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# Incidence and risk factors of procedure-related adverse events in a medical intensive care unit: a prospective observational study

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## THESIS

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By

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BORN ON 09/07/1996

TO OBTAIN A MEDICAL DOCTORATE

## KEYWORDS :

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## JURY

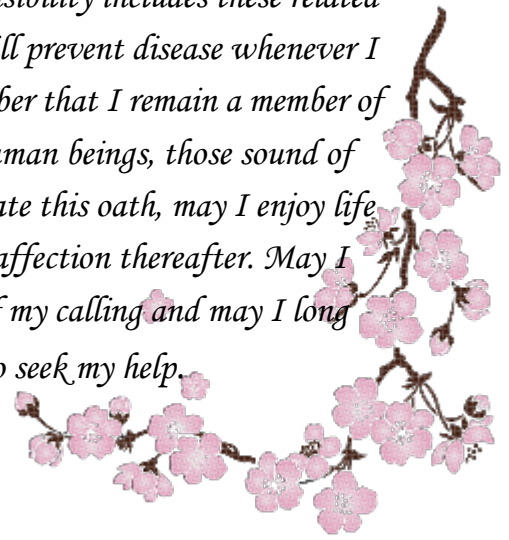
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# Hippocratic Oath

*I swear to fulfill, to the best of my ability and judgment, this covenant: I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow. I will apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of overtreatment and therapeutic nihilism. I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug. I will not be ashamed to say "I know not," nor will I fail to call in my colleagues when the skills of another are needed for a patient's recovery. I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. Above all, I must not play at God. I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick, I will prevent disease whenever I can, for prevention is preferable to cure. I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm. If I do not violate this oath, may I enjoy life and art, respected while I live and remember with affection thereafter. May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help.*



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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

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## **DEDICACIONES**

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*To my warrior parents, Nora and Khalid,*

*No words or expression can express my gratitude for all you have offered and endured for me, and I know you will always provide for me. Your presence by my side was a source of courage that helped me overcome all the obstacles.*

*I offer this work as recognition for the sacrifices, concern, and prayers I was showered with through the years.*

*I hope to be able to honor you more and more and be the image of your wishes.*

*Mama, Baba, je vous aime*

*To my little sister Aicha,*

*I'm proud of what you've accomplished and who you've become. Thank you for putting up with my grumpiness at times. Keep on aiming high; even more significant achievements await you. A big sister will always be there to support you.*

*To my stubborn sister Hajar,*

*You might think that you're all grown up now, well you're not! Annoying you is my favorite pass time (unfortunately for you). Keep growing tall and keep growing great. I'll always be behind you.*

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*In memory of my maternal grandpa Ba Driss,*

*This year we lost you, but you'll always be in our hearts.*

*"اللهم إن رحمتك وسعت كل شيء، فارحمه رحمةً تطمئن بها نفسه، وتقرّ بها عينه"*

*In memory of my paternal grandparents touria and zinelabidine*

*"اللهم يمن كتابهما ، ويسر حسابهما وثقل بالحسنات ميزانهما وثبتت على الصراط أقدامهما ، وأسكنهما في أعلى الجنّات ، بجوار حبيبك ومصطفاك صلى الله عليه وسلّم"*

*To my Beta reader Ryma,*

*Thank you for handling my crazy attitude, Reading my work, and providing feedback. Continue to have big dreams. Work diligently. You have a great future ahead of you.*

*To all the ADIB family,*

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*To all the EL HORRE family,*

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*To my Totally Spies: Houda, Yasmine, Salma, Bouchra*

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more to come. Inchaallah you will see Anas & Ryma just as great as you  
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*To my dear friend Manar,  
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with all the happiness in the world.*

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You're the friend I meet along the way that made the journey worthwhile.  
I'll keep wishing for your happiness and joy.*

*An Frau El haous und an alle meine Freunde  
Die ich beim Deutschlernen kennengelernt habe,  
Ihr habt einen besonderen Platz in meinem Herzen  
Ich wünsche ihnen Alles gute und viel Erfolg*

*And lastly,  
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I wanna thank me for never quitting.  
I wanna thank me for trying to do more right than wrong.  
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Mic drop*

*To all those who I might have forgotten to mention but not appreciate  
To all those who love and appreciate me  
To all those who marked my life in a small or a big way*

*I dedicate this work to you*

---

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---



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**Chairman of my thesis**

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**Judge of my thesis**

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**Judge of my thesis**

*Associate professor at the medical intensive care department  
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Judge of my thesis

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*I pray that joy and success never depart from your lives.*

*And to all those who contributed to the elaboration of this work in one  
way or another.*

*Please find here the expression of my endless gratitude*

---

# **ABBREVIATIONS**

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## Liste des abréviations :

<b>AE:</b>	adverse event
<b>IE:</b>	iatrogenic event
<b>WHO:</b>	world health association
<b>ICU:</b>	intensive care unit
<b>MICU:</b>	medical intensive care unit
<b>SOFA score:</b>	sequential organ failure assessment score
<b>CCI:</b>	Charlson comorbidities index
<b>OR:</b>	odds ratio
<b>LOS:</b>	length of stay
<b>AIDS:</b>	acquired immune deficiency syndrome
<b>IV:</b>	intravenous
<b>PO:</b>	per os
<b>MRSA:</b>	multi-resistant staphylococcus aureus

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# INTRODUCTION

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Error is an inherent condition of most, if not all, human activity. As it happens, medicine does not escape from this notion. And during its practice, it will undoubtedly be very plausible that the maxim attributed to Hippocrates, « Primum non-nocere» – the first thing is to not harm– will be violated more often than desired.

