Imperial College London

Low Value Care in Surgery

Thesis submitted for PhD

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Declaration of Originality

I declare that the research described in the present thesis were undertaken by myself, under the tutelage of Professor Elias Mossialos, Dr Joachim Marti and Professor the Lord Ara Darzi. This thesis and the work described herein, is my own except where explicitly referenced and has not been submitted for a higher degree.

Malik, Humza T - Aug 14 2019

Copyright Declaration

Abstract

Background

Value has been defined as the ratio of quality outcomes to cost. Perfect value would represent infinitely beneficial outcomes associated with minimal costs. Of interest to the present study are interventions where outcomes are minimal, and costs may be high as they may provide an opportunity for disinvestment, improving the overall value of care whilst providing efficiency gains.

Methods

A Scoping Narrative Review was performed in order to understand incumbent approaches towards dealing with low value care. International lessons from different processes were identified and encompassed into a conceptual logic orientated framework for de-adoption. To identify low value care in surgery a Systematic review of peer reviewed high-level literature was performed to identify candidate interventions for de-adoption. Subsequently a granular assessment of the behaviour of passive de-adoption was performed through a retrospective longitudinal observational study based upon administrative hospital data.

Results

A comprehensive conceptual model that takes an integrated approach to de-adoption was assembled from lessons learnt when dealing with low value care previously. It identified three stages in the de-adoption cycle which are necessary for success: identification, implementation and re-evaluation. Each process should be performed at multiple planes: national (macro), local (meso) and provider / patient (micro) levels in order to have a holistic effect. The identification of low value interventions may be from exploring peer reviewed literature, as demonstrated from the systematic review or exploring geographical variation of care. Said review identified 71 low value procedures, of which 5 interventions which carried the highest economic burden were postulated to cost the health system £135 million per annum. Subsequent granular review identified that passive levers have not resulted in de-adoption of a surgical low value interventions – e.g. delayed cholecystectomy. This is due to the presence of exnovator providers whom are concurrently de-adopting innovative interventions as other providers are adopting them.

Conclusions

Low value care represents a significant burden in the current health service. This thesis has evaluated its incidence and economic burden in general surgery. Service transformation is necessary and may be achieved through the holistic integrated approach recommended here. Policy makers have already sought this novel information and encompassed it into national policy, with the objective of achieving higher value care through effective de-adoption.

Contents

Data Access Request Service (DARS) Application

1: General

Request Number	DARS-NIC-72318-M4W8J-v0.11
Request Title:	Evaluating the Rate of Deadoption of Interval Cholecystectomy, a Low Value Intervention, and Diffusion of Index Cholecystectomy, a High Value Intervention
DSA Start Date	05/07/2017
DSA End Date	05/07/2018

1a. Summary

Reason for Referral to Approval Group: Independent Review – For Recommendation

Agreement Type Application: New

Summary of data changes

1b: Data Controller(s)

- **Imperial College London**

Data Controller Imperial College London

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Organisation Type: Academic

Data Controller Type: Sole Data Controller

HSCIC Framework Contract Reference:

Contract Expiry Date:

Security Assurances for Data Controller

Type: IG Toolkit

Version: 14

Date Completed: 30/03/2017

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Chapter 1

Introducing Low Value Care

Study Objectives

Clinicians, patients and providers have a myriad of conflicting goals with regards to healthcare resources. It has been suggested that to unite all groups' objectives a greater emphasis on value of care delivered is key, thus reducing costs, improving health of the population and improving care experience. The present study aims to bring the topic of low value care to the fore of thinking in current English Surgical Health Policy; to identify low value surgical interventions and offer a means of de-adoption when supported by best evidence. Although motivation is financially clear there are mixed emotions in encountering this from the clinical community. The overwhelming effort should be to make a change in current health policy, thus impacting both financial objectives of money saving but also improving care quality by reducing low value care.

The study is organised around central concepts of low value, which in this study is considered to be an umbrella term that encompasses concepts of 'medical waste', procedures that are 'clinically ineffective', 'cost ineffective' or 'obsolescent.'

Study Context

Improving value for money is not a new ambition of the National Health Service, with the National Institute of Health and Clinical Excellence (NICE) commencing a formal agenda in the area in 2006. (1) More recently the international 'Choosing Wisely' movement has aimed to address this issue; with the objectives of promoting of physician and patient conversation to reduce unnecessary interventions. (2)

Refraining from ineffective practices has the rare potential to both improve patient care and concurrently reduce the cost of care delivery. The initial problem lies with identifying universally low value interventions. A commonly used method is to assess the evidence upon which the procedure is recommended. Since Archie Cochranes' initial insights we are guided to practice evidence-based medicine thereby choosing to 'implement technologies guided by evaluation, especially randomised controlled trials.' Therefore, as clinicians we are taught from an elementary level to base our decision making on published knowledge. However, 'best evidence' is a dynamic concept. There are obviously trends and practices that become outdated. These low value procedures, also known as medical 'reversals' have important implications for current use.

An example of the is the use of interval cholecystectomy. Surgical removal of the gall bladder is gold standard for the treatment of acute cholecystitis and gallstone pancreatitis; it is the timing of said intervention that has attracted debate. Surgical orthodoxy until circa. 2010 dictated that when a patient was admitted with acute cholecystitis or indeed gallstone pancreatitis they should be resuscitated, treated medically and subsequently re-admitted at an interval for surgical resection. However recent evidence has questioned this approach, with equal outcomes and superior cost effectiveness for an index admission operation (3, 4, 5). The previous concerns of increased risk of complications and bile duct injury have been disproved.

The monetary burden of delayed surgery is significant. In 2014 there were 72 572 admissions with right upper quadrant pain, with a 30-day readmission rate of 16.75%, which amounts to a total cost of £13 546 200 (6, 7). Further, savings of £820 per patient with index cholecystectomy have been estimated. (Caution must be taken here given the cited study is a German RCT and costs were calculated based on Diagnosis Related Group classification of

Germany in 2010 (8)). Therefore, with 72 572 non-operative admissions with right upper quadrant pain even if 80% of these patients were operated on acutely (a conservative estimate of operative suitability) then potentially £47 607 232 could be saved per annum (10, 15).

Despite this knowledge the more resource intensive interval cholecystectomy is still being commonly performed. It may that the current reimbursement incentives are not inviting hospitals to change practice – whereby a trust may be paid twice for interval cholecystectomy but only once for index. Such arguments make the argument for de-adoption of this low value intervention stronger. Other concerns such as the lack of radiology / gastroenterological support is questionable, given the recent findings of the getting it right first-time movement which has demonstrated significant variation with some trusts able to perform index cholecystectomy in up to 80% of cases. Another reason for persistent use of delayed surgery is the clinician's role – the surgeon making the decision ultimately does not want to change practice; preferring incumbent traditions that have not caused problems in preference to perceived hazardous interventions. This aversion to risk is likely to play a role in decision making and will impede alteration of practice – stressing the importance of the role of the decision-making clinician in successful deadoption.

Another example is inguinal hernia repair for the minimally symptomatic individual. Classical teaching promotes surgery to prevent hernia strangulation, which in itself carries mortality. However, two contemporary randomised controlled trials have demonstrated that in the short term watchful waiting is as safe as surgical repair, with the rate of hernia accident (incarceration or strangulation) being 0.11% in the over 65s, thereby illustrating that inguinal hernia repair is a low value procedure (9, 10). It should be noted that long-term follow up from the North American hernia trial suggested there was significant cross over from study arms, with a significant proportion of patients requesting surgery following conservative management previously. (11). Conversely, Kaplan-Meier estimates from said trial demonstrated that after 10 years 32% of patients would still be suitably managed without an operation. Given that there were 54 894 hernia operations performed in 2014 in the UK, at a cost of £1612 per patient, potentially 17 566 procedures may be considered low value with £28 316 521 of efficiency savings (7, 12, 13).

This example demonstrates the importance of the procedure being offered within the appropriate clinical context and it should be the clinician's responsibility to align practice within this context. A surgeon should attempt to identify those persistently symptomatic individuals who would gain the most from repair and aim to provide high value care to them in contrast to those scenarios where a patient may only have cosmetic concerns. Furthermore, blanket deadoption of inguinal hernia repair would result in less uncomplicated day-case operations with optimal outcomes and an increase in emergency surgery where further complications such as bowel resection may ensue; carrying its own burden of cost and overall poorer outcomes to the patient. Evaluation of the value of emergency hernia repair at a population level is difficult as in the developed world most of the inguinal hernia are repaired before they ever cause a problem, however in order to consider elective hernia repair as low value its alternative should be fully assessed.

It is therefore important that disinvestment in low value interventions should be framed within the correct clinical populations to whom the intervention is of little benefit. This has the advantage of promoting pertinent deadoption whilst preventing blanket deadoption which would result in many high value interventions being reduced. The challenge lies in identifying those cases where clinical context dictates the intervention as low value; which is a duty the responsible surgeon needs to undertake.

National strategy should seek to reward effective clinicians for delivering highest value care, setting precedent for colleagues to follow. Other supply side policy interventions could then further encourage the deadoption of low value interventions; particularly at a population level. Clinical decision support, clinician education and feedback would all impact to encourage the disinvestment of ineffective interventions with overall improvement in patient care.

Policy makers may also consider demand side interventions to aid deadoption of low value care. These would target the patient in attempt to control the culture of belief that 'more care is better care.' Yet most evidence regarding consumer education campaigns comes from research on underuse; with findings suggesting that such efforts are weak instruments for changing patient behaviour (14). Alternative routes may be to share the cost of care with the patient, however this challenges the very nature of the health service that is offered here in the UK. Furthermore cost sharing will cause for reduced use of both high and low value services as it is unlikely the patient will be able to decipher between the two. Again the role of the clinician becomes important, they can guide the patient through education to the importance of pertinant use of resources and therefore take a lead in the control of low value interventions.

The motivation of said thesis is driven by such examples, whereby there is conflicting behaviour between clinicians, evidence and policy. Furthermore there is a distinct lack of understanding in the drivers of persistent use of low value interventions and other approaches to de-adoption. Therefore the present study will seek to identify low value interventions, understand previous methods of de-adoption of low value interventions and create a framework that may offer a logical process to deal with low value interventions. A granular assessment of a single low value intervention will then be performed to understand incumbent processes that exist which may be addressed through policy. With this new knowledge on previous successes and failure it is the objective of the study to introduce new policy levers that may instigate change, as set out in table 2.

Previous Approaches to De-adoption

With a grounded understanding of low value interventions that are being used the next step would be to ask what the best method of de-adoption should be ? Ultimately a well-informed tool that may be functionally applicable which identifies the best method of de-adoption would be the objective. In order to create this a narrative review of previous efforts of de-adoption, both locally and internationally will be performed. This will then offer an idea of the tools, those changes which permitted change and also an understanding of those changes that inhibited change. A number of passive and active approaches have been used previously with mixed success. This narration will learn from previous experience in order to assemble a model of de-adoption.

Identification

Therefore, beyond defining theoretically and conceptually what encompasses low value care (as has been presented) concrete interventions that are currently being practiced need to be identified. In this context, an initial step would be to establish a systematic and transparent strategy to identify low value clinical services for review, with reference to general surgery. This identification of interventions should include those interventions which may achieve similar goals of quality of care at a higher cost as well as those that do not confer improved outcomes. This will be an effort to highlight differences between optimal practice and current practice.

Model of De-adoption

The ultimate aim of the narration will be to create a framework of de-adoption that may be applied in order to attain appropriate de-adoption of low value interventions. Although the framework in essence is likely to be conceptual – it may offer opportunities to have evidence supported disinvestment and therefore significant health policy implications, that is the ultimate aim of the present study.

Evaluation

The next step will be then be to evaluate the role of these low value interventions, by means of evaluating their impact both on our patient population (in terms of measuring the frequency of use of these interventions) as well as the impact on the health budget (by estimating the monetary significance of the continued use of these low value interventions.) The ultimate intention will be both to estimate the burden of these low value interventions and also guide policy onto which interventions to focus for the greatest gain.

Granular Behavioural Assessment

Once an idea of low value interventions is attained a detailed understanding of low value interventions will be necessary. The target here would be to examine the rational behaviour of current clinicians to change surgical practice. Given the immense academic scrutiny applied to the diffusion of innovative ideas the present study chooses to attempt to evaluate non-diffusion, or de-adoption of antiquated innovations, in particular in attempt to model those procedures that have been previously proven to be inferior and evaluate the practice of de-adoption.

