RESPONSE TO W.H.O. EVIDENCE FOR VACCINE SAFETY AND EFFECTIVENESS

***Trevor Gunn, BSc, RSHom**, corresponding on behalf of The Informed Parent has forwarded a series of questions to Dr. C. J. Clements, EPI, Global Programme for Vaccines and Immunisation, of the World Health Organisation (WHO). Replies have thus created an opportunity for dialogue on the issue off immunisation safety and effectiveness. A response to Dr Clements reply has been recently sent and the following, summaries the points raised ie: the inadequacies in vaccine testing and the inadequacies in the rationale behind mass immunisation. We shall of course be happy to print follow-up responses from the WHO when available. (Informed Parent)*

Many measles vaccine efficacy studies relate to their ability to stimulate an antibody response, (sero-conversion or sero-response). An antibody response does not necessarily equate to immunity, the WHO was asked for evidence showing how sero-response relates to protection in a real disease situation. Dr Clements thought we were implying that "whatever seroconversion level is measured, there will be no protection".

However that was not the case, the point being made was that the level of antibody needed for effective immunity is different in each individual and as Dr. Clements agreed, immunity can be demonstrated in individuals with a low or no detectable levels of antibody.

Similarly in other individuals with higher levels of antibody there may be no immunity. We therefore need to stay clear on the issue: How do we know if the vaccine is effective for a particular individual when we do not know what level of antibody production equals immunity?

Dr. Clements agreed, "...there is not a precise relationship between seroresponse and protection...". This places a greater reliance on obtaining efficacy results of immunisation from population studies. In the UK the government Health Authority quotes figures of the measles vaccine as being 90% effective.

Inevitably this leads us to ask the question; 90% effective in doing what? Reducing incidence by 90%? Reducing severity by 90%? Reducing death rate by 90%? Creating antibodies in 90%?

It does in fact mean that, 90% of the recipients of the vaccine, produce a certain level of antibodies to the viral agents in the vaccine, 10% have produced no or undetectable levels of antibody. This information has NOT been derived from population studies

and as we have already acknowledged, this does NOT indicate what percentage of those people are actually immune, (or, for that matter, how long that apparent immunity lasts).

So, to state that the vaccine is 90% effective is somewhat misleading and at any rate inaccurate with regard to a statement of immunity in a real disease situation.

Therefore the question of vaccine effectiveness can only be answered by population studies that, as stated by Dr. Clements, "do not concern themselves with the response of the individual, rather the protection afforded against the disease to the population immunised".

Dr Clements has therefore quoted references to such studies. Unfortunately they are all studies in developing countries, and as noted in the same studies, the results cannot be directly extrapolated to developed countries. The fear of many individuals in the UK faced with the decision to immunise, is that the risks of vaccination may be greater than that of diseases such as measles, in countries of the developed world. We should like to know of such studies in the so-called developed world and why so few, if any, have been carried out.

We shall nevertheless look at five of the seven studies referenced, as it can sometimes be possible to make worthwhile comparisons with other countries. (One study omitted, P. Canrelle et al, Eds. Paris, as this has proved difficult to obtain in the UK, but again looks at survival rates in a developing country, Senegal, Africa. Also the reference Bolotovski et al, only looks at the difference in antibody responses comparing different types and concentrations of vaccine, and does not compare vaccinated with non-vaccinated).

Reference: P.Aaby et al, Pediat Infec DisJ 8:197-200,1989

This paper looks at the impact of measles vaccination on childhood death rate, (childhood mortality), in Bandim, Guinea-Bissau, Africa. The study acknowledges that if it can be demonstrated that the vaccine is safer than natural measles and is reasonably effective in reducing the incidence of measles, there are still two possible impacts that measles vaccine could have on childhood mortality. On the one hand the weakest children are likely to die from any number of infections, if measles vaccination could prevent measles and therefore measles related deaths, it may still create no overall reduction in mortality as children would be as likely to die from another infection. On the other hand if measles itself causes weakness and malnutrition, effective measles vaccination could lead to a reduction in deaths.

