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Report on the

Intercountry workshop on rotavirus surveillance

Cairo, Egypt
21–23 September 2004



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1. INTRODUCTION

The first intercountry workshop on rotavirus surveillance was held in Cairo, Egypt from 21 to 23 September 2004. The meeting was attended by participants from 12 countries of the World Health Organization (WHO) Eastern Mediterranean Region and by professionals from various medical institutes and hospitals of the Region. Also present were staff from WHO headquarters, Rotavirus Vaccine Program (RVP), Centers for Disease Control and Prevention (CDC), Atlanta and the Naval Medical Research Unit (NAMRU-3), Cairo. Representatives from GlaxoSmithKline (GSK) Biologicals and from Merck and Co., Inc. also attended the meeting.

The objectives of the meeting were to:

- review current rotavirus surveillance activities in the Eastern Mediterranean Region and share experiences of the different countries;
- review available data on rotavirus epidemiology and strain prevalence from potential network members;
- identify suitable options for establishing or strengthening rotavirus surveillance within the potential member countries;
- develop a plan for establishing a rotavirus surveillance network in the Region.

The workshop was opened by Dr. Mohamed A. Jama, Deputy Regional Director, WHO Regional Office for the Eastern Mediterranean (EMRO), who welcomed the participants and expressed his appreciation of the support being provided by WHO headquarters and the WHO collaborating centres represented at the meeting. Dr Jama reminded the participants that diarrhoeal diseases continued to be one of the leading causes of illness and death in children, particularly in developing countries where an estimated 1.3 billion episodes and 4–6 million deaths occur annually among children aged under 5 years. In the Eastern Mediterranean Region, diarrhoeal diseases were estimated to cause 300 000 deaths and more than 10 million disability adjusted life years, annually. He highlighted the fact that rotavirus was the most common cause of severe diarrhoea in infants and young children, both worldwide and within the Region.

Dr Jama drew the participants' attention to the fact that environmental improvements were unlikely to have a great impact on the incidence of severe disease and that the only control measure likely to have a significant effect was vaccination. He underlined the ongoing efforts to support rotavirus surveillance and vaccine development, globally. WHO had established the Initiative for Vaccine Research (IVR) to guide, provide vision, enable, support and facilitate the development, clinical evaluation and worldwide access to safe, effective and affordable vaccines against infectious diseases of public health importance, especially in developing countries. WHO also encouraged measures to determine the burden of rotavirus diarrhoea in developing countries, in order to provide the necessary information for advocacy

and risk–benefit analyses for the introduction of new vaccines. Dr Jama concluded by highlighting the fact that WHO had already developed a generic protocol for hospital-based and community-based surveillance of rotavirus to assist countries in conducting suitable rotavirus surveillance activities.

Dr Suleiman El Busaidy, Director of Public Health Laboratory, Oman, was elected as Chairman of the meeting and the Rapporteur was Dr Kamal Fouad. The programme of the meeting, the list of participants and the questions discussed during group work are included in the back of this report as Annexes 1, 2 and 3, respectively.

2. EPIDEMIOLOGY OF ROTAVIRUS INFECTION

2.1 Epidemiology of rotavirus: global overview

Dr R. Glass

The need for improved understanding of the epidemiology and disease burden of rotavirus has become a global priority as new vaccines may be becoming available for prevention. The global burden of rotavirus disease is enormous. Every child is infected early in life. It is estimated that there are around 114 million episodes, 24 million outpatient visits, 2.3 million hospitalizations and around half a million deaths caused by rotavirus diarrhoea, annually. This means that about 1 in 5–8 cases requires medical attention, and 1 in 30–80 is hospitalized. However, despite global recognition of the need for a rotavirus vaccine, determination of the problem is rarely made in many countries and the local burden of disease goes unrecognized and under appreciated.

2.2 Rotavirus virology and diagnostics

Dr R. Glass

Natural infection with rotavirus leads to immunity against severe disease, so the goal of vaccines in development is to mimic the protective immunity induced by natural infection. Diagnostic immunoassay for rotavirus is inexpensive, sensitive and simple to use. As new vaccines move towards development and their use is globally recommended, local surveillance activities will be essential to gather background data from countries where diarrhoea remains a major health problem for children.

There is always massive virus shedding of rotavirus in the diarrhoeal stools of the infected child, amounting to approximately 10¹² particles/g of stool. This allows for detection of the virus by several methods, including electron microscopy (characteristic virus morphology), antigen detection by enzyme immunoassay or latex agglutination, and ribonucleic acid (RNA) detection by polyacrylamide gel electrophoresis (PAGE) or reverse transcription polymerase chain reaction (RT-PCR). Out of these, antigen detection by enzyme immunoassay using available commercial kits is the easiest, cheapest and most sensitive method for rotavirus diagnosis. RT-PCR, however, is the method of choice for characterizing strains and should be performed in a reference laboratory. Knowledge of strains before and after vaccine introduction can be very useful. It is to be noted, also, that stool specimens of

the patients contain large quantities of the virus and can be stored for years at 4 °C. Samples can, therefore, be collected periodically and sent to a reference laboratory for strain characterization

3. ROTAVIRUS VACCINE DEVELOPMENT: CURRENT SITUATION

3.1 MERCK vaccine

Dr A. Shaw

RotaTeq, Merck's pentavalent live attenuated rotavirus vaccine, is based on the WC3 strain of bovine rotavirus. The vaccine is comprised of five reassortant bovine rotaviruses, each carrying the human virus surface protein that determines the major serotypes of circulating human strains. This approach combines the safety of the bovine virus with the immunogenicity of the major human rotaviruses. Merck and its collaborators at the Children's Hospital of Philadelphia chose this multivalent reassortant approach to a vaccine based on epidemiological information that shows immunity against rotavirus to be largely serotype-specific. The vaccine is given orally in three doses, 1–2 months apart, with the first dose as early as 6 weeks of age. The vaccine is supplied as a ready-to-use liquid in a convenient plastic squeeze tube. Storage is at 2–8 °C.