These objectives are summarised in Table 2

Table 1 - Summary of Study Objectives

Study Title	Objective of Study	Research Questions	Information Source	Methodology
International Approaches to Low Value Care	To Gain an Understanding of the current health policy landscape in managing Low Value Care	How have various high-income nations addressed the problem of Low Value Care? Which Interventions have been Utilised? Have there been any Successful Interventions that may be learned?	- Peer Reviewed Literature - Policy Papers	Scoping Narrative Literature Review
Functional Framework to Guide the De-adoption of Low Value Interventions	To Compose a Framework by which De-adoption of Low Value Interventions may be employed. This framework may serve as a benchmark for future disinvestment campaigns to prioritize, identify, implement and evaluate their likelihood for success.	Which Strategies may one employ in order to effectively De-adopt Procedures of Low Value ?	Key Findings from Scoping Review previously Performed	Logic oriented Conceptual Framework
Identifying Low Value Care in General Surgery	To perform a systematic and transparent review that Identifies Potential Low Value Clinical Services for Review,	Which General Surgical Interventions are Low Value? What is their Incidence and Monetary Burden?	Multi-Platform Search - Peer Reviewed Literature - Targeted Database Search	Systematic Literature Review

	with reference to General Surgery		- Opportunistic Sampling National Reference Costings	
Evaluating Trends in Use of Early [EC] (High Value) and Delayed [DC] (Low Value) Cholecysectomy for Acute Cholecystitis and Gallstone Pancreatitis	To perform a Granular Assessment of the Passive behaviour of Providers to an Established Evidenced Based Surgical Innovation which demonstrates Superiority over Incumbent Practices	Is there any Evidence of De-adoption of Delayed Cholecystectomy and Adoption of Early Cholecystectomy in England - Ie. Has there been a Change in Practice ? What are the Trends of De-adoption of DC ? Are there any Characteristics that individual Providers Demonstrate which may result in their behaviour ?	Administrative Dataset of Patient Level Data (Hospital Episode Statistics)	Retrospective Longitudinal Observational Study

Defining Low Value

"Primum non nocere"

Non-maleficence, the original ethical principle outlined by Hippocrates imparts the objectives of the perfect health professional. That is the need to provide optimal care for our patients and avoid harm in the first instance. One may argue that harm is also represented by imperfect care, non-optimal treatments. It is this idea which is represented by low value.

Value of care has been defined as outcomes achieved over unit cost spent. Outcomes (the numerator of the equation) are multi-dimensional beyond the individual disease, with costs (the denominator) representing the total costs of the patient's cycle – often requiring extra costs in one domain of patient care resulting in a reduction of overall costs of the patient's journey. (15)

Full value will be extensive beneficial outcomes for minimal costs. If value of care is placed at the forefront patients will benefit primarily as they will gain from optimal care in the most efficient method. Unlike quality of care value acknowledges cost. This key alteration in principle provides an opportunity for a national approach to care as opposed to care directed at the individual – thus placing its relevance in health policy. (16)

The initial definition of Value was offered by Porter et al. in 2008 (17). He used this definition to project the importance of assessing and measuring outcomes to inform medical care, particularly in the United States. Improvements in value would fundamentally benefit patients, with secondary improvements on efficiency and benefits to providers and policy makers. Therefore, all stakeholders within the health system would thrive where value was maximised. As value is measured according to outcomes and not inputs, the emphasis would be on optimal care as opposed to volume of care. Thus, the ideal health provider would not have treated huge numbers of patients but treated a fewer number of patients well, without the bane of complications and repeated admissions – both costly and difficult to manage. It is also important to note that value is not static and may vary with the individual interpreter's disciplinary background (e.g. clinicians vs. policymakers), focus (individual patients vs. population) and attitude.

Further descriptions of Value have been adjusted, most notably the description by the Right Care group, who identify three types of Value. Firstly; personal value, this reflects the individuals gain from an intervention / procedure – high value would be efficient appropriate care with optimal outcomes. Secondly: technical value; also regarded as technical efficiency, making sure resources are used most efficiently with minimal waste. Thirdly is allocative value, taking a population viewpoint to ensure that resources are allocated equitably thus ensuring the each member of society is allocated equitable value of care. (18)

Improved value has been regarded by some health providers simply as another synonym for 'cuts', 'cost reductions' and 'efficiency savings.' It is important to separate this view from the theoretical benefits of value. If cost savings were the primary objective made in the absence of improved patient outcomes then any gains may well be false, with inappropriate care being offered ultimately resulting in reduced benefit to the patient.

Improving value through the de-adoption of low value interventions may offer an avenue of salvation for struggling health budgets. Thus formulating a framework that identifies and de-adopts interventions with little or no benefit becomes pertinent – which serves as the motivation for this present study.

Different phrases and approaches have been used to describe 'Low Value care', each with a slightly different approach to the same problem. Its synonyms include "inappropriate care,"(19, 20, 21) "unnecessary care,"(22) "overuse," "overtreatment," "overdiagnosis," "misuse," or "waste" (16, 23), and 'medical reversals.'(24). Thus, the phrase 'low value' should be considered an umbrella term for all health care with little or no benefit to the patient.

Overuse / overutilisation can be considered as the efficacy of treatment; particularly when considered under the auspices of small area geographical variation. Here overutilisation will be demonstrated as excess intervention, suggesting that some treatment when offered is not necessary (25). From an individual patient point of view overuse may be considered to be the use of excess investigations, treatment that does not improve outcomes for said patient, thereby encompassing the value paradigm. Overuse represents a key principle of clinical heterogeneity in low value care evaluation – often an intervention is effective in certain clinical scenarios and 'overused/misused' in another; clinical context defines the appropriate value of care. Thus, it is crucial that an intervention is framed in the correct clinical setting in order to define its value accurately.

Appropriate care has been defined previously by the RAND corporation as an intervention whereby the benefits of the intervention outweigh the risks by a considerable margin such that the intervention is worth doing, in the presence of well-established indications for a procedure (26, 27). Thus, inappropriate care would be where indications for treatment is limited and the risk of harm to a patient outweighs possible benefits. It does not take into account costs. Similarly, 'unneccesary care' is considered to be diagnostic or treatment service that provides no demonstrable benefit to a patient. (28) The 'appropriateness' of an intervention has also been defined by ISQua (International society for quality in healthcare) as a combination of the 'indication' (I.e. to do the thing right] and 'procedural quality' [doing the right thing] Both combined are the 'process quality'. This standpoint demonstrates that poor care may relate to selecting the wrong procedure / technology or indeed performing an effective procedure on the incorrect patient subgroup. (29)

Medical 'waste' has also been identified as care which does not confer a benefit for the patient but may carry a risk. In theory medical waste may occur if the physician is misinformed, if the patient is misrepresented and/or the physician succumbs to patient demands. Ultimately where the patient's benefit is not placed at the forefront of decision making. Economic medical 'waste' is defined as care where the value of benefit is less than the expected costs. Here the cost effectiveness of the chosen technique is inferior to an alternative intervention, i.e. the present intervention is lower value then an equally effective alternative. Waste has also been described to be broader in definition encompassing inefficiency due to failure of care coordination, administrative complexity, pricing failures as well as fraud. (30)

My opinion is that value should be regarded as an umbrella term that encompasses all the aforementioned concepts, taking a top down approach would result in imperfect quality whilst incorporating sub-optimal costs. Thereby using the definitions to create a framework. (Table 1). It is important to recognize that this framework provides a structure to review low value care; often the boundaries between each sub-group are not obvious with a low value intervention taking place in several categories at the same time. The framework thus separates low value interventions loosely into those which are clinically ineffective, those whose use results in greater harm then benefit, those interventions where there is insufficient evidence to support routine use, interventions which are outdated / obsolete and those which are cost ineffective.

Framework to Define Low Value Care

Table 2 - Framework to Define Low Value Care

<table>
<tr><td rowspan="11">Low Value Care</td><td rowspan="8">↓ Outcomes</td><td rowspan="4">Clinically Ineffective</td><td>‘Medical Waste'</td></tr>
<tr><td>‘Overuse'</td></tr>
<tr><td>‘Overutilisation'</td></tr>
<tr><td>‘Strong Evidence vs Weak Evidence</td></tr>
<tr><td rowspan="2">Harm > Benefits</td><td>‘Inappropriate Care'</td></tr>
<tr><td>‘Misuse'</td></tr>
<tr><td>Obsolescence</td><td>‘Medical Reversals'</td></tr>
<tr><td>Insufficient Evidence</td><td>‘Misuse'</td></tr>
<tr><td rowspan="3">↑ Costs</td><td rowspan="2">Cost Ineffective</td><td>‘Economic waste'</td></tr>
<tr><td>‘Costly with similar outcomes'</td></tr>
<tr><td>Non-Compliance</td><td>‘Broad definition of 'waste'</td></tr>
</table>

Clinically Ineffective

These are procedures / techniques / investigations which are ultimately not in the best interests of an individual patient. Effectiveness must be evaluated with strong evidence in comparison to an alternative to justify use. NB. An alternative may be simply to offer no treatment / investigation etc. 'Overuse' and 'overutilisation' whereby the 'indication quality' is unsuitable are all examples of clinically ineffective care

Harm > Benefit

This subgroup are those interventions whereby the benefits of the procedure are outweighed by risks and possible harm. It represents the RAND definition of 'appropriate care,' whereby a measureable demonstrable benefit must be relevant for the patient.

Insufficient Evidence

These are often newer, experimental treatments justified by logic but not by currently supplied by the necessary evidence to justify use. This also represents practice which have been entrenched in medical teaching without being subject to the modern rigor of evidence based medicine.

Obsolescent

These are antiquated interventions reliant on aged data for their use. It also encompasses the idea of a medical 'reversal', whereby newer more relevant evidence has outshone previous evidence and ultimately changed practice. Those therapies which were previously considered effective now considered unsuitable and thus low value.

Cost ineffective

This subgroup are those procedures which do offer value to the patient but not optimal value in compared to a suitable alternative due to their inherent cost. This category focuses on the denominator of the value equation, and therefore increased costs results in falling value. It is important to note that with time and improved efficiency these treatments may well become effective and no longer low value. ‘economic waste.’

Non-Compliance

This represents services which are inefficient and not in line with expected avenues of care and clinical guidance. This encompasses the broad definition of ‘waste’(d) interventions to include inefficient administrations, inefficient care pathways and pricing failures as described by Berwick et al. These will all result in excess costs and ultimately lowered value of care.

Origins of the Value Equation

Patients and clinicians are often alarmed by stories of struggling NHS budgets and pessimistic financial outlooks such as the expected £30 billion funding gap in the English National Health Service (NHS) by 2020/21(31). In response health care reforms have offered remedies that often only offer short-term solutions. (32) In order to establish sustained cost reduction over time that changes ideology and moves care from volume to value the 'quality' of care movement should be understood.

Quality

An updated definition of quality was outlined in the Institute of Medicine's 1990 report: 'Medicare a strategy for quality assurance' whereby quality was defined as:

> *'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.' (33)*

Prior to conversations about 'value' in healthcare the focus was on 'quality' of care. These were underpinned by Donabedian's conceptual framework that was initially described in 1966. (34) This concept outlined a triad of 'structure, process and outcome' in attempt to evaluate the 'quality' of care.

'*Structure*' is the setting, financing, buildings, equipment and administrative systems of providers through which care proceeds. It is the context through which care is delivered. These factors control how providers and patients interact within a healthcare unit. '*Process*' describes the transactions between patients and providers, the sum of all actions that make up healthcare. These include diagnosis, treatment, aftercare as well as patient education and preventative measures. It can further be subdivided into '*technical*' processes of how care is delivered as well as '*interpersonal*' processes – which is the manner of how care is delivered. (34)

'*Outcomes*' represent the recovery, restoration of function of both the individual patient and population. Outcomes are obvious indicators of quality, they offer concrete measurable objectives that an intervention is attempting to achieve. The concrete nature of these outcomes makes them amenable to measurement and comparison. However, these measurable outcomes are not always relevant to the process that is being assessed. An example of a commonly noted outcome is all-cause mortality, frequently measured in many oncological interventions however for a minor surgical procedure it may be irrelevant; furthermore, it does not take into account the outcomes which are more subtle and difficult to measure. Less discrete outcomes should also be considered, including patient experience.

It is from Donabedian's initial observations that the numerator of the value equation was highlighted.(35) This is because outcomes are seen as the culmination in quality of care, making the assumption that ideal structure will result in excellent process and optimal outcomes. Similarly, poor outcomes are influenced by flawed structure and process. Therefore, when considering the value equation one needs to understand the contribution of process and structure. 'This discussion of process and outcome may seem to imply a simple separation between means and ends.' (34) Despite limitations to the use of outcomes as criteria of medical care they are considered the 'ultimate validators of the effectiveness and quality of medical care,' as it is the overall objective of medical care, to improve one's measurable health. (34)

Notions such as ‘overuse’ of unnecessary care and ‘underuse’ of essential care became recognized as ‘quality of care problems,’(33) Therefore the study of variation by the Dartmouth group was also embraced within the quality discussion.(19)

Donabedian was also interested in the role of competition within the healthcare system. It has been described that those providers whom are unable to offer optimal quality, cost-effectiveness and beneficial outcomes should be permitted to fail as patients seek alternate options. This healthy competition results in the exit of sub-standard players with the services displaced to superior alternatives. The net result is improved quality of care, at lower costs that are beneficial to the patient and population. Yet this idea of permitting hospital services to be disbanded is something that is not readily accepted by the public or even considered in a single payor system.(34)

There have been initiatives to improve quality, including the US governments’ quality review based on geographical variation as well as the formation of organizations to develop accreditation and examine quality of care in the outpatient departments (20, 21, 22) Brook argues that despite these measures progress in this subject is questionable, with no comprehensive report in their improvements in care. It is argued that quality is now defined ‘with more validity and reliability but there is little information about which mechanisms for improving quality work better than others.’(16) Health Policy has found difficulty in gathering evidence that confidently evaluates quality and incumbent methods are unable to account for differences in patients context; there is often a positive skew in regions where patient populations are better-educated with higher incomes and less complex comorbidities.(23)

Given the difficulty in comprehensively measuring and defining high quality of care, and the presence of struggling health budgets the focus shifted from purely improving the health of the patients to refining health *and* establishing a business case for quality. Therein an alternate method of evaluating quality was conceived.

