



# A Two-Pronged Approach to Understanding Quality and Safety Events at the Dental Office

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**A TWO-PRONGED APPROACH TO UNDERSTANDING QUALITY AND SAFETY EVENTS  
AT THE DENTAL OFFICE**

A Thesis Presented by

*Enihomo Mary Obadan-Udoh, DDS, MPH*

to

The Faculty of Medicine

In partial fulfillment of the requirements

for the degree of

Doctor of Medical Sciences

*Research Mentors: Elsbeth Kalenderian, DDS, MPH, PhD, Associate Professor*

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Boston, Massachusetts

April 2016

**SIGNATURE PAGE**

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April 2016

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To err is human, to cover-up is unforgivable, to fail to learn is inexcusable.

-Sir Liam Donaldson

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## ABSTRACT

**Objectives:** Owing to the limited number and scope of studies in dentistry regarding quality and patient safety, the overarching goal of this thesis was to understand the nature and occurrence of quality and safety events in dentistry using a two-pronged approach – biomedical literature and patient-reported experiences.

**Methods:** I conducted two exploratory studies: the first was a detailed retrospective review of published case reports on dental patient safety events; the second was a cross-sectional study of 450 patients at a large dental teaching practice in South Africa about their quality and safety experiences using a self-administered questionnaire.

**Results:** 180 case reports (270 cases) were identified through the literature search. Most reports came from Europe and North America. The most commonly-reported safety event was wrong treatment or unnecessary treatment following misdiagnosis (23%). 11% of case reports ended in the death of the patient. On the other hand, the patient survey revealed that 45.5% had experienced one or more safety events during dental visits in South Africa (1.6 events per respondent). Intra-oral hard tissue injury, such as adjacent tooth damage during treatment, was the most commonly reported event by patients (30.4%). ‘Never events’ such as wrong tooth extractions or wrong-site procedures, occurred in 7% of patients. The combined quality rating was fair; about 41.4% of participants rated the quality of dental care they received as sub-optimal. Access to care was ranked the lowest among patient-defined quality dimensions.

**Conclusion:** Quality and safety events occur in dentistry, and are quite common. Published case reports offer a window into the types and severity of quality and safety events in dentistry. Although the literature is very skewed to reports of significant events and is thus not representative of all AEs that happen, it is a valuable source of information especially in the absence of a centralized reporting system. Patient reports much better let us understand the effects and sequelae of AEs. More work is needed to move the profession forward in our understanding of these events so that we may prevent them.

### **A Patient's Story: *"The girl with the yellow teeth"***

The time was 2am on Friday, October 4, 1984 in the bustling metropolitan city of Luamba. Mrs. G paced frantically across the dimly lit bedroom, trying to pacify the crying baby girl strapped to her back. It had been a long night; her daughter developed a fever earlier in the night and seemed inconsolable. At midnight, she contemplated rushing out to the local community clinic when her daughter wouldn't stop crying but thoughts of the 'area boys' laying in wait for unaccompanied women gave her second thoughts. Against her better judgment, she settled on watching her through the night, occasionally mopping her face with a cold cloth and administering spoons of painkillers.

As dawn approached, with tired eyes from lack of sleep, she hurriedly jumped into her white Santana Volkswagen car, forgetting her baby was strapped behind her. She was suddenly jolted back to reality when she heard the loud screams from her baby girl who was almost suffocated between her mother's back and the car seat. After wading through the early morning Luamba traffic and breaking every traffic law imaginable, Mrs. G finally arrived at the clinic as they opened the cubicle to commence patient registration for the day. She joined the queue, albeit uneasy, as her daughter's condition seemed to be worsening. She tried to attract the attention of a nurse who passed by but everyone seemed nonchalant and none came to her aid. After about 30 minutes, an elderly nurse noticed her, performed a quick examination and moved her to the front of the line amidst grumbles from other waiting patients.

In the doctor's room, a tall, lanky middle-aged man, with a stethoscope around his neck sat staring at his notes. He barely looked up while she explained her ordeal and within ten minutes, she walked out of the room with a scribbled note for the pharmacy. She made a mad dash to the pharmacy, which was at the other end of the clinic premises and presented the little piece of paper to them. After keeping her for what seemed like eternity, they returned to the cubicle window to inform her that the pharmacy was out of stock for that particular medication, so she needed to return to the doctor to get a new prescription. At this time Mrs. G was completely exasperated; it was almost noon and she hadn't had anything to eat all morning.

By the time she made it back to the clinic, she met the elderly nurse who informed her that the doctor had stopped taking patients for the day because he wanted to close by noon. After lots of pleading, the nurse offered one last remedy, she crossed out the note and scribbled another medication, explaining to Mrs. G that these medications were “essentially identical” and would help eradicate her daughter’s fever. Innocently, Mrs. G went ahead to get the “new prescription” from the pharmacy and by evening, her little girl had stopped making a fuss, her temperature had largely become normal and all was well in the world, or so it seemed...

Fast-forward a few years; Mrs. G observed that as her little girl’s “milk teeth” exfoliated, the new teeth that emerged had a yellowish tinge. At first she thought nothing of it and increased the intensity of tooth brushing. When it became obvious that the yellow stains were not going away, Mrs. G took her daughter to a dentist who traced the origin back to the ‘identical’ prescription (Tetracycline) that the elderly nurse gave to the little girl. Unknown to the nurse, its use had recently been banned in pregnant women and children under the age of 12 years because of the characteristic colored band that it created on the teeth of children amongst other adverse effects. These stains were intrinsic and not amenable to tooth brushing or cleaning. Her little girl’s teeth were discolored for life! The only solution was to cover them up when she turned 18 years old. Mrs. G was crushed and wished she had insisted on seeing the doctor before accepting changes to the prescription.

Meanwhile, her little girl had secretly endured teases and jeers from her classmates who called her the “girl with the yellow teeth”. She became withdrawn and hated school. The climax came when her class teacher called her “yellow teeth” while trying to get her attention one day. The next morning, when Mrs. G woke her little girl up to prepare for school, but to her surprise, her little girl began crying. After much probing, she learned that her daughter had been the butt of jokes from bullies and this made her loathe school. Mrs. G got her daughter dressed and accompanied her to the principal’s office. The principal apologized profusely and summoned the class teacher, who should have known better, to her office. On realizing the effect of her words, the class teacher apologized to Mrs. G and her little girl. In

a slight twist of fate, the class teacher became the little girl's hero, defending her and protecting her from the hurtful words of middle school children.

That little girl was me! I was a victim of an adverse drug event that changed my life forever. I had so many questions but most importantly, I was determined to be an answer. I welcome you into this journey that began in 1984.

## CHAPTER ONE: THE BIG PICTURE (INTRODUCTION)

### **First, Do No Harm** (*Primum Non Nocere*)

The story of the modern patient safety movement will not be complete without reference to the ancient Latin aphorism, “primum non nocere”. Often mistaken to be part of the Hippocratic oath,<sup>1</sup> its context is attributed to the phrase “...And these two things in disease are particularly to be attended to, to do good, and not to do harm...” in the book, *Epidemics*, one of a seven-part book series called the Hippocratic corpus.<sup>2, 3</sup> Some authors have also attributed the phrase to a citation of the works of Thomas Sydenham by the English physician, Thomas Inman in his 1860 book titled, *Foundation For A New Theory And Practice Of Medicine*.<sup>4-6</sup> Subsequent mentions by an American surgeon, Lewis Stimson<sup>7, 8</sup> suggest the popularity of the modern maxim “First, do no harm” in the early 1900s.<sup>6</sup> Irrespective of its true origin, the statement underscores the role of healthcare providers during any patient encounter. At a minimum, every patient should leave the healthcare system the same way they came in, if not better, definitely not worse. In other words, “first, do no net harm”.<sup>5</sup> Therein lies the crux of the patient safety movement; the “freedom from accidental injury due to medical care or medical errors”.<sup>9</sup> It is the generally accepted belief that most health professionals do not harbor intentions to cause harm or injury to their patients, which begs the question: why do adverse events<sup>1</sup> occur in healthcare?

### **James Reason, The ‘Swiss Cheese’ Model And Errors In Healthcare**

Errors are defined as “an unintended act (either of omission or commission) or one that does not achieve its intended outcome”.<sup>10</sup> The majority of errors that occur in healthcare do not lead to adverse events.<sup>10</sup> James Reason, using the Swiss cheese model of system accidents, explained that adverse events only occur when a series of holes in the defensive layers of a healthcare system (latent conditions) like slices of cheese, align themselves momentarily with active failures at the point of service delivery.<sup>11</sup> Active failures are usually human errors made by those in direct contact with patients and can be in the form of slips, lapses, fumbles, mistakes or procedural violations.<sup>11, 12</sup> Latent conditions oftentimes lay dormant in the

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<sup>1</sup> Adverse events are defined as unintended harm to a patient caused by healthcare management rather than the patient’s underlying disease process and requires additional monitoring, treatment or hospitalization, or may result in death.

system for years and until there is a breakdown in a series of defense layers (Policies/procedural, Professional, Team, Individual, Environmental, Equipment),<sup>13</sup> may not lead to the occurrence of adverse events. These latent conditions include: an error-inducing work environment such as, time pressure, understaffing, inadequate equipment, fatigue, and inexperience or enduring systemic weaknesses like, untrustworthy alarms and indicators, unworkable procedures, design and construction deficiencies.<sup>11</sup>

Traditionally, medicine has sought to name, blame and shame the individual(s) involved in adverse events at the point of service delivery due to the belief that the primary cause was negligence, incompetence, or malicious intent.<sup>10, 11</sup> They often did not seek to identify the underlying causes (latent conditions) that made it possible for such errors to lead to injuries in the first place.<sup>10, 11</sup> This was due in part to the high moral and ethical standards that are expected of healthcare professionals and the concept of infallibility.<sup>10, 14</sup> Indeed, most physicians strove for error-free practices and the culture was to cover-up mistakes for fear of litigation or punishment.<sup>10, 14</sup> However, the Swiss cheese model and systems approach to errors altered this traditional thinking<sup>10-12</sup> and reinforced the theory that “every system is perfectly designed to get the results it gets”.<sup>15</sup> Therefore, if adverse events were to be prevented, we needed to look beyond the individual, and into systemic changes.<sup>11</sup>

Expanding on the systems theory, Van der Schaaf et al went further to develop the Prevention and Recovery Information System for Monitoring and Analysis (PRISMA-Medical)<sup>16, 17</sup> This was an adaptation of an existing near miss management system that had been used by the steel and chemical industry for use in healthcare. It comprised mainly of three components: a) The Causal Tree Incident Description Method; b) The Eindhoven Classification Model (ECM) Of System Failure; and c) The Classification Matrix.<sup>16</sup> They demonstrated through this incident analysis tool that active conditions and latent failures can be successfully identified, collated and classified in a meaningful manner which can potentially help managers to develop effective strategies for preventing these incidents.<sup>17</sup> Some suggested strategies include: redesigning hardware, software or device interfaces (technology/ equipment); completing or improving formal and informal procedures (procedures); completing or improving available sources of information and communication

structures (information and communication); improving training programmes (training); increasing the level of voluntary obedience to generally accepted rules by applying positive behavior modification (motivation); handling the problems at a higher organizational level (escalation); and evaluating the safety culture (reflection).

In his paper on Errors in Medicine, Lucian Leape also recommended the following strategies: reduced reliance on memory, improved information access, error proofing, standardization, and training.<sup>10</sup> In a nutshell, healthcare professionals need a fair and just culture that promotes transparency but maintains accountability.<sup>10, 18, 19</sup> We need to efficiently a) identify active and latent conditions in the system through reporting, and b) learn from near-misses or adverse events when they occur, for example, through root cause analyses and investigations. The ultimate goal is to be proactive (preempt conditions that lead to adverse events) rather than reactive (respond to adverse events after they have occurred).<sup>10</sup> Eventually, healthcare systems will need to embrace the concept of high reliability organizations and learn from other industries like the military, aviation, nuclear power and electrical engineering,<sup>11, 20, 21</sup> in order to overcome the high rates of harm<sup>9</sup> that happen to patients.<sup>22-24</sup>

### **The Harvard Medical Practice Study (HMPS) And Other Landmark Reports**

Although studies of adverse events date back to the 1850s, when a Hungarian physician, Ignaz Semmelweiss, linked infection transmission to poor hand hygiene,<sup>25</sup> perhaps the first insight into the alarming rates of adverse events in the modern patient safety era originated from the Harvard Medical Practice Study (HMPS).<sup>26-30</sup> Using a model based on the California Medical Insurance Feasibility Study,<sup>31</sup> the HMPS examined a random sample of over 31,000 medical records of discharged patients from New York hospitals in 1984.<sup>30</sup> The authors estimated that 3.7% of hospitalized patients had experienced an adverse event and 27.6% of them were due to negligence.<sup>27</sup> Diagnostic errors were mostly due to negligence (75%).<sup>28</sup> These adverse events led to death in 13.6% of cases and caused permanent harm in 2.6%.<sup>27</sup> Adverse drug events accounted for 19% of all adverse events and were the most common type, followed by wound infections (14%).<sup>28</sup> This study sparked a worldwide inquiry into the incidence of adverse events<sup>32</sup> and together with another study from Utah-Colorado

hospitals,<sup>33</sup> informed the population estimates given in the landmark report by the Committee on Quality of Healthcare in America, Institute of Medicine (IOM), titled *To Err is Human: Building a Safer Health System*<sup>9</sup>. The report revealed that 44,000 to 98,000 deaths occurred annually in the United States as a result of medical errors.<sup>9</sup> These errors were costing an estimated \$17 to \$29 billion annually.<sup>9</sup>

Globally, an avalanche of studies was launched using a similar methodology to the HMPS after the publication of the IOM report.<sup>32, 34</sup> In the Netherlands, the adverse event estimate for acute care hospitals was 5.7%.<sup>35</sup> Other countries in which these studies were conducted include Canada (7.5%),<sup>36</sup> Spain (8.4%),<sup>37</sup> Denmark (9%),<sup>38</sup> United Kingdom (UK, 10.8%),<sup>39</sup> Portugal (11.1%),<sup>40</sup> Sweden (12.3%),<sup>41</sup> New Zealand (12.9%),<sup>42</sup> France (14.5%), Australia (16.6%)<sup>43, 44</sup> and one study with a combined estimate from eight developing countries (8.2%).<sup>45</sup> Other US studies were conducted in later years<sup>46, 47</sup> and a more recent study using a different methodology (global trigger tools<sup>2</sup>) put the US estimate at 33.2%.<sup>48</sup> This high rate was explained by the increased sensitivity of the trigger tools for identifying patient records with a high likelihood of containing an AE. Similarly, specialized and discipline-specific studies were conducted to establish the incidences of adverse events in pediatrics,<sup>49-52</sup> surgery,<sup>53-56</sup> intensive care units (ICUs),<sup>57, 58</sup> emergency departments,<sup>59</sup> home care,<sup>60</sup> ambulatory or primary care,<sup>61-63</sup> dermatology,<sup>64</sup> adverse drug events,<sup>65-70</sup> and elderly patients.<sup>71, 72</sup>

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<sup>2</sup> A trigger is defined as an easily identifiable, focused item in a patient record representing an opportunity that may lead to an adverse event. The global trigger tool methodology uses 'triggers' or clues to identify medical records with a high likelihood of containing an adverse event.



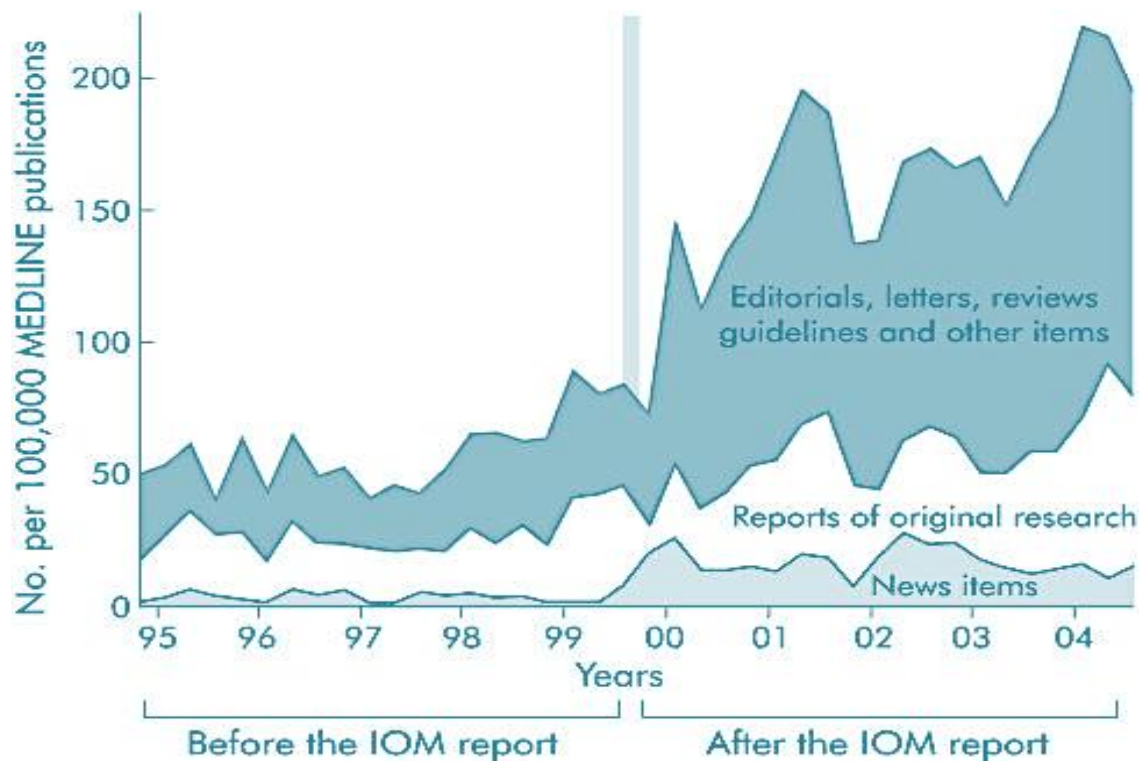


Figure 1.1: Patient safety publications before and after publication of the IOM report “*To Err is Human*”.<sup>34</sup>

The IOM report recommended four goals in order to achieve a better safety record: a) Establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety; b) Identify and learn from errors by developing a nationwide public mandatory reporting system and encourage health care organizations and practitioners to develop and participate in voluntary reporting systems; c) Raise performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of health care; d) Implement safety systems in health care organizations to ensure safe practices at the delivery level.<sup>9</sup> This led to a series of congressional hearings and the disbursements of large-scale funding to governmental agencies, such as the Agency for Healthcare Quality and Research (AHRQ), to conduct widespread research, develop evidence-based tools/approaches, and make policy recommendations to reduce medical errors and the occurrence of adverse events in the US.<sup>26</sup> Subsequent efforts led to the development of the national patient safety goals (NPSG) by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).<sup>26</sup>

Around the same time (1999), the UK Department of Health released its landmark report titled, *An Organization With A Memory*,<sup>73, 74</sup> which highlighted the weaknesses in the National Health Service (NHS) and its handling of adverse events. The report made the following ten recommendations:

- a) Introduce a mandatory reporting scheme for adverse health care events and specified near misses;
- b) Introduce a scheme for confidential reporting by staff of adverse events and near misses;
- c) Encourage a reporting and questioning culture in the NHS;
- d) Introduce a single overall system for analyzing and disseminating lessons from adverse health care events and near misses;
- e) Make better use of existing sources of information on adverse events;
- f) Improve the quality and relevance of NHS adverse event investigations and inquiries;
- g) Undertake a program of basic research into adverse health care events in the NHS;
- h) Make full use of new NHS information systems to help staff access learning from adverse health care events and near-misses;
- i) Act to ensure that important lessons are implemented quickly and consistently;
- j) Identify and address specific categories of serious recurring adverse health care events.<sup>74</sup>

This led to the establishment of the National Patient Safety Agency (NPSA), which oversaw the establishment of the National Reporting and Learning Systems (NRLS), a central national database of patient safety incident reports.

### **The Global Patient Safety Movement**

As more countries raced to join the global patient safety movement, it appeared that the developing countries of the world were lagging behind.<sup>75</sup> The World Health Organization (WHO), in order to galvanize the global patient safety efforts, endorsed a resolution at the fifty-fifth world health assembly (WHA55.18), urging all member states to “pay the closest possible attention to patient safety”.<sup>76</sup> In 2004, following this resolution, the World Alliance for Patient Safety (now called the WHO Patient Safety Program) was formed.<sup>77</sup> Its core mission was to “coordinate, facilitate and accelerate patient safety improvements around the world” by: 1) leading and advocating for change; 2) generating and sharing knowledge and

expertise; and 3) supporting member states in their implementation of patient safety actions.<sup>78</sup> Subsequently, regional offices<sup>3</sup> endorsed resolutions outlining their strategies for improving patient safety in their region.<sup>79</sup>

Six overarching priority areas were identified for the global patient safety movement. They included: 1) Global Patient Safety Challenge; 2) Patients for Patient Safety; 3) Taxonomy for Patient Safety; 4) Research for Patient Safety; 5) Solutions for Patient Safety; and 6) Reporting and Learning.<sup>77</sup> Several global campaigns were also launched to address these priority areas, such as *“Clean Care Is Safer Care”*, *“Safe Surgery Saves Lives”*, *“My Five Moments For Hand Hygiene”*, *“High 5s”*, and *“Safer Primary Care”*.<sup>78, 80</sup> Resources and tools developed through these efforts include: Patient Safety Checklists e.g. surgical, childbirth, trauma, H1N1; Guidelines for Adverse Event Reporting and Learning Systems;<sup>81</sup> International Classification for Patient Safety (ICPS);<sup>82-84</sup> Minimal Information Model for Patient Safety; Training Guides and Workshop Materials e.g. Multi-professional Patient Safety Curriculum Guide, Learning From Errors.

