ZZQ

AGENCY FOR QUALITY
IN DENTISTRY
a unit of the Institute of
German Dentists

GUIDELINE

SUBJECT **Fluoridation measures**

Short version April 2006

WHAT ARE GUIDELINES?

Guidelines are systematically developed aids to decision-making concerning the medical or dental procedures appropriate for preventive measures and specific health problems. They constitute a consensus among a number of experts from various disciplines and/or working groups arrived at by a defined process that has been made as transparent as possible. Rather than rigidly prescribed directives, they are guides, or “corridors for action and decision”, for the safeguarding and improvement of healthcare, as well as instruments of quality assurance and quality management. They are intended to minimize the risks of treatment and to provide the motivation for a scientifically based medical approach, while at the same time taking account of patient needs and attitudes. Guidelines are drawn up in accordance with the latest state of medical knowledge without regard to the current extent of benefits offered by individual insurance systems.

Another function of guidelines is to evaluate the current status of knowledge in relation to specific health problems and medical action. They also serve for resolving conflicting views and for weighing the advantages of a given procedure against the risk of harm. In addition, a guideline should specify its aims, the significance of the health problem in question and the relevant target group.

The systematic gathering and collation of the available literature for the compilation of a guideline takes due account of the current levels of published (scientifically validated) evidence.

Finally, guidelines serve to answer the following questions: What is necessary and reasonable? What is superfluous? What is obsolete?

CLASSIFICATION OF EVIDENCE LEVELS (FROM AWMF 2001, MODIFIED)

CRITERION	TYPE OF EVIDENCE
A	Evidence based on meta-analyses of randomized controlled studies Evidence based on one randomized controlled study
B1	Evidence based on at least one well-designed controlled study without randomization Evidence based on at least one well-designed quasi-experimental study
B2	Evidence based on well-designed non-experimental descriptive studies (e.g. cross-sectional studies)
C	Evidence based on reports or opinions of groups of experts, consensus conferences and/or clinical experience of recognized authorities; case studies

A classification by recommendation levels is arrived at on the basis of the above criteria by a consensual process involving all parties concerned; account must also be taken of such considerations as patient preferences, clinical relevance and feasibility of application in the routine medical situation. The recommendation levels are:

A Strong recommendation **B** Recommendation **O** Recommendation open

Fluoridation measures

1. INTRODUCTION, DEFINITION AND BASIS OF DATA

The Guideline on fluoridation measures discusses the question of whether, and if so how, effective caries prevention can be achieved by the familiar measures of fluoridation. It summarizes the present state of scientific knowledge for dentists and doctors, patients, health professionals and anyone interested in the subject, and presents evidence-based recommendations on the use of fluoride.

The compilation of this Guideline is based exclusively on clinical studies with the target variable "caries reduction" in the primary and permanent dentition. *In vitro* studies of the reaction and mode of action of fluorides were deliberately excluded, even though a large number of original papers and reviews in prestigious international journals show convincingly that the efficacy of fluorides in caries prevention is based principally on their local application to already erupted teeth. On the other hand, pre-eruptive fluoride supplementation in dental hard tissue has only a minor, if at all measurable, effect in caries prophylaxis. The action of fluorides on hypersensitive tooth necks or on root caries was not considered. Nor were studies of fluoride toxicology included, although the known toxicological facts were allowed for in the formulations on fluoride use. Other substantially excluded publications are those concerned with specific patient groups, such as patients undergoing radiotherapy, patients with fixed orthodontic appliances or patients in residential care. In the case of long-term studies, only the results of the most recent publication were considered.

A guideline on fluoridation measures must take account of the current epidemiological data on the prevalence of caries in different age groups. One reason why it is so difficult to derive appropriate recommendations from this material is that at present the population has numerous sources of fluoride at its disposal and is therefore subject to multiple exposure. The effect of an individual measure can no longer be quantified.

Again, in recent studies it is virtually impossible to distinguish between the fluoride preparation under examination and "confounders" (oral hygiene measures, anti-cariogenic

food ingredients, social factors or non-evaluable effects of various constituents of a fluoride-containing product such as cations or foaming agents). Furthermore, for a long time now it has not been feasible on ethical grounds to conduct placebo-controlled studies, as these would involve withholding a demonstrably effective caries prevention measure from a given population group.

Owing to the decline in the prevalence of caries and its simultaneous polarization among young people, recent studies ought also to allow for primary caries activity in the relevant test and control groups. In addition, very large groups would be necessary to ensure adequate statistical significance.

Only the most important fluoride preparations were considered in the compilation of the Guideline on fluoridation measures. Studies of fluoridated dental floss, fluoridated toothpicks and the like were disregarded. The Guideline therefore relates to the methods commonly used in Germany – namely, fluoride tablets, fluoridated table salt, fluoride toothpaste, fluoridated mouth rinses, fluoride gels and fluoride varnishes.

Fluoride application is only one aspect of the wider field of caries prophylaxis. In view of the multifactorial nature of carious pathology, the occurrence and progression of caries at population level cannot be entirely prevented by fluoride application alone. Hence caries is not a manifestation of fluoride deficiency.

For compilation of the Guideline, a literature search on the relevant fluoridation measures was conducted in the medline (PUBMED) and Embase databases, together with a manual search in the journals *Oralprophylaxe*, *Deutsche Zahnärztliche Zeitschrift* and *Schweizerische Monatsschrift für Zahn-, Mund- und Kieferheilkunde (Acta Helvetica)*. Only original papers and meta-analyses in English or German were considered. In addition, existing guidelines and authoritative recommendations by other scientific bodies, as well as, where necessary, review articles were taken into account. The chosen search period was 1980 to 2004. Where the search results for this period were inadequate, recourse was had in individual cases to earlier publications or review articles. The evidential levels given were taken into account in the evaluation of the original papers.

