An appropriateness review of urgent in-hours non-trauma CT brain scans at a single tertiary referral centre in South Africa - are we scanning rationally?

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"I often say that when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind."

- **William Lord Kelvin**

Dedication:

To my wife and son whose love and support are immeasurable, inexpressible and daily disprove Lord Kelvin's notion.

Table of Contents

Declaration page i

a. List of Abbreviations ii

b. Glossary of Terms iii

c. List of Graphs v

d. List of Tables v

e. List of Equations v

f. List of Figures v

Abstract 1

1. Rationale 3

2. Introduction and Background 4

3. Literature Review 6

3.1. Clinical guidelines 6

3.2. Non-trauma CT brain guidelines 6

3.3. Other Radiology Guidelines 9

3.4. Ionising radiation and its biological effects 10

3.5. CT Effective Dose calculation and its role in dose estimation 12

3.6. The project in context: Comparison to other literature 13

4. Hypothesis, Study Aims and Objectives 15

4.1. Research hypotheses 15

4.2. Study Aims 15

4.3. Study Objectives 15

5. Study Design 17

5.1. Study Population 18

5.1.1. Inclusion criteria 18

5.1.2. Exclusion criteria 18
5.2. Materials and Methods 19
5.2.1. Ethics 19
5.2.2. Data Collection 20
6. Study Results 24
7. Discussion 34
8. Recommendations 37
9. Conclusion 39
9. Acknowledgements 40
10. References 41
11. Appendix A – Informed Consent 45
11. Appendix B – Research Tools 46
12. Appendix C – Ethical Approval 48
13. Appendix D – Extension of Ethical Approval 49
14. Appendix E – GSH Research Permission 50

Declaration page

I, Donovan George Jacobs, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree at this or any other university.

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a. List of Abbreviations

ACR - American College of Radiologists

AEC - Automatic Exposure Control

CT - Computed Tomography

$CTDI_{vol}$ - Computed Tomography Dose Index (Volume)

DICOM - Digital Imaging and Communication in Medicine

DLP - Dose Length Product

ED - Effective Dose

FDA - Food and Drug Administration

Gy - Gray; derivatives include milli-Gray (mGy; where 1 mGy = 0.001 Gy)

GSH - Groote Schuur Hospital

ICRP - International Commission on Radiological Protection

IAEA - International Atomic Energy Agency

kVp - kilo-Volt peak

mAs - milli-Amps per second; units describing the *tube current-time product*

MDCT - Multi-Detector Computed Tomography

PACS - Picture Archiving and Communication System

RCR- Royal College of Radiologists

RSNA - Radiological Society of North America

Sv - Sievert; derivatives include milli-Sievert (mSv; where 1 mSv = 0.001 Sv)

UCT - University of Cape Town

b. Glossary of Terms

Computed Tomography (CT) – a technology that produces virtual slices of an imaged structure, using computer processing of x-rays.

Digital Imaging and Communication in Medicine (DICOM) – an open-source standard of recording medical images with embedded information such as patient details, radiation dose and a digital report. It was developed by the American College of Radiologists and National Electronic Manufacturer's Association to ensure inter-operability between different electronic medical records made by different vendors.

Gray – the SI unit of absorbed radiation dose, defined as the amount of energy deposited into a kilogram of tissue and expressed in joules per kilogram ($J.kg^{-1}$). This unit is a mathematical quantity and does not take any biological effect into account. (Contrast with: Sievert)

In-hours – time between 08h00 and 16h00, which is considered standard business hours for the purposes of this study.

Interpolation – a mathematical method of inferring the value of an unknown data point, based on known values of data related to it.

Multi-detector Computer Tomography (MDCT) – a CT scanner that contains a detector array consisting of more than one detector in the z-axis, which can scan more than one tissue slice at a time.

Phantom – (also known as an *imaging phantom*) is a device that mimics the response of human tissue to a particular imaging modality. It can be used for machine calibration, research or education depending on the design.

Picture Archiving and Communication System (PACS) – a digital system which allows for storage and access to images and reports of radiological investigations.

SI Units **(French:** *Système international d'unités*) – the *metric* standard of weight and measures initially defined in Paris in 1875 (van Assendelft, Mook & Zijlstra, 1973). The aim of these units is to be practical and consistent for scientific study. Some of the defined units used include the metre, kilogram and Joule.

Sievert – The SI unit representing the biological effect of one joule of energy in one kilogram of human tissue (1 Sv = 1 joule per kilogram), named after Rolf Maximilian Sievert who was a renowned physicist in the field of radiation dosage measurement. It describes equivalent dose, effective dose and operational dose quantities; and is used to measure the health effects of low level ionizing radiation.

Tube current-time product (mAs) – is the product of x-ray tube current (in milli-amperes) and exposure time (in seconds) per rotation of the CT scanner tube (Mayo-Smith & Hara, 2014).

Urgent Request – any request for imaging investigation that should be completed as soon as possible, as any undue delay could result in a poor patient outcome.

c. List of Graphs

Graph 1 - Age Distribution 25
Graph 2 - Actual CT scan performed 26
Graph 3 - Calculated ED of CT scans included in the study 27
Graph 4 - Referral category of each CT scan reviewed 28

d. List of Tables

Table 1 - *k* coefficient used to determine the ED from CT scan DLP 13
Table 2 - Interpretation of Kappa Values (as per Viera (Viera & Garrett, 2005) 23
Table 3 - CT studies completed during study period 24
Table 4 - Consultant categorisation of CT request appropriateness 29
Table 5 - CT scan outcome by category 30
Table 6 - Researcher request appropriateness vs. CT scan outcome 31
Table 7 - Consensus consultant request appropriateness vs. CT scan outcome 32
Table 8 - Weighted Kappa outcomes for each investigator 33

e. List of Equations

Equation 1 - Mathematical representation of absorbed dose 11
Equation 2 - Alternative formula for calculating ED based on CT scan DLP 12

f. List of Figures

Figure 1 – Example of a radiation dose report from GSH Siemens Somatom Emotion 16-slice CT scanner 26

Abstract

An appropriateness review of urgent in-hours non-trauma CT brain scans at a single tertiary referral centre in South Africa - are we scanning rationally?

Jacobs, D.G., Andronikou, S., Hartley, T., Said-Hartley, Q.M., Wojno, M.J.

Aim:

To determine if urgent, non-trauma in-hours CT head scan requests in the GSH department of radiology are being appropriately requested and completed, as well as determining the radiation dose for each study. Secondly, to make recommendations to improve local practice based on the findings of this study.

Methods:

A retrospective study was undertaken of 100 qualifying in-hours urgent, non-trauma CT head scans completed at the GSH department of radiology between 01/10/2015 and 31/03/2016. All qualifying CT request data and dose records were collected and anonymised, after ethical and institutional approval. Three radiologists at GSH were enlisted to review the request information. Each request was reviewed and categorised by both the researcher and each consultant individually to determine the indication and appropriateness. The researcher used previously published, objective criteria (Rothrock Criteria) to review requests, while the radiologists used their own interpretation of accepted local practice. The researcher recorded positive and negative scan outcomes, radiation doses and calculated the Effective Dose (ED) for each study. Results were recorded in Excel and statistical analysis using weighted Kappa analysis was undertaken.

Results:

Study cohort CT scans made up 15.6% of the total emergency head CT scans over the study period. The mean patient age was 52.3 years (range: 18.8-87.4

years). One-third (34; 34%) were older than 60 years with 33 (97%) having at least 2 positive Rothrock criteria. Most CT scans (86%) consisted of a single study, while the remaining comprised two or more. Average ED was 3.27 mSv (range: 1.03-4.33 mSv). 52 (52%) participants had abnormal CT findings, independent of age-group. Discrepancy in assigning study indication and appropriateness between the researcher and consultants was present, with at best moderate agreement (weighted-Kappa range 0.09-0.52). The researcher showed slight to fair agreement between scan outcome and request appropriateness using the Rothrock criteria (weighted kappa 0.20; 95% CI: 0.06-0.35, p=.00861), while the consultant consensus performed slightly worse (0.10; 95% CI: -0.05-0.26, p=.19728).

Conclusion:

Retrospective application of the Rothrock criteria to patient referrals produced better correlation with outcome than current departmental practice. However, there is at best moderate agreement between consultants with regard to classification of referrals which could negatively affect the application of Rothrock criteria in practice. Incorporating the Rothrock criteria into published departmental guidelines, in conjunction with other interventions to improve clinician requesting practices, is recommended. The formation of a Quality Assurance team and the use of existing dose-reducing techniques may assist in reducing radiation doses further.

