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Proposing a model for auditing data quality of long-term periodontal outcome studies

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ABSTRACT

Objective: The assessment of the success of conventional periodontal therapy is based on retrospective studies from private practice and university clinics. Due to their marked heterogeneity, it is difficult to assess the data quality and rate these studies. The aim is to test a model for auditing and rating the data quality of periodontal outcome studies.

Methods: The method was adapted from the NIH Health Care Systems Collaboratory model, which uses three data quality dimensions: completeness (including all the relevant variables), consistency (ensuring that the same variables are compared) and accuracy (proportion of data in error with a gold standard). The model was applied to studies from a Norwegian specialist practice and data from the Norwegian Health database to test if the auditing process was workable using *real world* data.

Results: Forty-seven risk and prognostic factors were included for completeness. Seven variables were specified for consistency: tooth loss, smoking, systemic conditions, oral hygiene, individual tooth prognosis, maintenance profiles and timing of extractions. The factors tested showed a 95.7% completeness and an average accuracy deviation from the gold standard of −2.3% for each of the risk/prognostic factors and an overall study score of 93.3%.

Conclusions: It was possible to develop a method for auditing and rating the quality of periodontal outcome studies. The model was tested using both *real world* data including risk and prognostic factors from individual outcome studies and national big data. The application of the model to these sets of data showed a high accuracy of the risk/prognostic factors and a close relationship with national big data.

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Periodontal therapy; treatment outcome; data auditing; data verification

Introduction

It has been shown that periodontal treatment followed by a systematic follow up save most of the teeth for the majority of patients (see for example [1–3]). These types of studies from private practice and university settings represent the evidential basis for the success of periodontal therapy. The pragmatic cohort studies, often described as card studies in the medical literature rely on data collection during routine periodontal therapy to measure outcomes [4]. Comparing these studies is difficult due to their marked heterogeneity and the uncertain representativeness of the treatments performed, both at the local and national levels.

The outcome studies are performed on patients with different demographic, ethnic and social backgrounds, treated in diverse health systems and socioeconomic settings in a variety of countries. It has been suggested that quality of care measures cannot be transferred directly between countries without an intermediate process to allow for variation in professional culture and/or clinical practice [5]. To complicate matters further, patients attending university clinics are often different and receive different treatments to patients in private practice. It has been shown that the two groups belong to different social backgrounds, have different pattern of care seeking and attach importance to different aspects of care continuity [6]. Furthermore, patients attending private practice have lower long-term attachment loss and tooth loss than patient attending university clinics [7]. The impact of the contextual factors for these studies has not received attention [8].

The scientific standard of the cohort studies has also been variable. A systematic review on long-term tooth loss studies identified 527 potentially eligible articles where only 13 retrospective case series were of a significant standard to be included [3]. A bias risk assessment revealed that eight of these studies had medium methodological quality and five had low quality. There was considerable heterogeneity between the studies with diverging results; tooth loss varied between 1.5% and 9.8% while the number of patients who did not loose teeth varied between 36% and 88.5%.

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The National Institutes of Health (NIH) has developed a Health Care Systems Collaboratory model to validate, standardize and verify data from electronic health records and patient reported outcomes [9,10]. The model was created to deal with the challenges involved in collecting data from heterogeneous practice settings, variation in health services, disparate information systems and differences in data capture. Adapting the Collaboratory model to long-term periodontal outcome studies could improve the ability to perform internal and external data assessments.

A number of studies from the same periodontal practice setting in Norway have reported on the long-term outcomes, costs of periodontal and implant therapy as well as patients' behaviour, habits and inputs [2,11–21]. Using the Health Care Systems Collaboratory model in combination with these studies could provide examples of improved data quality assessments of long-term periodontal outcome studies.

One of the key factors in the assessment using the Health Care Systems Collaboratory model is the verification of the studies to assess representativeness. The gold standard for verifying individual clinical studies is big data from national electronic databases where all the citizens are included, have equal access to treatment and have the same insurance level benefits. So far, verification at this level has been difficult to achieve.

