NHSBT Board
28 September 2017

Annual Review of Key Risks

1 Status – Public

2 Executive Summary

Ideally the Board should review risks to the delivery of NHSBT's statutory and strategic objectives on an annual basis (and preferably in advance of the annual planning round). Although the GAC conducts risk reviews across NHSBT's business areas on a periodic basis, the last formal consideration of risk by the Board was during the Board development day in May 2015. In support of this three inputs are provided:

- A summary of the risk register (ie what it currently reports).
- The risk section from July 2017 Board Performance Report (a summary of the above).
- A "PESTLE" style, bottom up review of the risk environment per Business (to consider any new / changing risks in our environment and as a prompt for any further discussion at subsequent Board meetings).

3 Action Requested

The Board is asked to review the existing risks and potential trends and:

- Confirm that it is content with the existing description of our risk environment and that it appears to be reasonable and complete
- Identify any areas of concern which may merit greater future scrutiny by the Board and which should be addressed within the next iteration of our five year plan

4 Background

NHSBT has a performance framework that provides frequent opportunity to recognise and manage risk. This is based on:

- A full collection of business strategies that capture clear objectives and targets.
- A performance reporting culture based on integrated monthly reporting supported by business performance reviews at the Board (twice per annum per Division).
- Three strong "control pillars" that reflect NHSBT's unique function as a monopoly supplier of critical biological products and services to the NHS (CARE, Quality Management and Business Continuity).
- The Business Transformation function (ie providing programme management during a time of major change).
- Periodic review of risk by business area, on a rotational basis, by the GAC.

Ideally the Board should review risks to the delivery of NHSBT's statutory and strategic objectives on an annual basis (preferably in advance of the annual planning round). The last formal consideration of risk by the Board, however, was during the Board development day in May 2015.

During the workshop the Board considered a number of issues that were raised in a previous ALB workshop attended by some of NHSBT's NEDs. These were:

- The need for "reverse stress testing" (what would break the organisation, how could that happen, what are the mitigations).
- The cultural blockages to strong risk management (groupthink, not managing the things that matter, ineffective control functions, blockages to upward reporting).
- The challenge in managing the "software" vs the "hardware" (and, for example, the tendency to manage the risk register rather than the risk).
- Controls and assurance processes (and the 3 levels of assurance model).

In parallel, via the GAC, this led to a reappraisal of NHSBT's risk management strategy and supporting processes, and has recently led to the introduction of the Covalent system to manage the risk register. This, however, has mostly focused on the "hardware" and hence it is timely that the Board now reconsider risk rather than risk management. It is also timely in that the Board has previously identified that the organisation has been less good at anticipating risk and has tended to recognise risk as it crystallises (hence managing the issue rather than the risk).

Therefore, in support of providing the Board with an opportunity to consider risk, three inputs are appended to the paper:

- A summary of the current risk register
- A copy of the risk section from the July 2017 Board Performance Report
- A high level "PESTLE" style review of the risk environment per Business

As a result of the first two inputs (ie the current description of the risks facing NHSBT) the Board is asked to consider whether it is content with the existing description of our risk environment and that the risk register in particular appears to be reasonable and complete. Using the third input as a prompt the Board is further asked to consider whether there are any areas of concern which may merit greater future scrutiny by the Board (for example, as a specific agenda item, horizon scanning workshop or covered as part of an upcoming strategy refresh). Ideally any new risks, and plans for their mitigation, should be captured within the next iteration of our rolling five year business plan.

Based on the high level PESTLE review it is arguable that the risk environment facing NHSBT is as high as it has ever been based on:

- The two major IT / change programmes running concurrently in Blood and ODT and the potential impact on business continuity and cost (both investment cost and opportunity cost through a lack of organisational capacity to drive other initiatives)
- Ongoing demand decline for red cells and the ability to match with capacity reduction in Blood (especially in blood donation)
- Public reaction / reputation to changes in blood donation (focus on fixed centres, fewer larger mobile sessions, less frequent collection in parts of the country)
- Demand / supply challenges at component/group level (O negative red cells. A negative platelets, Ro etc)
- The ongoing financial pressures facing the NHS and the ability of NHSBT to recover the costs of the above in prices

Author

Rob Bradburn, Finance Director

Appendix 1 – Summary of the NHSBT Risk Register

Total Residual Risk – July 2017	Red	Amber	Green
125	11	109	5

Likelihood					
			2		
	1		5	4	
	1	3	12	21	5
		3	9	9	12
		1	3	5	29
	Impact				

High residual risks (risk score of 15 or above)

