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Research Article

Clinical audit of Heparin use in Rift Valley General Hospital, Nakuru County, Kenya

Alice N. Gichobi [a,*], Stanley N. Ndwigah [b], Kipruto A. Sinei [a], Eric M. Guantai [a]

[a] *Department of Pharmacology and Pharmacognosy, School of Pharmacy, University of Nairobi, Kenya*
[b] *Department of Pharmaceutical Chemistry, School of Pharmacy, University of Nairobi, Kenya*

* **Corresponding author**: Department of Pharmacology and Pharmacognosy, School of Pharmacy, University of Nairobi, P.O. Box 19676-00202 , Nairobi, Kenya; **Tel:** +254-72-5820525; **Email**: alicegichobi14@gmail.com

Background: Heparin is a high risk medicine that may cause significant harm if not used properly. It is ranked among the top 5 "high alert" medications by the Institute of Safe Medication Practices because of its low therapeutic index and potential for serious adverse outcomes. Adherence to guidelines and protocols, as well as careful monitoring of heparin use, is important in maximizing benefits of its use and minimizing on harm.

Objective: The aim of this study was to examine the processes and outcomes of heparin use in adult in- patients at the Rift Valley General Hospital through the conduct of a clinical audit.

Methodology: A structured clinical audit tool was developed through consolidation of information from various sources. The structures supporting heparin use were physically assessed, including the availability of policies, guidelines or protocols, protamine and laboratory reagents. The processes and outcomes of its use were audited through the prospective observation of heparin dosing, administration and monitoring among eligible adult in-patients.

Results: Clinical audit revealed there were no policies, protocols or guidelines to guide heparin use at Rift Valley General Hospital. Delayed or lack of heparin monitoring were observed. Heparin termination was done well by introduction of warfarin at least three days before stopping heparin in majority of the patients. The overall clinical audit score at Rift Valley General Hospital was 60.6% which showed minimal compliance to the performance threshold/standard of heparin use.

Conclusions: Clinical audit for heparin use in RVGH concluded inadequate compliance to the set standards. There is need to avail guidelines, protocols or policies in the institution and conduct regular monitoring to ensure use of heparin is improved and maximum benefit is realized.

Key words: Heparin, clinical audit, monitoring.

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1. Introduction

Heparin is the most common parenteral anti-thrombotic drug most widely used for the prevention and initial treatment of venous thromboembolism, for hemodialysis and cardiopulmonary bypass procedures and, with aspirin, for the management of acute coronary syndromes (European Medicines Agency, 2011, Scientific and Standardization Committee Communication, 2001). Heparin is on the World Health Organization's (WHO) List of Essential Medicines, a list of the most important medications needed in a basic health system. Heparin is also in the Kenya Essential Medicines List (KEML). As such, heparin should be available for use in patients from the National Referral Hospital right down to the Sub- District level of care.

Heparin is a high risk medicine that may cause significant harm if not used properly. Heparin therapy is associated with safety problems and the potential for

medication errors which may have serious/ significant consequences. Heparin has a low therapeutic index with potential to cause bleeding or clotting. Its use should be monitored to prevent possible errors and maximize benefits of use (ISMP Medication Safety alert, 2011). Heparin induced thrombocytopenia (HIT) is a prothrombotic complication mediated by auto antibodies against heparin-platelet complexes with a prevalence of between 10% -30% and fatal outcomes in 5%–10% of cases (Douglas et al, 2013). HIT occurs less commonly with low molecular weight heparin (LMWH) than with unfractionated heparin (UFH) (Hirsh et al, 2001). A report on the Royal Hospital for Women reported the incidence of HIT was 1-3% and 0-0.8% for UFH and LMWH respectively (Quality and Patient Safety Committee, 2015).

While there are no documented reports of incidence and prevalence of heparin induced adverse outcomes in Kenya, the Seventh American College of Clinical Pharmacy (ACCP) Conference on Antithrombotic and Thrombolytic Therapy, indicated that the risk of hemorrhagic complication associated with IV (UFH) increases with increasing heparin dosages and age (> 70 years) (Baglin et al, 2006). Monitoring of the anticoagulant effect of heparins is recommended, especially in the management of acute venous thromboembolism (VTE). This allows maximum antithrombotic effect with minimal risk of bleeding through over-anticoagulation. However, accurate laboratory monitoring is often difficult (Baglin et al, 2006). The activated Partial Thromboplastin Time (aPTT) is used to monitor therapeutic doses of UFH in venous thromboembolism. A target ratio versus mid-point of normal range of 1.5 to 2.5 is typically employed. This is principally based on evidence that delay in the achievement of adequate anticoagulation is associated with an increased rate of thrombosis recurrence or progression (Scientific and Standardization Committee Communication, 2001).