The aim of this study is to evaluate a proposed method for data quality control of long-term periodontal outcome studies using the NIH Health Care Systems Collaboratory model for verification of local and national representativeness.

The hypothesis is that it is possible to construct and illustrate such a working method using *real world* data and verify the results on a regional and national level.

Materials and methods

Datasets used for the present study

The following datasets using *real world* data were used to test and illustrate the proposed quality control method:

A population based database

The Norwegian Health Economic Administration Database was used to analyse the prevalence of treated periodontitis in a cross-sectional register-based study as well as the treatment distributions between the dental health professionals [22]. This database contained all Norwegians aged 20 years and above who received reimbursement for periodontal treatment in 2013, altogether 166,707 patients [22]. National medical data were accessed to establish the level of smoking and systemic diseases [23].

A practice based set of data

This database contained 5646 patients from a specialist practice in periodontics located in the south-western part of Norway. Representative subpopulations of this database have been used in a number of quality control/assurance studies [2,11–21]. The specialist practice was established in 1986 and receives referrals from general dental practitioners, community dentists and physicians in Norwegian rural communities with a total population of 25,000–30,000. The area has approximately 25 dentists split evenly between private practice and the community dental service. The primary investigator is a specialist certified by the Norwegian Directorate of Health. During a period of more than 30 years, this practice has been the only specialist practice in periodontics in the area. Virtually, all patients in need of periodontal therapy in the catchment area were registered in the practice records and the periodontal treatments were completed by the same clinician [18]. In Norway, all patients receive travelling expenses if they attend the nearest specialist clinic [24].

Study design

The proposed method was adapted from the NIH Health Care Systems Collaboratory model, which assesses the quality of data used in clinical research [9,10]. Their point of departure is that population based data represents the golden standard which studies using small samples sizes should be compared against. The model relies on a multidimensional definition of data quality, which consists of three main parts: completeness, consistency and accuracy.

Completeness and consistency concern comparing the prevalence of risk and prognostic variables from the national population based database with the prevalence of the same variables from the specialist practice. Three studies from the specialists practice were used for the comparison [2,12,17]. For testing of accuracy, the data from one specific study [2] was compared with the national population based database. In comparison of variables for long-term periodontal therapy, tooth loss was chosen as the primary outcome.

We made the comparison at the database level. This is because it was not possible to merge the data from The Norwegian Health Economic Administration Database to the data from the specialist practice. To merge the data, we would need the same personal identifier in both sets of data. We did not have such an identifier.

Completeness

This refers to the presence of the relevant and appropriate factors with sufficient and correct data elements, i.e. are all the variables present in the small studies. The studies will be compared as a proportion of a set of variables. The following variables/prognostic/risk factors were required for assessing studies on the long-term periodontal treatment outcome and are defined as the complete set of variables [3,25,26] (Table 1): age, gender, ethnic background, smoking, systemic conditions, initial diagnosis (stages I–IV with grading), teeth present at the initial examination, individual tooth prognosis, oral hygiene (good, moderate, poor), close family history with periodontal disease, level of acceptance of initial therapy, compliance with maintenance therapy,

Table 1. Showing the variables/prognostic/risk factors required for assessing studies on the long-term periodontal treatment outcome, defined as the complete set of variables.

Variables	Categories
Numbers of patients included in the study	
Gender	Male, female
Age (years)	20–29, 30–39, 40–49, 50–59, 60–69, 70–79, 80+
Smoking	
Systemic conditions	Diabetes, obesity, others
Diagnosis (stage)	I, II, III, IV
Teeth present at initial examination	Average
Individual tooth diagnosis	Good, uncertain, poor, hopeless
Dropouts	Acceptance initial therapy, compliance (10 years)
Oral hygiene	Good, moderate, poor
Family history	Close relatives with periodontal disease
Ethnic background	
Outcome	Tooth loss due to periodontal disease (tooth/patient/year)
	Tooth loss all reasons
Observation years	
Maintenance therapy strategy	Periodontal office carried out all
	Periodontal office share with referring dentists
	Periodontal office offer no maintenance
Prognostic factors	Age > 60 years, smoking, male
Practice philosophy	Extraction of uncertain teeth initial therapy
	Keeping uncertain teeth initial therapy
Re-treatment during maintenance	Proportion of re-treatment (13 years)
	Proportion of surgical re-treatment (13 years)
Proportion of refractory/aggressive patients	
Operators/clinicians	Single, multiple
Statistical method	Regression analysis

observation period, level of retreatment, proportion of refractory/aggressive patients, practice philosophy (are teeth extracted at the initial therapy phase or during maintenance therapy), single or multiple operators and statistical methods.

