

NHS Lothian

Immunisation clinical queries

Internal Audit Report - final
January 2026

An overhead photograph of five medical professionals in a hospital hallway. One man in a white lab coat is looking at a document, while others in blue scrubs and white lab coats are looking at their phones or other documents.

Level of assurance:	
Design	Moderate
Effectiveness	Substantial

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EXECUTIVE SUMMARY

LEVEL OF ASSURANCE: (SEE APPENDIX II FOR DEFINITIONS)

DESIGN	MODERATE	Generally, a sound system of internal control designed to achieve system objectives with some exceptions.
EFFECTIVENESS	SUBSTANTIAL	The controls that are in place are being consistently applied.

SUMMARY OF FINDINGS (SEE APPENDIX II)

H	0	
M	0	
L	7	
TOTAL NUMBER OF FINDINGS: 7		

PURPOSE

The purpose of the review is to provide management and the Audit Committee with assurance over the design and operational effectiveness of the controls in place with relation to immunisation clinical queries, and management with advice where the controls can be improved further.

BACKGROUND

It was agreed as part of the 2025-26 Internal Audit Plan that Internal Audit would conduct a review of the arrangements around Immunisation Clinical

Queries at NHS Lothian.

The Immunisation queries team is made up of four members along with admin support: an Immunisation Nurse Consultant, a Senior Immunisation Nurse Specialist, an Immunisation Nurse Specialist and a Vaccination Pharmacist.

There is a Standard Operating Procedure (SOP) in place which outlines the approach to handling queries. A dedicated mailbox is in place for the receipt of queries which is accessible to each member of the team. Queries will only be received via this mailbox due to the level of detail needed to handle a query.

Queries are triaged on a Monday with team meetings taking place twice weekly to monitor progress. An excel spreadsheet is used to track queries.

Average number of queries received depends on the time of year and whether there are any immunisation campaigns ongoing; over the period June-August 2025 the number of queries averaged 20 per month.

The Clinical queries team reference Immunisation Against Infections Disease: the Green Book which acts as a guide to the UK vaccination schedule for health professionals.

The team reports into the Quality and Safety Group with further escalation routes to the Immunisation Delivery Board and the Immunisation Oversight Board. Some queries may also require external escalation to Public Health Scotland. There is currently no regularly scheduled performance reporting and there are no KPIs in place.

More detail on processes in place can be found at Appendix I.

CONCLUSION

As part of our work, we have identified seven findings, all of which were rated as low significance.

The Immunisation clinical queries process is operating sufficiently, although with some opportunities for improvement, and has a clear set of controls in place to manage queries as they come in and ensure that responses are in line with correct procedures and medical advice.

The SOP clearly sets out the end to end process for a query. A dedicated mail box that each member of the immunisation clinical queries team has access to is used to receive all queries. Twice weekly meetings are used to discuss complex queries or queries requiring escalation. Our sample had an average response time for internally resolved queries of 2.11 days.

Findings from the audit relate to definition of roles and responsibilities within the team. We noted that whilst the query log was able to handle the current number of clinical queries, further controls may strengthen the ability to manage increased loads in the future and improve the audit trail for queries. Currently there is limited monitoring and reporting of KPIs. Along with KPIs, key themes, trends and common queries could be shared with relevant parties to improve transparency and act as a lesson learned mechanism.

Also the team may benefit from developing training materials on the process and how to effectively respond to clinical queries. There were four cases in our sample where we found that queries did not have close notes attached, with two of these queries having no clinical notes associated with them. The process may benefit from gathering feedback from users to develop it in the future.

Overall we can provide moderate assurance over the design and substantial assurance over the effectiveness of controls in place in relation to the immunisation clinical queries process.



