

Short Internal Business Case

Project Title	Anaemia Service
Division	Anaesthetics and Theatres Diagnostics and Therapeutics
Department/ Directorate	Theatres Haematology
Clinical Sponsor	Dr Richard Noble
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Document Revision	

Completion of this template

The following pages of this template set out the structure and expected content for each section of a Short Internal Business Case.

Where possible for ease and to ensure consistency standard wording has been included.

Guidance on how to complete a Short Internal Business Case can be found at Appendix1a.

Where text is in brackets and italics only the relevant wording should be included, the other should be deleted.

1. Executive Summary

The Royal Cornwall Trust has a nationally recognised Surgical Patient Blood Management (PBM) service, which has shown a substantial year on year decrease in the use of blood transfusion to support surgery.

The surgical PBM is currently not appropriately remunerated. In respect of intravenous iron, the trust is presently claiming an HRG which does not fully acknowledge the service (appendix3). However the reduction in blood transfusion and reduced length of stay and hospital acquired comorbidity fully justifies the service.

National government Guidelines support the introduction of alternatives to transfusion for all anaemic patients (primary and secondary care) and not just those undergoing elective surgery.

Through a commissioned service we would like to set up an improved patient pathway incorporating both the pre-operative service and with provision for all patients with anaemia in primary and secondary care. For the specific intervention of administration of intravenous iron we would wish to agree a tariff.

Our objective is to make early diagnoses and provide the facility for early intervention. We anticipate that approximately 1/3rd of non-elective admissions presenting with anaemia could be converted to stable elective cases and so avoid acute admission. While providing a central portal for the referral and treatment of anaemia.

The Royal Cornwall Hospitals NHS Trust commissioning Board is asked to approve the business case for an Anaemia Service.

2. Strategic Context

The Royal Cornwall Hospital has a nationally and internationally recognised surgical Patient Blood Management (PBM) Service which has the primary aim of reducing the patients' risk from transfusion by employing different modalities.

From 2003 the PBM service has been monitoring its use of blood in elective surgery, with Primary Total Hip (THR) surgery as a marker. This has seen transfusion drop from 47% in 2002 to 2% in 2014. Appendix 2 shows the reduction in transfusion for primary THR from the inception of the service, transfusion rates have again dropped to around 4-5% from 2008 - 12, with 2013/14 seeing a further drop.

Over the past few years, there have been numerous national and international papers published on PBM, discussing the appropriateness of and alternatives to Red Cell Transfusion. The Government has been working in conjunction with NHS Blood and Transplant on producing recommendations on ways to reduce red cell transfusion.

The Government White Paper, *Patient Blood Management - An evidence-based approach to patient care, June 2014*, describes Patient Blood Management (PBM) as -

“an evidence-based, multidisciplinary approach to optimising the care of patients who might need transfusion. It encompasses measures to avoid transfusion such as anaemia management without transfusion, cell salvage and the use of anti-fibrinolytic drugs to reduce

bleeding as well as restrictive transfusion. It ensures that patients receive the optimal treatment, and that avoidable, inappropriate use of blood and blood components is reduced”.

The Health Circular HSC 2007/001 - Better Blood Transfusion - *Safe and Appropriate Use of Blood* states “The safe and appropriate use of donor blood and alternatives to donor blood are important public health and clinical governance issues”.

“2015 Audit of Patient Blood Management in Scheduled Surgery” - As part of the audit programme for the National Comparative Audit of Blood Transfusion (NCABT). NHS Blood and Transplant and the Royal College of Physicians are conducting an audit of Patient Blood Management in Scheduled Surgery. This audit is supported by the Royal College of Anaesthetists and the Royal College of Surgeons

NICE guidelines on PBM are pending publication in Aug 2015.

Anaemia in primary care is extremely common and may be the presenting complaint of many other pathologies each of which may require different treatment.

Early and appropriate intervention is contingent on timely and accurate diagnosis of anaemia. An integrated pathway has been shown to assist General Practitioners both in identifying the correct care pathway for further investigation and in treating the anaemia itself.

Nationally the identification of patients with Iron Deficiency Anaemia (IDA) has increased by 16.8% over the past two years. The same period has seen a 10% increase in non-elective admissions. Patients admitted with a primary or secondary diagnosis of IDA have a 31.4% increased risk of requiring readmission. Reducing the 30 day admission nationally for non-elective patients could potentially save £2.73 million.

