

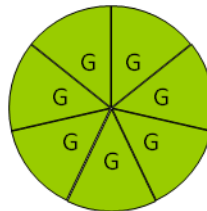
# Internal Audit



## Prescribing Follow-Up

February 2016

### Report assessment



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## Introduction

NHS Lothian identified, through horizon scanning processes, a significant challenge around the increased costs of medicines for 2015/16. The financial plan for 2015/16 had anticipated an increase in expenditure of £12 million but it is now thought that costs could increase by £22 million. It is therefore necessary that action is taken to ensure that all allocations for medicines from SGHSCD are secured and that steps are taken internally to manage and offset this increase.

Management has implemented an enhanced process for developing and managing the medicines budget within each acute directorate. The new process sets out the steps to be taken by directorates to identify actions to manage budgets within the agreed limits, as well as the scrutiny of those actions by senior management and clinicians.

The role of the Acute Prescribing Forum (APF) in challenging work performed at a directorate level to offset overspends will also be defined. Management has to identify whether a medicines contingency fund is still required and, if it is, the criteria for accessing the fund will be defined within the new process.

It is important that the new processes contain sufficient controls for management to monitor and report on whether it is implemented consistently across the organisation, and whether it is achieving the objective of managing prescription costs within the available funds.

## Scope

Internal Audit completed a two-stage review of the new pathway for authorisation of acute prescribing.

Stage 1: This followed a consultancy approach. Internal Audit attended meetings at which the development of the process was discussed, with a focus on identifying the controls management proposes to introduce. Internal Audit considered whether those controls were adequate.

Stage 2: Following implementation of the new process, we performed a follow-up audit to determine whether the identified controls are operating effectively.

Stage 1 was completed in April 2015, and this report sets out the results of our Stage 2 work.

## Acknowledgements

We would like to thank all staff consulted during this review, for their assistance and cooperation.

## Executive Summary

### Conclusion

The financial controls supporting acute prescribing are adequately designed to manage and mitigate the key risks. However, we identified some areas where these controls are not operating effectively. In particular, the pathway of authorisation for acute prescribing should be authorised and implemented, and reporting and monitoring of the achievement of LRP targets should be strengthened.

### Summary of Findings

The table below summarises our assessment of the adequacy and effectiveness of the controls in place to meet each of the objectives agreed for this audit. Definitions of the ratings applied to each action are set out in Appendix 1.

No.	Control Objective	Control objective assess't	Number of actions by action rating			
			Critical	Significant	Important	Minor
1	A formulary has been agreed by the organisation.	Green			1	
2	Each directorate has an approved, detailed, realistic budget for medicines at the start of the financial year.	Green				
3	Directorates identify and plan for anticipated pressures on approved budgets arising from new medicines, cost increases in existing medicines, and LRP.	Green			1	
4	Directorate action to manage cost pressures through efficiencies are reviewed by the General Manager and Associate Medical Director and approved by the Chief Officer and, in particular, monitor whether the use of non-formulary drugs are going to exceed budgets.	Green		1		
5	Where efficiency actions by directorates are not sufficient to meet cost pressures within the approved budget, the Chief Officer approves referral to the Acute Prescribing Forum.	Green		1		

6	The Acute Prescribing Forum reviews reports from directorates about actions taken to manage cost pressures and the extent of any remaining gap, and considers whether criteria for accessing the Medical Contingencies Fund have been met.	Green			1	
7	Any use of the Medical Contingencies Fund is approved by the Finance & Resources Committee, following the recommendation of the Acute Prescribing Forum.	Green			1	

### Control Objective Ratings

Action Ratings	Definition
Red	Fundamental absence or failure of controls requiring immediate attention (60 points and above).
Amber	Control objective not achieved - controls in place are inadequate or ineffective (21 – 59 points).
Green	Control objective achieved – no major weaknesses in controls but may be scope for improvement (20 points or less).