EXECUTIVE SUMMARY

SUMMARY OF GOOD PRACTICE

During the course of our review, we identified a number of areas of good practice, as follows:

- ▶ There is a clear Standard Operating Procedure in place with a process map showing the query process from a query being received, to reviewed by staff, to being replied to and closed. The SOP is available through the staff Sharepoint along with the shared query logs and is regularly reviewed and kept up to date.
- ▶ There is an intranet site that is used to explain to healthcare staff the purpose of the immunisation queries mailbox and how to contact the service.
- ▶ The Clinical queries team meet twice a week to discuss queries received and approve draft responses; this ensures timely response to queries.
- ▶ The staff that were interviewed as part of the audit demonstrated an understanding of their roles and responsibilities and could give clear recount of the procedures.
- ▶ As part of the audit, we saw evidence of a service improvement log which is used to capture issues identified through clinical queries that highlight areas of improvement on the immunisation service. We noted examples where improvements identified were raised with Public Health Scotland and edits made to guidance.
- ▶ There is a clear pathway and criteria for queries that need to be escalated to the Immunisation Co-ordinator before they are responded to.
- ▶ Incidents or adverse events related to immunisations are recorded on DATIX per the standard NHS Lothian process. During our sample testing, we noted one instance in which incorrect immunisation actions were identified through the query process and this was appropriately recorded on DATIX as a result.
- ▶ We reviewed a sample of 15 queries from a total of 147 over the past six months and, where queries remained internal with the team, they had an average response time of 2.11 days.

- ▶ We selected a sample of 15 queries from a population of 147 queries, covering the period March to September 2025. In all cases in our sample we found that responses to queries were developed from a clear template that included personalisation and polite language and that the language was consistent across our sample free from excessive technical jargon.
- ▶ Responses referenced the Green Book chapters to show sources of information to back up points. We utilised our proprietary technology solution which incorporates AI functionality to test alignment of responses for our sample of 15 queries with the information included in the Green Book and found no issues with alignment.
- ▶ All responses from our sample clearly addressed the original queries.
- ▶ The clinical queries team attend Public Health Scotland meetings along with representatives of 14 other health boards in Scotland where queries or best practice can be shared.

SUMMARY OF FINDINGS

Notwithstanding the areas of good practice identified, we also identified opportunities for improvement, which are summarised below:

- ▶ **Query log** - From our sample of 15 queries we noted that four queries did not have close notes attached, two of which also had no clinical notes from meetings attached. In addition to this we noted ways the log could be developed to enhance the audit trail of queries.
 - i. Include the date query was received and closed separately to help with noting priority of query, along with including number of days query has been open can help with assessing priority
 - ii. Whether escalation is required
 - iii. Who the query is assigned to, to prevent any duplication of effort on the same queries
 - iv. Decision log of each meeting showing attendance and responses approved
 - v. Final outcome/response separately set out.
 - vi. References and guidelines used in the queries



EXECUTIVE SUMMARY

- ▶ **KPI reporting** - We noted that whilst the number of queries per Vaccine were reported we noted this could be expanded to include other KPIs including time to closure, and number of queries per week. These could be benchmarked against averages to show performance of the team, along with the KPIs.
- ▶ **Log Completion** - We noted one case from our sample where an incomplete email had been copied across to the log. As email texts are manually copied across there is a risk that text is missed. In addition, this doesn't allow for any attachments to be copied across.
- ▶ **Training** - Whilst there are standard operating procedures in place and a team to help with onboarding, there is no specific clinical queries onboarding training in place.
- ▶ **Feedback** - In the past, there was a function that allowed those raising queries to provide feedback to the team, however we noted feedback has not been collected since the query process was revised in February 2025.
- ▶ **Documentation of individual duties**- Whilst the roles and responsibilities clearly state the expectations for each member of the team they could be enhanced to define responsibility for approval of policies and procedures as well as approval and ownership of final responses and closing of queries.
- ▶ **Lessons learned** - There is an opportunity for sharing of lessons learned; trends and common queries are noted by the clinical queries team these could be displayed to health care staff through an intranet or newsletter.

DETAILED FINDINGS



DETAILED FINDINGS

RISK: IF PROCESSES FOR HANDLING IMMUNISATION QUERIES ARE INEFFICIENT OR NOT CONSISTENTLY APPLIED, IT COULD LEAD TO DELAYS IN RESPONSE TIMES, UNRESOLVED BACKLOGS, AND INCONSISTENT FOLLOW-UP ACTIONS, POTENTIALLY IMPACTING THE EFFECTIVENESS OF CLINICAL OPERATIONS AND TRUST IN THE SERVICE.

