

Case Report Form for oral health assessments – methodological considerations*

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Abstract: Information on the oral health condition of the target population is required to enable the development of policy strategies for oral health promotion. This information needs to be substantiated by reliable data obtained through regular oral health assessments. Countries around the world have set up oral health data-registration systems that monitor the oral health of the population. These systems are either integrated in the public oral health care service or in national surveys conducted on a regular basis. This paper describes the conception and development of a Case Report Form for oral health assessments and introduces a recently developed electronic data-registration system for data capture in oral health surveys. The conception and development of a Case Report Form poses a number of challenges to be overcome. In addition to ensuring the scientific quality of its contents, several requirements need to be met. In the framework of national oral health surveys, handwritten data capture has proven accurate, but entails an important workload related to the printing and transporting of the forms, data transfer and storage of the forms, as well as the time required to perform these tasks. On the other hand, electronic data capture enables time saving and better performance. However, the advantages of this system may not be fully acknowledged by general practitioners, and their motivation to employ information and communication technologies may need to be encouraged. In the long term, the inclusion of electronic data registration in university training is probably the best strategy to achieve this.

Descriptors: Oral Health; Medical Informatics Computing; Health Care Surveys; Epidemiology; Data Collection.

*Paper presented at the “Oral Health Promotion: Expanding the Boundaries of Knowledge” International Symposium, held at the 16th Congress of the Brazilian Association for Oral Health Promotion (ABOPREV), June 30 to July 2, 2011, Brasília, DF, Brazil.

Declaration of Interests: The author certifies that she has no commercial or associative interest that represents a conflict of interest in connection with the manuscript.

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Introduction

In the late 80s, the First International Conference on Health Promotion in Canada established that the process of health promotion should ensure equal opportunities and resources to enable all individuals to achieve their fullest health potential.¹ To accomplish this goal, the adoption of public health policies, supportive environments and community actions were recommended, in addition to the development of personal skills and the setting of new guidelines for health services. In this context, the responsibility for health promotion should be shared among individuals, community groups, health professionals, health service institutions and governments.^{2,3}

Submitted: Jan 11, 2012
Accepted for publication: Apr 28, 2012
Last revision: Sep 18, 2012

Failure to provide health promotion has led to inequalities in health, as observed in countries with different levels of care existing across populations, resulting in poor health and poor quality of life, limiting school or work attendance and creating low self-esteem.³⁻⁶ When it comes to health promotion, it is important to understand that oral health should be included in the context of a broader general health perspective, and in the existing framework of health care in different countries and populations. According to the World Health Organization, oral health is an integral part of and essential to general health, and oral health is a determinant factor for quality of life.⁷

While the role of biological determinants in oral health is well documented,^{5,8,9,10} social and behavioral determinants have increasingly been studied for their influence on oral health.¹¹⁻¹⁴ Recently, it was suggested that the control of oral conditions such as dental caries and periodontal diseases should be based on management models for chronic diseases, in which multiple strategies are applied to target determinants at the individual, the family, and the community levels.^{6,7} According to this model, a recent study among Brazilian preschool children showed that caries reduction over a 10-year period was associated with child age, family income, parental education and presence of fluoride in the drinking water.⁵

Information on the oral health condition of the target population is required to enable the development of policy strategies for oral health promotion. This information needs to be substantiated by reliable, representative, longitudinal and recent data.¹⁵ Data with these characteristics can be obtained only through regular oral health assessments. Countries around the world have set up oral health data-registration systems that monitor the oral health of their population. These systems are either integrated in the public oral health care service or in national surveys conducted on a regular basis. In 2008, the Belgian National Institute for Health and Disability Insurance (INAMI-RIZIV) implemented an oral health data-registration and surveillance system for oral health surveys. The Belgian Health Care System is private only, and general practitioners are the

foundation of the oral health care delivered in the country, including the assessment of the population's oral health through national surveys. A Case Report Form for oral health assessments and a questionnaire to estimate oral health behaviors and attitudes were developed to put the framework of this system into place. It contained information about visits to the dentist, dental treatment, diet, complaints and quality of life.¹⁵ This paper presents the conception and development of this Case Report Form for oral health assessments, and introduces a recently developed electronic system for data capture in national oral health surveys.

