

**RESEARCH AND ACTION  
FOR THE PROMOTION OF ORAL HEALTH  
WITHIN PRIMARY HEALTH CARE**



**ORAL HEALTH PROGRAMME  
WORLD HEALTH ORGANIZATION**

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# RESEARCH AND ACTION FOR THE PROMOTION OF ORAL HEALTH WITHIN PRIMARY HEALTH CARE

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# **1. INTRODUCTION**

## **1.1. Recognition of oral health problems in developing countries**

Traditionally, oral health has had low priority in the health activities of developing countries. The main reasons for this were firstly, that most resources devoted to health had to be directed towards the control of communicable diseases and secondly, because in many populations oral health has been relatively good and thus the need for oral health services has been limited. However, in the last twenty years, major changes have occurred in oral disease patterns globally. In industrialised countries for example, oral health has markedly improved whilst in developing countries there has been a general deterioration. These patterns and trends have been monitored and demonstrated by the WHO Global Oral Data Bank (GODB). The increase of dental caries in many developing countries, the high prevalence of periodontal diseases, and the resulting pain, infection, and impaired masticatory functions are causing an increasing burden on populations in these countries. Compared to these two universally prevalent diseases, other oral disorders are of quantitatively minor importance although some serious lesions must be considered.

It has been clearly demonstrated in industrialised countries for the last 15 years that control and prevention of caries and periodontal disease is possible. The experience and knowledge gained throughout this period should be adapted and made use of in all countries in the world to maintain or improve oral health. Since 1967, WHO has provided systems for assisting Member States with a wide range of activities in the oral health sector. However, in a great number of developing countries, the effects of these activities have been minimal, mainly as a result of insufficient recognition and understanding of the problem, but also because of lack of models to demonstrate what can be achieved in the prevention of oral diseases at a cost compatible with available resources.

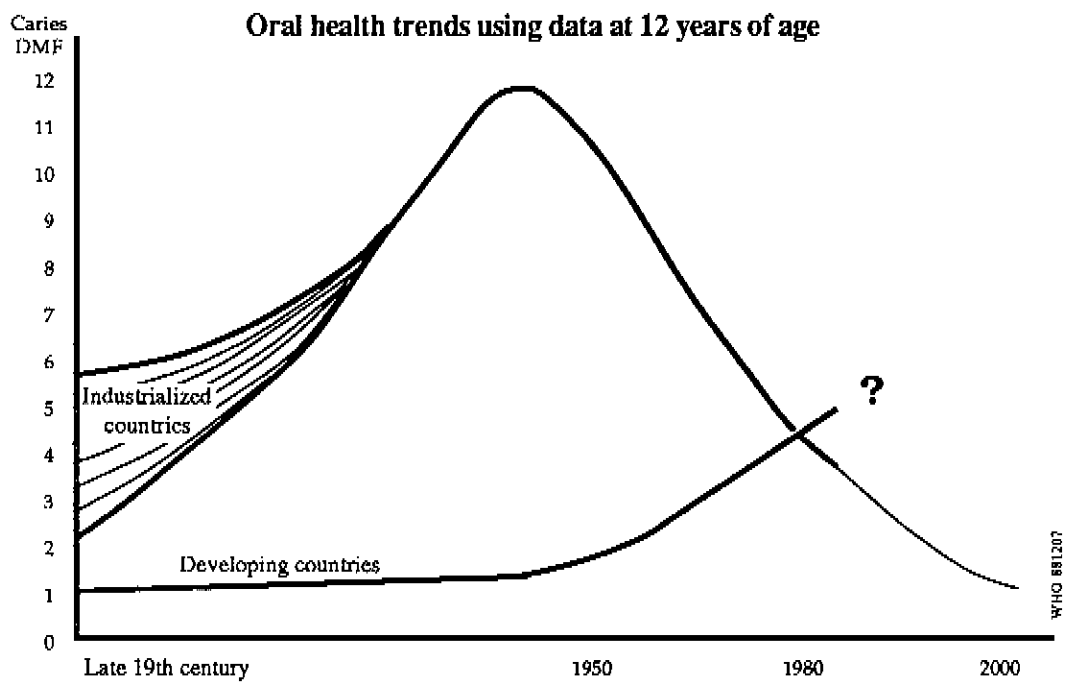


Fig 1. Oral diseases in industrialized countries have decreased since 1960. Oral Health services research is needed to ensure that the same decrease can occur in developing countries.

## **1.2. The need for health services research**

Many countries are now in the process of developing oral health care systems. However, before proceeding to commit resources to training and infrastructure, the testing of a care programme in a small area of the country should be considered. Such a study may demonstrate what can be achieved through oral health care programmes on a community basis and with limited resources .

The successful elements of these projects could then be implemented in other areas of the country. Countries with established oral care programmes should also encourage health services research projects to provide information for improving the cost effectiveness of their services. This special need for health services research, to study care programmes for use in developing countries with varying levels of resources, was highlighted by the WHO Oral Health Review and Research Advisory Group (OHRRAG) at its 1985 meeting.

Since the etiology and patterns of oral diseases are broadly similar in all countries, it is scientifically justified to use the same preventive interventions in both developing and industrialized countries. However, the cost effectiveness and feasibility aspects of implementation in developing countries, where oral disease levels are generally lower, need to be studied. The overall benefit of a comprehensive care programme as well as the effectiveness of specific elements of oral health programmes may be evaluated through health services research. Particularly in situations with restricted resources and multiple health and development problems, it is essential to be able to justify use of resources for oral health, and to demonstrate to staff involved, the effects of their efforts. It is also important not to raise expectations beyond what is feasible, as it may have negative political consequences and negative effects on morale of the population and their participation in other health activities.

### **1.3. Oral health in primary health care**

One major reason for the lack of success of oral health programmes may be the attempts to build oral health services that are separate and additional to the general health care structure. This weakness has been recognized in some developed countries who now incorporate oral health education in all health promoting efforts. In developing countries with scarce resources, it is even more essential that oral health activities are seen as part of the primary health care strategy and integrated into the regular health activities.

Primary health care is based on promotion of self help and self care, family responsibility for health and community involvement. It also emphasises the provision of simple health services to all sectors of the population and the possibility to recognize and refer complicated treatment needs. Thus the primary health care structure usually covers most sectors of society.

The incorporation of oral health into primary health care is one way to achieve economically feasible action for oral health maintenance. The overall health resources for the community will be utilized avoiding separate supervisory and logistic support systems. Furthermore, the possibility of conflicting messages being promoted will be more easily recognized and avoided.

### **1.4. Gathering information on oral health care systems**

One purpose of this document is to encourage integration of oral health care into primary health care and to promote the undertaking of health services research to test and evaluate the outcome of different care programmes. It is hoped that through such research efforts from different parts of the world, a range of models providing oral health care within the general health structure will be established, evaluated and, also, properly documented.

Interchange of such information should be encouraged among countries with similar oral health problems. WHO can undertake a major responsibility for the gathering of data from different programmes and disseminate such information through its various structures.