### Main Findings

In 2015/16, acute prescribing was allocated an annual budget of £103.4m. As at November 2015, year-to-date expenditure (£52.8m) was overspent by £1.1m against the year-to-date budget (£51.7m). In addition, the annual LRP target for acute prescribing in 2015/16 is £1.9m and as at October 2015 only £0.3m had been delivered. Although the remaining £1.6m is anticipated to be delivered through agreed initiatives, it will remain a challenge to deliver these savings by the end of March 2016, especially with the impact of the winter period still to be taken into account.

We identified a number of areas of good practice in place to manage prescribing expenditure. A formulary is in place which sets out all the medicines available for prescribing by clinical staff. The formulary is easily accessed through the Lothian Joint Formulary website. There is also a formal process for adding new medicines to the formulary. All requests must be made through the completion of a Formulary Application Form (FAF), which is then subject to review and approval by the Formulary Committee. The FAF must be signed by the relevant clinical director, to confirm that there is sufficient budget available for the new medicine. Costs associated with the reviewed applications are also provided.

The Finance Team holds meetings with the relevant service managers and general managers as part of the budget setting process to discuss and agree budget allocations for the year ahead. Once the budgets have been agreed they are communicated to the Acute Prescribing Forum (APF).

NHS Lothian has, through the APF, introduced a medicines management system for acute services to apply a degree of financial management, linked to forward planning and active monitoring. This includes services being asked to attend and present service updates to the APF throughout the year, a revised horizon scanning process, and implementation and monitoring of formal Local Reinvestment Plans (LRPs) to deliver savings and efficiencies.

We identified two significant areas for improvement during the review:

- A documented procedure “Pathway of Authorisation for Prescribing in the Acute Sector” has been created by the APF, to introduce a process for the review and authorisation of the use of medicines where funding is not readily available through the existing directorate budget. However, the procedure has not yet been approved and implemented. There is therefore a lack of formality around access to contingency funding.
- Efficiency savings to be delivered through LRP schemes during 2015/16 amount to £1.9m. As at October 2015, only £0.3m of these savings had been delivered. This left £1.6m or 84% of the annual target to be delivered within the remaining five months to March 2016. Delivery of the LRP schemes is crucial in delivering a balanced financial position within acute prescribing. Whilst management expects a large element of the LRP savings to be delivered later in the year this will still be extremely challenging.

Further details on this point, as well as a number of less significant issues, are set out in the Management Action Plan, at page five of this report.

## Management Action Plan

<b>Control objective 1: A formulary has been agreed by the organisation.</b>	
<b>1.1: The costs of non-formulary medicines are not reported to all relevant forums.</b>	<b>Important</b>
<p><b>Observation and risk</b></p> <p>In exceptional circumstances clinical staff can submit a Non-formulary Medicine Request Form to the Pharmacy Team when clinical staff want to prescribe medicines that are not on the Lothian Joint Formulary. When completing the Non-formulary Medicine Request Form, clinical staff are required to enter an estimated annual cost per patient. The Non-formulary Request Form should then be authorised by the Clinical Director or nominated Budget Holder.</p> <p>On a quarterly basis the Medicines Management Principal Pharmacist provides a report to the NHS Lothian Medicines Utilisation &amp; Review Group (MURG) and the Drugs &amp; Therapeutics Committee (D&amp;TC). The report details expenditure on medicines issued for the acute division. The report also includes the number of Non-formulary Request Forms received by the acute division. However, the associated costs of the non-formulary medicines that have been requested are not included.</p> <p>There is a risk that the MURG and D&amp;TC do not have the necessary information to determine whether expenditure on non-formulary medicines is appropriate. This may lead to action not being taken in a timely manner where the use or cost of non-formulary medicines is outwith expectations.</p>	
<p><b>Recommendation</b></p> <p>Reports to the MURG and the D&amp;TC should be expanded to include the costs of non-formulary medicines. Reports should provide sufficient detail regarding the type of medicines, specialties and sites to allow scrutiny and oversight from these forums.</p>	
<p><b>Management Response:</b></p> <p>The MURG report prepared for the UHD D&amp;TC includes the number of non-formulary request forms for medicine and the indication for use, presented by site and speciality. The responsibility of the Committee is to review the report and determine whether the trends of non-formulary use are appropriate, and whether an application for addition to the formulary is required from the service. This would be considered only if the Committee anticipate a move to using the product in more patients than the occasional exception to the current formulary. This has the result that the formulary remains fit for purpose and provides adequate control to detect non-formulary medicines use and engage with the service if necessary.</p> <p>The cost of the medicine is not required by the Committee for the assessment and does not contribute much more to the oversight process.</p> <p>It is important that cost is considered at an earlier stage in the process and controls are in</p>	