Considering that heparin has a low therapeutic index and has potential to cause significant harm including death, it is important that its use is monitored closely to ensure that patients get maximum benefits. Harmful events with heparin have been associated with lack of use of policies, guidelines and proper monitoring (Payne et al, 2015). Finding out if guidelines and protocols on heparin use are being used by way of conducting a clinical audit is one way to ensure that patients are protected from avoidable harm. This study set out to develop an evidence-based Clinical Audit Tool for the evaluation of heparin use, and to apply this tool to examine the processes and outcomes of heparin use in adult in-patients at the Rift Valley General Hospital, Nakuru through the conduct a clinical audit.

2. Methods

2.1 Study site

The study was carried out at Rift Valley general hospital (RVGH), the largest public teaching and referral hospital in Nakuru County, Kenya. It is currently the fourth largest government referral hospital in Kenya serving most of the South and Central Rift Valley and neighboring counties.

2.2 Clinical Audit

2.2.1 Development of the Clinical Audit Tool

A clinical audit tool was developed to address three aspects of heparin use i.e. the structures, processes and outcomes which characterize heparin use. The optimum standards of heparin use, audit criteria and targets/ levels of performance were set theoretically from Kenya's Clinical Guidelines for Management and Referral of Common Conditions at Levels 4 – 6 : Hospitals (Kenya's Clinical Guidelines, 2009) and the Antithrombotic Therapy for Venous Thromboembolic Disease. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition) (Kearon et al, 2008) which formed the basis of comparison with actual practice at RVGH. The structure and format of the clinical audit tool was adapted from the Leicestershire partnership NHS Trust (August 2008) (www.leicspart.nhs.uk).

2.2.2 Implementation of the audit

The implementation of the audit involved collection of data on the structures, processes and outcomes of heparin use, using the clinical audit tool developed. The structures supporting heparin use were physically assessed, including the availability of policies, guidelines or protocols, protamine (heparin antidote) and laboratory reagents. The processes and outcomes of heparin use were audited through the prospective observation of heparin dosing, administration and monitoring among eligible adult in-patients. Patients were interviewed for information on satisfaction of care. The audit was structured into four audit criteria, where each audit criteria addressed a specific aspect of heparin use (**Table 1**). The questions under each criterion aimed to describe in a measurable way what care should be delivered, and included policies, procedures and requirements.

2.2.3 Analysis of audit data

Data analysis involved comparison of clinical audit data that was retrieved with the pre-set audit criteria and targets/ levels of performance. Simple descriptive statistics were used to analyze the data i.e. averages and percentages. Each audit criterion (**Table 1**) had several questions with each question answered Yes having a score of 10 and each No having a score of 0. Averages were calculated to obtain overall criterion score. These scores were then compared with the pre-set audit criteria and targets/ levels of performance to inform how use of heparin at RVGH compared with the set standards. After the audit, a Quality Improvement Plan was developed to address the gaps that were identified.

2.3 Ethical Considerations

Ethical approval was sought and obtained from KNH/UON Ethics and Research Committee (**P644/10/2015**). Institutional approval was also sought and obtained from RVGH (**RII/VOL.I/08**). Special patient identifiers were used by the investigator instead of names to ensure confidentiality. Informed consent was sought for patient descriptive information interviews (satisfaction on patient care).

