A medical audit of the management of cryptococcal meningitis in HIV-positive patients in the Cape Winelands (East) district, Western Cape

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Abstract

Background: Cryptococcal meningitis (CM) has become the most common type of community-acquired meningitis. CM has a poor outcome if the initial in-hospital treatment does not adhere to standard guidelines. The aim of this audit was to improve the quality of the care of human immunodeficiency virus (HIV) positive patients with CM in the Cape Winelands District.

Method: Following an initial audit in 2008, the researchers and a new audit team introduced interventions, and planned a second audit cycle. The folders of 25 HIV-positive adults (admitted to three district hospitals, one regional hospital, and one tuberculosis hospital) were audited.

Results: Spinal manometry was performed more consistently in the regional hospital, than in the district hospitals. Reasons for failing to reach the 14-day amphotericin B target were in-patient deaths, drug stock problems, and renal impairment. The renal monitoring of amphotericin B treatment was suboptimal. The quality of care at district hospitals appeared to be comparable to that found at the regional hospital. The in-patient referral for antiretroviral treatment (ART) counselling was better in the district hospital setting. However, both levels of care had difficulty in achieving the four-week target between the onset of amphotericin B and onset of ART.

Conclusion: Deficiencies in the quality of care remained. Between the prior and current audit cycles, there was no consistent improvement in care at the regional hospital. An integrated care pathway document has been developed, and adopted as policy in the Cape Winelands district. Its impact on the quality of care will be evaluated by a dedicated audit team in the future.

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Introduction

Cryptococcal meningitis (CM) is caused by an opportunistic encapsulated yeast, *Cryptococcus neoformans*. Despite recent expansion of antiretroviral treatment (ART) programmes in developing countries, CM remains a major opportunistic infection, and a leading cause of mortality in acquired immune deficiency syndrome (AIDS) patients.[1] CM has become the leading cause of community-acquired meningitis (ahead of tuberculous and bacterial meningitis), and if not treated correctly, has a significant mortality.[2] In 2009, the global incidence of CM ranged from 0.04-12% per year among persons living with human immunodeficiency virus (HIV)/AIDS. Sub-Saharan Africa had the highest yearly burden estimate (median incidence 3.2%, 720 000 cases, range 144 000-1.3 million). In regions with primarily less developed countries, the estimated case fatality was 55%. However, in sub-Saharan Africa, it was estimated to be 70%.[3]

Medical audit is central to the process of continuous quality improvement. Quality of care is one of the pillars of clinical governance, the concept that refers to the accountability of a health care system to ensure the correct standard of care for its patients.[4] Medical audits are not new in the HIV context.[5-7]

A CM audit at Northdale Hospital, Pietermaritzburg, KwaZulu-Natal, reviewed 18 CM cases diagnosed in July 2006.[8] The key concerns were management of CM-associated raised intracranial pressure (ICP), general CM management uncertainties, and follow-up challenges regarding ART and long-term fluconazole adherence. The key recommendations included addressing resource needs (manometers), paying attention to the diagnosis and management of raised ICP, and addressing the need to develop a local CM treatment guideline.

In a 2005 report from two hospitals in Washington, DC, USA, researchers emphasised the importance of adherence to the Infectious Diseases Society of America (IDSA) guidelines for CM management.[9,10] Deviations in the management of raised ICP were observed in 88% of patients with poor neurological outcome. Aggressive management of raised ICP was associated with an improved outcome. This report recommends that measurement of ICP be performed in all patients evaluated for meningitis in treatment settings with a high prevalence of immunosuppression.

A recent South African guideline for CM, published in 2007, stressed the importance of improving the initial acute management of CM, as this will maximise the patient's chances of initial survival, and subsequent entry into the ART programme.[11]

CM patients are treated in the district and regional hospitals of the Cape Winelands (East) district. The clinical outcomes of these patients were perceived as poor by the treating team. However, no data were available to show whether the quality of care could explain these poor outcomes. In addition, no data were available to determine whether generalist care at a district hospital was comparable to specialist care at the regional hospital.