## **1.5. Purpose of the document**

This document will attempt to provide information on the process of health services research and indicate how oral health care programmes can be developed and evaluated. It is not intended to be an exhaustive methods manual. Rather the process is outlined, methods and approaches are suggested and further reading at various levels is recommended. It is hoped that this information will stimulate the undertaking of such research and that the collected experience will contribute to the development of guidelines and standard methods for oral health services research and evaluation. Such standard procedures will facilitate meaningful comparison and analysis of the comparative advantages of different care models in different situations.

## **1.6. Recommended reading**

Taylor C E. The use of health systems research. WHO, Geneva 1984.

Brorsson B, Wall S. Assessment of medical technology. Problems and methods. Swedish Medical Research Council, Stockholm 1985.

Alternative systems of oral care delivery. Report of a WHO Expert Committee No 750 WHO Geneva 1987.

## **2. ELEMENTS IN ORAL HEALTH SERVICES RESEARCH**

### **2.1. Questions to be addressed by health services research**

Health services research, HSR, is mainly concerned with the long term health promoting effects of an activity when it is used in normal life, that is, outside a controlled experimental situation. The activities evaluated in HSR may range from rather limited activities within a small community, to a pilot test of an alternative care delivery model in several administrative districts. In connection with the planning of oral health services in different societies, there are a number of questions that may be addressed by health services research. Some of these questions are illustrated in Fig.2.

In addition to assessing the appropriate mix of preventive and curative care in different communities, it is important to assess the relative efficiency of different preventive programmes at various disease levels. Although most countries recognize the importance of prevention, little is known concerning the feasibility and efficiency of various preventive options in the complex reality of inadequate health services and limited resources. This chapter will briefly summarize oral health situations in different communities and available preventive options; it will indicate also some examples of care programmes that may be suitable for testing in various situations.

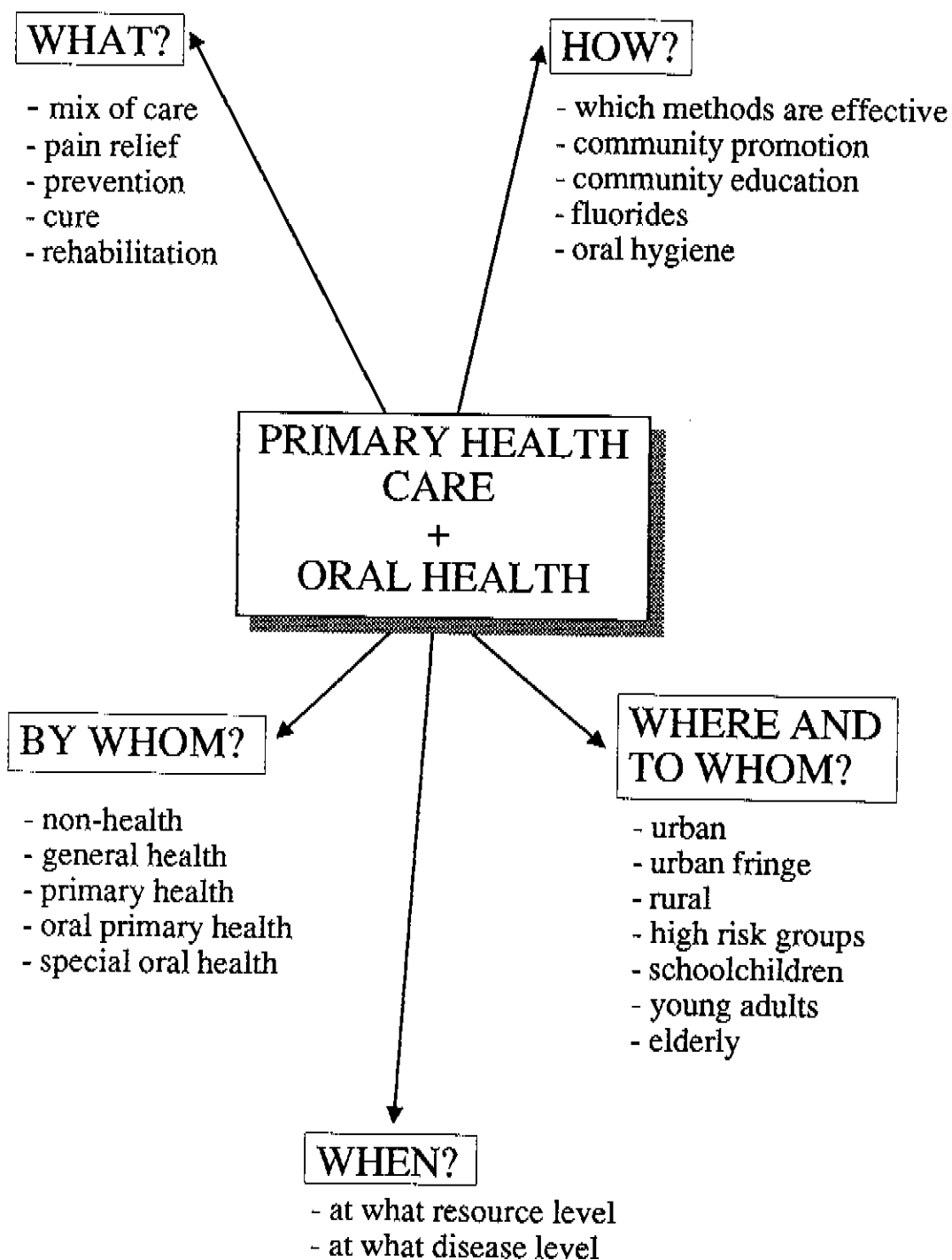


Fig 2.  
Questions that need to be addressed by oral health services research.

## 2.2 Oral health situation

In the selection of curative services and preventive options for an intervention programme, due concern must be given to the level of the disease in the community, as well as to the possible resources available for the task. Since the level of dental caries has been closely related to the affluence of society, oral health situations may be classified as in Table 1. Generally, the level of dental caries increases with the level of affluence in the country. However, significant variations in caries levels may be seen between different groups within a country. It should also be noted that many industrialized countries have managed to reduce the caries level significantly and, thereby, have broken the classical trend of increasing caries levels with increasing affluence.

Table 1. Classification of Country Situations

Oral disease level (mean DMFT) at 12 years of age	Available resources GNP/capita/yr	Level of Health Infrastructure and Personnel
very low (0-1.1 DMFT)	very low US\$ <299	Very limited No primary health care at community level. Oral health personnel at regional level only.
low (1.2-2.6 DMFT)	low US\$ 300-699	Limited Primary health care at community level, no oral care. Oral health personnel may be found at district level.
moderate to high (2.7 - 6.5 DMFT)	moderate US\$ 700-1,499	Primary health care at community level with some degree of oral care. Oral health personnel in most districts.
very high (6.6 - )	high >US\$ 1,500	Primary health care at community level with oral care. Oral health personnel in all districts.



Oral examination is an important part of primary health care

### **2.3. Preventive options**

There are a number of oral disease preventive methods that have been tested extensively and proven to be effective, both in clinical trials and general use in countries and communities. These essential preventive elements are:

- oral health promotion and education
- improvement of oral hygiene
- appropriate use of fluorides
- controlled intake of sugar

In this section the most usual preventive activities and methods are briefly described.

