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**Risk Factors for Healthcare Associated Infections after Elective General Surgery in Nepal.** 

> Degree Project in Medicine Programme in Medicine, Institute of Medicine, Sahlgrenska Academy, University of Gothenburg

> > By Isak Moen

Supervisors: Prof. Göran Kurlberg Prof. Yogendra P. Singh Dr Bikal Ghimire

# THE SAHLGRENSKA ACADEMY



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Isak Moen

Programme in Medicine

Gothenburg, Sweden 2018

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## Abstract

Degree Project in Medicine: Risk factors for healthcare associated infections after elective general surgery at Tribhuvan University Teaching Hospital, Kathmandu, Nepal.

#### By Isak Moen Programme in Medicine, Sahlgrenska Academy, Gothenburg, Sweden, 2018

**Background/Introduction**: Healthcare Associated Infections, HAI, and the risk factors associated with it are poorly studied in low-income countries. It is known is that there is a higher incidence of HAI there compared to wealthier regions, and that the impact of HAI is greater both on patients and on the healthcare system itself. Apart from this details are scarce. Most studies have focused on patients undergoing emergency operations or patients admitted to intensive care units, leaving the incidence and risk factors for HAI for patients undergoing elective surgery an unexplored issue.

**Objectives**: To determine the incidence of HAI, i.e. surgical site infections, blood stream infection, pneumonia and urinary tract infection in patients undergoing elective surgery at Tribhuvan University Teaching Hospital, Kathmandu, Nepal and to examine associated risk factors.

**Methods**: A prospective cohort study of patients admitted to surgical wards following elective abdominal, urological, breast and thyroid operations between March 2<sup>nd</sup> 2018 and March 30<sup>th</sup> 2018. Patients were examined daily while admitted and followed up using a phone call questionnaire 30 days after their date of surgery.

**Results**: Out of the 99 participants who were reached by phone call, none were diagnosed with infection. 4 had been diagnosed with HAI while admitted to hospital, resulting in a cumulative incidence of 4%. The incidence rate was 1.37 infections per 1000 patient-days, including follow-up. The cohort had a mean age of 47 years old. The sexes were evenly represented (47.5% female). 66% of the participants had no significant comorbidities. A third of the patients (33) had undergone laparoscopic cholecystectomy. 85% of performed surgeries were classified as clean or clean/contaminated. In the patients with HAI there was a higher incidence of preoperative anaemia, and the surgeries they had undergone were to a higher extent major and

lengthy (time of surgery > 2 hours). The mean length of stay of patients with HAI was 31.5 days, compared with 5.86 days in the non-infected group.

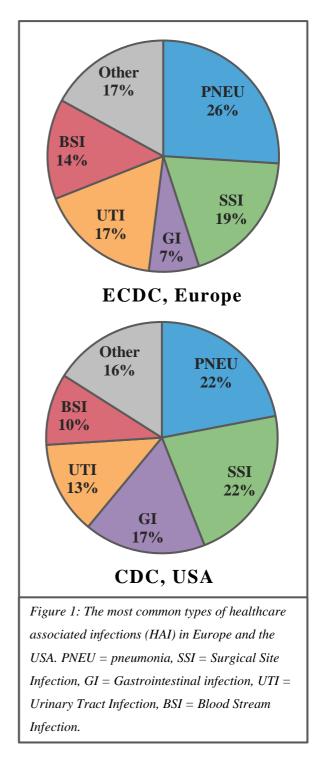
**Conclusions**: This comparatively low estimation of the incidence of HAI indicates that planned surgery in young and relatively healthy patients confers a low risk of infection.

**Key words**: Healthcare associated infection, surgical site infection, elective surgery, risk factors, Nepal

### Introduction

Nosocomial infection, or Healthcare Associated Infection (HAI), is the most common complication to hospital stay worldwide, affecting hundreds of millions of patients each year [1, 2]. Contracting an infection during admission to hospital, or as a consequence thereof, increases the mortality rate, healthcare costs and the risk of an extended hospital stay [3]. Furthermore, the increased use of antibiotics associated with nosocomial infection leads to an increase in bacterial resistance [4], a growing issue globally [5, 6]. It has been shown that over 70% of bacteria causing HAI are already resistant to at least one type of antibiotic [1], making them more difficult to treat. Hospital-acquired infections are, to a large extent, a needless burden on the healthcare system; in the US it has been estimated that 55-75% of HAI could be prevented, saving thousands of lives and avoiding billions of dollars' worth of excess medical costs [7-9]. In Sweden the cost of HAI was estimated to be 7 billion Swedish crowns per year in 2013-2016, 11% of the total cost of somatic healthcare [10].

Figure 1 shows the latest data on the incidence of HAI in Europe and the USA as reported by the ECDC [11] and the CDC [12] respectively. Urinary Tract Infections (UTI), gastrointestinal infections and Surgical Site Infections (SSI) are common but do less damage in terms of increased costs and mortality rates per case as compared to pneumonia and blood-stream infections [1, 9]. The risk factors for HAI can be divided into two groups: intrinsic risk factors, related to patient attributes, and extrinsic risk factors, related to the wards and healthcare workers. Intrinsic risk factors for HAI include pre-operative anaemia, under- or overweight and comorbidities such as diabetes or Chronic Obstructive Pulmonary Disease, COPD [13, 14]. Extrinsic risk factors include admission to the Intensive Care Unit (ICU), deficient hygiene, and prolonged use of invasive devices such as urinary catheters, central vein or arterial catheters, and surgical drains [3, 4, 15-17].



#### **Risk factors for surgical site infections**

Surgical site infections, SSI, are among the most common hospital-acquired infections both in higher income regions, such as in Europe and the USA, and in low income countries [18-20].

While the most important risk factors for developing SSI are linked to the patient's condition [21], there are also those related to the surgical procedure itself. This includes surgery time longer than two hours, surgery with a high degree of urgency and open procedures (as opposed to a laparoscopic approach) [13, 22, 23]. Another factor that increases the risk for SSI is contaminated or dirty wound classification. Based on the bodily location, potential breaks in sterile procedure and the presence or absence of prior infections surgical wounds are classified as clean, clean/contaminated, contaminated or dirty. The latter two groups are associated with a higher risk for SSI [13, 16].