FINDING 1 - LOG COMPLETION			TYPE
<p>It is important that the Query Log is accurate and shows the complete journey of each query, along with actions taken and advice given.</p> <p>From our sample of 15 queries from a sample of 147, we noted one case where an email that had been copied into the Log was missing sections. This is likely due to emails being manually copied and pasted into the excel spreadsheet log. This method of recording discussion also does not allow the attachments to be included in the log.</p> <p>We also noted from our sample that four queries did not have to close notes attached to the discussion section, and two queries did not have clinical notes attached to show the discussion at clinical query meeting.</p>			<p>DESIGN & EFFECTIVENESS</p> 
<p>IMPLICATION</p> <p>Manual copying and pasting of emails into spreadsheets is prone to errors and is time-consuming. This method can lead to operational inefficiencies, diverting valuable time and resources from patient care. Without complete and accurate logs, it becomes challenging to ensure accountability and transparency in clinical decision-making processes. This can hinder audits and reviews, making it difficult to assess the appropriateness of actions taken.</p>			<p>SIGNIFICANCE</p> <p>LOW</p>
RECOMMENDATIONS	ACTION OWNER	MANAGEMENT RESPONSE	COMPLETION DATE
<p>We recommend embedding emails into the log instead of copy and pasting them to ensure that all text is included as well as any attachments.</p>	<p>Kirsty McLellan</p>	<p>Whilst embedding emails may create one record for reviewing and auditing purposes, it would be impractical for various reasons and could introduce more risk:</p> <ul style="list-style-type: none"> The central inbox is maintained and holds all correspondence in relation to clinical queries, this is where we would look to if the log did not provide enough of an audit trail. Including emails in the log would be an additional administrative task and create opportunities for error when transferring data over. The log is a working document designed to be shared on screen and support discussion. Including all emails in this would make it 	<p>N/A</p>



DETAILED FINDINGS

RISK: IF PROCESSES FOR HANDLING IMMUNISATION QUERIES ARE INEFFICIENT OR NOT CONSISTENTLY APPLIED, IT COULD LEAD TO DELAYS IN RESPONSE TIMES, UNRESOLVED BACKLOGS, AND INCONSISTENT FOLLOW-UP ACTIONS, POTENTIALLY IMPACTING THE EFFECTIVENESS OF CLINICAL OPERATIONS AND TRUST IN THE SERVICE.

FINDING 1 - LOG COMPLETION			TYPE
RECOMMENDATIONS	ACTION OWNER	MANAGEMENT RESPONSE	COMPLETION DATE
		<p>unusable for this purpose</p> <p>Mitigation:</p> <ul style="list-style-type: none"> All emails are filed and held in the shared inbox in their original form with attachments. There is no barrier to accessing this information if it is required by the team of NHS Lothian. 	
<p>Consider introducing a regular review process whereby queries are reviewed to confirm that all emails have been attached, clinical notes are complete and align with the advice given, ensure that the query was fully answered and that the health care professional was satisfied with the response.</p>	Kirsty McLellan	<p>This is something we may consider. We do gather feedback from staff via a survey on how well they think CQs works for them.</p> <p>The log allows us to track clinical queries and their progress. They are closed when the team are content with the response and will be re-opened if staff have further questions or require clarification.</p>	Feb 26



DETAILED FINDINGS

RISK: IF PROCESSES FOR HANDLING IMMUNISATION QUERIES ARE INEFFICIENT OR NOT CONSISTENTLY APPLIED, IT COULD LEAD TO DELAYS IN RESPONSE TIMES, UNRESOLVED BACKLOGS, AND INCONSISTENT FOLLOW-UP ACTIONS, POTENTIALLY IMPACTING THE EFFECTIVENESS OF CLINICAL OPERATIONS AND TRUST IN THE SERVICE