Studies exist that appear to support both theories. Supporters of vaccine programmes adhere to the view that measles vaccination does effectively reduce childhood mortality. However this paper does acknowledge the fact that the vaccinated and unvaccinated groups are NOT strictly comparable in any of the studies supporting this view.

By comparing groups of children with apparently different vaccination status, this study suggests that measles vaccination reduces mortality by 30%.

However, their comparisons in this study would lead one to have serious misgivings about their conclusions. The group used as a "non-vaccinated" group were in fact vaccinated between certain dates. They were found to have undetectable levels of antibody and therefore it was assumed that the vaccine did not work, hence this was used as a 'control' non-vaccinated group.

Most of a second group of 123 individuals, vaccinated at another time were found to have responded and were therefore used as the vaccinated group. However 15 of this vaccinated group did not seroconvert and they were excluded from the results! Three of these children died!

In trying to assess the effectiveness of a vaccine in populations exposed to real disease situations, it will obviously be very misleading to exclude those that do not apparently seroconvert. These may constitute the very percentage of those that suffer adversely in the real disease situation. Therefore results excluding these individuals may obviously favour the effectiveness of the vaccine.

Reference: Clemens et a!, American J Epidem Vol 128, No. 6, 1330-39

This study looked at the impact of measles vaccination on childhood mortality in rural Bangladesh. Again the study acknowledges the fact that groups looked at were not strictly comparable for many reasons stated in the paper. In addition one factor overlooked was the effect of selecting individuals for vaccination on the basis of having apparently lacked a history of measles. This may select out those that have had measles at a young age and using the same rationale expressed in the study, these may well be the weaker section of the community most likely to die of measles or go on to die from underlying comorbid illnesses aggravated by contracting measles at an early age.

The paper goes on to say that their results cannot necessarily be extrapolated to programs in other countries, where measles vaccine may be given according to different age criteria or where a different relation may exist between measles and the subsequent risk of death.

Reference:Koenig et al, Bulletin of WHO 68 (4): 441-447 (1990)

This was an extension of the above previously quoted study conducted at the same centre in rural Bangladesh. Again concentrates on survival, defining a period of three years as a long term study.

Reports from studying two periods were given, one found a reduction of mortality of 46%, the other 36%. One of the reasons given for this difference was that, an area from which non-vaccines were drawn experienced higher childhood mortality than the vaccinated area as a result of a localised outbreak of dysentery. Consequently the vaccine appeared to be more effective than might otherwise have been.

This highlights the difficulty in using separate areas with different localised disease conditions for comparing the effects of vaccination. Again the report states that caution must be exercised in extrapolating the results of the present study to settings other than Bangladesh.

Reference: E. Holt et al, Paediatrics Vol.85, No 2, p188-194, Feb 1990

This was a study of the effect of measles vaccination on childhood mortality in a pen-urban slum in Tahiti. This showed much higher rates of reduction in mortality. It was not so clear as to why this was the case. It was suggested that the earlier age of vaccination compared to other studies could have been responsible. This is , 9 months (studied over a period of 30 months), as compared to 10 months (studied over a period of 40 months). It does seem hard to imagine why this difference of one month should make such a large difference in survival.

There was no mention in the paper that this may also relate to the shorter period studied. It has been reported that "gains in survival of a vaccinated group tend to diminish over time to approach a survival rate of unvaccinated individuals". (The lancet April 4, 1981 765). The weakest children most at risk go on to die from other infections, (as discussed in the first paper above, P.Aaby et al Ped lnf Dis).

This study does show however that socio-economic factors make a huge difference with regard to childhood survival. Improvements in living standards having almost as much an effect on reducing mortality as that predicted using vaccination.

Given the interest of the WHO in responding to questions, and their desire to show convincing evidence, one would assume that these studies were some of the better ones. Yet as we can see, they are sadly inadequate.