Methodology

Case Report Form for oral health assessments

The conception and development of the Case Report Form posed a number of major challenges. In addition to ensuring the scientific quality of its contents, the form should present a user-friendly layout that would be easy to work with by general practitioners, would cover all the main subjects in dentistry, would include oral health assessments for different age groups starting at 5 years of age, would include a short description of all criteria applied, would occupy a maximum of the two sides of an A4 sheet of paper, would require no more than 30 minutes to fill out, and would present oral health assessments within the logic of the clinical examination. The Case Report Form was developed to fit into, and not overly disrupt, the dental practice work flow. Accordingly, the Case Report Form could be used to assess the oral health of selected participants examined either in a dental practice or in the participant's household. These two options should be tested for their operational feasibility in the country and the most advantageous should be chosen to conduct the national oral health survey. The selection and number of participants should be established, ensuring representativeness of the population of the country for the different age groups, starting at the age of 5. Written informed consent should be obtained from the selected participants before the commencement of the survey.

The identification of participants in the Case Re-

port Form was made by means of a unique National Register Number containing the individual's date of birth and gender. In the case of non-participation in the oral survey, the reason was given by checking the appropriate box. The identification of the general practitioner who performed the oral health assessments was made by a code number. Each participant should be assigned to one dental practitioner only to obviate double examination. This rule should be followed strictly, since each practitioner should only be paid for the oral health assessments of those patients assigned to him/her.

The subjects included in the Case Report Form were orthodontics, cariology, periodontology, and prosthodontics. Accordingly, the oral health conditions that were selected for the Case Report Form are described below:

1. Anterior dento-facial anomalies: space conditions and malocclusions¹⁶ were recorded for participants age 12 or older.
2. Oral hygiene status: measured by the Plaque Index¹⁷ and recorded in selected teeth for participants in all age groups.
3. Periodontal status: measured by the Dutch Periodontal Screening Index - DPSI,¹⁸ which recorded gingival bleeding, calculus and periodontal pockets by sextants in participants age 15 or older.
4. Tooth wear: recorded as attrition, abrasion and erosion¹⁹ in participants age 12 or older.
5. Anterior developmental defects of enamel: identified in terms of hypoplasia⁹ and fluorosis—TF Index²⁰—in participants age 12 or older.
6. Dentition status: recorded according to the World Health Organization²¹ at tooth level. Also, the number of teeth with sound exposed roots, teeth with decayed/filled exposed roots and implants were recorded for all age groups.
7. Prosthodontic status: recorded separately for maxilla and mandible, for the presence of bridge, partial denture and full denture,²² for all age groups.
8. Number of functional occlusal contacts: recorded for the right and left hemi-arch. A separate registration was made for participants wearing removable denture(s), with and without the