(Goddard A and Phillips C (2014) 'Ferronomics. An economic report on the hidden cost of anaemia management)

RCHT has set out its plans for 2012-2017, it aims to be the main provider for acute and specialist health care in Cornwall, but also

- Build partnerships and networks to develop an increased range of services and clearer pathways of care for the patients we serve.

3. Current Service Arrangements

Existing Pre-operative Optimisation Service:

The current PBM service at the RCHT is centred on the patient undergoing elective surgery. Within this service there is no scope to treat patients from the community.

To facilitate the service, the team consists of two full time nurses, and a half time nurse (funding from external companies for the past two years increased the half time role to full time, finished September 2014). Clinical Support is provided by a consultant Anaesthetist, with 5 hours administration and clerical support per week.

The current service has a dedicated area within the pre-operative clinic at the RCHT, where pre-operative interventions are administered.

The pre-op optimisation programme targets patients undergoing surgery, where we consider there is a risk of transfusion. These patients are flagged to the PBM team and if appropriate,

optimised prior to surgery, using alternatives to transfusion (Oral / Parenteral iron, Darbepoetin) and the outcome of all interventions is recorded.

The service also implements a comprehensive competency based Intra Operative Cell Salvage Programme, for patients undergoing surgery. Further interventions that supplement the programme include identification of patients at increased risk of bleeding, Point of Care testing and use of anti fibrinolytic drugs.

The service is further backed up by a comprehensive PBM database allowing for continuous monitoring e.g. the need for blood transfusion and length of stay

Currently there is a day case HRG from the optimisation of patient's pre operatively. However the HRG for treatment of Iron Deficiency Anaemia is not realised, an alternative outpatient HRG is currently used for the optimisation of the patient's pre operatively.

However we have shown through this cultural change, that the reduction in transfusion and length of stay supports the costs of the service (appendix 1)

Example of change in practice, before we employed any PBM strategies in primary Hip Arthroplasty surgery our transfusion rate was 47% (which incurred a cost of £98,000 for transfusion only)

Our recent figures now show a significant reduction in transfusion for targeted surgical procedures (Appendix 1) where a multi-disciplinary approach to Patient Blood Management is employed.

Further savings could be made in Gastrointestinal and Gynaecology surgery where there is a higher incidence of both iron deficiency and transfusion. The potential for reduction in transfusion rates is proportionately greater.

There is no current service arrangement for PBM in any area other than pre-optimisation for elective surgery. There is no facility for the elective administration of IV iron to patients in primary care. An IV iron service could prevent the need for admission in approximately 1/3rd of patients with severe anaemia allowing elective outpatient investigation if it were made available.

4. Drivers of Change

The drivers of change for this service are –

1. The need for early identification of anaemia in primary care leading to early triage to the appropriate specialty for further investigation
2. To implement a centralised referral and treatment portal for the management of anaemia in both primary and secondary care.
3. Early diagnosis of the cause of anaemia, supporting a centralised directed intervention to prevent non-elective admission
4. An anticipated reduction in cost to primary care by conversion of approximately 1/3rd of patients presenting acutely with anaemia to elective investigation and management.
5. The need for proper remuneration to secondary care with a formal commission for provision of administration of intravenous iron

5. Description of Proposed Scheme

An algorithm for the initial investigation and management of anaemia will be hosted on the Referral Management System (an internet site widely used by primary care). There will be clear guidance on local primary care management of anaemia together with advice on referral when necessary.

General Practitioners commonly prescribe oral iron for less severe iron deficiency with an identified cause. Where the cause is not clear, where the anaemia is severe enough to compromise the patient and where oral iron is not tolerated or effective, then the algorithm will offer further help through the PBM system.

The differential diagnosis of the cause of anaemia in the presence of co-morbidity is often complex: there will be supervision of the diagnostic and advisory elements of PBM by a Consultant Haematologist.

Where the diagnosis of iron deficiency is made early every attempt will be made to treat using oral rather than IV iron. There will be clear guidance on when to consider IV iron.

The recognised indications for IV iron are increasing: there will be clear guidance on which indications are supported by evidence and how to assess patients for intolerance to oral iron. For example oral iron is often poorly tolerated and ineffective in inflammatory bowel disease and the evidence for parenteral iron is unequivocal. Parenteral iron may also overcome problems with compliance, or with a rate of blood loss which cannot be corrected by oral iron alone and which might otherwise require transfusion.

In addition to uncomplicated iron deficiency anaemia there is accumulating evidence of clinical improvement with parenteral iron in the anaemia of chronic disease (ACD). ACD is an anaemia caused by bone marrow suppression by inflammation. It is a common co-morbidity for inflammatory disorders (infection, arthritis, malignancy etc). Up to 30% of ACD can be improved by intravenous (but not oral) iron. At present there is no test which anticipates response to IV iron in ACD. The PBM will provide a service for a therapeutic trial of IV iron where appropriate including assessment of response.

