Adherence to and effectiveness of guidelines for routine investigations of adult patients with mental and behavioural disturbances

By

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Declaration

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ACEP	American College of Emergency Physicians
Cr	Creatinine
CT	Computed Tomography Scan
DALYs	Disability adjusted life years
DAP	Data analysis plan
EC	Emergency Centre
ECM	Enterprise content management (electronic medical records)
ESKD	End Stage Kidney Disease
GMC	General Medical Condition
HECTIS	Hospital and Emergency Centre Tracking Information System
HGT	Human blood glucose test
HIV	Human Immunodeficiency Virus
LMIC	Low- and Middle-Income Countries
LOS	Length of Stay
LP	Lumbar Puncture
MMed	Master of Medicine
MHCU	Mental Health Care User
MPH	Mitchells Plain District Hospital
Na	Sodium
NHLS	National Health laboratory Services
POU	Psychiatric Observation Unit
RPR	Rapid Plasma Reagin
SASH	South African Stress and Health Survey
TPHA	Treponema Pallidum Hemagglutination Assay
TSH	Thyroid Stimulating Hormone
USA	United States of America
WCG	Western Cape Government
VDRL	Venereal Disease Research Laboratory
WCC	White Cell Count
WHO	World Health Organisation

PART A: MANUSCRIPT IN ARTICLE FORMAT

Title page

Routine investigations for patients with mental and behavioural disturbances: a descriptive analysis.

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Abstract

Background

The process of medical clearance aims to exclude a general medical condition as an underlying cause for the mental and behavioural disorder and involves routine screening with special investigations. Mitchells Plain District Hospital's emergency centre follows the Western Cape Provincial guidelines when screening for general medical conditions in these patients. Adherance and effectiveness of these guidelines is unknown.

Aim

This study aimed to determine the effectiveness of and adherance to the Western Cape Provincial guidelines for routine investigations of adult patients with mental and behavioural disturbances presenting to a district level emergency centre.

Methods

This descriptive study was conducted at Mitchells Plain Hospital in Cape Town, South Africa. Data was collected from existing electronic registries over a 6-month period. Adult mental health care users were risk stratified into the probability of having a general medical condition according to provincial guidelines and the results of their special investigations were described against their outcome.

Results

Of the 688 patients included in this study, 66% had abnormal vital signs and of the 312 patients who received special investigations, 56% were abnormal, including 18% who were clinically significantly abnormal. Abnormal special investigations changed the clinical outcome for 3 (<1%) patients. Adherence to the provincial guidelines was reasonable (82%) but non-adherence resulted in numerous unnecessary investigations.

Conclusion

The results of this study support the existing evidence that clinical assessment and clinician gestalt should guide the need for special investigations and that there is no benefit to routine screening in the EC. The results also demonstrate reasonable adherence to the current guidelines even though this rarely changed patients' outcome. Decisions were based on clinical findings and clinician gestalt, and not abnormal special investigations or vital signs – which were both prevalent.

Background

Mental and behavioural disorders are one of the leading causes of morbidity worldwide.(1) The burden is however disproportionately distributed with 80% occurring in low- and middle-income countries (LMICs) where nearly 20% of health related disabilities are attributable to mood, psychotic, and substance abuse disorders.(2) In South Africa, the twelve months prevalence of mental health disorders is 16.5%, with an estimated lifetime prevalence of 30.3%.(3) The reported prevalence in the Western Cape Province is the highest nationally with a twelve month and lifetime prevalence of 39.4%.(4,5) Despite the significant burden, mental and behavioural disorders continue to be a low priority with regards to resource allocation.(6,7,8)

The process of medical clearance aims to exclude a general medical condition (GMC) as an underlying cause for the mental and behavioural disorder and involves routine screening with special investigations.(9,10) The goal is to identify potential treatable medical conditions prior to transfer to a psychiatric ward or alternatively to refer the patient to a medical in-patient department if required.(11) Historically (1980), this process was reported to add significant value with between 34% and 46% of patients with mental and behavioural disorders found to have newly diagnosed significant underlying medical conditions.(12) However, evidence suggests that appropriate laboratory investigations should be guided by clinical history, vital signs and physical examination and not performed routinely.(13,14,15) Patients with a primary mental and behavioural complaints with normal vital signs and a normal physical exam have less than 1% chance of having a clinically significantly abnormal laboratory results.(16,17) A study conducted at a local district level hospital by Credé et al (2011), demonstrated that routine laboratory screening provides no additional information in the assessment of patients with mental and behavioural disturbances on presentation at the EC. (18).

Zwank et al. (2020) performed a before-and-after study at a tertiary hospital where an institutional policy to eliminate routine laboratory tests for all patients with mental and behavioural disorders was implemented.(19) Special investigations were subsequently performed at the discretion of the treating clinician. This drastically reduced EC length of stay by a mean of 5.5 hours, reduced total hospital length of stay by 16 hours and decreased the EC laboratory costs per patient by 78%. More importantly though, there was no significant increase in adverse events, number of medical referrals and no deaths reported.(19) There were some concerns regarding patients who may have laboratory abnormalities that may be missed without routine blood tests, however, evidence suggests that there is low utility of these results, if the abnormalities were not clinically suspected based on patients' presenting complaints and physical examination findings.(9,10,20) This approach is supported by both local and international publications as well as professional bodies.(14,18,21,22,23,24)

Routine screening comes at a cost. Despite the financial burden, staffing requirements, risk of needle injuries and patient discomfort, it contributes significantly to EC crowding and staff and patient safety. "Crowding exists when there is no space left to meet the timely needs of the next patient requiring emergency care" (Selway et al 2017).(25) Crowding negatively affect EC quality of care, increases medical errors and increases morbidity and mortality of all

patients in the EC.(25,26) With prolonged EC length of stays, the risk to patient and staff safety also increases as patients with mental and behavioural disturbances are often difficult to contain in a chaotic EC environment, especially as their behaviour is often unpredictable. The risk-benefit ratio between appropriate screening practices (the right patient at the right time in the right place) and decreasing the risks associated with EC crowding and staff safety, should be evaluated.

Mitchells Plain District Hospital's emergency centre follows the Western Cape provincial "guideline for routine investigations for exclusion of general medical conditions in patients presenting with mental and behavioural disturbances." (Addendum 2) These guidelines are aimed at reducing length of stay of these patients in the emergency centres. The western cape guideline categorises patients with mental and behavioural disturbances into three groups: (i) High risk patients (features of GMC present); (ii) Known mental health care user (MHCU) with no high-risk features for GMC (low risk and known); and (iii) Index MHCU with no high-risk features (low risk and index) based on their clinical features. Special investigations are then tailored to their risk-category, with index MHCU and any MHCU with high-risk features of a GMC, requiring routine special investigations as well as investigations that are clinically indicated. (Addendum 2). The guideline were based on the findings of a study by Credé et al. (2011), which showed that routine laboratory screening provides no additional information in the assessment of patients with mental and behavioural disturbances on presentation at the EC.(18) There is however no data that describe adherence and effectiveness of the above guidelines. The data from Credé et al, was sourced more than 10 years ago and the mental health disease burden and community profiles may have changed since then. The aim of this study therefore was to assess the adherance to and effectiveness of the Western Cape Provincial guideline for routine investigations of adult patients with mental and behavioural disturbances presenting to a district level emergency centre.

Method and design

Study design

This study is a descriptive analysis and data was collected retrospectively from existing databases and registeries.

Study setting

This study was conducted at Mitchells Plain Hospital (MPH) in Cape Town, South Africa. The hospital is in the Mitchells Plain Health District of the Western Cape Province Metro Region. The hospital is 32 km from Cape Town's central business district and provides services to an estimated population of 600 000. (27) It serves low-to middle-income communities of Mitchells Plain and mainly low-income communities of Philippi, a large nearby informal settlement.

Study population and sampling

Inclusion criteria:

All adult patients > 18 years old with mental and behavioural disturbances who presented to Mitchells Plain Hospitals emergency centre July 2019 to December 2019, were eligible for inclusion. The definition of mental and behavioural

disturbances for the purposes of this project included any diagnosis from the World Health Organisation (WHO) ICD-10 Version: 2019 Chapter V: Mental and Behavioural Disorders (F00-F99).

Exclusion criteria

Patients who were admitted directly to the psychiatric department and bypassed the EC were excluded as well as those who were discharged directly from the EC, transferred to a different hospital, or directly admitted to another discipline. Patients who are clinically delirious with a clear cause (GMC), are referred to the appropriate discipline – these pts are not included in this study as the guideline does not apply to them. The guideline is designed for patients with no clear GMC.

Data collection and management

Data were collected in three phases. In Phase I, a retrospective reviewed of data of all included patients was performed. Data were extracted from the electronic registry, Hospital and Emergency Centre Tracking and Information System (HECTIS) along with patients' demographic details, their disposition category, folder numbers and initial vital signs on triage. An ICD-10 search from within the database was done by the database manager and de-identified data was exported to a spreadsheet. Folder numbers were used to track patients through all the phases of data collection. All patients with a World Health Organisation International Classification of Diseases (WHO ICD) 10^{th} revision (2019) diagnosis code that is included in Chapter V: Mental and Behavioural Disorders (F00-F99), were included.

Clinical records of patients identified from Phase I were accessed from the electronic medical records (Enterprise Content Management - ECM) during phase II. ECM is an official electronic database for the Western Cape Health Department where all clinical notes are stored electronically. The notes were scrutinised, and patients were grouped into three categories, based on the details present at presentation: (i) those with no high-risk features for a general medical condition (GMC) present and a known mental health user; (ii) those with no high-risk features for a GMC and an index presentation and (iii) those who had high-risk features for a GMC present. These risk categories were based on WCG guideline. The South African Triage Scale (STATS) was used to group patients in various triage categories basing on their presenting complaints, vital signs and clinical discriminators.(28) The SATS groups (colour coded as green, yellow, orange and red) according to the severity of their illness at the time of presentation to the EC. An adult MHCU who is aggressive on presentation is triaged orange indicating that such a patient needs very urgent care.(28) In this study, the following thresholds were used for normal vital signs: systolic blood pressure: 90 – 139 mmHg, diastolic blood pressure: 60 – 89 mmHg, heart rate: 60 to 100 bpm, respiratory rate: 12 - 20 bpm, oxygen saturation: 94 – 100%, and temperature: 35 – 37.5^{o}C.(29)

In phase III of the data collection process, the results of all special investigations done on admission by EC were obtained from the National Health Laboratory Services (NHLS) database and were classified into normal, abnormal, or clinically significantly abnormal. This was also done for results of special investigations done within 48 hours of admission by the psychiatric department to ensure that patients with clinically significantly abnormal results, who were not otherwise investigated by EC, were not missed. Clinically significantly abnormal values were based on

evidence and international consensus and defined thresholds for what is considered likely to contribute towards psychotic symptoms.(14,18,30,31,32) Table 1 summarises the reference values that were used.