1. Rationale

The Radiology Department at Groote Schuur Hospital (GSH) is a state-funded imaging department with constrained radiological and human resources. Due to the diverse nature of in-hours Computed Tomography (CT) brain requests the department continually strives to balance the needs of the clinician, departmental resources and the safety of the patient at an internationally acceptable standard. To do this, the GSH Department of Radiology constantly reviews and revises its practices through education and research.

This study aims to identify ways in which the Department of Radiology at GSH can reduce inappropriate CT scan numbers, defined as studies performed for an incorrect indication, use of an incorrect study protocol or sub-optimal imaging modality. Inappropriate studies result in unproductive use of departmental resources with workload increase and reduced availability of limited CT scan time with little clinical benefit for the patient and requesting physician, as well as unnecessary patient radiation exposure.

In-hours (08h00-16h00) CT studies were targeted in this study as the duty consultant would be available to assist in decision-making and prioritising emergency scans perceived by them as appropriate. This was an attempt to remove the potential after-hours bias of registrars erring on the side of caution and allowing scans to be completed rather than potentially missing pathology.

By identifying strategies to reduce the number of inappropriate scans, ensuring the correct region is scanned, and investigating methods that reduce radiation dose, we may improve CT practices and reduce long-term patient morbidity.

2. Introduction and Background

Groote Schuur Hospital (GSH) is a tertiary level state-funded medical facility located in the City of Cape Town municipality within the Western Cape Province of the Republic of South Africa. The hospital services an adult population of approximately 2.65 million people within the Cape Town metropole (StatisticsSA, 2012), with the nearby Red Cross War Memorial Children's Hospital responsible for the treatment of the province's approximately 1.09 million children under 18 years of age (StatisticsSA, 2012). The hospital has a dedicated emergency unit, general and specialised medical and surgical services with an in-patient capacity of 975 beds. There are multiple out-patient clinics, for all the represented disciplines and some 441 470 patient day equivalent visits were completed in 2016 (Western Cape Government Health, 2016).

The GSH department of radiology is serviced by 5 full-time consultant radiologists, 5 sessional radiologists and 21 registrars (trainee radiologists). In terms of advanced imaging, the department currently has access to 1 MRI scanner and 3 CT scanners (Siemens Somatom Emotion 16-slice scanner, Toshiba Aquilon 160-slice scanner and a NewTom Conebeam CT scanner), with only the Siemens Somatom Emotion 16-slice scanner available for full-time (both in- and after-hours) head and neck studies. This CT scanner was manufactured in 2007 and uses filtered back projection for image reconstruction (Siemens AG, 2007). A total of 21959 CT scans were completed in 2016, of which 11921 were CT scans of the head (Brandon Vigaro, Personal Correspondence, 04/09/2017).

Since its introduction, CT scanning has revolutionised the field of radiology (Brenner & Hall, 2007). Due to the improved speed of image acquisition and image density, CT scanners can offer a large amount of valuable information to the radiologist and the clinician. However, as CT scanning involves exposure to radiation, there are potential health risks to patients if the technology is incorrectly used.

Reduction of inappropriate in-hours urgent non-trauma CT brain scans at the GSH department of radiology would assist in improving allocation of limited CT scanning resources, reduce costs, improve waiting times for other categories of patients and decrease unnecessary patient radiation dose.

3. Literature Review

An extensive literature review was undertaken by the authors and is reported below with appropriate citations, in the Harvard-University of Cape Town style with a full bibliography available in the References chapter.

3.1. Clinical guidelines

The use of clinical guidelines in medicine continues to rise worldwide, as clinicians and policy-makers attempt to standardise healthcare while dealing with increased demand for services, rising costs and access to more expensive technologies (Woolf et al., 1999). The benefits of clinical guidelines include standardisation of care, improved clinical decisions and better patient outcomes (Woolf et al., 1999), however they may not always have positive effects.

Guidelines are often based on expert recommendations rather than evidence-based medicine, may be influenced by external factors such as cost and may not take into account an individual patients unique clinical presentation (Woolf et al., 1999). Guidelines are also often designed for specific clinical settings, may therefore not be suitable for resource-constrained "developing world" situations and need constant updating when new information becomes available (Andronikou et al., 2017). Despite these drawbacks, guidelines can assist inexperienced clinicians and trainee radiologists when making imaging decisions within the local resource-constrained radiological environment.

3.2. Non-trauma CT brain guidelines

In 1978, 200 CT scanners were sold in the United States of America (USA) (Manchester Royal Infirmary, 2014) and today the number of scanners has been estimated in the thousands. As CT scans became easily accessible within the United

States of America (USA), the number of CT scans increased to an estimated 85 million CT scans in 2012 (Brenner, 2012).

Due to this large number, and the increasing cost of medical imaging, the American College of Radiologists (ACR) began issuing recommendations on appropriate imaging modalities for certain clinical indications. A standardised rating system is used in each guideline, with values from 1 to 9. Values of 1 to 3 are considered "*usually not appropriate*"; 4 to 6 as "*may be appropriate*"; and 7 to 9 being rated as "*usually appropriate*" (Douglas AC, Wippold FJ, 2014).

The Royal College of Radiologists (RCR) has published a set of guidelines for imaging, known as *iRefer*, which has been scientifically validated (Remedios & France, 2012). These guidelines are available to all members of the RCR and to other medical practitioners as a download for smartphones and tablet devices (Remedios & France, 2012). The guidelines recommend investigations based on the cost, diagnostic impact and effective radiation dose (Remedios & France, 2012). The rating system used is similar to the ACR guidelines discussed earlier. By making the guidelines available to all practitioners involved in ordering imaging, inappropriate requests can be reduced. The RCR further encourages the use of other strategies to reduce unnecessary radiological procedures, including advocating "meticulous vetting"(Remedios & France, 2012) of imaging requests.

The ACR and iRefer guidelines are useful within the setting of a well-resourced, developed nation and rely heavily on Magnetic Resonance Imaging (MRI) as the modality of choice for many non-traumatic neurological indications. The GSH Department of Radiology has access to only one MRI machine which is operated during office hours and for specific after-hours emergencies only. The waiting list for out-patient cases is up to 68 days (Beningfield, 2014). This severely limits the availability of MRI for all patients and precludes the effective and rational use of the

ACR Appropriateness Guidelines or the RCR *iRefer* guidelines in the context of non-traumatic neurological emergencies.

The United Kingdom NICE Guidelines are clinical decision-making guidelines for certain neurological presentations, laid out in clinical decision pathways. Many of the non-trauma clinical pathways, for example dealing with headaches, do not advise specific radiological imaging but rather suggest further investigation or referral (Carville et al., 2012).

The locally published Kimberley Head Rule was derived from the NICE guidelines for adult head trauma, but attempts to add a unifying non-trauma component to make decision-making easier in a "resource-limited environment" (Bezuidenhout et al., 2013). The Kimberley rule added categories of non-traumatic focal neurological deficit, seizure, sudden onset headache, and vomiting (extra-cranial causes excluded) to the criterion for CT brain. The rule was found to be clinically useful with an overall sensitivity of 90% (95% CI: 86-95%) but not specific (45%; 95% CI: 41-50%); with application in the setting of trauma more sensitive than in the non-trauma setting.

In 1997, Rothrock and colleagues (Rothrock et al., 1997) published scientifically-based criteria for urgent non-trauma CT head scans, after a prospective study. The group found good correlation between certain clinical complaints, clinical data, and clinically significant scan outcomes. The top four clinical criteria with clinically-significant outcomes were: an age greater than or equal to 60 years, altered mental status, headache with vomiting, and focal weakness (Rothrock et al., 1997).

In the presence of one of the four above-mentioned criteria, there was good correlation with positive CT head findings. High sensitivity (100%; 95% CI: 94-100%)

and negative predictive (100%; 95% CI: 98-100%) values, further suggested that these criteria were valid and clinically appropriate.

Rothrock and his colleagues found that up to 28% of the urgent, non-trauma head CT scan requests in their cohort could be rejected without missing one significant abnormality, simply by using the criteria described above and refusing requests that do not fulfil the described clinical criterion.

The Rothrock criteria have since been evaluated in two separate studies. One, completed by Tan el al. (Tan et al., 2009), undertook another prospective study with 1911 patients and although they were not able to validate Rothrock's results, found the criteria a "useful guide". The second study, undertaken by Tung et al. (Tung et al., 2014), showed similar results to Rothrock and advised that patients under 60 years old with no focal neurology, no history of headache with vomiting, or altered mental status could have their CT scan deferred without risk to patient outcome.

The Rothrock criteria offer a simple, easy to understand and implementable guideline with potential positive cost, equipment and human resource benefits for the GSH department of radiology context.

3.3. Other Radiology Guidelines

Local radiation safety guidelines are encouraged within the United Kingdom's National Health Service can be found at the Derby Teaching Hospitals. This policy document describes the roles and responsibilities for both requesting clinicians and radiologists, with some recommendations that include the referring clinician considering the risks of any procedure before requesting a study, the requesting clinician logging-on to their own electronic ordering profile to order an examination and the inclusion of a concise but relevant clinical history in the request (including

previous medical history or surgical procedures) with an appropriate timescale (Barnard, 2011).