2. EVIDENCE-BASED RECOMMENDATIONS ON FLUORIDATION MEASURES

2.1 Toothpastes

The use of fluoride toothpaste is an effective measure in caries prevention. The preventive effect in the permanent dentition increases with the fluoride concentration of the toothpaste and frequency of use.

Recommendation level: A

The efficacy of low-fluoride toothpastes (250-500 ppm fluoride) has not so far been adequately verified in clinical practice; the relevant results are inconsistent.

Recommendation level: O

2.2 Fluoridated table salt

Fluoridation of table salt is an effective measure in caries prevention. The efficacy of salt fluoridation increases the more widely this measure is adopted in different situations (such as the home, communal catering facilities, restaurants or bakeries). The general use of fluoridated table salt is recommended.

Recommendation level: B

2.3 Fluoride tablets

Fluoride tablets are effective in caries prevention. Since the preventive effect in erupted teeth depends on the local action of the fluoride, the tablets should be sucked regularly. The use of only one form of systemic fluoride provision (tablets or table salt) is recommended.

Recommendation level: A

Where fluoride tablets are used in children under the age of six, a fluoride history must be taken so as to avoid excessive fluoride absorption from other sources.

Recommendation level: A

Fluoride tablets need not be taken during pregnancy, as their use has no effect on caries prevalence in the primary dentition.

Recommendation level: A

2.4 Application of fluoride varnish

The application of fluoride varnish is an effective measure in caries prevention. Fluoride varnish can be applied in children and adolescents twice a year or more frequently and independently of other fluoridation measures.

Recommendation level: A

In children with caries activity the frequency of fluoride varnish application should be greater than twice a year, as this is more effective in reducing caries.

Recommendation level: B

2.5 Fluoride gels

Fluoride gel application is an effective measure in caries prevention and can be carried out independently of other local fluoridation measures provided that the gel is not swallowed.

Recommendation level: A

The efficacy of fluoride gels in preventing caries is independent of the application method; the form of application depends on patient compliance and should therefore be tailored to the individual patient.

Recommendation level: A

2.6 Fluoride mouth rinse solutions

Given low caries activity and regular oral hygiene using fluoride toothpaste, the use of fluoride mouth rinses is not recommended.

Recommendation level: A

In persons at increased risk of caries the controlled use of mouth rinses leads to a reduction in the rate of caries development and can therefore be recommended irrespective of the use of other fluoride preparations.

Recommendation level: A

3. FLUORIDATION MEASURES BY AGE

(See tables.)

4. UPDATE RECOMMENDATIONS

This Guideline will be updated in 2008.

5. REFERENCES

Arbeitsgemeinschaft der wissenschaftlichen medizinischen Fachgesellschaften (AWMF): Das Leitlinien-Manual von AWMF und ÄZQ. Z Ärztl. Fortbildung Qualitätssicherung 95 Suppl. (2001) 1–84.

6. SCIENTIFIC AND PROFESSIONAL ASSOCIATIONS INVOLVED IN FORMAL CONSENSUS TECHNIQUES:

Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde (DGZMK)
Deutsche Gesellschaft für Zahnerhaltung (DGZ)
Deutsche Gesellschaft für Kinderzahnheilkunde (DGK)
Deutsche Gesellschaft für Kieferorthopädie (DGKfO)
Deutsche Gesellschaft für Kinderheilkunde und Jugendmedizin e.V. (DGKJ)
Deutsche Akademie für Kinderheilkunde und Jugendmedizin e.V. (DAKJ)
Bundesverband der Zahnärzte des Öffentlichen Gesundheitsdienstes e.V. (BZÖG)

7. WHERE TO FIND FURTHER INFORMATION

The complete Guideline (in German) on fluoridation measures, based on the systematic evaluation of the relevant literature and two expert conferences, together with a list of references, can be found on the home page of the Agency for Quality in Dentistry:

www.zzq-koeln.de under **Schwerpunkte/Leitlinien**

The theses for the Guideline are available in English under **Core Activities/Clinical Guidelines**

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[Tables]

FLUORIDATION MEASURES: BASIC PROPHYLAXIS

Years	**0**	**2**	**4**	**6***	**8**	**10**	**12 →**
Fluoride toothpaste and fluoridated table salt							
	Once a day	Twice a day		Twice a day			
	Children's fluoride toothpaste			Fluoride toothpaste for adults			
	Regular use (in the home or communal catering facilities)						
Possible alternative:							
Fluoride toothpaste and fluoride tablets	Non-fluoride toothpaste	Children's fluoride toothpaste		Fluoride toothpaste for adults			
	When prescribed by the doctor or dentist: to be sucked once a day						

* For children aged under 6 years total daily fluoride intake should not exceed 0.05–0.07 mg F/kg body weight.

POSSIBLE ADDITIONAL FLUORIDATION MEASURES, ESPECIALLY WHERE INCREASED CARIES RISK APPLIES

<table>
<tr><th>Years</th><th>0</th><th>2</th><th>4</th><th>6*</th><th>8</th><th>10</th><th>12 →</th></tr>
<tr><td>Use at home:</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Fluoride gel
or alternatively
Fluoride rinse solution</td><td></td><td></td><td></td><td colspan="3">Weekly

several times a week</td><td></td></tr>
<tr><td>Application by dentist under dentist’s supervision:</td><td colspan="7"></td></tr>
<tr><td>Fluoride varnish
or alternatively
Fluoride gel</td><td></td><td colspan="6">Twice a year, or more frequently if increased risk applies</td></tr>
</table>

* For children aged under 6 years total daily fluoride intake should not exceed 0.05–0.07 mg F/kg body weight.