Table 1: Reference values for laboratory investigations

Laboratory investigation	**Values considered abnormal enough to contribute towards psychotic symptoms**
Sodium	<125 or >160 mmol/l
Creatinine	>200 µmol/l
White cell count	<4 or >15×10^9/l
Lumbar puncture	Any polymorphs/µl >3 lymphocytes/µl Protein >0.45 g/l Positive Gram stain/India ink stain/syphilis serology positive
HIV rapid test	Positive
Syphilis serology (rapid plasma reagin) TPHA	Positive
Thyroid-stimulating hormone	0.27 - 4.20 mIU/l

Adopted from Credé et al.(14,18,30,31,32)

The final sample only included mental health care users that were referred to the psychiatric department for admission. Patients was grouped into three categorised according to their risk of GMC as a cause of their mental and behavioural disturbance symptoms as per the WC guideline. Results of special investigations performed by both EC and the psychiatric department were assessed to determine whether they changed patients' outcome. A change in outcome of patients was defined as the need for patients to be transferred to a medical department from the psychiatric ward. In addition, whether or not psychiatric inpatients received medical consultations (co-management) as a psychiatric inpatient, was also documented. Random case files (5%) were cross-checked by the study investigators to ensure that data collection was accurate.

The effectiveness of the guideline was defined as how well it can distinguish between patients with mental and behavioural disorders as a result of a GMC and mental health care users requiring psychiatric admission. To determine adherence, the proportion of patients who had special investigations according to the guidelines was calculated and expressed as a percentage per risk category.

Data analysis

All variables were described with summary statistics. Categorical variables were described as proportions or percentages and tabulated, as necessary. The Fisher's exact and Chi^2 tests were used to identify non-random associations with regards to categorical variables, depending on the variable characteristics. The central tendency of

continuous variables was described as medians and quartiles were used to indicate spread . Statistically significance was defined as a $p<0.05$ and data were analysed using Statistical Package for Social Sciences (SPSS) Statistics Version 27.0 (IBM Corp. Released 2019. Armonk, NY: IBM Corp.).

Ethical considerations

Even though this study involved a vulnerable population, it posed a very low risk to patients as data was deidentified to protect their identities. The data collection procedures only involved a folder and database review and no patient intervention or interaction occurred. Ethical approval was granted by the Human Research Ethics Committee of the University of Cape Town: HREC REF:678/2020 and institutional approval was obtained from MPH via the National Health Research Database: WC_202012_014

Results

A total of 19,162 adult patients presented to MPH EC during the study period of which 960 (5%) were eligible for inclusion into the study. A sample of 688 (72%) were included and Figure 1 provides a breakdown of the 272 (28%) exclusions. Among the excluded patients are 17 (2%) who had a clear diagnosis of a delirium for various reasons and was subsequently referred to the relevant inpatient departments for admission.

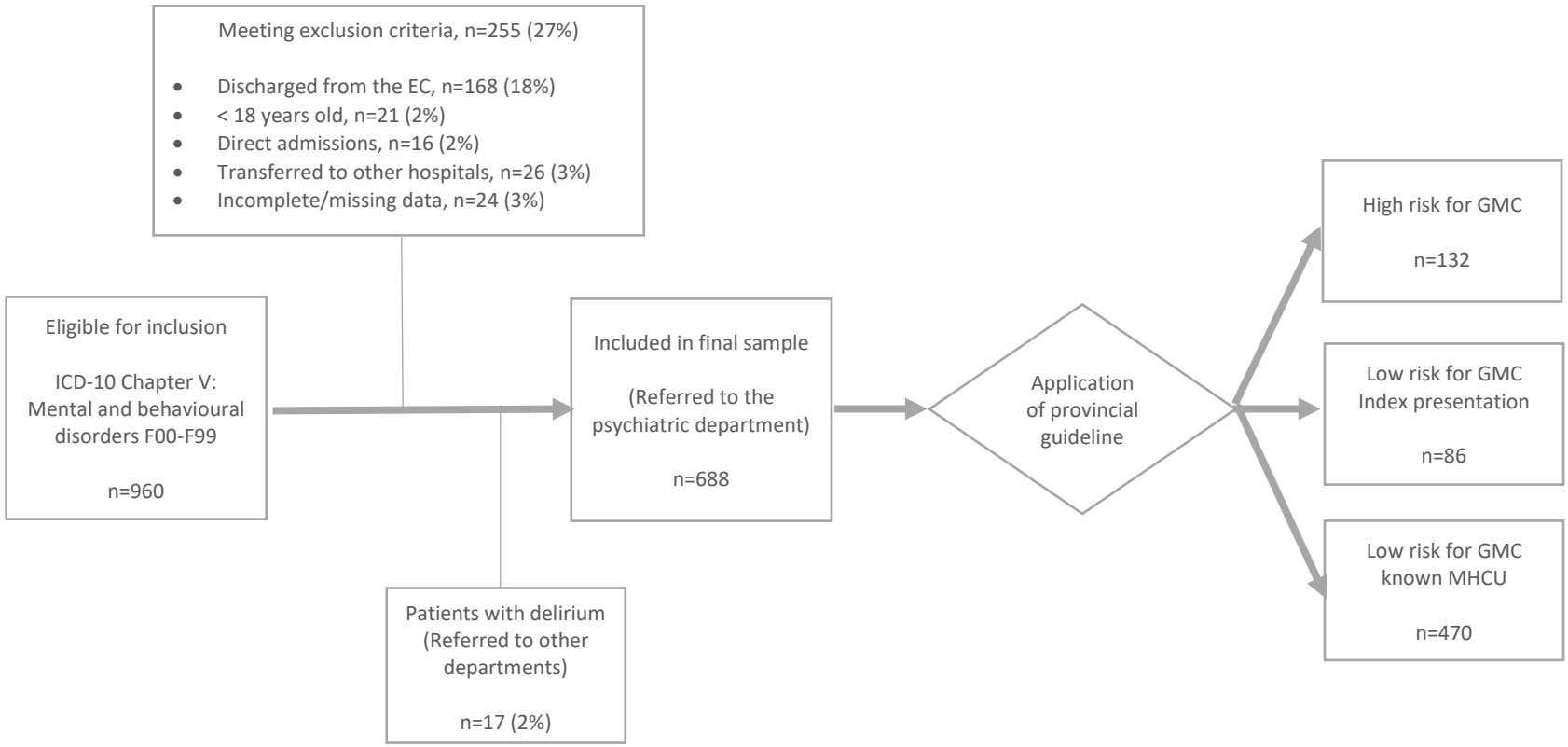

Figure 1: Flowchart of study participants

Table 2 below provides demographical and clinical details of the sample for each admission category. The sample had a strong male preponderance 455 (66%) and nearly 551 (80%) of all patients were younger than 45 years old. Based on their clinical details, 470 (68%) were known mental health users with no features of a GMC, 86 (13%) were index mental health care users with no high-risk features of a GMC, and 132 (19%) had clinical features that increased their risk of having a GMC. The ratio of 2:1 male predominance extended to the categories where no high-risk features for GMC were present but nearly 50% (60 out of 132) of all MHCUs with high-risk features of a GMC were female, a statistically significant increase ($p<0.05$). Of those with an index presentation and without high-risk features for a GMC, 41% (35 of 86) were in the 18 – 25 years age group, the highest of all age-categories. This age group also contributed to the highest proportion 34% (45 of 132) of mental health care users with high-risk features of a GMC.

99% of the patients were triaged as orange and the majority (99%) were known MHCU. Of those with high-risk features of a GCM, four (3%) were triaged red, a significantly higher proportion than the other categories ($p<0.05$). MHCU with schizophrenia, schizotypal and delusional disorders contributed the most to the psychiatric burden with 491 (71%) of all admissions.

Table 2: Demographical and clinical details for each admission category: n (column%)

	Total n=688	Low risk for a GMC		High risk for a GMC n=132 (19%)
		Known MHCU n=470 (68%)	Index presentation n=86 (13%)	
Gender				
Male	455 (66%)	316 (67%)*	67 (78%)*	72 (54%)
Female	233 (34%)	154 (33%)	19 (22%)	60 (46%)*
Age categories				
18-25	151 (22%)	71 (15%)	35 (41%)*	45 (34%)*
26-35	237 (34%)	175 (37%)	27 (31%)	35 (27%)
36-45	163 (24%)	124 (26%)	15 (17%)	24 (18%)
46-55	74 (11%)	52 (11%)	6 (7%)	16 (12%)
56-65	45 (7%)	33 (7%)	3 (4%)	9 (7%)
>65	18 (3%)	15 (3%)	0	3 (2%)
Triage category**				
Green	2 (0.3%)	2 (0.4%)	0	0
Yellow	2 (0.3%)	1 (0.2%)	0	1 (0.8%)
Orange	677 (99%)	464 (99%)*	86 (100%)	127 (96%)
Red	6 (1%)	2 (0.4%)	0	4 (3%)*
Diagnosis category				
F00-F09: Organic, including symptomatic mental disorders	1 (0.1%)	1 (0.2%)	0	0
F10-F19: Mental and behavioural disorders due to substance use	50 (7%)	35 (8%)	6 (7%)	9 (7%)
F20-F29: Schizophrenia, schizotypal and delusional disorders	491 (71%)	343 (73%)	62 (72%)	86 (65%)
F30-F39: Mood disorders	124 (18%)	85 (18%)	15 (17%)	24 (18%)
F40-F49: Neurotic, stress-related and somatoform disorders	8 (1%)	2 (0.4%)	1 (1%)	5 (4%)*
T50.9/Z91.5: Intentional self-harm/overdose	13 (2%)	4 (1%)	2 (2%)	7 (5%)*
Other	1 (0.1%)	0	0	1 (1%)
Process times (hours: minutes), median (IQR)				
Time to triage	0:31 (0:13-1:02)	0:31 (0:14-1:05)	0:21 (0:12-0:57)	0:33 (0:13-0:56)
Time to consultation	2:09 (0:50-4:41)	2:09 (0:49-4:40)	2:13 (1:14-5:09)	2:13 (0:49-4:23)
Time to disposition	2:39 (0:55-8:42)	1:32 (0:39-3:35)	8:08 (4:11-15:47)	10:52 (5:18-17:49)
Time to exit	2:52 (0:55-6:31)	3:17 (1:18-7:00)	2:13 (0.09-6:22)	2:04 (0:18-5:16)
EC length of stay	12:19 (7:33-20:51)	10:47 (6:39-17:12)	17:35 (11:34-25:59)	18:54 (10:51-25:56)

Percentages may not add to 100% because of rounding

GMC general medical condition; MHCU mental health care user; IQR inter quartile range.

