Risk adjusted mortality rates:

Do they differ if based on administrative data (Hospital Standardised Mortality Ratio) versus a physiological predictive model (APACHE IV®)?

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University of Cape Town

South Africa

This dissertation forms part of the 60-credit requirement in partial fulfilment of the M Phil in Emergency Medicine (Patient Safety).

The research project was performed in completion of the dissertation for the above mentioned degree and is the candidate's independent work. No parts of the work, or the entire work, have been submitted to any other institution for a degree. This work has not been published to date.

Signature: Signed by candidate

Signature removed

Date: 26/2/2015

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Section A

Research Proposal

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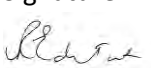
This research proposal forms part of the 60-credit requirement in partial fulfilment of the M Phil in Emergency Medicine (Patient Safety).

Declaration:

I, Rene Toua, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

Signature: 

Date: 14 August 2013

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Abstract

Background: The measurement of, and reporting on clinical outcomes, is an integral part of clinical governance but no consensus has been reached about which measures to use and the validity thereof.

Objective: To compare an administrative predictive model (Hospital Standardised Mortality Ratio [HSMR]) with a physiological predictive model (APACHE®IV) to determine the correlation in the predicted risk adjusted mortality rates.
To determine whether stratifying the patients into low (<10%), medium (<50%) or high (>80%) risk bands will lead to more accurate comparisons.

Design: Prospective cohort study

Setting: 63 critical care units in 34 private acute care facilities across South Africa

Methods: Both HSMR and APACHE®IV are calculated routinely in all participating facilities and the research study will use the data generated. An additional audit process will be implemented to determine and ensure the integrity of the data.

Ethics: The healthcare facilities have standard processes in place to ensure confidentiality and the statistician analysing the data is employed by the healthcare group and bound to a confidentiality agreement. Ethics approval has also been obtained by the University of Cape Town ethic committee before the approval of the research proposal.

Introduction

The healthcare industry, private as well as public, is under increasing pressure to provide proof of "quality service" and guaranteed clinical outcomes. The "Deficit Reduction Act of 2005" lead to Medicare (United States), since 1 October 2008, not reimbursing hospitals for a number of complications or co morbidities that is deemed to be preventable. (1) South African funders of medical aid schemes are placing increasing pressure on private healthcare providers to take responsibility for some preventable adverse events that take place in their facilities and carry the accompanied financial risk. Ruff *et al* has stated that "outcomes" and "process re-engineering" are critical in the development of a "re-engineered" health sector. (2) Discovery Health is a private health insurer and on the forefront of innovation in managed healthcare. They have developed a number of case-mix tools: "Diagnosis Related Groupings (DRG's) - for hospital events; an Episode Grouper (for multiple ongoing and simultaneous member events); and Adjusted Clinical Groups (a system that develops a composite member risk score and promotes population-wide segmentation analysis and management)" which is used in negotiating tariffs and contracts. (2) The healthcare funders have information on all aspects of patient care e.g. radiology, pathology, pharmacy, etc and is able to calculate a "cost-per-event" for healthcare encounters. They use the data to extrapolate the quality of clinical care, patient outcomes, negotiate tariffs and build networks of service providers. (2)

In the private healthcare institutions, included in the study, administrative data is used as a proxy measurement for clinical outcomes as the clinical information available in the files is mostly captured by nursing staff and very few doctors' record clinical findings in the patient folder. Hospital Standardised Mortality Ratio (HSMR), Re-admissions (patients admitted within 30 days of discharge), Extended Length of Hospital Stay (ELOS), Adverse Patient Events and Antimicrobial usage is measured and reported on monthly. HSMR is used as a means of identifying institutions with a higher than expected mortality index and thus proxy for possible poor quality of care. Hospital management however was mostly opposed to the measure and felt that it didn't accurately reflect the care rendered.

Background and Rationale

The "International Classification of Diseases (ICD) is the standard diagnostic tool for epidemiology, health management and clinical purposes. This includes the analysis of the general health situation of population groups. It is used to monitor the incidence and prevalence of diseases and other health problems" (3) In May 1990 the Forty-third World Health Assembly accepted ICD-10 and WHO member states started implementing it since 1994. Development has already started on the 11th revision and it's expected that this will be finalised by 2015. (3) ICD-10 coding was implemented as a South African diagnostic coding standard on 1 July 2005. The Medical Schemes Act 131 of 1998, Regulation (5) f states that in order to facilitate payment of an account it has to contain an ICD-10 code related to the episode of healthcare.(4) The purpose of diagnostic coding standards is to translate healthcare conditions and diseases from descriptions to alphanumeric code. This simplifies the process of storing, retrieving and analysis of the information. As standardised definitions and coding rules are used it can also be used to compare outcomes (morbidity and mortality rates) globally. (4)

Current Procedural Terminology (CPT) is a numeric, 5-digit code used to identify the services rendered by the practitioners. In South Africa we are currently using the American Medical Association "Physicians' Current Procedural Terminology" fourth version. The main section of the CPT body is listed as six sections:

- Evaluation/Management 99201-99499
- Anaesthesia 00100-01999
- Surgery 10040-69990
- Radiology 70010-79999
- Pathology/Laboratory 80048-89398
- Medicine 90281-99607

CPT-4 coding is used in the private healthcare facility for billing of surgery and procedures. South African Dental Association (SADA) codes are used for dental procedures. (5)

At the private healthcare institution the clinical information in the patient folder is translated into ICD-10, CPT-4 and or SADA codes by a case-manager or dedicated clinical coder and recorded on the Patient Administrative System (PAS) database where it is stored on the local server and transferred to a central server nightly. The information is then "dumped" in the data warehouse on a weekly basis. All patient records have at least a primary diagnosis code as this practice is legislated and the codes generate a hospital account. (5)

The training of coders and case managers is done "in-house" by five regional clinical information specialists and consists of: "intermediate ICD-10 course (5 days of formal learning), advanced ICD-10 course (5 days of formal learning) and CPT-4 (5days of formal learning)" The learning material was developed in-house and includes training on the use of SADA codes. The candidates write an examination one week after completion of the course and a certificate of competence is issued. Staff is sometimes trained as "relief" coders and do not use the skill regularly. Training is repeated if coding audits show poor results, no standard benchmark exists, with a possible lack of knowledge or insight. Coding quality and accuracy is currently verified by formal bi-annual, on-site audits, performed by the regional clinical information specialists on a statistically significant sample of hospital folders. The folders is selected by the in-house statisticians to reflect the acuity and "mix" of the patients seen in the hospital e.g. patients admitted to critical care units, day cases, etc. A sample of the files audited is then re-audited by the clinical coding specialist, "audit of the auditor", and is presented as a score out of 100. This score is adjusted up or down if any significant discrepancy is found.

Measuring quality of care in hospitals is complex as it varies extensively. The "Donabedian framework" is commonly used and is based upon: "3 quality-of-care dimensions that is structure, process and outcome" The three measures are interrelated but outcome measures are more commonly used. (6) Hospital Standardised Mortality Ratio (HSMR) is a well known outcome+ indicator, developed by Jarman in 1999, and widely used in the healthcare industry in countries like Canada, the United Kingdom, the United States, Sweden, France and Australia. (6) It is perceived as a proxy for quality of care and used to track performance over time with the objective of improvement. In the Netherlands HSMR was made public since 2011. (6) Concurrently, there are various concerns about the accuracy thereof. (7) HSMR is an adjusted measure, consisting of a ratio

of the observed deaths versus expected deaths. The number of expected deaths is calculated by using statistical modelling, based on the case mix and a number of other variables. The reference value for HSMR is 100 with values above reflecting potentially poor clinical outcomes and values below the opposite. (8) Statistical models can only adjust for known variables. Important factors in the adjustment for the case-mix can be unknown or not taken into account and the case-mix not accurately adjusting for differences and this is known as the "case-mix adjustment fallacy". (8)

The "constant risk fallacy" occurs when a variable is unevenly distributed amongst different populations and risk adjusting for the average effect can underestimate it in one group and overestimate it in another. (8) The number of clinical codes per hospital account, "coding depth" and coding accuracy, can also add to this bias. (9) HSMR has a "low signal (preventable deaths) to noise (unavoidable deaths) ratio" as in most hospitals the number of preventable deaths are so low that changes in the small number will not significantly affect the entire mortality index. Areas of poor quality are often isolated in specific areas in a hospital and measuring a global standardised mortality ratio (SMR) will not identify the areas of concern.(10)

In investigating a false high HSMR limited resources is wasted, institutions stigmatised and faith in data is lost. Conversely a false low HSMR diverts the attention from a real concern and can lead to false reassurance. (11) In South Africa mortality rates are not made public and it is measured in different ways by the different role players in the industry. In the public sector crude mortality rates or mortality per 1000 patient days is used. (12) The private healthcare industry also varies in their manner of measuring mortality rates with crude mortality rates and HSMR used by the 3 largest private healthcare groups. (11)

Acute Physiology Age Chronic Health Evaluation (APACHE) IV is a proprietary prognostic model that has been developed to predict mortality rates and compare patient outcomes across different critical care units. APACHE was originally developed by Knaus and his colleagues in 1981 and the intent was to classify "groups" of patients according to severity of illness. The original intent was never to use it for individual patients. The APACHE model was refined over the time period with APACHE III being developed in 1991 and updated in1998. This was necessitated by discrepancies between predicted and clinical outcomes. The third version was remodelled to APACHE IV, recently incorporating different predictor variables, refining statistical calculations but keeping the physiological variables and weights the same. (14) Clinical data (measuring the "worst" physical parameters) is collected over the first 24 hour time period after admission to the critical care unit and used to determine an "APA CHE" severity score and a standardised predicted mortality ratio. It is crucial to collect accurate data and use standardised definitions.

Vincent, *et al.* have shown that there are various limitations to the use of severity scoring in prognostication, e.g. data input (wide inter- as well as intra-observer variation), geographical location (variation in different population) and lead-time bias (early resuscitation in the emergency department may lead to more "normal" vital signs being recorded) (13) Only a small percentage of critical care units utilise the prognostic scoring models and this may lead to bias as it may be units using evidence based protocols and delivering a high quality of care that choose to implement such a system. Low risk patients can "dilute" the SMR and "hide" a high index. Illness severity may thus be a confounder and stratifying the SMR into low (<10%), medium (<50%) or high risk (>80%) bands may eliminate part of this bias. (15)

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Patient administrative data, whether a critical care fee was rendered on the account, is used to identify patients that may be eligible for inclusion onto the APACHE IV database. The "level of care" (LOC) is billed as "Specialised Critical Care", "Intensive Care" or "High Care" according to a score obtained from the "Clinical Criteria for Specialised Units" document. This document is unique to this private healthcare group and records the patient specific clinical information and determines LOC classification on the severity of illness and the treatment rendered. (Addendum A).

Research Question

Is there a difference in the risk adjusted mortality rate when calculated using administrative data (HSMR) compared to a physiological predictive model (APACHE IV®) in adult patients admitted to critical care units over a 6 month time period in a private healthcare group in South Africa?

Aim & Objectives

Aim:

- To determine whether there is any conformity between the HSMR and SMR (physiologic predictive model) in critically ill adult patients in a private healthcare group in Southern Africa.
- To ascertain whether stratifying the patients according to illness severity leads to a more accurate comparison

Objectives:

- Compare the HSMR with the SMR (APACHE IV)
- Compare the HSMR with the SMR (APACHE IV) in patients with a low (10% or less), medium (50% or less) or high (80% or more) predicted mortality

Methodology

Study design

A cross sectional study will be performed.

Study setting and population

The study will be conducted amongst adult patients admitted to critical care units (intensive care and high care units) in all eligible hospitals of a private healthcare group, Mediclinic, in South Africa (see Addendum B). The Mediclinic group has 49 hospitals in South Africa of which 40 renders intensive care. There are 68 intensive care units in these 40 hospitals. The geographical spread of the hospitals is balanced across most of South Africa
and this will aid in improving the external validity of the study. All patients eligible for inclusion on the APACHE IV database will form part of the cohort. The following patients will be excluded as per APACHE IV database rules: patients younger than 16 years; burns patients; patients admitted with chest pain in order to rule out acute myocardial infarction and patients with a critical care unit stay of less than 4hours. Patients receiving specialised care in a general ward due to bed constraints will be entered onto the database.

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Data collection and management

APACHE IV®

APACHE IV data will be collected manually on a pre-printed document containing all the database fields. (Addendum C) The midpoints of the physiological parameters are indicated on this document, and this aids in ease of completion and accuracy of data. The data is collected by using varied methods in the various critical care units. In the majority of units the data is collected by a designated person (usually the unit manager) as part of their daily task, in other units the nursing staff member caring for the patient completes the document and a few hospitals have a dedicated data collector. The data is routinely collected as part of the daily tasks. The data is then entered into an electronic database (usually by an administrative person) and is "dumped" into a data warehouse from where it is analysed. The documents are completed on discharge from the unit or after 24 hours from admission to the critical care unit has elapsed but some fields (discharge from hospital - date and time) will only be completed at a later stage. This information is not used in the calculation of the SMR and will not affect the data. The hospitals are currently upgrading the database from APACHE III to APACHE IV and all the relevant role-players have been retrained.

APACHE IV® Audit

A comprehensive audit program will accompany the new upgrade and will be done as part of the normal routine. This will help to gauge the quality of the data collected. The APACHE IV® Score on these patients, randomly selected for auditing, will be completed by a trained auditor, unit manager or nursing manager, and the SMR compared. The audits will be conducted monthly in order to detect and rectify errors early and ensure the validity of the data an " audit of the auditor" will be conducted on a statistically representative, random sample, selected at the end of the data collection time period. The SMR will be compared to determine the degree of correlation and at least 80% correlation is required. In the event of incomplete data or illegible entries the patient documentation will be consulted to gather the correct information.

Data Analysis - HSMR

Statistical methodology was developed by the organisation to adjust mortality rates for patient level risk factors and death was "treated as a binary response variable and used a logistic regression model to measure the relation with patient risk variables in order to adjust for case-mix differences. The Mediclinic case-mix methodology was designed and developed by Mr Jannie van Schalkwyk. (16) The outcome is an expected value per admission reflecting the probability that the admission will result in death". (Addendum D) The variables taken into account are primary diagnosis, secondary diagnosis, age, gender, co morbidities, treating speciality and body-mass index. The archiving system is well controlled and files are seldom lost but in the event that this may happen the patient (and the corresponding APACHE IV entry) will be excluded from the cohort. A comparison will be made to ensure that patients are included in both the HSMR and the APACHE IV calculations. The analysis will be made from the available data in the warehouse and will be analysed by hypothesis testing. The electronic data as well as the completed forms with the data fields are part of the routine data and are handled according to standard business practices.

Timeframe

The approval of the research proposal will take an estimated 2-3 months and as the researcher will not be applying for external funding no additional time will be required. The data will be collected over a 6 months time period and data collection will start on 1 Jan 2014 and continue until 30 Jun 2014 or as soon as possible thereafter. The preliminary statistical modelling will start before all data is gathered and will be updated with the final information. The aim is to complete the study no later than the end of July 2014. This does leave only a limited time for the completion of the article but statistical modelling will start sooner and the model updated with the final numbers.

Budget

October 2013 to March 2014				
Item	**Description**	**Unit Cost**	**Number of units**	**Total cost**
Consumables				
APACHE IV® Score	Form to capture information	R0.67	50 000	**R33 500**
Office supplies	Pens, etc	R2.45	100	**R245**
Research travel				
Travel	Travel to sites	R4.50/km	600km	R2 700
Minor research equipment				
Database	Development of an Microsoft Access Database - capture audit results	Researcher to compile		**NIL**
Personnel				
Statistician	Currently employed by private healthcare group and services included in daily work program	NIL		**NIL**
Research assistants	Auditing data entered on the APACHE® Score form	R500/session	5 sessions	R2500
Sundries	Editing, printing, binding, etc			R2 000
Total				**R40 945**

Note:

The cost marked in "bold" is incorporated in the operational costs of the company and will not apply to the researcher. The statisticians are employed by the healthcare group and conducting research is an integral part of their daily output. The total cost to the researcher is **R7 200** and will be carried by the researcher.

Strengths and Limitations

The private healthcare institute has a well functioning clinical information department and uses information to monitor patient outcomes and quality of care. APACHE® is well known and the institution has been using APACHE III® for a number of years. A large number of patients (between 40 000 - 50 000) are captured on the database yearly and this will add to the external validity of the study. A number of dedicated, highly skilled and experienced statisticians is part of the team and actively evaluates data gathered and monitor patient outcomes. Clinical information e.g. coding, etc is audited regularly and comprehensive training done to eliminate deficiencies identified.

The APACHE IV data that is gathered is highly dependent on the knowledge, insight and skill of the person gathering and entering the data into the database. The task is often delegated to a junior person or data even entered before the 24 hour time period has elapsed. The migration from APACHE III to IV is accompanied by a comprehensive retraining program and the assignment of individuals accountable for data accuracy. This should mitigate this risk. The company does as yet not have 100% compliance on the APACHE IV database. If patients are selectively excluded from the database this could lead to bias. However, compliance is generally above 90% and is constantly monitored. The unit manager of the critical care unit is responsible for the accuracy of the data and compliance. At present a monthly compliance report is distributed to each unit but with the development of APACHE IV integration with the patient administrative system is being developed. The information on the patient administrative system will be incorporated in the database and eligible patients listed. This integration will make central monitoring of compliance feasible. A hospital with a compliance of less than 90% will be instructed to investigate and add the patients that were not included. The use of patient administrative data to determine if a patient qualifies for the P CHE IV database may lead to inaccurate in/exclusions. The use of a "criteria score" (in-house checklist) will help to mitigate this risk.

ICD-10 coding is used to translate clinical data (from a document completed in by nursing staff) into coded form and diagnosis related groupings (DRG's). The transfer of information may be incomplete or inaccurate as no doctors notes are kept in the patient file; the nursing staff may not complete the document correctly or comprehensively; or the coder may not code all the information or use inaccurate codes or sequencing. Historically palliative care patients have been excluded from the HSMR calculation. In this model these patients are not excluded as an ICD-10 code for palliative care is not rendered. This is partly due to the confusion as to the appropriate definition and the reimbursement model of the private healthcare funders. The inclusion of patients admitted for palliative care into the HSMR calculation may lead to a value that is higher than the true value and may thus not be comparable to other HSMR models. The identification of patients admitted for "palliative" or "end-of-life" care is currently not possible with the information at hand.

(7) The HSMR looks at all codes on an account (regardless of sequencing), identifies the one with the highest weight and incrementally add weights for the other codes according to a predetermined algorithm. This minimises the effect of incorrect sequencing of the codes. Bi-annual audits measure the accuracy of clinical coding. New reports comparing coding depth are currently being developed.

Ethical considerations

Ethical approval has been received from the institution and is included (see Addendum E). Ethical approval had been granted by the corporate in-house "Research Committee" at the head office of the institution and is applicable to all hospitals. There is no need to obtain approval from all hospital managers individually. All patient information is treated as confidential and although individual patients will be identified in the gathering of data, all the staff involved in the collecting and analysis of data is currently employed by the company and are bound by a confidentiality agreement. The final datasets for the analysis will be analysed by the resident statistician and no raw data with patient identifiers published or made available as part of the outcome of the research project. If the need arises to disseminate individual patient information to a wider audience all patient identifiers will be removed.

Relevance

The care of patients in critical care units contribute significantly to healthcare costs. In the public sector the numbers of critical care beds are limited and patients often denied critical care due to a shortage of resources. In the private sector there are more beds available but healthcare funders are lobbying for stricter admission criteria to critical care units as it is a large "cost driver" in their industry. The imminent National Health Insurance (NHI) plan, with the government contemplating purchasing services from the private sector, will also put pressure on the private sector to provide proof of clinical outcomes. It is important to have reliable, well understood, measures of patient outcome and the proposed study will help clarify the correlation between current outcome measures as utilised in a South African context.

Data Dissemination Plan

The results of the study will be shared externally as well as internally in the company

Internal:

- Presentations to the executive committee as well as the operational committee
- Presentation to the clinical governance committee
- Presentations to the regional clinical governance structures for further dissemination to the front line stakeholders at hospital

External:

- Printed media
    - poster presentation at conference
    - submission of the article to a peer reviewed subject specific journal
    - copy of the dissertation to be made available in the library of the University of Cape Town

Electronic media

- submission of the article to a peer reviewed journal on the world wide web (if not published in a printed format by another journal)
- discussion of the results on discipline specific blogs

- Personal
  - submission of conference abstracts

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MEDICLINIC

Support Document for

Clinical Criteria for Specialised Units form

Clinical Criteria Committee

Updated: Feb 2013

Contents

Clinical Criteria for Specialised Units Form

Overview

Purpose

The purpose of the Clinical Criteria for Specialised Units form is to determine the correct level of care for a specific patient, according to the patient"s condition.

It also serves as a tool to obtain accurate coding information.

The correct level of care and the coding information is used in the case management process in the hospital.

Scope

This form is completed by the CCU nursing staff and the information gathered is used by the Case Coordinator in the hospital, for updating clinical information and for negotiations with medical funds.

Background

Previously, level of care was determined on the grounds of the amount of nursing input required for a patient. This method proved inaccurate and it was decided that the patient"s condition would serve as a better indicator as to what level of care a patient requires.

About the Form

In this document the form and its content will be described in general. Specific keys are used to guide the user through the interpretation of the form.

Important

The criteria are not used on patients in normal wards to determine if they should be send to a specialised unit. Only after the treating doctor admitted the patient to the specialised unit this criteria are used to determine to correct LOC.

Sections on the form

The form is divided into the following sections/tables (Each of these will be discussed separately later in this document):

- Comorbidities
- LOC (Level of Care) Movement (date and time)
- Respiratory System indicators
- Cardio Vascular System indicators
- Neurological System indicators
- Renal System indicators
- Other
- Medication IVI
- Laboratory Imbalances
- Monitoring/Invasive lines
- Emergency Procedures
- IVI Medication with **
- Additional Notes

For how many days does the form provide?

The form can be used for a period of seven (7) days per patient, after which a new form must be completed. Date columns are provided for each section of the form.

As always, the previous days" information is indicated on today"s date, and the worst scenario of the last 24 hours is indicated on the form.

What is the standard method of ticking off the indicators/conditions?

A normal tick ( ) is placed next to every indicator/condition the patient conforms to for that specific day.

What if the patient has a condition that does not appear on the form?

With the exception of the Comorbidities columns where extra lines are provided for additional entries, the rest of the sections were carefully designed to only include those conditions that would have an effect on the level of care.

Note that diagnosis was deliberately excluded, since it"s not an accurate indication of the required level of care.

How do I interpret the keys?

The keys used on the form are *, ** and ***. These keys can be found next to specific indicators/conditions and indicate whether the patient should be in HIC, CCU or SICU. Some conditions do not have any key next to it. Besides the keys itself, the number of ticks also serves as an indication of what level of care the patient should occupy.

Although the keys used are explained on the form, we will discuss these in more detail by means of scenarios, later on in the document.

Sections on the Form

Each section will be discussed separately.

Only the sections and the indicators that need some discussion will be elaborated on with regards to definitions and circumstances.

Comorbidities

The 15 most frequently reported comorbidities (according to Mediclinic coding statistics) were listed here. Additional lines were added to provide for extra comorbidities to be listed if necessary.

Comorbidity	Description
Hyperlipidaemia	Hyperlipidaemia refers to high blood cholesterol or high blood triglycerides
Hypercholesterolaemia	Hypercholesterolemia refers to high blood cholesterol

Patient Status

In this section we indicate the patient"s level of care movement by completing the dates and times at which a patient moved into and out of a specific unit. This section should be completed extremely accurately.

Provision is also made for indicating the date and time periods when a patient was ventilated.

This information can be used to check whether or not the patient must still be in a specific unit.

Other Important Info

Additional lines have been provided to include information unrelated to comorbidities, but which has clinical relevance. Examples include the presence of a permanent pacemaker or important surgical information.

Respiratory System

Please note the following indicators/conditions in this section:

Indicator	Description
Mechanically ventilated with FiO_2 ≥ .6**	Indicates that this patient is in a type 2, 3 or 4 respiratory failure according to the P/F ratio >200.
NPPV** Non-Invasive Positive Pressure Ventilation	NPPV is the delivery of mechanically assisted or generated breaths without placement of an artificial airway. Both CPAP and BiPAP are considered as NPPV. Significant percentages of patient who receive this modality are acutely ill or have severe underlying disease. The patient does not have to be continuously ventilated non-invasively; it can just be for short periods at a time when not coping without ventilatory support.
Extubated < 24 hrs **	Patient should be in CCU for up to 24 hours post extubation. Not all extubations are successful, and the patient must be monitored for up to 24 hrs for possible re-intubation
Intubated but not ventilated **	This patient has an endotracheal tube in place, but is not ventilated. This is often to maintain an open airway and help reduce the risk of aspiration. The patient will require suctioning and close monitoring to prevent complications
Oxygen >40% *	Oxygen therapy per mask greater than 40% or oxygen therapy via nasal cannula (> 5 LPM)
Saturation < 90% on O_2 > 40% *	Indicative of hypoxia despite oxygen therapy and may indicate impending respiratory failure.
Respiratory acidosis *	This is going to require PN interpretation. A respiratory acidosis is a pCO2 > 6.1 KPa (irrespective of compensation). It indicates decreased gas exchange
Respiratory alkalosis *	This is going to require PN interpretation. A respiratory alkalosis is a pCO2 < 4.6 KPa. There are multiple causes and often it is a compensatory response to metabolic acidosis
Respiratory rate > 30 bpm*	There are increased oxygen demands and the respiratory rate increases in order to meet this demand. It is indicative of underlying problems and the patient requires close monitoring (HICU at least)
Bronchospasm / Stridor*	These are symptoms of airway obstruction. Patients are at risk for impending respiratory failure
< 2 hourly nebulisations	This is applicable to patients in acute bronchospasm (usually an acute asthma attack)
< 2 hourly suctioning	When the patient is being suctioned more frequently than 2 hourly. This is mostly applicable to a non-intubated patient who has difficulty maintaining their airway. This is not suctioning of the mouth but rather oro/naso-pharyngeal suctioning to clear secretions and keep the airway patent
Tracheostomy	Note the difference between a Tracheostomy in this section versus a Tracheostomy in the Emergency Procedures section.

Cardio Vascular System

Please note the following indicators/conditions in this section:

Indicator	Description
Cardiac arrest within the 1st 24 hours**	If the patient had cardiac arrest, the patient should be in CCU for at least the 1st 24 hours.
Sternotomy within 24 hours ***	This indicator refers to any heart and lung surgery viewed as „open heart" surgery.
Acute MI ≤ 24 hours with + Trop I/T**	The cardiac markers Troponin T or I are positive indicative of a myocardial infarction, irrespective of whether the patient has had an ST-elevation myocardial infarction (STEMI) or a non-ST elevation myocardial infarction (NSTEMI).
Angina *	Angina is classified as stable or unstable. Unstable angina is chest pain at rest, and indicates partial clot formation in a coronary artery causing decreased blood supply to the heart muscle. This decreased blood supply results in „chest pain" as a symptom.
PTCA** / Stent ** < 12 hrs	The patient status is CC due to the nature of the procedure and / or the presence of a foreign body. Percutaneous coronary intervention (PCI) includes balloon angioplasty with or without placement of a stent. A PTCA is invasive enough to warrant CC monitoring. Potential complications include thrombosis and haemorrhage
Acute Dysrhythmia*	Please note that this include ALL ACUTE Dysrhythmias. CHRONIC Dysrhythmia is NOT INCLUDED unless a Chronic Dysrhythmia becomes ACUTE.
Elective Cardioversion < 12 hours *	Note on the difference between the cardioversion indicated in this section, and the Cardioversion indicated under Emergency Procedures of which the latter will require CC. It is most commonly done for atrial fibrillation, atrial flutter and ventricular tachycardia (with a pulse). Elective cardioversion is electrical cardioversion (also known as direct - current or DC cardioversion). A dysrhythmia can also be chemically cardioverted (for example with Amiodarone). Elective cardioversion is a procedure whereby a synchronized electrical current (shock) is delivered through the chest wall to the heart through pads or paddles that are applied to the skin of the chest and/or back. The purpose of the cardioversion is to interrupt the abnormal electrical circuit(s) in the heart and to restore a normal heartbeat.
Temporary pacemaker-dependent **	This is going to require the PN interpretation. The temporary pacemaker is external and prone to the development of problems. This is usually only a temporary measure until the underlying problem is resolved or a PPM is inserted. The patient must be PM dependent i.e. they do not have an adequate cardiac output without the PM.
Perm. Pacemaker - post insertion 12 -24 hrs *	Note that the patient status is High Care following the insertion of a PM. This is necessary for monitoring of potentially life threatening complications, which include the development of a pneumothorax, dysrhythmias and haemorrhage.
Vasopressor/Positive Inotrope dependent **	Note on the fact that the patient must be TOTALLY DEPENDENT. This is the indication for cardiac failure. The patient can be dependent on vasopressors or positive inotropes to maintain an adequate cardiac output (see list of drugs on the last page of the last page of the clinical criteria document).
Vascular Stent < 12 hrs **	ANY other vascular stent falls under this category. This would include coronary, aortic, carotid and cerebral stents. Patient requires close monitoring because of the possibility of developing acute thrombosis or haemorrhage which would be life threatening.
Hypovolaemia *	This is going to require the PN interpretation. A dramatic reduction in circulating volume as a result of the patient's underlying condition. Symptoms include an elevated pulse rate, diminished blood pressure and

	signs of decreased perfusion (poor capillary refill, weak peripheral pulses)
Tachycardia	Pulse rate > 100 bpm (in adults)
Bradycardia	Pulse rate < 60 bpm (in adults)
Increased capillary leak with oedema	This includes Oedema.

Neurological System

Please note the following indicators/conditions in this section:

Indicator	Description
Glascow coma scale < 8** Gloscow coma scale 9 - 12* Glascow coma scale 13 - 14	Patient usually not able to maintain or protect their own airway Patient can usually protect their own airway, but needs constant monitoring Patient usually just confused / disorientated
Raised intracranial pressure*	According to the Monro-Kellie Hypothesis, the cranial compartment is incompressible and the volume inside the cranium is fixed. The cranium and its constituents (blood, CSF & brain) create a state of equilibrium. If there is any increase in volume in one of the cranial constituents, it must be compensated by a decrease in volume of another. Normal ICP is 0-15mmHg. An ICP > 20mmHg can crush brain tissue, shift brain structures, contribute to hydrocephalus, cause the brain to herniated and restrict blood supply to the brain. Following a cardiac arrest, a patient can have a resultant hypoxic brain injury. The hypoxic injury results in cerebral vasogenic oedema and is likely to result in raised intracranial pressure.
Ventricular drain **	An intraventricular drain can be inserted into one of the lateral ventricles for diagnostic or intracranial pressure relief purposes. Once placed, the catheter can be connected to a transducer for continuous pressure monitoring or to an external collection system for drainage.
Polyuria	Defined as a urine output > 3L/day. Needs to be considered if the urine output > 200ml/hr for 2 consecutive hours. The clinical history is very important to correlate this as a true sign. This is going to require the PN interpretation.
Brain/Spinal surgery	Refers to any brain/spinal surgery, including surgical procedures such as a laminectomy or discectomy.

Renal System

Please note the following indicators/conditions in this section:

The first 3 indicators are based on the RIFLE criteria (Journal of Intensive Care Medicine 22(4); 2007) for acute renal dysfunction (ARD). The Rifle classification defines 3 grades of increasing severity of ARD as Risk (R), Injury (I) and Failure (F). The MOST severecriteria is the one that should be selected - i.e. if the serum creatinine is 2 X baseline, but the urine output was < 0.5ml/kg/hr X 6hrs (and not 12hrs), the patient would fall into the Injury class and not the Risk class (see below). Also see Addendum C.

