

**OUTCOMES OF A PROGRAMME OF QUALITY IMPROVEMENT TO IMPROVE ATTAINMENT
OF CLINICAL INDICATORS IN A CHRONIC DIALYSIS POPULATION**

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ABSTRACT

The University of Manchester

Submitted by Dr Sajeda Akhter Hussain Youssouf

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Outcomes of a programme of quality improvement to improve attainment of clinical indicators in a chronic dialysis population

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The management of people on dialysis is complex and requires a multi-disciplinary multi-professional approach. Observational studies in dialysis care have demonstrated a correlation between key clinical indicators and survival. However, achieving change in such a complex setting is difficult, with limited evidence from controlled studies of the effectiveness of interventions to improve these indicators. There is little evaluation of how best to implement and sustain known best practice into clinical care.

UK renal registry data shows that whilst overall standards have improved, variation between units remains unchanged. This variation demonstrates that feedback alone is not enough to implement best practise, and that it is also necessary to understand cultural, structural, organisational and process factors.

Quality Improvement (QI) is the process by which change can be implemented in systems. Methodologies vary, and highlight the need for bespoke approaches tailored to fit the clinical context.

In 2010 the Salford Royal renal network introduced a two-year programme of QI to improve clinical indicators in dialysis care. Results were followed up on completion of the programme to establish whether outcomes were sustained.

This thesis starts with a literature review summarising the evidence to date on modifiable factors affecting outcomes in renal replacement therapy and the rationale for addressing these factors in our chronic dialysis population, the development of QI in healthcare, and the evidence for its use to improve outcomes in renal replacement therapy.

The first aim of this thesis was to analyse the outcomes of the Salford quality improvement programme. This found that the programme was successful in improving attainment of clinical indicators, and there was evidence of a reduction in hospitalisation and its associated costs. The second aim was to analyse in more detail one aspect of the programme- reduction in peritonitis. Key themes that emerged from this were the role of audit and continuous measurement, the importance of local leadership, learning from best practice elsewhere, and a patient-centred approach to reducing avoidable harm. The last question centred on the sustainability of results. Review of two years' follow up data on urea reduction ratio and bacteraemia identified that whilst not all changes to practice were sustained, both improved clinical outcomes were broadly sustained. However, additional themes emerged from the analyses, highlighting the need to embed ongoing continuous review into practice.

Finally, I have described potential future work arising from this thesis.

Declaration

No portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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Acknowledgements

This research project would not have been possible without the staff and dialysis patients at Salford Royal Hospital Foundation Trust. I hope the findings of this thesis will benefit future patients with kidney disease, and inspire the staff to continue to strive to excel in their care and dedication for their patients.

Firstly, I owe a significant debt of gratitude to Dr Janet Hegarty, who acted as both my clinical manager and research supervisor during my time at Salford and beyond. Her ideas, honesty, support and guidance encouraged me to discover new ways of thinking and to develop interests beyond what I already knew. I am deeply grateful to Professor Philip Kalra for his expertise and advice on academic matters, and support and encouragement to complete this thesis.

Special thanks go to Dr Azri Nache, who preceded me in my role as quality improvement fellow in the department of renal medicine at Salford and facilitated the improvement projects. As a friend and mentor, his frank and honest counsel helped me steer a course through occasionally stormy waters. I would also like to thank Professor Donal O'Donoghue for his help and generosity in opening up new opportunities, and my academic advisor Dr Graham Wood, for providing a friendly ear when required.

This project would also not have been possible without Emma Flanagan for her IT expertise, invaluable assistance in collecting data, and her teaching about data quality and data systems, and I thank her for her time and enthusiasm.

I wish to thank my family and friends; my parents, who have always supported me and encouraged me to excel; those friends who took this path before me and made it look so effortless- how differently I see it now..., and those near and far who were always ready to listen, critique, and laugh if need be. Lastly, my sincerest thanks go to Donald Wilson, whose support and belief in me the last three years has been inspirational.

Preface

This thesis is presented in the alternative format and comprises a series of studies analysing the outcomes of a programme of quality improvement in a dialysis population and discussion of factors contributing to the results.

The introduction summarises the literature to date on factors affecting outcomes in dialysis care and the rationale for using quality improvement methodology to implement changes to practice.

The methods section describes the data sources, study population, outcome definitions and specific quality improvement methodology used in the programme.

Each results chapter presents the results of the outcome studies conducted to review the results of the QI programme and subsequent follow up analyses. Results chapters are given the title of the publication as published or as prepared for submission for publication. The first results chapter has been accepted for publication in a peer-reviewed medical journal, the second has been submitted and the others are in the format prepared for publication.

Details of journals and publishers are summarised in the section entitled “Published and Presented Work” and given again at the start of each chapter. Where appropriate, a link to the relevant IPR policy giving permission for reproduction in this thesis is provided. The content of the results chapters is presented exactly as has been submitted with modifications made only for consistency of style. For each chapter a section has been added before the abstract to describe the context of the study in relation to the other chapters in this thesis.

Due to the alternative format some overlap exists between the introductory sections, methods sections and referencing. In line with University policy each chapter is individually referenced.

The Author and Author's Contribution

Prior to undertaking this research project I had some experience of literature review and critical appraisal but little experience of medical research or statistical analysis. I have developed skills in statistical analysis through courses at the Universities of Manchester and Liverpool, online learning, and textbooks on medical statistics.

This research was conducted by myself whilst working (on projects distinct from those described in this thesis) as a quality improvement fellow at Salford Royal NHS Foundation Trust. Specifically, these projects were to improve patient engagement and experience of care, and to improve staff culture and engagement. This role gave me further insight into quality improvement in practice.

The quality improvement programme herein described was conducted before I started my role. The quality improvement programme was devised by Dr Janet Hegarty and facilitated by my predecessor, Dr Azri Nache, in his role as quality improvement fellow. "Real-time" data collection was therefore conducted by Dr Azri Nache as "data for improvement". For the purposes of carrying out this research and conducting statistical analyses all data was verified, manually cleaned, cross-checked and analysed by myself in order to ensure it met the standards for publication as academic research.

All study designs, analyses, and collection and cleaning of follow up data were conducted by myself. All manuscript drafts were written by myself. In addition to this, I have assisted in the design of data capture and reporting systems for the Salford renal network, and have summarised improvements in outcomes for the Salford Royal NHS Foundation Trust annual "Quality Accounts" reports during my time there. Further details of contributions made by colleagues are presented in the section entitled Published and Presented Work.

Published and Presented Work

The following chapter has been accepted for publication. Contribution of all co-authors is acknowledged here.

Effect Of A Quality Improvement Program To Improve Guideline Adherence And Attainment Of Clinical Standards In Dialysis Care: Report Of Outcomes In Year 1

Sajeda Youssouf, Azri Nache, Chandrakumaran Wijesekera, Rachel J Middleton, David Lewis, Aladdin E Shurrab, Edmond O’Riordan, Lesley P Lappin, Donal O’Donoghue, Philip A Kalra, Janet Hegarty
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PA Kalra- proof reading, main editor
J Hegarty- QI programme co-ordinator, co-author, main editor

The following papers have been included as thesis chapters and are awaiting submission

Effect Of A Quality Improvement Program To Improve Guideline Adherence And Attainment Of Clinical Standards In Dialysis Care: Report Of Outcomes In Year 2

Sajeda Youssouf, Azri Nache, Chandrakumaran Wijesekera, Rachel J Middleton, David Lewis, Aladdin E Shurrab, Edmond O’Riordan, Lesley P Lappin, Donal O’Donoghue, Philip A Kalra, Janet Hegarty

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Improving Patient Safety In Peritoneal Dialysis Using A Quality Improvement Initiative To Reduce Infections In A UK Renal Network

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The following presentations to learned societies have resulted from work related to this thesis:

Sustained Improvement In PD Peritonitis Rates Over 18 Months Following Completion Of A Formal Quality Improvement Collaborative Project

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Reduction in Catheter-Related Bacteraemia in a Renal Network using Quality Improvement Methodology

S Youssouf, A Nache, J Hegarty

Poster presentation at the American Society of Nephrology annual meeting, Atlanta, December 2013

List of Abbreviations

ANZDATA	Australia and New Zealand Dialysis and Transplant Registry
AVF	Arterio-Venous Fistula
AVG	Arterio-Venous Graft
BMI	Body Mass Index
CABG	Coronary Artery Bypass Graft
CAPD	Continuous Ambulatory Peritoneal Dialysis
CCPD	Continuous Cycling Peritoneal Dialysis
CKD	Chronic Kidney Disease
CPG	Clinical Practice Guideline
CQI	Continuous Quality Management
CXP	Calcium Phosphate Product
DBP	Diastolic Blood Pressure
DM	Diabetes Mellitus
DOPPS	Dialysis Outcomes and Practice Patterns Study
EBM	Evidence Based Medicine
EBPG	European Best Practice Guidelines
ERA-EDTA	European Renal Association-European Dialysis and Transplant Association
ESA	Erythropoietin Stimulating Agent
Hb	Haemoglobin
HD	Haemodialysis
HR	Hazard Ratio
ICU	Intensive Care Unit
IDWG	Interdialytic Weight Gain
IHI	Institute for Healthcare Improvement
ISPD	International Society for Peritoneal Dialysis
KDIGO	Kidney Disease Improving Global Outcomes
KDOQI	Kidney Dialysis Outcomes Quality Initiative
LV	Left Ventricular
mSGA	Modified Subjective Global Assessment
NCDS	National Cooperative Dialysis Study
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
OR	Odds Ratio
PD	Peritoneal Dialysis
PDSA	Plan Do Study Act
PRS	Practice-related Risk Score
RR	Relative Risk
RRT	Renal Replacement Therapy
SBP	Systolic Blood Pressure
SMR	Standardised Mortality Ratio
TACurea	Time-Averaged Concentration of urea
TQM	Total Quality Management
UKM	Urea Kinetic Modelling
UK RA	United Kingdom Renal Association
UKRR	United Kingdom Renal Registry
URR	Urea Reduction Ratio
USRDS	United States Renal Data System

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

- 1. Evidence for the Relationship Between Clinical Indicators and Outcomes in Dialysis Care**
- 2. The Role of Quality Improvement in Improving Outcomes in Healthcare**

1. Evidence for the Relationship Between Clinical Indicators and Outcomes in Dialysis Care

1.1 Introduction

The demand for and uptake of renal replacement therapy is increasing worldwide. There have been significant advances in technology and knowledge about dialysis care but despite this, mortality in this group of patients remains high. What is known is that there is significant variation in practice and outcomes in patients on dialysis, both within and between countries[1]. Analysis of this has taken the form of comprehensive retrospective registries such as the United States Renal Data System (USRDS), UK renal registry, ANZDATA and the ERA-EDTA registry. Most of these collect data on agreed variables from participating centres, and publish annual reports. There are also prospective observational studies of practice and outcomes, notably DOPPS, an international multi-centre observational study of haemodialysis practice[1]. Knowledge gained from randomised trials, observational studies and expert consensus forms the bases of national and international standards and guidance on optimum dialysis care[2,3]. These standards include processes and indicators known to impact on patient outcomes, such as type of vascular access and dialysis dose [4,5]. Despite the availability of best evidence, variation even within countries exists, highlighting the need for further evidence on effective implementation of best practice to achieve these standards.

Most clinicians would agree that mortality and quality of life (which would include indicators such as hospitalisation and days spent in hospital) are important clinical outcomes in the care of patients on renal replacement therapy. Information on mortality is found in national registries, and several observational studies have described mortality and hospitalisation in dialysis [6-8].

1.1.1 Modifiable Factors that Impact on Outcomes in Haemodialysis

1.1.1.2 Dialysis Dose

Measures of dialysis dose

In 1981 the National Cooperative Dialysis Study (NCDS) study of 151 patients reported higher hospitalisation in patients randomised to receive a lower dialysis dose (measured as TACurea, or time-averaged concentration of blood urea nitrogen), providing the first randomised trial evidence of the importance of dose of haemodialysis[9]. A re-analysis of

the data introduced the concept of Kt/V as an expression of urea clearance[10]. Over the next few years, other methods of measuring dialysis clearances were developed, including Kt/V and urea kinetic modelling (UKM) of urea reduction ratio (URR). The latter is limited by not being completely accurate but is a simple measure of clearance that has been adopted widely. A majority of centres in the UK use URR as an audit measure, and it is the measure reported by the UK renal registry in its annual reports.

Evidence for minimum dialysis dose delivered

A further retrospective analysis demonstrated 60% higher mortality with URR<60% than >65% (equating to single pool spKt/V >1.3)[11]. Subsequent observational data suggested a correlation between higher spKt/V and lower mortality until publication of the HEMO study in 2002, which analysed the effects of “standard” versus “high dose” dialysis (spKt/V 1.3 or 1.7) and low versus high flux membranes in HD, and found no benefit on mortality of higher doses of dialysis or higher flux membranes[12]. Most clinical practice guidelines (CPG) recommend spKt/V of >1.3 or URR of >65% as a minimum target[13], adding that clinicians should aim for 70% in order to ensure as many patients as possible reach the minimum target. However, subgroup analysis of the HEMO study found that women had lower mortality with higher Kt/V (RR 0.81, p=0.02), even after accounting for body size[14], therefore a higher minimum is recommended in women and smaller men [15]. The DOPPS study of clinical practice in haemodialysis care has similarly demonstrated better mortality with Kt/V>1.2, with better outcomes at higher levels of Kt/V in women[16]. This relates to the limitations of these measures in calculating small solute clearance, and highlights the disparity between dialysis dose and dialysis adequacy.

Dialysis Dose and Dialysis Adequacy

Whilst dialysis dose as measured by URR or Kt/V is used as a standard marker of dialysis delivery, it is limited in that it only captures clearance of a small solute- urea- as an approximation of overall dialysis adequacy. It does not, however, capture fluid removal, middle molecule or large molecule removal. In addition, dialysis adequacy is increasingly recognised as a more global quality of life measure, including but not limited to overall wellbeing and nutrition. The HEMO study demonstrates the need for other markers of adequacy, and the need for caution and individualisation of treatment.

In addition, there is evidence that duration of dialysis is also associated with lower mortality. Further analysis from DOPPS showed that in conventional in-centre thrice-weekly dialysis,

for every 30 minutes longer dialysis time, there was a 7% lower mortality[17], independent of dialysis dose. Longer duration of dialysis is also associated with better survival, better cardiovascular mortality and sudden death, lower blood pressure, better intradialytic weight loss, lower phosphate and potassium, and higher haemoglobin and albumin[18]. Longer dialysis, implying better clearances, has also been shown to improve haemoglobin without any increase in ESA or iron use[19].

Another area of study has been frequency of dialysis. The first frequent haemodialysis network (FHN) trial studied the effects of daily in-centre six times weekly haemodialysis versus conventional thrice weekly dialysis on composite endpoints of death and change in LV mass, or death and physical functioning. It found a significant improvement in those on frequent HD[20]. However, a further trial by the same group comparing nocturnal haemodialysis with thrice weekly in-centre HD found that whilst treatment time and weekly Kt/V were significantly higher in the nocturnal group, there was no significant difference in mortality in this group[21].

This heterogeneity of evidence for measurement and interpretation of dialysis dose demonstrates that no single marker of adequacy exists. However, for practical reasons audit by national and international registries tends to use small solute removal as a surrogate marker.

1.1.1.2 Vascular Access

The arterio-venous fistula (AVF) has long been recognised as the gold standard for vascular access in haemodialysis[22], and is well-established as being associated with lower all-cause and infection-related mortality than venous catheters in prevalent and incident HD patients, as well as resulting in fewer infections and lower hospitalisation[6,23-27]. At a patient level, a US study calculated the relative risk of death for those with a catheter is 1.54($p<0.002$) in diabetic patients, and 1.7 ($p<0.001$) in non-diabetics [23], whilst a recent analysis of facility-level practices found a 20% increased risk of death for every 20% greater catheter use within a dialysis facility[26]. This was true after adjusting for case-mix, and reflected both infection-related and all-cause mortality. It has also been estimated that up to 36-43% of the higher mortality found in US HD patients in comparison to European patients could be attributed to vascular access practice. An analysis of DOPPS data from five European countries found that vascular access-related complications were the single commonest cause of hospitalisation in HD patients in the UK[6]. This was in contrast to other European countries such as Italy, and

may reflect the significantly higher prevalence of catheters for access in the UK. Despite this, the use of venous catheters for vascular access continues to increase, even after adjusting for patient factors and case mix[26,28], with wide variation between countries in rates of catheter use.

Complications associated with catheter use for haemodialysis.

Venous catheters are associated with increased thrombotic complications and poor blood flow resulting in lower dialysis dose[28], the development of biofilm, which serves as a nidus for infection, higher risk of bacteraemia and its associated complications such as osteomyelitis and endocarditis, and central venous stenosis[29].

In the UK infection is second only to cardiovascular disease as a cause of mortality in haemodialysis patients[30]. Catheter use confers a higher risk of infection than arterio-venous fistulae for haemodialysis, therefore as well as increasing AVF use, identifying ways to reduce this risk in those who continue to dialyse via a catheter remain paramount.

Risk factors for catheter-related blood-stream infection (CRBSI) have been studied in prospective and retrospective analyses. Duration of catheter use is a key risk factor, as is previous episodes of bacteraemia[31-33]. The presence of diabetes, peripheral atherosclerosis or a vascular cause of renal disease, hypertension and increased corrected calcium have been shown to increase risk[31-35], whilst low serum albumin and anaemia increase the risk of all vascular access-related infection[36], suggesting poor wellbeing and chronic inflammation are key factors. Nasal staphylococcus aureus carriage, local infection and catheter dysfunction necessitating the use of urokinase also contribute[31]. Another issue has been whether greater comorbidity in patients dialysing via a catheter confers a higher risk of bacteraemia. A study in 2009 set out to answer this question by analysing infection rates in two groups of patients dialysing via a catheter- one that subsequently went on to have an AVF for access or a renal transplant, the other that was deemed unfit for transplantation and for AVF, and found no significant difference between infection rates in the two groups[37]. However, another, prospective, study found that a greater comorbidity score does confer a higher risk of infection[33].

Not all of these risk factors are modifiable, but a deeper understanding of risk can assist in stratifying risk and preventive strategies in those with tunnelled venous catheters. For modifiable risk factors, a summary of the evidence for interventions to reduce CRBSI is listed in Table 1 below.

Table 1. Evidence for strategies to reduce catheter-related bacteraemia

Measure	Evidence	Comment
Sterile precautions	Epic2 guidelines[38]	Extrapolated from infection studies
Exit site care with chlorhexidine	Chaiyakunapruk et al 2001[39]	Meta-analysis of trials comparing chlorhexidine with povidone-iodine
Bactericidal locks	Jaffer et al 2008[40]	Meta-analysis of trials comparing antimicrobial lock solutions (ALS) to heparin. No evidence of increased resistance
	Snaterse et al 2010[41]	Systematic review of trials comparing ALS to heparin. Includes non-dialysis catheters
Prophylaxis of colonisation with staphylococcus aureus	Taconelli et al 2003[42]	Meta-analysis showing prophylaxis effective at reducing staphylococcus aureus infection
Topical exit site antibiotics	Johnson et al 2002[43]	Randomised controlled trial demonstrating mupirocin superior to no topical exit site agent
	James et al 2008[44]	Meta-analysis. Antibiotics are superior but evidence of publication bias
	McCann et al 2010[45]	Systematic review. Topical mupirocin effective at reducing CRBSI

Despite high awareness about the importance of placement of definitive access, the rate of catheter use was found to have increased internationally between 1996 and 2007[28], demonstrating that despite the presence of a knowledge base, lack of implementation strategies can hamper efforts to implement best practice. An analysis of UK renal registry data in 2010 found that the prevalence of AVF use was 69.8%, with a small positive association between definitive access use (AVF or AVG) and survival. The type of access in use explained 6% of the variation in mortality between dialysis centres[46].

A review of clinical practice recommended four strategies to reverse the tide of increased catheter use in HD; (1) reduce exposure to catheters from the start of HD, (2) reduce the

time from referral to access creation, (3) develop the expertise for success in first cannulating new AVF after a shorter period of time, (4) an increased emphasis on AVF creation in surgical training[47].

1.1.1.3 Nutritional status

Patients on dialysis frequently have multiple co-morbidities, with both these, and CKD itself contributing to nutritional status in this group. There is an inverse relationship between BMI and mortality, in contrast to the non-dialysis population, with BMI<20 conferring the highest relative risk of mortality, and even moderate obesity (BMI 35-39.9) conferring a lower relative risk of death (RR 0.76, p=0.02) than in those of normal weight (BMI 23-24.9)[48,49]. Suggested explanations for this include more stable haemodynamic status, and survival bias, and protein-energy wasting in patients with normal BMI in comparison to those with higher BMI[50]. BMI is a poor marker of nutritional status, and a more accurate measure may be assessment of abdominal fat deposition in HD patients, which has been shown to correlate with inflammation in both renal and non-renal populations[51,52]. Other nutritional indicators, including serum albumin, modified subjective global assessment (mSGA) nutrition score, and serum creatinine show a strong inverse correlation with mortality [53]. One analysis found a 33% higher risk of mortality in US dialysis patients identified as severely malnourished by the mSGA, as those who were not malnourished[54]. In incident haemodialysis patients a decrease in serum albumin and BMI at 6 months is associated with a significantly higher mortality risk[53], whilst in the HEMO study an increase in serum albumin and BMI at low levels (< or =25) at 6 months was associated with lower mortality independently of dialysis dose and dialyser[55]. The question of whether underdialysis correlates with low albumin was also analysed in the HEMO study. This found that Kt/V and membrane flux were not predictive of serum albumin at baseline[56]. When the effect of standard versus high-dose dialysis on nutritional parameters were analysed in three years follow up, it was found that nutrition declined in both groups over time, although this effect was less marked in the high dose group[56]. Serum albumin is the strongest predictor of mortality (RR 1.38, p=0.0001) when compared with other modifiable indicators such as vascular access, haemoglobin, interdialytic weight gain, phosphate and URR, in prevalent HD patients[16].

Several interventional studies have attempted to address nutritional status in dialysis patients. Intradialytic parenteral nutrition did not improve survival in malnourished HD patients in a 2-year multicentre randomised trial[57]. However, two recent studies of oral

nutrition on dialysis have shown both improved nutritional status and improved mortality at one year[58,59]. Other studies have sought to address inflammation, one of the key drivers of poor nutrition. Recently, a study of selenium supplementation demonstrated an improvement in some clinical indicators (notably SGA and MIS score), suggesting a role for alleviating oxidative stress and inflammation in improving nutritional status [60]. However, serum albumin is not just affected by nutritional status, making it a difficult target to address in interventional studies.

1.1.1.4 Blood Pressure and Interdialytic Weight Gain

Blood pressure in HD patients remains the subject of some controversy, with conflicting evidence about its measurement, optimum BP, relationship to fluid status, and outcomes—both mortality and quality of life, such as days spent in hospital and number of hospitalisations.

Patients routinely have BP measured before and after dialysis, and these measures usually form the basis of decisions around BP management in HD patients. However, questions remain about the validity of these measurements as prognostic markers for outcomes, including mortality. Dialysis unit pre and post dialysis BP has been found to be an inaccurate predictor of interdialytic BP[61], whilst in one study, home systolic blood pressure has been shown to more accurately predict mortality risk than dialysis unit blood pressure readings[62]. However, most analyses of the association between blood pressure and outcome have used unit BP readings, and these remain standard practice in most centres.

The U-shaped curve of mortality for blood pressure in HD, with mortality highest in those with low pre- or post-dialysis BP, is well described. Iseki et al demonstrated that low post-dialysis DBP was associated with higher mortality[63], whilst Zager et al described the U-shaped curve of post-dialysis SBP and mortality in HD patients, with highest mortality for SBP >180mmHg or <110mmHg, whilst low SBP pre- and post-dialysis was associated with increased all-cause and CV mortality [64]. A study of pre-dialysis BP and mortality also found an increased relative risk of death of 1.86 (95% CI 1.46-2.38, $p=0.0001$) with SBP <110mmHg[65]. Lowest intradialytic SBP (adjusted OR for death 0.79, 95% CI 0.64-0.98) and orthostatic hypotension post-dialysis (adjusted OR 0.82, 95% CI 0.67-0.98) are also associated with higher two-year mortality[66]. In addition, the relationship between low BP and mortality is not normalised in a low risk cohort without cardiovascular disease[67].

At a facility level, an analysis of DOPPS data grouped prevalent HD patients with pre-dialysis SBP>110mmHg in each dialysis facility into 5 BP categories. Analyses of survival were performed, relative to the percentage of patients in each BP category in a HD unit, to identify the optimum range of BP for most patients in a unit. Facilities with a higher percentage of patients outwith SBP 130-159mmHg were found to have higher mortality. At a patient level, SBP<130mmHg was associated with higher mortality, whilst higher SBP (>180mmHg) was not[68]. One possible explanation for the finding that “normal” BP targets in HD patients are associated with higher mortality, despite the overall higher cardiovascular risk in this group, is that unit BP does not accurately reflect true home blood pressure. A comparison of home and ambulatory BP recordings and mortality found that mortality was lowest with home SBP 120-130mmHg and ambulatory BP 110-120mmHg, with no correlation between dialysis unit BP and mortality[62].

The role of blood pressure control and optimum BP remains controversial. DOPPS has shown large variation in the prescription of antihypertensive medications in HD, and an association between angiotensin receptor blocker use at a facility level and all-cause and cardiovascular mortality, even after adjusting for predialysis SBP[69]. The results of two recent meta-analyses of randomised trials of blood pressure control in haemodialysis patients were mixed. Heerspink et al found a survival benefit with BP treatment, but the trials analysed were heterogeneous, with diverse end points and no BP target[70]. Agarwal et al found that BP-lowering medications reduced cardiovascular events in hypertensive HD patients, but whether this was due to BP lowering or other cardioprotective effects of medication was uncertain. In addition, there was evidence of publication bias[71].

There remains a complex interplay between BP, IDWG and vascular disease in RRT that has yet to be fully elucidated. What is known is that fluid overload is a significant contributor to morbidity in HD, with one analysis of USRDS data showing that 14% of HD patients had >1 admission for fluid overload in a year[72]. Observational evidence from DOPPS demonstrates an association between IDWG of >5.7% of body weight (equating to 3.99kg in a 70kg man) and mortality[73]. This is partly as a result of the higher ultrafiltration rate needed with high IDWG, thus increasing the risk of intradialytic hypotension, which in itself is associated with a higher risk of mortality (RR1.09, p=0.02)[17]. In addition, chronic volume overload has been shown to be a predictor of all-cause mortality[74]. The DRIP trial, a randomised trial of dry weight reduction in dialysis patients found a reduction in postdialysis weight of 0.9kg in 4 weeks and a reduction of 6.9/3.1mmHg in ambulatory BP. The authors

also noted an increase in symptoms of hypotension, but no deterioration in quality of life. However, the short follow up did not look at mortality risk.

These results demonstrate a heterogeneity of evidence and opinion on blood pressure in HD and its relationship to IDWG, cardiovascular risk and mortality, although consensus remains that fluid management remains a cornerstone of good haemodialysis care. What has been less studied however, is how best to achieve that goal.

1.1.1.5 Anaemia

Low levels of haemoglobin (<10g/dl) are associated with higher mortality and increased hospitalisation in HD[75]. In addition, anaemia co-segregates with co-morbidity, further predicting poor outcome. The optimum haemoglobin target in HD was for some time the subject of significant debate. The Normal Hematocrit (NHT) trial randomised patients with heart disease to receive epoetin with a target haematocrit of 30% versus 42% (normal range). The trial found better quality of life in patients treated to a target Hb in the normal range, but a trend towards higher mortality and higher access failure, and was halted early[76]. A subsequent reanalysis of the NHT data in 2012 found a significant increased risk of death, hospitalisation and myocardial infarction with no improvement in quality of life associated with higher haemoglobin[77], in keeping with recent studies, notably TREAT, looking at anaemia in CKD patients not on dialysis [78]. Several meta-analyses have similarly identified no mortality or morbidity benefit of using erythropoietin stimulating agents (ESAs) to increase Hb to >12g/dL[79]. One purported benefit of treating Hb to normal levels was thought to be an improvement in cardiovascular risk. Further evidence against this comes from a study looking at LV volume, which found that full correction of anaemia did not have beneficial effects on cardiac structure in comparison with partial correction, with a trend to an increase in cerebrovascular events in the higher haemoglobin group[80].

Erythropoietin use

Several analyses have pointed to worse outcomes with higher ESA doses in HD patients. One study reported a higher risk of death with higher ESA doses in patients with Hb 10-12.9g/dL and increased hospitalisation with Hb>10g/dL [81]. A US study of ESA use found that greater ESA and iron use were associated with lower mortality at lower haematocrit levels (<33%), but increased mortality at higher haematocrit levels (>36%)[82]. Several studies have found an association between better responsiveness to ESA and lower mortality in HD and non-HD patients[83-85]. An analysis of NECOSAD, a Dutch multi-centre prospective cohort study of

dialysis patients, found that patients with Hb<11g/dL with an above median ESA dose (>8000U/week in HD and 4000U/week in PD) had an adjusted HR for all-cause mortality over 5 years of 1.37 (95%CI 1.04-1.8) and 2.41 (1.27-4.57) as compared to patients who responded to lower doses of ESA[86].

Causes for ESA hyporesponsiveness include inadequate haemodialysis [87], low iron stores and chronic inflammation. CRP has been shown to be predictive of all-cause mortality and cardiovascular mortality in HD[88]. It may correlate with comorbidity[89], decreasing ESA effectiveness and leading to higher ESA requirements[90]. Causes of inflammation in dialysis patients include infections, heart disease, chronic kidney disease and dialysis, obesity and genetics. 35-65% of HD patients have high CRP. This chronic inflammation results in reduced iron availability for erythropoiesis, suppressed erythropoiesis and decreased responsiveness to ESAs [91,92].

The use of IV iron to replete iron stores and increase haemoglobin was found to be effective even at higher levels of serum ferritin (up to 1200mcg/dL) in the DRIVE study, with no increase in adverse events over the 12-week study period [93]. However, whilst there is now a well-established body of evidence for the use of IV iron in RRT patients, and long term safety data, there is currently a lack of long term safety data of its use at higher levels of ferritin.

Given the controversies around high doses of ESAs and the lack of evidence for higher haemoglobin targets in RRT care, guideline bodies now recommend the use of the lowest possible ESA dose to avoid transfusions, with individualisation of treatment for patients[94].

1.1.1.6 Phosphate

The majority of evidence for controlling serum phosphate levels in renal replacement therapy comes from observational data. Block et al described the relationship between high phosphate and mortality in an analysis of USRDS data, which found an increased risk of death, after adjustment for other key variables including age and diabetes mellitus. Phosphate >6.5mg/dL (>2.1mmol/L) was associated with RR of death of 1.27, relative to a phosphate level of 2.4-6.5mg/dL (0.8-2.1mmol/L), with no change when adjusted for dose of dialysis, nutritional parameters or markers of non-compliance[95]. Saran et al analysed several parameters indicating non-adherence with therapy and mortality from the DOPPS cohort [73], and found an increased risk of mortality with phosphate >2.4mmol/L, RR 1.17 p=0.001, a finding confirmed in other studies[96,97]. Other studies have confirmed the

association between high phosphate and increased mortality and hospitalisation [98] whilst a systematic review of 35 studies of the evidence behind the association between high phosphate and mortality found a greater mortality risk with higher phosphate levels despite heterogeneity across studies[99].