Studies were assessed for the following:

- Proportion of missing risk and prognostic variables.
- Dropouts (proportion of cases: (a) not accepting initial therapy and (b) not complying with maintenance therapy).
- Proportion of remaining eligible cases present (percentage of records with sufficient data to calculate an outcome).

Consistency

This is defined as whether the same risk and prognostic variables are compared between studies and that there is agreement on how these factors are measured.

Some of the risk/prognostic factors require further specification to ensure that the variables are being compared on an equal basis for periodontal outcome studies: the difference between total tooth loss and tooth loss due to periodontal diseases, how smoking is recorded (at initial examination, average cigarettes, smoking pack year, etc.), systemic conditions, oral hygiene, individual tooth prognosis, maintenance strategy (frequency and if periodontal offices do all, share with referring dentist or offer no maintenance therapy) and practice philosophy regarding timing of the extractions (when the majority of extractions take place; during initial therapy or during the maintenance phase). The latter is particularly pertinent for the outcome results as long-term tooth loss is measured during the maintenance phase. This means that extractions of teeth with uncertain prognosis before the maintenance therapy phase will generally result in better overall outcomes than if extractions are delayed into the maintenance therapy. This has a wider implication as it has been shown that teeth with uncertain and poor prognosis can survive for a long time during the maintenance therapy [2]. Individual tooth prognosis and oral hygiene were determined according to Fardal et al. [2] (for details see Supplemental material).

Accuracy

This refers to the closeness of agreement between a specific study and the gold standard. The specific study and the gold standard had the following overlapping risk/prognostic variables that could be compared: gender, age range of the population, smoking, prevalence of systemic conditions, treatment prevalence, number of new cases per year, treatment distribution between surgical and non-surgical periodontal therapy, outcome/tooth loss (considering ethnic background).

We suggest that verification using databases with lower power than the gold standard, for example, regional governments, insurance companies or practice-based networks will result in inferior levels of representativeness. The comparison hierarchy should range from identifying actual errors as with the gold standard at the top, through identifying discrepancies that may or may not be an error to the lower end of merely indicating that discrepancies may exist.

Data impact assessment

The comparison of the variables from the practice based studies with the variables from the national database along

the dimensions of completeness, consistency and accuracy were used to test the quality of the small sample studies. We provided an overall proportional scoring and a rating of the quality.

Ethics approval

The following approvals exist for extraction of data: The Norwegian Regional Committee for Medical and Health Research Ethics (reference number 2013/1844), the Norwegian Social Science Data Services (reference number 37354/3/MB) and the Norwegian Data Protection Authority (reference number 14/00193-4/CGN).

Results

Description of the populations used for comparisons with gold standard

- The Norwegian Health Economic Administration Database (gold standard): 166,707 patients out of a total of 3,797,822 persons over the age of 20 years received periodontal treatment. More women than men received treatment with a predominance for patients aged 60–69 years [22].
- Study population from dental practice: 100 patients (68 females, 32 males) average age 46 years, range 25–69 years [2].

Completeness

- *Proportion of missing data elements:*
  The studies by Fardal et al. [2,12] and Fardal and Linden [17], representing the practice population of 5646 patients showed there were missing data from two out of the 47 variables (4.3%), i.e. completeness of 95.7%. The two missing data items were a lack of information on other systemic diseases apart from diabetes and obesity and a lack of data on total tooth loss.
- *Dropouts:*
  There was acceptance and compliance with (a) initial therapy of 96.8% and (b) long-term compliance with maintenance therapy of 87% [12].
- *Proportion of eligible cases:*

The remaining patients all had records with sufficient data to calculate an outcome.