Indicator	Description
Serum Creatinine 1.5 X baseline OR Urine output < 0.5ml/kg/hr X 6hrs *	Indicates Risk (R) of renal failure according to the RIFLE criteria (see above).
Serum Creatinine 2 X baseline OR Urine output < 0.5ml/kg/hr X 12hrs *	Indicates Injury (I) to the kidneys according to the RIFLE criteria and patient is at high risk for the development of acute renal failure.
Serum Creatinine 3 X baseline OR Urine output < 0.3ml/kg/hr X 24hrs ORAnuria X 12 hrs **	Indicates Renal Failure (F)
Acute renal dialysis **	This refers to continuous or intermittent routine cycles of hemodialysis, irrespective of mode (CVVH/CVVHD/CVVHDF). This indicator is not applicable to a patient with longstanding chronic renal failure receiving routine intermittent hemodialysis.
Chronic Renal Failure *	It is difficult distinguishing between persistent acute renal failure and end-stage kidney disease and these criteria probably cover both.

Other

Please note the following indicators/conditions in this section:

Indicator	Description
Major Blood Transfusion**	Major blood transfusion is defined as replacement of the total blood volume within 24 hours. The formula is found on the last page of the form. Major blood transfusion includes all blood products.
Autotransfusion*	Patient receiving autotransfusion should at least be in HICU, due to high risk.
Post-operative monitoring* 24 - 48 hours	Note that there is no provision made for ECG monitor, because this is a standard procedure. This indicator is for patients that require more intense post operative monitoring than provided by wards. E.g. Knee Replacement.
Cont. Invasive/Non-invasive monitoring ≥ 4hrs every 15-30 minutes**	Due to the difficulty defining the term Hemodynamic Instability, this indicator basically replace this term. The indicator implies that the patient is unstable and would include Hemodynamic Unstable patients. This does not include Post-operative monitoring (as described in the previous row)

Medication IVI

Note that the IVI Medication Key at the back of the form serves as a guideline as to which types of medication falls within a specific indicator. This is ONLY applicable to IVI Medication. Medication indicated with ** are CCU drugs and the patients status remains CCU for up to 6 hours post discontinuation of these drugs.
Please note the following indicators/conditions in this section:

Indicator	Description
Positive inotropic support **	Inotropic drugs increase the contractility of the heart and are often required in cardiac failure, septic shock or post surgery. The list of drugs is named in the table of intravenous medication.
Vasopressors **	Vasopressors increase the systemic vascular resistance and are used in conditions where there is vasodilatation and vasoconstriction is required to improve the blood pressure. The use of small amounts of adrenaline in an epidural infusion does not count as „Vasopressors" as the effect is localised.
Insulin*	It is recommended that critically ill patients have their blood glucose narrowly controlled to improve outcomes (the margin varies depending on disease). Blood glucose is elevated as part of the stress response.
Sedation**	Drugs that have the ability to suppress a patients breathing and ability to protect their own airway.
TPN	It is extremely important that case management is informed when TPN is administrated, in order for accounts to be changed accordingly. Examples of TPN include; Isotec, Intralipid and Vamin.
Opioid*	Refers only to opioid analgesia (not all intravenous analgesia, e.g. Perfalgan). The route of administration can be as patient-controlled analgesia (PCA), via an epidural catheter or intravenously (whether intermittently or continuously) or intramuscularly. Opioids can cause opioid-induced sedation and respiratory depression.
Precedex®*	See addendum A for MCSA Policy regarding administration of this drug.
Abnormal high levels of therapeutic medication **	This refers to abnormally high drug levels of medication administered for therapeutic reasons - examples include high drug levels of digoxin or amikacin. This does not refer to intentional drug overdose or organophosphate poisoning.

Laboratory Imbalances

Please note the following indicators/conditions in this section:

Indicator	Description
Positive DIC screen **	This indicates that the patient is in Haematology failure. DIC screen includes INR, aPTT, fibrinogen, D-Dimer levels.

Monitoring / Invasive Lines

Please note the following indicators/conditions in this section:

Indicator	Description
ICP monitor 1st 24 hours***	For the first 24 hours post insertion the patient is in SICU.
ICP monitor > 24 hours**	After the 1st 24 hours, as long as the ICP monitor is in situ, the patient is in ICU.
Central venous O_2 saturation *	A normal $SVcvO_2$ is > 70%. The value is decreased if there is decreased tissue perfusion, and thereby increased oxygen extractions at a tissue level.

Emergency Procedures

Please note that these indicators are EMERGENCY procedures that occurred while the patient is already in HICU/CCU.

IV Medication with **

Please note that IVI medication marked with ** are indicated as CCU patients. The patient remains CCU for up to 6 hrs post discontinuation of IVI medication marked with **

Additional Diagnostic Information

Any comment that could add to the background of the patient"s clinical condition can be indicated in this section. Be sure to indicate the date of the comment. This section is also used if the required LOC could not be explained throughout the criteria. It is also suitable for indicating a planned procedure, planned discharge and any other relevant information not mentioned in the rest of the document. DO NOT PROVIDE A SUMMARY OF INDICATORS ALREADY CHOSEN.

Completing the Form

The method/procedure of completing the form will be explained by means of a scenario.

Scenario: A patient was transferred to a specialised unit the previous day, e.g. 6 July 2011 at 11:30

Today, 7 July 2011, you have to complete the Clinical Criteria for Specialised Units form according the patient"s condition the last 24 hours.

Step	Action	Note
1	Stick a patient sticker onto the form in the space provided (top left-hand corner)	
2	Write the diagnosis of the patient onto the form in the space provided (top right-hand corner)	
3	Write today"s date (e.g. 7 July 2010) in the first date column of the first section you want to complete.	
4	Read through all the indicators/condition in that specific section and tick off that which is relevant to the patient.	
5	Repeat steps 3 and 4 for all the applicable sections.	
6	After ticking off all the applicable conditions, check the keys for each marked indicator/condition (i.e. *, **, ***) and interpret it according to the key-table on the form.	E.g. If a box (indicator/condition) with *** is ticked off, the patient should be in SICU, if 3 ticks were made in boxes that are not marked with * ** or *** the
7	Complete / update the Patient Status section.	
8	The completed form must be sent to the Unit Manager.	
9	After the form is evaluated and found to be accurate and complete, it must be given to the Case Coordinator	

Addendum B Critical Care Units entering patients on APACHE IV database

Central Region

- MC Bloemfontein
- MC Hoogland
- MC Howick
- MC Kimberley
- MC Newcastle
- MC Pietermaritzburg
- MC Victoria
- MC Welkom

Northern Region

- MC Emfuleni
- MC Highveld
- MC Morningside
- MC Nelspruit
- MC Potchefstroom
- MC Sandton
- MC Vereeniging
- Wits Donald Gordon Medical Centre

Peninsula Region

- MC Cape Gate
- MC Cape Town
- MC Constantiaberg
- MC Durbanville
- MC Louis Leipoldt
- MC Milnerton
- MC Panorama
- MC Upington

Tshwane Region

- MC Brits
- MC Heart Hospital
- MC Kloof
- MC Legae
- MC Limpopo
- MC Medforum
- MC Muelmed
- MC Thabazimbi
- MC Tzaneen

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Sticker

Primary Diagnosis: _____

Secondary Diagnosis: _____

Surgical Diagnosis: _____

Secondary Diagnosis: _____

CLINICAL CRITERIA FOR SPECIALISED UNITS

REPORT ON WORST CASE SCENARIO IN LAST 24 HOURS		AUTHORISATION *(I hereby certify that mentioned must be admitted to)*					Signature
PATIENT STATUS		**Level of Care**	**Level of Care Movement**				
Specialised Critical Care	* * *	**Specialised Critical Care**	Date	Time	Date	Time	
	Three (3) or more organ failures	From		:		:	
Critical Care	* *	To		:		:	
	Seven (7) Ticks without * or ****	Ventilator: From		:		:	
High Care	*	To		:		:	
	Three (3) Ticks without *** or ** or *			:		:	

COMORBIDITIES				Critical Care	Date	Time	Date	Time
Chronic Iscaemic Heart Disease		Asthma		From		:		:
Unstable Angina		Obesity BMI> 30		To		:		:
Hypertension		Chronic Arterial Fibrilation/Flutter		Ventilator: From		:		:
Hyperthiriodism		Epilepsy		To		:		:
Hypercholesterolaemia						:		:
Diabetes (Insulin dependent)				**High Care**	Date	Time	Date	Time
Diabetes (Non-Insulin dependent)				From		:		:
Chronic Renal Failure				To		:		:
Congestive Heart Failure				Monitor: From		:		:
Hyperlipidaemia				To		:		:
Chronic Obstructive Pulmonary Disease						:		:

✓ = present; IV = Intravenous

CL 2416

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Report on worst case scenario in previous 24 hours

Date							
RESPIRATORY SYSTEM							
Respiratory arrest within 24 hours **							
**Mechanically ventilated with FiO^2 ≥ .6% ** **							
Mechanically ventilated **							
Noninvasive Positive Pressure Ventilation **							
Extubated <24 hours **							
Intubated but not ventilated **							
Oxygen O_2 > 40% *							
Saturation <90% on O^2 ≥ 40%*							
Respiratory acidosis *							
Respiratory alkalosis *							
Respiratory rate >30 per minute *							
Bronchospasm / Stridor *							
<2 hourly nebulisations							
<2 hourly suctioning							
Tracheostomy							
CARDIO VASCULAR SYSTEM							
Cardiac arrest within 24 hours **							
Sternotomy <24 hours ***							
Acute MI + Trop I/T **							
Angina *							
Ischaemic ECG changes *							
PTCA ** / Stent ** <12 hours							
Ablation * / Rotablator * <24 hours							
Acute Dysrhythmia *							
Elective Cardioversion < 12 hours *							
Temporary Pacemaker-dependent **							
Perm. Pacemaker- post insertion 12 - 24 hrs *							
**Vasopressor / Positive Inotrope dependent ** **							
Vascular Stent <12hours**							
Hypovolaemia *							
Tachycardia							
Bradycardia							
Hypotension							
Hypertension							
Increased capillary leak with edema							
Poor Peripheral perfusion >3 seconds							

Report on worst case scenario in previous 24 hours

Date							
NEUROLOGICAL SYSTEM							
Glasgow coma scale ≤ 8 **							
Glasgow coma scale 9 - 12 *							
Glasgow coma scale 13 -14							
Raised intra cranial pressure *							
Status Epilepticus **							
Occurrence of seizures in last 24 hours							
Ventricular drain **							
Polyuria							
Brain / Spinal surgery							
RENAL SYSTEM							
Serum creatinine 1.5 x baseline **OR**							
Urine output <0.5ml/kg x 6 hr *							
Serum creatinine 2 x baseline **OR**							
Urine output <0.5ml/kg/hr x 12 hr *							
Serum creatine 3 x baseline OR							
Urine output <0.3ml/kg/hr x 24 hrs OR							
Anuria x 12 hrs **							
Acute renal dialysis **							
Chronic renal failure *							
Metabolic acidosis *							
Metabolic alkalosis *							
OTHER							
Major blood transfusion **							
Autotransfusion *							
Epidural *							
Post-operative monitoring * 24 - 48 hours							
Cont. Invasive/non-invasive monitoring							
≥ 4 hours every 15-30 minutes **							
Pyrexia >38.3°C							
Subnormal temperature <35.5°C							

Report on worst case scenario in previous 24 hours

Date								
MEDICATION IVI								
Positive inotropic support **								
Anti-dysrhythmics **								
Platelet aggregation inhibitors *								
Fibrinolytics **								
Insulin *								
Sedation **								
Vasodilators ** / Vasopressor **								
Muscle relaxants **								
Ca Channel blockers **								
Diuretics								
TPN								
Opioids *								
Precedex ©*								
LABORATORY IMBALANCES								
Hypo Serum Na ≤ 130 mmol/l *								
Hyper serum Na ≥ 150mmol/l *								
Hypo serum K+ *								
Hyper serum K *								
Hypo serum glucose *								
Hyper serum glucose								
Increased serum osmolarity *								
Raised Bilirubin								
Acute Hb <8gr/dl/L *								
Raised cardiac markers *								
Abnormal high levels of therapeutic medication **								
Toxic levels of medication **								
Platelet counts ≤ 100 *								
Abnormal INR								
Positive DIC Screen **								
Ph ≤ 7,20 **								
Raised serum amylase *								
Albumin ≤ 20 *								

Report on worst case scenario in previous 24 hours

Date							
MONITORING / INVASIVE LINES							
ICP monitor 1st 24 hours ***							
ICP monitor >24 hours **							
PA catheter **/ Atrial line **							
Sheath post angiogram <12 hours **							
IABP **							
A-line *							
Central Venous O_2 saturation monitoring *							
Noninvasive cardiac output monitor							
CVP line							
Acute dialysis catheter							
EMERGENCY PROCEDURES WITHIN 24 HOURS							
Transvenous pacing **							
Transcutaneous pacing **							
Intubation **							
Emergency Tracheostomy **							
Pericardial tap 1st 24 hours **							
Emergency Cardioversion **							
Defibrillation **							
Intercostal drains							

Intravenous Medication with **	Date Start	Time Start	Date Stop	Time Stop
		:		:
		:		:
		:		:
		:		:
		:		:
		:		:
		:		:
		:		:
		:		:

✓ = present

ADDITIONAL DIAGNOSTIC INFORMATION

Date	
/ /	
/ /	
/ /	
/ /	
/ /	
/ /	
/ /	

INTRAVENOUS MEDICATION KEY	
Positive Inotropic Agents	eg. Dobutamine, Dopamine, Digoxin, Adrenaline
Anti-dysrhythmics	eg. Amiodarone, Lignocaine, Adenosine
Vasodilators	eg. Tridil ®, Isoket®, Nitrocine®, Trandate
Platelet Aggregation Inhibitors	eg. Aggrastet®, Integrillin®, Reopro®
Vasopressors	eg. Adrenaline, Noradrenalin, Phenylephrine
Fibrinolytics	eg. Actilyse®, Metalyse®, Streptase®
Muscle Relaxants	eg. Nimbex®, Pavulon®, Scoline®
Sedatives and Opioids	eg. Sublimaze®, Ultiva®, Rapifen®, Sudenta, Tramadol, Dormicum®, Diprivan®, Morphine, Pethidine, Precedex®
Ca Channel Blockers	eg. Nimotop®, Verapamil

ORGAN FAILURE

Respiratory System : Mechanically Ventilated with FiO_2 ≥ .6%

Cardiac System : Vasopressor Dependent

Renal System : Acute Renal Dialysis

Haematology : Positive DIC Screen

MAJOR BLOOD TRANSFUSION

Definition: Major blood transfusion is the replacement of the total blood volume within 24 hours

Formula: Total blood volume = 70ml blood/kg body mass

Calculation: 70ml *(blood)* x _____ kg *(total weight of patient)* = _____ ml *(total blood volume)*

APACHE IV® SCORE

Report on worst values obtained in first 24 hours of admission to your unit
Completion of all fields are mandatory

GENERAL PATIENT INFORMATION

Patient File Number		
Physician		
Admission Date & Time to Hospital	20 / /	
Admission Date & Time to CCU	20 / /	
Date of Birth	/ /	
Gender	Female / Male	
Chronic Health Status	None / Other	Leukaemia / Multiple Myeloma
	AIDS	Immunosuppression
	Hepatic Failure	Cirrhosis
	Non-Hodgkin's Lymphoma	HIV Positive / ARV Treatment
	Solid Tumor with Metastases	Diabetes Mellitus
CCU Admission	Admit from nursing unit in your hospital	Admit from another hospital
	Admit from operating room	Admit from emergency centre
Operative Patient	Yes / No	
Emergency Surgery	Yes / No	
Readmission to Unit	Yes / No *Answer yes if admit from non Apache unit to your unit*	

PATIENT PHYSIOLOGY INDICATORS

Pulse Heart rate furthest from 75 bpm	bpm		**Glucose** furthest from 7.2 mmol/L	n.a	mmol/L
Blood Pressure enter worst value for assessment period	mmHg		**CRP** highest value	n.a	mg/L
Temperature furthest from 38°C	°C		**Hematocrit** furthest from 46.5%	n.a	%
Core Body Temperature Indicate Yes if above temperature is core body temperature	Yes	No	**White Blood Count** furthest from 11.5 cu/mm	n.a	cu/mm
Mechanical Ventilation any time within 24 hour period	Yes	No	**Urine Output**	n.a	ml/24 hour
FiO_2 Fraction if ventilated			**Chronic Dialysis**	Yes	No
Respiratory Rate *furthest from 19 breaths/min*	breaths/min		**Creatinine** furthest from 76.2 umol/L	n.a	µmol/L

CCU = Critical Care Unit
bpm = beats per minute

CI 3108

PATIENT PHYSIOLOGY INDICATORS

Blood Urea Nitrogen (BUN) highest value	n.a	mmol/L	**PaO_2** PaO_2 of worst blood gas	n.a	kPa mmHg
Sodium furthest from 145 mmol/L	n.a	mmol/L	**$PaCO_2$** $PaCO_2$ of worst blood gas	n.a	kPa mmHg
Albumin furthest from 35 g/L	n.a	g/L	**pH** pH of worst blood gas	n.a	
Total Bilirubin highest value	n.a	µmol/L	**Anaesthetised/Sedated/Paralysed**	Yes	No

GLASGOW COMA SCALE

If patient is ventilated but not sedated / paralysed / anaesthetised obtain the worst score in 24 hour time period.
Note the different verbal section for ventilated patients that are not sedated / paralysed / anaesthetised.

EYES	VERBAL NOT VENTILATED	MOTOR
Open Spontaneously	Orientated	Obeys Commands
Open to Speech	Confused	Localizes Pain
Open to Pain	Innappropriate Words	Withdraws from Pain
No Eye Opening	Incomprehensible Sounds	Flexion to Pain
	No Verbal Response	Extension to Pain
	VERBAL: VENTILATED BUT NOT SEDATED	No Motor Response
	Orientated	
	Confused	
	No Verbal Response	

Admission Diagnosis	

If a CABG was done complete the following fields:	
Ejection Fraction	
Medication Dependant Diabetes	Yes / No
Was Internal Mammary Artery (IMA) used	Yes / No
Myocardial Infarction during Hospitalisation	Yes / No
Redo CABG	Yes / No
Number of Grafts	

If Diagnosis of Acute Myocardial Infarction then indicate if Thrombolytic Therapy was given	Yes / No

DISCHARGE INFORMATION

Discharge Date & Time from CCU	20 / /			
Status on Discharge from Unit	Alive		Deceased	
	Discharged to	Other Acute Care Facility	Cause of Death	Natural Causes
		Step-down		Unnatural Causes
		Home		
		Nursing Unit		
		Nursing Unit Transferred to		

Data Collector Signature: _____ **Date:** _____

Addendum D Medi-Clinic Case Mix Methodology

Introduction

Case mix refers to the characteristics of patients served by a health service provider, where some patients are at greater risk of having less successful treatment outcomes than other patients. Health service providers have no control over these characteristic and therefore the need exist to keep them fixed in comparative analysis. The ability to measure heterogeneous case mix of hospitals has been recognized for some time as a critical ingredient for improving the management of hospitals and health systems through planning and quality assurance, as well as achieving equity in hospital reimbursement. Without the capability to measure case-mix differences, the comparative analysis of hospital outcomes and attempts to establish the reasonableness of those outcomes often reflect in oversimplification of the issues involved and may result in spurious and misleading findings.

History

The case mix concept has been introduced in the USA more than twenty-five years ago in order to measure hospital productivity and to promote quality of care. The DRGs (Diagnosis Related Groupings), developed by a team of researchers led by Robert Fetter and John Thompson at Yale University, were selected by HCFA (Health Care Financing System) in 1983 as the case mix classification system for the MEDICARE prospective payment system (PPS).

The DRG was the first “health management tool” to group patients in clinically meaningful categories with homogeneous resources consumption. All diagnostic categories and procedures based on medical record summaries could be coupled with financial data about resource uses, for individual patients, in order to differentiate high and low cost care. Even if shortcomings were underlined since their beginning, DRGs are still used in the USA as the main tool for case based, clinical encounter focused, payment.

Many other countries have adopted the case mix concept after long periods of testing and accepting, but with large variations in data collection, information standards, grouping tools, financing methods and quality of care developments all over the world. Each country has developed a local clinical and political culture about case mix tools. Case mix development in South Africa is being driven by the private health sector for their own use, namely to improve the standard of clinical data used in interactions in the industry. These include a range of financial uses from information system creation, budget setting and contracting around alternative reimbursement models. The CMS (Council of Medical Schemes) are developing an awareness of its value within the sector. However, this is a recent development and previous attempts by 3M and by a handful of university and parastatal based academics did not achieve sufficient impetus.

Analytical Approach

Medi-Clinic is under increasing financial pressure to improve outcomes with fewer resources available. Therefore the need exists to evaluate units in our business in a justifiable manner (controlling differences in characteristics of patients treated in each unit) in order to focus resources in the right areas. We therefore evaluated the DRG system to address case-mix

differences in our units. The system is designed to produce groups of patients homogeneous with respect to some measure of resource use (LOS or cost) and is undoubtedly one of the best-known methods of patient classification, but limitedly takes into account severity of illness by including indicator variables for the presence and absence of surgery and in some versions comorbidity. Furthermore DRG is based on the principal that diagnosis drives cost in contradiction with our faith that costs are driven mainly by procedure or treatment.

We believe that a lot of detail about the type and severity of a patient which is both meaningful and readily available comes from the codes on the discharge summary. However, the number of possible codes is too large to handle without collapsing them into groupings. We therefore have adapted the CCRG (Clinical and Cost Related Groupings) which is a unique in-house system of mutually exclusive groupings of CPT-4 (Current Procedural Terminology), ICD-10 (International Statistical Classification of Diseases) and SADA (South African Dental Association) codes into a hierarchical structure of subgroups, groups and categories. We also implemented a computer algorithm deciding which codes explain the outcome the best.

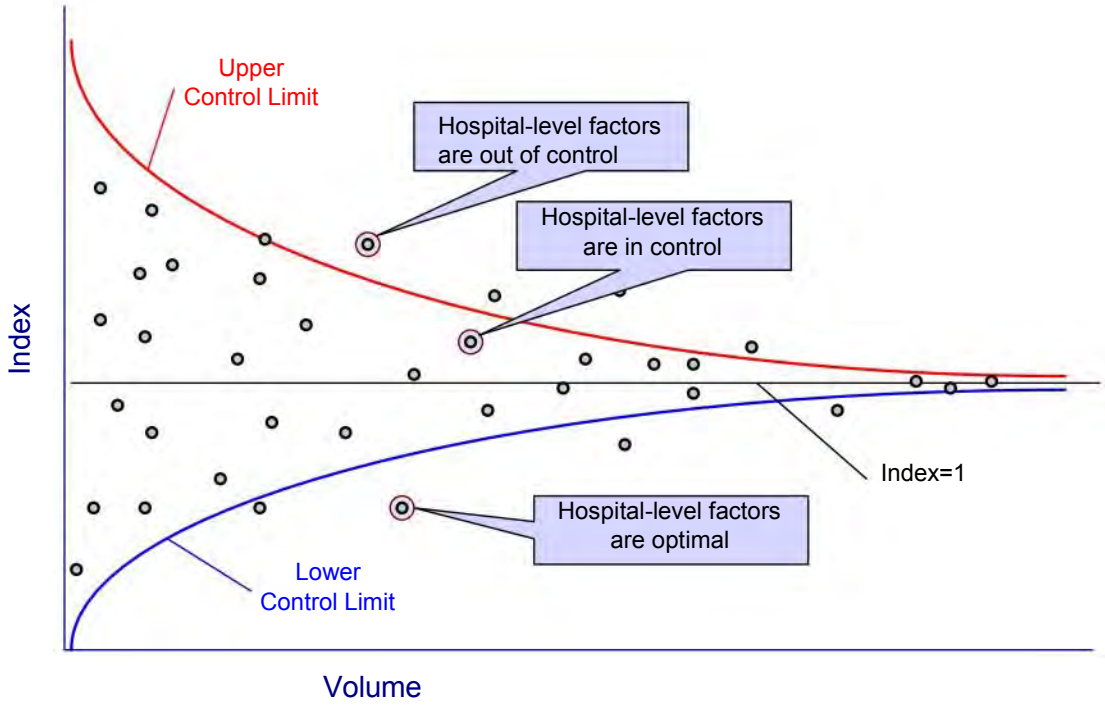
We developed the HRM (Hospital Risk Model) which entails a generic method that permits the actual outcome (costs, length of stay, mortality- and other quality outcomes) to be compared to statistically modelled “expectations”, given the mix of patients at a level. The method will statistically account for the number, mix and severity of cases because outcome variables are dependent on these factors. The model further provides breakdown analysis to quantify the magnitude of impact and interactions of these variables to assist in making more informed decisions.

The basic strategy employs the specification of a mathematical equation describing the outcome of interest as a function of a set of explanatory variables by means of OLS (ordinary least squares), GLM (generalized linear models), logistic or multinomial stepwise regression techniques. The explanatory variables describe characteristics of a case that are expected to affect the outcome (such as the clinical condition for which was rendered, the presence of other conditions that could complicate the stay and the patient‟s profile). These equations are estimated, that is, numerical values are computed for the parameters of the function that describes the impact of each “explanatory variable” on the outcome variable. Case mix can then be accounted for by computing the value of this function, using these estimated parameters, for the data values representing the specific characteristics. The result of this process is an expected value that is a mathematical function of a hospital‟s case mix, severity and demographic profile of the patients. For example, a hospital that treats more severely ill, elderly people will be expected to have higher costs than a hospital that treats a generally healthy and young population for a similar set of procedures.

Although calculations can be complex, interpreting the output is relative easy to do. The model makes use of the index methodology to describe the magnitude and importance of differences. It is convenient to group explanatory (characteristic) variables to belong to one of two mutually exclusive groups: those which are demographic or contribute to the disease status or degree of illness of the patient (patient-level factors) and those which represent the hospital environment or determined how a patient is cared for from hospital admission to discharge (hospital-level factors). The underlying strategy is to divide the actual observed outcome by the predicted outcome on the basis of patient-level factors. This result, defined as the index, provides information about the percentage deviation from the expected. If the

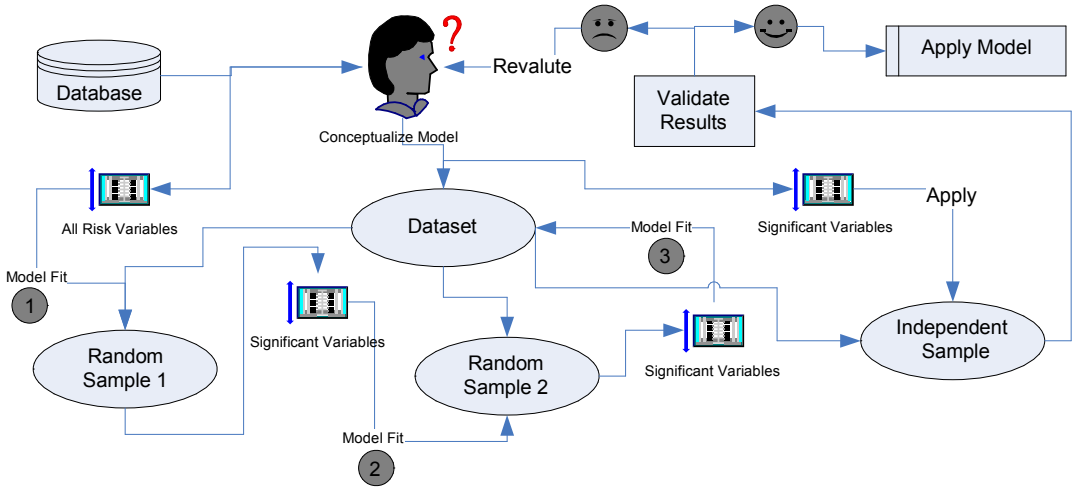
index is greater than 1 the patient has had a higher outcome than expected; if negative, the outcome was lower than expected. Random variation might explain part of any such discrepancy in an individual patient. However, if the overall index is significantly greater than 1, this presumably reflects hospital-level factors which tend to lead to a negative outcome. Similarly an overall index significantly less than 1 will reflect hospital-level factors that tend to lead to positive outcomes. In order to determine significance of cut-off levels we apply parametric or non-parametric statistical control limits, depending on the type of situation, to determine acceptance and rejection regions. Figure 1 below illustrates the application of the index methodology for hospitals.

Figure 1 - Illustration of Medi-Clinic Case-Mix Index



Model Validation

The question will arise to exactly what extent and how accurate the model describes risk in reality. We realise that model validation are essential parts of the model development process if the model are to be accepted for decision making, so not only do we strive to design our coding and grouping systems to accurately reflect reality, we also make use of statistical and model designing techniques to validate the model. Often the validation of a model seems to consist of nothing more than quoting the coefficient of correlation R^2 statistic (statistical measure that represents how well the model approximates real data points). Unfortunately, a high R^2 values does not guarantee that the model will describe reality well. In order to address this issue we have designed the model building process to remove random effects, hence improve the model fit and consistency. The diagram below layout the process we follow.



The process basically entails the selection of two random samples from the original dataset. All risk variables defined are fitted through random sample 1 to come up with a list of significant variables. These variables are then fitted on the second random sample in order to remove random significant variables identified in the first phase. These variables are then fitted on the full dataset to calculate the final model parameters. The model is then fitted on an independent sample and actual values compared to statistical modelled expectations. If the modelled values do not closely describes the actual outcomes, model parameters are reevaluated iteratively until a satisfactory level of accuracy is reached.

Trends & Analysis

Another application of the capability to measure case-mix differences is the ability to do comparative analysis over time. We would like to share some of the interesting trends we have identified with the reader. It is important to note that in order to do this type of analysis one needs to look at all patient-level factors to get the full picture of patient risk in order making the right interpretations. Also it is important to note that the trends are for Medi-Clinic in general and will not necessary be the same for different components of the business. Medical insurance legislation changes for example can cause trend changes for the insured population that will not necessarily impact the private population.

Figure 3 indicates a decline in patient-level risk over time. The four lines on the figure represent four different models based on four different years. The spread between these lines will be representative of inflation differences. It is worthy to note that the four models are consistently showing the same seasonal trends, which is an another indicating of accurate and reliable model results. Why are we experiencing this trend, while at the same time we see our population is ageing over time as illustrated in Figure 3?