The last paper goes on to state, (as have others), that "the definitive test of the papers hypothesis would require a prospective randomised placebo-controlled trial that we believe would be unethical". We shall therefore look at the issue of a placebo-controlled trial and the question of ethics.

Double-blind placebo-controlled trial.

This involves a comparison of the results from a placebo group, (a group of individuals that do not take the active medication), with an equivalent group that have had the active medication. Double-blind refers to conditions where the individuals in the trial and those administering the drugs do not know what is active medication and what is placebo.

I would like to bring your attention to an article published in the Lancet, January 12 1980, the vaccine reviewed was the BCG, (immunisation against tuberculosis). It reported that though the protective efficacy of BCG, was not rigorously assessed, this BCG was increasingly used in Europe during the 1920's.

From 1935 to 1955 the first well controlled trials of BCG were organised only after a serious accident in the production of the BCG vaccine had left 72 children dead from tuberculosis within a few months of inoculation. Of these trials, the Lancet goes on to comment that, "their results varied strikingly and mysteriously", from 0% to 80% effectiveness. (Note the results of the above measles vaccine studies on childhood mortality varying from little more than 0% to 90%). Consequently in the 1970's, the largest controlled field trial ever done on the BCG vaccine, was organised, with 260,000 participants, comparing equal sized vaccine and placebo control groups. Not only did the results show NO evidence of a protective effect but slightly more tuberculosis cases have appeared in vaccinated than in equal sized placebo control (non-vaccinated) groups.

As a consequence of this trial, the BCG vaccine was continued to be used. It appears as though evidence of its ineffectiveness had made no difference whatsoever.

Most of the previous BCG studies were unable to establish the ineffectiveness of the BCG vaccine. Assuming there was no intention to falsify results, this must have been due to the inadequacies of the trials. Trials that did not take into account other factors, for example:

•Comparing groups that were not strictly comparable.

• Inconsistencies in disease classification, between groups and also inconsistencies before and after vaccination.

•Inaccuracies in diagnosis.

•Studies may not have taken into account natural declines in disease rate that generally occur when other living conditions improve.

When deciding whether to vaccinate against measles we appear to have a similar situation. The above trials in developing countries, have specifically admitted to not having strictly comparable groups of vaccinated and non-vaccinated. They also warn of the dangers of allying those results to situations in the developed countries i.e. the UK. One study shows quite graphically the impact of improved living conditions on mortality.

Certainly there are no studies with double-blind placebo-controlled trials. What would be the results of such a trial on measles vaccination?

It has been mentioned that placebo-controlled trials would be unethical now. This does not explain why they were not carried out in the first place. Dr Clements states that the measles vaccines were introduced when there was no alternative to measles epidemics. In the UK over 95% reduction in mortality had occurred BEFORE the introduction of measles vaccine. This is undoubtedly due to aspects of increased standards of living, a point that is further demonstrated by the results of the Tahiti study referenced by Dr Clements.

There are in fact many primary health care measures and conditions of diet and life-style that have had a dramatic effect on measles mortality, unfortunately these factors are overlooked by drug companies which leads to statements where one feels the only measures available are drugs, i.e. vaccines, which is of course not true.

We therefore have a situation where it is difficult to assess the impact of measles vaccination especially in a developed country, such as the UK, where few, if any, adequate trials have been carried out.

We also have to consider the possible effects of the vaccine.

With regard to safety Dr Clements states that, "As far as adverse events are concerned, a placebo group is not necessary because one can measure the frequency of a given sign or symptom in the general population and compare that rate to the same sign or symptom in vaccine recipients." This is sufficient for comparing risk of adverse effects of a new measles vaccine with the risks of an existing vaccine, but does not give any indication of the risks of the present vaccine compared to not being vaccinated.