Iatrogenic events (IEs), also known as adverse, are defined as any injuries or illnesses resulting from medical care [1]. In Greek, "latros" means "doctor" or healer, and "gennan" means "as a result"; hence the literal translation to "as a result of a doctor."

The World Health Organization (WHO) [2] has estimated that medical practices and iatrogenic events are responsible for about 10 million disabling injuries and deaths per year. Even in institutions with sizable financial and technological resources, it is observed that almost one out of ten hospitalized patients will undergo these events. The after-effects of adverse events (AEs) in the care provided outside the hospital are much less known.

Studies as early as the 1950s and 1960s reported on adverse events; however, the subject has not been commented upon and remained largely neglected. Moreover, a plethora of newer evidence surfaced in the early 1990s with the publication of the Harvard Medical Practice Study results in 1991 [3].

Nevertheless, no recommendations were published until more than a decade later, in 2005, with the World Alliance for Patient Safety guidelines being drafted. These guidelines introduced adverse event reporting in light of the growing focus on reporting and learning to improve the safety of patient care [4].

In Morocco, a National Strategy for integrating pharmacovigilance, haemovigilance, and material surveillance was adopted [5]. Still, no data are available to assess the phenomenon.



## **Incidence and risk factors of Adverse Events in a medical intensive care unit: a prospective observational study**

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As investigations and care technics expand, AEs-related these procedures face a higher frequency and intensity of recurrence. Within the intensive care units, with life support treatments and intensive monitoring, a slight error in the management can raise important medical, ethical, legal, and economic issues [6,7].

For these reasons, we conducted a study in a medical ICU to identify the incidence, risk factors, types and mortality related to AEs.

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## **PATIENTS ET METHODS**

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## **1. Definition**

An AE is defined as a clinical or paraclinical event, unwanted for the patient, attributable to the care (strategies and acts of treatment, diagnosis, prevention, and rehabilitation) and not to the natural evolution of the disease [8–10].

## **2. Study design**

### **A. Type and duration of the study:**

Our research was a prospective and observational study at the adult medical Intensive Care Unit (MICU) of the Mohammed VI<sup>th</sup> University Hospital of Marrakesh. It lasted ten months, from November 2021 to August 2022.

### **B. Department description:**

The Medical intensive care unit is a department of 8 functional beds having at its service 3 residents and 2 interns both rotating over a period of 6 months .

At the paramedic level, 10 nurses provide care to patients, working shifts of 12 hours/2 days with a distribution as following: a team of 3 nurses during the day, with an allocation of 2.6 patients per nurse , and a team of 2 nurses at night with an allocation of 4:1.

### **C. Population:**

We enrolled all patients admitted to the medical intensive care unit during the study. We excluded patients younger than 16 years, patients who had an AE before admission to our department, and/or those who presented either a pressure ulcer, a nosocomial infection or a drug related AE.

### 3. Data collection:

We developed a form for this research (annex 1). The doctor in charge completed it, which included the following:

- General data: age, sex, cause of admission, medical background, diagnosis.
- Clinical data: We divided the adverse events into three sub-groups (Drug-related, procedure-related, and care-related)
- The Charlson Comorbidity Index [11] categorizes patients' comorbidities based on the International Classification of Diseases diagnosis codes found in administrative data, such as abstract hospital data. Each comorbidity category has an associated weight (from 1 to 6). The higher the score, the more likely the predicted outcome will result in mortality or higher resource use.
- SOFA score (The sequential organ failure assessment score) [12]: is used to track a person's status during the stay in the ICU to determine the extent of a person's organ function or rate of failure. The score is based on six scores for the respiratory, cardiovascular, hepatic, coagulation, renal and neurological systems.
- OMEGA score [13]: The Omega score is the therapeutic activity scale constituted of 45 items scored 1-10 and divided into three categories: category 1, tasks recorded only the first time they are carried out; category 2, tasks recorded each time they are carried out; category 3, tasks recorded each day they are carried out. The total score is calculated by adding the points in the three categories at ICU discharge
- Therapeutic data: The medical treatment provided following an AE.
- Evolution: Duration of stay, improvement or persistence of symptoms, complications, and mortality due to an AE.

#### **4. Data analysis**

The continuous variables were represented as means and standard deviations or medians and quartiles and compared with the student t-test. The categorical variables were expressed as frequencies and percentages and compared with the Chi-2 test. We have used SPSS software (release 10.0, SPSS Inc., Chicago, IL, USA) for all statistical analyses. We defined the p-value as statistically significant when less than 0.05.

The incidence represents the rate of AEs during the study period to the total hospitalized population [14].

The incidence rate represents the rate of new cases of AEs observed within a given period to the total population within which these cases have arisen during the same period [15].

#### **5. Ethical aspects**

The Research Ethics Committee of the Faculty of Medicine and Pharmacy of Marrakesh approved the study (N°10/2022). The data collected was strictly confidential. The research protocol did not affect the patient's health, safety, or privacy.

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# RESULTS

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## 1. Baseline characteristics

During the study period, 204 patients were hospitalized in the medical ICU. Patients were predominantly females (56%), middle-aged ( $49 \pm 20$  years), and most had been admitted from the Emergency Department (65%). One hundred fifty-eight patients (78%) had at least one comorbidity. The most common were: diabetes (28%), hypertension (18%), and smoking (16%) (Table I).

The median of the Charlson Comorbidity Index was 1.79. The median SOFA score was 5.5, and the median OMEGA score was 32 (Table I).

The most frequent causes of admission were respiratory (17%) and neurological (17%) diseases, followed by diabetic ketoacidosis (13%) and septic shock (11%) (Table I).