Consequently, the nexus of quality and cost became relevant. That is the need for optimal health outcomes provided at minimal cost; within which lies the value equation – maximal outcomes achieved per unit pound spent.

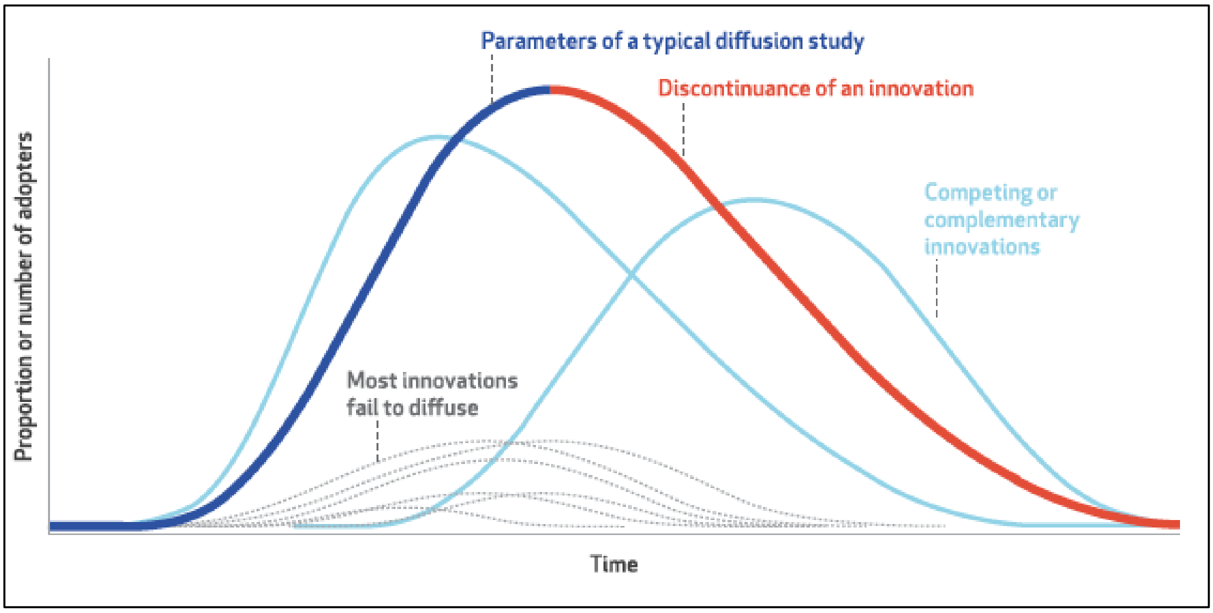
Innovation

Innovation dissemination is a concept that has been evaluated extensively in academia. Most distinctly is Everett Rogers' 'Diffusion of innovations' philosophy which describes the 'S-shaped curve' after reviewing farming practices in Iowa in 1962.(36) This initial work has remained prominent as it offers simple concepts that have a practical impact when considering novelties in industry.

The classical definition of 'diffusion' involves an 'innovation that is communicated through certain channels over time among the members of a social system', it is a social process that occurs among people in response to learning about an innovation, such as a new-evidence base to treat a patient. (36) The key variables within this model include time of adoption, adopters and ability to implement. Initially an Innovation was regarded as an idea or practice and adopters were the individual practitioners. Beyond this an innovation has been conceptualized to be a movement that behaves as a 'product' which is judged in a cost: benefit circumstance in order to make decisions on adoption. (37)

Rogers graphed cumulative adoption against time, resulting in the formation of an S-shaped curve. (Figure 1 – blue slope) The curve represents an initial slow rate of adoption in turn giving way to an exponential uptake of the idea after the intervention has achieved consensus, followed ultimately by another slow phase where few non-adopters remain. This elegant theory predicts diffusion of a successful innovation in the majority of instances, however there are exceptions to the rule.

Figure 1 - Everett Rogers' Diffusion of Innovations S Shaped Curved (41)



In health policy if there are national incentives or attention towards a certain idea the initial 'lag' phase may be shorter. Alternatively, if the idea is not immediately relevant the initially shallow phase may be longer. Therefore the point of consensus, where wholesale change in practice occurs as a result of widespread opinion acceptance is important – as this represents the 'take-off' and can heavily influence how rapidly an innovation is brought into routine practice.(38) Therefore influences on the initial 'lag' phase are crucial to the diffusion of a practice, particularly when the complete curve is considered.

Other concepts of innovation diffusion are displayed in the aforementioned figure. The roles of competitors should be considered, these complimentary / destructive innovations may influence the consumer and are relevant to cumulative adoption of the primary innovation. Where the competitor is complimentary the lag time may be shorter, it may also influence the gradient of incline in the 'lag' and 'exponential' phases.

Failures are important, as the majority of innovations never reach the general consensus and are not wholly adopted – diffusion is an atypical outcome. The impact of failures on the successful innovation needs to be considered, a competitive failure may extend the ‘lag’ time of an innovation.

More relevant to the present study is the nuance that adopting an innovation often means abandoning a previous one, therefore the end of the curve – which is often not considered – is important. This has been described as the ‘undiffusion’ curve or alternatively the ‘de-adoption’ curve.(39) The shape of the ‘de-adoption’ curve has not been demonstrated, the cumulative frequency of abandoning a procedure should be plotted to see whether it is the mirror of the adoption process or whether it displays a different character. This knowledge is central to the discussion of disinvestment in order to understand the best methods of removing a low value intervention from practice.

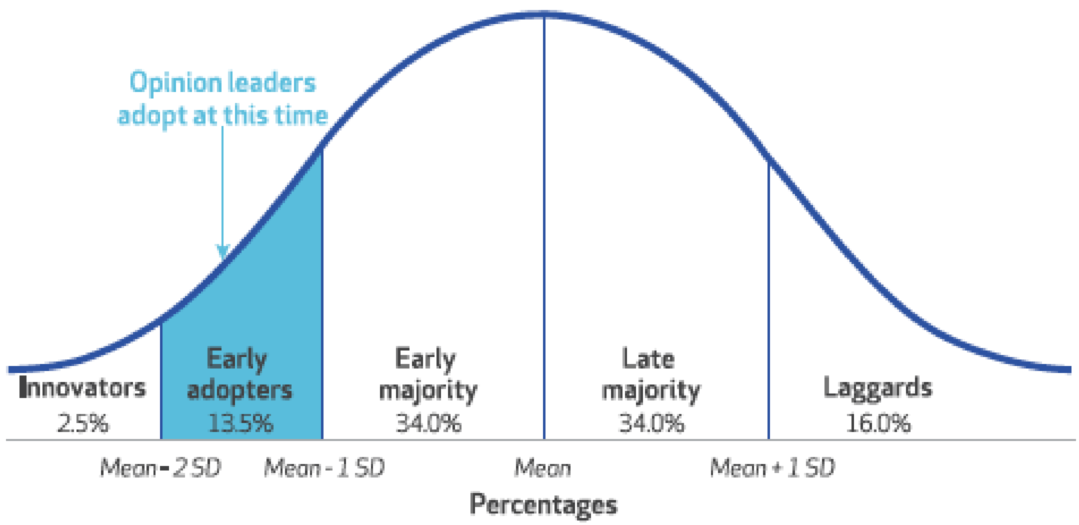
Often the concern with innovation is its inability to diffuse rapidly. Examples are extensive, historical examples include slow diffusion of the life-saving sauerkraut diet in combat of scurvy by the innovator Captain James Cook of the east India company, which took circa. 48 years to become incorporated into routine practice.(40) More recently the ‘greenhouse model’ of nursing home care, that offers a succession of developmental changes within nursing homes with the objective of empowering residents’ control in decision making.(41, 42) The evidence-based greenhouse model is considered a successful innovation, yet despite generous funding, the predicted number of 300 nursing home models using this intervention by 2018 is still minimal, particularly when considering there are 15, 583 facilities which should be offering this mode of treatment. Therefore, this innovation that has been present for 14 years, has not reached the exponential phase of adoption.

In order to understand what impacts rate of diffusion, the individuals that are responsible for adoption should be considered. The influential members of the social system, the so-called 'change agents' and 'opinion leaders' impart knowledge by influencing an adoption decision. Opinion leaders are those who have capacity to tip the balance of general consensus. An example is the outlook towards tobacco smoking and its prevalence. Traditionally smoking was considered the norm, not viewed as dangerous to health. Yet with public advertisement through influential opinion leaders and national incentives (change agents) to improve population health public perception has changed. The normative state was now altered, I.e. smoking not accepted publicly – this has resulted in reduced prevalence of smokers. (43, 44) This is further influenced by the community to which the innovation is applicable – those resource rich educated societies, with a greater concentration of professionals exhibit better ability to source, understand and make use of innovations. (45)

Furthermore, the attributes of the innovation itself influence its ability to diffuse smoothly. When an individual learns about a new product or idea, their initial response is to evaluate the idea, what are the benefits, what are the drawbacks and how easily can this be involved in my day to day practice – would this displace my current practice, is it superior to my current practice and if so how much bother would the entire replacement of practice cause me? Such interrogation results in an assessment of the 'pros and cons' of said innovation, that then influences whether the consumer would consider them fit for adoption, which in itself contributes to adherence and diffusion. Often the individual is not prepared to make these assessments personally but rely on their network of colleagues to offer guidance. This is where the prominence of 'opinion leaders' who offer trusted judgement to colleagues both locally and nationally. The heuristic nature of these individuals often reflects an emotional desire for status and that allows the decision maker to save time while reducing uncertainty. This also reflects the innate 'innovativeness' of individuals.

Rogers' meta-review categorised the nature and needs of individuals to innovate by their time of adoption. He described 'innovators' as the first to adopt, due to their exploratory nature and the excitement and novelty of the new idea. These personalities are followed by the 'early adopters', some of whom are opinion leaders – this is following a measure appraisal that an innovations advantages outweighs its disadvantages. Beyond these are the 'early' and 'late' majorities – represented by the majority of individuals who accept practice and incorporate it into their own when the innovation represents the norm. Finally, are the 'laggards,' these are those individuals who are not susceptible to social pressures, feel free to take their time but more importantly are more critical of the innovation, often identifying or considering flaws when others do not. (Figure 2)

Figure 2 - Distribution of Adopter Innovativenes based on Time of Adoption (41)



These descriptions not only apply at the individual level but may also be considered at a provider / trust level. There will be hospitals where innovations are readily welcomed by the structures that are in place, in contrast and more commonly there are less elastic institutions which require significant inertia to adjust practice. Often this inertia is not enough until there is enough national pressure to adhere to updated best evidence.

Another concept that illustrates the spread of an idea is the social ‘contagion’ process. At the periphery of the relational network are the innovators, those who are experimental in nature and often dispersed from societal norms / pressures. Central to the network are the ‘opinion leaders’ and ‘change agents,’ who observe the periphery and then adopt the innovation if they judge it to have important advantages. The majority are between the periphery and centre who observe the central opinion leaders and follow their expertise. Their actions are often ‘imitative’, in that they regard the actions of their ‘homophilus’ colleagues who share the same background, training and motivations.(36, 46) Therefore certain actions taken up by similar colleagues often results in ‘wholesale’ actions with movement into the exponential phase of the S curve. This virtual network that relies on organisation, community and the advice-seeking behaviour of a social system forms an outside-inside-outward movement of ideas that when graphed cumulatively represents the S-shaped diffusion curve. (47)

The academic model known as the ‘diffusion of innovations’ offers a practical and elegant concept to approach innovations within health policy, it also begins to explain the motivations of policy makers and offers understanding as to the reasons why decisions are made or delayed. Of interest to the present study is what happens to an incumbent practice, that is institutionalised when confronted by a competing innovation that exhibits superiority or even new evidence that advises that doing nothing is superior.

Convention would suggest that the obstructions to de-adopting incumbent practices include preference for those interventions that are tried and tested, regret at leaving behind the sunk costs of treatment and potential loss of revenue. Yet the process of abandonment has not been investigated with similar fervour as has the interest in adoption. There is no coherent, detailed model for de-adoption that characterises the people involved in the process, the practice that drives it and a curve describing its progress over time. This is complicated by incoherent terminology that has been used in to describe this concept.

Although the presumption is that the 'de-adoption' curve will be the inverse of the diffusion curve an individual's natural response to 'gain' and 'loss' are not mirrored. 'Loss' aversion and 'risk' avoidance are ideas that will influenced a delayed and less elastic 'de-adoption' curve. That is when directly compared 'losses loom larger than gains.'(48)

Therefore, if the target of policy is transformation of service; through the de-adoption of low value interventions an understanding of innovation diffusion is pertinent. Beyond this the different avenues and descriptions of abandonment need to be considered. These include de-adoption, decommissioning, exnovation and disinvestment.