*Statistically higher proportion ($p<0.05$) **Triage categories were based on the South African Triage Scale (28)

Table 3 depicts all abnormal vital signs for each admission category with subsequent psychiatric department outcomes. A total of 455 (66%) of the all the patients included in the final sample had one or more abnormal vital sign. The most prevalent abnormal vital signs were diastolic blood pressure (32%), heart rate (29%), and systolic blood pressure (28%). One patient (0.2% of all patients who had one or more abnormal vital sign) with both an abnormal heart rate and an abnormal, diastolic blood pressure had a change in outcome (transferred to a medical ward), while 7 patients (1.5% of all patients who had one or more abnormal vital sign) had medical consultations as a psychiatric inpatient. The distribution of abnormal vital signs showed little variation between the categories with known MHCU 314/470 (67%), index presenters 52/86 (60%) and those with high-risk features for GMC 89/132 (67%) having one or more vital signs abnormal.

Table 3: Vital signs on presentation for each EC admission category with subsequent psychiatric department outcomes(29)

	Total n (% of sample)	Emergency Centre admission category n (row %)			Psychiatric department outcomes n (row %)	
		Low risk for a GMC		High risk for a GMC n=132 (19%)	Medical transfer (to medical ward)	Medical consultation (in psychiatric ward)
		Known MHCU n=470 (68%)	Index presentation n=86 (13%)			
All vital signs normal	233 (34%)	156 (67%)	34 (15%)	43 (19%)	2 (1%)	1 (0.4%)
Any abnormal vital sign	455 (66%)	314 (69%)	52 (11%)	89 (20%)	1 (0.2%)	7 (2%)
Abnormal vital signs						
Heart rate (per minute)	189 (29%)	132 (70%)	20 (11%)	37 (20%)	1 (1%)	4 (2%)
Systolic blood pressure (mmHg)	180 (28%)	114 (63%)	20 (11%)	46 (26%)	0	6 (3%)
Diastolic blood pressure (mmHg)	210 (32%)	149 (71%)	21 (10%)	40 (19%)	1 (1%)	4 (2%)
Oxygen saturation (%)	6 (1%)	5 (83%)	1 (17%)	0	0	0
Respiratory rate (per minute)	39 (6%)	26 (67%)	5 (13%)	8 (21%)	0	1 (3%)
Temperature (degrees Celsius)	13 (2%)	6 (46%)	1 (8%)	6 (46%)	0	0
POC Haemoglobin (g/dL)	79 (14%*)	49 (62%)	8 (10%)	22 (28%)	0	3 (4%)
POC Blood glucose level (mmol/L)	33 (5%)	21 (64%)	6 (18%)	6 (18%)	0	1 (3%)

Percentages may not add to 100% due to rounding; GMC general medical condition; POC point of care;
*Haemoglobin (g/dL) performed in only 583 (85%) patients

Table 4 depicts the abnormal special investigations on presentation for each EC admission category with subsequent psychiatric department outcomes. Special investigations were performed in 312 (45%) of the sample of which 137 (44%) were normal, 56 (18%) clinically significantly abnormal (including Rapid HIV, TPHA, RPR, Chest X-Ray, CT Brain, and lumbar puncture) and 119 (38%) not clinically significantly abnormal. This equates to a total of 175 abnormal results - 25% of the entire sample. Three patients (<1%) had a change in outcomes (transferred to the medical department from the psychiatric ward) while 5 patients (2% of all patients who had special investigations), had medical consultations as a psychiatric inpatient (co-managed). No clinically significantly abnormal sodium and creatinine results were present and of the 14 clinically significantly abnormal white cell counts and 14 thyroid stimulating hormone levels, none required transfer to the medical department and was co-managed as psychiatric inpatients. The only patient with clinically significantly abnormal results who had a change in outcome was a MHCU with neurosyphilis.

Table 4: Abnormal special investigations on presentation for each EC admission category with subsequent psychiatric department outcomes

	Total		Emergency Centre admission category n (row %)			Psychiatric department outcomes n (row %)	
	n (% of Sample)	n (% of special investigations performed)	Low risk for a GMC: Known MHCU n=470 (68%)	Low risk for a GMC: Index presentation n=86 (13%)	High risk for a GMC n=132 (19%)	Medical transfer (to medical ward)	Medical consultation (in psychiatric ward)
Sodium (Total)	268 (39%)	83 (31%)	21 (25%)	26 (31%)	36 (43%)	1 (<1%)	3 (4%)
(125-134) or (146-160) mmol/l		83 (31%)	21 (25%)	26 (31%)	36 (43%)	1 (<1%)	3 (4%)
<125 or >160 mmol/l		0	0	0	0	0	0
White cell count (Total)	297 (43%)	71 (24%)	27 (38%)	17 (24%)	27 (38%)	1 (<1%)	1 (<1%)
10.4-15 x 10^9/l		57 (19%)	21 (37%)	14 (25%)	22 (39%)	1 (2%)	1 (2%)
<4 or >15 x 10^9/l		14 (5%)	6 (43%)	3 (21%)	5 (36%)	0	0
Creatinine (Total)	299 (43%)	28 (9%)	14 (50%)	5 (18%)	9 (32%)	1 (4%)	1 (4%)
97-200 μmol/l		28 (9%)	14 (50%)	5 (18%)	9 (32%)	1 (4%)	1 (4%)
>200 μmol/l		0	0	0	0	0	0
TSH (Total)	135 (20%)	40 (30%)	10 (25%)	12 (30%)	18 (45%)	0	1 (3%)
(0.27-0.62) or (3.03-4.2) mIU/l		26 (19%)	8 (31%)	9 (35%)	9 (35%)	0	1 (4%)
<0.27 or >4.2 mIU/l		14 (10%)	2 (14%)	3 (21%)	9 (64%)	0	0
Rapid HIV test	252 (37%)	11 (4%)	3 (27%)	3 (27%)	5 (46%)	0	0
TPHA	269 (39%)	20 (7%)	11 (55%)	3 (15%)	6 (30%)	1 (5%)	0
RPR	20 (3%)	9 (45%)	4 (44%)	1 (11%)	4 (44%)	1 (11%)	0
Chest X-Ray	15 (2%)	2 (13%)	2 (100%)	0	0	0	0
CT Brain	5 (0.6%)	1 (20%)	1 (100%)	0	0	0	0
Lumbar puncture	24 (3%)	2 (8%)	0	0	2 (100%)	0	0

GMC general medical condition; TPHA Treponema pallidum hemagglutination; RPR rapid plasma reagin (Syphilis); TSH Thyroid stimulating hormone
MHCU mental health care user; Percentages may not add to 100% due to rounding.

Table 5 depicts the abnormal special investigations performed by the psychiatric department within 48 hours after admission, for each EC admission category with subsequent psychiatric department outcomes. Special investigations were performed in 146 (21%) of the sample of which 86 (59%) were normal, 27 (18%) clinically significantly abnormal (including Rapid HIV, TPHA, RPR, Chest X-Ray, CT Brain, and lumbar puncture) and 33 (23%) not clinically significantly abnormal. This equates to a total of 60 abnormal results - 9% of the sample. No patients were transferred to the medical department from the psychiatric ward but 7 patients (5% of all patients who had one or more abnormal results), received medical consultations as a psychiatric inpatient. No clinically significantly abnormal sodium results were present but of the clinically significantly abnormal creatinine, white cell count and thyroid stimulating hormone results, none required transfer to the medical department and was co-managed as psychiatric inpatients.

Table 5: Abnormal special investigations performed by the psychiatric department within 48 hours of admission for each EC admission category with subsequent psychiatric department outcomes

	Total		Emergency Centre admission category n (row %)			Psychiatric department outcomes n (row %)	
	n (% of Sample)	n (% of special investigations performed)	Low risk for a GMC: Known MHCU n=470 (68%)	Low risk for a GMC: Index presentation n=86 (13%)	High risk for a GMC n=132 (19%)	Medical transfer (to medical ward)	Medical consultation (in psychiatric ward)
Sodium (Total)	73 (11%)	22 (30%)	16 (73%)	1 (5%)	5 (23%)	0	1 (5%)
(125-134) or (146-160) mmol/l		22 (30%)	16 (73%)	1 (5%)	5 (23%)	0	1 (5%)
<125 or >160 mmol/l		0	0	0	0	0	0
White cell count (Total)	95 (14%)	25 (26%)	19 (76%)	3 (12%)	3 (12%)	0	2 (8%)
10.4-15 x 10^9/l		18 (%)	15 (83%)	2 (11%)	1 (6%)	0	0
<4 or >15 x 10^9/l		7 (%)	4 (57%)	1 (14%)	2 (29%)	0	2 (8%)
Creatinine (Total)	78 (11%)	3 (4%)	3 (100%)	0	0	0	0
97-200 μmol/l		2 (%)	2 (100%)	0	0	0	0
>200 μmol/l		1 (%)	1 (100%)	0	0	0	0
TSH (Total)	57 (8%)	6 (11%)	5 (83%)	0	1 (17%)	0	1 (17%)
(0.27-0.62) or (3.03-4.2) mIU/l		4 (%)	3 (75%)	0	1 (25%)	0	1 (17%)
<0.27 or >4.2 mIU/l		2 (%)	2 (100%)	0	0	0	0
Rapid HIV test	58 (8%)	5 (9%)	3 (60%)	1 (20%)	1 (20%)	0	1 (20%)
TPHA	56 (8%)	4 (7%)	3 (75%)	1 (25%)	0	0	0
RPR	7 (1%)	2 (29%)	2 (100%)	0	0	0	0
Chest X-Ray	11 (2%)	3 (27%)	1 (33%)	1 (33%)	1 (33%)	0	0
CT Brain	26 (4%)	8 (31%)	4 (50%)	1 (13%)	3 (38%)	0	2 (25%)
Lumbar puncture	2 (0.3%)	0	0	0	0	0	0

GMC general medical condition; TPHA Treponema pallidum hemagglutination; RPR rapid plasma reagin (Syphilis); TSH Thyroid stimulating hormone
MHCU mental health care user; Percentages may not add to 100% due to rounding

Table 6 depicts a summary of special investigations and adherence to guidelines for each EC admission category and the subsequent psychiatric department outcomes. The EC adhered in 91% (78/86) of the index presenter category, 77% (361/470) of the known mental health user category and 95% (125/132) of the high risk for GMC category. The overall adherence was 82%. Non-adherence did not affect the outcomes for patients in the index presenter and high risk for GMC categories but resulted in 109 patients receiving unnecessary special investigations (not indicated) in the known mental health care user category.