Diabetes increases the risk of SSI mainly through hyperglycaemia leading to increased microbial proliferation [24]. Impaired function of both immune cells and endothelial cells may also contribute to the increased risk of infection [14]. The use of steroids, chemotherapy or other immunosuppressive drugs weakens the patient's resistance to infection, and has been showed to significantly increase the risk of SSI in previous studies [14, 25]. Malignant tumours can have systemic effects, including weight loss and anaemia [26]. It is therefore not surprising that it has been linked to an increased risk of SSI [4, 16]. Male sex has been associated with a higher risk for SSI in several studies [4]. While the reason for this difference is not clear, it has been speculated that thicker muscle layers leading to longer operating times may be part of the explanation [27]. Female sex, on the other hand, has unsurprisingly been associated with a higher risk for healthcare associated UTI [28].

Although many of the factors that influence the risk of SSI are fixed, some can be altered and yet others require special preparations. Prevention strategies against SSI therefore include preoperative administration of antibiotics [1] and optimising operation rooms in terms of ventilation, temperature and sterilisation. Additionally, in select cases of elective surgery it may

be wise to delay the operation until the patient has been optimised [18]. This includes treating any detected infections, encouraging smoking cessation and improving blood-glucose levels prior to surgery [18, 29].

In the middle of the 19<sup>th</sup> century Ignaz Philipp Semmelweis discovered that the mortality rate at the obstetric clinic where he worked could be greatly reduced by having the physicians wash their hands with chlorine and lime between performing autopsies and examining patients. In his own day he was ridiculed and his results rejected [30]. In the present day it is known that the microorganisms that cause HAI are most often part of the transient flora, which can be removed by hand washing. Improving hand hygiene is therefore considered one of the cheapest and most efficient ways to decrease HAI incidence [5]. Furthermore, other aspects of the clinical environment, such as the floors of operating rooms and the metal covers of medical charts, have been found to be colonised to a high extent. In many cases multidrug resistant strains of bacteria have been found [31-33]. This is another source of pathogens that could be disarmed with the help of proper hygiene.

#### Healthcare Associated Infection in Low-income countries

While the incidence rates and associated risk factors for HAI have been thoroughly studied in high income countries, the same cannot be said for low income countries. From the majority of low- and middle income countries, no data has been published on the subject of HAI. [2]. Furthermore, where studies have been conducted they are often of comparatively low quality [20] and lack standardised definitions, making comparisons between studies difficult or impossible [34]. As a result of this, the reported incidence of HAI varies greatly in otherwise similar low-income settings, ranging from 5.7 to 19.1 cases per 100 observed patients. These numbers set the incidence of HAI between 2 and 20 times higher than the ones seen in high-

income countries [2, 35]; lower socioeconomic status is related to a higher risk for HAI [3]. While this certainly marks HAI as an important issue, the paucity of reliable data deters national health policy makers from focusing on HAI as a major health issue [36]. Presently more high quality studies are needed [37].

The difference in HAI incidence between high and low-income countries is attributed to overcrowding and understaffing, among other factors. The nurse-to-patient ratio is directly related to the risk of HAI [3]. However, while a lack of resources is part of the explanation for the difference seen between different regions, it has been suggested by the WHO in their "Guidelines for Safe Surgery" that it may not be the most important one. Concerning SSI, they argue the importance of the lack of systematisation in low income regions as it impedes the available resources from being properly used [38].

What can be done to reduce the incidence of HAI in low-income countries? Compared to the interventions needed in high-income countries, the ones most useful in this environment can be quite modest. As stated above, improving hand hygiene is one of the cheapest and most efficient ways of reducing the incidence of HAI [5, 17]. This is especially relevant in low-income countries such as Nepal, where hand hygiene guidelines are poorly implemented [39]. Concerning further strategies to reduce HAI, most control programmes and guidelines available were developed in and adapted for high-income countries. They may therefore not be applicable in the healthcare system of a low income country, but must be modified to suit local needs and capabilities [40].

#### Nepal and Tribhuvan University Teaching Hospital

Nepal is a country in southeast Asia, neighbouring India in the south and China in the north. There were 28 million inhabitants in Nepal in 2013, with the majority living in rural areas of the country. The life expectancy at birth in Nepal was 68 years in 2012, with Chronic Obstructive Pulmonary Disease, COPD, being the leading cause of death [41]. Using Healthdata.org to make a comparison with other countries in the same World Bank income group reveals that Nepal has had a lower than average percentage of deaths related to maternal and neonatal disorders since 2003 and 2008 respectively [42]. The latest figures (from 2013) from WHO indicate an under-five mortality of 40 per 1000 live births and a maternal mortality of 190 per 100 000 live births, close to the average of the WHO region of South East Asia [41].

Tribhuvan University Teaching Hospital, TUTH, was built in 1983 with the aid of the Japanese government. One of the largest hospitals in the country, with 15 specialised departments [43], it receives referrals from all over the country. The hospital is government funded in part, so that while there are out-of-pocket part of expenses the cost of healthcare is lower than in other local health facilities. Furthermore, out of the total of 663 beds, 9% (61) are "free beds" reserved for poor individuals in need of care [43].

In the treatment of patients admitted to TUTH medication, dressings and food all had to be brought in from outside the hospital by the patients' relatives. For this reason most patients had a few relatives present at all times, often seen camping in the hallways. As visitors may bring pathogens into hospital, or between admitted patients, Kilinc et al have theorized that they could increase the risk of HAI [44]. The authors suggest issuing protective gowns to neutralise this risk. Healthcare workers are another potential spreader of bacteria within the hospital, as they move from patient to patient [45]. It is therefore crucial that proper hygiene is maintained (see the cover page of this report). However, the sister-in-charge of the female surgical ward stated that in her section they had "47 beds, 16-17 nurses, doctors and other personnel and only 1 bottle of hand sanitiser" [46].

A systematic literature review of the burden of HAI in southeast Asia published in 2015 by Lin Ling et al. [37] found a pooled prevalence of HAI of 9.0%, lower than previous studies had suggested though still 25-125% higher than the corresponding figures in Europe [11] and the US [12]. They still urged that "The pooled SSI rate (7.8%)... suggests the urgent need SSI interventions". However, studies from Nepal were not included in this review. In 2012, a study of abdominal surgeries at TUTH in Nepal found an SSI rate of 23% [23]. While abdominal surgeries are known to have a high risk of SSI [14], this number is still indicative of the problem HAI poses at TUTH.

