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Reliability methodology in caries epidemiological studies conducted in the Nordic countries between 1990 and 2001

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Objective To describe and analyse the reporting of methodology relating to reliability in caries epidemiological studies conducted in the Nordic countries between 1990 and 2001. *Basic research design.* ***Basic research design*** Literature searches were conducted in the Medline database, and reference lists of all obtained publications were scrutinised for additional studies. Publications fulfilling the inclusion criteria were assessed for study design, and methodological aspects relating to reliability were assessed according to recommendations for evidence-based medicine (EBM). The frequency of endorsement of the assessed items was analysed. Moreover, the type and strength of evidence was evaluated. ***Main outcome measures*** Reporting of predetermined methodological items relating to reliability and the frequency of endorsement of the assessed items were of primary interest. ***Results*** Initially, 724 publications were located in the literature searches. Of 133 eligible publications obtained, 32 fulfilled the inclusion criteria and remained throughout the analyses. The majority of the studies reported the reliability methodology, which was generally inadequate. The frequencies of endorsement ranged from 0% to 69 %. All publications contributed to a low strength of evidence. In this context, it was proposed that prospective longitudinal studies with a random sample selection be classified as type-2 (2b) level of evidence. ***Conclusion*** There seems to be a need to improve the reporting and the methodology relating to reliability in caries epidemiological publications. Reporting of random sample selection and at least two of the items assessed seems to discriminate between high and low quality with respect to the reported methodology relating to reliability.

Key words: dental caries, dentistry, epidemiology, evidence-based medicine, public health, reliability, validity

Introduction

Caries epidemiological data are considered a useful and necessary tool for planning and purchasing dental health care (Nuttall, 1983; Swedberg, 1999). In Denmark, Finland, and Sweden, national caries epidemiological data for children have been routinely collected in dental practices since the early 1970s, whereas routine registrations in Iceland and Norway were initiated during the 1980s (von der Fehr, 1994). Thus, extensive caries epidemiological data from national registrations are available for the Nordic countries. These data have frequently been published in scientific journals to describe caries prevalence (e.g. Poulsen and Scheutz, 1999; Sundberg, 1996). Moreover, several more limited regional epidemiological data sets from routine registrations in dental practices have been reported in the literature (e.g. Nielsen and Esmark, 1992; Swedberg and Noren, 1999). Although, routinely collected data are useful and often reliable, the registrations have not been scientifically conducted. Of interest in this context are the traditional epidemiological indices, which have been used to measure dental health care needs and demands, often in a screening context (Locker, 1997). One of the most widely used oral epidemiological indices is the caries epidemiological DMF index, which measures objective, variables of dental health (Klein *et al*., 1938). In public health research, 'validity' is defined as the accuracy of the measurements (i.e. the truth), whereas 'reliability' is defined as repeatability of the results (Daly *et al.,* 1997).

In a previous study, the validation methodology in publications describing epidemiological registration methods for dental caries was systematically reviewed, and a checklist for quality assessment of validation methodology was constructed based on recommendations for EBM (Sjögren *et al*., 2003). The literature searches were thoroughly conducted using the Medline, the various Cochrane Library databases, and by hand-searching reference lists (Sjögren *et al*., 2003).

This study was initiated to further investigate methodological aspects of caries epidemiology. The primary aim was to assess the methodology and quality of reporting methodologies relating to reliability in caries epidemiological publications in the Nordic countries.

Method

Literature searches

The Medline database was searched (Aug 2002) for dental caries epidemiological publications from the Nordic countries between 1990 and 2001 by using and combining the terms: 'Denmark', 'Finland', 'Iceland', 'Norway', 'Sweden', 'dental caries', 'dental caries/epidemiology', 'dental health surveys', and 'dmf index', limited to publication years 1990-2002. Additional publications were located by searching the reference lists of the articles obtained. If the year the study was conducted was not reported in the article, the year of acceptance for publication, or the year the manuscript

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was submitted for publication was used instead. The literature searches were conducted with the aim of locating a sample of publications fulfilling the predetermined inclusion criteria: epidemiological studies conducted in the Nordic countries between 1990 and 2001, measuring the percentage of caries-free individuals (CF%), the DMF or dmf index (or components thereof); studies that were focused on the World Health Organisation indicator age groups (World Health Organisation, 1994; 1996), or ages commonly encountered in the literature, namely 3 years, 5-7 years, 12 years, 15 years, 16 years, 19 years, 35-44 years, and 65-74 years.