A study conducted by Akinola and his colleagues demonstrated that clinicians do not adequately complete radiology request forms and there is associated evidence that a poorly completed request form results in a higher incidence of inaccuracy in radiology reports (Akinola, Wright & Orogbemi, 2010). They further recommended that a review of all radiology requests by a radiologist be undertaken, in order to reduce unnecessary investigations and exposure to radiation.

The current imaging practice within the department of radiology at GSH is based on consultant and senior registrar verbal teaching of junior staff on the accepted local practice. Attempts are currently being made to implement written imaging protocols within the department to enable more consistent imaging of patients.

3.4. Ionising radiation and its biological effects

X-rays are a type of energy in the form of electromagnetic waves with the ability to excite, remove or "ionise" electrons from the atoms which are exposed to them. Exposure to ionising radiation occurs both from the background environment (e.g. cosmic rays or radon gas from rocks), as well as from artificial sources (e.g. nuclear weapons testing or x-ray exposure from medical imaging such as CT scan) (United Nations Scientific Committee on the Effects of Atomic Radiation, 2017).

The *Système international* (SI) unit for absorbed radiation dose is the Gray (Gy), defined as the energy in joules (J) absorbed by each kilogram of exposed body tissue ($J.kg^{-1}$), and is an indication of the physical amount of radiation absorbed. In calculations, the absorbed dose is described as the value *D* :

$$\boldsymbol{Absorbed\ dose = D\ (Gy)}$$

Equation 1 - Mathematical representation of absorbed dose

The concept of effective dose (ED) was introduced in 1975 by Wolfgang Jacobi (Jacobi, 1975) and adopted by the International Commission on Radiological Protection (ICRP) in 1977. It is a single measure used to predict the risk of cancer development in tissues exposed to ionising radiation (Christner, Kofler & McCollough, 2010).

The effects of high dose-radiation exposure are well known due to studies of people exposed to disasters such as the atomic bomb, with development of certain dose related side effects known as deterministic effects. These effects occur at particular radiation doses, dependent on the radiosensitivity of the exposed tissues and occur consistently at these doses. An example of this would be hair loss (epilation) after a dose of more than 3 Gray (Gy) (Bushong, 2008).

The effects of smaller, inconsistent radiation exposures over a period of time are not fully understood but a linear no-threshold (LNT) relationship between radiation dose and cancer development has been assumed, with the effects extrapolated from radioactive disaster survivors. While there is debate in the literature about the LNT model, it remains a "best-fit" model. Patient age, gender and the imaged anatomical region all impact on the risk of cancer development (Shah, Sachs & Wilson, 2012).

Recent research completed by Mathews and his colleagues on paediatric patients showed an increase in cancer rates of up to 24% post-CT scan (Mathews et al., 2013) and this number was widely reported in the media. The Life Span Study of the Japanese Atomic Bomb survivors (Ozasa et al., 2012) confirms a statistically significant increase in some cancer formation in patients under 19 years of age

exposed to radiation but shows no statistically significant increase in thyroid cancer rates for older individuals. The American Association of Physicists in Medicine suggests that medical imaging at doses under 50mSv for single or 100mSv for multiple procedures have a small and potentially non-existent risk of cancer increase (Shah, Sachs & Wilson, 2012).

The Sievert (Sv) is the SI unit indicating the biological effect of an absorbed dose (D); it is also recorded in joules per kilogram ($J.kg^{-1}$). One Sievert is also equivalent to a thousand milli-Sieverts (or expressed differently 1 mSv = 0.001 Sv). ED does not estimate the amount of radiation exposure by an individual (McCollough, Christner & Kofler, 2010), as it is calculated in part by using a standardised imaging phantom. ED does however allow for comparison of radiation doses between different investigation modalities and proof of compliance with regulated dose limits.

3.5. CT Effective Dose calculation and its role in dose estimation

In order to estimate the effective dose (ED) received by the individuals reviewed in this study during their CT scans, the recommendations of the European Commission (2000) was followed (Christner, Kofler & McCollough, 2010). The dose-length product (DLP) in milli-Gray-centimetres (*mGy.cm*), calculated automatically by the CT scanner, was multiplied by a conversion factor *k* as demonstrated:

$$\boldsymbol{ED = k \times DLP}$$

Equation 2 - Alternative formula for calculating ED based on CT scan DLP

The conversion factor (*k coefficient*) for head scanning, expressed in milli-Sieverts per milli-Gray-centimetres (mSv/(mGy.cm)) was previously determined by multiple groups with the most recent detailed in the table 1 below:

	DLP to E - ”k” Conversion Coefficients [mSv / (mGy x cm)]					
Region	Jessen et al. (1999)	EC (2000)	EC Appendix B (2004)	EC Appendix C (2004) and NRPB-W67 (2005)	AAPM Report 96 (2008)	Phantom (cm)
Head	0.0021	0.0023	0.0023	0.0021	0.0021	16

Note: EC = European Commission; NRPB = National Radiological Protection Board; AAPM = American Association of Physicists in Medicine

Table 1 - *k* coefficient used to determine the ED from CT scan DLP

The resultant ED value was reported in milli-Sieverts (mSv) and can be compared to previously published CT head dose estimates.

Mettler and his colleagues (Mettler et al., 2008) compiled a catalogue of adult effective doses from a range of sources and concluded that the recommended ED for a single-phase head CT was 2 mSv (range 0.9 – 4.0 mSv). Another study published in 2009 reported similar results, with a routine head CT resulting in a median radiation dose of 2 mSv, with a range of 0.3 – 6 mSv (Smith-Bindman et al., 2009). These doses are widely accepted and used as the recommended doses for multiple websites including that of the American College of Radiologists, Radiology Info (http://www.radiologyinfo.org/en/info.cfm?pg=safety-xray), which states the average acceptable radiation doses for different imaging modalities as well.

3.6. The project in context: Comparison to other literature

Little literature is available on this topic, in comparison to that involving head CT scans in trauma. A PubMed (www.ncbi.nlm.nih.gov) web search for “urgent AND non-trauma AND CT brain” revealed only twenty-one publications, of which two

were relevant to this study (accessed on 07/03/2016). By comparison entering a similar search altered for traumatic injury ("urgent AND trauma AND CT brain") identifies a total of eighty-two publications.

At GSH there is a lack of accepted internal departmental guidelines for trainees and other staff to utilise when prioritising patients for CT scan. Although senior staff guide daily practice based on their own experience, the lack of formal guidelines leads to varying individual approaches, inconsistencies within our practice and may lead to increased numbers of inappropriate scans.

4. Hypothesis, Study Aims and Objectives

4.1. Research hypotheses

a. Urgent, in-hours non-trauma CT brain scans within the GSH radiology department are being inappropriately performed due to the absence of objective departmental guidelines.

b. Radiation doses for in-hours urgent, non-trauma CT scans completed in the radiology department of GSH, on the Siemens Somatom Emotion 16-slice CT scanner are above recommended thresholds due to scanner age and lack of advanced dose reduction capabilities.

4.2. Study Aims

This study aims to review the in-hours ordering and performance of urgent non-trauma CT brains, within the GSH Department of Radiology, to determine whether the requests are appropriate, the scan procedure is appropriate and to determine the radiation dose for each scan.

The secondary aim is to make recommendations for improving the utilisation of manpower and equipment in the context of local practice, based on the findings of this study.

4.3. Study Objectives

The objectives of this study are to:

1. Determine whether urgent, non-trauma in-hours CT brain scans at the Department of Radiology, GSH, are ordered and completed appropriately, according to local and international criteria.

2. Determine the frequency of positive and negative findings demonstrated on completed urgent, in-hours, non-trauma CT brain scans (outcome of CT scan) within the Department of Radiology, GSH.

3. Determine if the Effective Dose (ED) of the completed urgent in-hours CT brain scans meets with published international standards.

4. Identify and recommend any changes in CT scanning practice that could reduce unnecessary use of constrained local equipment and staffing resources.

5. Study Design

The study was undertaken as a retrospective, descriptive cross-sectional review of urgent, in-hours (08h00-16h00) patient requests for CT head scans. In-hours studies were selected to ensure consultant involvement in application of local guidelines, and in order to prevent bias caused by trainees accepting all CT requests.

The study included the use of procedural parameters and dose records of CT scans completed at the GSH department of radiology.

The three-member panel of radiologists involved in the study were required to complete a written consent form which is attached within the Appendix A. Each panellist was made aware of the possible benefit and potential harm this study could produce, and each was allowed the option to withdraw their participation at any time. The panellists were considered to be co-investigators and have been recognised via co-authorship in this study.

