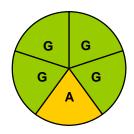
# **Internal Audit**



# **Homecare Services**

March 2015

# **Report Assessment**



# **Distribution List**

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**Medical Director** 

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# Page 1 Introduction Page 2 Executive Summary Page 4 Management Action Plan

Appendix 1: Definition of ratings



# Introduction

Under homecare arrangements, NHS Lothian pays private providers to deliver medicines and other items directly to patients' homes. In some cases, nurses from homecare providers may administer medicines to patients.

Several clinical services use homecare providers. Homecare services are most commonly issued in the treatment of cancer, rheumatology, multiple sclerosis, haemophilia and HIV. Over 1,500 patients mainly with long-term conditions are covered by homecare, with NHS Lothian relying on several main providers, including and and are covered by homecare.

In September 2013, the Royal Pharmaceutical Society issued Professional Standards for Homecare Services. NHS National Services Scotland has set up a Short Life Working Group including representatives from NHS Lothian to review the national framework for contracting and managing homecare providers.

# Scope

The objective of the audit was to evaluate the adequacy and effectiveness of internal controls associated with homecare services provided by NHS Lothian. We reviewed governance processes for managing homecare services including contract management, performance monitoring, records management and confidentiality.

Our review focussed on the control framework in place for NHS Lothian to manage and oversee the operation of homecare services.

# **Acknowledgements**

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



# **Executive Summary**

# Conclusion

The controls NHS Lothian has in place over Homecare Services are not adequate or effective in providing assurance that homecare services are managed effectively. This review identified several opportunities for improving processes and practices which will benefit future management of homecare services.

However, it is important to note that NHS Lothian staff had recognised that controls over homecare services required improvement in advance of this audit, and pharmacy staff have been working to address a number of the matters raised in this report.

# **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 assessment				ating
			Critical	Significant	Important	Minor
1	Providers of homecare services are selected in line with Standing Financial Instructions, Scheme of Delegation and best practice.	Green		1		
2	Contracts and agreements are in place setting out responsibilities	Green		1		
3	The delivery and quality of services is monitored, including patient experience.	Amber		2	1	
4	Confidentiality is maintained over patients' records and data.	Green		1		
5	The cost of services is monitored	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**

During the early part of 2014 the former Associate Director of Pharmacy identified a number of weaknesses in the governance framework for homecare services. A report outlining key recommendations was presented to the Prescribing Review Group and a number of these recommendations, including the appointment of a Pharmacy Lead for Homecare Services, have been implemented.

We identified six significant risk areas for improvement during the review:

- Formal procedures should be developed to define the processes for engaging a homecare provider. This should include processes for initiating homecare services, identifying a suitable supplier, ensuring procurement rules are followed and approving expenditure.
- A contract register showing all current contracted homecare service providers should be developed.
   Processes for tracking and monitoring contracts, including updating and communicating the contract register should be defined and documented.
- The roles and responsibilities of the Healthcare Governance Committee, the Prescribing Review Group, Pharmacy, Procurement and clinical areas for ensuring homecare services are delivered in line with existing contracts, agreements and service delivery requirements should be defined and formalised.
- Information Governance should work with Pharmacy to develop a register of NHS Lothian patients currently receiving homecare services. Roles, responsibilities and procedures for updating and maintaining this register should be defined.
- NHS Lothian should establish and document processes via Service Level Agreements to ensure confidentiality of its patient data by third party homecare service providers.
- An analysis of homecare services to evidence Value for Money (VFM) should be completed, including an
  analysis of financial and non-financial costs and benefits. The results of this exercise should be reported
  to relevant management groups or committees and results should be used to inform future homecare
  strategies.

Further details of each of these points, along with two further important points, are set out in the Management Action Plan.



# **Management Action Plan**

Control objective 1: Providers of homecare services are selected in line with Standing Financial Instructions, Scheme of Delegation and best practice

# 1.1 Formalising procedures for procurement of homecare services

**Significant** 

# Observation and Risk

NHS Lothian is required to comply with its Standing Financial Instructions (SFI's). These require that National Services Scotland Procurement undertake procurement activities on a National basis on behalf of Health Boards and Boards shall implement these nationally negotiated contracts. The SFI's also require there to be adequate segregation of duties and approval mechanisms for non-pay expenditure.