**Table I: Baseline characteristics of patients**

Characteristics	Values N=204
Age (mean; years)	49±20
Sex (%)	
Male	44
Female	56
CCI (median [Quartiles])	1.79 [0;2]
SOFA (median [Quartiles])	5.5 [3;9]
OMEGA (median [Quartiles])	32 [19;58]
Origin department (%)	
Emergency department	65
Other departments	29
Private hospital	4
Other hospitals	2,50
Medical history (%)	78
Diabetes	28
Hypertension	18
Smoking	16
Obesity	2
Cardiopathy	12
Hepatopathy	4
Haemopathy	5
Autoimmune disease	6
Chronic respiratory disease	8
Surgical history	11
Causes of admission (%)	
Respiratory diseases	17
Neurological diseases	17
Diabetic ketoacidosis	13
Autoimmune diseases	12
Septic shock	11
Infections	10
Poisoning	9
Cardiovascular diseases	8
Other	3



## **2. Adverse events occurrence:**

In our study, 24% of the patients had AEs (49 out of 204). The 49 patients presented 72 AEs with 1.5 adverse events per patient with an incidence rate of 352.94 per 1000 patients per year. The most common procedural complications were central venous catheterization 27%, peripheral venous catheterization 22%, intubation, and mechanical ventilation 10%. The most prevailing care-related AEs were keratoconjunctivitis 8% and corneal ulcer 1% (Table II).

**Table II: Adverse events types**

Adverse events	Values N=72
<b>Procedure-related (%)</b>	
Central venous catheter	
Obstruction	10
Cervical compressive Hematoma	8
Femoral compressive Hematoma	4
Retraction	3
Pneumothorax	2
Peripheral venous catheter	
Phlebitis	14
Extravasation	4
Obstruction	4
Intubation and mechanical ventilation	
Dental fracture	4
Accidental extubation	4
Post extubation dyspnea	1
Barotrauma	1
CPA by ventilation delay	0
Arterial catheter	
Hematoma	3
Bleeding	1
Urinary bleeding	4
Inhalation pneumonia	3
Chest tube	
Emphysema	1
Occlusion	1
Tracheostomy	
Decannulation	8
Dialysis catheter	
Hematoma	4
Acute pulmonary edema	3
<b>Care related (%)</b>	
Keratoconjunctivitis	8
Corneal ulcer	1

### 3. Outcomes

The median hospital stay length for patients with an AE was 7 [4;15]. The overall mortality was 62% (126 out of 204). Out of the 126 patients who died, 3% had an adverse event as a direct cause of death.

### 4. The univariate analysis of risk factors

The univariate analysis showed a significant association between AEs and young age, high OMEGA score, length of stay, central venous catheter placement, urinary catheter, feeding tube, and tracheostomy (Table III).

**Table III: Univariate analysis of factors associated with the occurrence of AEs in the MICU**

Characteristics	Patients with AEs N=72	Patients without AEs N=155	p-value
Age (mean; years)	42±19	52±20	0.004
Females (%)	69	80	0.1
Medical history (%)	57	56	0.9
SOFA score (median [Quartiles])	4 [2;9]	6 [3;8]	0.8
OMEGA score (median [Quartiles])	40 [19;81]	32 [19;52]	0.001
ICU LOS (median [Quartiles]; days)	7 [4;15]	5 [3;7]	<0.001
PIVC (%)	99	100	0.4
CV Kt (%)	75	48	0.001
A Kt (%)	20	10	0.08
Intub- vent (%)	61	48	0.1
Urinary catheter (%)	86	69	0.026
Nasogastric tube (%)	84	52	<0.001
Tracheostomy (%)	24	5	<0.001
Chest tube (%)	12	4	0.054
Dialysis Kt (%)	18	10	0.1

## 5. The multivariate analysis of risk factors

The multiple logistic regressions showed that extended stay duration was an independent risk factor of adverse events (Table IV).

**Table IV: Multivariate analysis by multiple logistic regression of variables associated with the occurrence of AEs in the medical ICU**

Variable	OR	CI (95%)	p-value
Length of stay (%)	1.1	1.03-1.14	0.001

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## **DISCUSSION**

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## **I. Background:**

The concept of medical injury has been around since ancient times and throughout history; it was notably addressed by Hippocrates and carried down through the term iatrogenesis. In the following generations, notable experts have handled this same issue.

In England, the first paper was issued in 1956 in the New England Journal of Medicine. It reviewed the topic of diseases related to medical advancement and was later turned into a further detailed book entitled "iatrogenic disease"[16]. Moreover, in the United States of America, the Medical Insurance Feasibility (MIF) Study in California, published in 1978, was also one of the first studies to measure the outcome of iatrogenic injuries. The MIF first launched a study to estimate compensations for patients who suffered some disability post-medical interference. With the creation and use of new classifications, the MIF used the expression "Adverse effect" of treatment or procedures, thus putting a label to this subdivision of post-treatment occurrence [17].

In 1995, the study "The Quality in Australian Health Care Study" highlighted the elevated risk of adverse events that occur in the hospital, which resulted in more extended hospital stays and increased mortality rates [18]. And in 2002, the Adverse Events in surgical patients in an Australian study called attention to the possibility of reducing AEs and their preventability [19]. To Err is Human: Building a Safer Health System (1999) is a study with evidence stating that hospitals and the healthcare field are not as safe as they are meant to be. We can attribute this to the fact that one of the leading causes of death in the US is associated with medical error [20]. Two studies have been conducted, one reviewing the 1984 data of admissions of all the New York (NY) hospitals [21] and the other using the 1992 data of Utah (UT) and Colorado (CO) [22]. They demonstrated that the incidence rate of adverse events related to errors was 58% in NY and 53% in UT and CO. Additionally, 98.000 American deaths have been reported

each year due to preventable adverse events, surpassing the number of deaths due to motor vehicle accidents, breast cancer or AIDS [23].