To further specify the study selection, the following exclusion criteria were predefined: studies describing epidemiological data from sub-populations that were not representative of the general population; non-scientific epidemiological survey data from national, regional, or World Health Organisation-registrations; and studies based solely on radiographic data. The study selection was completed before the quality assessments were initiated.

Strength and type of evidence

The publications included were assessed for study design and ordered according to the hierarchic strength of evidence, from the strongest level, type-1 evidence, to the weakest, type-5 evidence, as previously described (Sjögren *et al*., 2003). In addition to RCT, to adapt to an epidemiological context, type-2 evidence was proposed for prospective longitudinal studies with a random sample selection, and is here denoted type-2b.

Quality assessments and frequency of endorsement

The reporting of reliability methodology was analysed using a previously developed checklist with items related to the scientific methodology in a publication about diagnostics or epidemiological screening (Figure 1; modified from Sjögren *et al*., 2003). The reporting of "benchmark examiner" (i.e. principal examiner as standard), "blinding", "gold standard", and "second independent sample" were evaluated, as were the methodologies of "blinding", and "gold standard" (Jaeschke *et al*., 1994; Sackett *et al*., 2000; Sjögren *et al*., 2003). These items were not previously used in an ordinal scale. Thus no numeric scores were given, and the presence or absence of the items was dichotomised as "yes" or "no" answers, as was the adequacy or inadequacy of the methodology conduct (Figure 1; Sjögren *et al*., 2003).

The frequencies of endorsement were calculated for each item, as previously described (Jadad *et al*., 1996; Sjögren *et al*., 2003).

Methodology reported
1. Was the study described as validated or was the methodology used for reliability (or validation) described? (Yes/No)
I.e. if the words "validation" or "reliability" were not used, a description of reliability or validation methodologies should be present. E.g. inter- or intra-examiner consistency, or other methods.

Gold standard
2. Was the index/registration method compared against a gold standard? (Yes/No)
I.e. was it stated that a gold standard was used? (modified from Jaeschke *et al*., 1994; Sackett *et al*., 2000).

2.1. If a gold standard was used, was the methodology appropriate? (Yes/No)
I.e. was a histological (histopathological) standard or other true gold standard used? A gold standard examiner (e.g. a benchmark examiner) is not an appropriate substitute for a true gold standard (modified from Jaeschke *et al*., 1994; Sackett *et al*., 2000).

Benchmark examiner
3. Was a benchmark examiner or principal examiner used? (Yes/No)
I.e. were registrations done against an experienced senior examiner or a gold standard examiner who served as a reference standard?

Blinding
4. Was the registration described as blinded from the investigators? (Yes/No)
I.e. were the words blinding, masking (or similar) used in the reliability context? (modified from Jaeschke *et al*., 1994; Sackett *et al*., 2000).

4.1. If the reliability methodology was blinded, was the blinding appropriately conducted? (Yes/No)
I.e. was it stated that those who conducted the reliability registrations and the investigator were not the same people, and/or that the reliability registrations were blinded for the investigators registrations when reliability was assessed (and vice versa)? (modified from Jaeschke *et al*., 1994; Sackett *et al*., 2000).

Independent sample
5. Was the index/registration method tested in a second independent sample? (Yes/No)
I.e. was it stated that the index or method of registration was confirmed in a second independent sample that was different from the initial sample set? (modified from Sackett *et al*., 2000).

Figure 1. *Checklist for quality assessment of reliability methodology (modified from Sjögren et al., 2003)*

Results

Literature searches

The literature searches initially located 724 publications, of which 134 originated from Denmark, 187 from Finland, 26 from Iceland, 93 from Norway, and 284 from Sweden. The 133 publications deemed relevant were obtained and analysed. Of these, a total of 32 publications, two of which were congress abstracts, fulfilled the inclusion criteria of this study. The included publications (n=32) are listed in Table 1.