In phase II and phase III clinical trials, the manufacturer has established the appropriate dose of vaccine to provide good immunogenicity throughout its storage period and demonstrated the consistency of manufacturing processes. Concomitant use with other routine paediatric vaccines has been explored, and the manufacturer will soon finish a large 70 000 subject study designed to reveal any potential link with intussusception. This study has been carried out in 11 countries across Europe, North and Central America and Asia, and it includes over 500 study sites. While this study is still blinded, the manufacturer has seen no evidence of concentrated intussusception after any dose in either group. In all studies that have been unblinded, so far the pentavalent vaccine has consistently shown approximately 70% efficacy against disease of any severity and approximately 100% efficacy against severe disease. There has been no excess of fever, diarrhoea or vomiting in vaccinees compared to placebo recipients.

Merck is committed to making this vaccine available worldwide and is working with the appropriate national and international agencies to achieve this goal.

3.2 GlaxoSmithKline vaccine

Dr R. Abu Elyazeed

GlaxoSmithKline Biologicals is developing a live, attenuated monovalent G1P1A P[8] human rotavirus vaccine candidate (Rotarix) for global use. The vaccine strain, RIX4414, was derived from the 89-12 vaccine strain of proven efficacy by cloning and tissue culture passaging.

The vaccine has been tested in over 9400 subjects in phase I and phase II clinical trials in Asia, Africa, Europe, North and Latin America. Given in an oral two-dose schedule within existing local, routine childhood vaccination schedules, Rotarix was well-tolerated with a reactogenicity profile similar to placebo in terms of incidences of solicited symptoms including fever, diarrhoea or vomiting. No significant difference in incidence of serious adverse events was observed between vaccine and placebo recipients, and no deaths were reported to be related to vaccination. All trials implemented the necessary procedures for prompt detection and treatment of intussusception. The safety of the vaccine was continuously monitored by an independent data-monitoring committee, and no intussusception signal related to vaccination was identified.

The vaccine was highly immunogenic in previously uninfected infants in terms of anti-rotavirus IgA antibody seroconversion rate and vaccine take-up (70%–100%). The protection afforded by all coadministered infant vaccines was maintained. Similar vaccine efficacy was observed in the different regions included in the trial, with up to 90% efficacy against severe and up to 73% efficacy against any rotavirus gastroenteritis during the first season. After dose 1, a reduction in rotavirus gastroenteritis episodes and a decrease in the incidence of severe rotavirus gastroenteritis disease were already observed in vaccinees compared to placebo recipients. In settings where multiple serotypes such as the emerging G9 serotype were circulating, the vaccine elicited cross-protective efficacy of up to 83% against severe rotavirus gastroenteritis due to non-G1 serotypes. Efficacy extended over two consecutive rotavirus seasons, reaching up to 85% and 72% against severe and any rotavirus gastroenteritis, respectively.

This data package is currently submitted to national regulatory agencies in over 10 countries in Latin America and four countries in Asia and will be submitted to the European regulatory agencies later this year. The first licence applications were granted by the Mexican and Dominican Republic regulatory agencies in July 2004. Meanwhile, Rotarix is being evaluated in large multi-country phase III trials involving over 70 000 infants in Latin America, Asia and Europe to validate the safety and efficacy profile of the vaccine. One large trial evaluating 63 000 infants, recruited in 11 Latin American countries and Finland, was designed to specifically assess the risk of intussusception or other serious adverse events.

Discussion

The following points of interest were highlighted.

- Although environmental sanitation and hygiene do not have a big role as preventive measures for rotavirus diarrhoea, they should not be omitted as they are of utmost importance in prevention of other diarrhoeal diseases.
- Rotavirus has been found to be genetically stable and could survive for years at 4 °C.
- The rotavirus vaccine can be administered at birth as there is no intussusception at such an age.

- Introduction of rotavirus vaccine should take place in areas where intussusception could be easily monitored by the health facilities.
- Rotavirus vaccine proved to be effective when administered concomitantly with oral polio vaccine. However, the vaccines have not been tested to be incorporated with oral polio vaccine, particularly Rotarix, as it is a lyophilized vaccine which should be prepared instantaneously.
- Shedding of the vaccine virus has not yet been completely tested. Similarly, neither mucosal immunoglobulin IgE nor serum immunoglobulin following administration of the vaccine has been fully assessed.
- Cross-protection might take place between the different serotypes not included in the vaccine.
- In some studies of the two vaccine trials, the socioeconomic profile of the children included has been looked. Most of the studies have been carried out in Latin America, South East Asia and Africa, where the majority of the world's developing countries lie. This will provide data on the reaction for immunogenicity of the vaccine in developing countries. Although the end of results of the studies have not yet been finalized, they will be in the near future so as the effect of socioeconomic factors can be generalized and applied.
- It is premature to discuss the price of the vaccine. This is an important issue for the decision-makers, mainly dependent on the demand. With increases in demand, the price should go down to become affordable for developing countries.

4. BURDEN OF DISEASE IN THE EASTERN MEDITERRANEAN REGION

4.1 Surveillance and burden of rotavirus and other diarrhoeal diseases: current situation

Dr F. Mahoney

Since the discovery of rotavirus, there have been numerous studies on the epidemiology of rotavirus diarrhoea in the Middle East. There have been a few population-based surveys and many hospitalization-based studies carried out, in diverse settings.

Some of the earliest studies on rotavirus as a cause of diarrhoea were conducted in Bilbeis, Egypt in the early 1980s. It was found that the incidence of rotavirus diarrhoea was highest among children aged 6–11 months and that over 50% of all children had at least one episode by the age of 12 months. Additional population-based studies were conducted in Egypt in 1995–1996 in the community of Abu-Humus in the Nile Delta. These studies found very similar rates of rotavirus diarrhoea when compared to the studies in Bilbeis.