Surgical site infection has been the traditional focus for studies into the subject of HAI [47]. In low-income regions this is still the most common focus, constituting over half of the studies in a large review article [20]. Furthermore, while most studies have focused on emergency surgeries or patients in intensive care, this study will focus on elective surgery, a largely unexplored topic in low-income countries. The hypothesis is that HAI are much less frequent in elective surgery.

# **Objectives**

The primary objective of this study was to determine the incidence of surgical site infection, pneumonia, urinary tract infection and blood stream infection following routine, general surgical procedures at Tribhuvan University Teaching Hospital in Kathmandu, Nepal. The secondary objective was to correlate these findings to patient- and ward-related risk factors.

### Method

This was a prospective cohort study, using the guidelines of the National Healthcare Safety Network, NHSN, (of the American Centre for Disease Control and Prevention, CDC) to identify surgical site infection, pneumonia, urinary tract infection and blood-stream infection [48]. The cohort was collected on all days except Sundays (as no elective surgery was performed on these days) in the period from the 2<sup>nd</sup> of March to the 30<sup>th</sup> of March. Patients admitted to surgical wards after undergoing elective gastrointestinal, urological or breast/thyroid-related surgery were eligible for inclusion in the study. Patients under 18 years of age were excluded. Patients undergoing surgery not classified as an operative procedure according to the NHSN, i.e. those not involving incisions into the skin or mucous membranes, were excluded. Patients who had undergone another operation or had had a blood stream infection they may have presented with could have been be related to either event. For the same reason, patients who had unrelated surgery during the 30 days after their initial operation, as revealed on follow-up, were also excluded from the study.

Patients eligible for inclusion in the study were approached by the investigator, informed of the purpose and lay-out of the study and asked to participate. When language allowed this conversation was held in English. In cases where language barriers were present, and as an

additional source of information for all potential participants, a consent form that had been translated to Nepali was provided (see appendix 1). Hospital staff or patient relatives were used as translators when needed. At time of inclusion the patient was asked to provide 2 phone numbers, which were later used to contact the patient 30 days after the date of surgery.

Information regarding examined patient- and ward-related factors (see table 2) were extracted from the charts. In cases where data was missing this was procured by interviewing patients or health personnel. During the time the patients included in the study were admitted they were visited daily by the investigator and asked in English or Nepali for signs of potential infection, including: pain, fever, cough, diarrhoea or urinary discomfort. When necessary simple physical examinations were performed. The patient's chart was checked for new files regarding complaints, physical examinations or results of microbiological cultures. When signs of an infection were present, or a diagnosis of infection was noted in the chart, they were checked against the definitions by the NHSN. In cases when a healthcare associated infection was noted.

30 days after the date of surgery the participants were called by a secretary at the surgical department to assess the presence or absence of infection using a questionnaire. The section examining surgical site infection was based on the questionnaire used in the study "*Reliabilty and validity of using telephone calls for post-discharge surveillance of surgical site infection following caesarean section at a tertiary hospital in Tanzania*" by Nguhuni et al [49], shown to have a specificity of 100% and a sensitivity of 72%. All other parts of the questionnaire were prepared by the investigator (see appendix 2). The study endpoint was presence or absence of surgical site infection, pneumonia or urinary tract infection at the time of the phone call follow-up or in the period since surgery.

Surgical procedures were classified as minor, intermediate or major according to the procedural

database of Bupa, a large healthcare insurance company [50].

Table 2. Examined patient factors				
Extrinsic patient factors				
Admission date				
Date of surgery				
Type of surgery				
Wound classification				
Clean				
Clean/Contaminated				
Contaminated				
Dirty				
Total operation time*				
Use of postoperative surgical drain				
Ward (data not shown)				
Patients per room				
Hospital stay length				
e risk factors for Healthcare Associated				
Infection, HAI.				
Abbreviations:				
Metabolic equivalence of Task, METs; American Society of Anaesthesiologists; Chronic				
Obstructive Pulmonary Disease, COPD.				
*Total time under anaesthesia was used as a proxy for this measurement, see discussion.				

Table 2: Examined patient factors

# **Statistical Methods**

Because of the small number of detected cases it was not deemed appropriate by to perform

statistical tests, since the results would not have been trustworthy. Descriptive statistics were

performed using IBM® SPSS® Statistics version 24.

### **Ethics**

This study was mostly observational in nature, and as such did neither interfere with nor alter the care given the participants. Patients eligible for inclusion were provided written information in Nepali concerning the purpose of the study, the consequences of participation and their right to leave at any time. The data collected has been handled confidentially and all results are anonymous. This study has been approved by the Review Board of Tribhuvan University's Institute of Medicine (see appendix 3). Care has been taken to align this study with the principles of the Helsinki Declaration.

#### Results

168 abdominal, urological and breast- or thyroid related procedures were executed between the  $2^{nd}$  of March and the  $30^{th}$  of March 2018.

Of these a total of 53 procedures were excluded (see figure 2). 40 potential cases were excluded due to the surgical procedure in question not being defined as an operative procedure by the NHSN [51]. 6 procedures involving patients under 18 years of age were excluded. Over the course of the inclusion period another 7 patients were excluded due to undergoing another operation within the 30 day follow-up period.

2 patients declined to be in the study. 3 potential participants were lost due to undergoing elective surgery without subsequent admission, 3 due to discharge from hospital on the same day of their surgery and further 2 patients due to breaks in communication.

2 patients could not be contacted during the follow-up. 4 patients were excluded on follow-up due to having undergone additional surgery in the follow-up period.

Data from both the admission period and the follow-up was available for a total of 99 participants. 4 participants had developed HAI during admission to hospital, 0 after discharge.

2 patients had developed surgical site infection, 1 patient had developed pneumonia and 1 patient had developed blood stream infection. In the patient with blood stream infection, Extended Spectrum Beta-Lactamase (ESBL) producing E. coli was detected. In the other patients the associated bacteria was not noted.

