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Newsletter of the 'Scaling Up Zinc For Young Children with Diarrhoea in Bangladesh' (SUZY) Project

Dear Readers,

Welcome to the 2nd issue of SUZY News. In April, we hosted the first international conference about zinc treatment for childhood diarrhoea. You'll find a short summary of the conference in this newsletter. More details, including the presentations that were given at the conference, are available on our homepage at http://www.icddrb.org/activity/SUZY.

Meanwhile, planning has begun for a second conference. We have learnt that there are a number of projects underway in several countries exploring the benefits of zinc supplements and the effects of zinc treatment for diarrhoea, pneumonia, malaria and other illnesses. However, there is limited opportunity for discussion and the exchange of information on issues related to zinc. That's what we would like to change.

"Bringing Zinc to the People" will be held on 17-18 April 2005, in Dhaka. This conference will offer a platform for discussion and the exchange of information and experiences for people working with zinc. We will organise thematic sessions regarding the use of zinc for treatment of several illnesses, the role of zinc in nutrition, technology transfer issues and experiences in the marketing of zinc products. More information will be available soon on the SUZY homepage.

For the planning of this conference we are very interested in hearing from people and projects using zinc in their work, whether this is for research purposes or for actual treatment. If you are using zinc in a health context, please contact us. Send us an e-mail at s_liza@icddrb.org or a fax to let us know, what you are doing. If you know someone who uses zinc in a health

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The Ist International Conference on Scaling Up Zinc Treatment for Young Children with Diarrhoea

- Sumona Liza, Information Dissemination Manager, SUZY Project

The 1st International Conference on Scaling Up Zinc Treatment for Young Children with diarrhoea, entitled "Recent Research Findings in Support of Scaling Up Zinc", was held on 19th April 2004 at ICDDR,B's Sasakawa auditorium in Dhaka. Md. Lutfor Additional Rahman Chowdhury, Secretary of the Ministry of Health and Family Welfare, was the chief guest and inaugurated the conference. Presentations highlighted the status of research, technology transfer, zinc tablet production and the progress of the marketing campaign.

Dr. Abdullah-Hel Baqui from John Hopkins University, Baltimore, discussed the background of 'Zinc as a treatment for childhood diarrhoea'. He focused on the historical perspective of zinc research, the evidence base for the role of zinc in diarrhoea, program and policy directions and the challenges for the public health community.



Presentation of Dr. Abdullah Hel Baqui

Dr. Abdullah Brooks discussed the 'Efficacy of zinc as an adjuvant in the management of acute pneumonia in children'. He discussed possible mechanisms of action in both preventive and treatment trials aiming to determine the effect of zinc on the

duration of severe pneumonia and hospitalisation and to measure zinc effects on signs of lower airway obstruction.

Dr. Olivier Fontaine, WHO, discussed recent developments in the clinical management of acute diarrhoea and referred to the new WHO recommendations for the management of diarrhoea.



1st International Conference on Zinc

Dr. Lauren Blum, principal investigator of the formative research, shared preliminary findings at the conference. The overall aim of the research is to understand key issues affecting the treatment of diarrhoeal illnesses in children. Specific objectives include identifying local beliefs and causal explanations associated with childhood diarrhoeal disease and delineating treatment patterns including home remedies and health seeking behaviours during illness episodes. The information will be used to develop a culturally appropriate mass media campaign as well as one-onone messages to be delivered by the health care providers.

Dr. Charles Larson, head of the SUZY project, discussed the current status of

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context, please tell him or her about us.

What else can you look forward to in this edition of SUZY News? Dr. ABM Mominul Hague and Charles Larson provided us with a report about the zinc safety monitoring study that is currently being conducted at ICDDR,B. Dr. Lauren Blum writes about questions people are concerned with when they are using zinc tablets. We also report about the new WHO/UNICEF recommendations regarding zinc and we provide a short portrait of Nutriset, the company that developed the formula for our zinc tablets.

I hope you'll enjoy SUZY News 2.

Ralf Ernst

Information Dissemination Advisor SUZY Project



With the signing of memorandum of understanding between SMC and ICDDR,B a major milestone of the SUZY Project was achieved

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the baseline observational surveys: management practices, acceptance and compliance. In his discussion he covered aspects of the behavioural and formative study, incidental case study, coverage surveys and other research projects currently under way.

Ms. Beatrice Simkins from Nutriset discussed latest developments in the production of zinc tablets and aspects related to technology transfer and the selection of local producers of zinc tablets.

Ms. Parveen Rashid, managing director of the Social Marketing Company, emphasised in her presentation issues related to the import, distribution, and marketing of zinc tablets in Bangladesh.

