Characteristics of adverse events in primary health care in Brazil

Características dos eventos adversos na atenção primária à saúde no Brasil

Características de los eventos adversos en la atención primaria de salud en Brasil

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Abstract

This study aimed to evaluate the occurrence of incidents in primary health care in Brazil. Fifteen health professionals working in Family Health Strategy units agreed to anonymously and confidentially record incidents over the course of five months, using the questionnaire Primary Care International Study of Medical Errors *(PCISME) questionnaire adapted to the Brazilian context. The overall rate of incidents was 1.11%. The rate of incidents that did not reach patients was 0.11%. The rate of incidents reaching patients but without causing harm was 0.09%. The rate of incidents reaching patients and causing adverse events was 0.9%. Eight types of most frequent errors and administrative failures were identified. Communication failures were the most common contributing factor to incidents in primary health care (53%). The findings show that incidents occur in primary health care (as elsewhere in the health system), but research in this area is still incipient.*

Patient Safety; Health Evaluation; Primary Health Care

Resumo

Neste estudo procurou-se avaliar a ocorrência de incidentes no cuidado à saúde ao paciente na atenção primária brasileira. Quinze profissionais de saúde que trabalham em unidades da Estratégia Saúde da Família aceitaram registrar de forma anônima e confidencial, incidentes ocorridos com os pacientes durante cinco meses, através do questionário Primary Care International Study of Medical Errors *(PCISME) adaptado para o contexto brasileiro. A taxa de incidência envolvendo todos os incidentes foi de 1,11%. A taxa de incidentes que não atingiram os pacientes foi de 0,11%. A taxa de incidência de incidentes que atingiram os pacientes, mas não causaram dano foi de 0,09%.A taxa de incidência de incidentes que atingiram os pacientes e causaram evento adverso foi de 0,9%. Foram identificados oito tipos de erros e os erros administrativos foram os mais frequentes. A comunicação foi citada como sendo o fator contribuinte mais comum para ocorrência de incidente na atenção primária à saúde (53%). Os achados desse estudo demonstram que os incidentes também ocorrem na atenção primária à saúde, entretanto deve-se considerar que as pesquisas neste campo ainda são incipientes.*

Segurança do Paciente; Avaliação em Saúde; Atenção Primária à Saúde

Introduction

Many health care professionals and institutions that believed they were providing quality care have recently discovered the risks of incidents for patients. Studies in various countries have revealed alarmingly high rates of adverse events, thus calling the attention of policymakers, administrators, health professionals, and patients [1]. A significant number of strategies have been proposed to improve quality and thus attenuate health care risks [2]. Patient safety has been acknowledged as one of the most important attributes in improving quality of care [2].

The report *To Err is Human* [3] published by the U.S. Institute of Medicine in 1999, based on a retrospective review of hospital patient charts in New York, Colorado, and Utah, revealed the magnitude of the problem and sparked efforts to improve patient safety. Subsequent studies also focused on hospital care, leaving a knowledge gap concerning the nature and frequency of incidents and harm reduction for patients in primary health care [4].

An international effort is underway to conduct more studies on patient safety in primary health care. A systematic review [4] showed that although studies are still incipient, several methods have been used more extensively to measure harm and understand its causes. Such methods include analysis of incidents in reporting systems. The most frequently found incidents in primary health care in these studies have been associated with medication and diagnosis, and the most relevant contributing factors for incidents have been communication failure between members of the health care team.

In recent years in Brazil, with the implementation of the Family Health Strategy (FHS), access to services has expanded, thus increasing the number of patients treated in PHC [5]. The FHS accounts for a major share of the care provided by the Brazilian Unified National Health System (SUS) [5]. The model seeks to adopt patient care practices that are more comprehensive, interdisciplinary, and humanized, in which communication among health professionals is essential.

In the search for continuous improvement of health care quality in Brazil, the Ministry of Health has developed models for evaluating the quality of care provided by the FHS. The year 2005 witnessed the tool *Evaluation of Quality Improvement in the Family Health Strategy* (AMQ) [6], followed in 2011 by the *National Program for Improvement of Access and Quality in Primary Care* (PMAQ) [7]. The PMAQ [7] spearheaded a national evaluation of health care conditions in FHS units: quality of care was classified as fair in some 44% of services. The evaluations showed that 62% of health professionals failed to follow the recommended protocols for initial clinical workup, and that only 38% of health professionals in the units reported using clinical protocols in urgent care.

Although research on patient safety in primary health care is still incipient, there are several methods available in the international literature to evaluate incidents related to patient care in primary health care. A recent systematic literature review [8] detected no studies on the theme in Brazil, thus revealing a gap in knowledge on the Brazilian reality.

Two important questions arise: (i) do safety incidents or adverse events occur in the primary health care setting in Brazil, as in other countries? (ii) are the types of safety incidents and the most frequent contributing factors in primary health care in Brazil similar to those that occur elsewhere in the world?

The current study thus sought answers concerning the occurrence of incidents in patients, the types and severity of incidents in primary health care, and contributing factors in the Brazilian context.

Material and methods

Study design

An observational, descriptive, prospective study was performed in 13 FHS units in urban areas in municipalities belonging to the coastal lowlands region of the State of Rio de Janeiro, Brazil, after obtaining authorization from the municipal health administrators to invite health professionals in these units to answer a questionnaire on incidents related to patient care.

Context and participants

Twenty professionals working in the municipal health departments in the coastal lowlands region of Rio de Janeiro were selected as a convenience sample. These professionals, ten physicians and ten nurses, recorded the care provided in the Information System on Primary care (SIAB), with a weekly workload of at least 20 hours in these units. The participants recorded their gender, age, professional training, time since graduation, specialty, and time working in the FHS.

Participants were asked to anonymously and confidentially record at least ten incidents detected during their work shift over the course of five months, from October 1st, 2013, to February 28th, 2014. Participants could choose whether to answer electronically or on paper. To guarantee

the professionals' anonymity, the questionnaires were identified with a letter for each profession, "P" for physicians and "N" for nurses, and were numbered from 1 to 125 as they were completed and returned.

During the initial contact, participating health professionals received an explanation on the terms used in the questionnaire and a list with descriptions of examples of possible incidents and a tutorial for completing the questionnaire.