denture(s) in their mouth.²²

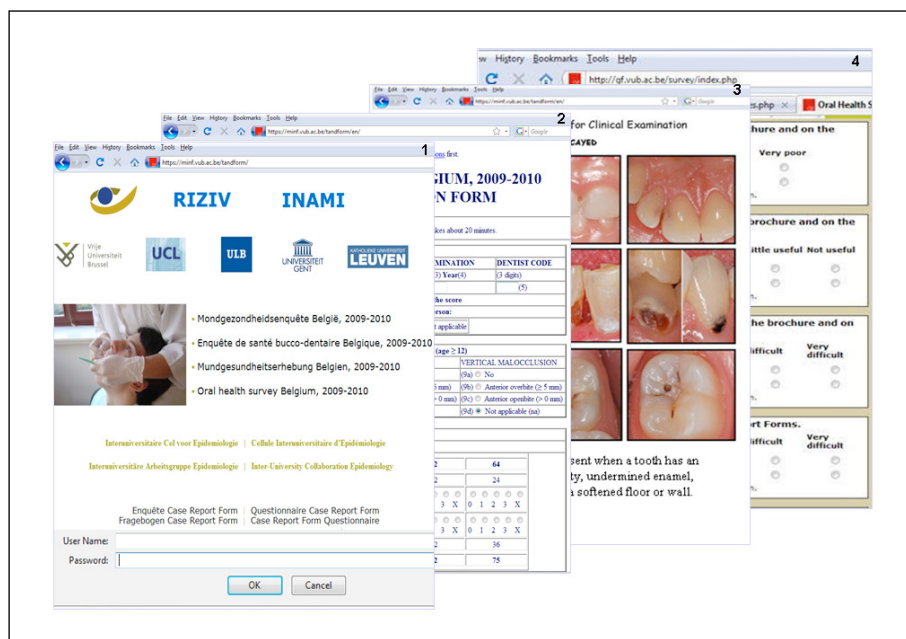
The methods and criteria selected to diagnose these oral health conditions were based on methods and criteria that were reliable, validated, easy to implement and record, that required a limited period of time to be carried out and that allowed comparison with other countries. The general practitioners were informed and trained in the registration of the oral health conditions. They were calibrated using a series of full-mouth recordings simulating the clinical examination of patients, set up in a Power Point presentation.¹⁵ The Case Report was prepared in two formats: paper and electronic. These were identical in terms of design, contents and information. The two formats were required since a transitional period was needed to migrate completely from paper format to electronic format.

A booklet called “Illustrated guidelines for clinical examination” was developed in order to assist the general practitioners in carrying out the clinical examination during the oral health survey.¹⁵ Finally, the data registered in the Case Report Form should provide an accurate picture of the oral health status of a population at different stages of its life cycle and of its treatment needs. The Case Report Form was tested by general practitioners working at university hospitals who agreed to carry out clinical examinations using the Case Report Form according to illustrated guidelines. These general practitioners were asked to provide as many comments as possible about any aspect of the documents that could be improved. Additionally, they were asked to provide information about the time required to read the guidelines and to fill in the Case Report Form.

Electronic data capture

The development and implementation of the Oral Survey-B²³ electronic data capture system for oral health surveys was based on the system being tested, validated and evaluated for its advantages and disadvantages, in comparison with traditional handwritten data capture. Moreover, the design of the system and its interfaces should satisfy the appropriate regulations and good clinical practice rules. Figure 1 illustrates the system's user interfaces

Figure 1 - Oral Survey-B system interfaces (1-4) appropriate for electronic data capture. This illustration is reproduced with the kind permission of S. Kager AG, Basel.



which were developed for data capture.

A convenience sample of general practitioners attending continuing education meetings in different parts of the country was drawn to test and validate the system. The practitioners were asked to capture benchmarked data from 6 series of full-mouth recordings simulating the clinical examination of 6 patients which were set up in a PowerPoint presentation. In each series of full-mouth recordings, there were 63 items of data to be recorded. A randomized one-period crossover design was used with two formats of data capture, *i.e.* electronic followed by handwritten or handwritten followed by electronic. Six benchmarked handwritten forms were then transferred to the electronic format. Following the data capture, the practitioners answered an on-line questionnaire inquiring into the advantages and disadvantages of the electronic and handwritten data capture according to a 5-point ordinal scale ranging from the worst to the best judgment. The questions addressed the understanding, usefulness and quality of the instructions given for data capture, the degree of difficulty in capturing data, the degree of difficulty in implementing data capture in private practice for epidemiological purposes, and the preferred format of data capture.

The system itself included data validation con-

trols for plausibility and completeness, which catch many potential errors during data capture. If a partially completed electronic case report form was submitted to the server, the user received a message explaining the rejection of the form and the reason(s) why. The data were stored on a secure server.

Results

A total of 15 general practitioners age 22 to 55, working at university hospitals, examined 50 patients in different age groups in order to test the Case Report Form in paper format as well as the illustrated guidelines. A list was drawn up of the difficulties to complete the Case Report Form and inaccuracies observed in the illustrated guidelines. The necessary changes were made in order to assure the appropriate use of the Case Report Form and the illustrated guidelines by the general practitioners. The time required to carry out the clinical examination by more than two-thirds of general practitioners was estimated between 20 and 25 minutes. The Case Report Form and the illustrated guidelines were considered appropriate for oral health assessments in surveys carried out by general practitioners.