The guideline correctly categorised the three patients that were transferred from the psychiatric ward to medical department as high-risk patients. However, the use of the guideline could not change the patients' management plan in the EC. The three patients who were transferred to the medical department had the following reasons: Patient 1 was a 41 year old female who had an abnormal TPHA and RPR – the institutional policy is that MHCU are referred before these results are available as the turnaround time for TPHA results is long; Patient 2 was a 57 year old female who had a clinically significantly Vitamin B12 deficiency (not screened routinely in the EC on admission; Patient 3 was a 76 years old male patient who developed seizures in the psychiatric ward and had a normal CT brain scan.

Table 6: Summary of special investigations and adherence to guidelines for each EC admission category and subsequent psychiatric department outcomes

	Total		Emergency Centre admission category n (row%)			Psychiatric department outcomes n (row %)	
			Low risk for a GMC				
	n (% of Sample)	n (% of special investigations performed)	Known MHCU n=470 (68%)	Index presentation n=86 (13%)	High risk for a GMC n=132 (19%)	Medical transfer (to medical ward)	Medical consultation (in psychiatric ward)
Emergency Centre							
No special investigations performed	376 (55%)		361 (96%)	8 (2%)	7 (2%)	0	3 (<1%)
Special investigations performed	312 (46%)		109 (35%)	78 (25%)	125 (40%)	3 (1%)	5 (2%)
All special investigations normal		137 (44%)	53 (39%)	34 (25%)	50 (37%)	0	1 (<1%)
Any abnormal special investigations		175 (56%)	56 (32%)	44 (25%)	75 (43%)	3 (2%)	4 (2%)
Clinically non-significant		119 (68%)	35 (29%)	32 (27%)	52 (44%)	2 (2%)	4 (3%)
Clinically significant		56 (32%)	21 (38%)	12 (21%)	23 (41%)	1 (2%)	0
Psychiatric department							
No special investigations performed	542 (79%)						
Special investigations performed	146 (21%)						
All special investigations normal		86 (59%)	57 (66%)	10 (12%)	19 (22%)	0	4 (5%)
Any abnormal special investigations		60 (41%)	44 (73%)	6 (10%)	10 (17%)	0	3 (5%)
Clinically non-significant		33 (%)	26 (%)	2 (%)	5 (%)	0	0
Clinically significant		27 (18%)	18 (67%)	4 (15%)	5 (19%)	0	3 (11%)
Adherence	**564 (82%)**		**361 (77%)**	**78 (91%)**	**125 (95%)**	**3 (<1%)**	**5 (<1%)**
Non-adherence	**124 (18%)**		**109 (23%)**	**8 (9%)**	**7 (5%)**	**0**	**3 (<1%)**

Discussion

This study demonstrates an 82% adherence to the provincial guidelines for routine investigations for exclusion of general medical conditions as a cause for mental and behavioural disturbances. The findings also suggests that the application of the guideline did not significantly change patients' outcomes as decisions were based on clinician gestalt instead of results of special investigations. This is consistent with the findings of other studies assessing the use of laboratory investigations for medical clearance in patients with mental and behavioural disturbances.(13,14,15,23) Even though abnormal vital signs and abnormal special investigations were prevalent, they rarely resulted in a change in outcomes as only 3 (<1%) patients out of 312 who received special investigations had a change in outcome – all for a valid reason. Though adherence was reasonable, non-adherence resulted in financial waste (>100 patients receiving unnecessary investigations) with no change in patient outcomes.

The high proportion of MHCU with abnormal vital signs (66%) was surprising, considering the fact that abnormal vital signs could be considered a high-risk criterion to predict a GMC.(29) Despite its prevalence, abnormal vital signs rarely changed the outcome as only 1 (0.2%) MHCU out of those who had abnormal vital signs, had a change in outcome (medical transfer from psychiatric ward). Variation in vital signs is common and evidence suggests that using groups or combinations of abnormal vital signs, together with clinician gestalt, is superior to one abnormal vital sign in isolation. (33) The single patient that was transferred to the medical department had an abnormal heart rate and diastolic blood pressure. Further research should aim to assess which abnormal vital signs or combinations of abnormal vital signs have clinical value to predict undesirable outcomes in MHCU.

Abnormal special investigations were prevalent (56% of patients who received special investigations) and included several clinically significantly abnormal results (18% of patients who received special investigations). Despite the high prevalence, it resulted in only 3 patients being transferred to the medical department from the psychiatric ward. Of the 56% clinically significant abnormal results, only 1 patient was referred to the medical department, despite there being 14 patients with clinically significant abnormal white cell counts and 14 with clinically significant abnormal thyroid stimulating hormone levels. Asymptomatic leucocytosis in patients seeking emergency care is fairly common and often transient; however, when it is coupled with clinical signs of a potential GMC, it has much more value to predict serious pathology.(34) The fact that these MHCU were declared medically fit and referred to the psychiatric department despite the abnormal special investigations questions the value of routine screening. The disposition of MHCU was therefore based on the clinician gestalt and

not on the actual results. This practise is supported by the existing body of evidence that demonstrates that testing beyond what is clinically indicated for medical clearance in MHCU rarely changes clinical care.(13,14,21,35,36) The three patients who had medical transfers from the psychiatric department was not as a result of a failure of clinical assessment or a lack of screening investigations.

Abnormal special investigations often resulted in MHCU receiving medical consults as a psychiatric inpatient (co-management). This is not surprising as comorbid conditions are prevalent in MHCU, and most medical conditions can be safely managed while admitted in the psychiatric ward.(37) This questions the utility and cost-effectiveness of performing screening investigations in the EC as opposed to the psychiatric ward, considering that GMC as a cause for mental and behavioural conditions can be screened for reliably and safely via a thorough clinical assessment and clinician gestalt.(13,23) From a risk-benefit ratio point of view, patients who wait for special investigations in the EC have a much longer EC length of stay, increases crowding and affects staff and patient safety. In our sample, none of the index presenters' special investigations affected their outcome and none required medical transfer, despite the presence of abnormal results. They however stayed for nearly 8 hours longer in the EC for each MHCU. There is therefore a strong argument that medical workup that does not affect patient outcomes should ideally then be performed in the psychiatric ward, especially if a medical department is available for consultations, to decrease EC crowding and allow patients to get to definitive care as soon as possible.

No previous studies have assessed effectiveness and adherence to the Western Cape guideline for exclusion of general medical conditions in adult patients presenting with mental and behavioural disturbances. Adherence to the provincial guidelines was reasonable (82%) but non-adherence resulted in financial waste (>100 patients receiving unnecessary investigations) with no change in patient outcomes. Reasons for non-adherence was not explored in this study and the financial impact was not quantified. Additional special investigations performed within the first 48 hours as psychiatric inpatients also did not result in change in clinical outcomes, further strengthening the argument against routine screening.

Limitations

This study sample involved a single facility and only included data over six months. With regards to external validity, the authors are of the opinion that results are generalisable, because medical clearance in the public sector is standardised and follows the same provincial guideline. The study results are particularly valid for facilities with both medical and psychiatric departments on site (in the

same facility). Psychiatric hospitals with no medical department (e.g., specialist psychiatric hospitals) may require further investigation. Even though data on other investigations were collected (including drug levels, Vit B12, urine analysis, pregnancy tests, HIV viral loads and CD4 counts, creatine kinase, drug tests etc, it was not reported on as this project focused on routine investigations only, according to the provincial guideline.

Future studies should prospectively investigate the impact of no routine testing on patient outcomes, EC crowding, hospital expenditure and length of stays. Future studies should also involve multiple facilities and include speciality hospitals.

Conclusion

The results of this study support the existing evidence that clinical assessment and gestalt should guide the need for special investigations and that there is no benefit to routine screening in the EC. The results also show good adherence to the current guidelines even though this rarely changed the patients' outcome. Decisions were based on clinical findings and clinician gestalt, and not abnormal special investigations or vital signs – which were both prevalent. Regarding the risk-benefit ratio, the argument for screening to occur in Emergency Centres is strongly challenged as the effects on crowding ,staff and patient safety outweighs the lack of benefit from routine special investigations in addition to a thorough clinical examination and clinician gestalt.

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Competing interests:

The authors declare no competing interest.

Author contributions:

SJ and CH developed the concept. SJ CH and CV and MD constructed the proposal. CH was responsible for the ethical clearance and facility approval. SJ and MD performed the data collection and CH performed the data analysis. CH, SJ, MD, and CV contributed significantly to the final article.

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Disclaimer:

We declare that the views expressed in this submission are our own and do not reflect the official position of the University of Cape Town.

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PART B: Addenda

Addendum 1: Author guideline: South African Journal of Psychiatry

https://sajp.org.za/index.php/sajp/pages/view/submission-guidelines#part_1

https://sajp.org.za/index.php/sajp/pages/view/submission-guidelines#part_2

https://sajp.org.za/index.php/sajp/pages/view/submission-guidelines#part_3

https://sajp.org.za/index.php/sajp/pages/view/submission-guidelines#part_4

https://sajp.org.za/index.php/sajp/pages/view/submission-guidelines#part_5

Addendum 2 : Circular H221 of 2014: Guideline for routine investigations for inclusion of General Medical Condition in a behaviourally disturbed patient

Western Cape Government
Health

Office of the SG: Chief Of Operations
REFERENCE: 16/4
ENQUIRIES: Dr EH Engelbrecht

For Attention:

Chief Executive Officers:	Central, Regional and Psychiatric Hospitals
Chief Directors:	Metro and Rural District Health Services, General Specialist and Emergency Services, Health Programs, Strategy and Health Support
District Managers:	Metro District Health Services Sub-structures and Rural Districts
Chief Operational Officers:	Central Hospitals, General Specialist and Emergency Services
Members of PCGCs:	Anaesthetic Services, Emergency Medicine, Medicine, Obstetrics and Gynaecology, Orthopaedic Services, Paediatrics, Psychiatry, Surgical Services

CIRCULAR H 221 OF 2014

GUIDELINE FOR ROUTINE INVESTIGATIONS FOR EXCLUSION OF A GENERAL MEDICAL CONDITION IN A BEHAVIOURALLY DISTURBED PATIENT

This guideline replaces Circular 107/2011: Protocol 4 of Standardised Psychiatric Guidelines: The exclusion of General Medical Conditions.

Any admission to a psychiatric hospital or unit is strictly defined in terms of the Mental Health Care Act (MHCA) 17 of 2002 and Regulations, both with regard to the patient's consent to admission and capacity to give consent, as well as with regard to the nature of the illness, which should be psychiatric in origin and not primarily due to a General Medical Condition (GMC).

This purpose of this guideline is thus to assist the physician in assessing the risk for an underlying GMC and specify the required investigations.

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For your further attention and implementation.