When there was an opportunity to conduct safety and efficacy trials comparing vaccinated and non-vaccinated, vaccine producers chose not to carry these out. We know that many studies are from developing countries and with regard to safety we see that studies have been grossly inadequate. As late as 1975 in the Transactions of The Royal Society of Tropical Medicine (R.G.Hendrickse) it is stated "No figures (of vaccine risk) are available from developing countries". This is not to be confused with there being no risk, but that the risk cannot be assessed because "No figures are available.."

To illustrate this point further, the US National Academy of Sciences published a report in Sept 1993 in which the American Academy of paediatrics reaffirmed "its long standing position that the benefits of immunisation far outweigh the risks". However, Russell Alexander, a panel member and professor of epidemiology at the University of Washington, says he is disappointed that the panel did not compare the risk of vaccination with the risks of going unvaccinated!

How was it therefore possible to come to the conclusion that the benefits of immunisation outweigh the risks when there was no comparison with unimmunised? The benefit of a procedure is a statement of advantage over another procedure, or the advantage over not carrying out the procedure at all. Since there was no comparison of immunisation with another procedure, or with being unimmunised, the conclusions of the American Academy of Paediatrics are not based on scientific reasoning and are almost meaningless. Their position only serves to illustrate the prejudice that exists within many of those interested in promoting vaccines.

Studies now emerging do in fact link measles vaccination with adverse effects. For example Crohn's Disease, an inflammatory bowel disorder, with associated pain, digestive disturbances and joint abnormalities. (The Lancet vol.345 April 29 1995). This can be a serious disease and may take years to develop fully, but can start in childhood with digestive disturbances and consequently developmental problems.

As stated by the manufacturers of measles vaccine, adverse effects include:

fever, rash, conjunctivitis, coryza, pharyngitis, bronchitis, convulsions, encephalitis, thrombocytopenic purpura and even death.

There are many difficulties to overcome, in obtaining an accurate answer to the question of 'vaccine damage risk' i.e. the real frequency of adverse effects . Firstly, the sources of data for adverse reactions, are obtained from orthodox medical doctors notifying the health authorities and the relevant pharmaceutical companies.

Many doctors admit, and it is generally accepted, that the number of adverse reactions reported are an underestimate of the true value. Official experts readily acknowledge that this is partly because they are unsure of the reactions and partly because they do not want to report an accident they feel they may have caused.

It is interesting to note, that in countries where reporting is compulsory, the number of adverse effects to vaccines are higher than those where reporting is voluntary (UK). In the UK doctors are 'asked' to report adverse reactions, but there is no formal requirement to do so.

In the UK the situation has also been recently made worse by the additional factor of financial incentives for doctors, to encourage them to achieve the highest possible immunisation 'targets'. This means that doctors who vaccinate the largest percentage of patients on their books, stand to gain the most. Whilst those who exercise greater discretion in the administration of vaccines, due to adverse reaction or because they are willing to support parents who do not wish their children to be immunised, are financially penalised.

There are also certain time restraints placed on the appearance of symptoms, if they are to be attributed to the vaccine. For example, symptoms of adverse reactions must be apparent in an individual within 72 hours for the whooping cough vaccine and 8-20 days for the live vaccines of measles, mumps, rubella and polio.

However, just as it may take many years to die of a serious disease, of which there may have been no apparent symptoms in the early stages, it may take equally as long for the effects of medical procedures to manifest as recognisable disease symptoms. There are therefore obvious drawbacks to such strict time restrictions.

The withdrawal of the Urabe strain of mumps virus used in MMR vaccine illustrates quite clearly the phenomena of under-reporting with regard to adverse effects. The Urabe strain was thought to be linked to meningitis because the vaccine virus particles were isolated from the cerebrospinal fluid of affected children. Canada stopped using the vaccine in 1989. In the UK however, where alternative strains of mumps vaccine were not so readily available, various studies were conducted to assess the risk.

