1)Using Statistical Process Control to Monitor Anastomotic Leak

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1.1. Abstract

Background

Surgery remains a cornerstone in the treatment of bowel diseases, such as those involving cancer or inflammation. In the majority of patients, a section of bowel is resected and the remaining bowel is re-joined surgically using sutures or staples (bowel anastomosis). However, in some cases this anastomosis can break down (Anastomotic Leak (AL)), causing significant complications for the patients including increased mortality, prolonged hospital stay and worse cancer outcomes. Despite the significance of this complication most hospitals do not prospectively measure their leak rate or engage in activities to reduce it. Another key postoperative outcome which can act as a surrogate marker of performance is Postoperative Length of Stay (PLoS)

One way to address this is to promote the use quality improvement (QI) methodologies such as Statistical Process Control (SPC). This involves mapping the data points in time order and seeing if the process is stable between a set of upper and lower parameters (i.e. confidence intervals) and observing whether there has been a statistical change.

Methods

The aim of this study was to retrospectively map AL rates and PLoS using Statistical Process Control at Royal Devon and Exeter Foundation NHS Trust. This was to provide a baseline measurement as part of the first phase of a QI project as well as investigating the suitability for SPC chart analysis for monitoring postoperative outcomes. All patients undergoing colorectal resections with ileo-colonic, colo-colonic colorectal, colo-anal or ileo-anal anastomoses from 01//01/2010 to 30/04/2017 were included in this study. AL

was defined as cases where there was subsequent return-to-theatre, radiological drainage or medical management of the AL. SPC charts were used to map AL rates to establish whether variation in the rate over time was due to “common-cause variation” or “special-cause variation.” The G-Chart, a type of SPC chart used to count the number of events between rare incidents was used to map AL. I-Charts were used to map median monthly Postoperative Length of Stay (PLoS).

Results

The AL rate is relatively low at this hospital with a return-to-theatre rate of 4.3% and an overall rate of 6.1% (once conservatively managed ALs and radiologically drained leaks were included). The overall median PLoS was 6 days. The SPC charts show that there is a reasonable chance of special cause variation for the Elective, Stapled and Right-sided AL charts, with some overlap with the former two categories. SPC charts for Sutured ALs and Left-sided ALs both only exhibited common cause variation. SPC charts for all six sub-groups monitoring PLoS indicated periods of special cause variation.

Discussion

In terms of the AL rate, 4.3% is a very acceptable return-to-theatre rate in line with other studies. The rate of 6.1% is difficult to interpret given that not all cases of medically managed ALs would have been identified. The overall median PLoS was also consistent with the literature.

This is the first phase of a QI project to reduce rates of AL at Royal Devon and Exeter Foundation NHS Trust which can now take place prospectively and an intervention can be planned and implemented. Also, now that the methodology is in place, SPC charts can also be used to ensure patient safety over time, acting within a Quality Assurance context.

Despite their ability to identify retrospective periods of SCV, the findings in SPC charts monitoring AL and PLoS will now need to be corroborated with the historial clinical context as SPC charts cannot identify which factors have caused the shift. In summary, this dissertation demonstrates that using SPC charts are a feasible methodology to retrospectively map AL and PLoS rates in a Colorectal Unit.

1.2. Contents

1.3. List of Figures

1.4. List of Tables

1.5. Author's Declaration

I certify that all the material in this dissertation which is not my own work has been identified and no material is included for which a degree has been previously conferred on me.

Total Word Count: 20424

1.6. Abbreviations

- Anastomotic Leak – AL
- Antiretroviral therapy – ART
- American Society of Anaesthesiologists - ASA
- Association of Surgeons of Great Britain and Ireland - ASGBI
- C-Reactive Protein – CRP
- Clinical Document Management – CDM
- Common Cause Variation – CCV
- Cumulative Summation Chart - CUSUM chart

- Enhanced Recovery After Surgery – ERAS
- Exponentially Weighted Moving Average - EWMA
- Healthcare Database Advanced Search – HDAS
- Health Research Authority – HRA
- Individuals Chart – I Chart
- Inflammatory Bowel Disease - IBD
- International Study Group of Rectal Cancer - ISREC
- Interrupted Time Series – ITS
- Lower control limit – LCL
- National Bowel Cancer Audit - NBOCA
- National Health Service - NHS
- National Institute of Healthcare Excellence – NICE
- Nil per os - NPO
- Office of Population Censuses and Surveys – 4.7 - OPCS-4.7
- Picture Archiving and Communication System – PACS
- Postoperative Length of Stay - PLoS
- Plan-Do-Study-Act cycle - PDSA cycle
- Quality Assurance - QA
- Quality Improvement – QI
- Randomised-control-trial – RCT
- Range chart – (R) chart
- Return-to-theatre - RTT
- Selective Decontamination of the Digestive Tract - SDD
- Sequential Probability Ratio Test – SPRT
- Sigma Chart – (S) chart
- Special Cause Variation – SCV
- Standard Deviation - SD
- Statistical Process Control – SPC
- Surgical site infection - SSI
- Ulcerative Colitis – UC
- Upper control limit – UCL

1.7. Glossary

- Anastomotic leak – leak of luminal contents (such as faecal material) from a surgical join (1)
- Common cause variation – variation as a result of random causes (2)

- Geometric (G)-Chart – a type of Statistical Process Control chart based on the geometric distribution designed to monitor rare events. (3)
- Individuals (I) chart – SPC chart used to monitor variables data.(4)
- Intestinal anastomosis - a section of bowel is resected and the remaining bowels are re-joined (5)
- Quality improvement - a systematic, formal approach to the analysis of practice performance and efforts to improve performance. (6)
- Special cause variation – variation as a result of assignable causes
- Statistical Process Control – an analytical technique used to plot data over time. It allows the user to understand variation in a process.(7)

1.8. Acknowledgements

Firstly I would like to thank my Mom, Dad and my sister Jasmine. I would also like to thank my supervisory team, Rob Bethune, Ian Daniels, Neil Smart and Iain Lang. I learnt lessons from them about work and life that I will take with me in the future. I would also like to thank medical students, Susannah Kingsbury, Robert Clowes and Shriyam Patel who assisted with data collection. I would also like to thank Royal College of Surgeons (London) who provided an invaluable grant that allowed this research to be possible.

1.9. Grants

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1.10. Posters

“Using Quality Improvement Methodology to reduce Anastomotic Leak Rate” N Thakral, RN Clowes, SF Kingsbury, S Patel, HE Sellars, RM Bethune. Presented at Association of Surgeons of Great Britain and Ireland (ASGBI) International Surgical Congress, 3-5th May 2017, Glasgow.

“Using quality improvement methodology to monitor the rate of left-sided and right-sided anastomotic leak” N Thakral, RN Clowes, SF Kingsbury, S Patel, F McDermott, NJ Smart PhD, I R Daniels FRCS, RM Bethune FRCS. Presented at European Society of Coloproctology (ESCP) 12th Scientific Annual meeting, 20-22nd September 2017, Berlin.

2)Introduction

1.11. Introduction and Dissertation Outline

“The goal is to turn data into information and information into insight.”

Carly Fiorina (8)

Background and rationale for project

Surgery remains a cornerstone in the treatment of bowel diseases, such as those involving cancer or inflammation. In the majority of patients, a section of bowel is resected and the remaining bowels are re-joined (bowel anastomosis). Several hundred intestinal resections are carried out every week in the UK and in the vast majority an anastomosis is formed; the bowel ends are joined together surgically, using sutures or staples. (5) However, these anastomosis can break down (Anastomotic Leak (AL)), causing significant complications for the patients including an increased rate of mortality, increase in cancer recurrence rates and prolonged postoperative length of hospital stay. (9-11) It is currently still difficult to predict why anastomoses leak. (12)

Despite the significance of this complication, most hospitals do not prospectively measure their leak rate or engage in activities to reduce it. Many research studies have evaluated different methods to reduce the leak rate and several centres have done retrospective audits for quality assurance purposes. A possible method of looking at anastomotic leaks is by using Quality Improvement (Q) methodologies such as Statistical Process Control (SPC). This involves mapping the data points in time order and seeing if the process is stable between a set of upper and lower parameters. Then interventions can be planned and implemented whilst prospectively measuring the leak rate and analysis the data to see if a statistically significant change has occurred. Another key postoperative outcome is “Postoperative Length of Stay,” the length of time a patient stays in hospital after their operation, this can also act as an indicator of the effectiveness of care. (13)

One type of SPC chart, which was used in this dissertation, is a G-Chart that measures the number of cases in between significant events (in this case AL). Often a similar concept is described in common parlance when monitoring adverse outcomes in factories, there being an awareness of the “days since last accident.” Another type of SPC chart known as an I chart (see “Types of SPC chart” in “1.14 Quality Improvement” for more information) was used to map Postoperative Length of Stay.

Using SPC Charts to map Anastomotic Leak and Postoperative Length of Stay can provide a prospective, easy-to-maintain methodology to monitor the rate of AL. After the baseline rate has been mapped, an intervention can be subsequently implemented to test whether it makes a change.

Dissertation outline

In **“Part 1,”** the Table of Contents are outlined, in **“Part 2”** the key concepts regarding AL and SPC are outlined, as well as a literature review of SPC charts in Surgery. In **“Part 3”** the methodology regarding the use of SPCs is outlined, in **“Part 4”** the results are outlined and in **“Part 5”** the discussion regarding the colorectal resections and SPC data are discussed and future perspectives are given.

1.12. Colorectal Surgery

To assess the patient's physical status before surgery, a five-point classification system was created by the American Society of Anaesthesiologists (ASA); "ASA I" is a normal healthy patient; "ASA II" is a patient with mild systemic disease; "ASA III" is a patient with severe systemic disease and "ASA IV" is a patient with severe systemic disease that is a constant threat to life.(14) The risk of postoperative complications closely relates to the ASA grade. (15)

There are several operations commonly carried out in Colorectal departments. These include right hemicolectomies (a procedure where a portion of the distal ileum, the caecum, ascending colon and the transverse colon to the right of the middle colic artery is removed. (16) There are also Extended right hemicolectomies (this expands a right hemicolectomy to include the transverse colon over the splenic flexure). Left-sided resections include the sigmoid colectomy (removal of the sigmoid colon) (17) as well as the anterior resection of the rectum, where part or the whole of the rectum is removed along with sigmoid colon). (18)

In many cases where intestinal resection is carried out, the remaining two ends of bowels are joined to restore intestinal continuity. The word anastomosis derives from the Greek words for mouth, stoma and against, ana. Anastomosis therefore means "against mouth" or "mouth to mouth" in modern parlance. It refers to the apposition of two hollow organs and joining them together. It can apply to organs of the digestive tract (e.g. stomach to jejunum), the urinary tract (e.g. ureter to bladder), as well as to blood vessels (e.g. vein graft to artery).(19)Intestinal anastomoses include small bowel-to-small bowel, small bowel-to-colon (ileocolic), colon-to-colon (colo-colonic), colon-to-rectum (colorectal), and small bowel to-rectum (ileorectal).(20) A variety of different materials can be used to perform the anastomosis, but the choice (i.e. sutures or staples) in many cases is dictated by personal preference.

If the immediate strength of the anastomosis is in doubt, then a proximal temporary stoma (usually an ileostomy or a colostomy) may be constructed to “defunction” the bowel and closed a few weeks later, in order to divert the faeces away from the healing anastomosis. Several studies have suggested that a “defunctioned” stoma decreases the incidence of clinical AL, (21, 22) however other authors have reported no difference in AL despite a reduced incidence of reoperation. (23) There are several other disadvantages for patients undergoing an ostomy operation. Firstly, many patients will be left with a stoma for several months because of the low clinical priority for reversal. (24) Also stoma reversal itself is associated with increased risk of AL and mortality (25, 26).

Postoperative Complications after Colorectal Surgery

In a nationwide UK study, median Postoperative Length of Stay in Colorectal patients was shown to have reduced from 10 days in 1998 to 7 days in 2010.(13) That said, these are still various postoperative complications that can prolong hospital stay in patients undergoing colorectal surgery. One of the more common postoperative complications is surgical site infection (SSI). Colorectal procedures are, at best, clean-contaminated procedures, and there is sometimes gross contamination of both the peritoneal cavity and the surfaces of the surgical wound. In open colorectal surgery the incidence of SSI varies from 2-25%. (27, 28) Another more common postoperative complication is Small

Bowel Obstruction. This can occur in the early phase of colorectal surgery, with report rates of 1.2-8.2%. (29, 30)

Another significant postoperative complication is Anastomotic Leak (AL). This is a serious complication specific to intestinal surgery where there is a breakdown of the intestinal anastomosis. At least 1/3 of the mortality after colorectal surgery is attributed to AL. (31) This will be explored further in the section “1.13 Anastomotic Leak.” Patients can also experience ileus, when they are unable to tolerate solid intake and has not yet passed stool. (32)

1.13. Anastomotic Leak

Introduction

Between 2-7% (33-35) of anastomoses breakdown and there is a leak of luminal contents (such as faecal material) (1) from the surgical join. The lowest leak rates are found with ileo-colic anastomoses (1 to 3%) and the highest occur with colo-anal anastomosis (10 to 20%). (36)

Definitions

Anastomotic Leak (AL) encompasses a wide spectrum of clinical severity, ranging from small, contained leaks without systemic symptoms to widespread peritoneal contamination with accompanying severe sepsis, multiple organ failure and/or death.(37) An attempt to address the uncertainty was made in 2010 by the International Study Group of Rectal Cancer (ISREC), who defined AL as “a communication between the intra- and extra- luminal compartments owing to a defect of the integrity of the intestinal wall at the anastomotic site.” The majority of definitions use clinical signs (pain, fever tachycardia), radiological signs (fluid and/or gas containing collections) and intraoperative findings (gross enteric spillage and/or anastomotic disruption. (38, 39)

The current state of research has been further complicated by the lack of a standard validated definition and reporting of AL into clinical trials; many studies fail to take into account subclinical or radiological leakage, despite the recognised association with poor bowel function and anastomotic stricture formation. (40)

It remains the most serious complication of colorectal surgery. It is associated with increased mortality (41-46), increased morbidity (increased rates of re-operations, radiological interventions and permanent stomas (47)) and increased costs (48).

Risk factors for Anastomotic Leak

Identifying significant preoperative, intraoperative and postoperative risk factors can guide choices regarding treatment plan, allow modification of risk as well intraoperative decision-making; such as whether to undertake an anastomosis or whether a defunctioning stoma should be created. Preoperative risk factors for AL may be modifiable or non-modifiable.(37)

Modifiable preoperative risk factors for AL include; alcohol (49); smoking (50); chemotherapy (specifically ciclosporin A (51) and tacrolimus (52)); prolonged corticosteroid use (53, 54); poor nutrition and perioperative intravenous antibiotics (55). Also “Selective decontamination of the digestive tract” (SDD) is used in the United States, some surgeons routinely use non-absorbable antibiotics such Tobramycin and Amphotericin B may reduce the risk of AL, (1) a systematic review comparing SDD with intravenous antibiotics and intravenous antibiotics alone demonstrated an AL rate of 3·3 and 7·4 % respectively (P =0·002). (56)

Non-modifiable risk factors for AL include; male gender (35, 39, 57); underlying pulmonary (58) and vascular disease (59). Emergency resection is also an independent risk factor for AL compared to elective operations.(60) Also the more distal the anastomosis, the larger the AL risk, (61, 62) also for rectal procedures, the distance from the anal margin is also a significant predictor for AL.(39, 57, 61).

Intraoperative risk factors for AL include whether the procedure is sutured or stapled (A randomised-control-trial (RCT) showed a significantly increased rate of radiological ALs in the sutured cohort, however there was no difference in clinical ALs); whether the procedure is laparoscopic or open (although a meta-analysis of open versus laparoscopic rectal resections demonstrated no differences in AL rates (63); individual surgeon (64) and whether a defunctioning stoma was made (this can reduce the extent of complications but may not necessarily reduce the AL rate. (23) There are also many other significant risk factors for AL which can be explored further in the 2015 study by McDermott et Al. (37)

Diagnosis of AL

Prompt diagnosis of AL is essential for effective management (1) and delayed diagnosis of AL is associated with worse outcomes. (65) Signs and symptoms may be non-specific, including cardiac arrhythmias such as atrial fibrillation. (66) Postoperative ileus is uncommon after uncomplicated laparoscopic surgery and should lead to urgent assessment for AL. Rectal bleeding/passage of blood mucus per rectum should also raise suspicion for AL after a rectal anastomosis.

(1) AL can also present as an entero-cutaneous fistula between the intestinal anastomosis and the wound. This usually occurs after a sub-clinical AL and abscess formation that discharges along the pathway of least resistance; it presents as an apparent wound infection discharging with enteric content. (67)

In terms of bloods, serum C-Reactive protein (CRP) can be a useful marker, especially if it is very high (>150mg/L) on postoperative days 3-5, (68, 69) especially if the serum albumin continues to fall/fails to return postoperatively. (1). It is not always essential to image a unwell patient with suspected AL as it may give rise to an unnecessary delay in management; however in modern practice imaging is performed prior to surgery as CT scanning has become more readily available. (70). The diagnostic accuracy for suspected AL can be improved with rectal and intravenous contrast. Although extravasation of contrast is rarely detected, identifying additional findings suggestive of an AL (e.g. peri-anastomotic collections), increases the rates of AL detection to between 80-100%.(71)

Subsequent and definitive management

The ISREC grading system for Anastomotic Leak (72) can provide a useful starting point to understand how leaks are managed.

Grade A leaks are diagnosed using radiological findings, i.e. a fluid collection around the anastomotic site, leakage of contrast through the anastomotic site, or a newly observed enteric contents leaking through a drain/enterocutaneous fistula, without accompanying clinical complaints. These can be managed without surgical/radiological intervention. In a stable but symptomatic AL patient, antibiotics are first line treatment, these can be useful for smaller peri-anastomotic collections, not amenable to percutaneous drainage. These leaks are not always formally diagnosed with imaging and the collection may be very small.(70) Grade B leaks require active therapeutic intervention but are manageable without re-laparotomy. Often radiological drainage of peri-anastomotic collections is the most common intervention. Grade C leaks require re-laparotomy, surgical treatment is performed with the goal of controlling life-threatening sepsis. The traditional operation with takedown of the anastomosis and end colostomy is most often performed, but washout with drain placement and diverting loop ileostomy may also be appropriate.(70)

Despite the critical relevance of ALs to the outcome for the patient, the majority of hospitals do not prospectively measure postoperative outcomes such as their leak rate or actively engage in activities to reduce them. To reduce AL rates locally, it is key to first understand the principles of QI in healthcare and the different approaches that can be used.

1.14. Quality Improvement

Quality improvement (QI) is a systematic, formal approach to the analysis of practice performance and efforts to improve performance. (6) In essence, quality is how good we are at healthcare and it encompasses several domains including; patient safety (minimising medical errors and adverse events); effectiveness (maximising intended health outcomes); patient-centeredness (focusing on patient and family comprehension, goals and priorities in making treatment decisions); efficiency (providing care that is maximally cost-effective); equity (providing care of equal quality regardless of gender, ethnicity, region, socioeconomic status). (73, 74).