Of the 20 professionals invited to participate in the study, three physicians refused to participate and two nurses failed to return the questionnaire in time, even after a second contact. Of the 17 professionals who agreed to participate, 15 (88%), or seven physicians and eight nurses, returned the properly completed questionnaires. Among the participating professionals, 12 (80%) were females and three (20%) were males. Age varied from a 24-year-old nurse to a 72-year-old physician.

Data collection instrument

Among the methods described in the literature [8] to evaluate patient safety in primary health care, the current study opted to apply a questionnaire for health professionals based on the Australian study *Primary Care International Study of Medical Errors* (PCISME) [9]. This questionnaire aims to evaluate whether some incident occurred during care, and if so, to characterize it and determine its severity and contributing factors.

The questionnaire was chosen because it was pioneering and available online at no cost and had already been replicated in several countries, including a Portuguese-language translation for a study in Portugal [10].

The PCISME questionnaire was translated and adapted to the Brazilian context by an expert panel using the modified Delphi method [11]. Our study followed the stages used in the Australian study, adopting the available guidelines. The main adjustment to the Brazilian context was the inclusion of nurses for answering the questionnaire rather than only physicians as in Australia, due to the organizational characteristics of primary health care in Brazil.

The questionnaire consists of 16 open and closed questions for physicians and nurses to record patient incidents that had occurred in the FHS units, with guaranteed anonymity, where each questionnaire was used to record a single incident.

Variables and data analysis

The answers to the questionnaires were organized to allow identifying the reasons for incidents; those that did not reach patients; those that reached patients but did not cause harm; and those that reached patients and caused harm. To calculate incident rates, the numerator was the sum of incidents reported by participants and the denominator was the sum of patient consultations performed by participants during the five-month period (information recorded in the SIAB (Departamento de Informática do SUS. Sistema de Informação da Atenção Básica. http://www2.datasus.gov.br/SIAB/index.php, accessed on 30/Oct/2014). The result of this fraction was multiplied by one hundred.

The study adopted the definitions used in studies on patient safety in the International Classification for Patient Safety (ICPS) of the World Health Organization (WHO) [12]. The ICPS defines an incident as an event or circumstance that could have resulted or did result in unnecessary harm to the patient, from intentional or intentional acts. The incident may or may not reach the patient. When it does, it may or may not cause harm. When it does not cause harm, it is called a harmless incident, and when it causes harm it is called an adverse event. Patient safety is defined as the reduction of risk of unnecessary harm associated with health care to an acceptable minimum [12].

Table 1 was created to describe: the types of incidents, contributing factors, their consequences for patients, and the severity of harm. Contributing factors were classified according to the definitions found in studies on safety in primary health care [8] and grouped as: failures in communication with patients; failures in communication between professionals; administrative failures; failures in care; and communication failures in the health care network. We calculated the proportion of contributing factors that were classified and the severity of harm among the incidents recorded in the questionnaires.

A scale was used to classify the severity of harm: minimal harm (recovery within a month), moderate harm (recovery from a month to a year), permanent harm, death. There was also the option: "I have no way to classify the harm" [9].

Often the health professionals (physicians in particular) assessed the existence of error or harm according to its consequences for the patient. Therefore, a patient safety expert redefined the types of incidents attributed by the participants according to the ICPS definition [12].

Errors that contributed to incidents were classified as in studies that used the PCISME [9,10]

Table 1

General characteristics of 125 patients according to type of incident.

Characteristics/Categories	Incidents that did not reach the patient n (%)	Reached the patient but did not cause harm n (%)	Adverse events n (%)	Total n (%)
Sex				
Male	10 (17.5)	11 (19.3)	36 (63.2)	57 (45.6)
Female	11 (16.2)	26 (38.2)	31 (45.6)	68 (54.4)
Age bracket (years)				
≤ 9	1 (10.0)	4 (40.0)	5 (50.0)	10 (8.0)
10-19	1 (12.5)	2 (25.0)	5 (62.5)	8 (6.4)
20-59	15 (23.4)	21 (32.8)	28 (43.8)	64 (51.2)
≥ 60	4 (9.3)	10 (23.3)	29 (67.4)	43 (34.4)
Presence of chronic diseases				
Yes	13 (15.5)	21 (25.0)	50 (59.5)	84 (67.2)
No	8 (19.5)	16 (39.0)	17 (41.5)	41 (32.8)
Social vulnerability				
Yes	5 (8.6)	17 (29.3)	36 (62.1)	58 (46.4)
No	16 (23.9)	20 (29.9)	31 (46.3)	67 (53.6)
Total	21 (16.8)	37 (29.6)	67 (53.6)	125 (100.0)

in other countries: errors in office administration; investigation errors; treatment errors; communication errors; payment errors; errors in health care workforce management; errors in the execution of a clinical task; diagnostic errors. According to the PCISME [9], errors in office administration indicate: chart completion errors; appointment errors; errors in the patient flow through the health care system; logistic errors leading to lack of inputs and medicines; errors in the maintenance of a safe physical environment; difficulties in access to specialists; switches in names of medicines, incorrect interpretation of prescriptions in the pharmacy, health care professionals refuse treatment to patient. Each error's proportion was calculated in relation to the total errors.

Ethical considerations

Informed consent was obtained from each participant, guaranteeing subjects' anonymity in disclosing the results, freedom to withdraw consent at any moment, and information on final use of the information produced by the study.

The study was approved by the Ethics Research Committee of the Sergio Arouca National School of Public Health, Oswaldo Cruz Foundation (ENSP/Fiocruz), case n. 303.649, on June 14, 2013.

Results

A total of 125 incidents were recorded out of 11,233 patient consultations (Departamento de Informática do SUS. Sistema de Informação da Atenção Básica. http://www2.datasus.gov.br/SIAB/index.php, accessed on 30/Oct/2014) performed by participating health professionals during the five-month period. The overall incident rate was 1.11% (95%CI: 0.93-1.32). Since according to the questionnaire each incident corresponded to an error, the error rate can also be considered 1.11%. The rate of incidents that did not reach patients was 0.11% (13/11,233; 95%CI: 0.06-0.20). The rate of incidents that reached patients but did not cause harm was 0.09% (10/11,233; 95%CI: 0.04-0.16). The rate of incidents that reached patients and caused harm (adverse events) was 0.91% (102/11,233; 95%CI: 0.74-1.10).