In 2009, an international expert working group published priority research areas ranked according to the stages of economic development.<sup>85</sup> The goal was to provide a starting point for countries as researchers sought to find solutions to their patient safety problems.<sup>85</sup> Fifty topics relating to patient safety were identified and reviewed through a three-stage modified Delphi process.<sup>85</sup> Rankings were assigned for developing, transitional and developed countries using the following criteria: frequency; magnitude and distribution within the population; effect on the efficiency of the health system; availability, feasibility, and sustainability of solutions; and urgency or political backing required to tackle the problem.<sup>85</sup>

The top six research priority areas (table 1.1) for developing countries were: Identification, development, and testing of locally effective and affordable solutions; Cost effectiveness of risk reducing strategies; Counterfeit and substandard drugs; Inadequate competences, training, and skills; Maternal and newborn; and Healthcare associated infections.<sup>85</sup>

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<sup>3</sup> WHO regional offices for Africa (AFRO), the Americas (PAHO), South-East Asia (SEARO), Europe (EURO), the Eastern Mediterranean (EMRO), and the Western Pacific (WPRO).

Transitional countries had similar research priorities to developing countries but differed in the following four areas out of the top ten priorities: Lack of communication and coordination, Poor safety culture, Latent organizational failures, and Developing better patient safety indicators.<sup>85</sup> The top six priorities for developed countries differed significantly from those assigned to the developing nations; Lack of communication and coordination, as well as latent organizational failures ranked highest on their research priority list.<sup>85</sup>

Table 1.1: Top six ranked global priority research areas.

	<b>Developing Countries</b>	<b>Countries with Economies in Transition</b>	<b>Developed Countries</b>
<b>1.</b>	Counterfeit & substandard drugs	Inadequate competence & training skills	Lack of communication & coordination (including coordination across organizations, discontinuity & handovers)
<b>2.</b>	Inadequate competence training & skills	Lack of appropriate knowledge & transfer	Latent organizational failures
<b>3.</b>	Maternal & newborn care	Lack of communication & coordination (including coordination across organizations, discontinuity & handovers)	Poor safety culture & blame-oriented processes
<b>4.</b>	Health care-associated infections	Health care-associated infections	Inadequate safety indicators
<b>5.</b>	Unsafe injection practices	Maternal & newborn care	Adverse drug events due to drugs & medication errors
<b>6.</b>	Unsafe blood practices	Adverse drug events due to drugs & medication errors	Care of the frail & elderly

Available at: [http://apps.who.int/iris/bitstream/10665/44205/1/9789241598620\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44205/1/9789241598620_eng.pdf)

Global partnerships to implement change in the identified priority areas are being developed. The Global Catalyst Group for Institutional Health Partnerships is one of such partnerships and comprises five organizations including: American College of Healthcare Executives; International Hospital Federation; The European Esther Alliance; Tropical

Health and European Trust (THET) and the African Partnership for Patient Safety (APPS).<sup>78</sup> The APPS, headed by Dr. Shams Syed, has led the charge for intercontinental learning and resource sharing by forging within and between country hospital-to-hospital partnerships between African countries and European or US hospitals.<sup>78</sup> The APPS has also developed a situational analysis and evaluation framework, to provide a roadmap for patient safety teams across hospitals in the region. Through its work, ministries of health for various African countries, South Africa inclusive,<sup>86</sup> have begun expressing an interest in developing national patient safety policies.<sup>78, 87</sup>

### **Dentistry and Patient Safety**

Despite the many international efforts that followed the dawn of the modern patient safety era, it took almost a decade for the dental profession to start systematically asking questions about patient safety in dentistry.<sup>88</sup> Several opinion pieces sounded calls to action and offered a roadmap for dental researchers to begin exploring this relatively nascent field of inquiry.<sup>13, 88-93</sup> Although this field is still in its infancy, researchers in various countries sought to answer this call. There have been studies conducted on various aspects of dental patient safety including: voluntary provider reporting;<sup>94, 95</sup> retrospective record reviews – random<sup>96, 97</sup> and using dental trigger tools;<sup>98</sup> centralized database analyses – using reports from consumers,<sup>99-101</sup> dental providers<sup>102</sup> and malpractice complaints;<sup>103</sup> dental checklists;<sup>104-109</sup> and safety culture among dental professionals.<sup>110-112</sup> The findings from these studies are just as varied as their methodologies, and there are yet to be nationally representative estimates for the incidence of adverse events in dentistry (DAEs). Notwithstanding, they have provided useful insights into the nature and types of adverse events that occur in dentistry. At a minimum, they confirm that adverse events do in fact occur at the dental office and these events are neither restricted to certain geographic locations nor specialty type.

Patient visits in general dentistry bear some similarity to most primary care or ambulatory care visits in that they are often multiple and intermittent, i.e., no prolonged hospital stays. It is therefore logical to expect that adverse events that occur in these settings (for example diagnosis-related harm or poor test result follow-up)<sup>68, 113-115</sup> will carry over into the general dental setting. While this is true, dentistry differs from primary care in that, most of the

procedures performed at the dental office are surgical in nature and often invasive.<sup>90</sup> Dentists often deal with complications of surgical procedures, routinely perform highly technical procedures in complex environments, work in teams, use a multitude of devices and tools, and do not prescribe as many medications as their medical counterparts in primary care.<sup>13, 110</sup> In addition, due to the short length of dental visits, most adverse events that originate from a dental office might not be picked up until after several hours or days. This implies that patients oftentimes present at the emergency room, the physician's office or another dentist's office, making it nearly impossible to capture these events.<sup>90</sup> These differences underscore the need to develop tools for dental patient safety research. Adapting the Swiss cheese model of accident causation, Bailey et al illustrate how adverse events can occur at the dental office (Figure 1.2).<sup>13</sup>

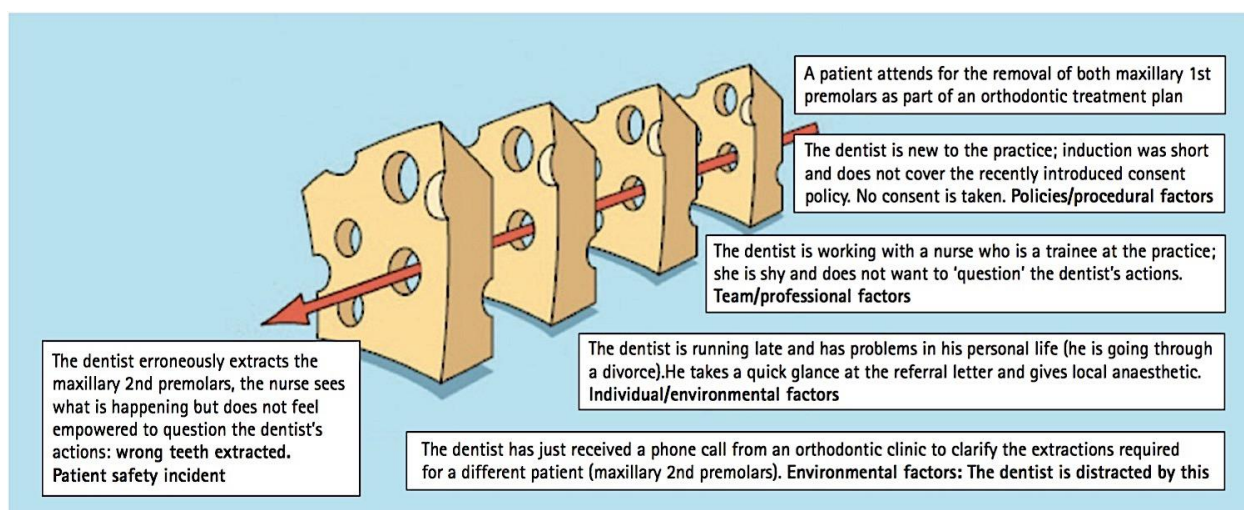


Figure 1.2: Hypothetical Illustration of a patient safety incident occurring in a dental practice<sup>13</sup>

In order to develop a patient safety initiative for dentistry, the first step is to identify the threats to patient safety.<sup>88, 116</sup> This involves a scalable and sustainable strategy for detecting dental errors and the causes of adverse events<sup>91</sup> that will foster learning and prevent a recurrence of these events. Indeed, it would be a slow, painful process if dentists were to learn from their own mistakes alone, and it would come at great costs to their patients.<sup>13</sup> One way to circumvent this outcome is to develop a centralized dental adverse event reporting system where providers and/or staff can submit their experiences of near misses and

adverse events soon after they occur.<sup>81</sup> The UK (NRLS) and Finland (Haipro) have such systems, however, studies have shown an underutilization by dentists and a general lack of awareness of its existence or importance.<sup>94, 102</sup> Ideally, a mandatory reporting system would exist, however, a voluntary reporting system that provides prompt feedback with detailed results of a root cause analysis can be effective. A relatively recent approach that has been adopted by our medical colleagues is patient incident reporting.<sup>117-122</sup> One reason for this recent focus on patients is the increasing awareness of the need to deliver patient-centered care and for the active involvement of patients in their care.<sup>123, 124</sup> The recognition that the patient is the ultimate consumer of healthcare and is present throughout the continuum of care also adds value to the argument. It is one way to identify threats to the safety of the dental care delivery system. At a minimum, it helps to uncover areas that are in need of further investigation. If this is to become a viable method for detecting adverse events, standardized instruments need to be developed, in order to capture information that is both useful and reliable.

In the absence of a centralized adverse event database, another useful but somewhat unexplored way to understand the nature of dental adverse events is through case reporting. Given the predominant solo-practitioner<sup>4</sup> nature of most dental practices in the US (69.6%)<sup>125</sup>, the advent of a case-report journal for reporting dental adverse events will be beneficial. This will give providers author credit (published manuscripts) for the effort required to submit the report and fosters a learning system, where providers feel safe to discuss shortcomings in practice in a non-litigious manner. It will also offer a standardized platform where relevant information can be synthesized from these experiences; for example, the use of a standardized reporting template will ensure that providers do not leave out relevant information. Table 1.2 below suggests how the existing case report guidelines (CARE)<sup>126</sup> can be expanded to provide additional information regarding safety.




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<sup>4</sup> A dentist who works in a dental practice with no other dentists and who owns the practice. Solo dentists are one type of owner dentist along with nonsolo owner dentists.

Table 1.2: Proposed Modification To CARE Guidelines

CARE Checklist <sup>126</sup>	Proposed Addition(s) for Patient Safety Case Report Journal
Introduction	Origin of AE (e.g. errors, proximal cause)
Patient Information	Provider Information (skill level, years of experience, specialty); Clinic Information (where AE originated, type of practice, size)
Clinical Findings	Mechanism of occurrence (how AE occurred); Type of harm
Timeline	Chronological sequence of events (phase of patient care when AE originated and was detected)
Diagnostic Assessment	Root cause Analysis; Contributing factors
Therapeutic Interventions	Ameliorating Actions; Recovery Actions
Follow up and Outcomes	Severity of harm (temporary or permanent; mild, moderate or severe; ED visit; death)
Discussion	Organizational steps to reduce recurrence
Patient Perspective	Lessons learned; patient interview

After careful consideration of the existing body of work conducted by dental researchers across the globe, and the identified gaps (limitations in scope, perspective and geographic locations) in the literature, I decided to conduct the following research studies as part of my doctoral thesis. The following manuscripts are presented in subsequent chapters.

-  Chapter Three: Lessons Learned from Dental Patient Safety Case Reports
-  Chapter Four: Patient-Reported Dental Safety Events: A South African Perspective
-  Chapter Five: Perceptions of Quality and Safety Among South African Dental Patients



## CHAPTER TWO: OBJECTIVES AND SPECIFIC AIMS

The overarching goal of this thesis was to explore the nature and occurrence of quality and safety events in dentistry using a two-pronged approach – biomedical literature and patient-reported experiences. The rationale was that patients and published case reports were untapped reservoirs of valuable information regarding the types, nature and severity of quality and safety events in dentistry as well as their associated risk factors. We proposed two exploratory studies to evaluate this hypothesis: the first was a detailed retrospective review of published case reports on dental patient safety events; the second was a cross-sectional study of patients at a large dental teaching practice in South Africa regarding their quality and safety experiences.

Our primary objectives were to address some gaps identified in the literature by:

- 1) Bringing in the patient's perspective
- 2) Expanding the scope of studies to include all possible dental quality and safety events
- 3) Evaluating their occurrence in resource-poor settings such as sub-saharan Africa where no previous study had been done

The specific aims that were addressed through these studies include:

- 1) Demonstrate that quality and safety events occur at dental offices
- 2) Assess the types and severity of quality and safety events that occur at the dental office
- 3) Measure the prevalence of patient-reported quality and safety events at the dental office
- 4) Evaluate the factors (patient characteristics) associated with experiencing a quality or safety event at the dental office
- 5) Describe the events following the experience of a quality or safety event at the dental office

**CHAPTER THREE: LESSONS LEARNED FROM DENTAL PATIENT SAFETY CASE  
REPORTS<sup>127</sup>**

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## **ABSTRACT**

**Background:** Errors are commonplace in health care, including dentistry. It is imperative for dental professionals to intercept errors before they lead to an adverse event and to mitigate their effects when an adverse event occurs. This requires a systematic approach at both the profession level, encapsulated in the Agency for Healthcare Research and Quality's patient safety initiative framework, as well as at the practice level, in which crew resource management is a tested paradigm. Supporting patient safety at both the profession and dental practice levels relies on understanding the types and causes of errors, which have not been well studied.

**Methods:** The authors performed a retrospective review of dental adverse events reported in the literature. Electronic bibliographic databases were searched, and data were extracted on background characteristics, incident description, case characteristics, clinic setting where adverse event originated, phase of patient care that adverse event was detected, proximal cause, type of patient harm, degree of harm, and recovery actions.

**Results:** The authors identified 182 publications (containing 270 cases) through their search. Delayed treatment, unnecessary treatment, or disease progression after misdiagnosis was the largest type of harm reported. Of the reviewed cases, 24.4% of those patients involved in an adverse event experienced permanent harm. One of every 10 case reports reviewed (11.1%) reported that the adverse event resulted in the death of the affected patient.

**Conclusions:** Published case reports provide a window into understanding the nature and extent of dental adverse events; however, the overall dearth of publications on adverse events in the dental literature points to the need for more study.

**Practical Implications:** Siloed and incomplete contributions to dentistry's understanding of adverse events in the dental office are threats to dental patients' safety. Publishing more, and more comprehensive, case reports on adverse events is recommended for dental practitioners.

**Key Words:** Dental care; patient safety; adverse events; case reports.

## INTRODUCTION

Patient safety is fundamental to the delivery of high-quality dental care<sup>1,2</sup> and is 1 of the 6 aims for health care organizations described by the Institute of Medicine in its 2001 report, “Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century.”<sup>3</sup> Dental practitioners and dental institutions alike are committed to care that is safe, timely, efficient, effective, equitable, and patient centered, in keeping with these aims.<sup>4</sup> At the same time, error is fundamental in health care, as our medical counterparts demonstrated more than 2 decades ago,<sup>5-8</sup> and errors (lapses, slips, mistakes<sup>8,9</sup>) are commonplace in dentistry.<sup>10-12</sup>

Several theories have been formulated to explain the mechanism of errors and how unchecked, latent systemic factors, threats, or failures (for example, provider fatigue or inexperience, understaffing, poor supervision, faulty equipment, teamwork, vague organizational policies or procedures, and poor safety culture) can lead to the occurrence of an adverse event (unintended harm or injury to a patient due to medical or dental management rather than his or her underlying condition<sup>7,9</sup>).<sup>13,14</sup> Some of these theories include the Swiss Cheese Model by James Reason<sup>13</sup> and the University of Texas Threat and Error Management Model by Robert Helmreich.<sup>14</sup> It is our imperative as dental professionals to intercept errors and identify the latent systemic factors in our dental practices before they lead to the occurrence of adverse events or mitigate their effects after an adverse event occurs.<sup>2</sup>

The dental profession can learn from the successes of other industries including aviation, oil and gas, nuclear power plants, and the military, which have developed sophisticated safety systems for minimizing errors and accidents.<sup>13,15</sup> Crucial to the success of safety systems is the emphasis on regular, good quality, safety data collection, and its prompt analysis and dissemination, which fosters learning for all of those connected with the dental practice.<sup>14</sup> Non-punitive incident reporting systems, such as the Aviation Safety Action Program,<sup>16</sup> which detailed incident analysis and accident investigations, and routine reviews of de-identified aggregated flight data, such as the Flight Operational Quality Assurance,<sup>17</sup> are some examples of safety systems that enable the understanding of the nature and extent of errors, contributing conditions, and inform the development of countermeasures necessary

for improving aviation safety.<sup>14</sup> Countermeasures targeting human factors and human effectiveness through crew resource management (CRM) training have led to improved safety behaviors and attitudes among aviation workers.<sup>18</sup> Our medical colleagues have pioneered efforts to translate these lessons into health care by establishing voluntary reporting systems<sup>19</sup> (for example, US Food and Drug Administration adverse event reporting system,<sup>20</sup> US Pharmacopeia MEDMARX, The Joint Commission's sentinel event reporting system and national nosocomial reporting system) and adopting crew resource management training<sup>18</sup> (for example, anesthesia crisis resource management in operating rooms, MedTeams in emergency medicine, and NeoSim in pediatrics).<sup>18</sup> Although these safety programs and systems are siloed, they are steps in the right direction and dentistry will benefit from adapting some of these systems<sup>21,22</sup> as the profession moves toward developing a comprehensive patient safety initiative.<sup>23</sup>

With the exception of a few pioneer efforts,<sup>12,21,23,24</sup> the dental profession has essentially watched from the sidelines as medicine moved toward developing patient safety initiatives. The time has now come for dentistry to commit to patient safety by systematically addressing adverse events and errors in dentistry.<sup>23</sup> As a first step of a dental patient safety initiative, we need to “ identify the threats to dental patient safety by identifying errors and causes of patient injury associated with the delivery of dental care.”<sup>23,25</sup>

In the absence of a broad-based resource to capture errors, adverse events, and their causes, we turned to the biomedical literature, an existing source of information regarding these events, which resulted in the creation of a database of events from multiple specialties across various clinical settings worldwide. Our primary objective was to characterize the types of patient safety events reported in the literature and raise awareness about identifying and tracking errors and their causes.

## **METHODS**

We conducted a retrospective review of published case reports and case series on dental patient safety from 1970 through June 2013. This study did not involve any direct interaction with human patients.

**Search methods:** We searched electronic bibliographic databases (PubMed, Embase, Web of Science, and CINAHL) using the following key words: patient safety, medical errors, adverse effects, dental care, dental procedures, dental treatment, and facility. The final search date was June 30, 2013. The search yielded 4,837 publications. After the removal of duplicates, 4,729 unique articles were identified for screening.

**Review process:** A preliminary screening of the titles of these 4,729 articles resulted in the exclusion of 2,449 articles that were not relevant to our objective. An example of an article that was captured by our search but not relevant was “Penetrability of Dentinal Tubules in Adhesive-lined Cavity Walls.”<sup>26</sup>

Further exclusion of articles after abstract reviews was based on the following criteria: non-English-language publications (n=124); non-dental focus (n=567); quality improvement focus without adverse events (n=663); adverse events due to patients’ underlying condition (n=29); guidelines, editorials, systematic reviews, clinical trials, observational studies, opinion pieces on dental adverse events and related patient safety issues (n=664). The final phase of the review process involved assessing the full text of the remaining 233 articles, resulting in the exclusion of 51 studies (2 non-English, 29 non-case reports, and 18 case reports without adverse events). Thus, 182 publications comprised the final selection for inclusion in the final synthesis (Figure 3.1).

**Data extraction:** Two independent reviewers (E.M.O., Sawsan Salih) extracted data from these case reports and case series using an adverse event data collection form developed by the authors. Background characteristics were collected on authors, as well as the publication year, country, citation, and, if available, the accession number (PubMed ID).