Previously, calcium phosphate product (C_xP) had been thought to be associated with mortality, but conflicting evidence for this means it has been removed from the most recent KDIGO guidelines[100]. Hypophosphataemia is a more complex phenomenon than high phosphate. It similarly correlates with increased mortality in dialysis patients, but this is thought to relate to its association with poor nutritional status[101].

The best way to manage high phosphate in RRT patients remains the subject of debate. Increased time on dialysis, in particular nocturnal dialysis, has been shown to favourably impact on serum phosphate levels in several studies[18,97]. A recent comparison of the safety and efficacy of phosphate binders found that all three classes of binders reduce serum phosphate levels, but Lanthanum may result in increase adherence by reducing pill burden[102]. However, there remains a paucity of evidence for a role for phosphate binders in reducing mortality. A prospective cohort study demonstrated lower mortality in incident haemodialysis patients treated with phosphate binders[103], however, a DOPPS analysis of phosphate binder prescription in HD found that whilst patients on binders had better survival, these patients had better nutritional status overall[101]. A recent systematic review included 18 studies and found lower mortality with the use of non-calcium-based as compared with calcium-based phosphate binders[104]. Of note however, is that the review did not compare mortality in those on binders versus no treatment, and noted a risk of publication bias, and a subsequent letter suggested inclusion of additional studies may negate the findings of the review[105]. Interestingly, a post-hoc analysis of the HEMO study looking at dietary phosphate restriction and outcomes found greater survival in patients on an unrestricted phosphate diet (adjusted HR 0.73 95% CI 0.55-0.92), with only a non-significant increase in serum phosphate levels in this group[106]. These findings suggest controversy remains over the role, risks and benefits of phosphate lowering using binders and dietary restriction in reducing mortality in haemodialysis care.

1.1.1.7 Cardiovascular Risk

The risk of cardiovascular disease in CKD is significantly higher than in the general population[107], and cardiovascular disease remains the leading cause of mortality in

haemodialysis patients, accounting for 27% of deaths in a recent UK renal registry report[30]. However, the pathogenesis of cardiac disease in CKD patients involves both traditional atherosclerotic processes and a distinct CKD-related process of arteriosclerosis due to disorders of bone and mineral metabolism. Consequently the role of some traditional preventative measures, such as cholesterol-lowering agents, remains the subject of debate. Whilst meta-analyses suggest a benefit for cholesterol-lowering with agents such as statins in early CKD[108], the only randomised-controlled trial of cholesterol-lowering for primary prevention in CKD was not powered to detect a difference in mortality or cardiovascular events in its subgroup of 3023 dialysis patients[109] and there remains a lack of consensus on their role in advanced CKD and dialysis[110]. Similarly, traditional management of blood pressure has also been challenged by the U-shaped curve of association between blood pressure and mortality in dialysis patients described above.

1.1.1.8 Other Dialysis Practices Associated with Outcomes

As described above, the majority of studies reporting outcomes in RRT are observational, with limited trials of treatment or specific interventions. Several analyses of observational data on multiple clinical indicators have provided further insights into outcomes in this population.

Non-adherence with dialysis care, including missing treatments, poor dietary adherence, shortened dialysis time and high interdialytic weight gain, is associated with increased mortality[73]. The same analysis also found that missing dialysis treatments and high phosphate levels were associated with increased hospitalisation, whilst the presence of a dietician at a centre was associated with a lower risk of excessive interdialytic weight gain.

Table 1.2: Adjusted relative risk of mortality and percentage of patients outside guideline target by practice pattern (adapted from Port et al[16])

Selected Indicator	Out of Target Value	Percentage of Patients Outside Range (from DOPPS II US)	Relative Risk of Mortality from DOPPS I	P value
Dialysis Dose spKt/V	<1.2	12.1%	1.16	0.025
Phosphate	>5.5mg/dL	49.2%	1.11	0.005
Haemoglobin	<11g/dL	27.2%	1.14	<0.001
Nutrition-IDWG	>5.7%	12.5%	1.22	0.002
Albumin	<3.5g/dL	20.5%	1.38	<0.0001
Facility Catheter Use	>28% vs <7%	50%	1.23	0.01

An analysis of DOPPS data estimated the potential patient-life years gained by adhering to modifiable HD practices (management of anaemia, dialysis dose, albumin, IDWG, phosphate

and catheter use) over a five-year period[16]. Significant numbers of patients were outside the recommended target for each indicator (12.1-50%), with adjusted RR of mortality ranging from 1.11 (phosphate >5.5mg/dL) to 1.38 (albumin <3.5g/dL). This demonstrates a significant potential for improvement in dialysis care to attain clinical targets and improve outcomes.

The DOPPS database was used to develop a quality index (PRS, practice-related risk score) for facilities, based on four modifiable practices; percentage of patients with Kt/V >1.2, Hb>=11g/dL, albumin >=4g/dL and catheter use in each facility. A higher PRS score correlated with higher mortality. Significantly, a fall in a facility's PRS score from DOPPS I to DOPPS II, was associated with reduced mortality [111].

The EQUAL study, a prospective observational study of prevalent US haemodialysis patients, compared attainment of clinical indicators at baseline and at 6 months after enrolment. The authors found that increased attainment of clinical indicators (albumin, URR, Hb, CxP, and AVF) was associated with better outcomes (death and hospitalisation), with decreasing mortality the more targets were attained. As reported in other studies, albumin was the strongest predictor of mortality[112].

A retrospective analysis of incident HD patients in the US found that values within guidelines for spKt/V, haematocrit, albumin, calcium, phosphate and PTH were associated with an 89% reduction in mortality (HR 0.11, 95%CI 0.06-0.19)[96].

A study of predictors of mortality in incident HD patients found that age, serum calcium, low albumin, low phosphate, heart failure and no pre-dialysis care were associated with a significantly higher risk of early death, with highest mortality in the first 120 days after dialysis initiation[113].

1.1.2 Modifiable Factors that Impact on Outcomes in Peritoneal Dialysis

1.1.2.1 Dialysis Dose

Dialysis dose in peritoneal dialysis is also expressed as Kt/V, but this is a different measure to that used in haemodialysis, so Kt/V cannot be compared between the two. Total clearance, or Kt/V in PD is calculated as the urea removal by dialysis plus urea removal by residual renal function.

$$\text{Total} \frac{Kt}{V_{\text{urea}}} = \text{Renal} \frac{Kt}{V_{\text{urea}}} + \text{Dialysate} \frac{Kt}{V_{\text{urea}}}$$

Current guidelines from the UK Renal Association recommend a minimum total weekly Kt/V of ≥ 1.7 . Creatinine clearance can also be measured as an alternative to Kt/V, and the recommended minimum is at least $\geq 50\text{L/week}/1.73\text{m}^2$ [114]. However, this represents a minimum, and both the ISPD and RA recommend that adequacy should be interpreted clinically, with higher targets in patients who have uraemic symptoms or suboptimal biochemical indices[115]. The CANUSA study looked at the relationship between dialysis adequacy and nutritional status and mortality, morbidity and technique failure. It found that a fall of 0.1 in Kt/V_{urea} resulted in an increased risk of death of 5%, and recommended a minimum Kt/V in CAPD of 2.0, and higher for patients on CCPD[116]. However, a subsequent reanalysis of the data found that residual renal function declined over time, and that it was this fall in residual clearance that was associated with higher mortality[117]. Similarly, the ADEMEX trial went on to compare higher versus lower peritoneal clearances, and found that despite an achieved Kt/V of 1.62 vs 2.13, and an achieved CrCl of 46 vs 57 L/week/1.73m², there was no difference in survival at 2 years follow up between the groups (68% vs 69%, $p=0.9842$)[118]. However, both ADEMEX and a further trial of adequacy, found that whilst higher peritoneal Kt/V did not have a role improving mortality, patients in the lower target Kt/V groups tended to have more uraemic symptoms[119].

1.1.2.2 Ultrafiltration and Fluid Management

Residual renal function and urine output are associated with survival in PD[116], whilst total fluid removal is associated with worse clinical outcomes, especially in anuric patients[120]. A secondary analysis of the ADEMEX study found decreased mortality for every 100ml increase in urine output (RR 0.93 95%CI 0.89-0.97, $p=0.0007$), and a higher risk of mortality with peritoneal ultrafiltration $<400\text{ml/day}$ (RR 1.53, 95%CI 1.175-1.995, $p=0.0016$)[121]. The EAPOS study also highlighted worse outcomes when total UF was $<750\text{ml/day}$, and as a result current UK guidelines recommend consideration of conversion to HD if ultrafiltration is persistently below this level[122].

1.1.2.3 Nutritional status

Patients on PD lose protein via the dialysis effluent and have lower average serum albumin levels than patients on HD, and serum albumin levels have been shown to predict all-cause and cardiovascular mortality in this patient population[123]. Other causes of poor nutrition

in patients on PD are multifactorial and similar to patients on HD- chronic inflammation, poor appetite and intake (despite absorption of carbohydrate from glucose-based dialysate) and comorbidity, as well as loss of residual renal function[124]. In addition, the serum albumin threshold at which mortality risk increases is lower for PD than HD patients[125]. The CANUSA study reported lower mortality with higher serum albumin (RR 0.94, 95%CI 0.9-0.97 for every 1g/L increase), and found no association between Kt/V and serum albumin[116]. Both the ADEMEX study and Lo et al found no association between achieved Kt/V and nutritional status[118,119].

Whilst PD dialysate is predominantly glucose-based, other types of dialysate have been developed for use in peritoneal dialysis. The use of amino acid-based dialysate has been shown to improve nutritional status in dialysis patients, but there is no evidence of improved survival with its use[126].

1.1.2.4 Anaemia

Much of the evidence for anaemia management in PD comes from extrapolation of studies in HD, and limited observational data. One retrospective analysis found lowest mortality and hospitalisation with Hb 11-11.9g/dL in non-diabetic patients, lowest hospitalisation with Hb>12g/dL in diabetics, with highest mortality in patients with Hb<10g/dL[127].

Data from registry analyses has shown that patients on PD have lower median doses of ESA than those on HD[128] for a comparable level of Hb. However, the relationship of ESA hyporesponsiveness and poor outcome is comparable. Data from the NECOSAD study, a Dutch observational study of HD and PD patients, revealed an increased hazard ratio for death (2.41, 95%CI 1.27-4.57) over 5 years in PD patients with Hb<11g/dL above median doses of ESA (>4000U/week), in common with findings about the implications of ESA resistance in HD patients[86].

1.1.2.5 Peritonitis

PD peritonitis is a major complication of PD and is a leading cause of hospitalisation, technique failure, membrane failure, and death. Peritonitis rates vary internationally. The Australian PD registry reported a peritonitis rate of 0.59 episodes per year at risk, or 1 in 20 patient months, between 2003 and 2008[129]. An observational Brazilian study of 114 centres and 3226 patients had an overall peritonitis rate of 1 in 30 patient months[130]; the most recent ISPD guidance on peritonitis continues to recommend a target of no more than

1 infection in 18 patient months, whilst highlighting that peritonitis rates of 1 in 41-52 months, or 0.29-0.23 episodes per year at risk, are achievable, and rates as low as 0.06 episodes per patient year (1 in 200 patient months) are quoted in some centres[131,132]. In the UK, a retrospective review of PD from Scotland of 1918 peritonitis episodes over 7 years found a peritonitis rate of 1 in 19.9 patient months and a mortality rate of 2.8% and technique failure of 14.9%[133]. A more recent Scottish registry report however revealed improvement in overall peritonitis rates to 1 in 27 patient months, although considerable between-centre variation remains[134]. A review of peritonitis in North Thames analysed 1467 episodes of peritonitis over 2 years, with a death rate of 3.5%[135]. An analysis of mortality in the death of RRT patients in Scotland between 2008 and 2011 found that peritonitis was the leading single cause of death in PD patients[136]. The Australia and New Zealand dialysis and transplant registry (ANZDATA) reported a peritonitis rate of 0.59 episodes per year at risk, or 1 in 20 patient months, between 2003 and 2008[129], which has gradually fallen over time to a rate of 0.38 episodes per year at risk, or 1 in 32 patient months, in the latest ANZDATA report[137]. A recent review highlighted that publication of data spurred multi-faceted efforts to improve peritonitis rates in recent times [138]. These included improvement of existing guidelines, a team approach for Continuous Quality Improvement (CQI), development of key performance indicators to meet evidence-based practice, and publication of a “Call to Action” guideline highlighting gaps in Australian practice. However, as with the Scottish findings, a 3-fold variation in peritonitis rates between centres remains. It should also be noted that direct comparison between peritonitis rates between countries is difficult due to differences in case mix, health systems, reporting of episodes of peritonitis, size and selection of PD centres, and utilisation of PD as a mode of RRT.

Research on peritonitis has focussed on understanding its causes, prevention, and optimum treatment, as well as complications and outcomes. Several UK series have shown that the majority of PD peritonitis is caused by gram-positive organisms[133,135,139], whilst anaerobic and gram-negative infections may arise from bowel translocation. The International Society for Peritoneal Dialysis (ISPD) recommends antibiotics at the time of catheter placement, monitoring of infection rates, patient education, prompt treatment of exit site infections and prevention of infection from other sources to reduce infection rates [131].

1.1.3 Summary

There is clear observational evidence of a correlation between several clinical indicators and outcomes in dialysis care, of which poor nutritional status as measured by serum albumin seems to confer the highest risk of mortality. There is ongoing research into whether these relationships are causal. However, targeting and modifying these indicators, particularly in incident dialysis patients, is an important strategy in improving the quality of dialysis care, and may also improve clinical outcomes.

2. The Role of Quality Improvement in Improving Outcomes in Healthcare

2.1 Quality in healthcare

In a landmark report in 2001 the Institute of Medicine termed the gap that exists between what can be provided by healthcare knowledge and the ability of the healthcare systems to translate it into practice as the “quality chasm” (“Crossing the quality chasm”)[140]. It defined six domains of quality in healthcare- safety, effectiveness, patient-centredness, efficiency, timeliness and equity, and provided a rationale and framework for the redesign of US healthcare, much of which could be applied elsewhere. This framework included (1) incorporating patient experience; (2) redesigning the “microsystems” that actually provide care; and (3) the organisations that house these microsystems; (4) addressing the laws and regulations, including postgraduate training and education, that shape these organisations. In recent years there has been an increased interest in research into the science of improvement, with the adoption of formal quality improvement (QI) initiatives in healthcare.

2.1.1 Evidence Based Medicine

Evidence-based medicine is defined as the explicit use of the best available evidence to inform the care of individual patients. The term was first coined in 1991 and the following year an article in JAMA synthesised its principles in the teaching and practice of medicine[141]. Some 10 years prior, the Cochrane Collaboration had been established to critically appraise evidence into best practice. The systematic collation and review of empirical evidence into guidelines for use by clinicians since then has had notable successes, including venous thrombo-embolism (VTE) prophylaxis, and the success of systematised cardiac care in reducing mortality. However, implementation of research outputs and guidance can be slow. Systematic review and guideline development from bodies such as NICE, KDIGO, and the UK Renal Association take time, and implementation into clinical practice is complex. Furthermore, the increasing volume of clinical guidelines raises questions about the manageability of adherence.

2.1.2 Factors Affecting the Implementation of Clinical Guidelines in Clinical Care

There have been several systematic reviews examining adherence to published guidelines in the UK. One review of studies into barriers to guideline adherence identified multiple

factors, including lack of awareness, familiarity or agreement, self-efficacy, and external barriers such as lack of resources or time[142].

A study looking at the implementation of published NICE guidance in acute trusts, mental health trusts and primary care trusts found variable uptake at best[143]. Features of trusts consistent with high compliance included; a commitment to managing the process of implementing guidance, strong clinical governance function, appropriately resourced, a culture of consensus recognition of the legitimacy of NICE, involvement of clinicians in the guideline process and targeted audit of areas of non-compliance. In addition, the authors highlighted evidence from the literature of other factors also impact on adoption of guidance.

A further review of guideline implementation in 2011 identified factors including the proliferation of guidelines from multiple bodies, guideline length, accessibility, complexity and volume, and organisations' failure to consult healthcare professionals as decreasing compliance. It proposed organisational solutions, including the adoption of "lean" thinking to decrease the number of policies, improved consultation with healthcare professionals when writing guidelines, the use of software to monitor if guidelines have been read and understood, raising awareness amongst senior management, and improving access, such as by revising keywords on local intranets[144].

One barrier to adherence to clinical guidelines described in the above evaluations is the lack of agreement with guideline content and lack of consultation with healthcare professionals in the development of guidelines. This raises the question of whether guideline adherence does in fact improve outcomes. Here the evidence is unclear. A systematic review of studies examining the association between quality of care as measured by adherence to evidence-based standards of clinical care ("process measures"), and variability in hospital mortality rates found only an inconsistent association[145]. Its authors concluded that the positive association was weak but the study was limited by variation in methodology, incomplete risk-adjustment, varying definitions of mortality and the need to develop more subtle measures of quality of care, such as nurse-patient contact and teamwork measures.

There have however been several detailed and specific studies into guideline implementation and outcomes, most notably the WHO surgical safety checklist, sepsis pathways, and ICU care bundles. The surgical safety checklist has been successfully implemented in a number of international settings and healthcare systems and has been

shown to decrease mortality[146], and analyses of implementation strategies and barriers to adoption have also been conducted. These highlight the need for adequate training and leadership, organisational support, regular audit, and local adaptation and feedback as factors necessary for successful implementation[147,148]. Research into reasons for failure to implement checklists highlighted duplication with existing checklists, a perceived lack of benefit, poor healthcare professional communication and a lack of education and training[149]. These findings correlate with those of the reviews above.

2.1.3 Implementation of Best Practice: The Development of Quality Improvement in Healthcare

Systematic review and guideline development are one step in the pursuit of quality in healthcare. However, they do not answer the question of how to implement the evidence and guidelines that have been produced. Quality Improvement in healthcare is defined by the Institute of Medicine as:

“The combined and unceasing efforts of everyone to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning).”

It aims to implement in routine practice the processes required to produce the outcomes established by best available evidence. Traditional randomised trials are designed to answer specific questions, and control for confounders, so that variation/randomness is eliminated in order to gain new knowledge. Implementation of best available practice requires an understanding of the variation that exists in clinical practice in order to identify the changes required to improve clinical care. The key elements are the combination of a change (improvement) with a method (an approach or specific tools).

In 2005 Shojania and Grimshaw characterised the development of QI in healthcare, through efforts to implement evidence-based medicine through four overlapping phases[150].

Box 1: Evolution of quality improvement in healthcare. From Shojania and Grimshaw, 2005

1. Passive diffusion (“if you publish it, they will come”)
2. Guidelines and systematic reviews (“if you read it for them, they will come”)
3. Industrial style QI (“if you TQM/CQI it, they will come”)
4. Systems reengineering (“if you completely rebuild it, they will come”)

They also characterised the barriers to translating evidence into practice:

1. Structural- financial disincentives, lack of skill mix, inadequate facilities or equipment
2. Peer group- local standards and beliefs
3. Professional- knowledge, skills, attitude and beliefs
4. Patient factors- requests for specific tests or treatment, an informed choice not to pursue care that is recommended

Following on from this, the principles underlying QI in healthcare have been summarised by the Health Foundation as understanding the problem, processes and systems within an organisation, analysing the demands, capacity and flow of the service, choosing the tools to bring about change, and evaluating and measuring the impact of a change[151]:

With these principles in mind, change does not simply rely on identifying a problem and the clinical solution it requires, but understanding the context in which the solution is to be implemented. Guideline development has traditionally been seen as the endpoint of change. However, it misses the second ingredient essential to successful improvement- a method by which to implement it.

The Cochrane Effective Practice and Organisation of Care (EPOC) study group has identified two domains for implementation strategies- organisational and health professional-orientated[152]. These are summarised in Table 2 below.

Table 2.1: Proven strategies for the implementation of best practice in healthcare

Organisational strategies	Description	Health professional-oriented strategies	Description
Structural	Changes in the physical structure of the facilities or information management	Educational activities	To increase a provider's knowledge on best practice
Staff-oriented	Changes in roles, responsibilities, numbers or types of staff	Audit and feedback	Any information or summary of clinical performance over a period of time
Financial	Economic measures or sanctions aimed at providers or institutions	Treatment protocols/algorithms	To support providers with performing a desired clinical action

Patient-oriented	Directly involving patients to improve practice	Reminders	To prompt providers, can be manual or computerised
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In their review Shojania and Grimshaw identified several strategies associated with improved outcomes, using examples from diabetes and hypertension care. These included:

- Multifaceted interventions- effective interventions combined elements from two or more categories of care, and were more likely to involve active than passive strategies.
- Targeting provider behaviour (health professional-oriented)- passive education was generally ineffective, whilst reminders and decision support were effective if integrated into workflow. The success of audit and feedback depended on credibility of the reports.
- Patient education.
- Organisational change- for case and disease management programmes.

In addition, design and execution of strategies to successfully implement best practice should reflect local factors and thus is context-dependent- implementation strategies that are successful in one scenario may not necessarily work in another[153].

2.1.4 Improvement Methodologies

The science of improvement is well-established, and several tools have been established and evaluated. There are, however specific techniques common to differing QI methodologies that have been demonstrated to contribute to the success of QI in implementing best practice. These include:

1. Barrier analysis as an input for strategy development
2. A predefined opportunity for improvement
3. A predefined improvement target
4. Data-driven monitoring of the effect
5. Dedicated resources
6. Continuous Quality Improvement Expertise

(Summarised from Van der Veer 2011[154])

A summary of several examples is described below.

2.1.4.1 Improvement Collaboratives

Improvement collaboratives bring together groups of multidisciplinary practitioners from different healthcare organisations or within a healthcare organisation to work in a structured way to improve one aspect of the quality of their service. Several different types of collaborative have been described, and features common to a collaborative include; multi-professional teams within a subject area working together and sharing an improvement strategy, a focused subject, work on an area that has variations in care, use of experts, learning about improvement methods, a defined change testing method, measurable targets, meetings to share experiences and learn from other teams, and support for teams to test changes[155].

The Institute for Healthcare Improvement (IHI) Breakthrough Series

The IHI was formed in 1991 with the aim of improving quality and safety in healthcare. The institute has produced a number of reports, toolkits and papers. In 1995 the IHI breakthrough series white paper described a methodology for the implementation of improvement projects using a short term learning system where different teams come together to work on a common goal[156]. Generally, it describes a method whereby different groups of multidisciplinary health care professionals come together to work in a structured way to improve one aspect of the quality of their service. Teams are provided with evidence and coaching in QI theory, tools and change management skills, with learning sessions interspersed by action periods. It also promotes the use of rapid cycle testing using the PDSA cycle in healthcare. To date the IHI has conducted collaboratives with over 2000 teams, with other organisations also adopting the methodology without formal IHI involvement.

The model consists of 8 key elements:

1. Topic selection
2. Faculty recruitment
3. Enrolment of participating organisations and teams
4. Learning sessions
5. Action periods
6. The Model for Improvement



Figure 1.1: The Model for Improvement

7. Summative congresses and publications
8. Measurement and evaluation

2.1.5 Examples of the Use of Quality Improvement Collaboratives in Healthcare

Northern New England Cardiovascular Disease Study Group

This collaborative has used prospective data collection to drive improvements in outcomes following cardiac interventions since 1986, and demonstrated that structured intervention including data feedback, training in quality improvement methodologies and site visits to other centres has reduced mortality in key areas and crucially, reduced variation between centres[157-159].

The Vermont Oxford Network Neonatal Intensive Care Quality Improvement Collaborative

This demonstrated reduction in infection rates in neonatal intensive care units that participated in an intervention that included training in quality improvement, with review of performance data, implementation of potentially better practices and site visits over a three year period[160].

The Keystone ICU Project

In 2006 Pronovost et al reported the results of the Keystone ICU project- multifaceted interventions were implemented across a network of ICUs in Michigan, including coaching of team leaders, development of a safety culture, implementation of a checklist and weekly

phone calls to support staff[161]. Results showed a sustained 60% reduction in catheter-related bloodstream infections over 18 months. They identified the ingredients required for large scale knowledge translation as: summarizing the evidence, identification of local barriers, performance measurement, and ensuring all patients receive the intervention- which in turn requires engagement, education, execution and evaluation. The most well-known example of a multifaceted intervention to improve quality of care is the WHO surgical safety checklist, and several studies have described implementation strategies since its introduction.[146,148,162]

2.2 Quality Improvement in Renal Replacement Therapy

2.2.1 Patient safety in dialysis care

A recent review of deaths in HD in Scotland identified organisational, environmental/technical factors and human factors that may have contributed to deaths, highlighting the need for a coordinated approach to care and the need for QI initiatives to improve the safety of RRT by focussing on healthcare-associated infection, more effective communication and medication error[136]. In a review of patient safety in CKD, Pippias and Tomson[163] called for QI approaches to the development of a safety culture in order to improve outcomes. A further review of quality and safety in the US and UK highlighted a paucity of research on the quality of healthcare in the UK, and suggested that more accessible data, a regulatory requirement to report safety, public reporting and continuous quality improvement approaches could help induce measured improvements in the quality of care[164].

2.2.2 Best Practice in Renal Replacement Therapy Care

There is a clear body of evidence linking specific indicators with outcomes in dialysis care, but a paucity of interventional studies identifying whether amelioration of these indicators improves outcomes, and how best to implement best practice. The difficulties of doing randomised trials means that surrogate endpoints are often used in trials in dialysis care, meaning there is limited evidence for the effect of some interventions on clinical outcomes[165]. Clinical performance measures can be divided into those that measure patient outcomes such as mortality or quality of life, those that measure intermediate outcomes that have been shown to be associated with morbidity and mortality (such as phosphate, URR, haemoglobin) and process measures, such as AVF use, that are known or believed to impact on outcomes[166]. A review of performance management in CKD

highlighted that process measures (such as statin use) should be linked to outcome measures (such as cardiovascular events or mortality)[167]. The authors also recommended that performance monitoring initiatives for quality should be evidence-based, reliable and measurable, with no unintended consequences.

2.2.3 Practice Variation

The establishment of international and national registries, such as the USRDS and the UK renal registry has acted as a source of comparative data and benchmarking. The UK renal registry (UKRR) has shown that there is considerable variation in attainment of targets between UK centres, and that whilst overall attainment has improved, variation between centres remains[168]. Some of this variation can be accounted for by case mix- a US study found that up to 12% of variation can be accounted for by patient level case mix effects[169], but not all variations in the quality of care can be explained by case mix alone [170] and is more likely related to heterogeneity of care, indicating that there is an opportunity for improvement in dialysis practices which may translate into improved clinical outcomes. A report into learning from this practice variation in order to improve quality recommended adequate data collection from multiple centres, reporting this data in run charts to support teams in monitoring the effects of their QI effort, selecting a “package” of actions to implement and designing a strategy to do so, and finding ways to incentivize the improvement effort[171]. However, it should be noted that comparative data is dependent on the quality of data, and “league tables” should not be used as absolute benchmarks[166].

Factors affecting centre effects in dialysis care include structural factors, such as staffing ratios, institutional processes such as the organisation of outpatient review, and clinical processes, such as the use of protocols. Other qualitative effects, such as ethos and culture may contribute, but are harder to measure. However, interventions to improve teamwork and culture (which were measured using standardised quantitative tools) have been shown to improve the safety climate in intensive care units[172]. A study of centre effects in US dialysis facilities with above and below average mortality identified stronger physician communication, better overall coordination and staff mix, more resourceful and knowledgeable dieticians and patients who were more empowered to be part of their care in centres with lower mortality. They estimated that patient activation could account for up to 31% of the variation in mortality between centres[173].

A qualitative survey of healthcare professionals of what they identified as best practice identified the nature of multidisciplinary team (MDT) conferences, technician proficiency in protecting vascular access, nurse training in education around fluid, vascular access and nutrition, staff performance audits and communication and teamwork amongst staff as best practice in dialysis care[174].

A review of clinical guidelines in dialysis care in the UK found that implementation strategies were not considered by guideline developers, or considered late in the development process. Strategies to overcome barriers were education and care pathways, regular meetings, clinical audit and feedback for improvement, outreach, patient-mediated strategies, reminder systems, and the use of opinion leaders. No single model for effective implementation was identified, but they recommended that implementation should be planned around routine organisational activity, using a “bottom-up” front-line or microsystem approach to implementation, with rapid sequential small tests of change using PDSA cycles, followed by spread of changes that have resulted in improvement[168]. The authors highlighted that with the publication of de-anonymised data relating to RRT outcomes in the UK by the renal registry, overall outcomes and adherence to clinical guidelines has improved over time, but variation remains between centres, and what is missing is dissemination of good practice from best performing units.

A further review found that subjective variation in how guidelines are interpreted by clinicians can increase practice variation. Selecting the right implementation strategy- health care professional oriented, patient oriented, organisational or financial is key to successful implementation. The European Best Practice Group aims to develop activities to facilitate better implementation of guidelines, including transparency of the guideline development process, involving patients in guideline development, matching guidelines to national contexts, and making recommendations actionable[175].

2.2.4 The Evidence for Quality Improvement in Renal Replacement Therapy

RRT care is complex; the majority of patients have multiple co-morbidities, often low performance scores, and require the involvement of multiple health care professionals. As such, it lends itself to multifaceted interventions for improvement. In recent years there has been an increased focus on QI in kidney care, but reporting has been patchy, or inconsistent. With the development of SQUIRE, a formal reporting methodology for QI[176], and MUSIQ, a model for understanding the influence of contextual factors in QI[177], a more structured evaluation for QI for RRT care should be achievable. This section describes examples of the use of QI to implement best practice in RRT care, and, where evaluated, specific interventions or techniques associated with the effectiveness of an initiative.

2.2.5 Studies of Quality Improvement in Renal Replacement Therapy

A recent review of QI in RRT identified 93 initiatives describing planned attempts to accelerate the uptake of best RRT practice into clinical care[154]. The authors used the Cochrane EPOC group's standards to analyse the implementation strategies used in initiatives, and found that whilst all studies used at least one of the methods described to deliver best practice, the use of specific QI techniques was variable, the exception being in those interventions targeting vascular access. Only 26 of the studies were controlled, of which only 22 were protected against bias, and included for evaluation of the effectiveness of specific QI initiatives. The use of multiple techniques was found to be more effective than a single strategy, although no specific QI technique was found to be associated with the effectiveness of an initiative ($p=0.184$). The authors also found that the most frequently used strategies were patient or staff-orientated, reflecting the multidisciplinary nature of RRT care, and the importance of self-management in chronic disease. The authors concluded that interest in how to improve the delivery of evidence-based care to patients on RRT remains high, and further research into implementation should be prioritised in future. To date this remains the most comprehensive review of the use of QI in RRT care.