place to consider the available budget when the Clinical Director signs-off the Non-formulary Request Form.

**Management Action:**

The Medicines Utilisation & Review Group, Drugs & Therapeutics Committee and Acute Prescribing forum will consider whether the costs associated with the use of non-formulary medicines should be monitored and reported within the MURG reports or separately within the financial report presented each month to the Acute Prescribing Forum.

**Responsibility:** Director of Pharmacy

**Target date:** 30 April 2016



**Control objective 2: Each Directorate has an approved, detailed, realistic budget for medicines at the start of each financial year.**

We identified no significant issues in relation to this control objective.

Prior to the start of each financial year staff within Management Accounts meet with General Managers and Service Managers as part of the budget setting process for the year ahead. Staff were advised by Finance of the budget for acute prescribing for 2015/16, which included the base budget for the year ahead (£96.6m) plus £7.5m uplift determined by the Pharmacy's estimates of growth from current trends and expected developments. An additional £2.6 million was provided for Individual Patient Treatment Requests (IPTRs). Anticipated LRP of £3.1m was deducted leaving the total budget for 2015/16 at £103.6m. The Acute Prescribing Forum (APF) was informed of the 2015/16 budget per directorate / service at its meeting on 28 April 2015.

For the first eight months of this financial year, there has been an overspend in acute medicine of £1.1m against budget. In response to this and further anticipated overspend against budget NHS Lothian has, through the APF, introduced a medicines management system for acute services which supports an annual planning cycle around medicines use through forward planning, active monitoring and financial management.

For example, the APF has created an annual schedule where it invites services to attend meetings of the APF to discuss efficiency schemes for prescribing. This includes regular updates from the services on the effectiveness of the LRP schemes. Clinical Directors and Service Managers are required to complete an Acute Prescribing Forum Service Update Template for each meeting they are asked to attend. This includes recording actions being carried out to address challenges and achievements made to date. Service representatives are invited within the updates to use a colour-coding system to report whether or not they are on target to meet milestones / benefits.

In addition, the Medicines Management Pharmacist – Acute Division has revised the horizon scanning process, which is used to identify potential pressures and any changes in practice. The horizon scanning process now involves Clinical Pharmacists, Clinical Directors and General Managers, which was not the case previously. At the time of our audit, the process had only started operating recently so there has not yet been an opportunity for management to assess the effectiveness of this process. Meetings have been held between the Finance Business Partner and Pharmacy to discuss the horizon scanning process and the impact on LRP and business unit budgets.

Finally the Medicines & Prescribing Initiatives LRP Review Group reviews and assesses medicine and prescribing initiatives for feasibility prior to inclusion in LRP templates. The Group also supports teams in developing a monitoring framework for each LRP medicines/prescribing initiative.

Service updates, horizon scanning and LRP performance are regularly reported to the APF.