Strength and type of evidence (Table 2)

None of the publications was a systematic review. In 19 of the studies a random selection of the studied sample was reported. However, none of the studies had a control group as could have been expected in a 'true' RCT (Jadad *et al*., 1996). According to EBM criteria, all studies contributed to type-3 strength of evidence (Richards and Lawrence, 1998). Eight studies were prospective longitudinal, in four of which a random sample was allocated. Moreover, 24 cross-sectional studies were assigned a type-3 level of evidence. In analogy with RCTs for therapy or prevention studies, we suggested that, in an epidemiology context, prospective longitudinal studies with a random sample selection should be assigned type-2 level of evidence, here denoted type-2b.

Quality assessments and frequency of endorsement (Table 3)

The methodology relating to reliability was reported in the majority of the 32 publications. The most commonly reported methodology was intra- and/or inter-examiner consistency. Benchmark examiners were reported in eight publications, two of which used the benchmark examiner as gold standard. None of the publications reported an appropriate methodology of blinding, gold standard or assessment in a second independent sample. The "benchmark examiner" and "methodology reported" items were reported in the frequency interval of 25-69 %, thus within the 15-85 % interval in which items are considered potentially discriminative for high- and low-quality publications in a quality assessment instrument (Jadad *et al*., 1996).

Table 1. Included caries epidemiological studies conducted in the Nordic countries 1990-2001 (n=32)

*Included study (*Ref. No.*)*	*Country of conduct*	*Year of conduct*	*Included age groups*	*Urban / rural population*[†]
Amerante *et al*., 1998	Norway	1997[*]	5, 12, 18	u
Ankkuriniemi and Ainamo, 1997	Finland	1991	17-29	r + u
Antoft *et al*., 1999	Denmark	1993	18-25	r + u
Asmyhr *et al*., 1994	Norway	1990	19-20	r + u
Bjarnason *et al*., 1993a	Iceland	1991	12	u
Bjarnason *et al*., 1993b	Sweden	1991	18-19	u
Bjarnason *et al*., 1997	Iceland	1994	15	u
Bolin *et al*., 1996	Sweden	1994	5, 12	u
Ekstrand *et al*., 1994	Denmark	1991	20	r + u
Eliasson, 1998 (abstract)	Iceland	1991, 1996	6, 12, 15	ns
Eriksen *et al*., 1995 (abstract)	Norway	1993	35	u
Flinck *et al*., 1999	Sweden	1994	12	r + u
Grindefjord *et al*., 1993	Sweden	1992[*]	3	r + u
Grindefjord *et al*., 1995	Sweden	1992[*]	3	u
Holbrook, 1993	Iceland	1990, 1991	5, 6	u
Holst and Schuller, 2000	Norway	1994	35-44	r + u
Holst *et al*., 1999	Sweden	1994	6	r + u
Hugoson *et al*., 1995	Sweden	1993	3, 5, 15, 40, 70	u
Hugoson *et al*., 2000a	Sweden	1993	40, 70	u
Hugoson *et al*., 2000b	Sweden	1993	3, 5, 15	u
Källestål and Wall, 2002	Sweden	1995	12	r + u
Köhler *et al*., 1995	Iceland	1991	12	u
Mattila *et al*., 2000	Finland	1991, 1992	5, 6	r + u
Nordström *et al*., 1995	Sweden	1990	70	u
Prytz Berset *et al*., 1996	Norway	1993	35	u
Saemundsson *et al*., 1992	Iceland	1990	6, 12, 16	r
Schuller and Holst, 1998	Norway	1994	35-44	r + u
Seppä *et al*., 1998	Finland	1992, 1995	6, 12, 15	u
Seppä *et al*., 2000	Finland	1993, 1995, 1998	3, 6, 12, 15	u
Wendt *et al*., 1992	Sweden	1990	3	u
Wendt *et al*., 1999	Sweden	1993	6	u
Wänman and Wigren, 1995	Sweden	1990	35, 65	r + u

[*]Year study was conducted not stated; thus for Grindefjord *et al*., 1993 and 1995, the year of submission of Grindefjord *et al*., 1993 was considered to be the year the study was conducted. Similarly, for Amerante *et al*., 1998 the year the study was accepted for publication was considered the year it was conducted. [†] ns = not stated, r = rural population, u = urban population.

