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Patient safety in dental care: A challenging quality issue? An exploratory cohort study

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Abstract

Objective. Little is known about patient safety in primary oral healthcare. The aim of this study was to describe and analyze patient safety incidents in primary oral health care. ***Materials and methods.*** A random sample of 1000 patient records from 20 dental practices was reviewed retrospectively over 60 months. All adverse events (AEs) were noted: unintended events happening during treatment that resulted or could have resulted in harm to the patient. ***Results.*** A total of 46 (95% CI = 33–59) AEs was identified, of which 18 (95% CI = 10–26) were considered preventable. From these, 15 related to treatment, 10 to diagnostics and one to communication. ***Conclusions.*** The low incidence of AEs and absence of major harm to patients suggests that primary oral care is safe for patients. However, the low quality of record keeping may imply underestimation.

Key Words: *Patient safety, quality of oral care, health services research, risk, epidemiology*

Introduction

Many clinical activities are associated with risk of harm to patients. Since in 2000 the report 'To err is human' [1] was published in the US, patient safety has gained worldwide research attention [2–5]. Not all adverse events (AEs) reflect sub-optimal patient safety, but those that are preventable do so. Interest for patient safety is also growing in other healthcare sectors, e.g. primary medical care showed a prevalence of 5–80 AEs per 100 000 consultations [4]. In Western European countries most patients receive for the greater part their healthcare in primary care settings.

In oral healthcare, patient safety has not received explicit attention so far and focused research is lacking. General dental practice is characterized by a high volume of regular visiting patients [6] and clinical procedures as well. Research on patient safety in primary care is complicated and a gold standard for identifying AEs is not available [7]. Using patient records as a method to identify AEs has the advantage of a clear sampling frame, but its validity highly depends on the quality of record keeping [8].

The aim of the present study was to assess the prevalence, preventability and potential consequences of AEs occurring in primary oral care settings.

Materials and methods

We conducted an observational study in general dental practices in the Netherlands, which was based on reviews of computerized patient records. Research procedures and measures were tested and were found to be both feasible and reliable [9,10].

Sample of practices and patients

A stratified sample of 40 general dental practices in the Netherlands was included using practice size and degree of urbanization as stratification factors. Eventually, 20 practices agreed to participate. For each

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Table I. Patient characteristics as a result of records reviewed 5 years retrospectively (n = 1000).

Gender	
Male	47%
Female	53%
Age	
9 years or younger	5%
10–21 years	15%
22–29 years	9%
30–39 years	15%
40–49 years	19%
50–59 years	18%
60–69 years	12%
70 years or older	7%
Deprivation category[a]	
socio-demographic status least deprived	58%
socio-demographic status most deprived	42%
Symptomatic visit (emergency)	28%
Oral health-related risk status in record	40%
Oral health- and medical-related risk status in record	8%
Chronic medical condition	7%
Special conditions (i.e. dental fear)	5%
Patient at risk (dental, medical or otherwise)	43%
Communication problem occurred	0%
Number of patient contacts	
1–10	36%
11–20	50%
21 or more	14%
Patient's dental contact > 1 professional within same dental practice	35%
Patient's dental contact > 1 dental practice	16%
Report patient history	94%
Report present oral health condition	93%
Report dental care planning[b]	47%
Report informed consent[b]	28%
Report emergency out-of-hours dental care[c]	96%
Report medical patient history (> 24 years)[d]	39%
Report periodontal condition (> 24 years)[d]	35%
Quality of record keeping[e]	
Poor (0–33%)	11%
Fair (34–66%)	37%
Good (67–100%)	52%

[a] According to the Dutch standards of the Netherlands Institute for Social Research(SCP). The Hague; 2003.
[b] n = 325.
[c] n = 28.
[d] n = 733.
[e] Based on the relevant aspects regarding optimal record keeping activities in dental practice, we calculated a sum-score per patient. As a consequence this score should be related to the ideal score which could potentially be reached given the individual patient characteristics found in the patient record under review (for example: no emergency visit in a weekend means no report in record; younger than 23 years of age implies no periodontal risk score in record). Accordingly, for each patient we calculated which proportion (%) of the potential aspects of recording which should be present were actually found in the patient record. The distribution of percentages is subsequently combined in three categories as described.

practice, 50 patients who had visited or contacted the practice between January and April 2009 were randomly selected in the retrospective review of patient records, resulting in a total of 1000 patient records.