2.2.5.1 Vascular Access

The largest QI initiative in RRT care is the Fistula First Breakthrough Initiative, a national project in the US whose aim is to increase the use of AVF for haemodialysis[178]. Observational data from DOPPS and national registries had highlighted the high rate of catheter and AV graft (AVG) use in the US[179], and the additional healthcare burden

associated with this. The initial aim of the initiative was to increase AVF fistula rates in prevalent patients to 40%, using key “change concepts” and a collaborative method similar to the IHI Breakthrough Series. It reached this goal ahead of target, and subsequently set a goal of 66%. An evaluation in 2007 reported that whilst the initiative had increased AVF use in prevalent patients, paradoxically catheter use also increased over the same period, as much of the increase in AVF use came from a fall in graft use[180]. It should be noted, however, that this rise in catheter use was in keeping with international trends[47]. This illustrates the importance of careful measures both of intended outcomes, and “balancing” measures, or other, potentially unforeseen, outcomes. A revision of the fistula first initiative as a result has been “fistula first, catheter last”[180,181].

Polkinghorne et al described a QI programme to increase the use of AVF in incident patients that included audit of previous results, barrier analysis including surveys of clinical staff, and design of a multifaceted intervention with actions tailored to address each barrier. They described an increase in incident AVF from 56% to 75% ($p=0.007$) after implementation. They identified the use of a vascular access nurse to coordinate the surgical pathway, who also had sole responsibility for prioritising patients, and audit and feedback of outcomes, as key factors in the success of the initiative [182].

Other QI initiatives in vascular access care have focused on reducing catheter-related bloodstream infection. One UK programme, in a centre with high catheter use (76% of patients), described using a US Centres for Disease Control (CDC) scheme with CDC collaboration, involving active surveillance and reporting in catheter management in dialysis care. This resulted in a significant decrease in HD catheter related bacteraemia in a UK unit, with a fall in the bacteraemia rate from 3.2/100 patient months to 1/100 patient months when standardised for catheter access. Hospitalisation and antibiotic use also fell in the group[183]. The implementation method included embedding rigorous surveillance into routine care, monthly data reviews by the lead clinician and lead nurse, and reporting anonymised data to the CDC dialysis surveillance network for analysis.

Similarly, a collaborative report of the implementation of a QI programme in 17 HD centres in the US described monthly reporting of data to the CDC, implementation of an evidence-based intervention package, CDC support hand hygiene and vascular access audits, and regular feedback to staff. They found a decrease in access-related bloodstream infections from 0.73/100 patient months to 0.42/100 patient months post intervention[184]. However, other studies have had varying success. A multifaceted intervention to reduce CRBSI in a

haemodialysis unit in 2014 did not reduce infections, but found that compliance with the intervention was variable[185]. It concluded that inconsistent compliance was due to organisational and external environmental factors.

2.2.5.2 Dialysis Dose

A report by Fink et al in 2002 described a series of interventions, including measurement of adequacy, workshops for QI, setting improvement goals, monitoring by a medical review board (MRB), and site visits from MRB staff (with pre-specified goal). They found an overall increase in URR across centres, with reduction of variation in attainment of URR between centres, although the distribution of URRs within centres didn't change[186].

McLellan et al conducted a randomised trial of 42 dialysis centres to improve dialysis adequacy, using QI methodology involving feedback, workshops, educational materials, and CPG assistance with development of QI plans. They identified an increase in blood flow rates ($p=0.02$) in intervention centres, as well as a 3% increase in URR (68.9 to 70.9%), compared to 0.09% increase in non-intervention centres ($p=0.03$)[187].

Palevsky et al reported using data collection and feedback to monitor effect, barrier analysis, education, CQI expertise to improve compliance with the dialysis prescription in HD patients. Interestingly, compliance with dialysis prescription decreased, but URR increased, with an increase percentages of patients with $URR>65\%$ from 69.7 to 75%. The authors speculated whether this was because the prescription was scaled up accordingly in patients who were not achieving target URR[188].

2.2.5.3 Anaemia

Several QI initiatives to improve anaemia management in RRT care have been described. A report by Irving et al described the outcomes and barriers to implementing the Care of Australians with Renal Impairment (CARI) guideline for anaemia. They found that factors associated with improved outcomes included nurse driven protocols, an iron management decision aid, fewer nephrologists per HD unit, and a proactive rather than reactive management protocol. Barriers identified were a lack of knowledge or trust in the guideline, an inability to implement the recommendations and an inability to agree on a uniform unit protocol[189]. This is in keeping with the findings from systematic reviews that empowering and supporting front-line staff to make decisions, coupled with provider involvement in

guideline development and consensus around protocols, as key to the success of an improvement project.

The majority of QI initiatives for anaemia use a combination of treatment protocols, staff education, and staff-oriented strategies- particularly nurse or pharmacist-led care to implement best practice[190,191].

2.2.5.4 Peritonitis

ISPD guidelines recommend continuous quality improvement as a tool to reduce peritonitis, with evidence that a multi-professional team approach is key[138]. There is now a body of evidence that using a quality improvement approach is successful in reducing infection rates. A multifaceted CQI to reduce peritonitis achieved an improvement from 1/7.5 patient months to 1/36.5 patient months by introducing regular retraining, using equipment from a single manufacturer and protocol changes[192]. Nasso et al described implementing sequential action methods to improve peritonitis rates in their cohort by increasing education for patients and nurses, and creation of a home visit form. After finding no improvement to their rate after a 12 month period, further action items were developed, resulting in an improvement in their peritonitis rate[193]. This describes the testing, action planning and continuous feedback used in testing and implementing change in QI.

2.2.5.5 The Impact of Studies Using Quality Improvement in Renal Replacement Therapy on Clinical Outcomes

The RightStart QI programme used a multifaceted programme of case manager-led patient education coupled with focused management of anaemia, dialysis dose, nutrition, vascular access, medication review, psychosocial assessment and encouragement to enrol in self-care and rehabilitation activities in the first 90 days for incident HD patients, and compared the results of these interventions with time-concurrent matched controls[194]. They reported a statistically significant difference in albumin in the RightStart group, and a decrease in mortality across all time points (90 days, 180 days, 1 year), with 1-year mortality 17 vs 30 per 100 patient years ($p < 0.001$). Hospitalisation was also decreased in the RightStart group. There was no difference between the other clinical parameters, although it should be noted that this difference in mortality was achieved despite a failure to achieve a significant reduction in catheter use at 90 days.

Wilson et al reported the results of implementation of the IMPACT (incident management of patients, actions centred on treatment) programme for the management of incident HD patients in a large dialysis provider in the US. It was designed to address four modifiable haemodialysis practices associated with lower mortality- anaemia, vascular access, and hypoalbuminaemia and dialysis adequacy using a continuous quality improvement method[195]. Multidisciplinary teams of staff were trained to implement four components of care for new patients starting dialysis in participating centres. These were a structured new patient intake process, a 90 day patient education programme that included an educational booklet to be used in tandem with a 90 day patient management programme focussing on modality, access and nutrition and fluid education, anaemia management and medications, with checklists and timelines to maintain adherence, and monthly patient monitoring reports to identify low performing units or additional interventions required. Incident patients receiving standard care were identified as a control group. The IMPACT group had significantly higher rates of preferred vascular access at six months (mean 0.6, 95%CI 0.57-0.63), compared to controls (mean 0.52, 95%CI 0.5-0.54) $p<0.001$, that was sustained at year. Whilst there was no significant difference in attainment of the other clinical indicators, importantly, mortality was better in the IMPACT group at one year (deaths per 100 patient years in treatment group 17.8, 95%CI 15.2-20.4, compared with 23, 95%CI 20.7-25.2, $p<0.01$). This chimes with observational data that shows vascular access is a major contributor to higher mortality in dialysis care.

One QI initiative integrated pharmacy care in US dialysis units, including medication delivery, automatic medication refills, medication reviews, telephoned assistance[196]. When compared with a control group, the intervention group had significantly lower mortality and hospitalisation rates at one year, thought partly to be due to better monitoring of medication use and better adherence with medications.

2.2.6 Summary

There is increasing recognition of the importance of quality and safety in healthcare, and the need for an evidence-based approach to care. This has been aided by the development of guidelines and protocols, based on reviews of research evidence and expert opinion, in order to aid clinical decision-making. However, questions remain around the most effective strategies for implementation of guidelines for best practice, with mixed reports of the success of initiatives. This is compounded by a lack of evidence from research into whether adhering to guidelines improves mortality. Quality improvement methodology originated in

industry and has evolved in healthcare with the development of specific techniques with which to implement best practice. These can be summarised as identifying a target for improvement, analysing the barriers to improvement and designing strategies to overcome such barriers with continuous data-driven monitoring of the effect, supported by QI expertise. Within the realm of kidney disease, there is a body of observational evidence that has been used in the development of guidelines for best practice in dialysis care, but wide variation in delivery of care continues to exist both within and between countries. There is emerging evidence that using quality improvement methodologies to improve clinical indicators can be effective but overall there is a lack of research, and notably little data on the sustainability of these initiatives.

3 Conclusion

The association between clinical targets in dialysis care and mortality is well described, and there is evidence from interventional studies of the effect of attaining quality of care targets on outcomes and hospitalisation. Only a few QI initiatives have been described in kidney care, with mixed outcomes. The next step is to evaluate strategies to improve quality of care indicators in dialysis, their impact on clinical outcomes, and their sustainability.

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CHAPTER 2: AIMS AND OBJECTIVES OF THE RESEARCH PROJECT

There is a large body of observational evidence that supports the association between clinical indicators and outcomes in dialysis care. This forms the basis of national and international guidelines and reporting of outcomes in national registries. Wide variations exist both within and between countries in the delivery of care and attainment of clinical targets. What is lacking is evidence for implementation of clinical guidelines and improving attainment of targets.

Salford Royal NHS Foundation Trust has had a programme of Quality Improvement to improve attainment of clinical indicators in its dialysis population since 2010. Evidence for the effectiveness of QI collaboratives in healthcare, and nephrology in particular, is scanty, despite increasing awareness of QI and considerable interest in it at a national level. Much improvement takes place in a context where its efficacy cannot be reported, due to the limitations of “real-time” studies. There is increasingly a recognised reporting paradigm (SQUIRE) for effective reporting and evaluation of QI research.

The purpose of this research is to evaluate

- 1) Outcomes of the QI programme in impacting dialysis quality of care indicators in the Salford Renal Network dialysis population
- 2) A detailed analysis of one aspect of the QI programme- reduction in peritonitis- to further analyse the steps and processes involved in making changes to clinical practice
- 3) Longer term follow up of two aspects of the QI programme (URR and reduction in catheter-related blood stream infection) to evaluate sustainability of the improvement

As this thesis is presented in the alternative format, the aim of each results chapter, and its position in relation to these aims and objectives, is restated at the start of each chapter.

CHAPTER 3: METHODOLOGY

As this thesis is presented in alternative format, the methods used for each analysis are included in each results chapter, therefore overlap with the information presented here. However, this chapter includes further detailed data on study design, data collection, and analysis.

3.1 Ethical approval and funding

The QI collaborative was discussed with the Salford ethics and research committee, and as an improvement project was deemed not to require ethical approval. Follow up analyses were conducted within the improvement framework. Further discussion with the research and ethics committee on the need for ethical approval for other data from semi-structured interviews with staff members also deemed that approval was not required.

3.2 Quality Improvement methodology used

The QI programme used a modified version of the Institute for Healthcare Improvement (IHI) Breakthrough Series collaborative methodology to implement changes to processes of care. This has been described in the literature review above and was chosen because it is well-established and has been used successfully in healthcare improvement initiatives.

3.3 Data sources and data collection

Pre-intervention data was collected by Dr Azri Nache on patient demographics and baseline clinical data. This was obtained from the hospital electronic patient record with the assistance of a data analyst within the IT department, and manually checked for accuracy. Retrospective data collection on infections was obtained from microbiology records. Real-time data had been collected on peritonitis infections on a paper record, which was transferred into a database during the improvement project as part of the project work.

Data during the improvement projects was collected in real time from the electronic patient record. All pre-intervention data and data collected for improvement, rather than research, was verified and cleaned by myself to ensure accuracy for the purposes of this research.

Post-intervention data was obtained retrospectively from the electronic patient record and manually verified for accuracy.

Other sources of data included:

▣ A quantitative context analysis was undertaken before and after the improvement projects using the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Survey

- ☐ A quarterly team assessment using the Institute for Healthcare Improvement Collaborative Assessment and a self-created assessment tool were taken during the improvement project
- ☐ Documented tests of change performed and problems encountered
- ☐ Central project and improvement team minutes of meetings
- ☐ Surveys of staff and patients conducted as part of the improvement work
- ☐ Correspondence (letters and emails)

Part of this data had been collected by the Dr Azri Nache, the previous QI project facilitator and was stored on password-protected hospital computers. In my role as Quality Improvement Fellow in the department I verified and analysed this data, and collected subsequent data which was stored on password protected hospital computers.

3.4 Study design, inclusion and exclusion criteria

All dialysis units in the Salford renal network were included in the initial QI projects. Long-term follow-up analyses included analysis of data from three dialysis units. National registries report outcomes in prevalent patients, who have been on RRT for >90 days. For the purposes of improvement, all dialysis patients, including incident patients, were included in reporting a unit's outcomes.

Inclusion criteria

All incident and prevalent patients on dialysis on the first of the month in units undergoing evaluation

Exclusion criteria

Patients who died within the calendar month undergoing evaluation

Data from patients who were inpatients at the time of monthly blood tests

Patients on dialysis less than three times per week

Patients on dialysis more than three times per week

3.5 Recorded Information:

Patient demographics (age, gender)

Co-morbidities (Diabetes Mellitus (DM), smoking, Ischaemic Heart Disease (IHD), Congestive Cardiac Failure (CCF), Peripheral Vascular Disease (PVD), Cerebrovascular Disease (CbVD))

Prevalence of arteriovenous fistula

Cause of end stage renal failure

Pre-dialysis blood pressure

Laboratory data (haemoglobin, pre and post dialysis urea, phosphate, calcium, parathyroid hormone (PTH))

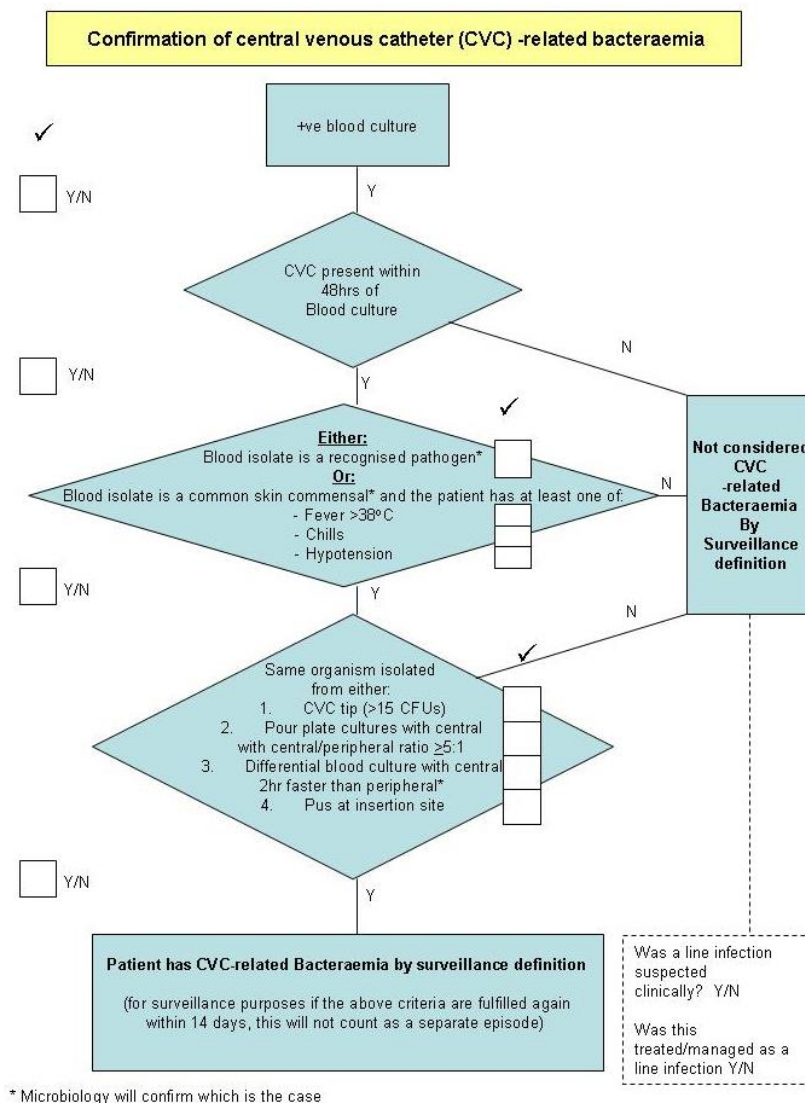
All researchers are trained in Good Clinical Practice. Patient data are handled in accordance with the Data Protection Act of 1998 and the University of Manchester Data Protection Policy as required by the Code of Research Conduct (<http://documents.manchester.ac.uk/display.aspx?DocID=2804>).

3.6 Event definition

Catheter-related bacteraemia

This was defined using a hospital definition adapted from the epic2 guidelines[1] as shown in figure 2 below

Figure 2. Definition of catheter-related bacteraemia



Peritonitis

Peritonitis was defined as clinical features of peritonitis (abdominal pain or cloudy dialysate) and dialysate white cell count >100/mcL. Further peritonitis episodes were defined as per the ISPD guidelines[2]. Episodes of relapsing peritonitis were recorded but not included in the overall peritonitis rate, whilst recurrent and repeat were, as per ISPD methodology.

Pre-dialysis blood pressure

Pre-dialysis blood pressure was extracted from the electronic patient record and measured using standard electronic blood pressure cuffs. An average of the monthly pre-dialysis blood pressure was used

Attainment of target haemoglobin

Percentage of all patients in a dialysis unit attaining Hb 10-12mmol/L as measured by on a midweek pre-dialysis sample as part of monthly bloods

Urea Reduction Ratio

Percentage of all patients in a dialysis unit attaining URR>65% as measured by on a midweek pre and post-dialysis sample as part of monthly bloods

Phosphate

Percentage of all patients in a dialysis unit attaining target phosphate <1.8mmol/L as measured by on a midweek pre-dialysis sample as part of monthly bloods

3.7 Laboratory analyses

Standard biochemical and haematological parameters are recorded from samples processed at clinic visits. All blood samples are collected by trained phlebotomy, nursing or medical staff.

3.8 Summary of statistical methodology

Statistical analyses for chapters 1, 2 and 3 were performed using MedCalc release 12.5.0 (MedCalc software, Mariakerke, Belgium). Subsequent analyses were performed using SPSS version 22 (IBM) under licence to the University of Manchester.

Continuous data were visualized using scatterplots, histograms and quantile plots to identify outlying data points and to assess the distribution of the data. Where a non-parametric distribution existed either a non-parametric methodology was used in analysis or a transformation applied to approximate normality (natural log transformation for positively skewed data, square-root or natural log transformation for negatively skewed data). Parametric continuous data are presented as mean±standard deviation, non-transformed nonparametric data are presented as median [interquartile range] and categorical data as number [percentage]. Continuous data were compared between groups using either ANOVA or t-test and categorical data compared using Chi-squared test.

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CHAPTER 4. RESULTS

CHAPTER 4.1

Effect Of A Quality Improvement Program To Improve Guideline Adherence And Attainment Of Clinical Standards In Dialysis Care: Report Of Outcomes In Year 1

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Preface

There is little published evidence for the implementation of clinical guidelines and best practice in dialysis care. This chapter addresses the first question of this thesis- whether a quality improvement programme using established QI methodology is successful in achieving targets for dialysis quality of care indicators in a dialysis population, and the lessons learned from using this process.

This study has been accepted for publication in Nephron. Table numbers have been adapted for the thesis format, and tables and figures included in supplementary online material for the purposes of publication have been integrated into the manuscript and included here.

ABSTRACT

BACKGROUND: Best practice in dialysis is synthesized in clear international guidelines. However, a large gap remains between this and actual delivery of care. We report outcomes for the first year of a multifaceted dialysis improvement programme in our network.

METHODS: 1 year collaborative involving 3 haemodialysis units and a peritoneal dialysis programme involving 299 dialysis patients. Each unit addressed a different indicator (unit A- catheter related bloodstream infection (CRBSI), B- pre-dialysis BP, C- dialysis dose, D- anaemia) with a shared aim to match the top 10% in the UK. Tailored multifaceted approaches using a modified collaborative methodology with an aim, framework, driver diagram, learning sessions, facilitated meetings, plan-do-study-act (PDSA) cycles, and continuous measurement.

Analysis of outcomes, costings, erythropoietin stimulating agent (ESA) and iron use, and safety culture attributes.

RESULTS: Unit A reduced CRBSI from 2.65 to 0.5 per 1000 catheter days ($p=0.02$). Unit B improved attainment of target BP from 37.5 to 67.2% ($p=0.003$). Unit C improved attainment of target urea reduction ratio (URR) from 75.8 to 91.4% ($p=0.04$). Peritoneal Dialysis Unit D improved attainment of target Hb from 45.5% to 62.7% ($p=0.01$), with no significant change in the indicators in a non-intervention unit. Safety culture attributes improved. Costs associated with admission for fluid overload and infection, erythropoietin, iron and thrombokinase use decreased 36% (£415,620 to £264,143).

CONCLUSIONS: Units that took part in this collaborative improved guideline adherence compared both to their own pre-intervention performance and a non-intervention unit. Such multifaceted interventions are a useful methodology to improve dialysis care.

INTRODUCTION

International standards on optimal kidney care have been synthesised by bodies such as the European Best Practice Guidelines[1], Kidney Disease Improving Global Outcomes (KDIGO)[2], the National Institute for Health and Clinical Excellence (NICE)[3,4], and the UK Renal Association (UKRA)[4]. Despite this, a gap remains between expert recommendations and what is actually delivered, with variation in achievement of standards within and between countries[5]. This variation is ubiquitous and was coined the “quality chasm” in a seminal report in 2001[6].

If the ‘what’ to achieve is clear, “how” best to achieve it is not. Systematic reviews examining highlight that there is no convenient single approach for effective implementation[7,8]. Further evidence suggests success is more likely with a choice of aims that are perceived as priorities, bespoke strategies, multifaceted approaches, strategies to overcome barriers to change, and senior leadership support[9,10].

Aim

In 2010 we set up a renal quality improvement programme, aiming to match the top 10% of centres in the UK on key quality of care indicators, regardless of other epidemiological, financial or clinical factors. We set each team a different clinical indicator as a target for improvement over one year.

Our network- the NHS Greater Manchester West Renal Network- had 4 haemodialysis units and a PD programme at the time of the study, serving a population of 1.3 million. The UK Renal Registry (UKRR) is an independent registry of dialysis providers’ performance that reports de-anonymised provider outcomes and is the central data source used by the National Health Service (NHS) to calculate funding for renal replacement therapies (RRT)[3]. Our achievement of national standards of dialysis care had not changed significantly since UKRR benchmarking began. Funnel plot analysis excluded outlier performance status[11-14]. Life expectancy in Greater Manchester is one of the lowest in the UK and case mix had been considered a potential factor affecting outcomes[15].

SUBJECTS AND METHODS

The project was discussed with the local Research and Ethics Committee; as a QI project ethical approval was not required. Twelve months’ preparatory work was undertaken, including baseline data, patient level costings, stakeholder engagement, and evaluation of

evidence. There is evidence that context- the environment in which the intervention is implemented- along with the intervention itself and implementation method, is critical to success[16], therefore an Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture[17] was used to assess context in each unit. Baseline audit revealed units had wide variation in performance on national audit standards, with no single common indicator that needed improvement. The surveys were completed anonymously by network staff with a 77% response rate. Data showed a spread of teamwork and safety attributes, with teamwork within units, event reporting, organisational learning, manager expectations and actions promoting safety, and support for patient safety, scoring highly. We used a modified Institute for Healthcare Improvement Breakthrough Series collaborative methodology[18] to set each team a different clinical indicator needing improvement in that unit to address for one year. The aims and framework were chosen by an expert faculty of dialysis and improvement experts, multi-professional opinion leaders, and patients' representatives. All teams were part of the NHS Greater Manchester West Renal Network. All units worked to an overarching aim of matching the top 10% of units in clinical performance in the UK Renal Registry.

The improvement aims were as follows:

Haemodialysis Unit A – Reduce haemodialysis catheter-related bloodstream infection (HDCRBSI) from 2.65 per 1000 catheter days at baseline to <0.6 per 1000 catheter days.

Haemodialysis Unit B – Increase attainment of pre-dialysis blood pressure (BP) <140/90 mmHg from 37.5% (6th centile of units) at baseline to >60% of patients (top 10% of units)

Haemodialysis Unit C – Increase attainment of urea reduction ratio (URR) >65% from 75.8% (7th centile) at baseline to >90% of patients (top 10%).

Peritoneal Dialysis Unit D – Increase attainment of target haemoglobin of 10.5-12.5 g/dl from 45.5% (bottom 10%) to >65% of patients (top 10%). This was the UKRA and European best practice guideline at the time and has subsequently been updated.

Haemodialysis Unit E Increase attainment of pre-dialysis blood pressure (BP) <140/90mmHg from 42.3% (5th centile) at baseline to >60% of patients

Transplant Team F – for 95% of patients to be adherent with a Cardiovascular Bundle.

All clinical indicators chosen have been shown to influence survival[19]. Dialysis dose and haemoglobin had a clear national standard[20] and there is widespread acceptance of the morbidity associated with HD CRBSI and septicaemia[21-23]. The UK national standard for BP in HD was withdrawn in 2007[20], due to concerns about the U-shaped relationship between systolic BP and mortality[24] and the prognostic value of pre-dialysis BP readings[25]. The Expert Faculty felt that although BP does not exclusively reflect volume, fluid management is a hallmark of excellence, with salt restriction and ultrafiltration “first-line” management of hypertension in HD[26].

The Executive Medical Director acted as the board-level project sponsor. Participating teams consisted of 3-4 person multi-professional teams of frontline staff, which met weekly, designed and performed plan-do-study-act (PDSA) cycles[27], engaged their wider unit and undertook measurements, supported by a trained facilitator. Changes in practice were defined through understanding baseline performance, examining evidence- including case reports and conference abstracts, examining local processes, and visiting better-performing units. The work was guided by a framework set by the Expert Faculty (Figure 4.1.1). By project end, this allowed units to build a “change package” of proven successful interventions (Table 4.1.1).

Figure 4.1.1:_Driver diagram outlining framework for improvement

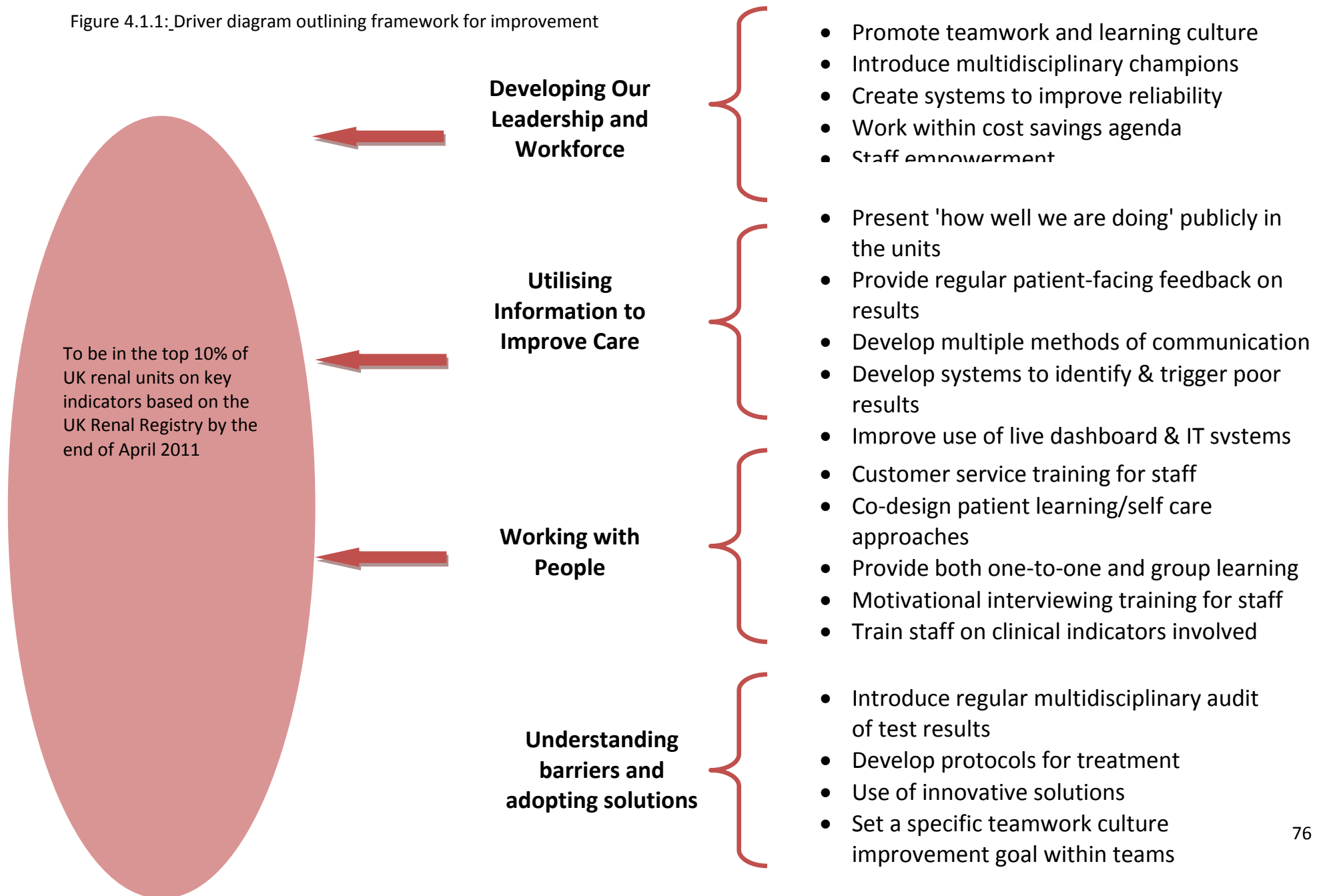


Table 4.1.1. Key changes made in each unit as part of QI collaborative

Unit	Indicator	Changes
Unit A	Reduce CRBSI	Set days and times for dressings Different coloured aprons when accessing lines Small dressing trolleys Bioconnectors ANTT connect-disconnect Handwashing Exit site surveillance tool Exit site and bacteraemia database Traffic light system for lines Algorithm for high risk lines Predict next infection Tinzaparin/heparin protocol Patient information leaflet
Unit B	BP	Division of staff into teams to ensure continuity of care for patients Nurse-led blood pressure protocol for patients with high BP Nurse rounding with senior nurse or shift coordinator to troubleshoot problems Tailored dialysis observation chart Electronic daily goals MDT review of BP Promote use of blood volume sensor monitoring Staff education on salt and fluid Patient education on salt and fluid
Unit C	Improve URR	Nurse-led URR protocol Review and change of prescriptions during dialysis Monthly live reporting of URR and VA Saline recirculation Anticoagulation protocol to reduce clotting of dialysers Exercise on dialysis
PD Unit D	Target Hb	Repatriation of ESA management from separate ESA team to PD team Nurse prescriber within PD team Monthly anaemia MDT review IT reporting system for blood tests Extended ESA prescription duration

A full time research fellow managed the day-to-day project, supported by a senior nurse and doctor acting as co-directors. All frontline QI activity was carried out within the normal resource envelope.