There have been numerous hospital-based studies evaluating the etiology of rotavirus diarrhoea in the Region. Generally, these studies indicate that rotavirus is the primary cause of disease in 25%–40% of hospitalized patients with diarrhoea. The frequency of rotavirus as the cause of disease was generally lower in studies of outpatients with watery diarrhoea. Most studies reported the highest frequency of rotavirus diarrhoea among children aged 6–12 months, with low levels of disease among those aged over 3 years. Clinical findings included a high frequency of dehydration. Variations were found in the seasonality of disease between different countries and within selected countries. Generally, the studies did not identify any consistent risk factors for disease, suggesting that rotavirus affects children from all levels of the socioeconomic strata.

There are few genotype data on rotavirus as a cause of diarrhoea in the Region. The limited studies suggest that G1–4 are the most common G serotypes. One study reported a high prevalence of untypable disease; however, no other studies reported this finding.

Studies of RotaShield demonstrated an increased incidence of intussusception among children who received the vaccine. It is therefore anticipated that monitoring intussusception rates will be necessary to evaluate adverse events following immunization with rotavirus. There have been 12 studies from the Region on intussusception; however, only one of these provided incidence data. Thus, data on intussusception are limited and need to be developed as a baseline to monitor the impact of a vaccine on rates of intussusception.

No studies have been conducted in the Region to evaluate the impact of rotavirus in terms of disease burden and/or health care costs. CDC estimates there are approximately 65 000 deaths per year due to rotavirus in the Region. Most of the deaths occur in the low-income countries, which are logically those that have a limited ability to purchase new vaccines.

4.2 Natural history of rotavirus in Egypt

Dr J. Sanders and Dr A. Al Marsafy

Several studies, both population-based and hospital-based, have been conducted in various regions of Egypt over the last 25 years. The population-based studies tend to show that rotavirus accounts for only about 5% of the cases of diarrhoea seen each year. However, when looking at only “severe” cases of diarrhoea through the hospital surveillance studies, it becomes clear that rotavirus accounts for approximately 33% of severe cases of diarrhoea. A consolidation of the data from both types of study shows that rotavirus is ubiquitous throughout Egypt, infecting most children by the age of 3. The greatest incidence of infection occurs in children aged 6–12 months, reaching approximately 0.61 episodes per person per year. There are no sociodemographic associations with infection, but there is a slight wintertime predominance of disease. Rotavirus infection is the most common cause of dehydrating diarrhoea in Egypt and the most commonly identified serotypes are G1, G2, and G4.

4.3 Review of past studies of diarrhoeal disease in Kuwait

Professor J. Albert

There are currently no ongoing studies in Kuwait on rotavirus diarrhoea; however, a rotavirus disease burden study based on the WHO generic protocol will be initiated soon. The past data from Kuwait is based on three publications (from 1980, 1984 and 1989) conducted over durations of between 10 and 15 months. One thousand and four hundred children were studied, between 1 month and 5 years of age. The diagnostic tests used were ELISA and electron microscopy, and the rotavirus-positive rate was found to range from 15.3%–44.7%.

4.4 Islamic Republic of Iran: burden of disease

Dr F. Farahtaj

The mortality rate among children aged under 5 years age group in the Islamic Republic of Iran is 64 per 1000 live births. Diarrhoea is one of the most debilitating and fatal diseases in the country. It is estimated that there are 2720 deaths from rotavirus annually, with the seasonal peaks for rotavirus diarrhoea being spring and autumn.

In an epidemiological study of rotavirus diarrhoea among Iranian children, conducted between October 2001 and August 2002 in Sharekord, 146 out of 259 of children aged under 5 years were found to be rotavirus-positive by RT-PCR. Positive cases were most frequently observed from November–February.

A study of the molecular epidemiology of rotavirus infection among hospitalized children aged under 5 years with acute gastroenteritis has been taking place in Markaz Tebbi Paediatric Hospital, Teheran. Between January 2004 and September 2004, 43 out of 156 evaluated children were positive for rotavirus with ELISA, 26 out of 43 were positive with RT-PCR and 15 cases were found to be G9 with multiplex RT-PCR.

4.5 Iraq: burden of disease

Dr K. Jassim

In Iraq, the diagnosis of rotavirus infection began at the end of March 2003 using the Latex agglutination test, which is distributed to hospitals. However, due to the current situation in the country, a shortage of kits and diagnostic facilities means that confirmation of rotavirus infection is no longer performed.

4.6 Jordan: burden of disease

Dr K. Joma'a

The population of Jordan is around 5.5 million, 800 000 of whom are aged under 5 years. There are obvious climatic differences within the country's borders, with high temperatures in the Jordan Valley and Aqaba region and a cooler climate in the north and middle. In Jordan, as in other developing countries, diarrhoea represents a public health problem. Within the country, there is currently a surveillance system for diarrhoeal disease in

all governorates and this has been functioning well since 1981. Specimens are taken from around 10% of all diarrhoea cases to identify the causative agents. Currently, however, only bacterial and parasitical causes are looked for in public health facilities whilst viral etiology is not. Constraints that have been highlighted are the transportation of stool samples and the inconsistent notification of physicians. A baseline estimate of the burden of rotavirus gastroenteritis does not exist on a national scale and it is important for one to be established. The current presence of a surveillance system for diarrhoea in Jordan will make it easier to add a surveillance programme for rotavirus.

In 2003, the number of cases of gastroenteritis in Jordan was 54 702 in children under 5 years of age, with an annual incidence rate for the total population of 19.1 per 1000. The highest incidence rates of diarrhoea are in the Jordan Valley and the peak season is summer. However, as the causative agents in more than 90% of cases are not known, it is preferred to evaluate rotavirus infection throughout the year due to the peak seasonal variations shown by previous studies.