5.1. Study Population

The study population consists of individuals from the approximately 2.65 million adults living in the Cape Town Metropole, seen either as walk-ins from the Groote Schuur Hospital's own emergency department or as referrals from other outside primary and secondary care centres within the hospital drainage area. This state-funded facility is one of multiple referral centres in the province, including the Red Cross War Memorial Children's Hospital which is responsible for caring for the 1.09 million children in the province.

The study cohort was accessed via a systematic collection of data from the GSH department of radiology PACS system, starting from 31 March 2016 and working backwards, applying the exclusion criteria below, until a sample size of 100 qualifying studies was reached using the inclusion and exclusion criteria below.

5.1.1. Inclusion criteria

All in-hours (08h00-16h00) CT brain scans performed using the Siemens Somatom Emotion 16-slice CT scanner at the Department of Radiology, GSH, within the period 1 October 2015 to 31 March 2016 were included.

5.1.2. Exclusion criteria

The following scans were excluded from the study:

1. All in-hours CT brain requests for acute trauma-related indications.
2. All non-urgent CT brain requests, defined as requests not flagged as urgent by the referring clinician through the use of the "Urgent" request status marker on the ordering software.
3. In-hours scans that included other regions of the body such as cervical spine, chest, abdomen and pelvis.
4. CT scans of individuals younger than 18 years of age at the time of scan.

5. Patients with multiple CT brains, in which the urgent study was not the first presentation (i.e. patients in whom imaging findings were already known).
6. Corrupt images or those which were inaccessible.

5.2. Materials and Methods

5.2.1. Ethics

The University of Cape Town (UCT) Faculty of Health Services ethics review board approved the study proposal before the research project was undertaken (Ethics Approval number: HREC 276/2016, attached in Appendix C). No consent was necessary from patients, as the project required no additional patient CT imaging, posed no additional risk to the patients enrolled and fell within the mandate of the Helsinki Declaration of 1964 (and its subsequent amendments).

An extension of ethical approval was sought, and approved, during the write-up of the study results and is attached in Appendix D. The GSH Chief Executive Officer (CEO) also granted permission to access the electronic patient requests and associated CT scan reports stored on the hospital Picture Archiving and Communication System (PACS) before the project commenced (see Appendix E).

The master data set was gathered from the Picture Archiving and Communication System (PACS) system of the Department of Radiology, GSH, over the selected study period. The data set included anonymised study requests and reports, with all identifying patient information replaced with a number cipher. All qualifying scans were collated by the primary researcher into a Microsoft Excel spreadsheet that contained the anonymised CT scan meta-data.

The consultants assisting in this study only had access to previously anonymised data. This data presented on a questionnaire, an example of which can be found in Appendix B, was removed from the investigators directly after they had completed

the study. The questionnaire responses were captured. The master data set will be held by the primary examiner for a period of time, as deemed appropriate by the faculty, before being destroyed.

5.2.2. Data Collection

Inappropriate CT studies, which are defined as studies performed for an incorrect indication or study protocol, were identified in two groups.

The primary investigator used an internationally validated and objective screening tool for urgent, non-traumatic CT brain requests developed by Rothrock (Rothrock et al., 1997), which included: *Age ≥60 years, focal neurological deficit, headache with vomiting, and altered mental status*. A request was deemed appropriate by the researcher if it fulfilled at least one of the Rothrock criteria stated above. The Rothrock criteria were used as the standard measure of urgent, non-trauma CT brain scan appropriateness, as the criterion is objective and has been scientifically validated.

The primary investigator collected data under the following categories:

a. Demographics and age category:

Patient gender and date of birth (to determine age at the time of the scan) were recorded. The referring ward, GSH out-patient clinic, or external institution were also recorded to determine where most in-hours, urgent non-trauma scans originated from to assist in targeting any future interventions.

b. Referral category:

The patient's medical history was categorised according to one of eleven variables, used by Rothrock et. al in their original paper, namely: *Headache, Altered Mental State, Focal Weakness, Seizure (First time seizure), Gait disturbance,*

Syncope, Dizziness (or Vertigo), Vomiting, Altered speech, Sensory deficit, or *Other.* This was done in an effort to replicate the data collection process of the validated Rothrock criteria and make comparing outcomes as scientifically valid as possible.

c. Scan procedure requested and performed:

The type of scan requested (uncontrasted, contrasted, pre- and post-contrasted or CT angiogram), as well as the type of scan actually performed were recorded.

d. Scan outcome:

The researcher categorised each CT scan outcome, based on the final CT scan report, as one of the following options: *Normal, Acute Stroke – Haemorrhagic, Acute Stroke – Non-haemorrhagic, Intracranial Bleed – Sub-arachnoid, Intracranial Bleed – Subdural, Intracranial Bleed – Other, CNS Malignancy, Intracranial Aneurysm/AV malformation, Hydrocephalus (or shunt malfunction), Dural venous sinus thrombosis, Infection,* or *Other*.

These outcomes were recorded and the frequency of normal and abnormal findings on qualifying CT scans was determined in order to show if a relationship between clinical symptoms (determined by requesting physicians and recorded on the CT request) and CT study findings (determined by the finalised CT report) exists.

e. CT dose parameters and Effective Dose calculation:

The researcher collected and analysed CT dosage, based on data points collected after every scan, including kVp, mAs, CTDI-vol and DLP. The Effective Dose (ED) of each CT scan was determined by multiplying the pre-recorded DLP and an internationally validated *k* coefficient for head CT of 0.0021 mSv/(mGy.cm), as described by the latest EC and AAPM recommendations (as per section 3.5). The Effective Dose range median and mean were determined and compared against the

internationally published recommendations, as described by Mettler and Smith-Bindman respectively (Mettler et al., 2008; Smith-Bindman et al., 2009).

A 3-person panel of radiology consultants employed by the GSH Department of Radiology was enlisted as co-investigators who each independently assessed the same urgent, non-trauma CT head scans that were reviewed by the researcher. The panellists individually reviewed the CT request data and categorised the indication into one of eleven variables, namely: *Headache, Altered Mental State, Focal Weakness, Seizure (First time seizure), Gait disturbance, Syncope, Dizziness (or Vertigo), Vomiting, Altered speech, Sensory deficit,* or *Other.*

The consultants then scored the appropriateness of the request, based on their own perception of acceptable local practice within GSH, using a 4-point Likert scale - *Inappropriate, May Be Appropriate, Appropriate or Not Able to Decide (see A*ppendix B*).*

The consultant responses were recorded in a Microsoft Excel database and analysed via a weighted *Kappa coefficient* to determine if urgent, non-trauma CT brain requests and the study outcomes could be more accurately predicted by using objective criterion over individual practice.

The weighted kappa was chosen as it assigns less weight to agreement when the categories are on a continuum (Viera & Garrett, 2005), allowing the combination of categories “appropriate” and “may be appropriate” to obtain a more clinically relevant result.

The Kappa statistic is displayed as a range of values from 0 to 1, with zero representing less than chance agreement and one perfect agreement. Table 2 below illustrates the different values and their accepted agreement ratings.

Kappa Value	Agreement
<0	Less than chance agreement
0.01-0.20	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement

Table 2 - Interpretation of Kappa Values (as per Viera (Viera & Garrett, 2005)

A consensus view was then obtained by applying a majority rule to the consultant opinion. For example, if all three consultants agreed that a study was appropriate, then the recorded consensus view was “appropriate”. If there was no majority view, then the category applied was labelled as a “not able to decide”.

The authors compared the Rothrock agreement between one reader (the researcher) using the Rothrock criteria against the consultant interpretation of appropriateness, which was collated in order to determine inter-measure concordance. The Rothrock criteria were used as the standard measure of appropriateness as it is an objective and scientifically validated measure. Analysis by cross tabulation with weighted *Kappa coefficient* was then undertaken.

6. Study Results

Study Demographic Data

A total of 10960 CT scans were completed in the department of Radiology at GSH within the study time period, 1 October 2015 to 31 March 2016. A total of 6315 (57.6%) involved the head, neck and face with 5427 (49.5%) involving the head only. A small number (639 or 11.8%) of brain-only studies were marked as urgent with 132 (2.4%) marked as urgent without a history of trauma. These are summarised in Table 3 below.

