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SOME PROBLEMS IN THE CLASSIFICATION OF ACUTE RESPIRATORY
 INFECTION IN YOUNG CHILDREN AND QUESTIONNAIRE DESIGN*

by

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Acute respiratory infections (ARI) are widely recognised to be one of the most important causes of childhood morbidity and mortality, especially in developing countries. As a result, the World Health Organization has urged member States to accord high priority to research directed to the development of simple and effective methods for their treatment and prevention. International agencies also have been requested to give support to relevant programmes and the International Union Against Tuberculosis has responded with proposals for international collaborative studies of the problem.

There is at present, however, no agreed protocol of methods for research into ARI, although plans exist for projects in various parts of the world. It is clearly highly desirable that the methods used allow international comparisons to be made. Also the methods must be both simple enough to be practical in countries with limited resources and sophisticated enough to produce results which will advance knowledge significantly. An important gap at present is the lack of a questionnaire and clinical classification of ARI which satisfactorily meets the needs of both epidemiologists and clinicians. Epidemiologists require a classification which is simple to construct and reproducible in use, so that valid comparisons can be made between population groups in field surveys or in clinical trials. Clinicians require a classification which is relevant to diagnosis and management decisions, particularly at the primary care level. It must, therefore, have clear prognostic and therapeutic implications. These requirements are not easy to reconcile within a single classification. It seems essential to break away from traditional diagnostic labels and definitions with their confusion of anatomical, pathological, aetiological and symptomatic derivations. Instead, it is suggested that a short list of clearly defined critical signs and symptoms need to be compiled which, for epidemiological purposes, can be aggregated into classes or, for clinical purposes, can be used to predict likely aetiological agents and to construct flow charts with management decision end points. The range of features included in the list should be capable of accurately distinguishing as early as possible those patients who are in serious danger from those with comparatively minor infections in whom treatment is less critical or unnecessary.

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The work reported in this paper was part of a pilot project carried out in Lucknow, India, as a contribution to the development of a research protocol for international studies of ARI in young children. It focuses particularly on the problems of clinical classification and of designing a suitable questionnaire.

AIMS AND PURPOSES OF THE CLINICAL RECORD

The main aim of the proposed questionnaire is to provide a simple standardized record for use in international collaborative studies of epidemiological, clinical and laboratory aspects of ARI in children.

Its specific purposes will be :

- 1) To facilitate epidemiological studies of the personal, environmental and social factors that characterise children who contract ARI, particularly those associated with high risk of severe illness or death in different communities.
- 2) To describe patterns of clinical features in illnesses caused by particular microbial agents both within the same community and between different communities.
- 3) To identify those critical symptoms and signs which parents can easily observe or which primary health workers could be taught to recognise, and which should be regarded as signals of serious deterioration in a child's condition, or indicators of the need for medical attention, or that would be of value in constructing simplified treatment schemes.

For these purposes the record will need to satisfy the following criteria :

- (a) The content of the record must be standardized so that precisely the same questions are asked and the same signs and other facts are elicited and recorded on each and every patient included in the study.
- (b) The questions should be relevant to a variety of different environmental situations and appropriate to the range of cultures and health service systems within which they are to be used.
- (c) The symptoms and signs included in the clinical examination should be discriminating, that is shown to distinguish clearly between various risk groups and to be reliable predictors of clinical course and/or aetiology.
- (d) The responses to questions and the clinical findings must be demonstrated to be valid that is capable of accurately reflecting the true state of affairs, and reproducible, that is give the same results when used by different observers on the same patient.

The questionnaire which was developed and subjected to trial in Lucknow was designed with the above purposes and criteria in mind.

GENERAL CONSIDERATIONS RELATING TO THE QUESTIONNAIRE DESIGN

Many questionnaires have been constructed for use in surveys of acute respiratory infection, though they have usually not been tested prior to use by appropriate epidemiological techniques. A characteristic of many such questionnaires is that they demand very detailed and comprehensive clinical observations. This arises because of failure to distinguish between the requirements of a questionnaire for use by clinicians in individual patient care and one for survey or research use. Decisions on patient management may be determined by a wide range of factors which are frequently idiosyncratic. Also, the

clinician, when managing an individual patient, needs to be alert to unusual and potentially dangerous situations, no matter how rarely they may arise. For this purpose he may need to make a large range of observations, which he usually does in an unstructured way according to clinical indications in the individual at the time. In epidemiological studies, the purpose is usually to define group characteristics and this requires a highly structured approach. While it is accepted that within groups individual variations in clinical response will occur, these do not invalidate group comparisons and, therefore, they are of less significance than in the clinical situation. Moreover, the proliferation of clinical detail leads to the accumulation of a mass of data that cannot be analysed or interpreted epidemiologically. It is essential to recognize these differences between the clinical and epidemiological expectations of a questionnaire and the corollary that the large range of questions which clinicians must keep in mind in the individual patient is inappropriate and can be an encumbrance in epidemiological studies.

