Internal Audit

Acute Prescribing

June 2020

Internal Audit Assurance assessment:

Objective One	Objective Two	Objective Three
Significant Assurance	Significant Assurance	Significant Assurance

Timetable

Date closing meeting held: No meeting held, client responded directly to draft report

Date draft report issued: 3 April 2020

Date management comments received: 16 June 2020

Date Final report issued: 16 June 2020

Date presented to Audit and Risk Committee: 22 June 2020

Contents

1. Introduction

1.1 In 2018/19 NHS Lothian had a total spend on medicines of £148 million in primary care and £112 million in secondary care. The 2019/20 Financial Plan recognised that the most significant element of anticipated growth in spend relates to drugs prescribed within secondary care, driven by a combination of activity related growth and predictions around the financial impact from Scottish Medicines Consortium (SMC) decisions. An example relates to the introduction of new drug therapies for Cystic Fibrosis with anticipated additional costs of £6 million.

1.2 The Lothian Joint Formulary provides drug prescribing guidance on first and second choice drugs for all general practice and hospitals in Lothian. The main aim of the formulary is to promote safe, effective and economic prescribing. There will be appropriate prescribing which is out with formulary choice, but it is important that the majority of prescribing complies with the formulary and where it does not that there is clear monitoring and review. The content of the formulary is maintained with the support of working groups, comprised of clinical and pharmacy staff, who consider current prescribing patterns, clinical evidence, safety, cost effectiveness and patient acceptability. The proposals from working groups are then approved by the Formulary Committee. The formulary committee is a subcommittee of the Area Drug and Therapeutics Committee which is responsible for medicines governance within NHS Lothian. The ADTC reports to HealthCare Governance Committee.

1.3 Within clinical areas there should be review of prescribing to ensure good formulary compliance and discussion and review of non-formulary choices within clinical teams and with general managers. This is to ensure both good clinical care and appropriate use of resources. The Acute Prescribing Forum (APF) works with clinical specialities to review prescribing practices and allocate, monitor and agree actions to support optimal use of the acute prescribing budget within the NHS Lothian Financial and Strategic Plan. The APF have established a medicines management system for acute services to enable an annual planning cycle for medicines, linked to forward planning, active monitoring and financial and clinical management. The forum links closely with service management within the Acute sector. A similar function is undertaken by the Primary Care Prescribing Forum with further reporting of drug pressures reported to the Finance and Resources Committee.

Scope

1.4 The Internal Audit Prescribing follow up report of January 2016 identified a number of areas of good practice including the process by which medicines are reviewed and considered for formulary inclusion. We did not repeat this work. We have instead considered how prescribing costs are managed within budgets on a directorate level, including how budgets are set and the processes undertaken to ensure drugs are prescribed within formulary and actions taken to address any non-compliance. We considered reports provided to the Acute Prescribing Forum, and how this forum supports clinical teams and managers to monitor and challenge areas of overspends, and what actions are taken to mitigate this.

Acknowledgements

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

2. Executive Summary

Summary of Findings

2.1 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 3.

No.	Control Objectives	Assurance Level	Number of Findings			
			Critical	High	Medium	Low
1	If prescribing costs are exceeding budgets, action is taken within the clinical areas to address this by Clinical Service Managers and Business Partners for the service(s).	Significant Assurance	-	-	-	1
2	Clinical Service Managers and Business Partners have a process in place to assure themselves that drugs are being prescribed in line with formulary; and when a non-formulary medicine is deemed appropriate that the correct processes are followed to seek approval for use.	Significant Assurance	-	-	-	-
3	The Acute Prescribing Forum review prescribing practice and budget information to allow them to effectively seek to understand and constructively challenge practice in order to make optimal use of the prescribing budget.	Significant Assurance	-	-	-	-
Total			-	-	-	1

Conclusion

2.2 The controls supporting acute prescribing are adequately designed to manage and mitigate the key risks. However we have identified one improvement opportunity around the identification of and planning for future financial pressures.

Main findings

2.3 We identified a number of areas of good practice in place to manage prescribing expenditure. Clinical Service Managers were able to confirm that Finance provide each month a Financial Update, which includes expenditure on drugs. Further analysis of expenditure and prescribing patterns takes place at least monthly between the Clinical Service Manager and Specialist Pharmacists.