Regardless of the existence of different registries for the identification, processing, and reporting of AEs (US Food and Drug Administration's system, Dutch healthcare inspectorate), there are many limitations to evaluating the real incidence rate; such as the retrospective nature of the studies, the criteria defining the adverse events and the specificity of the hospital departments where they occurred.

## **II. Baseline characteristics:**

### **1. Age:**

The mean age of our patients was  $42 \pm 19$  years. Our study population was younger than western studies. On the other hand, they are comparable to studies from other developing countries. Nationally, the average age of our patients is close to that found in the military training hospital of Rabat, with a mean of  $46.5 \pm 15$  years [24]. Like most studies published, age contributes to the occurrence of AEs. The Luo J. and al. study published in 2016 focused on the pattern of events across the different population ages. It concluded that the older the population, the higher the risk of developing an AE during hospitalization. Furthermore, it confirmed higher diversity levels of adverse events compared to the younger group [25]. These results could be attributed to physiological changes, polymedication, associated comorbidities, or poor compliance due to cognitive impairment or depression [26] (Table V).

**Table V : reported age among patients who presented an AE in the ICU**

Studies	Country	Year of publication	Number of cases	Average age
Aikawa, G [27]	Japan	2021	246	69 [56;75]
Ghali, H [28]	Tunisia	2020	1357	43.5±25.3
Kongsayreepong, S [28]	Thailand	2016	4652	71–75
Kerouley, R [30]	Brazil	2016	355	60.2±18
Rutberg, H [31]	Sweden	2014	960	66[18;96]
Bekkali, H [24]	Morocco	2014	813	46,5±15
Merino, P [32]	Spain	2012	1017	62±17
Our study	Morocco	2022	204	49±20

## 2. Gender:

The gender distribution of our patients found a female predominance, with 56% of patients. It may be related to sex differences in diagnoses and comorbidities. These results were mismatched with most studies [24, 27,28, 30–32, 34]. However, sex was not a significant risk factor [33] (Table VI).

**Table VI: reported age of patients who presented an AE in the ICU.**

Studies	Country	Year of publication	Number of cases	Females %
Aikawa, G [27]	Japan	2021	246	46
Ghali, H[28]	Tunisia	2020	1357	41
Parellada Blanco J [34]	Cuba	2018	551	32
Kerouley, R [30]	Brazil	2016	355	57.4
Bekkali, H [24]	Morocco	2014	813	36
Rutberg, H [31]	Sweden	2014	960	49
Merino, P [32]	Spain	2012	1017	35.5
Our study	Morocco	2022	204	56



### **3. Comorbidities:**

Our study included a majority of patients with a history (78%), with diabetes in 28% and hypertension in 18% of the cases. The median Charlson comorbidities index was 1.79 [0;2]. Although none of the comorbidities were defined as risk factors in our study, many reviews stated otherwise. Ghali and al.[28] concluded that a history of autoimmune diseases, respiratory diseases, and surgical history were valid risk factors. Indeed, the univariate analysis showed a significant association with an OR being at 2,9 [1,64 – 5,13], 3 [1,6 – 5,61], and 3 [1,6–5,61], respectively, with  $p < 0.001$ . Kerouley and al.[30] and Forster and al.[35] indicated that the majority of patients, 92% and 70%, who developed an AE had a CCI > 1.

### **III. Incidence:**

The incidence of adverse events was the subject of many studies. They all highlighted a higher incidence in the ICUs compared to other departments [36]. Despite more than a decade of efforts to improve patient safety, progress remains slow, and the incidence of AEs does not appear to decrease over time. Giraud and al.[37] and Garrouste and al.[38] reported 31% and 39.2% of the incidence of AEs, respectively. This rate was similar to Keroulay and al.[30] study (32,4%) and less than Chapuis and al.study with 58% [39] and Aikawa and al. [27]study with 51%. This difference could be explained by the difference in the locations where these studies were conducted. Several studies were conducted in a single hospital, such as those in Tunisia [28, 40] and Italy [41,47]. On the other hand, the multi-centric study of Wilson and al. [43] assessed the frequency and nature of adverse events in selected hospitals in developing or transitional economies. It noted an incidence between 2.5% and 18.4% (Table VII).

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**Table VII: reported incidence and types of AEs.**

Study	M&M	Type	Incidence	Types of AEs
Ennafiri, Morocco, Rabat, 2016 [46]	1 ICU in a university hospital N=197	Prospective	63.8%	-related to the invasive procedure - drug-related adverse events - care related
Francisco Molina, Colombia 2018, [44]	1 ICU in a university hospital N=134	Retrospective	52.1%	-pressure ulcers -complications or reactions to medical devices -lacerations or skin defects -delayed diagnosis or treatment
Imehoui, Morocco Marrakech 2018 [49]	H, ICU of a military training hospital	Retrospective	51.51%	- nosocomial infections -procedure-related events -thromboembolic complications - atrophic disorders
Rodrigues Serafim, Brazil, 2017 [48]	ICU of a tertiary hospital N= 138	Prospective	50.7%	- Pressure Ulcers -Skin Lesions -Unplanned Oro/Nasogastric Enteral Feeding Tube Removal
Garrouste, France 2012 [38]	O, 12 MICUs and SICUs	Prospective	39.2%	-catheter-related bloodstream infection -nonbacteremic pneumonia -deep and organ/space surgical site infection -gastrointestinal bleeding
Kerouley, R , brazil 2016 [30]	1 ICU in a university hospital N=355	Prospective	32.4%	-pressure ulcers -damage from vascular catheter handling -damage from ventilation handling -damage from urinary or gastric catheter handling -hypoglycemia
Wilson and al, Egypt, Jordan, Kenya, Morocco, Tunisia, Soudan, Yemen, South	ICUs in 26 hospitals, N=15548	Retrospective	8.2% (varies between 2.5% and 18.4 %)	-diagnosis and treatment errors -procedural-related AEs -nonprocedural related ( bed falls, fractures, treatment