There are various structured approaches that can be taken to evaluate quality in healthcare, these include:

Clinical Audit

Clinical audits are used to check clinical care meets defined care standards and monitor improvements to address shortfalls. It is based against pre-existing standards and data is collected (often used for Quality Assurance (QA) purposes), compared to standards. After this period an intervention is often implemented and a re-audit is then carried out. This allows the outcome of choice to be re-assessed to see whether there have been improvements. Clinical audit be split into four stages; Preparation and planning (including for re-audit); Measuring performance; Implementing change; sustaining improvement (including re-audit).(75)

Audits are a well understood, established methodology supported by an administrative structure and can be a useful tool to benchmark performance. That said, they can also be slow and there is little evidence that clinical audit is effective at driving improvement. (76) This is because in practice completing the audit cycle can be challenging, conventional methods often do not allow reliable conclusions unless audit is done retrospectively over long periods of time.(77)

Plan-do-study-act cycle

The Plan-Do-Study-Act (PDSA) cycle expands on clinical audit by taking it further by focussing on the development, testing and the implementation of interventions. The PDSA cycle involves repeated, rapid, small-scale tests of change, carried out in sequence or in parallel to assess the extent if the changes prior to these being implemented on a larger scale. This can enable a small group of stakeholders to assess the effects of a change without causing large scale disruption to service quality. The stages involved include; Plan (plan the change to be implemented – predict expected changes and make logistical arrangements); Do (temporarily implement the change); Study (review the data before and after the change (using run/control charts (will be explored in more detail in section "1.14 Quality Improvement"); Act (plan the next test; establishing future modifications that can be made and which changes to implement).(75, 78)

Model for improvement

A widely used method to implement change in healthcare is the "Model for Improvement." This model is effective when a procedure, process or system needs changing or a new procedure, process or system is introduced for measurable QI. This model has two distinct phases.In the first phase, there are three stages, the "Aim," "Measurements," and "Test."

The "Aim" involves establishing what is the studying trying to accomplish, it should be specific in content and nature as well as realistic. "Measurements" are a key component to QI and is essential to measure the effects of implemented changes. They are the tool which will help to establish whether any changes to the data have occurred. SPC charts are often used to map outcomes in this step. These include outcome measures, process measures and balancing measures. Outcome measures are the primary measures that users would like to address, ranging from rates of wound infection to walking distance after a total knee replacement. Process measures are used to assess the system, not necessarily a clinical outcome, such as quality of weekend handovers or discharge summaries. However, they are often linked to clinical outcomes and by improving them, one would expect clinical outcomes to also improve. Balancing measures are used to quantify the undesired or the side effects of any change. They are a crucial but often forgotten measure when a change is implemented in a system. In the handover example, this could an increased in the time taken to complete the handover. (79) The third stage is the “test” phase where various ideas are pooled together to ascertain which will result in the desired improvements.

The second phase involves implementing the Plan-Do-Study-Act cycle is used to implement changes into clinical practice. The cyclical nature allows for changes to be refined and improved through repeated cycles of testing and learning, proving a vehicle for continuous improvement. (80)

Measurement and Quality Improvement

Measurement is a key element of QI projects and is the method by which it is assessed whether or not a project has met its aims. Now that the concepts of QI and QA have been outlined, it is important to have a formal understanding as to the differences between collecting data for improvement, collecting data for assurance and collecting data for research.

When data is used for research, the hypothesis is fixed, whereas when it is used for improvement, the hypothesis changes. When data is used for assurance, there is often no hypothesis. Also when data is used for research, large amounts of data are collected “just in case” whereas in improvement, just enough sequential data points are collected to satisfy the aim of the study. In terms of bias within a quality improvement project, confounders are often accepted as “part of the system” whereas in research, the aim is to eliminate bias and in QA studies, bias is often measured/adjusted for.(76)

Lean and Six Sigma

Lean and Six Sigma are Quality Improvement strategies used to eliminate waste in healthcare systems and redirect resources so healthcare provision is more efficient, improved and consistent. Lean and Six Sigma are two separate concepts that are often combined.

Lean focuses on mapping processes with the relevant stakeholders to identify inefficiencies in healthcare and to take actions to improve them. Common areas that are targeted include "just in case" processes, duplicate activity and holding excess inventory. Six Sigma uses its own improvement cycle with the acronym "DMAIC". It is made up of; Define (state the problem, specify the patient group and identify the goals of the project); Measure (decide what and how to measure markers of performance, collect baseline and data after changes are made); Analyse (identify gaps between actual and desired performance, describe causes for these gaps and rank potential solutions); Improve (decide on interventions, identifying those which are the easiest and most effective to implement and Control (make a plan to monitor outcomes and perform regular updates). The advantages are similar to the Model for Improvement and PDSA, in that they can reduce waste and improve processes. The disadvantage is that this can be a time consuming endeavour and engaging all staff with the final endeavour can be difficult. (76)

Driver Diagrams

Within these Quality Improvement frameworks, driver diagrams can be used plan improvement strategies. These are similar to the structured tree diagrams used in operational research. They can be used to map perceived theories of cause and effect within the complex systems (see Figure 1), i.e. identifying changes will lead to which desired effects and the subsequent achievement of the aim.

They have three levels, the goal, primary drivers and projects/activities. The goal is an underpinning of the aim of the study. Primary drivers are factors relevant to achieving the main goal (or "sub-goals"). These can be broken down into Secondary drivers where necessary. This ultimately leads to actionable steps/activities that can be undertaken by the clinical team to improve outcomes.(81)

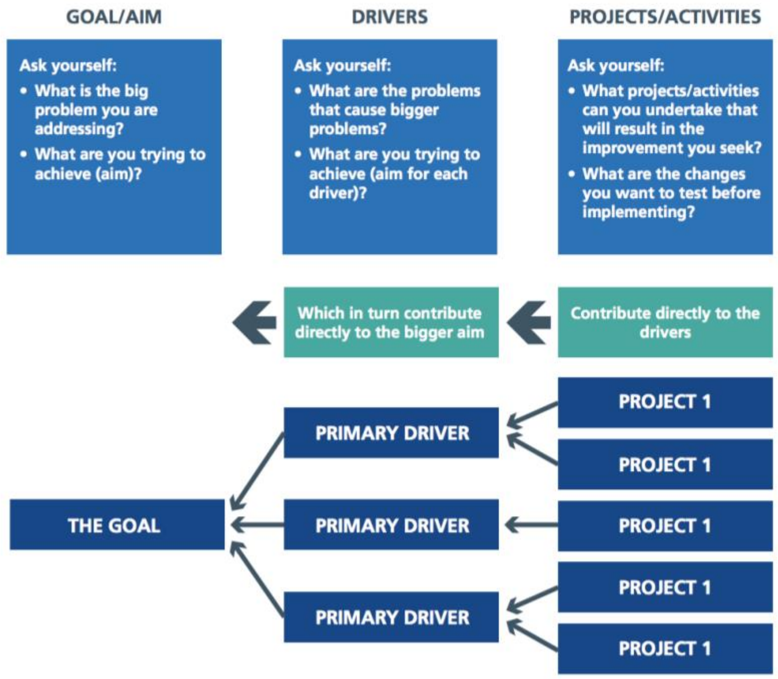


Figure 1 – Driver diagrams, taken from NHS Improvement (2018) (81)

Ethics for QI

Taking into account the QI methodologies which have been explained, it is also important to consider ethical considerations in QI. Whilst ethics is not a common challenge associated with carrying out QI projects, any activity that poses a risk of psychological or physical harm should have a screen to establish whether ethical considerations are required. A poorly designed QI project can itself result in ethical challenges as the project is unlikely to achieve a valid and reliable assessment and may also not produce improvements in patient care. As in other medical research, the ethical principles of autonomy, beneficience, non-maleficience and justice remain of paramount importance in assessing ethics in QI. In terms of assessing whether an activity needs a research ethics review, it is important to differentiate QI projects from Clinical Audit, Clinical Research and Public Health practice. (82)

Table 1 below from the Health Research Authority (HRA) clearly outlines these categories and whether there is a need for a Research Ethics Committee review.(83)

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT	USUAL PRACTICE (in public health including health protection)
The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to investigate the health issues in a population in order to improve population health Designed to investigate an outbreak or incident to help in disease control and prevention
Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey. Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What are the health issues in this population and how do we address them?" Designed to answer: "What is the cause of this outbreak or incident and how do we manage it?"
Quantitative research - addresses clearly defined questions, aims and objectives. Qualitative research – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, quantitative or qualitative methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions. Qualitative research – seeks to understand better the perceptions and reasoning of people.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.	Involves an intervention in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.	Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing routine data supplied under license/agreement or administration of interview or questionnaire to those in the population of interest. May also require evidence review.
Quantitative research – study design may involve allocating patients/service users/healthy volunteers to an intervention. Qualitative research – does not usually involve allocating participants to an intervention.	No allocation to intervention: the care professional and patient/ service user have chosen intervention before service evaluation.	No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.	No allocation to intervention.
May involve randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment/ care/ intervention.
Normally requires REC review but not always. Refer to http://hra-decisiontools.org.uk/ethics/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.

Table 1 – Differences between Research, QI, Audit and Public Health Practice – taken from Health Research Authority (2017)(83)

The HRA also has a tool to establish whether a project requires ethical approval.(84) It is imperative to understand the differences between when data is used for research as opposed to data being used for improvement or for assurance (as described earlier in section “Measurement and Quality Improvement”.) It is also important to have an awareness of the specific considerations relevant to Surgical QI.

Surgical QI

Approximately 234 million major surgical procedures are undertaken each year worldwide. Surgical practice is dependent upon practices, pathways, teams and individuals acting within and between systems in a complex organisation. Improvements can therefore occur by improving the systems in which teams and individuals work. However complex systems with dependent and interdependent components can be difficult to change. During the process of designing and implementing an intervention, there is a need for an iterative approach along with continuous measurement of performance. (79)

Within Surgical QI, there is a need to generate rapid high-quality evidence for interventions that can improve surgical outcomes. Waiting for the definitive results of large multi-centre trials can take years and delay the adoption of effective interventions. That said, it is also important to always prioritise patient safety above surgical innovation.(53, 85) It is also important to have an awareness that despite evidence for new surgical interventions being readily available within the literature, there are often there are barriers to implementation of these changes. Implementation science is an emerging field of inquiry for healthcare providers, focussed on minimising the delays of putting research into action. (86) There is also a need in Surgical QI for appropriate training and resources for clinical research staff. Many practising surgeons have not had any formal QI training and QI mentors are few and far between. (85)

There are also several obstacles specific to improving outcomes in surgical care. There needs to be appropriate levels of accountability for adverse events. Whilst improving surgical outcomes often requires multi-disciplinary team-based care, individual surgeons are often solely held accountable for complications. This traditional model of the final responsibility lying with the surgeon can result in a narrow focus which may fail to identify any existing system failures in the clinical environment.(85) In Surgical QI, often outcomes are measured using the methodologies encompassed in Statistical Process Control.

Statistical Process Control

The basic theory of Statistical Process Control (SPC) was developed by Dr Walter Shewhart (87), a statistician at the Bell Laboratories in the USA. He observed that repeated measurements from a process will exhibit variation; he realised that this observation could be applied to any process.

Understanding what caused variation within industrial processes allowed for changes to be made to improve both process and output. In the 1950s, William Edwards Deming converted post war Japan into a centre of manufacturing excellence with the effective use of SPC. (2) It has subsequently been used in various fields including medicine, environment, economics, text analyses and informatics. The most valuable part of SPC is the charts that are produced. These provide a graphical representation of an outcome over time. SPC has also been taken up by healthcare organisations with an aim to understand health care systems and improve processes. SPC charts can be used within a Quality Improvement as well as a Quality Assurance capacity.(2) Prior to exploring how SPC techniques are applied, it is first useful to have an understanding of variation.

Defining Variation

Shewhart recognised that a process can contain two types of variation. Variation can either be the result of random causes (common cause variation (CCV)) or to assignable causes (special cause variation (SCV)). Common cause variation is the variation is inherent in every process, however this is usually minimal and in line with the as the regular “rhythm” of the process. If common cause is the only type of variation that is present, then the process then the process is said to be stable and “in control.” Special cause variation illustrates that there are unusual occurrences within the process which are the result of factors not inherent to the process. (2)

Variation can be mapped over time using SPC charts and by studying it at the source, the process can be monitored, controlled and improved. Methodologies used in SPC to monitor outcomes over time include run charts, SPC charts, Cumulative Summation (CUSUM) charts and Exponentially Weighted Moving Average (EWMA) charts. The next sections will outline these techniques.

Run charts and Control charts

Run charts and control charts are the two most popular SPC tools that are used. This is because they are simple to construct, with no specialist software required. They are also easy to interpret - only a few basic rules are required to identify the type of variation with only a minimal necessary understanding of the statistical theory.

A run chart is a time-ordered sequence of data, much like a line graph where the independent variable is time. A centreline is drawn horizontally through the chart (indicating the mean/median of the outcome measure – depending on the user's choice) and the chart can be subsequently interpreted to identify the type of variation present in the process.(2)

One example involves a project to improve weekend handover, with an aim to have 95% of the jobs handed over to the weekend staff to be clear and actionable. The chart below (Figure 2) shows the % jobs successfully handed over 15 weeks.(88)

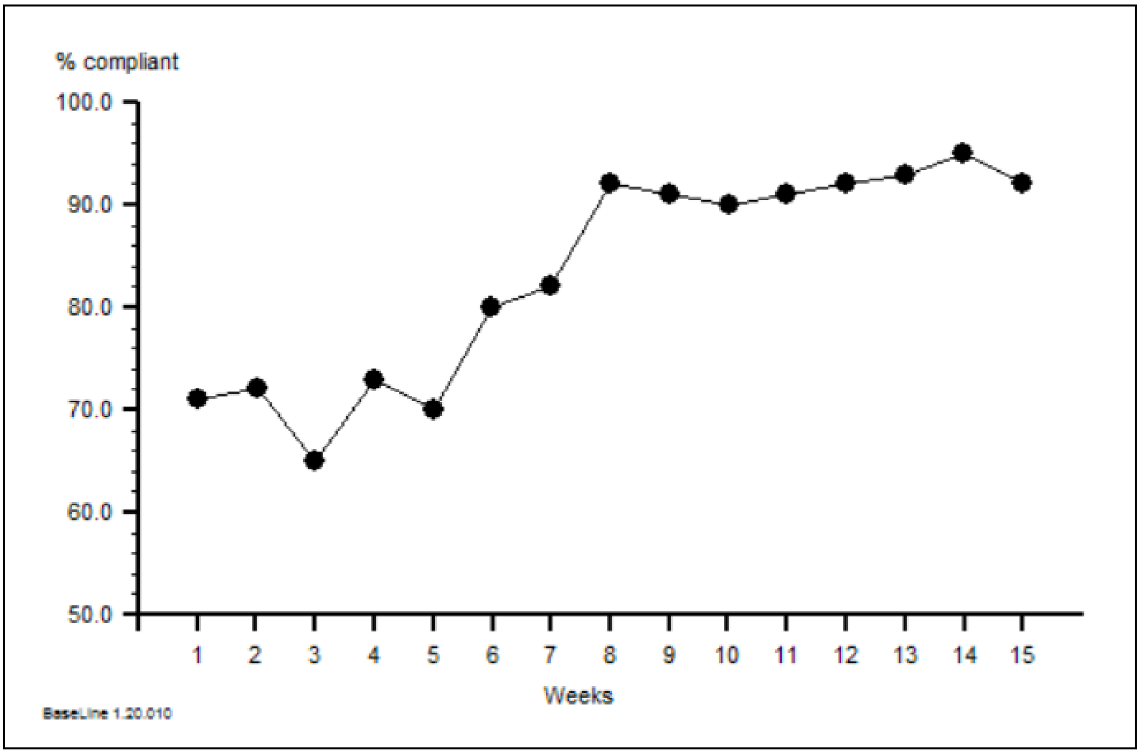


Figure 2 – Graph showing % of Weekend Jobs Handed over successfully

This chart shows the mapping of a baseline to establish the natural rate of variation in the process over time. An intervention was implemented at 4 weeks, which is associated with a higher rate of jobs being successfully handed over.

Shewhart control charts are very similar but they also bring the addition of control limits (usually set 3 sigma (sigma is a statistical term that is very similar to standard deviation (SD)) from the mean (99% of all values would be expected to lie within these limits). There is an "upper control limit" (UCL) and a "lower control limit" (LCL) (see *Figure 3*) (89)). Any negative control limits are usually rounded up to 0, as plotting points beneath these is impossible. Control limits are used to map the extent of natural variation in a process. (89)

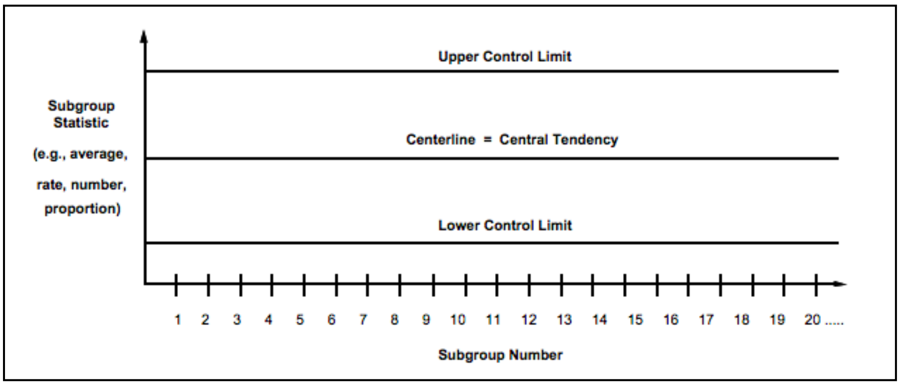


Figure 3 – General format of a Statistical Control Chart

Using SPC charts to improve Quality in Healthcare

In order to use SPCs to improve healthcare processes, two different phases should be undertaken.(90) The first phase involves constructing a chart using retrospectively (or ideally prospectively) collected data to provide a baseline and to determine the natural variability in a process over time. This observed variability (i.e. Common-cause variation) allows the construction of control limits. There is a choice to change these if necessary (see section "Adjusting Control Limits" in this section). 99% of common cause variation would be expected to lie within these constructed control limits. Phase 1 is very important, as there must be a construction of reliable control limits for monitoring future processes. After Phase I, a process is said to be in "control" because the probability distribution representing the quality characteristic is constant over time.

The second phase involves constructing a chart prospectively to monitor the process over time, allowing identification of trends, cycle and improvements.

Often this phase involves implementing an intervention, which may result in a statistically significant change in the outcome, shown on the chart as SCV. After the change is made, the control limits can also be recalculated. (91-93).

Establishing control limits

Once SPC charts have been made, they can then be interpreted to make various conclusions as to the type of variation present in the process and whether it is stable. It is also important to note that the control limits used in SPC charts vary in terms of the number of SDs in comparison to more traditional research studies (where 2 are considered an adequate measure of data variance). This is because in more traditional studies approximately 95% of the values lie within 2 SDs of the mean, so even if the process is stable and in control, the false positive rate would be at 5% for each value (as opposed for 0.27% for a 3 SD chart). Unlike one-time hypothesis tests, SPC charts commonly consist of 20-25 data points, with each contributing to the overall false positive probability. If 2 SDs were used in an SPC chart of 25 data points, then there would be an unacceptably high false positive rate of $1 – 0.95^{25}$ = 27.7%. Whereas using 3 SDs has a reasonably acceptable rate of $1 – 0.9973^{2}$ = 6.5%. (94)

In order to interpret control charts, a set of Mathematical rules can be used to assess whether there is a special or common cause variation. There are known as Nelson’s Rules (see Table 2).(91)

Rule	SPC chart notes
1	One point is more than 3 sigma from the mean – this sample is out of control.
2	Nine (or more) points in a row are on the same side of the mean – a possible indication of a shift in the process
3	Six (or more) points in a row are continually increasing (or deceasing) respective of their relationship to the mean – a possible indication of a shift in the process.