DR BETH ENGELBRECHT

SG: CHIEF OF OPERATIONS

DATE: 2014-12-24

GUIDELINE FOR ROUTINE INVESTIGATIONS FOR EXCLUSION OF A GENERAL MEDICAL CONDITION IN A BEHAVIOURALLY DISTURBED PATIENT

October 2014

This replaces Circular H107/2011: Protocol 4 of Standardised Psychiatric Guidelines: The exclusion of General Medical Conditions.

Psychiatric Units in district and regional hospitals performing 72-hour assessments should be called PSYCHIATRIC OBSERVATION UNITS (POU).

Reasons for review of Protocol 4

- Routine testing without indication has poor detection rate (Assessment of routine laboratory screening of adult psychiatric patients presenting to an emergency centre in Cape Town. Crede A, Geduld H, Wallis L. S Afr Med J 2011; 101:891-894.) In addition, the tests are costly.
- Completion of tests is currently being used as a prerequisite before transfer from the Emergency Centre (EC) to POUs. The consequence of this is delayed treatment and increased length of stay. Another consequence is the contribution to EC overcrowding, which has been shown to be associated with increased mortality. (Association between Length of Emergency Department Boarding and Mortality. Singer A, Thode H, Viccellio P et al. Acad EM 2011. 10:1553-2712.)
- Clarity of definition of roles and responsibility of ECs and POUs is needed.

PURPOSE OF THIS GUIDELINE

Any admission to a psychiatric hospital or unit is strictly defined in terms of the Mental Health Care Act (MHCA) 17 of 2002 and Regulations, both with regard to the patient's consent to admission and capacity to give consent, as well as with regard to the nature of the illness, which should be psychiatric in origin and not primarily due to a General Medical Condition (GMC). This guideline will assist the physician in assessing the risk for an underlying GMC and specify the required investigations.

The portal of entry for the behaviourally disturbed patient in need of exclusion of a GMC is through the EC. The responsibility of the EC is to exclude a GMC as a primary cause and to provide initial containment. Once a GMC is excluded, the patient is to be transferred to a POU. The EC is an unsuitable location for a behaviourally disturbed patient, in terms of containment as well as safety issues for the patient, staff members and other patients and their visitors.

In any case of disagreement over the suitability of referrals, the matter must be referred to the relevant consultants and negotiated at consultant-to-consultant level.

This guideline will:

- Outline the flow of behaviorally disturbed patients through the care continuum
- Clarify the roles and responsibilities of ECs and POUs
- Define low and high risk criteria for a GMC

GUIDELINE FOR ROUTINE INVESTIGATIONS FOR EXCLUSION OF A GENERAL MEDICAL CONDITION IN A BEHAVIOURALLY DISTURBED PATIENT

October 2014

- Outline investigations required to exclude a GMC in ECs
- Outline investigations required to exclude a GMC in patients meeting low risk criteria in the POUs

This guideline conforms to the following principles

- Care should be centered around the patient. Every patient accessing emergency care has the right to quality emergency care. Every mental heath care user has the right to be managed in a safe, secure space that is conducive to their recovery.
- The 72-hour psychiatric observation process should take place in a dedicated in-hospital space, the POU, which, by definition, excludes the EC.
- The Psychiatry and Emergency Medicine Provincial Clinical Governance Committees agree that the EC is the least optimal clinical space in the hospital for continued psychiatric containment.
- Completion of forms and awaiting tests results should not delay movement of a patient from the EC to the POU or acute in-patient ward within the hospital itself.
- Responsibility for the care of a patient admitted under the MHCA for 72-hour assessment falls to the admitting team regardless of physical location of the patient.
- In the case of co-existing chronic non-stabilised medical illness, the medical illness must be controlled and an appropriate management plan be determined and agreed upon with the admitting doctor providing the psychiatric service.

The following issues are not covered by this policy:

- Referral pathways
- EMS inter-hospital transport logistics
- Sedation guidelines
- Security requirements in EC and POU
- Infrastructure of EC "Secure Examination Room" and POU
- Escalation policies in the event of EC and POU access block and overcrowding
- Community-based Crisis Intervention Teams
- Special groups: Adolescents; Geriatrics; Forensics
- Direct referral to psychiatric hospitals in the case of relapsed patients discharged from a psychiatric hospital within 3 months and aggressive patients despite adequate sedation.
- Roles of POUs in terms of Level 1 and 2 services at District and Regional Hospitals
- Equitable access to specialist psychiatric beds within the GSA.

1. Responsibilities of ECs and POUs

An EC is any facility that provides, and has infrastructure for, emergency care, and here includes all hospital-based ECs and the 24 hour Primary Health Care Community Health Centres. With respect to behaviourally disturbed patients, the EC's role is to screen for GMC as the primary cause of the behavioural

disturbance. This screening takes the form of a thorough history, examination, mental state examination and special investigations of a patient at high-risk for a GMC. Simultaneous to this screening, initial containment of the patient also occurs, including the sedation and institution of treatment as appropriate.

The EC is responsible to ensure that the MHCA Form 4 and one of the required Form 5's are completed in patients who need involuntary admission. This process should take no more than 6 hours from arrival to admission. Governance is under Family Medicine at PHC facilities and small District Hospitals, Emergency Medicine at large District Hospitals and Regional Hospitals, and General Medicine at Central Hospitals.

The POUs are in-patient areas providing 72-hour psychiatric assessment of behaviourally disturbed patients. These units are responsible for the care of the patient from referral to the psychiatry service until transfer to a Psychiatric Hospital or discharge back into the community. The POU is responsible for the 72-hour psychiatric observation (as outlined by the MHCA), the definitive treatment of the psychiatric illness, further investigations that may be required in patients who are low-risk for a GMC and completion of relevant MHCA forms. These forms are to be completed within 24 hours of arrival.

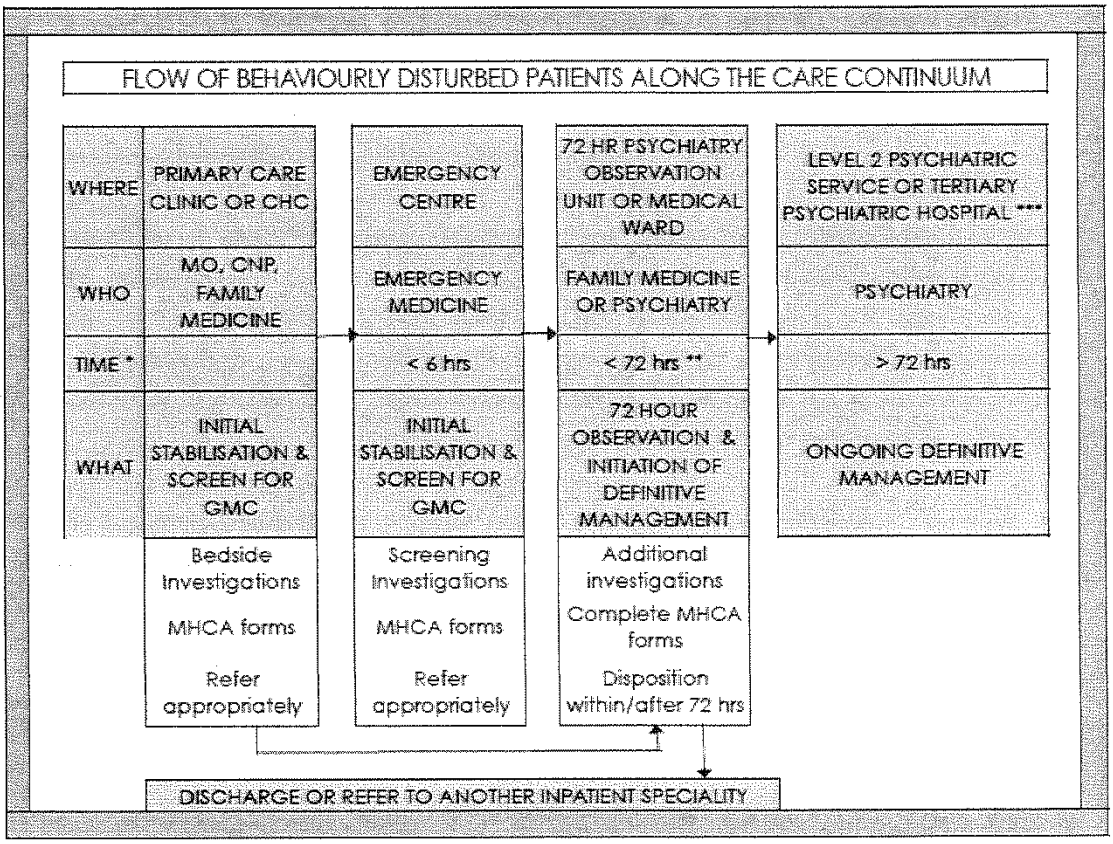
The presence of a significant GMC that may be the cause of the disturbed behavior is an EXCLUSION criterion for admission through the MHCA. In cases of significant psychiatric and medical co-morbidity the decision to admit into a medical ward with consulting psychiatry versus the POU is a joint decision between the inpatient teams of psychiatry and medicine.

Should a patient be referred from EC incorrectly to an inpatient team, such as a medically ill patient to psychiatry or vice versa, those inpatient teams are to co-ordinate care further, and the patient is not to be referred back to the EC. The matter must then be discussed with the EC in line with correct clinical governance feedback practice.

GUIDELINE FOR ROUTINE INVESTIGATIONS FOR EXCLUSION OF A GENERAL MEDICAL CONDITION IN A BEHAVIOURALLY DISTURBED PATIENT

October 2014

2. **Flow Diagram of behaviourally disturbed patients through the care continuum**



* All time frames expressed are ideal as per international standards.

** This recommends the time frame as per the MHCA regulations, not the provincial policy that refers to a 72 + 48 hour time-frame.

*** The division and location of levels of psychiatry services is outside the scope of this document, hence reference to psychiatry services above the 72-hour assessment period.