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				admissions, anesthesia )
Africa, 2012 [43]				
Parelladad J, Cuba , 2018 [34]	ICU in a military training hospital N= 551	Prospective	19.41%	<ul style="list-style-type: none"> <li>-pneumonia and tracheobronchitis associated with mechanical ventilation</li> <li>-obstruction of the artificial airway</li> <li>-central venous catheter infection</li> <li>-accidental extubation</li> <li>-atelectasis associated with ventilation</li> <li>-Tracheal stenosis</li> <li>-Subcutaneous emphysema related to pleurotomy or ventilation</li> </ul>
Ghali, H Tunisia, 2020 [28]	8 ICUs in a university hospital N=1357	Prospective	12.4%	<ul style="list-style-type: none"> <li>- nosocomial infections</li> <li>- drug allergies</li> <li>- pressure ulcers</li> <li>-unscheduled readmissions</li> <li>- bed fall</li> <li>- drug admission errors</li> </ul>
Bouafia, Tunisia, 2015 [40]	14 ICUs in a university N=1428	Prospective	11.3%	-
Bakkali, H, morocco, Rabat, 2014 [24]	ICU of a military training hospital, N=813	Retrospective	5.4%	<ul style="list-style-type: none"> <li>-Respiratory events</li> <li>-cardiovascular events</li> <li>-neurological events</li> <li>-care relayed</li> <li>-other</li> </ul>
Albino and al, Italy, 2017 [41]	ICUs in 4 university hospitals and 32 regional hospitals N=11293	Retrospective	5.3% in the university h. 1.8% in regional H.	-
Sommella, Italy 2014 [47]	An acute care hospital	Retrospective	3.3%	-
Chapuis C, France 2019 [39]	1 MICU in a university hospital	Prospective	58%	<ul style="list-style-type: none"> <li>-clinical process/procedures</li> <li>-medication/ IV fluids</li> <li>-medical device/equipment</li> <li>-nutrition</li> </ul>

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				-blood procedures -oxygen/gas/vapor
Merino P, Spain, 2012 [32]	ICU of 76 hospitals. N=1017	Prospective	58%	-medication errors -equipment's failure -nursing care related -accidental withdrawal of vascular accesses -mechanical ventilation failure
Aikawa, G, japan, 2021[27]	1 ICU in a university hospital N=246	Retrospective	51%	-adverse drug events -procedural complication -surgical complications -nosocomial infections -therapeutic errors -diagnosis c errors
Giraud, T, France, 1993 [37]	2 ICUs N=382	Prospective	31%	-
Sauro, M Canada, 2020 [45]	30 ICUs N=49447	Retrospective	25%	-
Danielis, M, Italy, 2021 [42]	4 ICUs in a university hospital	Retrospective	1.7/100 intensive care-patient	-medication/ intravenous fluids issue -resources and organizational management -medical device/equipment - clinical processes/procedures
Our study	1 ICU in a university hospital	Prospective	24%	-procedure-related -care related

According to the Schwendimann and al.review [50], which included 25 studies conducted in 27 countries, 10% of patients were affected by at least one AE.

Many variables should be considered when interpreting these results:

- The lack of consensus about the terminology and definitions
- The nature of the study: In this case, the prospective studies showed higher incidence than the retrospective ones. It is likely attributed to the prospective studies having fewer potential sources of bias and confounding than retrospective ones. In a pilot study, Michel and al. [51] concluded that a prospective data collection method would be most appropriate for conducting epidemiological studies on AEs in the ICU. Moreover, an

## Incidence and risk factors of Adverse Events in a medical intensive care unit: a prospective observational study

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Australian team reported that the retrospective approach retains some interest and is complementary to a prospective analysis [52].

- The constraints of the voluntary reporting method included underreporting owing to time restrictions, a lack of adequate reporting mechanisms, legal liability, the refusal to disclose one's errors, ambiguity about the clinical importance of the events, and a lack of follow-up [53–54].
- A monitoring system requires multiple ways of identifying medical errors and adverse events (Table VIII). In the USA, the Institute for healthcare improvement (IHI) developed a standard detection technique for AEs. It utilizes triggers to identify and measure the number and the degree of harm caused by the AEs [55]. In Europe, the European Network for Patient Safety (EuNetPaS) developed a patient safety culture and implemented methods to ensure it. At the hospital level, different reporting systems are available to healthcare workers [56].

**Table VIII: summary of the leading indicators used in each category.[57–61]**

<b>Process indicators</b>
Mechanical ventilation
Semi-recumbent position during mechanical ventilation
Overinflation of the endotracheal balloon
<b>Sedation</b>
Appropriate sedation
Screening for ventilator weaning readiness
Sedation interruption
Sedation monitoring
<b>Medication</b>
Medication administered to the wrong patient
Error administering anticoagulant medication
Error prescribing anticoagulant medication
Error administering vasoactive drugs
Error administering insulin
Death or severe disability associated with hypoglycemia

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## **Incidence and risk factors of Adverse Events in a medical intensive care unit: a prospective observational study**

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### **IV lines**

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Screening for readiness for removal of central venous catheter

Death or severe disability associated with intravascular air embolism

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### **Management**

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Appropriate use of prophylaxis against gastrointestinal bleeding in patients receiving mechanical ventilation