### **- Oral health promotion and education**

This includes a variety of activities designed to facilitate the understanding of behavioural and environmental factors that will improve or protect oral health. It includes the dissemination of information to promote awareness and knowledge of oral health problems and self care preventive measures. Health education messages contain information on oral hygiene, dietary guidance and use of fluorides. They may be transmitted by radio or television, or included in other health promotion activities and messages being given by primary health care workers, school teachers or others.

### **- Improvement of oral hygiene**

Efficient cleaning of teeth at least once a day removes most dental plaque which is an important factor in the development of gingivitis. Oral hygiene is promoted through oral health education and instruction. Oral hygiene instruction is given to individuals or groups of people. This activity requires considerably



Improving oral hygiene - Efficient mouth cleaning depends entirely on the knowledge, attitudes and skills of the individual.

more effort and resources than promotion or group health education. Efficient mouth cleaning depends entirely on the knowledge, attitudes, and skills of the individual. It also requires access to suitable tooth brushes.

Traditional chewing sticks, used in many societies, may have sufficiently good effect without harmful side effects, and may be recommended where commercially manufactured tooth brushes cannot be afforded.

#### - **Appropriate use of fluorides**

Fluorides have a proven caries reducing effect, especially on smooth surfaces, when administered properly. They can be provided regularly in several ways:

- water fluoridation at community level requires a central water supply and a well-functioning dispensing and monitoring system.
- fluoridated salt is used as a vehicle to provide fluorides in some societies where salt production can be controlled.
- fluoridated toothpaste is widely used in countries where economic resources permit.
- fluoride mouthrinse is an alternative method of fluoride application to teeth. It may be implemented as a twice-monthly or weekly procedure in schools or as a daily family self-care activity.
- topical application of fluoride solutions or varnishes applied by trained personnel may be another, although more expensive, option for special risk groups.

Where there is excess fluoride in the environment, and especially in the drinking water, causing dental or skeletal fluorosis, defluoridation measures to remove the excess are recommended.

### - Controlled sugar usage

The frequency of intake of sugar appears to be a decisive factor contributing to the development of dental caries. A strictly controlled intake of sugar would have a major impact towards the prevention of caries. However, the possibilities of success in such efforts are dependent on factors that are difficult to control. Availability of sugar in a society is geared by government policy, income and price level. The individual consumption pattern can to some extent be influenced by counselling; but such counselling has limited chances of success if given outside the context of general nutritional advice. Special care must be taken to avoid conflicting messages, especially in areas where there is a shortage of food. It should be recognized that dietary habits in relation to sugar consumption are difficult to change, but in general a prudent use of refined carbohydrates should be promoted.

## 2.4. What components could be included in a care programme?

The question of what kind of oral care programmes may be suitable in different communities has been widely discussed. The need for emergency care has generally been recognized in most societies. The development and availability of curative services have usually depended on the ability of the people to pay for such services. Similarly popular demand cannot be expected to push for preventive care. The interest in prevention usually comes from public health planners, who recognize a growing oral disease problem and understand the gains for society that may be achieved through successful preventive programmes.

It will always be difficult to compare the benefits of a preventive programme with those of emergency care and other services. Still, planning would be facilitated through a better understanding of what benefits can be expected at certain costs in different kinds of programmes. In relation to preventive care, it should be possible to identify what minimum inputs are necessary to achieve any effect at all, and to assess at what disease

level it is more profitable and feasible to prevent than to provide treatment, realizing that prevention is always preferable, even if it is as, or more costly than cure or repair.

Thus it is strongly recommended that any strategy tested is implemented in such a way that the experience is properly documented. The knowledge gained should be systematized so that elements of success can be demonstrated, and the different aspects analysed and compared with other programmes. This document does not give recommendations on the specific programme elements that should be included in care programmes in different countries. Oral health services research may involve a variety of intervention activities. What is important is that the experiences are properly evaluated.

Examples of various activities that may be included in a care programme are presented in Table 2. Single activities or the combination of activities in oral health programmes may be tested. It is hoped that the testing of different options at different resource levels will bring valuable insights that can be globally shared.

## **2.5. Recommended Reading**

Prevention of Oral Diseases WHO Offset Publication No103  
WHO Geneva 1987 ISBN 924.170103 Sf 14.

**Table 2**

**Activities that may be evaluated in oral health programmes in various combinations depending on the disease level and available resources.**

<b>School based activities</b>	<b>Community based activities</b>
School teacher and health personnel undertake:	Health personnel at village or district level undertake:
*Pain relief	* Oral emergency care provided or referred
*Oral health education - Advice on eating habits - Oral hygiene advice (groups)	* Oral health promotion
	* Oral health education
* Oral hygiene instruction (individuals) - traditional methods - tooth brushes	* Oral hygiene instruction
* Screening and referral	* Screening and referral
* Fluoride supplement - fluoride mouthrinse - topical fluoride application - tooth pastes	* Fluoride supplement - fluoride mouthrinse - tooth pastes
* Fissure sealing	* Water or salt fluoridation
* Scaling	* Scaling
* Limited restorative care	* Limited restorative care

### 3. COMMUNITY SITUATION ANALYSIS

#### 3.1. Purpose of situation analysis

The development and evaluation of oral health components in a Primary Health Care Programme requires a situation analysis of the community where the project is to be implemented. The initial choice of the area may be based on the results of a pathfinder survey, that describes the oral health situation in a population. In this and following chapters this process of research and action is described; from the initial collection of available information, the identification of important research questions to be answered in population studies, the subsequent design of health care programmes, and the evaluation of those programmes (Figure 3).

