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Introduction of a Preoperative Protocol for Management of Iron-Deficiency Anemia in Patients undergoing Elective Colorectal Surgery

Edel Marie Quinn
Royal College of Surgeons in Ireland

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Introduction of a Preoperative Protocol for Management of Iron-Deficiency Anaemia in Patients undergoing Elective Colorectal Surgery

Edel Marie Quinn

A Dissertation submitted in part fulfilment of the degree of MSc Healthcare Management, Institute of Leadership, Royal College of Surgeons in Ireland

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Declaration Form

Declaration:

“I hereby certify that this material, which I now submit for assessment in part fulfilment of the degree of MSc Healthcare Management is entirely my own work and has not been submitted as an exercise for assessment at this or any other University.”

Student’s Signature(s):  Edel Marie Quinn

Date:  09/05/2016

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Finally, I wish to thank my parents, who have always supported me in my academic endeavours and my partner, Niall, who has been patient and understanding when this project has been demanding of my time and always encourages me to achieve my goals.
Glossary of Terms and Abbreviations

Specialist Terms used in this Report

**Allogeneic Blood Transfusion:** Transfusion of blood from a donor who is a different person to the recipient (autologous blood transfusion refers to donation of a person’s own blood to themselves as the recipient, at a later date)

**Anaemia:** Reduction in levels of the oxygen carrying-molecule, haemoglobin, in the blood, below normal values

**Anaphylaxis:** A potentially fatal allergic reaction, causing difficulty breathing and dangerously low blood pressure

**Caldicott Guardian:** A senior person responsible for protecting the confidentiality of patient and service-user information within the National Health Service in the United Kingdom

**Colonoscopy:** An examination of the bowel using a telescope passed through the anal canal

**C-reactive protein:** A measurable protein in the bloodstream, which is a marker of levels of inflammation in the body

**Endoscopic resection:** Removal of a lesion, such as a polyp or tumour, at the time of an endoscopic procedure, such as colonoscopy, without the need for an operation

**Endoscopy Unit:** Area of the hospital where telescopic examinations and procedures are performed, including colonoscopy

**Ferritin:** A measurable protein, that reflects iron stores in the body. Ferritin also becomes elevated in states of inflammation and may give a false estimate of iron stores if there is active inflammation in the body at the time of measurement

**Haemolytic Transfusion Reaction:** A reaction where the body begins to destroy its own blood cells due to transfusion with donor blood which is incompatible with the recipient's blood type
Laparoscopic resection: Minimally-invasive (keyhole) surgery, using smaller incisions to perform operations

Multidisciplinary Team Meeting: A regular meeting held between members of different disciplines (commonly surgery, radiology, pathology and oncology) to achieve consensus on appropriate patient treatments

National Bowel Screening Programme (Scotland): People aged between 50 and 74 are invited to undergo screening for bowel cancer every two years, through submission of a stool sample. If the sample is positive for traces of blood, they are invited for colonoscopy

Preoperative Assessment Clinic: An outpatient clinic attended prior to surgery where fitness for surgery is assessed, potential anaesthetic risks identified and required preoperative investigations such as blood tests are performed, designed to reduce the number of patients admitted for surgery but then deemed unfit to proceed with surgery

Therapeutic Index: The amount of a therapeutic agent which must be administered to achieve the therapeutic effect required relative to the amount of the agent which causes ill effects or toxicity

Trans-anal procedure: Removal of a lesion, such as a tumour or polyp, from the lower end of the bowel, accessed through the anal canal. An incision is not required and no bowel is removed.

Transferrin saturation: A measure of how much iron is bound to the transferrin molecule in blood and thus available for use in forming new red blood cells. It is another measure of iron stores and is not affected by underlying inflammatory processes in the body, unlike ferritin.
Statistical Terms used in this Report

Confidence Interval (CI): An interval estimate of a population parameter; a 95% confidence interval means there is 95% certainty that the true result of the test lies within the range of values given.

Fisher's Exact Test: A statistical significance test used to analyse contingency tables, a measure of how significant a difference is between categorical groups.

Odds Ratio: A measure of association between an exposure and an outcome, the ratio represents the odds that an outcome will occur after a particular exposure compared to the odds of the outcome without that particular exposure.

p-Value: A measure of the statistical significance of a result; in this report p<0.05 was taken to be significant, that is there is <5% risk that the result obtained is due to chance rather than a true finding.

Student's t-test: A statistical comparison of the means of two populations.

Abbreviations Used in this Report

CI: Confidence interval  MDT: Multidisciplinary Team
CRP: C-reactive protein  NHS: National Health Service
FBC: Full blood count  NS: Non-significant
FCM: Ferric carboxymaltose  OD: Organisational development
g/dL: Grams per decilitre  PBM: Patient Blood Management
GP: General Practitioner  POAC: Preoperative assessment clinic
Hb: Haemoglobin  RBC: Red blood cell
IV: Intravenous
Abstract

Preoperative anaemia is a risk factor for poorer postoperative outcomes and patients undergoing colorectal cancer surgery frequently have iron-deficiency anaemia.

The aim of this project was to implement a preoperative anaemia management protocol for elective colorectal surgery patients.

An organisational development project was undertaken according to the Senior and Swailes organisational development model. A protocol for early detection of iron-deficiency anaemia, and treatment with intravenous iron replacement, for colorectal cancer patients was developed and implemented via a multidisciplinary team-based approach. Patient data was collected pre- and post-intervention to assess the impact of the project.

Implementation of the project resulted in increased rates of detection of preoperative iron-deficiency anaemia in the post-intervention cohort, with 71% of patients undergoing ferritin testing, compared to 30% of the pre-intervention cohort. Mean postoperative haemoglobin levels were significantly lower in patients with uncorrected anaemia, whereas those patients who underwent iron replacement therapy preoperatively had similar postoperative results to non-anaemic patients. Overall, postoperative transfusion rates decreased from 10% to 4% following introduction of the protocol.

Successful introduction of a perioperative anaemia management protocol has resulted in reduced preoperative anaemia rates in colorectal cancer patients. Expansion of the inclusion criteria could potentially lead to improved outcomes for additional categories of surgical patients.
Chapter One

Introduction
1.1 Background

Preoperative anaemia is a risk factor for poorer postoperative outcomes (Elhenawy, Meyer, Bagshaw, MacArthur, & Carroll, 2015; Leichtle, Mouawad, Lampman, Singal, & Cleary, 2011). Patients undergoing elective surgery are frequently anaemic, defined as having a haemoglobin (Hb) level less than 12g/dL (Ludwig et al., 2004). Studies have shown that preoperative anaemia exists in approximately one-third of patients undergoing non-cardiac surgery (Dunne, Malone, Tracy, Gannon, & Napolitano, 2002; Musallam et al., 2011). Studies in colorectal surgery have shown even higher rates of preoperative anaemia, with more than half of those with tumours of the right colon being anaemic (Dunne, Gannon, et al., 2002). Patients with preoperative anaemia are also more likely to require perioperative blood transfusion, and transfusion is additionally associated with increased perioperative morbidity (Elhenawy et al., 2015; Richards et al., 2015).

1.1.1 Organisational Context

Preliminary data from our institution showed an overall preoperative anaemia rate of 31% for patients undergoing elective colorectal resection for malignancy. Following discussions in our unit, it became apparent that management of preoperative anaemia was variable and not all consultants routinely attempted to correct anaemia in patients undergoing elective colorectal surgery. Additionally, there was no consensus on the best methods by which to correct preoperative anaemia. Early detection and correction of anaemia pre-operatively could lead to
improved patient outcomes and reduce the need for perioperative transfusion. (Enko et al., 2013) Hence, development of an evidence-based protocol for management of perioperative anaemia in our unit was planned.

1.1.2 Rationale for the Project

Correction of anaemia preoperatively has been increasingly recognised as important for patient outcomes. Many studies have shown preoperative anaemia to be associated with increased perioperative morbidity and mortality (Elhenawy et al., 2015; L T Goodnough et al., 2011), as well as being a risk factor for perioperative transfusion and its associated hazards (Elhenawy et al., 2015). The most effective strategy to avoid perioperative anaemia and transfusion requirements is to identify and correct preoperative anaemia whenever possible (L T Goodnough et al., 2011).

It is recommended that patients scheduled for major surgery should have a full blood count and iron status test (serum ferritin and/or transferrin saturation) 30 days before the scheduled procedure to allow implementation of appropriate treatment (Munoz, Gomez-Ramirez, & Campos, 2014). If iron-deficiency anaemia is detected, treatment should be instituted as soon as possible. Whenever there is enough time, oral iron supplementation should be attempted (Munoz, Gomez-Ramirez, & Campos, 2014). However, colorectal cancer operations are generally scheduled as quickly as possible. Several intravenous (IV) iron formulations are now available; an IV iron course is suggested in instances where a quicker response is
needed (Rineau, Chaudet, Carlier, Bizot, & Lasocki, 2014). In elective procedures, preoperative IV iron replacement seems safe, results in lower transfusion requirements, and hastens recovery from postoperative anaemia (Munoz, Gomez-Ramirez, & Campos, 2014).

Previous studies have shown that a protocol for management of preoperative anaemia can be successfully introduced, with improved patient outcomes. Enko et al. (2013) studied patients scheduled for major orthopaedic surgery and found anaemic patients who underwent anaemia treatment had higher preoperative haemoglobin levels immediately before surgery compared with untreated anaemic patients. Furthermore, treated anaemic patients retained higher postoperative haemoglobin levels and required 60% less transfusion than untreated anaemic patients (Enko et al., 2013).

The National Health Service (NHS) Enhanced Recovery Partnership Programme has highlighted the need to address anaemia in surgical patients as a correctable condition (Richards et al., 2015). A number of groups have now published suggested protocols for management of preoperative anaemia (L T Goodnough et al., 2011; Munoz, Gomez-Ramirez, Martin-Montanez, & Auerbach, 2014; Vetter, 2013), which could be adapted for use in our patient population. It was, therefore, decided to undertake a project to enable routine identification and correction of preoperative anaemia in elective colorectal patients in our unit.
1.2 Aims and Objectives

The aim of this project was to implement a preoperative anaemia management protocol for elective colorectal surgery patients, in order to reduce the rate of perioperative anaemia and its effect on patient outcomes.

The specific objectives are to:-

1. Retrospectively examine patient data to determine existing practice for identification and correction of preoperative anaemia, and to collate this data by 1st November 2015
2. Generate a new, standardised evidence-based protocol for preoperative anaemia detection and management in our colorectal unit, and achieve agreement with all involved parties for implementation of the protocol by 14th December 2015
3. Increase the rate of preoperative anaemia detection and correction, via administration of intravenous iron where appropriate, for elective colorectal patients over a three month trial intervention period between 1st January 2015 and 1st April 2016
4. Reduce the rate of immediate preoperative anaemia by at least 50% in this patient cohort when compared to the patient data collected prior to protocol implementation, by 1st April 2016
5. Evaluate barriers to implementation of the protocol, including resource implications, during the trial implementation period and make any required adaptations to the protocol by 1st May 2016

1.3 Planned Process

1.3.1 Setting and Timeframe

The project was performed in the Colorectal Unit of a large tertiary referral centre in Scotland. A senior surgical trainee within the department acted as lead change agent. Data was retrospectively collected from 95 consecutive patients undergoing colorectal cancer surgery in the year 2015, to establish baseline levels of preoperative anaemia in this cohort, baseline practice for detection and management of perioperative anaemia, perioperative blood transfusion rates and patient outcomes. This data was used to process map the patient journey from cancer detection to operation date, to identify potential intervention points in this journey. A standardised pathway for patients, incorporating an evidence-based preoperative anaemia management protocol, appropriate to our unit's current operating practices was developed. Once the protocol was agreed and implemented, data collection began. During an initial three month implementation phase, commencing January 2016, data was prospectively collected to evaluate the project.
1.3.2 Patient Selection and Stratification

All patients diagnosed with colorectal cancer were to have a haemoglobin, ferritin and C-reactive protein (CRP) level checked at initial presentation. Those patients scheduled for surgical resection, who were found to be anaemic and iron-deficient, were then to be selected for intravenous iron replacement prior to surgery. Data was collected from all patients undergoing elective colorectal resection, both anaemic and non-anaemic, regarding their perioperative haemoglobin levels, transfusion rates and complications.

1.3.3 Intravenous Iron Replacement

The protocol for intravenous (IV) iron replacement was drafted based on previously published protocols (Enko et al., 2013; L T Goodnough et al., 2011; Munoz, Gomez-Ramirez, & Campos, 2014; Munoz, Gomez-Ramirez, Martin-Montanez, et al., 2014). The draft protocol was then agreed with relevant professional groups involved in these patients’ care. Arrangements were agreed for patients to attend the hospital on a day-patient basis for IV iron therapy, as per a defined prescribing protocol, if identified to have anaemia with an iron deficiency picture. Iron therapy was to be administered if there was at least 10 days between therapy date and surgery date as iron given too close to the surgery date will not cause a substantial rise in haemoglobin levels (Munoz, Gomez-Ramirez, & Campos, 2014; Richards et al., 2015) and therefore the benefit of therapy is not achieved.
1.4 Planned evaluation

The main focus of evaluation was on patient outcomes, as outcomes are what matter to patients (De la Harpe, Kavanagh, & Turner, 2008). The project was primarily evaluated by comparison of patient data pre- and post-implementation of the anaemia management protocol, to assess whether anaemia detection and correction rates increased as a result of protocol implementation. Data was collected regarding preoperative Hb level, ferritin and CRP, reason for and type of colorectal resection, preoperative anaemia correction methods, perioperative complications, perioperative transfusion requirements, postoperative haemoglobin day 1 and day 3 post surgery and length of stay.