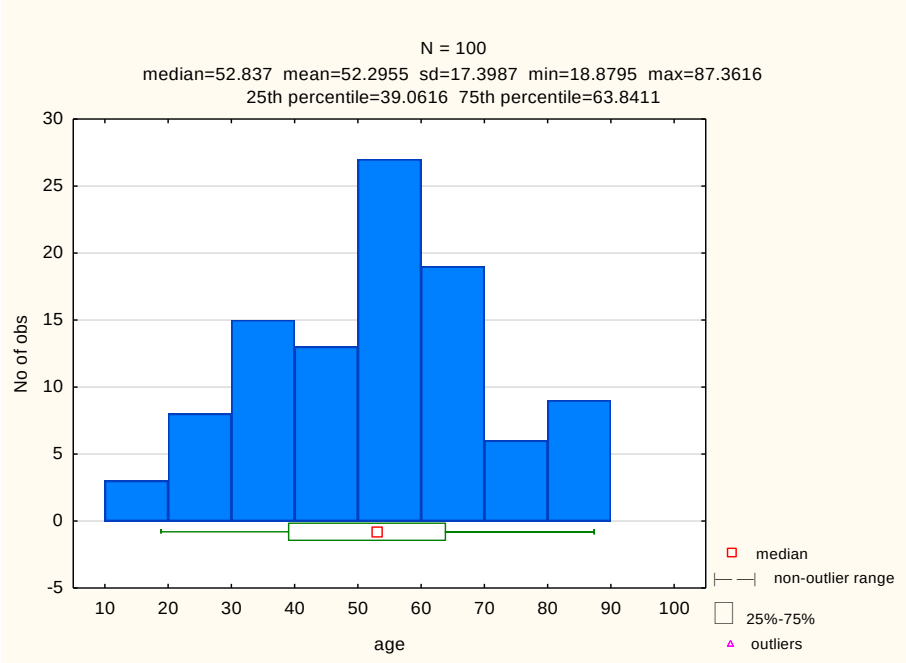
Total of All CTs for study period (01-10-2015 to 31-03-2016)	**10960**
Total of All CTs involving the Head, Neck and Face	6315
CT Brain only scans	5427
Urgent CT Brains	639
Urgent, Non-trauma CT Brains	132

Table 3 - CT studies completed during study period

A sample of 100 patient records were recruited for inclusion in the study after application of the inclusion and exclusion criteria as previously described. The study cohort made up 15.6% of the total emergency head CT scans undertaken during the study period, but less than one percent (0.91%) of the total CT studies and 1.84% of all brain CTs completed during the study period.

The study cohort included 55 males and 45 females with an age distribution range from a minimum of 18.8 years to maximum of 87.4 years, with a mean participant age of 52.3 years. Age distribution is summarised in Graph 1 below. Of the total included individuals, 66 (66%) were younger than 60 years of age.

Of the 34 individuals older than 60 years of age, 33 (97%) had two or more positive Rothrock criteria.

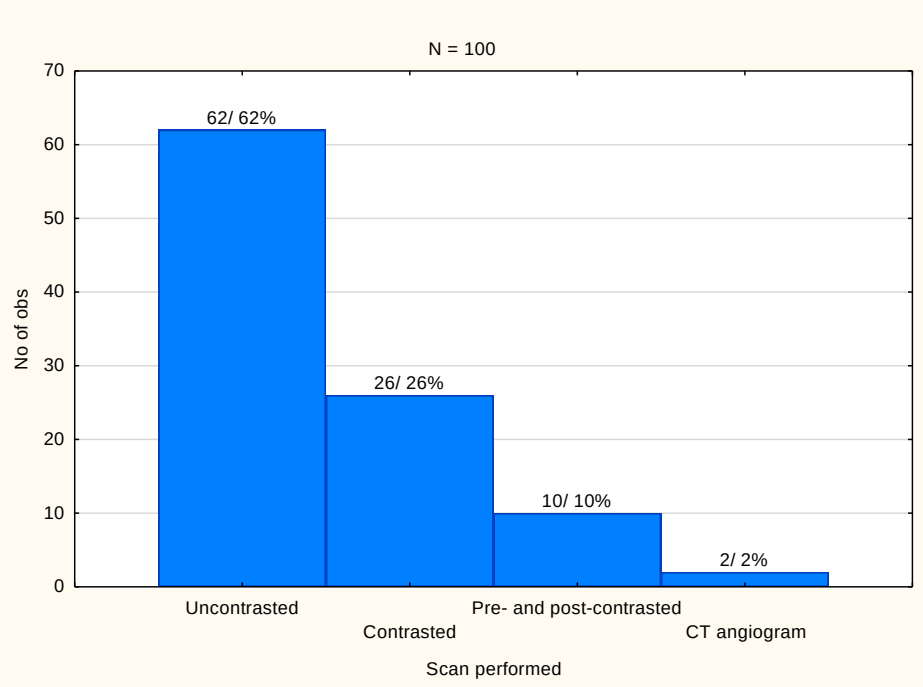


Graph 1 - Age Distribution

The majority of urgent, non-trauma CT brain requests were received at GSH through the Medical Emergency Unit (C15), totalling 66% of the study cohort. The remaining referrals were received throughout the hospital wards, with Medical ICU (C27) (4 referrals), Medical ward (G16) (3 referrals) and Dermatology ward (G23) (3 referrals) being the next largest contributors.

Uncontrasted CT scans were the most commonly requested investigation within the study cohort (66%), followed by Contrasted (26%) and combined Pre- and Post-contrast studies (8%).

The actual CT study completed did not differ significantly from the scan requested, with only 2 studies (2%) being completed as combined Pre- and Post-contrast CTs rather than a single uncontrasted phase scan (see Graph 2 below).



Graph 2 - Actual CT scan performed

Radiation Doses

Scans completed at GSH on the Siemens Somatom Emotion 16-slice CT scanner have the calculated phantom-based radiation doses captured as a Radiation Dose Structured Report (RDSR) as recommended in the Digital Imaging and Communication in Medicine (DICOM) standard demonstrated below in Figure 1.

24-Feb-2016 12:13

Ward:
Physician:
Operator:

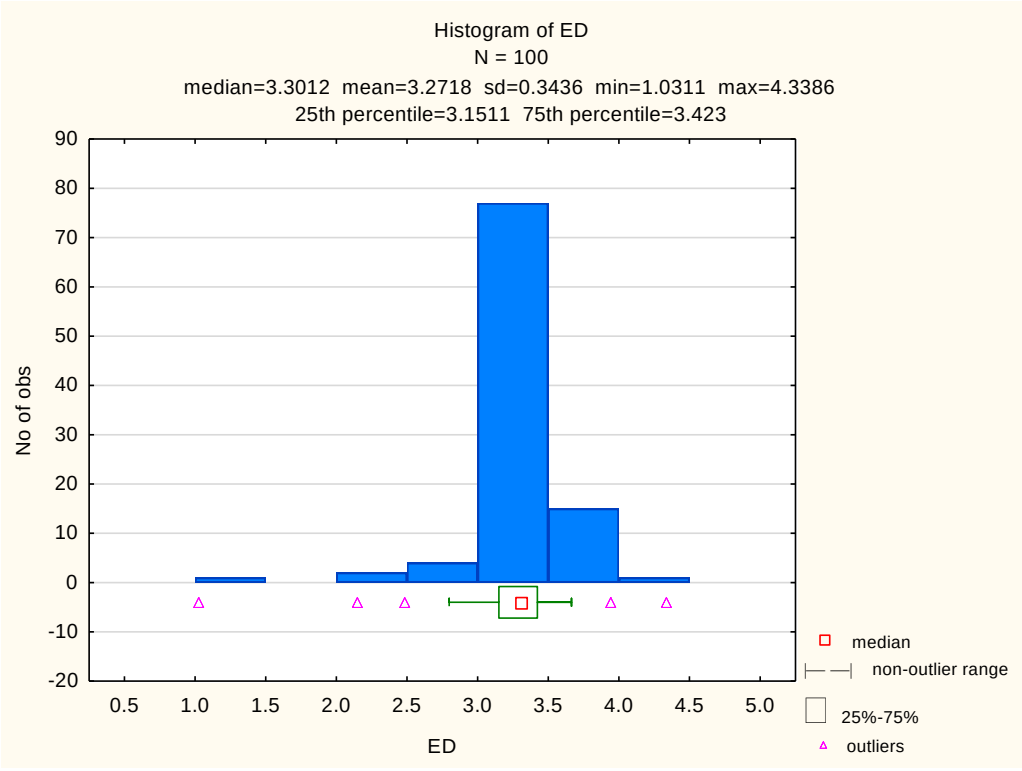
Total mAs 5767 Total DLP 1367

	Scan	kV	mAs / ref.	CTDIvol	DLP	TI	cSL
Patient Position H-SP							
Topogram	1	130				3.4	0.6
Brain	2	130	320	85.28	1367	1.5	0.6

Figure 1 – Example of a radiation dose report from GSH Siemens Somatom Emotion 16-slice CT scanner

All brain CT studies included in the study used a standard kVp (130V) and mAs (320 mAs) when performing the scan. The majority of CT scans included in this research comprised a single pre- or post-contrast study (86%), with the remaining scans comprising both a pre- and post-contrast study (13%). A single scan had 4 incomplete studies, as the patient was restless and the scan had to be abandoned and reattempted at a later stage.