Table 2. Study design, strength of evidence, and journal of publication for caries epidemiological studies conducted in the Nordic countries 1990-2001 (n=32)

Included study	*Study design*	*Random sample*	*Strength of evidence**	*Journal of publication*
Amerante *et al*., 1998	Cross-sectional	no	3	Community Dent Oral Epidemiol
Ankkuriniemi and Ainamo, 1997	Cross-sectional	yes	3	Acta Odontol Scand
Antoft *et al*., 1999	Cross-sectional	no	3	Community Dental Health
Asmyhr *et al*., 1994	Cross-sectional	no	3	Community Dent Oral Epidemiol
Bjarnason *et al*., 1993a	Cross-sectional	yes	3	Community Dent Oral Epidemiol
Bjarnason *et al*., 1993b	Prospective longitudinal	yes	2b	Swed Dent J
Bjarnason *et al*., 1997	Prospective longitudinal	yes	2b	Eur J Oral Sci
Bolin *et al*., 1996	Cross-sectional	yes	3	Int J Pediatr Dent
Ekstrand *et al*., 1994	Cross-sectional	no	3	Community Dent Oral Epidemiol
Eliasson, 1998 (abstract)	Cross-sectional	no	3	J Dent Res
Eriksen *et al*., 1995 (abstract)	Cross-sectional	yes	3	Caries Res
Flinck *et al*., 1999	Cross-sectional	no	3	Community Dental Health
Grindefjord *et al*., 1993	Cross-sectional	no	3	Caries Res
Grindefjord *et al*., 1995	Prospective longitudinal	no	3	Caries Res
Holbrook, 1993	Prospective longitudinal	no	3	Caries Res
Holst and Schuller, 2000	Cross-sectional	yes	3	Community Dent Oral Epidemiol
Holst *et al*., 1999	Cross-sectional	yes	3	Swed Dent J
Hugoson *et al*., 1995	Cross-sectional	yes	3	Swed Dent J
Hugoson *et al*., 2000a	Cross-sectional	yes	3	Community Dent Oral Epidemiol
Hugoson *et al*., 2000b	Cross-sectional	yes	3	Community Dent Oral Epidemiol
Källestål and Wall, 2002	Prospective longitudinal	no	3	Community Dent Oral Epidemiol
Köhler *et al*., 1995	Cross-sectional	yes	3	Community Dent Oral Epidemiol
Mattila *et al*., 2000	Prospective longitudinal	yes (centre)	2b	J Dent Res
Nordström *et al*., 1995	Cross-sectional	no	3	Swed Dent J
Prytz Berset *et al*., 1996	Cross-sectional	yes	3	Community Dental Health
Saemundsson *et al*., 1992	Cross-sectional	no	3	Scand J Dent Res
Schuller and Holst, 1998	Cross-sectional (Quasi-longitudinal)	yes	3	Community Dent Oral Epidemiol
Seppä *et al*., 1998	Cross-sectional (Quasi-longitudinal)	yes	3	Community Dent Oral Epidemiol
Seppä *et al*., 2000	Cross-sectional	yes	3	Caries Res
Wendt *et al*., 1992	Prospective longitudinal	yes	2b	Swed Dent J
Wendt *et al*., 1999	Prospective longitudinal	no	3	Swed Dent J
Wänman and Wigren, 1995	Cross-sectional	yes	3	Acta Odontol Scand

* Strength of evidence from the strongest (type-1) to the weakest (type-5) evidence assigning type-2b level of evidence for prospective longitudinal studies with a random sample allocation in a public health context (modified from Richards and Lawrence, 1998).

Table 3. Reliability methodologies reported in caries epidemiological publications conducted in the Nordic countries 1990-2001 (n=32)