Team development involved individual coaching, a team role inventory, group facilitation and peer support during learning sessions. The level of support was tailored to context and included a minimum fortnightly facilitated QI team meeting, telephone and email, and fact-finding visits. A formal project communication strategy included a newsletter, sharing of results, patient stories and face-to-face briefings.

The project directors used serial measurements and statistical process control (SPC) charting to track progress of the project. After participating units were trained in QI methodology during learning sessions, these were shared with the QI teams during facilitated meetings as a further tool for improvement.

The intervention period began after the first learning session in April 2010, and ran for one year. Within the first quarter, two of the units (Unit E HD, Unit F Transplant) dropped out due to lack of engagement. Four units therefore completed the project, which finished in May 2011. Relevant outcome data was also calculated for Unit E as a “non-intervention” unit to compare outcomes with the remaining four intervention units.

Units designed and carried out multiple small tests of change over the collaborative year, ranging from a total of 24 in Unit D to 42 in Unit A. Successful small tests of change were refined and implemented across the unit. A summary of the successful changes tested implemented by each unit is presented in Table 4.1.1.

Methods of Evaluation and Analysis

Universal data collected included demographics, laboratory variables, access type, dialysis-related hospitalisations, bed days and clinical details from the electronic patient record. Both pre-intervention (2009-2010, labelled Year 0), and intervention year (2010-2011, labelled Year 1) unit level data collected was dependent on the improvement aim (Table 4.1.2).

For HD Unit A, HDCRBSIs were defined as per a hospital wide protocol based on the Epic guidelines[28]. Rates were calculated by dividing number of infections by total catheter days and reporting annual rate per 1,000 catheter days.

URR and haemoglobin were obtained monthly from the last test in the month for each patient, excluding tests done whilst an inpatient.

Pre-dialysis blood pressure was calculated as an average monthly pre-dialysis blood pressure per patient.

Table 4.1.2. Summary of improvement aims and unit level data collected.

Unit	HD unit A	HD unit B	HD unit C	PD unit D	Non-intervention HD unit E
Number of patients	67	64	58	110	71
Improvement aim	Reduce HDCRBSI from 2.65 per 1000 catheter days at baseline to <0.6 per 1000 catheter days.	Increase attainment of pre-dialysis blood pressure <140/90 from 33% to >60% of patients.	Increase attainment of urea reduction ratio (URR) >65% from 75.8% to >90% of patients	Increase attainment of target haemoglobin 10.5-12.5 g/dl from 34.5% to >65% of patients	NA
Data collected	Unit catheter use Number and type of exit site infections Incidence of HDCRBSI Admissions related to HDCRBSI Outcome of HDCRBSI*	Vasoactive medication prescription and timing Pre and post dialysis weight Pre and post dialysis blood pressure using standard haemodialysis machine sphygmomanometers Interdialytic weight gain Fluid removal on dialysis Admissions related to fluid overload	Pre and post dialysis urea Vascular access Type of dialyser Blood flow rates on dialysis Anticoagulant use Dialysis duration	Haemoglobin Ferritin Iron saturation Intravenous iron use ESA dose	Catheter use Number and type of exit site infections Incidence of HDCRBSI Pre and post dialysis blood pressure using standard haemodialysis machine sphygmomanometers Pre and post dialysis urea Blood flow rates on dialysis Anticoagulant use Dialysis duration Haemoglobin Ferritin Iron saturation ESA dose
Balancing measures	Expenditure on thrombokinase	Intradialytic hypotension	Bleeding time after dialysis	Expenditure on ESA and iron	NA

We evaluated the effectiveness of our work by:

- (1) Comparing clinical outcome measures in a “before and after” evaluation within units, and to unit E that withdrew from the project before beginning any improvement work.
- (2) Defining appropriate balancing measures such as IV iron use in anaemia management, hypotension in BP management.
- (3) Analysing costs concentrating on admission, actual length of stay, procedures and dialysis related medications. This was conducted using internal financial software, which calculates costs of hospital admissions/interventions based on coding data.
- (4) Repeating the AHRQ Hospital Survey on Patient Safety Culture at project end.

Statistical Analysis

Data with a normal distribution was expressed as mean±standard deviation. Comparison between groups was performed using the t-test to compare differences in mean, the Mann-Whitney U test for non-normally distributed variables and Chi-square tests in the case of dichotomous variables. ANOVA was performed to test differences in means between groups, and Chi-squared to compare differences in categorical values between groups. A p-value of less than 0.05 was accepted as significant.

A post-hoc analysis of paired data from patients who were constant attenders was performed using a t test.

Statistical analysis was performed using MedCalc release 12.5.0 (MedCalc software, Mariakerke, Belgium).

RESULTS

Demographics from the four intervention units and the non-intervention unit are displayed in Table 4.1.3. There was no significant difference in age, time on dialysis or co-morbidities between units, with a high prevalence of diabetes, hypertension and vascular disease, comparable to that reported in registry data[29]. All 4 units who completed the collaborative achieved the goal of matching the top 10% of units in the country for their improvement aim. The SPC charts demonstrate that the first evidence of improvement occurred 3-6 months after study onset, in keeping with classic improvement trends (Figures 4.1.2a-d).

Table 4.1.3 Network Demographics

	Haemodialysis Unit A	Haemodialysis Unit B	Haemodialysis Unit C	Peritoneal Dialysis Unit D	Non-intervention unit E	P value
Patient Number	67	64	58	110	71	
Age (mean \pm SD) yrs	58.2 (\pm 15.3)	59.9 (\pm 15.2)	61.0 (\pm 15.9)	56.6 (\pm 15.1)	61.2 (\pm 16.4)	0.106
Dialysis duration in weeks (median \pm IQR)	97 (114)	92.5 (141)	102.5 (107)	92.5 (22)	81 (168)	0.807
% Male	62.5	60.9	60.3	56.3	54.9	0.862
Diabetes (%)	34.3	45.3	29.3	37.3	33.8	0.430
Hypertension (%)	89.6	78.1	86.3	84.5	80.3	0.394
Cerebrovascular disease (%)	10.4	6.3	17.2	9.1	14.1	0.427
Peripheral vascular disease (%)	9.0	12.5	6.9	9.1	8.5	0.868
Ischaemic heart disease (%)	32.8	48.4	37.9	34.5	39.4	0.363
Heart failure (%)	11.9	12.5	14.0	16	7.0	0.481

HD unit A had lower catheter prevalence (14.1%) at study onset but a higher rate of HDCRBSI than the non-intervention unit (catheter prevalence 23.9%, HDCRBSI 1.36 per 1000 catheter days) (Table 4.1.4). There was a significant decrease in HDCRBSI from 2.65 per 1000 catheter days in year 0 to 0.5 per 1000 catheter days ($p=0.012$) in year 1 in Unit A, with no change in the non-intervention unit. There was a similarly significant decrease in exit site infections from year 0 to year 1, from 4.65 to 1.25 per 1000 catheter days ($p=0.01$).

HD unit B addressed pre-dialysis BP (Table 4.1.5). At the end of the study there was a significant reduction in systolic BP in the intervention unit ($151.9\text{mmHg}\pm 26.4\text{mmHg}$ versus $130.1\text{mmHg}\pm 23.5\text{mmHg}$, $p<0.001$) and an increase in the proportion of patients achieving target blood pressure (37.5% versus 67.2%, $p=0.001$). Admissions related to fluid overload fell 50% from 12 admissions in Year 0 to 6 in Year 1. Total days in hospital due to fluid overload similarly fell from 155 to 47. Point prevalence of number and dose of anti-hypertensive medications decreased (average number of medications 2.1 Year 0, 1.6 Year 1). Notably, this did not result in an increase in intradialytic hypotension, as measured by two discrete samples of mean number of hypotensive episodes over one week at start and end of the intervention period (5.2 ± 1.4 versus 5.3 ± 1.8 , $p=0.55$).

In HD unit C (Table 4.1.6) the percentage of patients achieving $\text{URR}>65\%$ increased from 75.8% to 91.4% ($p=0.04$). There was a significant increase in tinzaparin usage (mean dose per HD session 3191 units ± 547 versus 3910 units ± 1150 , $p<0.001$); protocolised nurse-led heparin titration was a key change learned from best practice in a high-performing unit. There was no increase seen in bleeding time or clinically significant bleeding episodes, defined at minimum as requiring a pressure dressing. Interestingly a decrease in thrombokinase use was found indicating a potential positive effect on HD catheter function.

PD unit D (Table 4.1.7) improved attainment of haemoglobin within $10.5\text{--}12.5\text{g/dL}$ from 45.5% of patients pre-intervention to 62.7% post-intervention ($p=0.01$). There was no significant increase in darbepoetin use (41.5 versus 45.6 $\mu\text{g/week}$, $p=0.34$). Total intravenous iron use in unit D fell from 65,850mg in year 0 to 49,300mg in year 1.

Paired analyses comparing results in patients who were constant attenders during the study period revealed that in units B and D the significance of the improvement persisted (34.7% to 73.9%, $p<0.001$, and to 45.8% to 60.4%, $p=0.049$ respectively), whilst in unit C there was no significant difference in attainment of target URR in this group (77.8% to 93.3%, $p=0.18$).

Table 4.1.4: Catheter Related Bacteraemia Results Unit A

	Haemodialysis Unit A			Non-intervention unit		
	Pre-intervention	Post-intervention	P value	Pre-intervention	Post-intervention	P value
Catheter prevalence (%)	14.1	13.4		23.9	24.9	
Catheter-related bacteraemia rate (per 1000 catheter days)	2.65	0.50	0.02	1.36	1.15	0.74
Exit site infection rate (per 1000 catheter days)	4.65	1.25	0.01	3.24	3.35	0.94
Outcomes			% Change			% Change
Infections (n)	8	2	-75	8	7	-13
Death (n)	1	0	-100	0	0	0
Hospitalisation (n)	8	2	-75	7	6	-14
Length of stay (days)	138	34	-75	98	113	+15
Removal of catheter (n)	6	2	-67	3	2	-33

Table 4.1.5 Pre-dialysis Blood Pressure Results Unit B

	Haemodialysis Unit B			Non-intervention Unit E		
	Pre-intervention	Post-intervention	P value	Pre-intervention	Post-intervention	P value
Mean pre-dialysis systolic blood pressure (SD) (mmHg)	151.9 (±26.4)	130.1 (±23.5)	<0.001	148.7 (±25.2)	145.5 (±23.6)	0.43
Mean pre-dialysis diastolic blood pressure (mmHg)	82.1 (±17.4)	73.4 (±15.4)	0.003	77.6 (±17.5)	77.2 (±13.6)	0.9
Percentage of patients achieving BP<140/90 mmHg	37.5	67.2	0.001	42.3	43.7	1.0

Table 4.1.6 Dialysis Dose Results: Unit C

	Haemodialysis Unit C			Non-intervention Unit E		
	Pre-intervention	Post-intervention	P value	Pre-intervention	Post-intervention	P value
Mean urea reduction ratio (SD) (%)	70.4 (±8.3)	74.5 (±5.5)	0.002	68.7 (±8.5)	69.6 (±7.4)	0.47
Percentage of patients achieving clinical standard of urea reduction ratio >65%	75.8	91.4	0.04	69.0	69.0	0.58

Table 4.1.7 Anaemia: Community PD Unit D

	Peritoneal Dialysis Unit D			Non-intervention Unit E		
	Pre-intervention	Post-intervention	P value	Pre-intervention	Post-intervention	P value
Mean haemoglobin (SD) (g/dl)	10.6 (±1.4)	11.2(±1.5)	0.002	10.9 (±1.8)	11.2 (±1.6)	0.36
Percentage of patients achieving haemoglobin between 10.5 – 12.5 g/dl	45.5	62.7	0.01	57.7	53.5	0.74
Mean dose of darbepoietin (µg/week)	41.5 (±32.8)	45.6 (±40.9)	0.35	62.3 (±44.6)	67.4(±48.5)	0.51

Comparison of results between units

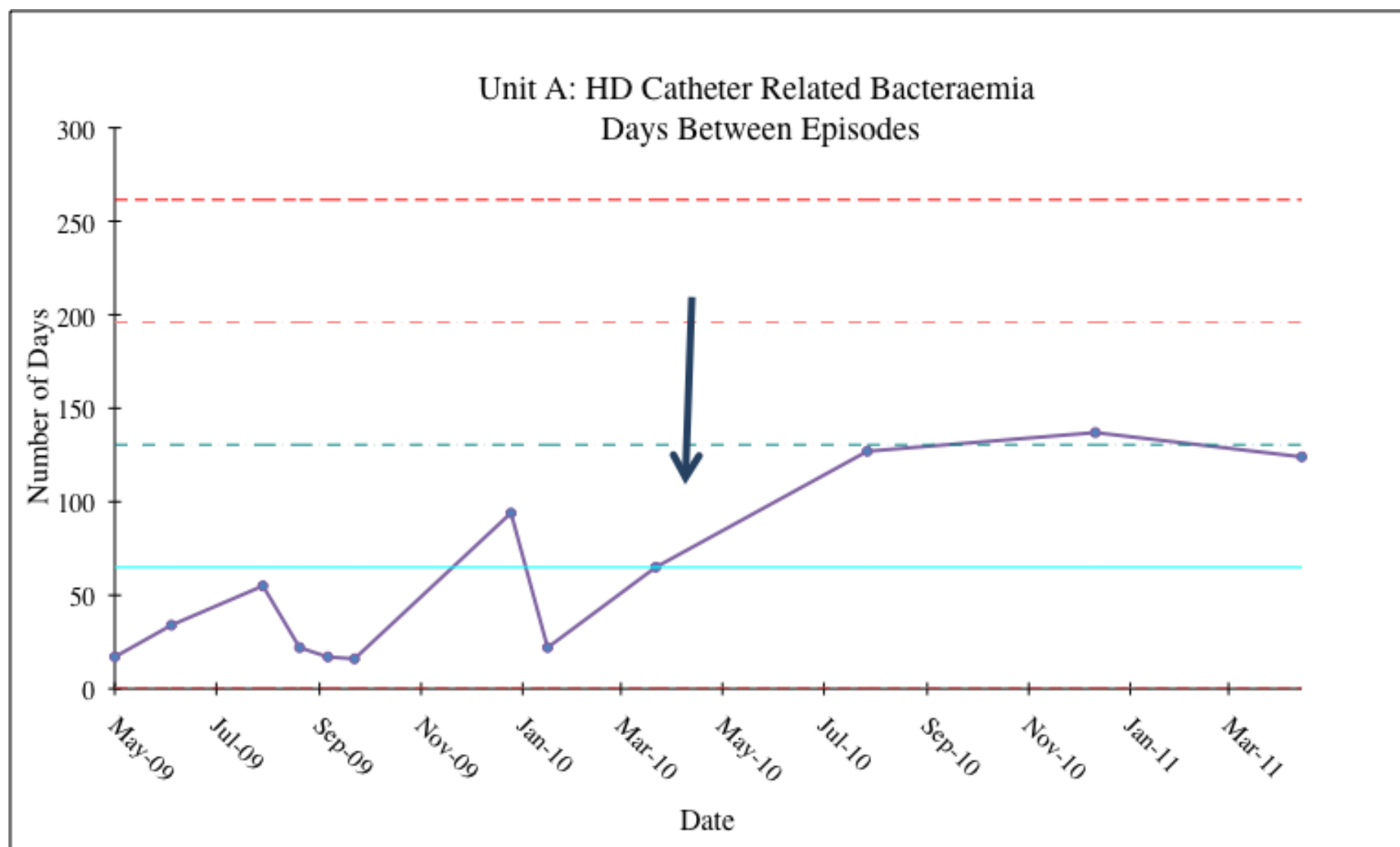
Table 4.1.4-4.1.7 also illustrate that there was no change in the clinical indicators targeted by each intervention unit (Units A-D) in unit E, the non-intervention unit that dropped out of the collaborative at onset.

In order to analyse whether, in concentrating on one indicator, performance against other clinical audit standards might be unintentionally adversely affected we analysed performance at unit level across all relevant indicators (HDCRBSI, URR, Anaemia, pre dialysis BP). This revealed no significant decline in the other parameters in intervention units (Table 4.1.8).

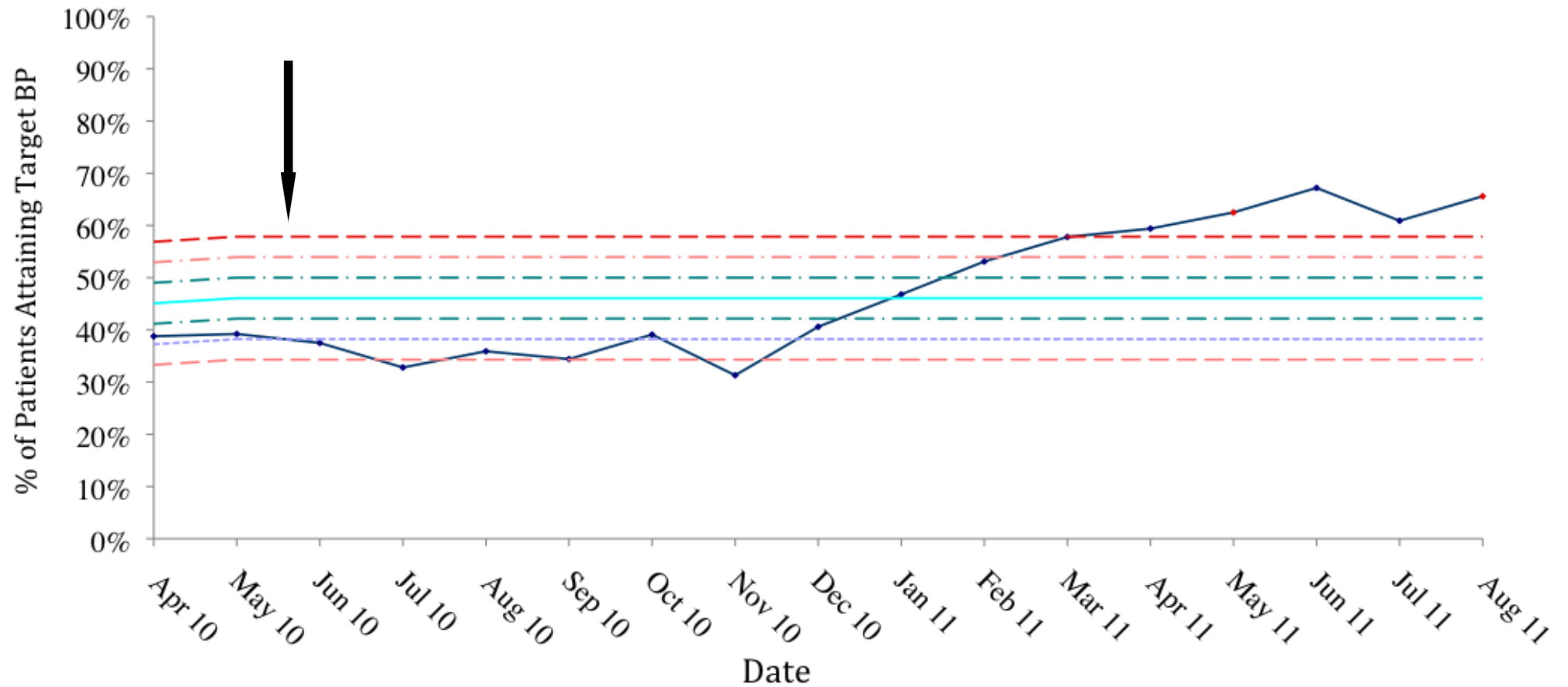
Table 4.1.8 Comparative results for all indicators in each unit including test for statistical significance. The intervention unit for each indicator is highlighted in red.

Unit	HD Unit A			HD Unit B			HD Unit C			PD Unit D			Unit E (non-intervention)		
	Pre	Post	P	Pre	Post	P	Pre	Post	P	Pre	Post	P	Pre	Post	P
HDCRBSI rate per 1000 catheter days	2.65	0.5	0.02	1.61	1.41	0.79	0.68	0.33	0.61	NA	NA	NA	1.35	1.15	0.74
Percentage of patients with BP <140/90 mmHg	40.3	44.4	0.62	37.5	67.2	0.001	47.1	42.1	0.67	NA	NA	NA	42.3	43.7	1.0
Percentage of patients with URR >65%	71.9	68.9	0.78	62.1	68.9	0.46	75.8	91.4	0.04	NA	NA	NA	69.0	69.0	0.58
Percentage of patients with Hb 10.5-12.5g/dl	52.2	54.1	0.82	46.4	49.6	0.72	48.2	64.8	0.08	45.5	62.7	0.01	57.7	53.5	0.74

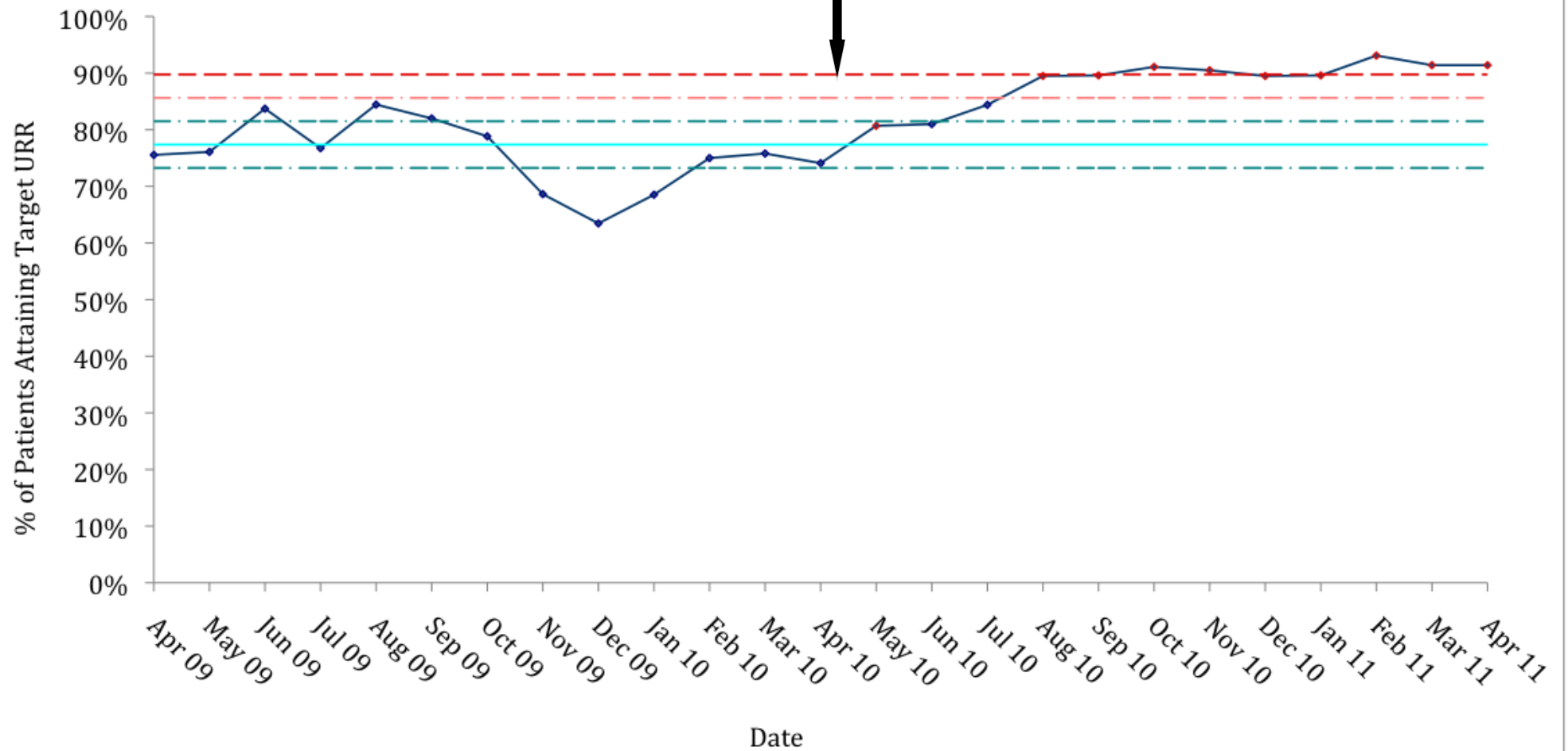
Figure 4.1.2 G chart and statistical process control (SPC) charts of results. (a) Unit A. Days between bacteraemia episodes. (b) Unit B. Percentage of patients with BP<140/90. (c) Unit C. Percentage of patients with URR>65%. (d) Unit D. Percentage of patients with target Hb. SPC charts for BP, URR, HB showing attainment of project aim by month for each unit and G Chart showing days between infections for HDCRBSI where each point represents an infection, with days between each infection plotted on the y axis. At least 1 year pre intervention data shown in units A, C and D. Unit B recorded data on paper charts prior to April 2010 therefore data samples were analysed pre-intervention and full retrospective pre-intervention data has not been obtained. The arrows on each chart represent the start of the QI project. The solid line on chart (a) represents mean number of days between infections prior to the intervention. The dashed lines represent standard deviations from the mean. The solid line on charts (b), (c) and (d) represents the average attainment of the target parameter prior to the intervention. The dashed lines on charts (b), (c) and (d) represent standard deviations from the mean.



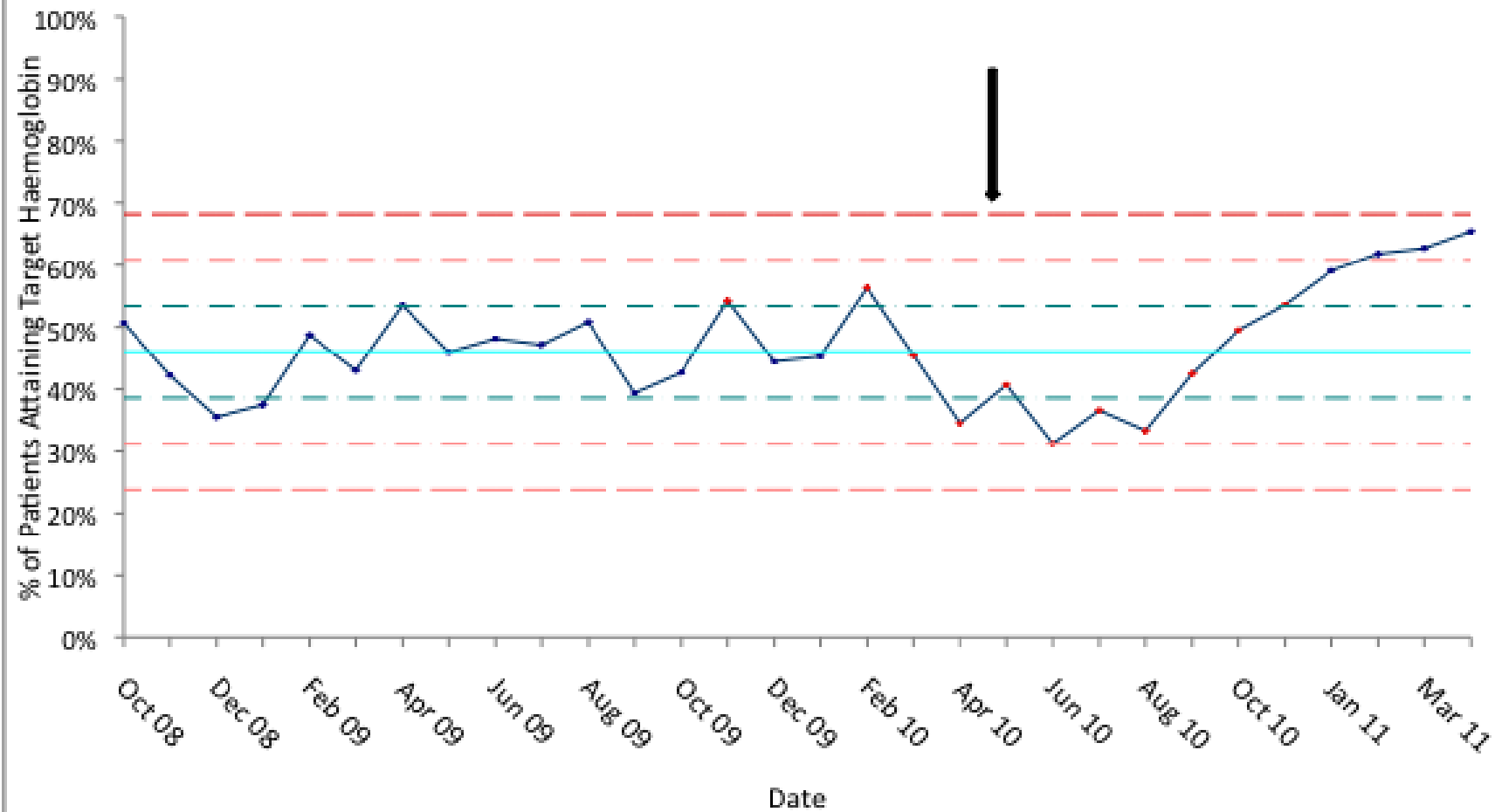
Unit B: BP<140/90 SPC Chart



Unit C: Dialysis dose
SPC Chart



Unit D: Anaemia SPC chart



Financial measures

Financial estimates were made as a measure for improvement. These were restricted to admissions relating to coded episodes of fluid overload and HDCRBSI, length of stay, and dialysis-associated medications, and found a reduction in admissions related to fluid and HDCRBSI in units A and B, with a significant reduction in associated costs (Table 4.1.9). Unit C (URR) achieved a 23% reduction in thrombokinase and erythropoietin use, whilst Unit D (anaemia) registered only a small and non-statistically significant increase in ESA use. Overall, costs directly related to ESA, iron use, thrombokinase use, and admissions to our hospital for fluid overload and bacteraemia (excluding standard costs of providing haemodialysis, other medication-related costs, and costs due to admissions for other reasons) were reduced 36%, from £415,620 to £264,143 (Table 4.1.9). Opportunity costs for the project were £80,500, which included 18 months' QI Fellow salary, equipment, and support costs for the expert faculty, stakeholder day and learning sessions. Work on the project carried out by the QI teams was carried out as part of the standard clinical day. This equated to an overall cost saving of £151,477 or 36%.

	Year 0 (£)	Year 1 (£)	Savings (£)
Cost of Bacteraemia associated admissions for Unit A Patients	92,004	18,706	- 73,298
Cost of Blood Pressure associated admissions from Unit B patients	85,261	29,053	- 56,208
ESA costs in Units A, C and D	229,083	210,501	- 18,582
Use of Thrombokinase in Units A and C	5,797	3,235	- 2,562
Iron use in community PD patients	3,475	2,648	- 827
Total	415,620	264,143	- 151,477

Table 4.1.9. Costs related to admissions for bacteraemia and fluid overload, ESA use, IV iron and thrombokinase use before and after the QI project. Admission data was derived from coding data and the hospital's patient-level costing financial tool. Medication costs were obtained from the hospital pharmacy.

Patient Safety Culture

There were improvements in all indicators in the AHRQ Hospital Survey of Patient Safety Culture across participating units at the end of the study period (Table 4.1.10). Of note, there was an increase in staff reporting high levels of satisfaction with team-working within units, perception of safety, and event reporting. The non-intervention unit did not demonstrate comparable improvements, with a decline in some parameters.