Disinvestment / Exnovation / De-adoption

> *"Men generally fix their affections more on what they are possessed of, than on what they never enjoyed. For this reason, it would be greater cruelty to dispossess a man of anything then not to give it to him."*

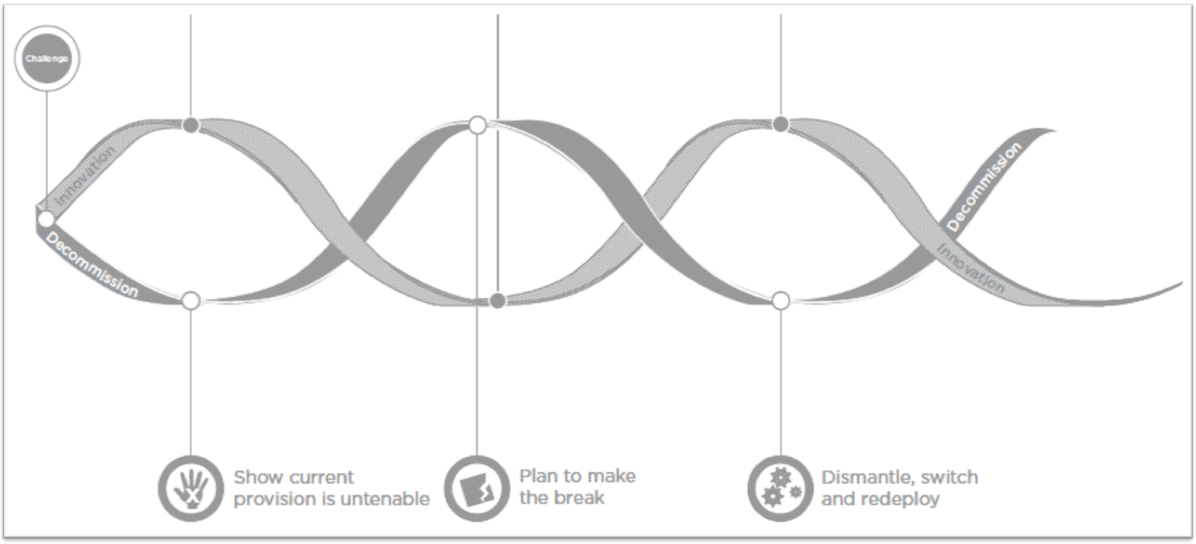
David Hume, 1826 (49)

Transformation of a service is a common ambition, whether within healthcare or the wider study of industry - a company is rewarded by its ability to seek a new avenue of practice fuelled by exciting research with the objective of disrupting the landscape of incumbent practice. It is for this reason much research and energy has been focused on this very change – adopting 'the new.'

However, innovations and their promotion are often insufficient for replacing established activities that are often still economically functioning. These antiquated incumbent practices should be progressively removed from practice yet often they persevere to prevent dynamic movements of a system forward. There are several examples of this, ranging from historical examples of Captain James Cook's fight against Scurvy(40) to the of the lack of penetration of renewable energy sources over the last 20 years despite political motivation (Ref German article) Therefore the focus on innovation should be complemented by due attention to abandoning practice– 'the old.'

The behaviour of innovation conceptually should be regarded as a spectrum of activity, with 'the new' exciting practices at the forefront or 'cutting edge' and 'the old'; antiquated interventions at the rear. For a well-functioning dynamic system, the curve would be very much heavily weighted at the front, lots of innovative procedures being performed. However, the reality is that despite extensive research and consideration to innovation the curve is similarly heavily distributed at the back, this is due to the absence of research and importance attributed to 'the old.'

Figure 3 - The Cylce of De-adoption taken from NESTA, The Art of the Exit, In Search of Creative Decommisioning (50)



With increased health care demand in the presence of an ageing population, increased levels of expectation amongst patients and the rising cost of new technologies the challenge to find options to aid government shortfalls has become more relevant. Therefore, beyond productivity gains the next logical step is for decision makers to disinvest in low value services and prioritise funding for specific high value services. (51)

An understanding of the conceptual nuances of de-adopting a practice should be considered. Till date the literature has a number of terms to describe this process of removing 'the old' these include 'de-aoption', 'disinvestment', 'exnovation' 'deimplementation' and at least 39 others (52, 53). It is important to devise a conceptual understanding of the different descriptions of such activities in order to accurately apply the correct terminology and attempt to orchestrate these nuanced differences into a conceptual framework. Furthermore, it has been argued that the language used to describe these approaches has a certain impact. ‘Disinvestment’ and ‘decommissioning’ are received poorly by patient populations in contrast to ‘de-adoption’ which although is received better does not encompass the full meaning of actions associated with it. (52)

Understanding 'Disinvestment'

The phrase 'disinvestment' has been inherited from industry vernacular into healthcare from as early as 1999 when the English National Institute for Health and Care Excellence was set up and recognized the need for such actions.(1, 54) Within industry the term was accepted as the removal of items which are now obsolete, including machinery and software etc. However, this binary stance is not applicable to the complex interactions within the healthcare industry.(52)

A commonly cited definition is from Elshaug and colleagues where disinvestment is defined as the:

> *"process of withdrawing (partially or completely) health resources from any existing health care practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain for their cost and are thus not efficient health resource allocations." (55)*

In essence, disinvestment seen as the antonym of 'investment' and involves either partial or full withdrawal of resources within a broad sense. Garner and Littlejohns consider disinvestment to be part of a broader agenda to improve efficiency and quality focusing on public health and prevention and ensuring that patients receive the right care at the right time in the right way"(1). Similar published considerations describe the role of disinvestment as being a reduction in service due to 'inappropriateness' as well as 'savings achieved through superior efficiency identified through benchmarking (eg. Lower cost for the same output).'(56) Frondsal and colleagues consider disinvestment to be at the end of Roger's innovation curve, where technologies which were previously embraced are no longer 'clinically or cost effective' and therefore withdrawn from use (57). Such description is also in keeping with the term 'Exnovation'.

Daniels et al. set out a framework to divide the nuances elements of disinvestment into ‘decommissioning,’ ‘restriction,’ ‘retraction’ and ‘substitution.’(58)

Decommissioning

Withdrawal or fully decommissioning of an intervention is where the funding of a particular service or treatment is removed, thus ensuring the service is no longer able to accept referrals. This is often the most controversial of approaches but is often associated with rapid results; however, in nature is difficult to implement due to often political obstructions. It is also associated with the complication of unmanaged substitution, that is the services that are decommissioned are not replaced, resulting in increased demand elsewhere within the health system (59). This unmanaged substitution may result in an overall increase in cost (60).

Retraction

‘Decommissioning’ represents the complete withdrawal of an intervention then retraction is considered the partial withdrawal of an intervention, so-called ‘partial disinvestment.’ This has the benefit of being met with less political reservations and is contemplated to mitigate the problems of unmanaged substitutions. This is conceptually representing the heterogeneity of interventions, whereby certain interventions are advised to be decommissioned with specific populations. A further benefit of retraction is the natural experiment that it offers, whereby the effects of withdrawal can be monitored ; successful approaches can then be rolled out to wider populations, alternatively barriers may be realized offering the opportunity to overcome these in the future.(61)

Restriction

Restriction of services to specific patient populations is also another element of disinvestment. Classically inappropriate interventions are not low value when given to an entire population, with high efficacy in certain patients and low in others. Attempting to manage the clinical heterogeneity is difficult without restricting services to defined sub-groups of individuals. This is difficult to manage both at a policy level as well as at a provider level because of the difficulty faced by front line medical staff in interpreting set criteria. Although there will be certain patients where the intervention is clearly indicated and contraindicated the majority of patient's land within a non-specific 'grey' area whereby historically patient choice dictates therapy. Restricting services in this way is often to maintain patient safety with the added advantage of cost-savings. The nature of this withdrawal of services has led to other descriptions such as 'rationing' which results in these actions being criticized by patients.

Substitution

Another form of disinvestment is substitution. This is the action of providing an alternative treatment or modality of treatment for a condition that is superior, efficient and more productive. This in turn results in cost savings. When regarded within the pharmaceutical sphere two modes of substitution were considered – firstly the generic prescription of a product that occurs after a specific patent has expired; this is often easily employed and not met with considerable obstacle offering savings smoothly. Alternatively, there is the therapeutic substitution of a drug with a superior, more effective cheaper alternative. (62) Although this is intuitively obvious this occurs less commonly, with delays in movement from traditional therapeutics to novel ones. Furthermore, substitution should be considered beyond medication prescriptions, the provision of community care in place of traditional inpatient care, clinical nurse specialists usurping the traditional roles of junior doctors and conservative treatment of previous surgical interventions for instance inguinal hernia repair may all be regarded as substitution (63, 64, 65).

Exnovation

The term was originally coined in American business literature in by John Kimberly in 1981 as the process 'whereby an organization decides to divest itself of an innovation that it had previously adopted.' (66) More recently it has been described more simply as 'reverse innovation.' Yet there has been some confusion as to the understanding this process confers with confusion between published business and health literature. (67)

Strictly speaking exnovation is the process of removal of innovations that do not improve organizational performance. This may be because they unsettle incumbent routine organizational performance, are too disruptive to routine operations and do not fit well with existing strategy. Consequently, exnovation applies the concept that occurs at the end of the innovation cycle. This is the idea that although an innovation is supposed to be universally superior (which is an inherent assumption when using the term innovaton) to the incumbent practice, and is initially welcomed and endorsed rapidly – after progression it was found not be in keeping with the ambitions of the department that have adopted it. As a result, the innovation is exnovated. Thus, the structural, organizational and behavioral responses to the innovation may not always result in acceptance and at the end of the life-cycle of innovation the process of exnovation occurs – it is for this reason it is considered the 'reverse of innovation.' Till date there has only been minimal reference to these activities in the academic literature to assess organizational influences of this behavior.(68, 69)

Exnovation of 'the new' interventions therefore are in response to the poor 'absorptive' capacity of a provider. (70) Health care delivery organizations have an inherent ability to accept and perpetuate 'the new' ideas, within which lies this notion that some innovations are not aligned with the organizations' 'internal capabilities' and furthermore do not contribute to external demands.

Front-line health care workers may well not welcome the innovation as it may be considered difficult, extra work and beyond their normal responsibility whilst not providing them with an overall reward. At a hospital level the external demands of the structure may not provide them the opportunity to endorse the innovation. At a national level, they may not be endorsed because of failings of political motivations to provide acceptability, due to lack of financial reward or motivation. The results of all of these obstructions may be that an initially endorsed 'new' innovation falls by the wayside. Cited examples include structured quality improvement and collaborative learning exercises that often have only minimal improvements on performance and patient outcomes.(71, 72, 73)

When retrospectively assessing exnovation it will always be difficult to distinguish removal of interventions because of leadership strategy or implementation failure due to inherent post hoc biases. Therefore, identifying the cause of exnovation is difficult.

Exnovation is different from ‘disinvestment,’ ‘retraction,’ and ‘de-adoption’ in that these terms reflect the strategic and deliberate abandonment of all incumbent organizational structures and processes whereas exnovation focuses solely on innovations; representing its position at the end of the diffusion curve. However others consider this also to be within the spectrum of disinvestment (57).

Although this difference is not well represented in the published (although minimal) medical literature, where it has been cited as similar in nature to de-adoption simply being incomplete. (67, 69)

Medical Reversal

This was a phrase introduced by Prasad and colleagues to represent an alteration in evidence base that results in abandonment of a treatment intervention to adhere to best practice.(24, 74) An example commonly cited is the use practice of percutaneous coronary intervention (PCI) in patients with stable coronary disease. This was considered the norm of practice until the publication of the COURAGE trial that compared the use of PCI with best medical therapy and found that an invasive procedure conferred no improvement in outcomes. Therefore, best medical practice had been ‘reversed’ from offering an invasive procedure back to classical treatment of optimal pharmaceutical therapy, resulting in the de-adoption of PCI for stable coronary disease. The implications of such ‘reversals’ are notable, as it implies that previous patients who were managed surgically were done so incorrectly during the years it was considered effective. Therefore, ‘reversal’ has conceptual similarities with exnovation, as it represents a change in practice that results in de-adoption at the end of the innovation curve although it is not strictly speaking applied only to innovations.

Niven et al.’s scoping review of the subject of disinvestment consolidates the muddled taxonomy of this topic. 43 terms were identified to have a similar definition, of those ‘disinvestment’ was most commonly used [39% of citations] followed by terms of ‘decrease use’ [24% of citations], discontinue [16%] and abandon [16%]. Terms that were considered to be more accurate including ‘de-implement’ and ‘de-adopt’ were rarely cited [4% and 3% respectively]. (53) Since publication the neologism ‘de-adoption’ has been nominated as the descriptor to standardise the literature, as it represents all conceptual nuances of the abandonment sphere.