Current processes for engaging homecare providers are not formalised and are inconsistent between clinical areas. There are currently no processes in place to inform clinical areas which service providers have been appointed through formal national or NHS Lothian procurement processes.

We also found that NHS Lothian staff members were unaware of the procurement processes that should be followed when purchasing new homecare services from providers that do no have an existing national or local contract.

There is a risk that NHS Lothian will engage the services of homecare providers that do not have a national contract in place or have not been appointed in line with NHS Lothian's procurement requirements, which may result in a failure to achieve best value.

### Recommendation

NHS Lothian should develop a comprehensive contract register for Homecare Service providers. This should be updated regularly by the Medicines Homecare Services Team and used to inform homecare prescribing practices.

Formal procedures should also be developed to define the processes for engaging a homecare provider. This should include processes for initiating homecare services, identifying a suitable supplier, ensuring procurement rules are followed and approving expenditure.

# Management Response

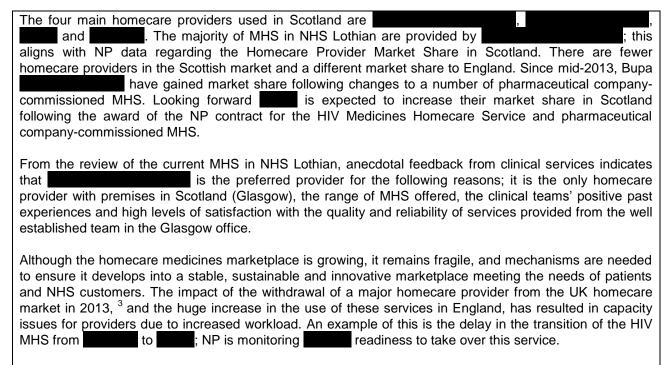
Homecare services for NHS patients are either commissioned directly by the NHS or are provided by the pharmaceutical company to support the distribution of their product. In the case of pharmaceutical company funded MHS, the pharmaceutical company chooses the homecare provider(s) and the level of service to be provided and the homecare service is included within the purchase price of the medicinal product (Bundled Homecare).

There are currently four NHS National Procurement (NP) Contracts for Medicines Homecare Services (HIV, Home TPN, Home Delivery Clotting Factors, and Pulmonary Arterial Hypertension). NHS Lothian is represented on the NP Commodity Advisory Panels (CAPs) for these national contracts.

The Pulmonary Arterial Hypertension MHS is under the remit of the Scottish Pulmonary Vascular Unit, NHS Greater Glasgow & Clyde. NHS Lothian utilises the other three national contracts. Therefore, NHS Lothian is using NP contracts for MHS where these are available. The NHS is charged costs for items such as deliveries, nursing visits and consumables for these NHS commissioned services.

The majority of MHS are commissioned by pharmaceutical companies. Pharmaceutical companies often restrict which homecare provider(s) they supply and supply with discount e.g. through the Patient Access Scheme (PAS). Some products are only available via the homecare supply route. Therefore NHS Boards do not have a free range of which homecare provider to use; NP has highlighted the associated risks and encourages pharmaceutical companies to offer a choice.





The NHS NSS Pharmaceutical Advisor, Procurement, Commissioning & Facilities co-ordinates the work of the National Homecare SLWG, to bring together all the UK (including the National Homecare Medicines Committee (NHMC) and the Department of Health (DH) Commercial Medicines Unit (CMU) homecare team), Scottish and Board aspects of MHS to ensure that these are addressed in a consistent manner across Scotland. The group is chaired by the Director of Pharmacy (DoP), NHS Lanarkshire and reports to the Scottish National Acute Pharmacy Services Networking Group and the NHS Scotland DoPs Group. NHS Lothian is represented on this group by the Medicines Homecare Pharmacist and the Associate Director of Pharmacy (Acute and SCAN).