The incidence of HAI was 4% (4/99). The total number of hospital days was 683, with an average length of stay of 6,9 days per patient. Subtracting the days after diagnosis of HAI leaves 610 hospital days, which results in an incidence rate of 6.56 per 1000 hospital-days. Including the follow-up period, the total number of days without infection was 2912, resulting in an incidence rate of 1.37 per 1000 person-days.

Tables 3 and 4 list data on examined general patient factors. Table 5 lists surgical data. Table 6 lists number and types of operations performed.

Table 5: Metric Values						
	Healthy					
			Std.			
	n	Mean	Deviation	Min	Max	
Age	95	47	15.37	19	89	
BMI	85	23.1	4.43	14.7	37.1	
LOS	95	5.86	5.74	1	39	
	HAI					
Age	4	34	22.20	20	67	
BMI	4	23.5	2.55	20.7	26.9	
LOS	4	31.5	14.15	17	50	
Table 3, showing the scalable values for participants, divided into groups of healthy and infected patients.						
Abbreviations: Body Mass Index, BMI; LOS, Length of Stay; HAI, Healthcare Associated Infection.						

Table 3: Metric Values

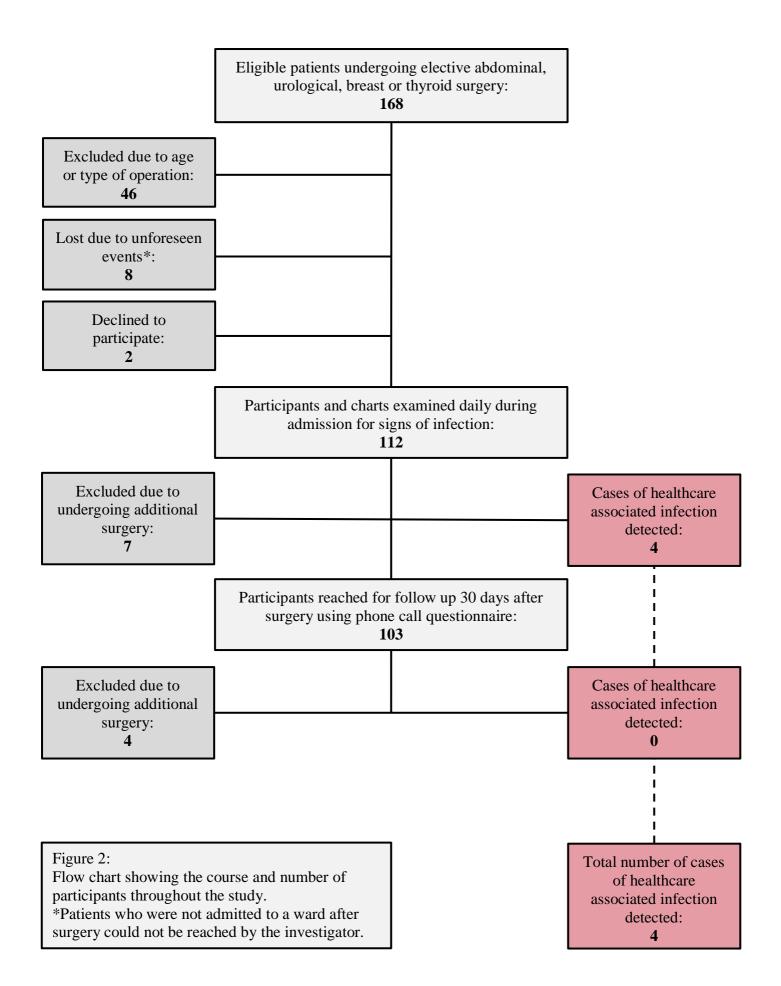


	Table 4: General Data			
	Healthy HAI			
	n (%)	n (%)		
Age Group				
<30	13 (13.7)	3 (75)		
31-50	46 (48.4)	-		
51-70	27 (28.4)	1 (25)		
>70	9 (9.5)	-		
Sex				
Female	45 (47.4)	2 (50)		
Male	50 (52.6)	2 (50)		
METs				
>4	85 (89.5)	4 (100)		
Other	5 (5.3)	-		
Missing data	5 (5.3)	-		
ASA score				
1	43 (45.3)	2 (50)		
2	40 (42.1)	1 (25)		
3	12 (12.6)	1 (25)		
Smoking				
Never	66 (69.5)	2 (50)		
Past	20 (21.1)	1 (25)		
Current	9 (9.5)	1 (25)		
Nutritional Status	) ().5)	1 (23)		
Underweight	10 (10.5)	_		
Normal weight	51 (53.7)	3 (75)		
Overweight	17 (17.9)	1 (25)		
Obese	7 (7.4)	-		
Missing data	10 (10.5)	_		
Preoperative Anaemia	10 (10.5)			
Absent	61 (64.2)	1 (25)		
Present	31 (32.6)	3 (75)		
Missing data	3 (3.2)	5(15)		
Beds per Room	3 (3.2)	-		
Single	14 (14.8)			
Double	, ,	-2(50)		
	33 (34.7	2 (50)		
General	48 (50.5)	2 (50)		
Length of stay	22 (22 2)			
<3	22 (23.2)	-		
3-6	41 (43.2)	-		
6-9	15 (15.8)	-		
9-12	8 (8.4)	-		
>12	9 (9.5)	4 (100)*		
Comorbidities <sup>†</sup>				
Any Comorbidity	32 (33.7)	2 (50)		
Immunodeficiency	7 (7.4)	-		
Diabetes mellitus	12 (12.6)	-		
COPD	2 (2.1)	-		
Malignancy	16 (16.8)	2 (50)		

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Table 4: Collected general data, divided into groups of Healthyand Infected (HAI) participants.

\* Includes days after diagnosis.

<sup>†</sup> Values represent prevalence of listed illnesses.

Abbreviations:

Healthcare Associated Infection, HAI

Metabolic Equivalence of Task, METs;

ASA Score, American Society of Anaesthesiologists;

Table 5: Collected surgical data, divided into groups of Healthy and Infected (HAI) participants:

Abbreviations:

Healthcare Associated Infection, HAI

Table 6: Types of surgery performed.