Chapter 2

International Approaches to Low Value Care

Introduction

Wasteful, unnecessary care is a recognised entity which requires action. Yet in the absence of clear evidence, successful policy mechanisms for disinvestment are lacking. Qualitative interviews with health decision-makers worldwide have demonstrated that disinvestment is regularly perceived as 'challenging' and 'contentious' (75, 76). Given this there has not been a common method to address these issues. With disinvestment vital to sustaining health services in the long term, it is prudent to learn from international approaches, the role of health technology (re)assessment and grassroots programmes.(77) Therefore a scoping review of previous practice towards addressing low value interventions will be presented. The motivation for performing a narrative review is to identify common thought processes between nations on how to deal with low value interventions, attempt a comparison between different countries in terms of successes and failures in order to learn from each others experience and create a well informed logic orientated framework – that is subsequently presented in Chapter 4.

Each party within the health system architecture has a different view of firstly whether it should be done and secondly of how it could be done. These confused objectives have often led to differing levels of success and often fractured relationships between policy makers and clinicians. One thing is clear, that no perfect mechanism of disinvestment has been identified till date.

Therefore, formulating a framework which identifies and de-adopts interventions with little or no benefit becomes relevant – which serves as the motivation for this part of the thesis.

Methods

A narrative literature review was performed with view to understanding approaches to disinvestment internationally; with results presented within this chapter.

From initial searches it became evident that although overuse of low value interventions is a priority study area internationally, few nations have implemented policy levers formally to address it. It became clear that four countries had commenced a formal agenda to focus on disinvestment: England, USA, Australia, and Canada. Therefore, it was decided to limit the study to these developed nations. However, the literature review did identify other interventions that heralded interesting approaches that were from other countries within Europe (notably France, Italy and the Netherlands), it was felt by the author that their interventions warranted mention in the study to give a more holistic view to de-adoption, with certain interventions specific to surgery.

It should also be noted that this thesis relates to Low Value Care in Surgery, therefore initially policy levers that effected surgical interventions were noted only, however it became evident during the review that there was significant paucity of such interventions – an overall motivation for this thesis. Therefore, generic policies that included surgical interventions have been captured and commented upon.

When reviewed in detail there were several different approaches that was taken towards de-adoption, for example Canada has a strong grass root program led by clinicians in the Choosing Wisely movement – a ‘bottom up’ approach whereas England has a prominent health technology assessment agenda led by NICE – a 'top down' approach. The heterogeneity within these approaches means making comparisons across nations challenging. To facilitate this, each countries' interventions were stratified according to the level the intervention was to have maximum effect – the 'macro', 'meso' and 'micro' levels; as evidenced by tables 3-6 that have regimentally stratified these interventions, although often an intervention did not specifically fit into a single level.

Interventions were broadly defined as supply side interventions and demand side interventions, depending on which stakeholder within the health care system they were to effect. This permitted an element of comparison by rationalising some heterogeneity, that may be seen in Table 7 where international approaches to de-adoption are summarised and compared.

By nature of publication bias and the delay in achieving a measurable change, (this is studied in much greater detail in Chapter 6), there will always be a limitation to explicitly defining success and failure from a disinvestment mechanism. Therefore an alternative approach to identifying a successful intervention must be made, this includes whether a program or service is copied / mirrored by another nation (such as the Choosing Wisely movement), whether it has been recognised as successful by other policy experts etc. This is commented on within this chapters' conclusions.

England

Structure of the UK Health System

The National Health Service is a universal, single payer healthcare system that receives funding from taxation and national insurance contributions which is free at the point of care.

NHS England (NHSE) is an arms-length body that prioritises quality, outcomes and ensures that providers are spending resources efficiently. Clinical Commissioning Groups (CCGs) fund, plan and procure healthcare services for local communities, while NHSE is responsible for commissioning specialised services and primary care. Thus, disinvestment as part of the wider processes of service reconfiguration, is one in a continuum of skills that CCGs are expected to learn (78).

More recently, the NHS has been asked to develop place-based sustainability and transformation plans (STPs) to identify local priorities and reorganise services. Given the challenging financial climate, these plans are expected to involve disinvestment of low value care.

In January 2019 the publication of the NHS Long Term Plan set the political agenda for the next 10 years. Increasing patient involvement, health technology, prevention and reducing duplication of medical services are priorities for action (36)

Disinvestment - NICE

The National Institute for Health Care Excellence (NICE) was established in 1999 with the objective of maximizing effective care. It performs technology appraisals providing recommendations relating to the approval of prescription medicines, as well as developing evidence-based guidelines. Historically, NICE has approved 83% of all assessed interventions. Its only mandate is that if a technology is approved the government is required to supply it within 3 months (1).

In 2005 the Chief Medical Officer recommended that NICE play a role in disinvestment, by "issu(ing) guidance to the NHS on disinvestment, away from established interventions that are no longer appropriate or effective, or do not provide value for money".(79)

Subsequently a pilot disinvestment programme was assembled in 2006 with the aim of identifying interventions that would save at least £1m per annum. In 2007 it was found to be unsuccessful with only a few identifiable candidates for blanket disinvestment and limited data to effectively evaluate the cost footprint. The pilot programme ultimately concluded the best way approach to disinvestment was through the publication of clinical guidance and associated recommendation against other practice that is 'do not do' lists. Although these lists do describe the most recent description of wasteful interventions they are simply educational resources available to clinicians supported by NICE, they require ownership and interest from Clinicians to actively change management. This passive actions do not result in fast effective change with recent research indicates these may be ineffective at changing clinical practice (80).

NICE's impact on clinical activity through guidance has had mixed evaluations, with findings that implementation is affected by professional support, evidence base and costs (81). However there have been published evidence of successful cessation of low value interventions (82) while other more complex guidance has been found to be well short of NICE recommendations (83).

The roadblocks encountered by NICE have highlighted common themes which have failed successful disinvestment strategies: particularly the importance of a wider societal acceptance including political will and a lack of evidence to justify controversial decisions. Furthermore, difficulty lies with blanket de-adoption, as often there are sub-groups where clinical context dictates effectiveness for an individual intervention. The data on use of low value treatments is also limited, with NICE unable to evaluate how closely clinicians follow guidelines and utilise 'do not do' interventions.

Furthermore, NICE has been criticised for its failure to couple mandates for investment with suggestions for disinvestment (84), leading to concern that local bodies will make haphazard disinvestments in response to pressures to fund new technologies (85).

Public Reporting

Following the lead established by the Dartmouth group the UK has taken steps to evaluate variation in practice. NHS England publishes interactive atlases of variation for the scrutiny of providers, patients and managers (18). The logic being that knowledge of variation will result in providers gaining ambitions to address overuse / underuse resulting in reduction of unwarranted variation. Unwarranted variation results in 1. Patient harm from overtreatment / overdiagnosis 2. Inequity of care due to underuse of high value interventions and 3. Waste, any treatments which do not add value to the patient pathway. This passive method of communicating information aims to provide opportunity for local approaches to disinvestment yet evidence has suggested the impact of such is limited, as its mere publication is not sufficient to influence decision making (86). This is another passive lever which requires ownership from the providers to alter management, although educational resources respect individual physician autonomy, and meso level (CCG / STP) autonomy they do not instigate rapid change.

QIPP Programme

The Quality, Innovation, Productivity and Prevention (QIPP) programme is an initiative developed by the DoH to provide quality improvements and £20bn in efficiency savings. Initially this target was set for 2014/15 which was later adjusted to 2020/21.

The underlying assumption of the QIPP approach, which originates from the US Institute for Healthcare Improvement (IHI), is that improved efficiency will lead to improved quality of care. Recently, the IHI has developed the Impacting Cost + Quality Programme. In 2010, a six-month pilot with a group of 40 US healthcare organisations, led to plans to remove a collective $30 million in 'excess' costs (87). There have been successes in achieving efficiency savings since 2010 as a result of freezing staff pay and cutting the national tariff. However, some evidence suggests a minimal reduction of six low value interventions in the first year of QIPP when compared with benchmark procedures. There has been success here through the use of active financial lever although the concern is stakeholder support and political will.

Evidence-Based Interventions Programme

This research led initiative was created to educate stakeholders on best practices in reducing patient harm and overuse of low-value clinical procedures, saving clinician time and medical resources. It was "developed as a joint enterprise between five national partners: the

Academy of Medical Royal Colleges, NHS Clinical Commissioners, the National Institute for Health and Care Excellence as well as NHS England and [NHS] Improvement". The programme identified 17 interventions; four of which should only be provided in case of "exceptional circumstances" that require an additional request, and 13 for when specific clinical conditions have been satisfied. (88) This Intervention introduces active levers led on a national macro level to instigate change actively. It is based crucially on well-founded research principles as well as formal evidence, therefore in theory should not be subject to the same political and clinician scrutiny as other top down approaches. However, it is still in its infancy and it is unclear on whether it will instigate the kind of meaningful change that is the objective of NHS England.

Getting it Right First Time (GIRFT)

The Getting It Right First Time (GIRFT) movement was designed as a pilot program for orthopaedic surgery to reduce variation in medical care. An analysis of the pilot demonstrated £30m in savings for 2014/2015 with a projected £20m for the following year. The movement was supported by participation from more than 70 trusts and 35 medical specialties. In November 2016, Health Secretary Jeremy Hunt claimed the program had the potential to produce £1.5bn in yearly savings for the NHS. The GIRFT program is led by the Royal National Orthopaedic Hospital NHS Trust and NHS Improvement as a system level intervention focused on reducing unwarranted variation in medical care, in turn leading to significant cost savings for the NHS (89). This active approach to systematically deal with variation in care offers hope, given it has already shown meaningful financial savings. It acts by supplying information to providers on best care strategies, inherent variation and tools to address them.

Financial Incentives

Encouraging patients and clinician adherence with financial rewards is a mechanism which has been employed to govern variation in quality and incentivize improved value for money. Although policy mechanisms that directly address low value interventions have not been employed rewards for high value care have been offered to shift the spectrum of care.

An example is the Quality and Outcomes framework (QOF) which links financial incentives to the quality of care provided. Quality is measured against a set of clinical indicators relating to aspects of care for chronic conditions, with GP practices rewarded for each target achieved. In 2009 the government introduced the Commissioning for Quality and innovation initiate (CQUIN) which rewarded excellence in care by linking part of clinician income to the achievement of quality goals. This was then reinforced by the introduction of Best Practice tariffs to reward care that was both clinically and cost effective. These supply-side mechanisms aim to maximise efficient care and minimize high-cost interventions where alternatives exist.

There is an overall acceptance that QOF has improved unwarranted variation within primary healthcare, although the extent of the impact remains questionable. Quality of primary care was improving before QOF was introduced, although its introduction had a dramatic effect in its first-year subsequent improvement in line with previous trends. Although improvement was evident in incentivized activities this was to the detriment of non-incentivised activities, for which performance became worse (90, 91). Furthermore, although improvements were achieved in measurable domains there is no great improvement in overall patient outcomes. Yet it has been identified that achievement of QOF indicators is associated with a measurable reduction in costs for hospital care (92). Long-term evidence for the effect of pay-for-performance in primary care on mortality in the UK: a population study – no significant effects on mortality (93).

Conclusion

Several government led initiatives have taken great steps towards identifying and reducing the use of low value care services across the United Kingdom. NHS England and NICE have published recommendations and guidelines on routine medical practices, elective surgeries, prescription medication, and primary care patterns that have been modified to encourage evidence and research in practice. Alongside increasing evidence-based interventions, education programs have been tailored to clinicians and patients with the hopes of increasing adherence and satisfaction. Evidence indicates selective disinvestment could contribute hundreds of millions of pounds to re-allocate within the country at large. Further integrating guidelines into practice will require engaging stakeholders at all processes on the continuum of care and changing complacent practice norms. Despite its appeal, reducing unnecessary services remains subjective as blanket de-adoption presents challenges for treating unique patients and those adverse to change.