3. **Definitions of low and high risk criteria for a GMC**

Low Risk

Absence of High Risk Criteria

High Risk: Any one or more of these criteria are present

History:

- First presentation with symptoms < 1 month duration
- Known SEVERE chronic medical condition

- HIV positive AND WHO Stage 3-4
- Current SEVERE alcohol intoxication or withdrawal
- Recent head injury
- Recent seizures with obvious post-ictal state or delirium
- First presentation over the age of 50 years

Examination:

- Acutely abnormal vital signs
    - Excluding isolated ECG confirmed sinus tachycardia
- Signs of a new general medical condition
- Altered level of consciousness
- Catatonia

Mental State Examination (MSE)

- Not fully orientated for 2 or more of time, place and person
- Fluctuating symptoms
- Non-auditory hallucinations
- More than one type of hallucination

4. Assessment and Investigations required to exclude a GMC in ECs

Assessment and investigations in low risk cases with psychiatric history

- Triage and Vital Signs
- Thorough physical examination
- Dextrostix
- Urine dipstix > 60 years old

Additional investigations in low risk cases with first presentation (no psychiatric history)

- WCC *
- Na, Creatinine
- VDRL ***
- TSH *** (If clinical suspicion of hypo- or hyperthyroid)
- HIV **

Assessment and investigations in high risk cases

- Triage and Vital Signs
- Thorough physical examination
- Dextrostix
- Urine dipstix
- CXR

- WCC* (Interpret result in context of the clinical picture)
- Na, Creatinine
- TSH *** (If clinical suspicion of hypo- or hyperthyroid)
- HIV **

Lumbar puncture (LP) is indicated in

- Clinical suspicion of meningitis (No contraindication to LP)
- Known VDRL positive (send for Syphilis serology)***
- HIV positive AND clinical AIDS (Stage 3-4)

CT head is indicated in

- Altered level of consciousness
- Any new focal neurological abnormality
- New onset seizures
- History of alcohol abuse and unexplained disorientation
- Clinical suspicion of meningitis with contraindication to LP

The decision to perform further investigations should be determined by specific clinical indicators.

* WCC results must be interpreted in context of the clinical picture

** The decision to do rapid HIV tests is done based on clinical suspicion, and the decision whether to do this in the EC versus the POU is at the discretion of the facility. These patients do not have capacity to consent, so capacity is waivered.

*** The results of VDRL/RPR (Blood or CSF), HIV and TSH should not delay transfer of the patient to the POU in a physically well patient, and the results can be sourced there. The decision whether to initiate these tests in the EC or POU is at the discretion of the facility.

Investigations in all patients before transfer to the POU

- Pregnancy test in all females of child-bearing age
- CXR if a history of current or previous PTB, or constitutional symptoms OR if known HIV positive

5. **Investigations to exclude a GMC in patients meeting low risk criteria in the POU.**

Any further investigations in addition to those outlined above, are to be done within the 72-hr observation ward. This includes awaiting VDRL (blood or CSF), HIV, and TSH that may have been done in the EC, in a physically well patient.

GUIDELINE FOR ROUTINE INVESTIGATIONS FOR EXCLUSION OF A GENERAL MEDICAL CONDITION IN A BEHAVIOURALLY DISTURBED PATIENT

October 2014

6. **Flow Diagram of Assessment and Investigation to exclude a GMC of a Behaviorally Disturbed Patient in the EC and POU.**

ALGORITHM GUIDING INVESTIGATIONS TO EXCLUDE A GMC IN BEHAVIORALLY DISTURBED PATIENTS

HIGH RISK CRITERIA ? Any ONE of the following	
History	First presentation with symptoms < 1 month duration Known SEVERE chronic medical condition HIV positive AND WHO Stage 3-4 Current SEVERE alcohol intoxication or withdrawal Recent head injury Recent seizures with obvious post-ictal state First presentation over the age of 50 years
Exam	Acutely abnormal vitals except isolated ECG confirmed sinus tachy Signs of new general medical condition Altered level of consciousness Catatonia
MSE	Not fully orientated for 2 or more of time, place and person Fluctuating symptoms Non-auditory hallucinations More than one type of hallucination

NO: LOW RISK

FIRST PRESENTATION ?

NO	YES
Triage	Triage
Vitals	Vitals
Examination	Examination
Dextrostix	Dextrostix
U dip > 60	U dip > 60
	AND
	WCC *
	Na, Creat
	VDRL ***
	TSH ***
	HIV **

YES: HIGH RISK

Triage
Vitals
Examination
Dextrostix
Urine dipstix
CXR
WCC*
Na, Creatinine
TSH ***
HIV **

LP IF:
Clinical suspicion meningitis (No LP C/I)
VDRL positive (Syphilis serology)***
HIV AND clinical AIDS (Stage 3-4)

CT HEAD IF:
Altered level of consiousness
New focal neurological abnormality
New onset seizures
Hx alcohol & unexplained disorientation
Clinical suspicion meningitis & LP C/I

The decision to perform further investigations should be determined by specific clinical indicators.
* WCC results must be interpreted in context of the clinical picture
** The decision to do rapid HIV tests on patients in the EC versus the POU is at the discretion of the facility.
***TSH only to be done if clinical suspicion of hyper or hypothyroidism
*** VDRL/RPR (Blood/CSF), HIV,TSH RESULTS should not delay transfer to a POU in a physically well patient

Investigations in all before transfer to POU: Pregnancy Test AND CXR if Hx of PTB or clinical suspicion

Addendum 3: Research Proposal

Dissertation Proposal

Adherence to guidelines for routine investigations of adult patients with mental and behavioural disturbances presenting to a district level emergency centre

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This study is in partial fulfilment of the Master of Medicine (Emergency Medicine) degree

Declaration

I, Dr Solomon Jere, hereby declare that the work on which this thesis 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 in this or any other university.

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I declare that this is my own work.
I am attaching the summary of the Turnitin match overview (when required to do so).

_____

Solomon Jere
04 August 2020

List of tables

List of Addenda

List of Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
Cr	Creatinine
CT	Computed Tomography Scan
DALYs	Disability adjusted life years
DAP	Data analysis plan
EC	Emergency Centre
ECM	Enterprise content management (electronic medical records)
GMC	General Medical Condition
HECTIS	Hospital and Emergency Centre Tracking Information System
HGT	Human blood glucose test
HIV	Human Immunodeficiency Virus
LP	Lumbar Puncture
MHCU	Mental Health Care User
MPH	Mitchells Plain District Hospital
Na	Sodium
NHLS	National Health laboratory Services
POU	Psychiatric Observation Unit
RPR	Rapid Plasma Reagin
TPHA	Treponema Pallidum Hemagglutination Assay
TSH	Thyroid Stimulating Hormone
WCG	Western Cape Government
VDRL	Venereal Disease Research Laboratory
WCC	White Cell Count
WHO	World Health Organisation
YLD	Years lived with disability

Abstract

Introduction

The Western Cape has the highest prevalence of mental illness in South Africa. (1) The first South African Stress and Health Survey (SASH) conducted in 2004 found that the Western Cape had the highest twelve months and lifetime prevalence of mental disorders. (2) The Mental Health Care Act 17 of 2002 stipulates that mental health care users requiring admission be observed for 72 hours in a psychiatric observation unit (POU) for assessment and treatment. The Western Cape provincial guideline for routine investigations for exclusion of a general medical condition in a behaviourally disturbed patient (Circular H221 of 2014) was released in 2014 (addendum 3). The aim of this study is to assess adherence to these guidelines.

Methodology

This will be a descriptive study collecting data retrospectively from existing databases and registries. This study will be conducted at Mitchells Plain Hospital (MPH) in Cape Town, South Africa. Data will be collected from the electronic data base for 6 months (1st July 2019 – 31st December 2019). All adult patients (≥18 years old) will be eligible for inclusion. A sample size of approximately 500-600 cases is expected. All variables will be described with summary statistics. Categorical variables will be described as proportions or percentages and tabulated as necessary. Statistically significance will be defined as a $p<0.05$ and data will be analysed using SPSS Statistics for Windows, Version 26.

Ethical Considerations

Existing data will be collected retrospectively from existing electronic databases and in no way will patient care be affected. Data will be de-identified, and the utmost of care will be taken to protect the identity of patients. Obtaining consent will be impractical and because the potential benefits of this study outweigh this low-risk study, a waiver of consent will be applied for, and institutional approval will be obtained from Mitchell's Plain Hospital.

Conclusions

This is the first study of its kind in the Western Cape and a reasonably large study with regards to the number of participants. The results of this study will provide us with information on adherence and effectiveness of the 2014 Western Cape Government guidelines. The results could also form the basis

for future studies to help improve the guidelines for assessment of mental health care users in the emergence centre.

Introduction

Background

"The Western Cape has the highest prevalence of mental illness in South Africa." (1) The first South African Stress and Health Survey (SASH) conducted in 2004, showed that the twelve months prevalence of mental health disorders in South Africa is 16.5%, with an estimated lifetime prevalence of 30.3%. (3) The Western Cape had the highest twelve months and lifetime prevalence of 39.9%. (4) In the Western Cape, mental health is one of the top five contributors to the burden of disease, contributing significantly to strain on health care resources. (3) The incidence and prevalence of mental disorders are expected to increase due to worsening socio-economic challenges such as poverty, expanding informal settlements, displacement, and conflicts in low-income areas. (4)

The Mental Health Care Act 17 of 2002 stipulates that mental health care users requiring admission be observed for 72 hours in a psychiatric observation unit (POU) for assessment and treatment. (5) Not all behavioural disturbances in adults are due to mental health disorders - general medical conditions (GMCs) such as HIV/AIDs, syphilis, meningitis, stroke may also present with behavioural disturbances. (6) These GMCs may also co-exist with or exacerbate underlying mental health disorders. When patients with mental and behavioural disturbances present to a hospital for help, they are first assessed in Emergency Centres (ECs), to exclude a GMC, before they get referred to the relevant in-patient department. The provincial guideline for routine investigations for exclusion of a general medical condition in a behaviourally disturbed patient (Circular H221 of 2014) was released in 2014 and replaces Circular H107/2011 Protocol 4: Standardised Psychiatric Guidelines: The exclusion of General Medical Conditions (Addendum 3). The recommendations were based on a study by Credé et al. (2011), which showed that routine laboratory screening provides no additional information in the assessment of patients with mental and behavioural disturbances on presentation at the EC. (7) The guideline was also aimed at reducing the length of stay of these patients in the EC, which is not a conducive environment for mental health care users (MHCUs).

The guideline further categorises patients into three groups, based on their predicted risk for GMCs: (i) High risk patients (features of GMC present); (ii) Known mental health user with no high-risk features for GMC (low risk and known MHCU); and (iii) Index mental health user with no high-risk

features (low risk and index presentation). Refer to addendum 3 for details. The high-risk criteria are outlined in table 1 below.

Table 1: High risk criteria

High risk criteria for general medical conditions (GMCs)	
History • First presentation with symptoms less than one month • Known severe chronic medical condition. • HIV positive and WHO stage 3 or 4. • Current severe alcohol intoxication • Recent head injury • Recent seizures with obvious post-ictal state or delirium. • First presentation over the age of 50 years.	*General Examination* • Acutely abnormal vital signs • Signs of a new general medical condition • Altered level of consciousness • Catatonia *Mental state Examination (MSE)* • Not fully oriented to 2 or more of time, place, and person. • Fluctuating symptoms • Non-auditory hallucinations • More than one type of hallucinations.