Prior to this study, an initial audit was performed in 2008 at Worcester Regional Hospital. Target standards were developed for each criterion of the CM management process. These criteria had to be well defined, as well as measurable against a level of performance.[12] The criteria were divided into three areas; structure, process and outcome. The audit of 14 patients' records highlighted the following findings. Target standards for completing 14 days of amphotericin B and eight weeks of high-dose fluconazole, were met in this period (June 2007 until July 2008); opening pressures (manometry) with lumbar punctures were carried out in only three of the 14 patients; no cases of amphotericin B-associated renal impairment were found (at the time, the misperception among the clinical team was that amphotericin B caused renal impairment in most patients); and all the patients were referred for ART commencement, but none of the patients had started ART by the target standard (four weeks from onset of antifungal treatment). The clinical team admitted unfamiliarity regarding the use of manometry, and the management of CM-associated raised ICP. The insights from this prior audit provided the motivation for this study, and helped to define the initial interventions.

Aim and objectives

This medical audit aimed to improve the quality of the clinical care of HIV-positive patients diagnosed with CM in the Cape Winelands (East) district by evaluating the clinical team's adherence to national treatment guidelines.

The objectives of the audit were as follows:

- To create appropriate target standards for the management aspects of CM.
- To demonstrate an improvement in the quality of CM care, using the cyclical audit process.
- To identify strengths and weaknesses in the quality of CM care at district and regional hospital level.
- To reflect on the quality of CM care at district hospital level, as compared to regional hospital level.
- To identify key interventions that may improve the quality of care of CM patients.
- To provide recommendations to the facilities and the Department of Health.

Method

Study design

The study followed the usual steps for medical audit as shown in Figure 1. Because of the information derived from a prior audit, described in the introduction, this study started the new audit cycle by implementing changes in clinical practice.

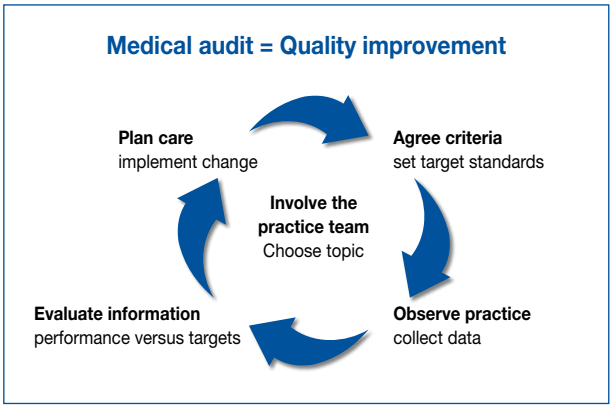

Figure 1: Quality improvement cycle

Setting

The study included all five hospitals in the eastern part of the Cape Winelands district. The Cape Winelands (East) district refers to the three subdistricts in the drainage area of Worcester Regional Hospital, Witzenberg (Ceres District Hospital), Breede Valley (Worcester Regional Hospital and Brewelskloof Tuberculosis Hospital), and Langeberg (Robertson and Montagu district hospitals). CM patients are admitted for in-patient amphotericin B treatment at all of these hospitals. On discharge, these patients are managed at various primary health care clinics in the drainage area of these hospitals. District hospitals are staffed by general medical practitioners, while the departments at the regional hospital and tuberculosis hospital are staffed by internal medicine specialists, and medical officers dedicated to the specific discipline.

The audit team

The clinical audit team of the Cape Winelands (East) district consisted of the researchers, the district's clinical programme co-ordinator for infection prevention and control, as well as audit champions from each of the subdistricts. The work of the audit team relied on the co-operation of all relevant healthcare personnel (managers, doctors, nurses, pharmacists, laboratory technicians and ART clinic personnel) at the facilities.

Step 1: Intervention: plan changes based on findings of the first audit cycle

Interventions were developed based on the results of the prior audit, which used the same methods as described here, but was confined to the regional hospital. During September and October 2009, the researchers arranged training sessions at each of the five hospitals. This educational intervention focused on the problem areas identified in the prior audit, especially the importance of adhering to the national treatment guidelines.[11] It was reinforced by posters and handouts describing the CM treatment guidelines. The audit team also liaised with local hospital management to ensure the procurement of spinal manometers, and with the ART clinic staff to ensure the speedy attendance to CM patients.

