NHS Blood and Transplant

NHSBT Board
January 28 2016

Governance Review of CARE

1. Status - public

2. Executive Summary

This paper provides an overview of the recent governance review of the Clinical Audit Risk and Effectiveness Committee (CARE) and related groups, and includes recommendations and next steps as agreed at January 2016 CARE and endorsed by GAC. The review concluded that the broad structure and scope of CARE arrangements, along with the Therapeutic Products Safety Group (TPSG), provide a high degree of assurance regarding the quality and safety of our products and services. CARE and TPSG will remain as separate groups. Minor changes to CARE membership, order and length of meetings were agreed to reduce duplication of discussion, allow CARE to focus on cross-directorate issues, and make modest cost savings. To replace current secondment arrangements, UK Forum have agreed to fund a permanent post of Lead Scientist, Safety Policy to work between SaBTO and JPAC.

3. Action Requested

The Board is asked to:

- Note the recommendations from the review.

4. Background

4.1 Following the attendance of Non-Executive Directors (NEDs) at CARE, the Medical and Research Director received complimentary remarks about the thoroughness of the overall CARE processes and the assurance these provide that we are a high performing organisation in key matters that affect donors and patients. However, one observation was that the same reports are often discussed in multiple fora, sometimes by the same people. A request was made from the Board to review CARE and related groups, consider whether the process could be made more LEAN, and whether the schedule of meetings could be aligned prior to each GAC to aid the flow of papers up to the Board.

4.2 The Assistant Director (AD) of Governance and Clinical Effectiveness led the review, the purpose of which was to: streamline the governance/assurance flow through appropriate meetings up to the Board, review Terms of Reference (ToR) of CARE and related groups, consider the merger of CARE and the Therapeutic Product Safety Group

(TPSG), and to consider how we further improve the current good; to ensure robust and efficient governance and assurance arrangements.

4.3 The review consisted of:

- Questionnaire to all CARE members
- In-depth discussions with Chairs of the Directorate CARE groups
- Review of National CARE ToR and Directorate CARE ToR
- Review of current Directorate reports to CARE
- Review of TPSG ToR and questionnaire to TPSG members
- Review scheduling of CARE and GAC to best align to ET and Board
- Review of CARE workplan and reporting requirements
- In-depth discussions with additional persons on request

5. Findings and recommendations/next steps

5.1 Outlined below are the key findings, recommendations and proposed next steps which were approved by CARE on 7th January 2016 and endorsed by GAC on 19th January 2016. .

5.2 On the whole, respondents felt that CARE works effectively and at a high level has a clear focus and function. However, there are some areas which could be improved and would benefit from greater clarity; those areas are outlined below. Areas that respondents felt worked effectively at CARE were: discussion of clinical issues/policies, provision of a broader understanding of clinical governance across the organisation, and regular discussion of issues that cross directorates.

5.3 In order to address comments raised regarding the size of the Committee, the seniority of attendees, level of detail discussed at the meeting, and efficiency regarding attendance, it is proposed the membership be amended to twelve core members as follows:

- Chair – Medical and Research Director
- Max of two representatives from each operational directorate – CARE agreed that normally this would be the AMD and Chief Nurse; however this can be varied by each directorate. It is proposed that Blood Donation and Manufacturing and Logistics have a maximum of three representatives across the two directorates. All Directors would have an open invitation to attend.
- AD of Governance and Clinical Effectiveness - to also represent Clinical Audit, Clinical Claims, and Information Governance. The Heads of these areas would attend periodically as part of the annual calendar of reports.
- One Quality Assurance (QA) representative - Director of Quality/AD of Quality and Regulatory Compliance
- One IT representative (new) – Chief Technology Officer (when appointed)

- One Business Continuity representative – frequency of attendance to be agreed
- Additional individuals will be invited as and when required according to the annual calendar of reports
- Two places will be available at each meeting for shadowing/observing.

5.4 A running theme through the feedback was that there was duplication at CARE of the discussions at Directorate CARE groups. Whilst there was an appreciation that a certain amount of duplication is to be expected and is appropriate when escalating issues, it was felt that there was too much focus on operational detail at CARE, leaving insufficient time to focus on cross-directorate learning and strategic issues. The proposal is therefore to keep the current CARE scope, but shift the focus at CARE away from detailed discussion of individual events to a focus on challenge, gaining assurance, overall review of any hotspots/areas of concern/areas of good practice, sharing learning, and areas which require escalation to ET, GAC and the Board. Examples of this shift would be:

- For Serious Incidents Requiring Investigation (SIRIs) – not to revisit the discussions had as part of the investigation and/or the Directorate CARE Group review, but to have an overall understanding of the incident, gain assurance of the actions being taken to address this, and challenge where there are any concerns regarding actions or next steps. A particular area of focus would be sharing the lessons from SIRIs across the organisation, with the aim of ensuring the same types of issues/root causes are not occurring elsewhere.
- For clinical audit, rather than re-visiting the detail of full audit reports; CARE would receive an audit summary, which would have key headlines only. CARE would focus on identifying any concerns or significant issues and/or where no improvements have been made since the last audit, with a challenge to Directorate CARE groups as to how these are being addressed and whether there is any additional support they require. The discussions regarding the overall audit programme would focus on whether the programme is running to plan and if there are any issues delivering the programme, and what action Directorate CARE groups, along with the clinical audit team, are taking to return the plan to schedule
- On a rotational/risk basis have a ‘deep dive’ into different topic/functional areas covered by CARE to gain assurance that the clinical governance and assurance processes are functioning effectively. This should complement, rather than duplicate, the risk presentations provided to ET and GAC.