The project was additionally evaluated with regard to compliance with the protocol and reasons for non-compliance sought. Data was also collected regarding extra resources required for protocol implementation (additional bed use, costs). This data will be used to revise the protocol for continued implementation.

1.5 Potential threats to implementation

Implementation of this project required buy-in and co-operation from the department of colorectal surgery, pharmacy, colorectal nurse specialists, the endoscopy unit and potentially the preoperative assessment clinic (POAC). The project was initially discussed formally with representatives of all involved specialties,
without any objections raised. Continued engagement with all parties was required to ensure successful implementation of the project as multidisciplinary engagement is vital to the success of cross-disciplinary change projects (Holley, 2009).

A small number of patients already attended the hospital for IV iron replacement preoperatively. However, as the project may identify more patients requiring this treatment, arrangements needed to be made for potentially increased numbers of patients attending the hospital for iron therapy. On some occasions patients have been brought in to overnight beds for their therapy; by using the day ward as part of this protocol, some of these costs could be offset through more efficient use of daytime resources. The demand for health services needs to be shaped so that patients are best served by the available resources (Pencheon, 1998) and efficient use of resources is key to this. As nurses on the day admissions ward are already trained to administer IV iron, patients were initially admitted to this ward for their therapy and feasibility of continuing this practice included in the evaluation of the study.

1.6 Ethical Approval

A waiver of need for ethical approval was granted by the West of Scotland Research Ethics Committee. Caldicott Guardian approval for the collection and analysis of anonymised patient data as part of this project was granted by the office of the Caldicott Guardian for the NHS Greater Glasgow and Clyde region.
1.7 Conclusion

This project was undertaken, as planned above, to introduce a standardised approach to detection and management of preoperative iron-deficiency anaemia in elective colorectal surgical patients, in a tertiary referral colorectal unit in Scotland. The implementation process will now be detailed further, beginning with a systematic review of relevant literature in Chapter Two, followed by in-depth discussion of the organisational development process in Chapter Three, evaluation findings in Chapter Four and discussion of the impact of the project in Chapter Five.
Chapter Two

Systematic Review of the Literature
2.1 Introduction

Red blood cells (RBCs) are the oxygen carrying cells of the blood. Oxygen is carried to all parts of the body bound to the haemoglobin (Hb) molecule within RBCs. Patients who have low levels of haemoglobin in their blood are termed anaemic; defined by the World Health Organisation as haemoglobin levels <12g/dL for females and <13g/dL for males (Theusinger et al., 2014). Generation of mature red cells requires adequate availability of iron, which is required for synthesis of red blood cells, where it plays a critical role in oxygen binding to haemoglobin (Steinbicker & Muckenthaler, 2013). Iron deficiency, therefore, results in anaemia and is one of the commonest causes of anaemia worldwide (Steinbicker & Muckenthaler, 2013).

If haemoglobin levels fall to a level where oxygen demand exceeds supply, then RBC transfusion is one of the few treatments that adequately restores tissue oxygenation (Klein, Spahn, & Carson, 2007). RBC transfusion involves the administration of concentrated red blood cells from a donor to a recipient. Although it has a very high therapeutic index (Klein et al., 2007), allogeneic blood transfusion carries with it a number of risks, such as transfusion-associated lung injury, haemolytic transfusion reactions (due to incompatible antibodies in donor and recipient blood), transfusion-related sepsis, blood-borne diseases such as Hepatitis (B and C) and Human Immunodeficiency Virus (HIV), anaphylaxis, transfusion related circulatory overload, graft-versus-host disease and post transfusion purpura (Vamvakas & Blajchman, 2009).
Preoperative anaemia has been shown to be an independent risk factor for perioperative RBC transfusion and for postoperative morbidity. Strategies to reduce preoperative anaemia rates, and therefore unnecessary RBC transfusions might be associated with improved postoperative outcomes (Elhenawy et al., 2015). Iron-deficiency is a correctable cause of anaemia; iron stores can be replenished through oral iron supplements or IV iron infusions. The aim of this literature review was to identify the evidence available to support preoperative correction of iron deficiency.

2.2 Search Strategy

In order to obtain papers pertinent to the topic of interest, two databases, Pubmed and Google Scholar, were searched in December 2015, for articles published in the preceding twenty years, using the search terms "preoperative/pre-operative", "iron deficiency/iron-deficiency", "anaemia/anemia" and "management". A total of 364 articles were returned between the two searches. Randomised and non-randomised trials, observational cohort studies and systematic reviews were included for analysis, if they assessed the use of iron replacement in any form to preoperatively correct iron-deficiency. Only papers in the English language were included.

On the basis of title alone, 290 papers were excluded from further analysis - 179 due to lack of relevance to the topic under study, 71 general review articles, 4 case reports and 36 articles in foreign languages. Seventy-four abstracts were
studied and 34 more articles excluded based on the above inclusion criteria. Forty full text papers were read in full and a final 25 papers included in this review.

From the literature reviewed, three distinct themes emerged - there are variable reported outcomes from correction of iron deficiency preoperatively; there are a number of different modalities of iron that can be administered to correct preoperative iron-deficiency; and the timing of iron-deficiency detection and correction is important. Each of these themes will now be examined in more detail.

2.3 Review of Themes

2.3.1 Theme One - The Effects of Correcting Preoperative Iron Deficiency

A number of studies have examined the effects of correction of iron-deficiency anaemia preoperatively. These studies have focused on a variety of different outcome measures - an increase in the patient's Hb level between diagnosis and date of surgery, complete correction of anaemia by the date of surgery, improved postoperative Hb levels, reduced perioperative blood transfusion requirements and length of hospital stay. It is these latter outcomes which are more clinically relevant for patients and service providers, as they reduce costs and patient risks, and improve patient turnover and service efficiency.
Correcting anaemia, in general, has been shown to be associated with improved patient outcomes such as reduced perioperative transfusion rates (Keeler et al., 2016; Lasocki et al., 2015), less perioperative complications in orthopaedic surgery (Lasocki et al., 2015), shorter hospital stays (Myers, O’Grady, Grady, & Dolan, 2004) and reduced mortality rates in cardiac surgery (Hogan, Klein, & Richards, 2015). Indeed, Keeler et al (2015) demonstrated in a regression analysis of 201 colorectal cancer patients that for every 1g/dL increase in preoperative Hb, the likelihood of requiring a perioperative transfusion was reduced in the order of 40%.

Some small cohort studies have supported the use of iron supplementation to improve Hb levels preoperatively. Simpson et al (2010) demonstrated in ten iron-deficient, anaemic patients with colorectal cancer, that administration of a single dose of IV iron preoperatively resulted in a mean rise in Hb level of 1.1g/dL over an average period of 27 days. Similarly, Keeler et al (2014) have shown that a single dose of IV iron resulted in a mean rise in Hb of 1.65g/dL in non-transfused anaemic patients with colorectal cancer, when given at least 14 days preoperatively. As this study included all causes of anaemia, better response rates may have been seen if only iron-deficient patients were chosen. Indeed, patients with lower transferrin saturation levels (a marker of iron deficiency) were more likely to respond to the IV iron (Keeler et al., 2014). Neither of these studies addressed more clinically relevant outcomes, such as reduced transfusion rates and perioperative complications.
There have, unfortunately, been few randomised trials or large cohort studies looking at the clinical effects of preoperative iron replacement. Edwards et al (2009) did examine the effects of IV iron given to colorectal cancer patients at least 15 days preoperatively in a prospective, randomised, blinded, placebo-controlled trial at a single centre. This study concluded that administration of IV iron preoperatively did not confer any benefit in terms of increasing preoperative Hb levels or reducing transfusion rates (T. J. Edwards, Noble, Durran, Mellor, & Hosie, 2009). However, this study included both anaemic and non-anaemic patients, did not reach the recruitment level required by its power calculation to detect a difference in Hb levels in treated versus untreated anaemic patients and used a lower dose of iron sucrose than usually used in clinical practice. It is therefore difficult to draw any meaningful conclusions from this study.

Calleja et al (2015) assessed the benefits of preoperative IV iron to correct iron deficiency in a multi-centre, non-interventional study of 266 patients undergoing surgery for colorectal cancer. One cohort of patients was treated with oral iron only, whereas the other patients were treated with IV iron 2-4 weeks preoperatively. Only 9.9% of the IV iron group required transfusion compared to 38.7% of the no IV iron group (p<0.001). The IV iron group also achieved significantly higher Hb concentrations at hospital admission, discharge and 30 days postoperatively and had a shorter length of hospital stay. There was no statistical difference in the rate of postoperative complications and re-interventions in the IV iron group (Calleja et al., 2015). Unfortunately, the no IV iron group in this study were analysed retrospectively and therefore potential confounders cannot be controlled for. However, the two
groups analysed underwent their treatment within one year of each other and therefore it is unlikely there would be much difference in surgical techniques and transfusion triggers between the two groups. Additionally, the sample size was powered to detect a difference in transfusion requirements, rather than just changes in Hb levels, lending further strength to their findings.

Okuyama et al (2005) reported a 5.4% increase in Hb levels by the time of surgery following at least a 2 week course of oral iron supplementation in patients with Hb<10g/dL undergoing colorectal surgery. Intraoperative transfusion rates were subsequently lower in the treated patient group compared to untreated anaemic patients in this small cohort study. The effects of correction of iron-deficiency were also examined by Kotze et al (2012), in a cohort of orthopaedic patients where preoperative anaemia levels were reduced from 25.3% at the time of listing for surgery to 10.3% after treatment with oral (if surgery was more than 4 weeks away) or IV iron, compared to a cohort where preoperative anaemia was not corrected. Iron deficiency correction resulted in significant reductions in perioperative transfusion rates for hip and knee surgery, as well as significantly reducing patient length of hospital stay. In a similarly designed cohort study, use of IV iron 2-4 weeks preoperatively in women undergoing abdominal hysterectomy was also shown to increase preoperative Hb levels compared to untreated patients, and significantly reduce postoperative transfusion rates (Diez-Lobo, Fisac-Martín, Bermejo-Aycar, & Munoz, 2007). Whilst all of these studies are observational, non-randomised studies with small numbers and therefore only provide moderate evidence, they are the best available papers providing support of the benefits of iron treatment preoperatively.
A number of systematic reviews have been performed in an attempt to assess the true benefits of correcting iron deficiency preoperatively. However, a review of iron-deficiency correction in cardiac surgery patients was only able to find low quality evidence in the literature and was unable to conclusively answer this question in patients undergoing cardiac surgery (Hogan et al., 2015). Similarly, Hallet et al (2014) performed a systematic review assessing the impact of perioperative iron treatment on transfusion rates in gastrointestinal surgery and found only poor quality, heterogenous data, which was generally powered to detect changes in Hb levels, not more clinically relevant differences in transfusion rates. Bortslap et al (2015) assessed use of iron therapy for correction of preoperative anaemia in colorectal cancer; their systematic search found three randomised trials and four cohort studies addressing this issue. Most of these studies were only of moderate quality and meta-analysis was not possible due to heterogeneity of data. All four cohort studies supported the use of iron supplementation, whereas the three randomised trials did not (Borstlap et al., 2015). However, each trial had methodological flaws and again, no definitive conclusions could be drawn from this data.

Correction of preoperative iron deficiency has been introduced in some units as part of an overall patient blood management (PBM) program, where additional techniques to reduce transfusion requirements such as intraoperative haemostatic measures and lower transfusion triggers have also been introduced (Enko et al., 2013; Leahy et al., 2014; Theusinger et al., 2014). As part of their PBM program, Theusinger et al (2014) reported a significant reduction of immediate preoperative anaemia in patients undergoing hip surgery from 17.6% to 12.9%, and in patients
undergoing knee surgery from 15.5% to 7.8%. Perioperative transfusion rates also significantly reduced in both sets of patients in this timeframe. However, this may have been, at least partly, due to additional intra- and post-operative measures in place to reduce transfusion rates. Following introduction of a PBM program, Leahy et al (2014) reported a reduction in perioperative blood transfusion in elective cardiothoracic surgery from 27% to 12.8% and Enko et al (2015) reported a 60% reduction in perioperative transfusion requirements in anaemic patients managed as per their PBM protocol. Similarly, Lasocki et al (2015) reported differences in perioperative anaemia and transfusion rates at European centres who have a PBM program compared to those who do not. Preoperative anaemia was significantly less frequent in PBM centres at 8% versus 18.5% (Lasocki et al., 2015), although the causation of the reduced anaemia levels is likely multifactorial. This multifactorial effect is seen in a number of observational studies, which makes it difficult to identify the true effects of iron deficiency correction.