The complete presentations are available online at http://www.icddrb.org/activity/SUZY.

Zinc Safety Monitoring: Initial Findings

- Dr. ABM Mominul Hoque, Charles Larson and Dr. Ali Miraj Khan

Research under the SUZY project includes a phase four clinical trial entitled "Safety Monitoring: Introduction of Routine Zinc Treatment for Children with Diarrhoea". The purpose of the research is to monitor for possible side effects of zinc treatment, uncommon reactions or toxicity. It is being carried out in the short stay ward of the Dhaka hospital of ICDDR,B and the PSKP clinic.

A team of six researchers is working on the project, aided by nine research assistants as well as many on-site health care workers. They are collecting information from hospital patient forms, by interviewing mothers and caretakers, monitoring patient condition, and

observing patients for side effects after zinc treatment. The research assistants are extensively trained in data collection, the interview process and zinc administration to patients. Other hospital healthcare workers received training in the form of seminars and workshops.

Currently, sixty to seventy patients with diarrhoea are observed daily in the two clinical units. The first location is a clinic for moderately ill patients, and the second is a ward for patients requiring c

ward for patients requiring closer observation and medical care. This is the first study to monitor the use of zinc in tablet rather than syrup form. Compared with previous studies, it is also one of the first to focus exclusively on side effects of zinc administration in young children with diarrhoea. Other differences with previous studies include a relatively lower dose of zinc, a

shortened observation time and improved masking of the metallic taste characteristic of zinc.

Roughly 1400 patients have been observed thus far. Preliminary results indicate that approximately 80% of patients admitted to the hospital have a history of vomiting during their illness. During the one-hour observation period following the administration of zinc, the incidence of vomiting is 25%. A major change incorporated into the protocol during the piloting phase of the study was to settle each child before giving zinc. Settlement is defined as a good level of activity in the child, no sign of dehydration, and the ability to hold oral rehydration solution for at least one



Training on Zinc treatment is given to the care givers

hour without vomiting. This definition of settlement was developed during the piloting phase of the Zinc Safety Monitoring study in response to initial reports that 40% of children were vomiting following administration of zinc. The concept was applied to distinguish vomiting that is attributable to illness rather than the administration

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of zinc. With the exception of vomiting and regurgitation, adverse events are very uncommon.

Despite the incorporation of the concept of settlement into the protocol, incidences of vomiting have still remained high at around 25% during the one-hour observation period after zinc therapy. The question now being asked is what various factors are causing this vomiting, and in what proportion. Possibilities include the illness, the zinc formulation, taste and texture of the tablet, and psychosomatic factors linked with being given medication.

In an attempt to differentiate these potential causes, a substudy is being designed, and is currently entering the piloting phase. The study will include three groups of 250 patients each and will take place over a period of six months. Two groups will be randomly and blindly assigned to receive either zinc treatment or a placebo. A comparison between these two groups will give an estimate of the amount of vomiting attributable to the zinc formulation as well as adverse reactions to the taste and texture of the zinc tablet. The third study group will consist of children randomly assigned to receive no additional treatment. This group should help delineate the amount of vomiting attributable to illness, and a comparison between this group and the placebo group should indicate the amount of vomiting attributable to psychosomatic factors.

It is important to note, however, that on average, the children enrolled in this hospital-based study are much sicker than those who would be receiving zinc therapy as part of the community-based SUZY project. Previous studies have administered up to 150mg of zinc a day in healthy patients without noting any vomiting. These findings suggest that interactions between illness. zinc formulation and other factors might combine to induce vomiting, and that these interactions may vary considerably depending on the severity of the illness. The Zinc Safety Monitoring study is thus providing a good indication of the possible side effects of zinc treatment, even in the sickest of children.

Questions about zinc tablets

- Dr. Lauren Blum and Nazneen Akhtar, Social and Behavioural Sciences Unit

One of the objectives of the formative • research is to identify recurring issues and concerns of community members living in our rural and urban research site related to the administration and use of zinc as a prevention and treatment for diarrheal illnesses. These questions will be included in counseling cards that will be used by a variety of health practitioners to refer to when dispensing zinc. The cards will include common problems and questions asked by community members with appropriate responses. Health providers will be given these cards during a training session and will be trained in the utilization of the cards.

The questions were elicited during indepth interviews with mothers and fathers of young children. The content reflects local beliefs and practices associated with the administration of medication to small children. Questions identified to date include:

- Can we mix the tablet with breastmilk to dissolve it?
- Can we mix zinc with food?
- Can we mix ORS with zinc to dissolve it?
- Can children take the tablet by sucking on it?
- If we give the child zinc more than ten days, would it cause any harm?
- What should we do if we miss a dose?