Figure 2 - Yearly Case Mix Comparison

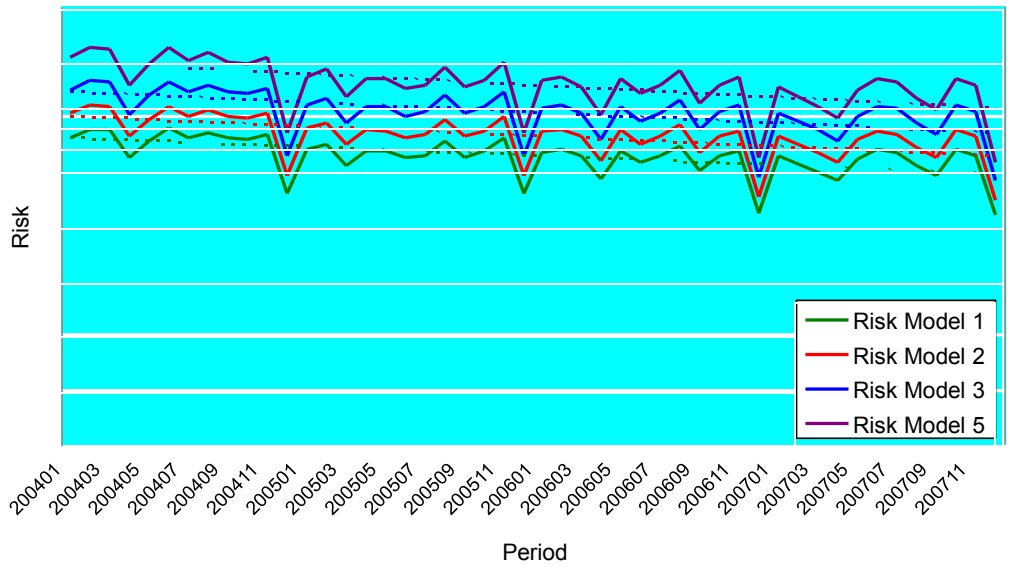
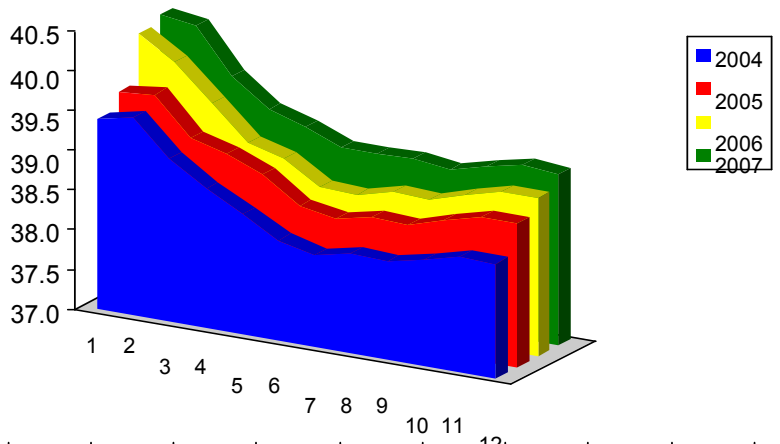
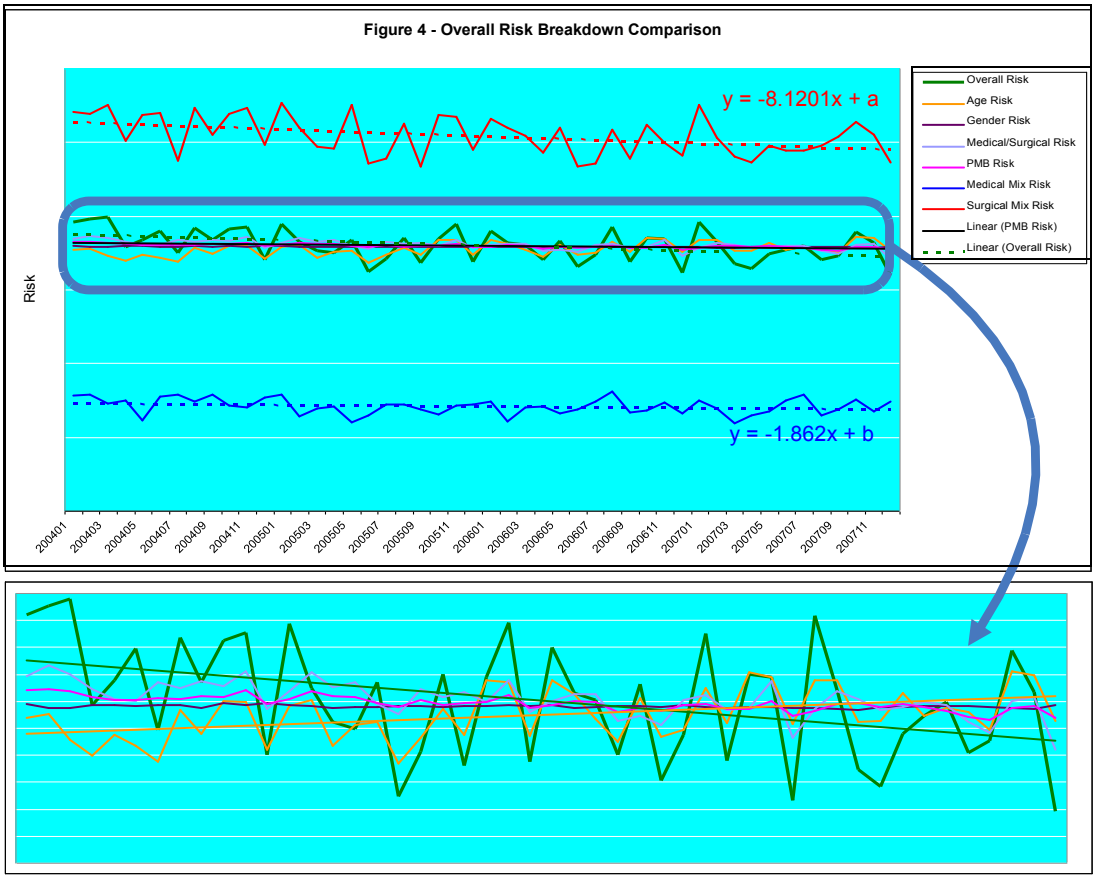


Figure 3 - Ageing of Population (Annual Running Averages)



	1	2	3	4	5	6	7	8	9	10	11	12
2004	39.4	39.5	39.1	38.8	38.5	38.3	38.2	38.3	38.2	38.3	38.5	38.4
2005	39.6	39.6	39.2	39.0	38.9	38.6	38.5	38.6	38.6	38.7	38.8	38.8
2006	40.2	39.9	39.5	39.1	38.9	38.7	38.6	38.8	38.7	38.9	39.0	39.0
2007	40.3	40.2	39.7	39.3	39.2	39.0	39.0	39.0	39.0	39.1	39.2	39.2

To explain this we have done a breakdown to understand which patient-level factors are causing the declining trend. We have decided to exclude outpatient cases, since emergency, wound care clinics and other outpatient units have grown considerable over time, hence impacting on the overall case-mix outcome. Also from an administrative point of view, more emergency-admission accounts are now split-billed that were previously billed as one account. This digress the number of cases and cause a diluted decrease of patient risk over time. Therefore we concentrated only on cases with theatre time or accommodation for the purpose of the analysis. Figure 4 illustrates the change in some of the different components of patient level risk namely age, gender, surgical- and medical-mix in general.



The first thing to note from Figure 4 is that the overall risk (green line) is still declining with the outpatient cases removed from the analysis. It is apparent from the graph that although the ageing of the population had a positive impact on the risk change, the overall risk change was dominated by decreasing surgical- and medical-mix changes indicated by the negative slopes of the respective trend lines. The medical risk change tends to dominate the impact on the overall risk over time. This is most probable caused by the increase in the portion of medical cases relative to surgical ones as illustrated in Figure 5. Interpreting this trend in combination with the decrease in medical risk, it can be an indication that the growth in medical cases is supplemented by an increase in low risk cases.

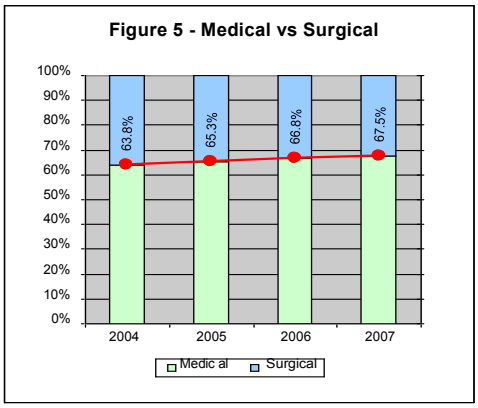
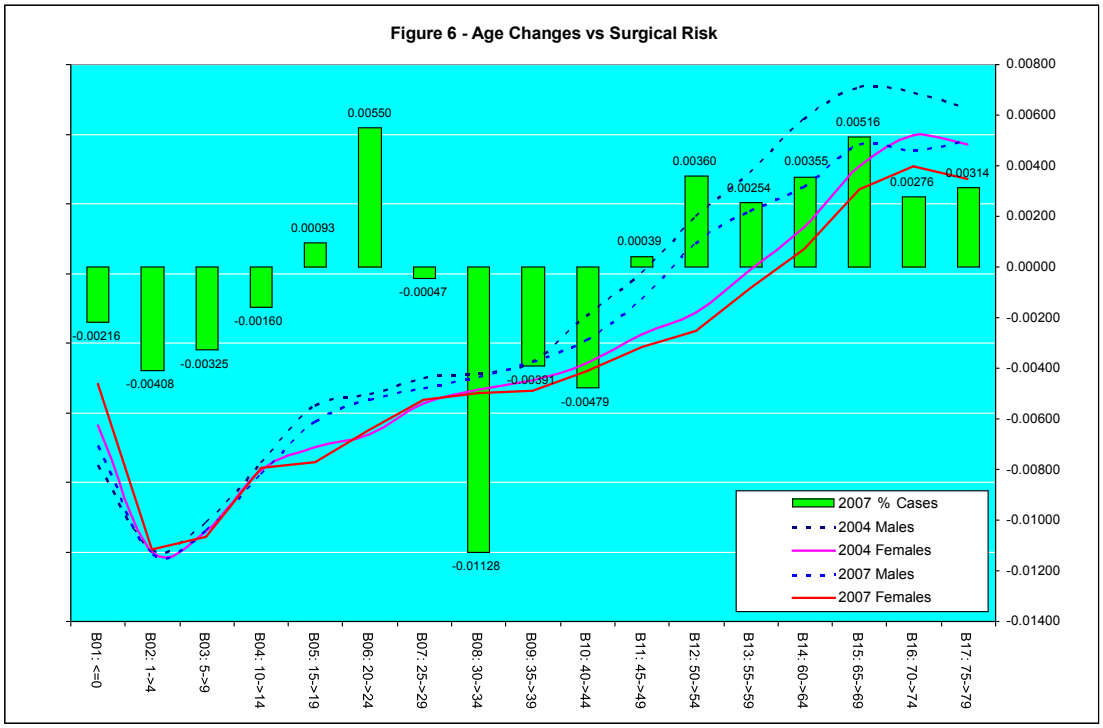


Figure 4 also shows a decline in the surgical risk of patients. We needed to have a better understanding of this, since it is not only contradictive to the ageing and increasing average theatre time of the population, but also in important from an operational point of view. We investigated the relation between age, gender and surgical risk. Figure 6 is an illustration of the sensitive relationship between these factors.



The solid and dotted lines represents surgical risk within each age category for 2004 and 2007 for females and males respectively and the spread will reflect the differences in surgical risk. The green bars indicate the change in specific age categories between the respective years. Positive values will be an indication of positive growth within the specific age category between years; similarly a negative value will indicate drops. Having a closer look at age categories B11-B15, clearly indicating growth in the older age categories, we see a drop in surgical-mix for the same categories as indicated by the spread difference. We can thus conclude that the change in surgical-mix outweighed the age risk change resulting in an overall declining surgical risk. In an attempt to understand the change in surgical mix we have done a further in depth analysis looking at the surgical procedures that are strongly correlated with surgical risk. The results are set out in the table below.

Procedure	Risk Category	Annual Change
Mitral valvuloplasty replacements	High	-6.490%
Aorta valvuloplasty replacements	High	-0.930%
Gastrectomy	High	-5.320%
CABG	High	-3.280%
Ophthalmological surgery	Low	10.080%
Plastic & Reconstructive surgery	Low	5.370%
Obstetrics and gynaecology	Low	7.420%
Minor Uro-Genital surgeries	Low	6.970%

We conclude that the drop in surgical mix was caused by some high risk procedures, but to a greater extend by an increase in a high number of low risk procedures. This fact together with the decrease in medical mix is the main drivers for a declining overall patient risk. Understanding the components of patient level risk is complex because of the intricate relation that exists between factors and therefore it is important to look at all risk factors to avoid oversimplification of the issues involved.

Summary

This analysis demonstrates the feasibility to have a case-mix adjustment system, using existing administrative data. The multivariate models used also shows that certain patientlevel characteristics could explain variations in risk. However, for a variety of technical reasons, the detailed results from these models should be interpreted with great caution since correlation between variables could lead to misinterpretation.

Mortality

Mortality as a quality outcome?

Healthcare providers have always been concerned about patient outcomes and evaluating outcomes as a means of determining the effectiveness of care. Much of the philosophical basis for outcomes measurement is derived from the early work of Florence Nightingale. Nightingale used mortality statistics to portray the low quality of care provided to British soldiers during the Crimean War. It has been said that Nightingale was the first person to use diagrams for presenting statistical data. Although this is most probable not true, she may have been the first to use them for persuading people for the need for change. Her methods indeed succeeded by reducing mortality from 60% at her arrival to 2% six months later.

That fact that patients die in hospitals every day is both an accepted fact of hospital care delivery and a reflection of avoidable hospital inefficiencies. These inefficiencies are subject to control and include poor infection control, inadequate or inappropriate use of medication falls as a result of poor supervision or understaffing, mistakes during surgery, and inappropriate level of care. Some, perhaps many, of these deaths might be prevented if all the factors that contribute to them are better understood. A study, for example, looking at the association between patient-to-nurse ratio and patient mortality concluded that, after adjusting for patient and hospital characteristics (size, teaching status, and technology), each additional patient per nurse was associated with a 7% (odds ratio, 1.07; 95% confidence interval, 1.03-1.12) increase in the likelihood of dying within 30 days of admission. Surely hospitals do not have control over worsening nursing shortages and legislation changes, but can use this information to address problem areas and optimally plan resources. The adjusted ratios should be seen as a kind of red flag for performance improvement and not a verdict.

As in most improvement efforts the process should start with measuring outcomes. It has been stressed in the case-mix article that these types of comparisons have little meaning unless adjustments are made for patient risk differences. One could thus conclude that hospital mortality rate, appropriately adjusted for patient risk variables, is an essentiality in measuring quality.

Methodology Used

We have developed a statistical methodology to adjust hospital mortality rates for patient level risk factors in order to make justifiable comparisons between hospitals. We also expanded this methodology to measure trends over time.

We treated deaths as a binary response variable and used a logistic regression model to measure the relation with patient risk variables in order to adjust for case-mix differences. The outcome is an expected value per admission reflecting the probability that the admission will result in a death.

$$E(y) = \frac{e^{\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_k x_k}}{1 + e^{\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_k x_k}} \quad \text{where} \quad y = \begin{cases} 1 & \text{Deceased} \\ 0 & \text{Survived} \end{cases}$$

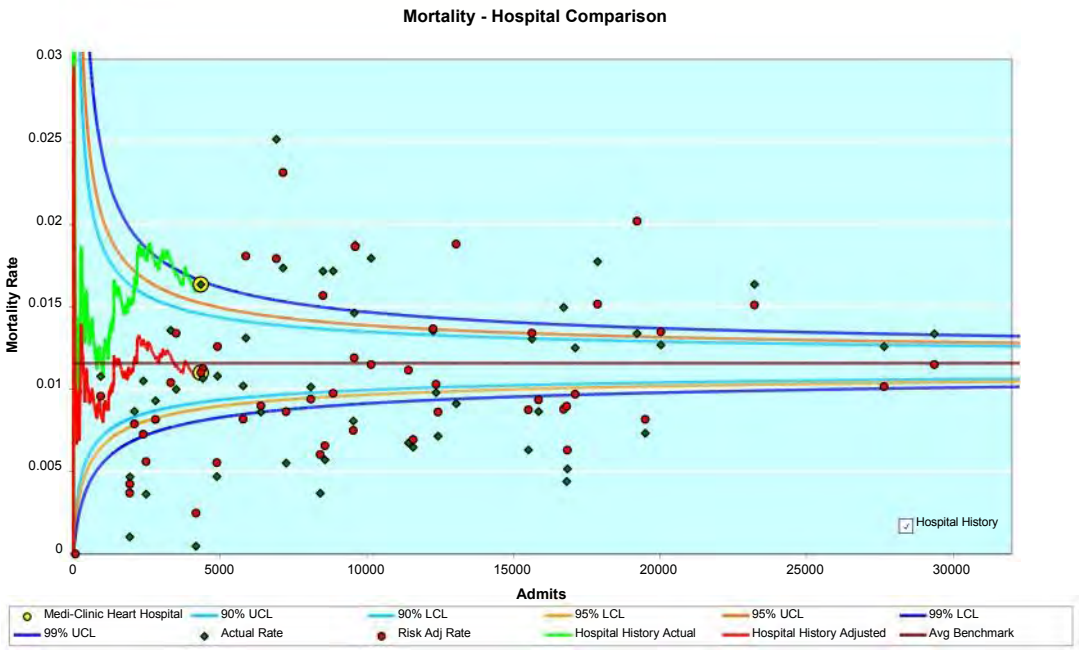
$$E(y) = P(Deceased)$$

The coefficient $\hat{\beta}_i$ in the logistic model estimates the change in the log-odds if x_i is increased by 1 unit, holding all other x's in the model fixed. Therefore the model can also produce an estimated increase in risk for each of the various risk variables. For example a patient odds of dying in hospital, treated for an Infectious or Parasitic disease, will increase with a factor of 1.17. More specifically, a patient treated for Tuberculosis, will have a 2.12 increase in the odds factor of dying in hospital. The difference in magnitude between the coefficients of these risk variables are a reflection of the dependence with the outcome variable.

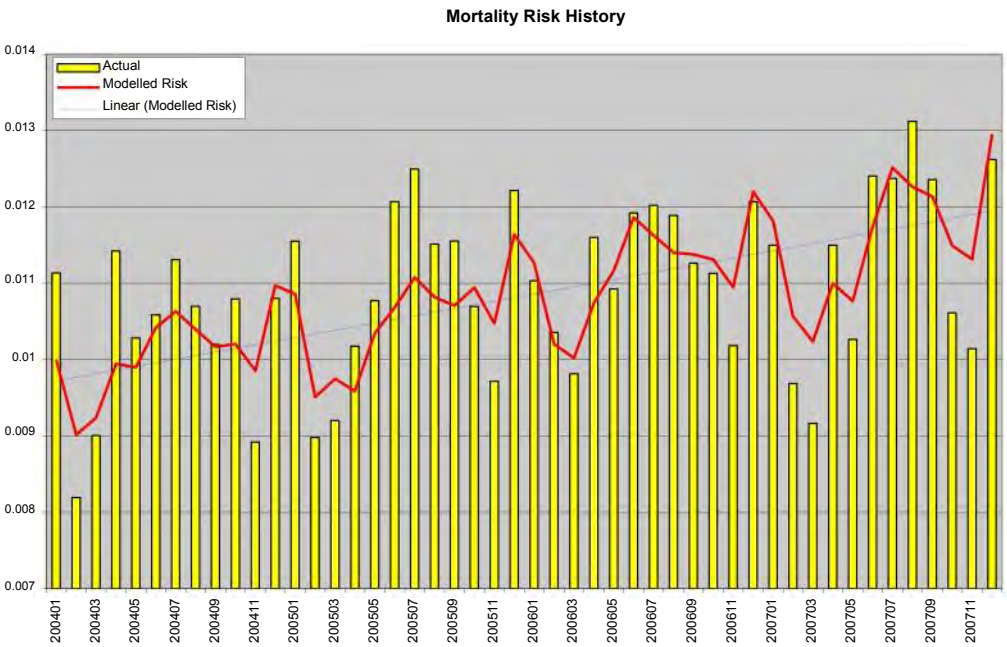
Trends & Analysis

The chart below is an illustration of mortality outcome of Medi-Clinic hospitals using statistical control charts. The horizontal axis represents volume and the vertical axis mortality rate. The curve lines are the control limits defined as 90%, 95%, and 99% confidence intervals with the purpose to identify units whose performance diverse significantly from the norm. The green dots represent crude mortality and the red dots risk adjusted mortality. The solid green and red line is the chronological accumulative mortality outcome of a single Medi-Clinic hospital, known to treat high risk cardiac cases, for crude and risk adjusted mortality respectively. The spread increase rapidly because of the high risk nature of these patients and the crude mortality are quickly out of control. The risk adjusted mortality stays within control, indicating that although the crude mortality is significantly higher then the norm; it is mainly contributable to patient level risk and not a reflection of inefficient hospital processes.

The idea is to measure this on continues basis and flag hospitals as soon as the outcome (mortality rate) is out of control. Doing this will ensure that high mortality rates, contributable to inefficient hospital processes, are proactively identified and managed, rather than a retrospective review at the end of the financial period. Understanding the issues involved will assist to design processes to prevent possible future occurrence

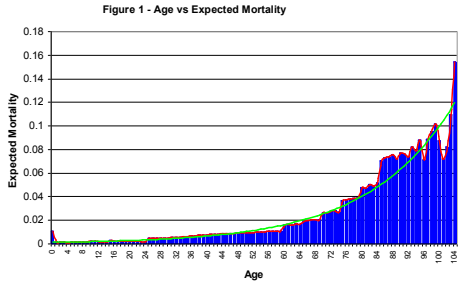


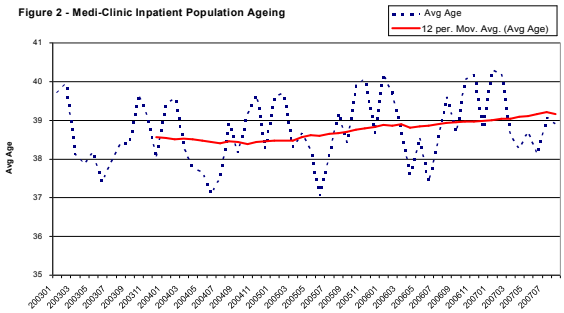
Like mentioned earlier it is also possible to do trend comparisons over time. The graph below illustrates crude and expected morality for Medi-Clinic for 2004 to 2007. It is important to note that although the crude mortality rate is increasing, the expected rate is also increasing, indicating an increase in the population risk for mortality.



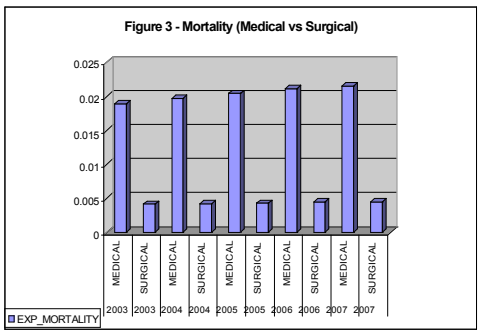
The reason for this increase can be explained by a change in various risk factors, but the main contributing factors are:

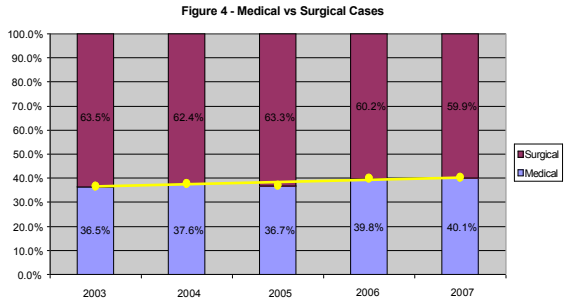
(1) Ageing of the population. Figure 1 shows that there is an exponential relation between mortality risk and age, apart from neonatal cases. Figure 2 shows that our population is ageing, hence one could conclude that our mortality risk is increasing due to an increase in age of the population.



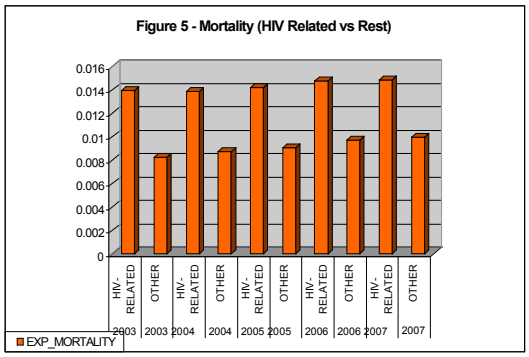


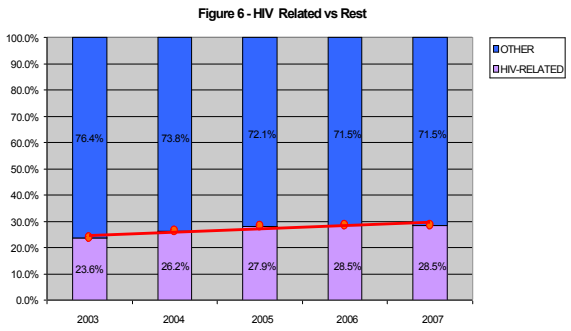
(2) Increase in the proportion of medical cases relative to surgical ones as illustrated in Figure 4. Figure 3 shows that mortality risk for medical cases are higher then for surgical ones, hence one could conclude that this is another reason for the increase.





(3) Increase in HIV related cases. Legislation and patient confidentially does not allow information around HIV cases to be captured, hence we needed to use clinical criteria to identify certain procedures that can be used as a proxy for HIV cases. Figure 5 shows that HIV-related cases have a higher mortality risk then the rest. Figure 6 shows a growth in the portion of HIV-related cases relative to the rest, hence another reason for the yearly increase in mortality risk.





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Dear René,

RISK ADJUSTED MORTALITY RATES: HOW DO THEY DIFFER WHEN CALCULATED WITH ADMINISTRATIVE DATA COMPARED TO PHYSIOLOGICAL PREDICTIVE MODELS?

Please be advised that Mediclinic hereby approves the application for the above-mentioned research.

Yours sincerely,

pp
DR MS SMUTS
CHIEF CLINICAL OFFICER

Section B

Hospital Standardised Mortality Ratio and related fields is a very wide subject encompassing a large body of knowledge. The limitations and scope of the dissertation doesn't allow for a literature search on such a wide topic. The high burden of disease of HIV and related illness in South Africa has a substantial influence on the clinical outcomes and as such the literature review is limited to this topic.

Structured Literature Review:

Does a varying prevalence of HIV influence risk-adjusted mortality rates?

Contents

List of Abbreviations

ART	Antiretroviral Therapy
HCFA	Health Care Finance Administration
HIV	Human Immunodeficiency Virus
HSMI	Hospital Standardised Mortality Index
HSMR	Hospital Standardised Mortality Ratio
NHS	National Health Service
SMR	Standardised Mortality Ratio
UK	United Kingdom
USA	United States of America
US	United States

Literature review

Introduction

The management of quality and care delivered to patients is dependent on the ability to accurately measure clinical outcomes. (1)(2) Mortality is used as one of a range of clinical quality measures used both as performance, as well as benchmark measure in comparing hospitals. (3)The main purpose of the research project is to compare the expected mortality rates as calculated by an administrative predictive scoring model to that of a physiological predictive model. This literature review focuses on the attributes of the Hospital Standardised Mortality Ratio (HSMR) as well as the influence of the Human Immunodeficiency Virus (HIV) on the predictive modelling. The availability of ART has changed the management of HIV and resulted in a reduction of mortality rates. Most mortality prediction models, including the one used by the researcher's healthcare organisation to calculate the expected mortality rates, was developed before the widespread implementation of antiretroviral treatment (ART) and may not accurately reflect the associated risk. However, by 2013 South Africa had 6 million people infected with HIV and 2.6 million people on ART.(4)

Firstly, the general development and applicability of the expected mortality models is discussed before presenting a systematised review of the literature on HIV in relation to predictive models to determine the influence of ART on all-cause mortality in HIV infected individuals in South Africa in the light of the current coding systems.

Background

Healthcare is a very complex process with a large number of non-linear inter-related variables and a low signal-to-noise ratio.(5) There are many "signals" in the healthcare environment mostly related to clinical events or trigger thresholds that alerts the healthcare staff to a change in patient condition.(6) The alarms, designed to improve patient safety, can become a hazard if they are ignored. Healthcare staff often ignores these alarms if there are a high number of false alarms, as a result of a low positive predictive value. Non-standardised alarms contribute to this phenomenon. (7) Similarly, the number of potential adverse events, preventable or actual deaths is low in relation to the number of outcomes i.e. "low signal-to-noise". The outcome is often influenced by a number of factors not related to the quality of care. (8) Variables included in measurements are routinely collected from inexpensive, administrative data mainly used for rendering an account. The findings during chart reviews often do not correlate well with the findings from administrative scoring models. (9) This limits the use of administrative data to quantify the quality of clinical outcomes.(10) Findings from predictive scoring models using administrative data as proxy may therefore not be externally valid beyond the hospital from which the model was

developed. As a result, secondary use of such data in other hospitals may result in unfair labelling due to biased conclusions or inaccurate data.(10) The use of diagnosis-specific outcome indicators derived from administrative data still needs refinement and can't be promoted in the current format. (10) Peter Pronovost, founder of the United States (US) Quality and Safety Research Group, and Richard Lilford, director of the United Kingdom's (UK) NIHR Collaboration for Leadership in Applied Health Research & Care for West Midlands, state that the quality of administrative data contributes significantly to the accuracy and reliability of outcome measures. (3) Proxy measures constructed with routinely collected administrative data is generally used to gauge the quality of care provided and benchmark hospitals. (11)Pronovost et al. made five recommendations for improving the quality of administrative data used as outcome measures: "ensure validity and transparency, develop standard surveillance, evaluate performance over time, build tools to prioritise measures and create an independent agency". (3)

Healthcare quality measurement can be divided into indicators for: volume, structure, process and outcome.(8) Measures that relate to volume, measure the number of procedures performed. As a rule of thumb, higher numbers, especially with regards to specialised procedures, are associated with improved outcomes. However, this association has not been proven in non-procedural care.(12) Structural measures relate to the accreditation and certification of practitioners and institutions. Process measures describe whether evidence based care processes is followed.(12) Outcome measures are believed to reflect the interplay of volume, structure and process; hence they are regarded as a reference standard. (8)

Standardised Mortality Ratio (Administrative data)

Death is an unambiguous, binary variable and reflects an outcome critically important to patients. A standardised mortality ratio (SMR) is one means to quantify the quality of care delivered in hospitals. The US Health Care Financing Administration (HCFA) was the first to publish such data in 1986. (13) The use of SMR as a measure of outcome was later discontinued, as the validity of the indicator was questioned. (14) Jarman et al. were commissioned to redevelop standardised mortality measurements for the UK National Health Service (NHS) in 1999.(15) The original model, amended by *The Doctor Foster Intelligence Group*, is used to calculate SMR's for English hospitals. Wide annual publication of the results started in 2001.(16) USA, Canada and the Netherlands currently publically reports on the hospital standardised mortality ratio (HSMR) and views it as an important clinical outcome measure.(17)

Crude hospital mortality ratios can't be compared directly as there are a number of factors, not related to quality of care, that may influence the rate. (18)Hospitals that treat patients who are younger or of lower acuity may have a lower HSMR and seem to perform more favourably, as compared to hospitals treating older and/or more complex cases that

subsequently may have higher indices and may therefore be perceived to perform poorly. (18)

The HSMR is used to rate, compare and track hospital performance over time. Pouw, et al. stated that the HSMR of different hospitals can only be compared to one another if the underlying distribution of case-mix variables is exactly the same or if the underlying hospital factors do not interact with the case-mix variables. (17)The case-mix of a hospital may vary over time and the changes in HSMR may be due to changes in case-mix and may not reflect the quality of care provided. (17)

As alluded to above, the prevailing case-mix within a hospital can have a profound impact on a number of measures, including the HSMR. Direct or indirect statistical standardisation methods are used to adjust for these differences.(17) These methods take a number of patient related factors into account such as age, comorbidities, deprivation score, reason for admission, etc. when adjusting. Direct measures standardise the case-mix to a reference population and across institutions. An expected mortality rate for a specific subgroup of patients is calculated e.g. acute pancreatitis in women aged 40 - 60 years old.(17) Indirect measures standardise the mortality rate to a reference mortality rate. Indirect standardisation methods are sensitive to changes in case-mix, while direct mortality standardisation is not influenced by differences in case-mix. The use of direct standardisation in practice is limited by sufficient volume of cases in subcategories.(17) Indirect standardisation calculates the expected number of deaths, using a logistic regression statistical model and a number of predetermined variables, and compares this to the actual number of deaths. (17) The mortality index is the actual number of deaths divided by the expected number of deaths and the index should ideally be <1. (17)

A number of factors not related to quality of care may influence the SMR

Case-mix adjustment (with models derived from indirect standardisation)

Case-mix adjustment is not a perfect science as it can only take into account previously identified and accurately measured factors. However, it is still believed to be fairer than comparing crude mortality rates.(19) Mohammed, et al. emphasised that case-mix adjustment may in itself bias HSMR. (13) Case-mix adjustment is influenced by the number and type of variables, the distribution of the variables in the population and the interaction between the case-mix variables and the hospital. (13) In order to achieve accurate case-mix adjustment, one needs the relationship of the variable and associated mortality risk to be constant amongst all populations (constant risk relationship), as a paradoxical increase may occur when the variable is unevenly distributed amongst the population (case-mix fallacy). (13) The number and selection of variables that are taken into account when adjusting for case-mix will also have a profound effect on the case-mix.(17). The use of SMR as a screening test results in a test with a high sensitivity and low specificity. (18) It is desirable to have a high sensitivity as one would not want to miss underperforming hospitals.