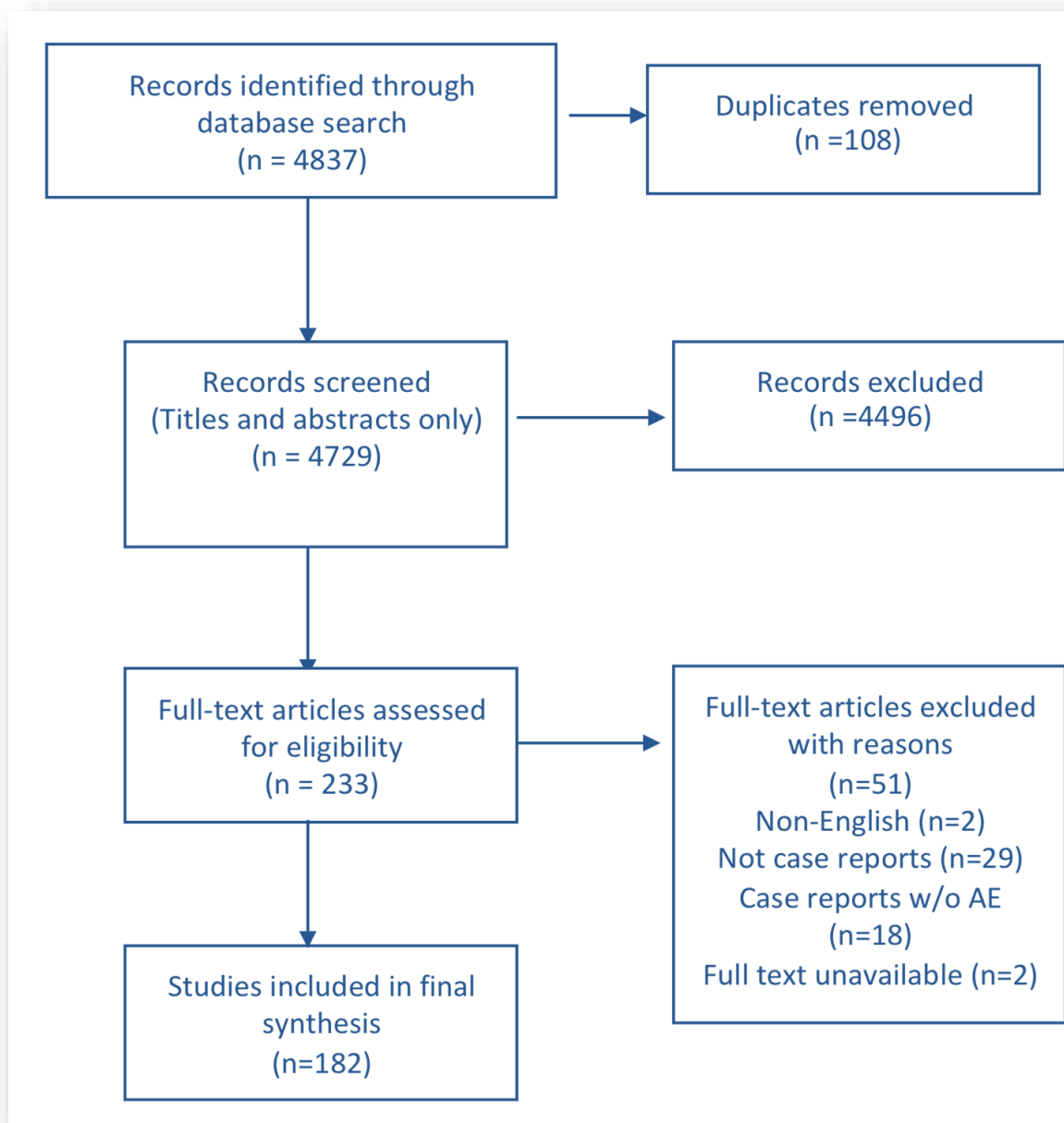


Figure 3.1: Dental AE Case Report Literature Review Process; AE: Adverse Event

Each case was further characterized as follows: incident description, case characteristics (age, sex), clinic setting where adverse event originated, phase of patient care during which the adverse event was detected, proximal cause, type of patient harm, degree of harm, and recovery actions. Through an iterative process among the authors (E.M.O., R.B.R., E.K.), preliminary classification categories (Appendix 3.1; available online at the end of this article)

were created for the types of patient harm. We used a consensus process to assign each case to its associated harm category. The degree of harm was assessed using a newly developed Dental Adverse Event Severity Scale (Appendix 3.2; available online at the end of this article), which is a modification of the Institute for Healthcare Improvement' s severity scale.<sup>27</sup> Further publications on the development process for this tool are forthcoming.

**Data analysis:** Data were transferred to a spreadsheet using Microsoft Excel and analyzed. Descriptive statistics were obtained for each main category. The results are shown in the next section.

## RESULTS

Two hundred seventy cases from 182 published dental adverse event case reports were reviewed for this study. Background characteristics from these dental patient safety case reports are shown in Table 3.1.

**Background characteristics:** There was a surge in the volume of publications between 1991 and 2000—37.9% contrasted to 7.1% in the preceding decade. According to the World Health Organization regional classification of countries,<sup>28</sup> 44% of the publications were from authors based in the region of the Americas (North and Latin America). The European region followed closely in frequency of publications with 37.4%. Over 50% of the patients in the reviewed cases were aged 25 to 64 years. Slightly more of the adverse events were reported to have occurred in men (52.2%) compared with women (47.4%). Approximately 2 of every 3 (64.4%) adverse events reported were detected after the patient had concluded the dental encounter or left the dental facility. Although 25.2% of the authors did not specify the clinical setting where the error occurred, 40% of the adverse events originated at a dental office compared with 34.8% in hospitals or university-based dental clinics. None of these percentages were standardized to any population size or number of available dentists and dental offices in the population because the aim of this review was not to establish a prevalence of dental adverse events.

**Degree of harm:** Using our newly developed Dental Adverse Event Severity Scale, the patients in the case reports were grouped according to the degree of harm that the patient experienced associated with the adverse event (Table 3.2). Inter-rater reliability with



respect to this newly developed scale was high between the 2 reviewers with a Cohen  $k$  of 0.85. Table 3.2 shows 24.1% of the adverse events required that the patient be either transferred to an emergency department (ED) for further evaluation or hospitalization, or else had their hospital stay prolonged if they were already hospitalized (Category F). A similar number of patients in the case reports reviewed were reported to have experienced permanent harm (24.4%; Category G1-G4) and in 1 of every 10 case reports, the event resulted in the death of the affected patient (11.1%; Category I).

**Type of harm:** Using the type of harm as categories, we created a list of dental adverse events (Appendix 3.1; available online at the end of this article); the largest category was “delayed appropriate treatment, disease progression, unnecessary treatment associated with misdiagnosis, or any combination,” comprising almost one-quarter of all reported cases (23%). Systemic complications involving the cardiovascular, respiratory, neurologic/cerebral, renal, and other body systems—including adverse reactions to dental devices, materials, or procedures — were the second largest harm category commonly reported (21.1%)(Table 3.3). Of the reported AEs, 23.1% were anesthesia-related, with general anesthesia accounting for 47.6% of these cases and local anesthesia accounting for 40.5% (data not shown). Only a few reports were related to nitrous oxide and intravenous sedation (11.9%) (data not shown). Patients often required some form of intervention or a combination of several interventions to wholly or partially recover from an adverse event including intraoral and extra-oral radiographs, advanced imaging (computed tomography, magnetic resonance imaging, endoscopy, bronchoscopy), laboratory investigations, medication, retreatment, changes to treatment plans, multiple dental visits, surgery, ED visits, or prolonged hospital admissions.

## **DISCUSSION**

Our results reinforce that there is a level of risk associated with everyday dental practice. Dental adverse events are a global phenomenon, making it imperative that dental professionals worldwide acknowledge this reality to galvanize efforts to minimize patient harm. Based on the fact that most adverse events go unreported,<sup>29</sup> and even fewer are published in peer-reviewed journals, we suspect that many more opportunities will exist for

learning about dental adverse events as more data sources become available. Our primary objective in this report was to characterize dental adverse events from the biomedical literature using case reports. This article represents a call to action for the dental profession on patient safety. Our findings suggest that:

- Dentistry needs a standardized way of communicating about errors and adverse events;
- Dental professionals need a venue in which they can efficiently report adverse events and near misses across a range of severities;
- Dental patient safety event case reports should be accompanied by a root cause analysis.

A dental patient safety classification system or taxonomy will enable us to communicate about errors and dental adverse events in a standardized manner. Categorizing the adverse events we identified in the case reports proved challenging due to the absence of an established dental patient safety taxonomy, as well as the tremendous variability in scope and content of the published case reports. Through a consensus process, we assigned each patient's case to a type of harm category (Appendix 3.1, available online at the end of this article). Delayed appropriate treatment, unnecessary treatment, and disease progression associated with misdiagnosis comprised almost one-quarter of all cases reviewed (23%)(Table 3.3). This corresponds with observations in outpatient ambulatory practices in which high rates of diagnostic errors have been detected.<sup>6</sup>

To understand the extent of harm experienced by the patients in the cases reported, we categorized harm based on their degree of severity (Table 3.2) and the required intervention using the Dental Adverse Event Severity Scale (Appendix 3.2, available online at the end of this article), which we developed. Our results illustrate that most patients whose adverse events were published within case reports experienced temporary harm significant enough to require a transfer to the ED or hospitalization (24.1%), intervention required to sustain life (6.7%), or resulted in permanent harm (24.4%) or death (11.1%). Although these aggregate numbers may be an overrepresentation of the true prevalence by virtue of reporting bias inherent to our data source, studies from Finland<sup>10</sup> have estimated the prevalence of permanent harm due to dental adverse events as 13%. These estimates serve as a wake-up call for the profession to begin systematically addressing adverse events in

dentistry. We need to develop safety systems and countermeasures using principles from other industries<sup>21,22</sup> (for example, CRM in aviation) to prevent errors, trap them before they lead to an adverse event, and mitigate their effects when they occur.<sup>14</sup>

The path has been illuminated by safety science in other domains, as described in the introduction:

- Establishing non-punitive incident reporting systems and conducting thorough root cause analyses when adverse events occur to foster better understanding of contributors to dental adverse events;
- Developing checklists,<sup>21,30</sup> protocols, and computerized decision aids to reduce reliance on memory;
- Promoting the use of electronic dental records<sup>31,32</sup> to improve access to patient information or test results;
- Using “forcing functions”— a means of preventing an undesired action— to minimize the probability of making mistakes when such mistakes could cause unintended harm (for example, a system that alerts the dentist when a drug to which the patient is allergic is prescribed, or sensors that monitor the depth of endodontic files during root canal treatments);
- Standardizing operating procedures to minimize variability based on dentists’ training or practice styles;
- Regular safety training for staff using a combination of didactic and simulation techniques which emphasize teamwork and working in emergency situations.<sup>8</sup>

In the absence of a broad-based dental patient safety reporting system, dental professionals can still contribute to the corpus of knowledge on dental patient safety events by writing and submitting manuscripts to peer-reviewed journals.<sup>33</sup> Our results indicated that a good proportion (40%) of the adverse events originated at dental offices, although the reporting authors were typically based in a hospital or university-based dental clinic. Private practitioners, who represent the bulk of dental providers in the United States, need to be actively engaged and incentivized to participate in the process of building this body of evidence. Journal editors are also encouraged to accept and publish more, and more detailed,

case reports on dental patient safety events. It is our recommendation that these reports should, in addition to the standardized reporting guidelines for case reports,<sup>34</sup> contain a root cause analysis and a follow-up to give a sense of the permanency of the harm.<sup>33</sup>

Admittedly, we recognize that the context of some case reports do not lend themselves to such detailed analysis, such as instances in which an event caused at clinic A was identified and reported by clinic B. Under ideal circumstances, clinic B would seek additional information about the factors that contributed to the event, but this may not be practical in all cases. Although it is not reasonable to propose that every lost temporary crown or perforated root should appear as a case report in a scientific or professional journal, a broad-based reporting system is a good forum for tracking the prevalence of these more common events.

To illustrate the potential sensemaking<sup>35</sup> and learning opportunities present in a case report, a causal tree was constructed on the basis of information provided in 1 report for which a root cause analysis was performed (Figure 3.2).<sup>36</sup> Causal trees, also called fault or risk trees, are powerful visual tools for depicting a causal analysis of a patient safety event.<sup>35</sup> They are useful for uncovering the underlying factors, circumstances, and decisions that contributed to the event.

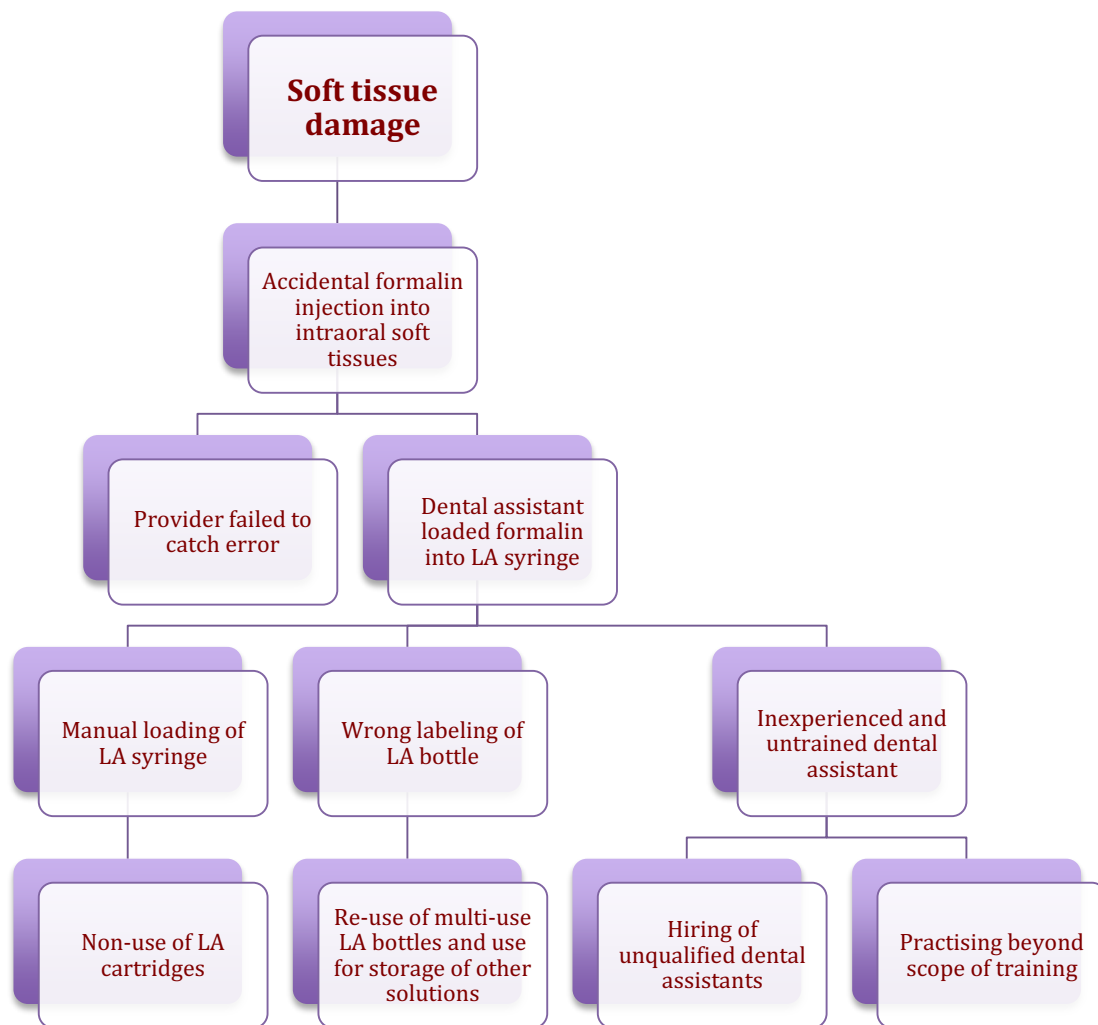


Figure 3.2: Sample causal tree diagram for a dental adverse event case report. From top to bottom, this figure illustrates how the occurrence of an adverse event (soft-tissue injury, top row) can be traced to its root causes (bottom row) by continuously asking why, when performing a root cause analysis. LA: Local anesthetic.

Figure 3.3 illustrates the benefits of examining case reports in the aggregate. This approach allows for the easy identification of common risk factors or latent failures that are critical to understanding dental adverse events and preventing their future reoccurrence.<sup>37</sup>

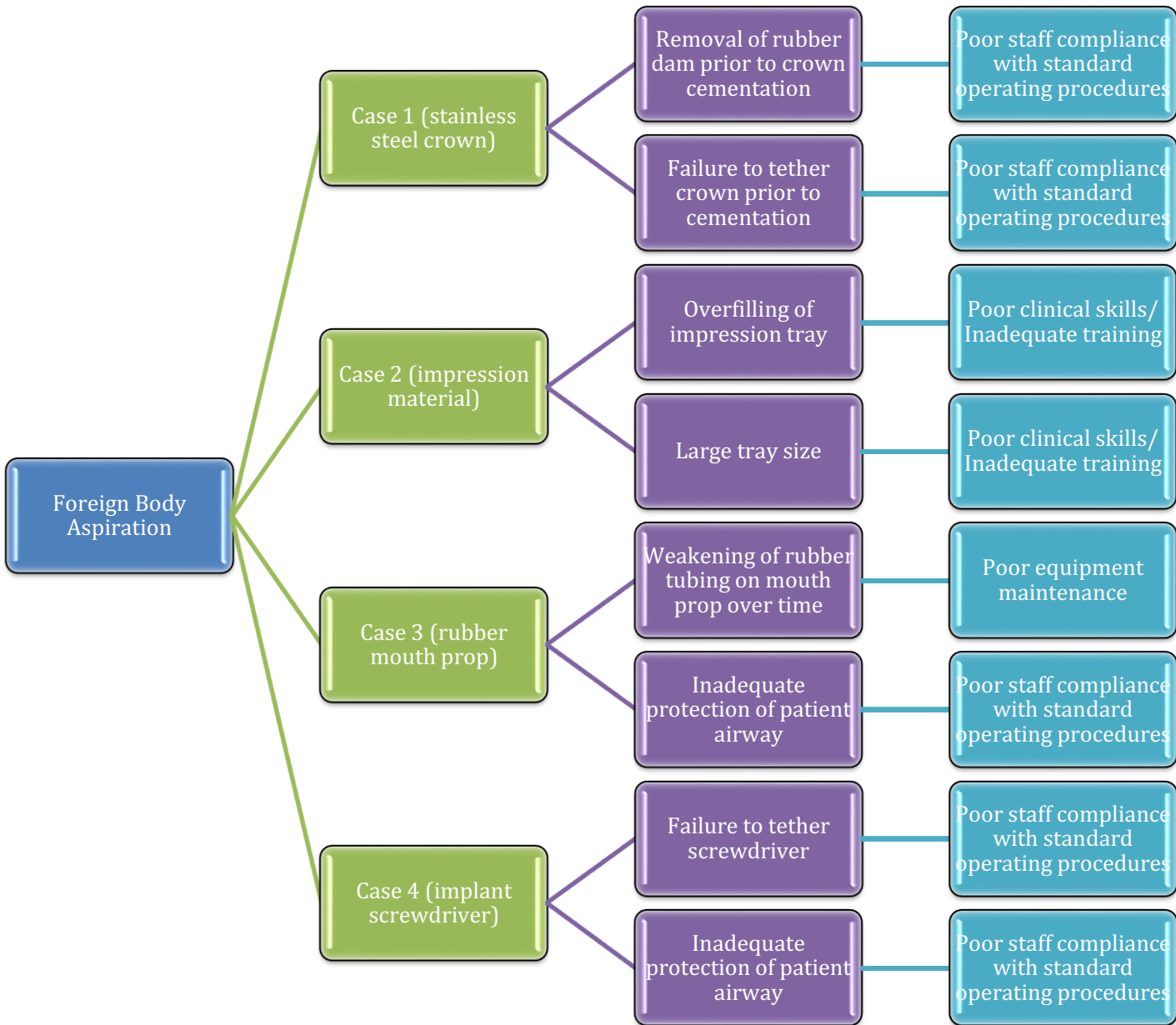


Figure 3.3: Hypothetical illustration of incident analyses from aggregated case reports. This figure shows, from left to right, that recurrent latent failures in a dental care delivery system (column 4) become apparent after the review of aggregated case reports and their specific incidents (column 2). In this case, the adverse event (foreign-body aspiration, column 1) occurred due to active failures (column 3) by frontline providers but can be traced to hidden latent failures in the care delivery system.

Consider another example of a case report that did not provide sufficient information for a root cause analysis:

A 78-year-old black male presented to the oral and maxillofacial clinic at Columbia University. He had been referred on an emergency basis from the adjacent senior dental student clinic when his lower and upper lips suddenly swelled during the performance of complete denture impressions. The impressions were being made using Permlastic, a polysulfide impression material... denied allergies... on exam, the patient appeared not to be in acute distress... displayed significant lower lip edema with moderate upper lip edema...patient was given Benadryl 50 mg intramuscularly and accompanied to the emergency room for observation. Patient was discharged after five hours of observation with significantly decreased labial edema.<sup>38</sup>

There was no documentation of any follow-up with the patient after this encounter; information about whether a patch test was done to confirm the implied cause of the edema and information about the continued clinical course of the patient would have added value to the case report. The authors also did not report on the factors that might have contributed to or mitigated against the occurrence and severity of this adverse event. This is not intended to serve as an indictment of the authors of the case report; it merely highlights the variability of content that has characterized case reports. However, it represents a missed learning opportunity for other dental professionals.

## **CONCLUSION**

Errors are commonplace in dentistry. It is our imperative as dental professionals to prevent errors from occurring, trap them before they lead to an adverse event, and mitigate their effects when they become adverse events. The dental profession can learn from the successes of other industries and adopt their safety systems, including establishing a broad-based non-punitive dental patient safety reporting system, performing root cause analyses, and translating CRM techniques into dentistry. Case reports provide a window into learning about the nature and extent of dental adverse events in the absence of a broad-based reporting system. The introduction of safety risk tools such as our adverse event severity scale to categorize events and their degree of harm will help investigators conduct further

research. Identifying dental errors and adverse events, and their causes, is the first step toward a dental patient safety initiative aimed at reducing adverse events profession-wide.

#### **SUPPLEMENTAL DATA**

Supplemental data related to this article can be found at:

<http://dx.doi.org/10.1016/j.ada.2015.01.003>.