Table 6: Types of surgery performed. Type of surgery	Class	Total	Excl.	Declined	Missed	Included
Neck	Clubb	Iotui	Linei.	Deennea	1110000	menudeu
Partial thyroidectomy	Major	2	0	0	0	2
Breast	1114101		U	Ū		2
Modified Radical Mastectomy (MRM)	Major	3	0	0	0	3
MRM re-operation	Major	1	0	0	0	1
Local excision of breast tumour	Inter.	5	0	0	4	1
Gynecomastia excision	Inter.	1	0	0	1	0
Upper Abdomen	mer.		0	0	1	0
Laparoscopic cholecystectomy	Major	33	1	1	1	30
Open cholecystectomy	Major	1	0	0	0	1
Extended cholecystectomy	Major	5	1	1	0	3
Whipple's operation	Major	4	0	0	0	4
Frey's procedure	Major	2	0	0	0	2
Proximal SplenoRenal Shunt (PSRS)	Major	1	0	0	0	1
Gastrojejunostomy	Major	2	1	0	0	1
Duodenojejunostomy	Major	1	0	0	0	1
Lower abdomen	Widjoi		0	0		1
Mesh hernia-repair	Inter.	7	0	0	0	7
Ileostomy closure	Major	2	0	0	0	2
Hemicolectomy	Major	2	0	0	0	$\frac{2}{2}$
Diversion colostomy	Major	1	0	0	0	
Hartmann's reversal	Major	1	0	0	0	1
Open appendicectomy	Inter.	1	0	0	0	1
Mesenteric mass removal	Major	2	0	0	0	2
Iliac lymphnode excision	Inter.	1	0	0	0	1
Kidney/Adrenal glands	Inter.			0		1
Kidney transplant	Major	6	0	0	0	6
Nephrectomy	Major	12	0	0	0	12
Radical nephroureterectomy	Major	12	1	0	0	0
Anatrophic nephrolithotomy	Major	1	1	0	0	0
Bladder/Urinary tract	Wiajoi	1	1			U
TURBT	Major	10	3	0	0	7
TURP	Major	10	0	0	0	1
Urethroplastic surgery	Major	8	3	0	2	3
PCNL	Major	6	0	0	$\begin{vmatrix} 2\\0 \end{vmatrix}$	6
Urethrotomy	Major	1	0	0	0	1
Optical internal urethrotomy	Major	1	0	0	0	1
Ureterorenoscopic lithotripsy (URSL)	Minor	7	7	0	0	0
Retrograde intrarenal surgery (RIRS)	Minor	26	26	0	0	0
Cystoscopy	Minor	20	20	0	0	0
Double-J catheter removal	Minor	3	3	0	0	0
Retrograde pyelogram	Minor	2	2	0	0	0
Posterior Urethral Valve (PUV) ablation	Major	$1^2$	$1^2$	0	0	0
Genitals	major	1	1	0		0
Vaginal stenosis dilation	Inter.	1	1	0	0	0
Skin	mer.		1	0		
	Inter	1	0	0	0	1
Limberg flap	Inter.	168	53	0	0	1
Total Table 6, showing number, types and classification	<u> </u>				-	105

Table 6, showing number, types and classification of surgeries performed at Tribhuvan University Teaching Hospital in the examined period.

Abbreviations: Excl., Excluded; Inter., Intermediate; TransUrethral Resection of Bladder Tumour, TURBT; Transurethral Resection of Prostate, TURP

#### Discussion

The cumulative incidence of Healthcare Associated Infection, HAI, in elective surgery at Tribhuvan University Teaching Hospital in Nepal was 4%, and the incidence rate 1.37 infections per 1000 patient days. This is lower than the results from other studies investigating HAI in low-income regions.

As stated in the introduction, data on the incidence of HAI in low-income regions is comparatively scarce. In a large review article published in 2010 by Bendetta Allegranzi et al. [20], the overall incidence of HAI was 7.4%, and the incidence of SSI in patients undergoing surgical procedures was 5.6%. This study found a cumulative incidence of 4%, almost half as much as the incidence from that report. While the focus on a subset of elective surgeries makes a direct comparison between the results of the two impossible, it is unlikely that the lower risk conferred by elective surgery can be the sole cause of the great difference between them.

In high income countries, the incidence of SSI after elective abdominal surgery has been found to be as low as 0.71%, following cholecystectomy in healthy patients [13], or as high as 17.3%, following rectal surgery [14]. The risk of HAI is dependent on the complexity and location of the surgery [14]. As laparoscopic cholecystectomy accounted for a third of the cases is this study (33/99), the low incidence of HAI recorded is understandable. In reviewing the risk factors for SSI in the USA, Philip S. Barie stated that most infections are related to patient factors [21]. In low-income countries, may not the balance be shifted the other way? Since the average age of the patients is lower, and surgical and ward related risk factors are exacerbated, perhaps the latter play a more important part in the development of HAI. This remains to be studied.

The number of HAI cases in this study was too low for statistical analysis to be reliable. However, some of the examined factors were gathered in such a way as to suggest support for previously known risk factors. Pre-operative anaemia is a known risk factor for SSI [13, 23]. In this study, 33.7% (31) of non-HAI patients had anaemia, while it the HAI-case group it was twice as common, affecting 75% (3) of patients. 50% (2) of the participants with a HAI had been previously diagnosed with a malignant tumour, compared to 16.8% (16) of the healthy participants, also supporting previous studies [16]. There was also a slightly higher proportion of patients with a history of smoking in the infected group: 50% (2) vs. 30.6% (29). None of this is surprising; patients in a worse preoperative condition have a greater risk of infection [21]. In this light one would have expected to observe a difference between the two groups in ASA score and METs, as these are used to assess a patients risks ahead of surgery. American Society of Anastaesiology (ASA) score groups patients based on current illnesses. A high ASA score has been associated with higher risk of HAI in previous studies [19]. MET, Metabolic Equivalent of Task, is used to calculate a patients functional capacity [52].

In the surgical data, the differences between the two groups were even more telling. Major procedures are known risk factor for HAI. However, in this study almost all included studies were listed as "major" (89.9%), and the differences seen were therefore small. In examining other previously determined risk factors, the HAI-case group was greatly overrepresented in some groups: All four patients with HAI (100%) had undergone open procedures with a surgery time over 2 hours and afterwards been fitted with surgical drains. The corresponding figures in the non-infected group were 50.5% (48) with open procedures, 35.6% (32) with surgeries over 2 hours and 35.8% (34) with postoperative drains. These factors have all been correlated with a higher risk of HAI [13, 16].