Consistency

- Tooth loss was specified as teeth lost due to periodontal disease. Total tooth loss was not recorded.
- Smoking was specified as smoking at the initial examination.
- Systemic conditions were limited to diabetes and obesity.
- Specifications of oral hygiene and individual tooth prognosis were according to Fardal et al. [2].
- Maintenance therapy was shared between the periodontal office and referring dentists on a life long basis (95%).
- Tooth extractions were delayed until after the initial therapy stage and carried out during the maintenance therapy in approximately 90% of the cases.

Accuracy

The comparisons with the gold standard showed that the overall percentage deviation was −34.1% and the average for each of the 15 variables was −2.3% (range −84.4 to 102.7%) (Table 2). The greatest variation was in the age ranges between the two populations. Other differences included the fact that the practice data showed 31% higher treatment prevalence than the national data, but only 5% higher than the regional (county) level data. The practice data reported 50% more periodontal surgery than the national data. The relevance of these findings on the outcomes is uncertain. The study data showed that 66.7% more patients lost teeth in the practice data than in the national data. However, this substantial difference was clinically misleading as it only related to differences of 0.54% and 0.90% of the patients. The results confirmed that very few patients lost teeth and thus the treatment was effective. It did however question whether proportional differences as suggested by Richesson et al. [9] provided the best descriptions for verification. The present study therefore used additional radar charts to better illustrate the relatively small differences between practice and national data (Figures 1 and 2).

The rating of the Norwegian National Health Service database was assessed at 100%.

Data impact assessment

The data quality and the ratings from this practice setting were used as a working example and assessed for completeness, consistency and accuracy (Table 3). The overall data quality rated in the top 10% (93.3%).

Discussion

The study presents a working model for assessing and comparing data quality of long-term observational periodontal outcome studies. The findings showed that the model was realistic by testing it with real world data. It also showed that it is possible to verify studies from an individual practice setting using national big data as the gold standard.

It has previously been recommended that a data quality assessment should be included as a separate section in all research articles [27]. The Norwegian National Insurance Scheme has, for over four decades provided a major contribution towards periodontal therapy for all citizens with no differences in the level of benefits. The country has one of the best dental attendances, supplies and distribution of dental health professionals, including periodontists in the world [28–31]. Using the Norwegian Health Economic Administration Database containing data on all 5.4 million

Table 2. Accuracy assessment between study and National data.

Variables	National data %	Study data %	% Difference	% Variation from National data
Gender				
Male	45	38	−7	−15.6
Female	55	62	7	12.7
Age				
20–29	2	0		
30–39	6.4	1	−5.4	−84.4
40–49	14.8	30	15.2	102.7
50–59	26.1	32	5.9	14.9
60–69	31	28	−3	−9.7
70–79	15	9	−6	−40
80+	4.6	0		
Smoking				
Systemic conditions	32	26	−6	−18.8
Diabetes	2.3–8	5.8	0	0
Obesity	6.1	0		
Treatment prevalence carried out by periodontists				
National	1.6	2.1	0.5	31
Regional	2	2.1	0.1	5
Non ethnic Norwegians	2.1	0		
New cases per year for periodontists	160	167	7	4.4
Treatment				
Nonsurgical	65	46	−19	−29.2
Surgical	35	54	19	54.3
Outcome				
Proportion of patients loosing teeth (SDA)	0.54	0.9	0.36	66.7
Non ethnic Norwegians	0.76	N/A		