4	Fourteen (or more) points in a row alternate in direction increasing the decreasing, irrespective of their relationship with the mean – this much oscillation is likely to be a SCV.
5	Two (or three) of three points that are >2 standard deviations from the mean – there is a reasonable chance of underlying SCV.
6	Four (or five) of five points in a row are > 1 standard deviation from the mean in the same direction - there is a reasonable chance of underlying SCV.
7	Fifteen points in a row are all within 1 standard deviation of the mean on either side of the mean – there is a reasonable chance of underlying SCV
8	There are eight points in a row with none within 1 standard deviation of the mean and the points are within both directions from the mean – there is a reasonable chance of an underlying SCV.

Table 2 – Nelson's rules(91)

Having an awareness of these rules is useful, however there are several software programs (such as the LifeQI® platform (95)) that can automatically construct control charts based on the data inputted and identify periods of special cause variation and common cause variation.

To make SPC Control Charts more effective, sometimes it is necessary to revise existing control limits when they are no longer useful. There are four circumstances when the original limits will need to be recalculated; when the initial calculated limits have less than 20 to 30 data points; when the initial Control chart has special cause variation and there is a desire to use calculated limits for future data analysis ;when improvements are made to the process and the improvements result in special cause variation. The centre line and control limits should subsequently be re-calculated for the new process; when the control chart remains unstable for an extended period of time (20 or more data points) and approaches to identify special cause variation have been exhausted.(96)

Types of SPC chart

The most appropriate type of SPC chart to analyse and interpret data depends on the type of data available to the user. If the data presented is "variables" data and can be measured (e.g. height, blood pressure), then the Individuals chart (I-chart) can be used. This assesses the outcome measure, (4) it does not assume any underlying distribution.(97) In other projects, attribute data is measured. This can be split up into non-conformities data (counts of defects per item or groups of item/groups of items e.g. number of falls per 1000 patients) and non-conforming data (number of defective items, e.g. number of small bowel obstructions. P-Charts" are used to monitor proportions (e.g. a whether a patient develops an infection after surgery or not) when the total number of a measure varies).(98) If the number of defects is infrequent, then Geometric (G)-Charts can be used. They are based on the geometric distribution and were designed to monitor rare events. The number of events in between each rare occurrence is counted, similar to the concept mentioned in common parlance, "days since last accident." G-Chart analysis is based on inverse sampling and can be used to detect process changes or verify improvements faster as the statistical significance of each event can be evaluated (and contributes to the overall analysis). This can be faster than waiting until the end of a week/month before the data can be analysed. (3)

<u>Other types of SPC charts</u>

To analyse more subtle changes in performance, Cumulative Sum (CUSUM) charts can be used. The CUSUM chart plots the cumulative sum of deviations from the target for individual measurements or subgroup means. (99) Also exponentially weighted moving average (EWMA) charts can be used, these charts weights observations in geometrically decreasing order so that the most recent observations contribute highly while the oldest observations contribute very little. (100) Like the CUSUM, EWMA is sensitive to small shifts in the process mean but does not match the ability of a Shewhart chart to detect larger shifts. For this reason, it is sometimes used together with a Shewhart chart. (101)

Using Statistical Process Control in Quality Assurance (QA) and Monitoring

In most countries, Quality Assurance is often subjective and takes place without explicit reference to pre-determined standards to practice. Quantitative methods such as using SPC charts to measure outcomes can lend credence to the quality assurance process. (102) The application of SPC charts to monitor outcomes based on routinely collected data can also provide an earlier, objective insight into patient safety measures within healthcare settings. Application of another less common SPC methodology, “sequential probability ratio tests (SPRT)” was retrospectively applied to two high profile examples, the Bristol Royal Infirmary paediatric cardiac surgery data and Harold Shipman’s data. (103) This study found that using the SPC charts would have provided an earlier warning of poor performance (which arguably could have led to an earlier intervention in these cases).

Strengths of Control charts

There are many strengths associated with SPC charts, although their primary use is to monitor and improve clinical processes using regular observation and statistical analysis. They can also be set up with relative ease in comparison to a formal research project. The limits used in control charts can also be adjusted depending on how sensitive or specific a signal needs to be. If limits are too narrow (high risk of false positive signal (type I error) causing a mistaken inference of special cause variation) then then the limits can be widened to >3 standard deviations (SD). On the other hand, if the limits are set too wide (high risk of false negative) the limits can also be narrowed accordingly. (94) This is particularly useful to reduce comparisons/rankings between centres or doctors. The control limits can be adjusted appropriately, so they only flag up if performance is not within safe standards. (104)

Limitations of Control charts

Control charts still require establishment of a baseline measurement and sometimes new data points are collected at a slow pace, for example, a surgeon performs no more than 1-5 procedures a day. This can be inconvenient if a larger sample size is required before statistical analysis can take place, i.e. if there is a long lag time from intervention to result. Also, in terms of their ability to assess variation, even a small variation in the process mean may require action from the clinical team, e.g. deterioration in the mortality rate, which requires early warning of poor performance early to ensure patient safety. Hence a control chart might not be sufficiently sensitive, in these circumstances a CUSUM or EWMA chart may be more useful.

Variation in case mix can also skew results so it is important to adjust for this in order to improve signal accuracy. The use of regression adjustment can filter out variability induced by factors outside the process being measured. This can avoid wasted efforts exploring non-existent problems and unfair accusations of poor performance towards practices where there are disproportionately high-risk patients. (102)

Comparing SPC charts to other research methodologies

SPC charts offer a unique analysis of quantitative data and it can be useful to understand how it compares to more established research methodologies such as RCTs, large-scale observational studies and time-series methodologies.

RCTs are perceived by many clinicians as a necessary process to truly determine the benefit of a new intervention, test or instrument in surgery. However there are several limitations inherent to the use of RCTs, including that they are only able to test one or two improvements at a time and difficult-to-treat populations such as the elderly are often excluded (affecting the external validity of the results). (91) One benefit of using SPC charts in a QI context is the focus on improving outcomes regardless of the specific effect of individual changes that are made, hence several interventions can be implemented all at once in a "care bundle".(105) It is also important to consider that the results from SPC data can be heavily influenced by confounding variables in comparison to RCTs. If a SPC chart indicates special cause variation, it is necessary to have an expert understanding of the process to identify possible reasons for any statistically significant change. (102)

Large-scale cohort studies

One method to tackle some of the challenges posed by undertaking RCTs is using quantitative observational methods such as cohort studies or case-controls. In Colorectal Surgery, wide scale collaborative observational studies are common such as The National Bowel Cancer Audit (NBOCA). (106) These large national datasets are particularly useful as they are often generally applicable and meaningful conclusions can be made. However, observational studies (along with SPC charts) are still limited by the risk of confounding variables and bias. In circumstances where RCTs lack external validity, it is also possible to use “Interrupted time series” (ITS) analysis.

Interrupted time-series designs

ITS analysis is a quasi-experimental design to assess the effect of interventions over time using regression modelling. ITS analysis use statistical methods to quantify changes before and after an intervention, to assess whether the estimated differences are statistically significant. The intervention “interrupts” the time series, hence the name. It can be used in circumstances where full randomisation or a case-control study is infeasible. Even well designed RCTs can result in systematic errors as excluded patient groups can mean the paper lacks external validity, ITS studies can analyse more “real-world” settings. (107)

ITS analysis is based on the assumption that observations from the established baseline period, predict where future data would lie in the absence of an intervention. Therefore, if an intervention is implemented, the observations will deviate from the predicted effect of the observations, (all other things being equal). ITS analysis is expressed in terms of a “level change” and “slope change.” (108) A “level change” is an approximate change in the value of the outcome measure that can be attributed to the intervention (using the timepoints immediately before and after an intervention). “Slope change” refers to the difference between the rate of change pre- and post-intervention (assuming that the pre-interventional change would have continued at the same rate as pervious and there were no other confounding variables affecting the rate of change prospectively).(107) Figure 4 illustrates a worked example of ITS analysis.

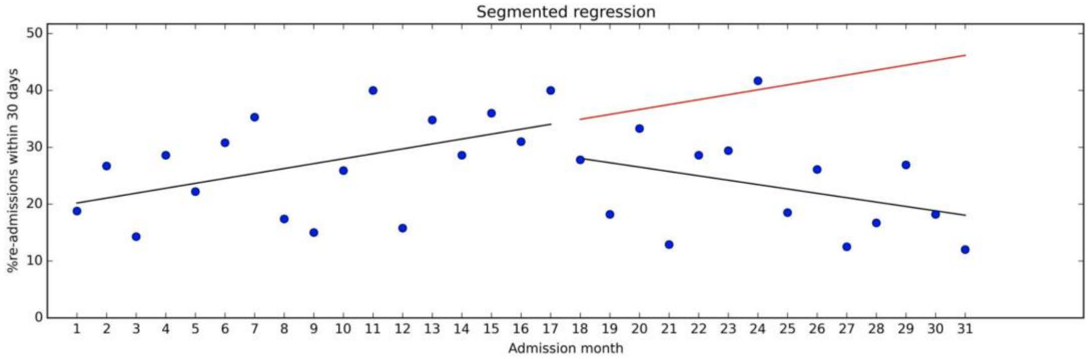


Figure 4 – Time series data for % re-admission within 30 days, with regression lines for the pre-intervention and post-intervention periods.

The overall level change was -5.2% (compared to the predicted value based on the pre-interventional trend). The slope during the pre-intervention period was 0.87 (i.e. on average there was a 0.87% monthly increase in re-admissions, post-intervention there was a 0.77% monthly decrease in admissions. This points to the conclusion that the intervention has had some impact on the readmission rates (assuming confounders are minimal). (108)

There are similarities between SPC charts and ITS analysis, the benefits include an ability for the methodology to control for secular trends in a time series. Using “T-test” analysis also allows users to identify compare pre-interventional and post-interventional outcomes and to explore whether there is a statistical difference between these two periods. However, if the data had already been trending in a certain direction for a period of time, a simple pre-intervention/ post-intervention design may incorrectly attribute statistical change to the intervention, whereas it may be the result of other factors. Also, the graphical representation of these charts can make them easier to interpret and can be used to provide information to stakeholders with varying levels of experience in scientific research. (109). The major limitation of both SPC charts and ITS analysis is that they are both often not controlled for covariates; the models assume that the characteristics of the populations remain unchanged throughout the study period. Both types of study can be negatively affected by other potential events occurring at the same time as an intervention, confounding the results of the study. (107)

Despite the apparent similarities, there tends to be little overlap when applying SPC and ITC analysis; SPC analysis is used to inform local decision making whereas ITS analysis is used in research, to generate evidence to allow decisions to be made in the future. There is a benefit in making QI projects that use SPC charts more scientifically rigorous as they can in turn also benefit research. Preparing a detailed protocol in advance (especially as often QI projects use "rapid cycle" adjustments and strategies (as outlined in the section "Plan-do-study-act cycle"), may lead to a more deep understanding into the outcomes being studied. If the aim of a project changes to becomes more research focused as opposed to QI focussed, (for example if the clinical team they want to explore the extent of a change as illustrated by the "level change" or to produce high quality evidence that supports evidence for a QI intervention) then ITS analysis could actually be used alongside SPC charts. (108)

Regression discontinuity methods of analysis

Another quasi-experimental design which can explore the causal effects of interventions is regression discontinuity methods of analysis. In this type of study, sample participants are assigned to an intervention group depending on whether they fall above or below an arbitrary cut off for a continuous variable. This assignment can be either "sharp" or "fuzzy". (110, 111) In "sharp" research designs, all people on one side the cut-off receive the treatment and all people on the other side do not receive the treatment. The effect of the intervention is approximated by using statistical models to compare outcomes of participant "just above" and "just below" the cut off. In "fuzzy" research designs, people on both sides of the cut off receive the treatment. However, the probability of receiving it becomes more likely at the cut off, this allows for crossover for patients receiving/not receiving treatment. This provides more flexibility for "real-world" studies, where the choice to provide a treatment based on the cut off is not as deterministic as in "sharp" designs.

Figure 5 (111) illustrates a worked example of fuzzy regression discontinuity using clinical data on the proportion of HIV patients who received early antiretroviral therapy (ART) within three months of presentation. (111) The circles show the proportion of patients treated at each CD4 count and the solid line is a line of best fit. Guidelines recommend starting ART at a CD4 count of <200cells/mm$_3$; the proportion of patients above this value receiving treatment noticeably declined. However, some of these patients were still being treated (likely due to other symptoms), hence the "fuzzy" nature of this study.

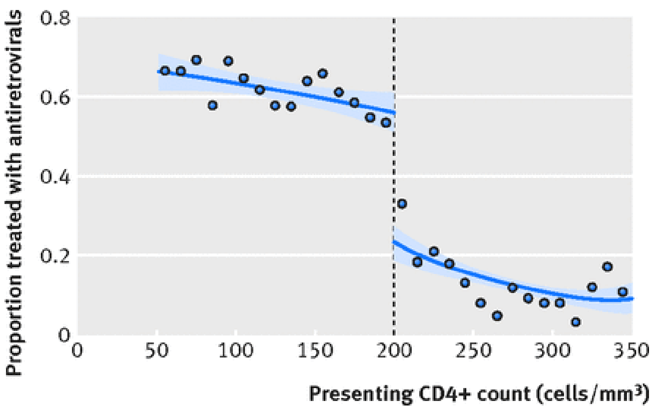


Figure 5 - Fuzzy regression discontinuity

The main strength of regression discontinuity is that it is a transparent method to estimate the causal effect of treatments/interventions when RCTs are not possible. Testing patients just before and just after the cut off, which are likely very similar, increases the validity of the clinical trial.

As previously mentioned, they also have a less rigid approach to stratification of participants into control and treatment groups and allow for projects to be carried out in more “real-world” circumstances in comparison to RCTs. There are also limitations associated with regression discontinuity projects, they can lack external validity; the estimates that are calculated are only applicable for those near the cut-off point. Also, these studies require large datasets to generate precise estimates, whereas SPC charts require much less data to get statistically significant results. Also many clinicians are less familiar with regression discontinuity methods of analysis and the types of questions that it can answer. (109)

Now that the main concepts of Statistical Process Control have been explored, the next section will focus on how they have been applied thus far within the surgical literature.

1.15. A Literature Review of the application of SPC Charts in Surgery

Introduction

This next section will highlight how SPC charts have been applied in surgery thus far. In terms of previous literature, there was two systematic review that assessed the role of SPC charts in healthcare (as opposed to surgery) (112, 113). There was also a systematic Review which assessed the use of different QI methodologies in Surgery (including Lean, Six Sigma and Statistical Process Control). (114) No previous studies have solely assessed how SPC charts have been applied in Surgery.

Methods

This literature review aimed to summarise and critically analyse primary research papers where SPC Charts had been used as a methodology to analyse outcomes in Surgery. Articles were critically analysed to assess their strengths and weaknesses as well as aiming to better understand the feasibility, value and implications in applying SPC charts to surgical practice.

Using NICE Healthcare Databases Advanced Search(115), a systematic search strategy was carried out on PUBMED, MEDLINE and EMBASE databases from their inception to 18th October 2019. Terms related to “Surgery” and “Statistical Process Control” were used, including; “statistical process control,” “statistical quality control,” “Shewhart” “surgery,” “surg*,” “operating theatre,” and “operating room.” It was not possible to use “SPC” in the search criteria due to the similarity to the acronym “suprapubic catheter.” To see a detailed breakdown of search terms used, see “Appendix 1.36

One reviewer (thesis author) independently screened abstracts, and subsequently full text articles for their potential eligibility for this study. Reasons for exclusions; papers where SPC methodologies other than Shewhart charts (e.g. CUSUM, EWMA charts) were used; papers which stated the use of SPC but there were no charts within the paper; papers where the study was published as an abstract, conference proceeding or e-poster as opposed to a full article; where SPC charts had been used to analyse outcomes in non-surgical contexts; animal studies; languages other than English; withdrawn studies and duplicate studies; papers where SPC charts had been applied to multiple departments some of which may have included surgical departments; papers where the primary focus was not primarily surgical, e.g. postoperative intensive-care related outcomes for postoperative patients; anaesthetic-related outcomes in theatre and obstetric and gynaecological papers were also not included. After removing excluded search results, full-text articles were screened again more thoroughly using the same exclusion criteria.

Extracted data points from each study included “type of surgery” and “year of study.” In terms of the “type of surgery performed,” where paediatric forms of specialist surgery, (e.g. paediatric orthopaedic surgery/paediatric cardiac surgery) these were collated into orthopaedic surgery, as opposed to “paediatric surgery” which encompasses paediatric gastrointestinal/urological surgery).

Results

The initial database searches yielded 417 articles. After duplicates were removed and the exclusion criteria was applied, 52 abstracts remained. Full articles were retrieved, and after screening for exclusion and inclusion criteria, data were abstracted from 34 articles. A PRISMA Flow diagram (116) outlining the literature review search process is outlined below in Figure 8.

Figure 6 shows articles by year of publication over time, showing papers published from 1996 to 2019. Over time, the number of surgical papers using SPC Charts have gradually increased with only 4 papers from 1995-2000 to 9 papers in the last 4 years alone. Figure 7 shows the number of papers by type of surgery, there is representation from all major surgical disciplines, but the largest number of papers are those where there are multiple specialities analysed in one paper.