However, false positive results may lead to the wasting of resources that could have been better utilised in addressing clinical risk. Hospitals may also be falsely labelled as poor performers and staff may manipulate data to improve the rankings, known as “gaming”. False negative results may allow critical care failures to be undetected.(18)

A focus on reducing mortality rates may also influence treatment decisions and lead to aggressive treatment of patients with a poor prognosis and lead to related inflated healthcare costs.(19) Girling, et al. state that SMR isn’t a suitable means to diagnose poor patient care if the percentage of preventable deaths is less than 15% of all deaths. (14) They also state that “most studies measure a proportion of deaths for which a potentially preventable factor was present, rather than an estimate of the proportion of deaths that were in fact preventable”. (14) The preventability of deaths varies across hospitals and the aggregation of data from a number of units to calculate hospital-wide SMR may dilute the results of specific poorly performing units. (14) The attribution of unexplained variation to poor quality of care may be erroneous and an example of the case-mix adjustment fallacy. (20)

Diagnostic coding

Diagnostic coding is used to translate the patient’s baseline clinical condition on admission, course of illness, management of illness and procedures performed to a standardised codified format that describes the episode of care. Diagnostic coding is also used to render an account.(21) Diagnostic coding is bound by strict definitions and rules. In spite of this, Hawkes, et al. state that research done by a healthcare analytics organisation (April 2005 to June 2009) illustrates that the number of codes per account has increased steadily and varies greatly amongst hospitals. (21) The inconsistent application of coding rules and definitions leads to poor coding practices. Inaccurate or incomplete coding of care episodes may lead to differential measurement errors that may over- or underestimate the expected number of deaths. (13) The coding of secondary diagnosis, comorbidities and the sequencing of codes on the account may all influence the expected mortality rate and thus the HSMR. (22)

Measures to improve the quality of coding, and especially the number of codes per account (coding depth), may lead to an improvement in the SMR that only reflects improved coding and not an improvement in the quality of care. (21) Diagnostic codes cannot distinguish between conditions that have been resolved and conditions that have residual effects and disability. This is in keeping with the inability of diagnostic coding to capture the functional status of the patient. (18) The severity of illness is not accurately reflected by the coding of co-morbidities, and variation in the functional status of patients may contribute to patients with similar risk profiles having vastly different clinical outcomes.(23)

Bottle et al. found that different coding practices generally had limited impact on the HSMR amongst institutions maintaining good coding standards; however palliative care coding had a notable influence and may introduce bias.(24) The ICD code "Z51.5" is used to indicate palliative care and Hawkes et al. stated that the use of the code had increased dramatically in England over the time period 2004 to 2009. (21) This was in keeping with palliative care exclusions. It was also found that the increased use of Z51.5 has led to a decrease in the HSMR, even though the crude death rate was reasonably stable.(21) A similar finding was made by Christopher Chong when he investigated changes in palliative care coding practices in Canada (2004 - 2010) in the time period after HSMR was made public.(25) The publication of the HSMR correlated with an increase in the use of palliative care coding and a decrease in the HSMR.(25)

The manipulation of diagnostic coding to decrease the HSMR and improve performance is a more sinister result of the publication of HSMR. (26) Some of the poorer performing hospitals may manipulate the diagnostic codes to game the system and improve their ratings. Several studies have commented on this phenomenon.(21)(25)(26)

Discharge practices

The discharge practices vary amongst hospitals and this has a variable influence on the HSMR. (27) Discharge practices may also introduce bias as patients who are discharged to a step-down unit, transferred to other hospitals or sent home before dying will decrease the number of actual deaths. The actual mortality rate is thus decreased; the expected remains the same, thereby lowering the HSMR.(27) This also holds true for the transfer of complex, high acuity cases to other facilities. The inclusion of early post-discharge mortality as a measure may help to minimise discharge bias and ensure more accurate comparison. However, obtaining accurate post-discharge data is, generally speaking, even more difficult than obtaining accurate in-hospital data; and none of the short term mortality measures are superior as all are able to be manipulated. (27)

Size of hospital

The size of the hospital plays a significant role in the stability of the HSMR over time as well as the placement of the hospital in the ranking. Smaller hospitals are expected to be outliers and are represented at either extremes of the scale.(28) It is known that smaller sample sizes are more prone to variation and a larger deviation from the mean.(29) Statistical modelling is one possible means to mitigate the effect but this only leads to a modest improvement.(18) It is also found that smaller hospitals may have a very different case-mix to the one used in the development of the statistical model, as they may render specialised care e.g. gynaecological hospitals.(30)

Readmissions

Jarman initially stated that no significant impact was seen on the HSMR if one considered number of readmissions over a one year period. (31) Jarman later amended his view and concluded that the inclusion of the number of admissions in a given time period may be potentially useful.(31) He did not clearly define an optimal time period to choose. (15,31,32) Van den Bosch, et al. found that patients who were readmitted more frequently had a lower predicted mortality rate for subsequent admissions. The reason for this finding is unclear but it's presumed to be partly due to differences in case-mix. (20)

A number of factors unrelated to patient characteristics or the quality of care delivered may influence the number of readmissions.(18) One such example is the institution's admission policy. Institutions have different ways in managing specific conditions like cancer. Some institutions may admit cancer patients for treatment whereas in others they may be treated as outpatients.(18) The frequency with which patients are treated for a specific condition may also be different, as treatment protocols differ, resulting in different readmission rates. (18) When patients are transferred to other facilities for more specialised care and are then subsequently readmitted to the referring hospital, it counts as a readmission for the first hospital (and a dilution of the numerator); in contrast, the receiving institution that treated the more complex case it only counted as one admission.(20) Other, unrelated, influences like culture, deprivation status and healthcare funding policy may also influence the readmission rate.(15) The patients who are more frequently readmitted may be fundamentally different from other patients and may be more resilient. (20) It was also found that frequently readmitted patients have more comorbidity, as expected, but are on average younger. In line with these findings, van den Bosch, et al. suggested that the admission frequency be included as a variable in calculating the HSMR.(20)

Low signal to noise ratio

The number of preventable deaths (signal) is a small percentage of all deaths (noise) and in a paper by Scott, et al. it is reported that 5% -10% of all hospitalised patients die. Most of these deaths are not due to poor quality of care but the normal disease process.(18) It is reported that adverse events may lead to increased cost per healthcare event, admission to a higher level-of-care or a longer length-of-stay but are mostly not fatal.(18) The HSMR as a screening tool has a low specificity (deaths are mostly not due to care failures) and sensitivity (most care failures do not cause death).(18) In a study by Scott, et al. it was reported that the HSMR was found to be within the normal range in two thirds of poor performing hospitals (190 US hospitals with 25% preventable death).(18) A HSMR that is within accepted norms can detract from quality improvement needs and obscure poor quality of care in a specific unit or ward.(18,19)

Low criterion validity

The HSMR doesn't correlate well when compared to other quality indicators and it is believed to be a poor predictor of preventable complications and poor clinical quality.(33) No difference was noted in the quality of care rendered by hospitals flagged as outliers when the adherence to best practice measures and disease related quality indicators for high risk conditions like acute myocardial infarction, pneumonia and stroke were measured. (18)

A systematic review (31 studies) found that the relationship between HSMR and quality of care is variable.(34) In the systematic review Pitches, et al. state that mortality is predicted on "three key variables - patient risk factors (case-mix), play of chance and quality of care". (34) Risk adjustment is believed to compensate for the differences in patient profiles. If the play of chance is taken into account, the rest of the difference has to be due to the quality of care delivered. This is fallacious reasoning as there may be unknown or un-measureable variables that have a major impact on the HSMR.(34) Pitches, et al. state: "there are three reasons why outcomes may vary even after case mix adjustment: (i) genuine differences in process measures of quality of care not measured in the study, e.g. vigilance of nursing staff which is harder to measure and therefore rarely captured in the study; (ii) differences in prognosis/risk, not captured in the study; and (iii) differences in definitions or in how definitions were applied in different places."(34)

Difference in reference populations

The different mortality prediction models include different variables and diagnostic categories with the percentage of variables varying from 28% to 95%.(9) A HSMR model that does not include all patients in the calculations but excludes certain diagnostic- or procedure categories may lead to a biased result.(18) Institutions and healthcare providers do not define diagnosis uniformly. When in-hospital mortality rates were compared to condition-specific quality of care measures, no association was found. (35) The models do not include measures to weight the severity of illness and functional status of the patients.(35) The model may have been calibrated and validated in a specific reference population and is now applied to a population that varies significantly in known and unknown ways from the reference population, leading to biased outcomes.(36)

Place of death and end-of-life care

The majority of patients die in hospital, rather than at home. This is largely due to a number of factors: the unpredictability of death, complexity of illness and need for technological intervention in palliative care, availability of home and hospice care, the admission and discharge policies, healthcare funding models, patient and family preference and culture and religious beliefs. (37) These factors are not related to the quality of care or preventability of death however has a profound impact on the HSMR.(37) Hospitals not only

vary in the number of palliative and end-of-life patients that they admit but also in the various other factors that influence decisions and treatment protocols.(38)

Uncertain stability over time

The HSMR is believed to be unstable over time and a number of reports highlighted the fact that there are marked short term changes in the HSMR. (18) These changes cannot be explained by clinical advances, seasonal or annual fluctuations or improved clinical outcomes and has raised concerns about the stability of the model over time.(18)

Variability in measurement

Shahian, et al. studied the correlation between four different proprietary SMR models when applied to the same population. The four different vendor models, when applied to the same dataset, gave discordant results. (9) The hospital level measures differed in methodology as well as inclusion criteria. The results were very different for the same hospital when calculated with different prediction models. A hospital could be branded as poor performing with one model and better-than-average with another model.(9) Shahian et al. believe the reason for the poor correlation between the models is the exclusion of certain diagnostic groups from some models.(9)

Table 1: A comparison of some of the features of the proprietary vendor models studied by Shanian et al. and the in-house HSMR developed by the healthcare organisation with some of the elements in the table directly copied from a table by Shanian et al(9)

	Characteristics of four vendor methods				**Healthcare organisation**
Method	UHC/Premier	3M	Thomson-Reuters	Imperial college/Dr Foster	In-house model
Diagnostic inclusions	80% of all observed deaths	All	All	80% of all observed deaths	All
Diagnostic exclusions					
• Palliative care			X		
• Diagnosis and procedures related to complications			X		
• Medically treated major or metastatic malignancy		X			
• Severe burns or trauma		X			
• Diagnostic strata with <1,000 discharges	X				
• Diagnostic strata with <50 deaths	X				
• Diagnostic strata with <1% predicted mortality	X				

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Patient exclusions					
• Neonates			X		
• Missing or invalid data elements or DRG		X	X	X	
• Transfers to another facility	X	X	X		
• Left against medical advice		X			
• Length of stay >365 days				X	
Type of model					
Simple logistic regression			X		X
Diagnosis-specific logistic regression	X			X	
Stratified indirect standardisation		X			

Table 1 (cont.): A comparison of some of the features of the proprietary vendor models studied by Shanian et al. and the in-house HSMR developed by the healthcare organisation with some of the elements in the table directly copied from a table by Shanian et al(9)

	Characteristics of four vendor methods				**Healthcare organisation**
	UHC/Premier	3M	Thomson-Reuters	Imperial college/Dr Foster	In-house model
Covariates in primary model					
• Age and sex	X	X	X	X	X
• Race	X			X	
• Socio-demographic factors	X			X	
• Admission source and type	X		X	X	
• Charlson comorbidity source				X	
• Elixhauser comorbidity score	X				
• Multiple interaction terms		X	X		
• Procedures	X	X	X		
• Distance travelled	X				
• Payer	X			X	
• Month and year of discharge				X	
• Do not resuscitate				X	

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The elements compared in the table above shows that the in-house develop mortality model includes all patients.

Education and staffing levels

Aiken, et al. reported on the difference in the education and knowledge levels of nursing staff. They found a reduction of 5% in the likelihood of 30-day mortality or failure to rescue with a 10% increase in the number of nursing staff holding a bachelor's degree.(39) In another study by Aiken, et al. it was found that every additional patient added to a nurses workload lead to a 7% increased risk of death within 30-days of admission, as well as a 7% increased risk of experiencing a failure-to-rescue incident.(40) Jarman, et al. had similar findings association, with the availability of general practitioners (GP's) in the population surrounding the hospital impacting the mortality rate. He stated that the lower the number of GP's per 10 000 individuals in the population surrounding the institution, the higher the mortality rate. (15) Heijink, et al. also found that a low level of GP's in the areas surrounding the hospital has a negative effect on the associated mortality rate. The exact reason for this is unclear but it is speculated that GP's may have a heavy workload, suffer from burnout and that this may contribute to poorer decisions on patient care.(41)

Review of literature related to HIV related mortality pre- and post ART in South Africa

Objective

In the researcher's healthcare organisation it is generally perceived that the contribution of HIV to the burden of disease is highly variable amongst regions and hospitals. The healthcare organisation under review is structured into five regions. The Northern and Tshwane Regions within South Africa are believed to have the highest incidence of HIV and HIV-related illness. These regions are in the north-eastern geographical regions of South Africa and cover four provinces: North West, Gauteng, Limpopo and Mpumalanga. KwaZulu-Natal is included in the Central Region. No studies of the data routinely warehoused in the healthcare organisation have been conducted to disprove, prove or quantify this perception. However, it is known that the prognosis and life-expectancy of HIV-infected individuals in South Africa have changed dramatically. This was especially evident in the years after the initiation of widespread and decentralised anti-retroviral treatment (ART) programs.(42)

According to an internal document (2008) detailing the case-mix and standardised mortality prediction methodology the author concluded: "*Increase in HIV related cases. Legislation*

and patient confidentially does not allow information around HIV cases to be captured; hence we needed to use clinical criteria to identify certain procedures that can be used as a proxy for HIV cases. Figure 5 shows that HIV-related cases have a higher mortality risk then the rest. Figure 6 shows a growth in the portion of HIV-related cases relative to the rest, hence another reason for the yearly increase in mortality risk."(43)

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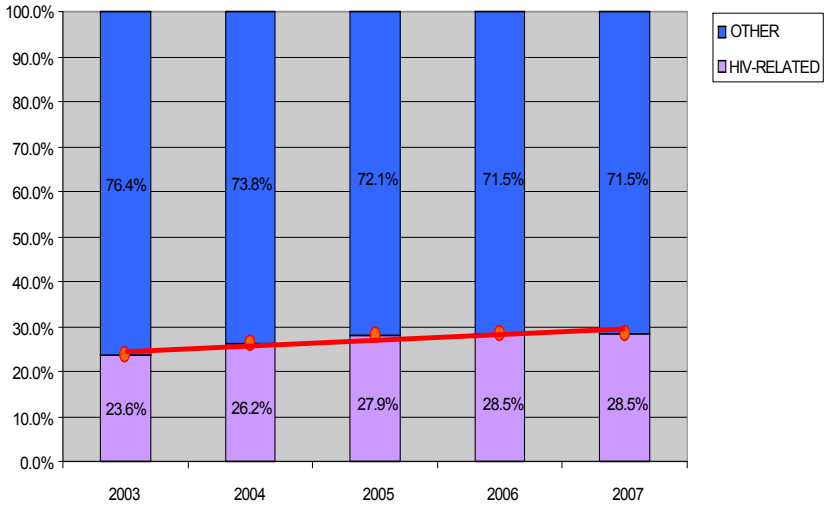
Figure 6 - HIV Related vs Rest



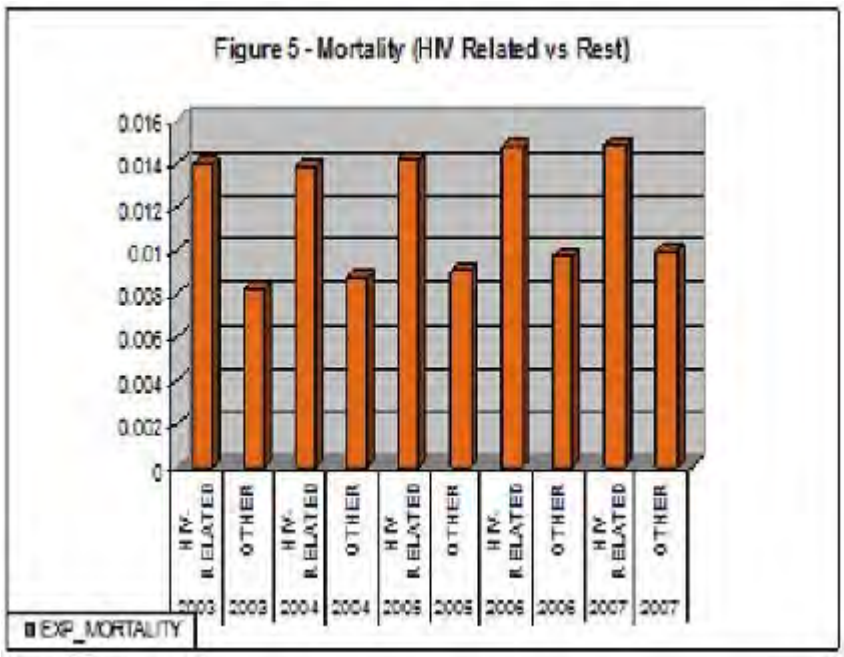


Fig 5 and 6 were copied from the internal memorandum by J van Schalkwyk and as such the numbering of the figures is not in line with the numbering in the document. (43)

The primary objective of the research project is to determine whether administrative and physiological predictive scoring models are comparable in relation to the expected mortality predictions generated. The influence of HIV and ART treatment programs is substantial and may lead to biased outcomes.(42) The diagnostic coding practices in the healthcare organisation have changed since the development of the model. HIV was not included in

diagnostic codes until mid-2010. The description of the ICD-10 code was printed on the bill and an internal policy was to exclude HIV from diagnostic codes for that reason.

Mid-2010 the format of the accounts changed and the clinical coders allocating the ICD-10 codes was instructed to code HIV and HIV related conditions when indicated. . Before the coding of HIV the ICD-10 code 'B33.3' was used as a proxy. The in-house mortality prediction model was developed in 2002, prior to the decentralised widespread implementation of public ART programs in South Africa. It was last updated in 2009, and B33.3 included in the weighting, however the weighting of all-cause mortality in people living with HIV wasn't taken into consideration. The weighting allocated to HIV in the mortality prediction model may overestimate the expected mortality in individuals suffering from HIV or HIV-related illnesses. A systematized literature review was thus conducted to determine the influence of ART on all-cause mortality in HIV infected individuals in South Africa.

Search strategy

A search was conducted using the search terms HIV, Standardised Mortality Ratio, all-cause mortality, prognosis and Sub-Saharan Africa. The Boolean search string that was used was: "HIV AND all-cause mortality AND Sub-Saharan Africa AND standardised mortality rate". Google Scholar, PubMed and EBSCO host was included and 143 publications were identified. Five additional articles were sourced from bibliographies. The search included publications in English and Afrikaans and placed no limitation on the date of publication. No manual library searches were conducted.

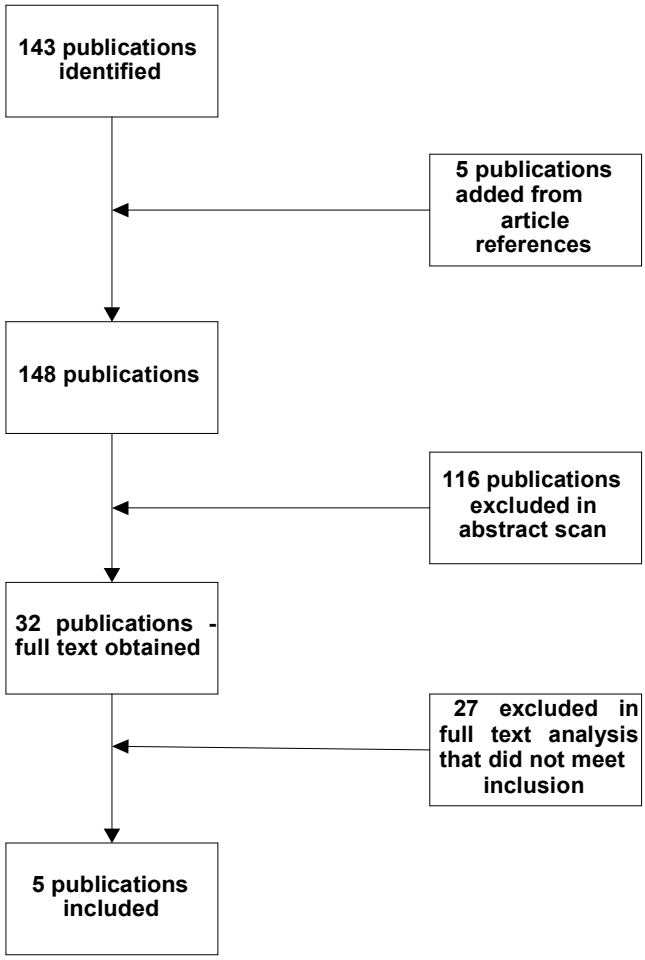


Figure 1: Flow-chart of literature selection

Inclusion criteria

Publications containing the following information:

- Adults and children suffering from HIV or HIV-related illness
- Public ART programs as intervention
- Studies limited to South Africa to investigate the influence of the decentralised ART programs on changes in the mortality rate
- All-cause mortality and/or life expectancy regarded as the primary end-point

Exclusion criteria

Publications containing the following criteria were excluded:

- Diagnosis-specific mortality outcomes
- Primary mortality related to other illnesses, for example mortality outcomes due to Multi-drug Resistant Tuberculosis
- Studies conducted in or referring to geographical areas in Sub-Saharan Africa with the exclusion of South Africa

- Studies referring to other interventions for example initiatives to encourage adherence to treatment programs like short message systems or home visits by lay healthcare workers
- Studies comparing the mortality rate in people suffering from HIV-related illness (not on ART programs) or AIDS to the general population

Table 2: Analysis of selected studies

Author	Format	Number of participants (n)	Time period/Length of follow-up	Population	Result
Brinkhoff, et al. (2009)	Cross sectional survey	13,249	14,695 person years	Patients enrolled in antiretroviral treatment programmes in Cote d'Ivoire, Malawi, South Africa and Zimbabwe (Global Burden of Disease Program)	Median age 34 years and 67% female. 85% of participants advanced disease. Excess mortality rate 17.5 (95% CI 14.5 -21.1) per 100 person-years in patients who started ART with a CD4<25 cells/µl and WHO stage III/IV and only 1.00 (0.55 -1.81) per 100 person-years in patients who started with 200 cells/µl above or with WHO stage I/II
Herbst, et al. (2009)	Prospective cohort study	74,500	2004 - 2006	Adults 25 to 49 years living in Umkhanyakude district in northern KwaZulu-Natal with N=7930 deaths (2000 and 2006)	Standardized mortality rates decreased significantly when compared to 2002-2003 from 22.52 to 17.58 per 1000 person-years (25-49 years of age) and 26.46 to 18.68 per 1000 person-years in women and men respectively
Bor	Prospective cohort study	101,000	2000-2011	Rural KwaZulu-Natal Changes in adult life	Adult life expectancy was 49.2 years in 2003 before the availability of ART in the public sector. Adult life expectancy

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(2013)				expectancy was measured during 2000 - 2011	increased to 60.5 years in 2011, a gain of 11.3 years
Slaymaker (2014)	Prospective cohort study	127,585	487,242 person years	Data from sites routinely testing patients for HIV in Malawi, South Africa, Tanzania and Uganda was collected and the difference in the mortality rate between HIV infected individuals and HIV negative individuals were calculated	Pre ART: HIV-attributable mortality: 45 to 88 deaths per 1,000 person years reducing to 14-46 deaths per 1,000 person years. The mortality rate (ages 15 - 54 all sites) decreased by 50% (HR =0.43, 95% CI: 0.32-0.58) after the availability of ART
Mee (2014)	Prospective cohort study	73 000		Agincourt Health and Socio-Demographic Survey site (AHDSS) located in Mpumalanga, South Africa. Data was gathered for a health and social study	Comparing 2007 - 2008 to 2009- 2010 a 30% decrease in age and gender standardised adult HIV-related and TB (HIV/TB) mortality was found with no change in mortality due to other causes. The changes in the mortality rate differed markedly amongst the communities. The biggest benefit was seen in areas with higher initial mortality rates.

Discussion of studies included

In 2009 there were 22 million people infected with HIV in Sub-Saharan Africa. These people had a life-expectancy of 10 years if untreated, whereas people living in the more affluent industrialised countries treated with ART had a mortality rate comparable to that of chronic disease sufferers. The provision of ART is costly and it was only in 2003 that ART became more widely available to people living in Sub-Saharan Africa. ART was provided by governmental programs and international humanitarian initiatives. Little information is available on how the mortality rates in Sub-Saharan Africa differed before and after initiation of the ART program.

In 2009, Brinkhof, et al. studied patients enrolled in antiretroviral programs (Côte d'Ivoire, Malawi, South Africa, and Zimbabwe) using information from the World Health Organization Global Burden of Disease (GBD) project as well as the International epidemiological Databases to Evaluate AIDS (IeDEA) initiative.(44) The cohort included 13,249 patients from all sites who were followed up for 14, 695 person-years. During that time 1,177 people died. Women made up the majority of the study participants (67%) and the median age of the cohort was 34 years. In 85% of participants where the severity of illness was known, the individuals were severely ill at the start of ART. Individuals starting ART with a CD4 cell count of less than 25 cells/µl and/ or World Health Organization (WHO) stage III/IV had an excess mortality rate of 17.5 (95% CI 14.5-21.1) per 100 person-years, while individuals starting with 200 cells/µl or above with WHO stage I/II had an excess mortality rate of 1.00 (0.55-1.81) per 100 person-years. SMR's were 47.1 (39.1-56.6) and 3.44 (1.91-6.17) respectively over the two years of follow-up. In patients starting antiretroviral therapy with CD4 counts of 200 cells/µl or above in WHO stage I/II (High CD4 count and early disease) and surviving year one of antiretroviral therapy, the excess mortality rate was 0.27 (0.08-0.94) per 100 person-years and corresponding SMR was 1.14 (0.47-2.77).

The findings of the study shows that the mortality rate is higher in individuals infected with HIV than in uninfected individuals however antiretroviral treatment programs reduce the mortality rate. Individuals starting treatment earlier and with less severe disease have a better prognosis and a mortality rate that compares to that of individuals living with chronic disease. One of the limitations of the study is that the authors compared the death rates to the national death rates and not with the deaths rates in the specific populations that were investigated. This may lead to biased results. However the findings are still significant and may be useful for future comparisons.(44)

Herbst, et al. conducted an open cohort, population-based, study utilising data collected by the demographic surveillance programme of the Africa Centre for Health and Population studies in the district of Umkhanyakude in northern KwaZulu-Natal, South Africa.(45) The cohort included 7930 deaths and participants were followed up for 517 856 person-years (January 2000 to December 2006). The prevalence of HIV increased from 1990 onwards and

reached 21.5% (15-49years age group) in 2004. The highest being 51% amongst women 25 - 29 years old and 44% amongst men 30 -34 years old.

In 2000 mortality was linked to HIV causes in 74% women and 61% men (15-44years); however in 2007 it was found that HIV related mortality had decreased steadily although the prevalence of HIV remained the same. A steady increase in the mortality rate is seen in all age groups from 2000 to 2003 with a decline in mortality rates by 2007. The 25-49 year old group had standardized all-cause mortality rates of 24.0 deaths per 1000 person-years in 2000 increasing to 33.0 deaths per 1000 person-years in 2003 and decreasing to 23.9.deaths per 1000 person-years in 2006.

A sharp decrease in HIV related mortality was found when the pre-ART (2002-2003) values were compared to the post-ART (2004-2007) values amounting to 22.5 to 17.6 per 1000 person years and 26.5 to 18.7 per 1000 person years in women and men (25-49 years old) respectively. It was found that mortality not related to HIV increased in women (4.5 to 7.3 per 1000 person years) however remained the same for men (men and women 25-49 years).(45)

Bor, et al. studied the influence of ART on HIV-related mortality and measured the changes in adult life expectancy. Adult life expectancy is defined as: *"the mean age to which a 15-year-old could expect to live if subjected to the full pattern of age-specific mortality rates observed in a population for a given period of time".*(42) Contrary to the methodology (United Nations East Asia model life tables) used by the South African government to extrapolate age-specific mortality rates, Bor, et al. measured mortality rates directly. The demographic surveillance data was obtained from the Health and Population Studies (Africa Centre) and was based on the observation of an open cohort (N= 101 286) in rural KwaZulu-Natal. Almost a third of HIV positive individuals (7% of study population) 15 years old or older had started ART by 2011.

In a study by Bor, et al. it was shown that adult life expectancy initially decreased from 52.3 years in 2000 to 49.2 in 2003. (42)After the initiation of public ART programmes life expectancy increased steadily and reached 60.5 in 2011. This is an improvement of an average 11.3 years. It was also found that the proportion of death in young adults declined and the median length of life increased by 18.1 years from 42.6 years in 2003 to 60.7 years in 2011. They found a clear temporal association with the start of the HIV pandemic and the associated rise in mortality rates as well as the introduction of decentralised, public ART programs and associated decreased mortality rates.(42)

Mee, et al. analysed data collected by the Agincourt health and socio-demographic survey site in Bushbuckridge sub-district, Ehlanzeni municipality in Mpumalanga. The area is predominantly rural and houses a large Mozambican population. The project was initiated in 1992 and by 2010 consisted of 90 000 persons in 16 000 households. The overall prevalence

of HIV was found to be 19.4 % (prevalence survey conducted August 2010 and May 2011) with the prevalence for females much higher than males, 23.9% versus 10.6%.

The cohort consisted of 105 149 persons, followed up for 320 945 person years and a crude mortality rate of 9.0 deaths per 1000 person years were recorded (1 January 2007 to 31 December 2010). The majority participants were female (53.2%) with the main causes of death HIV related illness 25.1%, pulmonary tuberculosis 19.2% and acute respiratory infections 17.0%. The HIV/TB mortality rate decreased by 27% (study time period 2007-2008 and 2009-2010) and mortality related to other causes decreased by 10% for the corresponding time period. Mee, et al. concluded that the establishment of a community clinic and the availability of ART contributed significantly to the decline in HIV/TB mortality in keeping with findings in a similar study in KwaZulu-Natal where mortality rates decreased by more than 50% after ART was initiated.(4)

The mortality rates amongst HIV infected adults were ten times higher than non-infected individuals and 90 -95% of deaths was attributable to HIV in the time period before the availability of ART. The mortality rates varied amongst the different populations and amongst different gender and age groups. (46) A study by Slaymaker et al. was undertaken in four regions in Sub-Saharan Africa collecting routine demographic and population HIV status information. The data was gathered from four sites: Malawi, South Africa, Tanzania and Uganda and collected demographic population-based data as well as HIV status. The projects are well established, collect data from epidemiologically different populations and has detailed mortality data pre- and post-ART readily available. The study conducted by Slaymaker, et al. stratifies the mortality rates in three streams: Five years before ART, five years while ART is being rolled-out and five years after established programs are available. The cohort consisted of 127 585 individuals age 15 years or older (HIV status known) contributing 487 242 person years. HIV-related mortality declined steadily from before ART was available to after establishment of ART programs from 45- 88 deaths per 1000 person years to 14- 46 deaths per 1 000 person years respectively. A reduction of greater than 50% in HIV related mortality (15 -54 years, across all sites) was found after the availability of ART when compared to the time period before the availability of ART. The mortality rates still remain higher than that of HIV negative people.(46)

Summary

The in-house hospital standardised mortality model was updated in 2009 without accurate data on the prevalence of HIV, or its geographic spread, disease severity and associated illnesses like multidrug resistant tuberculosis. The model may have underestimated the severity of illness and associated risk and lead to biased mortality indices, a false high rate. The opposite may also be true in that the population served by the private healthcare group may contain disproportionately more patients that are comply with first-world criteria and a

significantly lower prevalence of HIV and related illnesses. The improvement in life-expectancy of people living with HIV and treated with ART may have contributed to the model over estimating the risk of death and in populations with a high percentage of these patients may falsely lower the HSMR. The implementation of decentralised ART programs in the public sector have reduced the mortality rate of individuals living with HIV in South Africa and the reduced mortality rate may influence the risk prediction model.