2.4 Within the clinical specialities, prescribing is also discussed regularly through weekly multidisciplinary team meetings, which include clinical staff, pharmacists and Clinical Service Managers.

2.5 To support decision making, NHS Lothian's Medicines Management Team developed in April 2019 a flowchart to guide staff on the procedures to be followed when requesting non-approved medicine. Additional guidance has been developed by the NHS Lothian Medicines Information Service to instruct staff on the appropriate route to take when prescribing medicines (licensed/unlicensed and formulary/non-formulary).

2.6 The Acute Prescribing Forum has developed a template for services to complete which includes a summary of progress against medicines efficiency projects for the financial year, in addition to new medicine ideas or service initiatives under consideration, and identified risks or pressures related to medicines prescribing.

2.7 Each month, the APF is presented with an Acute Medicines Financial Performance report, which has been designed to provide the Forum with an of the acute medicines financial position, including the year-to-date position, efficiency programme status and reserve position.

2.8 There is also a formal process for adding new medicines to the formulary. All requests are 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.

2.9 The Medicines Utilisation Review Group (MURG) provides quarterly reports to the APF detailing formulary adherence in secondary care.

2.10 We identified one improvement opportunity during this review:

Low Rating

- Management should reconsider the introduction of the Pathway of Authorisation for Medicines Funding in Acute Services, to be referred to when cost pressures are impacting on the Boards ability to fund new medicines.

  Further details of this point is set out in the Management Action Plan.

3. Management Action Plan

Control objective 2: If prescribing costs are exceeding budgets, action is taken within the clinical areas to address this by Clinical Service Managers and Business Partners for the service(s)	
Finding 1: No direction given by finance on the use of the Pathway of Authorisation for Medicines Funding in Acute Services **Associated risk of not achieving the control objective: Financial pressure may not be effectively identified, prioritised and managed**	**Low**

Background

Medicines prescribing budgets are set each year by estimating the total expenditure for medicines currently in use, using the average historical growth and adjusted for any medicines where growth is not expected or will be higher/lower than average.

Projected spend on medicines already approved but not in use, or that are expected to be approved during current financial year is then considered and an estimated expenditure added.

Further projected expenditure is identified through utilisation of the Scottish Medicines Consortium's (SMC) horizon scanning initiative. In accordance with SMC's remit, the horizon scanning initiative encompasses new medicines as well as new indication, license extensions and new formulations of existing medicines.

Within the clinical areas visited during this audit (Cancer, Gastroenterology, Rheumatology, Urology & General Surgery), Clinical Service Managers were able to confirm that Finance provide each month a Financial Update, which includes expenditure on drugs. Further analysis of expenditure and prescribing patterns takes place at least monthly between the Clinical Service Manager and Specialist Pharmacists, although conversations can occur more frequently. The tableau financial monitoring system is also utilised extensively in monitoring financial performance.

Prescribing is also discussed regularly through weekly multidisciplinary team meetings, which include clinical staff, pharmacists and Clinical Service Managers.

Observation and Risk

In financial year 2018/19 Finance introduced a Pathway of Authorisation for Medicines Funding in Acute Services. This had been developed at the end of 2017/18 in response to a concern that the Board would exceed the amount of money in the reserve to fund new medicines due to the pressures for new cancer medicines. The pathway has been designed to introduce several approval levels in determining whether an anticipated cost pressure can be funded and requires input from the Acute SMT, Sustainability & Value Group and the CMT.

Consequently, there had been no requirement to invoke the escalation pathway in 2018/19 since the budgets had the required resource or there was sufficient in reserve to cover this.

In 2019/20 there no direction given by finance on the use of the pathway.
Recommendation Management should reconsider the introduction of the Pathway of Authorisation for Medicines Funding in Acute Services, to be referred to when cost pressures are impacting on the Boards ability to fund new medicines. The reintroduction of the pathway will ensure that there is additional ongoing review of prescribing efficiencies by management, and that decisions to fund prescribing activities are supported by appropriate information and senior staff input.
Management Response The Pathway of Authorisation for Medicines Funding in Acute Services was developed in anticipation of budget pressures that did not materialise. Management Action The horizon scanning exercises, coupled with the prescribing practices and financial projection models already in place have not identified any imminent or future budgetary pressures. The Pathway of Authorisation will be reconsidered only as and when circumstances require.