Table 4.1.10. Results of AHRQ Survey

	Intervention Units			Non-intervention unit		
	Pre-intervention (Year 0)	Post intervention (Year 1)	%change	Pre-intervention (Year 0)	Post intervention (Year 1)	%change
Teamwork across unit	50%	59%	+18	40%	52%	+30
Organisational Learning & Continuous improvement	74%	85%	+15	73%	68%	-7
Feedback & Communication	59%	84%	+42	50%	52%	+4
Communication openness	57%	69%	+21	44%	42%	-5
Overall perception of safety	57%	74%	+30	43%	39%	-9
Frequency of Event Reporting	58%	91%	+57	85%	70%	-18
Staffing	37%	52%	+41	34%	30%	-13
Handoff & transition	40%	52%	+30	40%	36%	-10
Manager expectation & actions promoting safety	71%	77%	+8	69%	50%	-28
Management support for patient safety	71%	78%	+10	76%	67%	-12
Non-punitive response to error	46%	52%	+13	35%	39%	+11

DISCUSSION

This improvement collaborative involving 299 dialysis patients was successful in one year in meeting its four aims of reducing HDCRBSI, and improving attainment of target pre-dialysis blood pressure, dialysis adequacy, and haemoglobin to match the top 10% in the UK. The project began with 6 units but 2 dropped out within weeks due to lack of engagement. This represents a 33% reduction in participating teams which is comparable to previous collaborative reports[30]. We were able to examine relevant outcome data for the HD unit that left the project as a non-intervention unit, which showed no significant change to the measured parameters. From this we inferred that without the multi-faceted interventions instituted, these parameters would not otherwise have improved.

Unit A achieved an 80% reduction in HDCRBSI in 12 months to a rate comparable with clinical trial interventions. A large scale Centers for Disease Control-sponsored QI project to reduce blood stream infections 17 facilities reported a fall in CVC-related infection rates from 2.46 per 100 patient months (0.81 per 1000 catheter days) pre-intervention, to 1.3 per 100 patient months (0.43 per 1000 catheter days)[22]. Following introduction of national UK reporting of MRSA bacteraemia in 2001 our units had already introduced best practice strategies resulting in reduction in MRSA bacteraemias, but other harms had not been reliably measured organisationally. Unit A also saw a significant reduction in exit site infections, suggesting that patient-facing strategies had also been impactful. A key learning point was that by setting a meaningful goal and empowering staff to generate and test hypotheses to solve the problem themselves, improved safety outcomes were achievable.

UK and international guidelines no longer suggest a target BP[2]. Instead, there is a recommendation to avoid extremes of BP, with attention to intradialytic hypotension (IDH). By using small scale iterative testing fluid was safely removed with no increase in sampled IDH. In contrast, an audit of HD practice in London showed better BP control was associated with an increased frequency of IDH[31]. The dry weight reduction in hypertensive HD patients (DRIP) trial also reported more symptomatic IDH[32]. We also demonstrated a reduction in fluid-related admissions in unit B. One of the influencing factors for change was in utilizing patient stories, clinical audit and financial data to demonstrate the adverse impact of these events to relevant stakeholders.

By the end of the intervention period, 91.4% of patients on unit C achieved an average URR of 74.5%. Of note, the significance of this difference at a patient level disappeared when paired analyses were applied, suggesting that much of the improvement came from better management of incident patients. International guidelines suggest that in order to achieve the standard of URR 65% in most patients, clinicians should aim for URR 70% in individuals.

Evidence also suggests that women and patients of low body weight may have improved survival with URR above 70%[33,34].

Management of anaemia for non-HD patients on ESAs within our network had traditionally been done by a nurse-led anaemia team. In this project ownership of anaemia management was transferred back to the PD team, with upskilling of a senior nurse to enable nurse prescribing and reduce delays in changes to treatment. Unit D achieved its aim without a significant increase in ESA use and with a fall in IV iron use. This correlates with our belief that the improvement came from clinical attention to detail, ownership and redesigning pathways of care.

By project end, knowledge gained from PDSA cycles allowed development of a change package or “how-to” guide of proven successful interventions, (Table 4.1.1). There is a sequence to ensure comprehension, engagement, and motivation to support change for the development of one change to practice[27]. Given the setting of several discrete dialysis units within a single network, we felt that a multifaceted strategy using a collaborative methodology[18] would be the best improvement approach in our population. One of the project’s challenges was in that units had different strengths and weaknesses in clinical performance and different patient populations at the outset (HD, PD and transplant). Choosing a single unifying clinical aim as in a traditional collaborative was not ideal as it would have meant, for example, not addressing HDCRBSI- a key safety issue in one unit. The design was therefore altered to give units their own clinical indicator to work on with a uniting common aim “To match the top 10% of UK Renal Units on key dialysis parameters”. One of the study’s strengths therefore has been in generating the knowledge base to achieve excellence in 4 different clinical indicators.

Another strength has been in analysing harm reduction in detail, enabling us to engage multiple stakeholders by highlighting achievable cost savings.

Following attainment of all 4 QI aims, a decision was made to run a second QI collaborative year, where units would address new (per unit) clinical indicators, and receive ongoing QI facilitator support whilst working to sustain the improvements made in year 1. Parallel interventions to sustain results include developing a “live” reporting of results, and an ongoing communications strategy.

Relation to other evidence

In a seminal paper in 2006 Pronovost et al reported a sustained 60% reduction in catheter-related bloodstream infection in ICUs in Michigan, using a collaborative method with

coaching of team leaders, development of a safety culture, implementation of a checklist and weekly phone calls to support staff[35]. The most well-known example of a multifaceted intervention to improve quality of care is the WHO surgical safety checklist, and several studies have described implementation strategies since its introduction[36-38]. Despite this evidence from other areas of health on implementation of best practice, a recent systematic review in RRT found only 93 out of 5000 reports specifically addressed improving dialysis care[7]. Commentators suggest that QI work is more widespread in US dialysis programmes than in Europe, but that it may be underreported[39,40]. QI collaboratives in dialysis care have had mixed outcomes; one group found an improvement in URR values and a reduction in centre variation over 10 years[41,42]. Another reported mixed outcomes; significant improvement in percentage achieving target Kt/V, phosphorus, and Hb>11g/dL, but no significant change in serum albumin or fistula prevalence, and an increase in Hb >13g/dL[43]. The Fistula First initiative aimed to increase AVF rates in prevalent patients using a collaborative method. An evaluation in 2007 reported that whilst the initiative had increased AVF use in prevalent patients, paradoxically, catheter use also increased, as much of the increase in AVF use came from a fall in graft use- emphasising the importance of impact evaluation[44,45].

The Dialysis Outcomes and Practice Patterns Study (DOPPS) and other data repositories demonstrate the frequency of non-achievement and variability of care[19,46-48]. Rocco et al studied 15,287 prevalent patients and determined that achievement of target haemoglobin, serum albumin, fistula use and dialysis adequacy was associated with improved mortality and hospitalization rates during the next 12 months[48]. In the EQUAL study Plantinga and colleagues demonstrated that attainment of increasing numbers of targets (dialysis dose, calcium-phosphate product, access type, haemoglobin, albumin) was associated with decreased mortality, fewer hospital admissions and reduced length of stay[46]. However, a possible explanation for these findings has remained that failure to achieve targets reflects “sicker” or more non-adherent patients, who are already more likely to have adverse clinical outcomes. There is some evidence to show that better achievement of dialysis clinical indicators is also associated with better quality of life measures[49].

There was demonstrable improvement in the AHRQ Hospital Survey on Patient Safety Culture in participating units (Table 4.1.10). No goal in improving teamwork or safety attributes was set[35]; the results were used instead to inform a deeper understanding of context. The change in safety culture however fits with research into team performance that

shows that team bonding is improved through shared tasks, shared goals, and moving to achieve goals[50]. Conversely, there was no improvement in the non-intervention unit, with a decline in some areas, highlighting the role of context in determining success. Recent UK data demonstrates that staff satisfaction measures correlate with outcomes such as mortality at an institutional level[51].

LIMITATIONS

As a QI project and not a randomised study, there are inherent potential confounding factors such as case-mix, differences between staff and other facility level characteristics. Changes to processes of care at an organisational level could also not be controlled for- as an example, our network changed brand of dialyser and introduced haemodiafiltration during the improvement year, making direct comparison of some process measures, such as dialyser surface area, difficult. In addition because the project went into a second improvement year with an additional level of complexity it is beyond the scope of this analysis to show sustainability data for the target outcomes from this first phase of intervention. Because HD Unit E left the project early on we continued to analyse its performance and this provides some evidence of natural variation in performance, although we interpret this with caution. Financial analyses were restricted to admissions specifically related to fluid overload, CRBSI and to dialysis related medications; therefore, any broader impact was untested.

CONCLUSION

Overall our project showed substantial improvements in attainment of clinical standards of care, and reduction in hospitalisation and bed days.

There is evidence that better achievement of key dialysis clinical indicators is associated with better life expectancy and quality of life. However, international data continues to show marked variation in achievement of these standards. This study shows how utilising quality improvement techniques has helped us meet ambitious levels of achievement in 4 key indicators of quality of care over 1 year in a dialysis network. Key determinants for success are supportive leadership, careful analysis of barriers to improvement, and engagement and empowerment of frontline staff to make changes to improve care. We believe that further development of QI as a tool for attaining clinical standards has the potential to improve health and wellbeing outcomes, in tandem with cost-effectiveness.

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CHAPTER 4.2

Effect Of A Quality Improvement Program To Improve Guideline Adherence And Attainment Of Clinical Standards In Dialysis Care: Report Of Outcomes In Year 2

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Preface

Chapter 4.1 reported successful improvement in attainment of clinical standards during the first year of the quality improvement programme compared to units’ pre-intervention performance and a non-intervention unit. The second year of the project identified further clinical indicators for units to work on as part of the collaborative.

This chapter aims to answer two questions. Firstly, by asking units to address new clinical indicators, it addresses the possibility that the improvement in clinical indicators in year 1 may have occurred even without QI input, given that this was not a controlled trial. Secondly, two units used change packages developed in year 1 by other units as the basis for improvements to care. This study looks at the implementation of successful “proven” interventions within a different dialysis unit in the same network, and the lessons to be learned from “spread” of change.

Abstract

Introduction: Best practice in dialysis is synthesized in clear international guidelines. However, a large gap remains between this and actual delivery of care. We reported improvement in attainment of clinical standards for one year of a multifaceted dialysis quality improvement programme. Following this a second improvement year was commenced to spread learning, sustain the changes and further improve standards in de novo clinical areas.

Methods: 1 year collaborative involving 5 teams working with 4 haemodialysis units and a peritoneal dialysis programme involving 438 dialysis patients. Each team addressed a different indicator (A- dialysis dose, B- catheter related bloodstream infection (CRBSI), C- cardiovascular risk, D- peritonitis, E- phosphate) with a shared aim to match the top 10% in the UK. Tailored multifaceted approaches using a modified collaborative methodology with an aim, framework, driver diagram, learning sessions, facilitated meetings, plan-do-study-act (PDSA) cycles, and continuous measurement.

Results: Unit A improved attainment of target urea reduction ratio (URR) from 68.9 to 91.1% ($p=0.002$). Unit B reduced CRBSI from 1.27 to 0.49 per 1000 catheter days ($p=0.01$). Unit C improved compliance with a cardiovascular bundle from 56 to 100% of patients ($p=0.001$). Peritoneal Dialysis Unit D reduced peritonitis from 1 in 13.7 to 1 in 21.8 patient months ($p=0.001$). Dietician Team E improved attainment of phosphate $<1.8\text{mmol/L}$ from 68.1 to 80.8% of patients ($p=0.001$).

Conclusion: The participating teams successfully used QI methodology to make improvements to quality of care indicators compared to their own pre-intervention performance. Locally new knowledge and process change was generated regarding cardiovascular risk, phosphate and peritonitis management, as well as spread of best practice in dialysis dose and CRBSI. The changes made highlight the need to understand local contextual factors in making changes to processes to care.

Introduction

Best practice in dialysis care has been synthesised into standards by national and international bodies using research evidence from observational studies and randomised control trials, where available[1-3]. Despite this wide variation continues to exist between achievement of recommended targets both between and within haemodialysis networks[4, 5]. This partly reflects a lack of evidence for how to implement guidelines to achieve best practice, and a gap in knowledge about the factors influencing implementation.

Systematic reviews examining these factors highlight that success is more likely with a bespoke approach that includes a careful choice of aims that are perceived as priorities, multi-faceted approaches, senior leadership support, and strategies to overcome barriers to change[6-8].

Aim

In 2010 we set up a renal quality improvement programme, with an aim to match the top 10% of centres in the UK on key quality of care indicators regardless of any other epidemiological, financial or clinical factors. Our network- the NHS West Sector Renal Network had 4 haemodialysis units and the fifth largest PD programme in the UK at the time of the project, serving a population of 1.3 million. In the UK the Renal Registry (UKRR) is an independent registry that reports de-anonymised provider outcomes and is the central data source used by the National Health Service (NHS) to calculate funding for renal replacement therapies (RRT)[9]. Our achievement of national standards of dialysis care had not changed significantly since UKRR benchmarking began. Funnel plot analysis excluded outlier performance status[10-13]. Life expectancy in Greater Manchester is one of the lowest in the UK and case mix had been considered a potential factor affecting outcomes[14].

The first phase of the project ran from May 2010 for one year, using a modified IHI Breakthrough Series collaborative methodology[15], where four teams were set a different clinical indicator to work on. Full results are reported in chapter 4.1. All the teams had significant improvements in their clinical indicators and achieved their aims by the end of the first year. Comparison with a non-intervention unit revealed it had no improvement in any of the indicators measured. In addition, comparison with outcomes in clinical indicators not addressed as a target for improvement in the project showed no decline in these outcomes.

A second improvement phase was commenced in May 2011; the aims of this phase were to sustain improvements made in year 1 and to work on new clinical targets for improvement. We report the results of this second phase below.

Subjects and Methods

The project was discussed with the local research and ethics committee, who deemed it a QI project, with ethical approval therefore not required. Twelve months' detailed preparatory work was undertaken prior to phase one of the project, including obtaining baseline audit data, patient level costings, stakeholder engagement, evaluation of the evidence base on best practice and an AHRQ Hospital Survey on Patient Safety Culture[16]. These data were used to match the improvement aim undertaken and its perceived difficulty, with the relative functioning of the unit. We used a modified Institute for Healthcare Improvement Breakthrough Series Collaborative methodology[15] to set five teams a different clinical indicator and aim to work on for one year. The aims and framework were chosen by an expert faculty consisting of local and national dialysis and improvement experts, local multi-professional opinion leaders, patients' and carers' representatives. Local performance data was made available to the faculty from the detailed project pre-work.

The haemodialysis network expanded in size to include a further satellite dialysis unit during 2010, whilst the two on-site haemodialysis units merged when the department moved to a new building in 2010.

The 5 aims were set as follows and summarised in Table 4.2.1 below

HD unit A	Increase attainment of URR>65% from 68.9% to >90% of patients
HD unit B	Reduce haemodialysis catheter-related bloodstream infection (CRBSI) from 1.27 per 1000 catheter days at baseline to <0.6 per 1000 catheter days.
HD unit C	Increase compliance with a cardiovascular care bundle from 56% to >90% of patients.
Community Dialysis D	Reduce peritonitis from 105 infections in a year (1 in 13 patient months) to 55 infections in a year (1 in 26 patient months)
Dietician team X	Increase attainment of phosphate <1.8mmol/L from 68% to >80% of dialysis patients.

Table 4.2.1. Summary of teams, dialysis units and aims.

Team	Team A	Team B	Team C	Team D	Team X
Unit	HD Unit A	HD Unit B	HD Unit C	PD Unit D	HD Units A,B,C,E PD Unit D
New Indicator	URR	CRBSI	Cardiovascular risk	Peritonitis	Phosphate

All of the indicators chosen have been shown to influence survival[17-19]. Dialysis dose has a clear national standard[20], and was successfully targeted by a different HD unit in the first phase of the collaborative. Given its clear association with mortality in observational and randomised trial data, it was felt that this was an essential indicator to work on, where the knowledge gained in phase one could be consolidated and extended. Similarly, there is widespread acceptance of the potential for morbidity and mortality associated with septicaemia[21, 22], and a different HD unit successfully reduced CRBSI in phase one.

It is known that a significant proportion of the excess mortality in dialysis patients is due to cardiovascular disease, where the incidence of cardiovascular deaths is 10-20 times higher than in the general population[23]. Although the causes of, and potential interventions for prevention of cardiovascular disease remain subject further investigation, guidelines exist recommending best practice in the prevention of cardiovascular deaths in haemodialysis patients. For this project an expert faculty consisting of multi-professional experts in dialysis care and QI developed a care bundle for dialysis patients in order to optimally manage their cardiovascular risk, using the UK Renal Association clinical practice guidelines as the basis for the bundle[24].

Peritonitis remains the leading cause of treatment failure in PD care, and is associated with hospitalisation, life threatening complications and death. The UK and international best practice standard is a peritonitis rate of less than 1 in 18 patient months[25]. Our network had peritonitis rates below this standard, making it a key marker of quality of care for the team to work on.

Phosphate also has a clear national standard[26], and has been shown to be associated with survival in several landmark observational series[17, 27]. The role of drug therapy and optimum management of phosphate has not been fully elucidated but controlled phosphate levels are a component of good quality dialysis care, and a QI approach to target high phosphate would be achievable and desirable. Hypophosphataemia significantly correlates with increased mortality in dialysis patients, but is more commonly associated with multi-morbidity and poor nutritional status, and there is little evidence on how this can be

impacted clinically. For this reason, low phosphate levels were not targeted for improvement in this phase. The dietician team worked together and with the QI teams on each of the units on this aim.

The executive Medical Director acted as the board-level sponsor for the project. Participating teams consisted of small multi-professional (3-4 persons) teams which would meet weekly, design and perform plan-do-study-act (PDSA) cycles, undertake measurements, and communicate to and engage the wider unit in which they worked, with the support of a trained facilitator. Candidate changes in practice were defined through examining best available evidence, including “grey literature” such as case reports and conference abstracts, understanding baseline data/performance, examining local processes and diagnosing any deficiencies or unwanted variation and learning from other better performing units. All of these efforts were conducted within a framework as laid out by the expert faculty so that the improvement efforts were guided and focused. By the project end, this methodology allowed units to build their own successful ‘change package’ of proven successful interventions.

Team development involved individual coaching, a team role inventory, group facilitation and peer support during learning sessions. The level of support was tailored to context and included a minimum fortnightly facilitated QI team meeting, telephone and email, and fact-finding visits. A formal project communication strategy included a newsletter, sharing of results, patient stories and face-to-face briefings.

The project directors used serial measurements and statistical process control (SPC) charting to track progress of the project. After participating units were trained in QI methodology during learning sessions, these were shared with the QI teams during facilitated meetings as a further tool for improvement.

The formal intervention period began after the first learning session in May 2011, and ran for one year. Units designed and carried out multiple small tests of change over the collaborative year. Successful small tests of change were refined and implemented across the unit. A summary of the successful changes tested implemented by each unit is presented in Table 4.2.2.

Table 4.2.2: Summary of changes made during the collaborative year

Unit	Indicator	Changes
Unit A	Improve URR	<ol style="list-style-type: none"> 1. Nurse-led URR protocol 2. Review and change prescriptions during dialysis 3. Monthly live reporting of URR and VA 4. Saline recirculation 5. Anticoagulation protocol to reduce clotting of dialysers 6. Exercise on dialysis
Unit B	Reduce CRBSI	<ol style="list-style-type: none"> 1. Set days and times for dressings 2. Different coloured aprons when accessing lines 3. Small dressing trolleys 4. Bioconnectors 5. ANTT connect-disconnect 6. Handwashing 7. Exit site surveillance tool 8. Exit site and bacteraemia database 9. Traffic light system for lines 10. Algorithm for high risk lines 11. Predict next infection 12. Tinzaparin/heparin protocol 13. Patient information leaflet
Unit C	CV bundle	<ol style="list-style-type: none"> 1. Create and maintain database of previous CV history and DM 2. Staff education on application of care bundles 3. Staff education on diabetes, BP and cardiovascular disease 4. Work with diabetes link nurse 5. Nurse rounding to assess smoking history and refer to smoking cessation clinics as appropriate 6. Consultant to review prescriptions on HD unit ward round to ensure all prevalent patients with CV history are on antiplatelet, statin and beta blocker unless contraindicated
Unit D	Peritonitis	<ol style="list-style-type: none"> 1. Continuous computerized monthly data collection, analysis and reporting of peritonitis rates via SPC charts with best practice benchmarks to the wider PD team 2. Assessment and standardization of staff training technique 3. Competency based patient training and assessment, with standardized

		<p>curriculum and checklist</p> <p>4. Reassessment of patient technique 8 weeks post self-care commencement and after an episode of peritonitis</p> <p>5. Multi-disciplinary (consultant physician, consultant microbiologist and nurses) review of peritonitis audit data</p>
Dietician Team X	Phosphate	<p>1. Staff survey to assess knowledge about CKD-MBD</p> <p>2. Patient survey to assess knowledge about CKD-MBD</p> <p>3. Patient and staff education package</p> <p>4. Named nurse support for patients on phosphate control</p> <p>5. Electronic flowsheet with monthly blood results</p> <p>6. Patient dietetics newsletter</p> <p>7. Microsystem changes</p> <p>-single issue MDTs</p> <p>-dietician led CKD-MBD MDT</p> <p>-task distribution on basis of skill</p>

Methods of Evaluation and Analysis

Overarching data collected included demographics, laboratory variables, access type, dialysis-related hospitalisations, bed days and clinical details from the electronic patient record. Unit level data collected was dependent on the improvement aim (Table 4.2.3).

For HD Unit A, CRBSIs were defined as per a hospital wide protocol based on the Epic guidelines[28]. Rates were calculated by dividing number of infections by total catheter days and reporting annual rate per 1,000 catheter days.

Peritonitis was defined as per the ISPD guidelines[29]

URR and phosphate were obtained monthly from the last test in the month for each patient, excluding tests done whilst an inpatient.

Table 4.2.3. Unit level data collected during QI collaborative year.

Unit	HD unit A	HD unit B	HD unit C	PD unit D	Dietician Team X
Number of patients	76	135	56	115	438
Improvement aim	Increase attainment of urea reduction ratio (URR) >65% from 68.9% to >90% of patients	Reduce HDCRBSI from 1.27 per 1000 catheter days at baseline to <0.6 per 1000 catheter days.	Increase compliance with cardiovascular care bundle from 58% to >90% of patients	Reduce peritonitis from 111 infections in a year (1 in 13 patient months) to 55 infections in a year (1 in 26 patient months)	Increase attainment of target phosphate <1.8 from 68.1% to >80% of patients
Data collected	Pre and post dialysis urea Vascular access Type of dialyser Blood flow rates on dialysis ESA and anticoagulant use Thrombolytic use Dialysis time	Unit catheter use Number and type of exit site infections Incidence of HDCRBSI Organism Outcome of HDCRBSI Mortality	Presence of cardiovascular risk factors Medications Demographics	Peritonitis episodes Organism Treatment Exit site infections PD catheter removal Transfers to level 3 care	Phosphate Calcium PTH Total phosphate binder and activated vitamin D use

Methods of statistical evaluation

Data with normal distribution were expressed using mean \pm SD and compared using chi-squared. Data with non-normal distribution were expressed using median \pm SD. Comparison between groups before and after intervention was done using the Mann-Whitney U test. P value <0.05 was considered significant.

We evaluated the effectiveness of our work by:

- (1) Continuous measurement of results for real-time evaluation of the project.
- (2) Defining appropriate balancing measures such as tinzaparin use and medication burden.

Statistical Analysis

Data with a normal distribution was expressed as mean±standard deviation. Comparison between groups was performed using the t-test to compare differences in mean, the Mann-Whitney U test for non-normally distributed variables and Chi-square tests in the case of dichotomous variables. ANOVA was performed to test differences in means between groups, and Chi-squared to compare differences in categorical values between groups. A p-value of less than 0.05 was accepted as significant.

A post-hoc analysis of paired data from patients who were constant attenders was performed using a t test.

Statistical analysis was performed using MedCalc release 12.5.0 (MedCalc software, Mariakerke, Belgium).

Results

Demographics from the dialysis units are displayed in Table 4.2.4. There were a total of 438 patients across at enrolment. Median age and time on dialysis was similar on all units, and similar to that reported in national registry data. There was a high prevalence of diabetes, hypertension and vascular disease across all units. All 5 teams significantly improved attainment of target clinical indicators during the collaborative year.

Table 4.2.4 Demographics of study population

	Haemodialysis Unit A	Haemodialysis Unit B	Haemodialysis Unit C	Peritoneal Dialysis Unit D	Haemodialysis unit E
Patient Number	76	135	56	115	56
Age (mean ± SD) yrs	59.4 (±14.3)	60.1 (±16.8)	61.2 (±18.6)	55.7 (±15.1)	61.6 (±14.4)
Time on HD in weeks (median±IQR)	112.5 (±)	105.7 (±)	147.2 (±)	96.3 (±)	140 (±)
% Male	63.2	64.4	58.9	52.1	47.4
Co-morbidity					
Diabetes (%)	40.8	36.3	30.6	38.3	38.6
Hypertension (%)	88.2	82.2	85.7	86.1	82.5
Cerebrovascular disease (%)	10.5	10.4	12.5	7.0	15.8
Peripheral vascular disease (%)	6.7	8.9	5.4	14.8	8.8
Ischaemic heart disease (%)	26.3	42.2	35.7	37.4	42.1
Heart failure (%)	11.8	10.4	8.9	18.3	15.8

Haemodialysis unit A achieved its aim of improving attainment of URR from 68.9% to 91.1% ($p=0.002$) of patients by the project end (table 4.2.5). Mean (SD) URR also improved from 69.4 (9.1) to 72.1 (9.2), $p=0.003$. There was no significant change in mean tinzaparin dose, which was 3907 units pre-intervention, and 3775 units post intervention. There was also a reduction in total unit ESA use of 30% from 2865mcg to 2015mcg per week. The number of thrombokinase infusions for catheter dysfunction fell by 68% from 34 to 11.

Haemodialysis unit B reduced the incidence of CRBSI by 48% from 1.27 per 1000 catheter days to 0.49 per 1000 catheter days ($p=0.01$). The incidence of exit site infections also decreased from 3.9 to 1.17 per 1000 catheter days (table 4.2.6). There was an 80% decrease in bed days associated with bacteraemia (363 to 74) and a reduction in costs related to admission by 80%, from £313,406 to £43,358.

Haemodialysis unit C increased compliance with the cardiovascular care bundle from 58% to 100% ($p=0.001$).

The community PD unit decreased infections from 105 (1 in 13 patient months/0.88 episodes per year at risk) to 64 (1 in 21.8 patient months/0.55 episodes per year at risk), ($p=0.01$). Exit site infections similarly fell from 1 in 34 patient months to 1 in 70 patient months ($p=0.03$). There was a significant decrease in hospital admissions (65 to 35) and days spent in hospital (635 to 235). There was a decrease in the need for PD tube removal and conversion to HD, as well as transfers to level 3 care (from 6 to 1).

The dietician team improved attainment of phosphate <1.8 by 17%, from 68.1% of patients to 80% of patients ($p=0.001$). Phosphate binder use did not change significantly (average 3.38 tablets per day pre-intervention to 3.37 tablets per day at the end of the intervention period (Table 4.2.8 and Table 4.2.9).

Table 4.2.5 Unit A Dialysis Dose Results

Haemodialysis Unit A	Pre-intervention	Post-intervention	P value
Number of patients	76	69	
AVF/AVG prevalence (%)	86.6	89.9	0.615
Mean urea reduction ratio (%)	69.4 (± 9.1)	72.9 (± 9.2)	0.003
Percentage of patients achieving clinical standard of urea reduction ratio >65%	68.9%	91.1%	0.001
Mean tinzaparin dose	3907	3775	0.538
Mean weekly ESA dose	40.3 (29.7)	29.2 (23.1)	0.011
Median weekly ESA dose +IQR	40 (30)	20 (28)	0.022
Mean blood flow	310	333	<0.001
Treatment time (min)	228	231	0.003

Table 4.2.6 Unit B Catheter-related bacteraemia results

Haemodialysis Unit B	Pre-intervention	Post-intervention	P value
Number of patients	135	142	
Catheter prevalence	26.7%	24.6%	0.783
Total infections (n)	15	5	
Catheter-related bacteraemia rate (per 1000 catheter days)	1.27	0.49	0.01
Exit site infection rate (per 1000 catheter days)	4.65	1.25	<0.001
Outcomes			% Reduction
Death	0	0	N/A
Hospitalisation	13	5	62%
Total days in hospital	363	74	80%
Removal of catheter	5	4	20%
Costs related to admission	£313,406	£43,358	80%

Table 4.2.7 Unit C Compliance with cardiovascular care bundle

Component	Action	% Complete Pre	% Complete Post
Smoking	If smoker referred for or advised re smoking cessation	43	100
Diabetes	If HbA1c >7.5 appropriate diabetic review activated	44	100
Blood pressure	If BP >140/90, completed BP protocol over past 6 months?	58	100
History of heart & vascular problems	Prescribe antiplatelet	100	100
History of heart & vascular problems	Prescribe ACE inhibitor or ARB	75	100
History of heart & vascular problems	Prescribe Beta blocker	88	100

Table 4.2.8 Dietician team E. Results for attainment of target phosphate <1.8.

	Pre-intervention	Post intervention	P value
% of patients < 1.8 mmol/L	68.1% of patients	80.8% of patients	p=0.001
Phosphate mean, mmol/L (SD)	1.53 (0.47)	1.43 (0.42)	P=0.0012
Calcium mean, mmol/L (SD)	2.24 (0.17)	2.38 (0.15)	P=0.0001
PTH mean pmol/L (SD)	35.89 (39.01)	17.72 (11.02)	P=0.0001
PTH mean, ng/L (SD)	338.53 (368.47)	167.15 (103.92)	P=0.0001

Table 4.2.9 Phosphate binder use pre and post intervention

	Pre-intervention	Post-intervention	Percentage change
Average calcium binder use (grams/patient/day)	0.56	0.56	0
Average sevelamer use (tabs/patient/day)	1.73	1.58	-9%
Average lanthanum use (g/patient/day)	0.28	0.3	+7%
Average alfacalcidol use (mcg/patient/week)	1.76	1.73	-0.2%

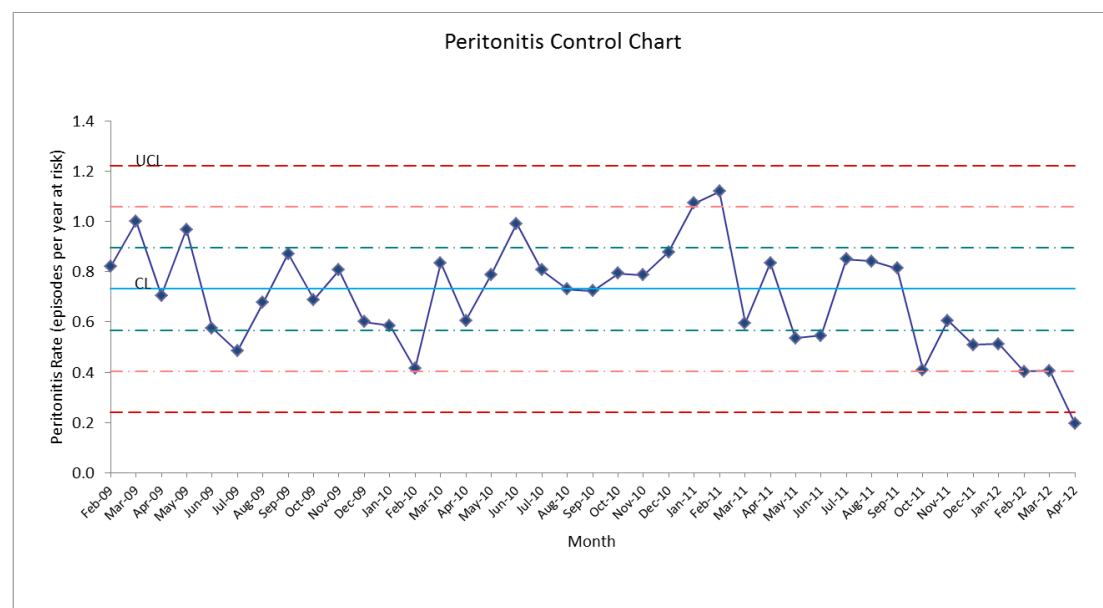


Figure 4.2.1. SPC chart showing monthly peritonitis rates expressed as episodes per year at risk in the PD population from February 2009 to April 2012. The QI project commenced in May 2011 and ran for one year. CL= Control line. The control line was generated from by averaging our peritonitis rate from January 2009 to just before project inception (April 2011)(8). UCL=Upper control limit; 3 standard deviations above the control line. LCL=Lower control limit; 3 standard deviations below the control line.