5.5 In order for CARE to optimally fulfil its role and function, and to provide the Board with robust clinical governance assurance and knowledge, there is a need to align the operational directorate reporting periods. Currently there is not necessarily complete consistency across the operational directorates as to the reporting periods in their clinical governance reports to CARE, which then escalates into the clinical

governance report to the GAC and the Board. The proposed recommendation is to align these as follows: for example the January CARE meeting would receive reports for the period of October-November, which would have been discussed at the December Directorate CARE Groups. This slight delay in reporting period reaching the Board was not thought to be unduly detrimental, as urgent items and other exception reporting would still be included for example for SIRIs or other urgent clinical governance issues.

5.6 A specific objective of the review was to consider merging CARE and TPSG to enable some efficiency gains. The general consensus, however, was that this was not advisable. The main reason for this was, as described above, the agreed move to CARE being less operationally focussed. TPSG takes decisions on safety policy where NHSBT has freedom to do so, and therefore discussion involves detailed consideration of scientific evidence. Although there is some overlap of membership, there are key members of TPSG who do not attend CARE currently. An interesting finding of the review was that many of the CARE members had not previously been aware of the TPSG. It is therefore proposed that:

- TPSG reports through CARE rather than directly to the ET as currently
- The Chair of TPSG (currently the Medical and Research Director) provides an update report to each CARE meeting, with a focus on key decisions taken. The TPSG meetings would be scheduled 2-monthly (currently 6-8 weeks) to be held prior to each CARE meeting. The ToR will be updated to reflect the changes agreed.

5.7 In response to the objective to make the process 'more LEAN' and to ensure the flow of papers up to the Board was efficient and effective; the following has either been actioned or was agreed:

- The schedule of meetings for the GAC has been amended and the order of meetings/information flow from 2016 onwards is: Directorate CARE groups to CARE to the GAC to the Board
- It was agreed that CARE adopts the Board template and guidance for its papers. The AD, Governance and Clinical Effectiveness will consider and agree beforehand any exceptions to this. One option could be for any exceptions to use the same basic template, with graphs and more detailed information included as appendices. Duplication with MQR content will be avoided as far as possible.
- CARE agreed to move towards reducing the length of the meeting to four hours; this should be achievable with a more strategic focus. This should include avoiding peak travel time for attendees.

5.8 With the aim of reducing the costs of the meeting, it was universally accepted that lunch ceases to be provided. The reduction in number of members will allow us to ensure that NHSBT venues are used. These

changes will equate to a minimum saving of £2700 per year. With regards to travel, the general consensus was that respondents would be happy for the venue to be moved to a more central location such as Birmingham, if this reduced the overall travel costs. It is therefore proposed to undertake a travel cost comparison for London vs. Birmingham and decide location based on cost.

5.9 In order to continue to raise the profile of clinical governance and CARE throughout the organisation, and to ensure broad awareness of key decisions, actions and recommendations from CARE, it was agreed that CARE adopt circulating three key messages from each meeting to the Senior Leadership Team.

6.0 Throughout a number of the discussions, and responses received as part of the review, there was a theme relating to the need for clarity regarding (i) the respective roles of QA and clinical governance, and (ii) the connection of clinical governance to Senior Management Teams (SMTs). To address (i), it was agreed that the Medical and Research Director and the Director of Quality would meet to discuss how greater clarity regarding respective roles could be provided to aid operational directorates. To address (ii), the AD of Governance and Clinical Effectiveness would work closely with SMTs and operational directorate representatives at CARE to ensure that clinical governance thinking is consistently and effectively embedded into SMT agendas and discussions.

6.1 Additional actions agreed were:

- The Clinical Governance framework approved by the Board in 2008 and updated in 2009 would be updated to reflect these changes
- The CARE ToR and workplan will be updated to reflect the agreed changes
- An annual thematic review of SIRIs will be produced
- The clinical impact of IT incidents to be included in Directorate CARE reports
- The AMDs, Chief Nurses, and AD of Governance and Clinical Effectiveness to review and agree the standing agenda items at Directorate CARE groups.

Author
Louise Cheung
Assistant Director
Governance and Clinical Effectiveness

Responsible Director
Lorna Williamson
Medical and Research Director