The service will be funded by establishing an appropriate HRG code for the administration of intravenous iron. Where IV iron is a necessary component of pre-operative optimisation an appropriate tariff will be sought for this additional service. Where an unexpected or undiagnosed anaemia is identified in pre-operative assessment, in addition to immediate treatment to allow surgery to proceed, this will be formally referred back to the referring GP for further investigation and referral as they see fit.

The existing pre-operative assessment service will be extended to allow IV iron administration for all other indications. This service will be offered to General Practitioners when they deem it appropriate, supported by the advisory service.

Referrals to PBM will also be accepted from the Acute GP service and from the Emergency Department when this might avert the need for non-elective admission (e.g. where blood transfusion might otherwise be necessary).

It is anticipated that, of those non-elective patients presenting with anaemia, 1/3rd of admissions could be avoided through a combination of: earlier identification of anaemia; a facility for outpatient administration of IV iron; re-routing of non-elective patients to the IV iron service with avoidance of admission, reduction in blood transfusion and conversion to elective investigation.

Referrals to PBM for inpatients will be accepted for the administration of IV iron where this might accelerate discharge.

The effect of PBM on non-elective and readmission rates will be carefully audited for the review and re commissioning of the service.

The PBM will attempt to reduce the use of IV iron where oral iron is appropriate and there is sufficient time for its efficacy. The pre-operative assessment clinic will initiate blood testing at the point of referral for elective surgery which should allow some patients currently receiving IV iron to be treated earlier with an oral formulation.

We anticipate an overall rise in the use of IV iron as there is currently an un-met need, and the indications (e.g. in inflammatory bowel disease and heart failure) are increasing. The increase in numbers at this time cannot be quantified

There has been some historical anxiety about the safety of administration of parenteral iron. When the diagnostic, advisory and governance roles of the proposed PBM system have been proven we propose that the administration of IV iron is devolved back to the community where this is requested. This would allow treatment closer to home using community facilities and might be especially appropriate in, for example, the East of the County and in the Isles of Scilly.

The combination of central diagnostics and governance with community administration would result in a high quality service but at the patients' convenience.

Site/space – Provision for IV iron will be at RCHT and WCH sites. Areas have been identified at both sites where this service could be provided without any additional capital cost.

The site at RCHT would continue to be within the pre assessment department. This has been discussed and agreed with Sarah Roby. Any future movement of pre assessment will take into account this proposed new service.

Once the service has been established devolution back to community hospitals or individual GP practices will be offered with PBM continuing a diagnostic, advisory and governance role.

Services – There will be additional demand on the Haematology department for the diagnostic and advisory role.

Specialities – Iron deficiency is a common presentation in patients with gastroenterological and gynaecological primary pathologies. Close co-operation with these departments will be essential to ensure that, when iron deficiency is treated within the PBM system, they are prepared to follow up with elective outpatient investigation.

Iron deficiency is also a common comorbidity in patients with primary diagnoses from cardiology, rheumatology and obstetrics.

Exclusions – There are no exclusions from this project

Constraints – Funding
Agreed Tariff

The following options were considered:-

1. To withdraw the provision of IV iron as part of the pre-operative optimisation service. This is currently unremunerated and the cost can not be sustained by RCHT. This would result in patients arriving at elective surgery in a less than optimal condition with a likely rise in blood transfusion, length of stay and co-morbidities including infection.
2. To combine the need for early diagnosis and management of anaemia by expansion of the existing pre-operative assessment service. This would continue the current high standard of peri-operative care whilst also offering potential savings to primary care through the reduction of non-elective admissions, and benefit the patients through earlier diagnosis and intervention.

Option (2) has been identified as the preferred option because the anaemia service will meet all national recommendations, while proposing a cost saving and improving quality of care.

The benefits of the preferred option are - *Quality of Care, cost savings, timely and appropriate interventions, and in due course with devolvement of administration of IV iron, treatment closer to home.*

The limitations of the preferred service are an agreed commissioned service.

6. Capital and Revenue Consequences of Proposed Scheme

The project *is not* part of the approved Capital Programme.

The surgical PBM service currently exists within the RCHT; we are now looking to commission an anaemia service that will allow the continuation of the pre op service while improving patient pathways that support a new treatment of anaemia service.