Measures

We used a broad definition of an adverse event which was defined as an unintended event during the care process that resulted, could have resulted or still might result in harm to the patient [11].

We considered patient safety at stake if the adverse event was preventable. An AE was labeled as 'preventable' in cases of an error in management, due to failure to adhere to broadly accepted professional standards. This assessment was based on expert judgment. Preventable AEs could have reached the patient, causing harm, but also being potential, i.e. not affecting the patient immediately. An AE was called 'non-preventable' if it was perceived to be unavoidable as part of a specific care process. Patients can also contribute to AEs, but we excluded events which were completely caused by a patient (e.g. not adhering to therapy).

Review of patient records

The included patient records were reviewed over a 5-year period. The review process comprised two stages: the identification of AEs (record review) took place in dental practice, whereas the systematic retrospective analysis (assessment) was carried out in expert meetings using a validated instrument for incident analysis [12]. Each team consisted of a dental expert and a non-dentist research-assistant and visited five dental practices. When a potential AE was detected, the dental record was made anonymous, printed and collected for analysis.

To assess the reliability of the review process and calculate the percentage of agreement by all dental experts independently, a random sample of 50 patient records was reviewed for AEs. Results were discussed until full agreement was reached.

Quality of record keeping

The quality of patient records was determined on the basis of the presence of essential aspects regarding record keeping professional standards and clinical practice guidelines. Accordingly, for each patient we calculated the proportion of potentially relevant items that were actually found in the patient record.

Data analyses

The incidence of AEs (preventable and non-preventable) over a 5 year period was described and bivariate analysis (using non-parametric Kruskal-Wallis testing; $p < 0.05$) was used. The preventable AEs were described in terms of type of event (diagnosis, treatment, communication related) and perceived causes of the event, using the PRISMA method and classified using the Eindhoven Classification Model (ECM) [12]. The ECM has been adopted by the World Alliance for Patient Safety from the World Health Organization [13]. Both actual harm caused and the probability of severe harm were determined using the international taxonomy of medical errors in primary care [14].

Results

Practice and patient characteristics

The 1000 patient records represented 13,615 patient contacts in total over a 5-year period. The most important practice and patient characteristics are described in Table I. For example it shows that the overall quality of record keeping performance was found to be poor in 11% of the records, fair in 37% and good in 52%.

Quality of record keeping

Overall, the quality of record keeping performance was found to be poor in 11% of the records, fair in 37% and good in 52% (Table I).

Preventable and non-preventable adverse events

In 46 (95% CI = 33–59) out of 1000 records, AEs (preventable and non-preventable) were identified (4.6%), from which 18 (95% CI = 10–26) were assessed as preventable (1.8% of all records) and 28 (95% CI = 18–38) as non-preventable (2.8%) (Table II). The prevalence of preventable AEs for all patient contacts was 18/13 615 = 0.13% (i.e. total number of patients involved/total number of patient contacts).

The agreement values regarding the identification of AEs between the four dental expert reviewers was 92%.

Table II. Reports of non-preventable and preventable adverse events (including potential AEs) causing harm (+/−) as a result of patient records reviewed 5 years retrospectively (n = 1000).

Actual harm	*n*	%
No adverse events	954	95.4
Adverse events	46	4.6
Non-preventable adverse events	28	2.8 +
Preventable adverse events	15	1.5 +
Potential preventable adverse events	3	0.3 −

Factors associated with adverse events

The probability an AE (preventable and non-preventable) occurred over a 5-year period was higher ($p < 0.05$) when patients were older ($p = 0.03$), visited the dental practice more frequently ($p = 0.00$), were seen for an emergency visit ($p = 0.00$) or used more than one particular dental practice ($p = 0.02$). Furthermore, the probability an AE (preventable and non-preventable) occurred was higher ($p < 0.05$) when GDPs had reported informed consent ($p = 0.00$) or record keeping quality was found poor or fair ($p = 0.02$). The probability of a preventable AE was found to be statistically significantly higher ($p < 0.05$) when patients were older ($p = 0.04$).