As described in the introduction, HAI is associated with an extended length of stay [3]. This also seems to be the case in this study: the average length of stay for healthy participants was 5.9 days, compared with 31.5 days for the participants with HAI.

Surgeries were classified as clean or clean/contaminated, depending on bodily location, when no breaches of sterile protocol were noted in the operation report. This was the case in 84 (84.8%) of the examined procedures in this study. Since "contaminated" and "dirty" wound classification has been associated with a higher risk of HAI [13], the high percentage of clean procedures in this study implies a low risk of infection. The most common type of surgery was laparoscopic cholecystectomy, which as stated above has been associated with a risk of infection of less than 1%. These two factors, the cleanliness of the operations performed and the low risk associated with them, may be part of the explanation for the low number of cases in this study.

Naturally, abdominal procedures requiring the opening of bowels exposes the patient to more potentially harmful bacteria than does surgery into a sterile part of the body; the surgical site is inoculated either from outside the body or from inside the operated organ [21]. In this study, elective general surgery was examined as a group. To separate types of surgery with different levels of risk of infection research into a smaller subset of operations would be interesting. This would naturally require a longer study period. It would also be interesting to examine other factors that have been associated with HAI that were not included in this study, for example congestive heart failure [13] and weight loss [25] and to follow gastrointestinal infection as another common HAI.

Antibiotic prophylaxis is a common way of combating the risk of infection. According to the national guidelines from the Ministry of Health of Nepal antibiotic prophylaxis is not generally required in "clean" surgery [53]. Still, measuring the frequency of its use in this study would have been valuable. Furthermore, since identifying which types of bacteria cause HAI is vital in determining how to treat them, focusing more on this issue is important in further studies. Number of days with invasive devices, such as central vein or arterial catheters, were not monitored except for the presence of absence of surgical drains. This could easily have been added to the current study method as a part of the daily follow-up.

The lack of cases in this study stems from the short period of observation. While a retrospective study could have greatly increased the number of patients, a study set up in such a way would face two great obstacles:

- The unreliability of the medical records over a longer period of time.
- The absence of an internationally standardised follow-up of all surgical patients.

As a result of these two factors, a retrospective study would have likely underestimated the true incidence of HAI by no small amount. In the 2011 "Report on the Burden of Endemic Health Care Associated Infection Worldwide" by the WHO [2], such a study would have been classified as being of low quality, since it would lack both prospective design and standardised definitions.

Hand hygiene has been described as the most important aspect in the reduction of HAI because of its low cost and great effectiveness. In a country such as Nepal, where hand sanitiser is so much less accessible in the wards compared to in a high-income setting, an interventional study into the effectiveness of hand sanitiser would be fascinating. One could start by getting a baseline value for the incidence of HAI and perhaps investigate the knowledge and attitude of the staff towards hand sanitiser. Thereafter expand the number of hand sanitiser bottles in the examined wards and give lectures on the proper use. After a time a new HAI incidence could be measured, thereby hopefully showing the great effect of adequate hygiene. Such results, if good enough, would help in persuading hospital management that investing in hand hygiene could save money that is now spent on the treatment of HAI.

How much later can HAI occur? For SSI, the most widespread norm is 30 days, or 90 days in certain cases. For other types of HAI, however, the definition varies from 2 days [54] hospital discharge, to 10 [55] or even 30 days [56]. In this study, all types of HAI were followed up at the same time, 30 days after the patients date of surgery. This is not the same as to say 30 days after leaving the hospital, and any infections that might have arisen after the follow-up phone call were missed.

The locally used definition for anaemia was difficult to come across. Specialist physicians gave values ranging from <10 g/dl for women and <11 g/dl for men to <13.5 g/dl and 14.5 g/dl respectively. The result of this would be defining between 19% and 72% of the patients in this study as anaemic. Finally anaemia was defined as per the definition by the WHO: haemoglobin level <11,8 g/dl for non-pregnant women and <12,8 g/dl for men, after adjusting for the elevation above sea-level [57]. For current smokers this limit was further adjusted by 0.03 points to <11,77 and <12,77 g/dl respectively. This defines 35.4% (34) of the patients in this study as anaemic, which is surprisingly high (see table 4). 32.4% (11) of the patients with anaemia had been diagnosed with a malignant tumour, in which anaemia is a common complication. Another 32.4% (11) had another one of the examined comorbidities. For most of them, however, and for the final third of the patients with anaemia at TUTH would be interesting.

One could use a stepwise approach to test patients for likely causes of anaemia, from chronic malnourishment or heavy menstrual bleedings, to undiagnosed parasitic infections or even malignancies.

MET, Metabolic Equivalent of Task, is a value used to standardise intensity levels of physical activity. At TUTH, it was used along with ASA-score in the preoperative assessment of patients. A patient was deemed fit to undergo surgery if capable of performing tasks requiring a MET score of 4.0, equalling "stair climbing, slow pace" [52]. This is a practical example of what this study aimed for: a known risk factor for surgery complications, "low functional capacity", used to determine which patients should undergo surgery.

#### Strengths and weaknesses

This study's main weakness is the lack of HAI cases. Whether this is due to an actual low incidence of HAI or to weaknesses in the study design is not certain. Elective, often simple, surgery in comparatively young and healthy individuals may contain a low risk of infection, even in the healthcare setting of a low income country.

The mode of follow-up was not optimal, but practically feasible. In previous studies, up to 84% of SSI cases have been found after discharge from hospital [58]. In this study not a single case was revealed on follow-up despite using a validated questionnaire with 72% sensitivity (see appendix 2), which may support the adequacy of the observed incidence. Another consideration is the follow-up time: while 30 days is the standard according to the NHSN, not all infections manifest in this period. In a study of elective cholecystectomy by Warren et al [13] using a 90 day follow up time, 19% of SSI were found later than the first 30 days.

During the admission period, there were two main difficulties in examining the patients for infection. The first was the language barrier: often the patients and the investigator did not share a language, and had to rely upon short phrases or signs. Most of the information had to be collected from the charts. However, they were the second problem: many times they were difficult to locate, and the writing was often short and difficult to interpret. These problems may have led to mild symptoms of SSI being missed, and a subsequent undervaluation of the incidence of HAI.