Studies based on voluntary reports gave reassuringly low estimates, one case of meningitis per 143,000 (notification by doctors) to 250,000 (voluntary reports by paediatricians). But when greater efforts were made to identify cases, for instance by cross-linking laboratory and hospital reports to vaccination records, the risk rose to between 1 in 4,000 and 1 in 21,000. These findings suggested significant under-reporting of Urabe vaccine-associated meningitis, and led to the withdrawal of the vaccine from the market in 1992. (*Parliamentary office of science and technology,*

"Vaccines and their future role in public bealth",July 1995. Also Dawbarns, solicitors, Kings Lynn, MMR & MR factsheet).

The benefit of immunisation is further diminished when we consider the duration of apparent immunity. Vaccine immunity is not as long lasting as that from the naturally acquired disease, we shall look at two consequences of this.

Firstly as immunity diminishes in adulthood there may be a delayed susceptibility to measles at an older age. Symptoms of which are generally more debilitating, with complications being more frequent and more difficult to treat than the natural childhood disease at the normal age.

In addition, as immunity diminishes in adulthood, vaccinated mothers have less immunity to pass on to their children than those that have contracted the disease naturally. Thus we see an increase in the number of measles cases in young babies where the risk of adverse effects are increased. Whereas children would normally be protected for the first year or so if maternal immunity had been acquired naturally.

It may therefore be necessary to give booster shots throughout life, in which case risk assessments will need to evaluate multiple immunisations over a longer period of time.

Therefore the question of the benefit of measles vaccine compared to the risk, in developing countries, can hardly be answered by reference to the studies given to date. The question is even more difficult to assess in developed countries such as the UK where it seems that we are assessing a questionable benefit compared to an unknown risk.

Perhaps the most interesting point of discussion comes from Dr Clements response to the question of ". . . the benefit of eradicating measles in the average child in the UK." Dr Clements states "By definition if measles is eradicated, the child is unlikely to get measles. So he or she will not develop complications or die from a disease he or she never gets. We are talking about the absence of a disease resulting in a reduced disease burden." He goes on to say... "How do fences around electricity pylons improve the health of children?" He continues... "Answer, they don’t, they reduce the chances of children touching or climbing on them and getting killed."

The analogy is a wonderful example of the thinking behind much orthodox medical treatment including that of immunisation. Firstly there is an assumption that the symptoms of measles have a wholly negative effect in the individual. I shall look at various examples including that of measles to see how this interpretation may be false.

A method of interpreting symptoms developed by Dr Randolphe Nesse, practising physician, Professor of Academic Affairs in the Department of Psychiatry, University of Michigan School of Medicine, and Dr George Williams, professor Emeritus of Ecology and Evolution at the State University of New York, member of the US National Academy of Science, has given rise to the term 'Darwinian medicine'. The concept although claimed to be new, has in fact been used by complementary therapists for centuries.

The basis of their rationale comes from acknowledging the fact that many symptoms are produced in order to maintain the health of the individual. The symptoms will, therefore, depend on the particular susceptibility of the individual and the conditions that the individual is currently subjected to. The term Darwinian medicine relates to the hypothesis that these symptoms have therefore evolved for the survival of that species and individual.

That is, the symptoms have a purpose, they are not merely malfunctions. Examples given are; the beneficial response of fever in combating micro-organisms during an infection; the role of diarrhoea in the evacuation of patheogenic organisms; the removal of iron from blood circulation in early bacterial infection appears as anaemia, this results in the decrease of the iron supply to the bacteria, which does not allow the bacteria to flourish; accompanied swelling when spraining a joint to stop motion and increase in scavenger cells to remove damaged tissue; morning sickness and its role in protecting the foetus from toxins.

The possible suppression of symptoms without understanding the larger context of their function may therefore lead to more serious consequences.

For example "Fever has only recently been revealed (*by the orthodox medical establishment*) as a beneficial response to infection. The response is triggered by bacterial toxins, and the resulting increase in body temperature is hostile to invading microorganisms. Reduce the fever - using aspirin, for instance -and the disease may last longer, as Timothy Doran of.John Hopkins University, Baltimore, has recently demonstrated in the case of chickenpox. "(New Scientist, 23-10-93). My italics.