Finally, a much needed ongoing double-blind, randomised, placebo-controlled clinical trial, assessing the benefits of IV iron use prior to major abdominal surgery in 500 patients, powered to detect the effect on blood transfusion rates (Richards et al., 2015), will hopefully provide more robust supporting evidence for this practice in the future.
Published studies have looked at preoperative iron replacement in both oral and IV forms. There have been some reported benefits of correcting preoperative iron deficiency with oral iron. Myers et al (2004) have shown that anaemic orthopaedic patients commenced on oral iron supplements preoperatively had a significantly lower transfusion rate compared to untreated anaemic patients, at 50% versus 88%. However, a 50% perioperative transfusion rate remains unacceptably high. Okuyama et al (2005) reported a 5.4% increase in Hb levels by the time of surgery following at least a 2 week course of oral iron supplementation in patients with Hb<10g/dL undergoing colorectal surgery. Use of oral iron has also been shown to prevent Hb falling further between the time of listing for surgery and the actual surgery date in colorectal cancer patients (Keeler et al., 2016). However, in their review of 201 patients, Keeler et al (2015) did not see any reduction in transfusion rates in anaemic patients treated with oral iron compared to untreated patients.

In recent years, use of intravenous (IV) iron has become more popular, due to the development of newer formulations with less side effects (Radia et al., 2013) and its quicker onset of action compared to oral iron. Initial studies focused on the feasibility and safety of using IV iron replacement to correct preoperative iron deficiency, by measuring serial changes in Hb levels. Simpson et al (2010) demonstrated in ten iron-deficient, anaemic patients with colorectal cancer, that administration of a single dose of IV iron preoperatively resulted in a mean rise in Hb
level of 1.1g/dL over an average period of 27 days. Eight patients responded to IV iron administration and there were no reported adverse effects. Similarly, Keeler et al (2014) have shown that a single dose of IV iron resulted in a mean rise in Hb of 1.65g/dL in non-transfused anaemic patients with colorectal cancer, when given at least 14 days preoperatively.

When the two modalities were compared, Rineau et al (2014) reported a significant advantage for IV iron over oral iron in both correcting preoperative anaemia and maintaining higher postoperative Hb levels in a cohort of 51 orthopaedic patients, when both groups were commenced on iron treatment 3 weeks preoperatively. Due to its quicker onset of action, IV iron is likely of more use than oral iron in treating iron deficiency in patients undergoing urgent or semi-urgent surgery. Calleja et al’s study (2015), also showed significant benefits for IV iron over oral iron in treatment of preoperative iron deficiency. Further data to support this should hopefully come from a prospective, multicentre randomised trial being conducted by Borstlap et al (2015). The trial protocol hypothesises a higher rate of preoperative Hb normalisation will be achieved with IV versus oral iron and patients will be randomised to either oral or IV iron within 4 weeks of surgery to assess if this is truly the case.

There are a number of different IV iron preparations available. Over time, newer formulations have been developed which can be administered more quickly and at higher doses. Radia et al (2013) describe a natural progression at their rapid
access anaemia clinic from initially using iron sucrose, then moving to low molecular weight iron dextran and finally ferric carboxymaltose (FCM). Both iron sucrose and iron dextran require administration of a test dose prior to commencement of the therapeutic infusion. Iron sucrose requires multiple doses to achieve therapeutic targets and iron dextran, whilst being a single administration, requires infusion over 4-6 hours (Radia et al., 2013). FCM, on the other hand, does not require a test dose and can be administered over 15 minutes, resulting in increased patient throughput, less time off work required for patients and shorter waiting lists for the anaemia clinic (Radia et al., 2013).

The different IV formulations have been compared across a number of small studies. Molto et al (2013) examined the differences between iron sucrose and FCM treatment in 86 elective orthopaedic patients with iron-deficiency anaemia. Both formulations were shown to be equally effective at increasing the patient’s Hb level. However, the FCM group achieved a greater total dose of iron in fewer administrations and this was felt to offer cost savings in view of reduced resource utilisation (Molto et al., 2013). Bisbe et al (2011) also compared use of IV FCM and iron sucrose in anaemic patients undergoing major elective surgery; they found that those receiving FCM attained iron replenishment significantly more frequently, with fewer treatment doses needed. Patients receiving FCM also had a higher final Hb level preoperatively and required less blood transfusions than patients who received iron sucrose (Bisbe, García-Erce, Díez-Lobo, & Muñoz, 2011). This study was limited by the use of retrospective data collection for the iron sucrose group but its findings are in support of other data in the literature, in favour of the use of FCM.
2.3.3 Theme Three - Timing of Iron Deficiency Detection and Correction

It takes time to correct iron-deficiency by iron replacement, which has implications if patients are scheduled for urgent or semi-urgent surgery. If iron deficiency is not detected within an appropriate timeframe to correct it, then patients run the risk of having to postpone their surgery or attend for their surgery without undergoing iron-deficiency correction. Therefore, timely diagnosis and intervention pre cancer surgery is important.

IV iron replaces iron stores quicker than oral iron (Rineau et al., 2014) but still needs a number of weeks to reach maximal effect. Todman et al (2015) have shown that administration of IV iron to 33 patients resulted in an average rise in Hb of 0.84g/dL at 2 weeks, 1.2g/dL at 3 weeks, 1.94g/dL at 4 weeks and 2.53g/dL at 8 weeks. Depending on the degree of anaemia, some patients may be able to receive their treatment close to their surgery date but most patients would need treatment at least 2 weeks preoperatively, in order to see any benefit. Calleja et al (2015) found that administration of 1000mg of FCM at a mean of 28 days pre-surgery resulted in significant increases in Hb levels at the time of admission for surgery. In line with these findings, Kotze et al (2012) developed their preoperative protocol, whereby patients scheduled for surgery in the next 2-4 weeks are administered IV iron, whereas oral iron is prescribed if there is more than 4 weeks to the scheduled surgery date. If surgery is less than 2 weeks away, there may be no benefit from administering iron, even in IV form, although this hasn't been specifically studied.
As part of their patient blood management program, Theusinger et al (2014) reassessed patients with anaemia 2 weeks post treatment and provided further treatment if they were still anaemic. Again, this requires that detection of anaemia occurs early in the patient pathway. Indeed, as Hb levels continue to fall from the point of diagnosis up to the date of surgery (Keeler et al., 2016), early identification and treatment of anaemia is vital to ensure the optimal treatment is given. For every 1g/dL increase in Hb the likelihood of transfusion can be reduced in the order of 40% (Keeler et al., 2016).

Some authors have suggested that preoperative IV iron can be given closer to the timing of surgery. Munoz et al (2014) described a retrospective review of a cohort of patients who underwent very short-term preoperative IV iron administration, given 2-3 days preoperatively in elective and emergency orthopaedic surgery. This timing of administration resulted in a significant reduction in transfusion rates from 36.9% to 24.2%, as well as reducing average hospital stay by one day. However, this study didn't achieve the low transfusion levels seen in other studies assessing the benefits of IV iron administration, which may reflect that patients hadn't realised the full benefits from their iron at the time of their surgery. Additionally, this study included emergency surgical cases who required their operations within a short time-frame. Planning service delivery for elective and emergency patients requires different considerations and one of the main differences is the element of timing. Elective surgeries can be scheduled some weeks in advance, allowing more time to identify and correct patient problems, when compared to emergency surgery.
Following identification of anaemia, there must be appropriate facilities to enable IV iron administration in a timely fashion. One suggested method is to develop a nurse-led anaemia clinic where patients undergo testing to determine the underlying cause of their anaemia, are referred to the day ward for their IV iron and followed up to ensure a response (Leahy et al., 2014). Whilst there are immediate set-up costs with developing such a clinical pathway, these costs may be offset by the benefits of the clinic. Guinn et al (2015) projected, via financial modelling of such a new perioperative anaemia clinic that if perioperative transfusion rates are reduced by 50% then this offsets the costs of the clinic. In addition, they adopted a narrower therapeutic window, based on retrospective analysis of patients most likely to require transfusion in their orthopaedic cohort. Rather than selecting all patients who were anaemic by WHO criteria, they subselected Hb levels between 11 and 12g/dL, depending on the index procedure planned, as their cutoff for treatment (Guinn et al., 2016). This approach reduces the number of patients attending for iron treatments, allowing those who do attend to be treated in a timely and efficient manner. However, such an approach would need to be audited carefully to ensure that some patients who would benefit from iron treatment were not being excluded.

2.4 Implications for the Project

This literature search had a number of implications for the planned project. There is a wealth of evidence available to support correction of anaemia preoperatively in order to reduce perioperative transfusion risks, perioperative
morbidity and even mortality. As the majority of colorectal patients with anaemia are iron-deficient, it seems appropriate to correct this deficiency in this cohort. Preoperative iron supplementation, in iron-deficiency anaemia, does result in higher preoperative Hb levels, although the evidence supporting its longer term effects is of moderate quality only. The risks of treatment are low, however, and so use of a potentially beneficial treatment is justified. Based on the available literature, IV iron seems more appropriate than oral for use in colorectal cancer patients, as surgery must proceed within a shorter timeframe due to the nature of malignant processes. Finally, iron deficiency must be identified early in the patient diagnostic pathway, to ensure there is enough time to correct it prior to surgery. Care must be paid to developing a patient pathway that allows for this identification and correction in a timely fashion.

2.5 Summary and Conclusion

The data available to support the correction of iron deficiency preoperatively is variable in quality and reported benefits. The only available trials claim not to demonstrate benefits but have been poorly designed. There is, on the other hand, strong observational evidence to support the finding that patients with preoperative anaemia have higher transfusion requirements and increased perioperative complications, and a large volume of evidence from cohort studies supporting correction of iron-deficiency to improve outcomes by raising Hb levels and reducing immediate preoperative anaemia rates.
IV iron offers advantages over oral iron in terms of its ability to increase Hb levels in a short time frame, which is particularly relevant for surgical patients who cannot defer their operation, such as those with malignancy. Studies have identified that the newer IV compound, FCM offers many advantages over older formulations due to its quicker administration time, ability to infuse a high dosage and greater effect at increasing haemoglobin levels.

Unfortunately, there has been no study performed designed solely to accurately identify the best timing of administration of iron preoperatively. From the best available evidence, it would appear that administration of IV iron at least 2 weeks preoperatively is needed to have a therapeutic effect by the time of surgery in most patients (Todman & Rao Baikady, 2015).

In conclusion, based on that discussed above, evidence supports development of a patient pathway to identify iron deficiency anaemia in a timely manner in colorectal cancer patients and correct their iron-deficiency preoperatively, through the use of IV FCM infusions.
Chapter Three

Organisational Development

Process
3.1 Choice of Organisational Development Model

Organisational change requires planning of the process. Many organisational change management projects fail due to lack of a valid framework for implementation, and management of organisational change (Todnem, 2005). One of the original widely adopted change models was that proposed by Kotter (1996). However, this model is not applicable to all change processes as it has a linear structure, which can make directional change difficult once the process has started. Additionally, it is a “top-down” model, designed for implementation from the top level of management, rather than an employee-directed model of change. One of the recurrent difficulties of implementing Kotter’s change model is reported to be that of “changing the behaviour of people” (Appelbaum, Habashy, Malo, & Shafiq, 2013, page 777). In a healthcare setting, no change will occur without attention to the behaviour of people.

Another frequently quoted change model is that of Lewin’s Three Stage Model (Burnes, 2004). This model describes a process of “unfreezing” the current situation in an organisation, “movement” to generate a system of changed practice, and “refreezing” the organisation where the change process is reinforced as the new status quo. Again, this model can have applicability problems in that it is very goal focused and seems orientated towards a single, defined period of change in an organisation, rather than appreciating that change is an evolving, and often continual process. However, if used in combination with Lewin’s other theoretical approaches to change, Field Theory, Group Dynamics and Action Research, then Lewin’s
framework for change and organisational development is seen as a wider, more robust approach (Burnes, 2004).

Many newer approaches to change management have their roots in Lewin’s and/or Kotter’s models. Over time, change model frameworks have been designed, which vary in terms of rate of change occurrence, how change comes about and scale of change (Todnem, 2005). Organisational development (OD) in healthcare is a complex process requiring changes within organisational culture and hierarchical systems, with a focus on people and personal relationships. Senior and Swailes describe a model of change for such “soft” systems, which emphasises not just the content and control of change but also the process by which change comes about (Senior & Swailes, 2010). Their model focuses on consideration of “needs and aspirations of individuals, the group processes that bind them together and the structures and systems that are forces for stability rather than change” as well as “the cultural, political and symbolic processes that act to maintain the current organisational paradigm” (Senior & Swailes, 2010, page 315).

People are at the core of organisations and therefore are at the core of organisational development, which is a fluid and, at times, multidirectional process, as illustrated in Senior and Swailes’ OD model for change, (Appendix 1, Figure 1). For these reasons, the Senior and Swailes model of OD was chosen for this project.
3.2 OD Process Implementation

The Senior and Swailes model was implemented in a broadly stepwise fashion as outlined below. Many steps in the model occurred in an overlapping timeframe or were revisited at a later stage in the project, as is expected in a continuously evolving OD project. Each stage will now be discussed in detail in turn.

3.2.1 Stage 1(a): Diagnose the Current Situation

This stage requires a full assessment of both the external and internal environments currently affecting the organisation (Senior & Swailes, 2010). Assessment of both environments is important to identify triggers for change and potential impediments to change. A PESTLE analysis (Srdjevic, Bajcetic, & Srdjevic, 2012) was performed to assess the external environment affecting this organisation, and a combination of process mapping (Biazzo, 2002) and audit of current practice performed to look at the current internal situation.