**Control Objective 3: Directorates identify and plan for anticipated pressures on approved budgets arising from new medicines, cost increases in existing medicines, and LRP.**

**3.1: Budget reporting to the Acute Prescribing Forum does not take any standard form and sometimes lacks detail.**

**Important**

**Observation and risk**

As part of the budget setting process, Finance staff meet with Service Managers and General Managers to discuss their budget allocation for the year ahead. The budgets are based on the previous year plus any uplifts applied and deductions for projected savings.

The budgets are then presented to the APF, broken down by directorate and service. However, the format of budget performance reporting throughout the year to the APF is inconsistent. We noted that verbal updates were provided to the APF in May and June 2015, with a formal Budget and Expenditure Report presented in July 2015. Verbal updates were then provided to the meetings of the APF in August and September 2015. We then noted that Efficiency and Productivity Group Performance and Progress Reports were presented to the APF in October and November 2015, which only focussed on LRP information.

There is a risk that the APF is not given sufficient financial information on a consistent basis in order to make informed decisions about performance against the acute prescribing budgets.

**Recommendation**

The Finance Business Partner who reports to the APF should agree a reporting structure and format with the APF. Written reports should be provided at each meeting which will allow the APF to easily scrutinise and monitor the financial position.

**Management Response and Action:**

It was recognised by APF that this needed to be addressed. Finance has taken a proactive approach and the issue has already been resolved. A single report has been prepared and shared with the APF on 26 January 2016. This report has been endorsed by APF. The monthly report will cover:

- 1) Year to date performance against budget
- 2) Performance trend
- 3) Actual LRP performance
- 4) Release against reserves both in year and on a recurring basis. This report will be used to inform APF and the prescribing resource group.

**Responsibility:** Finance Business Partner, Unscheduled Care

**Target date:** 26 January 2016

**Control objective 4: Directorate actions to manage cost pressures through efficiencies are reviewed by the General Manager and Associate Medical Director and approved by the Chief Officer and, in particular, monitor whether the use of non-formulary drugs are going to exceed budgets.**

**4.1: The Pathway of Authorisation for Prescribing in the Acute Sector document has not been approved by the Acute Prescribing Forum and implemented.**

**Significant**

**Observation and risk**

The APF has developed a Pathway of Authorisation for Prescribing in the Acute Sector process document. This has been created to allow individuals to determine whether funding is in place for a new medicine or identified cost pressure.

If funding is available a Formulary Application Form will be completed and submitted to the Lothian Formulary Committee for review and approval. The document sets out the procedure for escalating decisions about the use of a particular course of treatment in the event that funding is unavailable. The aim is to ensure that any potential decision not to deliver a particular course of treatment is made at the highest appropriate authority after consideration of all options. However, the Pathway has not yet been approved by the APF for implementation.

There is a risk that requests for medicine funding are not subject to appropriate review and approval. This could lead to expenditure on medicine without clarity on the funding source.

**Recommendation**

The Pathway of Authorisation for Prescribing in the Acute Sector process document should be approved by the APF as soon as possible. Once done it should be presented to the Finance & Resources Committee for further approval and implementation.

**Management Response:**

It is agreed that the Pathway of Authorisation should be completed as soon as possible.

**Management Action:**

The Pathway of Authorisation was discussed at the APF meeting on 26 January 2016. It was agreed that as there will not be a medicines contingency fund for 2016/17 further alterations are required. It is unlikely that this pathway will go to the Finance & Resource Committee as it is a process map for implementation in the service. The Chief Officer will agree the Pathway with the Director of Finance.

**Responsibility:** Director of Pharmacy and Medical Director, Acute Service (Co-chairs of the APF)

**Target date:** 29 February 2016

**Control Objective 5: Where efficiency actions identified by directorates are not sufficient to meet cost pressures within the approved budget, they are highlighted to the Chief Officer who will keep the Acute Prescribing Forum informed of progress.**

**5.1: There is a risk that the annual LRP target is not achieved.**

**Significant**

**Observation and risk**

Savings are required in order to deliver a balanced financial position. The required savings have been identified through a range of LRP schemes. For example, NHS Lothian anticipated that £0.3m savings would be made from Hepatitis C during 2015/16. We reviewed the latest LRP performance reports and noted the following:

- The year-to-date LRP target is £1m and only £0.2m had actually been delivered as at October 2015. This resulted in a year-to-date adverse position of £0.8m.
- The full year LRP target is £1.9m and only £0.3m had been achieved as at October 2015. This meant that, as at October 2015, £1.6m of the annual LRP target was still to be delivered.