After contracting measles and other childhood illnesses (e.g.. chickenpox, scarlet fever, whooping cough, rubella, mumps and may be others), it has been widely accepted by many health practitioners, including experienced orthodox paediatricians that this is often beneficial for the general health of many children. Specifically it has been shown that children contracting measles naturally were less likely to suffer from allergic conditions such as asthma, eczema and hayfever, (Lancer June 29 1996).

The effects of symptoms and illnesses may have consequences way beyond that of the acute problems immediately following a disease. For example, The Lancet 5 Jan 1985, reports on a study investigating the phenomenon of measles virus infection without the appearance of typical measles rash. The presence of measles antibodies in individuals is evidence of measles virus infection, however some do not produce the typical measles rash. In adulthood, (average age in the study was 38 years), for those with antibodies but NO rash, there was shown to be an increased incidence of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumours.

The report concludes that, at the time of infection, it may be dangerous to interfere with the immune response by administering a passive immunisation. It also states that "the absence of a rash may imply that intracellular virus escapes neutralisation during the acute infection and this, in turn, might give rise to the development of diseases subsequently".

The report does not question the implications of active viral immunisation where, of course, specific antibodies are produced without the appearance of typical measles rash. In addition we have no means of assessing this since we do not have studies that compare immunised with unimmunised.

It has been possible to demonstrate the benefit, in overall and long term health, of having certain types of disease symptomology. But can we show any negative effects of suppression of disease using vaccines?

Dr Michel Odent at The Primal Health research centre in London published a report in the Journal of the American Medical Association showing how the whooping cough vaccine increases the incidence of asthma by 5 to 6 times in those vaccinated compared to those unvaccinated. It appears as though the vaccine creates a chronic lung weakness in the form of asthma, whereas children that have been allowed to overcome whooping cough naturally may be strengthened in this area.

Therefore, in order to assess the benefit of a medical procedure, we need to observe its total affect on the health of the individual, over a sufficiently long period of time. Healthy individuals may not have symptoms of illness, for example, healthy individuals do not have raised temperatures, but they are capable of producing a raised temperature under certain conditions i.e. a fever, a very necessary response when dealing with an infection. There is a difference between a healthy individual not needing to create a fever and an individual unable to create a fever, the latter being the far unhealthier option.

It has been found that death rates increase in patients who are less able to produce a sufficiently high fever in response to infections (American Journal of Medicine. 68:344-355, 1980).

By eradicating measles with vaccination we are not necessarily creating healthy individuals, but perhaps suppressing symptoms thus producing individuals incapable of producing certain types of inflammatory reactions. Dr Clements response to the question of the benefit of eradicating measles does not take this into account. It is not necessarily the case that an individual without certain disease symptomology is necessarily healthier than an individual with those symptoms.

Dr Clements does acknowledge this. However, his analogy…….

"How do fences around electricity pylons improve the health of children? Answer, they don't, they reduce the chances of children touching or climbing on them and getting killed."

…….serves to illustrate the limited medical understanding with regard to the effects of vaccination and disease symptoms.

That is, measles cannot be analogous to an electricity pylon, i.e. a wholly negative burden. Previous medical practitioners have, removed tonsils, removed adenoids, suppressed symptoms of fever, etc., essentially interpreted the various parts and responses as unnecessary burdens and have later learned this to be not true.

The fence cannot be analogous to immunisation, as immunisation has consequences that affect the health of individuals. The fence may be more dangerous than what it is supposedly guarding. In addition we are learning that the act of guarding, (suppressing), can also be detrimental for overall and long term health.

We have then to face an additional question as to the value of immunisation compared to alternatives. Given that there may be a possible value in being able to display certain symptoms under given conditions. It seems likely that another way to avoid problems from measles, or any other illness, is to avoid the conditions that give rise to them and raise the level of health of individuals in order to overcome future problems effectively.