Step 2: Revision of old, and development of new, criteria, and target standards

The target standards used in the prior audit were reviewed, and new criteria were included from the guidelines published in *The South African Journal of HIV Medicine* and other

Table I: Comparison of actual performance and target standards (n= 25)

Criteria		Target standard	n	Actual performance n (%)	Target standard met
Structural criteria					
1.1	Availability of amphotericin B per eligible patient	100%	20	15 (75)	No
1.2	Availability of fluconazole per facility	100%	5	5 (100)	Yes
1.3	Protocol for the administration of amphotericin B displayed in the facility	100%	5	4 (80)	No
1.4	Availability of spinal manometers per facility	80%	5	2 (40)	No
Process criteria					
2.1	CT scan if depressed level of consciousness and focal neurology	100%	2	2 (100)	Yes
2.2	Requesting CLAT on Indian ink-negative CSF samples	100%	8	8 (100)	Yes
2.2	Use of CSF manometry in initial LPs	100%	25	11 (44)	No
2.4	ICP reading and opening pressure recorded during admission (including initial LP)	80%	25	20 (80)	Yes
2.5	Completing target of 14 days of IV amphotericin B	80%	20	9 (45)	No
2.6	Using correct dose of amphotericin B (1 mg/kg)	100%	20	19 (95)	No
2.7	Adherence to minimum standard of renal monitoring: U and E, Mg^9 tests while on amphotericin B (initial and two tests per week)	100%	18	8 (44)	No
2.8	Saline preload prior to daily amphotericin B dose	100%	20	17 (85)	No
2.9	Saline IV flush after daily amphotericin B dose	100%	20	12 (60)	No
2.10	Referral for inpatient ART counselling during admission	80%	11	9 (81)	Yes
2.11	Referral to ART clinic on discharge	100%	8	8 (100)	Yes
2.12	High-dose fluconazole for eight weeks (consolidation phase)	100%	7	7 (100)	Yes
Outcome criteria					
3.1	Commencement of ART by week four into antifungal treatment	80%	5	3 (60)	No
3.2	Percentage developing amphotericin B-associated renal impairment	< 20%	20	3 (15)	Yes
3.3	Percentage developing amphotericin B-associated thrombophlebitis	< 10%	20	2 (10)	Yes
3.4	Two months survival post-diagnosis	60%	18	6 (33)	No

CT: computed tomography, CLAT: cryptococcal latex agglutination test, CSF: cerebrospinal fluid, LP: lumbar punctures, ICP: intracranial pressure, IV intravenous, ART: antiretroviral treatment

literature.[11,13-16] The updated criteria and standards used in the audit cycle are listed in Table I.

Step 3: Collection of data to measure target standards

All HIV-positive patients aged 13 years and older who were diagnosed with CM and treated at the hospitals in the eastern part of the Cape Winelands district in the specified period, November 2009 to June 2010, were enrolled. Patients were identified by extracting diagnostic information from the National Health Laboratory Service database. Altogether, 25 patients were identified, and their folders reviewed.

Step 4: Analysis of the data, and comparison with target standards

The data were entered into MS Excel® and analysed to give simple frequencies. The results were then compared with the target standards for each criterion. Subgroup analysis was performed to enable comparison of the results for the regional vs. district hospitals. The results from this audit were also compared to the results obtained in the prior audit.

Ethical considerations

The Health Research Ethics Committee of the Faculty of Health Sciences, Stellenbosch University, approved the study protocol on 8 December 2009 (N09/08/205). The study protocol (research proposal 2010 RP 89) was also approved by the district health services and health programmes, Provincial Government Western Cape.

Results

The demographic and medical profiles of the 25 patients with CM are shown in Table II.

The results are presented in three sections: all hospitals, district vs. regional hospitals, and, finally, a comparison with the prior audit.

Table II: Demographic and medical profile of the study population

	Male	Female	Total
Number of patients in audit	13	12	25
Average age (years)	40	33	37
Average CD4 count at CM diagnosis (cells/µl)	131	82	108
Average in-patient stay for those patients who were discharged (days)	40	28	34
Number of patients with previous diagnosis of CM	2	1	3
Number of patients already on ART at CM diagnosis	3	2	5

ART: antiretroviral treatment

All hospitals

Table I presents the actual level of performance for each criterion for the whole audit population. This level is compared to the target standard.

Of the 25 patients, four patients did not receive amphotericin B. Three died prior to initiating treatment, and one had prior renal impairment. One patient receiving amphotericin B was excluded, as this patient had only just been admitted at the time of data collection. Of the 20 who started amphotericin B treatment, nine completed the 14-day course, three died before completing treatment, five did not complete treatment due to a lack of amphotericin B in stock, and three stopped treatment because of renal impairment.