Table 1: Standards for Heparin Use in Adult In-Patients

Audit Criteria	Standard/Threshold	Description
Structural features		
There are adequate supporting structural features in the organization to enable safe use of heparin.	100%	Structural features should be adequate to allow safe use of heparin
Competent staff		
There are sufficient competent persons to provide appropriate heparin use service.	100%	All staff handling heparin should be competent to avoid errors
Safe use of heparin		
Proper precautions are taken to ensure that patients requiring heparin are prescribed, administered and monitored appropriately.	100%	No inefficiencies are allowed during prescribing, administration and monitoring of heparin
Patient satisfaction on quality of care		
Patients are happy with the care that they receive in the institution	80%	Some patients may not be able to respond and caregivers may not be present

3. Results

The clinical audit tool (*appended*) was put together through a consolidation of information from various sources including the Clinical Guidelines for Management and Referral of Common Conditions at Levels 4 – 6 : Hospitals (Kenya's Clinical Guidelines, 2009) and the Antithrombotic Therapy for Venous Thromboembolic Disease. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition) (Kearon et al, 2008), the Leicestershire partnership NHS Trust (www.leicspart.nhs.uk), a clinical audit on Chronic Obstructive Pulmonary Disease (COPD) by (Moore et al, 2013), the Clinical Guidelines from the National Institute for Health and Clinical Excellence (NHS), specifically the (NICE Clinical Guideline 92, 2010) and the clinical audit forms by Healthcare Quality Quest Limited in the UK (www.hqq.co.uk).

The general structure consisted of six sections, as follows:

Section 1: this section was designed to collect information about the place/facility where audit takes place, audit period/date and wards/units involved.

Section 2: this section presents optimum standards for heparin use in adult in-patients, against which findings of clinical audit are to be compared.

Section 3: this is the data collection section of audit tool. There are series of targeted questions whose responses allow scoring and audit of each of four main criteria that were identified for this audit.

Section 4: this section presents instructions on how to score criteria, and provides a table to guide in calculation of scores per each criteria.

Section 5: this section is an overall summary of assessment of each criterion as per the relevant set standards of performance.

Section 6: this section presents a template for the Quality Improvement Action Plan. This informs the action points to improve quality of delivery of services. It also informs basis for a re-audit for purposes of completion of audit cycle.

A summary of the standard/ performance thresholds that were set for the clinical audit of heparin is shown in (**Table 1**). These threshold values act as checkpoints and help in monitoring the performance of a particular criterion by providing a benchmark value. It has been recommended that all criteria for standards of care are set at 100%. However, in cases where deviations from complete compliance may be tolerated, standards for such criteria can be set at 80% (Moore et al, 2013).

The key for interpretation of level of compliance from scores and pre-set performance thresholds was set as illustrated in **Table 2**.

Clinical Audit of Heparin Use at RVGH

Criterion 1 (performance threshold/standard set at 100%) had an observed score of 83.3% which according to the NICE guidance for interpretation of audit showed partial compliance. The deficiencies that were identified by the audit were absence of standard guidelines/ protocols or policies on heparin use and absence of anti-dote protamine sulphate.

Criterions 2 and 3 (performance thresholds/standards set at 100%) showed minimal compliance at 55.5% and 37.5% respectively. The audit identified that no staff had gone through post-qualification training on heparin use, LMWH-patients weights were not taken to determine doses, weight measurements were not repeated in course of treatment and renal function tests were not considered. Furthermore, UFH-baseline aPTT/INR was not routinely taken within 6 hours of initiation of therapy, and full blood counts (FBC) were not taken at least once every week.

Criterion 4 (performance threshold/standard set at 80%) had an observed score of 50% which meant that this criterion had minimal compliance to the performance threshold/standard. The audit identified that health care workers do not satisfactorily respond promptly to patients' calls.

The overall clinical audit at RVGH was found to be 60.6% which showed minimal compliance to the performance threshold/standard of heparin use. The summary of scores per criterion is shown in **Table 3** below.

Table 2: Key for interpretation of the Level of Compliance with the set Performance Threshold (Moore et al, 2013)

Performance threshold/ Standard at 100%		
Full compliance	Partial compliance	Minimal compliance
90% x 100%	70% x<89%	x< 69%
Performance threshold/ Standard at 80%		
Full compliance	Partial compliance	Minimal compliance
72% x 80%	56% x<71%	x< 55%

Table 3: Criterion Scoring Sheet

Criterion	Actual Criterion Score (AC)	Maximum Criterion Score (MC)= Total Number of Questions x Maximum Score (10)	Criterion Score as a percentage= (AC/MC x 100/1)
1	100	120	(100/120)*100 = 83.3%
2	50	90	(50/90)*100 = 55.5%
3	30	80	(30/80)*100 = 37.5%
4	20	40	(20/40)*100 = 50%

Overall audit score = (∑ AC/ ∑MC)* 100 = (200/330) * 100 = **60.6%**

4.0 Discussion

A tool for conducting regular clinical audits on heparin use was formulated and subsequently used to conduct the clinical audit of heparin use at RVGH.