A PESTLE analysis is a means of assessing multiple factors which may be triggers or obstacles to change within an organisation (Srdjevic et al., 2012). By using the different headings (political, economic, social, technological, legal/ethical and environmental), a thorough assessment of all factors relevant to complex systems and their multidimensional interactions with the environment is performed.
(Srdjevic et al., 2012). PESTLE analysis identified a number of external triggers to support changing unit practice in management of perioperative iron-deficiency anaemia, as well as potential barriers (Appendix 1, Table 1). Having a systematic approach to management of preoperative anaemia could be beneficial in meeting government treatment targets (The Scottish Government, 2016), reducing costs associated with longer hospital stays and transfusions, meeting patients’ expectations of best outcomes from surgery, and reduced usage of precious blood stocks. Additionally, technological advances in IV iron preparations available mean it is possible to administer such treatment more quickly and more safely than previously (Radia et al., 2013). Ethically, if a safer treatment is available to reduce risks associated with transfusion, then this treatment should be offered to patients. A potential barrier to change identified was the economic cost of IV iron preparations.

Assessment of the internal environment requires analysis of the organisation’s purposes and goals, structure and culture, leadership styles, individual commitment and motivation and relationships within and between groups (Senior & Swailes, 2010). Our organisational mission statement reads as follows:-

"...purpose is to deliver effective and high quality health services, to act to improve the health of our population and to do everything we can to address the wider social determinants of health which cause health inequalities" (NHS Greater Glasgow and Clyde, 2016)
The mission statement specifically calls on staff to act to improve the population’s health and this was used as an internal driver for change to improve our delivery of effective, high quality health services as per the aim of the organisation.

Assessment of organisational structure and culture with regard to existing preoperative anaemia management, and relationships between groups involved in preoperative patient management were performed by process mapping patient flow from referral to surgery date (Figure 2). The patient pathway is essentially a linear process and the sociotechnical analysis approach, where the social and technical aspects of an organisation are emphasised equally (Biazzo, 2002), was adapted. Patients are usually diagnosed with colorectal cancer at colonoscopy, following referral from their general practitioner (GP) or other health professional with symptoms, following abnormalities detected on imaging or as part of the national bowel screening programme (National Services Scotland, 2016). Colonoscopy in our unit is performed by surgeons, physicians and nurse endoscopists. Patients with colorectal cancer at colonoscopy are referred to the colorectal cancer multidisciplinary team via colorectal clinical nurse specialists and a final decision is made to proceed to surgery based on clinical, pathological and radiological findings. Thus, a great number of different health professionals are involved in patient management at various stages of the patient pathway. Any of these professionals may check Hb levels but there is currently no uniform practice and such testing is entirely performed at individual practitioners’ discretion. Similarly, treatment of iron-deficiency anaemia, if detected, occurs based on individual practitioners’ preferences.
In conjunction with the process mapping, patient data was collected to determine timing of preoperative anaemia detection and management, and patient outcomes. This data is presented in entirety in Chapter Four. It was clear, again, from the data collected that patients have Hb levels checked in a haphazard and variable fashion, based on individual practitioner preference, early on in the process. All patients undergo Hb testing at the POAC but the timing of this assessment is, again, quite variable. The majority of patients attend POAC less than two weeks before their scheduled surgery date, with some attending as close as 1 day preoperatively. This leaves little time for correction of iron-deficiency, when detected at this point. The data collected through this retrospective audit was used to inform the vision for change in Stage 1(b) of the project.

3.2.2 Stage 1(b) - Develop a Vision for Change

Development of the vision for change began with identification of additional staff members to support the change project. A consultant colorectal surgeon and pharmacist both expressed keen interest in becoming involved in the project. Early involvement of other staff members was important to ensure initial momentum was built. Even more importantly, support from a high-ranking staff member, such as a consultant, is vital to obtaining commitment from staff at the coal face (Sirkin, Keenan, & Jackson, 2005). This organisational development project required input from different disciplines involved in patient care; involvement of a consultant surgeon allowed for easier approach to other consultants to become involved and
involvement of a pharmacist was highly important for a project that evolved around changing medication management.

Once the retrospective data was collected and analysed, it was presented at the weekly colorectal unit meeting, along with published evidence supporting preoperative anaemia correction (Keeler et al., 2014; Leichtle et al., 2011; Simpson, Ng, Brookes, & Acheson, 2010). This meeting is attended by all eight consultant colorectal surgeons, all surgical trainees in the department, our clinical pharmacist and a senior colorectal nurse specialist. On the day of the presentation, the other colorectal nurse specialists were also invited to the meeting. Following the presentation, it was unanimously agreed that we should formalise a means of detecting and managing iron-deficiency anaemia in elective colorectal patients. A draft patient pathway was put to the meeting, based on available literature (Figure 3).

Initial discussion focussed on ensuring patients could be seen and assessed at POAC at least two weeks preoperatively to allow treatment of iron-deficiency, if detected at that point. However, due to the high demand for POAC appointments and government treatment targets for colorectal cancer restricting the ability to postpone surgery dates (The Scottish Government, 2016), it was felt that this would not be achievable for all patients undergoing cancer treatment. Focus then moved to identifying iron-deficiency in colorectal cancer patients at an earlier point in the process. It was suggested that patients should undergo testing at the time of colonoscopy. Currently, when a colorectal cancer is seen at colonoscopy, the
endoscopist refers the patient to one of the eight colorectal surgeons, via the colorectal nurse specialists. It was agreed that as part of this current process, the nurses would now also check results of blood investigations sent from the endoscopy unit for all new referrals. This would ensure timely planning of iron replacement, if necessary. As a result of this discussion, a new patient pathway was proposed (Figure 4), and plans began for implementation of this change management project.

3.2.3 Stage 2 - Gain Commitment to the Vision

Having gained consensus on a new pathway for anaemia detection and management from the colorectal surgery unit staff, it was important to ensure commitment to the process. This also required involvement of staff who had not been present at the unit meeting. A stakeholder analysis (Varvasovszky & Brugha, 2000) was performed to identify whose input would be most required to ensure successful implementation of the project (Figure 5). From this analysis, it was clear that it was vital to have buy-in from surgeons and colorectal nurse specialists, important to satisfy endoscopists, keep pharmacists and ward nurses informed and monitor junior doctors, administration staff and POAC nurses throughout the project.

All colorectal consultants and colorectal nurse specialists had agreed at the unit meeting to be involved in the project. This commitment to the vision was gained by presentation of hard data about the current situation. Even in our relatively small,
retrospective cohort of patients, we had been able to demonstrate that patients anaemic on the day of surgery had significantly lower Hb levels postoperatively and required more perioperative transfusion (full results presented in Chapter Four). In conjunction with presentation of published literature relating to better outcomes when preoperative anaemia is corrected, this established consultant body and nurse specialist commitment to the project. Ongoing commitment to the vision was sought by regular two-way communication with both groups as the project developed.

One of the key changes to the patient pathway was the requirement for colorectal nurse specialists to review blood results for patients at the time of referral. They already had some experience of this, as two of eight consultants already routinely checked patients' Hb and ferritin at colonoscopy. It was important to ensure the nurses didn't feel this additional work was a burden. Staff engagement with change is more likely if the additional effort required is not seen as too much extra work (Sirkin et al., 2005). Additionally, it was clarified that their role would be to inform the consultant of the results and final decisions regarding iron treatment would be made by consultants. In this way, it was clear that the nurses were not expected to take on an additional level of responsibility above their pre-existing duties. In times of change, people seek clarification of their role and lack of clear extent of responsibility can lead to tension and "black holes" of responsibility (Balogun, 2005), where there is a real possibility that no action will occur.
Liaising with patients regarding timing of their attendance for IV iron infusions is also part of the specialist nurses' role. As it was expected that numbers of patients requiring attendance for this would now increase, the nurses suggested development of a patient information leaflet, explaining reasons for infusion and the process of attending for infusion. The aim of this leaflet was to reduce the number and duration of telephone calls to the nurse specialists regarding iron infusions. It has been shown that patient information leaflets are welcomed by patients (Nathan, Zerilli, Cicero, & Rosenberg, 2007) and help to improve their knowledge and acceptance of their treatment (Adepu & Swamy, 2012; Gibbs, Waters, & George, 1990). In order to achieve these outcomes, leaflets must be easy-to-read, well laid out and provide authentic, unbiased information (Adepu & Swamy, 2012). It was agreed to develop this leaflet in conjunction with the lead pharmacist.

Where the iron infusions would take place was a matter for debate. The initial proposal was to continue the use of the elective surgical ward, as had been previously used for a small number of iron infusions. There were some concerns that the volume of infusions would impact on the nursing workload of this ward. It was also clear that infusions could take place in a day unit setting with the patient in a chair, rather than a ward bed (Calvet et al., 2012). However, there is currently no such surgical day unit in our institution and so our patients would have to be accommodated in a medical day unit. It was decided, following discussion with the consultant body, pharmacy and the ward nurse manager, to run the initial phase of the project through the surgical ward, in order to gather data on the exact volume of patients requiring infusions and the nursing time required to manage them. An
Acknowledgement was made that this component of the pathway may require adjustment as the project progressed.

The manner of IV iron prescribing was also discussed across the multidisciplinary team. The formulation of IV iron in use in our hospital requires dose calculations based on patients’ baseline Hb and their weight. As it is an uncommonly prescribed drug, many junior doctors would not be familiar with its prescription. Relying on junior surgical staff to prescribe an unfamiliar drug, with an associated dosage calculation, to unfamiliar patients incorporates many of the risks associated with prescribing errors (McDowell, Ferner, & Ferner, 2009; Nichols, Copeland, Craib, Hopkins, & Bruce, 2008). Our lead pharmacist has a prescribing qualification but could not commit to being available for every iron prescription required. It was felt that an easy-to-follow protocol and prescription chart should be available on the ward, specific for IV iron prescriptions. Through liaising with pharmacy, it was learned that an IV iron prescribing chart was currently being trialled in the orthopaedic unit of our hospital. It was felt appropriate to use this for our patient population also, to minimise duplication of such charts within one hospital. Standardised prescription charts develop familiarity for prescribers, ease the transition period when staff rotate amongst different departments or hospitals and help to reduce prescription errors (Coombes, Stowasser, Reid, & Mitchell, 2009). The prescribing chart was circulated to all colorectal surgeons to ensure no objections to its use for their patients and the pharmacist obtained a supply for use on the elective surgical ward.
Commitment to the vision from parties external to the colorectal unit, namely gastroenterologists and nurse endoscopists, was also required for success of the project. Colorectal cancer diagnoses are frequently made at colonoscopies performed by non-colorectal surgeons. As a high power, low interest group (Figure 5), it was important to keep endoscopists satisfied that their role in the process was both important, but also, not an onerous addition to their workload. Contact was made with the lead endoscopy clinician, a physician endoscopist. Data from the surgical audit, the rationale for change and the proposed new patient pathway were provided for his review. He responded very positively to the proposed plans and agreed to disseminate plans to all other endoscopy users. It was emphasised in his communication how the endoscopists could help improve the patient process, with minimal additional workload. Having his support made engagement with this external group easier and more productive. Having a “clinical champion”, a user of the system involved in feedback and changes to ensure optimizations of the system (Box et al., 2010), who leads introduction of the system into practice, was a key asset at this point of the project.

Maintaining the commitment of high interest parties, namely pharmacists and ward nurses, was also important for the success of the project. The lead pharmacist for our unit was instrumental in sourcing prescription charts and providing advice for the patient information leaflet at the leaflet generation stage. Constant two-way communication between the change agent and the pharmacist ensured the pharmacist felt her efforts were of value and would culminate in adoption of the project into routine clinical practice. The pharmacist also had a strong, pre-existing
relationship with the nurse manager of the elective surgical ward, having worked in
the organisation for longer than the change agent. This pre-existing relationship, with
mutual trust, was key during discussions about use of the elective surgical ward for
potentially higher throughput of patients requiring IV iron. Pre-existing trust amongst
group members is important when change is contemplated, as people are more
likely to look at task conflicts at face value and seek resolution, rather than hidden
agendas (Simons & Peterson, 2000). Because of the ability to believably reassure
the ward that an alternative would be sought if the volume of patients were too high,
the ward nurse manager was agreeable to accommodating the initial phase of the
project.

Two way communication between the change agent and all other team
members was vitally important for maintaining commitment to the project. Due to
differing work schedules, this communication took the form of both face-to-face
meetings and email communication. Electronic communication was particularly
useful as it allowed messages to reach involved parties at convenient times, as a
number of team members are involved in emergency service provision and would
often be unavailable in operating theatres. Electronic communication has also been
shown to facilitate equality of communication across group members, whereas in
face-to-face communication higher status individuals often tend to participate more
(Bordia, 1997). However, emails can often be lost in the large daily volume of emails
received (Jackson, Burgess, & Edwards, 2006), go unanswered or replies can be
delayed so it was important to use both modes of communication to optimise the
benefits of both. For important aspects of a project, face-to-face communication has
the greatest impact; it irons out ambiguities and ensures two-way communication is occurring, with communicators connecting adequately (Appelbaum et al., 2013).