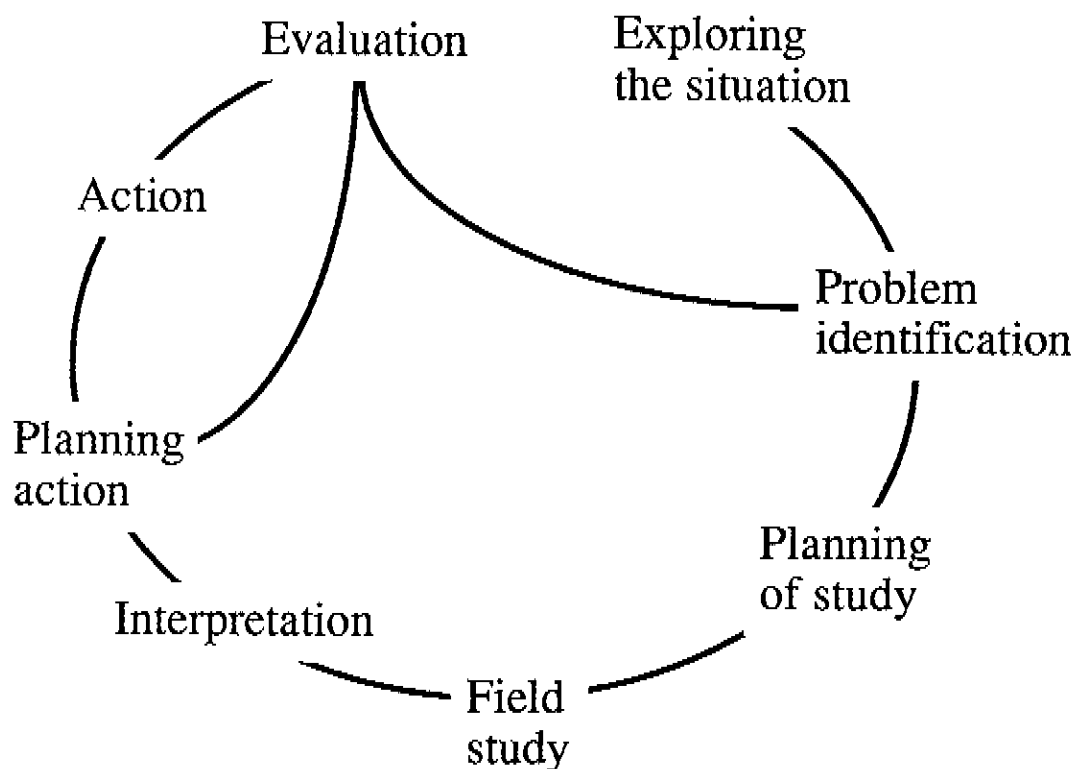


Figure 3. The process of research and action for promotion of oral health within Primary Health Care.

When the oral health activities to be integrated into PHC have a major emphasis on prevention of oral disease, the communities chosen to participate in the study must be selected with care. They should have disease levels of a magnitude which will give a reasonable chance of demonstrating the effectiveness of an activity. For example, it would be unwise to try to demonstrate the effectiveness of a caries preventive measure in an area where the mean DMFT at age 12 is 0.5. Such very low caries situations call for only simple monitoring activities to determine if caries starts to increase, supplemented as necessary with oral hygiene promotion. Also a programme, involving a heavy commitment in time by general health workers who already feel, and indeed are, overworked, is unlikely to succeed. Thus the main purpose of the situation analysis is to ensure that the current situation in the community, in which the research is to be implemented, is understood.

### **3.2. Exploring the situation**

One of the principle objectives of "Research and Action for the Promotion of Oral Health within Primary Health Care" is the demonstration to decision-makers of what can be achieved at a cost that is compatible with available resources. Therefore, it is important that the community itself and the local health personnel (e.g. the primary health workers) are engaged in the collection of relevant information as well as in the future implementation of the services.

The PHC approach requires that oral health be a component in general health care; hence, when carrying out the situation analysis, it is essential to liaise closely with established community health workers. Indeed, much of the information required will already be available from personnel currently engaged in health care. There are several other sources and methods of collecting this background information; official statistics, information from Ministries, from local authorities, etc.

A first visit in the area serves to establish contact and to gather general background information on existing administrative structures, socio-economic level, household organization and lifestyle. More time is needed to establish fruitful contacts with health workers, community leaders, school teachers, religious leaders and store keepers. Through communication and observation, and by asking questions, valuable information about the lifestyle of the community members, their habits, problems and priorities can be collected.



Information about the life style of community members, their habits, problems and priorities is needed.

### **3.3. Demographic information**

Demographic information about the community under study is needed to define the size of the target population. This information also provides the denominator and defines an appropriate sampling frame for further studies. Often fairly recent demographic data may be available from officials in the area; in this case the information will only need to be up-dated using information from village leaders or school teachers. If these data are not available, some demographic survey may be needed. This demographic survey may be linked to any other field survey or may be performed separately. Age, sex, and a few other relevant questions are asked in this population census.

### **3.4. Oral Health Information**

Often there is need for information on the oral health situation in the community; data from an earlier pathfinder analysis may be insufficient and more detailed or more recent data may be needed to describe the situation before any new health care interventions are considered.

Through the demographic study, the number of inhabitants and the age and sex distribution have been estimated. This is the population for which the oral health survey is intended. For a very limited area such as a small village, it may be possible to examine all individuals in the community. However, in most cases it is sufficient and necessary to limit the examination to a sample, i.e. a number of individuals selected to represent the population in the study area. There are various methods of performing the sampling; often some kind of cluster sampling is used. Villages, compounds of households or maybe school classes are selected from a list or a map in a random or a systematic way, and the survey is performed only in those units. Often the survey is limited to certain age groups (strata), selected so that the groups to be involved in the intervention activities are represented. In order to provide reference data to the WHO Global Oral Data Bank, the age group 12 years should be included. The age groups 35-44 and 55-64 years may also be included to give information on the progression of caries and periodontal diseases in the population. The size of the sample may be calculated using standard techniques. In most cases, the sample size should not be less than 50 persons in any one age group.

The oral examination should follow the standard procedure and criteria as described in the WHO Oral Health Surveys: Basic Methods manual. However, it is important to remember that the nature and level of the measurement criteria adopted will depend to a great extent on the aims of the treatment strategies being evaluated. For example, in a study in which the cost-effectiveness of fissure sealants was being investigated, it would be necessary to consider measuring the dental caries experience on a surface basis.

Similarly for the registration of periodontal status, specific indicators of interest i.e. bleeding, calculus, recession or pocketing need to be selected so that appropriate information on both "accumulated disease experience", as well as "remaining untreated disease" can be assessed. This approach would provide data similar to that provided by the DMFT and DMFS indicators, and could also ensure that the Community Periodontal Index can be calculated for the population thus providing a reference for future evaluations to be stored in the Global Oral Data Bank. In addition to the oral examination a simple questionnaire on, for example, oral cleaning and dietary habits may be included. Some questions that have been identified during the exploratory stage can also be included. The number of questions should be small (preferably not more than 10) and the questionnaire should be carefully designed and pilot tested before use in the survey.

### **3.5. Health promoting attitudes, beliefs and practices**

In a Primary Health Care strategy community participation is a cornerstone. To achieve this, a good knowledge is needed of current health related attitudes, beliefs and practices. Much of this information can be obtained from informal observations and contacts, and through in-depth interviews with community members. A limited number of questions may also be included in a survey. There are, however, limitations to the possibilities of a brief questionnaire to provide valid answers to many of these questions: what kind of attitudes to oral hygiene and other health promoting activities exist, what beliefs regarding oral health problems are common, and what measures of relevance for oral health are practiced in the community?



Much information can be obtained from informal observations and contacts with community members.

The sondeo technique has been suggested as an effective, rapid method for collecting this type of information. Members of the research team are paired with a local health or community worker, each pair then interviews several members of the community, using a brief check-list of topics. At the end of each day the interviewing pairs meet to discuss the information collected. After 2 or 3 days work a collective report is prepared. The technique usually ensures a balanced report and is excellent preparation for the development of community participation.

### 3.6. Specific surveys

In earlier steps of the situation analysis, information has been collected on the oral health situation, the general health situation, traditions, beliefs and health practices, etc. Most of those data are descriptive, i.e., answering the questions when? where? and who? Maybe a number of new questions and hypotheses have been generated, demanding an analytical approach, i.e., answering the question "why?"; Why do we have this caries situation in the community? Why do the inhabitants in the first village suffer more from tooth loss than those of the other village?