***Table 3**: England – Summary of Strategies for Disinvestment*

Intervention	Background	Financial or Education Incentivized	Strengths	Limitations	Improvements
PROVIDER (Meso-level)					
Getting It Right First Time (GIRFT)	• Initially a pilot program to reduce variation in orthopedic surgery • Led by the Royal National Orthopedic Hospital NHS Trust and NHS Improvement • Attempts to Manage Variation through Passive and Active Levers	Financial	• £30 million saved in 2014/2015 • Predicted savings of £20 million in 2015/2016 • Potential to produce £1.5 billion in yearly savings • Delisting of Interventions and Products for Use	• Active tools to facilitate participation	• Inclusion of health technology to support use
NATIONAL (Macro-level)					
The National Institute for Health and Care Excellence (NICE) – 2006 pilot	• Piloted a disinvestment program in 2006 to identify interventions that would save £1 million per year	Financial	• Multiple workshops • Believed best result would come from publishing guidelines	• Pilot program unsuccessful • Few interventions completely disinvested	• Framework for investing funds from disinvested care • Evaluation tools to measure physician compliance with

disinvestment program			and recommendations ("do not do" lists)	• Limited data to evaluate cost • Political will	guidelines and "do not do" interventions
NHS England – Atlases of variation	• Based on work by Dartmouth • NHS England publishes interactive atlases of variation in providing care	Education & Financial	• Interactive tool to asses unwarranted variation in care • Publicly accessible • Used to stimulate investment in high-value care	• Limited effectiveness • Passive production of information	• Requires an active prompt or facilitating method to encourage providers and patients to use the tool
The Quality, Innovation, Productivity and Prevention (QIPP) Program	• Goal to produce quality improvements and £20 billion in savings • Developed by the Department of Health	Financial	• Policy agenda • Efficiency savings (result of staff pay freezes) • Reduced six low-value care interventions in first year (2011) • Financial incentives for providers	• Projected savings delayed from 2014/2015 to 2020/2021 • Goal setting at national level but providers and commissioners accountable for achieving results	• Reducing low-value care and increasing efficiency requires engagement of patients and providers to lead change (grassroots movements)
Evidence-Based Interventions Program	• Joint effort by five organizations; NHS England, NHS Improvement, NICE, NHS Clinical	Education & Financial	• Identified 17 low-value care interventions; 4 used in exceptional circumstances, 13 if conditions met	• Benefit from grassroots support	• Integrating providers and patients through grassroots initiatives would result in complete

	Commissioners, the Academy of Royal Medical Colleges				stakeholder involvement
Reducing overprescribing ineffective medicines in primary care	• Similar to the Evidence-Based Interventions Program • Led by NHS England and NHS Clinical Commissioners Program	Education & Financial	• Identified 18 low-value medicines that should not be regularly prescribed • Estimated cost savings of £141 million per year	• Solely focused on pharmaceuticals	• Develop similar programs tailored to a wide range of low-value care practices within primary care

The United States

Policy experts and international organizations (The Commonwealth Fund, OECD, World Bank) have consistently identified the US as the sole outlier with the greatest healthcare expenditure, totalling at least USD $10,000 per capita, an estimated 20% of GDP by 2020 (94, 95). Pharmaceuticals account for a substantial share of waste and spending as the United States remains the only developed economy without government negotiation for pricing, thereby creating a system where prices are the maximum the market can bare. Significantly higher spending on health has not correlated with superior outcomes, quality of care, or patient satisfaction. As a result, payment networks in the US have developed initiatives to better align payment and quality; incentivizing decision making based on value for patients and providers. Value-based care strategies have received significant attention in the US and the United Kingdom for maximising efficiency and promoting affordability of essential healthcare services, thereby passively reducing wasteful care (94).

Health Technology Assessment (HTA)

The HTA landscape within the US is similarly representative of the dichotomy of providers and payers; fragmented and uncoordinated - constituting public and private sector involvement with state and federal influence (96). The US does not have a federal organization accountable for health technology assessment dissimilar to Canada (Canadian Agency for Drugs and Technologies in Health), Australia (Pharmaceutical Benefits Advisory Committee) and the UK (The National Institute for Health and Care Excellence). As a result, the US has opposed the use of cost-effectiveness in appraisals for new technology and pharmaceuticals (97). This fundamentally means there is no overt control on the cost implications of new treatment strategies that are introduced to market. This is in keeping with the American health philosophy where cost effectiveness is not a criterion for coverage, as demonstrated by Medicare's prohibition from using cost effectiveness as a component for decision making.

The Centers for Medicare and Medicaid Services evaluates new health technologies for prospective reimbursement and federal coverage through Medicare and Medicaid themselves. Due to the homogeneity in international guidance published by NICE, CADTH, and the Cochrane Collaboration, evaluations within the US have continually relied on these organizations in their own reviews (96). The US Preventative Task Force (USPSTF) has taken similar action to NICE and Choosing Wisely publishing evidence-based guidelines on the effectiveness of medical services. The USPSTF recommendations use letter grades to evaluate the benefit of healthcare services from grade A (high benefit) to grade D (no net benefit) (98).

In the absence of an effective HTA agency in USA the agenda of disinvestment and low value care within the US would either require the US Food and Drug Administration to expand its current evaluation beyond safety to clinical effectiveness or legislate that the current network of payors and insurance providers incorporate an HTA component to reduce wasteful care. An HTA body with remit to evaluate clinical effectiveness similar to France (French National Authority for Health) and Germany (Institute for Quality and Efficiency in Healthcare) would benefit payors and patients in the US with greater standards for efficiency and quality, stimulating a national debate on prioritizing high value care. Currently, the free market principle of the US healthcare prices encourages redundant and wasteful care which should be controlled through an additional appraisal focusing on optimal value and efficiency. In the absence of HTA it is likely low value treatments will continue to be introduced to the market .

Supply side Innovation - Alternative Payment models

Value-based insurance schemes have attempted to incentivize selection of interventions to discourage wasteful treatment by using co-payments and deductibles for patients. This supply side innovation aims to align financial incentives to the quality, efficiency and value of care delivered to the patient. In theory this can reduce low value care if patients have sufficient knowledge, however in practice it has been identified that patients are unable to differentiate and reduce effective and unnecessary care equally - how can we expect patients to make these complex decisions when provided with all the information if policy makers and clinicians struggle ? Alternative payment models include accountable care organizations, bundle payment models and value-based purchasing reimbursing providers for high value care while concurrently de-adopting low value interventions.

Co-Payments and Value Based Insurance

Increasing the use of benefit-based co-payments, value-based insurance design and pay-for-performance financing mechanisms obliges patients and providers to internalize wasteful expenditure and conform behaviour to efficient practice. Not only does this encourage patients to improve health literacy but also increase their involvement in treatment decisions. Interventions with the highest value are priced in the lowest tier of the formulary in contrast to those deemed low value, associated with higher co-payments or entirely out-of-pocket costs (10). Despite this value-based purchasing has yet to produce significant evidence for improvements in quality of care, cost reduction, or improved patient outcomes (11).

Accountable Care Organizations

In addition to value payment schemes, accountable care organizations (ACO) have gained importance in providing integrated care. An ACO is an integrated network of providers that assume financial risk for the cost and quality of care delivered to individuals (99, 100, 101) ACOs have prioritised coordination attempting to bring quality of care to the foreground adjacent to cost. In theory, the transfer of financial risk from the health care system to the ACO aligns financial incentives to reduce the use of wasteful interventions.

Several groups have evaluated the effect of ACO enrolment on de-adoption of low value interventions, with minimal benefits compared to FFS models. An example is the absence of reduced low value coronary revascularization in specialist cardiac care. It was supposed that the current incentives within Medicare ACOs was insufficient to limit the growth in spending and that 'refinements of current alternative payment models and risk-bearing contracts are still required to influence provider behaviour'. (102)

Bundled Payments

Bundled payments represent an alternative model that has also gained traction. It includes a single payment for a medical event be it hospital admission or assessment. The intention of the bundled payment model is to promote care coordination between providers. Its role in reducing low value interventions has yet to be demonstrated (103).

Demand Side Innovation

Increased premiums result in a cost shift from employers to employees due to greater out of pocket costs. Ultimately this results in the re-emergence of the healthcare consumer and displaces their role as a patient. ‘Consumer orientated’ healthcare significantly reduces service use and disproportionately benefits individuals with knowledge, although there remains concern over the choice of interventions which are abandoned, particularly as patients with increased financial liability reduce the use of both high and low value care (104, 105).

Choosing Wisely

The American Board of Internal Medicine (ABIM) created the ABIM Foundation in 1989 as a charity dedicated to the effective use of healthcare resources through physician education. The foundations’ recent work has focused on educating resource stewardship within the health system including; innovations and teaching methods focused on high-value care for medical students and providing funding for educational programs on the disvalue of unnecessary medical care both operating under the Choosing Wisely initiative (19). The initial 2012 movement has led to the establishment of 20 campaigns on low-value care worldwide in countries such as Australia, Brazil, Canada, the United Kingdom, and Japan. To date Choosing Wisely has published over 550 recommendations in partnership with 80 specialist societies and associations (20).

There have been setbacks to the Choosing Wisely programme, of note the withdrawal of the American Association of Clinical Endocrinologists. Further criticisms have been levied against individual societies, particularly those of the surgical nature not willing to make recommendations against their own financial interests. Of notoriety is the American Society of Orthopaedic Surgeons whom named the use of an over the counter supplement, the use of a heel wedge and use of wrist splints after surgery as services clinicians should consider refraining from. No orthopaedic intervention was on the list other than a rarely used needle lavage for Osteoarthritis (106). This choice of low impact procedures or 'low hanging fruit' is common to all surgical specialties, which given their high expenses appears to be a missed opportunity to make valuable changes.

Bhatia et al, proposed a measurement review process analyzing the impact of Choosing Wisely into three distinct outcomes; clinician attitudes, clinician behaviours and patient compliance. In addition, the use of patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs) allows the campaign to better target patient interests. The review signals the need for standardized measurement tools to allow for regional and international comparisons as a requirement for effective evaluation (107).

Choosing Wisely achieved initial success with physicians and healthcare facilities, but needs to engage insurance providers, health technology assessors, state and federal governmental agencies such as Medicare and Medicaid to stimulate adoption throughout the health system. Overuse of ineffective care is left to the individual consumer who is unfairly tasked with judging which insurance program, which intervention and which service is low value – ultimately resulting in excessive medical waste.

Table 4: United States of America – Summary of Strategies for Disinvestment

Intervention	Background	Financial or Education Incentivized	Strengths	Limitations	Improvements
PATIENT (Micro-level)					
Cost-sharing (108)	• Use of patient cost-sharing in insurance plans through co-payments, coinsurance and deductibles	Financial	• Reduces moral hazard • Financially rewarding patients for reducing use of irresponsible care (lower copayments, premiums) • Cost sharing has worked in guiding patient to select against low-value care	• Requires advanced patient health literacy to differentiate standards of care • Financial penalty for accessing care	• Limiting use of cost sharing schemes to explicit low-value services after educating patients on appropriate use
Choosing Wisely	• Targeted interventions to patients including social media, mobile applications, wallet cards	Education	• 9K + mobile app downloads • 200K “five questions to ask” wallet cards • 80 webinars	• Varied effectiveness depending on method of communication	• Active engagement services (mobile reminder to ask physician questions before entering appointment)
Parental education for antibiotics	• Randomized control trial to reduce low-	Education	• Using provider in educational prompts	• No reduction in use of low-value services for children	• Framing use of low-value services as dangerous to child

(Taylor, Kwan-Gett, & McMahon, 2005)	value use of antibiotics • Active arm parents received videos featuring their provider and pamphlets, control received a brochure		promotes familiarity and trust		health instead of irresponsible
PROVIDER (Meso-level)					
ETHAN (Emergency Telehealth and Navigation) Program	• Ambulance teleconsultations reducing inappropriate emergency department (ED) visits • Patients receive instant referrals to appropriate care	Education & Financial	• Referral to appropriate care (educational tool) • Saving ED and ambulatory services time and money • Reduced unnecessary ED visits 6.7%, saving approximately USD $1 million	• Difficult for patients without technological literacy • Potentially undervalues patients express need for medical care	• Developing a mobile application for patients to assess symptoms and access appropriate channel of care • Including providers
The Society of Hospital Medicine – Case study competition	• Partnership with Choosing Wisely • Case study competition to	Education	• Prizes awarded for best pediatric and adult recommendation • Direct clinician involvement in	• Requires greater patient facilitation	• Providing a platform for patients to be included in suggesting recommendations

	develop recommendations		formulating recommendations		
University of Southern California Medical Center – Preoperative tests	• Reformed guidelines to comply with Choosing Wisely recommendations	Financial	• Unnecessary preoperative consultations reduced by 64% • Wait times reduced by 181 days (median indicator) • USD $1.2K savings per patient	• Requires greater patient facilitation	• Implementing changes in quick succession can be overwhelming • Suggested gradual implementation with patient and provider consultations
NATIONAL (Macro-level)					
Choosing Wisely	• Encouraging patient and public engagement through the creation of low-value care lists with medical societies	Education	• Reached almost 100 million consumers • Led to the development of 19 international campaigns	• Lack of evaluation and reporting outcomes within the program • Absent stakeholder engagement outside patients and providers	• Requires active support, tools, and potential rewards to change existing practice behaviours • Use of health technology to facilitate adoption (EMRs)
R-SCAN	• Created by the American College of Radiology	Financial	• Based on 11 Choosing Wisely recommendations	• Program training	• Involving more stakeholders

	• Online tool facilitating radiologist and physician cooperation in improving image utilization		• Financial support from the Centers for Medicare and Medicaid Services' Transforming Clinical Practices Initiative (TCPI)		

Australia

The Australian 'Medicare' system was introduced in 1984, it provides comprehensive health care access to free treatment in public hospitals. Medicare's' three arms (public hospitals, medical services and pharmaceuticals) are supplemented by a growing private sector, which is supported (through subsidies) by government to cover in and out-patient treatment for services not covered by Medicare.

MBS, MSAC & PBAC

The MBS (Medical Benefits Schedule) is a fee for service system, where the government pays a fixed rebate for each service provided by Medicare. Additional items added to the MBS are assessed for safety, efficacy and cost-effectiveness prior to recommending use. Notably, Australia was the first country to introduce a mandatory requirement for comparative effectiveness and economic evaluation.

Reimbursement approval for these new services, as well as the withdrawal of reimbursement for existing services, rests with the Australian Government Minister for Health under advice from the Medical Services Advisory Committee (MSAC) and, for pharmaceuticals, the Pharmaceutical Benefits Advisory Committee (PBAC). The MSAC and the PBAC employ stringent review processes based on data and evidence that are available at the time of assessment (55).