The National Homecare SLWG enables the NHS Lothian pharmacy service to be informed of NP's discussions with homecare providers and pharmaceutical companies regarding medicine supply frameworks and options; this ensures that NHS Lothian is able to secure Best Value. For example, following a request from NP that Scotland be included in the CMU framework for the Homecare Lysosomal Storage Disorders (LSD) Service, NHS Lothian have confirmed their intent to use this CMU framework and that the Medicines Homecare Pharmacist will formally represent Scotland on the CMU's stakeholder group for the contract. The benefits to Scotland and NHS Lothian to joining the CMU framework for LSD include; it ensures governance, control over pricing, standardisation for Scottish patients regardless of whether the prescription is issued in England or in Scotland. Given the low volume of patients and resource constraints, it is unlikely that NP would have capacity to run a tender exercise independently in Scotland for the foreseeable future

# Management Action

A comprehensive contract register for homecare providers will be developed and maintained by the MHS Team. As the proposed MHS governance framework will recommend that all MHS are managed by the MHS Team, this contract register will not be provided to clinical areas to inform homecare prescribing practices, but rather a NHS Lothian Standard Operating Procedure (SOP) for Implementation of a New Homecare Service will be developed which will define an agreed process on how to manage the implementation of a new service. Any new service proposal will involve the establishment of a SLWG consisting of the clinical service's management team including medical and nursing representatives, clinical pharmacist and service manager and the MHS team. The SLWG will present the homecare proposal to the relevant Directorate Management Team with a full budget requirement analysis and governance arrangements for sign off. Services may only be initiated following Directorate sign off. This SOP will be based on good practice in NHS Greater Glasgow & Clyde.

A NHS Lothian Medicines Homecare Governance Group is to be established. It is planned that this group will hold its first meeting in May 2015. This multidisciplinary group will include membership from finance



and procurement services; this expertise will inform the work of the group to ensure compliance with SFIs, Scheme of Delegation and best practice, and to address recommendations in this report regarding procurement rules and contracts. The RPS Handbook<sup>2</sup> provides a framework to support organisations to ensure compliance with the contractual requirements for MHS. This group will develop formal procedures to define the processes for engaging a homecare provider; including processes for initiating homecare services, identifying a suitable supplier, ensuring procurement rules are followed and approving expenditure.



# Control Objective 2: Contracts and agreements are in place setting out responsibilities

# 2.1 Formalising contract management for homecare services

**Significant** 

### Observation and Risk

National Services Scotland Procurement undertakes procurement activities for the NHS nationally, including the establishment of national contracts with a number of healthcare service providers. NHS Lothian should use national contracts when they are available.

During January 2014, NHS Lothian Pharmacy conducted an analysis of current homecare services and identified that contracts were in place for just two of the 14 clinical areas covered by the review. It was unclear whether these were local service level agreements or national contracts.

There is currently a lack of clarity around the process for identifying and tracking existing contracts. Roles and responsibilities for contract management have not been established and there are no processes in place to ensure there are contracts between NHS Lothian and homecare service providers.

There is a risk homecare services providers could be engaged by clinical areas where there is no national contract or local agreement in place between NHS Lothian and the homecare service provider.

# Recommendation

As recommended at 1.1, an analysis of current homecare service providers should be completed and a contract register should be developed to identify and document services which are covered by contracts between NHS Lothian and third party contractors. Processes for tracking and monitoring contracts, including the update and communication of the contract register should be defined and documented.

# Management Response

The most recent review of current MHS activity in NHS Lothian identified that there are eight clinical services using MHS and thirty different MHS being provided. There are Service Legal Agreements (SLAs) for only five MHS. Some of the SLA documents may be out of date and some have been authorised by the local clinical team.

# Management Action

There will be clear guidance around contracting arrangements in the MHS governance framework (to be developed). It is proposed that the generic national SLA, which is currently being developed by the National Homecare SLWG, is utilised in NHS Lothian. The current draft SLA format will be adapted for use in NHS Lothian to allow this work to progress; once the generic national SLA has been finally approved it will be adopted for use in NHS Lothian. Current MHS will be reviewed to ensure that there are appropriate SLAs in place. The generic national SLA is based on a template specification developed by the NHMC and the DH CMU homecare team following consultation with homecare providers and the pharmaceutical industry (the NHS NSS Pharmaceutical Advisor, Procurement, Commissioning & Facilities contributed to this via membership of the NHMC).