Routine special investigations are not indicated for known mental health users with no high-risk features for GMCs. For those that present for the first time to seek help as a mental health user, routine screening investigations are however indicated and include a white cell count (WCC), sodium (Na), Creatinine (Cr), syphilis serology (TPHA) and HIV test (addendum 3). The thyroid stimulating hormone (TSH) test is recommended if clinical suspicion of hypo- or hyperthyroidism exists (severe mood symptoms). The guideline also recommends a lumbar puncture (LP) if a clinical indication is present, including a clinical suspicion of meningitis, a patient with active Syphilis, and an HIV positive patient with clinical AIDS (WHO stage 3-4). Patients with any high-risk features of a GMC require focused investigation and this may include a CT scan and other special investigations. All patients older than 60 years require a urine dipstick analysis and all patients require a full set of vital signs and a thorough clinical examination. MCHUs with high-risk features for GMC may end up being admitted to a different inpatient speciality, depending on the outcome of the special investigations.

Motivation

In December 2011, Credé at al. showed that routine laboratory screening provides no additional information to that obtained from a thorough history and clinical examination in patients with mental

and behavioural disturbances. (7) They found that special investigations changed the management of behaviourally disturbed patients in only 0.33% (2 out of 604) of the patients. The tests were also noted to be costly and delayed time to definitive care. The results of this study informed the development of the current guideline for routine investigations for exclusion of a GMC in patients with mental and behavioural disturbances: Circular H221 of 2014 (addendum 3). There is however no data that describe adherence to the above guidelines. In addition, the effectiveness of the guideline has never been assessed formally after its implementation. The data from Credé et al, has been sourced more than 10 years ago and the mental health disease burden and community profiles may have changed since then.

Aims

To assess adherence to guidelines for routine investigations of adult patients with mental and behavioural disturbances presenting to a district level emergency centre.

Objectives

1. To describe the demographics and diagnoses of all patients with mental and behavioural disturbances who were admitted from Mitchells Plain Hospital Emergency Centre during the study period.
2. To categorise all cases into three categories, based on the provincial guideline:
    a. No high-risk features for a GMC and a known mental health user
    b. No high-risk features for a GMC and an index presentation
    c. Any patient with high-risk features for GMC present
3. To assess adherence to the 2014 Western Cape Government guidelines for routine investigations to exclude GMCs in mental and behaviourally disturbed patients.
4. To describe the results of special investigations in patients where guidelines were adhered to, and in those where guidelines were breached.
5. To assess whether the results of special investigations changed the outcome of patients once admitted.

Methodology

Study design

This will be a descriptive study collecting data retrospectively from existing databases and registries.

Study setting

This study will be conducted at Mitchells Plain Hospital (MPH) in Cape Town, South Africa. The hospital is in the Mitchells Plain Health District of the Metro Region. The hospital is 32km from Cape Town's central business district and provides services to an estimated population of 600 000. (8) It serves low-to-middle income communities of Mitchells Plain and mainly low-income communities of Philippi, a large nearby township. The emergency centre (EC) admits 4-5 patients with mental and behavioural disturbances to the inpatient psychiatric department per day. Admissions range from 120-150, depending on the month-to-month variation with around 33% being female admissions. All patients with mental and behavioural disturbances present to the emergency centre, where they are assessed for the (i) need for admission and (ii) whether or not their symptoms are due to a general medical condition (GMC). MPH EC base their admission and medical clearance policy on a Provincial Circular H221 of 2014, which replaced *Protocol 4 (addendum 3).* After patients are assessed in the EC, they get categorised into three groups and special investigations are performed accordingly: (i) index presentation with no high-risk features; (ii) known mental health user with no high-risk features and (iii) patients with high-risk features. See addendum 3 for details. The psychiatric department comprises of one psychiatrist, three medical officers, an intern, and a family medicine registrar, and patients are admitted to two separate wards (male and female ward).

Study population and sampling

Inclusion criteria

All adult patients (≥18 years old) with mental and behavioural disturbances who presented to MPH EC will be eligible for inclusion. The definition of mental and behavioural disturbances for the purposes of this project will be any diagnosis from the World Health Organisation (WHO) ICD-10 Version: 2019 Chapter V: Mental and Behavioural Disorders (F00-F99). This group will include all admissions to the psychiatric ward, as well as patients with GMCs, who may have been admitted to a different department. Data will be collected for 6 months (1st July 2019 – 31st December 2019) and based on EC audits and hospital statistics, a sample size of approximately 500-600 cases is expected.

Exclusion criteria

Patients who are admitted directly to the psychiatric team and bypassed the EC will be excluded as well as those who are <18 years of age. Patients who were discharged directly from the EC will also be excluded (those not requiring admission).

Data collection and management

Data collection will be done in three phases:

Phase I

Data from eligible patients will be extracted from the electronic registry, Hospital and Emergency Centre Tracking and Information System (HECTIS)* along with their demographic details, their disposition, folder numbers and initial vital signs on triage. An ICD-10 search from within the database will be done by the database manager and de-identified data will be exported to a spreadsheet. Folder numbers will be used to track patients through all the phases of data collection. All patients with a (WHO) ICD-10 Version: 2019 code that is included in Chapter V: Mental and Behavioural Disorders (F00-F99), will be included. All patients that were discharged directly from the EC, will be excluded, as well as those who are ≤ 18 years of age.

Phase II

Clinical records stored on the Enterprise Content Management (ECM) database will be accessed for patients identified from phase I of data collection. The notes will be scrutinised, and all patients categorised into three categories, based on the details present at presentation: (i) no high-risk features for GMC and known mental health user; (ii) no high-risk features for GMC and index presentation and (iii) high-risk for GMC features present. This categorisation is usually documented in the clinical notes on the clerking sheet. Compliance to the guideline will be assessed by comparing the special Investigations performed with what is recommended. Clinical records will also be assessed to identify when GMCs are discovered as inpatients – this may or may not have affected the outcome or disposition.

Phase III

The results of all special investigations will be obtained from the National Health Laboratory Services (NHLS) database, and it will be classified into normal or clinically significantly abnormal. These values are based on evidence and international consensus and define thresholds for what is considered likely

to contribute towards psychotic symptoms. (9,10,11,12) Table 2 summarises the reference values that will be used.

Table 2: Reference values for laboratory investigations

Blood test	**Values considered abnormal enough to contribute towards psychotic symptoms**
Sodium	<125 or >160 mmol/l16
Creatinine	>200 µmol/l
White cell count	<4 or >15×109 /l8
Lumbar puncture	Any polymorphs/µl >3 lymphocytes/µl Protein >0.45 g/l Positive Gram stain/India ink stain/syphilis serology positive
HIV rapid test	Positive
Syphilis serology (rapid plasma reagin) TPHA	Positive
Thyroid-stimulating hormone	0.27 - 4.20 mIU/l

Source: Adapted from Credé et al (2011) (7) *

HECTIS: Hospital and emergency Centre Tracking Information System, an official Western Cape Department of Health Application, is being used instead of the paper-based patient register to track patients presenting to the emergency centre. HECTIS was primarily designed for administrative and management purposes in order to streamline and track patient processes in the Emergency Centre (EC), including their process times, triage scores, diagnoses, and dispositions. The data contained therein is useful source data for applied research relating to EC processes and flow. A patient gets registered on the database as soon as the patient registers an emergency centre visit on Clinicom. Patient details are pulled from the Clinicom database to minimise duplication of information. Thereafter the triage process (done by nurses) is documented on the system, including all the patient tracking information (which room or treatment area patient is in or moved to) and the process times. The doctors add the diagnosis via ICD-10 codes and the disposition (admitted, discharged, or referred etc.). All process times are also documented automatically. The variables fall into a number of broad categories:

- The EC register and audit
- ICD Chapter and diagnosis
- Triage TEWS and Tasks

This register is used in real-time by all nurses, all doctors and all clerks in the emergency centre and is securely accessed by individual username and password that provides permissions according to

category of user. The application and database servers are only available on the Western Cape WAN or via VPN.

Data is entered routinely for every patient in the EC and no consent for research purposes is requested. HECTIS was primarily designed for non-research purposes to replace the old paper-based registers. We are applying for a waiver of consent for this research analysing data in HECTIS. Researchers will only be able to access the data on HECTIS if ethical and facility approval is granted. Extracted data will be deidentified and analysed anonymously at the group level, and therefore poses negligible risk to potential research participants. The waiver of informed consent will not adversely affect participants' rights and welfare, nor will it influence the level or type of care received by the individual participants. Given the distressed nature of patients entering the healthcare system through the emergency centre, and the time sensitive nature of their medical care, obtaining informed consent in the emergency centre is not feasible. This is the only electronic database that captures patient information on triage, diagnosis, process times and dispositions. This research is therefore not practical without a waiver of informed consent.

The HECTIS is a clinical record subject to regulation under the POPI act. Data collection is ongoing, and the data will be maintained indefinitely in the registry. Extracted, deidentified data used for research purposes will be securely stored as per the approved protocol outlined in each request for research access received. Broadly, it is recommended that extracted data used for research purposes be kept securely for 5 years before it is deleted.

The Master database is hosted at SITA Observatory; The Disaster Recovery Site is hosted at SITA George (Oracle 12C database URL: healthp-db.sita-cloud.westerncape.gov.za; Database Instance Name: HEALTHP Port:1526). Currently, the following ECs utilise the HECTIS application: Mitchells Plain Hospital EC, Heideveld Hospital EC, and George Hospital EC. Groote Schuur Hospital EC (C14) will be moving onto the application shortly, and a number of other ECs are in the process of rolling out the application.

Authorised application users can access the data via the HECTIS application. Users of HECTIS are granted access and authorisation according to their clinical role, e.g., a clinician will access a different part of HECTIS than a triage nurse. All users log in via an active directory authenticated login and password. The student will be responsible for the entire data collection process.

Missing data or incomplete records

Because this will be a descriptive study and because it will not be testing a hypothesis, incomplete data will be included and described up to the point where it can no longer be analysed. Demographics will be presented for both missing and incomplete data so that it can be compared to those with complete data. This will allow for a comparison between cases and missing data. The investigators will make every effort to prevent missing data and a flow chart of cases and missing data/incomplete records will be presented. The expected effect is described in the limitations section.

Variables and data sources

A summary of the variables that will be collected can be found in the data analysis plan (DAP) in Addendum 1, as well as the data collection process in Addendum 2. Data required from phase I will be requested from the HECTIS database manager, who will export the data to an Excel spreadsheet remotely. Data required for phase II and III will be sourced from databases that can be accessed remotely. There will thus be no physical data collection at MPH hospital.

Data safety and monitoring

No identifying data will be collected, other than the folder numer and this is necessary to track patients through the different data collection phases . The data will be de-identified at the end of the data collection process. A study number will be assigned to each patient, and thereafter only study numbers will be used. Folder numbers will be saved against study numbers in a separate file in case of a query. Only investigators will have access to the files, and it will be password protected and saved in the investigator's password protected computer. Also, information obtained will be backed up in a cloud server which will also be password protected and accessed only by study investigators.