Risk	Consequence	Score
There is a risk of legal non-compliance with GDPR legislation, caused by a lack of IG resources (new – August 2017)	Resulting in reputational and regulatory non compliance (GPDR regulation)	4 (major) x 4 (likely)
Increased competition from other providers and Tissue Banks and or substitutes, which are considerably cheaper are being aggressively marketed against NHSBT Tissue products e.g. Pigs Skin against Human Skin	Demand from hospitals adversely impacted by NHS system resource constraints, which would impact on Tissues Income being reduced and growth plans slowed/halted.	4 (major) x 4 (likely)
NHSBT cost reduction plans below the target level required to maintain flat / reducing prices as per the 5 year strategic planning horizon.	The failure to develop clear cost reduction initiatives in time to realise savings, would impact on future financial and business plans required to maintain a red cell price at or below £124.46 (vs current strategic target).	4 (major) x 4 (likely)
Other than OBOS/TES-CRM there are no modern IT applications that support the overall customer fulfilment process especially with regard to the billing of diagnostic activities that are captured within Hematos.	The legacy billing systems are unlikely to be robust (to customer requirements) and resulting in: - Internal requests for system/billing changes not met; - Hospital requirements for revised information/data not met; - Changes due to ITS developments can't be supported. - Billing systems resilience - potential for incorrect billing; - Invoices not issued. - Cash flow shortages. - NHSBT unable to deliver on SLA requirement.	4 (major) x 4 (likely)

Red cell demand below plan; breaches the demand reduction reserve (DRR 2%) / budgeted demand level (1.461m - 2017/18) - could result in lost contribution in-year - reduced product demand from hospitals due to a variety of reasons (more appropriate use, lower than planned activity/reduced financial resources, more cell salvage activity etc.)	Loss of income and reduced contribution to fixed cost recovery, would lead to a short fall in both NHSBTs income & expenditure and cash flow position.	3 (moderate) x 5 (certain)
Potential reduction to demand for Frozen products (overall income £12m), with hospitals substituting NHSBT MB products with those of an alternative supplier (Octapharma). In the longer term there is also the potential risk of Cryoprecipitate being replaced/substituted by Fibrinogen (alternative supplier),	Resulting in the loss of income and reduced contribution to fixed cost recovery, with a short fall in both NHSBTs income & expenditure and cash flow position.	3 (moderate) x 5 (certain)
There is a risk that the currently established EU regulatory framework (EU regulations and transposed EU Directives) and NHSBT's opportunity to input to this for its therapeutic products (blood, tissues, cells, organs, investigational medicinal products {IMP}, clinical trials, advanced therapy medicinal products {ATMP}) and patient / donor diagnostic services (RCI, H&I, IBGRL, NTMRL and NBL) may be subject to revision caused by the UK's exit from the EU	This may result in more challenging UK laws that restrict therapeutic product import/export and require additional NHSBT resource to achieve compliance or alternatively and less likely, in a relaxation that provides less assurance of patient /donor safety and increased risk of litigation (Consumer Protection Act).	5 (catastrophic) x 3 (possible)
Requirement to implement a new material blood safety measure or intervention, due to DH instruction, which could require delay in other plans	Impact on targets and milestones contained within the strategic plan (no funding within the financial plan for additional costs).	5 (catastrophic) x 3 (possible)
Government/DH impose a targeted reduction to NHSBT central revenue funding	An increase to current cost improvement plans; and or Government & DH impose further cost reductions to the available level of Programme Funding / Capital	5 (catastrophic) x 3 (possible)
There is a risk that the replacement of Pulse by a number of interconnected different platforms causes disruption to current services	Resulting in the loss of functionality and the disruption of business process, which could damage the supply chain of blood products	5 (catastrophic) x 3 (possible)
There is a risk that critical (business facing) Technology Services will be impacted as a result of major IT incident(s) resulting in the business invoking its business continuity plans.	Resulting in the disruption of business processes which could limit the organisations ability to process work, and could lead to the disruption of blood products and any associated services	5 (catastrophic) x 3 (possible)

Appendix 2 – Principal Risks and Uncertainties per the 2016/17 Annual Report and Accounts

RISK MANAGEMENT

Risk register summary (net risk) and summary by themes

Corporate Risk Register Summary	Red	Amber	Green
125	11	109	5

The dependency and reliance on the SME that currently provides support for our critical operational systems (PULSE/Hematos) and, in particular, their ability to retain the necessary capability and service levels as we transition away to new systems as part of the CSM project.