In a cross-sectional, or prevalence study, background factors and disease status are measured at one point in time. Therefore, it may be difficult to judge, if the background factors have any causal relation to the disease. More valid information on causal relationships may be achieved in longitudinal studies, where the individuals are followed over a period of time, either prospectively or retrospectively. In a cohort study the individuals are followed from cause to effect, i.e. from health in a given setting to oral disease. In a case-referent study, individuals with certain oral health problems are studied as well as individuals without those health problems, comparing the earlier "exposure" to relevant background factors. Some examples of those study designs are given in Chapter 5. The choice of study design depends upon the research questions, available time and resources.

### **3.7. Recommended Reading**

Community health surveys. Practical guides for health workers 1-5. (may be ordered from WHO Regional Offices).

Lutz W. 1. Planning and Organizing a health survey. A guide for health workers. IEA, Geneva, 1981.

Lutz W. 2. Sampling: How to select people, households, places to study community health. A guide for Health Workers. IEA, Geneva, 1982.

Lutz W. 3. Finding and using information. A guide for Health Workers. IEA, Geneva, 1983.

Lutz W. 4. Questionnaire design. A guide for Health Workers. IEA, Geneva, 1986.

Hepburn W, Lutz W. 5. Interviewing and recording. A guide to Interviewer Training for Health Workers. IEA, Geneva, 1986.

Oral Health Surveys Basic Method 3rd ed. WHO Geneva, 1988.

Concepts of Health Behaviour research, WHO SEARO Regional Health Paper. No 13 1986 price Rs 60:00. ISBN 92 9022, 1828.

## **4. SYNTHESIS AND PROGRAMME DESIGN**

### **4.1. Synthesis of knowledge about the community**

The final design of an intervention study will be decided after all available information has been considered. The information gathered in the situation analysis will be judged against previous experience and knowledge derived from literature. Conclusions published from previous studies should not be adopted uncritically. A finding of statistical significance does not necessarily have "clinical" significance or relevance when considering the initiation of an intervention programme. It is necessary to find out under what circumstances the results were obtained and what methods were used in research design and evaluation. It is also important to recognize that information derived from a specific study becomes meaningful only in conjunction with other relevant information.

For instance, analysis of the relationship between caries and nutrition level among school children may indicate that children who maintain a traditional diet have little caries, while those who have adopted a "western" diet have more caries. The relevant message for health educators in this case appears to be "maintain traditional diet". However, those who have taken up a westernized diet may be well nourished, while malnutrition is common among those who eat traditional food. Thus, the health message in our intervention programme must be more specific than simply promoting traditional diet.

Another example: our situation analysis shows no significant difference in periodontal disease level between those that use a chewstick, and those who do not. Our conclusion could be that toothcleaning does not improve periodontal conditions and should not be promoted within the programme. On the other hand, we know that gingivitis does not develop if efficient toothcleaning is maintained and may conclude that a programme to promote proper cleaning methods should be tested.

## 4.2. The Primary Health Care context

Within a Primary Health Care system, there may be a variety of components being developed to respond to the major problems in the community. The most commonly implemented components are immunization, water and sanitation, maternal and child health (MCH) services, nutrition programmes, essential drug programmes, simple curative treatment and health education. The data collection during the situation analysis will have identified the components that exist, the ways in which the activities are being operationalized and the pattern of the communities' use of the services. In these activities participation of the community, its leaders and health workers, is essential. Thus it is very important to listen carefully to the local experiences and discussion of problems and priorities. The essence of this listening is to draw out an understanding of how health and oral disease prevention and control activities are linked and mutually influential, and to identify activities in existing Primary Health Care where the oral health component could most effectively be integrated into community activity patterns.

For example, in a community, MCH personnel may express the need for locally appropriate oral hygiene measures for the mothers to pass on to children. "Oral Care" can then easily be one of the regularly scheduled topics taught at MCH clinics. Alternatively, oral health promoting attitudes and behaviours learned by pupils in a school-based programme may be brought back to the family. Each programme should reinforce other health care activities whenever appropriate.

In another community a main concern may be to improve the taste and quality of their drinking water, and a survey demonstrates that fluorosis is a problem in the area. Locally made appropriate defluoridation units can be installed to cover both the primary intention of the community and the prevention of fluorosis.

Some countries have quite a number of trained oral health personnel, some of whom may be working at the Primary Health Care level; such personnel can contribute to the general health care of the population by passing on health messages, and by observing problems and referring people to appropriate care.



The ICOH defluoridator is an economic and practical method for household use.

One of the most important items of baseline information needed is whether the community really wants the proposed activity or not. If there is not clear recognition of need and a measure of likely demand, the programme will probably fail through lack of participation. With the above-mentioned participation - listening - learning - discussing - contributing process, it is possible to initiate a truly multi-sectoral development and expansion of the Primary Health Care system to include oral health.

### 4.3. Programme design

The programme design must be given careful attention. The situation analysis will indicate restrictions and limitations as well as point to possibilities for intervention. In situations where the introduction of preventive programmes is considered, the possible outcome of various interventions should be discussed in relation to the disease level. It is important to select only such activities which are expected to effectively maintain or improve oral health. It is also important to indicate desired goals and decide how the outcome of the programme should be monitored and evaluated. In situations where health goals have been achieved at a certain cost, a study may be designed to compare the effect of that programme with a less costly programme. A comparison of two "competing strategies" may also demonstrate the relative contribution of different components.

Table 3 gives some examples of "competing strategies" that may be tested and evaluated in different communities. In each situation two similar strategies are compared, but one contains some additional activities. Any combination of programme options can be tested in any situation. However, both strategies must be feasible and it must be assumed that at least the most ambitious programme will have a measurable effect in relation to the stated objective. It would be a waste of time and resources to compare two intervention programmes, if neither of them will produce a demonstrable effect.

Studies may also be designed to evaluate ways of implementing programme components, for instance to compare various ways of promoting oral hygiene or implementing fluoride mouth rinsing in schools. In the design of a comprehensive health service research programme, pilot studies may be carried out to evaluate the feasibility of programme components or the "programme package".

A research protocol must always be written. The protocol is a straight forward document which communicates the research problem clearly and describes precisely the steps to be taken in conducting the research and in analyzing the data collected. The protocol will guide the investigators in the collection of relevant information and in the whole cycle of research implementation.

The research protocol also provides the basis by which the research can be evaluated by health care planners or funding agencies. Funding agencies may request specific formats but the document should usually contain the components outlined in the attached "Guidelines for research protocol" (see annex 1).

Table 3. Examples of Study Design.