FINDING 2 - QUERY LOG	TYPE
<p>It is important that full records are kept of queries received and responses provided and that there is a comprehensive and accurate query log maintained to provide oversight of the status of queries.</p> <p>The Query Log for immunisation clinical queries is set up in excel and includes copies of emails, a section for notes from the clinical query meetings and log number. When responses are finalised, a close note is attached in the discussion section.</p> <p>We reviewed the Query Log to assess the suitability of its layout and contents, as well as a reviewing a sample of 15 queries from a population of 147 queries between March and September 2025 to confirm completeness of information.</p> <p>Clinical queries that either involve an adverse event or where there is not enough available information for the team to form a response, are escalated to the Immunisation Co-Ordinator for review and guidance on best way to respond. Escalated queries are then discussed at one of the two meetings held every week. Management advised that the Immunisation Co-Ordinator attends each of the meetings at which responses to complaints are reviewed and approved, however, there is no specific evidence maintained to confirm this. Therefore, we were unable to confirm for our sample of queries that these were specifically approved by the Immunisation Co-Ordinator.</p> <p>Whilst the log appeared to be working well with the current number of queries, we noted some further enhancements which could be made to the log.</p>	<p>DESIGN</p> 
IMPLICATION	SIGNIFICANCE
<p>There is a risk an unclear log of queries may lead to queries not being handled in line with policies and procedures, it can also increase the risk that if legal action is raised in the future on queries made there is not a clear auditable trail of evidence to show how decisions were made and how queries were responded to.</p>	<p>LOW</p>



DETAILED FINDINGS

RISK: IF PROCESSES FOR HANDLING IMMUNISATION QUERIES ARE INEFFICIENT OR NOT CONSISTENTLY APPLIED, IT COULD LEAD TO DELAYS IN RESPONSE TIMES, UNRESOLVED BACKLOGS, AND INCONSISTENT FOLLOW-UP ACTIONS, POTENTIALLY IMPACTING THE EFFECTIVENESS OF CLINICAL OPERATIONS AND TRUST IN THE SERVICE

FINDING 2 - QUERY LOG			
RECOMMENDATIONS	ACTION OWNER	MANAGEMENT RESPONSE	COMPLETION DATE
<p>We recommend adding the following functions and sections to the query log:</p> <ul style="list-style-type: none"> ▶ Include the date the query was received and closed separately, along with including the number of days a query has been open can help with assessing priority. ▶ Whether escalation is required to help highlight key queries for meetings. ▶ Who the query is assigned to, to prevent any duplication of effort on the same queries ▶ Keep a decision log of the weekly meeting to record who attended and which responses were approved. ▶ The final response/outcome. ▶ A noted of the sources and references used in response to queries 	Kellie Peacock/Kirsty McLellan	<p>The CQ log has been updated with the following recommendations:</p> <ul style="list-style-type: none"> • Date of query opened and closed. • Number of day open • Who the query is assigned too. • Discussions notes highlight responses approved. • Escalation required will be highlighted in working notes. 	Jan 2026
<p>We would also recommend having a separate tab for detailed notes/investigations linked back to the main tracker using the Query ID. Each note should be in a separate row rather than condensed into a single cell and clearly labelled with the date and author.</p>	Kirsty McLellan	<p>As previously stated for Finding 1. The required information is included in the log and in email exchanges with rationale and evidence detailed that supports decision making. Notes are often completed by business support. This would be an additional administrative task that we would not have capacity to complete with minimal impact on improvement.</p>	N/A



DETAILED FINDINGS

RISK: LACK OF PERFORMANCE OVERSIGHT RISKS FAILING TO IDENTIFY AND ADDRESS SYSTEMIC ISSUES, POTENTIALLY LEADING TO REPEATED ERRORS AND COMPROMISED PATIENT CARE.

FINDING 3 - REPORTING KPIS			TYPE
<p>To understand whether the clinical queries team are improving or maintaining performance, KPIs need to be recorded and reviewed to highlight any inefficiencies within the system and show how queries are being handled. Reporting on the key themes and trends in queries can help show where there are knowledge gaps within the organisation.</p> <p>Whilst there is a quarterly report on number of queries per vaccine that is reported to the Quality and Safety group, we noted that is an opportunity to develop and monitor further KPIs to show the performance of the service.</p>			DESIGN 
IMPLICATION			SIGNIFICANCE
There is a risk that the clinical team are unable to effectively measure and monitor performance of the function and therefore cannot address any weaknesses or dips in performance of the service.			LOW
RECOMMENDATIONS	ACTION OWNER	MANAGEMENT RESPONSE	COMPLETION DATE
<p>To enhance the current KPIs that are reviewed and reported we recommend considering recording the following KPIs:</p> <ul style="list-style-type: none"> ▶ Time from receiving a query to a response being sent ▶ First contact resolution rate ▶ Volume of escalated queries compared to non escalated ▶ Compliance with process 	Kirsty McLellan	<p>Added open/closed date into log to allow for reporting of timescales for resolution.</p> <p>Some queries will take longer than others as will have dependencies on other departments or national boards. They may also be complex and require a longer resolution time.</p> <p>Setting KPIs got clinical queries does not prioritise patient safety in this instance.</p> <p>Number of clinical queries can be reported and the Quality and Safety meeting and monitored there.</p>	Jan 26