Key points arising from the five studies:

- The all-cause mortality rate started to increase in the late nineties and reached a high in 2003 (before the onset of ART)
- The availability of ART, and especially the accessibility of community clinics providing ART and tuberculosis treatment, was associated with a sustained decline in the HIV related mortality rate - temporal relationship
- Mortality not related to HIV declined in some groups, however much less than that of HIV related mortality, and was left unchanged in other studies. The base mortality rate in the community influences the HIV related mortality rate
- HIV related mortality rates are variable amongst the different communities. HIV related mortality rates higher rates than the rest of the surrounding communities may be due to micro-epidemics
- HIV related mortality rates also vary amongst gender and age groups - young adult females have much higher rates
- The availability of ART and the early initiation of ART as well as the adherence to treatment programs have a major influence on the HIV related mortality rates
- In more affluent communities where ART is initiated early, the all-cause mortality rate is equal to that of individuals living with chronic disease. In Sub-Saharan countries the all-cause mortality rate of individuals on ART is still significantly higher than that of HIV negative individuals (4,42,44-46)

Conclusion

The evidence shows that the HIV related mortality rate is highly variable amongst populations. It depends on age and gender groups, and is influenced by the availability of ART and the early initiation and adherence to ART. The mortality rate still remains higher than that of HIV negative individuals. The mortality prediction model was developed by the healthcare organisation during the pre-ART period (2002). The model was updated in 2009 and selected the ICD-10 code “B33.3” as a proxy to try and establish the risk added by HIV infection. The inclusion of a proxy measure for HIV is not ideal and may introduce measurement errors and biased conclusions. The nature of the illness as well as the lack of good quality clinical information makes it difficult to gauge the accuracy with which the model adjusts for HIV.

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Section C

Predicting mortality rates: Comparison of an administrative predictive model (Hospital Standardised Mortality Ratio) with a physiological predictive model (APACHE ®IV) — a cross sectional study

[Article lay out as specified by the “Instructions to authors” for the journal *Critical Care*. Please see section D, addendum H. Figures and tables are supposed to be included as separate files. However, UCT specifies that only a single, combined file should be submitted hence the naming of the figures on the individual documents.]

Predicting mortality rates: Comparison of an administrative predictive model (Hospital Standardised Mortality Ratio) with a physiological predictive model (APACHE ®IV) — a cross sectional study

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Abstract

Introduction

The healthcare industry experiences ever increasing pressure to provide evidence of the value of the services provided to patients and funders. Quality indicators are seen as a means of quantifying value. Yet there is little agreements on which are the optimal measures to use. Death is clearly defined and easily measurable however, most deaths are due to the normal disease process. The actual mortalities can't be directly compared as healthcare institutions and patient populations differ. The biggest challenge is thus to accurately and simply predict the risk of death.

Methods

A cross sectional study was undertaken in a South African private healthcare group (40 hospitals with 68 critical care units). The predicted mortality as calculated with an administrative model (Hospital Standardised Mortality Ratio) was compared to a physiological model (APACHE ®IV) and considered for the combined cohort as well as stratified samples by prediction level (<10% predicted mortality, 10-50% predicted mortality or >50% predicted mortality). A one way analysis that included a bivariate linear regression, ANOVA and a Pearson's correlation analysis was done. A total of 47,982 critical and high dependency patients were scored from 1 June 2013 to 31 July 2014. 1921 records (0.4%) were excluded due to missing values, duplicate records and values not within parameters and 46 061 included in the sample.

Results

The mean age was 58.8 (95% CI 22-87) years, mean APS score 26.5 (95% CI 4-83) and APACHE ®IV score 36.3 (95% CI 9-95). The total crude mortality rate was 7.4%. The models correlated moderately when the combined cohort was evaluated **(**Pearson's correlation Index: 0.62 (95%CI 0.62-0.63 R-squared: 0.38). The stratified samples showed very good correlation for the <10% stratum (Pearson's correlation Index: 0.88, R-squared: 0.78 95%CI 0.878-0.882), good correlation for the 10 - 50% predicted mortality rates (Pearson's correlation Index: 0.78, R-squared: 0.61 95%CI 0.77-0.79) and no correlation for the >50% predicted mortality stratum (Pearson's correlation Index: 0.09, R-squared: 0.01 95%CI 0.03-0.15).

Conclusion

The administrative predictive model correlate well at equal or less to 50% predicted mortality rate, while not showing a correlation at high predicted mortality rates (>50%) and is not suitable for predicting mortality in the highest stratum.

Keywords

Standardised Mortality Rate; APACHE ®IV; administrative prediction model

Introduction

The healthcare industry is facing ever increasing pressure to improve and "prove" the value of care provided to patients and funders. [1] Healthcare funders are using proxy administrative measures, obtained from accounts submitted to the healthcare funders, to extrapolate the quality of care delivered. These measures are used to negotiate tariffs, build provider networks and design new service lines.[1] The measurement of mortality as an outcome indicator is widely used, as death is seen as an unambiguous variable critically important to patients. The actual number of deaths is reported on as the crude mortality rate however institutions differ on many fronts and crude mortality rates can't be directly compared.[2] Hospital standardised mortality ratios (HSMR), derived from administrative data, has been touted as a simple quality measure that can adjust for the differences between patients and allow hospitals to be compared to one another. The HSMR is influenced by a number of variables unrelated to the quality of care and doubt has been cast on the accuracy thereof. The ability to accurately predict the expected mortality rate remains challenging.[2]

Physiological predictive scoring models are believed to more accurately reflect the risk of death.[3] Enfield, et al. compared how well predicted mortality rates correlate when calculated with an administrative predictive scoring model versus a physiological predictive model in critically ill patients. They included 556 patients from two medical centres and found that at low predicted mortality rates (<10 %) the models correlated well but diverged at higher values. Enfield, et al. also concluded that the use of an administrative predictive scoring model is not suitable in critically ill patients.[3]

The healthcare organisation where this research was performed reports monthly on the HSMR for all patients. Acute Physiology and Chronic Health Evaluation (APACHE® IV) is additionally used to score all eligible critically ill patients. However, no research has previously been undertaken to compare these two measures. The purpose of this study was to compare the administrative predictive scoring model (HSMR) to that of the physiological predictive model (APACHE® IV) and to further stratify the patients into different risk samples to ascertain the correlation and performance of the models.

Materials and Methods

Ethics approval was granted by the Research Ethics Committee - University of Cape Town and the organisation's own Internal Ethics Committee. No individual consent was sought as de-identified patient data was summarised and used in the analysis. A cross-sectional study design was used to achieve the research objectives.

The main objective of the study was to ascertain if the predicted mortality rate calculated with an administrative model (HSMR) correlated with the predicted mortality rate calculated with a physiological model (APACHE® IV) in critically ill patients. The secondary objective was to determine whether the correlation differed in patients who were more

severely ill. The cohort was stratified into low (<10 %), medium (10 %-50 %) and high (>50 %) predicted mortality rates in keeping with the observed acuity of the patients and in line with the strata described in a study by Enfield et al. comparing a proprietary HSMR model to APACHE® IV [3] The administrative predictive model was based on international best practice/standard and developed in-house for operational use (detail available on request).

The Hospital standardized mortality index (HSMI) is defined as the ratio between the actual mortalities and the predictive mortalities (or hospital standardized mortalities) based on the underlying model used. The data was obtained from the healthcare organisation's data warehouse. The statistical analysis was performed by Mr Jacques de Kock. A one-way analysis that included a bivariate linear regression, ANOVA and a Pearson's correlation analysis was done with SAS Enterprise Guide Version 6.1 (Copyright © 2013 by SAS Institute Inc., JMP® 11.1.1 Statistical Discovery from SAS (Copyright © 2013 by SAS Institute Inc.) and Microsoft Excel™ 2010 (Copyright© 2010 by Microsoft Corporation. 47,982 records were captured and scored across 40 hospitals and 68 Critical Care Units. Of these records, 1,921 (04%) were excluded due to missing values, values not within parameters and duplicate records and 46,061records included in the sample for analysis.

Data were included for critically ill patients admitted to Mediclinic, a private acute care hospital group, in South Africa for the time period 01 July 2013 to 30 June 2014. All patients classified as critically ill, including high dependency patients, and admitted to a critical care unit were considered for inclusion. Patients were scored on the Clinical Criteria checklist and classified into intensive care, high dependency or general ward according to the score obtained. The clinical criteria scoring system was developed within the healthcare organisation in the late nineties with input from the healthcare funders. The objective was to create a standardised platform for 'level-of-care' (LOC) billing. The charging of LOC is based on the complexity of care (human resources required as well as the required environment) and internal and BHF billing guidelines. More information on the clinical criteria scoring system is available on request.

All patients admitted to intensive and high dependency units that met the entry criteria for APACHE® IV were included. Patients who had temporarily received specialised care in general wards due to CCU bed unavailability were also included in the cohort. The database exclusion rules were followed in selecting eligible patients: patients younger than 16 years, patients admitted with burns, patients admitted with chest pain in order to rule out acute myocardial infarction (AMI) and patients with a critical care unit (CCU) stay of less than 4 hours were excluded. There were no standard data collection processes and the unit manager, allocated nurse, nursing shift leader or data capturers collected the data as part of daily responsibilities.

Pre-printed forms were used to collect the data. The data collection was done after discharge from CCU or after admission to the CCU for more than 24 hours. The mid-points of the physiological variables were indicated on the data collection forms. This decreased the reliance of the staff on memory (definitions and values) and aided data accuracy. No easily

identifiable patient information was captured and only the visit number recorded. The data was subsequently transferred to an electronic, in-house developed application to enable secure storage of information (for data warehousing) and reporting. All responsible staff was trained early in 2013 as the organisation transitioned from the third version of APACHE® to the fourth. A comprehensive, internally developed e-learning module was also freely available to all staff.

Predictive scoring models

SMR (Physiological data)

APACHE® IV was chosen as it is routinely used as a quality measure by all CCU's in the healthcare organisation. APACHE ® IV was developed in the United States of America (USA) and the attributes of the model are well documented in the peer reviewed literature.[4] The attributes of the patient population that is admitted to the CCU's in the healthcare organisation may differ substantially from the original reference population of the model however the model was not recalibrated for local use. The version of APACHE® IV that is freely available on the internet was used to create an electronic database and the information was extracted from the data warehouse. The way in which the study was conducted may improve the external validity however calibration of the model for future use is desirable. [4]

SMR (Administrative data)

The HSMR model was developed in 2007 and last updated in 2009. Death is treated as a binary response variable and a logistic regression model used to adjust for differences in case-mix in order to calculate an expected mortality rate per admission. The algorithm identifies the driver code on the account from routinely collected demographic data, diagnostic codes (ICD-10) and procedural codes (CPT4). A number of patient level risk factors are also taken into account: age, gender, comorbidities, primary and secondary diagnosis, procedure performed and treating speciality. HIV was not coded in the healthcare organisation until mid-2010. This was due to the description of the ICD-10 code that was printed on the account impacting on patient confidentiality. The incomplete coding of the care episode resulted in the healthcare organisation having little background data to analyse and assign a weight to HIV. With the update of the HSMR model in 2009 the ICD-10 code 'B33.3' was used as a proxy to indicate the possible presence of HIV. Since mid 2010 descriptions of ICD-10 codes are no longer printed on the account and the coding of HIV in line with industry standards is encouraged. The HSMR is routinely calculated for all in-patients however only records from corresponding patients included in APACHE® IV were taken into account for this study.

Data integrity

APACHE® IV

The quality of the data entered was evaluated by informal audits and quality control measures. To ensure that patients eligible for inclusion weren't missed, a detailed analysis of compliance was done. A compliance report compared patients flagged as 'critical care' based on billing criteria to database entries to ensure that no patients were missed. Further information of fields left blank and marked as 'not available' was sought and if none could be found it was included in the model as normal values. A maximum of 12 fields could be marked as "not available" and an average of 6.7 fields per entry was marked as not available. The number varied amongst the hospitals and the number of "not available fields" entered was much higher in high care patients. The blood gas results were most often omitted. The integrity of the data contained in the warehouse was validated monthly. Where data was submitted to the database but the application didn't calculate a score, the records were re-scored and included in the set. In cases where some of the information was unavailable the records were excluded from the calculations. If a duplicate record was captured the first record was included and subsequent copies excluded.

HSMR

All files of deceased patients were audited by staff trained in clinical coding. This procedure was followed to ensure that the clinical and procedural coding accurately reflected the clinical care episode. Any incomplete or incorrect coding was rectified and updated in the warehouse. Additional information was sought from treating doctors where appropriate. The healthcare organisation has a structured audit process in place and clinical and procedural coding is audited quarterly. During the audits a random representative stratified sample is obtained per hospital with a further sample of these files subjected to an 'audit-of-the-auditor' process. The audits focus on missed or incorrect codes: 'primary diagnosis, secondary diagnosis, comorbidities and procedures' as well as the correct sequencing of codes.

Results

The mean age of the patients was 58.8 (95%CI 22-87), mean APS score 26.5 (95%CI 4-83) and mean APACHE ®IV score 36.3 (95%CI 9-95). The split between male and female was almost even with 51.9% males. The predicted mortality rate was 3.4% in the administrative and 6.2% in the physiological model. The crude mortality rate for the cohort was 7.4% (n = 3 400). (Table 1)

The comparison between HSMI for models using patient administrative data versus patient physiological data (i.e. APACHE IV) was made across the 40 hospitals for the combined cohort.

A relatively average positive linear fit between these (Pearson's correlation Index: 0.62 95%CI 0.62 -0.63, R-squared: 0.38) was found. Table 2 and figure 1 describe the bivariate fit of the HSMI physiological model versus the administrative model.

The data from the physiological model was ranked and grouped into quintiles according to the HSMR and was then compared to the administrative models for the corresponding quintiles. It was found that the total predicted mortality cases for the administrative model were higher than the total predicted mortality values for the physiological model, as well as the actual number of mortalities in each of the first three quintiles. In the fifth quintile the opposite was noticed and in the fourth quintile, the actual and predicted total mortalities for each model were relatively similar. (Figure 2)

A similar effect to dividing the sample in quintiles can also be realised when categorizing the predicted mortalities according to the following strata: '<10% predicted mortality, 10 - 50% predicted mortality and >50% predicted mortality' as illustrated in figure 3. The bivariate fit shows that the performance of the administrative and physiological models at low predicted mortality rates (<10%) is similar as illustrated in figure 4. At 10-50% predicted mortality rate there was a good correlation between the models (Pearson's correlation Index: 0.78 95%CI 0.77-0.79, R-squared: 0.61) and 10 - 50% predicted mortality both the administrative as well as the physiological model seemed to underestimate the predicted mortality rates however the physiological model performed better. (Figure 5)

The bivariate fit illustrated that there was a difference between the total predicted mortality for the two models at high predicted mortality rates (sample size n = 1 195 for 38 hospitals), as well as no significant correlation (Pearson's correlation Index: 0.09, R-squared: 0.01 95%CI 0.03-0.09) when the high predicted mortality stratum values are compared to one another. In the high predicted mortality stratum (>50%) the mortality prediction by the administrative model differed significantly from the physiological model and greatly underestimated the predicted mortality rate. The predicted mortality rate with the administrative model also decreased as the acuity increased. These findings are illustrated in figure 6 and tables 3, 4, 5, and 6.

Discussion

The findings of our study supported the findings of Enfield et al. in that the two models did not correlate well at high predicted mortality rates. Contrary to the existing literature, we found that the administrative and physiological predictive models both correlated well with predictions for predicted mortalities 10 - 50%. The administrative model greatly underestimated the predicted mortality in the highest stratum.[3] In most of these cases there was a better fit to the actual mortalities using the physiological model rather than the administrative model, but more noticeably the administrative model is not adequate to model mortalities in the fifth quintile. This may be due to a lack of information on the patient's physiological condition which may be necessary to predict mortality outcomes. A study by Shahian et al. illustrated that there were marked variability amongst proprietary mortality prediction models and the predicted mortality rate varied greatly when calculated with different proprietary mortality prediction models and applied to the same cohort. [5]

In our study the models correlated moderately well when the cohort was considered as a whole and not stratified. This may have been due to the inclusion of a large number [n = 28 516] of high dependency patients in the cohort. These patients were never categorised as critical care patients and have low predicted mortality rates that may skew the data. This finding was also reflected in the observed mortality rates which were 18.1% in the study by Enfield et al. and 7.4% in our study. [3] The accuracy of diagnostic and procedural coding is very important in the administrative model and the outliers may suggest hospitals with some degree of incorrect coding or incorrectly captured information. Outliers in the HSMI is especially evident in the >50% predicted mortality rate band (figure 6) where the bulk of the HSMI values is in the 5-15 range as calculated with the administrative model. This doesn't correlate at all with the HSMI for the corresponding values calculated with the physiological model (HSMI values 0.8 – 1.4). The HSMI for the administrative model consistently had higher indices (p-value < 0.0001) than the HSMI for the APACHE® IV model and this may have been due to critical care patients only forming a subset of the inpatient data that was used to build the model. The model may have only marginally adjusted for critical care patients and consequently underestimated the predicted mortality values. It follows that the administrative model is not a good predictor for tail end outlier cases, whereas the physiological model almost accurately predicted the correct number of mortalities in the highest stratum. The HSMR administrative model was not recently updated however the model will be updated in the near future and the addition of more variables may improve the performance thereof in the highest stratum.

There were a number of other limitations to the study. The APACHE®IV model wasn't calibrated for the cohort and there may have been other variables, not related to the model, which influenced the outcome. The burden of disease of HIV is large in Southern Africa and even though the study was conducted in a private healthcare group this may have had a major influence on the results. [6] The APACHE®IV model may not sufficiently risk adjust for HIV. The decentralised role out of antiretroviral therapy (ART) in the public sector has reduced the mortality rates of HIV substantially over the last decade. [6] The previous administrative invoicing practice in the healthcare organisation leading to HIV not being coded until mid 2010 may have influenced the predicted mortality rates. The manual data collection for APACHE ®IV as well as the informal audit process in validating the data accuracy may all impact on data quality. The clinical criteria score was developed in line with international best practice however may still have introduced bias.

Conclusion

The HSMR (administrative model) is a relatively easy and inexpensive means of calculating predicted hospital mortality ratios in all but the highest risk-group. The model show good correlation at 50% and less predicted mortality rates. However in patients with a high predicted mortality, >50%, the administrative model is inadequate in predicting the expected mortality rate. This may lead to a high mortality index in hospitals that offer more specialised care and have a higher case-mix that is due to the characteristics of the model and not related to poor quality of care.

The physiology model (APACHE®IV) more accurately predicted the outcome of patients in the highest stratum and a physiological model may be more suitable in this subset of patients. The inclusion of high dependency patients in the cohort may dilute the index and the suitability of the model in this population needs to be further investigated. The healthcare industry is searching for accurate, inexpensive and simple clinical outcome measures to gauge their performance, the value delivered to patients, and support quality improvement initiatives. Healthcare funders are looking for similar measures to gauge the value that is delivered to their members. The results of this study highlight the limitation of the current measures that are used and the need for refinement and validation of the model in the specific population.

Key Points

- The HSMR (administrative model) is comparable to the physiological model in predicting mortality rates in less ill patients (<10% predicted mortality), correlates moderately well in 10 -50% predicted mortality and may offer an inexpensive, easily computational model to predict mortality rates in these groups
- As the predicted mortality rate increases, the models diverge and show poor correlation at high (>50% predicted mortality) rates. The physiological model also more accurately predicts the mortality rate in the middle group (10 - 50% predicted mortality rate) however not as well as in the high predicted mortality group
- The physiological model (APACHE®IV) more accurately predicted mortality rates in critically ill patients however only the predictions from this model has been taken into consideration and it may not hold true for other models
- Ideally the physiological model needs to calibrated for the population it will be used in and the HSMR (administrative model) needs to be regularly updated

Competing interests

RT and JdeK are employed by the private healthcare institution. Both authors will have no financial or other gain from the study. Permission was obtained from the healthcare organisation to publish the study. All findings were reported on transparently.

Author contributions

RT conceived the study as part requirements of a Master's qualification. RT also designed and conducted the study and drafted the manuscript. JdeK performed the statistical analysis. TW was involved in the initial design, review of procedures and development of the manuscript. All authors read and approved the final manuscript.

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Figure titles and legends

Figure 1 Bivariate fit of HSMI

Bivariate fit of the HSMI for the physiological model versus the administrative model

Figure 2 Distribution plot by quintiles

Distribution plot of the number of mortalities as well as the predicted mortalities grouped by each quintile

Figure 3 Distribution plot by predicted mortality categories

Distribution plot of the number of mortalities as well as the predicted mortalities group by predicted mortalities categories

Figure 4 Bivariate fit of the HSMI for predicted mortalities <0.1

A bivariate of the HSMI for the physiological model versus the administrative model only for predicted mortalities <0.1 as observed in the physiological model

Figure 5 Bivariate fit of the HSMI for predicted mortalities 0.1-0.5

A bivariate of the HSMI for the physiological model versus the administrative model only for predicted mortalities 0.1- 0.5 as observed in the physiological model

Figure 6 Bivariate fit of the HSMI for predicted mortalities >0.5

A bivariate of the HSMI for the physiological model versus the administrative model only for predicted mortalities >0.5 as observed in the physiological model

Table 1 Patient population and model characteristics

Statistic	**Total**
Number of records	46 061
Mean Average Age in Years [with 95% C.I.]	58.8 [22; 87]
Gender Split (% Male)	51.9%
Cases Ventilated (%)	6.8%
Mean Average APS Score [with 95% C.I.]	26.5 [4; 83]
Mean Average APACHE® IV Score [with 95% C.I.]	36.3[9; 95]
Number of Mortalities (with rate)	3 400 (7.4%)
Predicted Mortalities - Administrative Model (with rate)	1 581 (3.4%)
Predicted Mortalities - Physiological Model (with rate)	2 853 (6.2%)

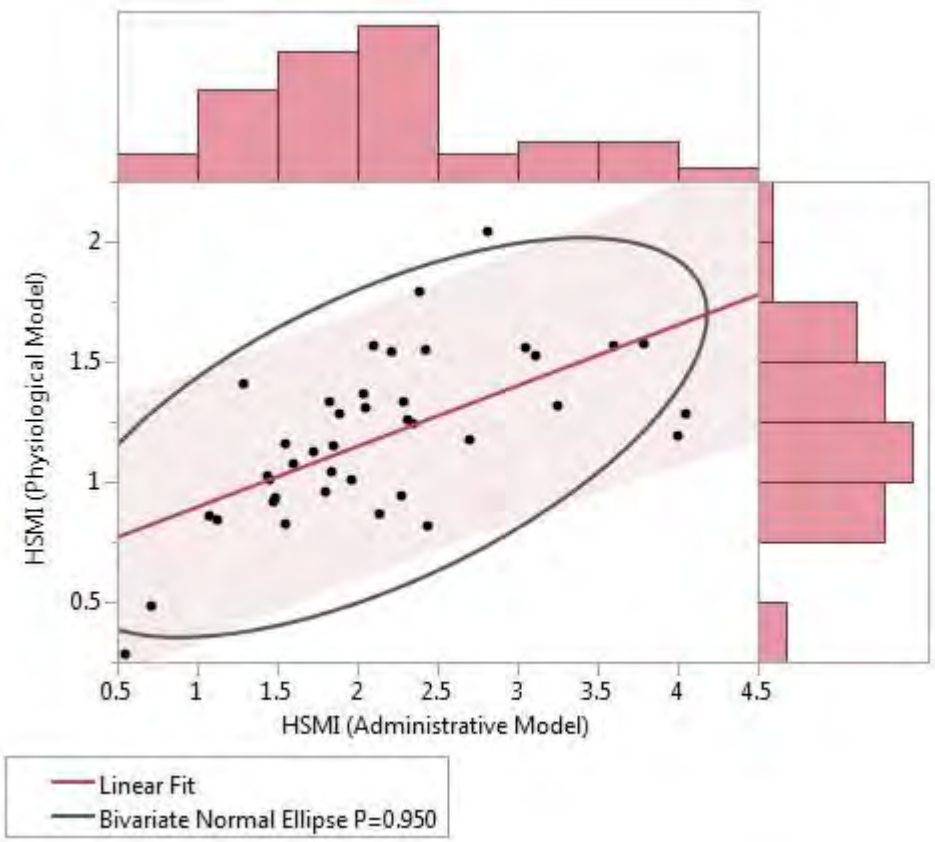
HSMI (Physiological Model)
2
1.5
1
0.5
0.5
1
1.5
2
2.5
3
3.5
4
4.5
HSMI (Administrative Model)
Linear Fit
Bivariate Normal Ellipse P=0.950

Figure 1

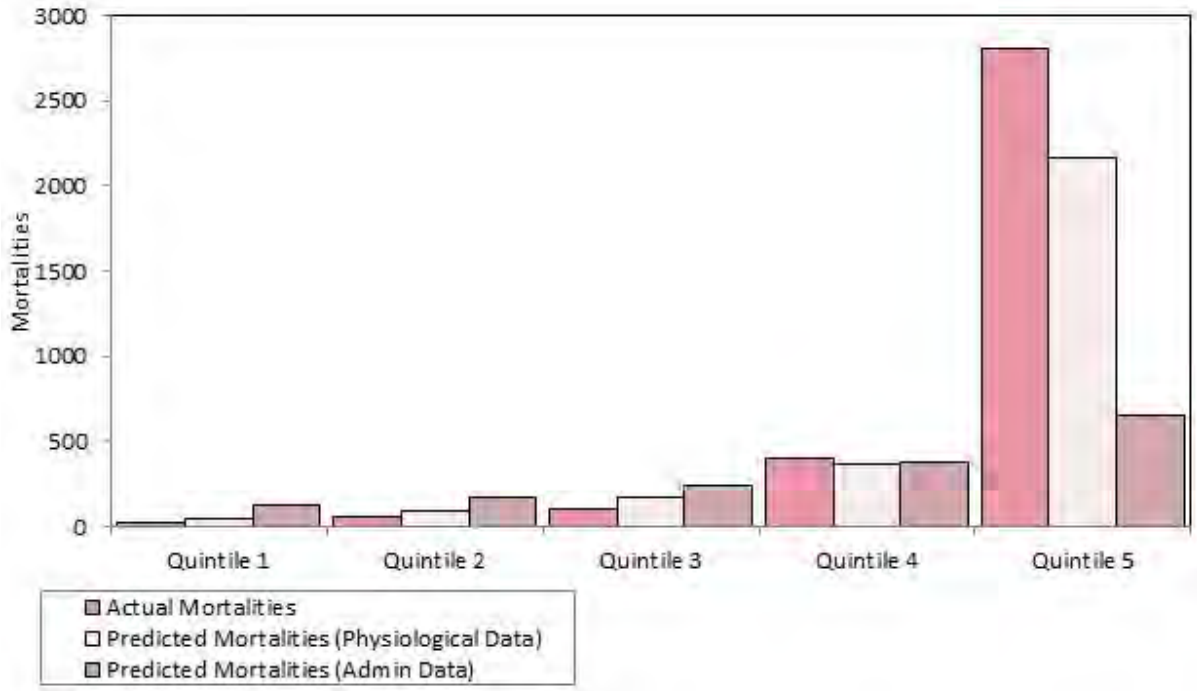
3000
2500
2000
1500
1000
500
0
Mortalities
Quintile 1
Quintile 2
Quintile 3
Quintile 4
Quintile 5
Actual Mortalities
Predicted Mortalities (Physiological Data)
Predicted Mortalities (Admin Data)

Figure 2

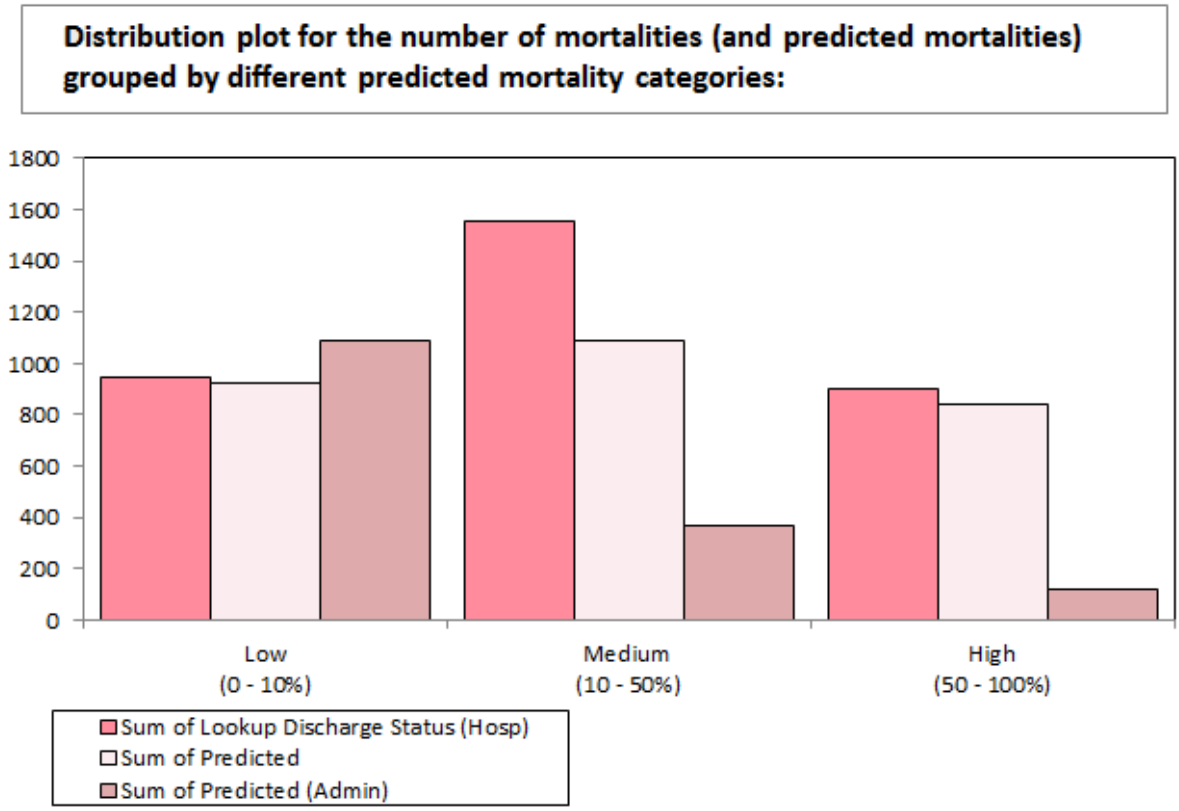
Distribution plot for the number of mortalities (and predicted mortalities) grouped by different predicted mortality categories:
1800
1600
1400
1200
1000
800
600
400
200
0
Low
(0 - 10%)
Medium
(10 - 50%)
High
(50 - 100%)
Sum of Lookup Discharge Status (Hosp)
Sum of Predicted
Sum of Predicted (Admin)