Clinical audit of Criterion 1 revealed that there were no standards or protocols of heparin use in the institution, and no protamine sulphate was available. It was found out that the tests used for heparin use monitoring (aPTT, INR and FBC) were introduced at RVGH in March 2016. However, the uptake is low due to cost constraints and some prescribers prefer sending patients outside RVGH for the same tests to be done by private practitioners in Nakuru town. In case of any emergency such as hemorrhage, hypersensitivity reaction or HIT, the possibility of patient dying is high without protamine in the facility.

Criterion 2 revealed that none of the staff had ever been taken through post- qualification training on appropriate heparin use. For improvement in the proper heparin use to be achieved, staff need to be orientated on guidelines, protocols and policies that guide heparin use. Similar findings were reported by (Vikrant et al, 2007). This study was carried out in the community hospitals in the United States and it found that guidelines, protocols, or policies on use of anticoagulants are often lacking.

Criterion 3 revealed some processes were closer to the required standard and need to be maintained, such as the introduction of warfarin at least three days before the cessation of heparin. However, the audit also revealed inadequate monitoring of heparin. The infrequent monitoring of heparin therapy has also been reported elsewhere by (Baglin et al, 2006) and (Quigley et al, 1988). These two are guidelines on the use and monitoring of heparin by the British Society for Haematology (British Committee for Standards in Haematology) and they acknowledge that monitoring of

heparin treatment is not frequently practiced and it is often difficult to achieve.

Criterion 4 revealed the patients are generally satisfied with the quality of care at the RVGH. The overall criterion score was 50%. This is probably because the staff is friendly. The implication of this finding may be that the patients are likely to recommend other patients to go to RVGH. A similar finding was found by (Aiken et al, 2012) in Europe and the United States who established that patients were more likely to recommend other patients to a particular hospital with good hospital environment. However we feel an improvement should be made on the responsiveness to patients' calls.

A Quality Improvement Plan was developed to address the gaps that were found after the audit. This plan recommended that standards/ protocols or policies addressing heparin use be put in place, and protamine sulphate should be availed in the hospital. It is also recommended that all staff involved in heparin use should be trained on its appropriate use, and that health care workers should respond to patient call without delays.

It was also recommended that the management of the RVGH review and address any gaps that they may find in the Heparin audit tool depending on the institutional needs. It's also hoped that the management of the RVGH will implement the recommendations of the Quality Improvement Action plan, and thereafter conduct a re-audit to complete the clinical audit cycle.

5.0 Conclusion

Clinical audit for heparin use in RVGH concluded minimal compliance to the set standards. This means that there is need to put some strategies as described above in place to ensure use of heparin is improved and there is maximum benefit obtained.

Conflict of Interest declaration

The authors declare no conflict of interest.

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CLINICAL AUDIT TOOL FOR HEPARIN USE FOR ADULT IN-PATIENTS

SECTION 1: GENERAL INFORMATION

Ward and health service:	**Facility:**	**Audit date/Period:**
Ward/Unit:	**Patient/ HCW No.:**	
Data Collector (Clinical Auditor):		

General Instructions:

- Data will be collected prospectively or retrospectively from existing records as the case may be.
- Use one clinical audit tool per patient or Health care worker audited.
- Each facility needs to determine those audit questions that are applicable to their facility / health service circumstances for review.
- Some questions and responses may not be applicable (e.g. at a ward/unit level) and can be adapted to suit individual requirements.

Scores: Yes = 10, No = 0, N/A = doesn't count in final score.

This clinical audit tool consists of six sections each with a specific function. All the sections should be filled in correctly and fully.

This is the first version of the audit tool, and future versions will build upon the existing scope and questions, and incorporate staff feedback and suggestions for improvement.

Feedback on this audit tool and the measurement plans is therefore encouraged, to ensure the tool meets the needs of Hospital and Health Services.