Of the 131 questionnaires that were returned to the researcher, six (4.6%) were excluded because the items "age", "patient's sex", and "result of the incident" had not been completed, and contact with the professional to complete the information was not possible because of anonymity. The final analysis included 125 valid questionnaires, each of which represented an incident.

Table 1 shows the 125 patients' general characteristics according to type of incident.

The majority of patients with recorded incidents were adults (n = 64, 51%) and females (n =

68, 54%). The majority of patients presented chronic diseases (n = 84; 67%) and had a complex health problem [12] (n = 50, 59%), described as a condition involving difficult clinical management [13], ranging from the presence of comorbidities to alcohol and/or drug addiction, including neurological and psychiatric disorders. Although the questionnaire did not ask to describe the patient's complex health problem, the participants referred to mental health problems in eight patients.

Nearly half of the patients (n = 59, 47%) were exposed to some form of social vulnerability [14]. Of these, 24 (40.7%) had low income, 23 (40%) were illiterate or had low schooling, 16 (27.1%) had problems with alcohol or drugs, (22%) lived in substandard housing conditions, 10 (16.9%) were unemployed, 10 (16.9%) had several children, and 29 (49.1%) had other unspecified conditions. As for the type of incident, the most frequent was adverse events (53.6%), followed by incidents that reached the patient but without causing harm (29.6%).

Table 2 lists the types of incidents, consequences for the patient, contributing factors, and severity of harm.

Table 2

Types of incidents, consequences for patient, contributing factors, and severity of harm.

Type of incident	Severity	Consequence	Contributing factors
Adverse events	Minimal harm	Drug allergy	Allergenic predisposition. Failure to take complete patient history (communication failure with patient)
Adverse events	Minimal harm	Decompensated diabetes	Lack of medicine in pharmacy (administrative failures)
Adverse events	Minimal harm	Decompensated schizophrenia	Lack of medication and appropriate prescription form (administrative failures)
Adverse events	Minimal harm	Pregnant woman with clinical complication	Delay in delivering lab test. Laboratory far from patient's neighborhood (administrative failures)
Adverse events	Minimal harm	Severe malnutrition	Elderly patient unable to explain problem to physician. Lives alone, little schooling, no family support. Professional with little time for the consultation (communication failure with patient)
Adverse events	Minimal harm	Complications of hypertension, required hospitalization	Did not understand correct use of medication. Took wrong dose, can't read (communication failure with patient)
Adverse events	Minimal harm	Medication did not produced desired effect in treatment of hypertension	Lack of proper clinical follow-up of patient. Failure in staff training (patient care failures)
Adverse events	Minimal harm	Elderly patient with hypotension and dehydration	Drug-drug interaction /wrong dosage of medication (patient care failures)
Adverse events	Minimal harm	Hyperglycemia	Lack of medication (administrative failures)
Adverse events	Minimal harm	Hospitalized for hypoglycemia	Patient fails to take medication or eat when alone. Failure in family and caregiver support (failures in staff communication)
Adverse events	Minimal harm	Intense headache	The only specialist in the municipality failed to make the patient's diagnosis or conduct an adequate physical examination, and ignored the referral from the FHS. Full agenda, overconfident; fatigue (patient care failures)
Adverse events	Minimal harm	Patient with heart disease stopped taking medication	Lack of funds to purchase medication (administrative failures)
Adverse events	Minimal harm	Patient with intense headache, without diagnosis	No access to neurologist and complex tests. Patient with serious social problem and stress requires support from health care unit and access to specialties (communication failure in the health care network)
Adverse events	Minimal harm	Complication in clinical condition	Patient refused to attend nursing consultation out of distrust for nursing care (communication failure with patient)
Adverse events	Minimal harm	Fever, local pain, and edema	Received wrong dose of vaccine due to error by nurse technician (patient care failures)
Adverse events	Minimal harm	Complication of a respiratory allergy	Patient failed to take medication. Shortage of medication in the pharmacy (administrative failures)

(continues)

Table 2 (continued)

Type of incident	Severity	Consequence	Contributing factors
Adverse events	Minimal harm	Complication of a respiratory allergy	Patient failed to take medication. Shortage of medication in the pharmacy (administrative failures)
Adverse events	Minimal harm	Gynecological complications	Failure in diagnosis by the only specialist in the municipality, who failed to conduct a physical examination and ignored the examination by the FHS. Full agenda, overconfident, fatigue (patient care failures)
Adverse events	Minimal harm	Decompensated hypertension + obesity	Failure in access to specialist. Communication failure within the multidisciplinary team (communication failure in the health care network)
Adverse events	Moderate harm	Complication of hypertension. In treatment for lupus	Patient stopped taking medication due to financial difficulties. Failure in access to medication in the municipal pharmacy (administrative failures)
Adverse events	Moderate harm	Nervous breakdown	Abandoned treatment. Communication failure between health team members in the FHS, mental health, and the hospital (communication failure with patient)
Adverse events	Moderate harm	Reduced mobility due to knee arthrosis	Physical therapist responsible for home care refused treatment (patient care failures)
Adverse events	Moderate harm	Complications in transfusion therapy	Blood bag switched (patient care failures)
Adverse events	Moderate harm	Patient hospitalized because of switched medications	Patient took medication incorrectly and in the wrong amount. Failure in family support and communication by health care professional (communication failure with patient)
Adverse events	Moderate harm	Hypoglycemia	Excessive dose of medication was prescribed and patient was hospitalized (patient care failures)
Adverse events	Moderate harm	Incorrect diagnosis of lupus	Lab tests analyzed incorrectly. Laboratory error leading to test reorder (patient care failures)
Adverse events	Moderate harm	Diarrhea	Medication expired. Pharmacy failed to observe expiration date (patient care failures)
Adverse events	Moderate harm	Diarrhea and fever	Nurse technician failed to notice child's last vaccination date and vaccinated on the wrong date. Failure in staff training and commitment (patient care failures)
Adverse events	Moderate harm	Facial paralysis due to allergy to dipyrone. Hospitalized.	Physician failed to take patient history and prescribed contraindicated medication (communication failure with patient)
Adverse events	Moderate harm	Tachycardia	Patient took medication that had expired. Lack of pharmacist in FHS units (administrative failures)
Adverse events	Moderate harm	Patient in crisis failed to receive care	Psychiatrist on vacation and no one saw the patient. Professional neglect (patient care failures)
Adverse events	Moderate harm	Abscess in leg	Incorrect technique in application of vaccine. Lack of experience and deficient professional training (patient care failures)
Adverse events	Moderate harm	Decompensated hypertension and hyperglycemia	Shortage of medication in pharmacy. Patient could not take medication (administrative failures)
Adverse events	Moderate harm	Altered blood glucose	Patient took wrong medication. Rushed appointments, without proper patient history. Failure in home follow-up by community health workers (communication failure with patient)
Adverse events	Moderate harm	Patient with seizure, unable to schedule appointment with neurologist	No appointment with specialist, no test results. Failure in organization of health care network (communication failure in health care network)
Adverse events	Moderate harm	Patient dehydrated, malnourished	Unable to obtain hospital admission. Family uninformed and low schooling (communication failure in health care network)
Adverse events	Moderate harm	Altered blood glucose	Patient does not follow staff instructions. Failure in follow-up by FHS team (communication failure with patient)
Adverse events	Moderate harm	Allergic reaction to medications	Failure in interaction between nursing staff and patient (communication failure with patient)
Adverse events	Moderate harm	Hypotension	Excess medication due to incorrect clinical management, due to failure to listen to patient. Rushed appointments (communication failure with patient)