1	<b>Strategy A</b>		<b>Strategy B</b>	
	<b>School-based</b> * Oral hygiene instruction using traditional methods * Advice on eating habits	<b>Community-based</b> * Oral health promotion and education * Oral hygiene instruction using traditional methods * Oral emergency care provided or referred	<b>School-based</b> * None	<b>Community-based</b> * Oral health promotion and education * Oral hygiene instruction using traditional methods * Oral emergency care provided or referred
2	<b>Strategy A</b>		<b>Strategy B</b>	
	<b>School-based</b> * Oral hygiene instruction using traditional methods * Fluoride mouthrinse * Advice on eating habits	<b>Community-based</b> * Oral health promotion * Oral emergency care	<b>School-based</b> * Oral hygiene instruction using traditional methods * Advice on eating habits	<b>Community-based</b> * Oral health promotion * Oral emergency care
3	<b>Strategy A</b>		<b>Strategy B</b>	
	<b>School-based</b> * Oral hygiene instruction using traditional methods * Fluoride mouthrinse * Advice on eating habits	<b>Community-based</b> * Oral health promotion and education * Oral hygiene instruction using traditional methods * Oral emergency care provided or referred	<b>School-based</b> * Fluoride mouthrinse	<b>Community-based</b> * Oral emergency care * Oral health promotion and education

4	<b>Strategy A</b>		<b>Strategy B</b>	
	<b>School-based</b> <ul style="list-style-type: none"> <li>* Oral hygiene instruction using toothbrush/traditional methods</li> <li>* Fluoride mouthrinses</li> <li>* Advice on eating habits</li> <li>* Scaling for high risk groups</li> </ul>	<b>Community-based</b> <ul style="list-style-type: none"> <li>* Oral health promotion and education</li> <li>* Oral hygiene instruction using traditional methods</li> <li>* Referral care</li> <li>* Scaling for high risk groups</li> </ul>	<b>School-based</b> <ul style="list-style-type: none"> <li>* Oral hygiene instruction using toothbrush/traditional methods</li> </ul>	<b>Community-based</b> <ul style="list-style-type: none"> <li>* Referral care</li> </ul>

5	<b>Strategy A</b>		<b>Strategy B</b>	
	<b>School-based</b> <ul style="list-style-type: none"> <li>* Oral hygiene instruction using toothbrush/ traditional methods</li> <li>* Fluoridated toothpaste/fluoride mouthrinses</li> <li>* Counselling of frequency of intake on reduction of refined carbohydrates</li> <li>* Fissure sealing</li> </ul>	<b>Community-based</b> <ul style="list-style-type: none"> <li>* Oral health prevention and promotion</li> <li>* Oral hygiene instruction using toothbrush</li> <li>* Screening, scaling and referral care</li> <li>* Oral emergency care and referral</li> <li>* Simple restorative care</li> <li>* Limited 1st referral level service at intervals</li> </ul>	<b>School-based</b> <ul style="list-style-type: none"> <li>* Oral hygiene instruction using traditional methods only</li> <li>* Counselling on reduction of frequency of intake of refined carbohydrates</li> <li>* Fissure scaling</li> <li>* Simple restorative care</li> </ul>	<b>Community-based</b> <ul style="list-style-type: none"> <li>* Oral emergency care and referral</li> <li>* Limited 1st referral level service at intervals</li> </ul>

6	<b>Strategy A</b>		<b>Strategy B</b>	
	<b>School-based</b> <ul style="list-style-type: none"> <li>* Oral hygiene instruction using toothbrush</li> <li>* Fluoridated toothpaste</li> <li>* Counselling on reduction of frequency of intake of refined carbohydrates</li> <li>* Fissure sealing</li> <li>* Simple restorative care</li> </ul>	<b>Community-based</b> <ul style="list-style-type: none"> <li>* Oral health promotion and education</li> <li>* Oral hygiene instruction using toothbrush</li> <li>* Oral emergency care and referral</li> <li>* Water or salt fluoridation in densely populated areas</li> <li>* Limited 1st referral level service at intervals</li> </ul>	<b>School-based</b> <ul style="list-style-type: none"> <li>* Oral hygiene instruction using toothbrush</li> <li>* Fluoridated toothpaste</li> <li>* Counselling on reduction of frequency of intake of refined carbohydrates</li> <li>* Simple restorative care</li> </ul>	<b>Community-based</b> <ul style="list-style-type: none"> <li>* Oral health promotion and education</li> <li>* Oral hygiene instruction using toothbrush</li> <li>* Oral emergency care and referral</li> <li>* Water fluoridation in densely populated areas</li> <li>* Limited 1st referral level service at intervals</li> </ul>

## 4.4. Logistics

There are many logistic problems which need to be considered carefully before implementing a project within the Primary Health Care structure. Some of these logistic considerations may seem to be insignificant for the planner, but they may create big problems, or even lead to the cancellation of a project if overlooked.

The proposed implementation of oral health programmes should be acceptable to the culture, religion, beliefs and life-style of the people; otherwise, conflicts may arise. It is also mandatory that expenses incurred by the community must be reasonable and affordable, and these must be discussed in full with the community, and a commitment made to try out the proposed system for a specified period.

### Administrative factors

Government permission to implement the project must be passed down through the proper lines of administration, so that all authorities at national, regional, district and community level are aware of the activity. This is especially important for health services research projects where programme options, that differ from existing activities, are to be tested. It must be realized that this process can take a long time and involve discussions with officials at many levels of authority. In addition to obtaining permission from officials the understanding and permission from key groups in the community such as elders and women's groups are essential. Neglecting this step may result in delays and misunderstandings during the implementation phases.

### Practical considerations

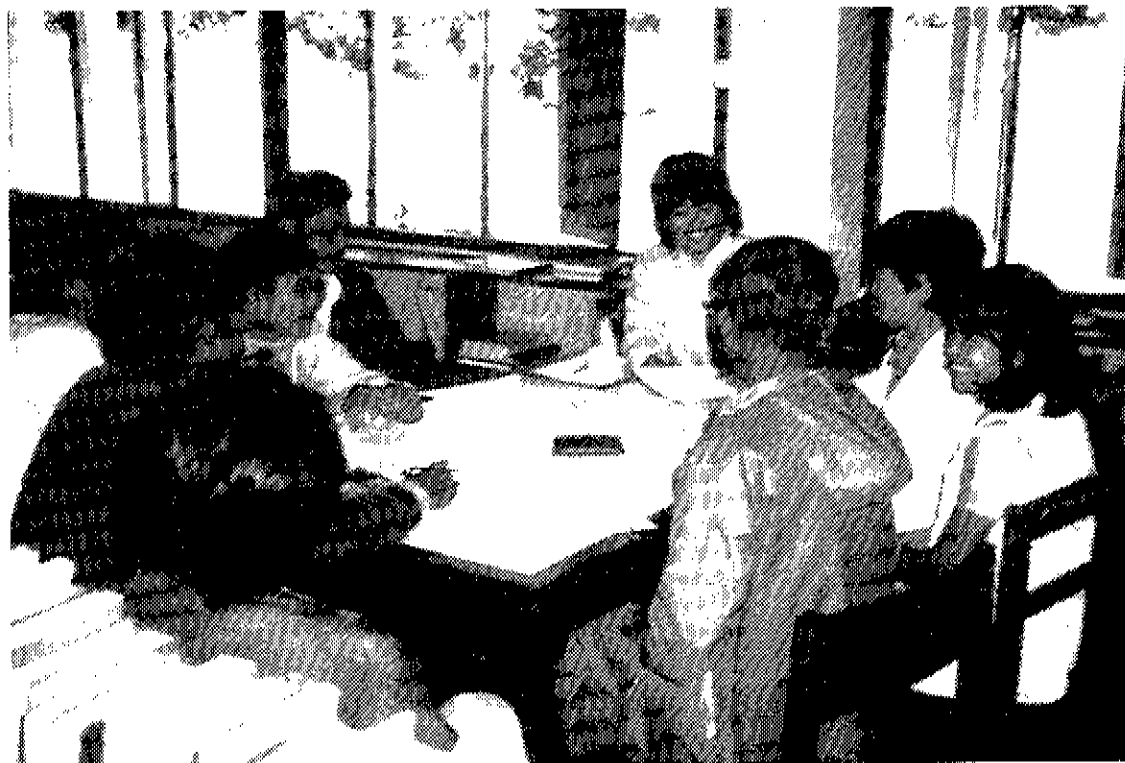
Factors relating to geography, climate, and physical facilities should also be considered. Certain locations may be difficult to reach due to seasonal rain or floods. Distance from the project area to the supervisory and monitoring unit should not be excessive, as this adds unnecessarily to costs and time involved. The demographic pattern of the area, in terms of household locations, schools and other community facilities or meeting places should be known, together with the public transport facilities. Use of local language is a must in all written messages and in the case of illiteracy, pretested pictures and oral communication must be used.