- Should we give our children another dose if they experience a second episode of diarrhoea?
- Can newborns or young infants take zinc? If so, is the dose the same?
- Can a breastfeeding mother take zinc instead of the young child?
- Can children above five years take zinc? Would it work for them as it works for children under five?
- Can we give zinc to a child without illness as a preventative?
- Are there any side effects of zinc?
 Can zinc be given with other medicines?
- Can we give zinc without consulting with a doctor?
- How can we distinguish the zinc blister packs from other medicines?
- What time of the day should we give zinc? Should it be given on an empty stomach or after the child has eaten?
- What is the cost of the zinc tablet? etc.



Two interviewee families for Formative Research

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Who is NUTRISET?

- Sumona Liza, Infomation Dissemination Manager, SUZY Project

Nutriset is the French company that developed the technology for the production of zinc dispersible tablets.

Michel Lescanne, a food engineer who has been involved in humanitarian programmes for many years, founded Nutriset in 1986. The company is specialised in the production of food and food complement products needed specifically humanitarian aid. Nutriset offers a range of products frequently used in humanitarian emergency situations around the world, specifically for the treatment of malnutrition. They include therapeutic milk, mineral and vitamin fortified porridge, Plumpy'nut® (a product used for rapid renutrition or supplementary feeding) and QBmix® (which is recommended for the prevention and treatment of nutritional deficiencies such as scurvy, pellagra and beriberi).

Nutriset works with world renowned and

very specialized consultants in nutrition, polymers and biochemistry. Since the very beginning Nutriset has been involved in the local production of some of its products and in technology transfers. Ethics, product quality and reactivity to emergencies are the guidelines and main concerns of Nutriset. Their products are made available to NGOs and UN agencies.

In 1998, the World Health Organization (WHO) decided to conduct a series of studies on the impact of zinc and iron on some widely spread illnesses and conditions. Zinc was available in form of syrups. However, syrups are expensive to buy and ship, the bottles are breakable and difficult to handle, and syrups are not as easy to measure.

Therefore, WHO asked Nutriset to develop a zinc tablet with the following specifications. The tablets had to be:

- dispersible under 45 seconds in a minimum of water, yet, not too sensitive to humid conditions;
- acceptable to adults, young children and babies and easily administrable;
- of reasonable taste: hiding zinc properly, yet not overly sweet;
- and of course cheap.

It took Nutriset and its partner Rodael Pharmaceutical Laboratory two years to create a product up to WHO standards. So far, the product has been tested in various field studies in India, Nepal and Zanzibar. At WHO's request, Nutriset and Rodael decided to accept the technology transfer to a Bangladeshi company in the scope of the SUZY project.

For more information you can visit Nutriset's homepage at www.nutriset.fr or mail to nutriset@nutriset.fr.

WHO/UNICEF Recommendations on Managing Diarrhoeal Disease

- Sumona Liza, Infomation Dissemination Manager, SUZY Project

In the light of recent scientific advances, WHO and UNICEF issued a joint statement revising their recommendations for the management of diarrhoeal diseases and introducing zinc into the management scheme. Three advances in particular guided the organisations in their decision:

- Development of an improved formula for ORS solution with reduced levels of glucose and salt which shortens the duration of diarrhoea and the need for unscheduled intravenous fluids;
- Demonstration that zinc supplements given during an episode of acute diarrhoea reduce the duration and severity of the episode, and
- Findings that zinc supplementation given for 10-14 days lower the incidence of diarrhoea in the following 2-3 months

According to the revised recommendations, mothers and other caregivers should:

 Prevent dehydration through the early administration of increased amounts of appropriate fluids available in the home and ORS solution, if on hand

- Continue feeding (or increase breastfeeding) during, and increase all feeding after the episode
- Recognize the signs of dehydration and take the child to a health-care provider for ORS or intravenous electrolyte solution, as well as familiarize themselves with the symptoms requiring medical treatment (e.g., bloody diarrhoea)
- Provide children with 20 mg per day of zinc supplementation for 10-14 days (10 mg per day for infants under six months old).

Health-care workers are asked to encourage and enable caregivers to follow the above recommendations. In addition, they are asked to use antibiotics only when appropriate, i.e. in the presence of bloody diarrhoea or shigellosis, and abstain from administrating anti-diarrhoeal drugs.

WHO and UNICEF also called on countries to develop 3-5 year plans to reduce mortality rates from diarrhoeal diseases, for example through prioritising the availability of ORS solution and zinc supplements, strategies to educate health care workers about ORS and zinc

supplements, promoting the availability of cost effective and easy to use zinc formulations and identifying obstacles to the use of ORS, zinc and home-based treatments in managing acute diarrhoea.



Zinc preparation



Zinc administration