DETAILED FINDINGS

RISK: A LACK OF STAFF TRAINING AND DEVELOPMENT COULD LEAD TO INCONSISTENT QUERY HANDLING AND MISSED OPPORTUNITIES FOR IMPROVEMENT, POTENTIALLY IMPACTING THE QUALITY OF SERVICE AND STAFF CONFIDENCE

FINDING 4 - TRAINING			TYPE
<p>It is important that all members of the Immunisation Clinical Queries Team have been provided with sufficient training to be able to execute their responsibilities effectively.</p> <p>Currently there is no formal training for members of the Team; staff noted that they have Standard Operating Procedures for guidance, also learn informally on the job through Team collaboration between the team.</p>			DESIGN 
IMPLICATION			SIGNIFICANCE
<p>There is a risk that, if staff are not provided with training in the process, the process may not be followed consistently, or mistakes may be made leading to incorrect advice given or a queries not answered in a timely manner.</p>			LOW
RECOMMENDATIONS	ACTION OWNER	MANAGEMENT RESPONSE	COMPLETION DATE
<p>We recommend developing induction training or seeking externally developed training for staff within the Immunisation Clinical Queries Team setting out the full process from start to finish along with an explanation of how to complete the query log, response language and tone and case studies.</p>	Kirsty McLellan/Kellie Peacock	<p>We will formally identify training requirements and add into the Clinical Queries SOP.</p> <p>Allow staff protected time for updates.</p>	June 2026



DETAILED FINDINGS

RISK: A LACK OF STAFF TRAINING AND DEVELOPMENT COULD LEAD TO INCONSISTENT QUERY HANDLING AND MISSED OPPORTUNITIES FOR IMPROVEMENT, POTENTIALLY IMPACTING THE QUALITY OF SERVICE AND STAFF CONFIDENCE.

FINDING 5 - FEEDBACK			TYPE
<p>Collecting feedback helps identify key issues in the process and allows the Team to make changes and refine the process to meet expectations and lead continuous improvement.</p> <p>Feedback used to be collected before the process for queries was updated in June 2025 and therefore feedback has not been collected since February 2025. Management have informed us that in the future they are looking to implement a feedback process for new complaints raised.</p>			DESIGN 
IMPLICATION			SIGNIFICANCE
There is a risk that any issues in the process will not be reported or highlighted to the team and therefore will not be rectified.			LOW
RECOMMENDATIONS	ACTION OWNER	MANAGEMENT RESPONSE	COMPLETION DATE
We recommend developing a mechanism to provide any health care professionals that use the service with the opportunity to feedback. The feedback should then be reviewed at team meetings and actions made based on the feedback to improve the process in the future.	Kellie Peacock/Tess Ellens	Q1 feedback currently underway to get feedback on current CQ process. This will be reviewed and findings shared with quality and safety.	Jan-March 26



DETAILED FINDINGS

RISK: LACK OF CLARITY IN ROLES, RESPONSIBILITIES, AND ESCALATION PATHWAYS, COULD LEAD TO CONFUSION AND DELAYS IN ADDRESSING COMPLEX OR HIGH-PRIORITY ISSUES, POTENTIALLY COMPROMISING PATIENT SAFETY AND ORGANISATIONAL ACCOUNTABILITY.