Figure 6 - Number of papers by year of Publication

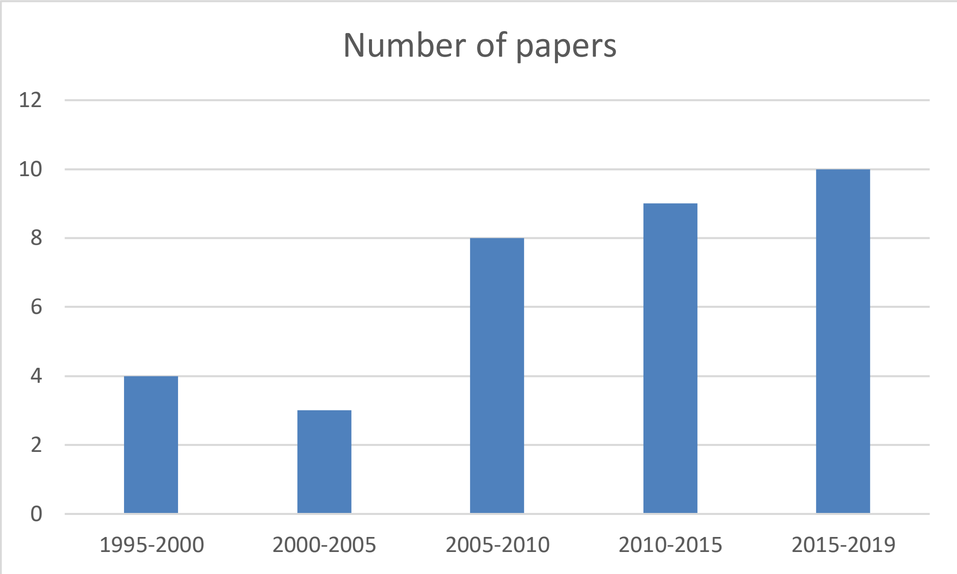


Figure 7 - Number of papers by type of Surgery

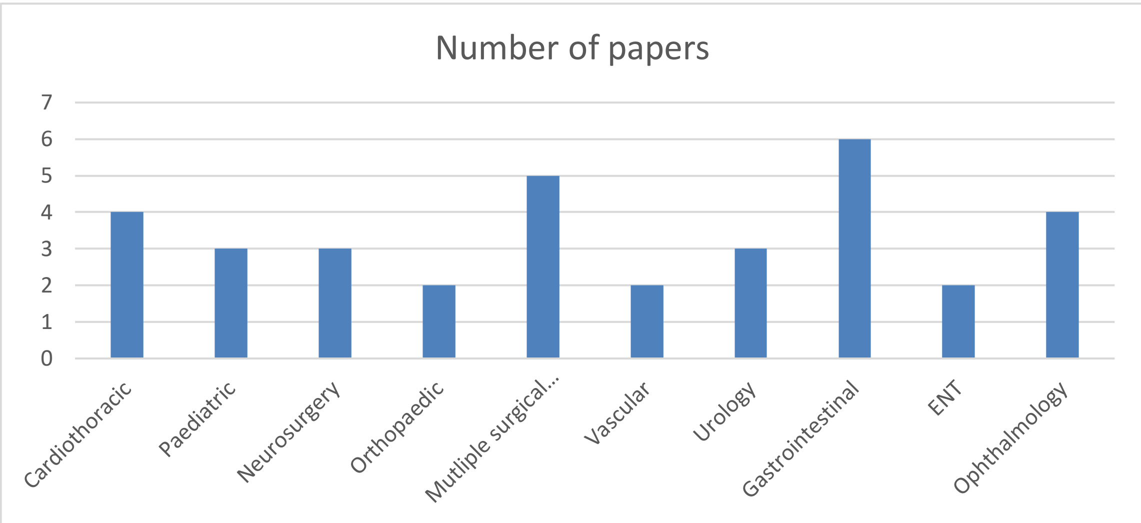
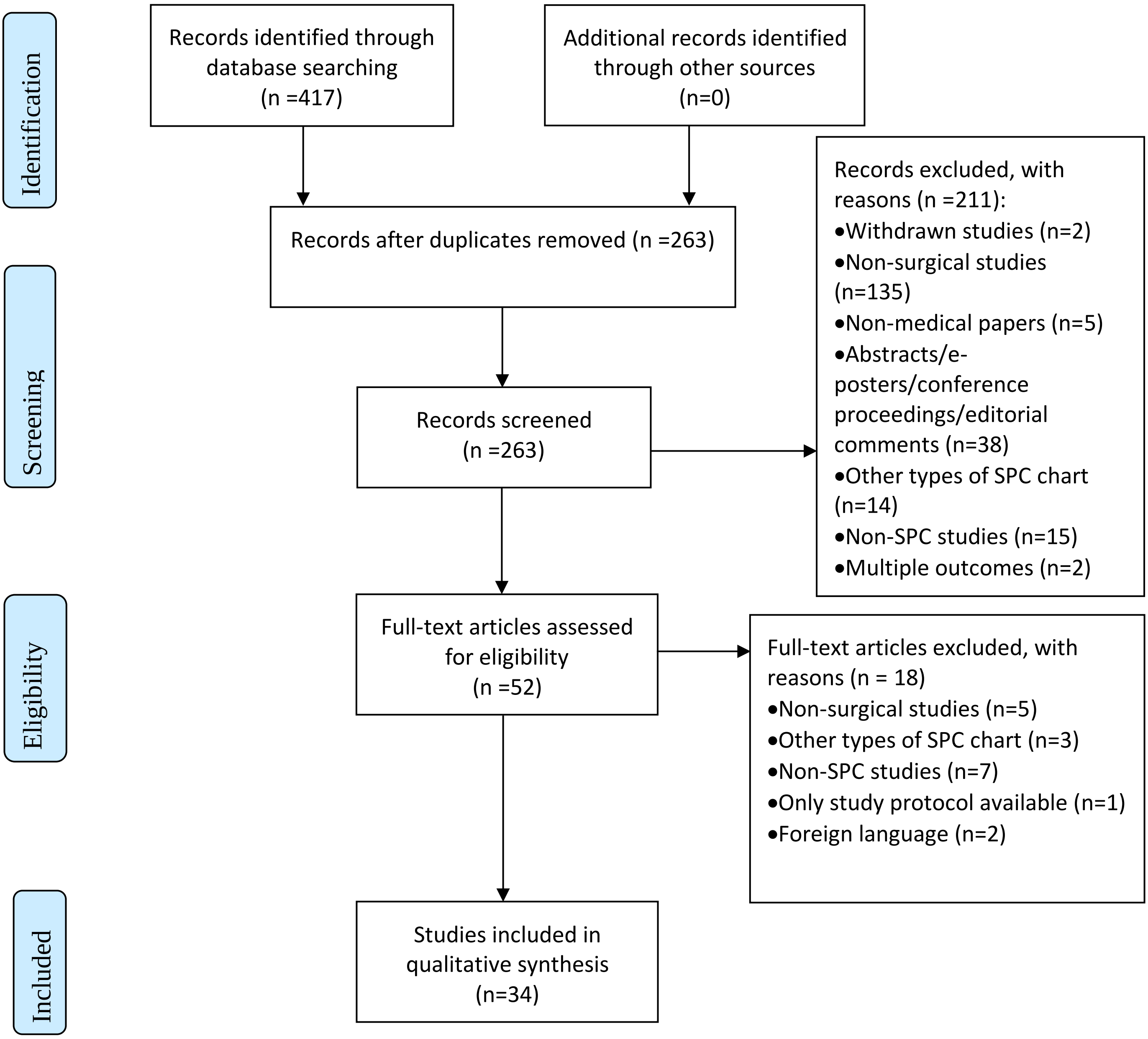


Figure 8 – Prisma flow diagram for SPC literature search



Discussion

A large proportion of papers within this analysis used SPC charts to monitor outcomes within a QI context, often comparing pre-interventional and post-interventional outcomes, however control charts were also used in Quality Assurance and Feasibility studies as well.

Strengths and weaknesses of papers that applied SPC Charts in Surgery

Many of the papers implemented interventions which already had an existing evidence base, for example in one paper, they implemented Integrated Clinical Pathways and teamworking training into the centre (117) as there was prior evidence that this improved outcomes in surgical populations.(118, 119) Many studies also used outcome measures with an existing evidence base, in one study assessing patient satisfaction, they used The Visit Rating Questionnaire, (120) a widely used survey instrument and benchmark for degrees of satisfaction across different systems of care.(121)

In papers when interventions did not rely as much on a previous evidence base, they often employed a use of structured QI methodologies to identify appropriate interventions. In one paper aiming to reduce postoperative length of stay in a paediatric population, they used driver diagrams to establish their interventions, i.e. they identified an “improved pain regimen” as a “Key Driver” and hence intervened with a standardised postoperative pain protocol.(122) Another study used the “Lean” model (see section “Lean and Six Sigma in 1.14 “Quality Improvement”), mapping the process to identify areas that could be improved by eliminated redundancy in the process as much as possible.(123) Using these formal methods of improvement allowed the increased understanding of surgical processes, helping to identify areas which can be improved.

Another strength of these papers was forming the methodologies with the awareness of the inherent limitations of using SPC charts. One of these weaknesses is that SPC charts are usually not adjusted for any control variables, hence confounding variables can significantly affect any conclusions that are reached from them. In one paper comparing outcomes between a group of surgeons that perform a higher number of cataract operations and a group of surgeons that perform a lower number, they adjusted the methodology accordingly to minimise the effect of confounding factors, i.e. they excluded complex cataract cases, such as those with posterior capsular rupture etc. (124)

An inherent weakness of using SPC charts is that they any changes that are identified in the form of “Special cause variation” require correlation with the clinical context (hence it is imperative to understand the clinical environment to postulate reasons for any significant variation in outcomes). They accounted for this in one project which involved monitoring variations in the cancellation rate for paediatric operations using SPC charts. They incorporated a qualititative element into the study, interviewing paediatric surgeons and anaesthetists as to why they thought that operations were cancelled over time. (125) This providing a better understanding of any potential reasons for cancellations, as well as promoting “buy in” into the project from the participating staff.

As well as monitoring and improving outcomes of interest, it is also important to have an awareness of any potential unintended consequences of implementing the project, in the form of balancing measures (see section “Model for improvement” in “1.14 Quality Improvement”) In a paper aiming to reduce postoperative length of stay in patients undergoing posterior spinal fusion using a multi-faceted “rapid recovery pathway,” they measured 30-day re-admissions to the emergency department. This was to ensure that patients being discharged earlier were not just being re-admitted with outstanding issues such as pain control. (126) In this case SPC charts could have also been used to monitor balancing measure such as re-admissions, it is always important to quantify any negative consequences of implementing an intervention where possible.

There were some common weaknesses of the papers that applied SPC charts to surgery, including that a large proportion of the studies were single centre trials, meaning that the studies were not as generalisable.(127) That said, it is important to understand that a reality of QI data is that it is primarily used within a local context. Also most studies did not indicate the type of chart used in their methodology (see section “Model for improvement” in “1.14 Quality Improvement” for more information on balancing measures). It is important that the correct SPC chart is applied the specific type of data collected in the study, otherwise it can lead to suboptimal analysis of the outcomes.

It is important to consider that although SPC charts can identify specific time periods where statistical variation has occurred, they do not provide much information regarding the cause for these variations. In a Saudi Arabian study assessing reasons for elective surgical cancellation on the day of surgery, they linked increased cancellation rates in March 2010 with the end of a winter season where Saudi Arabia had been affected by the global Influenza A pandemic. (128, 129) However, given the retrospective nature of the study, it can be difficult to assess to what extent the pandemic contributed to increased cancellation rates. SPC charts cannot confirm or deny whether this factor was causative, an association or a coincidence.

It is also important to evaluate to effects of the improvement strategies in these projects. In one study a national collaborative implemented an Enhanced Recovery After Surgery (ERAS) in joint replacement pathways. However, compliance to the ERAS protocol pre- and post- intervention only experienced a modest improvement in some sections. In one measure, compliance to the standardised anaesthetic protocol increased from 23% to only 42% in the knee replacement pathway. The authors postulated whether differences in number of clinical personnel available in each centre, served as a factor which affected their ability to proliferate the protocol at each hospital. (130)

It is also important to understand the role of both process measures and outcome measures when using SPC charts. One study that implemented a reduced preoperative nil per os (NPO) regimen to reduce patient length of stay mentioned "resistance to the revised NPO guidelines" within the department as a limitation of the study. (131) However this "resistance" was not quantified (for example by measuring "compliance to the reduced NPO regimen.") Measuring compliance to an intervention using process measures, can ensure that the protocols described in a research study are actually being carried out in practice. It is also important to acknowledge the importance of "buy-in" from the hospital staff and to identify any reasons if this is lacking. Process measures can also highlight certain benefits of implementing the intervention not directly related to patient outcomes. One paper implemented an intervention to reduce cancellations on the day of surgery in a children's hospital, (132) if the project had also mapped patient and parent satisfaction, this could have further highlighted the positive impacts of the QI project.

Preferentially SPC charts should be used to map outcomes measures, but many papers only looked at process measures making an assumption that there was a clear causal relationship between the process and the outcome. In a paper assessing compliance to “best-practice measures” in the acute management of glioma, they demonstrated improved outcomes in areas such as “VTE Awareness discussed” however there was no evidence that this yielded positive changes in significant outcome measures, e.g. improved survival or increased patient satisfaction. (133)

Feasibility of using SPC charts in Surgery

SPC charts were applied in a variety of contexts, from large nationwide studies involving multiple surgical disciplines and hundreds of hospitals (134) to focused QI projects assessing specialist paediatric outcomes.(122) Multiple studies were in fact “feasibility” studies, aiming to illustrate the practical application of implementing SPC charts to monitor outcomes.(135) In one project, length-of-stay was monitored in Colorectal patients and the authors expressed an intent to evaluate outcomes every month prospectively using SPC charts, to ensure “real-time” monitoring of performance.(136) As well as applying SPC charts to monitor outcomes, feasibility of the projects was affected by numerous other factors.

To monitor outcomes over long periods of time, organisational structures and stakeholders are required to take responsibility and ownership of projects. One project used a multidisciplinary team approach, involving multiple healthcare professionals to initiate a postoperative care bundle to reduce surgical site infections. They also listened to feedback from front-line clinical personnel to improve elements of the care bundle.(137) In another study, a national collaborative implemented an ERAS programme, working closely with local health boards, conducting site visits, and connecting local teams together.(130) Providing ongoing support for complex multi-centre interventions increases the likelihood that outcomes will be monitored after the study period has finished. It can however be challenging to sustain longevity in QI projects. In a study which used educational sessions to improve teamworking in a congenital heart surgery, the authors stated that they struggled with re-educating new team members about the specific protocols, as new staff would enter and old staff would leave the department. (117)

Another important factor to ensure project feasibility is to ensure that data collection can be carried out over long periods of time. In a project assessing non-technical skills in theatre cases, a rating scale was used by trained theatre nurses to assess various healthcare professionals with a second observer present to test the data collection tool and reliability of different data collectors. The labour-intensive element of the data collection process can increase the difficulty in maintaining measurement of outcomes over time. (138) In another study looking at postoperative glycaemic control in vascular patients, blood glucose was measured at 4 standardised determined times of the day; however, glucose can vary significantly throughout the day and when outcomes are this variable there is a risk that outliers will be missed from data collection. SPC charts are most effective when measurement is as continuous as possible: in this case the authors acknowledged that more regular measurements of glucose were infeasible due to cost constraints.(139)

<u>Value and implications to clinical practice of using SPC charts in Surgery</u>

SPC charts can be used to measure the effectiveness of quality improvement projects and they also can be used for quality monitoring and assurance.

They are often a key component of QI projects, in one study, a protocol was implemented to reduce length of stay in patients with gastroschisis and illustrated a reduction in length of stay using SPC charts.(122) As well as assessing patient outcome measures, SPC charts can also be used to assess processes measures, another project implemented improvement strategies to increase compliance to “best-practice measures” in patients with glioma. SPC charts showed improved percentage compliance as shown by “special-cause variation” over time.(133)

SPC charts can also be used to assess whether observed outcomes are comparable to accepted quality standards within surgical practice; thus being used as a quality monitoring tool. One paper compared ophthalmologists that performed a higher number of cataract procedures with those that performed a lower number of procedures using intraoperative markers of performance. Outcomes in both groups were relatively consistent, with actually less variability in outcome measures in the “low volume group.” (85) Whilst there will inevitably be differences in intraoperative performance between surgeons, SPC charts allow users to assess that the outcomes for surgeons are within a certain acceptable standard by assessing if any outliers or specific patterns are significant. It is also important that results are interpreted appropriately and there is an acknowledgement of confounding variables (especially as SPC charts are often not risk-adjusted).

Constructing control charts can also make users aware of their outcomes and act as a catalyst for change within clinical practice. In a paper assessing postoperative outcomes in thyroid surgery, they demonstrated a reduction in postoperative hypocalcaemia and the authors postulated whether this was due to the “Hawthorne effect” (increased caution under observation).(141) Despite the lack of an intervention, monitoring outcomes through SPC charts can in itself lead to improved practices and outcomes.

Using control charts can also empower multiple stakeholders by helping them to learn about the clinical processes they are studying and make decisions accordingly. In one project the provision of acute care surgery (ACS) was regionalised from six hospitals to three hospitals. They monitored the subsequent effects on time to surgery and length-of-stay (amongst other outcomes) to ensure that this revised model did not adversely affected patient outcomes. SPC analysis did not detect any significant variations in outcomes, allowing the authors to conclude that regionalising the provision of ACS provided adequate surgical coverage to the region. (142) Informing decision makers that the ACS model was a safe endeavour using SPC charts, promotes its use to other health authorities around the world. Using the graphical interface of SPC charts to monitor outcomes over time also provides an intuitive, user-friendly interface with which to interpret the time-series data.

Limitations of this study

This review is limited by decisions made during the screening process. Firstly, conference proceedings and abstracts were excluded as these were not considered detailed enough to effectively critically analyse the research methodology that the authors employed. In terms of the search criteria, “Quality Improvement” was not included as a search term. It could have led to the capture of more records in which SPC charts were used to monitor surgical outcomes however it would have led to thousands more papers to screen, which was not feasible within the time period of this project. When applying the exclusion criteria, several value judgements were made to ascertain what defined a “surgical” paper, for example patient outcomes in surgical patients were sometimes more “anaesthetic” in nature, e.g. perioperative volumes of blood transfused in patients who underwent cranial vault reconstruction patients was excluded from this study as it did not have a “surgical” enough focus. (143).

Another limitation of this paper is that only included papers where SPC control charts had been applied and did not review the use of alternative SPC methodologies, e.g. CUSUM charts, EWMA charts, etc, the justification being that this thesis only employs the use of Shewhart charts. Another limitation of this literature review involved critical appraisal of the papers involved, other than general critical appraisal strategies, there was no formal reporting strategy specific to assess papers that have applied SPC charts.

Conclusions

This literature review illustrated how SPC charts have been applied in surgery, the different ways that they can be used, as well as their strengths and limitations. Their use has gradually increased over time and they have been used across a variety of different surgical disciplines. Whilst they have their limitations, they are a simple, intuitive methodology that can be taken up by many centres to continuously measure surgical outcomes.

The next section will outline the rationale for this current project.

Rationale for this project

In previous studies, AL has been measured most commonly using RCTs(10) or cohort studies.(35) The initial project came about as a result of a junior doctor at the hospital mapping the AL rate for right hemicolectomies using G-Charts. Seeing the benefits of mapping AL, my project was then designed to be a larger study, assessing the feasibility of mapping the rates of AL. Another important marker of quality in Colorectal surgery is “Postoperative Length of Stay.” Particularly in the management of Colorectal cancer, the major expense in managing the disease is associated with the resection of the tumour and the associated PLoS.(13)

3)Materials and Methods

1.16.Aims

The aims of this study were to use SPC control charts to retrospectively map anastomotic leak (AL) rates and Postoperative Length of Stay (PLoS). This would allow users to assess whether this methodology was feasible and also for the data to act as baseline measurements for AL and PLoS, upon which an intervention can be implemented as part of a future quality improvement project.

1.17.Objectives

The objectives of this study were to better understand the utility of using SPC charts to retrospectively monitor the frequency of ALs over time (the number of cases between ALs as well as the number of ALs every 6 months) using G-Charts and I-Charts respectively. This study also intended to monitor the monthly median PLoS in patients undergoing intestinal anastomosis using Individuals charts (I-Charts). Key data points pertaining to AL in colorectal resections were collected, including relevant preoperative and intraoperative risk factors.

1.18.Study Design

In terms of conceiving this study, decisions made as to which relevant factors to analyse (i.e. stapled vs sewn anastomoses, emergency vs elective anastomoses and right-sided vs left-sided anastomoses) were discussed and formed with the thesis supervisor, Rob Bethune (Colorectal Surgeon) due to his expertise in understanding significant relevant risk factors in the day-to-day considerations in patients undergoing intestinal anastomosis. All patients undergoing ileo-colic, colic, colorectal and rectal resection with a subsequent intestinal anastomosis were identified in a centralised database created using relevant procedural codes. This project serves as the first part of a QI project where baseline measurements are established. Ethical approval from the Research Ethics Committee was not required for this study.

Setting

Royal Devon and Exeter Foundation NHS Trust in Exeter, UK is a large-sized university-affiliated hospital trust with 419 beds and there were 836,186 patient encounters in the year 2016. There are 7 colorectal consultants, serving a local population of approximately 412,000 people. Approximately 300 patients per year undergo resection of the colon and/or rectum (of which a proportion undergoes subsequent bowel anastomosis).

1.19. Participants

Inclusion Criteria

All patients undergoing colorectal resections with ileo-colic, colo-colic colo-rectal, colo-anal or ileo-anal anastomoses from 01//01/2010 to 30/04/2017 were included in this study. Relevant procedural codes from the NHS Data Dictionary Office of Population Censuses and Surveys (OPCS-4.7) Classifications of Interventions and Procedures were used (144), for patients undergoing surgery of the colon and/or rectum. These were identified by the Coding Department at Royal Devon and Exeter Foundation NHS Trust (See 1.35 - NHS OPCS Data Dictionary – 4.7 in Appendix for more information).

Exclusion Criteria

Firstly, any duplicates cases carried out were excluded. Then Colorectal cases where index procedures did not include a primary ileocolic, colo-colonic, colorectal or ileo-anal anastomotic procedure, e.g. an abdominoperineal resection, a small bowel-small bowel anastomosis or an ostomy operation without an anastomosis were also excluded. Cases where there was re-anastomosis of a stoma such as an ileostomy/colostomy reversal were also not included in this study.