# Control Objective 3: The delivery and quality of services is monitored, including patient experience.

# 3.1 Formalising homecare service governance processes

**Significant** 

# Observation and risk

The governance arrangements over homecare services are not formalised and the roles and responsibilities of Procurement, Pharmacy and clinical areas for the procurement of homecare services, the engagement of homecare providers and performance monitoring have not been defined. A national initiative is underway to obtain data that will allow monitoring of performance against an agreed KPI set. We were informed that the datasets are expected to be available by June 2015. The roles and responsibilities of the Healthcare Governance Committee and Prescribing Resource Group in the oversight of homecare services are also not defined.

There is a risk the quality of services will not meet the standards required by NHS Lothian or the performance requirements established in national contracts.

# Recommendation

The roles and responsibilities for the financial management of homecare services, including compliance with the SFI's and the management of national contracts should be formally defined. The roles of the Healthcare Governance Committee, the Prescribing Resource Group, Pharmacy, Procurement and clinical areas for ensuring that homecare providers are delivering services in line with the terms of national contracts, local service agreements and NHS Lothian's requirements should be established and documented.

# Management Response

The Acute Prescribing Forum (APF) has agreed that the main priority is to establish a NHS Lothian MHS strategy and governance framework to ensure compliance with national professional homecare standards. 1, 2

# Management Action

A multidisciplinary Medicines Homecare Governance Group will be convened to lead this work. It is proposed that the Area Drug and Therapeutics Committee (ADTC) will have responsibility for the development of the medicines homecare governance framework and its implementation with NHS Lothian. The Medicines Homecare Governance Group will report directly to the University Hospitals Division Drug and Therapeutics Committee for clinical and professional advice and to the Medicines Policies Sub-Committee for approval of policies and procedures. The Medicines Homecare Policy will be encompassed within the NHS Lothian Safe Use of Medicines Policy and Procedures. The ADTC reports to the Healthcare Governance Committee.

The Medicines Homecare Governance Group will be accountable to the Acute Prescribing Forum for performance monitoring with regards to progress with the medicines homecare work plan and timescales, and implications for the management of financial budgets. The APF reports to the Prescribing Resource Group.

This proposal will be discussed at the next meeting of the ADTC (10.4.15); the proposal will be revised to clarify the roles of the Healthcare Governance Committee and Prescribing Resource Group.

The MHS governance framework will formally define the roles and responsibilities for the financial management of homecare services, including compliance with the SFI's and the management of national contracts; and will establish and document the roles for Pharmacy, Procurement and clinical areas for ensuring that homecare providers are delivering services in line with the terms of national contracts, local service agreements and NHS Lothian's requirements.



# 3.2 Record keeping for homecare service patients

**Significant** 

### Observation and risk

There is currently no definitive register of NHS Lothian homecare service patients. Although there may be local records held within clinical areas there is no comprehensive record of homecare patients to provide a pan-Lothian view of the service.

If a provider were to go out of business or withdraw its services, there is a risk that NHS Lothian would not have sufficient information about the services provided to its patients by third parties to maintain patient treatment pathways efficiently or effectively.

# Recommendation

Pharmacy should work with Information Governance to develop a method of recording or establishing a register of NHS Lothian patients currently receiving homecare services. Roles, responsibilities and procedures for updating and maintaining this register should be defined.

# Management Action

The NHS Lothian Information Governance Manager has agreed (31.3.15) to advise on the action required to take forward this recommendation and to join the membership of the Medicines Homecare Governance Group. The MHS governance framework will define the roles, responsibilities and procedures for developing, updating and maintaining this register.



### 3.3 Risk management

**Important** 

# Observation and risk

Risks associated with homecare services have been identified in the paper agreed by the Prescribing Review Group in March 2014 and a recent review undertaken by the Medicines Homecare Pharmacist. The APF has agreed a work plan to manage the risks identified.