4.7 Morocco: burden of disease

Dr M. Braikat

In Morocco, diarrhoeal diseases are the most common cause of death among children aged under 5 years. Together with acute respiratory infections (ARIs), they are responsible for 40%–50% of cases of child mortality in those aged <5 years. The Moroccan National Health Information System provides data on diarrhoeal cases by age, sex, residence, type of diarrhoea (acute, persistent or bloody) and degree of dehydration (A, B or C).

Data from the national diarrhoeal disease control programme for the period 2001–2003 show that about 1 million episodes of diarrhoea are recorded annually, 97% of them are degree A (mild dehydration), about 2.5 % are of degree B (moderate dehydration) and only about 0.5 % of the total number of cases are of degree C (severe dehydration). Bloody diarrhoea represents about 0.35 % of the total number of cases. Laboratory tests for rotavirus confirmation are not performed in Morocco because of the lack of diagnosis kits and trained laboratory personnel.

4.8 Oman: burden of disease

Dr S. Albusaidy

Rotavirus surveillance has not yet been established in Oman, although a strong surveillance system is established for diarrhoeal diseases and the potential diagnostic facilities for rotavirus are available.

4.9 Pakistan: burden of disease

Dr A. Zaidi

Pakistan has a high burden of child mortality, with 103 deaths in children aged under 5 years per 1000 live births, annually. It has the fourth highest burden of child mortality in the

world and the highest burden in the Region, with 0.5 million annual deaths. It is estimated that 25% of these deaths (125 000) are attributable to diarrhoeal diseases. The available rotavirus data for Pakistan were reviewed to estimate the burden of diarrhoeal disease due to rotavirus infection. Limited data were available with no incidence figures, hospitalization rates, or mortality rates. However, several hospital-based and community-based studies estimating the proportion of diarrhoeal disease attributable to rotavirus were available. The percentage of diarrhoea due to rotavirus varied between 8%–38%, depending on how the patient population was selected. If a mean figure of 25% for the proportion of severe diarrhoea is used (those needing hospitalization, and at risk of dying if not hospitalized), it can be estimated that, 25 000 child deaths in Pakistan could be due to rotavirus disease, annually. This figure represents 40% of the burden of disease in the Eastern Mediterranean Region.

Data on strain prevalence are very limited. One study, using G typing, found G1, G2, G3 and G4 strains. A comparison between eight different studies carried out in Pakistan since 1985 has been carried out in view of rotavirus prevalence among infants with diarrhoeal disease. Diagnostic tests were also compared and found 27% positivity with ELISA and 38% with both ELISA and electron microscopy.

A hospital- and population-based study in two different areas of Karachi has been funded by the RVP and will start soon. Both areas are characterized by a well-defined catchment populations and health utilization patterns.

4.10 Sudan: burden of disease

Dr M. El Saeed

Sudan is one of the largest countries in Africa and has a poorly developed health infrastructure. The country has experienced various disease outbreaks in the last 10 years such as cholera, meningitis and Ebola fever, in addition to repetitive and frequent natural disasters such as draught and flooding.

Currently, there are no data regarding rotavirus surveillance at the national level. Only one study has been completed, which tested 101 stool samples for rotavirus. Twenty-six of the samples were found to be positive (26%) and out of those, 8 were positive for VP6 subgroup.

4.11 Syrian Arab Republic: burden of disease

Dr H. Laham

There is no surveillance system for rotavirus in the Syrian Arab Republic; however, the high burden of diarrhoeal disease in the country was highlighted.

4.12 Tunisia: burden of disease

Dr T. Abdelhalim

The first study of rotavirus epidemiology in Tunisia was conducted in 1986, in Tunis. It used rapid screening by latex agglutination and found 29% of samples to be rotavirus positive. In 1995, the Farhat Hached Hospital, Sousse began regular surveillance of rotavirus infection in the coastal region, including rapid screening, electrophoresis analysis and genotyping by RT-PCR. The mean rate of rotavirus diarrhoea was 24% from 1995–2003. The age distribution showed that 50% of infection was among children less than 1 year old. The peak incidence was observed in cooler months (January, February, October, November and December). The most common VP7 genotypes were G1, G2, G3 and G4, and G8 was isolated for the first time in 2001. The most common VP4 genotypes were P4, P6 and P8.

In a study conducted from 2000–2002 to evaluate the relationship between clinical severity and genotype of rotavirus, 210 samples were screened and 30.5% were found positive for rotavirus. The genotype distribution showed that G1P6 was the most common (42.9%). Out of the rotavirus-positive hospitalized children, 68.6% were admitted for diarrhoeal illness and 31.4% were infected during their hospital stay (hospital-acquired).

The most frequent clinical manifestations were diarrhoea (88.6%), vomiting (68.6%), dehydration (68.6%), fever (57.1%) and respiratory signs namely, cough and dyspnoea (48.6%). Rotavirus disease is particularly severe in infants aged 6 months–2 years. The clinical severity did not depend on genotype. Severity of illness seems to be influenced by host factors, such as age of children and malnutrition, but the same genotype may simultaneously induce a severe illness as an asymptomatic infection.

Further studies will be necessary to determine a nucleotide sequence in individuals of the same age (e.g. genes 4, 7 or 8) to discover whether deduced amino acid sequence differs between strains isolated from several patients of the same age and at the same time. There are three large laboratories designed for surveillance in Tunis, Sousse and Sfax. These laboratories welcome virologists for training in rotavirus diagnosis techniques.

4.13 Yemen: burden of disease

Dr A. Al Hababi

The mortality rate among Yemeni children aged <5 years of is one of the highest in the region, at about 105 per 1000 live births. The most common causes of death are diarrhoeal disease (about 29%), ARIs (22%), malaria (17%) and measles (12%).