Responsibility:	Target date:
Chair of Acute Prescribing Forum	31 March 2021

Control objective 2: Clinical Service Managers and Business Partners have a process in place to assure themselves that drugs are being prescribed in line with formulary; and when a non-formulary medicine is deemed appropriate that the correct processes are followed to seek approval for use

The Chief Medical Officer and the Chief Pharmaceutical Officer for the Scottish Government wrote to boards on 29 March 2018 with guidance on the implementation of the Peer Approved Clinical System (PACS) Tier Two, also known as PACS2, which replaces some of the processes previously covered by the Individual Patient Treatment Request (IPTR) policy.

The key purpose of the guidance is to provide a revised framework to support NHS Boards in the development of local policies to enhance the consistency of approach across all NHS Boards when considering medicines that have not been accepted for routine use in NHS Scotland.

In response to this, NHS Lothian produced an updated Individual Patient Treatment Request Policy to guide staff on the steps required where the use of a drug has not been approved by the Scottish Medicines Consortium.

There is a main Patient Treatment Request (PTR) panel and a separate cancer medicines management committee. The main PTR panel has three parts to the meeting; PACS1 applications, PACS2 applications and other PTR applications.

NHS Lothian's PTR administrator is responsible for maintaining a record of all applications and their decision.

To support decision making, NHS Lothian's Medicines Management Team developed in April 2019 a flowchart to guide staff on the PACS2 and PTR Procedures for non-approved medicine. Additional guidance has been developed by the NHS Lothian Medicines Information Service. This is in an additional flowchart to guide staff on the appropriate route to take when prescribing medicines (licensed/unlicensed and formulary/non-formulary).

Financial information is required when completing an individual Patient Treatment Request, however this is only an estimate and not considered by the panel when reviewing an application. Also, no financial details are necessary for those medicines submitted for using the Peer Approved Clinical System. Although the documentation that is completed in supporting the prescribing requests require clinical staff to include the outcomes that are proposed to be monitored and how these will used to determine stopping criteria.

While the Panel regularly considers the length of treatment, assessment intervals and the outcomes achieved, for majority of applications it relies on the clinicians to manage patients treatment appropriately. However there are instances where the Panel will specifically ask for feedback if the volume of applications is very high. For example:

- Prucalopride is restricted to an initial trial of 4 weeks. Clinicians then re-submit evidence of benefit to extend treatment.
- Budesonide is approved for a trial period of 6 weeks with a possible extension to 12 weeks as per the license. Feedback for the first 10 applications is requested. Most of

the patients did not proceed to treatment as it was required for long terms use which is currently out with the terms of the license.

- Pembrolizumab first line treatment requests. The Panel asked for feedback for months one to three of treatment to ensure that treatment was effective and if not it would be stopped.
- Dapoxetine, the Panel asks clinician's to do a 6 week trial and if they wish to extend treatment they must resubmit.

Control Objective 3: The Acute Prescribing Forum review prescribing practice and budget information to allow them to effectively seek to understand and constructively challenge practice in order to make optimal use of the prescribing budget

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

In February 2019, the Acute Prescribing Forum updated its Terms of Reference, the remit of the Forum includes:

- Oversight of the development and delivery of detailed efficiency and productivity prescribing plans which should include a review of the current separate approaches to horizon scanning, investment forecasting and budget setting across secondary care.
- Agree standardised reporting mechanisms for medicines use and expenditure across the acute sector to support delivery of prescribing plans; and provide templates and guidance to service to meet these requirements.
- Ensure development and monitoring of Prescribing budget delivery plans and efficiency initiatives through a rolling programme of review for specific service areas supported by the Associate Medical Director, Clinical Director/delegated deputy, Service Manager and Specialist Pharmacist.
- Have the ability via Medicines Utilisation Review Group to have oversight of the tracking of formulary approvals in year against the maximum limit agreed by Acute SMT; and escalate when this threshold has been reached in year.

The Forum reports to the Acute Senior Management Team by exception reporting against agreed service medicines efficiency projects and medicines prescribing budget pressures.

Each month, the APF is presented with an Acute Medicines Financial Performance report, which has been designed to provide the Forum with an of the acute medicines financial position, including the year-to-date position, efficiency programme status and reserve position.

The APF annual service schedule forms the work programme for the group. A maximum of 2 services per month are scheduled to provide an annual service update to the group; with a requirement to report back in four months for any outstanding actions or updates. This schedule is issued in December of each year to the services to advise them of the scheduled month for within the next calendar year they are required to report.