Types and consequences of preventable adverse events

From a total of 18 preventable AEs, three were characterized as potential AEs (did not reach the

Table III. Preventable adverse events and potential adverse events, categorized by domain, cause, actual damage and final harm.

	Adverse events	Domain[a]	Cause (ECM code)[b]	Actual damage[c]	Seriousness final harm[d]
1	Removal of permanent tooth by accident	Diagnoses treatment	HRI/ HRV	2.3	–
2	First molar removal (46) root fragment left *in situ*, no further testing, diagnoses and therapy	Diagnoses treatment	OC/ HRM	5	–
3	First molar removal (26) root fragment left *in situ*, no further testing, diagnoses and therapy	Diagnoses treatment	OC/ HRM	5	–
4	First premolar removal (45) root fragment left *in situ*, no further testing, diagnoses and therapy	Diagnoses treatment	HRI/ HRM	5	–
5	Root canal treatment: excessive filling, material in periapical alveolar bone, no further treatment	Treatment	HRV	5	–
6	Root canal treatment: fractured instrument *in situ* after root canal treatment, no further treatment	Treatment	OM/ HRI	5	–
7	Root canal treatment: file failure, during irrigation *in situ*, no further treatment	Treatment	OM/ HRI	5	–
8	Removal (13), broken root fragment left *in situ*, no further testing, diagnoses and therapy	Diagnoses treatment	PRF/ HRM	5	–
9	Root canal treatment: file fractured in 16 MB-canal, no further treatment	Treatment	OM/ HRV/ HRI	5	–
10	Root canal treatment: instrument broken during root canal treatment, perforation in other root canal	Diagnoses treatment	PRF/ HKK/ HRM	3.2	–
11	Root canal treatment 16: leakage in periodontal apical region NaOCL	Treatment	HRI/ HKK	3.2	–
12	Root canal treatment: perforation by opening, prognosis unfavorable	Treatment	HRI	3.2	–
13	Complicated removal first molar 46, fixed partial prosthesis lost and swallowed by patient	Diagnoses treatment communication	OC/ HKK	3.2	–
14	Root canal treatment: failure file broken, no further treatment	Treatment	OM/ HRI	5	–
15	Swallowing fixed full crown, no reported further treatment	Treatment	OC/ HRM/ HRI	5	–
	Potential adverse events:				
16	Removal third molar (38) without prior X-ray	Diagnoses	OC/ HRV	2.2	–
17	Removal third molars (28 & 18) without prior X-ray	Diagnoses	OC/ HRV	2.2	–
18	Removal third molar 38 without prior X-ray	Diagnoses	OC/ HRV	2.2	–

[a] Domains: organization/communication/prevention/diagnoses/treatment.
[b] Codes from Eindhoven Classification Model (ECM): TD, technical-design; TC, technical-construction; TM, technical-materials; O-EX, organizational-external; OK, organizational-knowledge transfer; OP, organizational-protocols; OM, organizational-management priorities; OC, organizational-culture; H-EX, human-external; HKK, human-clinical reasoning; HRQ, human-qualifications; HRC, human-co-ordination; HRV, human-verification; HRI, human-intervention; HRM, human-guarding the process; HSS, human-tactile intervention; PRF, patient-related factors.
[c] In 'Severity of outcome' according the International Taxonomy of Medical Errors in Primary Care: Score 1–5 (1 = no adverse event, 4 = death of patient, 5 = harm was not possible to determine).
[d] ++ most likely; + likely; – unlikely.

patient and/or had no tangible effect on the patient), which were all related to diagnostic performances. The remaining 15 preventable AEs were all classified as treatment-related, seven as diagnostics-related and one as communication-related (Table III).

No preventable AEs resulting in permanent damage or death could be identified. The analysis of the causes of the 18 preventable AEs provided a total of 37 causes. Most of the preventable AEs had a human (65%) or an organizational (30%) cause.

Discussion

Patient safety is a crucial feature of high quality of healthcare, which concerns many different aspects. This exploratory cohort study identified 18 preventable AEs and 28 non-preventable AEs found in 1000 patient records over a 5-year period.