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## TABLES

**Table 3.1: Background Characteristics of Dental Patient Safety Case Reports**

	<b>Frequency (n)</b>	<b>Percent (%)</b>
<b><i>Description of Publications</i></b>	<b><i>n=182</i></b>	<b><i>100</i></b>
<b><i>Publication Year</i></b>		
Before 1980	4	2.2
1981-1990	13	7.1
1991-2000	69	37.9
2001-2010	65	35.7
2010+	31	17.0
<b><i>WHO Region</i></b>		
Africa	1	0.5
Americas	80	44.0
Southeast Asia	12	6.6
Europe	68	37.4
Eastern Mediterranean	2	1.1
Western Pacific	19	10.4
<b><i>Description of Cases</i></b>	<b><i>n=270</i></b>	<b><i>100</i></b>
<b><i>Age (years)</i></b>		
Under 15	35	13.0
15-24	42	15.6
25-44	77	28.5
45-64	76	28.1
65+	27	10.0
Not specified	13	4.8
<b><i>Gender</i></b>		
Female	128	47.4
Male	141	52.2
Not specified	1	0.4
<b><i>Clinical Setting where AE Originated</i></b>		
Dental Office	108	40.0
Hospital	94	34.8
Not specified	68	25.2
<b><i>Phase of Care When AE was Detected</i></b>		
During Visit	96	35.6
After Visit	174	64.4

**Table 3.2: Degree of Harm\***

<b>Degree of Harm</b>	<b>Frequency (n)</b>	<b>Percent (%)</b>
	<b><i>n=270</i></b>	<b><i>100</i></b>
E1 (Temporary minimal harm w/ minimal intervention)	18	6.7
E2 (Temporary minimal harm w/ significant intervention)	12	4.4
E3 (Temporary significant harm w/ minimal intervention)	23	8.5
E4 (Temporary significant harm w/ significant intervention)	38	14.1
F (Temporary harm w/ emergency room transfer/ hospitalization)	65	24.1
G1 (Permanent minimal harm w/ minimal intervention)	3	1.1
G2 (Permanent minimal harm w/ significant intervention)	6	2.2
G3 (Permanent significant harm w/ minimal intervention)	16	5.9
G4 (Permanent significant harm w/ significant intervention)	41	15.2
H (Intervention required to sustain life)	18	6.7
I (Patient death)	30	11.1

\*See appendix 3.2 for details of the Dental Adverse Event Severity Scale

**Table 3.3: Overview of Dental Adverse Event by Type of Harm**

Type of Harm <sup>¶</sup>	Example of Patient Harm	Frequency (n)	Percent (%)*
		<i>n=270</i>	<i>100</i>
<b>Delayed appropriate treatment/ disease progression and/ or unnecessary treatment associated with misdiagnosis</b>	Melkersson-Rosenthal syndrome misdiagnosed as angioedema and dental abscess resulting in multiple tooth extractions	62	23.0
<b>Other systemic complications including adverse reactions to dental device/material/procedure</b>	Intra-cerebral hematoma following tooth extraction	57	21.1
<b>Allergy/ Hypersensitivity reactions</b>	Latex allergy (bitewing radiograph pack, rubber dam, prophylaxis cup)	29	10.7
<b>Systemic infection</b>	Cerebral abscess following dental procedure	28	10.4
<b>Soft tissue injury/ inflammation</b>	Accidental injection of formalin into soft tissues instead of local anesthesia (LA)	23	8.5
<b>Aspiration of foreign body</b>	Aspiration of rubber mouth prop	11	4.1
<b>Nerve damage or injury</b>	Paresthesia of infra-orbital region	11	4.1
<b>Hard tissue damage</b>	Root perforation during endodontic treatment	8	3.0
<b>Psychological distress/ disorder</b>	Anorexia nervosa induced by painful orthodontic treatment	7	2.6
<b>Toxicity/ drug overdose</b>	Injection of 1:1000 Adrenaline vs 1: 100,000	7	2.6
<b>Oro-facial infection</b>	Necrotizing fasciitis of infra-orbital region	6	2.2
<b>Poor hemostasis/ prolonged bleeding</b>	Following traumatic tooth extraction in hemophiliac patient	6	2.2
<b>Ingestion of foreign body</b>	Ingestion of endodontic file	5	1.85
<b>Other oro-facial complications</b>	Tear of suspensory ligaments in temporo-mandibular joint (TMJ) following excessive digital manipulation of chin by dentist	5	1.85
<b>Retention of foreign object(s) with 45equel (e)</b>	Breakage of surgical bur and retention within bone	3	1.1
<b>Poor aesthetic results post dental treatment</b>	Mal-positioned implants	2	0.7

## **SUPPLEMENTAL DATA**

### **APPENDIX 3.1: Dental Adverse Event Type Of Harm Classification**

- Allergy or hypersensitivity reactions.
- Aspiration of foreign body.
- Delayed appropriate treatment, disease progression, unnecessary treatment associated with misdiagnosis, or any combination.
- Foreign-body response or rejection.
- Hard-tissue damage.
- Harm not otherwise specified.
- Ingestion of foreign body.
- Nerve damage or injury.
- Ocular damage.
- Orofacial infection.
- Other orofacial complications.
- Other systemic complications, including adverse reactions to dental devices, materials, or procedures.
- Other wrong or unnecessary treatment.
- Poor esthetic results postdental treatment.
- Poor hemostasis and prolonged bleeding.
- Procedure on wrong patient.
- Procedure on wrong site.
- Psychological distress or disorder (including suicide).
- Retention of foreign object in patient with sequel.
- Soft-tissue injury or inflammation.
- Systemic infection.
- Toxicity or drug overdose.
- Transmission of infectious disease.

## **APPENDIX 3.2: Dental Adverse Event Severity Scale**

Category A: Circumstances or events that have the capacity to cause error.

Category B: An error that did not reach the patient.

Category C: An error that reached the patient but did not cause harm.

Category D: An error that reached the patient and required monitoring or intervention to confirm that it resulted in no harm to the patient. (US Food and Drug Administration [FDA] medical device type 1: patient treated with contaminated water in operatory— after follow-up no evidence of harm; expired material or drug.)

Category E1: Temporary (reversible or transient) minimal harm to the patient and required minimal intervention. (FDA medical device type 2: required intervention, healed, or resolved with no permanent defect or disability. Stable and stationary.)

Category E2: Temporary (reversible or transient) minimal harm to the patient and required significant intervention. (FDA medical device type 2: required intervention, healed, or resolved with no permanent defect or disability. Stable and stationary.)

Category E3: Temporary (reversible or transient) significant harm to the patient and required minimal intervention. (FDA medical device type 2: required intervention, healed, or resolved with no permanent defect or disability. Stable and stationary.)

Category E4: Temporary significant harm to the patient and required significant intervention. (FDA medical device type 2: required intervention, healed or resolved with no permanent defect or disability. Stable and stationary.)

Category F: Temporary harm to the patient, required transfer to emergency department, or hospitalization or prolonged hospital stay.

Category G1: Permanent minimal patient harm requiring minimal intervention. (FDA medical device type 3: required intervention, healed with permanent defect or disability. Stable and stationary.)

Category G2: Permanent minimal patient harm requiring significant intervention. (FDA medical device type 3: required intervention, healed with permanent defect or disability. Stable and stationary.) For example, lost tooth due to wrong extraction, iatrogenic pulpal damage.

Category G3: Permanent significant patient harm requiring minimal intervention. (FDA medical device type 3: required intervention, healed with permanent defect or disability.



Stable and stationary.)

Category G4: Permanent significant patient harm requiring significant intervention. (FDA medical device type 3: required intervention, healed with permanent defect or disability. Stable and stationary.) For example, lost tooth due to wrong extraction, needing implant or prosthesis replacement; iatrogenic pulpal damage needing endodontic treatment.

Category H: Intervention required to sustain life.

Category I: Patient death (FDA medical device type 4).

## **CHAPTER FOUR: PATIENT-REPORTED DENTAL SAFETY EVENTS – A SOUTH AFRICAN PERSPECTIVE**

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## **ABSTRACT**

**Background:** In recent years, there has been an increase in research studies highlighting patients' experiences of adverse events in hospital settings, as well as the role of patients in promoting safety. The integration of the patient perspective into dental patient safety research will enhance our collective understanding of dental adverse events (DAEs).

**Methods:** We conducted a cross-sectional study of adult patients at a large dental teaching practice in South Africa from May to June 2015. The aim was to evaluate their past experiences of DAEs at any dental clinic in South Africa. Descriptive statistics, bivariate and multivariate analyses were performed to identify the factors associated with an increased likelihood of experiencing a DAE.

**Results:** A total of 440 questionnaires were returned during the six-week study period (response rate-97.8%). Overall, 45.5% of participants reported experiencing one or more DAEs. 200 participants reported a total of 717 DAEs giving us a baseline DAE rate of 1.6 DAEs/respondent (or 3.6 events/respondent experiencing one or more DAEs). Our results suggest that respondents who were younger (18-24yrs), from high-income families (>R150,000 or 9200 USD), dissatisfied with their last dental visit and oral health had an increased likelihood of experiencing a DAE.

**Conclusion:** This study provides an insight into the nature of information that can be gleaned from dental patients regarding safety and helps to lay the foundation for patient involvement in patient safety reporting.

## INTRODUCTION

“Patient safety is the absence of preventable harm to a patient during the process of health care.”<sup>1</sup> In October 2004, the World Health Organization (WHO) launched a global campaign,<sup>2</sup> the World Alliance for Patient Safety, *later renamed the WHO’s Patient Safety Program*, to improve patient safety worldwide following a resolution by the 55<sup>th</sup> World Health Assembly (WHA 55.18) in May, 2002.<sup>3</sup> One of its six primary objectives was the active engagement of patients and patient organizations in the global patient safety movement through the Patients for Patient Safety (PFPS) program.<sup>2</sup> Over the past decade, the PFPS program has sought to empower patients and their families, bring the patient’s voice to the forefront of safety discussions, and promote the concept of patients as partners with healthcare workers in ensuring safety.<sup>4</sup> Similarly, in recent years, there has been an increase in research studies<sup>5-13</sup> highlighting the role of patients in promoting safety<sup>14-19</sup> as well as their experiences of adverse events across various hospitalized settings.<sup>20-25</sup>

These studies confirm the invaluable role of patients as an integral part of the patient safety team, oftentimes reporting events that were not identified by other safety reporting systems.<sup>7, 18, 26</sup> Patients have been deemed reliable in their assessment of adverse events<sup>20</sup> and are willing to share their experiences of adverse events in order to improve organizational safety and prevent their re-occurrence.<sup>18, 25, 27</sup> A survey of over 2000 discharged patients in the United States (US) revealed that over 70% of patient-reported events were classified as true adverse events after being reviewed by physicians.<sup>26</sup> In Japan, 2.4% of the outpatients and 4.0% of the inpatients surveyed experienced unsafe events and this percentage increased with a corresponding increase in hospital stay.<sup>28</sup> However, most of these patients (69.6% of the outpatients and 66.5% of the inpatients) did not report the event to the healthcare staff. Interestingly, the hospital safety reporting system only captured 17.1% of unsafe events reported by these inpatients.<sup>28</sup> A similar study conducted in Sweden also confirmed these observations; where medical providers involved did not report over 80% of adverse events in which patients were compensated following severe injuries.<sup>29</sup>

Despite the numerous studies conducted in medicine, the role of dental patients in patient safety has remained largely unexplored; indeed, the entire dental patient safety research field is a relatively nascent area of scientific inquiry. Starting with a call to action,<sup>30,31</sup> dental patient safety researchers have explored the use of global trigger tools for medical record reviews,<sup>32</sup> random chart reviews,<sup>33</sup> case report reviews,<sup>34</sup> user complaints' databases,<sup>35-37</sup> malpractice claims<sup>38</sup> and voluntary provider reporting<sup>39, 40</sup> to understand the nature of adverse events occurring in dentistry. These studies confirm the occurrence of dental adverse events (DAEs) and offer complementary perspectives to their understanding. In addition, the outpatient nature of most dental procedures often means an intermittent and limited contact with their dental providers. The implication is that most DAEs are discovered after the patient has concluded the dental visit (e.g., at home) and could lead to a missed learning opportunity should the patient fail to return to the clinic or provider where the DAE originated.<sup>34</sup> As the foundation is being laid for dental patient safety reporting systems, it is imperative that the patient's voice forms part of the discussion through patient-incident reporting systems.

In addition to the dearth of studies on dental patient safety, another critical issue is the dearth of studies from sub-Saharan Africa and developing countries.<sup>41</sup> Most studies on patient safety have been conducted in developed countries, particularly Europe and North America. Only 0.5% of published dental patient safety case reports reviewed originated from Africa.<sup>34</sup> A study of 26 hospitals within the Eastern Mediterranean (EMRO) and African (AFRO) WHO regions (including South Africa) revealed an average incidence of 8.2% (2.5% to 18.4%) for hospital-based adverse events, of which 83% were considered preventable and 30% resulted in death.<sup>42</sup> This suggests that adverse events might potentially be an even bigger problem in developing and transitional countries when compared to some developed nations such as the US (AE death rate: 3.8%).<sup>43</sup> Apart from hospital settings, outpatient settings around the world have estimated AE rates<sup>44-47</sup> that may be as high as 25% when considering drug-related events or 5% for diagnostic errors.<sup>48,49</sup> Therefore, we can infer that DAE rates will be potentially high in dental offices due to the predominantly outpatient nature of dental services and the sheer complexity of most dental services. In order to bridge the gap in knowledge around these critical areas of dental patient safety research,

collaboration between dental researchers at two institutions in the US and South Africa was established. A cross-sectional study among dental patients regarding past experiences of DAEs during dental visits in South Africa was conducted. The goal of the study was to assess and characterize the nature of DAEs that occur and are commonly encountered by dental patients in South Africa.

## **METHODS**

A survey of dental patients attending the clinic at a large dental teaching hospital in Pretoria, South Africa during the study period (May through June, 2015) was conducted using randomly distributed self-administered questionnaires. Inclusion criteria were: a) New and existing patients visiting the patient management section of the dental teaching hospital; and b) Adults (>18yrs). Exclusion criteria: a) patients presenting for emergency care. The necessary ethical approvals were obtained from the two educational institutions involved in the study.

**Questionnaire Development:** Due to the absence of existing validated questionnaires on dental patient safety, the research team developed and validated the survey instrument that was used in the study. Through an iterative process, questions and themes were selected from existing surveys used in medical settings: the Consumer Assessment of Healthcare Providers and Systems (CAHPS) dental plan survey<sup>50</sup> and the Medical Office Survey on Patient Safety Culture<sup>51</sup> both developed by the Agency for Healthcare Research and Quality (AHRQ), and modified. New questions were also created to reflect the patient experiences that are unique to the dental office.

**Validation:** Face validity was established by interviewing a sample of patients at the dental clinic site. The following components were assessed: clarity of the questions, ease and length of time required to complete questions and the relevance of the questions to their experiences. The feedback obtained from the patients was used to revise the questionnaire, e.g., the format and presentation of some questions made it difficult for patients to read and select the appropriate responses. The entire instrument was reformatted to ensure that

headings were repeated on every new page and that no questions were broken across two pages.

Content validity was done in three phases. First, a group of eight, comprising dentists, patient safety and survey experts from the US, reviewed the list of questions and assessed their relevance/ importance to the subject matter. Each person made recommendations for improvement and the survey was revised using this feedback. The next phase involved testing these questions among dental students in South Africa. A group of nine dental students were asked to complete the questionnaire and interviewed afterwards to obtain feedback regarding the content, structure and presentation of the survey instrument. Using feedback from the students, the questionnaire was again revised. The third and final phase of validation was from a panel of South African dentists. They reviewed the questions for its applicability to the South African participants and dental environment, and made recommendations for changes. The final instrument was submitted to the institutional review board/ Ethics Committee at both institutions and final edits were made to ensure compliance with ethical standards.

**Reliability:** The final instrument was tested for reliability using the test-retest methods and Cronbach's alpha was calculated to determine the internal consistency of specific sections of the questionnaire, e.g. "Experience of Unsafe Events." On day one, seven dental students were invited to complete the survey. After a washout period of one week, the same dental students were invited to complete a fresh copy of the survey. Their responses from the first test and the repeat test were compared to ensure that the survey yielded reliable results. The inter-rater reliability was very high (kappa statistic-0.98) and the Cronbach's alpha for the primary outcome "Experience of Unsafe Events" (25 items) was 0.83 (good internal consistency)

**Data Collection:** A member of the research team approached all new and existing patients in the waiting room of the teaching hospital. They were invited to complete the questionnaire immediately after check-in and asked to return the completed questionnaire at the end of their visit. The purpose of the study was explained to patients and the confidentiality of their

responses was assured. Patients were given an opt-out option and their consent was implied through their participation, as stated at the beginning of the questionnaire. All completed questionnaires were returned to a clearly marked box in the waiting room and no identifying information was obtained. At the end of each day, the research team collected the completed questionnaires for safekeeping and analysis.

**Data Analysis:** Data from the questionnaires were entered into REDCap<sup>52</sup> (an electronic data management tool). Data was then transferred to STATA 14 for quantitative data analysis. Descriptive statistics were obtained and are presented in Table 1. Bivariate analysis using the Fishers' exact or Pearson's chi-squared ( $\chi^2$ ) test and multivariable analysis using the generalized linear model of the Poisson family with a robust error variance were performed to assess the patient factors that were significantly associated with an increased likelihood of experiencing DAEs at South African dental clinics.

**Definitions and Measures:** The questionnaire was subdivided into five main sections: 1) Past dental history and Oral health, 2) Quality of past dental care, 3) Experience of dental adverse events, 4) Sequelae and follow-up events after DAE experience, and 5) Biographic data. This manuscript primarily focuses on section 3 (Experience of dental adverse events) and 4 (Sequelae and follow-up events after DAE experience) but utilizes variables from sections 1 and 5 as explanatory variables.

*Main Outcome:* The primary outcome measure was obtained by collapsing all the variables (25 items) from the question, "Experience of Unsafe Events" into a single binary categorical variable tagged "Dental Adverse Event (DAE) Experience" with response options "Yes" or "No". This new variable captures all patients who reported experiencing one or more DAEs during or after receiving dental treatment at any dental clinic in South Africa in the past.

*Explanatory Variables:* Several questions assessed the past dental history, dental and overall health status, and oral hygiene practices. Demographic factors were also assessed including: gender, age, race, educational level, economic status, employment status, marital status and number of children. All these factors were included in the analysis as independent variables



in the generalized linear regression model. Some variables were recoded and response options collapsed to increase the statistical power of the analyses. For example, the variable “Employment status” was collapsed from the initial nine options into three options (employed, unemployed and retired).

*Other Variables:* The cascade of events surrounding the DAE experience was assessed including: sequelae, lifestyle effects, clinic awareness of the event, satisfaction with clinic handling of the event, alleviating factors, and the pursuit of any litigation.

## **RESULTS**

450 questionnaires were distributed, of which a total of 440 questionnaires were returned during the six-week study period (response rate of 97.8%). This sample size gives a 95% confidence level that the sample estimates reflect the true estimate in the population within a 4.6% margin of error. No information was collected on the patients who declined to participate in the study.

**Sample Description:** Table 4.1 gives a detailed description of the sample participants according to demographic factors, past dental history and oral (or general) health status. In summary, there were more female respondents (62.7%) than male respondents; almost half (47.8%) of the participants were aged 25-44years; the majority of the respondents were predominantly white (64.9%), had at least a high school education (85.8%), children (67.8%) or were single (never married, divorced or separated) (65.1%); only 39% were gainfully employed and 57.8% fell within the low annual household income bracket (<R50,000). Over half of respondents (52.2%) had visited a dental clinic/practice within the preceding twelve months and the majority (57.7%) of those visits were at a state dental clinic. At least two out of every three respondents were satisfied or extremely satisfied with these dental visits, however that did not translate into a satisfaction with their oral health as over half (57.7%) reported their oral health as unsatisfactory, whereas the majority (85.2%) were satisfied with their overall health. 94.3% reported cleaning their teeth at least once daily, however, only 57.3% used a toothbrush and toothpaste (fluoride or non-fluoride) in their cleaning routine. A simple bivariate analysis using the chi-squared test revealed

significant associations between past DAE experience and respondents' annual household income ( $\chi^2$  test statistic (df): 6.74 (2); p-value: 0.03), the timing of the last dental visit ( $\chi^2$  test statistic (df): 29.85 (2); p-value: <0.0001), cleaning products used for oral hygiene ( $\chi^2$  test statistic (df): 4.8 (1); p-value: 0.03). The satisfaction with last dental visit was also marginally significant (( $\chi^2$  test statistic (df): 5.57 (2); p-value: 0.06)



Figure 4.1: Frequency Of Dental Adverse Events

Images created by Iconarray.com<sup>62</sup>.

**Description of Dental Adverse Event (DAE) Experience:** Table 4.2 shows the distribution of the types of DAEs experienced by the respondents. Overall, 45.5% (95%CI: 40.8%, 50.1%) of participants reported experiencing one or more DAEs (Figure 4.1). 200 participants reported a total of 717 DAEs resulting in an estimated baseline DAE rate of 1.6 DAEs per respondent (or 3.6 events per respondent experiencing one or more DAEs). The most commonly reported types of DAEs were intra-oral hard tissue damage, soft tissue injury or inflammation, and unexpected pain. It was difficult to assess the severity of these events, however, using the duration of the event as a proxy for severity, the majority of the DAEs (58.3%) lasted for less than one day (minutes to hours) which can be classified as mild, but about 14.3% lasted for several months to years, classified as moderate to severe. Serious DAEs such as wrong tooth extractions or wrong-site procedures, wrong medications or

anesthetic, allergic reactions to dental materials or medications, and foreign body aspirations occurred in 11.8% of cases (7.0%, 4.5% and 0.3% respectively).