The possibility of resistance to change was consciously considered at this point of the project. Whilst no-one voiced concerns about proceeding with the project, there was always the possibility of encountering silent resisters (O'Connor, 1993). The use of group meetings and email communication meant that not every team member had to voice their opinion. Surgery remains a hierarchical system and direct questioning of a senior consultant about their individual opinion would be difficult for many of the other team members, due to perceived differences in power and influence. Despite moves towards a more equal power base in hospital medicine, there remains a hierarchical culture in many institutions, where consultants are seen to wield the most power (Bate, 2000; Gaufberg, Batalden, Sands, & Bell, 2010) and can be difficult to approach. However, experience in working with this consultant body on other change projects had shown that all had spoken out at various points when they did not agree with proposals. It would therefore be expected that they would also voice any objections to this project. Nevertheless, it was important to monitor each person's participation in the project, with the aim of identifying any resistance at an early stage.
3.2.4 Stage 3 - Develop an Action Plan

Implementation of any organisational development project requires a plan of action specifying what actions are to be performed and who is responsible for each component (Senior & Swailes, 2010). In order to formalise this, a responsibility chart was developed (Figure 6), where each planned action was assigned a responsible person, a person acting in a support role and those whose approval was required for this action to take place (Senior & Swailes, 2010). Following, the rules of French and Bell (1999), responsibility for each action was assigned to just one person and the approval/veto role was limited as much as possible. This was to ensure that actions could be taken swiftly, without need for repeated cross-checking with multiple involved persons.

The support role is important, as this person provides needed assistance to the person responsible for the action (French & Bell, 1999). In many cases for this project, the support person was the change agent. However, as the project moves forward it will be important to assign this support role to other staff members. As the change agent is not a permanent member of staff, the longevity of the project will be reliant on the process being fully functional without the change agent’s presence. Thus, as the project evolves, the action chart will need to be appropriately modified.
The key actions identified for implementation of the project were defined as:-

1. Development of the patient pathway and circulation of the pathway to all relevant stakeholders to generate awareness of the planned change
2. Obtaining blood samples from patients diagnosed with colorectal cancer at the time of colonoscopy to check Hb, ferritin and CRP levels
3. Review of blood results from these patients to identify those with iron-deficiency anaemia
4. Identification of patients suitable for treatment with IV iron infusions
5. Provision of information to patients who are selected for IV iron infusion about their treatment rationale and process
6. Prescription of IV iron for patients attending hospital for same
7. Collection and analysis of patient, cost and process flow data
8. Evaluation of the organisational development project

Each action was reviewed to ensure it was relevant to the goals of the project, specific, integrated with other actions, and logically sequenced, as recommended by Senior and Swailes (2010). Adaptability of the plan is also important (Senior & Swailes, 2010) and early evaluation of the implementation process was planned to assess for any adjustments that needed to be made to the action plan. Primary responsibility for each stage of the project was assigned to various members of the multidisciplinary team, as illustrated in Figure 6. Once the action plan was agreed, implementation of the project proceeded in accordance with this chart.
3.2.5 Stage 4 - Implement the Plan

Senior and Swailes (2010) discuss key features to ensuring successful implementation of an OD project, specifically to build in short-term wins for team members and ensure ongoing engagement with all stakeholders. Whilst implementing the action plan, both aspects were incorporated in an attempt to ensure success of the project.

Short-term wins foster a feeling of positivity towards the project and provide an impetus for team members to wish to persevere with the project (Kotter, 1996). As the volume of patients expected to be suitable for IV iron infusion was relatively low, it was important to commence implementation at a time when there was such a suitable patient ready for treatment. Getting a suitable patient immediately engaged staff members and got the process off the ground. The first patient allowed all involved team members to co-ordinate the process - admission, infusion and proceeding to surgery. The process was completed without complication and gave team members a sense of confidence in repeating it for future patients.

Ongoing engagement with all stakeholders was a key component of implementation. In order to ensure development of the process as a norm for the department, the change agent provided a support role for all team members with initial heavy involvement in every stage of the process, gradually reducing over time and allowing team members to develop ownership of their roles and becoming
agents of change themselves, as "maintainers" of the changed system (Ottoway, 1983).

Consultants were key stakeholders in this project and so regular communication with them was vital to success of all aspects of the project. Firstly, consultants were provided with regular reminders about potential patients for iron replacement therapy. At the beginning of the project, the change agent reviewed each new referral to the weekly Colorectal Cancer multidisciplinary meeting and identified anaemic patients suitable for surgery. Each consultant that had a suitable patient was then contacted and requested to consider IV iron replacement for these patients. Secondly, engagement with the consultants was important when introducing the new IV iron prescribing chart. The chart was circulated to all and time allowed for review. Consensus was then achieved amongst all consultants prior to introduction of the prescribing chart for patients. Similarly, consultant input was necessary prior to distribution of the information leaflets for patients. Again, the proposed leaflet was circulated to all for review and feedback sought. Suggested improvements were taken on board, particularly a recommendation to simplify the language of the leaflet, to account for the reading age of the local population, which has been shown to average at a reading age of 11 years (NHS Greater Glasgow and Clyde, 2009).

The colorectal nurse specialists were another key stakeholder in this process and regular engagement was vital to developing their role in the project. The nurses
already had a similar role in terms of co-ordinating other test results and appointment times for patients but had not previously been involved in managing blood results. It was important when expanding their role that they felt comfortable undertaking additional responsibility and knew they were supported in this role, as discussed in Section 3.2.3. As a means of achieving this early on in the project, the change agent regularly communicated with the nurses regarding identification of suitable patients, interpretation of blood results and answering queries about the protocol that became apparent as it was implemented. Over time, it became clear that the nurses were now identifying suitable patients themselves without need for regular input from the change agent. However, it was important that a support network remained for dealing with unexpected results. When people have been assigned a new role or responsibility there must be a clear authority person assigned to help with difficult cases; specialist nurses assigned new roles can sometimes feel there is lack of support or isolation in their role (Raja-Jones, 2002). The nurses were at all times assured that results and management plans would be discussed with consultants prior to arranging appointments for IV iron administration.

Similarly engagement with the nurses was key for development of the patient information leaflet. Indeed, the production of a leaflet was the idea of one of the nurse specialists. Regular discussions were held between the colorectal nurses, the pharmacist and the change agent to formulate the final leaflet, which was the circulated to the colorectal consultants for approval, as discussed above.
Pharmacy had another key role in this project. Our clinical pharmacist works as a pharmacist prescriber, which meant she could both approve IV iron availability for the elective surgical ward when a patient was expected for admission but also prescribe the IV iron for each individual patient. This greatly helped with streamlining the process whereby once identified patients details were forwarded to our pharmacist, the IV iron was both ordered and prescribed in advance of their attendance at the ward. When patients attend for their IV iron, the ward nurses are immediately able to commence the planned treatment without waiting for a doctor, who may be engaged elsewhere. Additionally, this allows the ward to schedule attendances for IV iron infusions at a time suitable for their workload. Scheduling patients to attend mid-morning means the elective surgical patients are already admitted and the IV iron can be administered at a relatively quiet time on the ward, before patients begin returning to the ward post-operatively, thus integrating the new pathway with current work practices. The pre-existing relationship between the clinical pharmacist and ward manager was also key to smoothly introducing this process, as discussed previously.

Continued implementation of the project was reliant on regular assessment of progress and determination of successful outcomes. This will be detailed in the next section.
3.2.6 Stage 5 - Assess and Reinforce Change

"Soft" change models require use of multiple assessment methods, such as regular surveys/audits, interviews or focus groups, comparison of turnover with pre-change numbers and analysis of group performance levels (Senior & Swailes, 2010) to identify progress across the different facets of the project. Regular, prospective assessment of the process allows for early identification of success as well as determining areas requiring improvement.

In accordance with the above principles, prospective data collection was performed, with regular analysis of the results to identify progress and potential problematic steps. As will be discussed further in the evaluation section (Chapter Four), patient data was collected to assess compliance with the protocol as well as patient outcomes following implementation of the protocol. Interval audits were performed and specific groups of personnel targeted for reinforcement of the protocol, if found to be engaging less with the project. For example, it was noted that some of the patients who did not have Hb measured at the time of colonoscopy had had their colonoscopy performed by a senior trainee rather than a consultant. It became apparent that the focus of dissemination of the pathway had been to consultants and trained nurse endoscopists, whilst senior colorectal trainees also play a key role in performing colonoscopy. When this was identified, the protocol was additionally circulated to senior trainees to engage them in the process.
Making the change more permanent is another key part of Stage Five - the new order needs to be institutionalised (Senior & Swailes, 2010). In this project, it was vital to target permanent staff members as their lasting presence in the department is vital to long-term implementation of the project. In hospitals, there are many temporary staff, including the change agent for this project. One of the failings of projects instituted by temporary staff could be lack of longevity once the initiating staff leave the workplace. Changes in structures, policies, training and culture must take place to reinforce and consolidate the change (Senior & Swailes, 2010). Consultants, colorectal nurse specialists, pharmacists and nurse endoscopists occupy permanent posts in the department. Thus, developing their ownership of the project is vital to reinforcing the change and making detection and treatment of preoperative iron-deficiency anaemia a normal process within the department. Enabling the colorectal nurses to have the power and capacity to maintain the pathway without input from the change agent, is an ongoing process key to reinforcing the change. Addition of the IV iron infusion protocol to the hospital clinical therapeutics handbook (NHS Greater Glasgow & Clyde Area Drug and Therapeutics Committee, 2016) is a future aim that will further consolidate the project. The other key to success is continued buy-in from the consultants as continuity of the project is provided by the permanency of their role.

Financial implications of the project were also assessed during the lifespan of the project. A single administration of the IV iron solution used in our institution costs £191 per 1000mg dose infusion (Scottish Medicines Consortium, 2011). Patients require one or two infusions to replete their iron stores, depending on their weight.
According to the National Institute for Health and Care Excellence (2015), the cost of an initial unit red cell transfusion is £170.14 with each subsequent unit costing £162. In clinical practice, patients are generally prescribed a minimum of two units, meaning a minimum spend of £332.14 per transfusion episode. In addition to this, patients requiring transfusion frequently require an additional length of stay, with bed days in Scottish hospitals estimated to cost £246 per day (Joint Improvement Team, 2015). Estimates of potential cost savings from introduction of this project are further discussed in Chapter Four.

3.3 Summary

The soft systems change model uses constant evaluation of the process to develop the action plan based on lessons learned from implementation (Senior & Swailes, 2010). From the initial vision stage, to the assessment and reinforcement of change stage of this project, numerous additions, subtractions and revisions were made. Ongoing evaluation of this change management project has allowed redirection of the process, based on initial implementation findings, as discussed throughout this chapter. In the next chapter, there will be a detailed exploration of the evaluation methods used during this project and their findings.
Chapter Four

Evaluation
4.1 Importance of Healthcare Evaluation

Evaluation means "measuring the extent to which an intervention achieves its stated objectives" (Lazenbatt, 2002, page 71), and is of utmost importance in healthcare. When a change project is implemented, evaluation is vital to ensure the planned objectives were achieved. Without planned evaluation, then it is impossible to know if the project is succeeding or failing in its intent. Health managers should strive for quality care provision (De la Harpe et al., 2008), but knowing this has been achieved is only possible by evaluating the care provided.

Healthcare interventions are also expensive and funding assigned to one intervention means there is less available for other projects. It is therefore important to know that funded interventions are achieving positive outcomes for patients and populations. Without appropriate evaluation, programmes may continue to be implemented without knowing if they are beneficial or cost-effective, as demonstrated in a recent review of large scale quality programmes (Ovretveit & Gustafson, 2003).

Ideally healthcare evaluation should be outcome driven, as the objective of healthcare provision is provision of better health for everyone (De la Harpe et al., 2008). With this in mind, the evaluation stage of this project focused primarily on patient outcomes. However, achievement of positive outcomes requires a functional process; identification of positive or negative actions and responsibilities is not
always feasible from outcome measures alone (De la Harpe et al., 2008). Therefore, evaluation of the process is also necessary to assess for potential process improvements that may affect patient outcomes.

4.2 Evaluation Methods

Patient data was collected from two cohorts during this project - pre-intervention and post-intervention. Data collection pre-intervention was retrospectively obtained from a prospectively maintained colorectal cancer database, for patients undergoing colorectal cancer resection between December 2014 and July 2015. Post-intervention data was prospectively gathered on all new patients referred to the Colorectal Cancer Multidisciplinary team (MDT) meeting and all patients undergoing elective colorectal resection between 1st January and 4th April 2016. A before-and-after design allowed comparison of the effects of the project on patient outcomes, as well as providing information on the organisation and staff (Ovretveit & Gustafson, 2003).

Data collection allowed for a quantitative comparison of patient outcomes and generation of statistical data to summarise the findings. Categorical variables were compared using Fisher’s Exact test whilst continuous variables were compared using student’s t-test. Collection of data points from each stage of the protocol also allowed for identification of non-compliance with the protocol. Reasons for non-compliance were then explored by review of these patients’ case-notes.
4.3 Evaluation Results

Evaluation of this project was performed according to the specific objectives of the project, as laid out in Chapter One. The means by which each objective was evaluated will now be discussed in turn.

Objective One - To retrospectively examine patient data to determine how preoperative correction of anaemia is currently undertaken and how successful current practice is; to determine perioperative transfusion rates; and to collate this data by 1st November 2015

As planned, a retrospective audit was performed of 95 consecutive colorectal cancer resections. There were 56 males and 39 females in the cohort. Mean age was 68.1 (±12) years. As 3 patients underwent endoscopic resections only and a further 8 patients presented as emergencies requiring surgery on their index admission, a total of 84 patients were included in the final analysis. The majority (70%) of patients underwent open procedures; 52% were rectal resections and 48% colon resections. The mean preoperative Hb level was 137.5g/L and anaemia in this cohort was defined as Hb < 115g/dL.