None of the references have made any comparison to alternatives. One study does show the dramatic impact of improved living conditions on reducing mortality. Similarly UK statistics show a 95% reduction in measles mortality before the introduction of measles vaccination.

Dr Clements states "I do not know of a legitimate public health measure which could be administered and which could have a similar effect to vaccination in reducing disease incidence".

Again this serves to highlight the lack of interest in methods other than pharmaceutical. For example Vitamin A supplementation has been shown to reduce the mortality rate due to measles, in under 2 year olds, by seven times. (BMJ, 1987, 294). Many studies show increase eye problems and deaths in children with vitamin A deficiency. How would immunisation compare with vitamin A supplementation? Unfortunately we do not know. Finally, to illustrate the unstable nature of what we 'know' about vaccines; in the UK travellers are now advised by immunisation clinics that there is not an effective cholera vaccine. Dr Clements seems to disagree, in that this relates to emergency situations and that the problem is the amount of time needed to create an antibody response to the vaccine (two weeks).

"As a result the WHO recommends that in these emergency situations, the first line of defence should be providin safe clean water and proper waste disposal".

Which ever view we take, a strong criticism still exists and that is:

•The numbers of individuals that were given the vaccine with the impression that it was effective.
• 'The amount of time taken to establish this fact.
• 'The inadequacy of the initial trials in not establishing the ineffectiveness of the vaccine.
• 'The relative importance of alternatives, i.e. safe clean water and proper waste disposal.

Are we to believe that we have established the safety and effectiveness of other vaccines compared to safer alternatives?

THE W.H.O. RESPONDS

Dear Mr Gunn

Thank you for your long letter dated 16th January. May I compliment you on your careful and expansive response to my earlier letter. I very much respect your diligence at looking at the literature and carefully considering the issues.

You ask many questions in the text of your letter which would entail a considerable amount of work on my part to answer. While of great interest to you and me, I am not sure that it really benefits lay audiences. The point is that the Expanded Programme on Immunisation continues to believe in the value of child immunisation as being of overwhelming value to the human race. Until the unlikely moment we have developed perfect vaccines administered by perfect vaccinators, there will remain problems from time to time. But these problems in no way mitigate against the widespread use of the vaccines. Nonetheless, national policy makers must make wise (and often difficult) decisions on what vaccines to include in the national schedule.

I do not feel that it is the right medium to embark on a scientific point-by point defense of vaccines. My concession to this is to add that vitamin A administration with immunisation is part of EPI's policy.

Yours sincerely

Dr C J Clements

Medical Officer, Expanded Programme on Immunisation

Editor:

Dr Clements appears to want to avoid having to answer questions and respond to criticisms of immunisation by using certain excuses, ie "...no benefit to lay audiences" and "..this would entail considerable amount of work.."

He goes on to state, "The point is that the Expanded Programme on Immunisation (EPI) continues to believe in the value of childhood immunisation..." This appears to reflect a new position:

a) A desire to give the burden of responsiblity to a third party, ie the EPI. What are the belies of Dr Clements (Medical Officer for the EPI? After all, the EPI does not make decisions itself, but obviously those people of the EPI do.

b) Stating that the EPI "believes" does not reflect confidence in what the EPI has evidence for, in justifying their immunisation programme. Their belief is not in question, what is in question is what evidence is this based on. The implication of the above is that it may rely more on belief than evidence.

The refusal of the WHO to answer the letter will, if anything, be seen as evidence that immunisations are not as safe and effective as we have been lead to believe. This may lead to an increasing lack of confidence in mass immunisation.

If anyone would like to contact Dr Clements, directly, indicating that a response to the

questions raised WOULD be of great interest to you, the details are as follows:

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Tel: 00 41. (22) 791 4402/265 7, Fax: 0041(22) 791 4193

I would be interested in any responses you may receive!

For a complete copy of the questions forwarded to Dr Clements, please send a SAE to The Informed Parent, P0 Box 870, Harrow, Middx., HA3 7UW

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