### Appropriate technology and use of public services

Careful assessment of the services available to the population in the study area is needed so that activities planned will not be hampered by irregularities in services such as water, or power supplies or transport. All equipment and materials for the project should be appropriate for the actual working and living conditions of the area. This may involve the use of simple equipment that can be locally maintained or, in some situations, even high technology equipment, for instance, the use of a battery operated microcomputer to store, process and present study data.

### Team work

Team work, as a means of implementation of the project, is very important. Project personnel should, therefore, be carefully selected and monitored with this factor in mind, so as to avoid personal conflicts that would seriously damage the outcome of the project. Regular meetings should be held with all personnel involved to discuss problems, choose alternative strategies to solve these problems, to report progress and to give in-service training and guidance.



Team work is important. - Regular meetings should be held with all project staff.

## **4.5. Ethical considerations**

There are several ethical and legal issues to consider when conducting research which involves human subjects. The investigator must have the necessary qualifications and experience to conduct the research project adequately. The principal investigator of the research project has the ethical responsibility to assure safety of the subjects involved. The Declaration of Helsinki adopted by the 18th World Medical Assembly, Tokyo, Japan, 1974 should be carefully studied. This lays down the basic ethical principles applying to all research involving humans and provides a basis for determining the appropriateness of the proposed research.

Before the start of a field study, provision should be made to inform the community and get its feedback and consent. It is the responsibility of the investigator to obtain this informed consent from participants after analysing the potential benefit, the possible risk for discomfort from the research and to ensure confidentiality of all records. The members of the community and the health workers serving that community will know, thereby, what is being offered, how it is to be implemented and what outcome to expect. The planner should not hesitate to share scientific information in simple language to get the community participation and cooperation which is so essential for the success of the project.

## **4.6. Recommended Reading**

Guidelines for planning community participation activities in water supply and sanitation projects. WHO offset Publication No 96 Anne Whyte. ISBN 924 1700 96 3.

A clear presentation of check lists of different factors to be considered regarding the development of community participation; gives good guidelines and ideas for consideration for health projects.

Project formulation and proposal writing. Katja Janovsky. WHO/EDUC/87.187

Helsinki Declaration on biomedical research involving human subjects.

## **5. IMPLEMENTATION AND EVALUATION**

### **5.1. Monitoring activities**

When a programme has been initiated, close monitoring will be required in order to check that activities are being carried out according to plan and that the system is running smoothly. Usually health services are monitored for the purpose of control at the central level. Measures such as the number of patients treated, prescription of drugs and the number of health education lessons given, are the usual type of information required by administrators. However, in primary health care, health workers are encouraged to compile information as a useful tool for their own work. This approach is likely to improve the quality of the data, particularly when the parameters chosen are seen as useful and relevant to the person collecting the data. In health services research, care should be taken not to add unnecessarily to the reporting obligations of the health workers, and only a few relevant indicators should be selected. These should be identified in dialogue with the staff and pretested.

### **5.2. Data handling**

All data collected needs to be carefully checked for obvious errors. This procedure should be done immediately in connection with the data collection. Hand summaries may be done to get immediate impressions and feed back. Considerable amounts of data are collected in health services research and the use of microcomputers is recommended. However, training in the handling of data should not be limited to the use of microcomputers, but should most importantly deal with the principles of data analysis.

### **5.3. Evaluative studies**

Evaluation of oral health programmes takes time; evaluating the impact of a preventive programme on oral disease may be a matter of years, while politicians and donor agencies often demand the evaluation results within months. The choice of cost-effective research design in the assessment of the health promoting activity is, perhaps even more important in such a situation, where time and financial resources are limited.

The design options for an evaluative study generally fall into three groups: randomized experiment, non-randomized experiment and non-experimental (or observational) studies.

In a randomized experiment (or randomized control trial), the comparison takes place among groups which have been created through randomly allocated treatment or prevention for individuals, and the treatment group is controlled by the researcher. New drugs and new vaccines are examples of technologies often evaluated in randomized experiments. In a PHC setting such a design is neither feasible nor desirable.

In a non-randomized experiment, a prospective study is undertaken where the researcher has control over which individuals (or group of individuals) receive the intervention, how it is to be performed and how the follow-up is organized. Often this type of experiment is performed as a before-and-after-study: observations made before and after the start of the intervention are compared. A comparison group, not receiving the intervention, is also studied. However, for ethical reasons, the comparison group usually receives a treatment or intervention, which is known to be of benefit, and the study group receives the "new" intervention package.

An evaluation may be designed along the following lines:

<u>A before-and-after-study</u>	
Allocate one group of 8-9 year old school children to each option	
Option A	Option B
Fluoride mouthrinsing at school starting at 8-9 years	Fluoride mouthrinsing at school starting at 8-9 years
Oral health promotion activities at school (specified)	
Follow-up after 3 years	Follow-up after 3 years
DMFT increment	DMFT increment

Suppose that after three years we measure a DMFT mean increment of 2.1 for Option A and 2.3 for Option B. Tests for statistical significance, as well as clinical judgement show that the difference is not of any significant value. A conclusion could be that the programme B may be chosen, especially if programme A is carrying a considerably higher cost. However, a lot of other factors, which may be related to caries or to the allocation to Option A or Option B were not accounted for in the study design.

Suppose instead, that we have no opportunity to influence the application of the new intervention. Maybe the new intervention programme has been running in the area for some time. The allocation of individuals into "intervention" and "non-intervention" groups has taken place through subjective or "natural" selection. Then we have to restrict ourselves to non-experimental investigations or observational studies. Such studies need to be longitudinal, if the development of a disease in a population is to be followed. Two major study designs are available: prospective or retrospective cohort studies, and retrospective case-referent studies.

In the cohort design, the investigator starts with the individuals which have joined the intervention programme (the "exposed" individuals) and those who have not (the "non-exposed"). In Table 4 those two groups are found as row totals (a+b) and (c+d) respectively. The participants are then followed forward (either historically or prospectively) and they eventually get the disease or remain healthy as shown in the columns.