Timing of anaemia detection was variable across this cohort. A total of 78 patients (93%) attended POAC prior to their surgery. The mean time between
preoperative assessment and surgery was 11 (±10) days, with a range of 1-54 days. Twelve patients were identified as being anaemic at the time of their visit. A further eleven patients were noted to have been anaemic prior to their diagnosis but had been treated successfully with oral iron by the time of their attendance at the POAC. Six patients did not attend POAC and blood investigations performed elsewhere showed that three of these patients were also anaemic preoperatively. This gives a total anaemia at diagnosis rate of 31% (n=26).

Further assessment and management of anaemia was variable. Only 17 anaemic patients (65%) had a ferritin level measured to assess for iron deficiency, and no patient had a transferrin saturation level measured. One patient was found to have a folate deficient anaemia. Eleven patients had their anaemia corrected prior to their POAC appointment, predominantly with oral iron supplementation. A further three patients were prescribed oral iron at the POAC but only one achieved correction of their anaemia by their surgery date. One patient was admitted for IV iron following their POAC appointment but the infusion was given less than one week prior to surgery and their anaemia was uncorrected by their surgery date. This gave a total anaemia correction rate of just 46%, meaning fourteen patients attended for surgery still anaemic.

Mean postoperative Hb for the total cohort was 112.6g/L on Day 1 and 110.4g/L on Day 3. Patients with preoperative anaemia had significantly lower Hb readings on Day 1 and Day 3 postoperatively compared to non-anaemic patients.
Eight patients in the total cohort required postoperative transfusion; seven of these patients were anaemic preoperatively giving an odds ratio of transfusion of 24 (95% CI 2.7-210.3, \( p=0.004 \)) for anaemic patients compared to non-anaemic patients (Appendix 1, Table 2). There were no mortalities in this cohort and there was no difference in morbidity rates between anaemic and non-anaemic patients. However, anaemic patients had a longer mean length of stay at 18.8 (±11.7) days compared to non-anaemic patients at 11.1 (±8.7) days (\( p=0.042 \)).

This data was successfully collected and analysed by 1st November 2015. Data was subsequently presented to the key project stakeholders and used to generate the protocol for patient management, as now discussed in Objective Two.

**Objective Two - To use the data thus collected as a baseline from which to generate a new, standardised evidence-based protocol for preoperative anaemia detection and management in our colorectal unit, and achieve agreement with all involved parties for implementation of the protocol by 14th December 2015**

The data collected in the retrospective audit, in combination with the literature reviewed in Chapter Two, were used to generate an initial proposed pathway for patient management, as previously shown in Figure 3. This proposed pathway was presented to the colorectal departmental meeting on 23rd November 2015 and open discussion was invited to amend the pathway, as discussed previously in Chapter
Three. Suggestions from the group were used to generate the final pathway, as shown in *Figure 4*. This pathway was circulated in written form to all eight consultants for review on 16th December and a two-week review window offered.

There were no additional changes suggested by the group and complete agreement for implementation from 1st January 2016 was achieved. There was a delay in finalising the pathway due to a combination of work-related factors affecting both the change agent and key stakeholders, namely on-call emergency work commitments and annual leave. However, once commitment for implementation was achieved, successful implementation of the pathway was then prospectively evaluated as outlined under Objective Three.

*Objective Three - To increase the rate of preoperative anaemia detection and correction, via administration of intravenous iron where appropriate, for elective colorectal patients over a three month trial intervention period between 1st January 2015 and 1st April 2016*

A number of key data points were prospectively recorded for all newly diagnosed patients referred for discussion at the Colorectal Cancer MDT meeting between January and April 2016 - patient demographics, date of endoscopy, pathological diagnosis, date haemoglobin checked and result, ferritin levels and plan for surgery. Patients who were scheduled for surgery were then further assessed by collecting data on means and success of anaemia correction (where applicable),
date and type of surgery and postoperative outcomes. These results were then compared to the findings from a subgroup of the pre-intervention cohort of patients, those who underwent surgery between January and April 2015.

There were 54 new referrals to the Colorectal Cancer MDT between 1st January and 21st March 2016. Of these patients, 25 had their Hb level checked at the time of endoscopy and nine others had a Hb level checked in primary care at the time of their referral for endoscopy. A further six patients had been referred from sources external to our hospital group and four patients had benign findings at colonoscopy and therefore were not included in this analysis. This meant a total of 34 of 44 included patients (77%) had a Hb level available after endoscopy, compared to 64% in the same period in 2015 (Table 3).

Forty-eight patients underwent colorectal resection between 1st January and 4th April 2016 (post-intervention cohort), compared to 34 patients in the same period in 2015. Of these patients, 14 (29%) were anaemic at time of diagnosis, comparable to 13 patients (41%) in the first three months of 2015. Seventy-one percent of anaemic patients in the post-intervention cohort (n=10) had ferritin levels measured, compared to just 30% (n=4) of the pre-intervention cohort (p=0.05). In the post-intervention group, four patients had IV iron replacement alone, one patient had IV iron and oral iron replacement and four patients had preoperative oral iron replacement. IV iron replacement commenced a mean of 8.3 days preoperatively (range 3-15 days). Mean duration of oral iron treatment was 98.8 (±110) days.
preoperatively. Treatment resulted in a preoperative iron-deficiency anaemia correction rate of 86% and an overall anaemia correction rate of 55%. Between January and March 2015 just one of 13 patients had their anaemia corrected, a significantly lower rate of just 8% (p=0.023). Due to the lack of information on iron-deficiency rates in 2015 (lack of ferritin levels measured), a direct comparison of iron-deficiency correction was not possible.

Of 48 patients who underwent resection in 2016, 24 were female and 24 male. Mean age was 62.4 (±13.4, range 38-83) years. There were 37 colon resections, ten rectal resections and one transanal procedure, which was excluded for analysis of postoperative outcomes. Forty-four percent underwent laparoscopic procedures, with 54% being open. The mean Hb at diagnosis was 128.7g/dL. As discussed earlier, fourteen patients were anaemic at diagnosis. Six of eleven iron-deficient patients had their anaemia corrected preoperatively; three patients did not have their Hb rechecked immediately preoperatively and so their correction status was unknown. A total of five patients remained anaemic at the time of surgery, one who had been treated with oral iron, one who had a non-iron deficiency anaemia treated with preoperative transfusion and three non-iron deficient patients who were untreated.

Mean postoperative Hb for the total group on Day 1 was 109.5g/dL (±17g/dL) and Day 3 was 107.9g/dL (±18g/dL). Comparisons between anaemic and non-anaemic patients are shown in Table 4. In summary, patients with uncorrected
anaemia had significantly lower mean postoperative Hb compared to all others on both Day 1 at 93.9g/dL (p=0.001) and Day 3 at 94.9g/dL (p=0.014). Patients whose anaemia had been corrected had similar postoperative Hb rates compared to non-anaemic patients on both Day 1 (p=0.154) and Day 3 (p=0.377, Table 4). There were two postoperative transfusions in the entire cohort; one in a non-anaemic patient who had a postoperative haemorrhage requiring return to theatre to control bleeding, and one in a patient with uncorrected iron-deficiency. Overall morbidity rates were similar across all groups (Table 4). Length of stay tended to be longer in patients with uncorrected anaemia at 10 days, compared to 9.4 days for patients with corrected anaemia and 8.5 days for non-anaemic patients, although this was non-significant.

*Objective Four - To reduce the rate of immediate preoperative anaemia by at least 50% in this patient cohort when compared to the patient data collected prior to protocol implementation, by 1st April 2016*

Prospectively collected data from the post-intervention cohort of patients and retrospectively collected data from the pre-intervention cohort was used to assess this objective. Immediate preoperative anaemia rates were 16% (14 of 84 patients) in 2015, compared to 11% (5 of 45 patients) post-intervention in 2016. This gives a 31.25% reduction in immediate preoperative anaemia rates by 4th April 2016.
**Objective Five** - *To evaluate barriers to implementation of the protocol, including resource implications, during the trial implementation period and make any required adaptations to the protocol by 1st May 2016*

Barriers to implementation of the protocol were assessed by looking at reasons for non-compliance with the protocol and additional resources required to implement the protocol.

Each step of the protocol was examined to identify any patients whose pathway was not compliant and each was then assessed in more detail to evaluate reasons for non-compliance, through root cause analysis (Wilson, Dell, & Anderson, 1993). A total of 48 patients underwent colonoscopy locally, which resulted in detection of colorectal malignancy, between 1st January and 4th April 2016. Of these, fourteen patients (29%) had no bloods checked. Four patients had an unexpected finding of malignancy on biopsy and one patient was deemed clinically unfit at the time of endoscopy for any further intervention, which explained why their bloods had not been checked. This gave a total of 9 patients (18%) where the protocol was not adhered to by the endoscopist performing the colonoscopy. As a result of these findings, an additional reminder email was sent to all endoscopists, including senior trainees to request blood investigations be performed at the time of colonoscopy.
Of the patients who did have bloods sent, a further seven patients (20.5%) did not have a ferritin level checked, despite having a Hb checked. Ferritin measurement requires selection of an additional sample on the electronic blood request form and it is probable that many staff simply forget to do this, as it is not routine practice. The reminder email circulated made specific reference to requesting ferritin levels as well as a Hb as a means to hopefully increase compliance with this aspect of the protocol.

Identification of anaemic patients by colorectal nurse specialists improved as the project was implemented. Initially patients were identified by the change agent, who then liaised with the nurses and consultants to arrange IV iron infusions, where appropriate. Over time the nurses took full ownership of this role, liaising directly with the consultants and clinical pharmacists, without need for input for the change agent. Early in the project, one patient was identified as anaemic but with a high ferritin and high CRP. The change agent was contacted by the colorectal nurses to confirm the need to arrange additional testing in the form of transferrin saturation levels. Following this, the nurses reported they would feel confident to proceed with this step for future similar patients, without needing the additional support of the change agent.

Of eleven iron deficient anaemic patients identified, seven proceeded to IV iron infusions. Four patients were treated with oral iron alone, commenced in the community at the time of referral and two patients were treated with both oral and IV
iron. One patient did not proceed to surgery as palliative chemotherapy only was planned. Two patients were untreated, giving an 18% non-compliance rate with this aspect of the protocol.

Of the seven patients scheduled for IV iron, three began treatment >10 days preoperatively. One patient was treated just three days preoperatively and a further patient was treated eight days preoperatively. Two more patients who have commenced IV iron treatment are awaiting surgery dates, at the time of writing. Further attention to scheduling of infusion therapy is required to achieve full compliance with this aspect of the protocol.

Of the five patients who have already proceeded to surgery post IV iron, only two (40%) had their Hb rechecked on the day of admission to confirm correction of their anaemia. Taking of bloods on the day of admission is a responsibility of the admissions unit nurses and junior doctors. It became clear that communication with the admissions unit regarding the pathway implementation was deficient and therefore priority must now be given to raising awareness of the project amongst admissions unit staff.
Financial Implications

Resource implications were assessed by looking at the number of infusions required during the initial implementation period and potential cost savings due to reduction in anaemia rates. Of the five patients who have proceeded to surgery, a total of nine IV iron infusions was required. Each infusion costs approximately £191 (Scottish Medicines Consortium, 2011), giving a total cost of £1719 for the five patients. Each infusion also requires approximately 45 minutes of nursing time, fifteen minutes for administration and 30 minutes post infusion observation. The low rate of infusions needed meant there was less than one patient attending the ward per week for infusions, with nine infusions in eleven weeks. No additional ward staff was required to cover this commitment.

Potential cost savings from transfusion were extrapolated from pre-intervention data as there was not enough post-intervention transfusion data available. Pre-intervention data showed a 30% transfusion rate for anaemic patients postoperatively, with a mean two unit transfusion rate, which would cost £332.14 per patient (National Institute for Health and Care Excellence, 2015). If the five treated patients were untreated, a 30% transfusion rate would cost approximately £498.21. Additionally, patients with uncorrected anaemia have been shown on average to have a four day longer hospital stay, costing approximately £984 per patient (if each bed day is calculated at £246 (Joint Improvement Team, 2015)). Combined transfusion costs and extra bed days for these five patients could amount to a total
additional cost of £5418.21, if anaemia were untreated. It therefore appears on this provisional data that the costs and resource requirements for IV iron infusions are indeed, justified, with a potential cost saving of approximately £739.84 per patient. However, further prospective data is required to confirm this.

4.4 Summary

In summary, evaluation of this project has shown successful introduction of a protocol for preoperative iron-deficiency anaemia management, with resultant increase in detection of iron-deficiency anaemia and increased rates of correction of preoperative anaemia. Additional reinforcement of change is required to achieve full compliance with the protocol. Based on the data collected it is likely that full implementation of this protocol will result in reduced perioperative transfusion rates and potentially result in cost savings for the organisation. These findings will now be discussed further in Chapter Five.
Chapter Five

Discussion
5.1 Introduction

As shown in Chapter Four, implementation of this project was successful in meeting its overall aim to implement a preoperative anaemia management protocol for elective colorectal surgery patients, in order to reduce the rate of perioperative iron-deficiency anaemia and its effect on patient outcomes. In this chapter, the organisational impact of this change project will be discussed in more detail, particularly the means by which organisational change was introduced and how change management has enabled our patient outcomes to match those reported in the literature. In addition, strengths and limitations of the project will be discussed, with recommendations made for future practice.

