extent of cancer spread.

Curative surgery: Curative surgery is done when a tumour appears to be confined to a particular area. It is done at an early stage and can be accompanied by chemo or radiotherapy.

Debulking surgery: This is done to debulk a tumor when removing the entire tumor would cause too much damage to an organ or nearby tissues.

Palliative surgery: This type of surgery is used to treat complications of cancer in advanced or end stage. Palliative surgery can also be used to correct a problem that is causing discomfort or disability.

Other procedures include restorative or reconstructive surgery, preventive (prophylactic) surgery, laparoscopy, thoracoscopy, or mediastinoscopy.

Special surgery techniques: Some newer techniques have drastically changed the traditional perception of surgery due to the introduction of laser surgery, cryosurgery, radiofrequency

ablation or RFA, high intensity focused ultrasound (HIFU).

There are risks that go with any sort of medical procedure and surgery is no exception. Be sure to discuss your particular case with your doctor. S/he can give you a better idea about what is going to be done on you.

One common myth about cancer is — it may spread if it is exposed during surgery. Some people may believe this because they often feel worse after the operation. But they should keep in mind that cancer does not spread due to the exposure during surgery. If you delay or refuse surgery only based on this sort of myth, you are doing harm to yourself for sure.

If you have a solid tumor, sometimes surgery alone will provide a cure, but often chemotherapy, radiation therapy, or biologic therapy may be needed in addition.

Cancer survival rates or survival statistics tell you the percentage of people who survive a certain type of cancer for a specific amount of time. For instance, the 5-year survival rate for prostate cancer is 99 percent. That means that of all men diagnosed

with prostate cancer, 99 of every 100 lived for five years or more after diagnosis. When cancer patients live five years beyond the time of diagnosis and treatment, it is generally considered that they are cured.

Presently, there has been an increase in the survival rate for many cancers.

In Bangladesh, generally patients are reluctant to come timely to the expert doctors. When they present usually cancers spread outside the organs affected.

At present a 50 bed lone Govt hospital in Mohakhali, Dhaka is running with a department of surgical oncology doing varieties of high-tech operations. Very soon it will be expanded to 150-bed hospital. A post graduate course in Surgical oncology is also running in this institute.

Many people don't know this information and they can easily seek cancer care in this tertiary institute.

The author is a Fellow in Surgical Oncology (Japan) and Colorectal surgery (UK) and currently working as the Head of the Department of Surgical Oncology in National Institute of Cancer Research and Hospital, Mohakhali, Dhaka.

Children dying for lack of child-sized drugs: WHO

Children are dying for lack of drugs tailored to their needs, according to the World Health Organisation (WHO), which launched a global campaign recently to promote more research into child medicine.

More than half the drugs currently used to treat children in the industrialised world have not been specifically tested on youngsters, even though they metabolise medicines differently to adults.

As a result, clinicians lack clear guidelines on the best drug to use and often have to guess at the correct dose.

The problem is even worse in developing countries where price remains a major barrier. In the case of HIV/AIDS, the few existing pediatric therapies developed for children generally cost three times more than adults ones.

In a bid to address the problem, the WHO has drawn up the first international List of Essential Medicines for Children, containing

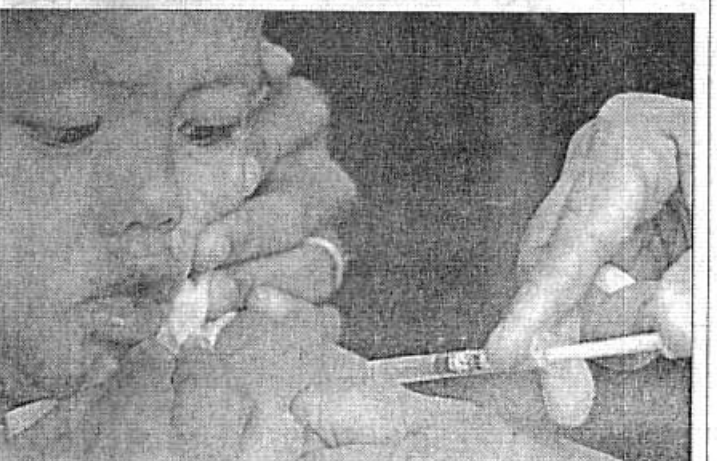
206 products deemed safe for children that tackle priority conditions.

Medicines that need to be adapted to children's needs include many antibiotics, as well as asthma and pain drugs. The WHO also wants more research and development of combination pills for HIV/AIDS, tuberculosis and malaria.

The agency is building an Internet portal linking to clinical trials carried out in children and will launch a Web site with the information early next year.

Testing medicines on children has always been a vexed issue, since good ethical practice requires informed consent from people participating in clinical trials, which is difficult to obtain in the case of children.

As a result, research-based drug companies have been wary of developing child-friendly medicines and generics companies have been slow to produce them at lower cost.



Integrated thalassaemia treatment centre is to set up in the city

STAR HEALTH REPORT

Bangladesh Thalassaemia Foundation and Bangladesh Society of Hematology has jointly organised a seminar entitled "The role of iron chelation in Thalassaemia: Present and future prospects" at BIRDEM auditorium recently. Eminent specialist physicians of the country discussed about the importance of iron chelation in the treatment of thalassaemia.