Of the 25 patients, 14 were not expected to start ART; nine died in hospital, two were already on ART, and three had only just been admitted at the time of data collection. Of the remaining 11, three died before their ART clinic appointment, and the remaining eight should have initiated ART.

Twelve patients died in hospital, and one patient died soon after discharge. At the time of data collection, three patients were still receiving initial treatment in hospital. Data on the monitoring of amphotericin B were missing on two patients, and data on the status of two patients eight weeks post-discharge were also missing.

District vs. regional hospitals

The data of six district-level patients and 14 regional-level patients, were used to analyse the differences in structure, process and outcome in CM management. The researchers excluded the data from Brewelskloof Hospital's five patients for this comparison, as they were treated in a dedicated tuberculosis hospital, and not a district hospital. Table III compares the demographic and medical profile of these patients.

Table IV compares the results from the district and regional hospitals. The target standard was met in both settings in seven criteria, and not met in both settings in eight criteria. Only the regional hospital met the target standard for three criteria: consistent availability of manometers, follow-up manometry, and occurrence of renal impairment during amphotericin B treatment. Only the district hospital met the target standard for two criteria, displaying the guidelines in the facility, and providing in-patients with ART counselling referrals.

Table III: Demographics: district vs. regional hospitals (2010 audit)

	District	Regional
Number of patients	6	14
Average age (years)	39	35
Average CD4 count at CM diagnosis (cells/µl)	105	108
Average in-patient stay (days)	20	26

Table IV: Results: comparison of level of performance: district vs. regional hospitals (2010 audit)

Criteria		Target standard	District hospitals			Regional hospital		
			n	Actual performance n (%)	Target standard met	n	Actual performance n (%)	Target standard met
1.1	Availability of amphotericin B per eligible patient	100%	6	5 (83)	No	10	6 (60)	No
1.2	Availability of fluconazole per facility	100%	3	3 (100)	Yes	1	1 (100)	Yes
1.3	Protocol for the administration of amphotericin B displayed in the facility	100%	3	3 (100)	Yes	1	0 (0)	No
1.4	Availability of spinal manometers per facility	80%	3	0 (0)	No	1	1 (100)	Yes
2.1	CT scan if depressed level of consciousness and focal neurology	100%	Nil patients met CT indications			1	1 (100)	Yes
2.4	Requesting CLAT on Indian ink-negative CSF samples	100%	1	1 (100)	Yes	3	3 (100)	Yes
2.2	Use of CSF manometry in initial LPs	100%	6	1 (17)	No	14	5 (36)	No
2.3	ICP reading and opening pressure recorded during admission (including initial LP)	80%	6	3 (50)	No	14	13 (93)	Yes
2.5	Completing target of 14 days of IV amphotericin B	80%	5	2 (40)	No	11	5 (45)	No
2.6	Using correct dose of amphotericin B (1 mg/kg)	100%	5	5 (100)	Yes	11	10 (91)	No
2.7	Adherence to minimum standard of renal monitoring: U and E, Mg tests while on amphotericin B (initial and two tests per week)	100%	5	2 (40)	No	9	4 (44)	No
2.8	Saline preload prior to daily amphotericin B dose	100%	5	4 (80)	No	11	9 (81)	No
2.9	Saline IV flush after daily amphotericin B dose	100%	5	2 (40)	No	11	5 (45)	No
2.10	Referral for in-patient ART counselling during admission	80%	3	3 (100)	Yes	7	5 (71)	No
2.11	Referral to ART clinic on discharge	100%	3	3 (100)	Yes	5	5 (100)	Yes
2.12	High-dose fluconazole for eight weeks (consolidation phase)	100%	3	3 (100)	Yes	5	5 (100)	Yes
3.1	Commencement of ART by week 4 into antifungal treatment	80%	3	1 (33)	No	6	2 (33)	No
3.2	Percentage developing amphotericin B-associated renal impairment	< 20%	5	2 (40)	No	11	0 (0)	Yes
3.3	Percentage developing amphotericin B-associated thrombophlebitis	< 10%	5	0 (0)	Yes	11	1 (9)	Yes
3.4	Two months survival post-diagnosis	60%	6	3 (50)	No	9	2 (22)	No

CT: computed tomography, CLAT: cryptococcal latex agglutination test, CSF: cerebrospinal fluid, LP: lumbar punctures, ICP: intracranial pressure, IV: intravenous, ART: antiretroviral treatment

Comparison with prior audit

Only the data from the regional hospital could be compared with the prior audit results. The demographic and medical profiles of these patients are shown in Table V, while Table VI compares the actual results. Only the criteria from the 2008 audit were used for this comparison. In both audits, the target standard was met in six criteria, and not met in an equal amount. In the 2010 audit, amphotericin B treatment was not available consistently. Although the criterion was still not met, the adherence to spinal manometry improved during the 2010 audit.