5.2 Organisational Impact of Introducing Change

Introduction of the preoperative anaemia management pathway required cooperation amongst multiple members of the multi-disciplinary team, as discussed earlier in Chapter Three. As a result of this, team member interactions increased and ownership of the pathway was shared across different disciplines. There was shared unity of purpose across medical, nursing and pharmacist staff and strong cross-disciplinary bonds were forged as a result of the pathway. This improved team cohesiveness could potentially have effects far beyond this project, as good
multidisciplinary team working is vital for improving many patient outcomes. A team which has an integrative vision, working closely together in a safe climate can overcome some of the social categorization problems identified in other multidisciplinary teams (Fay, Borrill, Amir, Haward, & West, 2006).

Implementation of this project required constant evaluation of progress and adaptation of the project when necessary. An organisational development project must be a fluid process, with an ability to change direction when organisational factors require this (Senior & Swailes, 2010). Our initial plan had been to use the POAC as the point of detection of iron-deficiency anaemia in our patients. POACs have been introduced in order to identify and correct patient problems which may affect their outcome from surgery, preoperatively (A. F. Edwards & Slawski, 2016). However, it became clear from our initial data that the majority of colorectal cancer patients attend POAC within eleven days of planned surgery. Identification of anaemia at this point in time would not allow adequate time for administration of IV iron, which should be given at least two weeks preoperatively (Kotzé, Carter, & Scally, 2012). When preoperative pathologies are identified in patients undergoing benign surgery, it is feasible to reschedule their surgery at a later date to allow further assessment or treatment of identified pathologies. However, in the case of colorectal cancer, timing of treatment is key due to the risks of disease progression. Additionally, Scottish government targets require that definitive cancer treatments begin within set timeframes from the time of referral (The Scottish Government, 2016). It became clear that identifying iron-deficiency anaemia at an earlier point in the patient pathway was necessary to allow time for preoperative IV iron infusions,
without delaying patient time to surgery. As a result of this, the pathway was
adjusted to use the endoscopy appointment as the point of detection of iron-
deficiency anaemia in patients diagnosed with colorectal cancer.

Use of endoscopy for detection of anaemia required further cross-specialty
collaboration for the success of this project. Expansion of the pathway to include the
patient's endoscopy visit drew further staff members into the process. Many of our
patients' colonoscopies are performed by nurse endoscopists who are not generally
involved in the patient pathway beyond the point of colonoscopy. When asking
endoscopists to request additional investigations for patients it was important to have
clear responsibility for managing the results of these investigations. Handover of
care from one medical professional to another has been associated with test follow-
up errors (Moore, Wisnivesky, Williams, & McGinn, 2003). As the endoscopists
already communicate new diagnoses at colonoscopy to the colorectal nurse
specialists, it was deemed appropriate that the colorectal nurse specialists would
follow both the biopsy results, as was the usual case, and the blood results. As the
nurses would already be liaising with the consultant surgeon for treatment planning,
it was felt the additional checking of blood results would merely be a widening of
their pre-existing role and indeed the nurses were happy to develop their role in this
manner, as has been shown previously to be the case with expanded nursing roles
(Magennis, Slevin, & Cunningham, 1999).
As with all organisational development projects, it became clear as the project progressed how important it was to communicate well with all staff members who deal with patients at various stages of the pathway. Initially, communication and involvement was focused on key stakeholders, namely consultants, nurse specialists, pharmacy and endoscopists. However, omission of inclusion of other staff members had effects on implementation of the pathway. As shown in Chapter Four, some patients who did not have bloods checked at colonoscopy had had their colonoscopy performed by a trainee. Also, repeat blood investigations were not performed for all at the time of admission for surgery, reflecting lack of awareness amongst staff on the admissions unit. It can be easy to focus attention on high interest, high-importance stakeholders when implementing a project. However, neglect of low-interest, low-importance groups (Figure 5) can affect the overall success of the project and must be borne in mind.

5.3 Patient Outcomes as a Result of the Change Project

As demonstrated in Chapter Four, implementation of this pathway succeeded in correcting iron-deficiency in 86% of iron-deficient patients and reducing overall immediate preoperative anaemia rates from 16% to 11%. As discussed previously in Chapter Two, it is beneficial to correct iron-deficiency anaemia preoperatively and this can be achieved through use of oral or IV iron, or both. Our findings lend further support to much of which has already been reported in the literature.
Cohort studies to have shown correction of anaemia preoperatively to be associated with reduced perioperative transfusion rates (Calleja et al., 2015; Keeler et al., 2016; Lasocki et al., 2015) and shorter hospital stays (Calleja et al., 2015; Myers et al., 2004). Our pre-intervention data showed a significantly higher risk of transfusion for patients with preoperative anaemia compared to non-anaemic patients, with anaemic patients twenty-four times more likely to require postoperative transfusion. Unfortunately, the number of patients in our post-implementation analysis is too small to assess for a difference in transfusion rates. However, the overall postoperative transfusion rate in this cohort was just 4% (two patients), compared to an overall postoperative transfusion rate of 10% in the pre-intervention cohort. This suggests implementation of our pathway may have an effect on transfusion rates; ongoing data collection is required to support this. With regard to length of stay, there is a trend toward longer length of stay in patients with uncorrected anaemia, compared to those with corrected anaemia or non-anaemic patients. Similarly, in the pre-intervention cohort, patients with uncorrected anaemia had significantly longer lengths of stay than non-anaemic patients. The exact reasons for these prolonged lengths of stay are unclear and are likely to be multifactorial rather than solely related to anaemia. However, similar results have been reported in the literature (Calleja et al., 2015; Kotzé et al., 2012; Myers et al., 2004). Anaemia alone hasn’t been shown to be an independent predictor of longer hospital stay and may be a marker of associated patient comorbidities, which affect postoperative recovery. Indeed, anaemia has been shown to be associated with overall poorer health and increased adverse outcomes in older people (Guralnik, Eisenstaedt, Ferrucci, Klein, & Woodman, 2004). Nevertheless, identification and
treatment of anaemia is to be recommended, in view of its contributory effect to reduction of hospital stay and the costs associated with this.

Correction of iron deficiency can be through oral or IV iron. We elected to use IV iron in our protocol due to its quicker onset of action (Rineau et al., 2014), which was important for cancer patients being scheduled for surgery. However, some patients were prescribed oral iron by their GP prior to undergoing colonoscopy and therefore were treated with oral rather than IV iron. A number of patients from both treatment groups succeeded in correcting their anaemia levels. Of five patients treated with IV iron, two patients treated more than 10 days before their surgery had their anaemia corrected by the time of their surgery. Treatment commenced a maximum of 15 days preoperatively, allowing a relatively short duration of treatment to correct anaemia. Unfortunately, the third patient who was treated >10 days preoperatively did not have a Hb check on admission. Duration of treatment with oral iron varied from 67 to 289 days in three patients whose anaemia was fully corrected by the time of surgery. A fourth patient treated externally with oral iron did not have their anaemia fully corrected by the time of surgery. Although the numbers here are small, our findings support those in the literature that IV iron corrects anaemia quicker than oral iron replacement (Rineau et al., 2014). Additionally, our findings support findings that IV iron within just 2 weeks of surgery can correct iron-deficiency anaemia (Kotzé et al., 2012). Therefore, our protocol requirement for IV iron treatment to begin at least 10 days preoperatively will continue as we collect more data in the future.
5.4 Strengths and Limitations

This project has a number of strengths. Firstly, an appropriate organisational development model was applied (Senior & Swailes, 2010), which allowed for continual adjustment of the project in line with organisational needs. The flexibility of the pathway design meant that the project developed as it was implemented. This resulted in immediate changes being made to the action plan when it was identified that previous plans would be unsuccessful. Potential time losses were thus avoided by not following original plans until a planned evaluation point.

Secondly, prospective data collection allowed for accurate evaluation of the outcomes. A complete dataset was collected on all affected patients post-implementation of the protocol. This provided robust data for the evaluation component of the project.

Finally, the pathway is generalisable in that it could be applied to other patient groups that are diagnosed with surgical conditions at the endoscopy unit, such as oesophageal, gastric, pancreatic and lung cancer patients. Use of the endoscopy unit to identify anaemia in these patients could also help streamline their future treatment.
There were also a number of limitations to this project. Use of the endoscopy unit to identify anaemia limits the pathway's usefulness to patients with malignancy. However, the principles of the pathway could also be applied to patients with benign conditions, with some minor adjustments. Patients with benign conditions scheduled for major surgery could have their Hb checked at the outpatient clinic or POAC and the same principles of iron-deficiency correction applied. As benign conditions do not require such prompt scheduling of surgery, there is less time pressure to make the diagnosis of anaemia as early in the patient pathway.

Another limitation of the project is that the protocol has only been applied in our own endoscopy units. This means that external referrals to our unit for surgery will likely not have had their Hb checked and therefore identification of their anaemia will occur at a later stage in their patient journey. This could be improved in the future by extending the preoperative anaemia management protocol to all hospitals within the health board region, to standardise the assessment and management process.

Finally, because of the short duration of implementation, only a small number of patients have progressed through the entire pathway and beyond their surgery. This means there is limited data available on postoperative outcomes to date. However, the project has succeeded in reaching its target of reducing preoperative anaemia rates and further data collection is planned to assess impact on perioperative transfusion rates.
5.5 Recommendations for future improvements

In view of the above findings, the following recommendations for future implementation of the pathway have been made:

- Ensure dissemination of information to all staff members in all departments involved with care of perioperative colorectal cancer patients, to ensure all aspects of the pathway are implemented

- Addition of the IV iron prescribing protocol to the drugs and therapeutics handbook to consolidate the pathway as normal practice in our unit

- Expansion of the pathway to other surgical conditions diagnosed in the endoscopy unit, to ensure appropriate early identification of anaemia in these patients

- Ensure sustainability of the project into the future by reassigning some of the support roles in the action plan to permanent staff and reduce reliance on the change agent for implementation
5.6 Conclusion

This organisational development project has successfully introduced a preoperative anaemia pathway, which has resulted in increased rates and earlier detection of iron-deficiency anaemia in colorectal cancer patients, increased rates of preoperative iron-deficiency treatment and reduced preoperative anaemia rates in this cohort of patients. It has done this through development of a multidisciplinary working group and frequent evaluation and reorganisation of the process. Continued implementation of this project will lead to further positive effects for this patient population and plans are now in place to broaden the inclusion criteria for the pathway. This should hopefully lead to improved patient outcomes for an even greater population of surgical patients in our organisation.
References


Appendix 1

Tables and Figures
**Figure 1:** Organisational Development Process as outlined by Senior & Swailes, in diagrammatic form. The change agent is central to facilitation of all stages of the change process. (Senior & Swailes, 2010)

<table>
<thead>
<tr>
<th>Factor Identified</th>
<th>Implication</th>
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<tr>
<td><strong>Political</strong></td>
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<tr>
<td>• Government targets for treatment times ¹</td>
<td>• There is a need to identify factors which may delay surgery in a timely fashion, to ensure target treatment times can be met</td>
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<td><strong>Economic</strong></td>
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<tr>
<td>• Shorter hospital stays are less costly per patient</td>
<td>• Reducing hospital stays reduce costs</td>
</tr>
<tr>
<td>• Transfusions are costly ²</td>
<td>• Reducing transfusion rates reduce costs</td>
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<tr>
<td>• IV iron is also expensive ³</td>
<td>• Costs may not offset benefits</td>
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<td><strong>Social</strong></td>
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<td>• Patients have improved knowledge and increased expectations of best outcomes</td>
<td>• Need to optimise patient treatment to meet expectation</td>
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<td>• Patient knowledge of risks of transfusion</td>
<td>• Need to avoid unnecessary transfusions</td>
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<td><strong>Technological</strong></td>
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<td>• Development of new intravenous (IV) iron preparations</td>
<td>• Allows shorter and safer administration of IV iron ⁴</td>
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<tr>
<td><strong>Legal/Ethical</strong></td>
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<td>• Need to avoid potentially harmful treatments of there is a safer alternative</td>
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<td><strong>Environmental</strong></td>
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<tr>
<td>• Blood stocks and availability</td>
<td>• Blood is a precious resource and must be used appropriately ⁵</td>
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</table>
Figure 2: High level process map of pre-existing patient flow from point of referral to surgery for colorectal cancer. As demonstrated, patients have a full blood count (FBC, including haemoglobin levels) performed at various stages in the process in a rather haphazard fashion. Similarly, treatment of iron-deficiency is non-uniform and some patients present for surgery with iron-deficiency anaemia. Timing of investigations prior to surgery is also widely variable.
Figure 3: Initial draft proposed patient pathway for detection and management of preoperative iron-deficiency anaemia (Hb = haemoglobin, CRP = C reactive protein, IV = intravenous)
**Figure 4:** New patient pathway for detection and management of iron-deficiency anaemia in colorectal cancer patients (see explanatory notes below)