(continues)

Table 2 (continued)

Type of incident	Severity	Consequence	Contributing factors
Adverse events	Moderate harm	Worsening of clinical condition due to delay in cancer diagnosis	Delay in test results and lack of specialist to examine patient (communication failure in health care network)
Adverse events	Moderate harm	Elderly patient with hypertension, not taking medication	Fails to pick up medication at pharmacy due to family breakdown. A family leaves elderly patient at home alone (failures in staff communication)
Adverse events	Moderate harm	Local pain, edema, fever	Unwanted effect from vaccine. Failure in patient orientation (patient care failures)
Adverse events	Moderate harm	Chest pain	Delay in care at emergency unit (UPA) (communication failure in health care network)
Adverse events	Moderate harm	Tachycardia	Switched medication. Failure in drug dispensing and problems with physician's handwriting. Lack of electronic patient chart (failures in staff communication)
Adverse events	Moderate harm	Dehydration in elderly patient	Failure in home visit. Failure in nursing triage (patient care failures)
Adverse events	Moderate harm	Worsening of chronic renal failure	Three to four-month delay in scheduling appointment with the only medical specialist (communication failure in health care network).
Adverse events	Permanent harm	Depression with suicidal tendency	Patient refuses treatment. No support from a mental health team (communication failure with patient)
Adverse events	Permanent harm	Amputation of lower limb	Lack of personal care/hygiene. Not following diet or prescribed medication. Lack of family support (communication failure with patient)
Adverse events	Permanent harm	Decompensated hypertension + obesity	Difficult access to specialist. Failure in health team communication (failures in staff communication)
Adverse events	Permanent harm	Decompensated diabetes resulted in foot lesion	Lack of patient's adherence to treatment. Lack of patient monitoring by FHS team (communication failure with patient)
Adverse events	Permanent harm	Atrophy of lower limbs	Incorrect diagnosis/lack of access to physical therapy (patient care failures)
Adverse events	Permanent harm	Stroke	Patient failed to follow physician's orientation. Failure to inform patient and family about severity of case (communication failure with patient)
Adverse events	Permanent harm	Decompensated chronic illness	Lack of patient monitoring by FHS team (communication failure with patient)
Adverse events	Permanent harm	Stroke. In treatment for hypertension	Difficult access to specialist (cardiologist) (communication failure in health care network)
Adverse events	Permanent harm	Complications of stroke	Lack of physical therapy service and follow-up by FHS (administrative failures)
Adverse events *	Permanent harm *	Brain lesion in infant with fetal distress	Lack of adequate prenatal care and lack of location for adequate care for patient (patient care failures)
Adverse events	Permanent harm	Amputation of lower limb	Delay in scheduling tests. Failure to schedule tests and medical appointment (patient care failures)
Adverse events	Permanent harm	Patient had leg amputated	Specialist failed to detect arterial obstruction. Delay in scheduling high-complexity exam (patient care failures)
Adverse events	Permanent harm	Liver disease	Specialist failed to make diagnosis. Apathy on the part of specialist. Lack of specialized tests: liver biopsy (patient care failures)
Adverse events	Permanent harm	Stroke	Failed to undergo complex tests due to lack of documentation. Social service was slow to act. Failure in humanization program (patient care failures)
Adverse events	Permanent harm	Rapid evolution of cancer before reaching specialist	Delay in appointment with specialist. Delay in biopsy result (communication failure in health care network)
Adverse events	Permanent harm	Complication of diabetic foot	Error and delay in care. Lack of proper technique and adequate place for changing dressing (patient care failures)
Adverse events	Permanent harm	Complication from drug-drug interaction	Lack of ethics and technical knowledge. Irresponsibility (patient care failures)
Adverse events	Permanent harm	Elderly patient with facial injury, redness, and edema	Physical abuse by family member. Failure of the FHS team to engage with social service (failures in staff communication)

(continues)

Table 2 (continued)