Discussion

This improvement collaborative has achieved all of its aims at the end of the one-year intervention period. Although there was no non-intervention group in this study, we can infer that this was due to the multi-faceted interventions instituted during the collaborative for several reasons. Phase one of the quality improvement collaborative used the same methodology to work on a different set of indicators and compared them to a non-intervention unit; all units achieved their aims with no change in the non-intervention unit. With the clear improvements demonstrated in phase one, it was felt that there was significant internal evidence of improvements to care demonstrated by the collaborative to enrol all units in phase two.

Unit A ended with 91.1% of patients achieving an average URR of 72.9%. International guidelines suggest that in order to achieve the standard of URR >65% in most patients, clinicians should aim for a dose of 70% in individual patients. In addition, research evidence suggests that women and patients of low body weight may have improved survival rates if the URR is maintained above 70%[30, 31]. Unit A used the change package developed by unit C in phase one as its basis for improvement. However, implementation of the change package revealed important differences between the units. Tinzaparin dose, which was tracked as a balancing measure, did not significantly change in Unit A. This differs to the results in Unit C during phase one, where there was a significant increase in tinzaparin use on the unit working to improve URR. This had been highlighted as best practice from a site visit to a high-achieving dialysis provider previously. Unit A had a higher average dose of tinzaparin at study onset than unit C (3907 versus 2985 units). These differences in balancing measures reflect the importance of testing of changes and continuous evaluation during implementation of multiple interventions as a tool to improve care.

Unit B successfully reduced its incidence of catheter-related bacteraemia by 48%, to a rate comparable to that quoted in the literature. Of note, whilst the total number of infections fell, the proportion of patients requiring line removal increased (5/15 pre-intervention, 4/5 post-intervention). Analysis of the organisms grown revealed that there were no infections due to skin commensals such as coagulase-negative staphylococcus post-intervention. It may be possible to infer from this that one of the key factors in reducing infections was stricter asepsis during connect/disconnect to the dialysis machine. There was also a significant reduction in exit site infections, implying that as well as changes to nursing practice, better patient education was also a contributor, and demonstrating the value of a multi-faceted

approach. Many proven interventions to reduce CRBSI were already in place in unit B prior to the intervention period. These included bactericidal catheter locks, standardised care bundles, and screening. Improvement strategies were based on a change package developed by a sister unit in the network that worked on CRBSI in phase one (Unit A). The process of implementation highlighted the importance of local factors when making changes to practice, and the need to adapt to different barriers. As an example, when changing to the use of different coloured aprons for connecting and disconnecting to the dialysis machine- a relatively straightforward change - a supply problem was identified in unit B, and a series of education sessions was needed for staff.

Catheter prevalence in Unit B was lower at the end of the study period. Unit B is the in-centre dialysis unit and the largest in the network, with a higher proportion of incident dialysis patients, who have higher rates of catheter use. However, an initiative to increase placement of definitive access across the network resulted in an overall improvement in AVF and AVG use. It should, however, be noted that there is a degree of month-by-month variability in catheter prevalence which isn't captured in these point prevalence figures.

Unit C was successful in implementing the cardiovascular care bundle in all patients. Care bundles originated in intensive care units, and are a group of interventions that when implemented together, produce better outcomes than when done individually. There is debate around the best way to modify cardiac risk in dialysis patients, with both classical risk factors, such as hypertension and diabetes, and non-classical risk factors, such as mineral bone disease and anaemia playing a role [23, 32, 33]. All of the indicators chosen for the bundle have clear evidence of mortality benefit in patients with cardiovascular disease and are in the UK Clinical Best Practice Guidelines for CKD management. Data was recorded on an audit sheet in the patient notes. The blood pressure protocol in the bundle consisted of advice on salt and water restriction, an assessment of fluid status and gradual reduction of dry weight accordingly, and review of medications. This approach was chosen rather than strict adherence to a blood pressure target in view of the complex interplay between fluid, salt and BP in haemodialysis patients, and aimed to address the increased cardiac risk associated with chronic volume overload. There was a perception that the interventions described in the care bundle were normal clinical practice, and hence already in place. However, a systematic approach with regular use of audit data to show evidence of compliance served as a driver for increased adherence.

Peritoneal dialysis unit D reduced its peritonitis rate by 39% to 1 in 21.8 patient months, or 0.55 episodes per year at risk. Peritonitis is a leading cause of treatment failure and

hospitalisation in PD. Previous initiatives had focused on meeting best practice for PD care as described in national and international standards, and introducing changes such as regular screening and antimicrobial washes, but peritonitis rates remained suboptimal. Detailed baseline clinical, microbiological and financial audit data informed a better understanding of the pattern and causes of infection, and was used to plan tests of change to practice. Continuous monitoring and reporting of peritonitis rates was introduced and changes tested included standardisation of training competency assessment, handwashing reviews in clinic, refresher training after an episode of peritonitis and regular microbiology meetings to review cases. A review in 2011 reported peritonitis rates of 0.06-1.62 per year at risk internationally, demonstrating variable attainment of the ISPD minimum standard[34]. This method showed classic improvement trends with improvements becoming apparent after a third of the project period (figure 4.2.1). The embedding of analytical tools into clinical practice allowed rapid identification of increases to infection rates and variations in practice. Dietician team E worked with staff and patients on all 3 dialysis units and PD to increase the percentage of patients attaining target phosphate. The association between hyperphosphataemia and increased all-cause and cardiovascular mortality in dialysis patients is well established, but controversy remains over the best way to manage this. Observational data from DOPPS has shown an association between increased phosphate binder use and survival, although binder prescription was also associated with better nutritional status[35]. A recent US study showed that dietary restriction of phosphate was not associated with decreased mortality, and may be harmful in some subgroups[36]. However, a retrospective study of 13792 patients from the US revealed lower mortality in patients who achieved K/DOQI target phosphate levels than those who did not[37]. The use of a phosphate-restricted diet and oral phosphate binders is the mainstay of phosphate management. Of note, in our analysis, improvement in attainment of target phosphate was not associated with an increase in phosphate binder use. Our approach involved the patient and all members of the clinical team, with continuous reinforcement and re-education. In our project, a staff survey revealed that the majority of staff had not received any education about CKD-MBD in the preceding 12 months, and most could not identify everyday foods that were high in phosphate. Similarly, patients were often confused about high potassium and high phosphate foods, as well as knowledge about medications and the role of binders. Staff and patient education was undertaken and process mapping of the phosphate pathway informed structural changes such as reorganisation of MDTs, use of IT systems for audit and tracking, and redesigning pathways for changing medication prescriptions.

This QI collaborative was the second year of an initiative to improve quality of care indicators in dialysis patients within our network. This allowed us to use knowledge gleaned from the first phase to inform processes in the second. Using a collaborative methodology with small tests of change performed using PDSA enabled us to break down the steps required to make changes- comprehension, engagement, motivation and buy-in to support change- and address each in turn. Overarching strategies included communication with the network as a whole via regular newsletters, one-to-one coaching, group facilitation and peer support during learning sessions.

One key learning point was in understanding differences in culture and context even within a single network. Two units worked on aims that had been addressed by different units in the network in phase one. They therefore had the change packages developed by these units to guide improvement. Both found that the packages were a starting point and a useful framework rather than a solution. Whilst many of the tests of change had the same starting point, different barriers to implementation existed in each unit, requiring alternative solutions. There is clear evidence from the literature that using traditional methods to implement changes to practice risks failure, and our experience in this collaborative is that even within a single network, implementation needs to be context-specific. Regular QI team meetings with a facilitator were crucial in this regard to aid understanding of the need for targeted or bespoke approaches.

DOPPS and other studies have shown a clear association between attainment of increasing numbers of dialysis quality of care indicators and lower mortality[38, 39]. However, to date, there remain few trials evaluating the effectiveness of implementation strategies in dialysis care. One randomised trial demonstrated intensive intervention with feedback, workshops, educational materials and technical assistance to be superior to feedback alone in improving URR across across a dialysis network[40], whilst an evaluation of the Rightstart programme compared outcomes in incident haemodialysis patients receiving intervention in the management of anaemia, dialysis dose, nutrition and an educational programme with a control group of incident patients not receiving specific interventions found that attainment of clinical targets (haemoglobin, albumin) was significantly higher in the treatment group. In addition, mortality and hospitalisation were also significantly reduced at 1 year[41]. Other studies have also demonstrated the effectiveness of multifaceted quality improvement approaches to address quality of care indicators in dialysis patients[42]. One of the strengths of our collaborative is the evidence developed over two years demonstrating improved attainment of clinical indicators using a well-established methodology adapted for use in our

study. Another was the comparison to a non-intervention unit in the first year of the study, which showed no improvement in indicators at the end of the study when compared to the intervention units. A limitation of the second phase of our study is the lack of a non-intervention group. Our primary aim was to use QI to improve quality of care for our patient population, and we felt evaluation of the first phase provided sufficient evidence for us to use this methodology as a tool for improvement for all patients.

Conclusion

There is evidence that achieving quality of care indicators not only improves mortality but is also associated with better quality of life in dialysis patients. Guidelines, outcome reporting and benchmarking have existed for many years within the renal community yet quality of care remains variable nationally and internationally. Our study demonstrates how using quality improvement techniques can produce rapid improvements in quality of care indicators in a dialysis network, and the importance of understanding local contexts in order to facilitate changes to clinical practice to the benefit of patient care.

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CHAPTER 4.3

Improving Patient Safety In Peritoneal Dialysis Using A Quality Improvement Initiative To Reduce Infections In A UK Renal Network

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Preface

The first two chapters of this thesis have demonstrated that the QI programme was successful in improving attainment of clinical quality of care indicators in a chronic dialysis population and describe the QI methodology used and changes identified for each indicator. This study looks at one particular successful aspect of the QI programme, to analyse the steps involved in identifying tests of change and the processes involved in making these changes to care, including the role of audit and feedback, the impact of local contexts, the role of senior support for improvement activity, and patient-facing strategies.

ABSTRACT

Problem Peritonitis is a critical safety issue for patients receiving peritoneal dialysis (PD) for end stage kidney disease (ESKD) and a leading cause of hospitalisation, treatment failure and death.

Design Modified collaborative, audit, model for improvement, tailored facilitation support, evidence-based clinical guidance.

Setting Peritoneal dialysis programme covering 115 adults under Salford Royal NHS Foundation Trust, covering half of Greater Manchester UK.

Key Measures for Improvement The outcome measure was rate of peritonitis. Clinical measures included admissions, bed days, catheter removal, transfers to critical care, death.

Strategy for change: One year of pre-intervention peritonitis data was collected. Retrospective audit was performed to understand local clinical context. The safety context was assessed using a Hospital Survey on Patient Safety[197]. Learning from the audit, clinical evidence and other high-performing units informed changes tested using Plan-Do-Study-Act (PDSA) cycles. Successful changes were implemented throughout the PD programme.

Effects of change: Rates improved from 1 in 13.7 patient months to 1 in 21.8 patient months (59% improvement) ($p=0.003$). Rates of catheter exit-site infection improved from 1 in 34.2 to 1 in 70.1 patient months ($p=0.007$). The number of hospital admissions decreased from 65 to 35. Days spent in hospital also reduced (635 to 235), as did transfers to critical care (from 6 to 1). Patient level costing analysis showed a reduction in admission-related costs from £401,619 to £122,092.

Lessons learnt: This project used local audit data and context analysis to significantly reduce peritonitis rates using multifaceted quality improvement techniques. Key changes included continuous measurement with SPC charts, competency-based training/assessment, re-assessment of patient technique at key touchpoints, multidisciplinary microbiology meetings, and catheter removal after recurring episodes of peritonitis.

INTRODUCTION

Background

There are over 56,000 end stage kidney disease (ESKD) patients in the UK[2], half of whom have renal transplants, with the remainder using either haemodialysis (42%) or peritoneal dialysis (PD) (6%) for treatment of their kidney failure. Globally the use of PD is increasing, with an estimated 196,000 patients treated with PD, representing 11% of the dialysis population, a number likely to rise[3].

UK National Institute for Health and Care Excellence (NICE) guidance states that for most patients the choice of dialysis depends on individual characteristics and preferences[4], but in certain groups PD is the treatment of choice. Systematic review indicates that PD patients rate their quality of life higher than people receiving hospital haemodialysis[5].

The main safety hazard of PD is device-associated harm leading to peritonitis. The four main sources of such infections are the connect-disconnect procedure to drain fluid in and out of the abdomen, translocation from the bowel, chronic PD catheter microbiological contamination, and retrograde spread from soft tissue infection near where the PD catheter exits the skin.

There is wide variation in peritonitis rates both within and between countries; a patient may expect peritonitis as rarely as once every 17 years, or as frequently as once every 7 months [6-8]. UK and international guidance recommends a peritonitis rate no greater than 1 in 18 patient months, or 0.67 episodes per year at risk[9]; international studies show that even better rates are achievable.

Peritonitis causes adverse outcomes such as hospitalisation, critical care admission, switch to haemodialysis (HD) and death[10]. UK harm analyses include a 3-year UK Renal Registry study linking hospital episode statistics (HES) data, which showed 4894 PD admissions, leading to 53,671 bed days and 220 deaths[11]. In a South Thames audit of 12 PD programmes over 1 year there were 52 deaths[7]. Switching to hospital-based haemodialysis due to PD technique failure can result in a negative impact on quality of life, and increased costs due to increased morbidity and the higher cost of HD. The Scottish Renal Registry Report 2013 reported peritonitis as the cause of technique failure in 38% of patients[12]. The recently published NHS five year forward view has highlighted the need for savings across the NHS whilst maintaining quality[13]. NICE health economic modelling shows that increasing the use of PD by 1% per annum would, after 5 years, create annual savings of £4m[4]. External contextual factors are therefore aligned regarding harm

reduction and decreasing attrition from PD programmes. The organisational characteristics of PD programmes tend to be similar; they operate from acute trusts and are usually small, highly motivated, led by specialist nurses who support patients at home, punctuated by formal clinic reviews.

At the time of the study, our home PD population comprised approximately 115 patients; the fifth largest programme in the UK[14]. The service was staffed by 8 WTE-equivalent staff, consisting of trained nurses and support workers, whose responsibility was to train patients in how to perform PD, support self-management, and troubleshoot complications, with a renal physician as the clinical lead. The PD team had been used to using regional audit to study their peritonitis outcomes; local peritonitis rates had been comparable with other units but had worsened in the 4 years prior to inception of this QI project. Life expectancy in Greater Manchester is one of the lowest in the UK and case mix had been referred to as a potential factor affecting outcomes[15]. Salford Royal as an institution was, at the time of the project, a 5000 employee Acute Trust with a commitment to be the safest hospital in the UK and a strategic framework in place to support this ambition.

Assessment of problems

This project was part of a wider programme of work to improve attainment of clinical quality of care indicators in dialysis. We used a modified collaborative methodology[17], where four clinical teams were set a different indicator to work on for one year. We identified peritonitis as the leading source of harm for our PD patients, and set an aim of halving our peritonitis rate from 105 episodes or 1 in 13.7 patient months/0.88 episodes per patient year, to 55 episodes or 1 in 26 patient months/0.46 episodes per patient year.

The programme was discussed with the research and ethics committee who agreed that no formal ethical review was required. The two main guidance sources regarding peritonitis come from the UK Renal Association (UKRA) Clinical Practice Guidelines 2010[18], and the International Society for Peritoneal Dialysis (ISPD) expert position paper[6]. Audit of our practice against this identified adherence to multiple components of recommended best practice (table 4.3.1) but also areas to target for improvement.

UK Renal Association Clinical Practice Guidelines	Level of evidence	Baseline adherence
We recommend that PD units should undertake regular audit of their peritonitis and exit-site infection rates, including causative organism, treatment and outcomes.	1B	Partial
[We recommend that PD units] should enter into active dialogue with their microbiology department and infection control team to develop optimal local treatment and prevention protocols.	1B	Partial
We recommend that flush-before-fill dialysis delivery systems should be used.	1A	Yes
We recommend that initial catheter insertion should be accompanied by antibiotic prophylaxis.	1B	Yes
We recommend that patients should undergo regular revision of their technique (at least annually or more frequently if indicated, such as after an episode of PD-related infection or a significant interruption to the patient performing PD) and receive intensified training if this is below standard.	1C	No
We recommend that invasive procedures should be accompanied by antibiotic prophylaxis and emptying the abdomen of dialysis fluid for a period commensurate with the procedure.	1C	Yes
We recommend that topical antibiotic administration should be used to reduce the frequency of Staph. aureus and Gram negative exit-site infection and peritonitis.	1A	No
We recommend that exit site infection is suggested by pain, swelling, crusting, erythema and serous discharge; purulent discharge always indicates infection. Swabs should be taken for culture and initial empiric therapy should be with oral antibiotics that will cover S. aureus and P. aeruginosa.	1B	Yes
We recommend that methicillin resistant organisms (MRSA) will require systemic treatment (e.g vancomycin) and will need to comply with local infection control policies.	1C	Yes
We recommend that initial treatment regimens for peritonitis should include cover for bacterial Gram positive and Gram negative organisms including Pseudomonas species until result of culture and antibiotic sensitivities are obtained.	1C	Yes

Table 4.3.1: Summary of UK Renal Association recommended best practice for prevention and treatment of peritonitis and local adherence at project inception

At the start of the project a detailed retrospective audit was performed of 60 patients who had started PD in the preceding three years and had had at least one episode of peritonitis to understand the local clinical context. Data collected included patient demographics, timing of peritonitis, kidney function at the start of PD training, associated exit site infections, and organisms. A comparison was made against a control group of 25 patients who had had no episodes of peritonitis for a minimum of one year after commencement of PD. A total of 143 episodes of peritonitis were analysed. The rate of peritonitis was similar for different types of PD and manufacturers of PD systems. The rate of early infections (within 3 months of commencement) was high, occurring in 25% of patients. In addition, 35% of patients had had more than 3 infections. When patients compared to the control group, patients with peritonitis were found to have started PD training at a lower eGFR, and had a higher prevalence of diabetes. Comparison between early and late episodes of peritonitis revealed that patients with early peritonitis were younger, with a higher urea at training. Analysis of organisms revealed a high proportion of infections caused by organisms implicated in environmental contamination and poor technique, including coagulase negative staphylococcus (21%), staphylococcus aureus (12%) and micrococcus (7%).

These results highlighted areas for targeted improvement, including patient training, those with multiple infection episodes, regular reassessment to prevent contamination and poor technique, and multidisciplinary team review of peritonitis episodes including microbiological review.

Key Measures for improvement

Peritonitis was defined as clinical features of peritonitis (abdominal pain or cloudy dialysate) and dialysate white cell count $>100/\text{mCL}$ [9]. Further peritonitis episodes were defined as per ISPD guidelines as relapsing, repeat or recurrent depending on timing of occurrence and type of organism[19] Exit site infections were defined as purulent drainage from the PD catheter exit site, with or without erythema[19]. Data collected included timing of exit site infection, organism, and relationship to peritonitis episode. Key measures for improvement were

- 1) Continuous measurement of peritonitis rates for real-time evaluation of the project.
- 2) Clinical outcomes including hospitalisation, days spent in hospital, catheter removal (temporary or permanent), transfers to critical care, and death due to peritonitis.

3) A detailed financial analysis of admissions relating to peritonitis. Patient level costing software was used to calculate the cost of admissions based on coding data following discharge.

Process of gathering information

Demographic data was collected from patient records. The PD team recorded details of all peritonitis episodes on a proforma. Each month frontline staff calculated and entered peritonitis rates into a statistical process control (SPC) chart. Details of outcomes were obtained from patient records and recorded on a rolling basis.

Analysis and interpretation

Peritonitis rates were calculated as the total number of episodes of peritonitis divided by number of patient months on PD[9], and expressed as the number of months between episodes and converted to episodes per year at risk. Comparison between the two groups was performed using the t-test to compare differences in the mean in normally distributed variables, the Mann-Whitney U-test for non-normally distributed variables, and chi-square tests in the case of dichotomous variables. A p-value of less than 0.05 was accepted as significant.

Statistical analysis was performed using MedCalc release 12.5.0 (MedCalc software, Mariakerke, Belgium).

Strategies for quality improvement/change

Detailed preparatory work including stakeholder engagement, data collection and analysis, and financial analysis was undertaken. Context was assessed using the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture [1] for internal project management and to inform facilitation methods; results when benchmarked against the rest of the network demonstrated the PD nursing team had good safety and team-working attributes. The executive Medical Director acted as board-level project sponsor. Three full-day learning sessions were held. A research fellow acted as facilitator and project manager, supported by two co-directors consisting of a senior nurse and doctor. The project team met weekly and used a Bate et al '6 challenges' [20] context assessment

monthly to diagnose progress, and plan and adapt facilitation interventions as required. The formal intervention period began after the first learning session in April 2011 and ran for one year.

The PD QI team consisted of four nurses, with senior support from the PD consultant. The team met every 1-2 weeks, with facilitator support, to design and test PDSA cycles and plan measurements, using the framework for change as a guide. Potential interventions were gleaned from UK and international best practice guidelines [9, 18], evidence in the literature, case reports and conference abstracts.

Tests of Change and supporting QI actions
Measurement and data analysis
Creation of an e-database of peritonitis & exit site infection
Real-time measurement of peritonitis & exit site infection with SPC charting to identify trends and benchmarks of best practice rates clearly demonstrated
Training of PD staff to maintain a peritonitis spreadsheet and understand SPC charts
Sharing of SPC charts with the wider team using a monthly email report and a "QI board"
Understanding the local pattern of peritonitis & exit site infection through analysis of clinical audit data
Multidisciplinary working
Regular multiprofessional review of peritonitis cases including consultant microbiologist
Staff member with responsibility for preparation of data before MDT meetings
Review of allocation and completion of tasks after MDT meetings
Staff Training
Training quiz for staff to identify learning needs
Invitation to PD suppliers to demonstrate optimum PD exchange technique to staff
Mapping of current training and PD exchange technique with that recommended by PD suppliers
Assessment of staff training technique
Retraining of all staff in standardized technique
Patient training
Competency redesign with checklist for patient training
Single competency assessor for patient training
Assessment of patient technique 8-weeks post commencement
Assessment of patient technique post peritonitis
Handwashing technique assessment using UV lightbox at clinic visits
Patient education around exit site care
Training quiz for patients to assess understanding at first review after training
PD technique and post-peritonitis review
Investigation of reason for peritonitis
3-strike rule for PD tube removal
Connection shield for a specific manufacturer dialysis connection system (Baxter)

Healthcare)
Checklist as an aide memoire when reviewing patients after an episode of peritonitis
Protocol reviews
Review of compliance with protocols from national UK Clinical Practice Guidelines
Predicting the next peritonitis episode - to identify and intervene on specific risks
Review of antibiotics
Introduction of antibiotics before other medical procedures such as colonoscopy
Best practice reviews
Detailed reviews of practice by phoning/emailing other sites
Visit to another network with excellent peritonitis rates
Review of literature for evidence of best practice
Review of "grey literature" of conference abstracts and case reports for evidence of tests of change
Communication
Filming and sharing of a patient story illustrating harm caused by peritonitis
Regular project newsletters to inform wider department of progress
Recruitment and engagement of a Microbiology champion from within the specialist nurse team
Key Changes For Sustain Planning
1. Continuous computerized monthly data collection, analysis and reporting of peritonitis rates via SPC charts with best practice benchmarks to the wider PD team
2. Assessment and standardization of staff training technique
3. Competency based patient training and assessment, with standardized curriculum and checklist
4. Reassessment of patient technique 8 weeks post self-care commencement and after an episode of peritonitis
5. Multi-disciplinary (consultant physician, consultant microbiologist and nurses) review of peritonitis audit data
6. Catheter removal after 3 episodes of peritonitis

Table 4.3.2 Tests of change and supporting QI actions performed during the collaborative year with summary of key changes critical to sustainability planning at project close

Prospective audit and reporting of peritonitis rates to the wider PD team with SPC charting was instituted. Each infection was reviewed in a fortnightly MDT meeting with a microbiologist with an interest in PD, to establish potential causes and track trends.

Our audit data had identified early infection to be a problem, leading to review of our staff and patient training protocols. PD suppliers were invited to demonstrate optimum PD exchange technique. Reassessment and standardisation of staff training technique was undertaken. All staff were re-trained regardless of experience. There is no clear evidence base on duration of training [6] therefore a competency-based rather than a time-based curriculum was developed. A visit to a better performing unit had identified that they had a

single staff member assessing competency. This was felt necessary to ensure consistency in assessing whether patients were competent to dialyse safely. Several tests of change were undertaken, but the small size of our team, fluctuations in staffing levels, and the need for staff to take on multiple roles made it difficult to establish definitively. As a compromise, a different staff member assessed competency to the person who had given training, although even this was difficult to implement reliably. In view of the audit data highlighting early infections as an issue, standardised reassessment of patient technique 8 weeks after commencing PD was introduced. Patient technique reassessment was also instituted after any peritonitis episode.

Audit data also highlighted that multiple episodes of peritonitis in a single patient were a particular problem. As well as causing morbidity, multiple peritonitis risks treatment failure and increases the risk of development of encapsulating peritoneal sclerosis (EPS), a rare condition causing recurrent obstruction of the bowel, resulting in severe malnutrition and often death[21, 22]. We therefore integrated systematic detection of multiple episodes into our prospective data collection. The introduction of fortnightly MDT meetings with the microbiology team, and a microbiology “champion” for peritonitis identified patients at high risk of further episodes so proactive interventions could be made - such as conversion to haemodialysis, retraining or PD catheter exchange if chronic catheter colonisation was suspected. In addition, patients with 3 episodes of peritonitis underwent catheter removal and temporary conversion to HD (the ‘3 strikes rule’) or catheter exchange.

Several interventions proven to reduce peritonitis that are recommended in the literature[6] were already in place in our unit (see table 1). One exception was on the use of prophylactic antibiotics at catheter exit sites, despite 1A evidence quoted in the UK Guidelines. The ISPD also recommends topical antibiotics effective against staphylococcus aureus and other gram-positive organisms, but quotes concerns from the literature of risk of increased resistant organisms and fungal infection in this population after prophylaxis[6]. This was cited by the microbiology team as a major clinical concern, due to an already relatively higher incidence of exit site infection with gram-negative organisms in our population. No consensus was reached thus the practice was not implemented.

Our unit already had protocols in place to ensure patients received prophylactic antibiotics prior to insertion to reduce the risk of peritonitis; these were updated to current evidence. In addition, prophylactic antibiotics prior to other procedures such as colonoscopy were introduced.

EFFECTS OF THE INTERVENTION

There were 115 patients at the start of the intervention period, with a high prevalence of diabetes (40%), hypertension (81.7%) and cardiovascular disease (38.3%). Median age was 58.5, lower than the UK average for patients on PD (62.7)[14]. Total number of infections fell 59% from 105 in one year, equating to 1 in 13.7 patient months/0.88 episodes per year at risk to 64 in one year, or 1 in 21.8 patient months/0.55 episodes per year at risk ($p=0.003$). Exit site infections fell from 1 in 34 patient months to 1 in 70 patient months ($p=0.007$). Analysis of outcome data (Table 4.3.3) revealed a significant improvement in morbidity associated with peritonitis, with a decrease in both hospital admissions (65 to 35) and bed-days (635 to 235). There was a decrease in the need for PD tube removal and conversion to HD, as well as transfers to critical care (level 3) (from 6 to 1). Internal financial analysis of admitted peritonitis episodes was performed using patient-level costing software. This revealed a reduction in expenditure associated with peritonitis from £401,619 to £122,092, reflecting the reduction in admissions to hospital and length of stay. In our cohort, there were no deaths due to peritonitis before or during the intervention period.

	1-year pre intervention	1-year intervention period	P Value
Peritonitis Rate (per patient-month / episodes per-year at-risk) P value	13.7 / 0.88	21.8 / 0.55	0.003
Exit-site infection Rate (per patient-month / episodes per-year at-risk)	34.2 / 0.35	70.1 / 0.17	0.007
	1-year pre-intervention	1 year intervention period	Percentage Change
Number of peritonitis episodes	105	64	-39%
Number of admissions	65	35	-46%
Total bed days	635	235	-63%
Transfer to >level 3 care	6	1	-83%
PD tube removal/Conversion to HD	12	3	-75%
Costs related to admission due to peritonitis	£401,619	£122,092	-70%

Table 4.3.3. Peritonitis rate and clinical outcomes before and after QI intervention

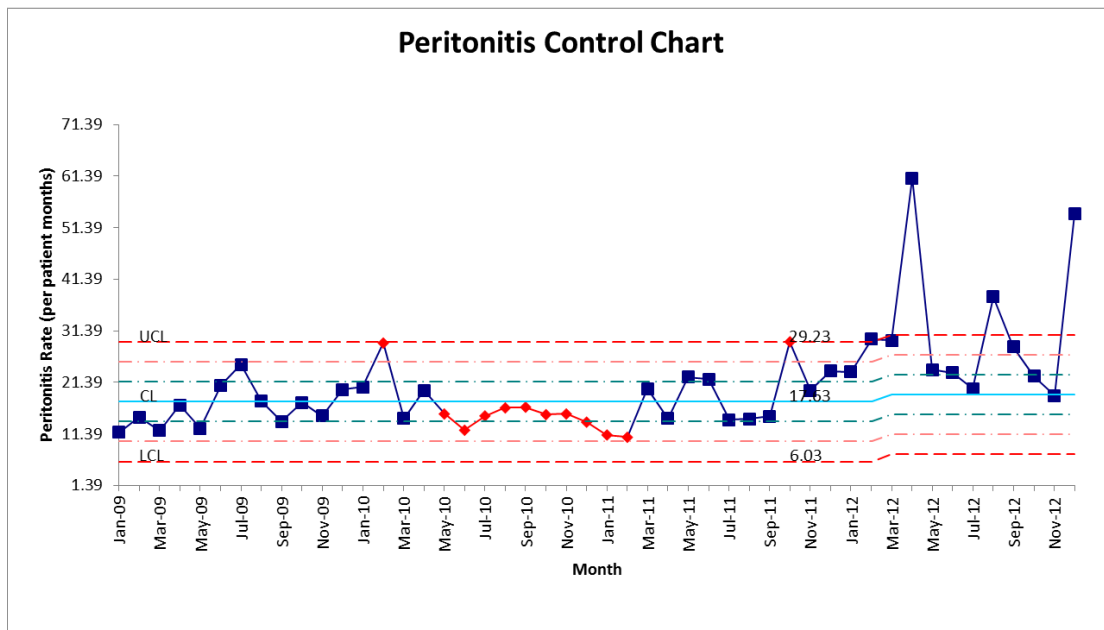


Figure 4.3.1. SPC chart showing monthly peritonitis rates in the PD population from May 2010 to December 2012, where increased values on the Y axis represent improvement ie more time between episodes of infection. The QI project commenced in May 2011 and ran for one year. CL= Control line. The control line was generated from by averaging our peritonitis rate from January 2009 to just before project inception (April 2011) [8]. UCL=Upper control limit; 3 standard deviations above the control line. LCL=Lower control limit; 3 standard deviations below the control line.