Australia has well-defined criteria and evidence-based policy processes for assessing emerging health technologies to gauge their efficacy. Underpinning the disinvestment movement, however, is a recognition that these assessment methods are novel, and that the processes to date have focused overwhelmingly on new practices and not on existing services. Australia, therefore like other countries, suffers from a legacy system whereby many existing health services in use prior to well-defined standards of cost-effectiveness have become a criterion for reimbursement. Thus, there is concern that interventions of limited effectiveness may still be in practice nation-wide, encouraging the need for disinvestment of low value care (109, 110, 111).

Approaches to Disinvestment

Australia has led efforts for cost containment by identifying low-value medical services since 1998 with the National Medicines Policy, a product of the World Health Organizations conference on appropriate drug prescribing and the *Revised Drug Strategy* report (104).

As of 2017 Australia has implemented several initiatives tailored to reducing low-value care services, the most of any country (98). Interventions have been multidisciplinary in nature spanning private medical services through the Medical Benefits Schedule (MBS), hospital and primary care, the lifesaving drug review, and the most recent Choosing Wisely campaign.

Medicare Benefits Schedule (MBS) Review

Previously named the Comprehensive Medicines framework (CMF), the Medicare Benefits Schedule Review was established in 2010 to conduct a review of Australia's MBS which listed the rebate price for patients undergoing private medical services (112). Of the 6000 healthcare services excluding pharmaceuticals offered under the MBS, only three percent had been evaluated for cost-effectiveness, safety and clinical effectiveness. The government funded the CMF to ensure current services provided sufficient value and met specified thresholds for clinical effectiveness and safety. The review consulted patients and providers while establishing opportunities for patients to include recommended submissions with 156 services of 5209 identified with potential low-value (55). This is a labour intensive enterprise that placed great importance on reassessment of incumbent practices, whether or not it had a measurable effect on use is yet to be seen.

Pharmaceuticals

As part of the Pharmaceutical Benefits Scheme (PBS) in 2005, limitations were placed on 59% of medicines with 27% requiring authorization from medical professionals (113). The Pharmaceutical Benefits Advisory Committee (PBAC) had previously taken a passive role in regulation, delegating responsibility to clinicians for prescribing medicines they deemed effective on the PBS list. The PBAC has since taken an active role, engaging in post-market reviews of authorized drugs on the PBS list to maintain cost-effectiveness and in turn, value for treatment. Findings from the review identified multiple opportunities to optimize existing prescribing patterns in medicines with low-value care without complete disinvestment.

Consultations from patients and providers were included in the entire disinvestment process and final recommendations from the PBAC were published online, including permanent changes made to the PBS (114, 115). This approach which requires prior authorisation from a national body has been effective in reducing low value care, due to the national active approach that requires individuals to 'opt out ' of high value care intervention alternatives. However political will must be in support as these levers are often met with scrutiny from the physician cohort whom feel their autonomy is threatened.

ASTUTE Health Study

The project was commissioned in 2009 separate from the Australian government. The aim was to develop a protocol for transparent decision making in assessing current practices for safety, clinical and cost-effectiveness.(116) The ASTUTE Health Study (Assessing Service and Technology Use to Enhance Health) acted as a forum encouraging participation between politics and clinical practice and succeeded in engaging diverse stakeholders to form a multidisciplinary committee evaluating practice norms. Participants were given evidence from systematic reviews from which discussions for disinvestment were led and published online. The key success from this intervention is the inclusion of several stakeholders to unite an objective, this in turn leads to effective support of any intervention which policy may choose to instigate. The weakness though is the passive nature of change, which although is relatively cost neutral and low maintenance inherently relies on stakeholder enthusiasm and motivation to envisage change. This is considered in more detail in Chapter 6

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Life Saving Drugs Program Review

The Life Savings Drugs Program provides free or subsidized care to citizens suffering from rare diseases for costs beyond the established effectiveness threshold. In 2016-2017, 393 people were provided with subsidized or free care totalling $116 million (117). There has been increasing demand for rare treatments with a 65% increase in patients covered since 2011. As a result of the continued growth in applications the government conducted a review to determine if effective criteria were in place for responsible access and cost-effectiveness.

There are nine medical conditions and 13 medicines currently funded by the program. Evidence from the review included greater transparency and assessment of medicines listed after 24 months for cost and usage analysis and negotiating prices similar to the PBS.

Conclusion

Australia's national government has facilitated most interventions tailored to reducing low value care. This has been supported by local partnerships from regional agencies and physician networks. Involvement of stakeholders through consultations including patients, providers, and policy officials has been a strong success.

***Table 5**: Australia – Summary of Strategies for Disinvestment*

Intervention	Background	Financial or Education Incentivized	Strengths	Limitations	Improvements
PATIENT (Micro-level)					
PROVIDER (Meso-level)					
ASTUTE (Assessing Service and Technology to Use to Enhance) Health Study	• Commissioned in 2009 to develop a protocol for transparent decision making in assessing safety, cost and clinical effectiveness	Education	• Facilitated participation between politics and clinical practice • Multidisciplinary committee evaluating practice norms • Used evidence from systematic reviews	• Significant time investment • Results published online	• Implement on a large scale involving more stakeholders • Active dispersion of results to change decision making
NATIONAL (Macro-level)					
Choosing Wisely	• Encouraging patient and public engagement through the creation of	Education	• 100+ recommendations • Identified administrative and	• Required separate government consultation	• Lacking active engagement mechanisms to

	low-value care lists with medical societies • Partnered with NPS MedicineWise, an independent organization		policy waste, not just clinical • "Too Much Medicine" documentary viewed by nearly 18 million		encourage providers to change behaviour
National Medicines Policy	• In 1998, identified low-value medical services • Response to the WHO's conference on appropriate drug prescribing	Education & Financial	• First national program to identify low-value services	• Limited success	• Greater stakeholder involvement • Partnership with local facilities and providers
Comprehensive Management Framework (CMF)	• Established in 2010 to review the MBS • Of 6000 current health services (excluding medicines) only 3% had been evaluated for effectiveness	Financial	• Opportunities for patients to include submissions • 156 of 5209 services identified as potentially low-value	• Complete disinvestment viewed as likely to be ineffective, face stakeholder opposition	• Educating stakeholders on dangerous use of harmful and wasteful care followed by complete disinvestment
Pharmaceutical Benefits Advisory Committee (PBAC)	• In 2005 the PBS limited use of select medicines requiring provider approval for access	Financial	• Selective disinvestment; 40% price reduction for	• Against complete disinvestment • "Anakinra" drug left the market due to price reductions	• Strategies needed to incentivize manufacturers to keep products in the market if only

	• Post-market review of medicines		certain Alzheimer's drugs • Restricted use based on patient criteria • Changes made to PBS		selectively disinvested
Life Saving Drugs Program Review	• Review to determine if effective criteria were in place for reasonable access and cost-effectiveness	Education & Financial	• Increased transparency of clinical and cost-effectiveness • Proposed additional review of listed medicines after 24 months • Negotiating prices similar to PBS	• No partial or complete disinvestment	• Re-assess the medicines and conditions listed on the Life Saving Drugs Program every 5 years

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Canada

Canada operates a single payer, publicly funded healthcare system known as Medicare (58). The provinces and territories are responsible for funding healthcare through the Canada Health Transfer, a funding mechanism from the federal government. Provinces and territories are responsible for further distribution to Regional Health Authorities (RHAs) and Local Health Integration Networks (LHINs) to deliver health services at the local level (118). Health coverage includes primary care, acute care, mental health, public health and long-term care to an extent. The federal government is accountable for regulating the efficacy and safety of medical technology, natural healthcare products and pharmaceuticals. Most recent estimates for healthcare spending have totalled $242 billion per year (119).

Embrett and Randall highlighted regional disparities in care, with providers in high-cost areas more prone to providing unnecessary medical care as a result of renumeration and technology availability (120). Increased use of low value services was correlated with increased socioeconomic status, frequency of secondary care attendance, and proportion of specialists to primary care physicians (121) .

Health Technology Assessment (HTA)

The Canadian Agency for Drugs and Technologies in Health (CADTH) is responsible for producing evidence-based decisions on health technology and pharmaceuticals; however they have faced challenges in restricting use to cost-effective applications. CADTH has recognized that expensive technology can benefit patients: yet processes such as artificial intelligence and robotics are ‘double-edged swords’ that ‘carry a fearsome price tag’ without always proving clinically superior. (119)

There remains no explicit cost-effectiveness threshold for new drugs and technology compared to the UK (£20-30K per QALY), Australia (USD $52.4K per QALY) and the US (USD $50K per QALY) (122, 123). Less than 50% of recommendations mentioned cost-effectiveness with thresholds of CAD $20K, $50K and $100K per QALY not predictive of a decisive outcome.

Common Drug Review (CDR)

CADTH conducts a review for new *and* existing medications with new indications (124). After a drug has been approved for use by Health Canada public drug plans determine eligibility for reimbursement. CADTH conducts analysis on clinical and cost effectiveness of drugs alongside patient experiences and safety at which point a recommendation is provided to the regional health plans on reimbursement. Similarly, to the European Medicines Agency, drugs must be evaluated against the current accepted standard to value additional cost-effectiveness against existing therapies. Similar to the Australian MBS Review this is a labour intensive task that may offer opportunity to remove archaic interventions from use although it has yet to be of proven benefit.

Stakeholder Involvement

Disinvestment of low value care has been led by the partnership between Choosing Wisely Canada and the Canadian Institute for Health Information (CIHI) (125). Both organisations have taken a leadership role in advocating for the reduction of commonly used treatments and tests that are un-supported by evidence and expose patients to unnecessary risk and harm.

Choosing Wisely Canada

Following the Choosing Wisely movement in the United States the Canada set up a similar program, in line with the Canadian Medical Association. With both national and regional campaigns that have addressed local variation more directly. Furthermore, five other national movements were established to address overuse; 'More is Not Always Better,' 'Students and Trainees Advocating for Resource Stewardship,' 'Using Antibiotics Wisely,' 'Opioid Wisely,' and 'Diving into Overuse in Hospitals' (125).

Conclusion

Canada shares similar motivations to other nations and has attempted to address the concern of low value care through the use of levers at both a macro and meso level. It celebrates an active Choosing Wisely campaign which both attracts national attention but also empowers stakeholders at a micro level. However it is yet to be seen whether these have a true effect on the de-adoption of low value interventions.

Table 6: Canada – Summary of Strategies for Disinvestment

Intervention	Background	Financial or Education Incentivized	Strengths	Limitations	Improvements
PATIENT (Micro-level)					
The EMPOWER (Eliminating Medications Through Patient Ownership of End Results) Cluster Randomized Trial	• Of 261 participants 62% engaged in conversations with their provider on stopping use of benzodiazepine therapy	Education	• Randomized trial with use of a control group • Positive results from "direct-to-consumer education" • Post six months 27% of patients ceased use of therapy compared with 5% in the control	• Significant gap in patients who engaged in conversations with their provider and those who stopped treatment (poor provider adherence?)	• Health literacy as a barrier for engagement • Involving physicians will lead to greater compliance of accepted standards
PROVIDER (Meso-level)					
Students and Trainees Advocating for Resource Stewardship *(STARS)*	• Pilot program from Choosing Wisely • Recruited two students from each medical school to design and lead initiatives of their creation within their school	Education	• Grassroots, student-led initiatives • Participation from all 17 medical schools • Led to campaigns in the Netherlands, USA	• Limited capability of students to implement change • Difficulty changing school curricula • 8 of 17 schools carried out initiatives	• Some schools befitted from impactful changes (e.g. curricula, skill building seminars) whereas others were less impactful (e.g. blogs) • Standardizing initiatives

					• Involving staff (professors)
North York General Hospital – Technology integration	• Reduced unnecessary lab tests (emergency, preoperative, intensive care) with the aid of technology, integrating recommendations in order entry systems, use of screensavers, blogs and social media	Financial	• Over CAD $157K in savings from one year • Reduced usage of ten common tests • Multiple forms of technology targeting providers and patients	• Solely focused on medical tests • Requires greater patient facilitation	• Integrating technology in clinician tools promotes compliance • Active method of ensuring continuing adoption • Technology solutions targeting patients could achieve greater benefits (phone and app reminders, wearable technology)
Alberta Health Services – Education and testing	• Multiple interventions focused on reducing medical waste; changed order forms, increased education on testing, appropriate use toolkit, eliminating automatic testing for select diagnoses	Education & Financial	• Changing order forms and increased education decreased testing by 92% within the first 9 months saving up to CAD $1.5 million • Appropriate use toolkit reduced antipsychotics in LTC facilities by 7%, with	• Greater involvement of patients needed	• Multidisciplinary interventions proved effective at leading change at different levels of care • Developing further interventions focused on patients would enable greater success

			Alberta achieving the lowest levels in Canada • Statistical toxicology tests now require additional approval, reducing use by 96%		
NATIONAL (Macro-level)					
Choosing Wisely Canada	• Encouraging patient and public engagement through the creation of low-value care lists with medical societies	Education	• Patient and public advisor role • Regional programs in 10 of 13 provinces and territories • 250+ recommendations	• Literature indicated compliance is not uniform, potential for renumeration effects • Lacking active support to facilitate clinician adoption	• Requires active support, tools, and potential rewards to change existing practice behaviours • Use of health technology to facilitate adoption (EMRs)
Ontario Reassessment Framework	• Selective disinvestment of tests, treatments, and procedures from CADTH's recommendations	Financial	• CAD $59 million saved • Amendment to fee schedules to comply with guidelines • Removal of insured services for patients	• Insufficient consultation with patients and stakeholders	• Policy tools mandated forced compliance • Involving patients and providers is necessary to improve public perception

Other Initiatives

Some European countries have taken similar steps using HTA and national drug appraisals to implement change at micro, meso and macro levels. England, France and Germany represent the largest economies in the European Union, provide universal health coverage, and have implemented multiple programs for disinvestment(126).