Figure 3

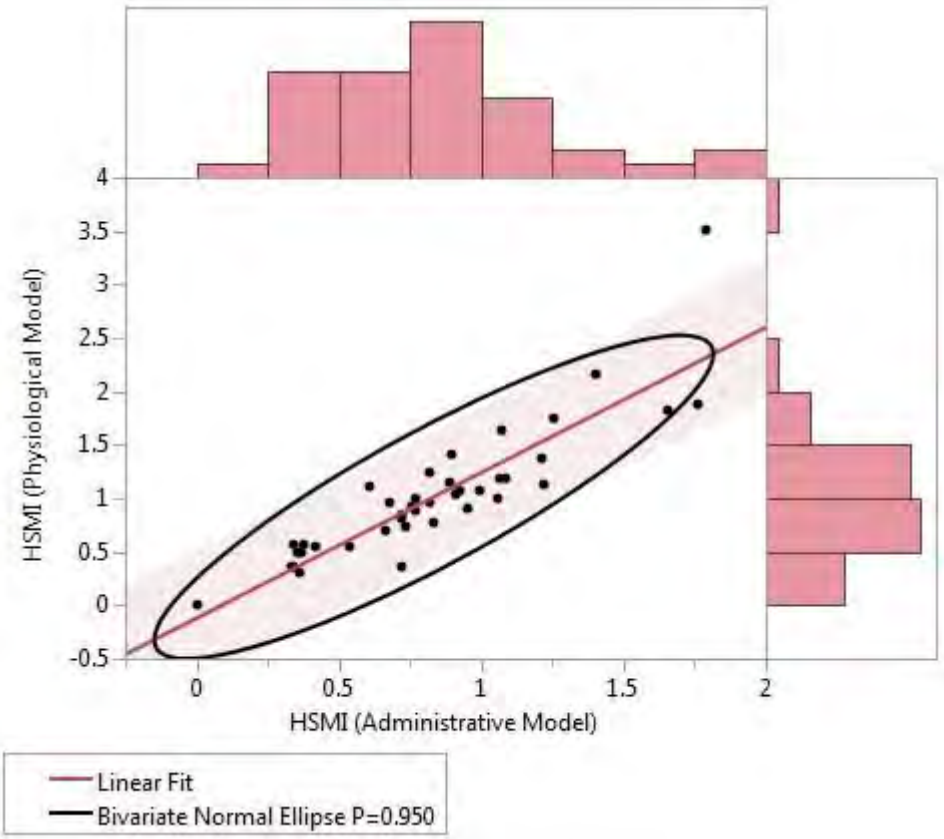
HSMI (Physiological Model)
HSMI (Administrative Model)
4
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
0
0.5
1
1.5
2
Linear Fit
Bivariate Normal Ellipse P=0.950

Figure 4

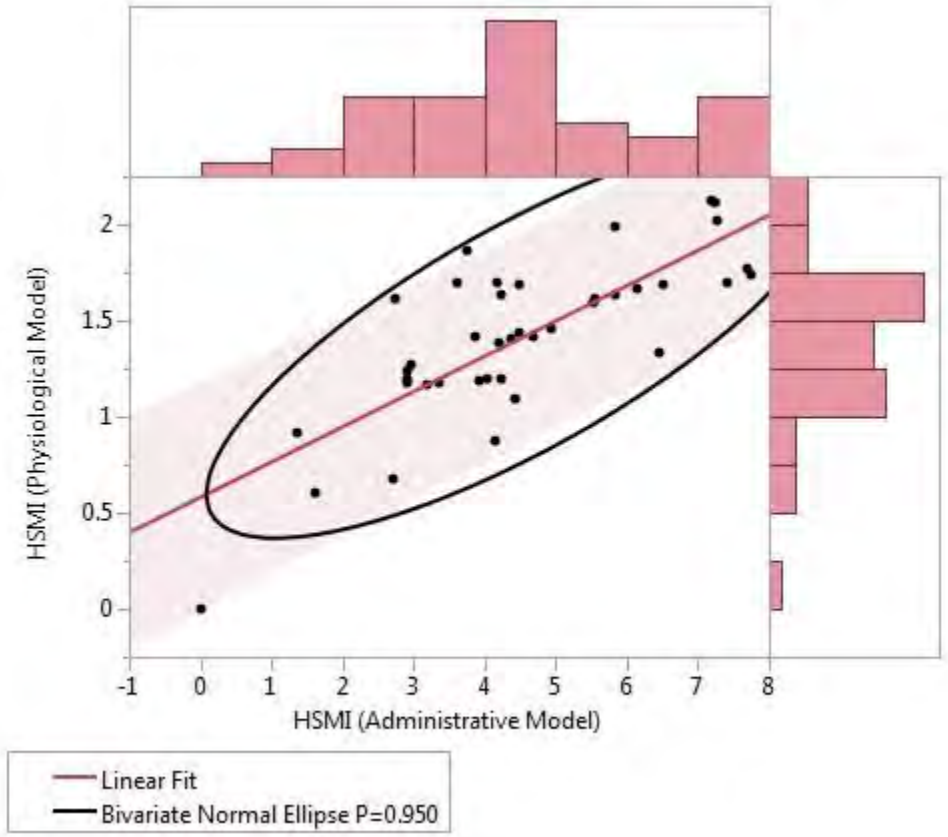
HSMI (Physiological Model)
2
1.5
1
0.5
0
-1
0
1
2
3
4
5
6
7
8
HSMI (Administrative Model)
Linear Fit
Bivariate Normal Ellipse P=0.950

Figure 5

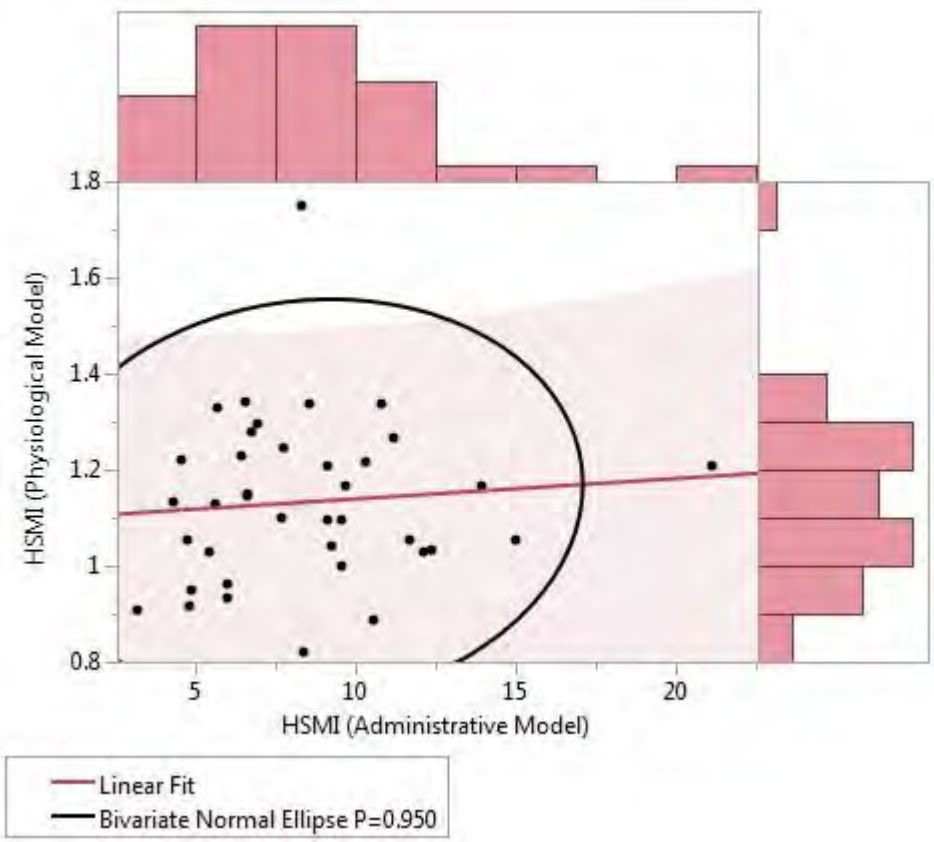
1.8
1.6
1.4
1.2
1
0.8
HSMI (Physiological Model)
5
10
15
20
HSMI (Administrative Model)
Linear Fit
Bivariate Normal Ellipse P=0.950

Figure 6

Table 2 Bivariate fit of the HSMI physiological model versus the administrative model

Linear Fit

HSMI (Physiological model) = 0.6485635 + 0.2524353*HSMI (Administrative Model)

Summary of Fit

RSquare	0.382442
RSquare Adj	0.366191
Root Mean Square Error	0.270484
Mean of Response	1.188491
Observations (or Sum Wgts)	40

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio
Model	1	1.7216926	1.72169	23.5327
Error	38	2.7801466	0.07316	**Prob>F**
C. Total	39	4.5018392		**<.**0001

Parameter Estimates

Term	Estimate	Std Error	T Ratio	Prob>[t]	
Intercept	0.6485635	0.119235	5.44	<.0001	
HSMI (Administrative Model)	0.2524353	0.052037	4.85	<.0001	
Correlation					
Variable	**Mean**	**Std Dev**	**Correlation**	**Signif. Prob**	**Number**
HSMI (Administrative Model)	2.138875	0.83233	0.618419	<.0001	40
HSMI (Physiological Model)	1.188491	0.339753			

Table 3 Detailed information of the stratified sample

Statistic	Cases included in Strata 1*	Cases included in Strata 2*	Cases included in Strata 3*	Pooled Information
N =	39,848	5,018	1,195	46,061
Mean Average Age in Years (with 95% C.I.)	57.8 [22; 86]	65.6 [28; 91]	62.3 [27; 89]	58.8 [22; 87]
Gender Split (% Male)	51.9%	51.6%	52.8%	51.9%
Cases Ventilated (%)	2.3%	27.8%	68.4%	6.8%
Mean Average APS Score (with 95% C.I.)	21.2 [4; 51]	38.4 [5; 126]	33.3 [6; 90]	26.5 [4; 83]
Mean Average APACHE IV Score (with 95% C.I.)	30.5 [7; 65]	49.0 [10; 140]	44.0 [11; 102]	36.3 [9; 95]
Number of Mortalities (with rate)	465 (1.6%)	1,522 (26.3%)	1,413 (12.0%)	3,400 (7.4%)
Predicted Mortalities - Administrative Model (with rate)	722 (2.5%)	311 (5.4%)	548 (4.7%)	1,581 (3.4%)
Predicted Mortalities - Physiological Model (with rate)	872 (3.1%)	869 (15.0%)	1,112 (9.5%)	2,853 (6.2%)

Table 4 Bivariate fit of the HSMI physiological model versus the administrative model (only for predicted mortalities less than 0.1 observed in the physiological model)

Linear Fit

HSMI (Physiological model) = 0.10572 + 1.3612494*HSMI (Administrative Model)

Summary of Fit

RSquare	0.781508
RSquare Adj	0.775759
Root Mean Square Error	0.292594
Mean of Response	1.023298
Observations (or Sum Wgts)	40

Analysis of Variance

Source	**DF**	**Sum of Squares**	**Mean Square**	**F Ratio**
Model	1	11.636257	11.6363	135.9197
Error	38	3.253228	0.0856	**Prob>F**
C. Total	39	14.889484		**<.**0001

Parameter Estimates

Term	**Estimate**	**Std Error**	**T Ratio**	**Prob>[t]**
Intercept	-0.10572	0.107324	-0.99	0.3308
HSMI (Administrative Model)	1.3612494	0.116761	11.66	<.0001

Correlation

Variable	**Mean**	**Std Dev**	**Correlation**	**Signif. Prob**	**Number**
HSMI (Administrative Model)	0.829399	0.40127	0.88403	<.0001	40
HSMI (Physiological Model)	1.023298	0.617885			

Table 5 Bivariate fit of the HSMI physiological model versus the administrative model for predicted mortalities between 0.1 and 0.5 and observed in the physiological model

Linear Fit

HSMI (Physiological model) = 0.5886158 + 0.1834806*HSMI (Administrative Model)

Summary of Fit

RSquare	0.611485
RSquare Adj	0.601261
Root Mean Square Error	0.269106
Mean of Response	1.417116
Observations (or Sum Wgts)	40

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio
Model	1	4.3312134	4.33121	59.8084
Error	38	2.7518906	0.07242	Prob>F
C. Total	39	7.0831039		<0.0001

Parameter Estimates

Term	Estimate	Std Error	T Ratio	Prob>[t]
Intercept	0.5886158	0.115271	5.11	<0.0001
HSMI (Administrative Model)	0.1834806	0.023725	7.33	<0.0001

Correlation

Variable	Mean	Std Dev	Correlation	Signif. Prob	Number
HSMI (Administrative Model)	4.515468	1.816278	0.781975	<0.0001	40
HSMI (Physiological Model)	1.417116	0.426167			

Table 6 - Bivariate fit of the HSMI physiological model versus the administrative model for predicted mortality rate >0.5 and observed in the physiological model

Linear Fit

HSMI (Physiological model) = 1.0990239 + 0.004246*HSMI (Administrative Model)

Summary of Fit

RSquare	0.007489
RSquare Adj	-0.02008
Root Mean Square Error	0.174238
Mean of Response	1.134941
Observations (or Sum Wgts)	38

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio
Model	1	0.0082470	0.008247	0.2716
Error	36	1.0929202	0.030359	**Prob>F**
C. Total	37	1.1011672		0.6054

Parameter Estimates

Term	Estimate	Std Error	T Ratio	Prob>[t]
Intercept	1.0990239	0.074484	14.76	<0.0001
HSMI (Administrative Model)	0.004246	0.008146	0.52	0.6054

Correlation

Variable	Mean	Std Dev	Correlation	Signif. Prob	Number
HSMI (Administrative Model)	8.459164	3.516185	0.086541	0.6054	38
HSMI (Physiological Model)	1.134941	0.172515			

Section D

Addendum A — Medi-Clinic's criteria for specialised units form

Addendum B — Support document for the "criteria for specialised units form"

Addendum C — Apache IV® score

Addendum D — Medi-Clinic Case Mix Methodology

Addendum E — Medi-Clinic approval to conduct study

Addendum F — UCT human research ethics approval to conduct study (data collection concluded by 30 Oct 2014)

Addendum G — Student declaration

Addendum H — Instructions for authors from the journal *Critical Care*

Addendum A

Sticker

Primary Diagnosis: _____

Secondary Diagnosis: _____

Surgical Diagnosis: _____

Secondary Diagnosis: _____

MEDICLINIC

CLINICAL CRITERIA FOR SPECIALISED UNITS

REPORT ON WORST CASE SCENARIO IN LAST 24 HOURS		AUTHORISATION *(I hereby certify that mentioned must be admitted to)*					Signature
PATIENT STATUS		**Level of Care**	**Level of Care Movement**				
Specialised Critical Care	* * *	**Specialised Critical Care**	Date	Time	Date	Time	
	Three (3) or more organ failures	From		:		:	
Critical Care	* *	To		:		:	
	Seven (7) Ticks without * or ****	Ventilator: From		:		:	
High Care	*	To		:		:	
	Three (3) Ticks without *** or ** or *			:		:	

COMORBIDITIES				**Critical Care**	Date	Time	Date	Time	
Chronic Iscaemic Heart Disease		Asthma		From		:		:	
Unstable Angina		Obesity BMI> 30		To		:		:	
Hypertension		Chronic Arterial Fibrilation/Flutter		Ventilator: From		:		:	
Hyperthiriodism		Epilepsy		To		:		:	
Hypercholesterolaemia						:		:	
Diabetes (Insulin dependent)				**High Care**	Date	Time	Date	Time	
Diabetes (Non-Insulin dependent)				From		:		:	
Chronic Renal Failure				To		:		:	
Congestive Heart Failure				Monitor: From		:		:	
Hyperlipidaemia				To		:		:	
Chronic Obstructive Pulmonary Disease						:		:	

· = present; IV = Intravenous

Report on worst case scenario in previous 24 hours								Report on worst case scenario in previous 24 hours							
Date								Date							
RESPIRATORY SYSTEM								**NEUROLOGICAL SYSTEM**							
Respiratory arrest within 24 hours **								Glasgow coma scale _< 8 **							
**Mechanically ventilated with FiO² _ .6% ** **								Glasgow coma scale 9 - 12 *							
Mechanically ventilated **								Glasgow coma scale 13 -14							
Noninvasive Positive Pressure Ventilation **								Raised intra cranial pressure *							
Extubated <24 hours **								Status Epilepticus **							
Intubated but not ventilated **								Occurrence of seizures in last 24 hours							
Oxygen O_2 > 40% *								Ventricular drain **							
Saturation <90% on O² _ 40%*								Polyuria							
Respiratory acidosis *								Brain / Spinal surgery							
Respiratory alkalosis *															
Respiratory rate >30 per minute *								**RENAL SYSTEM**							
Bronchospasm / Stridor *								Serum creatinine 1.5 x baseline **OR**							
<2 hourly nebulisations								Urine output <0.5ml/kg x 6 hr *							
<2 hourly suctioning								Serum creatinine 2 x baseline **OR**							
Tracheostomy								Urine output <0.5ml/kg/hr x 12 hr *							
CARDIO VASCULAR SYSTEM								**Serum creatine 3 x baseline OR**							
Cardiac arrest within 24 hours **								**Urine output <0.3ml/kg/hr x 24 hrs OR**							
Sternotomy <24 hours ***								Anuria x 12 hrs **							
Acute MI + Trop I/T **								Acute renal dialysis **							
Angina *								Chronic renal failure *							
Ischaemic ECG changes *								Metabolic acidosis *							
PTCA ** / Stent ** <12 hours								Metabolic alkalosis *							
Ablation * / Rotablator * <24 hours															
Acute Dysrhythmia *								**OTHER**							
Elective Cardioversion < 12 hours *								Major blood transfusion **							
Temporary Pacemaker-dependent **								Autotransfusion *							
Perm. Pacemaker- post insertion 12 - 24 hrs *								Epidural *							
**Vasopressor / Positive Inotrope dependent ** **								Post-operative monitoring * 24 - 48 hours							
Vascular Stent <12hours**								Cont. Invasive/non-invasive monitoring							
Hypovolaemia *								_ 4 hours every 15-30 minutes **							
Tachycardia								Pyrexia >38.3°C							
Bradycardia								Subnormal temperature <35.5°C							
Hypotension															
Hypertension															
Increased capillary leak with edema															
Poor Peripheral perfusion >3 seconds															

Report on worst case scenario in previous 24 hours

Date							
MEDICATION IVI							
Positive inotropic support **							
Anti-dysrhythmics **							
Platelet aggregation inhibitors *							
Fibrinolytics **							
Insulin *							
Sedation **							
Vasodilators ** / Vasopressor **							
Muscle relaxants **							
Ca Channel blockers **							
Diuretics							
TPN							
Opioids *							
Precedex ©*							
LABORATORY IMBALANCES							
Hypo Serum Na _ 130 mmol/l *							
Hyper serum Na _ 150mmol/l *							
Hypo serum K+ *							
Hyper serum K *							
Hypo serum glucose *							
Hyper serum glucose							
Increased serum osmolarity *							
Raised Bilirubin							
Acute Hb <8gr/dl/L *							
Raised cardiac markers *							
Abnormal high levels of therapeutic medication **							
Toxic levels of medication **							
Platelet counts _ 100 *							
Abnormal INR							
**Positive DIC Screen ** **							
Ph _ 7.20 **							
Raised serum amylase *							
Albumin < 20 *							

Report on worst case scenario in previous 24 hours

Date							
MONITORING / INVASIVE LINES							
ICP monitor 1st 24 hours ***							
ICP monitor >24 hours **							
PA catheter **/ Atrial line **							
Sheath post angiogram <12 hours **							
IABP **							
A-line *							
Central Venous O_2 saturation monitoring *							
Noninvasive cardiac output monitor							
CVP line							
Acute dialysis catheter							
EMERGENCY PROCEDURES WITHIN 24 HOURS							
Transvenous pacing **							
Transcutaneous pacing **							
Intubation **							
Emergency Tracheostomy **							
Pericardial tap 1st 24 hours **							
Emergency Cardioversion **							
Defibrillation **							
Intercostal drains							

Intravenous Medication with **	Date Start	Time Start	Date Stop	Time Stop
		:		:
		:		:
		:		:
		:		:
		:		:
		:		:
		:		:
		:		:
		:		:

· = present

ADDITIONAL DIAGNOSTIC INFORMATION

Date	
/ /	
/ /	
/ /	
/ /	
/ /	
/ /	
/ /	

INTRAVENOUS MEDICATION KEY		ORGAN FAILURE
Positive Inotropic Agents	eg. Dobutamine, Dopamine, Digoxin, Adrenaline	Respiratory System : Mechanically Ventilated with FiO_2 _ .6%
Anti-dysrhythmics	eg. Amiodarone, Lignocaine, Adenosine	Cardiac System : Vasopressor Dependent
Vasodilators	eg. Tridil ®, Isoket®, Nitrocine®, Trandate	Renal System : Acute Renal Dialysis
Platelet Aggregation Inhibitors	eg. Aggrastet®, Integrillin®, Reopro®	Haematology : Positive DIC Screen
Vasopressors	eg. Adrenaline, Noradrenalin, Phenylephrine	**MAJOR BLOOD TRANSFUSION**
Fibrinolytics	eg. Actilyse®, Metalyse®, Streptase®	**Definition:** Major blood transfusion is the replacement of the total blood
Muscle Relaxants	eg. Nimbex®, Pavulon®, Scoline®	volume within 24 hours
Sedatives and Opioids	eg. Sublimaze®, Ultiva®, Rapifen®, Sudenta, Tramadol, Dormicum®, Diprivan®, Morphine, Pethidine, Precedex®	**Formula:** Total blood volume = 70ml blood/kg body mass
		Calculation: 70ml *(blood)* x ———kg *(total weight of patient)* =——— ml *(total blood volume)*
Ca Channel Blockers	eg. Nimotop®, Verapamil	

MEDICLINIC

Support Document for

Clinical Criteria for Specialised Units form

Clinical Criteria Committee

Updated: Feb 2013

Contents

Clinical Criteria for Specialised Units Form

Overview

Purpose

The purpose of the Clinical Criteria for Specialised Units form is to determine the correct level of care for a specific patient, according to the patient"s condition.

It also serves as a tool to obtain accurate coding information.

The correct level of care and the coding information is used in the case management process in the hospital.

Scope

This form is completed by the CCU nursing staff and the information gathered is used by the Case Coordinator in the hospital, for updating clinical information and for negotiations with medical funds.

Background

Previously, level of care was determined on the grounds of the amount of nursing input required for a patient. This method proved inaccurate and it was decided that the patient"s condition would serve as a better indicator as to what level of care a patient requires.

About the Form

In this document the form and its content will be described in general. Specific keys are used to guide the user through the interpretation of the form.

Important

The criteria are not used on patients in normal wards to determine if they should be send to a specialised unit. Only after the treating doctor admitted the patient to the specialised unit this criteria are used to determine to correct LOC.

Sections on the form

The form is divided into the following sections/tables (Each of these will be discussed separately later in this document):

Comorbidities

LOC (Level of Care) Movement (date and time)

Respiratory System indicators

Cardio Vascular System indicators

Neurological System indicators

Renal System indicators

Other

Medication IVI

Laboratory Imbalances

Monitoring/Invasive lines

Emergency Procedures

IVI Medication with **

Additional Notes

For how many days does the form provide?

The form can be used for a period of seven (7) days per patient, after which a new form must be completed. Date columns are provided for each section of the form.

As always, the previous days" information is indicated on today"s date, and the worst scenario of the last 24 hours is indicated on the form.

What is the standard method of ticking off the indicators/conditions?

A normal tick ( ) is placed next to every indicator/condition the patient conforms to for that specific day.

What if the patient has a condition that does not appear on the form?

With the exception of the Comorbidities columns where extra lines are provided for additional entries, the rest of the sections were carefully designed to only include those conditions that would have an effect on the level of care.

Note that diagnosis was deliberately excluded, since it"s not an accurate indication of the required level of care.

How do I interpret the keys?

The keys used on the form are *, ** and ***. These keys can be found next to specific indicators/conditions and indicate whether the patient should be in HIC, CCU or SICU. Some conditions do not have any key next to it. Besides the keys itself, the number of ticks also serves as an indication of what level of care the patient should occupy.

Although the keys used are explained on the form, we will discuss these in more detail by means of scenarios, later on in the document.

Sections on the Form

Each section will be discussed separately.

Only the sections and the indicators that need some discussion will be elaborated on with regards to definitions and circumstances.

Comorbidities

The 15 most frequently reported comorbidities (according to Mediclinic coding statistics) were listed here. Additional lines were added to provide for extra comorbidities to be listed if necessary.

Comorbidity	Description
Hyperlipidaemia	Hyperlipidaemia refers to high blood cholesterol or high blood triglycerides
Hypercholesterolaemia	Hypercholesterolemia refers to high blood cholesterol

Patient Status

In this section we indicate the patient"s level of care movement by completing the dates and times at which a patient moved into and out of a specific unit. This section should be completed extremely accurately.

Provision is also made for indicating the date and time periods when a patient was ventilated.

This information can be used to check whether or not the patient must still be in a specific unit.

Other Important Info

Additional lines have been provided to include information unrelated to comorbidities, but which has clinical relevance. Examples include the presence of a permanent pacemaker or important surgical information.

Respiratory System

Please note the following indicators/conditions in this section:

Indicator	Description
Mechanically ventilated with FiO_2 $\geq$ .6**	Indicates that this patient is in a type 2, 3 or 4 respiratory failure according to the P/F ratio >200.
NPPV** Non-Invasive Positive Pressure Ventilation	NPPV is the delivery of mechanically assisted or generated breaths without placement of an artificial airway. Both CPAP and BiPAP are considered as NPPV. Significant percentages of patient who receive this modality are acutely ill or have severe underlying disease. The patient does not have to be continuously ventilated non-invasively; it can just be for short periods at a time when not coping without ventilatory support.
Extubated < 24 hrs **	Patient should be in CCU for up to 24 hours post extubation. Not all extubations are successful, and the patient must be monitored for up to 24 hrs for possible re-intubation
Intubated but not ventilated **	This patient has an endotracheal tube in place, but is not ventilated. This is often to maintain an open airway and help reduce the risk of aspiration. The patient will require suctioning and close monitoring to prevent complications
Oxygen >40% *	Oxygen therapy per mask greater than 40% or oxygen therapy via nasal cannula (> 5 LPM)
Saturation < 90% on O_2 > 40% *	Indicative of hypoxia despite oxygen therapy and may indicate impending respiratory failure.
Respiratory acidosis *	This is going to require PN interpretation. A respiratory acidosis is a pCO2 > 6.1 KPa (irrespective of compensation). It indicates decreased gas exchange
Respiratory alkalosis *	This is going to require PN interpretation. A respiratory alkalosis is a pCO2 < 4.6 KPa. There are multiple causes and often it is a compensatory response to metabolic acidosis
Respiratory rate > 30 bpm*	There are increased oxygen demands and the respiratory rate increases in order to meet this demand. It is indicative of underlying problems and the patient requires close monitoring (HICU at least)
Bronchospasm / Stridor*	These are symptoms of airway obstruction. Patients are at risk for impending respiratory failure
< 2 hourly nebulisations	This is applicable to patients in acute bronchospasm (usually an acute asthma attack)
< 2 hourly suctioning	When the patient is being suctioned more frequently than 2 hourly. This is mostly applicable to a non-intubated patient who has difficulty maintaining their airway. This is not suctioning of the mouth but rather oro/naso-pharyngeal suctioning to clear secretions and keep the airway patent
Tracheostomy	Note the difference between a Tracheostomy in this section versus a Tracheostomy in the Emergency Procedures section.

Cardio Vascular System

Please note the following indicators/conditions in this section:

Indicator	Description
Cardiac arrest within the 1st 24 hours**	If the patient had cardiac arrest, the patient should be in CCU for at least the 1st 24 hours.
Sternotomy within 24 hours ***	This indicator refers to any heart and lung surgery viewed as „open heart" surgery.
Acute MI ≤ 24 hours with + Trop I/T**	The cardiac markers Troponin T or I are positive indicative of a myocardial infarction, irrespective of whether the patient has had an ST-elevation myocardial infarction (STEMI) or a non-ST elevation myocardial infarction (NSTEMI).
Angina *	Angina is classified as stable or unstable. Unstable angina is chest pain at rest, and indicates partial clot formation in a coronary artery causing decreased blood supply to the heart muscle. This decreased blood supply results in „chest pain" as a symptom.
PTCA** / Stent ** < 12 hrs	The patient status is CC due to the nature of the procedure and / or the presence of a foreign body. Percutaneous coronary intervention (PCI) includes balloon angioplasty with or without placement of a stent. A PTCA is invasive enough to warrant CC monitoring. Potential complications include thrombosis and haemorrhage
Acute Dysrhythmia*	Please note that this include ALL ACUTE Dysrhythmias. CHRONIC Dysrhythmia is NOT INCLUDED unless a Chronic Dysrhythmia becomes ACUTE.
Elective Cardioversion < 12 hours *	Note on the difference between the cardioversion indicated in this section, and the Cardioversion indicated under Emergency Procedures of which the latter will require CC. It is most commonly done for atrial fibrillation, atrial flutter and ventricular tachycardia (with a pulse). Elective cardioversion is electrical cardioversion (also known as direct - current or DC cardioversion). A dysrhythmia can also be chemically cardioverted (for example with Amiodarone). Elective cardioversion is a procedure whereby a synchronized electrical current (shock) is delivered through the chest wall to the heart through pads or paddles that are applied to the skin of the chest and/or back. The purpose of the cardioversion is to interrupt the abnormal electrical circuit(s) in the heart and to restore a normal heartbeat.
Temporary pacemaker-dependent **	This is going to require the PN interpretation. The temporary pacemaker is external and prone to the development of problems. This is usually only a temporary measure until the underlying problem is resolved or a PPM is inserted. The patient must be PM dependent i.e. they do not have an adequate cardiac output without the PM.
Perm. Pacemaker - post insertion 12 -24 hrs *	Note that the patient status is High Care following the insertion of a PM. This is necessary for monitoring of potentially life threatening complications, which include the development of a pneumothorax, dysrhythmias and haemorrhage.
Vasopressor/Positive Inotrope dependent **	Note on the fact that the patient must be TOTALLY DEPENDENT. This is the indication for cardiac failure. The patient can be dependent on vasopressors or positive inotropes to maintain an adequate cardiac output (see list of drugs on the last page of the last page of the clinical criteria document).
Vascular Stent < 12 hrs **	ANY other vascular stent falls under this category. This would include coronary, aortic, carotid and cerebral stents. Patient requires close monitoring because of the possibility of developing acute thrombosis or haemorrhage which would be life threatening.
Hypovolaemia *	This is going to require the PN interpretation. A dramatic reduction in circulating volume as a result of the patient's underlying condition. Symptoms include an elevated pulse rate, diminished blood pressure and

	signs of decreased perfusion (poor capillary refill, weak peripheral pulses)
Tachycardia	Pulse rate > 100 bpm (in adults)
Bradycardia	Pulse rate < 60 bpm (in adults)
Increased capillary leak with oedema	This includes Oedema.

Neurological System

Please note the following indicators/conditions in this section:

Indicator	Description
Glascow coma scale < 8** Gloscow coma scale 9 - 12* Glascow coma scale 13 - 14	Patient usually not able to maintain or protect their own airway Patient can usually protect their own airway, but needs constant monitoring Patient usually just confused / disorientated
Raised intracranial pressure*	According to the Monro-Kellie Hypothesis, the cranial compartment is incompressible and the volume inside the cranium is fixed. The cranium and its constituents (blood, CSF & brain) create a state of equilibrium. If there is any increase in volume in one of the cranial constituents, it must be compensated by a decrease in volume of another. Normal ICP is 0-15mmHg. An ICP > 20mmHg can crush brain tissue, shift brain structures, contribute to hydrocephalus, cause the brain to herniated and restrict blood supply to the brain. Following a cardiac arrest, a patient can have a resultant hypoxic brain injury. The hypoxic injury results in cerebral vasogenic oedema and is likely to result in raised intracranial pressure.
Ventricular drain **	An intraventricular drain can be inserted into one of the lateral ventricles for diagnostic or intracranial pressure relief purposes. Once placed, the catheter can be connected to a transducer for continuous pressure monitoring or to an external collection system for drainage.
Polyuria	Defined as a urine output > 3L/day. Needs to be considered if the urine output > 200ml/hr for 2 consecutive hours. The clinical history is very important to correlate this as a true sign. This is going to require the PN interpretation.
Brain/Spinal surgery	Refers to any brain/spinal surgery, including surgical procedures such as a laminectomy or discectomy.