Another reason for not allowing the questionnaire to become too long and unwieldy is that the success of a study depends heavily on its simplicity. A burdensome methodology will quickly flounder in practice. Some questions included in the pilot version of the Lucknow questionnaire may well be abandoned later after trials have established which questions are the most discriminating and reproducible.

The next consideration in formulating the questionnaire was that it had to be appropriate for children of different ages, for a variety of clinical conditions and for use in different cultures and health care systems. In general, questions to which it would be difficult or impossible to elicit reliable answers in infants and very young children (e.g. sore throat) should be avoided. Equally, questions about symptoms and signs which are very rarely present in ARI in children (e.g. haemoptysis) can be omitted without detriment. In the pilot questionnaire, questions on social and environmental conditions were worded in ways appropriate to the Indian situation and some of these may need to be modified before it could be used in other countries. However, questions that would be exclusively applicable to one country have been avoided since this would render the questionnaire inappropriate as a tool for international comparative studies.

The general design of the questionnaire uses a standard stem question (worded in full where necessary to ensure uniformity of interpretation) with multiple choice answers. This not only ensures that the same range of questions in identical form is asked for each patient but facilitates the completion of answers and their subsequent analysis.

The layout of questions and answers is important in relation to the coding and analysis of the data. When the content has been finalized, detailed consideration must be given to the format to ensure that it is convenient and simple both for the clinician to complete and for the epidemiologist to analyse.

The pilot questionnaire is in English. Doctors were left to translate it into the local language at the time of use. This is unsatisfactory owing to the risk that variations in translations could lead to slight differences in the meaning of questions. In due course, the questionnaire should be translated into the local idiom by one translator and then translated back into English by another. Any discrepancies can then be discussed and a revised version produced. The agreed version must then be subjected again to tests of reproducibility between two observers. This process will need to be repeated in each country making use of the questionnaire.

SELECTION OF ITEMS FOR THE QUESTIONNAIRE

Many items were considered for inclusion in the pilot questionnaire and space does not permit full and detailed description here of the reasons for selection or rejection of each candidate item. Instead, a selection of items that gave rise to particular debate is presented for discussion and comment.

The questionnaire can be divided into six sections :

Patient identity and general information
Environmental and social data
Past medical history
History of present illness
Clinical examination
Treatment and progress

Patient Identity and General Information

Age: This is an important variable but one that is hard to obtain reliably in populations where no birth records are kept and precise age is of little practical importance to the individual. Birth date in relation to significant calendar events is often easier to obtain and can be reasonably reliable, particularly for small children. In these circumstances, it may be prudent to ask both age and date of birth in order to check one against the other.

Respondent: Answers to some questions, particularly those about the child's medical history, may vary according to the respondent's relationship to the child. For this reason it was thought best to try always to get the mother to respond. This aspect of variability in questionnaire response seems to deserve further study.

Dates of Interview and Examination: A major difficulty arises because the clinical picture in a child with an acute respiratory illness can change from hour to hour, and certainly from day to day. Thus, for example, attempts to correlate clinical features with infecting organisms or comparisons between groups of patients could be seriously affected by differences in the stage of illness at which the interview and examination are carried out. In some studies, daily records of clinical features have been compiled at great expense. However, this enormously complicates the record and the analysis without clearly resolving the above problem, because there would still be difficulties in defining a standard reference date on which comparisons are to be made. Alternatively, the analysis could take account of the total duration of symptoms and signs, but this too would be subject to variation depending on the stage of illness at which consultation first took place, what account is taken of signs that fluctuate and whether or not treatment was given. The simplest solution, though not entirely satisfactory, seems to be to record and analyse firstly, findings at the time when the patient first attends for medical care, before specific treatment is given (which in most cases will be the height of the illness) and secondly the outcome of the illness (death or the presence of persistent respiratory symptoms) at some arbitrary interval after the initial examination.

Environmental and Social Data

Air Pollution in the Home: This arises from two main sources: the burning of fuel used for domestic heating or cooking and tobacco smoking. There is evidence that both types of pollution are associated with an increased risk of serious ARI in very young children. The difficulty is to measure them in any simple way, particularly taking account also of the adequacy of ventilation in the home where standards of housing vary enormously. It is proposed to use three questions on this subject, namely:

1. Domestic fuel

What fuel is used for cooking/heating?
(Solid fuel/kerosene/gas/electricity/other)

2. Tobacco smoking

How many persons in the household regularly smoke tobacco?
(defined as at least one cigarette daily or equivalent in other forms of tobacco).