Type of incident	Severity	Consequence	Contributing factors
Adverse events	Permanent harm	Liver disease in alcoholic patient	Failure in follow-up by FHS team to reduce patient's alcohol consumption (communication failure with patient)
Adverse events	Permanent harm	Atrophy of lower limbs in alcoholic patient	Failure in follow-up by FHS team to reduce patient's prolonged alcohol consumption and patient's failure to take medication (communication failure with patient)
Adverse events	Permanent harm	Worsening of Alzheimer disease in elderly patient	Patient fails to take medication correctly. Failure in follow-up by FHS team and family support (communication failure with patient)
Adverse events	Permanent harm	Psychiatric disorder	Lack of medication due to incapacity to dispense controlled medication (administrative failures)
Adverse events	Permanent harm	Stroke. Severe hypertension. Alcoholism	Patient's aggressive behavior and irregular use of medication. Failure in family support (communication failure with patient)
Adverse events	Permanent harm	Acute myocardial infraction. Hypertension, irregular use of medication	Patient's lack of awareness of health condition (communication failure with patient)
Adverse events	Permanent harm	Worsening of clinical status. Alcoholic, refuses to take medication or receive visit from community health workers	Alcoholism results in patient refusing treatment (communication failure with patient)
Adverse events	Permanent harm	Anorexia, depression, dehydration	Lack of access to psychiatrist and psychologist (communication failure in health care network)
Adverse events	Permanent harm	Torn biceps tendons	Diagnostic error by orthopedist, who failed to schedule surgery (patient care failures)
Adverse events	Permanent harm	Amputated foot due to diabetes	Incorrect dressing and treatment by nursing and physician staff (patient care failures)
Adverse events	Permanent harm	Neuropsychiatric disorder due to alcohol dependence	Lack of treatment for alcohol addiction (failures in staff communication)
Adverse events	Permanent harm	Worsening of clinical condition	Patient had to resubmit to preventive test due to failure to receive result. Organizational failure by laboratory and FHS (patient care failures)
Adverse events	Permanent harm	Evolution of obesity to grade 3. Decompensated hypertension	Difficulty in access to specialist and misinformation on proper nutrition. Lack of patient monitoring by FHS team (failures in staff communication)
Adverse events	Permanent harm	Atrophy of lower limbs	Lack of access to physical therapy (communication failure in health care network)
Adverse events	Death	Cardiovascular complications	Treatment delay at UPA (communication failure in health care network)
Adverse events	Death	Complication of chest pain	Hospital refused treatment. Communication failure between FHS and hospital (communication failure in health care network)
Adverse events	Death	Decompensated diabetes	Failure in patient follow-up by FHS (communication failure with patient)
Adverse events	Death	Hyperglycemia	Communication failure between FHS team and hospital (communication failure in health care network)
Adverse events *	Death *	Premature delivery due to urinary infection and hypertension. Newborn infant died	Pregnant woman was not referred to high-risk prenatal service, but seen by nursing staff. Failure in staff communication and noncompliance with protocol for high-risk pregnancy (failures in staff communication)
Adverse events	Death	Hypertension, requiring pacemaker, poorly assessed by specialist and died	Inadequate clinical assessment by cardiologist and inadequate tests (patient care failures)
Adverse events	Death	Acute respiratory failure, COPD	Patient refused treatment by FHS team, lives alone (communication failure with patient)
Adverse events	Death	Respiratory complications in elderly patient	Delay in treatment at UPA (communication failure in health care network)
Adverse events	Non-classifiable	Depression	Patient refuses treatment. No support from mental health team (communication failure with patient)

(continues)

Table 2 (continued)

Type of incident	Severity	Consequence	Contributing factors
Adverse events	Non-classifiable	Depression	Patient refuses treatment. No support from mental health team (communication failure with patient)
Adverse events	Non-classifiable	Evolution of obesity to grade 3. Decompensated hypertension	Difficulty in access to specialist. Misinformation on healthy eating. Lack of patient monitoring by FHS team (communication failure in health care network)
Adverse events	Non-classifiable	Uterine cervical cancer, despite annual Pap smear	Laboratory not prepared to conduct cytopathology tests, failure in quality inspection of laboratories (administrative failures)
Harmless incident	Non-classifiable	Pregnant woman with gestational diabetes, had premature delivery	Difficulty in access to specialist (communication failure in health care network)
Harmless incident	Non-classifiable	Patient had to redo lab tests	Material collected incorrectly. Failure in training lab technician (patient care failures)
Adverse events	Non-classifiable	Decompensated chronic illness	Patient missed appointment. Failure in follow-up by nursing staff and community health workers (communication failure with patient)
Adverse events	Non- classifiable	Respiratory failure in patient with HIV	Hospital refused treatment. Communication failure between FHS and hospital (communication failure in health care network).
Harmless incident	Non-classifiable	Patient with intense headache, unable to undergo cranial computed tomography	Reception forgot to schedule, and when they did schedule the test, there was no vehicle to transport the patient (patient care failures)
Adverse events	Non-classifiable	Psychiatric crisis	Skipped controlled prescription medication. Failure in access to specialist and in referral services (communication failure in health care network)
Harmless incident	Non-classifiable	Patient failed to take prescribed medication	Patient can't read and is unable to distinguish which medication to take. Failure in support and communication from community health workers (communication failure with patient)
Harmless incident	Non-classifiable	Patient's chart disappeared. Difficulty in conducting diagnosis	Patient chart filed in wrong place. Insufficient number of receptionists and insufficient training (patient care failures)
Harmless incident	Non-classifiable	Patient chart switched	Wrong medication prescribed for patient. Lack of electronic patient chart and trained reception staff (patient care failures)
Harmless incident	Non-classifiable	Patient chart disappeared. Difficulty prescribing medication	Patient chart filed incorrectly. Failure in training reception staff (patient care failures)
Adverse events	Non-classifiable	Patient undiagnosed, even when seen by specialists	Lack of professional interest. Lack of communication between professionals. Failure in completing referral and counter-referral form (patient care failures)
Incident did not reach patient	Non-classifiable	Wrong patient chart	Failure to check patient's name on patient chart. Failure at reception (patient care failures)
Incident did not reach patient	Non- classifiable	Postpartum patient missed infant care appointment	Missed scheduled appointment. Mother's carelessness. Heavy workload for community health workers (communication failure with patient)
Harmless incident	Non-classifiable	Patient was not referred to specialist and went untreated	Lack of professional accountability for not having referred patient to specialist (patient care failures)
Adverse events	Non-classifiable	Edema and pain in right leg in child	Error in vaccination site. Lack of experience and poor professional training (patient care failures)
Incident did not reach patient	Non-classifiable	Child's name was not on appointment list. Mother missed a day of work	Work overload. Absence of reception staff. Carelessness and lack of training (patient care failures)
Incident did not reach patient	Non-classifiable	Patient's name was not on appointment list. Missed a day of work	Long wait for appointment, and patient was not able to be seen (administrative failures)
Harmless incident	Non-classifiable	Mistaken diagnosis of diabetes	Mistake on blood test. No clinical examination was performed. Limited involvement by health care professional. Low-quality laboratories (patient care failures)
Incident without lesion	Non-classifiable	Patient had to return to health care unit because the blood sample was insufficient	Lab technician did not draw sufficient blood. Deficient technical training (patient care failures)

(continues)

Table 2 (continued)