FINDING 6 - DOCUMENTATION OF INDIVIDUAL DUTIES			TYPE
<p>Defined roles and responsibilities help ensure that tasks are not being duplicated, and that team members are clear on expectations of them within a process. They also ensure that there is correct segregation of duties in place to prevent self review</p> <p>We reviewed the SOP to assess its completeness and alignment with the immunisation clinical queries process being carried out. We also reviewed roles and responsibilities documented within the SOP and interviewed members of staff to confirm that their understanding of their role aligned with what was documented.</p> <p>Queries can be answered by any member of the team; however, for queries that involve adverse reactions or complaints, or where there is unclear guidance or uncertainty in forming a response to a query, these are to be escalated to the Immunisation Co-ordinator. From our review we noted that the roles and responsibilities documented within the SOP were general and did not capture the specific role of the Immunisation Co-Ordinator.</p> <p>We also noted that the SOP had a review due date of June 2025, meaning that it was six months overdue for review at the time of our audit.</p>			DESIGN 
IMPLICATION			SIGNIFICANCE
<p>There is a risk that if roles and responsibilities are not clearly documented, staff may be unclear as to what is required of them. There may also be an operational continuity risk if key members of the team are unexpectedly absent and there is a lack of guidance on their role.</p>			LOW
RECOMMENDATIONS	ACTION OWNER	MANAGEMENT RESPONSE	COMPLETION DATE
<p>We recommend setting out separate responsibilities for each member of the clinical queries team within the SOP.</p>	<p>Kellie Peacock/Kirsty McLellan</p>	<p>SOP will clearly identify roles and responsibilities of each team member. This will include requirement for pharmacy support.</p>	<p>June 2026</p>



DETAILED FINDINGS

RISK: A LACK OF STAFF TRAINING AND DEVELOPMENT COULD LEAD TO INCONSISTENT QUERY HANDLING AND MISSED OPPORTUNITIES FOR IMPROVEMENT, POTENTIALLY IMPACTING THE QUALITY OF SERVICE AND STAFF CONFIDENCE.

FINDING 6 - SHARING OF LESSONS LEARNED			TYPE
<p>Where there are common trends or frequently asked queries, it can be beneficial to communicate these to staff within an organisation, this can help reduce number of queries that are received and improve the satisfaction with the service.</p> <p>The intranet site for immunisation clinical queries directs health professionals to the email to use to contact the team, it also includes a link to a resources section which includes websites covering individual vaccines and a high-level overview of escalation and resources to use before utilising the clinical queries team.</p> <p>We noted that whilst information on the number of queries received for each vaccine every quarter is presented to the Quality and Safety Committee, common queries and themes were not being presented directly to health care staff within the organisation.</p>			DESIGN 
IMPLICATION			SIGNIFICANCE
<p>There is a risk that staff will ask similar queries or duplicate queries that increase the workload of the clinical queries team affecting the efficiency and time to respond and impacting other duties of the team members.</p>			LOW
RECOMMENDATIONS	ACTION OWNER	MANAGEMENT RESPONSE	COMPLETION DATE
<p>We recommend utilising the “Jab Gab” newsletter to share common queries that have been received, highlighting trends and themes that appear and sharing lessons learned.</p>	<p>Tess Ellens/Kirsty McLellan</p>	<p>Where appropriate, frequently asked questions can be shared in the monthly news letter.</p> <p>For more complex situations or where consultation with teams and escalation may be required these will be presented at the Quality and Safety group meeting.</p>	<p>June 2026.</p>

OBSERVATIONS



OBSERVATIONS

OBSERVATION 1 - AWARENESS OF PROCESS

We reviewed a sample of 15 queries over the past six months and noted that three queries were initially sent directly to a member of the team before being forwarded on to the central mailbox, which is not in line with the policy. Since this has occurred the team have updated the intranet site to inform health care professionals of the correct process (to send all queries to the central mailbox) and replies were sent to the health care professionals reminding them of the process.

OBSERVATION 2 - QUALITY AND SAFETY MEETINGS MINUTES

Management made us aware that they would be unable to share with us the minutes from the quality and safety committee meetings due the sensitive information contained in the meeting minutes, therefore we were not able to review the minutes to confirm discussion of the themes that are highlighted the number of queries per vaccine and if there was any challenge or decisions made in the meetings.

APPENDICES



APPENDIX I: BACKGROUND

In accordance with the 2024-25 Internal Audit Plan, it was agreed that internal audit would review arrangements around Immunisation Clinical Queriers at NHS Lothian

Standard operating procedures are in place which were developed in June 2025 by the Senior Immunisation Nurse Specialist and approved by the Immunisation Coordinator. The SOP outlines the process for managing clinical queries by the designated team of clinical professionals, with a flow chart showing the journey of a clinical query from receiving to response to closure. All queries are received through a central mailbox managed by the Business Support Officer who will add the queries to the clinical queries excel.