LESSONS LEARNT

Although our PD programme had collected peritonitis rates quarterly for a regional audit programme for 12 years, there was a lack of meaningful longitudinal analysis, which showed a decline over time. The reasons for this are multi-layered. Rates varied in most units participating in the audit, but tended to be comparable with each other, leading to a sense that variation was “natural”. When our peritonitis rates were worse, part of the difference was attributed to the relatively large size of our PD service; other series have sounded a note of caution in comparing rates between programmes of varying sizes[8]. In addition the perceived function of the data was for regional audit not improvement, so the activity was siloed from day-to-day care and processes. Audit data was presented at regional audit meetings predominantly attended by medical staff; comparative data against other units did not feature in the nursing team’s culture. Awareness about the best achievable UK rates was also lacking, partly due a paucity of reporting nationally. However, by 2010, there was evidence that other units had started to improve rates, whilst ours appeared to be declining, giving impetus to adopting it as a target improvement project. This local experience

illustrates what research has shown on guidelines and their implementation; namely that feedback and reporting of data does not necessarily of itself improve outcomes or reduce variation[12]. Commentators have highlighted that whilst dissemination and feedback are suitable for sharing guidelines, specific strategies are necessary for successful guideline implementation [23, 24]. Early work in our project focussed on transforming retrospective audit to monthly SPC charting with a dissemination strategy and benchmarking against best performers. This empowered a highly motivated team to take ownership of their data and of making changes to care, and set a motivating goal to work on.

Using traditional audit to understand infection patterns was an important methodology to provide a local data-driven platform to discuss clinical issues with consultants involved in acute peritonitis care, microbiology - who then became involved in MDT review and prevention, and nurses who could identify high-risk stages in the patient pathway warranting systematic approaches to change. One learning point is that it took several months to complete, leaving less time to test improvements during a 12-month project. In future work we would move this type of data analysis to the pre-project period.

The PD QI team performed several PDSA cycles for each change, and built its own “change package” over the improvement year that consisted of 6 key changes to care processes, training and measures. Cycles of testing allowed the team to build its own “evidence”, and tailor changes to reflect the local context. As an example, this method was crucial to the evolution of the “3 strikes” rule of catheter removal. Repeated episodes of peritonitis are known to increase risk for patients[25]. However, bed pressures, patient preference, pressures on surgical lists, and occasionally failure to track frequency of episodes due to time intervals between episodes and changes within the team meant that historically catheter removal had not reliably taken place. The introduction of multi-professional meetings highlighted these patients, and using PDSA cycles enabled testing and development of processes to address each block if and when it arose.

Although national and international guidance on reducing peritonitis recommends continuous quality improvement driven by a multi-professional team as a key structural component of a PD programme[6, 26], they also note that with an absence of definitive studies, opinion only can be offered on optimal training methods, frequency of retraining, and duration of training. Visits to other units, review of the “grey literature”, and iterative testing therefore were particularly important for these changes.

Qualitative, quantitative and theoretical work in QI emphasizes the role of context at multiple levels in shaping success or failure[27]. Within kidney care, research into the role of

context in implementing guidelines is limited, but one review highlighted strategies that include regular meetings, outreach, patient-mediated strategies, reminder systems, and engagement of influential opinion leaders[28]. Our project attempted to address barriers by building local consensus with championing by the senior consultant, an emphasis on local decision-making and ideas for change, and recruitment of influential local opinion leaders. These leaders framed the team's comparative performance positively, to create a sense of the team honestly appraising their starting place whilst working to reduce patient harm. The wider organisational context was also progressive, with a Quality Strategy operational since 2008 and visible Board level support.

Whilst there are reviews in the literature demonstrating the effectiveness of specific interventions such as antibiotics before catheter insertion[29-31], few studies have examined the impact of CQI programmes to reduce peritonitis. These are summarised in table 4.3.4[32-36] and illustrate that there is no one way to design or implement CQI, or a "fixed" way to improve outcomes. Each programme is heavily dependent on context and the healthcare system in which it operates, such as, for example, provision of "PD clothes" in the Chinese programmes that identified a poor home environment as contributing to peritonitis. What they have in common is careful analysis of data to understand risk factors and causes, and development of multifaceted solutions to address these factors. A common theme in all was the need for robust patient education, training and retraining.

Further analysis of our data identified a significant reduction in admissions to hospital, total bed days, transfers to critical care and conversion to HD. Although this data needs to be interpreted with caution, it may suggest that as well as reducing total infections, the profile of infections may also have changed, or that increasing patient education may have resulted in more prompt presentation, and the additional vigilance around infection led to earlier treatment. A home therapy like PD can act as a preferred lifestyle choice but all dialysis places a strain on individuals and families. Individuals may experience hopelessness, anxiety, financial worries, subfertility, loss of sexual function, and loss of independence. Anxiety and depression are common [37]. Patient stories from our network describe distressing experiences from more severe infections (including pain, facing acute surgery, and being counselled about the risk of colostomy formation and death), decreased confidence performing PD following peritonitis, fearfulness about future episodes and family/carer stress about responsibility. One UK study demonstrated that a higher incidence of peritonitis was independently associated with lower patient satisfaction [37]. Surfacing the human

dimension of harm was an important component of engaging stakeholders within and outwith the service in the potential benefits of this work.

This QI project took place within a small team in a highly specialised area of care. Whilst the size of the team brought project management benefits in terms of organising QI meetings and communication, it also brought challenges. For example, moving from a time-based to a competency-based model for training patients was subject to 'squeeze' if the training took longer than managers had been used to historically. The small, specialised nature of the PD programme meant they had historically had limited visibility to the wider organisation. The organisational learning therefore was in the significant impact improvement work in a niche area - that would not have been targeted in hospital-wide initiatives - could have on hard outcomes such as admissions and bed days.

Financial data was used as measurement for improvement[38], which was critical in reinforcing key messages on potential benefits of this work. Both senior clinicians and managers lacked awareness of the details of the financial impact of admissions with peritonitis. For the NHS as a whole, renal replacement therapy is expensive, acquiring 1% of the total NHS budget to treat a condition with a prevalence of 0.05% in the UK. It is interesting to conjecture how significant savings could be achieved by targeting this and the mirror problem of haemodialysis catheter-related harm in the much larger HD population.

Table 4.3.4 Comparison of other studies using quality improvement techniques to reduce peritonitis.

Study	Duration of QI intervention	Peritonitis rate pre QI intervention	Peritonitis rate post QI intervention	Improvement Techniques Used	Changes
Nasso, Canada, 2006[32]	24 months	1 in 26 patient months	1 in 36 patient months	1. Four initial interventions introduced 2. Subsequent root cause analysis using fishbone diagram Staff interviews about processes of care Identification of best practice from high-performing units	1. Analysis of peritonitis data Education for staff Education for patients Change to treatment protocols 2. Home visit protocol Reassessment of training technique at 8 weeks Training community nurses to provide support
Qamar, USA, 2009 [33]	17 years	1 in 24 patient months	1 in 48 patient months	No technique described- retrospective analysis of peritonitis rates over 17 years of implementation of a series of quality initiatives	92-95 Randomised control trial of exit site prophylaxis 96-99 Compact assist device introduced for spiking fluid bag 2000-2004 RCT of exit site prophylaxis 2005-2007 Implementation of gentamicin for routine exit site care and retraining of all patients
Wang, China, 2014 [34]	15 months	1 in 40.1 patient months	1 in 70.8 patient months	Establishment of multiprofessional CQI team Fishbone analysis prior to study onset Action plan for implementation using plan-do-check-act cycles	Changes to training and retraining programmes including an exam and written test Antibiotics at the time of catheter insertion Identification of and intervention in patients at high risk of peritonitis eg those with diarrhoea, nutritional

					supplements in those with poor nutrition Dedicated “green channel” with specialist clinic and phone line for patients on PD
Yu, China 2014 [35]	5 years	1 in 7.5 months	In 36.5 months	Creation of a CQI team Consultation with international expert faculty Root cause analysis using fishbone diagram	Change to method of collecting PD fluid for analysis Retraining nursing staff Retraining patients every 6-12 months Periodic risk assessment Educating patients at monthly visit Ensure prompt reporting of contamination and prompt treatment Switch from plastic to titanium adaptors Antibiotics prior to GI procedures Topical antibiotics at the exit site
Borg, USA, 2003 [36]	45 months	1 in 7.5 patient months	1 in 36.5 patient months	Outcome monitoring	Training of all new patients in a single manufacturer’s system Change from plastic to titanium adaptors Patient retraining at 6 and 12 months after initial training then annually More vigorous treatment regimen for contamination

Limitations

This study is limited by the lack of control data inherent in QI initiatives, the limited nature of before and after data, and the limited nature of the financial analysis, which looked only at admission-related costs. Because this project was housed within a larger QI programme we have not segmented out potential costs attributable to running this part of the overall programme.

CONCLUSION

Peritonitis is a leading cause of morbidity and mortality in patients on PD. This improvement initiative has demonstrated improved quality of care for patients in our network, kept patients out of hospital, enabled better and safer self-management, and maintained them on their dialysis treatment of choice for longer. The use of a QI collaborative methodology enabled teams to understand their own performance, rapidly test changes to care. The use of audit data, as well as other mixed methods such as surveys, redesign of data capture methods, and better design of MDT processes, were key features of the steps required to identify changes to improve care. Senior leadership support reinforced the drive to improvement. Over time this led to a culture shift whereby peritonitis was not viewed as an inevitable complication of treatment with peritoneal dialysis, but rather a potentially avoidable harm. However, international literature demonstrates much better peritonitis rates than those we achieved in our improvement year setting us a clear challenge for future practice.

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CHAPTER 4.4

Factors Leading To Optimising and Sustaining Dialysis Unit Clinical Performance In Achieving Adequate Dialysis Dose In Haemodialysis Patients

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Preface

The first three chapters have analysed the outcomes of the quality improvement programme during two successive improvement years. What has been illustrated is that using QI methodology can improve guideline adherence, attainment of clinical indicators and outcomes in a dialysis population. In addition, we have shown that the development of a best practice “change package” by one unit can be successfully implemented elsewhere, but requires adaptation to local contexts. However, carrying out improvement work involves additional resource, and there are mixed reports about the sustainability of quality improvement initiatives once projects have been completed and additional resource and support withdrawn. This chapter analyses attainment of target URR in two dialysis units (A+C in chapters 4.1 and 4.2 above) for two years after completion of the QI project. It seeks to evaluate whether the improvements in attainment of target URR were sustained, whether changes to care made during the improvement years were sustained, and features that may have contributed to the findings.

ABSTRACT

BACKGROUND: Dialysis adequacy is an essential measure of quality of care in dialysis and has been shown to correlate with clinical outcomes. Guidelines recommend that haemodialysis patients should achieve a urea reduction ratio (URR) of more than 65%, but despite this UK Renal Registry data shows wide variation in achievement of target URR in UK dialysis units. In 2010-2012 the Salford Renal Network successfully improved attainment of target URR in two dialysis units using quality improvement (QI) methodology. We analyse sustainability of results two years after completion of the QI projects.

METHODS: Retrospective analysis of sustainability of improvement in attainment of target URR in two units in our dialysis network after completion of a quality improvement project. Analysis of sustainability of changes made by review of process measures to identify features contributing to long term outcome.

RESULTS: Both units were successful in sustaining improvements to attainment of target URR for a further two years following the end of the improvement project. Changes introduced included nurse-led changes to prescriptions during dialysis, multidisciplinary review of dialysis adequacy & vascular access, saline recirculation, nurse-led anticoagulation protocol, staff and patient education, changes to the blood sampling protocol, live Kt/V measurement. Not all changes to processes of care were sustained during the follow up phase, but improvement to dialysis adequacy was maintained.

Table 4.4.1: Pre and Post intervention and sustain URR

	Pre-intervention	End of phase 1	End of phase 2	Sustain	P value
Unit A					
Percentage of patients with URR > 65%	75.8	91.4	91.1	98.2	0.001
Mean URR, % (SD)	70.3 ± 8.3	74.5 ± 5.5	73.4±6.8	74.7±6.7	0.004
Unit B					
Percentage of patients with URR > 65%	71.9	68.9	91.1	93	0.001
Mean URR, % (SD)	66.5±12.6	69.8 ± 7.7	72.9 ± 9.2	72.3±6.0	0.003

CONCLUSION: URR is a key dialysis quality of care indicator impacted by multiple clinical, organisational and patient-related factors. Involvement of front-line staff in decision-making in care enabled development of a structured MDT approach and sustained improvements to dialysis URR in our renal network.

INTRODUCTION

National and international guidelines outline best practice in dialysis care using research evidence from international observational studies and randomized trials. However, despite the existence of such guidelines, and the availability of research evidence to inform best practice, wide variation continues to exist in achievement of standards both within and between HD networks.

Following publication of a seminal report on variation in quality in healthcare in 2001[1], there has been increasing recognition of the need to understand the factors that influence implementation of best practice, and there is now a body of evidence for systematic implementation tools to improve delivery of care and clinical outcomes[2, 3]. However, there is limited evidence assessing the sustainability of quality improvement projects beyond the initial implementation and evaluation period. In projects that have sustained improvements, factors contributing to sustainability include an infrastructure that supports improvement, ongoing leadership support, continued feedback of results, teamwork, skills gained, and improvements in culture[4, 5].

Dialysis dose, as measured by urea reduction ratio (URR), is a crucial component of quality of care and is strongly associated with clinical outcomes in chronic haemodialysis patients. In the UK, Renal Registry data demonstrates that adequacy of dialysis has improved overall from 74% of dialysis patients attaining $URR > 65\%$ in the 2002 report to 88.6% in the 2014 report [6]. Some of this improvement can be attributed to better technology; dialyser surface area, pore size and pore density contribute to membrane performance, defined as the potential to remove urea, middle molecules (measured by ability to remove β_2 -microglobulin), and water adjusted for transmembrane pressure. However, wide variation continues to exist between centres.

Enhancing fluid, middle molecule and solute clearance is accomplished clinically by increasing dialysis time, and blood and dialysate flow rates. These in turn can be impacted by clinical factors such as vascular access, anticoagulation and occurrence of side effects or complications during dialysis. In a “real-world” context, other factors, such as patient choice, staff education, transport times and frequency of review add an additional layer of complexity when making changes to improve care.

In 2010 we set up a dialysis quality improvement programme in our network. We sought to determine whether we could match the top 10% of centres in the UK for performance on

key quality of care indicators in dialysis. The first phase of the project ran from April 2010 to April 2011, where four teams were set a different clinical indicator to work on for one year. A second improvement phase was commenced in May 2011 for a further year.

Aim

Unit C worked on dialysis dose as measured by urea reduction ratio (URR) in year 1 of the project, with an aim for >90% of patients to achieve URR>65% within one year. The project was taken up by Unit A in year 2. Both units were successful in meeting their aim. The aim of this study is to analyse 2 years' follow up in these units following completion of the formal improvement projects. Specific aims are to analyse

- 1) Whether the improvement was sustained
- 2) Whether the changes implemented during the QI year (process changes) were sustained
- 3) Whether it was possible to identify factors influencing the sustainability or otherwise of changes to practice

METHODS

The Quality Improvement (QI) project set clinical teams a different clinical indicator and aim to work on for one year. Details of the design, aims and framework of the project are described in earlier chapters of this thesis.

During the improvement project participating QI teams would meet weekly, design and perform plan-do-study-act (PDSA) cycles (Table 4.4.1) and undertake measurements, with the support of a trained facilitator. In year 1 Unit C used this methodology to build a successful 'change package' of proven successful interventions. Following successful completion, the change package was implemented by Unit A in year 2. Formal QI support and feedback as described ended on completion of phase 2 (Figure 4.4.1). Measurement of URR continued in keeping with network MDT processes and renal registry submissions. Key changes made to processes of care are listed in table 4.4.2.

Table 4.4.2. The PDSA cycle used to test changes

	Step	Who	When	Where
	Describe the test of change to be performed			
Plan	List the tasks needed to set up the test of change			
	Predict what will happen when the test is carried out			
	Describe the measures to determine if the prediction succeeds			
Do	Describe what happened when the test was run			
Study	Describe the measured results and how they compare to the predictions			
Act	Describe what modifications to the plan will be made for the next cycle from what you learned			

Figure 4.4.1. URR collaborative project timeline

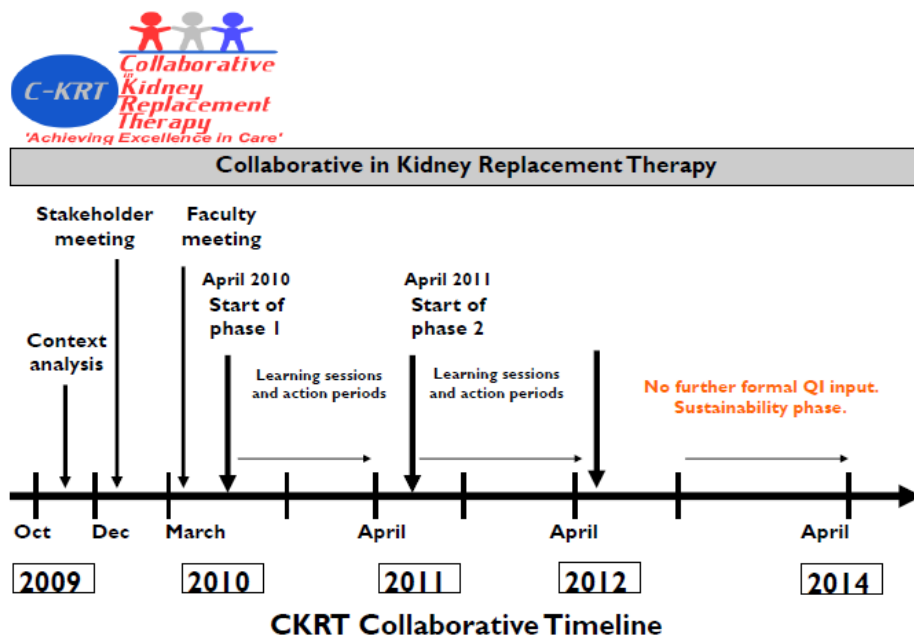


Table 4.4.3. Changes in processes to care made during the QI collaborative year

Change	Who	How
Nurse-led URR protocol	Doctor, unit manager and URR link nurse	MDT to analyse evidence and develop flow chart for staff Implementation via nurse education and one to one learning sessions
Review and change prescriptions during dialysis	All unit staff led by the coordinator	Staff education about VA surveillance Review of prescriptions as part of daily goals Early contact with vascular access teams if any concerns about VA
Monthly MDT review of URR and vascular access (VA)	URR and vascular access link nurse in conjunction with MDT	Review of monthly blood results Communicate action plan to named nurse and ensure it is recorded in daily goals Review following month
Saline recirculation pre dialysis	All nursing staff on unit	Educate nurses on saline recirculation using small group teaching and demonstration Cascade to all staff Review monthly
Anticoagulation protocol to reduce clotting of dialysers	Doctor and all nursing staff on unit	Adoption of nurse-led anticoagulation protocol from best-performing unit Anticoagulation assessment sheet Cascade to staff via one to one education

Exercise on dialysis	Doctor and all staff on dialysis unit	<p>Identify patients willing to try exercise on dialysis</p> <p>Powerpoint presentation and education of staff on how to safely monitor exercise on HD</p> <p>Pre-exercise health assessment to ensure patients are suitable</p> <p>Monitor obs before every exercise session</p>
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Overarching data collected during the improvement years included demographics, laboratory variables and clinical details from the electronic patient record. Specific data collected included pre and post dialysis urea, vascular access, type of dialyser, blood flow rates on dialysis, dialysis time, ESA and anticoagulant use, IV iron use, and thrombokinase use.

Follow up data collection and analyses were conducted retrospectively. Data collected included pre and post dialysis urea, vascular access, type of dialyser, blood flow rates on dialysis, dialysis time, and ESA and anticoagulant use.

Evaluation of whether the changes implemented during the collaborative year were sustained was conducted by surveying dialysis unit staff on their knowledge of the quality improvement project, and awareness and use of the change package.

Methods of statistical evaluation

Comparison between groups was performed using the t-test and ANOVA to compare differences in means, the Mann-Whitney U-test for non-normally distributed variable and chi-square tests in the case of dichotomous variables. A p-value of less than 0.05 was accepted as significant.

Statistical analysis was performed using IBM SPSS version 22, on licence to the University of Manchester.

We evaluated outcomes by:

- (1) Analysing attainment of target URR in the two 2 years following completion of the QI collaborative
- (2) Identifying which changes to processes of care were sustained and which weren't
- (3) Identifying potential factors affecting sustainability to changes in care processes

RESULTS

Demographics from the two intervention units pre-intervention are displayed in Table 4.4.3.

Mean age and time on dialysis were similar on both units, with a high prevalence of diabetes, hypertension and vascular disease, comparable to that reported in national registry data[7].

Table 4.4.4 Network Demographics

	Haemodialysis Unit C	Haemodialysis Unit A
Patient Number	58	67
Age (mean \pm SD) yrs	61.0 (\pm 15.9)	58.2 (\pm 15.3)
Dialysis duration in weeks (median \pm SD)	113.5 (\pm 81.9)	105.9 (\pm 85.3)
% Male	60.3	62.5
Diabetes (%)	29.3	34.3
Hypertension (%)	86.3	89.6
Cerebrovascular disease (%)	17.2	10.4
Peripheral vascular disease (%)	6.9	9.0
Ischaemic heart disease (%)	37.9	32.8
Heart failure (%)	14.0	11.9

Both units were successful in achieving the aim of >90% of patients attaining URR>65% during their respective intervention year and sustained it during 2 years of follow up (table

4.4.4). Unit C improved attainment of target URR from 75.8% of patients pre-intervention to 91.4% of patients after phase 1, and sustained this change in phase 2 and for a further 2 years after the intervention ($p=0.001$). Unit A started the intervention in phase 2 and was successful in improving attainment of target URR to $>91.1\%$ of patients and sustaining the improvement for a further 2 years ($p=0.01$). Analysis of URR in Unit B at the end of phase 1 (when there was no QI intervention for target URR taking place in this unit) shows no improvement from pre-intervention.

In Unit C there was a significant increase in tinzaparin usage (mean dose per HD session 3191 ± 547 units versus 3910 ± 1150 units, $p<0.001$) during its collaborative year working on URR. Unit A had an increase in average dose of tinzaparin during phase 1 due to its work to reduce catheter-related bacteraemia, in which tinzaparin doses were increased in order to maintain catheter patency (2895 versus 3465 units, $p=0.02$). Therefore whilst there was an increase in dose during its URR improvement year, this was not significant (3465 versus 3775 units, $p=0.23$). Attainment of target haemoglobin improved in unit C, despite an overall fall in ESA use ($p<0.001$), whilst in Unit A there was a significant fall in ESA use from pre-intervention to after phase 2 (48.3 ± 33.1 vs 29.2 ± 23.1 , $p=0.004$), but this subsequently rose again, with no significant change in attainment of target haemoglobin ($p=0.241$).

Both units demonstrated broad sustainability of the improvements over 2 years following the end of the collaborative. However, there was point-to-point variation over time, reflecting the importance of continuous measurement to identify random or special cause variation. In addition, Unit A closed for refurbishment for a period of 3 months from January to March 2013, and its patients were dialysed in other units within the network, repatriating to their “home” unit during March 2013. Therefore results from January to March 2013 have not been reported, due to the changes in dialysis centre resulting in variable coding of dialysis centre, changes to working patterns, and incomplete results for this month.

Unit C had a slight non-significant increase in average dialyser surface area during the study period, whilst unit A saw a fall in average dialyser surface area during follow up. Conversely, average treatment time fell in unit C but rose in unit A during follow up. Both units had an increase in average blood flow rates on dialysis. There was no significant change in either unit in type of access used.

Table 4.4.5: Pre and post intervention and sustain URR

	Pre-intervention	End of phase 1	End of phase 2	Sustain	P value
Unit C					
Number of patients	58	56	55	60	NA
% dialyzing via AVF	82.8	89.1	85.7	86.7	0.785
Percentage of patients with URR > 65%	75.8	91.4	91.1	98.2	0.001
Mean URR(SD)	70.3 ± 8.3	74.5 ± 5.5	73.4±6.8	74.7±6.7	0.004
Mean ESA dose per week (SD)	60.3 (37.2)	43.1 (35.7)	32.7 (34.1)	15.7 (20.4)	<0.001
Median ESA dose per week (IQR)	50	30	20	20	
Average dialyser surface area	1.72	1.80	1.82	1.77	NS
Average tinzaparin dose	3191	3910	4934	4218	<0.001
Treatment time	235	234	236	231	<0.001
Blood flow rates	340	337	341	349	<0.001
Average Hb	11.2	11.2	10.9	11.1	0.249
% attaining target Hb	48.2	64.8	63.6%	65.5%	0.269
Unit A					
Number of patients	67	76	69	79	
% dialyzing via AVF	85.9	86.6	89.9	87.3	0.93
Percentage of patients with URR> 65%	71.9	68.9	91.1	93	0.001
Mean URR, % (SD)	66.5±12.6	69.8 ± 7.7	72.9 ± 9.2	72.3±6.0	0.003
Mean ESA dose per week (SD)	48.3 (33.1)	40.3 (29.7)	29.2 (23.1)	40.8 (41.4)	0.009
Median ESA dose per week (IQR)	40	40	20	30	
Average dialyser surface area	1.78	1.79	1.81	1.56	<0.01
Average tinzaparin dose	2985	3906	3775	3730	<0.001
Treatment time	227	228	231	235	<0.001
Blood flow rates	286	310	333	327	<0.001
Average Hb	11.3	11.6	11.2	11.0	0.06
% Attaining target Hb	52.2	54.1	62.9%	68%	

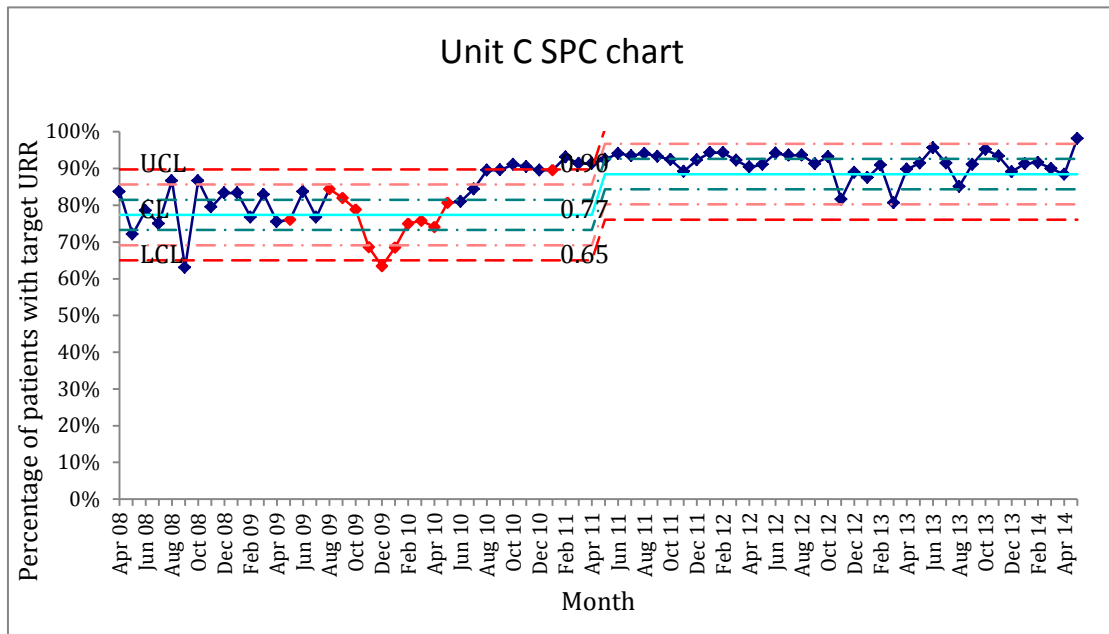


Figure 4.4.2a. SPC chart

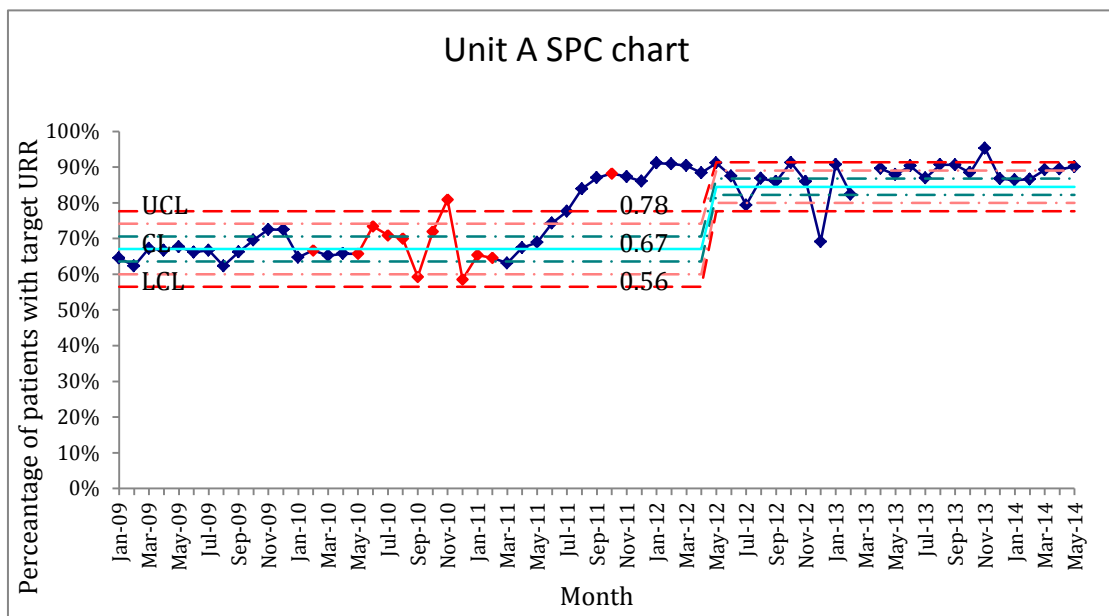


Figure 4.4.2b. SPC chart

Figure 4.4.2. SPC charts showing monthly URR from at least 2 years pre-intervention to 2 years post intervention. The QI project commenced in May 2010 in Unit C and May 2011 in Unit A. CL= Control line. The control line was generated from by averaging attainment of target URR from the start of the charts to just before project commencement (May 2010 in Unit C, May 2011 in Unit A). UCL=Upper control limit; 3 standard deviations above the control line. LCL=Lower control limit; 3 standard deviations below the control line. Following completion of the project and improvement in attainment of target URR, a new control line was generated of the average attainment of target URR during the improvement year.