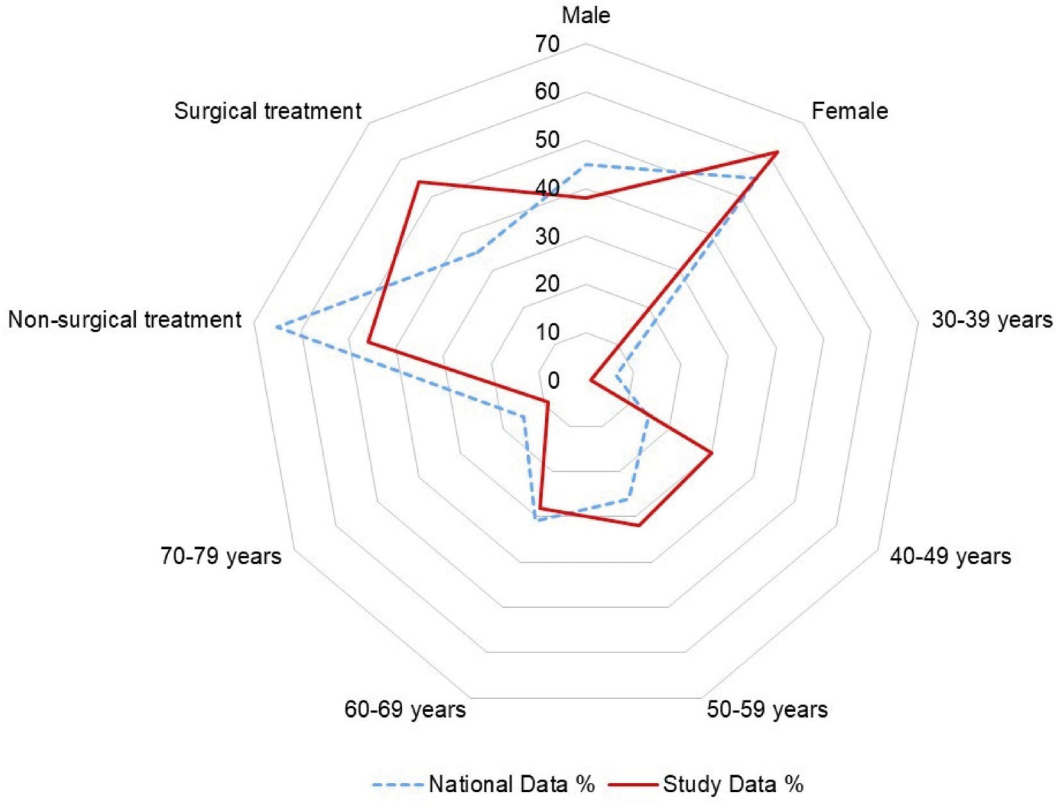

Figure 1. Accuracy assessment. National data and study data. Gender, age and treatment.

citizens provided an opportunity to verify the practice-based studies.

The present model utilized the three main data quality dimensions (completeness, consistency and accuracy) recommended by the NIH Health Care Systems Collaboratory model. The inclusion of a large number of risk/prognostic factors with clear definitions is important to provide an accurate and appropriate reflection of the individual study data. A recent systematic review on the outcome of long-term periodontal therapy only included five prognostic factors (smoking, diabetes, cardiovascular disease, gender and teeth with furcation involvements) [32]. This does not for example take into consideration a report showing that having a close relative with periodontal diseases accounted for 65% of long-term tooth loss [11]. With the oversight of such an important factor, the included factors will not show

Figure 2. Accuracy assessment. National data and study data. Treatment prevalence and tooth loss.

Table 3. Overall data assessment impact.

Dimensions	Optimal number of variables available	Number of variables provided in study	Proportions (%)
Completeness	47	45	95.7
Dropouts			
Acceptance initial therapy			96.8
Compliance maintenance			87.0
Remaining eligible cases with sufficient data			87.0
Consistency	8	7	87.5
Accuracy			
Gold standard	20	19	95.0
Gold standard rating			100
Accuracy rating			97.7
Total			93.3

a correct picture of what is important for the outcome. The lack of prognostic factors is not due to the fault of the systematic reviews, but due to a limited inclusion of such factors in the individual studies. Using the present method, the reviewers will be able to assign a quality score for the studies partly based on how many prognostic factors there are included.

In addition to demographic, systemic and oral parameters, the variables also included information on the practice profile, for example, information about the clinician's philosophy regarding the timing of extractions. These are all important for the consistencies of the data for external comparisons and for the development of a common platform for data infrastructure. It is for example vital that tooth loss from periodontal diseases is not compared with total tooth loss as it has been reported that the former may only make up 30% of the total tooth loss in some areas [33]. Furthermore, it is also important to accurately state how smoking is recorded due to the difficulties involved in assessing the effects of long-term smoking habits. Some patients may increase, decrease and possibly start to smoke again during the long-term observation period. Recent evidence shows that smoking can affect periodontal conditions for up to 18 years after cessation [34].