Appropriate use of thromboembolism prophylaxis

Appropriate use of early enteral nutrition

Early management of severe sepsis, septic shock

Surgical intervention in traumatic brain injury with subdural and/or epidural brain trauma

Monitoring of intracranial pressure in severe traumatic brain injury with abnormal CT findings

Delay in surgical treatment

Change of route for quinolones IV/PO

Screening for MRSA on admission

Pain management in unsedated patients

Events during ICU transport

Bed falls

Pressure sores

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### **Complications**

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Pneumonia associated with mechanical ventilation

Accidental extubation

Accidental removal of a central venous catheter

Catheter-related bloodstream infections

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### **Outcome indicators**

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ICU mortality rate

Hospital mortality rate

Percentage of ICU patients with ICU stays longer than 7 days

Mean ICU length of stay

Mean days on mechanical ventilation

Rate of readmissions < 72 hours

Family satisfaction

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### **Structural indicators**

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#### **Institutional variables**

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Process for ensuring staff competencies

Transitional period to integrate new healthcare workers

Clear task identification

Absenteeism, magnitude of personnel turn-over

Adverse-event reporting system

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#### **Task variables**

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Availability of protocols

Policy to prevent medication errors

Policy to register outcomes

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**Team variables**

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Adequacy of staffing  
Nurse-to-patient ratio  
Availability of an intensive care practitioner 24 h a day  
Pharmacist present during ICU rounds  
Communication or conflicts among team members

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#### **IV. Types of adverse events: (Table VII)**

Two types of medical errors and adverse events are reported: those related to medications and those related to procedures or the ICU environment. Medication errors are more frequent in ICU than in non-ICU settings and are more likely to be severe and cause harm [62]. In France, according to Garrouste et al., Medication errors are estimated to account for 78% of all medical errors in ICUs, with an average of 1.75 medication errors per patient per day. In South Africa, a study found that 11.09% of the medication prescribed over a month in an ICU presented at least one error, with a total rate of 621.1 per 1000 patients days and 110.9 per 1000 prescriptions [63]. In Saudi Arabia, Khoja and al. reported that 18.7% of drug prescriptions contained errors, but only 0.15% were considered serious [33]. In Brazil, in the Kerouley and al.study [30], similar to ours, the AEs reported were most related to clinical processes and procedures. Primary bloodstream infections came first (6.1%), followed by pneumonia (4.7%) and central vascular access infection (3.4%). The Schwendimann's scoping review [50] reported that AEs were often a result of procedural consequences and injuries (40%), followed by medication- or drug/fluid-related events such as medication errors (19.3%) and healthcare-associated infections and allergic reactions (17.7%).

Numerous interventions to address the frequency and impact of medication errors have already been developed. The WHO aims to reduce severe avoidable medication-related harm by 50% globally by 2024 [64].

## V. Risk factors:

The risk factors identified could be subdivided into modifiable and non-modifiable factors. Age and SOFA score were our study's only significant non-modifiable risk factors. Length of stay, central venous catheter, tracheostomy, and urinary/nasogastric tubes are modifiable risk factors. Our results were consistent with other studies where exposure to invasive care procedures, medical devices, and medication intake were well documented as risk factors for developing an AE. According to Sauro and al.[45], AEs were associated with having two comorbidities or more (OR=1.4 [1.3-1.4]), being admitted to the ICU from the operating room or another hospital ward (OR=1.8, [1.7-2.0], and OR=2.7[2.5-3.0], respectively) and being readmitted to ICU during their hospital stay (OR=4.8[4.7-5.6]) [43]. Ghali and al.[28] identified central vein catheter (OR=5.9 [3.3-10.6]), the urinary catheter (OR=1,6 [1,1-2,5]), tracheostomy (OR=24,3 [4,7-126,5]), blood transfusion (OR=3,58 [2,1-6,1]), and surgical intervention (OR=1,94 [1,38-2,84]) as risk factors.



## VI. Outcomes:

Adverse events in our study prolonged the hospitalization by two days and accounted for 3% (3 cases out of 126) of mortality. These results are also congruent with the Ghali and al. study [28], in which AEs were responsible for extending hospital stay in 32.1% of cases and 3.8% of mortality. Additionally, it provoked permanent disability in 7.8%, and vital prognosis engaged in 5.3% of patients. Besides, adverse events were responsible for 2.4 days, 19 days, and 30 days increase in the duration of ICU hospitalization in Ahmed and al.[65], Kerouley and al.[30], and Forster and al.[35] studies.

**Table IX: length of stay and mortality reported for patients who presented an AE.**

Study	LOS ( days)	Mortality %
Ghali, Tunisia, 2020 [28]	–	3.8
Ahmed, USA, 2015 [64]	2.4	–
Keroulay, Brazil, 2016 [30]	19	49.3
Forster, Canada, 2008 [35]	31	–
Aikawa, Japan, 2021 [27]	2	3
Sauro, Canada, 2020 [45]	5.4	36.9

## VII. Limitations

Our study had some limitations. First, some parts of the patient's medical history, severity scores, types of AEs, and demographical data were missing. This has led to filling in the blanks retrospectively. Second, we have faced the difficulty of checkups and the lack of trigger tools that make detection easier since it was vastly examiner dependent. Third, it was a monocentric study, so we enrolled a small sample; two hundred four patients were admitted to the MICU during the ten months, yet we deem that this population's largeness was insufficient.

## **VIII. Recommendations**

Every member of the healthcare team can play a part in decreasing the incidence of adverse events. Therefore, the medical system needs to :

- Identify and disclose the most clinically significant adverse events to all the staff involved.
- Implement team work culture.
- Establish an adverse events reporting system.
- Evaluate the medical and para medical staff through simulation sessions.
- Raise awareness among health professionals of the importance of recognizing risk factors.
- Put in place the protocols of care to be held in case of their occurrence.
- Promote the concepts of patient safety and the risk management.