Included study	*Methodology reported **	*Benchmark examiner*	*Second independent sample*	*Blinding reported*	*Reported blinding appropriate*	*Approprate gold standard*	*Gold standard*
Amerante *et al*., 1998	Intra- and inter-examiner consistency	no	no	no	nr	no	nr
Ankkuriniemi and Ainamo,1997	Calibration of examiners	no	no	no	nr	no	nr
Antoft *et al*., 1999	Calibration of examiners	no	no	no	nr	no	nr
Asmyhr *et al*., 1994	Nr	no	no	no	nr	no	nr
Bjarnason *et al*., 1993a	Intra-examiner consistency	no	no	no	nr	no	nr
Bjarnason *et al*., 1993b	Nr	no	no	no	nr	no	nr
Bjarnason *et al*., 1997	Nr	no	no	no	nr	no	nr
Bolin *et al*., 1996	Intra- and inter-examiner consistency	yes	no	no	nr	no	nr
Ekstrand *et al*., 1994	Nr	no	no	no	nr	no	nr
Eliasson, 1998 (abstract)	Nr	no	no	no	nr	no	nr
Eriksen *et al*., 1995 (abstract)	Nr	no	no	no	nr	no	nr
Flinck *et al*., 1999	Intra- and inter-examiner consistency	yes	no	no	nr	yes	no
Grindefjord *et al*., 1993	Inter-examiner consistency	no	no	no	nr	no	nr
Grindefjord *et al*., 1995	Intra- and inter-examiner consistency	no	no	no	nr	no	nr
Holbrook, 1993	Nr	no	no	no	nr	no	nr
Holst and Schuller, 2000	Calibration of examiners	no	no	no	nr	no	nr
Holst *et al*., 1999	Intra- and inter-examiner consistency	yes	no	no	nr	yes	no
Hugoson *et al*., 1995	Calibration of examiners	no	no	no	nr	no	nr
Hugoson *et al*., 2000a	Calibration of examiners	no	no	no	nr	no	nr
Hugoson *et al*., 2000b	Calibration of examiners	no	no	no	nr	no	nr
Källestål and Wall, 2002	Intra- and inter-examiner consistency	yes	no	no	nr	no	nr
Köhler *et al*., 1995	Nr	no	no	no	nr	no	nr
Mattila *et al*., 2000	Intra- and inter-examiner consistency	yes	no	no	nr	no	nr
Nordström *et al*., 1995	Inter-examiner consistency	no	no	no	nr	no	nr
Prytz Berset *et al*., 1996	Intra- and inter-examiner consistency	no	no	no	nr	no	nr
Saemundsson *et al*., 1992	Nr (consultation)	no	no	no	nr	no	nr
Schuller and Holst, 1998	Calibration of examiners	no	no	no	nr	no	nr
Seppä *et al*., 1998	Intra- and inter-examiner consistency	yes	no	no	nr	no	nr
Seppä *et al*., 2000	Intra- and inter-examiner consistency	yes	no	no	nr	no	nr
Wendt *et al*., 1992	Nr	no	no	no	nr	no	nr
Wendt *et al*., 1999	Calibration of examiners	no	no	no	nr	no	nr
Wänman and Wigren, 1995	Inter-examiner consistency	yes	no	no	nr	no	nr
Number of publications reporting the assessed item	22	8	0	0	0	2	2

* Corresponding to the previously used item 'Validation reported' (Sjögren et al., 2003), nr = not reported.

Discussion

The reporting of reliability methodology was generally inadequate in this sample of Nordic caries epidemiological publications. This study was primarily explorative, and publications were located by searching the Medline database as well as by hand-searching reference lists. The objective of the literature searches was to allocate a sample of publications fulfilling the predetermined inclusion criteria, and a literature search strategy with a relatively low specificity was chosen (Haynes *et al*., 1994; Sjögren and Halling, 2002). Potential false inclusions (or exclusions) were considered less significant. Thus, with this approach a large number of false search inclusions had to be excluded manually.

In three of the included publications, the year the study was conducted was not reported (Amerante *et al*., 1998; Grindefjord *et al*., 1993; 1995). Therefore, for one of these studies, the year it was accepted for publication was considered to be the year it was conducted (Amerante *et al*., 1998), whereas for the remaining two studies, which partially described the same sample, the year the first manuscript was submitted was considered the year the study was conducted (Grindefjord *et al*., 1993; 1995).

A reliable test must be able to reproduce similar results when repeatedly used to measure the same variable in the same group (Daly *et al.,* 1997), but the accuracy of the results depends on the validity of the test method (Sjögren *et al*., 2003). Hence, if the test method is invalid, reliable examiners yield repeatable but inaccurate test results. The reliability of an epidemiological study is largely dependent on the methodology in the sample selection, and random sample allocation is regarded as the most reliable method for obtaining an unbiased (selection bias), representative sample (described in detail in Jaeschke *et al*., 1994; Sjögren *et al*., 2003). We found that the majority of the caries epidemiological studies included in this sample reported a randomised sampling procedure. However, a discrepancy is often seen between the way the study was conducted and the study report (Hill *et al*., 2002). Thus, publications in which random allocation was not reported should not automatically be deemed to be of lower quality.