There are four members of the clinical queries team along with a Business Support Administrator. This team is lead by the Immunisation Co-ordinator who will review any escalated queries from the team along with signing off SOPs and other policies. The rest of the team is made up of a Senior Immunisation Nurse Specialist, Immunisation Nurse Specialist, and a Lead Pharmacist. The team reports up to the Lead Consultant for Health Care.

Near misses and adverse events are reported through the NHS system Datix which is used to record, manage and learn from patient safety events. The is used for patient safety, medication errors, vaccine errors and adverse events. In addition to this the UK use The Yellow Card Scheme to report adverse instances associated with vaccines, these are used by Medical and Healthcare Products Regulatory Agency (MHRA) to ensure that medicines and medical devices are safe and working properly.

Most queries are managed in house by the team, if required they can reach out to other departments and Public Health Scotland for further guidance.

Queries that are received are reviewed and answered either by a member of the team Monday to Friday or are reviewed at one of the two weekly meetings held with the team. Regular meetings are held every Wednesday and Friday with a small afternoon meeting on Mondays for any queries received over the weekend. Meetings are used for more complex queries or where queries need to be escalated. Escalation is required where there is an uncertainty in the response for a query or adverse events or there in unclear guidance to form a response to a query. The clinical queries log is used to track the progress of queries with the emails copied and pasted to the log along with clinical notes from meetings. Once a final response has been developed by a member of the team this is sent to the querier with any references and sources used to answer.

The team monitor the number of queries that are received for each vaccine and report this each quarter, over the past quarter there was 61 queries received.

The standard operating procedures and support from the team are used as training, along with this the team refer to the Green book, immunisation against infections disease. The book covers the key areas and principles, practices and procedures for each of the key vaccines along with the schedules and adverse events to look out for.

Alongside the query log there is an improvement log maintained which is used to capture issues identified through the clinical queries that highlight areas for improvement in the immunisation service, queries are handled in the same procedure as standard procedures.



APPENDIX II: DEFINITIONS

LEVEL OF ASSURANCE	DESIGN OF INTERNAL CONTROL FRAMEWORK		OPERATIONAL EFFECTIVENESS OF CONTROLS	
	FINDINGS FROM REVIEW	DESIGN OPINION	FINDINGS FROM REVIEW	EFFECTIVENESS OPINION
SUBSTANTIAL	Appropriate procedures and controls in place to mitigate the key risks.	There is a sound system of internal control designed to achieve system objectives.	No, or only minor, exceptions found in testing of the procedures and controls.	The controls that are in place are being consistently applied.
MODERATE	In the main there are appropriate procedures and controls in place to mitigate the key risks reviewed albeit with some that are not fully effective.	Generally, a sound system of internal control designed to achieve system objectives with some exceptions.	A small number of exceptions found in testing of the procedures and controls.	Evidence of non-compliance with some controls, that may put some of the system objectives at risk.
LIMITED	A number of significant gaps identified in the procedures and controls in key areas. Where practical, efforts should be made to address in-year.	System of internal controls is weakened with system objectives at risk of not being achieved.	A number of reoccurring exceptions found in testing of the procedures and controls. Where practical, efforts should be made to address in-year.	Non-compliance with key procedures and controls places the system objectives at risk.
NO	For all risk areas there are significant gaps in the procedures and controls. Failure to address in-year affects the quality of the organisation's overall internal control framework.	Poor system of internal control.	Due to absence of effective controls and procedures, no reliance can be placed on their operation. Failure to address in-year affects the quality of the organisation's overall internal control framework.	Non-compliance and/or compliance with inadequate controls.

RECOMMENDATION SIGNIFICANCE

HIGH	A weakness where there is substantial risk of loss, fraud, impropriety, poor value for money, or failure to achieve organisational objectives. Such risk could lead to an adverse impact on the business. Remedial action must be taken urgently.
MEDIUM	A weakness in control which, although not fundamental, relates to shortcomings which expose individual business systems to a less immediate level of threatening risk or poor value for money. Such a risk could impact on operational objectives and should be of concern to senior management and requires prompt specific action.
LOW	Areas that individually have no significant impact, but where management would benefit from improved controls and/or have the opportunity to achieve greater effectiveness and/or efficiency.
ADVISORY	A weakness that does not have a risk impact or consequence but has been raised to highlight areas of inefficiencies or potential best practice improvements.