SECTION 2: STANDARDS FOR HEPARIN USEIN ADULT IN- PATIENTS

Performance threshold/standards are the minimum acceptable performance standards or the maximum allowable limits. The threshold values act as checkpoints and help in monitoring the performance of a particular criterion by providing a benchmark value.

Audit Criteria	Standard/Threshold	Description
Structural features		
There are adequate supporting structural features in the organization to enable safe use of heparin.	100%	Structural features should be adequate to allow safe use of heparin
Competent staff		
There are sufficient competent persons to provide appropriate heparin use service.	100%	All staff handling heparin should be competent to avoid errors
Safe use of heparin		
Proper precautions are taken to ensure that patients requiring heparin are prescribed, administered and monitored appropriately.	100%	No inefficiencies are allowed during prescribing, administration and monitoring of heparin
Patient satisfaction on quality of care		
Patients are happy with the care that they receive in the institution	80%	Some patients may not be able to respond and caregivers may not be present

SECTION 3: AUDIT DATA COLLECTION TOOL

This section contains the criteria used to perform the audit. There are four criteria each of which consists specific questions to assess heparin use in an institution.

Instruction:

- Use one clinical audit tool per patient or Health care worker audited.
- Each facility needs to determine those audit questions that are applicable to their facility/ health service circumstances for review.
- Some questions and responses may not be applicable (e.g. at a ward/unit level) and can be adapted to suit individual requirements.

CRITERION 1: Structural features

This section examines the adequacy of supporting structural features in the organization to enable safe use of heparin.

Source of data and specific instruction: Data to be extracted from physical check in the pharmacy, laboratory, wards, Health Management information System (HMIS) and the human resource department (HRD). The auditor may seek the help of a staff in the relevant departments for guidance.

NOTE: Only one form to be used for this section

	QUESTION	**RESPONSE**
1.1	Are there protocols, policies and guidelines for heparin use?	Yes ( ) No ( )
1.2	Are the following staff available in your facility per cadre?	
	i. Consultants	Yes ( ) No ( )
	ii. Medical Officers	Yes ( ) No ( )
	iii. Pharmacists	Yes ( ) No ( )
	iv. Clinical Officers	Yes ( ) No ( )
	v. Nursing Officers	Yes ( ) No ( )
	vi. Pharmaceutical technologists	Yes ( ) No ( )
	vii. Laboratory technologists	Yes ( ) No ( )
1.3	Are laboratory reagents available for performing relevant tests?	
	FBC	Yes ( ) No ( )
	aPTT	Yes ( ) No ( )
	INR	Yes ( ) No ( )
1.4	Is Protamine Sulphate available in the Pharmacy/service user areas?	Yes ( ) No ( )

CRITERION 2: Competent staff

This section examines if there are sufficient competent persons to provide appropriate heparin use service.

Source of data and specific instruction: Data to be obtained from interviewing the Health care workers. The staff to be interviewed are those that handle heparin at any point during prescribing, dispensing, administration or monitoring.

NOTE: One form for each staff interviewed.

	QUESTION	**RESPONSE**
2.1	What is your cadre?	Physician/ Consultant( ) Medical officer ( ) Med. Officer intern ( ) RCO ( ) CO Intern ( ) Nursing Officer ( ) Pharmacist ( ) Other (specify) ( )
2.2	How many years have been in service?	<5 Years ( ) 5-10 Years ( ) >10 Years ( )
2.3	Have you ever received post-qualification training on heparin use?	Yes ( ) No ( )
2.4	If yes in Q 2.3, which specific area were you trained on?	Prescribing ( ) Dispensing ( ) Administration ( ) Monitoring ( )
2.5	Do you have any protocols/ standards or guidelines in place for heparin use?	Yes ( ) No ( )
2.6	If yes in Q 2.5, which specific resources do you use?	_____ _____ _____ _____
2.7	Do you have antidote Protamine Sulphate available to you when using heparin?	Yes ( ) No ( )
2.8	How do you monitor heparin therapy?	
	aPTT	Yes ( ) No ( )
	INR	Yes ( ) No ( )
	FBC	Yes ( ) No ( )
2.9	How often do you monitor FBC for HIT?	
	Weekly	Yes ( ) No ( )
	After every two weeks	Yes ( ) No ( )
	Never	Yes ( ) No ( )

CRITERION 3: Safe use of heparin

Proper precautions are taken to ensure that patients requiring heparin are prescribed, administered and monitored appropriately.