The total time under anaesthesia was measured as a proxy for total surgery time in this study as this information was more readily available and more reliable than actual total surgery time. However, as total surgery time is more often used this reduces the comparability of the findings with other studies, an already known problem of studies from low income countries [20, 34].

Patients undergoing surgery without being admitted were not included in the study for practical reasons. It would have been difficult and time-consuming to locate them, since the schedule of surgery in the out-patient department was fluid and prey to erratic changes. However, since they probably represented the most healthy patients and the most minor operations available their exclusion shifts the field of study slightly, focusing on the more complicated elective cases that needed admission to the hospital.

34% of participants in this study were diagnosed with a significant comorbidity. This may be an underestimation, as some patients exhibited symptoms of chronic illness without having any such diagnoses listed. Height was routinely missing from the records. In those cases self-reported height was used, which may be inaccurate. When information about weight was missing, there was no way of attaining it, since no scale could be procured. Other missing data could usually be found or recorded with the help of interns and nurses.

# Conclusion

The results from this study, however, indicate a low incidence of HAI after elective general surgery at TUTH in Nepal. No statistical correlations could be drawn due to the low number of cases. However, descriptive analysis of probable patient risk factors seems to offer support for the results of previous studies. If accurate, the low incidence recorded suggests that the risk of HAI is low for patients undergoing elective surgery. Therefore, they may not be a future target group in efforts to reduce HAI.

#### Populärvetenskaplig sammanfattning

#### Riskfaktorer för Sjukvårdsrelaterad Infektion efter Rutinoperationer i Nepal

Sjukvårdsrelaterade infektioner är den vanligaste komplikationen till sjukhusvistelse i världen [1]. De leder till ökat lidande och ökad dödlighet. Dessutom behöver drabbade patienter ytterligare behandling i form av antibiotika eller kirurgi och behöver ofta stanna kvar på sjukhuset längre än vad som annars krävts. Sjukvårdsrelaterad infektion står därför för en betydande andel av Sveriges årliga vårdkostnader (7 miljarder kronor årligen 2013-2016, 11% av vårdbudgeten) [10].

Många studier har gjorts på ämnet, de allra flesta i höginkomstländer. Det är känt att vårdrelaterad infektion är vanligare i låginkomstländer, vilket bland annat förklaras med att det är färre personal per patient och att hygienenstandarden på sjukhusen är lägre [3, 5]. Hur stort problemet är och exakt vilka riskfaktorer som är de viktigaste i låginkomstländer är dock inte känt.

Bland de studier som gjort i låginkomstländer så har de flesta fokuserat på infektioner efter akut kirurgi eller på intensivvårdsavdelningar [20]. Därför undersökte denna studie rutinoperationer. Syftet var att ta reda på hur många som fick infektion under den undersökta tiden (incidens) och att se om det fanns några faktorer som ökade risken att drabbas. De undersökta infektionerna var postoperativ sårinfektion, urinvägsinfektion, lunginflammation och "blodförgiftning" (sepsis).

Studien utfördes på tre kirurgavdelningar på Tribhuvans universitetetssjukhus i Kathmandu, Nepal och pågick i totalt 60 dagar. Under de första 30 dagarna kontaktades alla de patienter som genomgick rutinoperationer på de undersökta avdelningarna. De informerades om studien med hjälp av ett samtyckesformulär på nepalesiska (se appendix 1). De som gick med på att vara med i studien följdes upp dagligen under den tid de var inneliggande på sjukhus för att hitta tecken på infektion. Dessutom samlades patientdata in från deras journaler. I den andra fasen kontaktades patienterna per telefon 30 dagar efter deras operationsdag, och de frågades återigen efter tecken på infektion.

Totalt kunde data från 99 patienter undersökas, varav bara fyra hade fått en vårdrelaterad infektion. Det ger en kumulativ incidens på ca 4%, vilket var ovanligt lågt. Kanske förklaras det av att det är lägre risk för komplikationer efter planerade operationer. På grund av att det var så fall av infektion kunde ingen statistisk analys utföras. Man såg dock att alla de som drabbats hade genomgått långa, svåra operationer och att tre av dem hade lågt blodvärde inför operationen. Dessa faktorer har visats vara kopplade till ökad risk för sjukvårdsrelaterad infektion i tidigare studier, och resultatet av den här undersökningen pekar också åt det hållet.

Sjukvårdsrelaterad infektion är fortfarande en viktig och farlig komplikation till sjukhusvistelse, även om den här studien tyder på att risken är lägre vid planerade operationer.

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# Appendices

- Appendix 1: Consent Form (first page is the one handed out, the second page is the English version).
- Appendix 2: Follow-up Form.
- Appendix 3: Approval from the Institutional Review Committee of Tribhuvan University Teaching Hospital's Institute of Medicine.

Patient ID: Bed number:





सहमति फारम

# त्निभुवन विश्वविद्यालय शिद्धरग ग्रस्पतालमा सामान्य सर्जरी पछि सर्जिकल साइट संक्रमरगको लागि जोखिम कारक

प्रिय सर या महोदया,

श्वसन संक्रमरण सर्जरी पछि एक सामान्य जटिलता हो, लामो समय सम्म दुखाइ र विस्तारित उपचार समयको काररण। लद्धरगहरू हल्का र गम्भीर देखिन्छन्, र पनि केहि ग्रवस्थामा जीवनमा खतरा हुन सक्छ। यो शर्तलाई ग्रफ राम्रो बुभन र ग्रन्ततः राम्रो रोकथाम प्रदान गर्न हामी सामान्य सर्जरी पछि घाव संक्रमरण को विकास को लागि विभिन्न जोखिम कारकहरु मा एक जांच को संचालन गर्दै छन्। तपाईं यस ग्रध्ययनमा भाग लिन सोध्नु भएको छ। यदि तपाइँ सहमत हुनुभयो भने, हामी तपाईंको सर्जरी पछि तपाईंको स्वास्थ्य र पुनःप्राप्ति सम्बन्धी केही प्रश्न नहरू सोध्न २० दिनमा सम्पर्क गर्नेछौं। जबकि तपाईंको योगदानको लागि कुनै मौद्रिक द्वतिपूर्ति छैन, तपाईंको सहयोग यस ग्रस्पताल र भविष्यको बिरामीको लागि ठूलो सहयोग हुनेछ।