In the 2008 audit, three out of the 13 patients were already on ART before the CM diagnosis. Seven out of the 13 patients died before week 4 of antifungal treatment. Therefore, only three patients could be evaluated for the ART work-up criterion.

Table V: Demographics: Worcester Regional Hospital audits (2008 and 2010)

	2008	2010
Number of patients	13	14
Average age (years)	35	35
Average CD4 count at CM diagnosis (cells/µl)	110	108
Average in-patient stay (days)	No data	26

Discussion

The audit focused on the three key areas of the CM in-patient treatment period, namely CSF manometry, amphotericin B treatment and ART initiation and referral. The key issues and recommendations are very similar to those of the two audits in KwaZulu-Natal and Washington, DC mentioned in the introduction

Table VI: Comparing of actual performance of Worcester Regional Hospital (2008 vs. 2010) to the target standards

Criteria from initial audit		Target standard	2008			2010		
			n	Actual performance n (%)	Target standard met	n	Actual performance n (%)	Target standard met
1.1	Availability of amphotericin B per eligible patient	100%	9	9 (100)	Yes	10	6 (60)	No
1.2	Availability of fluconazole per facility	100%	1	1 (100)	Yes	1	1 (100)	Yes
1.3	Protocol for the administration of amphotericin B displayed in the facility	100%	1	0 (0)	No	1	0 (0)	No
2.1	CT scan if depressed level of consciousness and focal neurology	100%	4	4 (100)	Yes	1	1 (100)	Yes
2.2	Use of CSF manometry in all LPs	100%	13	3 (21)	No	14	13 (93)	No
2.4	Requesting CLAT on Indian ink-negative CSF samples	100%	13	13 (100)	Yes	3	3 (100)	Yes
2.5	Completing target of 14 days of IV amphotericin B	80%	9	7 (78)	No	11	5 (45)	No
2.7	Baseline U and E and biweekly U and E	100%	13	12 (92)	No	9	4 (44)	No
2.11	Referral to ART clinic on discharge	100%	7	7 (100)	Yes	5	5 (100)	Yes
2.12	High-dose fluconazole for eight weeks (consolidation phase)	100%	7	7 (100)	Yes	5	5 (100)	Yes
3.1	Commencement of ART by week four into antifungal treatment	80%	3	0 (0)	No	6	2 (33)	No
3.2	Percentage developing amphotericin B-associated renal impairment	< 20%	9	0 (0)	Yes	11	0 (0)	Yes
3.4	Two months survival post diagnosis	60%	13	6 (46)	No	9	2 (22)	No

CT: computed tomography, CSF: cerebrospinal fluid, CLAT: cryptococcal latex agglutination test, IV: intravenous, ART: antiretroviral treatment

Spinal manometry was performed more consistently in the regional hospital than in the district hospitals, and spinal manometers were also more consistently available at the regional hospital. Spinal manometers were introduced to the district hospitals as part of the interventions, but were not readily available. At the regional hospital, the overall attention to spinal manometry had improved considerably between the prior and current audits. However, the use of manometry with the initial diagnostic lumbar puncture needs to be improved.

There were three main reasons for failing to reach the 14-day amphotericin B target. These were patient deaths, drug stock problems and renal impairment. An unexpected finding was the interruption of treatment due to lack of amphotericin B stock, which requires further exploration at local and regional pharmaceutical treatment committee meetings.

The renal monitoring of amphotericin B treatment was also suboptimal, possibly due to lack of awareness of the need to monitor renal function. Saline preloading (prior to the daily amphotericin B dose) was carried out well in both settings. However, saline flushing of the line after the amphotericin B dose was poorly documented in both settings. Both settings reported a low prevalence of amphotericin B-related morbidity, such as amphotericin B-associated thrombophlebitis and renal impairment, but documentation of these side-effects was consistently inadequate in both settings.