Primary Outcome Measure

Anastomotic Leak

Several different definitions were included (very similar to ISREC AL grading system, see Section 0Subsequent and definitive management). Return-to-theatre (RTT) definitions included re-laparotomy and subsequent take down of the anastomosis as well as per rectum insertion of Foley catheter under general anaesthetic. Cases where AL was confirmed by radiological drainage were also included (this was confirmed by the radiologist's report confirming AL or if the radiologist's report stated that there was an abscess adjacent to the anastomosis, which was subsequently drained using Ultrasound or CT guided drainage). ALs which were treated medically were confirmed by the radiologist's report confirming AL, also if the report stated there was an abscess adjacent to the anastomosis (considered AL for the purposes of this study). If there was abscess formation away from the anastomosis, this was not considered an AL. Also if the patient died and AL was detected on the autopsy, this was also included.

Secondary Outcome Measure

Postoperative length of stay (PLoS)

Postoperative length of stay was also measured as a quality indicator in patients undergoing anastomotic procedures. There is considerable interest in shortening hospital stays and the NHS has invested in various initiatives to optimise surgical pathways.(145)

Median monthly PLoS was selected to analyse as opposed to Mean monthly PLoS due to the large variation in PLoS observed in Colorectal patients; PLoS can vary from a few days in routine operations to several months when postoperative complications occur, hence measuring the median will mean that the calculations are less skewed. Due to the large potential variability of the PLoS data, median was considered a better statistic to compare different subgroups in this study as opposed to mean which was affected by outlying results.

1.20. Data Collection

Systems used

Once the relevant procedural codes for all colorectal cases were provided by the coding department, an Excel Spreadsheet was manually create by the thesis author, going through each case using Clinical Document Management® (CDM) system, Plato® and Picture Archiving and Communication System® (PACS) Insignia at Royal Devon and Exeter Foundation NHS Trust and ascertaining whether there had been an AL. Also each case was checked to ensure that the index operation had included a primary gastrointestinal anastomosis (as defined by the criteria in “1.19 Participants”). See “Section 1.34” in Appendix to see pre-determined definitions of “Right-sided and “Left-sided” procedures that were used.

In approximately 5% of the data abstracted cases, Three 4th Year medical students, Shriyam Patel, Robert Clowes and Susannah Kingsbury assisted with data collection under close supervision by the thesis author. They were trained to abstract whether an anastomotic leak had occurred. To ensure consistency of data collection each data collector was given a guidance sheet describing the different types of leak and went through approximately 10-15 practice cases prior to commencing their portion of data collection. In the remaining 95% of cases, data collection was carried out by the thesis author. PLoS was calculated by subtracting the discharge date from date of procedure.

1.21. Statistical Process Control

Statistical Process Control (SPC) charts were used to retrospectively map the rate of AL and PLoS in Colorectal Patients from 01/01/2010 to 30/04/2017. This allowed for baseline variation in the process to be established allowing further analysis to define on-going variation as “common” or “special” cause and whether the AL rate was stable and predictable over time. SPC charts were made using a statistical package, LifeQI® platform.(95) Pre-set tolerance intervals were placed at 3 Sigma. The mathematical term Sigma is extremely similar to standard deviation but not exactly the same as it takes into account the chronology of the data points. The statistical programme used Nelson’s rules to determine cases of common cause and special cause variation.

G-charts were used to count the number of cases between each anastomotic leak. Due to the relatively uncommon incidence of AL, this was deemed appropriate chart to use. G-Charts were used to map data ALs for all elective, emergency, right- sided, left-sided, sutured and stapled anastomotic procedures.

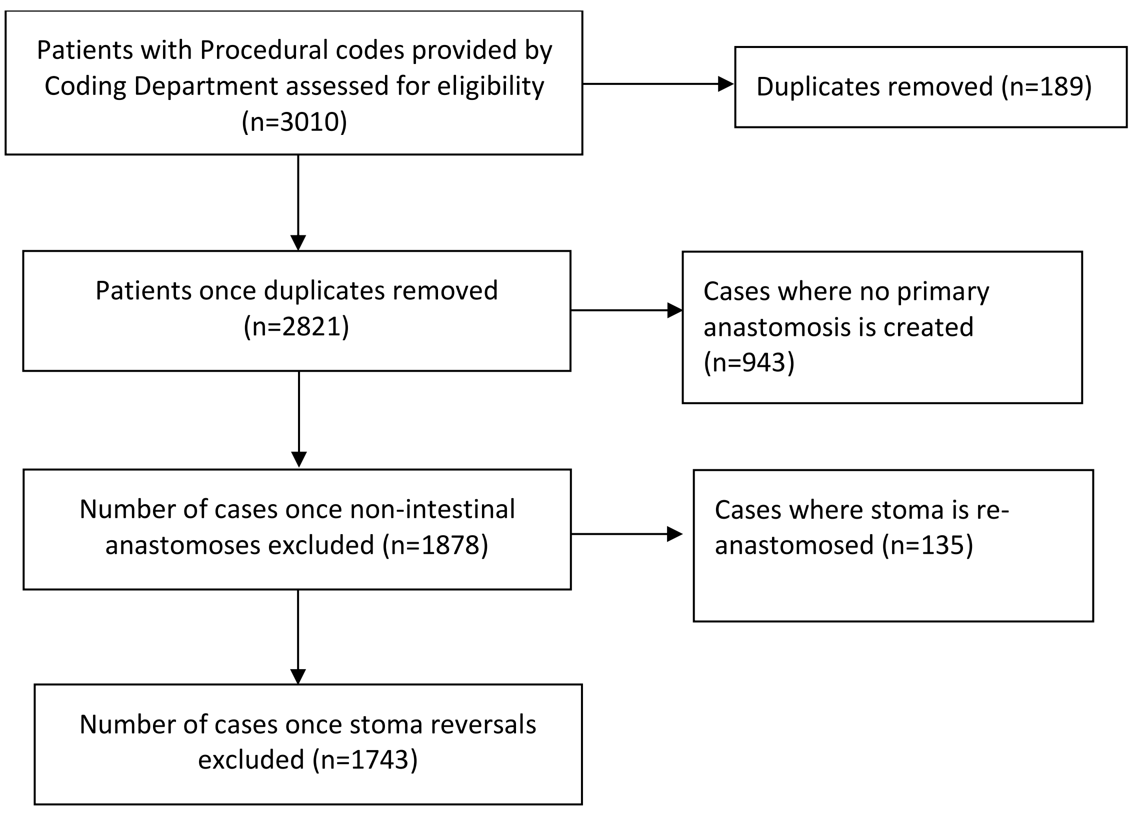
I-Charts are used to detect trends and shifts in the data, and thus in the process. The individual chart must have the data time-ordered; that is, the data must be entered in the sequence in which it was generated. I-Charts are also a more intuitive approach to represent data in comparison to G-Charts. There were used to map ALs every 6 months (given the rarity of ALs, the chart would have been unlikely to detect any changes unless subgroups were made). I-Charts were also used to monitor median monthly Postoperative length of stay.

4)Results

There were initially 3010 patient records brought up by the inclusion criteria. Once the exclusion criteria (see 0Exclusion Criteria) was applied and duplicates were excluded, the final count was 1743 ileo-colonic, colo-colonic colorectal, colo-anal and ileo-anal anastomotic operations carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017 (see Figure 9 below for a flow diagram explaining the application of the exclusion criteria).

There was an AL in 107/1743 cases (a rate of 6.10%). In 75/107 cases the patient returned the theatre to undergo surgery for the AL. Therefore the return-to-theatre AL rate was therefore 75/1743 or 4.3%. In 9/107 cases the AL was drained radiologically and in 22/107 cases the AL was managed medically, using antibiotics. In 1/107 cases the patient died prior to medical management and AL was discovered upon autopsy. The overall mean PLoS in this population was 9.2 (SD 10.1) and the median PLoS was 6.

Figure 9 - Flow diagram to illustrate applying of exclusion criteria to records



The demographic data for each patient subgroup is highlighted in the section below.

1.22. Demographics and perioperative data

Table 3 - All Anastomoses (n=1743)

Preoperative Factors						
Mean Age at procedure (SD)	67.0 (15.2)		Age range = 86		Median age = 70	
Gender (n,%)	Male (893, 51.2%) Female (850, 48.8%)					
Elective vs Emergency (n,%)	Elective (1405, 80.6%)		Emergency (n=338, 19.4%)			
ASA Grade (n,%)	I (193, 11.1%)	II (74, 50.0%)	III (277, 15.9%)	IV (13, 0.7%))	V (1, 0.1%))	Unknown (511, 29%)
Patient Cohort (n,%)	Primary Colorectal Cancer (1197, 68.7%)	Diverticular (142, 8.1%)	Inflammatory Bowel Disease (166, 9.5%)	Volvulus (53, 3.0%)	Other benign (160, 9.2%)	Other malignant (24, 1.4%)
Intraoperative Risk factors						
Cases with stoma created (n,%)	Yes (253, 14.5%)			No (1490, 85.5%)		
Initial surgical approach (n,%)	Laparoscopic (841, 48.3%)		Open (898, 51.5%)		Unknown (4, 0.2%)	
Conversion to open (n,%)	Yes (92, 5.3%)		No (1641, 94.1%)		Unknown (10, 0.6%)	
Sutured and Stapled Anastomoses (n,%)	Sutured (466, 26.7%)		Stapled (1270, 72.9%)		Unknown (16, 0.9%)	
Left-sided and Right-sided anastomoses (n,%)	Left-sided (775, 44.5%)			Right-sided (884, 50.7%)		

Table 4 - Elective Anastomoses (n=1406)

Preoperative Factors						
Mean Age at procedure (SD)	67.2 (14.8)		Age range = 85		Median age = 69	
Gender (n,%)	Male (n=745, 53.0%) Female (n=660, 46.9%)					
ASA Grade (n,%)	I (158) (11.2%)	II (634) (45.0%)	III (213 15.1%)	IV (9, 0.6%)	V (0, 0.0%)	Unknown (391, 27.8%)
Patient Cohort (n,%)	Primary Colorectal Cancer (1004, 71.4%)	Diverticular (119, 8.5%)	IBD (131, 9.3%)	Volvulus (13, 0.9%)	Other benign (1188. 4%)	Other malignant (19, 1.35%)
Intraoperative Risk factors						
Cases with stoma created (n,%)	Yes (238, 16.9%)			No 1168, 83.1%)		
Initial surgical approach (n,%)	Laparoscopic (806, 57.3%)		Open (597, 42.5%)		Unknown (2, 0.1%)	
Conversion to open (n,%)	Yes (85, 6.0%)		No (1321, 94.0%)		Unknown (0, 0.0%)	
Sutured and Stapled Anastomoses (n,%)	Sutured (138, 9.8%)		Stapled (1072, 76.2%)		Unknown (5, 0.4%)	
Left-sided and Right-sided anastomoses (n,%)	Left-sided (716, 50.9%)			Right-sided (618, 44.0%)		

Table 5 - Emergency anastomoses (n=338)

Preoperative Factors						
Mean Age at procedure (SD)	65.9 (17.3)		Age range = 81		Median age = 72	
Gender	Male (148, 43.8%) Female (190, 56.2%)					
ASA Grade (n,%)	I (35, 10.4%)	II (114, 33.7%)	III (64, 18.9%)	IV (4, 1.2%)	V (1, 0.3%)	Unknown (120, 35.5%)
Patient Cohort (n,%)	Primary Colorectal Cancer (198, 58.6%)	Diverticular (23, 6.8%)	IBD (35, 10.4%)	Volvulus (40, 11.8%)	Other benign (42, 12.4%)	Other malignant (5, 1.5%)
Intraoperative Risk factors						

Cases with stoma created (n,%)	Yes (15, 4.4%)	No (323, 95.6%)	
Initial surgical approach (n,%)	Laparoscopic (35, 10.4%)	Open (301, 89.1%)	Unknown (2, 0.6%)
Conversion to open (n,%)	Yes (7, 2.1%)	No (329, 97.3%)	Unknown (2, 0.6%)
Sutured and Stapled Anastomoses (n,%)	Sutured (138, 40.8%)	Stapled (198, 58.6%)	Unknown (4, 1.2%)
Left-sided and Right-sided anastomoses (n,%)	Left-sided (58, 17.2%)	Right-sided (266, 78.7%)	

Table 6 - Right-sided anastomoses (n=884)

Preoperative Factors						
Mean Age at procedure (SD) (n,%)	68.9(15.8)	Age range = 81	Median age = 73			
Gender (n,%)	Male (415) Female (469)					
Elective vs Emergency (n,%)	Elective (615, 69.6%)	Emergency (269, 30.4%)				
ASA Grade (n,%)	I (64, 7.2%)	II (351, 39.7%)	III (166, 18.8%)	IV (11, 1.2%)	V (1, 0.1%)	Unknown (291, 33.0%)
Patient Cohort (n,%)	Primary Colorectal Cancer (624, 70.6%)	Diverticular (13, 1.5%)	IBD (112, 12.7%)	Volvulus (30, 3.4%)	Other benign (89, 10.1%)	Other malignant (16, 1.8%)
Intraoperative Risk factors						
Cases with stoma created (n,%)	Yes (10, 1.1%)	No (874, 98.9%)				
Initial surgical approach (n,%)	Laparoscopic (380, 43.0%)	Open (501, 56.7%)	Unknown (3, 0.3%)			
Conversion to open (n,%)	Yes (37, 4.2%)	No (847, 95.8%)	Unknown (6, 0.7%)			
Sutured and Stapled Anastomoses (n,%)	Sutured (270, 30.5%)	Stapled (602, 68.1%)	Unknown (12, 1.4%)			

Table 7 - Left-sided anastomoses (n=775)

Preoperative Factors						
Mean Age at procedure (SD) (n,%)	66.3 (11.29)	Age range = 67		Median age = 68		
Gender (n,%)	Male (432, 55.7%) Female (343, 44.3%)					
Elective vs Emergency (n,%)	Elective (717, 92.5%)			Emergency (58, 7.5%)		
ASA Grade (n,%)	I (116, 15.0%)	II (346, 44.6%)	III (105, 13.5%)	IV (2, 0.3%)	V (0 0.0%)	Unknown (205, 26.4%)
Patient Cohort (n,%)	Primary Colorectal Cancer (543, 70.1%)	Diverticular (129, 16.6%)	IBD (11, 1.4%)	Volvulus (20, 2.6%)	Other benign (64, 8.3%)	Other malignant (63, 8.1%)
Intraoperative Risk factors						
Cases with stoma created (n,%)	Yes (192, 24.8%)			No (583, 75.2%)		
Initial surgical approach (n,%)	Laparoscopic (433, 55.9%)		Open (340, 43.9%)		Unknown (1, (0.1%)	
Conversion to open (n,%)	Yes (53, 6.8%)		No (718, 92.6%)		Unknown (4, 0.5%)	
Sutured and Stapled Anastomoses (n,%)	Sutured (274, 35.4%)		Stapled (599, 77.3%)		Unknown (1, 0.1%)	

Table 8 - Sutured anastomoses (n= 466)

Preoperative Factors						
Mean Age at procedure (SD)	68.2 (15.4)	Age range = 82		Median age = 71		
Gender (n,%)	Male (228, 48.9%) Female (238, 51.1%)					
Elective vs Emergency (n,%)	Elective (328, 70.4%)			Emergency (138, 29.6%)		
ASA Grade (n,%)	I (53, 11.4%)	II (181, 38.8%)	III (105, 22.5%)	IV (7, 1.5%)	V (0, 0.0%)	Unknown (120, 25.8%)

Patient Cohort (n,%)	Primary Colorectal Cancer (305, 65.5%)	Diverticular (55, 11.8%)	IBD (38, 8.2%)	Volvulus (18, 3.9%)	Other benign (44, 9.4%)	Other malignant (6, 1.3%)
Intraoperative Risk factors						
Cases with stoma created (n,%)	Yes (19, 4.1%)			No (447, 95.9%)		
Initial surgical approach (n,%)	Laparoscopic (100, 21.5%)		Open (363, 77.9%)		Unknown (3, 0.6%)	
Conversion to open (n,%)	Yes (12, 2.6%)		No (450, 96.6%)		Unknown (4, 0.9%)	
Left-sided and Right-sided anastomoses (n,%)	Left-sided (173, 37.1%)			Right-sided (270, 57.9%)		

Table 9 - Stapled anastomoses (n= 1270)

Preoperative Factors							
Mean Age at procedure (SD) (n,%)	66.4(15.5)			Age range = 86		Median age = 69	
Gender (n,%)	Male (660) Female (610)						
Elective vs Emergency (n,%)	Elective (1072, 84.4%)				Emergency (198, 15.6%)		
ASA Grade (n,%)	I (139, 10.9%)	II (568, 44.7%)	III (172, 13.5%)		IV (6, 0.5%)	V (1, 0.1%)	Unknown (384, 30.2%)
Patient Cohort (n,%)	Primary Colorectal Cancer (889, 70.0%)		Diverticular (88, 7.0%)	IBD (126, 9.9%)	Volvulus (35, 2.8%)	Other benign (114, 9.0%)	Other malignant (17, 1.3%)
Intraoperative Risk factors							
Cases with stoma created (n,%)	Yes (231, 18.2%)				No (1039, 81.8%)		
Initial surgical approach (n,%)	Laparoscopic (735, 57.9%)			Open (534, 42.0%)		Unknown (1, 0.1%)	
Conversion to open (n,%)	Yes (80, 6.3%)			No (1185, 93.3%)		Unknown (5, 0.4%)	
Left-sided and Right-sided anastomoses (n,%)	Left-sided (607, 47.8%)				Right-sided (602, 47.4%)		

1.23. Using G-Charts to Map Anastomotic Leak

Elective anastomoses

There were 1405 Elective Anastomotic operations carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017. ALs occurred in 82/1405 of these cases (a rate of 5.80%). The median number of ALs between each leak was 11. The G-Chart (Figure 10) shows that between 17/02/2011 and 10/04/2012, there are 15 consecutive points in the inner third of the chart between the -1 and +1 sigma limits, meaning that there is a reasonable chance of special cause variation during this time. There are also several outliers in this chart; however with G-charts these outliers do not represent a statistically significant change.

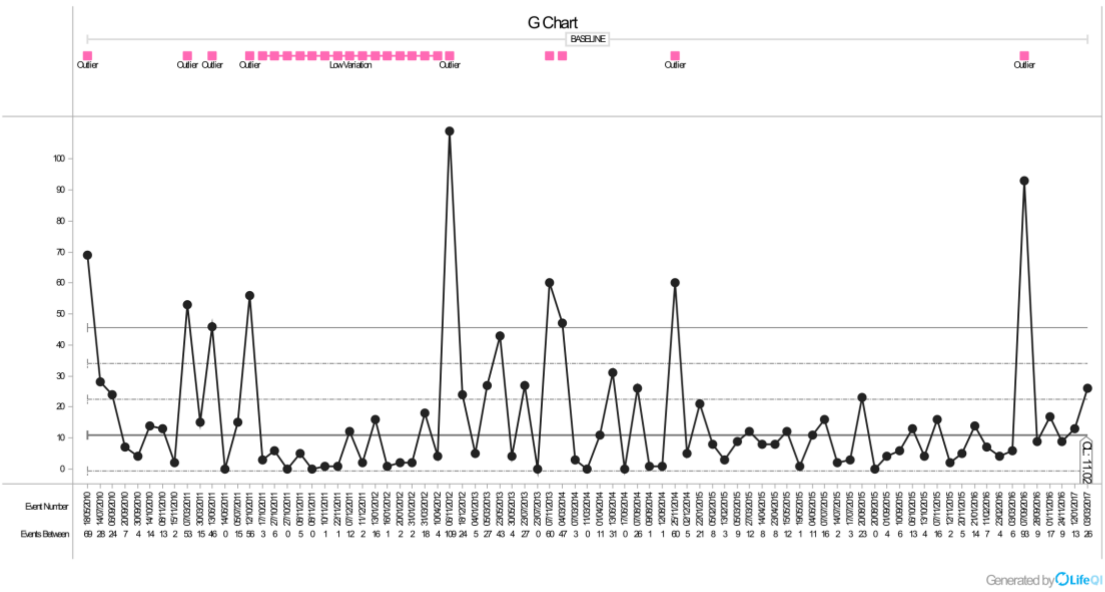


Figure 10 - G-Chart Showing the number of cases between ALs in Elective Cases

Emergency Anastomoses

There were 338 Emergency anastomotic procedures carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017. Anastomotic Leak occurred in 25 of these cases (a rate of 7.40%). The median number of cases between each AL was 9.0 cases. This SPC chart (Figure 11) is in control, with the variability being due to common-cause variation and not representing any statistically significant change.