**Dental Adverse Event (DAE) Experience and Associated Factors:** A factorial multivariable Poisson regression model with a robust error variance was used to identify which explanatory variables remained significant after controlling for other variables. Table 4.3 shows the adjusted prevalence risk ratios (PRR). There were significant associations between DAE experience and the following explanatory variables: age (18-24yrs), annual household income (high income ( $\geq$ R150, 000 or 9200 USD)), satisfaction with last dental visit (dissatisfied and extremely dissatisfied), and oral health status (not satisfied with dental health). Gender, race, employment status, educational status, oral hygiene habits were not significantly associated with the experience of DAEs.

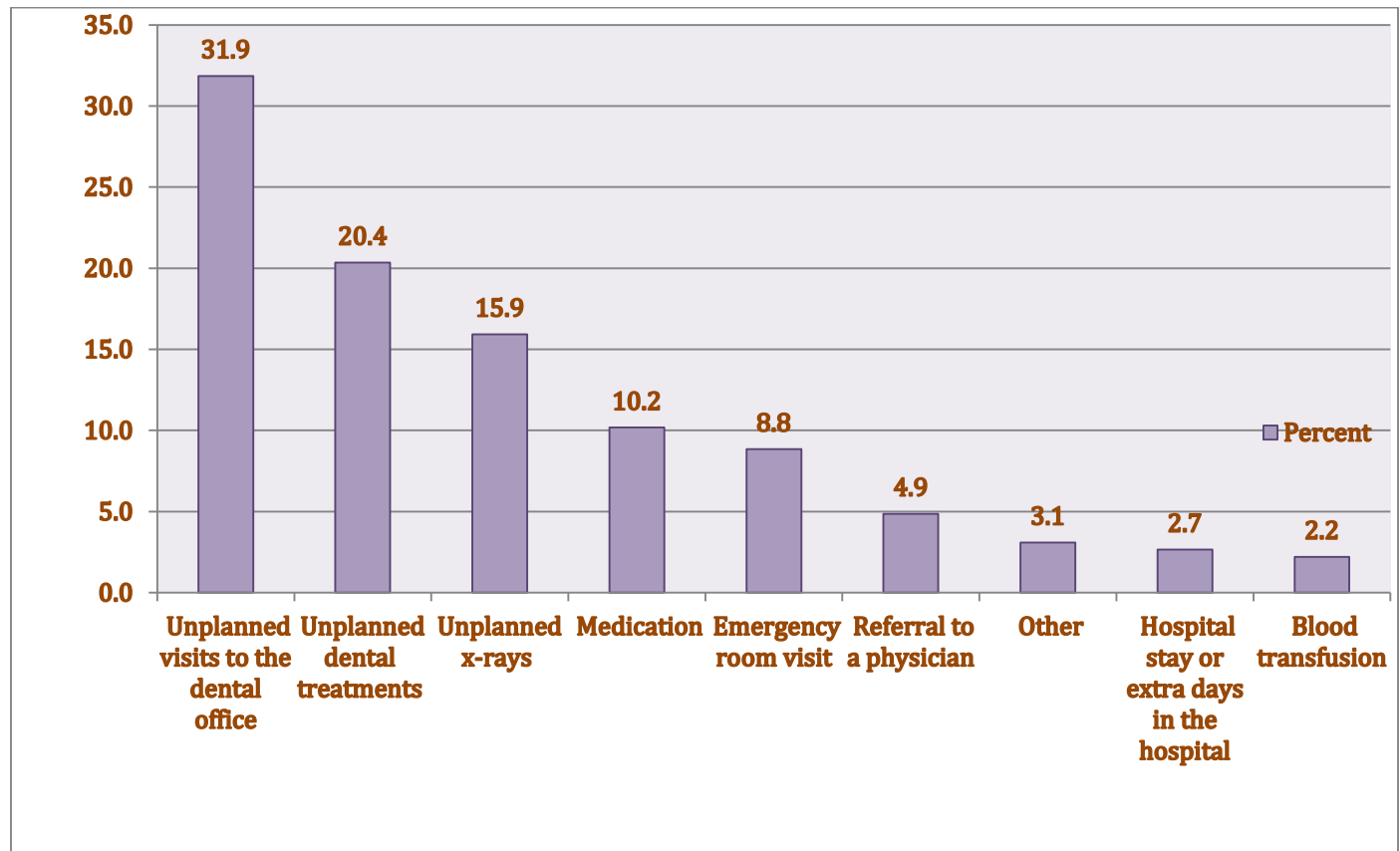


Figure 4.2: Sequelae Of DAE Experience

**Sequelae of DAE and Satisfaction with Clinic Handling:** 41.4% (95% CI: 35.6-47.2%) of respondents reported having a follow-up event, e.g., unplanned dental treatment or blood transfusion, while 38.9% (95% CI: 33.1-41.7%) reported experiencing a significant lifestyle effect, e.g., worry or sleep trouble. The distributions of these experiences are shown in Figures 4.2 and 4.3. In addition, 62.5% (95% CI: 54-71%) reported that the clinic was aware of the event and took steps to make them feel better about their DAE experience (60.9%; 95% CI: 50.7-71%). 72.7% (95% CI: 64.8-79.4%) were satisfied with the clinic handling of the event. Only 4 respondents (2.1%) had ever filed a lawsuit against the clinic. Respondents who reported that the clinic was aware of the event (adjusted PRR: 2.03 (95% CI: 1.2-3.45), p-value: 0.01) and took steps to make them feel better (adjusted PRR: 2.34(95% CI: 1.4-3.91), p-value: <0.001) had an increased likelihood of being satisfied with the clinic handling of the event. The elderly (65yrs+) and the unemployed were also more likely to be satisfied with the clinic handling of the event.

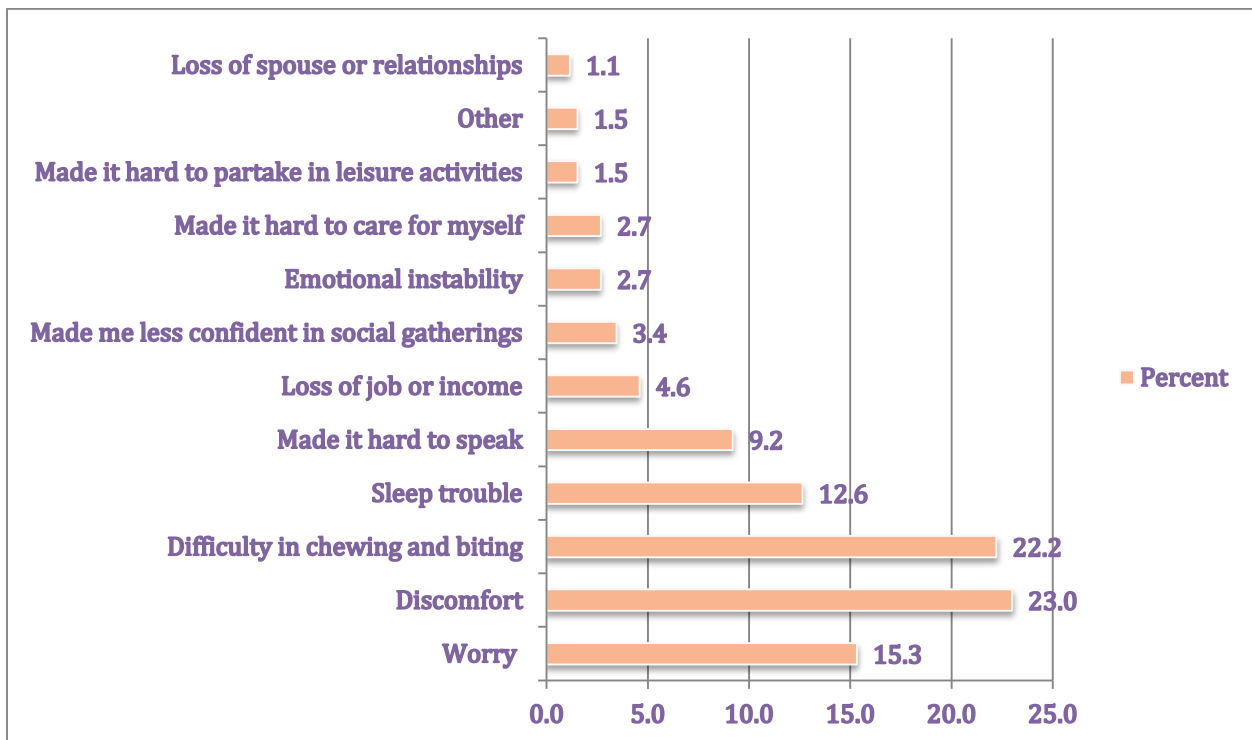


Figure 4.3: Lifestyle Effects Following DAE Experience

## **DISCUSSION**

In order to enhance the safety of patients, adverse events need to be prevented from occurring or their effects mitigated when they occur.<sup>3</sup> To achieve this goal, healthcare organizations need to be able to learn from their mistakes through reporting systems, investigations and cross-organization data sharing. More importantly, they should be able to anticipate mistakes and organizational weaknesses that could potentially lead to the occurrence of an adverse event. Ultimately, the goal should be to improve the quality of care delivery by increasing knowledge, restructuring processes, aligning motives and working together to ensure that every patient leaves the organization better than they came in.<sup>3</sup> The nature of safety reporting systems (varying sensitivity to DAEs) make it imperative that the voices of dental patients' are brought into the discussion in order to paint a holistic picture and aid in our understanding of DAEs. Since patients are keen observers of their own care, patients can be a good source of information regarding adverse events in dentistry and should be active participants in ensuring patient safety.<sup>5, 27, 53</sup> To the best of our knowledge, this is the first study to assess the prevalence of DAEs among dental patients using self-reporting. In particular, this is the first patient safety study to be conducted among dental patients in sub-Saharan Africa. Our results therefore capture the unique perspective of the dental care experience through the patient's eyes, and add a missing piece to the puzzle of dental patient safety research.

The overall prevalence (45.5%) of DAEs among a sample of South African dental patients underscores the magnitude of the dental patient safety problem and indicates the need for a targeted response aimed at improving the overall dental care experience for patients in South Africa and indeed worldwide. This estimate is similar to findings from a US-based study using dental trigger tools where about 50% of dental charts reviewed over a six-month period contained DAEs.<sup>32</sup> In Finland, the estimate was more conservative when providers were surveyed, about one out of three dentists reported that their patients had experienced a safety incident in the preceding year.<sup>39</sup> More studies are needed to assess the true prevalence of DAEs in dentistry across various dental care delivery settings as a critical part of identifying threats to patient safety, the first element for developing a patient safety initiative.<sup>30, 54</sup> Dental patients also need to be better engaged as partners in identifying and

reporting these incidents, especially where providers have otherwise become injured to them, in order to build a safer dental care delivery system.

When compared to other patient-reported DAE estimates in hospital settings, the estimated prevalence of DAEs from this study is significantly higher than those obtained in Japan where 2.4% of outpatients and 4% of in-patients had experienced an AE.<sup>28</sup> Estimates from US patients were closer at 21.1% to 29%,<sup>23, 24, 26, 55, 56</sup> and Switzerland at 50.6% for ‘undesirable events’<sup>57</sup>. One reason for the difference in estimates might be the lack of standardized definitions, methodologies, patient-reporting instruments, classifications, as well as the sheer differences in the health system structures of these countries. Studies with longer durations and the cumulative incidence of events from studies using other observational methods tend to reflect similar estimates.<sup>25</sup> Therefore, while the comparison of patient-reported AEs across studies, medical discipline, care settings and countries might be challenging due to the above-mentioned reasons, they highlight important trends. To ensure the reliability of information obtained in this study, we provided patients with a list of unsafe events to choose from, thereby eliminating ambiguity; we also validated the questions to ensure that the patients interpreted them appropriately.

The severity of DAEs experienced by respondents was assessed using a proxy variable for the duration of the event; 14.3% of patients had experienced an event that lasted for several months to years. This corresponds with the study of Finnish dentists that found 13% of events reported caused permanent harm injury or harm to the patients.<sup>39</sup> Although our study was unable to assess DAEs that caused permanent harm or led to the death of the patient, for obvious reasons, a review study of published case reports revealed that 24.4% of cases caused permanent harm while 11.1% led to the death of the patient.<sup>34</sup> It is important to note that only 0.5% of these published case reports were from sub-Saharan Africa. The commonly reported follow-up events after a DAE experience were unplanned dental visits, unplanned dental treatment, unplanned x-rays and medications, which made up over three quarters of all sequel events in our study. Similarly, intra-oral soft-tissue injury (24%) and hard tissue damage (30%) were the predominant types of DAEs experienced by patients. This contrasts with earlier studies where wrong or unnecessary treatments following misdiagnosis ranked

highest (23%) among published case reports<sup>34</sup> and findings in primary care clinics which also emphasized diagnostic errors.<sup>49</sup> The difference might be due to the data sources and the technical knowledge required to evaluate diagnostic errors, which patients do not readily possess, thus underscoring the need for a multi-pronged approach towards measuring and understanding DAEs.

Other concerns with patient reporting that can potentially affect reporting rates include the power imbalance between providers and patients, illness severity, cultural and linguistic barriers and the fear of being perceived as difficult or challenging the provider's knowledge.<sup>14, 16, 18</sup> However, these concerns invariably affect the success of treatment regimens and providers will do well to provide a safe environment where patients and their families feel empowered to speak up, not just for the sake of preventing or catching errors but to be successful clinicians. Some tactics to address diagnostic errors recommended to patients include the following: relaying symptoms clearly, paying attention to timing details, keeping accurate records, being properly informed about their condition, medication and test results, following up with test results, and establishing the certainty of a provider's diagnosis.<sup>18, 58</sup> Other recommendations include training on patient-provider communication particularly the art of initiating questions or communicating effectively, simulation exercises and educational videos or tutorials for patients, and the use of patient advocates or coaches to facilitate patient engagement.<sup>18</sup> Ultimately, the goal of having more proactive and involved patients makes them more knowledgeable consumers and will help to reduce the risk of diagnostic errors.<sup>18</sup>

Apart from better patient engagement, another advantage of involving patients through patient-reporting systems is to capture DAEs that would otherwise go unnoticed, can potentially lead to emergency room visits, or be the reason for seeking legal action or disenchantment with the clinic and its providers. This approach affords the clinic an opportunity to address the patients' concerns or experiences, a theory that is supported by our study findings. We demonstrated that for patients whom the clinic was aware of the event (62.5%) and took steps to make them feel better (60.9%), they were more likely to be satisfied with the clinic handling of the event. Primarily, injured patients tend to be angrier

when errors are not disclosed or the clinic is slow in responding to their complaints about the error.<sup>25, 59</sup> The clinic also has an opportunity to improve systems and restructure processes to prevent a recurrence. It is interesting to note that only about 2% of respondents had ever filed a lawsuit against a clinic despite the high prevalence of DAEs. This can be attributed to cultural differences where the litigation and tort system in South Africa against medical professionals is not as robust as in some western countries. It might also be due to the lack of awareness of patients regarding their rights to high quality dental care and the mild or temporary nature of the reported DAEs. However, with the world becoming increasingly interconnected, health professionals in South Africa need to be prepared for the changing tides.

Central to the primary objective of this study was the assessment of factors associated with an increased likelihood of experiencing a DAE. Table 4.3 shows the adjusted prevalence risk ratios of the predictor variables significantly associated with the experience of a DAE from a generalized linear model (Poisson family) with robust variance estimation. Our results suggest that respondents who were younger (18-24yrs), from high-income families (>R150,000 or 9200 USD), dissatisfied with their last dental visit and oral health status had an increased likelihood of experiencing a DAE. These findings contrasts an earlier study conducted in the US where individuals who were from wealthy households, middle-aged (30 to 65 years), divorced, separated or widowed and African-American, had a reduced likelihood of reporting medical errors.<sup>56</sup> They also reported that an increased number of doctor visits, previous experiences of AEs and exposure to quality information of hospitals, led to increased likelihood of reporting error experiences. The link between previous experiences of AEs within one's household was also reported by Agoritsas et al and was associated with hypersensitization.<sup>57</sup> Conversely, a Canadian study found significant associations between the female gender and the reporting of AEs but this was not the case in our study.<sup>60</sup> In primary care clinics, multiple visits were associated with an increased occurrence of DAEs.<sup>47</sup> Similarly, when a patient is unhappy with the treatment received, their oral or general health status, they tend to be more critical of the healthcare system and provider. It is therefore important for researchers to distinguish between patient dissatisfaction, which is a function of their expectations, and the actual experience of an



event that caused harm.<sup>61</sup> A real-time observational study of patients with immediate follow-up when they report experiencing a DAE will give providers and researchers the opportunity to distinguish between these cases.

Clearly, exploring the patient's perspective expands our collective understanding of DAEs. It offers an insight into the areas that are of importance to patients and gives health professionals an avenue to meet these needs given limited resources. Rather than focusing on the traditional metrics such as prolonged hospital stay, physical harm and death, it helps us to humanize the effect of DAEs, for example, the effect on relationships, income and lifestyle. In this study, patients emphasized sleep trouble, difficulty with chewing and worry as the most frequently encountered lifestyle effect of experiencing a DAE. Unplanned dental visits, dental treatments and x-ray exposure also topped the chart for sequelae of DAEs. Ultimately, understanding DAEs through the eyes of the patient gives us a sense of shared responsibility, increases the accountability of providers and enhances patient engagement. Organizations therefore need to develop specific policies that foster patient involvement in safety efforts. Patient advocacy groups need to be empowered and strong partnerships with national and international chapters encouraged.

As we move forward in dental patient safety research, it is imperative to develop tools and methods that can be utilized to capture and analyze AEs that are unique and specific to the dental environment. Studies are needed that compare DAEs across various care dental delivery models (e.g. private vs. public clinics) and different countries using varying methodologies that can be triangulated to provide confirmation of the true existence of the reported events (e.g., voluntary provider reporting vs. chart reviews vs. patient reports). It is also important to begin to develop effective strategies for eradicating or minimizing the occurrence of DAEs. This study presents a unique opportunity for South Africa to pave the way for dental patient safety research on the African continent. Other African countries can adopt this protocol to assess baseline rates of DAEs and move towards developing strategic national policies on safe healthcare practices.

## **CONCLUSION**

Amidst calls for the dental profession to rise up to tackle patient safety, several efforts are ongoing. This study provides an insight into the nature of information that can be gleaned from dental patients regarding safety. It confirms that DAEs occur in dentistry and at much higher rates than have been recorded by colleagues in medicine. Therefore, researchers should be encouraged to conduct further inquiries into patient safety as a new field of dental research.