The ability to supply in case of the loss of a key facility (e.g. Filton, Speke) or the loss of critical IT systems (Pulse, Hematos, networks etc). The risk of critical system loss is increasing on the back of the significant changes that are planned (e.g. new desktop, CSM etc.) and the significant complexity and inter-dependency between them.

Inability to supply as a result of planning / supply challenges through:

- (at the macro level) limited visibility with regard to longer term blood demand trends and especially when current demand decline will be offset by the anticipated impact of demographic trends
- significant differential short term demand trends at group / component level (eg O neg red cells, A neg platelets)

The scale of the transformation programme across NHSBT will create a significant challenge on the capacity and capability of NHSBT to safely execute the change (both ICT and business resources) and a potential distraction to delivering business as usual.

The ability to maintain blood prices remains highly dependant on our ability to manage the combined impact of :

- the need to fund the significant investment in CSM (and uncertainty regarding the phasing of the spend and timescale)
- the organisational focus required to safely implement CSM and a slow down in the delivery of underlying BAU efficiency improvements
- ongoing reduction in red cell (and now platelet) demand and the loss of related income and contribution
- being able to generate significant productivity improvements in Blood Donation especially (given the inherent productivity gap and high contribution to overall costs) and the significant impact on service configuration required.

Ongoing reduction in demand will require significant changes to the configuration of blood collection services in order to not just maintain productivity but deliver the increased Blood 2020 targets. This would involve fewer / larger mobile sessions, greater use of fixed donor venues and much less collection activity in certain parts of the country. This could result in adverse donor reaction (and potentially attendance) if not managed and communicated well and an impact on

supply if, for example, sufficient numbers of O neg donors cannot be retained.

The high prevalence of manual, paper based and verbal processes throughout NHSBT's operations, especially within reference testing and in the duty office within organ donation and transplant. Although these are mitigated by appropriate manual control checks, and new systems are removing transcription in some areas, there is a residual risk that these are ineffective and cause transcription errors that could lead to the death or harm of NHS patients.

Risk to delivery of TOT 2020 strategic targets driven by :

- adverse trends in the donor pool
- inability to change consent levels
- lack of funding required for supporting business cases in respect of consent strategy and new technologies
- lack of transplant capacity.

Changing clinical/commissioning intentions in Stem Cells - ie Cord Blood / BBMR, as a recommended treatment, impacting on the outcomes and therefore the future viability of these services.

One new high/extreme risk has been registered this month:

There is a risk of legal non-compliance with GDPR legislation, caused by a lack of IG resources, resulting in reputational and regulatory non-compliance. (**Clin-013, Residual Risk Score 16).**

A number of emerging risks may be reported in the following months regarding:

- emerging data on donor health and the results of the Interval and Compare trials (impact on donor numbers and testing costs)
- dependence of the NTxD system on a third party supplier (individual)

APPENDIX 3a – STRATEGIC RISKS / OPPORTUNITIES, BLOOD COMPONENTS

Opportunity / Risk	Trend	Comments
Political / Stakeholder		
Triennial Review		No material issue
New spending review		Likely / may impact on price planning
Shared services		No initiatives at present
Economic / Competition		
Product - substitution		**Issue** – potential impact of transexamic acid and iron therapies
Competitor		Limited risk in red cells/platelets. **Issue in FFP** business loss occurring
Demand		Ongoing decline in red cells - **increasingly difficult to remove capacity/costs** (especially in blood donation), upward pressure on prices.
Differential demand – component/group level		**Issue - NHS ability to manage universal component demand** **Issue - balancing supply / demand**. Impact on losses/waste
Supplier		Limited purchasing power re key consumables
Brexit		Impact on costs - currency
Social		
Altruistic model - loss of support/effectiveness		No perceived risk
Demographic trends – patient level		**Issue re sickle cell trend / Ro supply** – need to increase black donors
Demographic trends - population level		Demand expected to increase at some point / need for donor capacity versus current reduction
Donor population		Issue - over reliance on frequency. Issue - over reliance on older donors / loss of younger donor base
Donor health		Issue – iron depletion re frequent donation. Potential for increased donation intervals/new testing processes. Impact on testing and recruitment costs.
Technological		
Substitution via stem cell technologies		Limited near term risk for red cells / platelets. Issue: funding requirements for existing R&D programme
Legal		
GPDR regulations		**Issue – limited IG resource / ability to comply with new regulations**
Environmental		
New pathogens in the blood supply		Prion risk – no change.