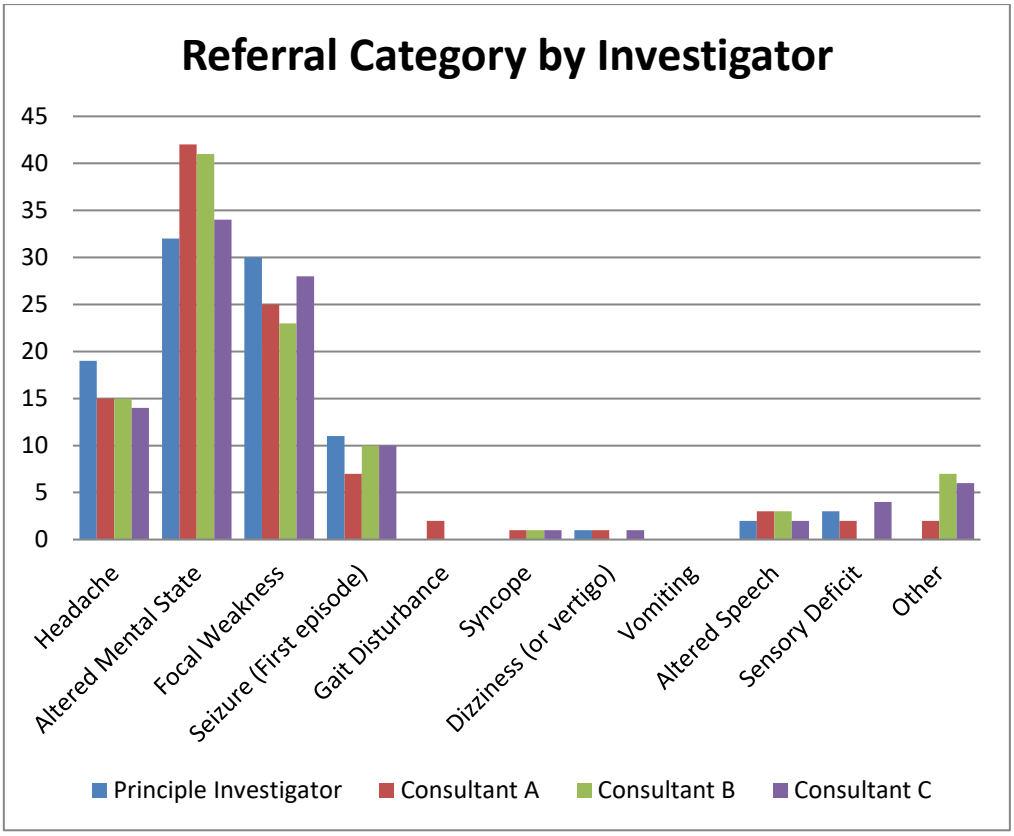
The Effective Dose (ED) of radiation was calculated by using the formula described in section 5.2, with the product being described in milli-Sievert (mSv). The mean value obtained for all CT scans within the cohort was 3.27 mSv, with a lowest value of 1.03 mSv and a maximum ED of 4.33 mSv. The mean ED for the 86 single-phase CT scans included in the cohort was marginally higher at 3.31 mSv, with a range from 2.79 mSv to 4.33 mSv. ED categories are summarised in Graph 3 below.



Graph 3 - Calculated ED of CT scans included in the study

Referral Category

The researcher and consultant panel each categorised the patient request information into one of 11 categories, illustrated in graph 4 below, with the last category designated as “Other” to include any descriptions not covered by the remaining options.



Graph 4 - Referral category of each CT scan reviewed

The researcher and the consultant panel categorised the majority of referrals for urgent, non-trauma CT brain studies into four categories, namely: headache, altered mental state, focal weakness or seizure. There was, however, significant variability in the numbers of studies assigned to each category.

The remaining referral categories made up a maximum of 14% of the total referrals and again there was again some variability in numbers.

CT Scan Appropriateness Categorisation

The researcher categorised each referral using the Rothrock criteria to decide whether they were appropriate or not. This resulted in a majority (81%) of requests being labelled as appropriate while 17% were considered inappropriate. A further two studies (2%) could not be categorised due to insufficient clinical information with which to apply the Rothrock criteria.

In a similar manner but using their individual interpretation of what constitutes an appropriate request, a panel of three consultants was also asked to categorise the included CT requests as “Appropriate”, “Inappropriate”, “May be appropriate” or “Not able to decide”. The results are summarised in Table 4 below.

Consultant	Appropriate	Inappropriate	May be appropriate	Not able to decide
A	72 (72%)	22 (22%)	5 (5%)	1 (1%)
B	58 (58%)	7 (7%)	35 (35%)	0
C	56 (56%)	21 (21%)	23 (23%)	0

Table 4 - Consultant categorisation of CT request appropriateness

The consultant consensus opinion, as previously detailed in the methods section, found 67% (n=67) of studies were appropriate, 16% inappropriate and “may be appropriate” in 11%. The “not able to decide” category was used in 6% of cases.

CT Scan Outcome:

The outcome of each completed investigation was recorded by the researcher to determine the frequency of positive and negative findings. Any normal CT study report, or one in which the finding was considered either a normal variant or unrelated to the patient's presenting complaint was recorded as "normal". The remaining findings were recorded as "abnormal" and categorised as per the Materials and Methods section. Table 5 below summarises the CT scan outcomes by category.

CT Outcome Category	n=100
Normal	52
Acute Stroke - Non-Haemorrhagic	22
Acute Stroke - Haemorrhagic	1
Intracranial Bleed - Subdural	7
Intracranial Bleed - Subarachnoid	3
Intracranial Bleed - Other	4
Malignancy	7
Dural venous sinus thrombosis	1
Infection	1
Other	2

Table 5 - CT scan outcome by category

A small majority of studies were found to have a pathological finding (52%) and the remaining findings were considered normal (48%) using the definition described above. Of the 34 individuals older than 60 years of age, 18 (53%) had abnormal CT scan results.

In order to compare the perceived study appropriateness and clinical outcomes, using a two-way summary table, the previously collected appropriateness categories were simplified and categories merged. The patients categorised in the "not able to decide" consensus view were removed from the statistical analysis, to

prevent bias. The remaining “appropriate” and “may be appropriate” results were merged, in order to simulate the most likely clinical scenario of a study being completed by a radiologist, even if there was some doubt about the appropriateness of the request..

98 cases were included in the statistical analysis of request appropriateness using the Rothrock criteria against study outcome, with two cases being removed due to their categorisation as “not able to decide”. This is summarised in Table 6 below.

The majority of requests were considered “appropriate” (81%), while the remainder were considered “inappropriate” (17%). A total of 51 out of the 98 included outcomes (52%) were abnormal, with the remaining 47 (48%) study outcomes normal. The weighted Kappa demonstrated a slight- to fair agreement between scan outcome and request appropriateness using the Rothrock criteria (weighted kappa 0.20; 95% CI: 0.06-0.35, p=.00861).

	Outcome Normal	Outcome Abnormal	**Total**
Inappropriate Request	13	4	**17**
Appropriate Request	34	47	**81**
Totals	**47**	**51**	**98**

Table 6 - Researcher request appropriateness vs. CT scan outcome

The consensus consultant comparison between request appropriateness and outcome, involved 94 patients as 6 were removed due to the lack of consensus view. The majority of studies were again thought to represent appropriate referral 78 (84%) while a smaller number 15 (16%) were deemed inappropriate. This is summarised in Table 7 below.

The spread of outcomes was evenly distributed, with a small majority being abnormal (49; 52%) and the remaining outcomes being normal (45; 48%). The

weighted Kappa showed a less than chance to fair agreement (0.10; 95% CI: -0.05-0.26; p=.19728).

	Outcome Normal	Outcome Abnormal	**Total**
Inappropriate Request	10	6	**16**
Appropriate Request	35	43	**78**
Totals	**45**	**49**	**94**

Table 7 - Consensus consultant request appropriateness vs. CT scan outcome

As can be seen in Table 8 below, the greatest degree of inter-observer correlation with regards to request appropriateness occurred between the investigator using the Rothrock criteria and consultant A (kappa=0.52; moderate agreement). A similar correlation level was demonstrated between consultant A and consultant C (kappa=0.52; moderate agreement), while the poorest inter-observer correlation with respect to request appropriateness was noted to be between the researcher and consultant C (kappa=0.09; slight agreement).

In terms of CT study outcome and request appropriateness judged by the researcher, the weighted kappa value indicated fair agreement (kappa=0.20; range: 0.06-0.35).

There was fair agreement between the consensus consultant opinion and researcher using the Rothrock criteria with a small improvement in the weighted kappa inter-observer rating to 0.29 (range: 0.03-0.52).