Type of incident	Severity	Consequence	Contributing factors
Incident without lesion	Non-classifiable	Patient had to return to health care unit because the blood sample was insufficient	Lab technician did not draw sufficient blood. Deficient technical training (patient care failures)
Harmless incident	Non- classifiable	Pregnant returned from hospital without adequate treatment, entered labor in the FHS unit	Lack of hospital beds. Lack of professional preparedness. Humanization (communication failure in health care network)
Incident did not reach patient	Non-classifiable	Patient charts switched due to identical names	Inadequate completion of registration forms. Failure in training for reception staff. Lack of electronic patient chart (patient care failures)
Incident without lesion	Non-classifiable	Patient with abdominal pain and bleeding, unable to schedule ultrasound	Failure in referral and counter-referral (communication failure in health care network)
Incident without lesion	Non-classifiable	Patient with hypertension, unable to schedule with cardiologist	Patient in financial straits. Failure in scheduling appointment in the SUS (communication failure in health care network)
Adverse events	Non-classifiable	Complication in patient with neurological disease	Medication administered incorrectly (patient care failures)
Adverse events	Non-classifiable	Complicated tonsillitis	Only used home remedies such as herbal teas. Failure to access pediatrics or FHS (failures in staff communication)
Incident without lesion	Non-classifiable	Patient decided not to take medication	Lack of information and low schooling. Failure in family support (communication failure with patient)
Incident without lesion	Non-classifiable	Patient missed medication	Lack of medication in pharmacy (administrative failures)
Incident did not reach patient	Non-classifiable	Patient arrived at scheduled time, but physician had already left	It was raining and patient was left with no transportation to return home. Failure by physician to comply with 40-hour workweek (patient care failures)
Incident did not reach patient	Non-classifiable	Pregnant woman arrived late, physician had already left	Patient lives far from health care unit (administrative failures)
Incident did not reach patient	Non-classifiable	Switched medication on prescription	Carelessness in dispensing. Physician's handwriting illegible. Lack of electronic patient chart (failures in staff communication)
Incident did not reach patient	Non-classifiable	Tests switched	Carelessness in delivering medication. Physician's handwriting illegible (failures in staff communication)
Incident did not reach patient	Non-classifiable	Patient was refused scheduling of tests, on grounds that he was not carrying any identification	Excess bureaucracy. Sluggish social service. Failure by patient to demand accountability (patient care failures)
Incident did not reach patient	Non-classifiable	Patient unable to schedule tests	Patient unable to enter scheduling line. Failure in referral and couter-referral (communication failure in health care network)
Incident did not reach patient	Non-classifiable	Elderly patient refused to take influenza vaccine	Misinformation. Failure in specific orientation / communication for the elderly (communication failure with patient)
Incident without lesion	Non-classifiable	Patient received another patient's test result.	Lack of electronic patient chart (patient care failures)
Incident without lesion	Non-classifiable	Community health workers failed to inform patient properly about family planning	Community health workers did not understand nursing staff's request and transmitted erroneous information. Failure in training (failures in staff communication)
Incident did not reach patient	Non-classifiable	Patient not treated at the health care unit	Power outage at the FHS unit, due to lack of a generator (administrative failures)

COPD: chronic obstructive pulmonary disease; FHS: Family Health Strategy; SUS: Brazilian Unified National Health System; UPA: Emergency Unit.

* The incident occurred with the child, not the mother.

As for severity of harm, among the patients that suffered adverse events, 32 (26%) experienced permanent harm, 27 (21%) presented moderate harm, and 18 (15%) suffered minimal harm. All the deaths (8) were classified as adverse events, of which 50% (4) occurred due to communication errors in the health care network, 25% (2) due to communication errors with the patient, 12.5% (1) due to communication errors in the health care team, and 12.5% (1) due to treatment errors. In 32% (40) of the incidents it was not possible to classify the severity, occurring in 42 % (17) in treatment errors, 20% (8) of communication errors in the health care network, 15% (6) in communication errors with patients, 13% (5) in administrative errors, and 10% (4) in communication errors in the health care team.

Factors contributing to incidents were: treatment errors (n = 44, 34%), administrative errors (n = 16, 13%), and communication errors (n = 65, 53%). The latter were classified as communication errors with patients (n = 30, 24%), in the health care network (n = 23, 19%), and within the health care team (n = 12, 10%).

The data obtained from the questionnaires allowed classifying the errors according to the typologies used in the Australian and Portuguese studies (Table 3). Payment errors with service providers did not apply to the Brazilian study's context. This was the approach used to compare the Brazilian study's results with those of other countries that used the PCISME questionnaire (Table 3). Administrative errors (26%) were the most frequent type in the Brazilian study, followed by communication errors (22%).

Physicians were the professionals most frequently involved in patient care errors, as in the Portuguese [10] and Australian [9] studies, namely 30% (38), followed by nurses with 13% (17), pharmacists with 12% (15), and community health workers with 5% (6). In 17% (22) of the reports, the patients themselves were identified as directly responsible for the error.

The largest proportion of errors occurred in the physician's office (25%), corroborating results from other countries. In second place came the hospital (15%), which was also seen in the Australian study (Table 4).

Eighty participants (64%) reported that they were aware of a previous occurrence of the same type of error. Meanwhile, 25 (20%) of the interviewees stated that it was rare for the same type of error to be recorded in other patients, and 20 (16%) said that the same type of error that occurred in the recorded incident is frequent in other patients.

Discussion

The overall incident rate was 1.11%, corresponding to the same error rate. In the Australian study [9] with the same methodological design, the error rate was 0.24%. The other studies that used the PCISME questionnaire did not calculate the specific rates of various types of incidents, probably because the taxonomy proposed by the WHO is quite recent [9,10,15].

Although primary health care mainly treats less complex cases, 82% of the incidents led to or caused harm to patients, including many severe cases (25%) and deaths (7%), unlike studies elsewhere in the world [16,17], which have mostly reported harm with minimal severity.

Table 3

Proportion of types of errors that contributed to incidents detected in the Brazilian, Portuguese, and Australian studies.

Errors	Brazilian study n (%)	Portuguese study n (%)	Australian study n (%)
Administrative errors	32 (26)	19 (48)	26 (20)
Errors in the investigation of tests	7 (5)	10 (25)	17 (13)
Treatment errors	24 (19)	2 (5)	38 (29)
Communication errors	27 (22)	6 (15)	20 (15)
Payment errors	0 (0)	0 (0)	1 (1)
Errors in human resources management	3 (2)	1 (2)	2 (1)
Errors in the performance of clinical tasks	17 (14)	0 (0)	7 (5)
Diagnostic errors	15 (12)	2 (5)	21 (16)
Total	125 (100)	40 (100)	132 (100)

Source: table based on Makeham et al. [9] (Australian study) and Sequeira et al. [10] (Portuguese study).