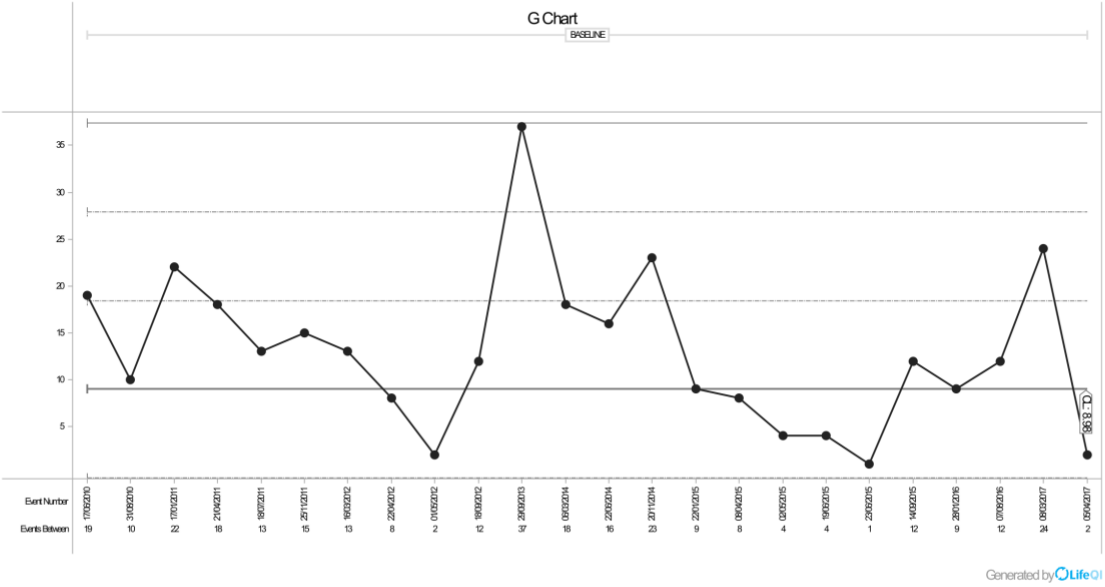


Figure 11 - G-Chart Showing the number Emergency cases between Emergency ALs

Right-sided Anastomoses

There were 884 Right-Sided emergency & elective anastomotic procedures carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017. Anastomotic Leak occurred in 49 of these cases (a rate of 5.50%). The median number of cases between each AL was 11.30 cases. The G-Chart (Figure 12) shows that between 25/11/2014 and 03/03/2016, there are 15 consecutive points in the inner third of the chart between the -1 and +1 sigma limits, meaning that there is a reasonable chance of special cause variation during this time. There are also several outliers in this chart; however, with G-charts these do not represent a statistically significant change.

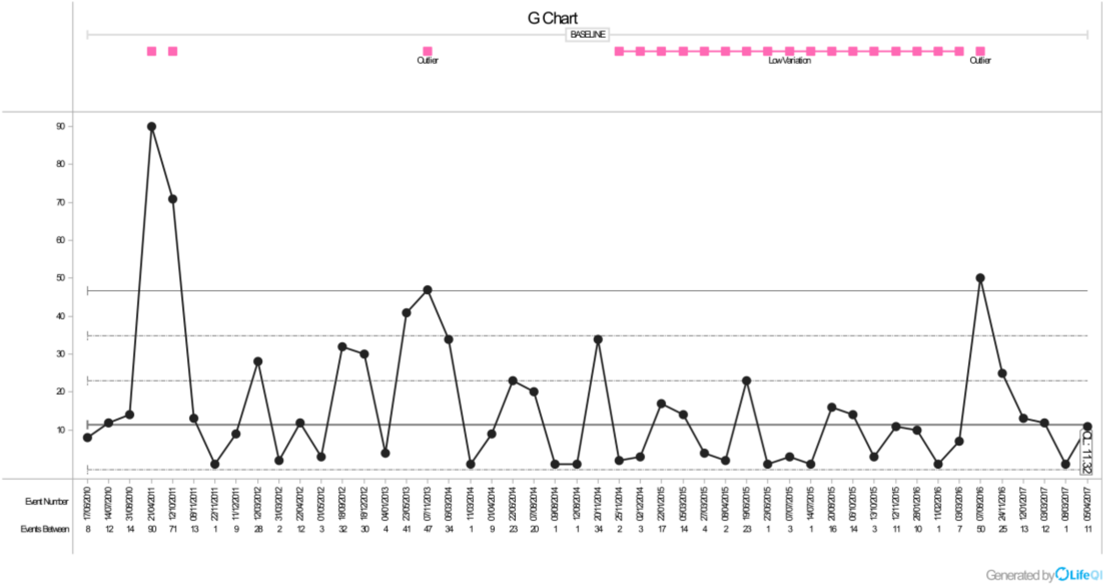


Figure 12 - G-Chart Showing the number of cases between Right-Sided ALs

Left-sided Anastomoses

There were 775 Left-Sided emergency & elective anastomotic procedures carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017. Anastomotic Leak occurred in 52 of these cases (a rate of 6.80%). The median number of cases between each AL was 9.20 cases. This SPC chart is in control (Figure 13), only common cause variation is present.

There are some outliers shown in this graph, but these are not significant for G-Charts.

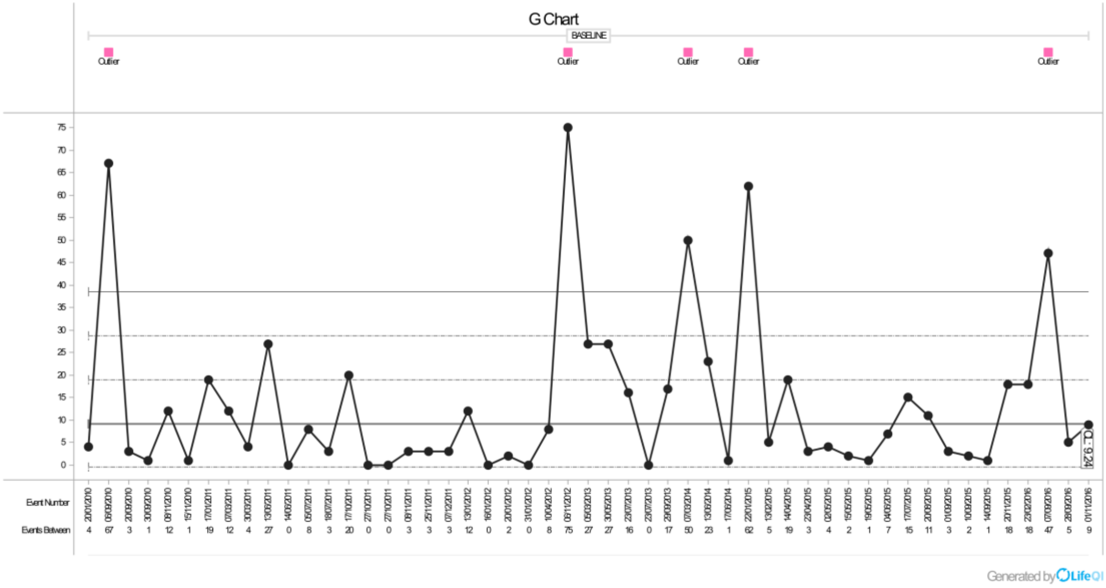


Figure 13 - G-Chart Showing the number of Left-Sided cases between Left-Sided ALs

<u>Sutured Anastomoses</u>

There were 466 Sutured anastomotic procedures carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017. Anastomotic Leak occurred in 35 of these cases (a rate of 7.50 The median number of cases between each AL was 7.80 cases. There are also several outliers in this chart; however with G-charts these do not represent a statistically significant change. This SPC chart is in control (Figure 14), with the variability being due to common-cause variation.

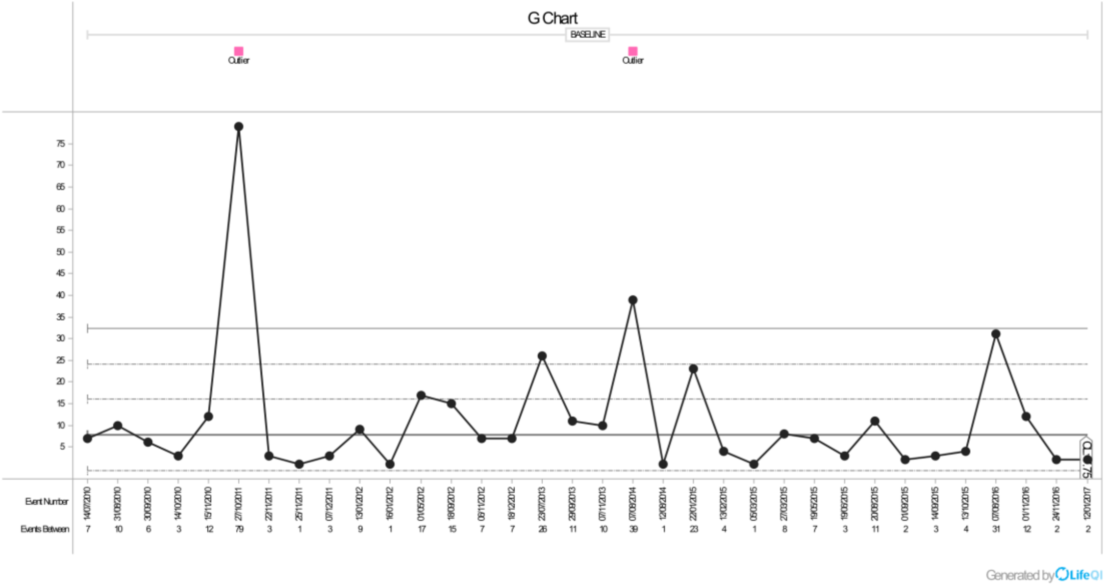


Figure 14 - G-Chart Showing the number of Sutured cases between Sutured ALs

<u>Stapled Anastomoses</u>

There were 1270 Stapled anastomotic procedures carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017. Anastomotic Leak occurred in 72 of these cases (a rate of 5.70%). The median number of cases between each AL was 11.60 cases. The G-Chart shows (Figure 15) that between 14/04/2015 and 03/03/2016, there are 15 consecutive points in the inner third of the chart between the -1 and +1 sigma limits, meaning that there is a reasonable chance of special cause variation during this time. There are also several outliers in this chart; however with G-charts these do not represent a statistically significant change. In 17/1743 anastomoses it was unclear from the operation note whether the primary anastomosis was made with sutures or staples.

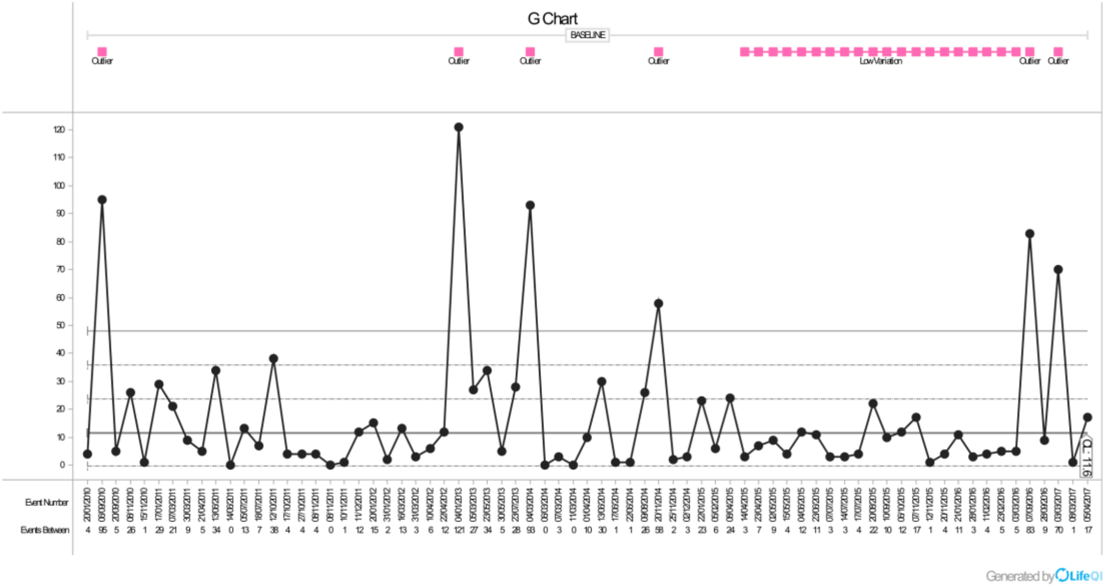


Figure 15 - G-Chart Showing the number of Stapled cases between Stapled ALs

1.24. Using I-Charts to Map Anastomotic Leak

There were 1743 anastomotic procedures carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017. Anastomotic Leak occurred in 107 of these cases with a median number of 7.10 leaks every 6 months. This SPC chart (Figure 16) is in control, with the variability being due to common cause variation.

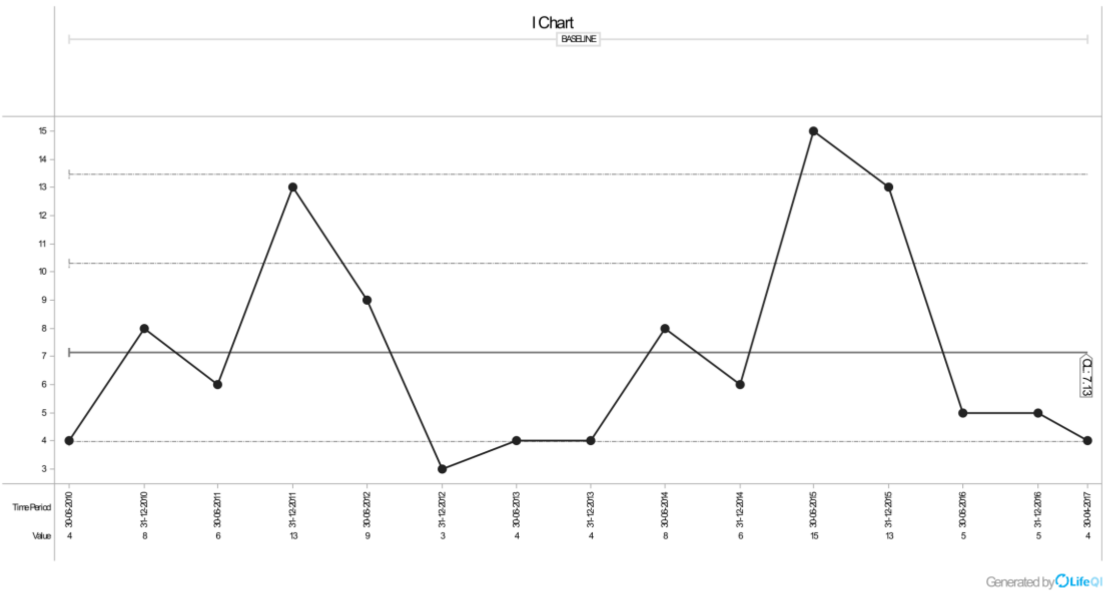


Figure 16 - I-Chart Showing the number of ALs every 6 months

1.25. Using I-Charts to Map Postoperative Length of Stay

Elective anastomoses

There were 1405 elective procedures carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017, with a mean PLoS of 8.3 (SD 9.5) and a median PLoS of 6. The chart below (Figure 17) shows special cause variation with a run of eight points below the centreline from March 2012 to March 2013 and May 2013 to May 2014 respectively.

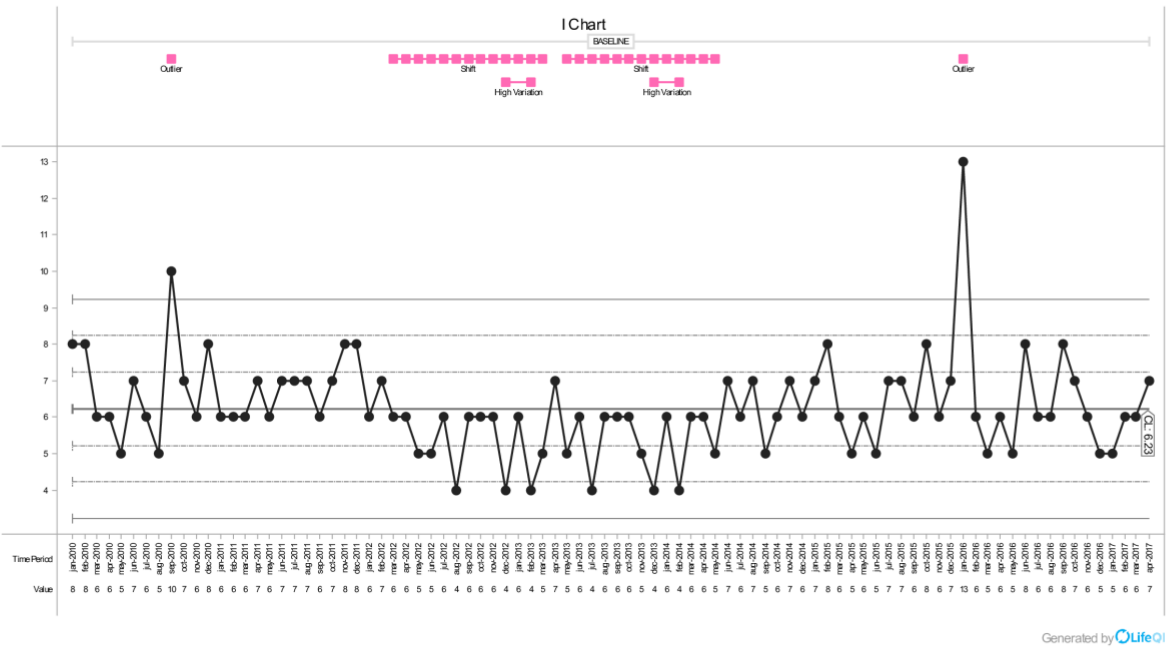


Figure 17 - I-Chart showing the median monthly PLoS in patients undergoing Elective Anastomoses

Emergency anastomoses

There were 338 Emergency anastomoses carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017, with a mean PLoS of 12.7 (SD 11.5) and a median PLoS of 13. The chart below (Figure 18) shows one outlying point more than three standard deviations from the mean in September 2013.