Chairman of the Hematology Department of Bangladesh Sheikh Mujib Medical University (BSMMU) and President of Bangladesh Society of Hematology Professor Dr Jalilur Rahman was present as the chief guest while President of Paediatric Society of Bangladesh Professor Dr M A Mannan and Secretary General of Bangladesh Society of Hematology Professor Dr M A Khan were present as Special Guests in the seminar.

Thalassaemia is a genetic disease of blood which patients inherit from their parents. They need blood transfusion of 1-2 bag blood in every 2-4 weeks. Iron gets deposited in the body of



Speakers at the seminar: From left Prof Dr Khairul Amin, Gen. Secy, Dhaka Shishu Hospital Thalassaemia Center, Dr Syeda Masuma Rahman, Asst Prof, Safe Blood Transfusion Programme, Prof Dr Jalilur Rahman, President, Bangladesh Society of Hematology, Prof Dr M A Khan, Secy Gen., Bangladesh Society of Hematology, Dr Md Abdur Rahim, Secy Gen., Bangladesh Thalassaemia Foundation.

the patients as a consequence of regular blood transfusion. Patients start suffering from different diseases like heart failure, liver cirrhosis, diabetes, retarded growth and so on due to the toxic effects of deposited iron.

Assistant Professor of Hematology Department of BSMMU and Scientific Secretary of Bangladesh Society of Hematology Dr Aminul Kabir presented the keynote paper in the seminar. He said, "Patients should take

iron chelating agents like Desferol or Kelfer to survive with thalassaemia. Desferol should be taken 5-6 days a week. It is taken by a subcutaneous small and portable pump. Besides, patients should take drug like Kelfer three times a day. Patients must be monitored closely to observe any side effect of these drugs."

Dr Abdur Rahim, Secretary General of Bangladesh Thalassaemia Foundation informed the seminar that many patients can not avail the iron chelating

agents due to the scarcity of the drugs in the market and lack of proper guidelines. As a result of continuous lobbying of the Foundation, recently Novartis Bangladesh has marketed Desferol in Bangladesh. Now patients get all sorts of iron chelating agents from the Foundation office and they are served with regular monitoring.

Bangladesh Thalassaemia Foundation opened the elements about setting up an Integrated Thalassaemia Treatment Centre. Patients will get a comprehensive care with blood transfusion and iron chelation in this centre. The Foundation will collect blood for the patients so that patients and their guardians need not go through the hassle of blood collection. Moreover, they will be served with the laboratory services to be monitored. Initially 200 patients will be enrolled in this centre.

Drugs like Desferol and Kelfer are badly essential for the survival of thalassaemia patients. Chief Guest of the seminar Professor Dr Jalilur Rahman urged the government for tax exemption upon these drugs.

Momenta Pharmaceuticals announces receipt of FDA letter

M-Enoxaparin ANDA not approvable in current form

STAR HEALTH REPORT

Momenta Pharmaceuticals Inc. (Nasdaq:MNTA) announced that its collaboration partner, Sandoz Inc. (Sandoz), a division of Novartis, had received a letter from the U.S. Food and Drug Administration (FDA) on November 5, 2007, stating that Sandoz abbreviated new drug application (ANDA) for Enoxaparin Sodium Injection is not approvable says a press release.

The FDA's letter stated that the ANDA was not approvable because the application does not adequately address the potential for immunogenicity of the drug product and recommended that Sandoz and Momenta meet with the Office of Generic Drugs to determine what additional information should be provided to adequately address this concern. Sandoz and Momenta are working together to identify the additional information that is necessary to obtain approval of the ANDA.

"In a follow-up call, the FDA clarified that all applications for enoxaparin products must address the potential for immunogenicity of the drug product. We believe that we can address what we anticipate to be the FDA's concerns, based on our detailed characterisation of enoxaparin and on the current medical and scientific literature," said Craig A. Wheeler, President and Chief Executive Officer. "Our path forward will be determined in conjunction with Sandoz and the FDA."

Momenta Pharmaceuticals is a biotechnology company specialising in the detailed structural analysis of complex mixture drugs. Momenta is applying its technology to the development of generic versions of complex drug products, as well as to the discovery and development of novel drugs. The Company's most advanced product candi-

date, M-Enoxaparin is designed to be a technology-enabled generic version of Lovenox®. Within the Company's discovery programme, it is seeking to discover and develop novel therapeutics by applying its technology to better understand sugars' functions in biological processes, with an initial focus in oncology.

Whereas this is the scenario in the developed world, in some third world countries like ours, Enoxaparin Sodium Injection is being produced, marketed and sold by some pharmaceutical companies.

Enoxaparin sodium, a low molecular weight heparin used to prevent and treat deep vein thrombosis and pulmonary embolism. In fact, it is an anticoagulant (blood thinner) that prevents the formation of blood clots. This medicine is used following knee or hip replacement surgery and following abdominal surgery in patients at high risk of developing a blood clot. Enoxaparin is also used with aspirin to prevent complications of certain types of angina and heart attacks, and with warfarin to treat deep vein thrombosis (a type of blood clot). The drug is a patent and research product of the Sanofi-Aventis pharmaceutical company, originating in France.

Since full molecular structure of Enoxaparin Sodium is not yet discovered and the patent is not open to produce its generic version, production and marketing of the drug by some other pharmaceutical companies may pose serious health risk of the critical patients eminent cardiologists of the country think alike. They urge the Drug Administration to consider the matter as a serious public health issue and take necessary steps.

Additional reporting can be found at Star Health published on December 10, 2006. Source: <http://www.thedailystar.net/2006/12/10/0612106103100.htm>