7. Service and Other Project Dependencies

There are no other Capital Programme commitment dependencies with this area of the hospital **OR** the following Capital Programme commitments dependencies have been identified:-

A risk assessment of the project has been undertaken that covered both the delivery aspects and post project/scheme completion risks. The following risks were identified:-

- *Change in Pre-operative setting – loss of intervention area*

8. Procurement Strategy

The project/scheme will be delivered by the staff who currently manage the surgical Patient Blood Management service, with clinical support from Haematology

There are no specific requirements or constraints that need to be considered as part of the procurement strategy.

We would look to implement a strategy that would see us standardising interventions (IV irons) available throughout the trust.

9. Project Milestones

The table below contains details of the key milestone dates

Activity	Date
Pre-contract	
Business Case Completed	31/12/2014
Business Case submitted for Consideration	02/01/2015
Post Contract	
Agreement of service	31/03/2015
Audit of baseline activity	30/04/2015
Audit of effect on non-elective admission	31/01/2016
Review of service and re-commissioning	31/03/2016

10. Appendices

10.1 Capital Consequences

10.2 Revenue Consequences

9. Record of Approval

Clinical Sponsor or DGM	Name of DGM signing on behalf of Division(Print): Signature: Date:
Associate Director of Contracting & Performance	Name (Print): Signature: Date:
Head of Financial & Contract Management	Name (Print): Signature: Date:

Deputy Director of Finance	Name (Print): Signature: Date:
Operational Management Group	Name of DGM signing on behalf of Group (Print): Signature: Date:
Finance Director	Name (Print): Signature: Date:
Chief Operating Officer	Name (Print): Signature: Date:
Investment Sub Committee or EMT ie CSDP Board/ HI Board/ Estates Committee/ Med Cap Equip Committee	Sub Committee Title: Name (Print): Signature: Date

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Appendix 1

***Data on Primary Hip Arthroplasty November 2013 –November 2014**

All data pulled from Galaxy and winpath by the Performance and Information Unit RCHT.

Number of Primary THR's - 601

Average Length of Stay or all cases - 5 days (5.3 days)

Transfused cases - 16 patients (2.6%)

Average Transfusion - 2 units (2.2 units) all blood given peri operatively.

Average Length of Stay if transfused - 8 days (An increase of 3 days if transfused)

Reviewing the literature the national transfusion rate is quoted anything from 10 - 32%.

We (Blood Conservation) have always worked on an average of 25% as national average, which seems to be widely accepted. Employing this figure would show a total of 150 patients for transfusion (an extra 132 patients), with those 132 patients taking up an approx extra 400 bed days.

The extra 132 patients would account for approximately two months of Primary THR surgery.

Cost of extra bed days at £240 per day = £95,000
(£240 x 3)

Cost of extra transfusion at £125 per unit = £33,000
(£125 x 2 x 132)

Total Cost if the above figures were realised = £128,000

* The figures above are based on transfusion rates, increasing to levels before the optimisation programme was introduced and analysing data supplied by Performance and Information Unit, RCHT.

Appendix 2

Year	THR % Blood usage (Orthopaedics)
2002	47%
2004	26%
2006	16%
2008	13%

Data supplied by Dr Lars Jakt Blood Conservation Clinical Lead (Retired), in conjunction with Business Intelligence unit (now the Performance unit), RCHT.

Figures required for Business Case 2009 (Surgical Blood Conservation, service) – approved.

Appendix 3

		(2) Follow-up attendance																
		Attended																
		Apr/2014		May/2014		Jun/2014		Jul/2014		Aug/2014		Sep/2014		Oct/2014		Nov/2014		
		Activity	HRG 4 Tariff	Activity	HRG 4 Tariff	Activity	HRG 4 Tariff	Activity	HRG 4 Tariff	Activity	HRG 4 Tariff	Activity	HRG 4 Tariff	Activity	HRG 4 Tariff	Activity	HRG 4 Tariff	
(50) ANAESTHETICS	FAUJO/DNT	25	£5,105	21	£4,410	22	£4,475	24	£5,040	21	£4,410	17	£3,280	21	£4,410	17	£3,570	Total £34,700 (8 months)

Avg Monthly Tariff £204 £210 £203 £210 £210 £192 £210 £210

HRG **QZ14B**

Activity 168 cases

Average Income £4,337.50

Drug Costs Pre op Iron spend (8 months) £19,972

Peri op iron spend (A/A) £1,200

In patient Iron Spend (A/A) £1,500

Darbepoetin spend (A/A) £8,324

Total **£30,996**

HRG Income **£34,700**

Surplus **£3,704**