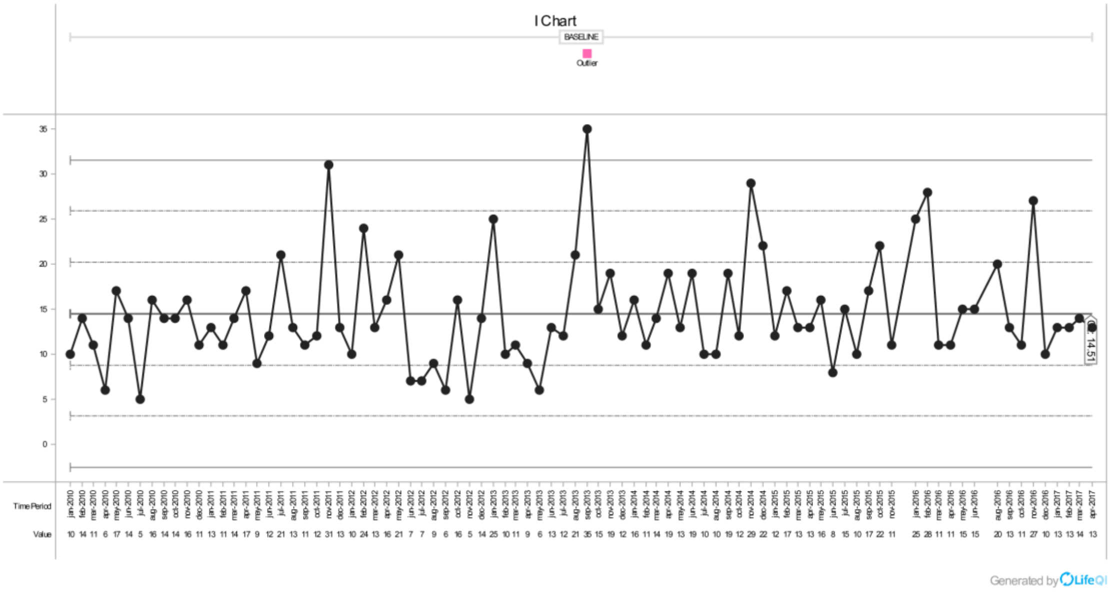


Figure 18 - I-Chart showing the median monthly PLoS in patients undergoing Emergency Anastomoses

<u>Right-sided Anastomoses</u>

There were 884 anastomoses carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017, with a mean PLoS of 9.8 (SD 10.5) and a median PLoS of 7. The chart below (Figure 19) shows special cause variation with a run of eight points below the centreline from January 2010 to August 2010, May 2011 to January 2012 and June 2012 to May 2013 respectively. There were also three outlying points, more than 3 standard deviations from the centre line.

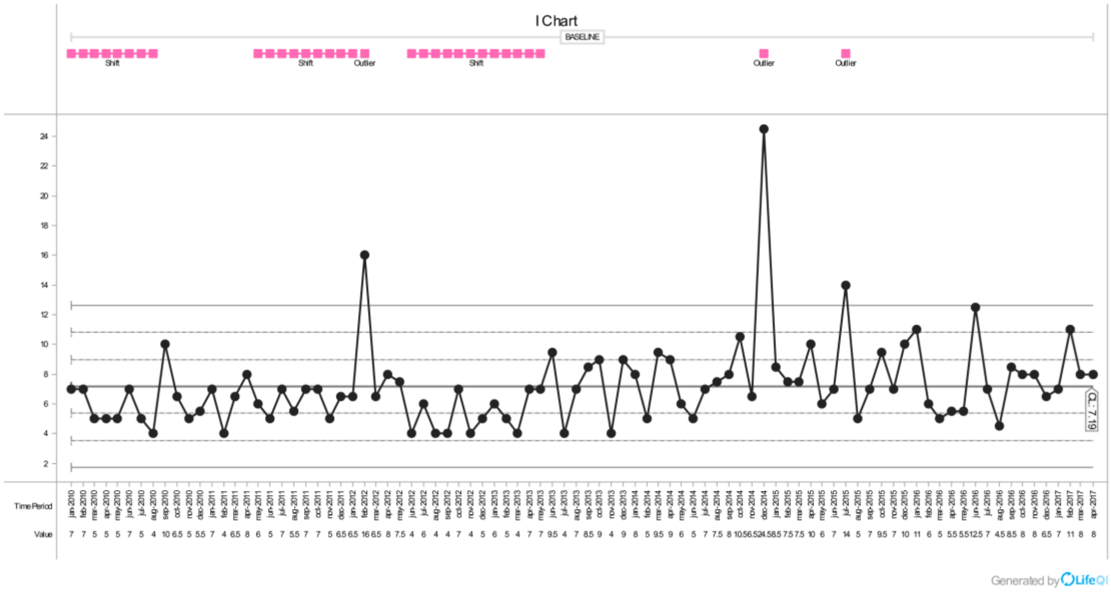


Figure 19 - I-Chart showing the median monthly PLoS in patients undergoing Right-sided Anastomoses

<u>Left-sided Anastomoses</u>

There were 775 anastomoses carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017, with a mean PLoS of 8.5 (SD 9.8) and a median PLoS of 6. The chart below (Figure 20) shows special cause variation with a run of eight points below the centre line from April 2012 to September 2013, two out of three points between the +2 and +3 sigma limits in November 2011 and January 2012 respectively and 2 outlying points, more than 3 standard deviations from the centre line.

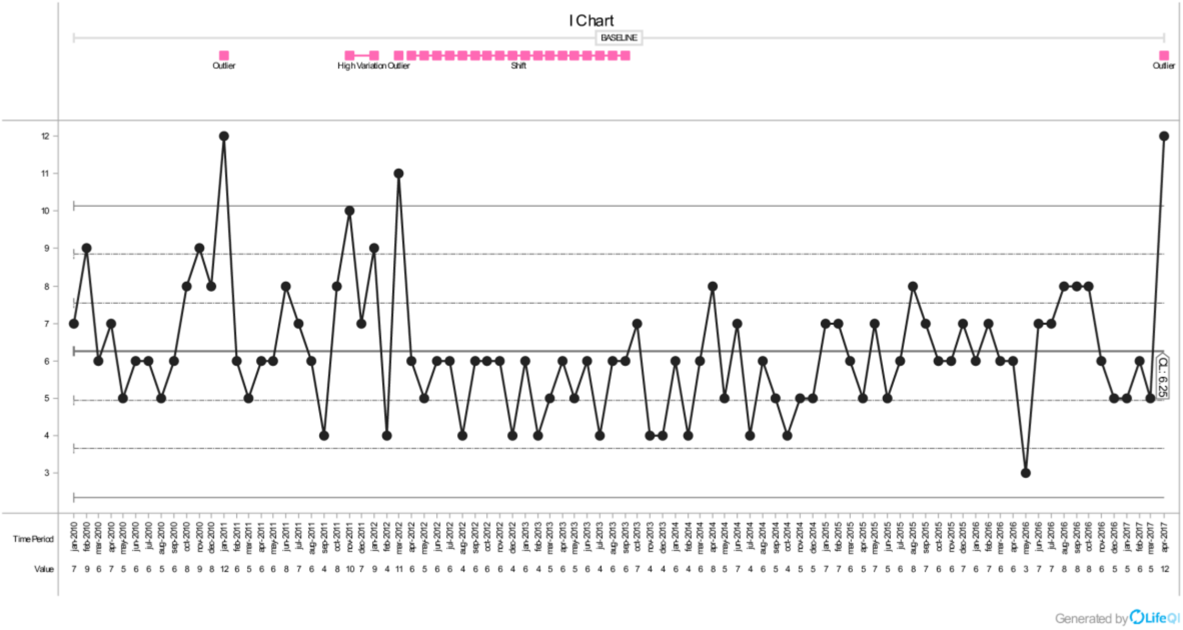


Figure 20 - I-Chart showing the median monthly PLoS in patients undergoing Left-sided Anastomoses

Sutured Anastomoses

There were 466 anastomoses carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017, with a mean PLoS of 10.8 (SD 12.2) and a median PLoS of 8. The chart below (Figure 21) shows special cause variation with a run of eight points below the centreline from March 2011 to January 2012 and November 2012 to June 2013 respectively. There was also two outlying points, more than 3 standard deviations from the centreline.

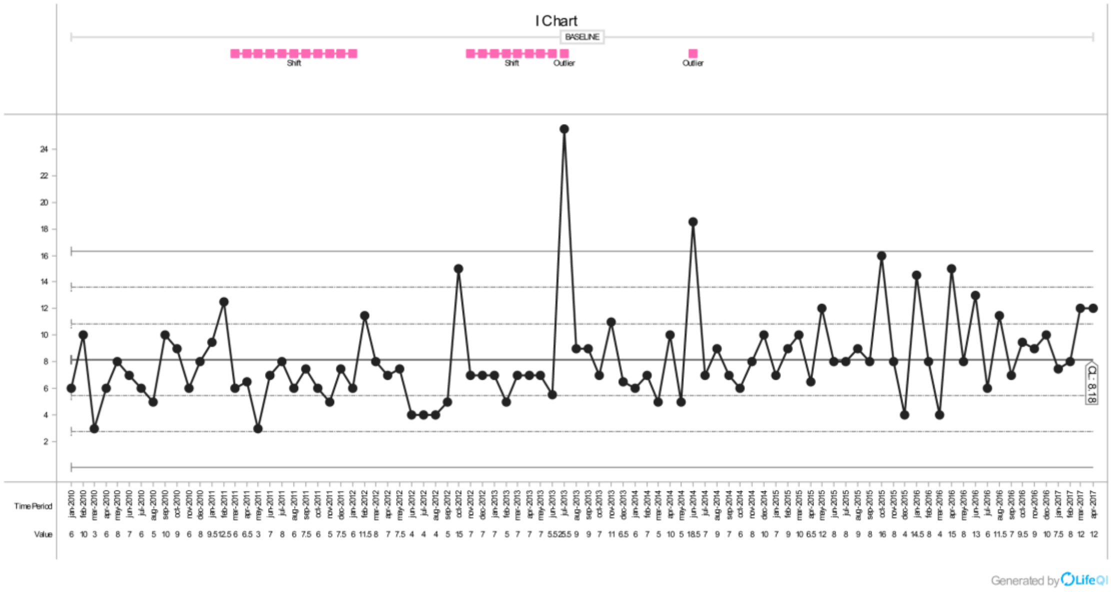


Figure 21- I-Chart showing the median monthly PLoS in patients undergoing Sutured Anastomoses

<u>Stapled Anastomoses</u>

There were 1270 anastomoses carried out at the Royal Devon and Exeter Foundation NHS Trust from 01//01/2010 to 30/04/2017, with a mean PLoS of 8.6 (SD 9.1) and a median PLoS of 6. The chart below (Figure 22) shows special cause variation with a run of eight points below the centreline from March 2010 to November 2010 and June 2012 to March 2013 respectively. There was also two outlying points, more than 3 standard deviations from the centre line.

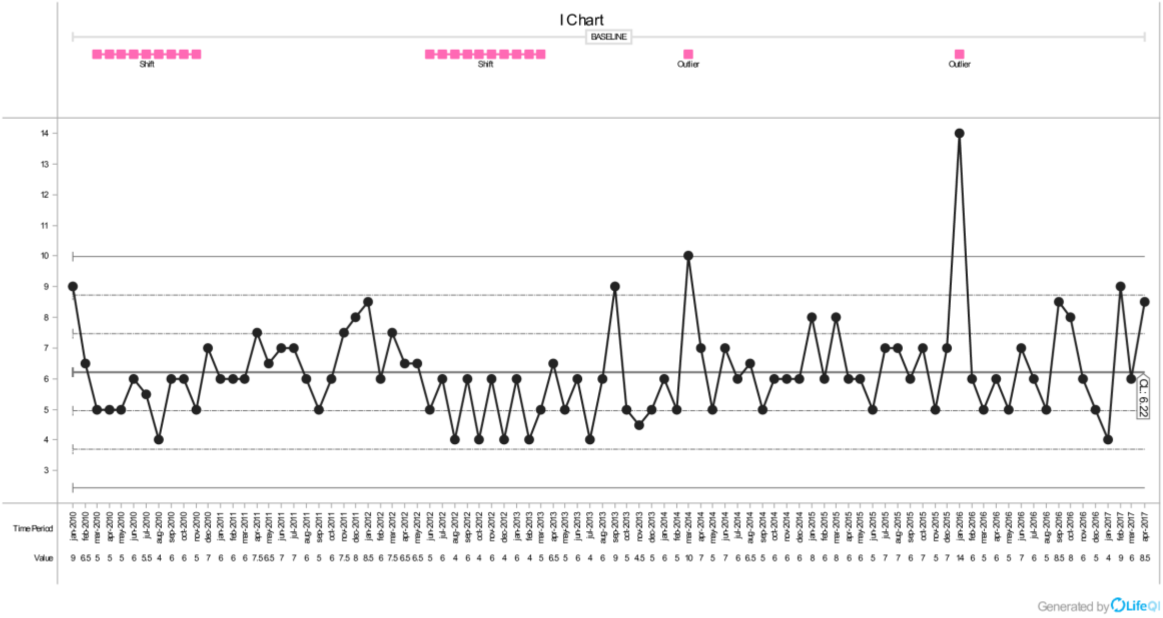


Figure 22- I-Chart showing the median monthly PLoS in patients undergoing Stapled Anastomoses

5)Discussion

This chapter will interpret the results of using SPC charts to monitor AL and PLoS; explore the strengths and weaknesses of applying SPC in this circumstance as well as the strengths and limitations of the study.

1.26. Interpretations of the data

The RTT AL rate was 4.3% was similar to published rates in the literature, which are generally between 2 and 7%.(33-35) The overall AL rate (when including radiologically drained ALs and CT defined ALs) was 6.10%, however this figure is likely to be under-representative as the CT-defined ALs were difficult to diagnose and not always documented on discharge summaries.

For Elective Anastomoses, there was a “reasonable chance” of an increased leak rate from 17/02/2011 and 10/04/2012. There are no obvious clinical reasons that have been identified as to why this occurred; there were no significant changes in the patient population being treated and nor within the consultant body. The SPC charts for Right-sided ALs and Stapled ALs also both indicate special cause variation within an overlapping timeframe, from 25/11/14 to 03/03/16 and 14/04/15 to 03/03/2016 respectively. In this hospital, right hemicolectomies are most commonly carried out using a stapled anastomotic technique. There would be benefit in constructing a G chart investigating the number of cases between right hemicolectomies as well as the number of cases between extended right hemicolectomies. It is also important to remember that although these SPC charts indicate a “reasonable” chance of special cause variation, this is not certain and the findings shown will need further be corroborated within the clinical context.

Also there are differences between the subgroups analysed. The median number of cases between Elective ALs is higher than the number of cases between Emergency ALs (11.0 and 9.0 respectively) indicating a higher AL rate in Emergency Procedures. This is consistent with the literature where emergency resection is an independent RF for AL. (60)

The median number of cases between Right-sided ALs is higher than the number of cases between Left-sided ALs (11.3 and 9.2 respectively) indicating a higher AL rate in Left-sided Procedures. This is also consistent with the literature where the more distal the anastomosis in the GI tract, the larger the AL risk. (61, 62)

The median number of cases between Stapled ALs is much higher than the number of cases between Sutured ALs (11.6 and 7.8 respectively) indicating a higher AL rate in sutured anastomoses. However, this statistic may have been confounded due to a higher proportion of emergency cases within the sutured group in comparison with elective cases (29.6% and 15.6% respectively as shown in Table 8 and Table 9). That said, in a RCT comparing sutured and stapled anastomoses, there was an increased rate of Radiological ALs in the sutured cohort.(10)

Using 3 sigma for the control limits appeared to be appropriate for monitoring variations in the AL rate, with some changes identified, but not excessive outliers or special cause variation illustrated.

The I-Chart mapping AL showed approximately 7 ALs every 6 months. This provides a more intuitive analysis for service users to understand how SPC charts can be applied to measure AL rates. It is also important to note that in the I-chart and G-Charts for sutured ALs and left-sided ALs, there was no evidence of any special cause variation, only common cause variation was present.

In terms of PLoS, the overall median demonstrated in this study was in line with findings from the literature, where the overall median PLoS was shown to be 6-7 days. (13, 146, 147) The median PLoS in patients undergoing emergency anastomoses was higher than those undergoing elective anastomoses (13 and 6 respectively), the literature shows emergency colorectal procedures to be an independent risk factor for prolonged length-of-stay.(148) The median PLoS in patients undergoing stapled anastomoses was slightly higher than those undergoing sutured procedures (8 and 6 respectively). A Cochrane Review comparing stapled and sutured anastomoses did not show a significant difference in PLoS between these two subgroups.(149)

There are also numerous preoperative characteristics and postoperative events beyond the remit of this thesis which can influence PLoS and confound the results.(150)

For Elective anastomoses (Figure 17), there was evidence of a reduced median monthly PLoS from March 2012 to May 2014 with special cause variation present. The sustained nature of the decrease in PLoS could imply one or more changes had been made to clinical practice to result in this desired change in clinical outcomes. For Emergency anastomoses (Figure 18), there was only one outlying point present, with no other evidence of special cause variation, only common cause variation, indicating that the chart (despite one outlier) was in statistical control. For Right-sided anastomoses (Figure 19), the data was quite variable, with three distinct time periods with a lower PLoS and two outlying points. For Left-sided anastomoses (Figure 20) there was a reduced PLoS evident from April 2012 to September 2013. In the charts for Sutured anastomoses and Stapled Anastomoses (Figure 21), PLoS was reduced from March 2011 to January 2012 and November 2012 to June 2013 respectively. In Stapled Anastomoses (Figure 22), there was a reduced PLoS from March 2010 to November 2010 and June 2012 to March 2013 respectively.

Despite the choice to use median as opposed to mean, there are still 1-2 outliers in every chart which illustrated PLoS using I-charts. This indicates the significant variability in the data.

1.27. Strengths of applying SPC charts in this study

In this study, SPC charts have been used to measure retrospectively measure AL and PLoS and have identified time periods where there was special cause variation. These time periods can be now further examined and corroborated with the clinical context to postulate any potential reasons for these changes.

Using SPC charts have also provided a baseline measurement for AL and PLoS upon which an intervention can be implemented for a QI project to take place. With the control limits established, an evidence-based intervention can be implemented with an aim to lower the AL rate and PLoS.

The use of SPC charts also allows the user a graphical interface to monitor AL and PLoS over time. The control chart can be updated regularly by inputting data into a spread sheet recording colorectal resections and ALs and monthly PLoS and subsequently making SPC charts using software such as LifeQI®.

Using SPC charts has been shown to be a robust methodology to continuously monitor these outcomes over time. This study in particular has also illustrated the use of G-Charts, a less commonly used type of SPC chart used to monitor rare events (in this case 6.1% of cases). This study has shown they are a simple, easy-to-implement methodology within clinical practice. The project has also illustrated how I-Charts can be applied to monitor outcomes in surgery and that they are a simple, intuitive graphical interface to interpret time series data.

This project started as the first stage of a QI project but the long-term potential of this methodology is that it can evolve into measuring AL and PLoS for quality assurance, from a patient safety perspective. AL is a postoperative complication that carries significant morbidity and mortality for colorectal patients, monitoring the AL rate will ensure that certain minimum standards are being provided to this patient cohort.

1.28. Limitations of Applying SPC charts to this data

The most significant limitation of using SPC charts is that they cannot demonstrate causation reliably, and so the data must be correlated with the clinical context. In this study, despite the fact that special cause variation has been identified in the SPC charts monitoring AL and PLoS, it may be challenging to investigate specific reasons for any changes given the historical nature of the data analysed. In terms of monitoring median monthly PLoS in Colorectal patients, the I-Charts for Right-sided (Figure 19), Sutured (Figure 21) and Stapled anastomoses (Figure 22) all showed multiple periods of time where the number of PLoS days were lower. Whilst this may be simply be due to the variability of the process which needs to be investigated further, the data might need to be re-analysed with wider control limits (perhaps four sigma instead of three), so the baseline measurement is more in control prior to the implementation of an intervention.