Monthly reporting to the APF on LRP achieved currently focuses on reasons for variances and key progress updates since the previous month. The Medicines and Prescribing Initiatives LRP Review Group has supported clinical management teams in developing a monitoring framework for each LRP initiative, however there is no means currently to record any corrective actions for LRP schemes to achieve the planned savings and report these into the APF.

These targets will be hugely challenging given that the impact of the winter period is still to be factored in. It was noted that a large element of the LRP is expected to be delivered later in the year. However, despite this there is a risk that the required LRP savings are not achieved by year-end. This may result in overspends in acute prescribing.

**Recommendation**

A full review of the 2015/16 LRP schemes should be carried out to assess the extent to which the remaining level of savings are achievable. The output from this review should be reported to the APF, with corrective actions also reported and monitored thereafter.

In future financial years, it may be beneficial to risk assess LRP schemes, with a view to the majority of savings schemes being low risk. This will allow the APF to be more informed about the likelihood of delivering the planned level of savings. Where the majority of savings schemes are medium or high risk then the APF can ask that further work is done to try and identify low risk schemes or actions put in place to reduce the risk level of the existing schemes.

**Management Response:**

For 15/16 there is very little time or opportunity to influence the delivery of LRP and so a full review of 15/16 schemes will afford little return. APF still consider that significant additional

LRP will be delivered in year based on Hep C rebates and on some additional national procurement efficiencies yet to be booked.

Moving into 16/17, LRP will no longer be used to measure performance. Instead all areas are being asked to have a balanced financial plan, which will include a combination of efficiencies, cost reduction programmes and avoidance of spend.

**Management Action:**

As part of the recovery plans being developed each CMT is being asked to risk assess the deliverability of their plans. Progress against plans will be tracked regularly and there are formal quarterly meetings where each service will discuss progress against their plans with the Senior Management Team (SMT).

APF has a programme of monthly meetings organised for the year ahead to discuss with priority clinical areas their issues and plans around medicines. Priority areas are those with highest spend, highest growth or clinical areas who have not yet attended APF.

Where Acute SMT requests further oversight of medicines use, this will be referred to the Acute Prescribing Forum.

**Responsibility:** Chief Officer and APF

**Target date:** throughout 2016/17

**Control objective 6: The Acute Prescribing Forum reviews reports from directorates about actions taken to manage cost pressures and the extent of any remaining gap, and considers whether criteria for accessing the Medical Contingencies Fund have been met.**

**6.1: The Acute Prescribing Forum is being presented with two separate LRP updates / reports at each meeting.**

**Important**

**Observation and risk**

Before the start of the calendar year, the Business Support Manager, Efficiency and Productivity Team meets with the Director of Pharmacy and the Medical Director, Acute Services to identify those service areas with increased expenditure and invite senior staff within those areas to identify efficiency measures. The various savings schemes are then presented to the APF.

The APF receives monthly updates throughout the year from the Pan Lothian Service Director on progress against each LRP scheme within acute medicine. The APF also receives an Efficiency & Productivity Group Performance and Progress report at each meeting; this report also details progress against LRP targets. However, we reviewed the two reports and noted that the information reported is not always consistent for the same period. For example, in October 2015 the Pan Lothian Service Director reported that the current year-to-date position was £0.212m achieved, yet the Efficiency & Productivity report recorded that the current year position to October 2015 was £0.168m.