There is no surveillance system for rotavirus in Yemen. Only one study on the prevalence of rotavirus among children with diarrhoea has been conducted in the country, by Dr Khalid Al-Kharsa in 1999 in Sana'a. It clearly showed that the most common causes of diarrhoea are rotavirus (20.8%) enteropathogenic *Escherichia coli* (12%), *Shigella* spp (7.6%) *Salmonella* spp (5.6%) and *Campylobacter* (<1%). Rotavirus was most frequently detected in

infants aged <1 year, the peak being between 6 and 12 months. Breastfeeding was found to have no effect on protection against rotavirus.

Discussion

After the participants had presented on the situation in their individual countries, the following points were highlighted and discussed.

- Rotavirus is the most common cause of severe diarrhoeal disease, with a significant mortality rate.
- Diagnostic facilities are very limited in many countries and diagnostic tools need to be more widely available in all countries.
- Limited data are available about the genotypes circulating in the different countries. When studies of the two vaccines are terminated, new information will be available on mass prevention and to limit the morbidity and mortality from the disease. Surveillance data on burden and genotype distribution is needed to guide vaccine introduction.
- Diarrhoeal diseases, including rotavirus diarrhoea, are not perceived as a public health problem in some countries, e.g. Tunisia. However, documentation of the burden of disease in these countries is still necessary.
- The rotavirus sentinel surveillance sites in a country should be representative of the country as a whole.
- The consistency and uniformity of diagnostic procedures used for surveillance was emphasized, to allow comparison of the surveillance data within the country and between countries of the Region.
- It was noticed that there are a lot of data within the academic institutions, such as the university hospitals, that have not come to the attention of ministries of health. Utilization of such data and collaboration between the ministries of health and academia was reiterated.
- Reducing the cost of hospital treatment seems to be of utmost importance as a motive for establishing a surveillance system and vaccine introduction.
- More attention should be focussed on surveillance for rotavirus, because of the huge number of cases and subsequent mortality, rather than on other diseases with less public health impact. Currently, laboratory surveillance for the cause of diarrhoea is being implemented in some countries. However in Jordan, for example, 10% of diarrhoeal cases are investigated to identify the cause, but mainly for fear of cholera despite the fact that cholera hasn't been identified in the country for a long time. The current system could be utilized for the surveillance of rotavirus as well.

5. ESTABLISHING A ROTAVIRUS SURVEILLANCE NETWORK

5.1 Introduction to generic protocol on rotavirus surveillance

Dr E. Mohsni

The Generic Protocol for Hospital Based Surveillance to Estimate the Burden of Rotavirus Gastroenteritis in Children was developed by WHO to guide the establishment of rotavirus surveillance. The main objective behind setting up rotavirus diarrhoea surveillance systems is to determine the burden of the disease and its epidemiology, and provide information for decision-making on vaccine introduction. Once the vaccine is introduced, rotavirus surveillance will be used to monitor the impact of the rotavirus vaccination programme. Several models can be used for collecting information on rotavirus diseases. Hospital-based surveillance seems to be the most suitable for rotavirus diseases, considering that:

- rotavirus vaccines target severe cases that are usually hospitalized. Hospital-based data are, therefore, important to help decide on vaccine introduction and monitor the vaccine impact in the future;
- hospitalized cases are easy to detect;
- hospitalizations represent a significant financial burden on the health resources, which is an important factor for decision-making regarding vaccine introduction;
- laboratory confirmation is important and laboratory services could be available at hospitals;
- hospital-based surveillance will provide a good opportunity to incorporate intussusception surveillance;

Setting up a rotavirus hospital-based surveillance will necessitate:

- nominating a surveillance coordinator, with clear responsibilities and terms of references;
- selecting the most suitable surveillance sites, according to recommended criteria;
- nominating one focal point at each site and agree on the different tasks to be performed;
- agreeing on a clear coordination mechanism (site visits, meetings, etc);
- reviewing local literature (diarrhoeal disease control programme data; previous studies on diarrhoea and/or rotavirus, etc);
- agreeing on case definitions (suspected case and confirmed case);

- developing surveillance forms and documents (including diarrhoeal hospitalization logbook, rotavirus diarrhoea case report form and laboratory stool specimen logbook);
- ensuring proper stool specimen collection, handling and transportation as well as use of adequate rotavirus detection methods

In order to assist with properly selecting hospitals to contribute to the surveillance network, the document proposes a community-based survey on utilization of health care services for gastroenteritis in children. The main objective of this survey is to determine the proportion of children with severe diarrhoea who receive treatment at hospitals that might be proposed for participation in the rotavirus survey. In addition to that, this survey will provide an estimation of the proportion of gastroenteritis in children aged under 5 years that will be missed by a hospital-based surveillance system. This estimation could be used to adjust the hospital-based data and get a better estimation of the true disease burden.

5.2 Introduction to the health service utilization survey

Dr G. Armah

The anticipated availability of rotavirus vaccines and the desire for an early introduction of these vaccines in developing countries highlights the need for new data on rotavirus epidemiology and disease burden. Hospital-based surveillance of rotavirus gastroenteritis in children aged under 5 years is one of the activities to determine burden of disease. In order to correctly estimate the proportion of children using the hospital facility for diarrhoea treatment, the proportion of hospitalizations due to diarrhoea and the proportion due to rotavirus infection, there is a need to perform a health services utilization survey using tools developed by WHO.

The survey, which is based on a stratified cluster survey methodology, will help in the determination of the hospital utilization pattern for diarrhoea among the carers of children in the surveillance area and the proportion of children with diarrhoea in the community who actually receive treatment at the designated selected hospital. It will also help to reveal the action taken by mothers whose children had diarrhoea during the 1 month period preceding the study and what mothers do when their children have gastroenteritis.

5.3 Need for surveillance to guide vaccine introduction and evaluation

Dr C. Nelson

Experience with the slow introduction of hepatitis B and *Haemophilus influenzae* type b (Hib) vaccines in developing countries has taught us that financing is a major impediment to the introduction of any new vaccine. With the formation of Global Alliance for Vaccines and Immunization (GAVI) and the Vaccine Fund in 2000, vaccine uptake in developing countries increased rapidly. However, Hib uptake has lagged behind hepatitis B uptake and, after an initial surge, the rate of uptake has begun to slow.