Climate change – spread of pathogens / donors exposed through travel		Risk – new pathogens (impact on safety/costs eg HEV) Risk – spread of pathogens (impact on supply/costs eg WNV)
Business Continuity		
Loss of a key facility (especially Filton)		Site assessments undertaken and complete – action plans developed.
Loss of key systems (especially Pulse / OBOS)		Increasing issue as CSM progresses
Key system replacement		Issue – current status of CSM project
Availability of critical IT skills (eg Savant)		Should be eventually mitigated by CSM but an increasing issue during transition

APPENDIX 3b – STRATEGIC RISKS / OPPORTUNITIES, ORGAN DONATION AND TRANSPLANT

Opportunity / Risk	Trend	Comments
Political / Stakeholder		
Taking Organ Transplantation to 2020		**Issue - not on trend to achieve targets**
Restrictions on funding		**Issue – limited funding** (impact on public communications and funding of new technologies)
Developing opt out legislation (Scotland/England)		**Issue – increasing probability of change**
National priorities diverge / inability to manage a UK model		
Ability to influence pathway external to NHSBT		Risk that allocation policy(s) may not always be followed
Donor characterisation		Burden falls on NHSBT - ability to deliver / fund
Economic / Competition		
NHS re-organisation / fewer donors available		Fall in the number of audited deaths (especially DCDs)
Insufficient transplant capacity		
Impact of Brexit on transplant capacity		
Social		
Changing societal values with regard to altruistic donation		
Demographic changes - demand		Need to improve BAME donation
Demographic change - supply		Older, more obese donors – impact on organ number/quality
Variable approach to risks at transplant centres		Fall in waiting lists, less pressure to allocate kidneys from marginal donors.

Technological		
Perfusion technologies		Opportunity – subject to funding
Xenotranspants / stem cell technologies		Not in the near term
Legal		
Organs fall under consumer law (treated as products)		
Environmental		
New pathogens in the population		
Safety – Clinical Pathway		
Dependence on manual / verbal processes		Ongoing risk of transcription error.
Process complexity / 24/7 working in the Duty Office		Exacerbated increased activity levels per strategy.
Non standard reporting		Risk of transcription error
Hospitals operating to own standards / accreditation / quality – retrieval & acceptance of organs		Risk of unexpected outcome/outcome not anticipated
Business Continuity		
Loss of the Duty Office		Dark-site accommodation in place. Risk on relocation to Filton
Loss of key systems (especially NTxD, EOS)		ODT hub eventually mitigates
Loss of key systems (especially NTxD, EOS)		ODT hub eventually mitigates
NTxD - dependency on SME/old technology		ODT hub eventually mitigates
Reliance on core group of staff with knowledge		Especially regarding IT / process improvement

APPENDIX 3c – STRATEGIC RISKS / OPPORTUNITIES, DIAGNOSTIC and THERAPEUTIC SERVICES

Opportunity / Risk	Trend	Comments
Political Stakeholder		
Funding for cord blood banking withdrawn		
Impact of new commissioning arrangements		Potentially positive in some areas (eg TAS)
Lack of traction in regen med development		
Economic / Competition		
Tendering of services by hospitals		Especially H&I
Product substitution		Risk in Tissues
Competitor		Risks in most operating units (especially Tissues and Diagnostics)
Supplier		Limited purchasing power re key consumables

Brexit		EU regulatory framework re medical devices / impact on costs (currency)
Social		
Technological		
Haplotransplants		Loss of revenue in SC-DT
Cord blood as old technology		Loss of revenue in SC-DT
Legal		
Environmental		
Safety – Product and Process		
Risk of transcription error		Errors reducing on the back of SP-ICE / electronic requesting
Business Continuity		
Loss of a key facility (especially Speke)		Site assessment completed, plans being developed to mitigate risks.
Loss of key systems (Hematos)		DB upgraded
Hematos - dependency on SME/old technology		Contract extensions to be put in place
Development of new skills		Sales / marketing - especially regen med
Dependency on key individuals		CBC