## **Acknowledgements**

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## TABLES

**Table 4.1: Study Sample Characteristics**

Characteristic	Total, N (%)	DAE Prevalence, N (%)	$\chi^2$ Statistic (df)*	P-value
<b>Total</b>	<b>440(100)</b>	<b>200 (45.5)</b>	<b>(-)</b>	<b>(-)</b>
Gender				
Male	114(37.3)	62 (36.3)	0.17 (1)	0.69
Female	192(62.7)	109 (63.7)		
Age				
18-24yrs	39(13.3)	26 (15.9)	5.75 (3)	0.12
25-44yrs	140(47.8)	83 (50.6)		
45-64yrs	77(26.3)	39 (23.8)		
65yrs+	37(12.6)	16 (9.8)		
Race				
Black African	89(29.2)	49 (28.8)	2.36 (2)	0.31
White	198(64.9)	114 (67.1)		
Coloured or Mixed	18(5.9)	7 (4.1)		
Employment Status				
Employed	115(39)	64 (39.0)	1.92 (2)	0.38
Unemployed	135(45.8)	79 (48.2)		
Retired	45(15.2)	21 (12.8)		
Educational Level				
Less than high school (GR 12)	40(14.2)	18 (11.3)	3.46 (2)	0.18
High school graduate or vocational training	148(52.5)	90 (56.6)		
College graduate or higher	94(33.3)	51 (32.1)		
Children				
Yes	202(67.8)	108 (64.3)	2.16 (1)	0.14
No	96(32.2)	60 (35.7)		
Marital Status				
Single-never married	112(36.1)	69 (40.1)	4.58 (2)	0.1
Married or civil partnership	108(34.9)	61 (35.5)		
Divorced, separated or widowed	90(29)	42 (24.4)		
Annual Household Income				
Low income (<R50,000)	148(57.8)	87 (58.0)	6.74 (2)	0.03 <sup>§</sup>
Middle income (R50,000 to 149,999)	61(23.8)	29 (19.3)		
High income (R150,000+)	47(18.4)	34 (22.7)		
Last Dental Visit (Time)				
Less than 12 months	228(52.2)	120 (60.3)	29.85 (2)	<0.0001 <sup>§</sup>
More than 12 months	179(41)	79 (39.7)		

Characteristic	Total, N (%)	DAE Prevalence, N (%)	$\chi^2$ Statistic (df)*	P-value
No previous dental visit	30(6.8)	0 (0.0)		
Last Dental Visit (Location)				
State Dental Clinic	252(57.7)	114 (57.9)	1.16 (2)	0.56
Private Dental Clinic	147(33.6)	75 (38.1)		
Other. E.g. non-licensed	38(8.7)	8 (4.1)		
Satisfaction with Last Dental Visit				
Extremely satisfied or satisfied	295(69.1)	134 (68.0)	5.57 (2)	0.06
Neutral	76(17.8)	33 (16.8)		
Dissatisfied and extremely dissatisfied	56(13.1)	30 (15.2)		
Oral Health Status				
Satisfied with dental health	184(42.3)	81 (40.9)	0.29 (1)	0.59
Not satisfied with dental health	251(57.7)	117 (59.1)		
General Health Status				
Satisfied with overall health	369(85.2)	164 (82.8)	1.66 (1)	0.2
Not satisfied with overall health	64(14.8)	34 (17.2)		
Oral Hygiene Habits				
Clean teeth at least once daily	349(94.3)	171 (95.5)	0.94 (1)	0.33
Clean teeth less than once daily	21(5.7)	8 (4.5)		
Cleaning Product				
Toothbrush and fluoride toothpaste or non-fluoride toothpaste	212(57.3)	66 (36.9)	4.8 (1)	0.03 <sup>§</sup>
Others. E.g. chewstick	158(42.7)	113 (63.1)		

<sup>§</sup>significant p-value $\leq$ 0.05; DAE: Dental Adverse event; \*Chi-squared or Fishers Exact test

**Table 4.2: Distribution Of DAE Experience By Type**

Type of Dental Adverse Event (DAE)	Count (N)	Percent (%)
Allergy/ Toxicity/ Foreign body Response	32	4.5
Aspiration/ Ingestion of Foreign Body	2	0.3
Infections	19	2.6
Wrong-side/wrong-site, wrong-procedure, and wrong-patient events (WSPPs)	50	7.0
Pain	83	11.6
Intra-oral Hard Tissue Damage	218	30.4
Intra-oral Soft Tissue Injury/ Inflammation	172	24.0
Nerve Injury	39	5.4
Other Systemic Complications	16	2.2
Other Oro-facial Complications	76	10.6
Other Harm	10	1.4
Total Number of DAEs	717	100.0

**Table 4.3: Relationship Between DAE Experience and Explanatory Variables (n=440; Adjusted Prevalence Rate Ratio)**

Variables	Adjusted PRR <sup>†</sup> [95% Conf.-Interval], P>z
Gender	
Male	ref
Female	0.86(0.69-1.08), 0.19
Age	
18-24yrs	ref
25-44yrs	0.95(0.73-1.23), 0.69
45-64yrs	0.71(0.5-1), 0.05 <sup>§</sup>
65yrs+	0.47(0.22-1.01), 0.05 <sup>§</sup>
Race	
Black African	ref
White	1.03(0.78-1.35), 0.85
Coloured or Mixed	0.48(0.18-1.25), 0.13
Employment Status	
Employed	ref

<b>Variables</b>	<b>Adjusted PRR<sup>¶</sup> [95% Conf.-Interval], P&gt;z</b>
Unemployed	1.08(0.83-1.42), 0.55
Retired	1.26(0.65-2.46), 0.49
Educational Level	
Less than high school (GR 12)	ref
High school graduate or vocational training	1.28(0.86-1.89), 0.22
College graduate or higher	0.95(0.62-1.48), 0.83
Annual Household Income	
Low income (<R50,000)	ref
Middle income (R50,000 to 149,999)	0.86(0.6-1.23), 0.4
High income (R150,000+)	1.49(1.12-1.97), 0.01 <sup>§</sup>
Last Dental Visit (Time)	
Less than 12 months	ref
More than 12 months	0.91(0.73-1.15), 0.44
Last Dental Visit (Location)	
State Dental Clinic	ref
Private Dental Clinic	0.81(0.63-1.04), 0.09
Other. E.g. non-licensed	0.76(0.34-1.71), 0.51
Satisfaction with Last Dental Visit	
Extremely satisfied or satisfied	ref
Neutral	0.97(0.72-1.29), 0.81
Dissatisfied and extremely dissatisfied	1.44(1.15-1.82), <0.001 <sup>§</sup>
Oral Health Status	
Satisfied with dental health	ref
Not satisfied with dental health	1.3(1-1.68), 0.05 <sup>§</sup>
General Health Status	
Satisfied with overall health	ref
Not satisfied with overall health	1.12(0.88-1.43), 0.35
Cleaning Product	
Toothbrush and fluoride toothpaste or non-fluoride toothpaste	ref
Others. E.g. chewstick	1.2(0.92-1.58), 0.18

PRR: Prevalence rate ratio obtained from the Poisson regression model with robust variance estimation; CI- 95% confidence interval;

<sup>§</sup>significant p-value≤0.05; vs – versus

<sup>¶</sup>Adjusted for gender, age, race, employment status, economic status, educational status, past dental history, oral health status and general health status

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**CHAPTER FIVE: PERCEPTIONS OF QUALITY AND SAFETY AMONG SOUTH AFRICAN  
DENTAL PATIENTS**

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## ABSTRACT

**Background:** From the patient's perspective, quality of care can be defined as the ability of healthcare products and services to satisfy the stated or implied needs of its consumers (patients). As dental professionals, we have a moral obligation to deliver the best quality care that meets both professional standards and patient needs, the latter especially so, in an increasingly informed, consumer-driven society. The goal of this paper is to jumpstart the discussion on patient perceptions of quality as a useful tool for assessing dental care quality.

**Methods:** This study used a self-reported survey to assess the quality of care experiences among South African dental patients. Questionnaires were distributed to all non-emergency, adult patients (>18 years) at a large teaching dental practice in Pretoria, South Africa. The five primary outcome variables were: A) Access to Care B) Technical Quality, Efficiency and Effective Organization of Care C) Structure and Facilities D) Communication, Information and Courtesy; e) Global Rating of Safety.

**Results:** Overall, slightly above half (58.6%) of the participants had a positive view about the quality of dental clinics in South Africa. Age (middle-aged), race (coloured or mixed), marital status (married, divorced), child status (no children), employment status (retired), household income (>R150, 000 or 9200 USD) and educational status (high school or vocational education) were associated with an increased likelihood of having a higher rating of quality. Patients had the most positive perception (97.6%; mean: 3.8) of the question "The instrument used in treating me appeared clean" but rated the question "Whenever I was sent to a new dentist, I had to repeat the tests that I did at the previous dentist" very low (36.9%; mean: 2.1).

**Conclusion:** The extents to which patient needs and expectations are met often determine their perceptions of quality. Our study findings suggest that the dental profession is behind in meeting these expectations.

## INTRODUCTION

From the patient's perspective, quality of care can be defined as the ability of healthcare products and services to satisfy the stated or implied needs of its consumers (patients).<sup>1</sup> One of the six aims for healthcare quality is patient-centered care (*"providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions"*), as defined by the Committee on Healthcare Quality in America, Institute of Medicine (IOM).<sup>2</sup> The committee further described the core dimensions of patient-centered care as: 1) Respect for patient values, attention to patient preferences and expressed needs, 2) Coordination and integration of care, 3) Information, communication and education, 4) Physical comfort, 5) Emotional support- relieving fear and anxiety, 6) Involvement of family and friends, 7) Transition and continuity.<sup>2</sup> The Picker Institute lists similar concepts as the most important priorities for patients in healthcare but adds an eighth dimension, access to care.<sup>3</sup> Specifically pertaining to ambulatory care, they describe the following: Access to the location of hospitals, clinics and physician offices; Availability of transportation; Ease of scheduling appointments; Availability of appointments when needed; Accessibility to specialists or specialty services when a referral is made; and clear instructions provided on when and how to get referrals.<sup>4</sup> Most of these dimensions for patient-centered care were first described by Gerteis et al in 1993 where he identified: Respect for patients views, preferences and expressed needs; Co-ordination and integration of care; Information, communication and education; Physical comfort, Emotional support and alleviation of fear and anxiety; Involvement of family and friends; and Transition and continuity as the key factors in patient-centered care.<sup>5</sup>

The concept of patient-centered care often creates a conflict between patients and providers because patients prioritize different aspects of the care<sup>6-8</sup> and these priorities may influence their perceptions of quality of care.<sup>9</sup> Whereas some would argue that patient perceptions are subjective and therefore unreliable,<sup>10, 11</sup> others believe in the inherent value of these assessments because the patient is the primary recipient of care and therefore has the most important perspective.<sup>12</sup> They posit that there is indeed an instrumental value to patient perceptions of quality due to its far-reaching consequences on: the choice of providers or health plans, compliance with medical advice, health outcomes and the expression of



grievances or seriousness of malpractice claims.<sup>9, 12-16</sup> Therein lies the dilemma between the subjective versus normative assessments of quality in healthcare.<sup>9, 17</sup> Some researchers have proposed shifting the focus from patient satisfaction, a narrow and relative concept,<sup>1, 18</sup> to a more substantive and robust evaluation of patient perceptions of quality, using tools that measure the actual experiences of care.<sup>1, 9, 17, 19-23</sup> Although dentistry has entered the patient safety revolution, the development of such tools for measuring patient perceptions of dental quality is still at its infancy, even so, is the concept of patient-centeredness and its applications to dental care quality.<sup>24-27</sup>

In addition to the above-mentioned reasons, the desire to promote greater transparency and accountability of healthcare systems underscores the importance of quality measurement.<sup>9</sup> As dental professionals, we have a moral obligation to deliver the best quality care that meets both professional standards and patient needs, the latter especially so, in an increasingly informed, consumer-driven society.<sup>10, 28</sup> The American Dental Association (ADA) through the Dental Quality Alliance (DQA)<sup>29, 30</sup> and the United Kingdom Department of Public Health through the Dental Quality and Outcomes Framework (DQOF)<sup>31, 32</sup> have laid the foundation for the development of quality metrics in dentistry.<sup>27</sup> Efforts are also ongoing by the authors (R.R. and E.K.) through grant funding from the National Institutes of Health (NIH)/ National Institute Of Dental and Craniofacial Research (NIDCR) - R01DE024166-01A1, to implement dental quality measures in dental practices across the United States (US).<sup>33</sup> The goal of this paper is to jumpstart the discussion on patient perceptions of quality as a useful tool for assessing dental care quality. In the future, this will offer the profession a screening tool for the quick evaluation of dental practices for high performance or the identification of areas in need of improvement. Subsequent steps will involve defining key concepts and outcome measures for patient-reported dental quality as well as developing standardized instruments for measuring the same.

Surveys have typically been used to garner information about patient perceptions of quality.<sup>9, 34</sup> A national survey of dental patients in the United Kingdom by Tickle et al showed that about one fifth of respondents rated the quality of dental care they received as suboptimal.<sup>35</sup> The factors that were important in their assessment of quality were: “access

(40%), technical quality of care (35%), professionalism (30%), hygiene/cleanliness (30%), staff attitude (27%), pain-free treatment (23%), value for money (22%), and staff putting patients at ease (21%)".<sup>35</sup> Positive responses were associated with "good interpersonal communication, politeness and being put at ease" while negative responses were associated with poor wait times and high cost of care.<sup>35</sup> This study used a self-reported survey to assess the quality of care experience among South African dental patients.

## **METHODS**

**Survey Design:** The survey was developed by the authors through an iterative process and tested for validity and reliability (Cronbach's  $\alpha$  Coefficient: 0.77). A simple, convenience sampling method was used to collect information from all non-emergency, adult patients (>18 years) at a large teaching dental practice in Pretoria, South Africa. Patients gave their informed consent after reading an information leaflet detailing the research objectives and by completing the survey. Necessary ethical approvals were obtained from both collaborating institutions prior to the commencement of data collection.

**Definitions and Measures:** The questionnaire was subdivided into five main sections: 1) Past dental history and oral health, 2) Quality of past dental care, 3) Experience of dental adverse events (DAEs), 4) Sequelae and follow-up events after DAE experience, and 5) Biographic data. This manuscript primarily focuses on section 2 (Quality of past dental care) but utilizes variables from sections 1 and 5 as explanatory variables.

**Outcome Variables:** The five primary outcome variables were: A) Access to Care (7 items); B) Technical Quality, Efficiency and Effective Organization of Care (10 items); C) Structure and Facilities (6 items); D) Communication, Information and Courtesy (10 items); e) Global rating of safety. The first four outcome variables were obtained by categorizing the questions from section 2 into patient-defined dimensions of quality identified by Sofaer et al in their extensive review titled "Patient Perceptions of Quality".<sup>9</sup> The original seven dimensions were: 1) patient-centered care; 2) access; 3) communication and information; 4) courtesy and emotional support; 5) technical quality; 6) efficiency of care/organization; and 7) structure and facilities.<sup>9</sup> Each variable was assessed using items that were measured on a 5-point Likert scale ranging from 1 (Always), 2 (Usually), 3 (Sometimes), 4 (Never), and 5 (Not

Applicable). The final responses were collapsed into a 4-point scale and reverse coded to be more intuitive (negative responses were assigned lower values and vice versa). Option 5 (Not applicable) was treated as missing. All four categories had a combined Cronbach's alpha of 0.77 (acceptable) for internal validity (Table 5.1). The fifth outcome variable (global rating of safety) was generated from the question "In general, how safe are the dental clinics that you have visited in South Africa?" This question was assessed on a 10-point visual analog scale and collapsed into five categories ranging from 1 (extremely unsafe) to 5 (extremely safe).

*Explanatory Variables:* The past dental history, dental and overall health status, and oral hygiene practices were assessed. We also assessed the relationship between demographic factors such as: gender, age, race, educational level, economic status, employment status, marital status and number of children on each outcome variable.

**Statistical Analysis:** All statistical analyses were performed using STATA 14®. Percent positives were obtained by collapsing the upper two response options for each line item ('Always' and 'Usually' or 'Extremely safe' and 'Safe' for category 5) (Table 5.2). For inferential analyses, the five categories were converted into binary variables (low vs high quality) using the mean scores as the cut-off point. Bivariate analyses using Pearson's chi-squared test was used to identify the explanatory variables with significant relationships with the outcome variables (Table 5.3). Further statistical analyses were performed using generalized linear models of the Poisson family with robust variance estimates to generate adjusted prevalence rate ratios (PRR) and identify significantly associated variables with the dimensions of quality and safety.

## **RESULTS**

440 questionnaires were returned (97.8% response rate). The sample characteristics are given as follows: Females (62.7%), 25-44 years (47.8%), whites (64.9%), unemployed (45.8%), high school or vocational school education (52.5%), had children (67.8%), single-never married (36.1%), low income household (57.8%), dental visit within previous 12 months (52.2%), visited a state dental clinic for last dental visit (57.7%), satisfied or extremely satisfied with last dental visit (69.1%), not satisfied with dental health (57.7%),

satisfied with overall health (85.1%), clean teeth at least once daily (94.3%) and uses a toothbrush with fluoride or non-fluoride toothpaste (57.3%).

**Overall Perception of Quality and Safety:** Figure 5.1 shows the percentage of participants who had positive perceptions of quality and safety by dimension. Access to care received the least favorable rating of quality (mean score:  $2.8 \pm 0.68$ ). Only 48.6% of participants rated this dimension as high quality. The global rating of safety received the highest score (mean score:  $4.3 \pm 0.98$ ); over 80% of participants had a positive perception of safety. This rating was not correlated with their past experiences of DAEs (Pearson's rho ( $r$ ): -0.21). Overall, slightly above half (58.6%) of the participants had a positive view about the quality of dental clinics in South Africa (Figure 5.2). The item "Whenever I was sent to a new dentist, I had to repeat the tests that I did at the previous dentist" received the lowest percentage positive score (36.9%; 95%CI: 31.0-42.8), while the item "The instruments used in treating me appeared clean" received the highest score (97.6%; 95% CI: 95.9-99.3) (Table 5.2).

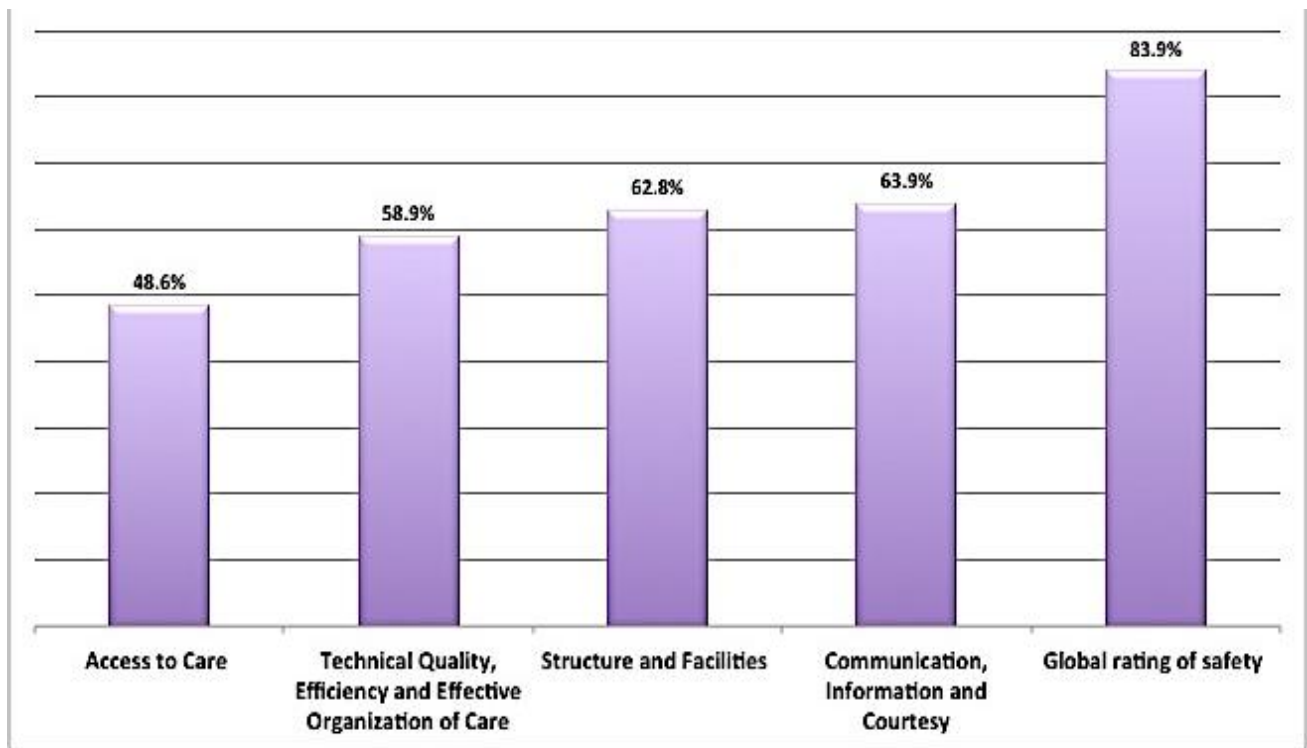
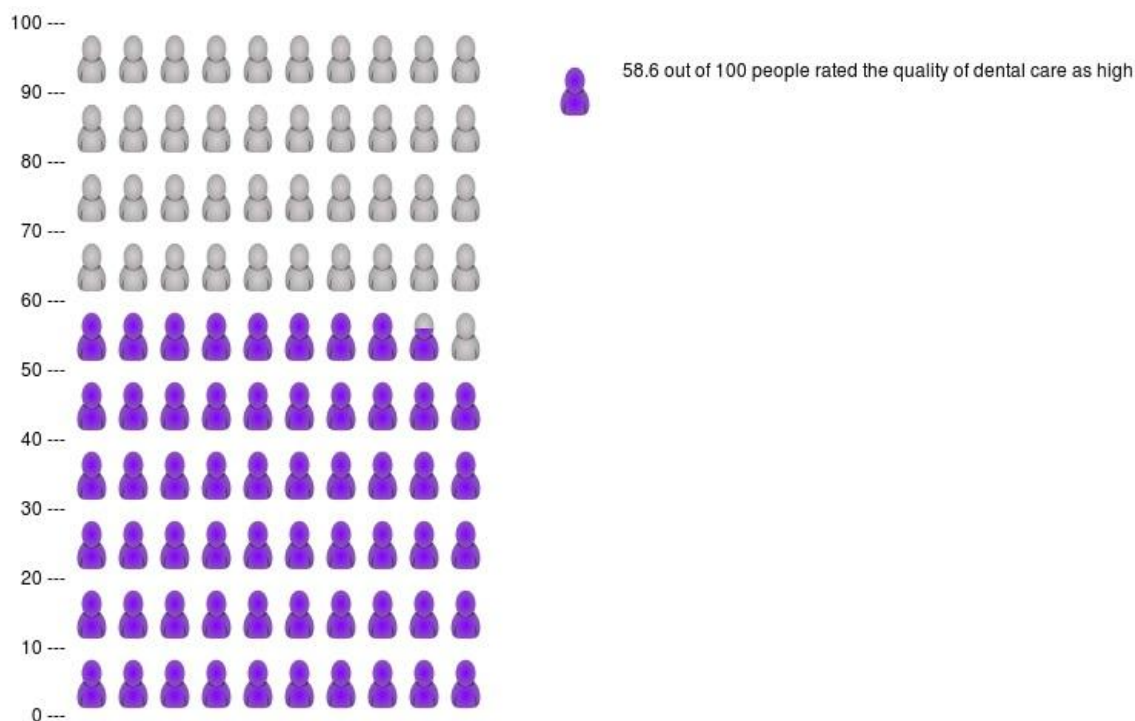


Figure 5.1: Perception of Dental Quality and Safety by Dimension



**Figure 5.2: Overall Perception of Dental Quality**

**Dimensions of Quality and Associated Factors:** Initial bivariate analysis using Pearson’s chi-squared ( $\chi^2$ ) test identified significant associations between: a) Access to care and gender, satisfaction with last dental visit; b) Technical quality and satisfaction with last dental visit, past DAE experience; c) Facilities and race, location of last dental visit, satisfaction with last dental visit, past DAE experience; d) Communication and race, satisfaction with last dental visit, oral health status, general health status, past DAE experience; e) Global safety rating and satisfaction with last dental visit, oral health status, past DAE experience. Satisfaction with last dental visit was significantly associated with all the dimensions of quality and safety; followed by past DAE experience, which was associated with all factors except access to care. (Table 5.3)

Table 5.4 shows the factors that are significantly associated with the dimensions of quality and safety after controlling for other covariates in the generalized linear model.

a) Access to care: Participants who had a high school, vocational (Adjusted PRR: 0.64; P: 0.04) or college education (Adjusted PRR: 0.41; P: <0.001), visited the dentist more than 12

months prior (Adjusted PRR: 0.7; P: 0.03), and experienced one or more DAEs (Adjusted PRR: 0.7; P: 0.02) were less likely to rate the access to care as high. On the contrary, high income (Adjusted PRR: 1.65; P: 0.03), married (Adjusted PRR: 2.63; P: <0.001) or divorced (Adjusted PRR: 2.3; P: <0.001) participants who had children (Adjusted PRR: 2.25; P: <0.001) and visited private dental clinics (Adjusted PRR: 1.45; P: 0.02), were more likely to rate the access to care as high.

b) Technical Quality: Similarly, participants who were middle-aged (25-44 yrs (Adjusted PRR: 2.11; P: 0.02); 45-64 yrs (Adjusted PRR: 2.18; P: 0.03)) coloured or mixed race (Adjusted PRR: 2.01; P: 0.01), high school or vocational school graduates (Adjusted PRR: 1.79; P: 0.04), and cleaned their teeth less than once daily (Adjusted PRR: 2.05; P: 0.01), were more likely to rate the technical quality as high. Individuals who had at least one dental visit in preceding the 12 months (Adjusted PRR: 0.69; P: 0.04) were less likely to rate the technical quality as high.

c) Structure and Facilities: Participants who were neutral about their last dental visit (Adjusted PRR: 20.29; P: <0.001), visited a non-licensed dental provider (Adjusted PRR: <0.01 P: <0.001) and belonged to the Middle income (R50,000 to R149,000 (Adjusted PRR: 0.65; P: 0.02)) economic bracket, had negative perceptions of the quality of the structure and facilities at the dental clinic. Retired participants (Adjusted PRR: 1.62; P: 0.01)) had positive perceptions of the quality of the structure and facilities at dental clinics.

d) Communication: Having a dental visit more than 12 months (Adjusted PRR: 0.71; P: 0.02), and being neutral (Adjusted PRR: 0.58; P: 0.01) or dissatisfied (Adjusted PRR: 0.46; P: 0.02) with the last dental visit was associated with a decreased likelihood of rating the quality of communication as high.

e) Global Safety Rating: Participants who were dissatisfied or extremely dissatisfied (Adjusted PRR: 0.59; P: 0.03)) with their last dental visits had a decreased likelihood of rating the overall safety of dental clinics as high.