Subsequent studies of the situation have shown that apart from financing, there are several issues that influence vaccine uptake including:

- the availability of a safe and effective vaccine
- disease burden
- health economics
- absence or limited negative impact of the new vaccine on existing vaccination programme
- support from clinical opinion leaders
- absence of any resistance from paediatricians and parents.

The rotavirus Accelerated Development and Introduction Plan (ADIP) has further studied the situation and presented their results as three pillars: establishing value, communicating value and delivering the vaccine.

Again, a key message is that at both the local and regional level, the magnitude of the problem needs to be described (disease burden) and these results need to be communicated to stakeholders involved in setting public health priorities and policy formation including the Ministry of Health, academic/research groups, paediatricians/medical societies and mothers.

Finally, if the vaccine is introduced it is important to demonstrate:

- the impact of vaccination on disease, through disease surveillance
- that the vaccine is safe, through adverse events following immunization surveillance
- that the vaccine has been integrated with the national immunization system in a way that has reinforced the programme.

In all these activities, regionally coordinated sentinel surveillance plays a fundamental and crucial role.

5.4 Asia and Latin America regional rotavirus surveillance networks

Dr J. Breese

A need remains for new data on rotavirus disease burden from prospective surveillance studies. Few data are available from the majority of countries, and much of the data that are available are either too old or insufficient for estimation of national disease burden. As a result of this, WHO has recommended that regional networks of countries be organized to address this gap in data in order to support national and regional decisions on rotavirus vaccine introduction.

Two current networks that serve as examples of what can be done are in Asia and in Latin America. The Asian Rotavirus Surveillance Network has been conducting surveillance using WHO's Generic Surveillance Protocol since 2001. It began with nine countries and will expand to 11 countries in 2004.

All countries report monthly data to a central coordinator and receive support from a regional reference laboratory. The networks require a variety of partners, both public and private.

All network member countries should:

- use common methods and consistent laboratory methods
- have shared goals
- have a mechanism for sharing data
- have a mechanism for communicating goals.

Networks can also serve as platforms for other projects.

5.5 African Rotavirus Network (ARN)

Dr G. Armah

The ARN was established in 1998 and has conducted four African rotavirus workshops and hosted three rotavirus symposiums at regional scientific meetings. During the past five years, over 3000 rotavirus-positive specimens from 20 countries across Africa have been detected from stools and characterized by molecular methods. The predominant strains detected were P[6]G1 and P[6]G3 strains and geographic differences in strain dominance were observed. G9 strains were also identified in several countries, indicating that the strain is also emerging in Africa.

An added value of the ARN has been the capacity development and training of young researchers in Africa, who will become the advocates of the future. With funding from WHO and RVP, the ARN will expand surveillance activities to more countries in order to assess the burden of rotavirus disease and the cost estimation of the disease in Africa.

5.6 Establishing a rotavirus surveillance network in the Eastern Mediterranean: regional perspective

Dr N. Teleb

Currently, two vaccines against rotavirus are in the final stages of being field-tested and are expected to be available on the market in the near future. However, introduction of new vaccines is usually delayed in the Eastern Mediterranean countries that need them most due to the absence of reliable surveillance data and a failure to demonstrate the cost-effectiveness of vaccine introduction.

Surveillance of rotavirus diarrhoea is almost non-existent in all countries of the Eastern Mediterranean Region, including affluent countries. All available information derives from research studies of academic institutions and does not come to the attention of policy makers. There is a dire need for establishing a system for rotavirus surveillance in the Region to demonstrate the burden of rotavirus disease and enable countries to make evidence-based

decisions on implementation of prevention and control strategies, including vaccine introduction.

It is recommended to establish a sentinel, hospital-based surveillance system, composed of selected representative hospitals in each country, as this is the most feasible and manageable system. Countries may also add one or more sites for conducting population-based surveillance, as is deemed feasible. Such population-based surveillance will provide better estimates of disease burden. Conducting cost-benefit studies in one of the sentinel sites is also required and linking intussusception surveillance is desirable

Establishing a regional network that links rotavirus surveillance between the different countries will provide a common protocol, method and standard for all the participating sites. It will also:

- enable the sharing of information, experience and resources
- assist in human resource development
- facilitate the provision of necessary supplies
- support quality assistance and quality control
- help build an infrastructure for long-term use
- coordinate the input of different partners
- provide the regional data necessary for regional planning.

Discussion

All the participants were interested in the idea of establishing a regional network for rotavirus surveillance. A number of related issues were explored.

- The challenges/constraints faced when establishing a network at country and regional level in other regions were discussed. The constraints included laboratory capacity, human resource development, data management, etc. It was found that it is preferable to start with a sentinel type of surveillance, in cities with large hospitals and institutions. Keeping the surveillance system as simple as possible in the beginning could be of help in later expansion.
- The role of regional support in the selection of suitable surveillance sites and for setting of selection criteria has been highlighted. Surveillance should start in institutions with suitable infrastructures. Expansion of the network at a later stage, after initiation of the system in a limited number of health facilities, is a must. However, the link with ministries of health must be there from the beginning.
- The importance of integration of rotavirus surveillance with surveillance of other causes of diarrhoea was emphasized. Taking in consideration that vaccine for other causes of diarrhoea, such as enterotoxigenic *Escherichia coli* or *Shigella*, are still far from being available and rotavirus vaccine is expected to be available in the near future, the starting point is surveillance of rotavirus surveillance.