Renal System

Please note the following indicators/conditions in this section:

The first 3 indicators are based on the RIFLE criteria (Journal of Intensive Care Medicine 22(4); 2007) for acute renal dysfunction (ARD). The Rifle classification defines 3 grades of increasing severity of ARD as Risk (R), Injury (I) and Failure (F). The MOST severecriteria is the one that should be selected - i.e. if the serum creatinine is 2 X baseline, but the urine output was < 0.5ml/kg/hr X 6hrs (and not 12hrs), the patient would fall into the Injury class and not the Risk class (see below). Also see Addendum C.

Indicator	Description
Serum Creatinine 1.5 X baseline OR Urine output < 0.5ml/kg/hr X 6hrs *	Indicates Risk (R) of renal failure according to the RIFLE criteria (see above).
Serum Creatinine 2 X baseline OR Urine output < 0.5ml/kg/hr X 12hrs *	Indicates Injury (I) to the kidneys according to the RIFLE criteria and patient is at high risk for the development of acute renal failure.
Serum Creatinine 3 X baseline OR Urine output < 0.3ml/kg/hr X 24hrs ORAnuria X 12 hrs **	Indicates Renal Failure (F)
Acute renal dialysis **	This refers to continuous or intermittent routine cycles of hemodialysis, irrespective of mode (CVVH/CVVHD/CVVHDF). This indicator is not applicable to a patient with longstanding chronic renal failure receiving routine intermittent hemodialysis.
Chronic Renal Failure *	It is difficult distinguishing between persistent acute renal failure and end-stage kidney disease and these criteria probably cover both.

Other

Please note the following indicators/conditions in this section:

Indicator	Description
Major Blood Transfusion**	Major blood transfusion is defined as replacement of the total blood volume within 24 hours. The formula is found on the last page of the form. Major blood transfusion includes all blood products.
Autotransfusion*	Patient receiving autotransfusion should at least be in HICU, due to high risk.
Post-operative monitoring* 24 - 48 hours	Note that there is no provision made for ECG monitor, because this is a standard procedure. This indicator is for patients that require more intense post operative monitoring than provided by wards. E.g. Knee Replacement.
Cont. Invasive/Non-invasive monitoring ≥ 4hrs every 15-30 minutes**	Due to the difficulty defining the term Hemodynamic Instability, this indicator basically replace this term. The indicator implies that the patient is unstable and would include Hemodynamic Unstable patients. This does not include Post-operative monitoring (as described in the previous row)

Medication IVI

Note that the IVI Medication Key at the back of the form serves as a guideline as to which types of medication falls within a specific indicator. This is ONLY applicable to IVI Medication. Medication indicated with ** are CCU drugs and the patients status remains CCU for up to 6 hours post discontinuation of these drugs.
Please note the following indicators/conditions in this section:

Indicator	Description
Positive inotropic support **	Inotropic drugs increase the contractility of the heart and are often required in cardiac failure, septic shock or post surgery. The list of drugs is named in the table of intravenous medication.
Vasopressors **	Vasopressors increase the systemic vascular resistance and are used in conditions where there is vasodilatation and vasoconstriction is required to improve the blood pressure. The use of small amounts of adrenaline in an epidural infusion does not count as „Vasopressors" as the effect is localised.
Insulin*	It is recommended that critically ill patients have their blood glucose narrowly controlled to improve outcomes (the margin varies depending on disease). Blood glucose is elevated as part of the stress response.
Sedation**	Drugs that have the ability to suppress a patients breathing and ability to protect their own airway.
TPN	It is extremely important that case management is informed when TPN is administrated, in order for accounts to be changed accordingly. Examples of TPN include; Isotec, Intralipid and Vamin.
Opioid*	Refers only to opioid analgesia (not all intravenous analgesia, e.g. Perfalgan). The route of administration can be as patient-controlled analgesia (PCA), via an epidural catheter or intravenously (whether intermittently or continuously) or intramuscularly. Opioids can cause opioid-induced sedation and respiratory depression.
Precedex®*	See addendum A for MCSA Policy regarding administration of this drug.
Abnormal high levels of therapeutic medication **	This refers to abnormally high drug levels of medication administered for therapeutic reasons - examples include high drug levels of digoxin or amikacin. This does not refer to intentional drug overdose or organophosphate poisoning.

Laboratory Imbalances

Please note the following indicators/conditions in this section:

Indicator	Description
Positive DIC screen **	This indicates that the patient is in Haematology failure. DIC screen includes INR, aPTT, fibrinogen, D-Dimer levels.

Monitoring / Invasive Lines

Please note the following indicators/conditions in this section:

Indicator	Description
ICP monitor 1st 24 hours***	For the first 24 hours post insertion the patient is in SICU.
ICP monitor > 24 hours**	After the 1st 24 hours, as long as the ICP monitor is in situ, the patient is in ICU.
Central venous O_2 saturation *	A normal $SVcvO_2$ is > 70%. The value is decreased if there is decreased tissue perfusion, and thereby increased oxygen extractions at a tissue level.

Emergency Procedures

Please note that these indicators are EMERGENCY procedures that occurred while the patient is already in HICU/CCU.

IV Medication with **

Please note that IVI medication marked with ** are indicated as CCU patients. The patient remains CCU for up to 6 hrs post discontinuation of IVI medication marked with **

Additional Diagnostic Information

Any comment that could add to the background of the patient"s clinical condition can be indicated in this section. Be sure to indicate the date of the comment. This section is also used if the required LOC could not be explained throughout the criteria. It is also suitable for indicating a planned procedure, planned discharge and any other relevant information not mentioned in the rest of the document. DO NOT PROVIDE A SUMMARY OF INDICATORS ALREADY CHOSEN.

Completing the Form

The method/procedure of completing the form will be explained by means of a scenario.

Scenario: A patient was transferred to a specialised unit the previous day, e.g. 6 July 2011 at 11:30

Today, 7 July 2011, you have to complete the Clinical Criteria for Specialised Units form according the patient"s condition the last 24 hours.

Step	Action	Note
1	Stick a patient sticker onto the form in the space provided (top left-hand corner)	
2	Write the diagnosis of the patient onto the form in the space provided (top right-hand corner)	
3	Write today"s date (e.g. 7 July 2010) in the first date column of the first section you want to complete.	
4	Read through all the indicators/condition in that specific section and tick off that which is relevant to the patient.	
5	Repeat steps 3 and 4 for all the applicable sections.	
6	After ticking off all the applicable conditions, check the keys for each marked indicator/condition (i.e. *, **, ***) and interpret it according to the key-table on the form.	E.g. If a box (indicator/condition) with *** is ticked off, the patient should be in SICU, if 3 ticks were made in boxes that are not marked with * ** or *** the
7	Complete / update the Patient Status section.	
8	The completed form must be sent to the Unit Manager.	
9	After the form is evaluated and found to be accurate and complete, it must be given to the Case Coordinator	

Addendum A

(Addendum to the Clinical Criteria Form)

Position paper of MCSA and The South African Society of Anaesthesiologist.

Dexmedetomidine (Precedex) Position Paper

Description

Dexmedetomidine hydrochloride (trade name Precedex) is a selective alpha 2 adrenoreceptor agonist with a central mechanism of action, and is used intravenously for its sedative, analgesic and anxiolytic effects.

Dexmedetomidine can cause a significant reduction in blood pressure and pulse rate, and has to be administered only under monitored conditions.

Registered uses (package inserts)

Precedex is a relatively selective alpha2-adrenergic agonist indicated for:

- Sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. Administer Precedex by continuous infusion not to exceed 24 hours.
- Sedation of non-intubated patients prior to and/or during surgical and other procedures.

Dosage and Administration

Dosing Guidelines

- Precedex dosing should be individualized and titrated to desired clinical response.
- Precedex is not indicated for infusions lasting longer than 24 hours
- Precedex should be administered using a controlled infusion device.
- The terminal elimination half-life (t1/2) of dexmedetomidine is approximately 2 hours and clearance is estimated to be approximately 39 L/h.

Monitoring

- Continuously monitor patients while receiving Precedex.

Overview

Given its original registered uses, dexmedetomidine was included in the Medi-Clinic ICU criteria, which impacted on the billing of ICU. Extension of indications and clinical application of the drug in other situations (even in general wards) causing conflict in terms of billing as well as the safety of clinical practices forced us to re-evaluate the situation.

A Precedex utilisation study at Medi-Clinic showed a steep upward trend, and that it was used in cases not receiving specialized care and sometimes in general wards as well. Although dexmedetomidine might now be seen as a safe and effective therapeutic agent in the management of a wide range of clinical conditions it was made very clear by both the distributing pharmaceutical company (Abbott Laboratories) as well as an updated policy statement (21 October 2009) from SASA that the drug MUST be used according to labelled instructions and that “the South African Society of Anaesthesiologists thus cannot recommend or condone the use of dexmedetomidine in a general ward setting”.

Medi-Clinic's position

- All previous policies and decisions on dexmedetomidine (Precedex) are cancelled.
- Dexmedetomidine (Precedex) is included into the ICU criteria at a minimum level of high care.
- Dexmedetomidine may be used, according to indications, in any setting where the patient can be monitored to the minimum level of a high care setting.
- Monitoring should continue for at least 2 hours post discontinuation of the drug.

Hannes Loots

Executive Clinical Services 30 November 2009

THE SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS

(Official group of SAMA)

Association incorporated under Section 21

Reg. No. 1927/000136/08

VAT No. 4680223379

P O Box 1105

CRAMERVIEW

2060

Telephone : 011 463 0684

Telefax : 011 463 1041

Email : sasa@uiplay.com

21 October 2009

The Product manager: Dexmedetomidine (Precedex)

Abbott Laboratories

Dear Sir,

Thank you for your enquiry concerning the use of dexmedetomidine in a general ward setting. This matter was referred to the members of the Council of the South African Society of Anaesthesiologists as well as to the members of the Education Business unit for consideration.

The literature was extensively reviewed including the Cochrane Library, NICE, and the Bandolier site. There is absolutely no data to support the practice of using dexmedetomidine in a general ward setting. All data suggests that this agent is capable of causing severe blood pressure depression as well as deep sedation. This implies that the use of dexmedetomidine does require constant monitoring.

We are all aware of the standard of nursing care in a general ward and thus constant monitoring by nursing personnel is not feasible. Furthermore there are not enough monitors available for use in general wards. The obvious implication of this situation is that patients who are on dexmedetomidine infusions in a general ward may not be adequately monitored and as such this may present as a potential medico-legal hazard.

The South African Society of Anaesthesiologists thus cannot recommend or condone the use of dexmedetomidine in a general ward setting.

Yours faithfully,

Dr Milton Raff

Addendum C

MEDICLINIC

APACHE IV® SCORE

Report on worst values obtained in first 24 hours of admission to your unit
Completion of all fields are mandatory

GENERAL PATIENT INFORMATION

Patient File Number		
Physician		
Admission Date & Time to Hospital	20 / / hh : mm	
Admission Date & Time to CCU	20 / / hh : mm	
Date of Birth	/ /	
Gender	Female / Male	
Chronic Health Status	None / Other	Leukaemia / Multiple Myeloma
	AIDS	Immunosuppression
	Hepatic Failure	Cirrhosis
	Non-Hodgkin"s Lymphoma	HIV Positive / ARV Treatment
	Solid Tumor with Metastases	Diabetes Mellitus
CCU Admission	Admit from nursing unit in your hospital	Admit from another hospital
	Admit from operating room	Admit from emergency centre
Operative Patient	Yes / No	
Emergency Surgery	Yes / No	
Readmission to Unit	Yes / No ***Answer yes if admit from non Apache unit to your unit***	

PATIENT PHYSIOLOGY INDICATORS

Pulse Heart rate furthest from 75 bpm	bpm		**Glucose** furthest from 7.2 mmol/L	n.a	mmol/L
Blood Pressure enter worst value for assessment period	mmHg		**CRP** highest value	n.a	mg/L
Temperature furthest from 38°C	°C		**Hematocrit** furthest from 45.5%	n.a	%
Core Body Temperature Indicate Yes if above temperature is core body temperature	Yes	No	**White Blood Count** furthest from 11.5 cu/mm	n.a	cu/mm
Mechanical Ventilation any time within 24 hour period	Yes	No	**Urine Output**	n.a	ml/24 hour
FiO_2 Fraction if ventilated			**Chronic Dialysis**	Yes	No
Respiratory Rate *furthest from 19 breaths/min*	breaths/min		**Creatinine** furthest from 76.2 µmol/L	n.a	umol/L

REVISED 04.12.2012

CCU = Critical Care Unit
bpm = beats per minute

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PATIENT PHYSIOLOGY INDICATORS

Blood Urea Nitrogen (BUN) highest value	n.a	mmol/L	**PaO_2** PaO_2 of worst blood gas	n.a	kPa mmHg
Sodium furthest from 145 mmol/L	n.a	mmol/L	**$PaCO_2$** $PaCO_2$ of worst blood gas	n.a	kPa mmHg
Albumin furthest from 35 g/L	n.a	g/L	**pH** pH of worst blood gas	n.a	
Total Bilirubin highest value	n.a	µmol/L	**Anaesthetised/Sedated/Paralysed**	Yes	No

GLASGOW COMA SCALE

If patient is ventilated but not sedated / paralysed / anaesthetised obtain the worst score in 24 hour time period.
Note the different verbal section for ventilated patients that are not sedated / paralysed / anaesthetised.

EYES	VERBAL NOT VENTILATED	MOTOR
Open Spontaneously	Orientated	Obeys Commands
Open to Speech	Confused	Localizes Pain
Open to Pain	Innappropriate Words	Withdraws from Pain
No Eye Opening	Incomprehensible Sounds	Flexion to Pain
	No Verbal Response	Extension to Pain
	VERBAL: VENTILATED BUT NOT SEDATED	No Motor Response
	Orientated	
	Confused	
	No Verbal Response	

Admission Diagnosis	

If a CABG was done complete the following fields:	
Ejection Fraction	
Medication Dependant Diabetes	Yes / No
Was Internal Mammary Artery (IMA) used	Yes / No
Myocardial Infarction during Hospitalisation	Yes / No
Redo CABG	Yes / No
Number of Grafts	

If Diagnosis of Acute Myocardial Infarction then indicate if Thrombolytic Therapy was given Yes / No

DISCHARGE INFORMATION

Discharge Date & Time from CCU	20 / / hh : mm			
Status on Discharge from Unit	Alive		Deceased	
	Discharged to	Other Acute Care Facility	**Cause of Death**	Natural Causes
		Step-down		Unnatural Causes
		Home		
		Nursing Unit		
		Nursing Unit Transferred to		

Data Collector Signature: **Date:**

Addendum D

Medi-Clinic Case Mix Methodology

Author: Mr Jannie van Schalkwyk

Introduction

Case mix refers to the characteristics of patients served by a health service provider, where some patients are at greater risk of having less successful treatment outcomes than other patients. Health service providers have no control over these characteristic and therefore the need exist to keep them fixed in comparative analysis. The ability to measure heterogeneous case mix of hospitals has been recognized for some time as a critical ingredient for improving the management of hospitals and health systems through planning and quality assurance, as well as achieving equity in hospital reimbursement. Without the capability to measure case-mix differences, the comparative analysis of hospital outcomes and attempts to establish the reasonableness of those outcomes often reflect in oversimplification of the issues involved and may result in spurious and misleading findings.

History

The case mix concept has been introduced in the USA more than twenty-five years ago in order to measure hospital productivity and to promote quality of care. The DRGs (Diagnosis Related Groupings), developed by a team of researchers led by Robert Fetter and John Thompson at Yale University, were selected by HCFA (Health Care Financing System) in 1983 as the case mix classification system for the MEDICARE prospective payment system (PPS).

The DRG was the first “health management tool” to group patients in clinically meaningful categories with homogeneous resources consumption. All diagnostic categories and procedures based on medical record summaries could be coupled with financial data about resource uses, for individual patients, in order to differentiate high and low cost care. Even if shortcomings were underlined since their beginning, DRGs are still used in the USA as the main tool for case based, clinical encounter focused, payment.

Many other countries have adopted the case mix concept after long periods of testing and accepting, but with large variations in data collection, information standards, grouping tools, financing methods and quality of care developments all over the world. Each country has developed a local clinical and political culture about case mix tools. Case mix development in South Africa is being driven by the private health sector for their own use, namely to improve the standard of clinical data used in interactions in the industry. These include a range of financial uses from information system creation, budget setting and contracting around alternative reimbursement models. The CMS (Council of Medical Schemes) are developing an awareness of its value within the sector. However, this is a recent development and previous attempts by 3M and by a handful of university and parastatal based academics did not achieve sufficient impetus.

Analytical Approach

Medi-Clinic is under increasing financial pressure to improve outcomes with fewer resources available. Therefore the need exists to evaluate units in our business in a justifiable manner (controlling differences in characteristics of patients treated in each unit) in order to focus resources in the right areas. We therefore evaluated the DRG system to address case-mix differences in our units. The system is designed to produce groups of patients homogeneous with respect to some measure of resource use (LOS or cost) and is undoubtedly one of the best-known methods of patient classification, but limitedly takes into account severity of illness by including indicator variables for the presence and absence of surgery and in some versions comorbidities. Furthermore DRG is based on the principal that diagnosis drives cost in contradiction with our faith that costs are driven mainly by procedure or treatment.

We believe that a lot of detail about the type and severity of a patient which is both meaningful and readily available comes from the codes on the discharge summary. However, the number of possible codes is too large to handle without collapsing them into groupings. We therefore have adapted the CCRG (Clinical and Cost Related Groupings) which is a unique in-house system of mutually exclusive groupings of CPT-4 (Current Procedural Terminology), ICD-10 (International Statistical Classification of Diseases) and SADA (South African Dental Assocation) codes into a hierarchical structure of subgroups, groups and categories. We also implemented a computer algorithm deciding which codes explain the outcome the best.

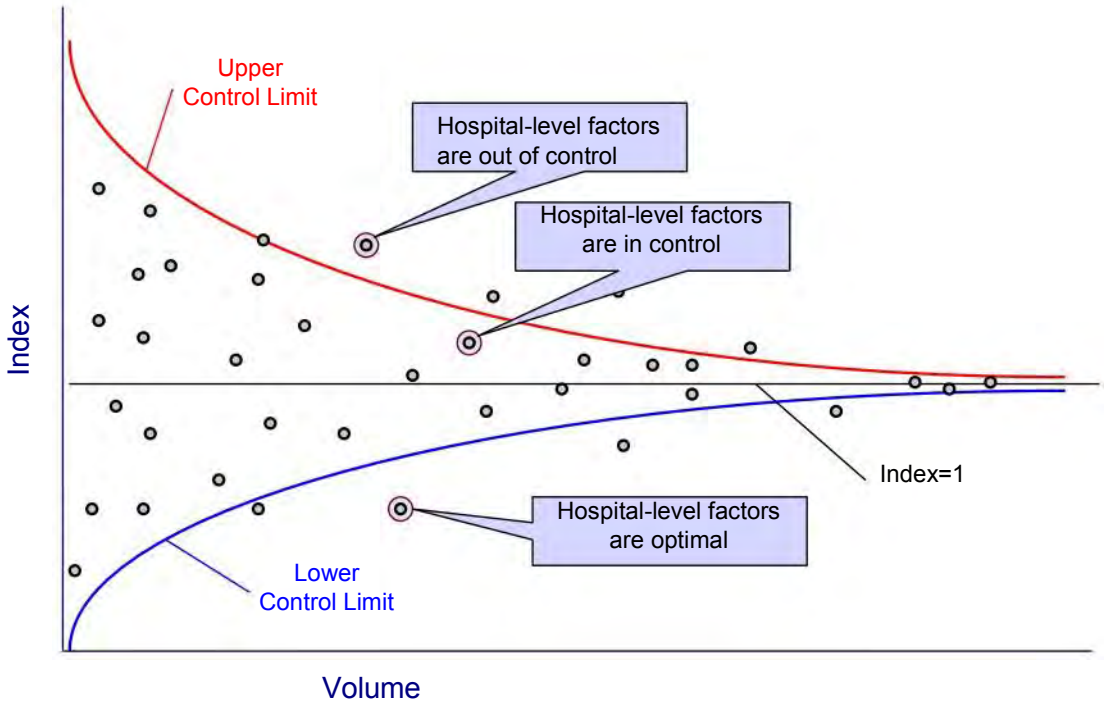
We developed the HRM (Hospital Risk Model) which entails a generic method that permits the actual outcome (costs, length of stay, mortality- and other quality outcomes) to be compared to statistically modelled "expectations", given the mix of patients at a level. The method will statistically account for the number, mix and severity of cases because outcome variables are dependent on these factors. The model further provides breakdown analysis to quantify the magnitude of impact and interactions of these variables to assist in making more informed decisions.

The basic strategy employs the specification of a mathematical equation describing the outcome of interest as a function of a set of explanatory variables by means of OLS (ordinary least squares), GLM (generalized linear models), logistic or multinomial stepwise regression techniques. The explanatory variables describe characteristics of a case that are expected to affect the outcome (such as the clinical condition for which was rendered, the presence of other conditions that could complicate the stay and the patient's profile). These equations are estimated, that is, numerical values are computed for the parameters of the function that describes the impact of each "explanatory variable" on the outcome variable. Case mix can then be accounted for by computing the value of this function, using these estimated parameters, for the data values representing the specific characteristics. The result of this process is an expected value that is a mathematical function of a hospital's case mix, severity and demographic profile of the patients. For example, a hospital that treats more

severely ill, elderly people will be expected to have higher costs than a hospital that treats a generally healthy and young population for a similar set of procedures.

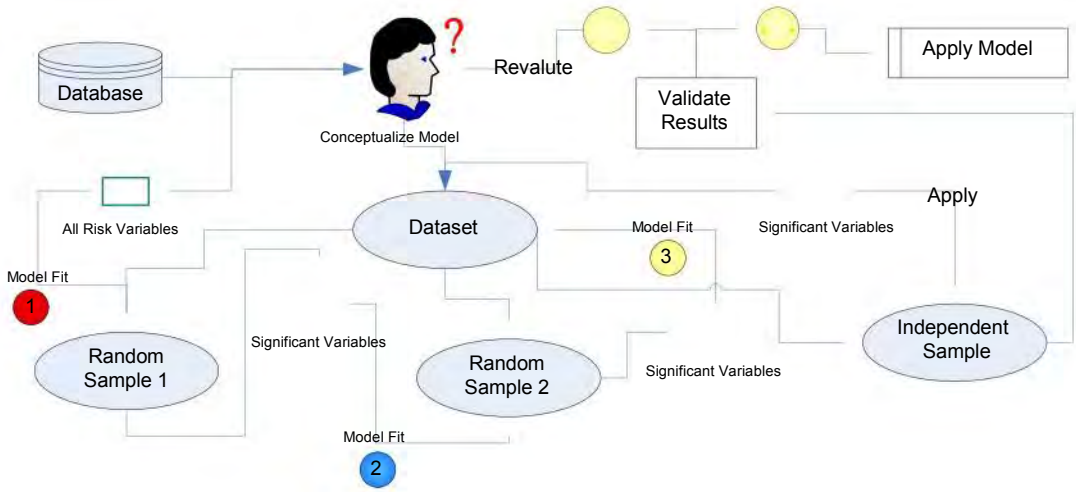
Although calculations can be complex, interpreting the output is relative easy to do. The model makes use of the index methodology to describe the magnitude and importance of differences. It is convenient to group explanatory (characteristic) variables to belong to one of two mutually exclusive groups: those which are demographic or contribute to the disease status or degree of illness of the patient (patient-level factors) and those which represent the hospital environment or determined how a patient is cared for from hospital admission to discharge (hospital-level factors). The underlying strategy is to divide the actual observed outcome by the predicted outcome on the basis of patient-level factors. This result, defined as the index, provides information about the percentage deviation from the expected. If the index is greater than 1 the patient has had a higher outcome than expected; if negative, the outcome was lower than expected. Random variation might explain part of any such discrepancy in an individual patient. However, if the overall index is significantly greater than 1, this presumably reflects hospital-level factors which tend to lead to a negative outcome. Similarly an overall index significantly less than 1 will reflect hospital-level factors that tend to lead to positive outcomes. In order to determine significance of cut-off levels we apply parametric or non-parametric statistical control limits, depending on the type of situation, to determine acceptance and rejection regions. Figure 1 below illustrates the application of the index methodology for hospitals.

Figure 1 - Illustration of Medi-Clinic Case-Mix Index



Model Validation

The question will arise to exactly what extent and how accurate the model describes risk in reality. We realise that model validation are essential parts of the model development process if the model are to be accepted for decision making, so not only do we strive to design our coding and grouping systems to accurately reflect reality, we also make use of statistical and model designing techniques to validate the model. Often the validation of a model seems to consist of nothing more than quoting the coefficient of correlation R^2 statistic (statistical measure that represents how well the model approximates real data points). Unfortunately, a high R^2 values does not guarantee that the model will describe reality well. In order to address this issue we have designed the model building process to remove random effects, hence improve the model fit and consistency. The diagram below layout the process we follow.



The process basically entails the selection of two random samples from the original dataset. All risk variables defined are fitted through random sample 1 to come up with a list of significant variables. These variables are then fitted on the second random sample in order to remove random significant variables identified in the first phase. These variables are then fitted on the full dataset to calculate the final model parameters. The model is then fitted on an independent sample and actual values compared to statistical modelled expectations. If the modelled values do not closely describes the actual outcomes, model parameters are re-evaluated iteratively until a satisfactory level of accuracy is reached.

Trends & Analysis

Another application of the capability to measure case-mix differences is the ability to do comparative analysis over time. We would like to share some of the interesting trends we have identified with the reader. It is important to note that in order to do this type of analysis one needs to look at all patient-level factors to get the full picture of patient risk in order making the right interpretations. Also it is important to note that the trends are for Medi-Clinic in general and will not necessary be the

same for different components of the business. Medical insurance legislation changes for example can cause trend changes for the insured population that will not necessarily impact the private population.

Figure 3 indicates a decline in patient-level risk over time. The four lines on the figure represent four different models based on four different years. The spread between these lines will be representative of inflation differences. It is worthy to note that the four models are consistently showing the same seasonal trends, which is an indicating of accurate and reliable model results. Why are we experiencing this trend, while at the same time we see our population is ageing over time as illustrated in Figure 3?

Figure 2 - Yearly Case Mix Comparison

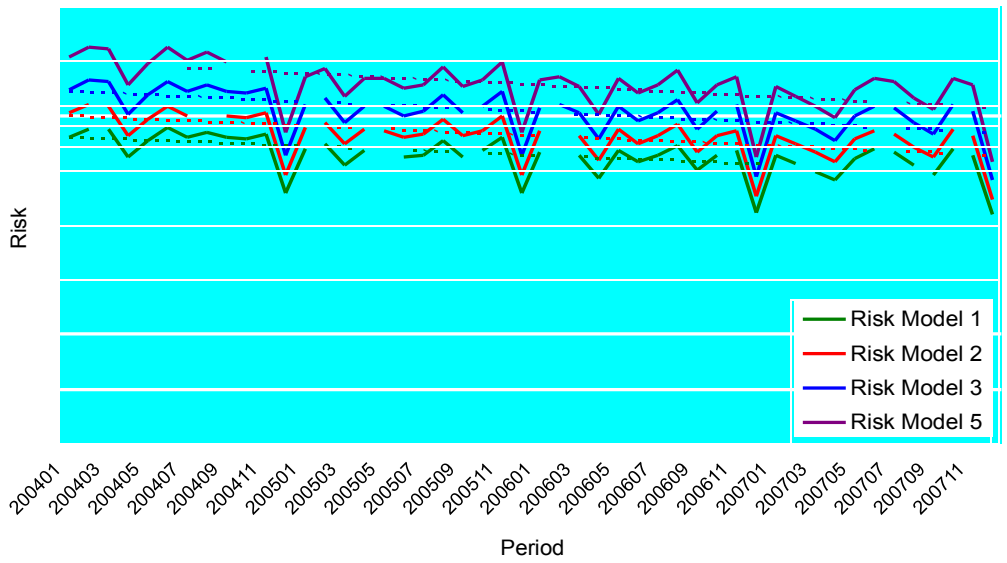
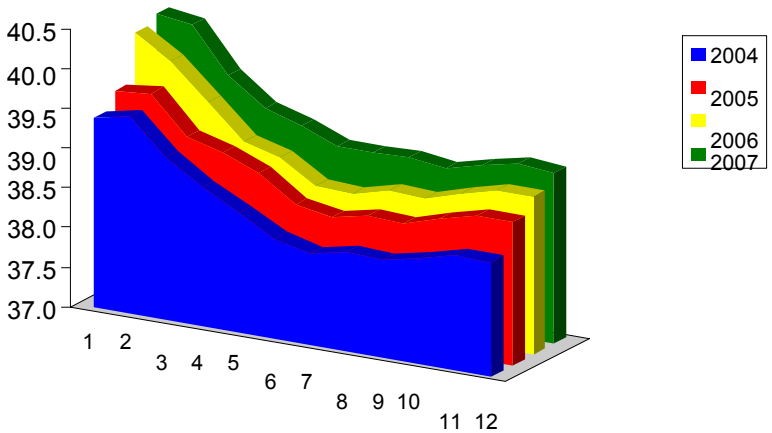


Figure 3 - Ageing of Population (Annual Running Averages)



	1	2	3	4	5	6	7	8	9	10	11	12
2004	39.4	39.5	39.1	38.8	38.5	38.3	38.2	38.3	38.2	38.3	38.5	38.4
2005	39.6	39.6	39.2	39.0	38.9	38.6	38.5	38.6	38.6	38.7	38.8	38.8
2006	40.2	39.9	39.5	39.1	38.9	38.7	38.6	38.8	38.7	38.9	39.0	39.0
2007	40.3	40.2	39.7	39.3	39.2	39.0	39.0	39.0	39.0	39.1	39.2	39.2

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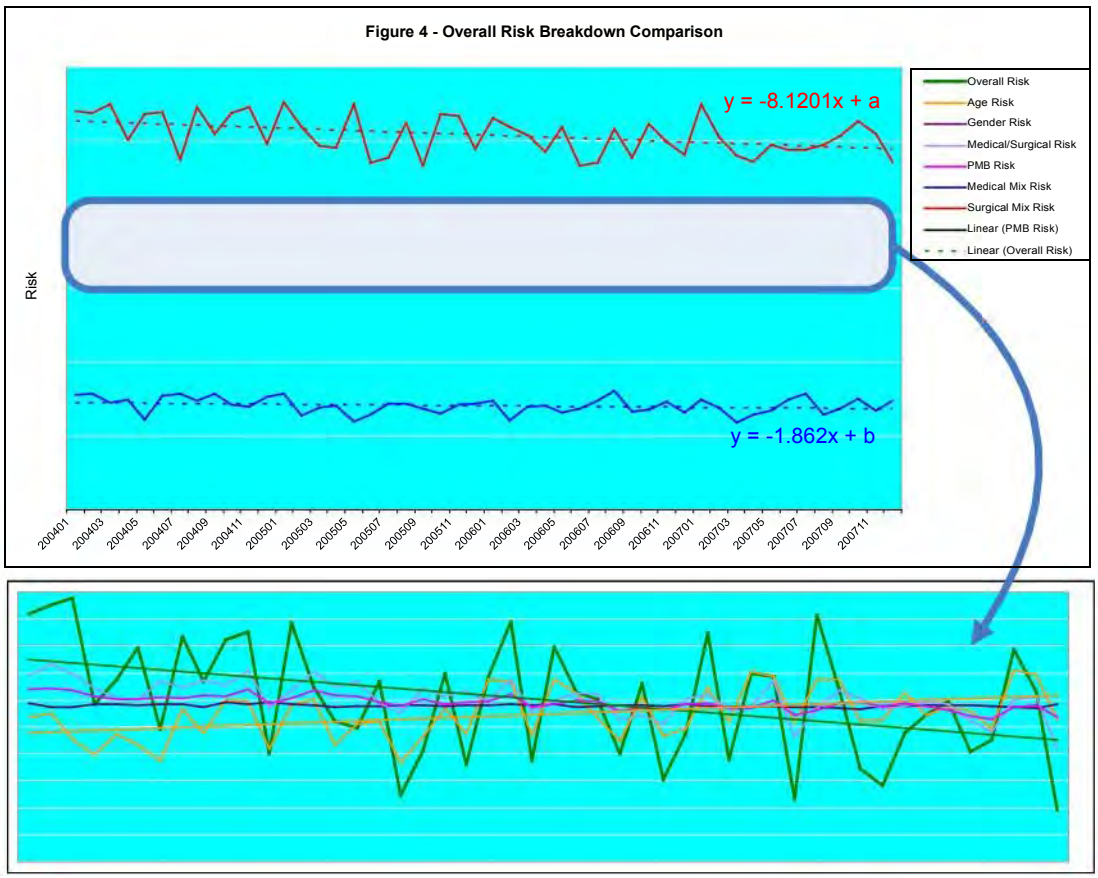
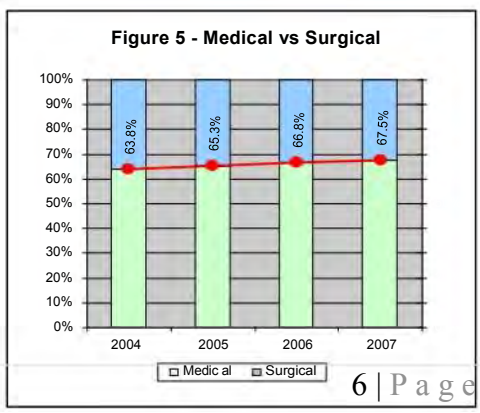
To explain this we have done a breakdown to understand which patient-level factors are causing the declining trend. We have decided to exclude outpatient cases, since emergency, wound care clinics and other outpatient units have grown considerable over time, hence impacting on the overall case-mix outcome. Also from an administrative point of view, more emergency-admission accounts are now split-billed that were previously billed as one account. This digress the number of cases and cause a diluted decrease of patient risk over time. Therefore we concentrated only on cases with theatre time or accommodation for the purpose of the analysis. Figure 4 illustrates the change in some of the different components of patient level risk namely age, gender, surgical- and medical-mix in general.