1. **Endoscopic appearances of colorectal malignancy**
2. **Endoscopist requests check FBC, CRP and serum ferritin on day of colonoscopy**
3. **Referral to Colorectal Service and Colorectal Cancer Nurse Specialists notified**
   - If Hb <11g/dL AND Ferritin is <30ug/dL
   - If Hb <11g/dL and Ferritin is >30ug/dL but CRP is elevated
   - If Hb >11g/dL or there is no evidence of iron deficiency
     - Check transferrin saturation
     - If transferrin saturation <20%
     - Responsible consultant notified; **if surgery planned** then admission arranged for IV iron\(^a,b\)
     - Admission to Ward 66 10-14 days before surgery for first IV iron infusion\(^c\) and 3-7 days before surgery for second infusion; to coincide where possible with pre-operative assessment appointment\(^d\)
   - Consider check B12 and Folate if anaemic and replace if appropriate
4. **Proceed with surgery as planned with repeat Hb on admission**
Explanatory Notes

a  IV iron admission should only be arranged when it has been confirmed the patient will be undergoing surgery; this generally means awaiting results of staging investigations. Where possible, surgery should be scheduled two weeks from the time of decision to proceed, to allow correction of anaemia in iron-deficient patients.

b  Contraindications to IV iron are dialysis-dependent renal failure, iron-overload induced hepatic dysfunction and previous hypersensitivity to IV iron.

c  The vast majority of patients will require 2 separate doses of IV iron to fully replenish their iron stores. In rare cases, where the patient weighs less than 40kg and their Hb is <10g/dL they will require three doses, a week apart. Ideally, in a two dose regimen, the first dose should be given 14 days before surgery. However, some studies have commenced IV iron treatment within 10 days of surgery. Each Ferinject infusion takes a minimum of 15 minutes and requires 30 minutes of observation post infusion. No test dose is required with Ferinject.

d  In order to minimise patient visits to the hospital, where possible, attempts should be made to schedule an IV iron appointment on the same day as the patient's preoperative assessment clinic appointment.
Figure 5: Stakeholder analysis - Assessment of relative power and interest of various staff members involved in management of preoperative iron deficiency anaemia
**Figure 6**: Responsibility Chart - This chart identifies which team member is responsible for each action required for implementation of the organisational development project (CA = change agent, CS = consultant surgeons, Ph = pharmacist, E = endoscopist, CNS = colorectal nurse specialists, T = trainee doctors, WN = ward nurses, R = responsible person, S = support, A = authority figure required to approve action, I = person to keep informed about the action)

<table>
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<tr>
<th>Step</th>
<th>CA</th>
<th>CS</th>
<th>Ph</th>
<th>E</th>
<th>CNS</th>
<th>T</th>
<th>WN</th>
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<td>I</td>
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<td>2. Obtain patient blood samples at time of colonoscopy</td>
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<td></td>
<td></td>
<td>R</td>
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<tr>
<td>3. Review bloods and identify iron-deficiency anaemia</td>
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<td>I</td>
<td></td>
<td></td>
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<td></td>
<td>R</td>
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<td>4. Identify patients suitable for IV iron infusion</td>
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<td>R</td>
<td>I</td>
<td>S</td>
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<td>5. Provide information to patients regarding IV iron</td>
<td>S</td>
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<td>S</td>
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<td>I</td>
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**Table 2:** Data from Pre-Intervention Audit - Data represented shows mean values for Haemoglobin (Hb) levels immediately preoperatively and on days 1 and 3 postoperatively, as well as overall transfusion, morbidity and mortality rates and mean length of hospital stay. Anaemic patients are compared to patients who were never anaemic or had their anaemia corrected preoperatively. NS = Non-significant

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Anaemia (n=22)</th>
<th>Corrected Anaemia &amp; Non-Anaemic (n=62)</th>
<th>Significance (p-value)</th>
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<tr>
<td>Mean Preoperative Hb</td>
<td>103.3g/dL</td>
<td>136.2g/dL</td>
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<tr>
<td>Mean Day 1 Hb</td>
<td>99.9g/dL</td>
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<td>Mean Day 3 Hb</td>
<td>97.9g/dL</td>
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<td>Transfusion Rate</td>
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<td>2%</td>
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<td>Morbidity Rate</td>
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<td>Mortality Rate</td>
<td>0%</td>
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<tr>
<td>Mean Hospital Stay</td>
<td>18.8 days</td>
<td>11.1 days</td>
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Table 3: Point of Detection of Anaemia Pre- and Post-Intervention

This table demonstrates at what point in time patients referred for elective colorectal cancer resection underwent Haemoglobin (Hb) testing. A comparison is made between patients referred between January and March 2015 versus January and March 2016, showing increased use of endoscopy as the point of detection of anaemia.

<table>
<thead>
<tr>
<th>Hb Tested by</th>
<th>Pre-Intervention Jan-March 2015 (n=25)</th>
<th>Post-Intervention Jan-March 2016 (n=43)</th>
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<tr>
<td>GP/Referral Point</td>
<td>7 (28%)</td>
<td>9 (21%)</td>
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<td>Endoscopy</td>
<td>9 (36%)</td>
<td>25 (58%)</td>
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<tr>
<td>POAC</td>
<td>9 (36%)</td>
<td>9 (21%)</td>
</tr>
<tr>
<td>On admission</td>
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</table>
Table 4: Post Intervention Results

A comparison is shown of Haemoglobin (Hb) levels pre-operatively (preop) and postoperatively on Days 1 and 3, for patients who were never anaemic, had their anaemia corrected, a combination of never anaemic and corrected anaemia, and patients who had uncorrected anaemia. Patients with anaemia had significantly lower starting Hbs but only patients with uncorrected anaemia had significantly lower postoperative Hbs, showing a corrective effect of iron replacement preoperatively on postoperative Hb levels. There were no significant differences shown in transfusion rates, perioperative morbidity and mortality rates or length of stay. (NS = non-significant)

<table>
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<th>Outcome</th>
<th>No anaemia (n=34)</th>
<th>Corrected anaemia (n=6)</th>
<th>p</th>
<th>No anaemia + Corrected anaemia (n=40)</th>
<th>Uncorrected anaemia (n=5)</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Mean Preop Hb</td>
<td>140g/dL</td>
<td>116.7g/dL</td>
<td>NS</td>
<td>131.3g/dL</td>
<td>96g/dL</td>
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<td>Mean Day 1 Hb</td>
<td>114g/dL</td>
<td>103.4g/dL</td>
<td>NS</td>
<td>113.1g/dL</td>
<td>93.8g/dL</td>
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<tr>
<td>Mean Day 3 Hb</td>
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<td>Morbidity</td>
<td>20%</td>
<td>20%</td>
<td>NS</td>
<td>20%</td>
<td>11%</td>
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<tr>
<td>Mortality</td>
<td>0</td>
<td>0</td>
<td>NS</td>
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<td>Mean stay</td>
<td>8.5 days</td>
<td>9.4 days</td>
<td>NS</td>
<td>8.6 days</td>
<td>10 days</td>
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Appendix 2

IV Iron Information Leaflet for Patients
Warning

Iron infusions (IV iron) can cause allergic reactions. In a small number of patients, these allergic reactions can become severe or life-threatening and can cause problems with your heart and blood pressure and/or cause you to faint or lose consciousness.

You should not be given IV iron if:
- you are allergic to the product or any other ingredients in the medicine
- you have experienced serious allergic (hypersensitive) reactions to other IV iron treatments in the past
- your anaemia is not caused by iron deficiency
- you are pregnant (or think you could be pregnant)

You should contact your Doctor or Nurse immediately if:
- you have any signs or symptoms of an allergic reaction during or shortly after your treatment
- examples of such symptoms include hives, rash, itching, dizziness, light-headedness, swelling of the lips, tongue or throat, difficulty breathing, shortness of breadth or wheezing

Having an Iron Infusion — Information for Patients

Please read this leaflet carefully and discuss any questions with your doctor or nurse

Contact Information
If you have any questions about your appointment for your iron infusion than you can contact your colorectal nurse specialist on 0141 222 0002.

We have arranged for you to attend our ward as your blood results have shown that you have iron deficiency anaemia: a lack of iron in the body. Iron is used to produce red blood cells, which help store and carry oxygen (necessary for life) in the blood. If you have fewer red blood cells than normal, your organs and tissues won’t get as much oxygen as they usually would.

What is an iron infusion?

Treatment of iron deficiency anaemia usually involves taking iron tablets. Sometimes your body does not respond to iron tablets quickly enough. If your doctor thinks it is necessary to increase your iron levels faster, such as prior to an operation, we can replace your iron through an iron infusion which will increase your iron levels much quicker than tablet form.

An iron infusion means replacing iron through a drip inserted into your vein.

An iron infusion is not a blood product or a blood transfusion.

Infusion Procedure

IV iron (Ferinject) can be given on the day ward.

When you arrive the nurse will take your pulse, blood pressure, temperature, weight and height. One of the doctors or nurses will put a drip in your arm and then start the infusion. The infusion will take about 19 minutes.

You will need to remain on the ward for at least 30 minutes after the infusion has finished. The nurse will check your pulse, blood pressure, and temperature again.

Some patients will need to return again for a second iron infusion to fully replenish their iron stores. Your doctor will arrange for this if required.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Potential side effects include:

- Headache
- Dizziness
- Rash
- Nausea and vomiting
- Abdominal pain
- Muscle cramps
- Diarrhoea
- Constipation
- Abnormal liver function
- Low or high blood pressure
- Injection site reactions
Appendix 3

Gantt Chart for Project
**Gantt Chart outlining Timeline of Project:** Coloured boxes delineate the months when various tasks related to project implementation were completed.

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Appendix Four

Poster Presentation
Perioperative Anaemia Management in Colorectal Surgery
Edel Marie Quinn – Student Number 14108844

Introduction & Background

Anaemia is common at the time of diagnosis of colorectal cancer and is most often due to iron deficiency. Correction of anaemia preoperatively has been shown to reduce perioperative transfusion rates, perioperative morbidity and even mortality.1

Preoperative iron supplementation results in higher preoperative haemoglobin (Hb) levels in patients with iron deficiency anaemia. Intravenous (IV) iron has a quicker onset of action than oral iron supplementation and thus is attractive for use in colorectal cancer patients, as surgery must proceed within a short timeframe. Iron deficiency must be identified early in the patient pathway, to ensure there is enough time to correct it prior to surgery.

Aims & Objectives

The aim of this project was to implement a preoperative anaemia management protocol for elective colorectal surgery patients.

The objectives were to:-

1. Determine how preoperative correction of anaemia is currently undertaken and how successful current practice is
2. Use the data thus collected to generate an evidence-based protocol for preoperative anaemia detection and management in our unit
3. Increase the rate of preoperative anaemia detection and correction in elective colorectal patients over a three month intervention period
4. Reduce the rate of immediate preoperative anaemia by 50% in this patient cohort
5. Evaluate barriers to implementation of the protocol

Methodology

This project was undertaken using the Senior and Swales Organisational Development (OD) model (Figure 1) as the project template. Figure 1: OD Model

Using data on current unit practice and evidence-based best practice, a new patient pathway for early diagnosis and management of iron-deficiency anaemia preoperatively was developed and implemented (Figure 2).

Figure 2: New Patient Pathway

- Malignancy at endoscopy
  - FBC, CRP, Ferritin checked
  - Iron deficiency anaemia detected
  - If surgery is planned → IV iron infusion
  - Iron infusion 210 days pre surgery
  - Recheck Hb at admission for surgery

Organisational Impact

Detection and treatment of anaemia at an earlier stage in the colorectal cancer patient journey was achieved through collaborative team working across the different disciplines involved in the patient pathway. As a result, a new model for patient management has been adopted into routine practice.

Evaluation

Key results are summarised in Tables 1 and 2.

Table 1: Anaemia detection occurred at an earlier point in the patient pathway following implementation of this protocol

<table>
<thead>
<tr>
<th>Hb Tested by</th>
<th>Pre-Intervention Jan-March 2016 (n=50)</th>
<th>Post-Intervention Jan-March 2016 (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBP Referral</td>
<td>79 (82%)</td>
<td>93 (92%)</td>
</tr>
<tr>
<td>Hb</td>
<td>9.3 (9.0)</td>
<td>9.8 (9.4)</td>
</tr>
<tr>
<td>Preoperative</td>
<td>Assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9.0 (9.2)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Post Implementation, Group B (uncorrected anaemia), had significantly lower pre- and post-operative Hb levels compared to Group A (Non-anaemic and corrected anaemia)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>(n=40)</th>
<th>(n=40)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Preop Hb</td>
<td>133.3g/dL</td>
<td>156.5g/dL</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean Day 1 Hb</td>
<td>113.1g/dL</td>
<td>91.3g/dL</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean Day 3 Hb</td>
<td>111.3g/dL</td>
<td>94.6g/dL</td>
<td>0.014</td>
</tr>
<tr>
<td>Transfusion rate</td>
<td>1</td>
<td>1</td>
<td>N.S.</td>
</tr>
<tr>
<td>Mean stay</td>
<td>8.5 days</td>
<td>10 days</td>
<td>N.S.</td>
</tr>
</tbody>
</table>

Immediate preoperative anaemia rates were reduced by 32%, from 16% to 11%, post protocol implementation. Overall transfusion rates also decreased, from 10% to 6%.

Conclusion

This project has lead to earlier detection of iron-deficiency anaemia in colorectal cancer patients, increased preoperative iron-deficiency treatment and reduced preoperative anaemia rates. Plans to broaden inclusion criteria should lead to improved patient outcomes for even more surgical patients in our organisation.

References