As previously described, the overall reporting of the used methodology was assessed as an item in itself (Sjögren *et al*., 2003). Evaluation of the intra- and/or inter examiner reliability was the most common reliability method. Surprisingly, about one third of the publications did not report the used methodology at all. None of the included studies reported blinding the reliability test investigator or the study test performer (Jaeschke *et al*., 1994). This could have been expected because inadequate blinding is related to incorporation of ascertainment bias into the study (Chalmers *et al*., 1983; Jaeschke *et al*., 1994; Schultz *et al*., 1995).

The use of a reference gold standard is considered important in epidemiological studies (Sackett *et al*., 2000). In this study, the use of a gold standard was reported in two out of 32 publications. However, in both of these studies the gold standard was inappropriate (benchmark examiner) according to the EBM recommendations (Jaeschke *et al*., 1994; Sackett *et al*., 2000). In caries epidemiological studies a benchmark examiner (or principal examiner) is relatively frequently used as an internal standard, replacing a true gold standard (World Health Organisation, 1997). Generally the benchmark examiner is an experienced epidemiologist who serves as an internal standard (World Health Organisation, 1997). In this sample, eight publications reported a benchmark examiner, in two of which the benchmark examiner was considered a gold standard.

Ideally, the reference gold standard registration should be done for all patients regardless of the test result (Fleming, 2002; Sackett *et al*., 2000). However, histological validation of all diagnosed teeth, in order to obtain a 'true' test result, would be ethically and technically impossible in a caries epidemiological study (Downer, 1975). Therefore, reliability testing is generally considered sufficient in a caries epidemiological survey (World Health Organisation, 1997).

All publications that met our inclusion criteria contributed to a relatively low (type-3) strength of evidence. This was an expected finding, explained by the fact that an RCT protocol is an unsuitable study design for an epidemiological study (Sackett and Wennberg, 1997). Thus, no RCTs could be located. As a consequence, systematic reviews consisting of several RCTs are also lacking in this area. However, four prospective longitudinal studies with a random sample selection were located. In EBM the evidence should be drawn from best available scientific evidence when systematic reviews or RCTs are unavailable (Sackett *et al*., 1996). Therefore, we propose that, in the absence of RCTs in an epidemiological context, prospective longitudinal studies with a random sample selection should hierarchically be ordered on a type-2 level of evidence, here denoted type-2b evidence.

As previously stated, a challenge resides in the development of relevant quality assessment instruments for non-randomised studies (Downs and Black, 1998; Sjögren *et al*., 2003). The quality assessment checklist was used here in a second independent sample of publications (Sjögren *et al*., 2003). In this sample, the "benchmark examiner" and "methodology reported" items were reported in the frequency interval of 15-85 %, in which items are considered discriminative for high- and low-quality publications in a quality assessment instrument (Jadad *et al*., 1996; Sjögren *et al*., 2003). In a previous study, four of the items, "benchmark examiner", "reported gold standard", "appropriate gold standard" and "validation reported" (i.e. "methodology reported"), were found to be within the 15-85 % interval (Sjögren *et al*., 2003). Moreover, in the present study, and in Sjögren *et al*., (2003), the frequencies of endorsement for random sample selection were 53 % and 83 %, respectively (Sjögren *et al*., 2003). Therefore, we propose that reporting of random sample selection should be included as a separate item in future quality assessments.

The present study also confirms that the "blinding" and "second independent sample" items are sparsely reported in caries epidemiological publications (Sjögren *et al*., 2003).

The present study was focused on methodological aspects relating to reliability in caries epidemiological studies from the Nordic countries. However, it is likely that the reporting of reliability methodology is largely

similar throughout this research area internationally. Further studies are warranted to confirm this. Clearly, the reporting of methodological aspects relating to reliability in caries epidemiological publications needs to be further developed and standardised. We suggest that the checklist used, with the addition of 'random sample selection', may prove useful for future quality assessments of caries epidemiological publications.

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