3. Ventilation

Is there an open fire in the living room?
Is there provision for (direct) smoke outlet
(chimneys, nearby window)?
Are there doors and/or windows on opposing walls?

Education of Parents: This is a relevant variable in any study of illnesses in which child-rearing practices may be significant determinants. The difficulty is in devising a question that takes account of international differences in educational systems. Some studies have used years of completed full-time education, but this is hard to measure where, for instance, school absenteeism is common and may seriously deplete real educational time. In these circumstances educational attainment may be a better index. It is proposed, therefore, to record for each parent either 'illiterate' (defined in the Indian census as unable to read or write one sentence) or the 'standard' attained at school (this represents the stage to which they advanced in the educational system irrespective of time spent in school: counterpart grading systems exist in most countries).

Past Medical History

Recurrent respiratory infection and/or diarrhoea: Such episodes are relevant both because of their debilitating effects and because, in some cultures, it is customary to withhold food and drink during acute febrile illnesses, causing a cycle of malnutrition and increased susceptibility to infection. The problem here lies in defining episodes of respiratory infection and diarrhoea in terms that mothers will understand and which will differentiate between chronic conditions and relapsing or recurrent infections. For this purpose, the character of symptoms has to be defined and time limits have to be placed on the duration of symptoms and the minimum interval free from symptoms between episodes. There are no universally accepted definitions which take account of all these parameters of an episode.

General physical growth and development: In general, "less robust" children are often regarded as more vulnerable to respiratory infection than those whose physical growth and development is "normal". The difficulty is in defining what is meant by "less robust" and "normal". It may be questioned whether the concept has any validity in relation to susceptibility to ARI at all and whether it can be differentiated from, say, adequacy of nutrition. Even if the concept is valid, there remains the difficulty of proposing an objective and reproducible index. One possibility would be to enquire about the child's physical growth and development in comparison with older children of the same parents when they were the same age. This question has not been validated and other alternatives probably should be tested in addition.

History of Present Illness

Runny/blocked nose and cough: These are symptoms which are clearly relevant to the clinical diagnosis of ARI and their presence should be recorded. The problem is that many small children suffer from these symptoms to a minor degree more or less constantly. It is proposed, therefore, to ask first whether either symptom was present "during the past three weeks", and then to ask how long ago it started and whether it is still present. Cough of less than two days duration will be disregarded on the grounds that a short transient episode of coughing is unlikely to carry respiratory significance. The differentiation of whooping cough can be difficult and the proposed marker questions are whether the cough made the child vomit and/or go red or blue in the face. All these criteria may be open to challenge.

Respiratory distress: Signs of abnormal respiration (particularly wheeze, rapid rate, cyanosis and chest indrawing) are important clinically because they often indicate the need for urgent medical attention. Reduction in mortality rates may depend critically on the early recognition of such signs and other indications that the child is seriously ill, such as refusal of food and/or vomiting. The difficulty is in determining whether or not mothers can reliably observe such signs and in devising questions that will mean the same to the mother as to the physician. The relevant questions in the pilot questionnaire are :

- "Has he/she been breathing unusually fast in the past week?"
- "Has his/her breathing sounded wheezy or whistling in the past week?"
- "Has he/she looked blue (other than after coughing) in the past week?"
- "Has he/she been refusing food in the past week?"
- "Has he/she vomited (other than after coughing) in the past week?"

In each case the parent is asked how many days ago the symptom or sign was first noticed and (where relevant) if it is still present, in order that the parents' observations can be compared with those of the doctor to see how well they correlate.

No direct question is asked about the chest indrawing, although it is said by some workers that mothers can recognise this sign. Instead there is a question which asks:

"Has he/she had any other abnormality or difficulty in breathing during the past week?"

If so, mothers are asked to describe the abnormality in order to explore what they observe and how this correlates with medical observations. This may clarify what questions on this subject might be worth including in future questionnaires.

Clinical Examination

Nutritional status: Many different indices of nutrition have been recommended for use in field surveys. It is essential that the index selected is simple to measure and one which could be correlated with resistance to infection. The indices most generally recommended are weight alone for infants under one year of age, and weight/height² for children aged 1 to 4 years. Within the latter age range mid-arm circumference has also been recommended as a relatively age-independent and simple measure. There seems to have been little work on measures of nutrition in relation to susceptibility to respiratory infection.