- Hospitalization from rotavirus constitutes a high proportion of diarrhoea hospitalization. The cost of hospitalization should be considered by decision-makers as a factor potentially contributing to deciding to introduce the vaccine. Collecting information about cost of hospitalization, therefore, should be a part of the surveillance. It is necessary to focus on hospitals where serious cases are admitted, provided that their data on utilization of health services is available.
- Funding is an important point to be considered for the establishing and maintenance of rotavirus surveillance in the countries.

6. GROUP WORK

6.1 Establishing regional rotavirus surveillance network: strategy, mechanism and challenges

Participants were split into two working groups to discuss all issues related to establishing rotavirus surveillance network at the national and regional levels (specific questions and points are listed in Annex 3). The first group was comprised of participants from Egypt, Islamic Republic of Iran, Jordan, Oman, Saudi Arabia and Tunisia. The second group made up of participants from Iraq, Morocco, Pakistan, Sudan, Syrian Arab Republic and Yemen.

A representative of each group presented the outcomes of their working group for panel discussion. The two groups concluded that the following are the essential elements to be taken into consideration for the establishment of the national rotavirus surveillance system and the regional network.

- Sentinel hospital-based surveillance should be adopted in the early stage of establishing the surveillance system. Later on, community-based surveillance could be adopted.
- Hospitals will be selected according to certain criteria, such as sizable admission, proportion of diarrhoea cases, capacity for dealing with severe diarrhoea cases, highly efficient laboratory capacity and good data collection capability. A defined catchment population is not essential at first.
- Case definition of severe diarrhoea, according to WHO classification, to be standardized for all surveillance sites.
- A focal point/coordinator must be designated in each hospital to follow-up the admitted cases of severe diarrhoea and to act as the link between clinical, laboratory and data management personnel.
- Overnight hospitalized patients will be the responsibility of a health staff member, who is designated by the focal point in the hospital.

- Two similar forms should be filled out at admission and at discharge of the cases.
- Laboratory staff should attend a training course, in order to capacity build.
- A volume container should be used to collect the stool specimen rather than rectal swab.
- Ensuring regular and sustainable supplies of laboratory materials is a priority.
- Genetic typing and characterization of the virus should take place after collection of 150–200 samples, to be performed in a reference laboratory.
- A quality control programme should be established.
- Monthly reporting to the secretariat of the Regional Working Group for Rotavirus Surveillance (WHO/EMRO) and monthly feedback to network members should occur.

Discussion

After presentation of the two working groups, the following points were raised by participants.

- External quality control, organized by WHO/EMRO, is important to maintain the high quality of the surveillance.
- In order not to overburden laboratory staff and considering the limited resources, only severe cases of diarrhoea (by definition) will be considered.
- Standardization of formats and data collection and analysis through WHO/EMRO should be carried out.
- Commitment and ownership by the higher authority is crucial for the establishment and sustainability of the surveillance system.
- Some laboratories for the children's hospitals don't have a -20 °C freezer. It was highlighted that adding glycerol to the stool sample could preserve it for some time, without freezing, at -20 °C.

6.2 Developing national plans for establishing rotavirus surveillance

Representatives from each country were asked to draft a national plan for establishing a rotavirus surveillance system. Participants from Jordan and Morocco presented the plans that were developed, as examples, for panel discussion.

Jordan: national plan of action

- The plan of action is over two years, beginning January 2005.
- Seven hospitals (sentinel sites) in six governorates (two in the capital) will be included in the surveillance system.
- Diagnostic equipment is available in six of the hospitals; the supply of basic requirements for surveillance is still required at the seventh hospital.
- Some equipment necessary for the hospitals' data management (computers, software, printers and internet connection) needs to be supplied in the first six months of 2005.
- Intussusception surveillance will be established together with rotavirus surveillance.
- US\$ 70 000 will be needed in addition for the supply of ELISA kits.
- The results will be disseminated after the two years surveillance have been completed.

Morocco: national plan of action

- Diarrhoea is currently under-reported in the country.
- Rotavirus surveillance working groups will be formulated to advocate the necessity of rotavirus surveillance to higher officials.
- Two children's hospitals, in Rabat and Tanga, will be included in the surveillance system.
- Training of laboratory staff, health staff and data management personnel will start by 2005.
- Kits, reagent and freezers are required before the surveillance system can begin.
- Transportation is available and poses no obstacle to surveillance.
- Internal and external quality control will be established, for which WHO support is required.
- Initiation of intussusception surveillance system in the same two sentinel sites.

Points of discussion and suggestion

- It was proposed that starting surveillance in just three or four sites in Jordan would be better in terms of management costs, as well as available support and resources. However, it was argued that in Jordan surveillance could easily be conducted in seven hospitals because of the already established surveillance system, plus the experience and commitment of decision-makers. Limitation of resources should be the determining factor for deciding the number of sites at which to begin surveillance. In addition, the involvement larger numbers of hospitals will help in building advocacy and commitment.
- WHO/EMRO is not able to supply all the reagents to all the countries. For sustainability, it was suggested that countries should consider national funding of the surveillance system and/or using the WHO country budget. It was also suggest that rotavirus surveillance should be a component of the joint WHO-country plan during the next round of joint programme review and planning missions.

- Surveillance of rotavirus should be integrated with other surveillance systems to diminish the cost. However, certain mechanisms could be available to support the system separately, as follows. Countries should submit realistic proposals to WHO/EMRO for possible support before the end of 2004. The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) could be the source for initial funding. Raising funds locally and approaching local donors in the country could be an alternative.