Rater 1	Rater 2	Weighted Kappa	Range
Consultant A	Consultant B	**0.29**	(0.06-0.52)
Consultant A	Consultant C	**0.52**	(0.27-0.70)
Consultant B	Consultant C	**0.36**	(0.12-0.59)
Researcher	Consultant A	**0.52**	(0.30-0.73)
Researcher	Consultant B	**0.17**	(-0.06-0.41)
Researcher	Consultant C	**0.09**	(-0.11-0.30)
Researcher	Consultant Consensus	**0.29**	(0.03-0.52)
Researcher	CT Outcome	**0.20**	(0.06-0.35)
Consultant Consensus	CT Outcome	**0.10**	(-0.05-0.26)

Table 8 - Weighted Kappa outcomes for each investigator

7. Discussion

Within the resource-constrained public health sector, the department of radiology at Groote Schuur Hospital continues to strive for practice that is evidence-based while maximising available resources. The aim of this study was to assess the practice of urgent in-hours, non-trauma CT scans and determine if more effective use can be made of both human and mechanical resources while ensuring that studies which are clinically appropriate can be completed timeously.

We determined that without published departmental guidelines, practice varies between individual consultants and junior staff. The consultant panel demonstrated at best a moderate inter-observer correlation (weighted kappa 0.29-0.52) when determining study appropriateness based on clinical history alone, with at best moderate correlation (weighted kappa 0.09-0.52) between the Rothrock criteria and individual consultants.

Within the study cohort, a small majority (52%) of participants had abnormal CT results and this statistic was consistent in all age-groups. While normal scan results may be useful in planning patient management, unnecessary radiation exposure carries potential increased cancer risk (Mathews et al., 2013) and uses already strained resources (Rothrock et al., 1997).

Application of the Rothrock criteria demonstrated a statistically significant correlation between CT request appropriateness and CT scan outcome (weighted Kappa 0.20; 95% CI: 0.06-0.35, p=.00861) in our setting, while the consultant consensus did not (weighted Kappa 0.10; 95% CI: -0.05-0.26, p=.19728). This suggests that the Rothrock criteria could be introduced as an objective and easily applicable screening tool, but it is not sensitive or specific enough to be the only decision criterion. This is consistent with the findings of Tan et. al, in their previously mentioned research (Tan et al., 2009).

Despite reading the same patient CT requests, there were inconsistencies between the principle examiner and consultant panellists in categorising the clinical indication for most CT requests. While there are multiple reasons that this could occur, the investigators have identified that the Radiology Information System (RIS) used by clinicians at GSH (currently *Physician Utility, Version 8.2.15.1* provided by *Phillips Healthcare Informatics*, a subsidiary of Koninklijke Philips Electronics, N.V.) to order radiological studies provides a simple text box for inputting of patient clinical data. There is therefore no consistent method in use by the referring clinician to describe the main clinical presentation or concern.

This is not a new observation, with multiple studies showing that radiological request forms are often inadequately completed by clinicians (Akinola, Wright & Orogbemi, 2010; Anjum & Ahmad, 2016).

Two-thirds (66%) of the referrals for in-hours, urgent non-trauma brain studies originate in the Medical Emergency Unit (C15) with in-patients making up the remaining 33%.

The mean radiation dose received by all patients in this this study was 3.27 mSv (range: 1.03-4.33 mSv), which falls within the accepted dose range published by both Mettler (Mettler et al., 2008) and Smith-Bindman (Smith-Bindman et al., 2009). The mean ED for the 86 single-phase CT scans included in the cohort was marginally higher at 3.31 mSv (range: 2.79-4.33 mSv). This is due to some partially CT scans being included in the dose estimation calculations resulting in the apparent radiation dose discrepancy. The average estimated dose of radiation is however above the accepted point value described (2 mSv) and should be reduced if possible

Each CT scan completed in the cohort used a standard radiation dose setting, with mAs of 320 mAs and kVp of 130 V. The recommended settings described in the user's manual for the Siemen's Somatom Emotion CT scanner include a $CTDI_{vol}$ of 79.65, an mAs of 270 and kVp of 130, which produce an effective dose of between 2.29 and 2.55 mSv(Siemens AG, 2007). The reference quantities can however be altered by using the automatic exposure control (AEC) software supplied by the vendor. Literature (Raman, Johnson & Deshmukh, 2013; Mayo-Smith & Hara, 2014) shows that tailoring the mAs and kVp to patient size can reduce radiation dose, however this should be balanced by the resultant image quality which may be sub-optimal if the incorrect parameters are used. The authors support the FDA recommendations to establish diagnostic radiation reference levels for CT scans completed in the department, improve radiation safety awareness and establish a local QA committee to address radiation dose reduction strategies (FDA, 2017).

The majority of CT studies (86%) within the study cohort were completed in a single phase which, when clinically appropriate, is the accepted departmental practice. This has the benefit of reducing overall CT scan times per patient, potentially increasing the number of patients that can be scanned, reduction of financial costs to the institution and patient, as well as radiation dose reduction.

8. Recommendations

The authors recommend that a departmental policy be implemented for all CT scan requests, including urgent non-trauma CT brain requests. This would involve describing the responsibilities of both the requesting physician and the radiologist. This policy should address the concept of an adequate request and suggested policy inclusions based on this study are that the risk of any procedure be considered, that the requesting physician uses their own electronic ordering profile on *Physician Utility* and that a concise clinical history be included.

With regards to the included clinical history, the inclusion of two vital points in each request is recommended: the main clinical presentation and major clinical concern. The main clinical presentation would include the patient's main symptoms or clinical signs and include categories such as "focal neurological fallout", "first episode of seizures" or "headache with vomiting". The major clinical concern would be the main condition the clinician wishes to confirm or rule out; examples would include "malignancy" or "intracranial bleed".

We recommend that wherever possible, only a single main symptom and clinical concern is included in each request by the referring clinician, rather than a long list of possible differential diagnoses. This will allow the radiologist to accurately assess a request, prioritize the request effectively and decide on the optimum protocol to use when imaging the patient.

The authors recommend that a Quality Assurance (QA) task-team be setup to address CT radiation dose policies, as recommended by the FDA (FDA, 2017b). A panel composed of radiographers, medical physicists and consultants should be established to review the current CT head imaging practices and radiation doses, to ascertain if scans with a lower radiation dose are viable. It is recommended that this panel look at different mechanisms to reduce radiation dose, including changing

mAs and kVp settings either manually or through AEC. Further, the panel should review and consider protocol implementation to reduce unnecessary dual-phase studies and investigate the feasibility of CT slice thickening, to reduce radiation doses.

It is further recommended that the departmental policy on CT scan ordering and the best practice guidelines developed above are disseminated to the clinicians based at Groote Schuur Hospital via an internal memorandum.

Further research is recommended on the impact of any of the recommendations undertaken above, to improve the service offered by the department while reducing costs, decreasing patient radiation exposure and improving operating efficiency and inter-departmental co-operation.

We propose a targeted intervention be undertaken with the staff of the Medical Emergency Unit, to ensure that they are made aware of the new policies and guidelines. This intervention should include interns, medical officers and registrars that work in the unit and may need to be repeated with each rotation of staff. A comparative study may be conducted after the introduction of the proposed requesting system to assess the outcomes of our recommendations.

9. Conclusion

Retrospective application of the Rothrock criteria to patient referrals resulted in moderate correlation with outcome while current departmental practice by a panel of consultants using their own practice criteria showed only fair correlation. There is however, at best, only a moderate agreement between consultants with regard to classification of referrals, which could negatively affect the application of Rothrock criteria in practice. Incorporating the Rothrock criteria into published departmental guidelines, in conjunction with other interventions to improve clinician requesting practices, is recommended.

While the average radiation doses in the GSH radiology department fall within the accepted limits described by Mettler and Smith-Bindman, they may be marginally higher than those recommended by Siemens AG.T he formation of a Quality Assurance team and the use of existing dose-reducing techniques may assist in reducing radiation doses further.

The suggested changes will likely improve daily departmental practice and ensure our urgent non-trauma CT brain scans are completed to an international standard and in a rational manner that balances both clinical expectation and available departmental resources.

9. Acknowledgements

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11. Appendix A – Informed Consent

Non-trauma, Urgent CT Head Study

Informed Consent Document

Thank you for agreeing to be part of this study; it is only through your assistance that this project will succeed. This study strives to maintain the highest ethical standards and correct ethical approval has been granted.

The aim of this study is to assess how we at Groote Schuur Hospital handle urgent in-hours CT heads, in the non-trauma setting, compared to other centres. All answers will be strictly confidential and any results will be anonymised to further ensure both patient and panel member confidentiality.