However, these papers do not address how risks arising from day-to-day delivery of homecare services are assessed and managed.

Key risks associated with the use of homecare services, including failure to provide safe, appropriate and efficient patient care in accordance with an NHS Lothian treatment plan or failure to achieve value for money through the use of homecare service providers may not be effectively managed if there are no formal risk management processes in place covering the use of homecare services.

### Recommendation

A formal risk assessment should be carried out for all clinical teams using homecare service providers. Guidelines should be developed to ensure that the risk assessment process is completed annually and reported to the Healthcare Governance Committee.

# Management Action

It is proposed that the Risk Assessment Tool, which is currently being developed by the National Homecare SLWG, is utilised in NHS Lothian. The current draft format will be adapted for use in NHS Lothian to allow this work to progress; once the final document has been finally approved it will be adopted for use in NHS Lothian.



# Control Objective 4: Confidentiality is maintained over patients' records and data

# 4.1 Confidentiality of homecare service patient information

**Significant** 

### Observation and risk

Homecare service providers have access to NHS Lothian patients' confidential information and should comply with patient confidentiality law. Data transferred between NHS Lothian and homecare providers should be completed safely and securely and third parties should have controls in place to ensure patient confidentiality is maintained.

NHS Lothian's Caldicott Guardian is required to oversee all procedures affecting access to person-identifiable health data. We were unable to determine whether the current arrangements for the transfer of information to third party homecare providers had been reviewed, approved and if required, signed-off by the Caldicott Guardian.

While there are some controls at a national level to monitor homecare service providers' processes for ensuring patient confidentiality local controls require improvement. NHS Lothian does not have a formal process for gaining assurance from homecare providers that their controls for ensuring patient confidentiality are adequate and operating effectively.

The NHS Code of Practice on Protecting Patient Confidentiality also requires that patients must be informed about the need to disclose information to external organisations during the course of their treatment. We found that current controls do not ensure consent forms are completed for all patients who receive homecare services.

There is a risk that confidential patient information will be compromised if controls over consent forms and the transfer of patient data to thirds parties are not improved.

# Recommendation

The arrangements for the transfer of patient data to third party homecare service providers should be reviewed and approved by the NHS Lothian Caldicott Guardian. NHS Lothian should establish and document processes via SLAs to ensure confidentiality of its patient data by third party homecare service providers. Controls should be implemented to ensure patient consent forms are completed for all patients treated through the homecare service. This might include exception reporting from databases used to capture information for homecare patients.

### Management Action

It is proposed that the Information Sharing Protocol, which is currently being developed by the National Homecare SLWG, is utilised in NHS Lothian and homecare providers. No objections were received from the National Information Governance Leads Group on the proposed national position on transferring patient information between providers. The Medicines Homecare Pharmacist is taking part in a conference call (8.4.15) with the NP Pharmaceutical Advisor, Head of Information Governance, NHS Ayrshire & Arran and the pharmacist representative on the National Homecare SLWG from NHS Ayrshire & Arran, to discuss the NHS Ayrshire & Arran Information Sharing Protocol to assess whether this will meet the needs of the SLWG.

The NHS Lothian Information Governance Manager has agreed (31.3.15) to advise on the action required to take forward this recommendation and to join the membership of the Medicines Homecare Governance Group.



# Control Objective 5: The cost of services is monitored

### 5.1 No analysis of homecare services to evidence Value for Money

Significant

# Observation and risk

Costs associated with homecare services are covered by budgets in individual clinical areas. The costs of homecare services are not distinguishable from other expenditure items, for example by the use of a separate cost code. NHS Lothian has never conducted a formal analysis of homecare services to evidence Value for Money (VFM); including an assessment of the total financial cost, other financial benefits such as potential VAT savings or the treatment benefits to its patients.

There is a risk that NHS Lothian will be unable to establish whether there is an overall benefit to the provision of homecare services. It may be unable to determine whether the service represents value for money or whether an alternative strategy, such as an in-house arrangement may be more cost effective or beneficial for patients.