सबै एकत्रित डेटा गुमनाम ढंगले हस्तान्तररा गरिनेछ, र म्रन्तिम म्रध्ययन रिपोर्ट प्रकाशित भएमा तपाईंको नाम न त तपाईंको नैदानिक डेटा व्यक्तिगत रूपमा पहिचानयोग्य हुनेछ। भाग पूर्रातया स्वैच्छिक हो। यदि तपाईं कुनै पनि समयमा म्रध्ययन गर्न चाहानुहुन्छ त्यसबाट हटाउन चाहानुहुन्छ किनकि किन कुनै काररा दिन म्रावश्यक छ। यसो गर्दा तपाईंले कुनै पनि ग्रन्य फायदाहरू म्रसर गर्नुहुने छैन जसमा तपाईं हकदार हुनुहुन्छ।

धन्यवाद!

प्रा.डा.योगेन्द्र प्रसाद सिंह

डा.बिकल घिमिरे

🛄 ३० दिन भित्रमा, मेरो कुनै शल्यकिया भएको छैन र कुनै संकमण लागेको छैन ।

नाम

हस्ताक्षर

अन्य कुनै सम्पर्क नम्बर

Patient ID: Bed number:



2074/11/15 2018/02/27



# **Consent Form**

## Risk factors for Surgical site infections after elective general surgery at Tribhuvan University Teaching Hospital

Dear Sir or Madam,

Wound infection is a common complication after surgery, causing prolonged pain and extended healing time. The symptoms range from mild to severe, and can even be life-threatening in some cases. To better understand this condition and to eventually offer better prevention we are conducting an investigation into different risk factors for developing wound infection after general surgery. You are being asked to participate in this study. If you agree, we will contact you 30 days after your surgery to ask a few questions regarding your health and recovery. While there is no monetary compensation for your contribution, your assistance would be a great help for this hospital and for its future patients.

All collected data will be handled anonymously, and in the event that the final study report is published neither your name nor your clinical data will be individually recognisable. Participation is entirely voluntary. If you at any time would wish to withdraw from the study you have the right to do so, without the need to give any reason as to why. Doing so will not affect any other benefits to which you are entitled.

Thank you!

Prof. YP Singh, Head of Surgery Dr Bikal Ghimire

Mr Isak Moen

I have not undergone surgery, nor had any major infections in the last 30 days.

Name

Signature

/\_\_\_\_/\_\_\_\_ Date

Telephone number

Alternative telephone number

ID						
Risk factors for surgical site infection after elective general surgery at Tribhuvan University Teaching Hospital						
		30 days after surgery follo	w-up phone call form			
Date	//	Days Post OP				
1) How has y	our general co	ondition been since discharge?				
	Good (1)	Fair (2)	Bad (3)			
2) a) Have y	ou been admit	tted to hospital since your operat	ion?	YES	NO	
b) If YES	: what was the	e diagnosis?				
c) If YES:	number of da	ays in hospital?				
3) Have you	been taking ar	ntibiotics since discharge?		YES	NO	
<i>c</i>	•	ischarging yellow liquid (pus), o since discharge?		YES	NO	

of has it done since so sin	1L5	NO				
b) Is there any pain or redness at the surgical wound, or has there been since discharge?			YES	NO		
c) Have you been having feve	rs since discharge	?	YES	NO		
d) Have you been told by heal that you have a wound inf	YES	NO				
e) Is there, or has there been, a of the wound, or protrusion	YES	NO				
5a) Have you had new or worse	YES	NO				
b) Have you started coughing up yellow mucous, or have you coughed up more mucous than usual since discharge?			YES	NO		
c) If YES (to question 5a or 5b): When did the this start?						
This week (1) 1-2 w	3-4 weeks ago(	4)				
6a) Have you had increased uri	nary urgency since	e discharge?	YES	NO		
b) Have you had increased urinary frequency since discharge?			YES	NO		
c) Have you had any pain while urinating since discharge?			YES	NO		
d) If YES (to question 6a, 6b or 6c): When did the this start?						
This week (1) $1-2$ weeks ago(2) $2-3$ weeks ago(3)			3-4 weeks ago(4	4)		

THANK YOU! Please email any questions, and the final results to gusmoeis@student.gu.se

त्रिभुवन विश्वविद्यालय चिकित्सा शास्त्र अध्ययन संस्थान डीनको कार्यालय, महाराजगंज पो.ब.नं.: १५२४, काठमाडौँ, नेपाल । फोन नं. ४४१०९११, ४४१२०४०, ४४१३७२९, ४४१६१८७

पत्र संख्या / Ref.:-316/6-11-E)2/0744/1075-



Tribhuvan University Institute of Medicine **Office of the Dean** Maharajgunj, P.O. Box: 1524 Kathmandu, Nepal Ph.#4410911, 4412040, 4413729, 4418187

मिति / Date:-

February 20, 2018

### **Research Department**

Mr. Isak Moen Medical Student University of Gothenburg Sweden.

#### **Ref: Approval of Research Proposal.**

Dear Mr. Moen,

Thank you for the submission of your research proposal, entitled "Health care associated infections in surgical wards at Tribhuvan University Teaching Hospital, Nepal".

I am pleased to inform you that after careful evaluation, the above mentioned research proposal has been approved by Institutional Review Committee (IRC) of Institute of Medicine (IOM), Tribhuvan University on February 20, 2018.

As per our rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in title, objectives, problem statement, research questions or hypothesis, methodology, implementation procedures, data management and budget may be made so and implemented only after prior approval from IRC. Thus, it is compulsory to submit the details of such changes intended with justifications prior to actual change in the protocol.

Please note that you can start recruiting the research participants only after getting approval letter from the IRC. You are also requested to follow the ethical guidelines of IRC of IOM.

After completion of your study you must submit a copy of final draft of your research to the Research Department.

If you have any further queries, please do not hesitate to contact us.

Prof. Dr. Yogendra P. Singh Member Secretary Institutional Review Board

<u>Cc</u> HOD Department of GI & General Surgery Maharajgunj Medical Campus IOM, Maharajgunj