Table 4

Place where errors occurred, in the Brazilian, Portuguese, and Australian studies.

Place	Brazilian study %	Portuguese study %	Australian study %
Physician's office	25	62	64
Hospital	15	7	12
Patient's home	11	0	8
Pharmacy	10	2	4
Reception	9	10	0
Laboratory	8	5	6
Nursing station	7	2	0
Outpatient departments (specialties)	4	0	0
Immunization room	3	0	0
UPA	3	0	0
Telephone contact	2	5	4
Imaging laboratory	1	7	2
Transportation	1	0	0
Transfusion therapy service	1	0	0
Total	100	100	100

UPA: Emergency Unit.

Source: table based on Makeham et al. [9] (Australian study) and Sequeira et al. [10] (Portuguese study).

In the Brazilian study, the most frequent place where the error occurred was the physician's office (25%), corroborating findings from other countries, followed by the hospital (15%). It is important to consider the impact that an incident in primary health care can have on patients when they are treated at other levels of care; an indirect quality indicator for primary care called hospitalizations due to conditions sensitive to primary care [18] accounts for some 20% of hospital admissions in the SUS.

The highest number of incidents was detected in older patients – over 40 years of age (n = 57; 83%), with chronic diseases (n = 17; 68%), similar to the results of studies in the United States [19] and Canada [20], where the proportions in older patients were 81% and 92%, and in chronic diseases, with 60% and 63%, respectively. Thomas & Brennan [21] highlights that patients over 45 years of age were significantly more prone to suffer an adevrse events, due to the increase in prevalence of chronic diseases, with associated comorbidities, as a consequence of the epidemiological and demographic transition. In a study [22] in Brazilian hospitals, the 60-and-over age bracket also suffered the most adverse events.

Social vulnerability is a permanent concern in Brazil, and in this study nearly half of the patients that suffered incidents were vulnerable. Vulnerable patients generally show low treatment adherence and little autonomy to participate in the prevention of incidents [14]. In 17% (22) of the reports, patients themselves were identified as directly responsible for the error, due either to lack of adherence to the proposed treatment or lack of understanding of their health condition's severity.

The data obtained from the questionnaires allowed identifying types of errors classified in the international typologies. Using the typology, the results proved very similar in the Brazilian, Portuguese, and Australian studies, with a high prevalence of administrative errors.

An overly generic classification of errors and contributing factors can hide important information. Analysis of the contributing factors in the Brazilian and Portuguese studies showed relevant situations. The article on the Australian study did not disclose the causes of errors.

In the Brazilian study, in 38 incidents the principal contributing factor was structural, such as lack of medicines, referral beds, or support for follow-up of psychiatric patients. These factors were not found in the study from Portugal. Another specific situation in the Brazilian study was the lack of the health professional's commitment to the patient, reported in nine cases.

Communication was the most frequently cited contributing factor to incidents in primary health care (53%). Communication failure between health professionals contributed to 10%

of incidents, and the professionals reported such difficulties as difficult staff communication, differences of opinion and professional views, and differences in academic training, patient safety culture, behavior, schooling, professional hierarchy, and accountability to the patient. This difficulty can be exemplified by the following quote from questionnaire 55, completed by a nurse:

"*Difficult staff communication leads to rework in the health care unit. People rarely admit an error in front of the administrator, for fear of reprisals. People tend to pass the buck, leading to friction in interpersonal relations. Conflict becomes virtually inevitable*".

In order to improve communication among health professionals, it is necessary to promote open communication, in which professionals feel free to talk about errors that could affect patients, while making them feel comfortable to question their hierarchical superiors on patient safety issues, thereby strengthening teamwork with shared capacity for changes and motivation to act on safety's side [23].

Communication errors between professionals and patients were described in 24% of the records. Low treatment adherence was associated with the professionals' difficulties in establishing personal ties and qualified listening with patients, besides lack of sharing information.

One physician recorded his concern with communication with patients in questionnaire 61:

"*Those of us that work in family health always talk a lot with the family members and take into account what the patient says. But some colleagues don't even ask the patient's name, don't even know what the patient's complaint is, and then they go and ask the patient why they didn't bring their test results to the appointment or take their medication. I consider the physician/patient relationship one of the most important patient safety factors. This dialogue establishes a relationship of trust*".

In another situation, even with his concern in establishing a good physician-patient relationship, the physician that completed questionnaire 20 reported difficulties with a patient:

"*The patient hardly participates in his own treatment, even when I talk with him. He doesn't get involved in his health problems, fails to take his medication, and keeps drinking and smoking*".

Such communication failures had already been evidenced by the PMAQ [7]: some 41% of interviewed patients reported difficulties in clarifying doubts with health professionals, and had to schedule a new appointment as a result.

In the process of improving communication between the health professional and patient, the patient-centered approach should be prioritized, respecting the patient as an active element in the care process, allowing him to help manage his own care, including a possible adverse event [24]. The health professional should provide the patient with information adapted to the individual and the situation, considering level of schooling, cultural and linguistic specificities, and cognitive development. Effective communication benefits the health professional-patient relationship and is a direct factor for treatment adherence [25]. Information for patients should be clear and written whenever possible, encouraging and training them to contribute to their own safety and explaining their prescription [26].

Some 19% of the records described communication failures between health services. The Brazilian Ministry of Health [27] describes the FHS as a regulator of the health system, seeking comprehensive access in the health services network. Effective communication in the health care network requires linkage between the various professionals comprising the health care team and between different technologically hierarchical levels of care. Some feasible strategies are known, such as the implementation of referral and counter-referral systems, electronic systems for appointments and tests, mechanisms for patients to move in the network according to the line-of-care logic, and the humanization program [27]. However, the network's problems are evidenced by the following quote from the physician that completed questionnaire 56:

"*The patient waits for months for an appointment with the specialist, since there is only one breast specialist in the system to meet the entire demand. The disease progresses and we in the Family Health Strategy can't do anything*".