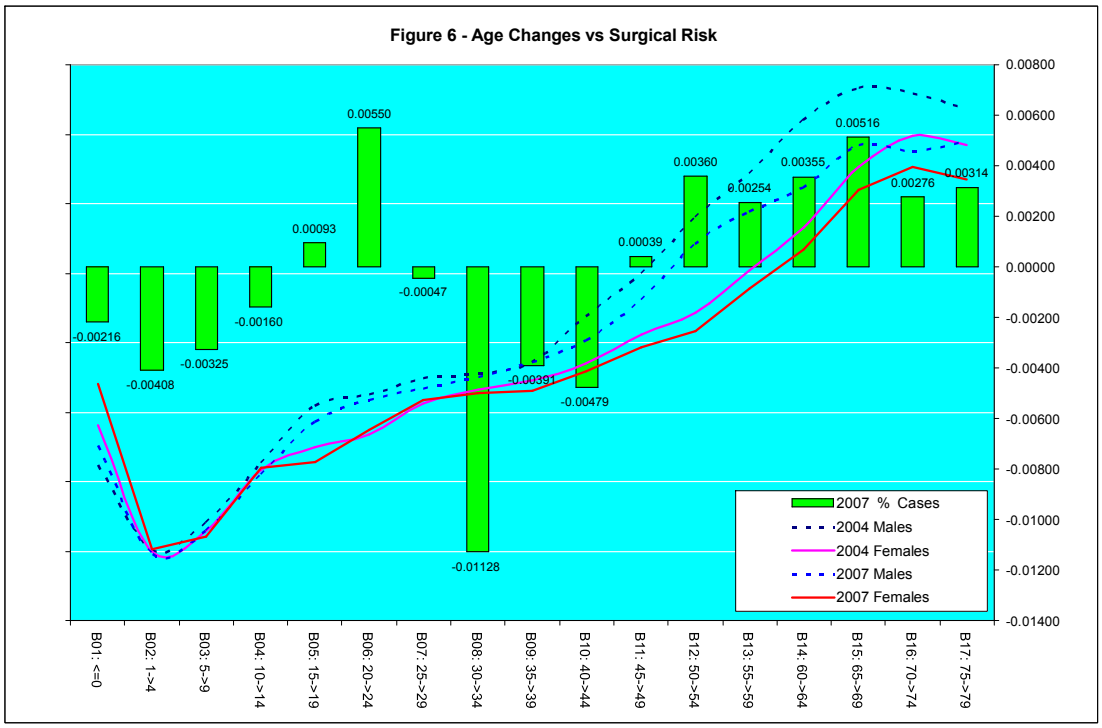


The first thing to note from Figure 4 is that the overall risk (green line) is still declining with the outpatient cases removed from the analysis. It is apparent from the graph that although the ageing of the population had a positive impact on the risk change, the overall risk change was dominated by decreasing surgical- and medical-mix changes indicated by the negative slopes of the respective trend lines. The medical risk change tends to dominate the impact on the overall risk over time. This is most probable caused by the increase in the portion of medical cases relative to surgical ones as illustrated in Figure 5. Interpreting



this trend in combination with the decrease in medical risk, it can be an indication that the growth in medical cases is supplemented by an increase in low risk cases.

Figure 4 also shows a decline in the surgical risk of patients. We needed to have a better understanding of this, since it is not only contradictive to the ageing and increasing average theatre time of the population, but also in important from an operational point of view. We investigated the relation between age, gender and surgical risk. Figure 6 is an illustration of the sensitive relationship between these factors.



The solid and dotted lines represents surgical risk within each age category for 2004 and 2007 for females and males respectively and the spread will reflect the differences in surgical risk. The green bars indicate the change in specific age categories between the respective years. Positive values will be an indication of positive growth within the specific age category between years; similarly a negative value will indicate drops. Having a closer look at age categories B11-B15, clearly indicating growth in the older age categories, we see a drop in surgical-mix for the same categories as indicated by the spread difference. We can thus conclude that the change in surgical-mix outweighed the age risk change resulting in an overall declining surgical risk. In an attempt to understand the change in surgical mix we have done a further in depth analysis looking at the surgical procedures that are strongly correlated with surgical risk. The results are set out in the table below.

Procedure	Risk Category	Annual Change
Mitral valvuloplasty replacements	High	-6.490%
Aorta valvuloplasty replacements	High	-0.930%
Gastrectomy	High	-5.320%
CABG	High	-3.280%
Ophthalmological surgery	Low	10.080%
Plastic & Reconstructive surgery	Low	5.370%
Obstetrics and gynaecology	Low	7.420%
Minor Uro Genital surgeries	Low	6.970%

We conclude that the drop in surgical mix was caused by some high risk procedures, but to a greater extend by an increase in a high number of low risk procedures. This fact together with the decrease in medical mix is the main drivers for a declining overall patient risk. Understanding the components of patient level risk is complex because of the intricate relation that exists between factors and therefore it is important to look at all risk factors to avoid oversimplification of the issues involved.

Summary

This analysis demonstrates the feasibility to have a case-mix adjustment system, using existing administrative data. The multivariate models used also shows that certain patient-level characteristics could explain variations in risk. However, for a variety of technical reasons, the detailed results from these models should be interpreted with great caution since correlation between variables could lead to misinterpretation.

Mortality

Mortality as a quality outcome?

Healthcare providers have always been concerned about patient outcomes and evaluating outcomes as a means of determining the effectiveness of care. Much of the philosophical basis for outcomes measurement is derived from the early work of Florence Nightingale. Nightingale used mortality statistics to portray the low quality of care provided to British soldiers during the Crimean War. It has been said that Nightingale was the first person to use diagrams for presenting statistical data. Although this is most probable not true, she may have been the first to use them for persuading people for the need for change. Her methods indeed succeeded by reducing mortality from 60% at her arrival to 2% six months later.

That fact that patients die in hospitals every day is both an accepted fact of hospital care delivery and a reflection of avoidable hospital inefficiencies. These inefficiencies are subject to control and include poor infection control, inadequate or inappropriate use of medication, falls as a result of poor supervision or understaffing, mistakes during surgery, and inappropriate level of care. Some, perhaps many, of these deaths might be prevented if all the factors that contribute to them are better understood. A study, for example, looking at the association between patient-to-nurse ratio and patient mortality concluded that, after adjusting for patient and hospital characteristics (size, teaching status, and technology), each additional patient per nurse was associated with a 7% (odds ratio, 1.07; 95% confidence interval, 1.03-1.12) increase in the likelihood of dying within 30 days of admission. Surely hospitals do not have control over worsening nursing shortages and legislation changes, but can use this information to address problem areas and optimally plan resources. The adjusted ratios should be seen as a kind of red flag for performance improvement and not a verdict.

As in most improvement efforts the process should start with measuring outcomes. It has been stressed in the case-mix article that these types of comparisons have little meaning unless adjustments are made for patient risk differences. One could thus conclude that hospital mortality rate, appropriately adjusted for patient risk variables, is an essentiality in measuring quality.

Methodology Used

We have developed a statistical methodology to adjust hospital mortality rates for patient level risk factors in order to make justifiable comparisons between hospitals. We also expanded this methodology to measure trends over time.

We treated deaths as a binary response variable and used a logistic regression model to measure the relation with patient risk variables in order to adjust for case-mix

differences. The outcome is an expected value per admission reflecting the probability that the admission will result in a death.

$$E(y) = \frac{e^{\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_k x_k}}{1 + e^{\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_k x_k}} \quad \text{where} \quad y = \begin{cases} 1 & \text{Deceased} \\ 0 & \text{Survived} \end{cases}$$

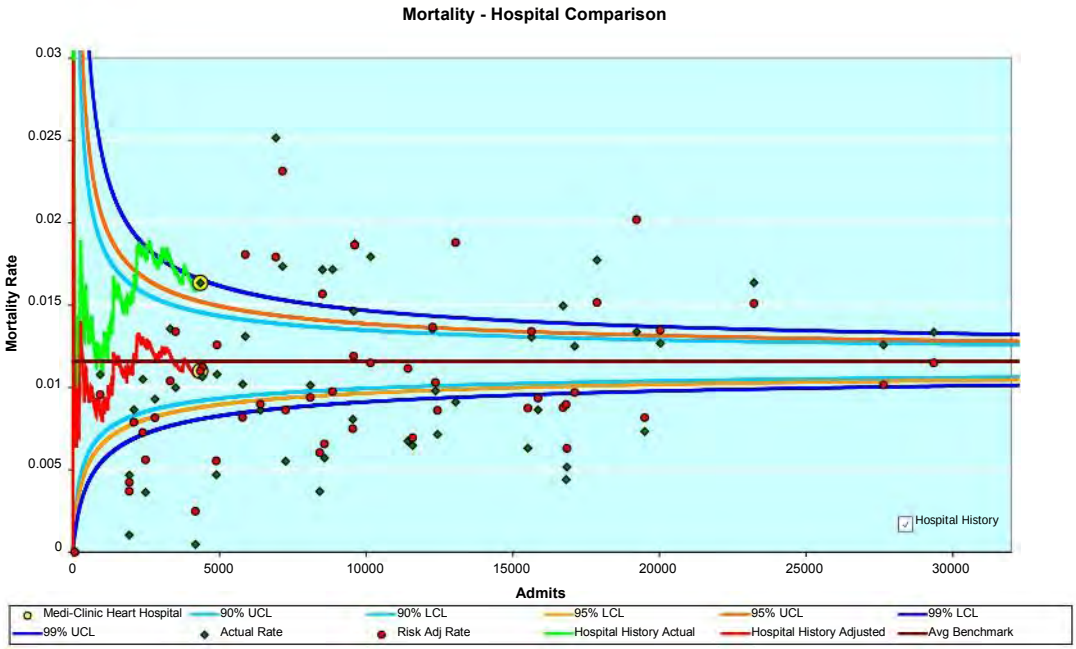
$$E(y) = \pi = P(Deceased)$$

The coefficient $\hat{\beta}_i$ in the logistic model estimates the change in the log-odds if x_i is increased by 1 unit, holding all other xs in the model fixed. Therefore the model can also produce an estimated increase in risk for each of the various risk variables. For example a patient odds of dying in hospital, treated for an Infectious or Parasitic disease, will increase with a factor of 1.17. More specifically, a patient treated for Tuberculosis, will have a 2.12 increase in the odds factor of dying in hospital. The difference in magnitude between the coefficients of these risk variables are a reflection of the dependence with the outcome variable.

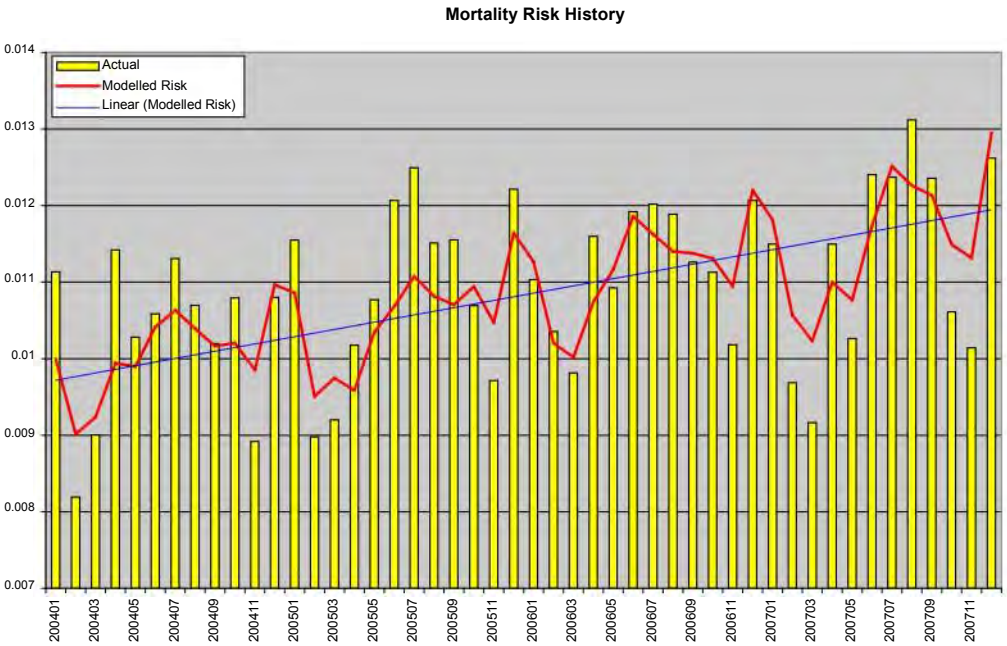
Trends & Analysis

The chart below is an illustration of mortality outcome of Medi-Clinic hospitals using statistical control charts. The horizontal axis represents volume and the vertical axis mortality rate. The curve lines are the control limits defined as 90%, 95%, and 99% confidence intervals with the purpose to identify units whose performance diverse significantly from the norm. The green dots represent crude mortality and the red dots risk adjusted mortality. The solid green and red line is the chronological accumulative mortality outcome of a single Medi-Clinic hospital, known to treat high risk cardiac cases, for crude and risk adjusted mortality respectively. The spread increase rapidly because of the high risk nature of these patients and the crude mortality are quickly out of control. The risk adjusted mortality stays within control, indicating that although the crude mortality is significantly higher then the norm; it is mainly contributable to patient level risk and not a reflection of inefficient hospital processes.

The idea is to measure this on continues basis and flag hospitals as soon as the outcome (mortality rate) is out of control. Doing this will ensure that high mortality rates, contributable to inefficient hospital processes, are proactively identified and managed, rather than a retrospective review at the end of the financial period. Understanding the issues involved will assist to design processes to prevent possible future occurrence.

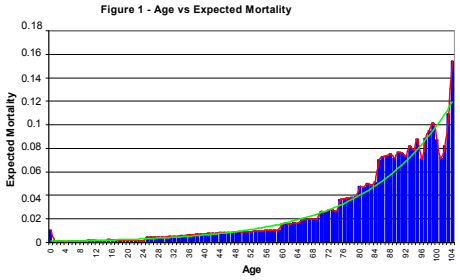


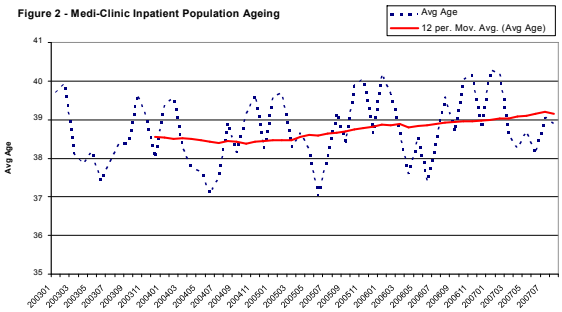
Like mentioned earlier it is also possible to do trend comparisons over time. The graph below illustrates crude and expected morality for Medi-Clinic for 2004 to 2007. It is important to note that although the crude mortality rate is increasing, the expected rate is also increasing, indicating an increase in the population risk for mortality.



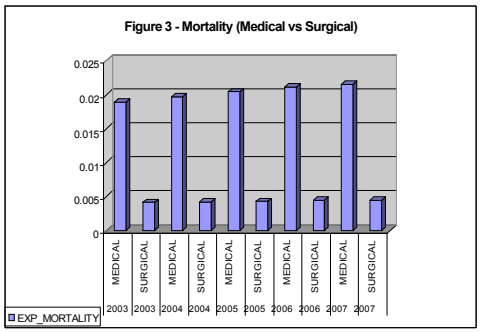
The reason for this increase can be explained by a change in various risk factors, but the main contributing factors are:

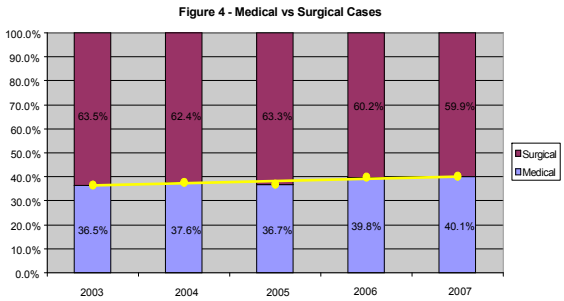
(1) Ageing of the population. Figure 1 shows that there is an exponential relation between mortality risk and age, apart from neonatal cases. Figure 2 shows that our population is ageing, hence one could conclude that our mortality risk is increasing due to an increase in age of the population.



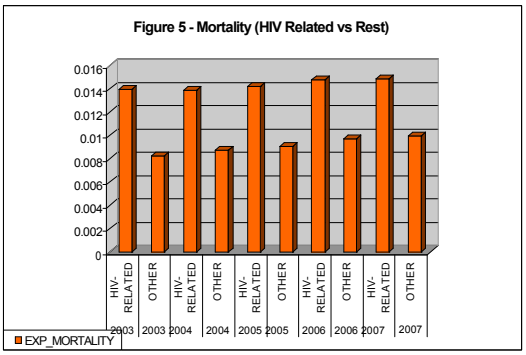


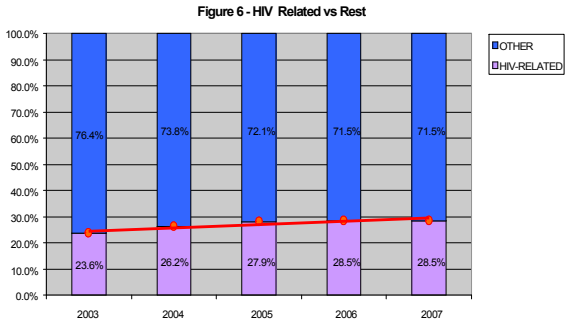
(2) Increase in the proportion of medical cases relative to surgical ones as illustrated in Figure 4. Figure 3 shows that mortality risk for medical cases are higher then for surgical ones, hence one could conclude that this is another reason for the increase.





(3) Increase in HIV related cases. Legislation and patient confidentially does not allow information around HIV cases to be captured, hence we needed to use clinical criteria to identify certain procedures that can be used as a proxy for HIV cases. Figure 5 shows that HIV-related cases have a higher mortality risk then the rest. Figure 6 shows a growth in the portion of HIV-related cases relative to the rest, hence another reason for the yearly increase in mortality risk.





Addendum E

MEDICLINIC

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04 June 2013

Dr René Toua
Mediclinic (Pty) Ltd
3rd Floor
Tijger Park 1
Willie van Schoor Drive
Bellville
7530

E-mail: rene.toua@mediclinic.co.za

Dear René,

RISK ADJUSTED MORTALITY RATES: HOW DO THEY DIFFER WHEN CALCULATED WITH ADMINISTRATIVE DATA COMPARED TO PHYSIOLOGICAL PREDICTIVE MODELS?

Please be advised that Mediclinic hereby approves the application for the above-mentioned research.

Yours sincerely,

for **DR MS SMUTS**
CHIEF CLINICAL OFFICER

Addendum F

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

07 October 2013

HREC REF: 572/2013

Dr R Toua
c/o Dr T Welzel
Emergency Medicine
Surgery
J46-56, OMB

Dear Dr Toua

PROJECT TITLE: RISK ADJUSTED MORTALITY RATES: DO THEY DIFFER IF BASED ON ADMINISTRATIVE DATA (HOSPITAL STANDARDIZED MORTALITY RATIO) VERSUS A PHYSIOLOGICAL PREDICTIVE MODEL (APACHE IV)?

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has formally approved the above-mentioned study.

Approval is granted for one year until the 30th October 2014

- Please note that there are minor grammar and spelling errors throughout the protocol, which need to be corrected.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period. (Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC reference no in all your correspondence.

Yours sincerely

pp TJ Burgess
PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Addendum G

Risk adjusted mortality rates: Do they differ if calculated with administrative data (Hospital Standardised Mortality Ratio) as compared to a physiological predictive model (APACHE IV®)?

STUDENT: Rene Toua (Du Toit)

MB ChB (Stell)

UCT

DTTREN004

SUPERVISOR: Tyson Welzel

UCT

This study is in partial fulfilment of the M Phil Emergency medicine (patient Safety)

Declaration:

I, Rene Toua, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

Signature: Date: 14 August 2013

Addendum H

Critical Care - Instructions for authors

http://ccforum.com/authors/instructions/research

Research Articles

See 'About this journal' for descriptions of different article types and information about policies and the refereeing process.

Submission process

Manuscripts must be submitted by one of the authors of the manuscript, and should not be submitted by anyone on their behalf. The submitting author takes responsibility for the article during submission and peer review.

Please note that all content published in *Critical Care* is entirely open access. *Critical Care* levies an article-processing charge on all accepted Research Articles that have not been directly invited by the journal; if the submitting author's institution is a BioMed Central member the cost of the article-processing charge may be covered by the membership (see About page for detail). Please note that the membership is only automatically recognised on submission if the submitting author is based at the member institution. Authors of invited Research Articles are entitled to a full waiver on the journal article processing charge and should complete a waiver request during the submission process.

To facilitate rapid publication and to minimize administrative costs, *Critical Care* prefers online submission.

Files can be submitted as a batch, or one by one. The submission process can be interrupted at any time; when users return to the site, they can carry on where they left off.

See below for examples of word processor and graphics file formats that can be accepted for the main manuscript document by the online submission system. Additional files of any type, such as movies, animations, or original data files, can also be submitted as part of the manuscript.

During submission you will be asked to provide a cover letter. Use this to explain why your manuscript should be published in the journal, to elaborate on any issues relating to our editorial policies in the 'About *Critical Care*' page, and to declare any potential competing interests. You will be also asked to provide the contact details (including email addresses) of potential peer reviewers for your manuscript. These should be experts in their field, who will be able to provide an objective assessment of the manuscript. Any suggested peer reviewers should not have published with any of the authors of the manuscript within the

past five years, should not be current collaborators, and should not be members of the same research institution. Suggested reviewers will be considered alongside potential reviewers recommended by the Editor-in-Chief and/or Editorial Board members.

Assistance with the process of manuscript preparation and submission is available from BioMed Central customer support team.

We also provide a collection of links to useful tools and resources for scientific authors on our Useful Tools page.

File formats

The following word processor file formats are acceptable for the main manuscript document:

- Microsoft word (DOC, DOCX)
- WordPerfect (version 5 and above)
- Rich text format (RTF)
- Portable document format (PDF)
- TeX/LaTeX (use BioMed Central's TeX template)

TeX/LaTeX users: Please use BioMed Central's TeX template and BibTeX stylefile if you use TeX format. During the TeX submission process, please submit your TeX file as the main manuscript file and your bib/bbl file as a dependent file. Please also convert your TeX file into a PDF and submit this PDF as an additional file with the name 'Reference PDF'. This PDF will be used by internal staff as a reference point to check the layout of the article as the author intended. Please also note that all figures must be coded at the end of the TeX file and not inline.

If you have used another template for your manuscript, or if you do not wish to use BibTeX, then please submit your manuscript as a DVI file. We do not recommend converting to RTF.

For all TeX submissions, all relevant editable source must be submitted during the submission process. Failing to submit these source files will cause unnecessary delays in the publication procedures.

Preparing main manuscript text

General guidelines of the journal's style and language are given below.

Overview of manuscript sections for Research Articles

Manuscripts for Research Articles submitted to *Critical Care* should be divided into the following sections (in this order):

- Title page
- Abstract

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- Keywords
- Article headings
- Introduction
- Methods
- Results and discussion
- Conclusions
- Key messages
- List of abbreviations used (if any)
- Competing interests
- Authors' contributions
- Authors' information
- Acknowledgements
- Endnotes
- References
- Illustrations and figures (if any)
- Tables and captions
- Preparing additional files

The **Accession Numbers** of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript should be provided, in square brackets and include the corresponding database name; for example, [EMBL:AB026295, EMBL:AC137000, DDBJ:AE000812, GenBank:U49845, PDB:1BFM, Swiss-Prot:Q96KQ7, PIR:S66116].

The databases for which we can provide direct links are: EMBL Nucleotide Sequence Database (EMBL), DNA Data Bank of Japan (DDBJ), GenBank at the NCBI (GenBank), Protein Data Bank (PDB), Protein Information Resource (PIR) and the Swiss-Prot Protein Database (Swiss-Prot).

For reporting standards please see the information in the About section.

Title page

The title page should list

- the title of the article
- the full names
- institutional addresses
- email addresses for all authors

The corresponding author should also be indicated.

Please note that the title should include the study design, for example "A versus B in the treatment of C: a randomized controlled trial" or "X is a risk factor for Y: a case control study". Please see the policy section in 'About *Critical Care*' for further details.

Abstract

The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Introduction**, the context and purpose of the study; **Methods**, how the study was performed and statistical tests used; **Results**, the main findings; **Conclusions**, brief summary and potential implications; **Trial registration**, if your research reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. **Trial registration**: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the CONSORT extension for abstracts.

Please minimize the use of abbreviations and do not cite references in the abstract. Please see also our guide for writing an easily accessible abstract.

Keywords

Three to ten keywords representing the main content of the article.

Introduction

The Introduction section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a brief statement of what is being reported in the article.

Methods

The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the methods section.

For further details of the journal's data-release policy, see the policy section in 'About this journal'.

Results and discussion

The Results and discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The Results and discussion sections may also be broken into subsections with short, informative headings.

Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

Key messages

These should be up to five bullet points summarising the main findings of your study.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

Competing interests

A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors must disclose any financial competing interests; they should also reveal any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

Authors are required to complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'.

When completing your declaration, please consider the following questions:

Financial competing interests

- In the past three years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.
- Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify.
- Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript? If so, please specify.
- Do you have any other financial competing interests? If so, please specify.

Non-financial competing interests

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Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.

If you are unsure as to whether you, or one your co-authors, has a competing interest please discuss it with the editorial office.

Authors' contributions

In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

According to ICMJE guidelines, An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; 3) have given final approval of the version to be published; and 4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support.

Authors' information

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

Acknowledgements

Please acknowledge anyone who contributed towards the article by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for each author, and for the manuscript preparation. Authors must describe the role of the funding body, if any, in design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. Please also acknowledge anyone who contributed materials essential for the study. If a language editor has made significant revision of the manuscript, we recommend that you acknowledge the editor by name, where possible.

The role of a scientific (medical) writer must be included in the acknowledgements section, including their source(s) of funding. We suggest wording such as 'We thank Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.'

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements section.

Endnotes

Endnotes should be designated within the text using a superscript lowercase letter and all notes (along with their corresponding letter) should be included in the Endnotes section. Please format this section in a paragraph rather than a list.

References

All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

Only articles, clinical trial registration records and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited; unpublished abstracts, unpublished data and personal communications should not be included in the reference list, but may be included in the text and referred to as "unpublished observations" or "personal communications" giving the names of the involved researchers. Obtaining permission to quote personal communications and unpublished data from the cited colleagues is the responsibility of the author. Footnotes are not allowed, but endnotes are permitted. Journal abbreviations follow Index Medicus/MEDLINE. Citations in the reference list should include all named authors, up to the first six before adding 'et al.'..

Any *in press* articles cited within the references and necessary for the reviewers' assessment of the manuscript should be made available if requested by the editorial office.

An Endnote style file is available.

Examples of the *Critical Care* reference style are shown below. Please ensure that the reference style is followed precisely; if the references are not in the correct style they may have to be retyped and carefully proofread.

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Examples of the *Critical Care* reference style

Article within a journal
Smith JJ. The world of science. Am J Sci. 1999;36:234-5.

Article within a journal (no page numbers)
Rohrmann S, Overvad K, Bueno-de-Mesquita HB, Jakobsen MU, Egeberg R, Tjønneland A, et al. Meat consumption and mortality - results from the European Prospective Investigation into Cancer and Nutrition. BMC Medicine. 2013;11:63.

Article within a journal by DOI
Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. Dig J Mol Med. 2000; doi:10.1007/s801090000086.

Article within a journal supplement
Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. Blood 1979;59 Suppl 1:26-32.

Book chapter, or an article within a book
Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. International review of cytology. London: Academic; 1980. p. 251-306.

OnlineFirst chapter in a series (without a volume designation but with a DOI)
Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. Top Curr Chem. 2007. doi:10.1007/128_2006_108.

Complete book, authored
Blenkinsopp A, Paxton P. Symptoms in the pharmacy: a guide to the management of common illness. 3rd ed. Oxford: Blackwell Science; 1998.

Online document
Doe J. Title of subordinate document. In: The dictionary of substances and their effects.

Royal Society of Chemistry. 1999. http://www.rsc.org/dose/title of subordinate document. Accessed 15 Jan 1999.

Online database
Healthwise Knowledgebase. US Pharmacopeia, Rockville. 1998. http://www.healthwise.org. Accessed 21 Sept 1998.

Supplementary material/private homepage
Doe J. Title of supplementary material. 2000. http://www.privatehomepage.com. Accessed 22 Feb 2000.

University site
Doe, J: Title of preprint. http://www.uni-heidelberg.de/mydata.html (1999). Accessed 25 Dec 1999.

FTP site
Doe, J: Trivial HTTP, RFC2169. ftp://ftp.isi.edu/in-notes/rfc2169.txt (1999). Accessed 12 Nov 1999.

Organization site
ISSN International Centre: The ISSN register. http://www.issn.org (2006). Accessed 20 Feb 2007.

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  - SWF (Shockwave Flash)
- Movies
  - MP4 (MPEG 4)
  - MOV (Quicktime)
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3. Ensure that all links are relative (ie "images/picture.jpg" rather than "/images/picture.jpg" or "http://yourdomain.net/images/picture.jpg" or "C:\Documents and Settings\username\My Documents\mini-website\images\picture.jpg") and no link is longer than 255 characters.
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- All pages should be numbered.
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- Please do not format the text in multiple columns.
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