Data Analysis

All variables will be described with summary statistics. Categorical variables will be described as proportions or percentages and tabulated as necessary. The central tendency of continuous variables will be described as medians and quartiles will be used to indicate spread. Non-random differences between categorical variables will be determined with the Chi^2 or Fisher's Exact test, depending on its characteristics. Statistically significance will be defined as a $p<0.05$ and data will be analysed using SPSS Statistics for Windows, Version 26.0 (IBM Corp. Released 2019. Armonk, NY: IBM Corp.).

Ethical considerations

Even though this study involves a vulnerable population, it poses a very low risk to patients.

Risk to patients

Existing data will be collected retrospectively from existing electronic databases and in no way will patient care be affected. Data will be de-identified, and the utmost of care will be taken to protect the identity of patients. Obtaining consent will be impractical and because the potential benefits of this study outweigh this low-risk study, a waiver of consent will be applied for.

Risk to community

This project is expected to benefit the community and may provide a foundation for future research. This study poses no risk to the community.

Risk to clinician

The study will not collect or analyse data specific data pertaining to any clinician.

Risk to institution

This study poses no risk to Mitchells Plain Hospital. Ethical approval will be obtained from the Human Research Ethics Committee of the University of Cape Town (UCT HREC). Thereafter, institutional approval will be obtained from Mitchells Plain District Hospital via the National Health Research Database (NHRD). There will be no reimbursement for participation.

Limitations and strengths

Strengths

This is the first study of its kind in the Western Cape and a reasonably large study with regards to the number of participants**.** The results of this study will provide us with information whether guidelines are being followed and whether they are effective or not. The results could also form the basis for future studies to help improve the guidelines for assessment of MHCUs in the EC.

Limitations

The actual adherence may not be accurate as sampling does not include MHCUs ≤ 18 years old or those who bypassed the EC (direct admissions). We do however expect that the excluded sample to be small and that it will likely have a negligible effect on the study outcomes. Even though the investigators will clearly describe and present the demographics of the missing/incomplete data, it may affect the outcome and conclusion if the number of missing data is significant. The investigator will try to prevent missing or incomplete data as far as possible and present the data in as much detail as possible to allow for comparison between the two groups.

Data dissemination plan

A publication in a peer-review journal is expected. The study will provide insight into the current use of the provincial guidelines at Mitchells Plain District Hospital. The results obtained from this study will be presented to the hospital and the Division of Emergency Medicine, and to key managers in the provincial health department. This could result in policy change and may suggest a need for training and further skills development of clinicians, e.g., if poor adherence to the guidelines is evident.

Project Timeline

Table 3: Project timeline

2020	***Jan***	***Feb***	***Mar***	***Apr***	***May***	***Jun***	***July***	***Aug***	***Sep***	***Oct***	***Nov***	***Dec***
EMDRC		X	X	X	X	X	X	X				
Ethics										X		
Hospital Permission											X	X
2021	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**July**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Data Collection	X	X										
Data Analysis			X	X								
Writeup				X	X	X	X					
Submission								X				

Resources and budget

Hardware available: Laptop, Flash disk

Software available: Word processing software, referencing software, data management software/(spreadsheet) and statistical analysis software – to use institutional subscription.

The Malawi government scholarship funds will provide the total budget of R3 699.15 for this study.

Table 4: Budget

March 2020 – May 2021				
Item	**Description**	**Unit cost**	**N° of Units**	**Total cost**
Consumables				
1. Antivirus software				R550.00
2. Materials and supplies				R750.00
3. Internet data	4 GB data bundle			R400.00
4. office supplies, printing & reproduction for data collection	Stationary-pens, notepads, files			R823.00
5. office supplies, printing & reproduction for reports	Printing-data collection, reports, paper			1 223.00
Research travel				
1. travel to sites	Travel to MPH: x 5 trips = 30km x 10 = 300km = +/- R400 (SARS rates)			R750.00
2. other, specify	Travel to UCT library: 5 trips= 5km x 10= 50km			R250.00
Contingency				**R176.15**
Total				**R 3 699.15**

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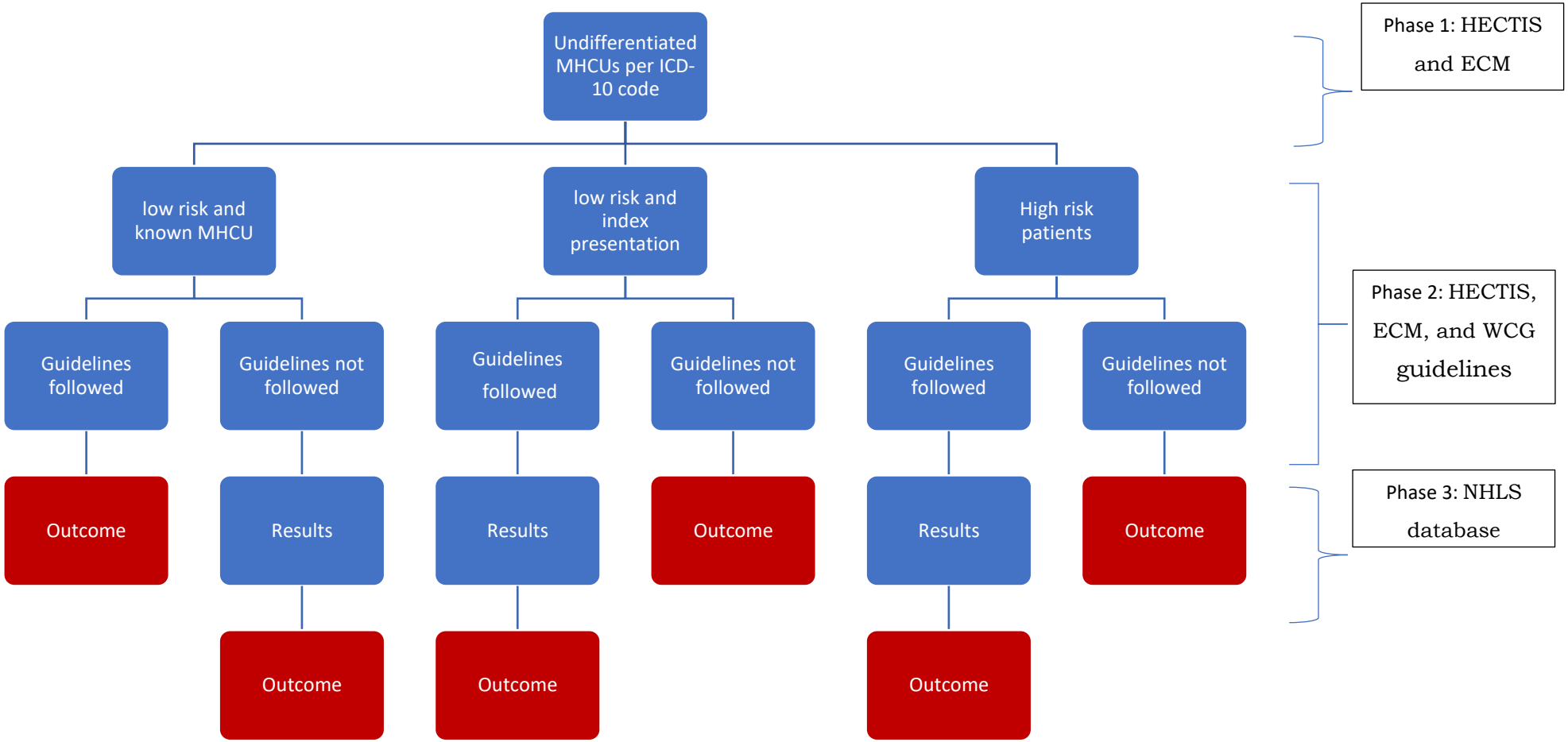
Addenda

Addendum 1: Data analysis plan

	Variable	Variable type	Source	Data analysis
Objective 1: To describe demographics, diagnoses, and dispositions.	Age Gender ICD-10 code (diagnosis) Disposition	Numerical discreet Categorical dichotomous Categorical nominal Categorical nominal	HECTIS	Descriptive statistics with proportions and percentages Chi^2 test or Fisher's Exact
Objective 2: To categorise all cases into three categories	Category	Categorical nominal	ECM	Chi^2 test or Fisher's Exact
Objective 3: To assess adherence to the guideline	Adherence (yes vs no)	Categorical dichotomous	ECM	Chi^2 test or Fisher's Exact
Objective 4: To assess how non-compliance affected outcome and disposition	Discharge diagnosis Final disposition	ICD-10 (ward diagnosis) Categorical nominal	ECM	Chi^2 test or Fisher's Exact
Objective 5: To describe the results of special investigations	Results (normal vs abnormal)	Categorical dichotomous	NHLS	Chi^2 test or Fisher's Exact

Addendum 2: Data collection process



Addendum 3: Circular H221 of 2014: Guideline for routine investigations for inclusion of General Medical Condition in a behaviourally disturbed patient

See addendum 2 on page 35.

Addendum 4: Human Research Ethics Committee Approval

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

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

09 December 2020

HREC REF: 678/2020

Dr C Hendrikse
Division of Emergency Medicine
F-51, OMB
Email: - clint.hendrikse@uct.ac.za
Student: sjere101@gmail.com

Dear Dr Hendrikse

PROJECT TITLE: ADHERENCE TO GUIDELINES FOR ROUTINE INVESTIGATIONS OF ADULT PATIENTS WITH MENTAL AND BEHAVIOURAL DISTURBANCES PRESENTING TO A DISTRICT LEVEL EMERGENCY CENTRE. (MMED CANDIDATE: DR S JERE)

Thank you for your response letter, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

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

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 30 December 2021.

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)

***The HREC acknowledge that the student:* - Dr Solomon Jere will also be involved in this study.**

Please quote the HREC REF in all your correspondence.

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, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

HREC/REF:678/2020ss

Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

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 Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) 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.

HREC/REF:678/2020ss

Addendum 5: National Health Research Department Approval

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 0866; fax: +27 21 483 6058
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_202012_014
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Dr Solomon Jere, Dr Mignon Du Toit, Dr Clint Hendrikse, Dr Candice Van Korningsbruggen, Dr Rukeya Kader

Re: Adherence to guidelines for routine investigations of adult patients with mental and behavioural disturbances presenting to a district level emergency centre

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Mitchells Plain Hospital	**Dr Jacek Marszalek**	**021 377 4782**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

DR M MOODLEY
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE:
CC

Dr Melvin Moodley
Director: Health Impact Assessment
09 MAR 2021