APPENDIX III: TERMS OF REFERENCE

EXTRACT FROM TERMS OF REFERENCE

PURPOSE

The purpose of the review was to provide management and the Audit Committee with assurance over the design and operational effectiveness of the controls in place with relation to immunisation clinical queries, and management with advice where the controls can be improved further.

KEY RISKS

1. If arrangements for handling immunisation clinical queries are not clearly defined or communicated, staff may be unaware of the correct procedures, leading to inconsistent handling of queries and potential misalignment with current clinical guidance.
2. Lack of clarity in roles, responsibilities, and escalation pathways, could lead to confusion and delays in addressing complex or high-priority issues, potentially compromising patient safety and organisational accountability.
3. Lack of performance oversight risks failing to identify and address systemic issues, potentially leading to repeated errors and compromised patient care.
4. If processes for handling immunisation queries are inefficient or not consistently applied, it could lead to delays in response times, unresolved backlogs, and inconsistent follow-up actions, potentially impacting the effectiveness of clinical operations and trust in the service.
5. If responses to queries lack adherence to guidelines, personalisation, clarity, consistency, or supplementary resources, it could result in miscommunication and dissatisfaction among clinical staff, potentially affecting the quality of patient care and operational efficiency.
6. A lack of staff training and development could lead to inconsistent query handling and missed opportunities for improvement, potentially impacting the quality of service and staff confidence

EXCLUSIONS/LIMITATIONS OF SCOPE

The scope of the review is limited to the areas documented under the scope and approach. All other areas are considered outside of the scope of this review. Our review will not provide assurance over all aspects of Immunisation Clinical Queries

Where sample testing is undertaken, our findings and conclusions will be limited to the sample tested only. Please note that there is a risk that our findings and conclusions based on the sample may differ from the findings and conclusions we would reach if we tested the entire population from which the sample is taken.



APPENDIX IV: STAFF INTERVIEWED

BDO LLP APPRECIATES THE TIME PROVIDED BY ALL THE INDIVIDUALS INVOLVED IN THIS REVIEW AND WOULD LIKE TO THANK THEM FOR THEIR ASSISTANCE AND COOPERATION.

KELLIE PEACOCK	SENIOR IMMUNISATION NURSE SPECIALIST	KEY CONTACT
KIRSTY MCLELLAN	IMMUNISATION NURSE CONSULTANT	KEY CONTACT
DERVILLA BRAY	LEAD PHARMACIST FOR IMMUNISATIONS	KEY CONTACT
TESS ELLENS	IMMUNISATION NURSE SPECIALIST	KEY CONTACT



APPENDIX V: LIMITATIONS AND RESPONSIBILITIES

MANAGEMENT RESPONSIBILITIES

The Audit & Risk Committee is responsible for determining the scope of internal audit work, and for deciding the action to be taken on the outcome of our findings from our work. The Committee is also responsible for ensuring the internal audit function has:

- The support of the organisation's management team.
- Direct access and freedom to report to senior management, including the Chair of the Audit & Risk Committee.

Internal controls covers the whole system of controls, financial and otherwise, established by the Board in order to carry on the business of the organisation in an orderly and efficient manner, ensure adherence to management policies, safeguard the assets and secure as far as possible the completeness and accuracy of the records. The individual components of an internal control system are known as 'controls' or 'internal controls'.

The Board is responsible for risk management in the organisation, and for deciding the action to be taken on the outcome of any findings from our work. The identification of risks and the strategies put in place to deal with identified risks remain the sole responsibility of the Board.

LIMITATIONS

The scope of the review is limited to the areas documented under Appendix III - Terms of reference. All other areas are considered outside of the scope of this review.

Our work is inherently limited by the honest representation of those interviewed as part of colleagues interviewed as part of the review. Our work and conclusion is subject to sampling risk, which means that our work may not be representative of the full population.

Internal control systems, no matter how well designed and operated, are affected by inherent limitations. These include the possibility of poor judgment in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Our assessment of controls is for the period specified only. Historic evaluation of effectiveness may not be relevant to future periods due to the risk that: the design of controls may become inadequate because of changes in operating environment, law, regulation or other; or the degree of compliance with policies and procedures may deteriorate.

FOR MORE INFORMATION:

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