There is a risk that the APF receives conflicting information regarding the performance of LRP schemes, and is therefore unable to make an accurate assessment on the effectiveness of the schemes.

**Recommendation**

The APF should consider the LRP reporting that it currently receives and the information it requires in order to effectively hold management to account for the achievement of LRP targets. Future APF meetings should receive LRP updates in a standard report format.

The Performance and Progress Reports should be used as a basis for presenting information to the APF. In completing the Performance and Progress Report staff are required to record reasons for variances between target and forecast, along with actions to reduce any gap. Key progress updates across services are also recorded, as well as any key risks and issues identified.

The report prepared by the Pan Lothian Service Director lists as an appendix all the LRP schemes and the LRP targeted / achieved. The APF should be presented with this information regularly.

**Management Response:**

As stated in response to issue 3.1 there is now one agreed finance report.

**Management Action:**

A single finance report will be prepared for APF (see response to issue 3.1). This will be the only LRP reporting that is returned to APF and will remove both duplication of effort and risk of inconsistent information.

**Responsibility:** Finance Business Partner,  
Unscheduled Care / Pan Lothian Service  
Director – DATCC

**Target date:** 1 April 2016

**Control objective 7: Any use of the Medical Contingencies Fund is approved by the Finance & Resources Committee, following the recommendation of the Acute Prescribing Forum.**

<b>7.1: Availability of and access to the Medical Contingencies Fund is unclear.</b>	<b>Important</b>
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**Observation and risk**

In April 2015, the Head of Primary Care Contractors Organisation Finance reported to the APF that a Scottish Medicines Consortium drugs reserve of £7.5m had been assigned to NHS Lothian. It was suggested that the funding should be allocated to specialties at the start of the financial year to reduce the risk that claims from the reserve are made simply to ensure budgets break-even. However, following consideration it was decided to proceed with a reserve release model. This involves historical performance being reviewed and once clear trends have been identified the funds will be distributed for the remainder of the financial year for the service to manage.

However, it was noted by the APF that there is currently a lack of clarity around the release of the funds. There is no clear picture of how much funding remains in the reserve. In addition, when funding is transferred to the directorate, it is unclear whether this is from the medicines contingency fund or just an ability to call on reserve.

There is a risk that the APF is not presented with an accurate picture of the funding available. This may mean that the APF is unable to make informed decisions on the use of new medicines while there is uncertainty around the source of funding.

**Recommendation**

The treatment of the Medical Contingencies Fund should be agreed between the APF and Finance. Financial reports to the APF should include amounts drawn from this fund to date and amounts remaining.

**Management Response:**

Moving into 16/17 it is not anticipated that there will be any reserve available . The only monies that will be retained centrally is £1.5m for IPTRs. These funds cannot be distributed recurrently given that they are by definition short term commitments.

**Management Action:**

Management teams have been informed of the position and are reviewing how this will impact decision making around new medicines. If there is a change and funding to support a reserve becomes available, any budget and subsequent spend will be reported as part of the single finance report as outlined in the response to issue 3.

<b>Responsibility:</b> Finance Business Partner, Unscheduled Care	<b>Target date:</b> 26 January 2016
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## Appendix 1 – Definition of Ratings

### Management Action Ratings

Action Ratings	Definition
<b>Critical</b>	The issue has a material effect upon the wider organisation – 60 points
<b>Significant</b>	The issue is material for the subject under review – 20 points
<b>Important</b>	The issue is relevant for the subject under review – 10 points
<b>Minor</b>	This issue is a housekeeping point for the subject under review – 5 points

### Control Objective Ratings

Action Ratings	Definition
<b>Red</b>	Fundamental absence or failure of controls requiring immediate attention (60 points and above)
<b>Amber</b>	Control objective not achieved - controls in place are inadequate or ineffective (21 – 59 points)
<b>Green</b>	Control objective achieved – no major weaknesses in controls but may be scope for improvement (20 points or less)