## DISCUSSION

Our results reveal a sub-optimal perception of dental quality among South African dental patients. 41.4% of participants did not view the services received at dental clinics as high quality. Compared to their counterparts in the United Kingdom (UK), they fared worse, where 20% of UK respondents rated their care as sub-optimal, although they only assessed one dimension of quality.<sup>35</sup> When categorized into specific dimensions of quality, access to care received the lowest quality rating from 51.4% of participants. This calls for more attention by dental stakeholders in South Africa, especially as 'access to care' was mentioned as the most important factor affecting a patient's perception of dental quality in the UK as well.<sup>35</sup> Despite this fair overall rating of quality, it is important to note that the majority of participants (83.9%) rated the dental clinics as "safe" or "extremely safe". This high global rating is consistent with expectations because patients tend to be skewed towards the more positive response options when asked about overall healthcare ratings.<sup>9</sup> Their true care experiences are usually highlighted when pressed for the details about specific aspects of care, such as, wait times and medication errors.<sup>9</sup> In this study, there was no correlation between the overall perception of safety and the actual experiences of DAEs by participants, corroborates this theory even further.

Participants who had a previous DAE experience were less likely to rate the quality of access to dental care as high. Duplicate tests, poor wait times and the difficulty in getting emergency appointments received the most negative responses while clinic cleanliness/ hygiene and staff courtesy/ respect received the most positive responses. These findings compare with a study about patient-reported measures of quality from five countries (United States, Australia, Canada, New Zealand, and United Kingdom).<sup>36</sup> The UK (36%) and Canada (37%) ranked lowest on emergency wait times, while the US ranked last on efficiency because patients had to repeat tests multiple times (22%), or repeat their medical history to multiple providers (57%).<sup>36</sup> Another study in the US identified waits and delays, poor communication, and problems with the environment and amenities as the most commonly reported problems with service quality.<sup>16</sup> They also found that despite the high incidence of service quality incidents, the patients (two-thirds) still rated the overall quality of care as excellent, which again confirms the theory that global ratings are skewed towards more positive

responses.<sup>16</sup> One explanation given was that patients consider their overall hospital experience when giving global ratings and this may not capture good experiences, such as emotional support or favorable clinical outcomes, that were not covered in the survey questions.<sup>16</sup>

Patient satisfaction emerged as the factor most associated with an increased positive perception of quality across all five dimensions of quality and safety (bivariate analysis). While satisfaction has been intricately linked to the perception of quality,<sup>11,37</sup> it is all but one perception of quality that is predominantly affected by one's expectations.<sup>38</sup> The conceptual framework described by Sofaer et al identified sociocultural norms, previous experiences, personal characteristics, knowledge of what to expect, extent of choice, patient needs, and reputation of provider as the baseline factors influencing patient expectations.<sup>9</sup> They surmised that patient expectations and patient experiences of care were the primary influencing factors on a patient's perception of care, which ultimately affects their definition and perception of quality.<sup>9</sup> The degree to which one's perception is affected by expectations and/ or experiences varies between individuals and over time within-person.<sup>9</sup> In dealing with this issue, Sixma et al demonstrated that a more reliable approach was to look at an algorithm of performance, importance and impact scores for the various aspects of healthcare.<sup>1</sup> Sixma's conceptual framework was based on the prior work of Zastowny et al<sup>39</sup> in the Patient Experience Survey (PES) and has influenced the development of instruments, such as the QUOTE<sup>20-22,40-44</sup> (QUality Of care Through the patient's Eyes) and CQI (Consumer Quality Index),<sup>19, 23, 45-50</sup> for assessing patient-reported care quality across various disciplines. Dentistry is yet to develop a validated patient-reporting instrument of its own.

In this study, patient characteristics such as age (middle-aged), race (coloured or mixed), marital status (married, divorced), child status (no children), employment status (retired), household income (>R150,000 or 9200 USD) and educational status (high school or vocational education) were associated with an increased likelihood of having a better experience of care and higher rating of quality. This is similar to findings from another study where being older, less educated, married and of a high social status was significantly associated with greater patient satisfaction.<sup>51</sup> One explanation for this finding is that



healthcare providers tend to be more respectful and responsive to the needs of middle-aged or older patients as well as wealthier individuals compared to younger and poorer ones.<sup>51</sup> Perhaps, on the contrary, highly educated and single patients have higher expectations of care quality and apply more stringent assessments to their ratings of care quality compared to less educated and married individuals. In a study by Haviland et al, race was also found to be a significant factor affecting one's rating of healthcare services.<sup>52</sup> This was consistent with findings by Tickle et al among dental patients in the UK.<sup>35</sup> Although our expectation was that the 'white' population would have higher ratings of care quality due to tenuous racial history of the sub-region<sup>53</sup>, it was the 'coloured or mixed' race that had significantly higher ratings of care quality (technical quality and effectiveness). This calls for a further exploration of the impact of socio-demographic variables on patients' perceptions of dental quality.

## **CONCLUSION**

Patient perceptions of quality offer an insight into our performance as dental providers. The extent to which the patient's needs and expectations are met often determine their perceptions of quality. Our study findings suggest that the dental profession is behind in meeting these expectations. Working to develop standardized instruments for dentistry will afford researchers the opportunity to assess patient experiences of dental care quality more reliably rather than just being limited to patient satisfaction measures. In the end, providing care that is patient-centered is an indication of quality and should be our ultimate goal.

## **ACKNOWLEDGEMENTS**

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## TABLES

**Table 5.1: Reliability (Internal Consistency)**

<b>Dimensions of Quality</b>	<b>Cronbach's <math>\alpha</math> Coefficient</b>
A) Access to Care	0.62
B) Technical Quality, Efficiency and Effective Organization of Care	0.83
C) Structure and Facilities	0.71
D) Communication, Information and Courtesy	0.92
<b>Overall</b>	<b>0.77</b>

**Table 5.2: Detailed Dimensions of Dental Quality and Safety, showing Percentage Positives and Mean scores**

<b>Dimensions of Quality</b>	<b>Percent Positive (95% CI)</b>	<b>Mean ± SD</b>
<b>A) Access to Care</b>		
I was able to get an appointment within <b>24hrs</b> for a <b>dental emergency</b>	55.3 (49.8-60.7)	2.6±1.1
I was able to get an appointment within <b>one month</b> of my preferred date for <b>routine check-up /cleaning</b>	59.7 (54.3-65.2)	2.7±1.0
I was able to get an appointment within <b>one month</b> of my preferred date to see a <b>dental specialist</b> (e.g. for surgery)	58.4 (52.5-64.3)	2.6±1.1
I got turned away when I could not afford to pay for my dental treatment*	77.8 (72.6-83.0)	3.3±1.1
I had to travel more than 45 minutes to get to the dental clinic*	56.3 (50.8-61.8)	2.6±1.2
I was able to see the dental provider within <b>one hour</b> of my appointment	46.7 (41.1-52.2)	2.5±1.0
I found it hard getting into the dental clinic because of my physical disability*	91.6(86.9-96.2)	3.7±0.8
<b>B) Technical Quality, Efficiency and Effective Organization of Care</b>		
The clinic staff asked questions to confirm my identity before I was taken into the treatment area	84.8 (81.1-88.5)	3.4±0.9
The dental provider asked questions to confirm my identity before starting treatment	74.6 (70.1-79.2)	3.1±1.1
The dental provider asked about changes to my overall health before starting treatment	66.6 (61.6-71.6)	2.9±1.1
The dental provider asked about changes to the medicines that I take regularly, at every visit	65.8 (60.6-70.9)	2.9±1.2
The dental provider appeared to understand my overall health history well	74.3 (69.6-78.9)	3.1±1.0
The dentist confirmed the location of my dental problem before starting treatment	93.3 (90.6-96.0)	3.6±0.7
Before starting treatment, the dentist confirmed that I didn't feel any pain after giving the injection	87.9 (84.2-91.5)	3.5±0.8
The dentist protected my throat (with gauze or an elastic sheet on a bracket) when there was a potential for something to go down my throat	78.0 (73.2-82.8)	3.2±1.1
The dentist followed up with me after any major treatment to ensure that I did not have any problems	56.0(50.1-61.8)	2.7±1.2
Whenever I was sent to a new dentist, I had to repeat the tests that I did at the previous dentist*	36.9(31.0-42.8)	2.1±1.1
<b>C) Structure and Facilities</b>		
The clinic was kept clean	95.9(93.8-98.0)	3.7±0.6
The treatment area was well organized	91.1(88.0-94.2)	3.6±0.7
The instruments used in treating me appeared clean	97.6(95.9-99.3)	3.8±0.5
The dental providers washed their hands before starting treatment	92.5(89.6-95.4)	3.6±0.7
I noticed blood stains in the treatment area*	93.4(90.5-96.2)	3.8±0.7
The dental staff used a lead cover/apron to protect me when I needed to have an x-ray	92.0(89.0-95.0)	3.7±0.7
<b>D) Communication, Information and Courtesy</b>		
The dentist listened to me carefully	89.0(85.6-92.4)	3.5±0.7
I believe the dentist understood my dental problems	87.7(84.2-91.3)	3.4±0.8

<b>Dimensions of Quality</b>	<b>Percent Positive (95% CI)</b>	<b>Mean ± SD</b>
The dentist explained the treatment that I needed in a way that I could easily understand	88.9(85.5-92.3)	3.5±0.8
The dentist asked for my permission before starting any major treatment	87.1(83.4-90.8)	3.4±0.8
The dentist told me what he or she was going to do before he or she did a procedure	89.1(85.7-92.5)	3.5±0.8
The dentist explained the things I needed to do at home in a way that I could easily understand after every treatment	85.2(81.2-89.1)	3.4±0.9
The staff spoke to me with respect	88.6(85.2-91.9)	3.6±0.8
The dentist spoke to the other dental staff with respect	94.6(92.3-97.0)	3.7±0.6
The dentist explained the results of any tests to me in a way that I could easily understand	88.6(85.2-92.0)	3.5±0.8
Whenever I was sent to a new dentist, the purpose of the referral was very clear to me	86.7(82.8-90.6)	3.5±0.8
<b>E) Global Rating of Safety</b>		
On a scale of 1 to 10, with 1 being 'extremely unsafe' and 10 being 'extremely safe', how safe (harmless) are the dental clinics that you have visited in South Africa?	83.9(79.3-88.5)	8.15±2.07

<sup>†</sup>Percentage positives were obtained by combining the responses from all participants who responded with "always" (4) or "usually"(3) on the likert scale (1 to 4); the higher the percentage, the more positive the experience; Percent positives for each construct represent the percentage of participants who selected the two highest response options for each line item ('Always' and 'Usually' or 'Extremely safe' and 'Safe' for category 5);

<sup>§</sup>The mean score represents the average score obtained from all participants for every item on the likert scale (1 to 4). Higher values represent more positive experiences by participants;

<sup>\*</sup>Original items were reverse-coded for data analysis to mirror the other items, which ranged from the least positive (1) to the most positive (4) experience.

**Table 5.3: Distribution of Patient-Reported Dimensions of Quality and Safety by Participant Characteristics (Bivariate Analysis)**

Characteristic	Total, N (%)	Access to Care	Technical Quality	Structure & Facilities	Communication	Global Safety Rating
<b>Total, N</b>	440	389	383	376	374	249
Mean ± SD	-	2.8±0.7	3.1±0.7	3.7±0.5	3.5±0.6	4.3±0.98
Percent Positive, %	-	48.6(43.6-53.6)	55.9(50.9-60.9)	62.8(57.9-67.7)	63.9(59.0-68.8)	83.9(79.3-88.5)
<b>Gender</b>						
Male	114(37.3)	60 (42.3) <sup>§</sup>	56(35.2)	66(37.3)	65(35.9)	80(38.65)
Female	192(62.7)	82 (57.8)	103(64.8)	111(62.7)	116(64.1)	127(61.35)
<b>Age</b>						
18-24yrs	39(13.3)	20 (15.2)	15(10.1)	21(12.5)	21(12.3)	28(14)
25-44yrs	140(47.8)	61 (46.2)	75(50.3)	78(46.4)	83(48.5)	97(48.5)
45-64yrs	77(26.3)	28 (21.2)	37(24.8)	47(28.0)	46(26.9)	48(24)
65yrs+	37(12.6)	23 (17.4)	22(14.8)	22(13.1)	21(12.3)	27(13.5)
<b>Race</b>						
Black African	89(29.2)	39 (27.7)	42(26.4)	51(29.1) <sup>§</sup>	47(26.1) <sup>§</sup>	45(21.74)
White	198(64.9)	91 (64.5)	103(64.8)	109(62.3)	117(65.0)	145(70.05)
Coloured or Mixed	18(5.9)	11 (7.8)	14(8.8)	15(8.6)	16(8.9)	17(8.21)
<b>Employment Status</b>						
Employed	115(39)	53 (38.4)	57(37.7)	65(38.9)	68(39.3)	79(38.92)
Unemployed	135(45.8)	59 (42.8)	67(44.4)	75(44.9)	79(45.7)	89(43.84)
Retired	45(15.2)	26 (18.8)	27(17.8)	27(16.2)	26(15.0)	35(17.24)
<b>Educational Level</b>						
Less than high school (GR 12)	40(14.2)	19 (14.5)	19(13.1)	23(14.3)	27(16.6)	26(13.27)
High school graduate or vocational training	148(52.5)	70 (53.4)	79(54.5)	87(54.0)	83(50.9)	98(50)
College graduate or higher	94(33.3)	42 (32.1)	47(32.4)	51(31.7)	53(32.5)	72(36.73)
<b>Children</b>						
Yes	202(67.8)	91 (65.5)	104(67.5)	117(68.8)	117(66.1)	134(65.69)
No	96(32.2)	48 (34.5)	50(32.5)	53(31.2)	60(33.9)	70(34.31)
<b>Marital Status</b>						
Single-never married	112(36.1)	41 (28.9)	52(32.1)	60(33.7)	59(32.2)	63(31.98)

<b>Characteristic</b>	<b>Total, N (%)</b>	<b>Access to Care</b>	<b>Technical Quality</b>	<b>Structure &amp; Facilities</b>	<b>Communication</b>	<b>Global Safety Rating</b>
Married or civil partnership	108(34.9)	58 (40.8)	58(35.8)	68(38.2)	69(37.7)	71(36.04)
Divorced, separated or widowed	90(29)	43 (30.3)	52(32.1)	50(28.1)	55(30.1)	63(31.98)
<b>Annual Household Income</b>						
Low income (<R50,000)	148(57.8)	60 (51.7)	80(59.3)	88(60.3)	92(59.7)	99(57.56)
Middle income (R50,000 to 149,999)	61(23.8)	32 (27.6)	29(21.4)	30(20.5)	36(23.4)	41(23.84)
High income (R150,000+)	47(18.4)	24 (20.7)	26(19.3)	28(19.2)	26(16.9)	32(18.6)
<b>Last Dental Visit (Time)</b>						
Less than 12 months	228(52.2)	113 (60.1)	126(59.2)	137(58.6)	141(59.2)	128(61.24)
More than 12 months	179(41)	75 (39.9)	87(40.8)	97(41.4)	97(40.8)	81(38.76)
No previous dental visit	30(6.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Last Dental Visit (Location)</b>						
State dental clinic	252(57.7)	109 (58.3)	134(63.2)	151(64.8) §	150(63.2)	128(61.84)
Private dental clinic	147(33.6)	72 (38.5)	70(33.0)	77(33.1)	80(33.8)	73(35.27)
Other. e.g. non-licensed	38(8.7)	6 (3.2)	8(3.8)	5(2.1)	7(3.0)	6(2.9)
<b>Satisfaction with Last Dental Visit</b>						
Extremely satisfied or satisfied	295(69.1)	149 (80.1) §	157(74.8) §	185(79.7) §	186(79.2) §	162(77.88) §
Neutral	76(17.8)	21 (11.3)	37(17.6)	25(10.8)	32(13.6)	30(14.42)
Dissatisfied and extremely dissatisfied	56(13.1)	16 (8.6)	16(7.6)	22(9.5)	17(7.2)	16(7.69)
<b>Oral Health Status</b>						
Satisfied with dental health	184(42.3)	88 (46.8)	97(45.5)	100(42.7)	115(48.5) §	100(48.08) §
Not satisfied with dental health	251(57.7)	100 (53.2)	116(54.5)	134(57.3)	122(51.5)	108(51.92)
<b>General Health Status</b>						
Satisfied with overall health	369(85.2)	167 (88.8)	189(88.3)	202(86.0)	213(89.5) §	184(88.04)
Not satisfied with overall health	64(14.8)	21 (11.2)	25(11.7)	33(14.0)	25(10.5)	25(11.96)
<b>Oral Hygiene Habits</b>						
Clean teeth at least once daily	349(94.3)	157 (97.5)	173(94.5)	192(97.0)	193(97.0)	189(95.45)
Clean teeth less than once daily	21(5.7)	4 (2.5)	10(5.5)	6(3.0)	6(3.0)	9(4.55)
<b>Cleaning Product</b>						

<b>Characteristic</b>	<b>Total, N (%)</b>	<b>Access to Care</b>	<b>Technical Quality</b>	<b>Structure &amp; Facilities</b>	<b>Communication</b>	<b>Global Safety Rating</b>
Toothbrush and fluoride toothpaste or non-fluoride toothpaste	212(57.3)	57 (35.2)	78(42.4)	80(40.6)	80(40.2)	66(33.67)
Others. e.g. chewstick	158(42.7)	105 (64.8)	106(57.6)	117(59.4)	119(59.8)	130(66.33)
<b>DAE Experience</b>						
Experienced no DAE	240 (54.5)	102(54.0)	117(54.7) §	127(53.8) §	126(52.7) §	91(43.54) §
Experienced one or more DAEs	200 (45.5)	87(46.0)	97(45.3)	109(46.2)	113(47.3)	118(56.46)

\*Binary variables for patient-reported dimensions of quality were obtained by categorizing constructs into "1" High quality (above the mean of collapsed items within that construct) and "0" Low quality (below the mean of collapsed items within that construct);

§ Significant p-values  $\leq 0.05$  for Chi-squared ( $\chi^2$ ) or Fisher's Exact Test



**Table 5.4: Patient-reported Dimensions Of Quality And Associated Factors**

	Access to Care	Technical Quality	Structure & Facilities	Communication	Global Safety Rating
<b>Age</b>					
25-44yrs		✓(+)			
45-64yrs		✓(+)			
<b>Race</b>					
Coloured or Mixed		✓(+)			
<b>Employment Status</b>					
Retired			✓(+)		
<b>Educational Level</b>					
High school graduate or vocational training	✓(-)	✓(+)			
College graduate or higher	✓(-)				
<b>Children</b>					
No	✓(+)				
<b>Marital Status</b>					
Married or civil partnership	✓(+)				
Divorced, separated or widowed	✓(+)				
<b>Annual Household Income</b>					
Middle income (R50,000 to 149,999)			✓(-)		
High income (R150,000+)	✓(+)				
<b>Last Dental Visit (Time)</b>					
More than 12 months	✓(-)	✓(-)		✓(-)	
<b>Last Dental Visit (Location)</b>					
Private dental clinic	✓(+)				
Other. e.g. non-licensed			✓(-)		
<b>Satisfaction with Last Dental Visit</b>					
Neutral			✓(-)	✓(-)	
Dissatisfied and extremely dissatisfied				✓(-)	✓(-)
<b>Oral Hygiene Habits</b>					
Clean teeth less than once daily		✓(+)			
<b>DAE Experience</b>					
Experienced one or more DAEs	✓(-)				

Significant variables after adjusting for gender, age, race, employment status, economic status, educational status, marital status, child status, past dental history, oral health status, general health status, oral hygiene habits and past DAE experience; ✓(+): Positively associated; ✓(-): Negatively associated

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## CHAPTER SIX: CONNECTING THE DOTS (DISCUSSION)

The studies presented above provide a glimpse into the various types of quality and safety events that occur at dental offices. Using a two-pronged approach (published case reports and patient reports), I have painted a picture of the nature, severity and sequelae of dental quality and safety events. Chapter three primarily looked at the use of published case reports to understand safety events and their sequelae among dental patients, while chapters four and five used patient reports to understand safety and quality events at the dental office respectively. In a nutshell, these studies confirm that quality and safety events do occur in dentistry and cause significant morbidity (and even mortality) to our patients. In the introduction, I established that a binding creed of all healthcare providers is to first, do no harm. Nonetheless, as demonstrated by these studies, dental providers are causing harm to their patients; it is time to begin systematically addressing patient safety in dentistry on a global scale.