The electronic system was validated by 52 general practitioners age 22 to 76, representing 40 municipalities across Belgium. The performance

of general practitioners in capturing electronic and handwritten data, and in the transfer of handwritten data to a database, was evaluated on the basis of completion of the forms and the overall percentage of errors. In regard to the electronic data capture, 86.5% of the practitioners had a correct completion rate of $\geq 95\%$. The corresponding rate for the handwritten data capture and transfer was 78.8% of the practitioners ($p = 0.25$, McNemar test). In addition, significantly lower percentages of errors were observed for the electronic data capture, in comparison with the handwritten data capture and transfer ($p < 0.001$, Signed Rank test). The average time spent on electronic data capture and transfer was 3.2 minutes versus 4.6 minutes for handwritten data capture and transfer ($p < 0.001$, Signed Rank test). Overall, young general practitioners spent less time on all types of data capture and transfer than older ones.

Two main disadvantages of the electronic versus the handwritten data capture and transfer options were identified by the practitioners. Firstly, the degree of difficulty perceived during data capture of oral health conditions was significantly higher for electronic capture. Secondly, the implementation of electronic data capture in private practice seemed more difficult ($p < 0.001$, Signed Rank test). Two-thirds of the dentists preferred handwritten data capture ($p = 0.002$, Chi-square test).

Discussion

Traditionally, oral health assessments in national oral health surveys are recorded in handwritten Case Report Forms and the data are later entered into a database for statistical analysis. Alternatively, in the United Kingdom, Survey Plus 2 software has been developed to record dental status, after which the data are entered on an Excel spreadsheet for further data analysis.²⁴ In Sweden, a mobile, personal digital assistant application (MobilDent PDA) was developed for oral health assessments, including back-office and database systems. A synchronization module in the office periodically transfers the personal digital assistant application data to the back-office and database systems.²⁵ Based on the framework of the Belgian oral health data-registra-

tion and surveillance system, we decided to develop a more efficient and productive system for comprehensive epidemiological oral health surveys than those available elsewhere, namely, an electronic data capture system designed for epidemiological surveys in dentistry including oral health assessments and questionnaires.

Our results showed that the handwritten and electronic data capture systems were accurate. Moreover, the development of a user-friendly electronic data capture system allowed reduction of the workload associated with conventional handwritten data capture and enabled general practitioners from geographically dispersed locations of practice in the country to capture, transfer and store data on a secure server in real time. Both handwritten data capture and the electronic system and its interfaces complied with the appropriate regulations and good clinical practice rules.²⁶ Even though general practitioners performed best in electronic data capture, they perceived it as being a more difficult task to carry out than traditional handwritten data capture. The fact that the practitioners were confronted with electronic data capture for the first time, whereas handwritten recording of oral health status was practiced during their university training, may partially explain this finding.

Conclusion

The conception and development of a Case Report Form poses a number of challenges to be overcome. In addition to ensuring the scientific evidence of its contents, several requirements need to be met. In the framework of national oral health surveys, handwritten data capture has proven accurate, but entails an important workload related to the printing and transporting of the Case Report Form, data transfer for statistical analysis, storage of the forms, as well as the time required to perform these tasks. On the other hand, electronic data capture enables time-saving and better performance. However, the advantages of this system may not be fully acknowledged by general practitioners, and further motivation of practitioners to use Information and communication technologies may be necessary. In the long term, the inclusion of electronic data registration in

university training is probably the best strategy to address this need,²⁷ as recently graduated dentists are more and more familiar with information and communication technologies.

Acknowledgment

As acknowledged during the lecture, the sponsor of the Data Registration and Evaluation of the Oral Health of the Belgian Population Project was the Belgian National Institute for Health and Disability Insurance (<http://www.inami.be/homefr.htm>).

The project team responsible for the development of the project consisted of:

- Prof. Peter Bottenberg - Vrije Universiteit Brussel (VUB)

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