The in-patient referral for ART counselling was better in the district hospital setting. This may be due to the seamless nature of services in the district hospitals. However, both levels of care had difficulty in achieving the target of four weeks between the onset of amphotericin B and the onset of ART. Creative ways of commencing ART by week 4 of antifungal treatment need to be explored by local role players. Patients with low functionality could be transferred to a step-down facility (subacute bed) for in-patient ART initiation. Community-based workers and families may support outpatient ART initiation in the patient's home. Subdistrict-specific community resources should be explored.

The quality of care at district hospitals appeared comparable to that of the regional hospital, although higher risk patients should be referred from the district level. These negative predictive factors regarding mortality risk have been described in the literature as high CSF fungal burden, raised ICP, low CD4 count, and other co-morbid factors.[17]

The constant turnover of junior doctors in the hospitals may have limited the impact of the initial educational intervention, and the regional hospital did not display the guidelines as a wall poster.

An integrated care pathway functions as a tool to adapt best evidence to a particular setting, such as the district hospital context where CM patients are treated sporadically by generalist healthcare workers. This strategy of developing

and disseminating local health district guidelines may be more effective than the passive dissemination of national or international guidelines.[18] CM care is complicated, and requires a standardised approach, which could be improved by development of a local integrated care pathway. An integrated care pathway forms all, or part of, the clinical record, and could be used for a CM database and data register, which may improve the quality of data used for subsequent audits. This database may also be utilised for other forms of research, such as long-term follow-up and outcomes of CM patients after completion of the in-patient treatment phase. The two-month survival figure of CM patients was still below the sub-Saharan reference value.[13] Integrated care pathways have human resource implications, as all new staff will require induction, whereas current staff will require ongoing training.[18,19] While the integrated care pathway acts as a template of the care to be provided, it is not intended to compromise clinical judgement. Integrated care pathways are dynamic documents that require periodic review, and change is to be expected as new evidence emerges.[20]

Limitations

Although all patients with CM were included in the audit, the total number was small, especially in some of the subgroups. The reliability of the results must be treated with caution when dealing with such small numbers. In addition, the data depended on accurate and complete record keeping by the medical staff, and this was often inadequate. The prior audit had slightly different criteria, and was only performed at the regional hospital.

Recommendations

Patients should continue to be managed at the district hospital, and those with adverse risk factors should be referred to the regional hospital.

The researchers developed an integrated care pathway for the integrated care of CM patients (available from the corresponding author), which has been presented to the audit team, and accepted by the Cape Winelands district office (distributed as Circular No 27/2011 on 9/9/2011). The integrated care pathway is based on the South African HIV Clinician Society guidelines, and the recently published 2010 Infectious Diseases Society of America (IDSA) CM management guidelines.[11,21] This integrated care pathway comprises a CM management flowchart, as well as a two-week in-patient calendar which should be part of the patient's clinical notes. This calendar prompts the clinical team (doctors, nurses and ART councillors) to perform evidence-based actions in the three key areas of the in-patient treatment phase: CSF manometry and management of raised ICP, amphotericin B treatment, and ART counselling and referral.

Follow-up audit cycles are recommended to evaluate the influence of this integrated care pathway, as well as the adherence of clinicians to the integrated care pathway. A dedicated CM audit team is recommended, consisting of the family physicians and the HIV/AIDS Sexually Transmitted Diseases and Tuberculosis (HAST) programme co-ordinators at subdistrict and district level, as well as the principal physician at the regional hospital. This team should use the best level of evidence to review the integrated care pathway and audit criteria on an annual basis. Consultation with provincial and national experts, such as the South African HIV Clinician Society, and infectious diseases academic units may be necessary to ensure the appropriate recommendations for rural and resource-constrained settings.

Conclusion

Criteria were developed to assess the structure, process and outcome of care for CM. Despite an educational intervention, significant deficiencies in the quality of care remained. Spinal manometers were not available at the district hospitals, and initial manometry was poorly performed at both levels of care. Completion of amphotericin B treatment was limited by a lack of medication, patient deaths, and development of renal impairment. Renal monitoring was suboptimal. Counselling for ART was better in the district hospitals, but all facilities struggled to initiate ART within four weeks. There was no consistent improvement in care at the regional hospital between the prior and current audit cycles. An integrated care pathway document has been developed and adopted as policy. Its impact on the quality of care will be evaluated by a dedicated audit team in the future.

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