Source of data and specific instruction: Data to be obtained from observation of processes during heparin use. Further information to be obtained from the patient files.

	QUESTION	RESPONSE
3.1	What type of heparin was prescribed?	( ) UFH ( ) LMWH
3.2	For LMWH, was patient weight taken before start of therapy?	Yes ( ) No ( )
3.3	Was patient weight repeated in the course of treatment?	Yes ( ) No ( ) N/A ( )
3.4	Was the patient's weight used as the basis for calculating the treatment dose with LMWH?	Yes ( ) No ( )
3.5	Was renal function considered during prescribing treatment dose with LMWH?	Yes ( ) No ( ) N/A ( )
3.6	For UFH, were APTT/ INR done 6 hours after initiation of treatment?	Yes ( ) No ( ) N/A ( )
3.7	Were APTT /INR repeated 3 days after initiation of therapy?	Yes ( ) No ( ) N/A ( )
3.8	Was FBC checked at least once every week?	Yes ( ) No ( ) N/A ( )
3.9	Was heparin use continued for at least 4 days after the initiation of warfarin?	Yes ( ) No ( ) N/A ( )

CRITERION 4: Patient satisfaction on quality of care

Majority of patients are satisfied with the quality of care that they receive in the institution.

Source of data and specific instruction: Data to be obtained from interviewing the patients and patient files. Where the patient cannot be able to respond to questions and a caregiver is available then the question can be directed to the caregiver.

NOTE: One form to be used for one patient

	QUESTION	RESPONSE
4.1	Are Health Care Workers (HCW) friendly to you?	Yes ( ) No ( ) Not sure( )
4.2	Do Health Care Workers (HCW) answer to your call promptly?	Yes ( ) No ( )
4.3	What do you feel about the overall quality of care?	Satisfied ( ) Not satisfied ( ) Don't know ( )
4.4	Were there any adverse effects following heparin use that is recorded?	Yes ( ) No ( )
4.5	If Yes in 4.4, were there investigations done to confirm if heparin was the cause?	_____ _____ _____ _____

SECTION 4: CRITERION SCORING SUMMARY SHEET

Scoring instructions: *Scores: Yes = 10, No = 0, N/A = doesn't count in final score.* A score of ten is assigned to every Yes answer and a score of zero to every No answer. In case the answer is not applicable, then there is no score assigned and that particular question will not apply when computing the final criterion score.

The Actual Criterion Score is obtained by adding up all the Yes answers multiplied by 10

Criterion	Actual Criterion Score (AC)	Maximum Criterion Score (MC) = Total Number of Questions x Maximum Score (10)	Criterion Score as a percentage= (AC/MC x 100/1)
1			
2			
3			
4			

Overall audit score = (∑ AC/ ∑MC)* 100

Interpretation of audit results as per NICE guidance:

Performance threshold/ Standard at 100%

Full compliance	Partial compliance	Minimal compliance
90% *x* 100%	70% *x*<89%	*x*< 69%

Performance threshold/ Standard at 80%

Full compliance	Partial compliance	Minimal compliance
72% *x* 80%	56% *x*<71%	*x*< 55%

SECTION 5: CRITERION ASSESSMENT PER SET STANDARDS

	CRITERION	PERFORMANCE THRESHOLD (%)	OBSERVED (%)	COMMENT
1	**Structural features** There are adequate supporting structural features in the organization to enable safe use of heparin. *See section 3, Criterion 1*	100%		
2	**Competent staff** There are sufficient competent persons to provide appropriate heparin use service. *See section 3, Criterion 2*	100%		
3	**Safe use of heparin** Proper precautions are taken to ensure that patients requiring heparin are prescribed, administered and monitored appropriately. *See section 3, Criterion 3*	100%		
4	**Patient satisfaction on quality of care** Patients are satisfied with the quality of care that they receive in the institution *See section 3, Criterion 4*	80%		

SECTION 6: QUALITY IMPROVEMENT ACTION PLAN

Criterion	Area of Non Compliance	Corrective Action to be Taken	Responsible Person	Timeframe	Review of Implementation of Action (Audit)

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