Also given the differences in pre-operative and intra-operative risk factors, the data for AL and PLoS may be confounded therefore it is difficult to make meaningful conclusions when comparing the SPC charts to one another. This can partially be addressed by making SPC charts with further subdivisions, for example, stapled emergency SPC charts and stapled elective SPC charts to preventing the presence of Emergency patients confounding the data (as Emergency patients are an independent risk factor for AL (60)). That said, in these SPC charts, all preoperative, intraoperative and postoperative pathways are considered “part of the system,” and the study charts will ultimately compare outcomes against themselves when an intervention is implemented. It is also possible consider risk-adjusting the data, once the heterogeneity in case mix has been quantified. (151)

With G-Charts, it is also important to consider that they measure “number of cases between each AL”, hence the number of cases being increased is a desired effect (assuming the rare event is negative, i.e. AL). This is however somewhat counter-intuitive, hence may make it a little more challenging to understand.

Another feature of SPC charts which is important to be aware of is that they are rooted an ethos of industrial methodologies. Whilst they can provide a fresh, intuitive methodology to monitoring outcomes, they were made primarily to monitor routine homogenous processes with an objective to maximise profit. Given the complex, holistic nature of clinical settings, to distil clinical processes to SPC chart performance may be too reductive in nature and hence they should be applied with caveats that SPC charts may not always provide a true representation of a clinical process, i.e. in this case understanding that multiple confounders may influence AL and PLoS.

1.29. Comparing this study to previous applications of SPC charts in Surgery

Whilst SPC charts have been previous applied in colorectal studies, (136, 152) this study marks the first time observed in the literature where SPC charts have been used to map AL in Colorectal Surgery. This study was also larger than most studies (n=1743), however there was a similarly sized ((n=1712) colorectal study identified (136) as well as larger national projects across specialties. (134)

This project also marks the first time where G-Charts have been applied in Colorectal surgery. G-Charts have previously been applied to other surgical disciplines.(153, 154) Also this was a single-centre study, in comparison to other SPC studies which are often national, collaborative efforts.(130, 134) Whilst these larger studies are more generalizable, in this study there can be more confidence that data collection was carried out as described in the methods in comparison to collaborative efforts where there can be more variability between centres.

Also this study served as the pre-interventional phase of a QI project. Within the literature there have been many surgical QI projects where SPC charts had been applied, with both a pre-interventional and post-interventional phase. (117, 122, 123, 126, 131-133, 137, 139, 140, 155, 156). This project aimed to establish a retrospective baseline phase to map process variability prior to intervening, much like a similar project benchmarking performance in laparoscopic cholecystectomies. (157) This project also assessed the feasibility in using SPC charts to monitor AL, similar to other projects that assessed the feasibility of SPC charts in surgical contexts. (124, 135, 136, 153, 154, 157)

Several previous surgical studies have applied SPC charts to map hospital length of stay. (131, 136, 152). One paper assessed how the reduced duration of a preoperative nil-by-mouth regimen would impact “extended hospital length of stay” (as defined as more than more than one postoperative hospital day) in patients undergoing bariatric surgery. This paper illustrated how SPC charts can be used alongside more traditional statistical analysis such as Chi-square and regression analysis. Though these methods were not utilised in this thesis, they can also be used to assess whether there are any statistical differences pre- and post-intervention.(131) In a colorectal study which also mapped PLoS using SPC charts, the authors found a similar finding to this study, a higher mean number of postoperative days was noted in the emergency group in comparison to the elective group. However, this may be confounded due to differences in preoperative risk factors in the emergency group, as these patients tended to have a higher BMI and higher mean ASA grade.

One important factor in this study the importance of “buy-in” from the senior team. As is elaborated in “1.31 Ethical reflections of the study,” one challenge of this study gaining the support from the clinical team to map SPC charts by individual surgeon, due to the sensitive nature of the data being analysed. In a project assessing performance amongst cataract surgeons, there was also initially some reluctancy to participate, due to a fear that individual outcomes might become known. To mitigate against this, they compared a subgroup surgeons that performed a high volume of cataract procedures against a subgroup that performed less. (124)

1.30. Strengths and limitations of the study

This is a large study with a retrospective data period of 7 ½ years, including 1743 patients and 107 ALs overall. These SPC charts can serve as a reliable baseline measurement upon which an intervention can be implemented. It is also one of the largest studies mapping AL using SPC charts and the first project mapping AL using G-Charts. This study illustrates the utility and simplicity in using SPC charts to map AL and PLoS in Colorectal Surgery and it is a feasible methodology to now monitor these outcomes prospectively.

A broad definition of AL was used in this study including; patients in which a re-Laparotomy was carried out and the anastomosis was taken down; cases where AL was treated via CT-guided drainage and cases where the AL was managed medically. Many studies which study AL, only examine the re-laparotomy dataset which could lead to an underreporting of the AL rate, as well as less precise “before” and “after” results as the overall numbers of ALs will be lower. Sequential cases for ALs that return-to-theatre and those were ALs were drained radiologically were also picked up by the coding searches and were all checked manually. PLoS was also a simple reliable statistic to calculate using the date of the operation and date of discharge as reference points.

There were several limitations of the data collection process itself. Firstly, the number of medically-managed ALs is likely to be under-representative and a less reliable statistic – these ALs are difficult to identify (see 0Diagnosis of AL) and they are not always tested for in clinical practice as they often resolve before a diagnostic scan is carried out. Also medically managed ALs were identified by checking discharge summaries however sometimes an AL diagnosis was sometimes not highlighted in the discharge summary, only in the handwritten medical notes. Manually checking each set of patient notes would have not been feasible within the timescale of this thesis. Also ALs after stoma reversal surgery were not included, these patients are another significant cohort in Colorectal Surgery, with an associated increased risk of AL and mortality.(25, 26) Contrast-enema ALs (where patients who underwent outpatient CT scans and contrast enemas after their initial inpatient stay, who were subsequently shown to have an AL) were not followed up. This was due to small numbers and the perceptions this would not greatly impact overall numbers of AL. Patients who only underwent small bowel-small bowel anastomoses were not included, as this patient cohort was considered to be a small and relatively different patient cohort compared to colorectal anastomoses.

Another limitation of the study is that despite the large volume of data manually collected, there are still some notable gaps in preoperative statistics, 511/1743 (29.3 %) of ASA grades were not available on the operative note and it was not clear whether the intestinal anastomosis was sutured or stapled in 16/1743 (0.9%) of cases. This might also be due to the retrospective nature of the data collected, gaps in data would have been less likely had the data been collected prospectively.

Another limitation of this study is the method in which the relevant risk factors for AL (and hence which perioperative datapoints to collect) were chosen. As described in section 1.15 “Study Design” in the Methodology section, the relevant risk factors were established prior to data collection with the assistance of the thesis supervisor as opposed to a systematic assessment of relevant risk factors implicated in AL as per the existing literature, hence certain risk factors which could have been analysed as significant for AL (For example SPC charts for patient cohorts such as IBD vs. Malignancy SPC charts) were not analysed in this study.

1.31. Ethical reflections of the study

After the previous misunderstanding in the first draft of the thesis (due to lack of understanding between the ethical requirements for QI and research), it became apparent that Ethical Approval from the local Research Ethics Committee was not required for this study (which has been amended in this submission). This project was a service evaluation project (as per the table in the section “Ethics for QI” in “1.14 Quality Improvement”) (83) and not a formal research project; only specific data points relevant to the AL rates were collected; the aim was to assess AL rates within current clinical practice, not to derive generalisable conclusions from the AL rates.

Another ethical challenge of this thesis involves the inclusion of relevant factors to analyse and make SPC charts relating to AL. “Individual Surgeon”(158) was identified as an independent risk factor for AL in Colorectal surgery. When it was discussed with the surgical research team whether “Individual Surgeon” should be analysed further as a subgroup, it was fed back that this was not considered to be an advisable avenue for further research at this time. This was due to the potential for unintended consequences, including surgeons comparing themselves against one another (as the data would only be pseudo-anonymised at best) and it might lead to the Consultant surgeons badgering the junior research team to reveal surgeon-specific outcomes. Given my role as a junior research member, I followed the advice given, understanding that certain data analysis may not be appropriate due to the sensitivity of the data being collected. However in doing so, I may have inadvertently introduced a bias into the study, given that not all relevant factors were analysed in their entirety.

1.32. Future research

In terms of the next steps within the project, now that there are clear baseline measurements for the AL rates, these outcomes can now be monitored prospectively. The prospective data collection will also include the significant patient cohort who undergo a re-anastomosis of a stoma (i.e. stoma reversal). There will also be efforts made to ensure that the data collected is more complete, with less gaps (particularly in terms of ASA grading). During the prospective data collection phase, an intervention can also be implemented.

Now that the SPC charts have been set up, they can also be used to monitor outcomes for QA purposes in future projects, ensuring that minimum standards of postoperative care are provided at this centre. Once the future intervention is implemented, the department can also explore the use of ITS analysis, if they would like to quantify the extent of change as a result of an intervention on the AL rate over time.

One area of research not explored in this dissertation for reasons explained is constructing SPC charts by "individual surgeon" (further elaborated in the section 1.31 "Ethical reflections of the study"). To mitigate against the reluctance of analysing this data, the charts could be constructed by subgroups, comparing surgeons by volume of procedures carried out, i.e. a "high volume" group and a low volume group, much like a paper comparing cataract surgeons. (124) Making surgeons aware of their outcomes also increases the likelihood of the Hawthorne effect, where outcomes may improve due to increase caution under observation. SPC charts are an effective methodology for monitoring outcomes over time; however their use should be implemented in a way that does not have any unintended consequences for clinical care or for healthcare professionals. As described in “1.26 Interpretations of the data” as there is overlap between special cause variation shown in both the Stapled and Right-sided anastomoses SPC charts, there might be a benefit in constructing a control chart assessing ALs in Right hemicolectomies. Within the SPC charts used to monitor PLoS, there were defined periods of time where there were lower numbers of PLoS days, however without a clear understanding of the clinical environment, these results can be challenging to contextualise. This AL and PLoS data could be further explored with a qualititative analysis of the historical context, for example, interviews with surgeons could be conducted with periods of special cause variation aiding as prompts to identify historical reasons for the changes identified.

In terms of future research within colorectal surgery, there needs to be standardised definition of AL. As of writing this thesis, there several different definitions of AL that are used and there can be therefore inconsistencies in reporting AL rates.(159) The ISREC classifications of AL with Grade A, B and C are a useful starting point to understanding the significant differences between different types of AL. That said, many articles in the literature only report AL rates as defined by cases that undergo a subsequent re-laparotomy and take down of the anastomosis (similar to a Grade C AL).

1.33. Conclusions and perspectives for the future

This is a large single-centre study, which marks the first time SPC charts have been used to map AL and the first time that G-Charts have been applied to Colorectal Surgery.

In terms of the data, the AL rate is relatively low at this hospital, with a return-to-theatre rate of 4.3%. The overall rate also low at 6.1% (however this is likely to be an under-representative dataset due to underdiagnosed/under-documented AL). The SPC charts show that there is a reasonable chance of retrospective special cause variation for the Elective, Stapled and Right-sided AL charts, with some overlap with the former two categories. These are results that will need to be investigated further with the Colorectal Team to establish whether there were any apparent historical reasons that could have led to the changes in AL rate.

PLoS was also monitored using I-Charts, the overall PLoS statistics were in line with the literature. All six SPC charts exhibited special cause variation where there were variations in the median monthly PLoS, however these findings will now need to be corroborated with the clinical team.

A core principle of Quality Improvement is that “what cannot be measured, cannot be improved.” Using these SPC charts has allowed us to establish a baseline measurement and establish the control limits for this project. Now an intervention can be implemented reduce rates of AL and the overall number of Postoperative days. As the methodology is in place, SPC charts can also be used to ensure patient safety over time, acting within a QA context. The simplicity and ease by which SPC charts can be constructed, lends their application to a wide variety of functions but AL and PLoS are good markers of postoperative care that can be taken up by the Colorectal Department.

There are also limitations inherent with using SPC charts. Despite their ability to identify retrospective periods of special cause variation, the findings in SPC charts still need to be corroborated with the clinical context as SPC charts cannot identify which factors have caused the shift. In summary, this dissertation demonstrates that it’s entirely feasible to retrospectively map the AL rate and PLoS in a Colorectal Unit.

Colorectal resection and anastomoses have been carried out for more than 150 years; however to improve outcomes for future patients, focussed efforts must be maintained to continuously measure AL and PLoS over time, then interventions can be implemented to ultimately improve the outcomes for patients undergoing colorectal surgery. In the immortal words of Deming “In God we trust, all others must bring data”.(160)

6)Appendix

1.34.Right-sided and Left-sided Colorectal Procedures

Use “Table 10” to see definitions used in this dissertation.

Table 10 - Right-sided and Left-sided Colorectal Procedures

Left-sided	Right-sided
1) Anterior resection	Right hemicolectomy
2) Anterior resection with Ileostomy	Right hemicolectomy with ileostomy
3) Sigmoid Colectomy	Extended right hemicolectomy
4) Sigmoid colectomy with ileostomy	Extended right hemicolectomy with ileostomy

1.35.NHS OPCS Data Dictionary – 4.7

H04 Total Excision of colon and rectum

- H04.1 – Panproctocolectomy and ileostomy
- H04.2 – Panproctocolectomy and anastomosis of ileum to anus and creation of pouc
- H04.3 – Panproctocolectomy and anastomosis of ileum to anus NEC
- H04.8 – Other specified total excision of colon and rectum
- H04.9 – Other specified total excision of colon and rectum.

H05 Total Excision of colon

- H05.1 – Total colectomy and anastomosis of ileum to rectum
- H05.2 – Total colectomy and ileostomy ad creation of rectal fistula HFQ
- H05.3 – Total colectomy and ileostomy NEC
- H05.8 – Other specified total excision of colon.
- H05.9 – Unspecified total excision of colon
- H06 Extended excision of right hemicolon
- H06.1 – Extended right hemicolectomy and end to end anastomosis
- H06.2 – Extended right hemicolectomy and anastomosis of ileum to colon
- H06.3 – Extended right hemicolectomy and anastomosis NEC
- H06.4 – Extended right hemicolectomy and ileostomy HFQ
- H06.5 – Extended right hemicolectomy and end to side anastomosis
- H06.8 – Other specified extended excision of right hemicolon
- H06.9 – Unspecified extended excision of right hemicolon

H07 other excision of right hemicolon

- H07.1 – Right hemicolectomy and end to end anastomosis of ileum to colon
- H07.3 – Right hemicolectomy and anastomosis NEC
- H07.4 – Right hemicolectomy and ileostomy HFQ
- H07.5 – Right hemicolectomy and end to side anastomosis
- H07.8 – Other specified excision of right hemicolon
- H07.9 – Unspecified other excision of righthemicolon

H08 Excision of transverse colon

- H08.1 - Transverse colectomy and end to end anastomosis
- H08.2 - Transverse colectomy and anastomosis of ileum to colon
- H08.3 - Transverse colectomy and anastomosis NEC
- H08.4 - Transverse colectomy and ileostomy HFQ

- H08.5 - Transverse colectomy and exteriorisation of bowel NEC
- H08.6 - Transverse colectomy and end to side anastomosis
- H08.8 - Other specified excision of transverse colon
- H08.9 - Unspecified excision of transverse colon

H09 - Excision of left hemicolon

- H09.1 - Left hemicolectomy and end to end anastomosis of colon to rectum
- H09.2 - Left hemicolectomy and end to end anastomosis of colon to colon
- H09.3 - Left hemicolectomy and anastomosis NEC
- H09.4 - Left hemicolectomy and ileostomy HFQ
- H09.5 - Left hemicolectomy and exteriorisation of bowel NEC
- H09.6 - Left hemicolectomy and end to side anastomosis
- H09.8 - Other specified excision of left hemicolon
- H09.9 - Unspecified excision of left hemicolon

H10 Excision of sigmoid colon

- H10.1 - Sigmoid colectomy and end to end anastomosis of ileum to rectum
- H10.2 - Sigmoid colectomy and anastomosis of colon to rectum
- H10.3 - Sigmoid colectomy and anastomosis NEC
- H10.4 - Sigmoid colectomy and ileostomy HFQ
- H10.5 - Sigmoid colectomy and exteriorisation of bowel NEC
- H10.6 - Sigmoid colectomy and end to side anastomosis
- H10.8 - Other specified excision of sigmoid colon
- H10.9 - Unspecified excision of sigmoid colon

H11 other excision of colon

- H11.1 - Colectomy and end to end anastomosis of colon to colon NEC
- H11.2 - Colectomy and side to side anastomosis of ileum to colon NEC
- H11.3 - Colectomy and anastomosis NEC
- H11.4 - Colectomy and ileostomy NEC
- H11.5 - Colectomy and exteriorisation of bowel NEC
- H11.6 - Colectomy and end to side anastomosis NEC
- H11.8 - Other specified other excision of colon
- H11.9 - Unspecified other excision of colon

H29 Subtotal excision of colon

- H29.1 - Subtotal excision of colon and rectum and creation of colonic pouch and ana to anus

- H29.2 - Subtotal excision of colon and rectum and creation of colonic pouch NEC
- H29.3 - Subtotal excision of colon and creation of colonic pouch and anastomosis of
- H29.4 - Subtotal excision of colon and creation of colonic pouch NEC
- H29.8 - Other specified subtotal excision of colon
- H29.9 - Unspecified subtotal excision of colon

H33 Excision of rectum

- H33.1Abdominoperineal excision of rectum and end colostomy
- H33.2Proctectomy and anastomosis of colon to anus
- H33.3Anterior resection of rectum and anastomosis of colon to rectum using staples
- H33.4Anterior resection of rectum and anastomosis NEC
- H33.5Rectosigmoidectomy and closure of rectal stump and exteriorisation of bowel
- H33.6Anterior resection of rectum and exteriorisation of bowel
- H33.7Perineal resection of rectum HFQ
- H33.8Other specified excision of rectum
- H33.9Unspecified excision of rectum

H47 Excision of anus

- H47.1Excision of sphincter of anus
- H47.8Other specified excision of anus.

1.36. HDAS Search String Strategy 18.10.19

#	Database	Search term	Results
1	Medline	("statistical process control" OR "statistical quality control").ti,ab	920
2	Medline	(shewhart).ti,ab	187
3	Medline	(1 OR 2)	1081
4	Medline	("surg*").ti,ab	1744570
5	Medline	("operating theatre*").ti,ab	3715
6	Medline	("operating room*").ti,ab	25458
7	Medline	exp "SURGICAL PROCEDURES, OPERATIVE"/	3008757
8	Medline	exp "OPERATING ROOMS"/	13071

9	Medline	exp "SPECIALTIES, SURGICAL"/	191746
10	Medline	(4 OR 5 OR 6 OR 7 OR 8 OR 9)	3972122
11	Medline	(3 AND 10)	149
12	EMBASE	("statistical process control" OR "statistical quality control").ti,ab	1375
13	EMBASE	(shewhart).ti,ab	206
14	EMBASE	(12 OR 13)	1542
15	EMBASE	("surg*").ti,ab	2391583
16	EMBASE	("operating theatre*").ti,ab	5337
17	EMBASE	("operating room*").ti,ab	34907
18	EMBASE	exp SURGERY/	4485550
19	EMBASE	"OPERATING ROOM"/	33561
20	EMBASE	(15 OR 16 OR 17 OR 18 OR 19)	5137995
21	EMBASE	(14 AND 20)	232
22	EMBASE	21 [English language]	231
23	Medline	11 [Languages English]	149
24	Medline	2 not 1	161
25	Medline	(10 AND 24)	19
26	EMBASE	13 not 12	167
27	EMBASE	(20 AND 26)	18

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