The contributing factors described as administrative failures [8] (13%) that compromise quality of services provided to patients and described in articles on safety in PHC include: lack of medical and surgical supplies and medicines, professionals pressured to be more productive in less time, patient chart errors, errors in receiving patients, inadequate infrastructure of the health unit, inadequate waste disposal at the health unit, overwork, and lack of computer and internet access.

A nurse describes a situation of administrative failure in questionnaire 26:

"*Administrators should be concerned about offering an acceptable minimum for working, since we've gone weeks without drinking water here at the health* [....]. *We can't close the clinic's doors, because we have to care for patients even if the working conditions are unhealthy*".

The national evaluation report by PMAQ [7] describes numerous management errors in the primary health care units. Only 30% of the units

evaluated by the PMAQ had one or more consultation rooms with a computer and internet connection, and only 18% of the health professionals in the units worked with electronic patient records. In only 45.5% of the units, patients were informed about available services, in 62% of the units the office hours were displayed to users, and the names and appointment hours for the attending healthcare professionals were available in 37% of the units.

Contributing factors listed as healthcare failures [8] (34%) were described as: drug treatment failures (mainly prescription errors); diagnostic errors; delay in diagnosis; delay in obtaining information and interpreting laboratory findings; failures in recognizing the urgency of the disease or its complications; and deficient staff knowledge. Participants recorded several suggestions on the questionnaires for improving care: implementation of electronic patient records, include a clinical pharmacist in the staff, continuing staff education, encouragement for a non-punitive culture, use of a support system for clinical decisions, clinical protocols, and staff involvement in strategies for implementing safe practice protocols. The nurse that answered questionnaire 102 stated:

"*When the health professionals converse and the work is integrated, discussing cases and evaluating problem situations, it is possible to avoid erroneous diagnostic interpretations, avoid blaming staff, and guarantee safer care for patients*".

The incident reporting system has been identified in the literature and by health authorities [28] as a mechanism capable of acting for quick correction of detected incidents. The system should be introduced as routine staff procedure, aimed at a safer culture. Even so, no participants in the current study mentioned it as a solution for the Brazilian context.

Final remarks

The theme of patient safety in promary health care has attracted increasing attention from the international health organizations [2] and from health systems in some developed countries, like Australia, United Kingdom, United States, and Portugal [29]. The theme has gained greater visibility in Brazil due to the National Program for Patient Safety [30] launched by the Brazilian Ministry of Health in 2013, which included primary health care as the locus for developing measures in patient safety improvement. Importantly, studies in this field are still incipient, and further research is needed.

The current study was one of the first to investigate incidents in primary health care in Brazil, and the results serve as relevant contributions to the field.

Adaptation of the PCISME questionnaire to the Brazilian context provided a specific instrument for measuring incidents in primary health care in the country, while calling attention to the harm occurring in these patients. Improvement of the questionnaire can help measure the frequency of patient care incidents and identify the contributing factors in Brazilian primary health care services.

The study showed that incidents are occurring in primary health care in a developing country like Brazil. Although the study was conducted in one health micro-region in the State of Rio de Janeiro, it may be representative of problems that occur elsewhere in the country. The fact that the findings are consistent with the literature suggests that they may be generalizable.

Resources such as strengthening teamwork with the inclusion of a pharmacist, support from information technology, continuing staff education, and involvement of patients appeared as important solutions in this field in both the field research and in the literature. An important challenge is awareness-raising of health policy-makers and health professionals for patient safety in primary health care. Difficulties with vulnerable patients are challenges for the system. The aim is to actively involve patients and their family in the process of care by providing them with information on safety measures and especially by giving them a voice in the process [31].

According to experts from the *Safer Primary Care* project [32], an important step for making care safer is the creation of an international information network, making the safety mechanisms for protecting patients in primary heaçth care known and applicable. Meanwhile, it is necessary to know and understand how cascades of errors lead to incidents. Incident reporting thus needs to be encouraged for such events to be investigated and to promote continuous learning to avoid incidents in the future. The creation of incident reporting systems is a way of collecting data that contribute to significant improvement in safety and quality of care. In order for such a system to be useful, it should be user-friendly, voluntary, and non-punitive, have safeguards for professional anonymity, be managed by trained personnel, and above all be a two-way mechanism [33].

Strengthening a culture of safety among health professionals is an important conditioning factor for institutional development of strategies to improve quality and reduce incidents in primary health care.

The study had some limitations: (i) there may have been low reporting of incidents due to some health care professionals' limited familiarity with the subject and the limited time for answering questionnaires; (ii) the results cannot necessarily be considered an expression of patient safety in primary health care as a whole, since this was a small convenience sample in one micro-region in one of Brazil's 27 states; and (iii) the reasons for incidents may have been underestimated due to the voluntary nature of incident reporting;

Despite revision by a patient safety expert to improve precision in the types of incidents reported, there may have been erroneous description of some errors according to their consequences for the patient, while the actual cause may not have been reported in some cases because of the participants' time constraints, thus compromising the reports' reliability [28].

Further research in this area should be part of Brazil's health policy agenda in order to ensure safer patient care.

Resumen

Este estudio trata de evaluar la ocurrencia de incidentes sanitarios con pacientes en la atención primaria de Brasil. Fueron aceptados quince profesionales de la salud que trabajan en las unidades de salud de la familia y registraron incidentes con pacientes durante cinco meses anónima y confidencialmente, a través del cuestionario Primary Care International Study of Medical Errors (PCISME), adaptado al contexto brasileño. La tasa de incidencia de todos los incidentes relacionados fue de un 1,11%. La tasa de incidentes que no llegan a los pacientes fue de un 0,11%. La tasa de ocurrencia de incidentes que afectan a los pacientes, pero no causó daño fue 0,09%. La tasa de ocurrencia de incidentes que afectan a los pacientes y causó eventos adversos fue de un 0,9%. Fueron identificados ocho tipos de errores y faltas administrativas que eran las más frecuentes. La comunicación se cita como el factor más común que contribuye a la ocurrencia de incidentes en la atención primaria de la salud (53%). Los resultados de este estudio demuestran que los incidentes se producen también en la atención primaria de la salud, sin embargo, hay que considerar que la investigación en este campo es aún incipiente.

Seguridad del Paciente; Evaluación en Salud; Atención Primaria de Salud

Contributors

The three authors collaborated equally in conceiving, implementing, and reporting the study.

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