Analysis of adherence to changes in the processes of care during the follow up period had mixed results. Staff on both dialysis units were aware that nurse-led quality improvement projects had taken place, and were enthusiastic about their role in improving care. Both units sustained several key changes; monthly MDT review of URR and VA, saline recirculation pre-dialysis, and titrating anticoagulant doses. Other changes were not maintained, notably exercise on dialysis, and review and change of dialysis prescriptions in real time, whilst the nurse-led URR protocol was partially sustained.

DISCUSSION

Clinical Outcomes

This before and after study following implementation of changes to processes of care after a QI intervention demonstrates improved attainment of target URR in two HD units in successive years that was sustained over 2 years following the end of the formal intervention.

Further analysis of results reveals some interesting points, notably the fall in ESA use and improvement in attainment of target haemoglobin over time. Part of the fall in ESA use can be attributed to the change in national guidance for target Hb from 10.5-12.5g/dL to 10-12g/dL during this period, following publication of research on the harm associated with higher Hb levels in dialysis patients. Another possibility is that increased blood flow rates, treatment times and improvement in dialysis adequacy are known to improve ESA responsiveness. In addition, there may be an unmeasured wider impact of changes in care practices as a result of the learning from the quality improvement project, suggesting a greater benefit in clinical care than that on the measured indicator.

Previous studies into the barriers to adequate dialysis have identified several key factors that correlate with dialysis adequacy[8]. These include patient compliance with treatment time, vascular access (VA) type, dialysis prescription, and clotting. A subsequent randomised control trial used a tailored intervention to address each of these factors and demonstrated a significant improvement in delivered dialysis dose in the intervention group [9]. The focus of the QI project was to optimise these components of care, by identifying ways in which the delivery of care could be changed to improve dialysis dose in our patients.

At study onset average treatment time was comparable to that reported in DOPPS II in Europe [10] in Unit C but lower in Unit A. Analysis revealed that treatment time improved significantly in both HD units during the intervention period (year 1 in Unit C, year 2 in Unit A). This was most marked in unit A, which also sustained the improvement in treatment time over 2 years. In unit C however, the improvement in URR was maintained despite a decrease in treatment time at the end of the follow up period.

In our intervention units AVF rates met or almost met the UK renal association target of >85% of prevalent patients dialysing via AVF. A vascular access (VA) pathway was already established which included weekly VA audit by VA specialist nurses, identification and intervention in “at risk” patients, and monthly multidisciplinary VA meetings maintained or improved high AVF rates in our population throughout the study period and beyond.

Evidence on dialysis prescription is limited, but DOPPS II data reveals average dialyser surface area of 1.62m² in the UK [10], below the average in our units at study onset. There was improvement in average dialyser surface area in both units, but a significant fall in prescription during the follow up period in Unit A. A number of possible factors may have contributed to this. A new brand of dialyser was introduced in our network, leading to adjustment in prescriptions that may not have been exactly comparable. Despite this, the improvement in dialysis adequacy was maintained in both units, highlighting the interplay between multiple factors in impacting on dialysis dose, and the need for a multifaceted approach to management.

Unit C titrated up anticoagulation dose during its improvement year (year 1) as part of its dialysis adequacy QI project. Unit A already used higher doses at onset of its dialysis dose improvement year (year 2). URR remained low however, suggesting under-anticoagulation and clotting was not as great a factor in this unit, and the advantage in testing and implementing multiple interventions.

Sustainability of changes in care

Both units implemented a change package of a series of tested proven interventions designed by unit A in year 1. Unit A adapted the package to its local context for use. It is important to note that the changes implemented describe the action required (“how”) to overcome barriers to adequate haemodialysis. Thus we know that optimising blood flow rates, treatment time and dialyser surface area will increase clearances, and this was

achieved by designing and implementing nurse-led protocols and titrate prescriptions during dialysis sessions rather than waiting for monthly review.

Reporting of URR identified which patients needed interventions to improve URR, which were then tested using PDSA cycles, with recognition that different interventions were needed in different patients. Enabling nurse-led changes to care processes allowed units to build their own “evidence”, with a view to sustaining the improvements made during the follow up period. This emphasises the importance of designing tailored interventions to act on feedback and reporting of data, supporting existing evidence that feedback alone does not improve outcomes.

Interviews with staff further identified training in QI and the exchange of ideas and information during learning sessions, and the opportunity to test their own ideas during action periods as crucial to the success of the projects. The confidence gained and development of new skills during the QI projects empowered staff to continue to remain proactive in maintaining changes during the follow up phase. However, as this analysis revealed, not all changes were sustained. Exercise on dialysis was not sustained at all during the follow up period. Support structures around this change, including servicing and repair of exercise bikes, and storage for additional bikes, were not robust, therefore this change failed to be embedded into clinical practice in the longer term.

In addition, both units underwent significant staffing changes during the follow up phase, with the departure of senior nursing staff and several QI team members. Therefore whilst staff were aware of previous quality improvement activities in their units, the lack of a “champion” to sustain all changes made meant, for example, that staff members weren’t always trained to or had the confidence to actively review dialysis prescriptions, and this tended to be done less consistently. Encouragingly however, several processes that were maintained, notably rigorous monthly MDT review, had been embedded into routine clinical care.

Relation to other evidence

Whilst there is ample evidence that demonstrates a recommended minimum URR, and observational data on the relationship between URR and outcomes in large cohorts such as DOPPS, there are few studies on how to improve URR at a unit or system level. Several large

US dialysis providers have published reports on improving dialysis outcomes as part of National Core Indicators Project (NCIP)[11] or specific Healthcare Quality Improvement Project (HCQIP) interventions. A HCQIP intervention aiming to improve URR and anaemia used a collaborative, data-driven approach, with analysis and distribution of data to centres, linking variations in care to the actions needed to improve care, with centres designing their own interventions. These were supplemented by workshops on adequacy, anaemia and quality improvement. They identified rapid analysis and dissemination of data as key to improving delivery of care[12]. A report from the NCIP identified centres with a high proportion of patients with URR<50% and provided interventions including QI workshops, educational programmes, on-site assistance and intensive supervision of these centres and reduced underdialysis (URR<65%) from 57% of patients to 34% with these interventions[13]. An RCT addressed three barriers to adequate haemodialysis- under-prescription, high rates of catheter use, and shortened treatment time, using patient education, prescription review and increased placement of definitive access in the treatment group, and found improved attainment of target URR. They identified reasons for failing to overcome barriers as use of low-flux dialysers, failure to convert to place definitive access, failure to increase blood or dialysate flow, and persistent shortening of treatment time[9].

Common themes arising from these studies are identifying a predefined opportunity for improvement, careful analysis of barriers, continuous monitoring and reporting of data, educational activities for staff and patients, and a non-punitive approach.

LIMITATIONS

As a before and after quality improvement study and not a randomised trial, there are inherent potential confounding factors such as case-mix, differences between staff and other unit characteristics. In addition, there was no control group in this study, limiting generalisability of findings. Other changes at an organisational and structural level could not be controlled for, such as change in dialyser brand, staffing levels and skill mix.

CONCLUSION

URR is a key dialysis quality of care indicator impacted by multiple clinical, organisational and patient-related factors. Involvement of front-line staff in decision-making in care

enabled development of a structured MDT approach and sustained improvements to dialysis URR in our renal network. This was despite organisaitonal changes that meant not all changes to processes of care were sustained. However, key changes to practice that were embedded into routine care include continuous monitoring and reporting of data, with rigorous MDT processes.

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CHAPTER 4.5

Sustainability of an intervention to reduce catheter-related bacteraemia in a renal network: Lessons from a quality improvement initiative

Sajeda Youssouf, Janet Hegarty

Preface

This builds on results in chapter 4.4. Reduction in catheter-related bloodstream infection (CRBSI) was a key successful aspect of the QI programme in two dialysis units over two years. It was implemented in a further unit in the Salford dialysis network, and follow up outcomes for a further two years in the three units that implemented changes to care are reported here. This is a small observational analysis of the findings on follow up of this project.

ABSTRACT

Background

Haemodialysis catheter related bloodstream infection (CRBSI) remains a significant safety issue in many HD units. Despite initiatives to increase the use of definitive access, 30% of patients in the UK still use catheters for haemodialysis. Two dialysis units in our network implemented a programme of quality improvement to successfully reduce catheter-related bacteraemia in our network over two years. The programme was rolled out to other units and rates were followed up for a further 2 years.

Methods

We used multifaceted interventions based on best available evidence and learning from best performing units as part of a quality improvement collaborative over a two-year period. We used plan-do-study-act (PDSA) cycles to rapidly introduce small-scale changes and implement them fully if successful. Successful changes were compiled into a change package for use elsewhere in our network. Data was collected prospectively for a further 2 years follow up following completion of the QI programme.

Results

This QI project was successful in reducing catheter-related bacteraemia in our network from 1.73 per 1000 catheter days to 0.92 over 2 years. In addition, the improvement was sustained and improved over 2 further years to 0.41 per 1000 catheter days. Further analysis of the data however revealed a higher rate of complications and higher length of stay during the follow-up period.

Conclusion

We demonstrated a significant improvement in our catheter-related blood stream infection rate, which has been sustained for 2 years following the intervention. Interestingly despite the low numbers occurring in the sustain period, all affected patients required hospitalisation with significant morbidity mortality and length of stay. This highlights the potential changing clinical profile of affected patients after successful QI initiatives which can be usefully studied to recalibrate a sense of local challenges for improving outcomes in the future.

Introduction

Over 2 million patients worldwide receive RRT, of whom the majority receive haemodialysis (HD). HD is usually performed in centre 3 times a week via a surgical AV fistula (AVF). However, a significant proportion of patients are unsuitable for AVF, due to late presentation to renal services, inadequate veins, calcification or stenosis of arteries, other vascular disease, other comorbidities, or other complications arising from fistula attempts, and require tunnelled venous catheters for access. These catheters are designed to be used long term but remain a potential portal of entry for bacteria and a significant cause of bacteraemia in this cohort. Observational data has shown that patients undergoing HD via catheter have higher morbidity and mortality than those with surgical AV fistulae[1].

The UK embarked on a number of infection prevention initiatives ('High Impact Interventions')[2], specifically targeting the HD population and widely credited with bringing down rates of MRSA. Our unit had introduced a catheter care bundle as part of this MRSA control programme, as well as introducing bactericidal lock solutions as a standard for all patients using HD catheters. Despite this our CRBSI rate was 1.73 per 1000 catheter days across our network, significantly higher than what is known to be achievable in the literature[3,4].

In 2010 we introduced a programme of quality improvement in our renal network. Dialysis unit A worked on reducing CRBSI in year 1, and developed a change package that was used by dialysis unit B to reduce CRBSI in year 2.

Aim

Both units were successful in reducing CRBSI rates in their respective improvement years. The change package was therefore rolled out to another unit (unit C) in our network on completion of the QI programme (end of year 2). No formal QI support was provided after year 2. We followed up CRBSI rates and outcomes of infections in all 3 units for a further 2 years following the end of the QI project.

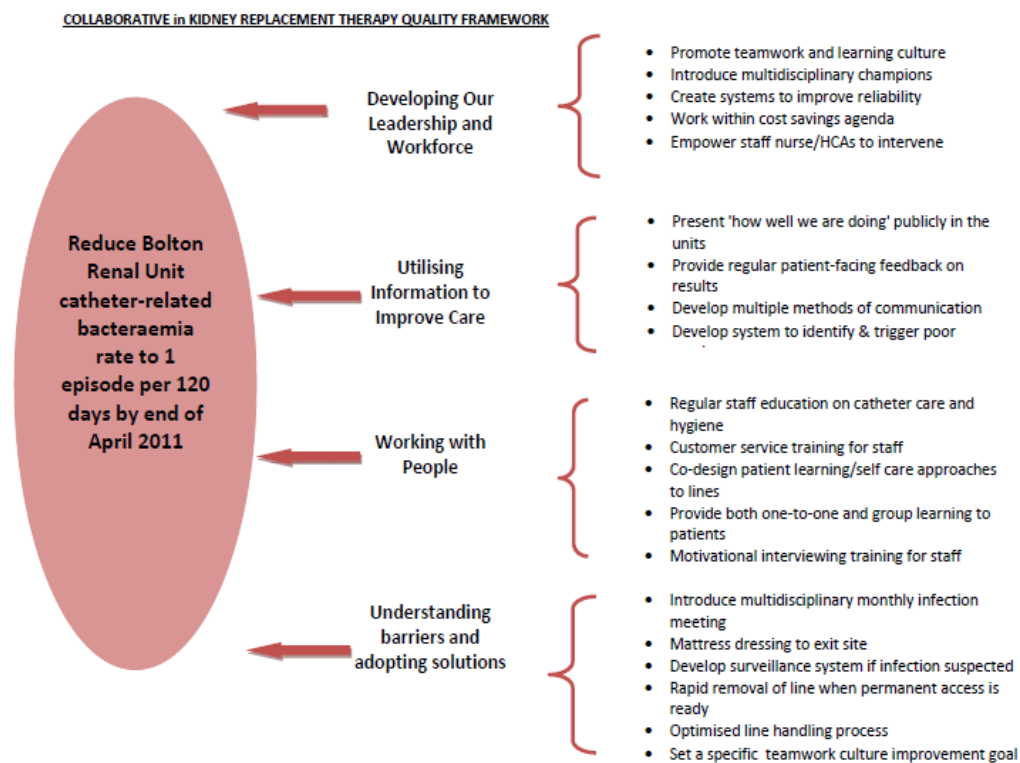
Methods

During the Quality Improvement (QI) project set clinical teams a different clinical indicator and aim to work on for one year. The aims and framework were chosen by an expert faculty, with local performance data made available to the faculty from detailed project pre-work. In keeping with collaborative methodology, the project had a senior sponsor, a QI facilitator

and project directors to oversee improvement work, and teams of frontline staff who would meet weekly to design and plan tests of change using plan-do-study-act (PDSA) cycles. Figure 4.5.1 shows the framework used to guide improvement activity by the QI team.

The project was part of a wider programme of work to improve attainment of clinical quality of care indicators in dialysis. Formal QI support and feedback ended on completion of year 2. Measurement of CRBSI continued in keeping with network MDT processes.

Figure 4.5.1 Driver diagram illustrating framework for improvement



Key changes implemented during the collaborative year are shown in table 4.5.1 below.

Table 4.5.1: Key changes implemented during the collaborative year

Change	Why	How	Sustained
Set days and times for dressings	Ensure consistency in changing dressings	Set days to change dressings to ensure changed regularly Dressings to still be checked at each HD session and changed if	Yes

		<p>needed</p> <p>Dressings to be checked and changed during “quiet periods” only</p>	
Types of dressings	Dressings to be clear so able to visibly see exit site	<p>All lines graded according to risk</p> <p>High risk patients to have extra coverage of chlorhexidine for 7 days in the form of biopatch or CHG dressing</p> <p>Exit site surveillance tool</p>	Yes
Different coloured aprons when accessing lines	To identify that a staff member is performing an aseptic technique therefore not to be interrupted	<p>Ensure different coloured aprons available</p> <p>Staff member not to leave the patient area wearing the apron</p> <p>Don't carry the drug keys</p> <p>Do not get called to the phone</p> <p>Do not get asked clinical questions</p> <p>Do not leave the patient area until the procedure is completed.</p>	No
Small dressing trolleys	Reduce the risk of cross-infection between procedures and ensure all equipment is prepared for the procedure	<p>Two trolleys available</p> <p>All equipment needed to be kept in one place</p> <p>Trolley prepared before going to the patient</p> <p>Equipment restocked at the end of each shift</p>	Yes
Bioconnectors	To provide further protection for the key parts in accordance with the ANTT	<p>Left in situ for 7 days</p> <p>Changed at the same time as dressings</p>	Yes

	procedure	changed	
ANTT connect-disconnect	All staffs are trained, assessed and competent in HDANTT procedure. All staff should be consistent in the application of HDANTT	All staff trained and audited in HD ANTT procedure Daily High Impact Audit completed. Assign secret shopper to observe.	Yes
Handwashing	To maintain asepsis	All staff checked using the UV light box Handwashing champion Reminder signs to wash hands Encourage staff to remind everyone to wash their hands on entering the unit	No
Exit site surveillance tool	Systematic and consistent way to assess exit sites	Grading system depending on appearance Instructions on action to take depending on score Recording of score	No
Exit site and bacteraemia database	Record and track infections systematically For use by MDT in root cause analysis	QI team to enter infections into database as they occur Include treatment and outcome as known	No
Traffic light system for lines	Identify patients at high risk of CRBSI	Triage to red/amber/green Scoring system based on blood flow, exit site, position, ease of aspiration	No
Algorithm for high risk lines	Intensive surveillance to reduce the risk of	Flowchart with steps to follow for high risk lines, including early	Yes

	line infection	intervention such as exchange to prevent infections	
Predict next infection	Weekly prediction in order to put interventions in place to reduce risk of developing infection	Analysis of VA, blood flow, anticoagulation, infection prevention procedures	No
Tinzaparin/heparin protocol	Maintain adequate blood flow	Protocol for nurse-led titration of heparin for flow Anticoagulation sheet for staff	Yes
Patient information leaflet	To give patients information on how to care for their line	What to do and what not to do with a line Signs and symptoms to look for All patients given a leaflet at the time of insertion	Yes

Overarching data collected included demographics, laboratory variables and clinical details from the electronic patient record. Specific data collected included date and type of infection, treatment, hospitalisation, complications, mortality, catheter removal, and outcome of infection.

This study analysed total network CRBSI rates across the 3 dialysis units for evaluation.

Methods of statistical analysis

Comparison between groups was performed using the t-test and ANOVA to compare differences in means, the Mann-Whitney U-test for non-normally distributed variable and chi-square tests in the case of dichotomous variables. A p-value of less than 0.05 was accepted as significant.

Statistical analysis was performed using IBM SPSS version 22, licensed to the University of Manchester.

Results

Demographics for the dialysis units are shown in table 4.5.2 below.

Table 4.5.2: Network Demographics at start of QI programme

	Haemodialysis Unit A	Haemodialysis Unit B	Haemodialysis Unit C
Patient Number	67	138	58
Age (mean \pm SD) yrs	58.2 (\pm 15.3)	59.9 (\pm 15.2)	61.0 (\pm 15.9)
Time on HD in weeks (mean \pm SD)	105.9 (\pm 85.3)	119.0 (\pm 106.9)	113.5 (\pm 81.9)
% Male	62.5	60.9	60.3
Co-morbidity			
Diabetes (%)	34.3	45.3	29.3
Hypertension (%)	89.6	78.1	86.3
Cerebrovascular disease (%)	10.4	6.3	17.2
Peripheral vascular disease (%)	9.0	12.5	6.9
Ischaemic heart disease (%)	32.8	48.4	37.9
Heart failure (%)	11.9	12.5	14.0

Demographics were similar across all three units. Catheter prevalence did not vary significantly during the study period. Rates of CRBSI fell significantly during the QI intervention and were sustained for 2 years following completion of the QI projects, although there was a trend to increased CRBSI in year 4. Total number of infections also fell. Further analysis of infection revealed an initial marked fall in hospitalisation and days in hospital, but this was not sustained, and hospitalisation and days in hospital increased significantly during the follow up period. In addition, there was a higher rate of

complications associated with infection (secondary infection such as endocarditis and level 3 care) in the follow up period, and a higher rate of catheter removal.

Table 4.5.3. Results

		QI intervention period		Follow up period		
	Pre-intervention	Year 1	Year 2	Year 3	Year 4	P value
Number of patients	273	263	269	269	281	
Catheter prevalence (%)	20.5	19.8	20	18.3	18.1	NS
Catheter-related bacteraemia rate (per 1000 catheter days)	1.73	0.92	0.31	0.28	0.41	<0.001
Outcomes						
Infections (n)	30	18	6	6	7	
In hospital or 30 day mortality (n)	1	0	0	0	2	
Hospitalisation (n)	24	15	6	6	6	
Total days in hospital	309	405	86	220	231	
Complications	2	2	0	2	2	
Removal of catheter (n)	13	8	5	4	4	

Discussion

The effect of a quality improvement project led and conducted by frontline staff was successfully spread and sustained in 3 haemodialysis units in our network over two years after completion of the project. Rates of CRBSI fell to within that for example quoted with use of antibiotic line locks[3] through culture and process change largely involving nursing care and patient education. Of note, CRBSI rates in our network varied significantly prior to the QI project, from 0 to 2.65 per 1000 catheter days. The introduction of a systematised change package, designed and led by front line staff, resulted in significant improvements to

rates during the QI collaborative. The continued improvement could be attributed to several factors. The focus on infection prevention during the two years of the QI collaborative embedded change and a view of CRBSI as preventable, rather than an inevitable consequence of the use of tunnelled lines. The fact that changes were designed and implemented by front line staff, who remained on the dialysis units and took ownership of the problem, leading by example and training other staff to take a similar approach, also sustained changes made. There is evidence that local champions are key sustaining improvement to care[5,6], and a key feature of this project within our network was the role of nursing staff on dialysis units as infection champions. This in turn led to increased awareness of infection prevention initiatives, further embedding the culture change that had taken place.

Further analysis of the collaborative identified that staff felt senior leadership support and time were important to the success of the project. During the follow up period a number of organisational changes occurred, most significantly restructuring of management teams and changes in dialysis unit managers. These issues were partly overcome however, by the role of local champions in sustaining change.

Interestingly, a closer analysis of the data reveals some unexpected findings. Most notably, hospitalisation increased and there were 2 deaths directly attributable to line infection in year two after completion. Further analysis of the data reveals that both these patients had significant complications and severe infection, and due to lack of access sites, had tunnelled lines as their definitive access. Whilst these numbers are small and should therefore be interpreted with caution, this finding has led to a further review within our network of the management of patients at high risk for CRBSI, with a recently published policy on the management of patients with long term catheters for access. Of note, there is an emphasis on prompt removal of catheters if a patient is unwell or there is evidence of metastatic infection, and the use of antibiotic locking solutions in patients on antibiotics for CRBSI.

Analysis of the change package revealed that not all changes were adhered to. Of note, the prediction of next infection and maintenance of a database of infections lapsed within 12 months of completion of the project. Several potential reasons can be considered for this. The database was designed by the project facilitator and maintained by staff for review in weekly facilitation meetings. On completion of the project, this additional work, with no

review, lapsed. Other changes were practical and embedded at the bedside- a change in clinical practice that had demonstrable effect and more directly correlated with success in the eyes of staff.

Limitations

This study is limited by its single centre design and lack of control for comparison. The small numbers of infections involved also make it difficult to draw generalisable conclusions. In addition, as it was an observational follow up study, it is possible that other confounders, such as hospital infection-prevention campaigns, may have contributed to sustaining the improvement.

Conclusion

This small observational analysis has demonstrated sustainability of an intervention to improve CRBSI over time through embedding changes to care, raising awareness of infection as preventable harm, and the use of local champions. The finding of increased morbidity during follow up however highlights the ongoing need for continuous review and careful analysis of broader outcome measures in order to sustain improvements after a successful QI intervention.

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CHAPTER 5. SUMMARY

5.1 Preface

This chapter summarises the findings of the previous chapters, and discuss how the results of the analyses have addressed the initial aim of the study.

Finally, I have summarised future work arising from this study.

5.2 Chapter summaries

Chapter 1: Introduction

This chapter summarises the evidence to date for improving outcomes in patients undergoing dialysis. Much of the evidence is observational, from large data repositories—including longitudinal international observational research cohorts such as DOPPS, and studies conducted using national registry data, such as the USRDS. Whilst there is a relative paucity of randomised controlled trial data on improving outcomes in dialysis care, there are several clinical indicators that are strongly associated with poor outcomes. The most significant of these is catheter use for haemodialysis, due to the significant increase in infection risk with catheters when compared to arteriovenous fistulae. In addition to this, anaemia, high phosphate, inadequate dialysis as measured by urea clearance, low albumin and high interdialytic weight gains are also associated with increased mortality in haemodialysis patients. There is evidence from clinical trials of dialysis dose that patients who have inadequate dialysis have higher mortality, and that treating haemoglobin to normal levels is associated with increased morbidity and mortality. However, whilst high phosphate is associated with increased mortality, there is no evidence that treating patients with phosphate binders to reduce levels is impactful on clinical outcomes. In addition, serum albumin is a difficult target to address in interventional studies.

Much of the evidence for improving outcomes in PD is derived from studies in HD. However, the biggest cause of morbidity in peritoneal dialysis care is peritonitis, and is the focus of much research on treatment and minimising infection rates.

There have been several small studies using multifaceted approaches to improve clinical indicators in dialysis care that have shown that improved attainment of these indicators is associated with better outcomes.

Dialysis care is complex, and requires a multi-professional multifaceted approach to care. Given the strong association between clinical indicators and outcomes, even in the absence of strong clinical trial data, guidelines exist at a national and international level

recommending standards in dialysis care. Despite this, variation continues to exist in the delivery of care.

Quality improvement is a process whereby a change to practice is combined with a method to implement the change. It is increasingly recognised in healthcare as a way to reduce variations in care and implement best practice. There are specific tools and methodologies used, but key processes are identification of a problem, analysis of barriers to improvement, and design and implementation of structured changes with continuous data-driven monitoring of the effect. Evidence for its effectiveness in healthcare exists, most notably in reducing infections on ICU, and the development of the WHO surgical safety checklist. Within kidney care there is evidence for its use in improving vascular access, and a continuous quality improvement programme is recommended by the ISPD to reduce peritonitis rates in PD programmes, but there is little evidence of its effectiveness in other aspects of kidney care.

However, given the variation that exists in the delivery of dialysis care, QI may be one potential way to reduce this variation and impact on clinical outcomes

Chapter 4.1: Effect Of A Quality Improvement Program To Improve Guideline Adherence And Attainment Of Clinical Standards In Dialysis Care: Report Of Outcomes In Year 1

This study addressed the question of whether QI methodology can be successfully used to improve attainment of clinical quality of care indicators in a dialysis population. The indicators were chosen because they have been shown to have an association with outcomes. The QI methodology chosen for this study, the IHI breakthrough series, is well-established. The study found that using QI was successful in improving attainment of clinical indicators, with no deterioration in other clinical indicators, and no improvement in clinical indicators in a non-intervention group. A key feature of this project was the role of frontline staff in designing and implementing changes to care, in order to build a “change package” of proven interventions to improve care. In addition, despite the additional resource required to conduct the work, improvement to clinical quality can result in significant financial savings.

Chapter 4.2 Effect Of A Quality Improvement Program To Improve Guideline Adherence And Attainment Of Clinical Standards In Dialysis Care: Report Of Outcomes In Year 2

This study looked at the outcomes of a second year of quality improvement in our dialysis network, to evaluate both further de novo projects and whether improvements could be “spread” between units within a network. Using the same methodology as year 1, this found that QI was an effective tool. An important learning point however was that even when proven interventions exist in the form of a change package, this needs to be tested and adapted to local contexts. A key feature of this project and the outcomes of phase 1 were that the use of medications, such as ESA for anaemia, and phosphate binders, did not significantly increase. This demonstrates that improvements to care are multi-faceted and occur in a real-world context, and require more than evidence from clinical trial data to be successful.

Chapter 4.3 Improving Patient Safety In Peritoneal Dialysis Using A Quality Improvement Initiative To Reduce Infections In A UK Renal Network

One of the questions that arises from the use of quality improvement at a “front-line” level to improve outcomes is how potential changes to care can be identified, and the influence of local contexts. This study analysed peritonitis reduction in more detail. Using QI effectively requires multiple techniques- baseline local audit was key to driving improvement, whilst other factors such as MDT working, patient-facing strategies, local influencers and senior leadership support can empower teams and enable a culture shift to take place within the team.

Chapter 4.4 Factors Leading To Optimising and Sustaining Dialysis Unit Clinical Performance In Achieving Adequate Dialysis Dose In Haemodialysis Patients

Whilst there is a body of evidence from a variety of healthcare contexts for the effectiveness of QI techniques in improving outcomes, reports on the sustainability of improvements are relatively scarce. This study analysed 2 years follow up data for attainment of target URR and found that the improvement was sustained, even though there was significant contextual upheaval (in the form of staffing changes) in the units, and not all changes to processes of

care were sustained. Several processes were embedded into clinical practice however, and this is key to sustaining improvements.

Chapter 4.5 Sustainability of an intervention to reduce catheter-related bacteraemia in a renal network: Lessons from a quality improvement initiative

This observational follow up study found that there was a sustained reduction in bacteraemia after completion of the QI programme but an increase in bed days and morbidity. This suggests a changing clinical profile of either the infections themselves or the patients who were getting infections. Most notably it highlights the importance of ongoing continuous review after successful QI initiatives to identify further challenges to improve care.

5.3 Overall summary

This study has demonstrated that quality improvement methodology can be used to improve clinical indicators in dialysis care, with some evidence from hospital admissions data that this can improve morbidity. Importantly, understanding of local processes, barriers, organisational structures and local data are key to motivating teams to take ownership of a problem. Changes to care frequently involve a series of complex steps that required structured implementation efforts. Key to sustaining improvements is embedding changes to practice into routine clinical care and ongoing ownership of the problem by frontline staff.

5.4 Limitations

This is an analysis of a quality improvement project that took place in a real world context, therefore was an uncontrolled study. In particular, it was not possible to control for confounders or external contextual factors, such as other improvement work being conducted within the department. The study also did not conduct a formal qualitative assessment of the programme, such as by interviewing staff, to better understand the reasons for the results.

CHAPTER 6: FUTURE STUDIES

There is one future study underway that is related to this thesis.

Three years follow up following implementation of a programme of quality improvement to reduce peritonitis rates in a PD population. Analysis of trends, organisms and outcomes

This study aims to look at the sustainability of the peritonitis QI programme for three years since completion of the QI initiative.

Other potential studies:

In order to better evaluate the outcome of the QI programme, it is necessary to review all clinical indicators in all dialysis units in the network. The reasons for this are twofold- firstly, to identify if there is any negative impact on other parameters when specific indicators are being targeted. Or conversely, to identify whether there is any benefit to wider clinical care with the use of QI.

Another future study that would be important to better understand the success of the improvement project would be a qualitative analysis of the culture and context within the department. QI activity, by its very real world nature, takes place within a broader context of a constantly changing organisational environment, at a microsystem and macrosystem level. Understanding the context in which the improvement work was conducted would also potentially benefit the design of future improvement projects.