More systemic conditions should ideally have been included. However, the effects of systemic conditions on long-term outcomes are difficult to assess. The relative risks of the various systemic diseases are not known which makes it impossible to compare the conditions. Some patients may develop disorders/diseases during the observation period, it is not fully understood if a disease, which is being controlled by treatment can still have an effect on periodontal diseases. Finally, it is uncertain what effects periodontal treatment itself may have on the disease.

The National data showed a considerably higher proportion of patients with non-Norwegian ethnic backgrounds being treated for periodontal diseases. It is thus important to declare for ethnic background and the distribution of ethnic background in the patient populations.

The present study utilized big data from the Norwegian Health Economic Administration Database for verification. The data were obtained from routine daily clinical practice. It was difficult to accurately assess the significance of the present findings and the goodness of fit due to the absence of other comparable periodontal outcome studies that could be linked to representative national databases. It is important that any type of clinical practice can be compared with national data to identify the practice profile and the representativeness. In the present study, the largest deviation was for the population age range of 40–49 years old. As this was much higher in the specialist practice, it may be suggestive of a number of initial referrals for this age range. This is in agreement with the average age of 46.6 years for patients at the initial examination for this specialist practice setting [2].

In addition to the use of a gold standard for verification, a gold standard operator could be considered to assess the data collection in the clinical setting. However, the practicalities of such an operator need to be worked out as well as a possible certification.

Although retrospective data from private practices have a low scientific rating, there is evidence that these observational studies can still play an important role [35]. Randomized controlled trials (RCTs) and/or systematic reviews involving high quality RCTs are the gold standards for clinical guidelines. However, it has been shown that the biological efficiency measured under strict experimental condition in the RCTs may be attenuated or not even take place in the real world [36]. In addition, RCTs only include a fraction of patients of interest due to inclusion and exclusion criteria and patients' unwillingness to participate [37]. Data from observational studies come from daily routine clinical practice without modification or screening using strict inclusion and exclusion criteria, thereby retaining the real world features [38]. It has also been shown that the accuracy of statistical variability and reliability are similar for RCTs and retrospective studies [39,40].

Although retrospective studies may be superseded by the development of big data research, the small data studies are still valuable due to their utilities in answering targeted questions. The future in small sets of data lies in the ability to make them more like big data by developing new data infrastructures that can pool, scale and link to create larger datasets. The sharing and reuse of small datasets may be combined with large datasets and analysed in a large data fashion [41]. To create a platform for data infrastructure, the present quality method is useful as it utilize relevance, appropriateness, transparency and reproducibility as the key components. This provides an understanding of which variables are relevant/appropriate, how categories are assigned, a reasonable assurance that the same processes are being used across comparable studies and ensuring that the results are representative for the region and/or the country of practice.

It must be stressed that the present method only considered the quality of data and not the full range of risk of bias assessments. Apart from the variables included in the present method, other aspects such as conduct of study, internal validity, random error, selective outcome reporting, study design, fidelity of the interventions and conflict of interest may be included in risk of bias assessments [42]. Presently, there is no consensus as to the best approach or preferred tools for assessing risk of bias. A large number of tools are available and their marked variations and relative merits are often problematic for the systematic reviewers. It has recently been suggested that risk of bias assessments should rely more heavily on data quality and not necessarily on study design, numerical quality scores and automatically downgrading for industry sponsorship [42]. This is in agreement with the focus of the present model.

Conclusions

Data audits within clinical settings should be extensively used as a major strategy to identify errors, monitor study operations and ensure high-quality data. The present study proposed a method based on the NIH Health Care Systems Collaboratory model to monitor data quality for long-term periodontal outcome studies in clinical settings. The findings showed that it is possible to assess quality in periodontal outcome studies using the proposed method.

Disclosure statement

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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