Exposure	Disease		Total
	Yes	No	
Yes	?	?	a+b
No	?	?	c+d

Analysis is then performed by comparing the rates of disease occurrence between the "exposed" and the "non-exposed".

To use the case-referent method to study the efficacy of an oral health intervention, we take a group of cases with the disease of interest (a+c) Table 5, and a group of referents (b+d), who do not have the disease, and we compare the past "exposure" to the intervention in the two groups. If the intervention is protective, we expect fewer cases than controls to have a history of receiving the interventive programme and a direct estimate of the programme efficacy may be made from the difference.

Exposure	Disease	
	Yes	No
Yes	?	?
No	?	?
Total	a+c	b+d

The case-referent study is usually carried out in a much shorter period of time, does not require so large a sample size and is less expensive. However, a number of problems and limitations are also associated with this design. The logical basis of this study approach is that the referents should represent the "population at risk", from which the cases have come. This population is often difficult to define, and it is not surprising, therefore that it is also difficult to decide how the referents should be chosen. Another common concern is that information on the "exposure" factors may be difficult to obtain either from records or from persons' memories.

#### 5.4. Cost effectiveness

Data collection for cost monitoring and evaluation must be planned in an economic and realistic way. Two types of costs must be considered in relation to oral health programmes:

- a. The internal costs of the programme: consisting of training costs, wages and salaries of workers and supervisors, materials, supplies, transportation (vehicles and fuel), data collection and data analysis.
- b. The external cost of the programme: the costs to the recipients travelling to receive care, cost of supplies (tooth brushes, tooth paste), and opportunity costs to the recipients, e.g income lost while travelling for referral care.

As an example, the cost of fluoride mouthrinse methods could be itemized as follows:

- \* internal costs: training health workers, wages and salaries, the fluoride solutions or tablets, costs for supervision, transportation and data analysis.
- \* external costs: the time used by the teacher or health worker and students during the actual mouth rinsing sessions, time which could be used for other activities.

Cost effectiveness analysis may be used to determine the least expensive way of achieving the stated objectives. Both the costs and the effects of the competing strategies must be quantified in such analysis.

## **5.5. The need for methodological development**

A host of experience exists from programmes that have attempted to improve oral health in developing countries. In many cases these efforts have been poorly documented, and neither failures or elements of success have been brought to the public. This may be due to the lack of "academic interest" and lack of baseline studies in the development of services. It may also be due to the lack of familiarity with the use of suitable and sensitive indicators to demonstrate effect. The familiar indices, DMFT and CPITN, recommended by WHO for oral health surveys, are fairly crude instruments designed to demonstrate rather large differences in oral health levels. There is therefore need to identify and test other, more sensitive measures or indicators of change in health or disease.

In addition to the measurements of health outcome, it would be desirable to find suitable indicators of success, for instance, of oral health education programmes. Oral health services research should include development of the kind of methods needed to evaluate communication models or to assess changes in attitudes. Such methods should be made familiar to oral health researchers and standardized so that global experiences can be compared.

In general it is the aim of WHO's Oral Health Programme to disseminate information on the development of effective and economic models for oral health within Primary Health Care and to encourage and support research in that area.

Some information on the WHO Programme for Research and Action in Primary Oral Health Care is given in Annex 2.

## 5.6. Recommended Reading

Statistics at Square One. Swinscow, T.D.V. British Medical Association Tavistock Square London 8th ed. 1983.  
This is an excellent introduction text.

Using and understanding Medical Statistics. DE Mattheus. V.T. Farewell Waterloo Ontario. 2nd ed. ISBN 3 8055 4719 6 Sfr 40, US\$ 26.75

Klarman, H.E.; Application of Cost-Benefit Analysis to the Health Services and the Special case of Technologic Innovation, International Journal of Health Services, 2, 325-353, 1974.

Lennon M.A., O'Mullane, D.M. and Taylor G.O.; A Pragmatic Clinical Trial of Fissure Sealants in a Community Dental Service Programme for 6-10 year-old Children, Community Dental Health, 1, 101-109, 1984.

Schwartz, D. and Lellouch, J.; Explanatory and Pragmatic Attitudes in Therapeutic Trials, Journal of chronic Diseases, 20, 637-648, 1967.

# Annex 1

## Guidelines for research protocol.

### Project title

A project title should serve to identify the project. The title should be short and as informative as possible.

### Responsible institution

The responsible institution(s), principal investigator, and researchers involved should be identified.

### Introduction

#### - Background and problem

This section should give background information including a review of relevant literature and lead to the clear statement of research problems. The public health relevance and justification for research should be indicated.

#### - Purpose

State the overall purpose and the specific objectives of the study. The research questions should be specified and, in relevant cases, hypotheses formulated.

### Materials and methods

This section should present the overall design and specify the methods involved. In health services research a description of the services (including preventive methods) must be included as well as an account of the research methods.

#### - Population

Describe the study population, characteristics of treatment and control groups, sampling methods and sample size.

#### - Methods

Specify the methods involved in the intervention and in the research design.

#### - Ethics

Indicate community collaboration and consent and ethical concerns.

#### - Data

Specify the type of data required, and how the data will be collected. Data collection forms and questionnaires may be annexed. Indicate methods for data analysis.

- Resources

Specify staff , facilities, equipment, and supplies needed.

- Training

Specify training required for field personnel.

- Time schedule

Indicate total duration of project and specify principal activities and phases.

- Problems

Indicate expected problems and justification of selected methods in relation to such problems.

**Researchers**

A more elaborate presentation of investigators, including Curriculum Vitae of researcher is usually required and should be included or annexed to the proposal.

**Research collaboration**

In collaborative studies, indicate the nature of the collaboration, the contribution of the various actors, exchange of information and visits.

**Research training**

Specify research training components leading to formal or informal qualifications.

**Budget**

A detailed budget should be specified and justified.

**Reporting**

Indicate reports, presentations and publications planned.

## **Annex 2**

### **WHO programme of research and action in primary oral health**

The aim is to develop effective and economic models for oral health within Primary Health Care and to encourage and support research on the delivery of oral care within general health programmes. Reports on primary oral health care projects are being collected for inclusion in annual Newsletters. These will be available to Regional and District dental officers, public health planners and administrators and researchers interested in the development and improvement of oral health and care.

These Newsletters will help to portray, realistically, the problems and opportunities of health services research projects in primary oral health.

If you are planning or developing a primary health care project in oral health, or a research project to study and evaluate an aspect or programme of primary oral health care, we would like to hear about your experiences.

This information about your work, problems encountered, solutions tried and results obtained, especially those that are unexpected, to be of interest and use to others, can be included in the annual Newsletter.

#### **How to obtain assistance**

The Oral Health Programme, WHO, can provide assistance with the following:

- advice on project design, methods and indicators
- promotion of contact with researchers active in the same or similar fields
- establishing contact with collaborating institutions having skills and experience in Health Services Research as well as research training capacity.

Requests for assistance should be sent to  
Oral Health  
Research and Action for Primary Oral Health Care  
World Health Organization  
20, Avenue Appia  
1211 GENEVA 27  
Switzerland