Physical signs in the respiratory system: The most controversial issues relating to physical signs arise from their lability and from lack of information as to which carry the greatest predictive value in relation to aetiology and prognosis of ARI. For this reason there is a tendency for items to be included in questionnaires on a purely speculative basis. Also there is very little information about which signs are most reproducible between observers. The arguments for and against recording changes in symptoms and signs and the duration of abnormalities have already been presented and it is concluded that, taking account of the problems of recording and interpreting the data, this is unlikely to be profitable. Further evaluation of the validity and reproducibility of individual respiratory signs and symptoms, however, is essential.

Treatment and Progress

Treatment: Two main reasons are commonly advanced for recording therapy. One is to monitor the process of medical care in different situations and for different types of patient. This has questionable value as an index of the quality of care unless standard indications for treatment have been agreed. The second reason is to evaluate the efficacy of treatment. However, this is not possible except in the context of a properly constructed clinical trial. A third reason for recording treatment is as an index of the doctor's assessment of severity of illness and as a qualifying variable in relation to outcome measures. Its inclusion in the pilot questionnaire is justified solely on these grounds.

Clinical outcome: Only two crude measures of outcome are proposed: death and continuing respiratory problems seven days after admission or first attendance. The latter outcome requires definition and will entail follow-up visits to patients who are discharged from hospital or who default within seven days.

VALIDATION OF QUESTIONNAIRE

It is essential that, as far as possible, the accuracy and reproducibility of answers to all questions and clinical observations should be tested. This can be done by comparing responses with independent objective evidence, by internal consistency checks comparing answers to one question with those to another similar question, and by comparisons between answers elicited and recorded by different observers. The first method is particularly difficult to apply in the case of a questionnaire such as this. For instance, most of the questions in the section "Environmental and Social Data" could only be checked by home visits and the use of other records which, if available at all in developing countries, may well be less accurate than the verbal response rather than more so. Equally, the medical history and results of clinical examination do not lend themselves to this type of checking owing to the lack of independent reference data. However, in some cases it is possible to compare the history against clinical observations and some such checks have been incorporated in the pilot questionnaire. Finally, it is possible to test the reproducibility of responses by having two or more observers independently questioning the mother and examining the child. This should be carried out in one or more countries where the cultural background and health care systems are different and in any country intending to use the questionnaire. The results will help to reveal ambiguity in the wording of questions and variations in the interpretation of answers and clinical findings. This will enable further improvements to be made in the questionnaire by the amendment or deletion of weak items.

CLASSIFICATION OF ACUTE RESPIRATORY INFECTIONS

It has already been pointed out that no simple classification of acute respiratory infections for international use has yet been agreed, though several have been proposed. It is essential that agreement should be reached before any of the major studies currently proposed or in progress becomes irrevocably committed to their own particular scheme, which could hamper and delay the adoption of an international standard classification.

The classification shown in the attached Table is based on answers to the specific questions which are included in the pilot questionnaire developed in Lucknow. Its validity is dependant on the validity of those questions, and its reproducibility on the reproducibility of the answers recorded, which have yet to be thoroughly tested. Two major criteria have been used in determining the proposed categories: anatomical site of infection and severity of illness. Anatomical site of infection is used because of its importance in terms of possible agents and the outcome of illness. Severity of illness is used because it is the prime criterion for determining initial management decisions. This classification is put forward without prejudice and will require further debate. Further experience may well lead to construction of more sound or more practically useful alternatives. But, provided the essential clinical features of illness are recorded in a standard manner, these can be combined in a variety of optional classifications.

CONCLUSIONS

There is a need for a simple standard questionnaire for use in epidemiological and clinical studies of acute respiratory infections in children. The many candidate items must be carefully sifted to exclude those that are not directly contributory to these purposes. Some of the difficulties in framing relevant questions are described. All items accepted for inclusion must be thoroughly tested for validity and reproducibility in the situation where it is intended to use the questionnaire.

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T A B L E

PROPOSED CLASSIFICATION OF ACUTE RESPIRATORY INFECTIONS

<u>CATEGORY</u>	<u>MAIN CLINICAL FEATURES</u>
<u>Upper Respiratory Tract</u>	
- Mild	Runny nose, red throat.
- Severe	Purulent exudate nose and/or throat.
<u>Middle Ear Infection</u>	Red drum and/or discharge.
<u>Middle Respiratory Tract</u>	
- Mild	Cough and/or hoarseness.
- Severe	Stridor.
<u>Lower Respiratory Tract</u>	
- Mild	Cough and/or wheeze, crepitations, rhonchi.
- Severe	Nasal flaring, chest in-drawing, cyanosis, resp. rate 50/min or more.
<u>Measles</u>	Upper and/or lower resp. signs with typical rash.

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