7. RECOMMENDATIONS

To the countries

1. All countries should review the plan of action for establishing surveillance systems for rotavirus diarrhoea developed during this meeting and finalize it according to country situation. The plan should be endorsed by the ministries of health and shared with WHO/EMRO by end of November 2004. The plan should cover:
 - a) approach(es) selected for rotavirus diarrhoea surveillance (sentinel/population-based)
 - b) selection of surveillance places and sites
 - c) coordination mechanism/identification of focal point
 - d) identification of resources
 - e) procedure of specimen collection and transfer
 - f) a clear mechanism for data collection, reporting and sharing of information with WHO/EMRO
 - g) technical assistance needed from WHO and other partners.
2. Countries should formulate national committees for rotavirus surveillance, with members taken from all sectors concerned. These should, as a minimum, include representatives from the Ministry of Health, paediatric societies, academic institutions and public health laboratories. National committees should be formulated as soon as possible and should contribute to developing the national plan
3. Wherever possible, countries should consider including representatives from different health care sectors at selected surveillance sites, e.g. from academic institutions, health insurance medical services and other non-Ministry of Health institutions.
4. Countries should build on available resources and ongoing activities for diarrhoea/rotavirus surveillance and use the infrastructures available to them, especially laboratory infrastructures e.g. national laboratories for polio/measles surveillance.
5. Countries should develop proposals for establishing rotavirus surveillance and submit them to WHO/EMRO before the end of 2004, for possible funding by interested partners.

To WHO and partners

6. WHO and potential partners should collaborate to develop a regional rotavirus surveillance network that functions to:
 - share resources
 - assist human resource development
 - coordinate input of partners
 - facilitate provision of necessary supplies
 - facilitate strain characterization, with regional reference laboratories
 - assist in quality control of participating laboratories
 - coordinate compilation of reports and sharing information.

7. WHO and other partners should formulate a regional working group on rotavirus surveillance (Regional Working Group for Rotavirus Surveillance), whose terms of reference should include:
 - providing technical assistance
 - reviewing the submitted proposals
 - supporting the raising of funds for implementation of the surveillance system at country level
 - monitoring progress.

8. WHO/EMRO should identify a regional reference laboratory for supporting strain characterization. Information on the prevailing strains should be made available to all participating countries.

9. WHO and partners should develop and make available the necessary software for the rotavirus surveillance network and assist in installation and training at country level.

10. WHO and its partners should develop and make available a laboratory manual on rotavirus laboratory surveillance methods.

Annex 1

PROGRAMME

Tuesday, 21 September 2004

08:00–09:00	Registration	
09:00–09:15	Opening session	<i>Dr M. A. Jama</i>
	<ul style="list-style-type: none"> • Opening remarks • Introduction of participants • Adoption of the agenda • Election of officers 	
	<i>Epidemiology of rotavirus infection</i>	
09:15–09:35	Epidemiology of rotavirus: global overview	<i>Dr R. Glass</i>
09:35–09:55	Rotavirus virology and diagnostics	<i>Dr R. Glass</i>
	<i>Rotavirus vaccines development: current situation</i>	
09:55–10:35	Merck vaccine	<i>Dr A. Shaw</i>
	GlaxoSmithKline vaccine	<i>Dr R. Abu Elyazeed</i>
10:35–11:00	Discussion	
	<i>Burden of disease in the Eastern Mediterranean Region</i>	
11:00–11:45	Surveillance and burden of rotavirus and other diarrhoeal diseases in the Eastern Mediterranean Region: current situation	<i>Dr F. Mahoney</i>
11:45–12:00	Natural history of rotavirus in Egypt	<i>Dr J. Sanders</i> <i>Dr A. Al Marsafy</i>
12:00–12:15	Cost benefit analysis of rotavirus infection in Kuwait	<i>Dr M. Molla</i>
14:15–17:45	Country reports: 10 minute presentation and 5 minute discussion on disease burden of rotavirus in each country	<i>Country participants</i>

Wednesday, 22 September 2004

	<i>Establishing a rotavirus surveillance network</i>	
08:30–08:50	Introduction to generic protocol on rotavirus surveillance	<i>Dr E. Mohsni</i>
08:50–09:10	Introduction to the health service utilization survey	<i>Dr G. Armah</i>
09:10–09:30	Need for surveillance to guide vaccine introduction and evaluation	<i>Dr C. Nelson</i>
09:30–09:50	Asian and Latin American: regional rotavirus surveillance networks	<i>Dr J. Breese</i>
09:50–10:10	African rotavirus surveillance network	<i>Dr G. Armah</i>
10:10–10:30	Establishing regional rotavirus surveillance network: regional perspective	<i>Dr N. Teleb</i>
10:30–11:20	Discussion	

- 11:20–17:00 Working groups
- Establishing regional laboratory network: strategy, mechanism and challenges
 - Developing national plans for establishing rotavirus surveillance:
 - population-based studies
 - hospital-based studies

Thursday, 23 September 2004

- 08:30–09:30 Presentation of the working groups
- 09:30–11:30 Group discussion: suitable approaches for a Regional rotavirus network: needs and challenges
- 11:30–12:30 Recommendations
- 12:30 Closing session

Annex 2

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Annex 3

GROUP WORK

Expected results

- Consensus on the mechanism/approaches for establishing rotavirus surveillance network
- Using this discussion as a basis for developing the national plan, using the template.

Discussion points for the group work

Reviewing need and objectives

- What are current laboratory procedures for patients with diarrhoea?
- Is there agreement on the need to establish rotavirus surveillance?
- Setting objectives.

Approaches and organization of rotavirus surveillance

- What approach(es) would be best for each country?
- What are the possibilities for population-based hospital surveillance?
- What is the selection criteria for the sentinel sites?
- How will rotavirus surveillance be organized?
 - focal point and responsible group in Ministry of Health
 - responsibilities at national level
 - responsibilities at facility level
 - laboratory capacity (regional, national), standardization, availability of kits
 - sample collection and transfer
 - data collection and flow
 - who will be responsible for completeness of reported data?
- How can we ensure continuous availability of supplies?
- What is the role of the central laboratory in maintaining these supplies and conducting quality control?

Additional studies

- Intussusception surveillance: how? and what are the constraints?
- Cost-effectiveness studies: feasibility and availability of information.

Issues

- What resources are needed?
- What constraints do you expect to encounter?
- How would you address these constraints?
- What assistance would you need from WHO/partners?