Given the substantial number of asymptomatic patients visits in primary oral care in The Netherlands, the estimated yearly number of AEs could be around 100 000. Nevertheless, from this perspective primary oral care appears to be safe.

Most of the preventable AEs stem from human and organizational problems. This study also found moderate quality of record keeping activities; ~ 50% did not meet the criteria. Thus, the quality of the records had a profound impact on the final results of this study, i.e. the prevalence found might be an underestimation of the potential patient safety events [15].

The exploratory nature of this study gives rise to acknowledging several limitations; 20 dental practices out of ~ 5600 in the Netherlands may not present a representative view of dental practice, despite the high number of patients and years of retrospective observation.

Furthermore, the voluntary self-selection of participating practices probably could have led to selection bias, i.e. an under-estimation of the prevalence of AEs. The reliability of the AE determination, based on the applied definitions and methods [11,12], could have been affected by the sub-optimal quality of record keeping as well as the lack of professional standards to reliably analyze the potential AEs. On the other hand, the percentage of agreement between assessors in this study was high.

More research data on patient safety aspects in oral care will be needed to identify both performance gaps and underlying causative factors.

First of all, this calls for development of validated measurement methods, as now a gold standard for identifying AEs is lacking [7]. AEs are mainly caused by a chain of events or system failures rather than isolated errors of individuals [16], so patient safety research should also be focused on structured retrospective and prospective risk analysis of unintended events as a result of an oral care process. Also, future research should focus in a multivariate and multi-level way on patients, GDPs' and practice level to better address the features of the PRISMA-modeling on AEs.

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References

[1] Institute of Medicine. To err is human: building a safer health system. Washington DC: National Academy Press; 2000.

[2] Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an international classification for patient safety: key concepts and terms. Int J Qual Health Care 2009;21:18–26.

[3] Thomson R, Lewalle P, Sherman H, Hibbert P, Runciman W, Castro G. Towards an international classification for patient safety: a Delphi survey. Int J Qual Health Care 2009;21:9–17.

[4] Sandars J, Esmail A. The frequency and nature of medical error in primary care: understanding the diversity across studies. Fam Pract 2003;20:231–6.

[5] Hobgood C, Hevia A, Hinchey P. Profiles in patient safety: when errors occurs. Acad Emerg Med 2004;11:766–70.

[6] CBS Statistics Netherlands. Statline Website November 15th 2010. The Hague: 2010. Available online at http://www.cbs.nl http://www.cbs.nl.accessed.

[7] Olsen S, Neale G, Schwab K, Psaila B, Patel T, Chapman EJ, et al. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. Qual Saf Health Care 2007;16:40–4.

[8] Mettes TG, Sanden WJ van der, Mokkink HG, Wensing M, Grol RP, Plasschaert AJM. Routine oral

examination: clinical performance and management by general dental practitioners in primary care. Eur J Oral Sci 2007;115:384–9.

[9] Harmsen M, Gaal S, van Dulmen S, de Feijter E, Giesen P, Jacobs A, et al. Patiëntveiligheid Patiënt safety in Dutch primary care in 2009. Nijmegen: IQ healthcare; 2009.

[10] Harmsen M, Gaal S, van Dulmen S, de Feijter E, Giesen P, Jacobs A, et al. Patient safety in Dutch primary care: a study protocol. Impl Sci 2010;5:50.

[11] Wagner C, van der Wal G. For a good understanding. Improving patient safety requires clear definitions. Med Cont 2005;60:1888–91.

[12] Snijders C, van der Schaaf TW, Klip H, van Lingen WPFF, Molendijk A. Feasibility and reliability of PRISMA-medical for specialty-based incident analysis. Qual Saf Health Care 2009;18:486–91.

[13] World Health Organization Alliance for Patient Safety. The conceptual framework of an international patient safety event classification: executive summary. Geneva: World Health Organization; 2010.

[14] The Linnaeus-PC Collaboration. International taxonomy of medical errors in primary care - version 2. Washington DC: The Robert Graham Center; 2002.

[15] Mettes TG, Bruers JM, van der Sanden WJM, et al. Patient safety in dental practice. Ned Tijdschr Tandheelk 2010;117: 628–36; Article in Dutch.

[16] Reason J. Human error: models and management. Brit Med J 2000;320:768–70.