# Recommendation

A specific cost centre for homecare services should be established to ensure that detailed cost data is available. An analysis of the VFM of homecare services should be completed, including an analysis of financial and non-financial costs and benefits. The results of this exercise should be reported to relevant management groups or committees so results can be used to inform future homecare strategies.

# Management Response

It is a requirement that all MHS are recorded via the hospital pharmacy computer system (JAC). This review identified that only five MHS are currently recorded via JAC.

The recent review of current MHS has identified that current MHS are heavily reliant on clinical staff resource, with associated workload pressures due to competing priorities. Once in situ, the MHS team will support the MHS governance framework which will remove many administrative duties for clinical staff; however it is recognised that clinical staff resource will still be required to support the clinical governance of MHS such as, appropriate selection of patients for MHS, patient information and consent, completion of patient registration forms, generating and screening prescriptions, communication with homecare provider(s) and pharmacy procurement regarding patients' ongoing needs e.g. decision to hold or discontinue treatment, monitoring and review of patients' treatment and clinical outcome measures.

The order of priority for implementing new and expanded MHS was based on the following assessment criteria; annual cost saving, patient numbers, patient benefit, clinical service benefit, pharmacy service benefit and ability to deliver. It is proposed that the process for analysis of MHS will be based on these criteria, therefore the recommendation in the Audit Report is evidenced in work undertaken to date.

Note the alternative models (listed below) for the provision of MHS for NHS Lothian patients that have been suggested. These options require further consideration as part of a wider review and options appraisal of MHS.

- Via a service specification with NHS Greater Glasgow & Clyde (this is the model used by NHS Lanarkshire).
- NHS Lothian to set up and provide MHS in-house.

Note the potential for the use of service models where medicines would be supplied from community pharmacies i.e. use of Hospital Based Prescriptions (HBPs) and shared care with GPs. This is primarily dependent on pharmaceutical companies giving community pharmacies access to their products. NHS Lothian would benefit by not having to pay VAT on medicines supplied to patients by community pharmacies.



# Management Action

Pharmacy procurement processes will be developed to ensure that all MHS are recorded via JAC. These processes will be developed in consultation with Finance and the Medicines Management Team, to ensure that costs associated with homecare medicines supplies are identifiable and can be reported on. Implementation of these processes will be the main priority for the MHS team once appointed and in situ. This will allow NHS Lothian to comply with national guidance<sup>5</sup> that homecare medicine supplies should be recorded through hospital pharmacy systems, and that this needs to be done in a specific manner so that this information is detected and reported through the Hospital Medicines Utilisation Database (HMUD).

Future work is required to quantify the following for MHS:

- Patients benefits
- Clinical service benefits and the clinical resource requirements
- Pharmacy service benefits and pharmacy resource requirements

The appraisal of alternative models (listed above) for the provision of MHS for NHS Lothian patients options require further consideration as part of a wider review and options appraisal of MHS.

The potential use of service models where medicines would be supplied from community pharmacy requires further consideration and exploration with patients and colleagues in primary care.

Responsibility: Acute Prescribing Forum Target date: 31 December 2015



# **Appendix 1 - Definition of Ratings**

# **Management Action Ratings**

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

# **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)

# References

- 1. Royal Pharmaceutical Society (September 2013). Professional Standards for Homecare Services.
- 2. Royal Pharmaceutical Society (May 2014). Handbook for Homecare Services in England.
- 3. NHS England Alert (April 2014). Minimising risks of omitted and delayed medicines for patients receiving homecare services. <a href="https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102151">https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102151</a>
- NHS Lothian Medicines Governance Structure (October 2013)
   <a href="http://intranet.lothian.scot.nhs.uk/NHSLothian/NHSLothian/BoardCommittees/AreaDrugTherapeutics/MedicinesGovernanceStructure/Documents/Medicines%20Governance%20Committee%20Structure%20CONTACTS%20Oct%202013.pdf</a>
- 5. NHS Directors of Finance and Directors of Pharmacy HMUD Short Life Task Group (March 2014). Guidelines for the recording of homecare medicines supplies through hospital pharmacy computer systems to enable detection and comparative reporting through the national hospital medicines utilisation database.