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## CONCLUSION

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The incidence of AEs in the intensive care unit is highly variable, as there are still difficulties in defining and collecting them. It seems essential to have indicators of these events. Their occurrence represents a severe problem as they impact the length of stay and mortality.

To improve patient safety, managing risks and preventing them is necessary by acting on the risk factors. The concept of "Risk management" is vital in every department to ensure the safety and quality of care. It is a collective approach that requires the full support of the healthcare team.

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# ABSTRACTS

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## **Abstract:**

### **Introduction:**

Adverse events (AEs) are responsible for increased mortality and length of hospitalization. Due to heavy monitoring and invasive procedures, the MICU is a field prone to iatrogenic errors. The main objective of this study was to determine the incidence, risk factors, and mortality related to adverse events in the medical intensive care unit.

### **Patients and methods:**

We conducted a prospective and observational study at the adult medical Intensive Care Unit of the Mohammed VIth University Hospital of Marrakesh. Over ten months, from November 2021 to August 2022. The study included hospitalized patients, excluding those younger than 16 years, patients who had an AE before admission to our department, and/or those who presented either a pressure ulcer, a nosocomial infection or a drug related AE.

### **Results:**

Altogether, 204 patients were admitted. Forty-nine patients presented 72 AEs. The overall incidence was 24%. Of the 72 AEs, 27% were secondary to central venous catheterization, 22% were related to peripheral venous catheterization, and 10% were consequences of intubation and mechanical ventilation. The most prevailing care-related AEs were keratoconjunctivitis 8%.

The risk factors detected were the young age, high OMEGA score, length of stay, central venous catheter placement, urinary catheter, feeding tube, and tracheostomy.

Adverse events in our study prolonged the hospitalization by two days and accounted for 3% of the overall mortality.

### **Conclusion:**

Leaders, administrators, and practitioners must reinforce the importance of improving the quality of care; assess risk management to prevent adverse events in a continuous dynamic process.

## Resumé:

### **Introduction:**

Les événements iatrogènes (EI) sont responsables de l'augmentation de la mortalité et de la durée de l'hospitalisation. En raison de la surveillance intensive et des procédures invasives, la réanimation médicale est sujet aux erreurs iatrogènes. Le principal objectif de cette étude était de déterminer l'incidence, les facteurs de risque et la mortalité liés aux événements indésirables dans l'unité de soins intensifs médicaux.

### **Patients ET méthodes:**

Nous avons mené une étude prospective et observationnelle au sein de service de réanimation médicale de l'hôpital universitaire Mohammed VI de Marrakech. Sur une période de dix mois, de novembre 2021 à août 2022. L'étude incluait tous les patients hospitalisés au cours de la période, à l'exclusion de ceux de moins de 16 ans, les patients qui avaient un EI avant leur admission et/ou ayant présenté soit une infection nosocomiale, des escarres ou une iatrogénie médicamenteuse.

### **Résultats:**

Au total, 204 patients ont été admis. Quarante neuf patients ont présenté 72 EI. L'incidence globale était de 24 %. Sur les 72 EI, 27 % étaient secondaires au cathétérisme veineux central, 22 % étaient liés au cathétérisme veineux périphérique et 10 % étaient des conséquences de l'intubation et de la ventilation mécanique. Les EI liés aux soins les plus courants étaient la kératoconjonctivite 8 %.

Les facteurs de risque détectés étaient le jeune âge, le score OMEGA élevé, la durée du séjour, le placement du cathéter veineux central, la sonde urinaire, la sonde nasogastrique et la trachéotomie. Les événements indésirables dans notre étude ont prolongé l'hospitalisation de 2 jours et ont été responsables de 3% de la mortalité globale.

### **Conclusion :**

Les leaders, les administrateurs et les praticiens doivent insister sur l'importance d'améliorer la qualité des soins, d'évaluer la gestion des risques afin de prévenir l'apparition d'événements indésirables dans un processus dynamique et continu.



## ملخص

### مقدمة

تعد الأحداث علاجية المنشأ مسؤولة عن زيادة الوفيات وطول فترة الاستشفاء. وبسبب المراقبة المكثفة والإجراءات الإيجابية، فإن وحدة الانعاش الطبي عرضة لمجموعة من الأخطاء. يعتبر الهدف الرئيسي من هذه الدراسة هو تحديد معدل الإصابة وعوامل الخطر والوفيات المتعلقة بالعلاج في وحدة العناية المركزة الطبية.

### المرضى والمناهج المعتمدة

أجرينا دراسة استباقية قائمة على الملاحظة في جناح العناية المركزة الطبية للبالغين في مستشفى محمد السادس الجامعي بمراكش. على مدى عشرة أشهر، من نوفمبر 2021 إلى غشت 2022. تضمنت الدراسة جميع المرضى الذين دخلوا المستشفى خلال هذه الفترة باستثناء أولئك الذين نقل أعمارهم عن 16 عاماً، والذين أصيبوا بمرض علاجي المنشأ قبل دخولهم قسمنا، و/أو أصيبوا بعدوى مكتسبة في المستشفى المرضى الذين تعرضوا لحدث قبل ولوجهم مصلحتنا، أو الذين أصيبوا بعدوى المستشفيات، التفرح السريري أو حدث جانبي متعلق بالأدوية.