A template report has been made available to services for completion and submission prior to the scheduled meeting. Information is reported against six headings:

- Background (prescribing budget/benchmarking).
- Summary of progress against medicines efficiency projects.
- Summary of delivery against medicines efficiency plans.
- New medicines ideas or service initiatives under consideration.
- Summary of items for escalation of identified risks or pressures related to medicines

prescribing, and
- Priorities for next period

Review of the Groups recent meeting agendas and minutes confirmed that the service reporting schedule is being followed, with the occasional exception. For example, Neurology did not present at the scheduled August 2019 meeting. With the quarterly update Septe

The Medicines Utilisation Review Group (MURG) also provides quarterly reports detailing formulary adherence in secondary care. The reports provide information on both adherence by expenditure (total spend and % spend) and adherence by volume. Adherence to the formulary remains above 90% for both usage and expenditure.

Also, where necessary additional reports are provided quarterly to the APF on specific topics, such as the use of a particular medicine (PrEP) or strategic priorities (Homecare Medicines Services Strategy).

Appendix 1 – Staff Involved and Documents Reviewed

Staff Involved

- Associate Director of Pharmacy
- Head of PCCO
- Medicines Management Pharmacist (Acute)
- Business Partner
- Specialist Pharmacists
- Clinical Service Managers
- Committee and PTR Administrator

Documents Reviewed

- .Acute Prescribing Forum Terms of Reference
- Service Updates to the Acute Prescribing Forum
- Flowchart for Medicines Management Applications and Forms
- Medicines Governance Committee Structure, February 2019
- NHS Lothian IPTR Policy
- Monthly Financial Reports for Clinical Areas
- PACS2 and PTR Procedures – Non-approved medicines process flowchart
- Non-formulary Medicines Request Form
- Procedure for Prescribing Non-Formulary Medicines
- Formulary Adherence in Secondary Care monitoring spreadsheet
- IPTR/ PACS Applications and extract from Database
- Pathway of Authorisation for Medicines Funding in Acute Services
- Monthly Acute Services Medicines Performance reports to the Acute Prescribing Forum

Appendix 2 - Definition of Ratings

Findings and management actions ratings

Finding Ratings	Definition
Critical	A fundamental failure or absence in the design or operating effectiveness of controls, which requires immediate attention
High	A key control failure has been identified which could be either due to a failure in the design or operating effectiveness. There are no compensating controls in place, and management should aim to implement controls within a calendar month of the review.
Medium	A control failure has been identified which could be either due to a failure in the design or operating effectiveness. Other controls in place partially mitigate the risk to the organisation, however management should look to implement controls to fully cover the risk identified.
Low	Minor non-compliance has been identified with the operating effectiveness of a control, however the design of the control is effective

Report ratings and overall assurance provided

Report Ratings	Definition	When Internal Audit will award this level
No assurance	The Board cannot take any assurance from the audit findings. There remains a significant amount of residual risk.	The controls are not adequately designed and / or operating effectively and immediate management action is required as there remains a significant amount of residual risk(for instance one Critical finding or a number of High findings)
Limited assurance	The Board can take some assurance from the systems of control in place to achieve the control objective, but there remains a significant amount of residual risk which requires action to be taken.	This may be used when: • There are known material weaknesses in key control areas. • It is known that there will have to be changes that are relevant to the control objective (e.g. due to a change in the law) and the impact has not been assessed and planned for. The controls are deficient in some aspects and require management action (for instance one 'high' finding and a number of other lower rated findings)
Moderate assurance	The Board can take reasonable assurance that controls upon which the organisation relies to achieve the control objective are in the main suitably designed and effectively applied. There remains a moderate amount of residual risk.	In most respects the "purpose" is being achieved. There are some areas where further action is required, and the residual risk is greater than "insignificant". The controls are largely effective and in most respects achieve their purpose with a limited number of findings which require management action (for instance a mix of 'medium' findings and 'low' findings)
Significant assurance	The Board can take reasonable assurance that the system(s) of control achieves or will achieve the control objective. There may be an insignificant amount of residual risk or none at all.	There is little evidence of system failure and the system appears to be robust and sustainable. The controls adequately mitigate the risk, or weaknesses are only minor (for instance a low number of findings which are all rated as 'low' or no findings)