The patient survey revealed that 45.5% of patients experienced one or more safety events when they visited the dentist in South Africa (1.6 events per respondent). To put this in context, the incidence of AEs from nationally representative samples of hospitalized patients across several countries given in the introduction ranged from 2.9% to 16.6%.<sup>33, 43</sup> Although the estimate from this study is by no means nationally representative and more work is still needed to establish baseline estimates for the incidence of DAEs across dental offices, it raises an alarm. The combined quality rating was similar; about 41.4% of participants rated the quality of dental care they received as sub-optimal. This percentage is higher than the UK study by Tickle et al<sup>128</sup> where about 20% of participants rated their care quality as sub-optimal using only one dimension of quality. However, what immediately stands out is the overwhelming number of patients who still rated the overall safety of dental care as 'safe' or 'extremely safe' despite the high rates of DAEs reported. One explanation can be the general unreliability of global rating scales (patient responses tend to be skewed in the positive direction) or the seeming low severity of harm experienced by patients (58.3% of cases were classified as mild). There was no global rating of quality, however, a prior DAE experience negatively affected the 'Access to care' quality rating and this was significant.

Regarding the types of DAEs captured by both data sources (case reports and patient reports), we observed that diagnosis-related harm topped the charts for the published case reports (23%) while intra-oral hard tissue injury, such as adjacent tooth damage, was the most commonly reported adverse event by patients (30.4%). The former, which were predominantly from Europe and North America, also tended to present more severe DAEs (permanent harm in 24.4%; death in 11.1%) than the latter, where only 14.3% of patient reports were classified as moderate to severe harm. However, ‘never events’ such as wrong tooth extractions or wrong-site procedures occurred in 7% of patients surveyed in the South African study. Furthermore, while most patients (62.5%) in this study reported that the clinic was aware of the event occurring and took steps to ameliorate the effect of the event (60.9%), most DAEs in the published case reports were detected after the patient had concluded the dental visit (64.4%) and in most cases the patient presented to another dentist, a physician or the emergency room for follow-up treatment. 41.4% of patients surveyed in the South African teaching practice reported having a follow-up event, of which unplanned dental visits, unplanned dental treatments and unplanned x-rays ranked the highest. Almost all published case reports, required a follow-up intervention. In 6.7% of these cases, an intervention was required to sustain life.

Categorizing the types of DAEs was a challenging issue because most DAEs did not fit within the typical AE categories used in medicine, e.g., the WHO International Classification for Patient Safety (ICPS).<sup>84</sup> There was considerable overlap between incident type categories and DAEs often cut across several categories. Also, events such as adjacent tooth damage (e.g. luxation or undermining of filling integrity) could not be captured by any of the ICPS incident types. My dilemma was to find “buckets” that were granular enough to capture each DAE without being too cumbersome for any meaningful interpretation by researchers. I focused primarily on categorizing the type of harm experienced by the patient, versus the error that led to the harm or the stage of treatment when the harm occurred. My initial list comprised 22 categories (see appendix 3.1; chapter three) but later evolved into twelve (Table 4.2; chapter four) categories through an iterative process. The table (6.1) below shows the final twelve dental incident types.

**Table 6.1: Dental Incident Type Categories**

1) Allergy/ Toxicity/ Foreign body Response
2) Aspiration/ Ingestion of Foreign Body
3) Pain
4) Infections
5) Wrong-side/wrong-site, wrong-procedure, and wrong-patient events (W-SPP)
6) Bleeding
7) Intra-oral Hard Tissue Damage
8) Intra-oral Soft Tissue Injury/ Inflammation
9) Nerve Injury
10) Other Systemic Complications
11) Other Oro-facial Complications
12) Other Harm

Similarly, because most DAEs don't lead to mortality, capturing the various nuances of morbidity in a severity scale proved a challenge. I started with an adaptation of the Institute for Healthcare Improvement's (IHI) severity scale<sup>129</sup> (categories E1-I; see appendix 3.2 in chapter three), and sub-divided categories E (temporary harm) and G (permanent harm) into four categories each, depending on the requirement for minimal or significant intervention. We have now evolved into a simpler severity scale shown in Figure 6.1 below. The scale still maintains the original E-I categories but divides both E and G into two - mild or moderate and severe harm. The flowchart starts from the left side and researchers move through a series of questions to determine which category to assign the DAE.

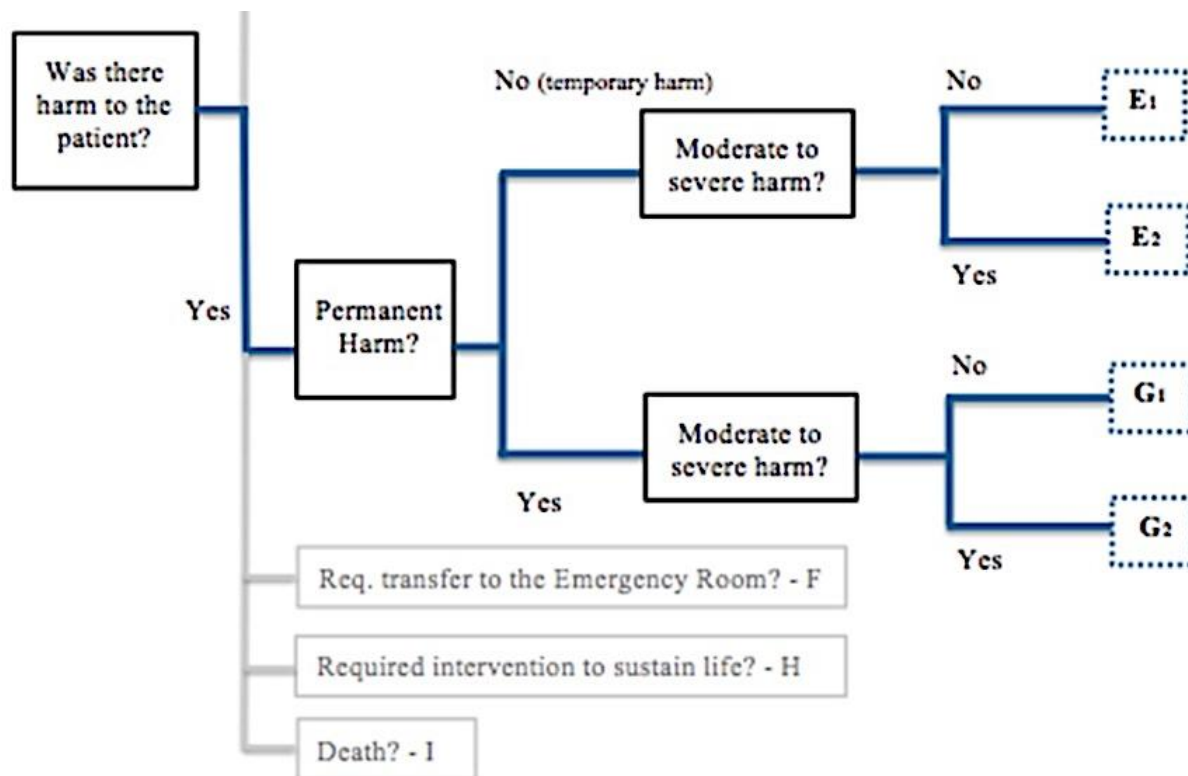


Figure 6.1: Flowchart for assigning a dental severity rating

The quality events were categorized into four main patient-defined dimensions as defined by Sofaer et al<sup>123</sup>. Some categories were collapsed for simpler analysis. The ‘access to care’ dimension received the lowest positive perception of quality (48.6%; mean: 2.8±0.7) while ‘communication’ received the highest positive perception of quality (63.9%; mean: 3.5±0.6). Patients had the most positive perception (97.6%; mean: 3.8±0.5) of the question “The instrument used in treating me appeared clean” but rated the question “Whenever I was sent to a new dentist, I had to repeat the tests that I did at the previous dentist” very low (36.9%; mean: 2.1±1.1). Items that assessed wait times (46.7%), ease of getting appointments (55.3%) and follow up with test results (56%) were the next lowest rated quality items. These findings are again similar to findings by Tickle et al where positive responses were associated with “good interpersonal communication, politeness and being put at ease” while negative responses were associated with poor wait times and high cost of care.<sup>128</sup> Access to care was judged to be the most important factor by the public in their assessment of quality. This implies that dental professionals are behind in providing good quality care to their



patients especially in the area of access to care and following up test results. However, we seem to do a much better job communicating with the patients and putting them at ease.

The factors associated with an increased likelihood of experiencing a safety or quality event varied. They have been discussed extensively in chapters four and five. In summary, patients were more likely to report a DAE if they were young (18-24 years), wealthy (annual household income:  $\geq$ R150,000 or 9200 USD), dissatisfied with their last dental visit and not satisfied with their dental health. Since there have not been many dental studies assessing dental patients' experiences of adverse events, it's difficult to compare our study findings. However, a study by Adams et al of New York state residents found that wealthy but middle-aged (30-65 years) individuals reported more experiences of medical errors.<sup>130</sup> On the other hand, satisfaction with last dental visit was significantly associated with high ratings for all the dimensions of quality. This feeds into the theory that patient satisfaction is intricately linked to a patient's perception of quality and should be dissociated from patient quality assessments by measuring their actual experiences of quality events,<sup>131</sup> for example, if a provider offered a standard treatment regimen associated with a definitive diagnosis.

### **Future Direction and Next Steps**

This dissertation highlights some key issues pertaining to dental quality and safety. Although it is by no means comprehensive, it lays a foundation for future studies using the two-pronged approach (published case reports and patient reports). The figure below (6.2) sums up how dental practice managers and organizational leaders might want to think about safety measurements and monitoring as we develop safety systems for dentistry. They offer a series of questions and prompts that are worth considering: 1) Has patient care been safe in the past? 2) Are our clinical systems and processes reliable? 3) Is care safe today? 4) Will care be safe tomorrow? 5) Are we responding and improving?

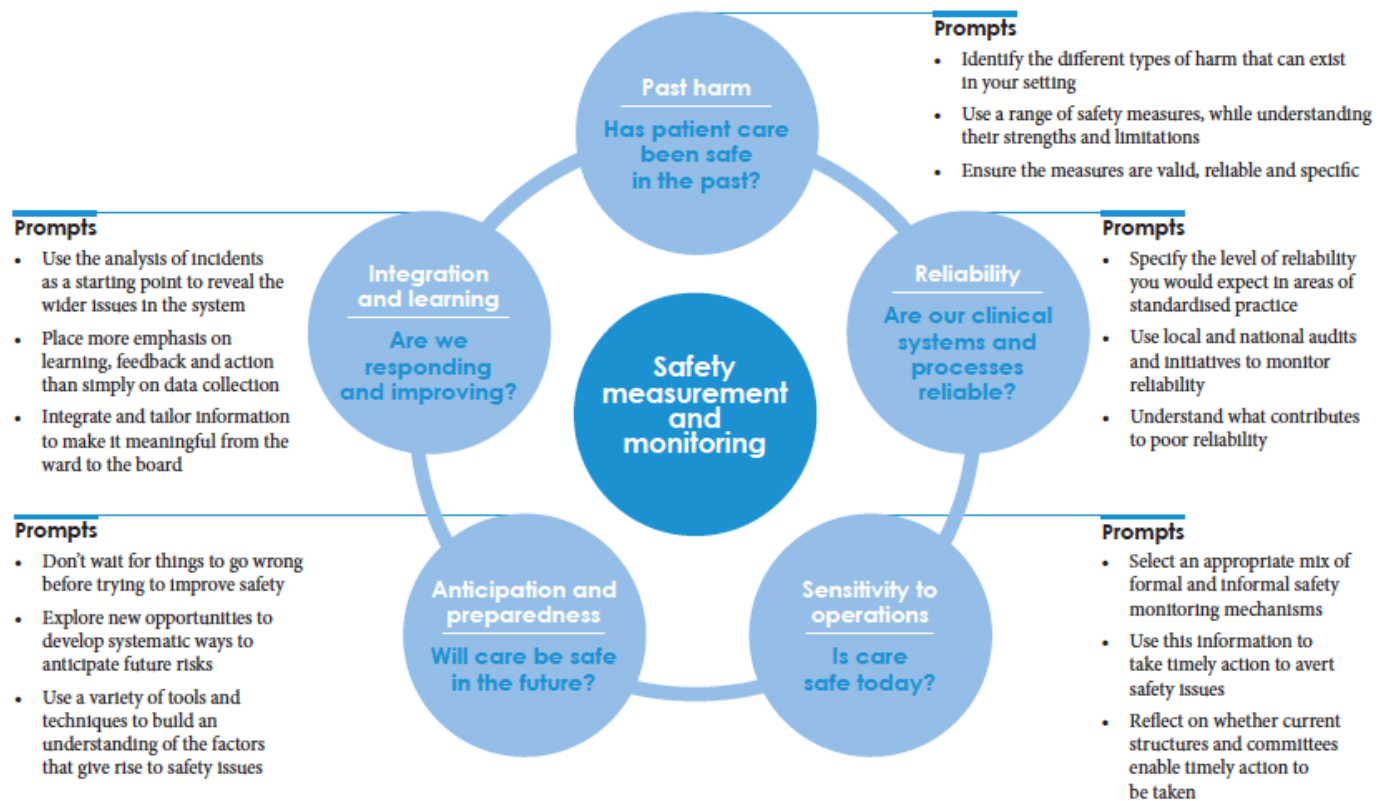


Figure 6.2: The framework for measuring and monitoring safety – and useful prompts for using it in practice  
[http://www.health.org.uk/sites/default/files/TheMeasurementAndMonitoringOfSafety\\_fullversion.pdf](http://www.health.org.uk/sites/default/files/TheMeasurementAndMonitoringOfSafety_fullversion.pdf)

In general, future dental patient safety research needs to involve:

- 1) Determining the true scope and magnitude of dental quality and safety events by conducting multi-site studies across various dental settings using a multi-pronged approach to establish nationally representative baseline rates for dental quality and safety events;
- 2) Comparing these rates among countries and across continents;
- 3) Developing a standardized dental patient safety taxonomy and defining key concepts/terms through a consensus process;
- 4) Establishing a centralized dental patient safety reporting system using both provider reports, chart reviews, patient reports and real-time surveillance;
- 5) Encouraging the development of a dental patient safety case report journal to foster provider reporting and learning in a non-threatening manner;

- 6) Developing and testing strategies that will address dental quality and safety issues with a view to reducing dental errors and improving the quality of dental care delivery systems;
- 7) Empowering dental patients and their families to participate actively in their care; to act as vigilant observers, partnering with providers to improve quality and safety;
- 8) Increasing patient and family engagement in safety research using mixed methods and when developing safety systems to ensure that these activities are patient-centered and that patients are kept abreast with the results of these research initiatives;
- 9) Formulating national patient safety policies that will guide all stakeholders and drive the direction of research towards the specific priorities for that country;
- 10) Forming global partnerships to promote the sharing of knowledge, tools and strategies across countries and continents, especially from developed nations to developing or transitional nations.

At every level (patient, provider, organizational, national and international), there is room for improvement. The table below shows the recommendations to improve patient safety in the WHO African region for policy, partnership and stakeholders based on an evaluation of the work of the APPS.<sup>87</sup>

Table 6.2: Recommendations for Improvement<sup>87</sup>

Policy	Partnership	Stakeholder
<ol style="list-style-type: none"> <li>1. Build capacity for national patient safety policy and strategic planning to leverage action on patient safety at the WHO Regional level.</li> <li>2. Disseminate the findings from this evaluation briefing to ministries of health in Africa as well as key organizations involved in APPS.</li> <li>3. Use the evaluation briefing to support advocacy efforts for the partnership-based approach as a powerful vehicle to improve patient safety and quality of care.</li> </ol>	<ol style="list-style-type: none"> <li>1. Build a strong patient safety partnership network, using WHO/SDS (Patient Safety) web-based mechanisms.</li> <li>2. Use the patient safety partnership network to deliver training and education (e.g. webinars, addressing the knowledge gaps highlighted in the evaluation).</li> <li>3. Use the network to further promote south-south collaboration.</li> <li>4. Review and simplify APPS resources.</li> <li>5. Consider broadening the pool of technical expertise available to support and advise the programme, e.g. engineers, behaviourists, anthropologists.</li> <li>6. Empower partners to undertake resource mobilization to address infrastructure constraints.</li> <li>7. Undertake an APPS-Private Organization's for Patient Safety collaborative project to address current lack of ABHR supplies.</li> <li>8. Strengthen sharing between partnerships e.g. using APPS web platform and other media.</li> <li>9. Synthesize information on key benefits accrued by "northern" partners participating in APPS.</li> </ol>	<ol style="list-style-type: none"> <li>1. Continue collaboration and advocacy with partnership focused organizations e.g. Tropical Health Education Trust (THET), ESTHER and others to promote the importance of funding future improvement work that builds on and consolidates APPS.</li> <li>2. Work with THET-Engineers without borders collaboration to address issues around maintenance and repair of patient safety related equipment.</li> <li>3. Strengthen patient and community engagement through active collaboration with relevant organizations.</li> </ol>

## CHAPTER SEVEN: CONCLUSION

I firmly believe that dentistry is at the cutting edge of defining quality and safety research. Although our medical counterparts have a head start, dentistry is catching up. While dentistry bears some similarity to outpatient, ambulatory or primary care medicine, there are unique features, such as the volume of surgical procedures performed at the dental office, which distinguish it from primary care medicine. The implication is that dentistry cannot just borrow strategies from primary care medicine, but the profession needs to chart its own course by developing strategies that are specific to the way dental care is provided. Ongoing research efforts<sup>98, 127</sup> have provided some of the tools used in this study, for example, the Dental Adverse Event Incident Types and the Dental Adverse Event Severity Scale.

Through this dissertation, I have shown that quality and safety events do occur in dentistry, and that they occur at higher rates than have been observed in hospital medicine. All specific aims were successfully achieved and the study findings confirm the rationale that patient reports and published case reports are reservoirs of valuable information regarding quality and safety events. I also successfully addressed the identified gaps in the literature by bringing in the patient's perspective, expanding the scope of DAEs reported and exploring a previously unexplored geographic location (Sub-Saharan Africa).

Several strategies and next steps have been proposed throughout this dissertation. What is clear however is that for the profession to move forward in establishing patient safety and quality as the standards of care, more work is needed. We first need to promote a good safety culture where dental providers can feel comfortable to report their experiences of quality and safety events. Then we need to establish a centralized safety reporting system for providers. In the absence of a centralized safety reporting system, patients can be tapped to offer some insight into their experiences through a patient safety incident reporting system.

Dental offices and organizations need to develop specific policies that foster patient involvement in safety efforts. Patient advocacy groups need to be empowered and strong partnerships with national and international chapters encouraged. In addition, providers should be encouraged to publish their experiences and lessons learned in a DAE case report

journal. We need to learn from these experiences by promptly analyzing any DAE reports and providing feedback to staff and providers in a systematic manner. Researchers also need to begin developing tools and testing strategies for tackling the identified incidents and their causes in order to minimize dental errors and the occurrence of DAEs.

In summary, a lot can be learned and has indeed been learned, from the work done by our medical counterparts, however, the dental profession is ostensibly at a point where it can also make an impact in outpatient patient-centered safety learning through the work that is being done.

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For fallibilism is the doctrine that our knowledge is never absolute but always swims, as it were, in a continuum of uncertainty and of indeterminacy.

—C. S. Peirce