### النتائج

إجمالاً، تم قبول 204 مريض. تعرض 49 مريضاً ل 72 حادث علاجي المنشأ بنسبة 24%. 27% من بينها ناتج عن القسطرة الوريدية المركزية، 22% تتعلق بالقسطرة الوريدية المحيطية و 10% بسبب انبوب التنفس الإختراعي والتهوية الميكانيكية. في حين ان التهاب القرنية هو أكثر حدث علاجي المنشأ المتعلق بالرعاية الطبية إنتشاراً بنسبة 8% من عوامل الخطر المكتشفة: صغر السن، وارتفاع نتيجة OMEGA score، وطول مدة الإقامة، ووضع القسطرة الوريدية المركزية، والقسطرة البولية، وأنبوب التغذية، وفغر القصبية الهوائية. أدت الأحداث السلبية في دراستنا إلى إطالة فترة الاستشفاء بمقدار يومين وكانت مسؤولة عن 3% من إجمالي الوفيات.

### خاتمة

للحد من الوقوع في هاته الأحداث الجانبية وجب على الجهات المسؤولة منح الأهمية لتحسين جودة الرعاية مع تقييم الاخطار والاضرار المحتملة بشكل مستمر

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# ANNEX

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**LES EVENEMENTS IATROGENES EN MILIEU DE REANIMATION – expérience du service de Réanimation Médicale CHU Mohammed VI**

**IDENTITE** Numéro d'ordre :.....Service d'Origine.....Age.....Sexe MF

**ANTECEDANTS**

**Med** : Dt HTA Dyslipidémie Tabagisme Obésité Inf. . Urinaire à répétition Cardopathie  
Néphropathie Hépatopathie hémopathie Mdie de système TTT immunosupp  
I.Resp.chronique  Pas d'ATCD

**Chir** : Jamais opéré Patient opéré pour.....score de Charlson.....

**MOTIF D'ADMISSION**.....

**TYPES DE GESTES** : VVP  VVcentrale  KT artériel  Intubation Ventilation Sonde Urinaire  
Sonde Gastrique Trachéotomie Drain thoracique Hémodialyse

**ISSUE D'EVENEMENT IATROGENE** : oui / non

**TYPE DE L'EVENEMENT IATROGENE** :

-Liée au geste : **VVP** :Veinite extravasation du produit oublié du garrot serré

**VV centrale** ::Pneumothorax  hémothorax  hématome compressif  Obstruction

**KT artériel** : hématome saignement lors du retrait **Intubation-vent** : Fracture dentaire   
Extubation accidentelle Dyspnée laryngée post extubation  Barotraumatisme

(pneumomediastin, atélectasie) Arrêt hypoxique par retard à la ventilation **Trachéotomie** :

sténose décannulation fistule tracheo-oesophagienne  **Sonde urinaire** : saignement

**Sonde gastrique** : nécrose du l'aile du nez inhalation du liquide du gavage **Cathéter de dialyse** : Hématome **Drainage thoracique** : Emphysème sous cutané Pneumothorax

**Ponction d'ascite** : hématome paroi abdo perforation d'organe creux **Transfusion Sg** :  
incompatibilité  OAP

-Liée aux soins : Keratoconjunctivite ulcère cornéen

-Autre :.....

**SCORE DE GRAVITE(le jour de l'EI)** : SOFA = / OMEGA =

**Mesures de réanimation suite à l'EI** : Remplissage Recours aux catécholamines  Ventilation  
mécanique Intubation  Trachéotomie Ressuscitation cardio respiratoire Sédation  
traitement spécifique : .....

**EVOLUTION** : durée de séjour en réanimation..... amélioration des symptômes

Persistance des symptômes

Complication : Neurologique Respiratoire  Hémodynamique

Le patient a-t-il : survécu décédé : suite à l'EI  suite à sa pathologie

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## قسم الطبيب

### أقسامها العظيمة

أنار أقبال الهفيم هنتي.

وأنصون حياة الإنسان في كافة أطوارها في كل الظروف

والأحوال الباذلة وسعيفي نقادها من الهلاك والمرض

والأموال القلق.

وأنأحفظ للناس كرامتهم، وأستر عورتهم، وأكتم سرهم.

وأنأكون نعلادوا ممنوسائل رحمة الله،

بأذار عايتي الطبية للقريبو البعيد، للصالحو الطالح، والصديقو العدو.

وأنأثابر علم طلب العلم، وأسخره لنفع الإنسان لا لأذاه.

وأنأوقر من علمني، وأعلم مني صغرتي، وأكون أختا كل من يفتي المهنة الطبية

متعاونين نعلابرو والتقوى.

وأنتكون حياتي مصداقا ليمان نيسريو علانيتي،

نقية مما يشينها تجاه الهورسول هو المؤمنين.

والله علما أقول شهيد



\*



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\*

سنة 2022 أطروحة رقم 342

# معدل و عوامل وقوع الاعراض الجانبية المتعلقة بالاجرات بمصلحة الانعاش الطبي : دراسة استشرافية رصدية الأطروحة

قدمت ونوقشت علانية يوم 01/12/2022  
من طرف

**السيدة : الحر بهية**

المزودة في 09 يوليوز 1996 بمراكش

**لنيل شهادة الدكتوراه في الطب**

الكلمات الأساسية

الاعراض الجانبية- معدل الوقوع - عوامل الوقوع- الإنعاش الطبي

اللجنة

الرئيس	السيد	س. يونس
		أستاذ في طب التخدير والإنعاش
المشرف	السيد	ع. هاشمي
		أستاذ في الإنعاش الطبي
الحكام	السيد	م. بوالروس
		أستاذ في طب الأطفال
	السيدة	م. الخياري
		أستاذة في الإنعاش الطبي
	السيدة	س. أيت بظاهر
		أستاذة في أمراض الرئة والسل