The outcomes of this study may demonstrate deficiencies in the performance of the studied CT investigations which carries a small risk of damage to your personal reputation, although this is unlikely. The aim of this study is to improve local practices and reduce, where possible, patient radiation dose.

You are advised that you may withdraw from this study at any time and for any reason.

Once the results have been collated, you will be contacted with the results and be able to access the full study document.

In a few minutes you will be asked to review some CT head scans. As you do this, please keep in mind how you would normally protocol the scan during a typical day at Groote Schuur Hospital, using the locally accepted practice.

Thank you again for giving of your valuable time to further this research project, please sign below to show your acceptance of these terms.

Consultant Signature:_____ Date:_____

Please feel free to contact the researcher for any further information, or for any queries:

Dr. Donovan Jacobs - Radiology Department, Groote Schuur Hospital, Observatory, Cape Town

Phone: (W) 021-404 4184 (C) 082-794 0785 Email: dr.donjacobs@gmail.com

11. Appendix B – Research Tools

CT Head Data Collection Tool: Principle Investigator (International Guidelines)

A) Patient Demographics:

Study Number: _____

Participant Date of Birth: _____ Patient Age at scan: DERIVED

Referring Ward / Clinic: _____

Patient Gender:

Male.....0
Female.....1

B) Referral Category:

Headache.....1
Altered Mental State.....2
Focal Weakness.....3
Seizure (First time seizure).....4
Gait disturbance.....5
Syncope.....6
Dizziness (or Vertigo).....7
Vomiting.....8
Altered speech.....9
Sensory deficit.....10
Other.....11
If Other, please specify: _____
Additional Comments: _____

C) Requested Scan Type:

Uncontrasted.....1
Contrasted.....2
Pre- and Post-contrast.....3
CT Angiogram.....4
Other.....5
If Other, please specify: _____

D) Request Appropriateness:

Inappropriate.....1
Appropriate.....2
May be appropriate.....3
Not able to decide.....4

ROTHROCK CRITERIA:
AGE ≥60 YEARS
FOCAL NEUROLOGICAL DEFICIT
HEADACHE WITH VOMITING
ALTERED MENTAL STATUS

INAPPROPRIATE = CT should not be completed as an urgent
APPROPRIATE = CT should be added to and completed as urgent
MAY BE APPROPRIATE = some merit for being urgent but you may have some doubt
NOT ABLE TO DECIDE = cannot determine whether or not a study should be added to the urgent list. This category would include unintelligible or blank requests.

E) Scan Performed:

Uncontrasted.....1
Contrasted.....2
Pre- and Post-contrast.....3
CT Angiogram.....4

F) Scan Outcome:

Normal.....1
Acute CVA – Haemorrhagic.....2
Acute CVA – Non-haemorrhagic.....3
Intracranial Bleed – Sub-arachnoid.....4
Intracranial Bleed – Subdural.....5
Intracranial Bleed – Other.....6
CNS Malignancy.....7
Aneurysm/AV malformation.....8
Hydrocephalus (or shunt malfunction).....9
Dural venous sinus thrombosis.....10
Infection.....11
Other.....12
If Other, please specify: _____

SCAN OUTCOME:
NORMAL – examination did not reveal any clinically significant findings (this includes scans with only incidental or non-contributory findings).
ACUTE CVA – HAEMORRHAGIC = CVA with haemorrhagic conversion.
ACUTE CVA – NON-HAEMORRHAGIC = CVA with no intracranial haemorrhagic conversion.
INTRACRANIAL BLEED – SAH = acute or chronic sub-arachnoid haemorrhage.
INTRACRANIAL BLEED – SDH = acute or chronic sub-dural haemorrhage.
INTRACRANIAL BLEED – OTHER = combination of the above two categories, post-neurosurgical haemorrhage or if the bleed does not fit into the categories listed above
CNS MALIGNANCY = primary malignancy or metastatic disease
ANEURYSM/AV MALFORMATION = abnormal arterial vessels or veins, or AV malformation
HYDROCEPHALUS (OR SHUNT MALFORMATION) = ventricular system is enlarged, or if an intracranial shunt appears to be functioning improperly (ie. Either not draining or over-draining csf).
DURAL VENOUS SINUS THROMBOSIS = clot within the dural venous sinuses, including the superior sagittal sinus and cavernous sinus.
INFECTION = suspicion of intracranial infective lesions, such as toxoplasmosis, tuberculoma, or neurocysticercosis.
OTHER = diagnosis does not fit into any of the above categories

G) Dose parameters and ED:

kVp: _____
mAs: _____
Total mAs: _____
DLP: _____
ED: _____mSv

CT Head Data Collection Tool: Local Guidelines

A) Patient Demographics:
Study Number: _____

B) Referral Category:
Headache.....1
Altered Mental State.....2
Focal Weakness.....3
Seizure (First time seizure).....4
Gait disturbance.....5
Syncope.....6
Dizziness (or Vertigo) 7
Vomiting.....8
Altered speech.....9
Sensory deficit.....10
Other.....11
If Other, please specify:

_____
Additional Comments:

_____

C) Requested Scan Type:
Uncontrasted.....1
Contrasted 2
Pre- and Post-contrast.....3
CT Angiogram.....4
Other.....5
If Other, please specify:

_____

D) Request Appropriateness:
Inappropriate.....1
Appropriate.....2
May be appropriate 3
Not able to decide 4

REQUEST APPROPRIATENESS GUIDELINE:
Please choose one of the following options, while thinking of the accepted practice at Groote Schuur Hospital.

If you had to protocol this request, how would you describe its merit in terms of the accepted practice of your organization? Please choose one of the following:

INAPPROPRIATE – if you feel the CT should not be completed as an urgent scan, and should be added to an elective or semi-elective list.
APPROPRIATE – if you feel the CT should be added to and completed as an urgent scan.
MAY BE APPROPRIATE – if you feel that the scan has some merit for being on the urgent list but you may have some doubt about that decision.
NOT ABLE TO DECIDE – if you cannot determine whether or not a study should be added to the urgent list. This category would include unintelligible or blank requests.)

12. Appendix C – Ethical Approval

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 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

12 May 2016

HREC REF: 276/2016

Prof S Andronikou
Department of Radiology
Division of Radiation Medicine
Radiology Street-NGSH

Dear Prof Andronikou

PROJECT TITLE: AN APPROPRIATENESS REVIEW OF URGENT IN-HOURS NON-TRAUMA CT BRAIN SCANS AT A SINGLE TERTIARY REFERRAL CENTRE IN SOUTH AFRICA - ARE WE SCANNING RATIONALLY? (MMED CANDIDATE - DR D JACOBS)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) 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 30 May 2017.

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/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student, Dr Donavon Jacobs will also be involved in this study.

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

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Yours sincerely

pp T Burgess

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 276/2016

13. Appendix D – Extension of Ethical Approval

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

ETHICS COMMITTEE
13 NOV 2017
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.11.2018
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	13/11/2017

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	17/10/2017		
HREC REF Number	276/2016	Current Ethics Approval was granted until	31/05/2017
Protocol title	**An appropriateness review of urgent in-hours non-trauma CT brain scans at a single tertiary referral centre in South Africa - are we scanning rationally?**		
Protocol number (if applicable)	276/2016		
Are there any sub-studies linked to this study?	☐ Yes ☑ No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Dr Donovan Jacobs		
Department / Office Internal Mail Address	Department of Radiology, C16 New Groote Schuur Hospital		

1.1 Does this protocol receive US Federal funding?	☐ Yes	☑ No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

14. Appendix E – GSH Research Permission

Western Cape Government
Health

GROOTE SCHUUR HOSPITAL
Enquiries: Dr Bernadette Eick
E-mail : Bernadette.Eick@westerncape.gov.za

Professor S. Andronikou
Department of Radiology
C-Floor – New Main Building

E-mail: dr.donjacobs@gmail.com

Dear Professor Andronikou

RESEARCH PROJECT: An Appropriateness Review of Urgent In-Hours Non-Trauma CT Brain Scans at a Single Tertiary Centre in South Africa – Are We Scanning Rationally (MMed. Dr D. Jacobs)

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research which is valid until **30th May 2017.**

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) No additional costs to the hospital should be incurred i.e. Lab, consumables or stationary may be used.
d) **No patient folders may be removed from the premises or be inaccessible.**
e) Please introduce yourself to the person in charge of an area before commencing.
f) Please discuss the study with the HOD before commencing.
g) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
h) Confidentiality must be maintained at all times.
i) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
j) **On completion of research, please submit a copy of the publication or report.**

I would like to wish you every success with the project.

Yours sincerely

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER
Date: 27th June 2016
BE/vms

C.C. Mr L. Naidoo
Professor E. Weimann
Professor S. Beningfield

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Observatory 7925

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www.capegateway.go.v.za