EuroScan

The International Information Network on New and Emerging Health Technologies is a partnership with research centres, governments, and international organisations towards the dissemination of evidence on innovative health technologies. Euroscan was created to support evidence-based decision making at an international level, utilizing shared resources and stakeholders. It prioritises early development and research of health technology, often involved in horizon scanning determining efficacy and safety. The organization maintains three working groups on information for pharmaceuticals, medical devices, and health infrastructure. Euroscan publishes early awareness and alert systems to assess the impact of emerging health technologies to better inform evidence-based decision making (127). This international approach to dealing with low value care demonstrates a global understanding of the problem in question. Its strengths are the involvement in multiple health partners and stakeholders that will confront political stubbornness to make promote the agenda of disinvestment. However, its ability to instigate change is similar to other passive movements, although providing clinician and patient education has been shown to improve performance in diagnostic test use whilst respective provider autonomy, there is no evidence to support overall reduction in low value care.

France

France’s disinvestment efforts have primarily focused on pharmaceuticals. They are one of few countries to use mandatory INN prescribing of generics and financial incentives for generic prescribing. Combining regulatory procedures with financial incentives allows France to target providers from a policy and fiscal perspective encouraging compliance. This seems to be a simple national lever which other nations may adopt in order to reduce costs of routine medication provision.

Prescrire

Prescrire is France’s equivalent to the Choosing Wisely campaign and has been operational for over 30 years. Editors publish monthly reviews on new drugs that provide additional benefits over existing treatment. From the 2014 annual drug review only three medicines offered a significant advantage with five “offered an advantage” of the 87 reviewed. In addition, Prescrire publishes yearly “drugs to avoid” lists, and in 2015 identified 71 drugs available in France that provided greater harm than benefit (128).

Transparency Commission

The Haute Autorité de Santé (National Authority for Health) created the Transparency Commission to review all existing pharmaceuticals on the French market for potential disinvestment. Medical value is assessed on four criteria to decide their inclusion on the reimbursable drugs list. The SMR assessment determines the percentage of co-payment under the Social Health Insurance scheme. Disinvestment has mainly taken the form of de-listing from the reimbursable drugs list and price reductions.

A comprehensive review in 2000 and 2004 evaluated all drugs on the market and led to disinvestment of 840 of the 1675 drugs on the reimbursable coverage list (113, 129). Significant public and industry pressure required subsequent re-evaluations with 238 of 763 drugs becoming re-listed. France's swift national approach to de-listing low-value drugs led patients to believe the drugs provided no medical value and "did not understand why drugs not worthy of reimbursement were still worthy to be sold on the market"(113). The national review succeeded in de-listing and reducing reimbursement rates for hundreds of ineffective medications with insufficient medical value (129). As a product of the review, the commission now conducts a "systematic re-assessment 5 years after the drug is first listed on the list of reimbursable medicines"(113). Similarly the Haute *Autorité de Santé* have furthermore taken the aggressive step of stopping the reimbursement of homeopathic medicine, due to the lack of evidence that they provide any benefit. Although it represents a 'low hanging fruit' as is often supported by clinicians all round and may only have limited effect on health budgets it does demonstrate the national stance towards addressing inappropriate care. However, France has been criticized for their slow action as the process of delisting ineffective drugs from the reimbursement list took nearly 20 years (130).

Italy

There have been limited national efforts in Italy to address low value interventions, although there have been some successful micro level initiatives that have demonstrated local interest to control health budgets.

A case study of particular interest to the Surgical theme of this thesis includes Gemelli University Hospital in Rome. They instigated a local 'proactive disinvestment process' methodology that identified surgical meshes for discontinued use within the hospital. This process was linked to HTAs for new technologies where clinicians had a decisive role in identifying new medical devices for use and defunct devices (surgical meshs) for disinvestment; their decisions were based on latest information of literature review, local data analysis and international specialist body recommendations to move towards regular use of lightweight meshes. Thereby there was multi-level stakeholder engagement at the time of decision making from the outset. At the time Gemelli Hospital was using over 70 different types of surgical meshes indicating inefficient purchasing.

Based on the clinician led decision matrix a guideline was issued within their unit. The guideline succeeded in reducing the use of heavier more costly meshes in the hospital by 65% (131). The program encountered varied challenges including opposition from surgeons due to existing medical norms and habits, negotiating contracts with vendors, data availability and time constraints.

This example at a micro level demonstrates the nature of low value care. Variation inside a single unit was responsible for the use of 70 different surgical meshes. Furthermore, despite an aggressive informed review process there was resistance from the senior members of the department, resulting in persistent use of costlier meshes in 35% of cases. Although this is a small micro level movement it elucidates the challenges that are encountered at a national level, with stakeholder resistance, limited success and systemic inertia which is always difficult to overcome. Furthermore, it also demonstrates the challenges of Low Value Care use within the Surgical Specialities. There is a basic reluctance of Surgeons to change from what is considered a winning formula. Therefore there will always be confrontation from a clinician who feels that his choice of mesh is substandard. It also demonstrates the weaknesses of clinician education; where despite best evidence and information there is a challenge in moving individual practice away from well set habits.

Netherlands

Dutch Guidelines

"The Dutch Federation of University Medical Centers recently initiated a 4-year program for reducing lower value services" (132). Guidance has been developed that provides a comprehensive list of services performed within hospital care for disinvestment and restricted use. 193 Clinical guidelines between 2010 and 2015 were found relating to low-value care services that were assessed. A total of 1366 services providing low-value were included within the guidelines in comparison to NICEs "do not do" list which consisted of 1006 recommendations. When compared to England, there were 330 more recommendations for service deadoption (132). England's list was less likely to recommend full disinvestment (68%) compared to the Netherlands (77%). Proposed evidence indicates that full disinvestment of 23 specified low-value surgical procedures will result in €60m of avoidable expenditure.

The identified list was integrated with the Dutch Association of Medical Specialists database on recommended low-value services. In addition, the eight university hospitals of the Netherlands began disinvestment pilot projects in June 2016 which targeted select services for disinvestment from the newly developed guidelines. The success of these programs is yet to be assessed.

Conclusion

Multiple interventions utilising technology, grassroots movements, and national efforts through policy include methods for reducing low-value care in Europe. Outside of France, the majority of interventions are recent and are in the initial stages of data collection.

***Table 7**: Other European Initiatives (excluding the UK) – Summary of Strategies for Disinvestment*

Intervention	Background	Financial or Education Incentivized	Strengths	Limitations	Improvements
PATIENT (Micro-level)					
PROVIDER (Meso-level)					
Medical society recommendations (Germany)	• Existing guidelines and recommendations prior to Choosing Wisely led by medical societies	Education	• Identified practice behaviour for low and high-value care • "Do not do" recommendations similar to UK's NICE	• Lacking patient involvement	• Active reminders to encourage clinician adoption (EHRs)
Proactive Disinvestment Process (PDP) - Case Study [Italy]	• Gemelli University Hospital used the methodology to identify surgical meshes for discontinuation	Financial	• Clinicians determined selective or full disinvestment • Reduced use of high weight meshes by 65%	• Opposition from surgeons • Negotiating contracts with vendors • Data availability and time constraints	• Greater facilitation of provider opinions • Inclusion of patients in decision making
Prioritizing services from Dutch guidelines (Netherlands)	• Consolidating recommendations on low-value care from various lists	Education & Financial	• 1366 services deemed low-value	• Significant focus on medical procedures and tests, little emphasis on medicines	• The major priority on the number of services identified as low-value and delisted could be superficial if they don't

	• Evaluated 193 guidelines between 2010-2015		• More likely to recommend complete disinvestment (77%) • Led to pilot programs in eight university hospitals • Disinvestment of 23 procedures would save €60 million		result in improved care and cost savings
PriTec Prioritization Tool (Spain)	• Led by the Osteba and Avalia-t in 2008 • Online program	Financial	• Evaluates redundancy in medical technology • Compares up to 50 medical technologies simultaneously	• Requires specialized, technical knowledge	• Disseminating the technology through health facilities and hospitals with training programs would reduce inefficient practices
NATIONAL (Macro-level)					
Choosing Wisely (Europe)	• Encouraging patient and public engagement through the creation of low-value care lists with medical societies	Education	• 11 European nations created local campaigns (France, Germany, Italy, etc.)	• Lack of evaluation and reporting outcomes within the program	• Further stakeholder participation and active enforcement mechanisms are needed to ensure compliance
Euroscan (International	• Partnership amongst governments,	Education	• Multidisciplinary participation	• Strong involvement of all levels of	• Involvement of all 27 EU member states (e.g.

Information Network on New and Emerging Health Technologies) [Europe]	international organizations, and research bodies • Sharing evidence on emerging health technologies		• Inclusion of wide range of stakeholders • Shared resource use	stakeholders except patients	supranational HTA by the EMA)
Uncertainties and Disinvestment project (Sweden)	• Created by the SBU in 2010 • HTAs performed without sufficient evidence	Education	• Promotion of evidence-based practice and decision making • Patients can submit recommendations online	• Outcome was a database and report, both passive engagement methods	• Succeeded with involving various stakeholders, however active engagement would likely result in increased compliance
Transparency Commission (France)	• Led by the National Authority for Health (HAS) between 2000-2004 • Reviewed all medicines on the French market for disinvestment	Financial	• Disinvested 860 of 1675 drugs on the reimbursable list • The commission currently re-assesses new drugs on the reimbursable list after first five years	• Public confusion • Significant opposition to disinvestment from corporations and public • Slow; nearly 20 years • Re-evaluations caused 238 drugs not to be de-listed	• Educating patients on disinvestment would reduce confusion and opposition

Prescrire (France)	• France's equivalent to Choosing Wisely • Operational for 30+ years	Education	• Monthly reviews of new drugs • Publishes yearly "drugs to avoid" lists • In 2015 identified 71 drugs providing more harm than benefit	• Primarily focused on pharmaceuticals • Lacking patient involvement	• Mainly focusing on unnecessary pharmaceutical use • More effort needed on reducing low-value clinical treatment and health technology

Conclusions

A complete assessment of the impact of low-value care interventions internationally is challenging as adjustments need to be made to account for differences in healthcare financing, private versus public expenditure, and universal health coverage. There have been a range of techniques employed that may be broadly considered passive or active policy levers at various levels in the health system with no single avenue providing over-riding success.

Table 8 presents a synopsis of these findings.

Table 8 International Comparison – Summary of Strategies for Disinvestment

Country	Number of interventions assessed				Key Techniques to Deal with Low Value Care	Strengths	Limitations	Success and results
	Micro	Meso	Macro	Incentive				
Australia	0	1	5	4 Active 4 Passive	• Systematic Review of Current Coverage of Insurance claims, both Surgical and Medical –Prior authorisation & De-listing (Medicare Benefit Schedule Review, PBS Review and PBSC) • Multi-stakeholder Interventions (ASTUTE)	• Maxmimising Priority setting by encouraging providers to educate themselves on the most dangerous / costly practices to disinvest. • System in place at a national level therefore easy for implementation at Meso / Micro levels, supported implementation. • Address the political and Physician support needs by multi-stakeholder interventions.	• Labour Intensive • Political and clinical opposition to complete disinvestment • Grassroots initiatives; patient involvement • Passive approaches all hold the inherent weaknesses, that is lack of inertia and reliance on providers to 'opt in' to effective care	• Strong Published Evidence to support Effectiveness. • Led to legislation for recurring drug reviews. • "Too Much Medicine" television broadcast viewed by nearly 18 million, demonstrating Public Support
England	0	1	6	6 Active 4 Passive	• Passive Approaches to Illustrate Variation in Practice (e.g., Atlases of Variation, GIRFT) • Financial Incentives that Affect Supply Side Initiatives (e.g., QOF framework – Pay for performance, QIPP program) • Supply Side Authorisation (e.g. Evidence Based Interventions Program, NICE's 'do not do')	• Political Will of acceptance from local policy makers, by allocating responsibility • Within health environment local providers respond well to financial incentives • Didactic prescription of guidance is easy to follow. • Pay for performance is effective at Priority Setting, directing clinicians to deal with the most costly / dangerous forms of low-quality care	• Political opposition • Passive dissemination of evidence has slow if any improvement in use of interventions. • Guidance always questioned by skeptical clinicians whose autonomy is threatened. • Time Consuming, delayed impact	• Good Evidence to Support Methods • Financial incentives for providers, with profitable movement • Significant cost savings made. • Promotion of evidence-based practice • Multiple publicly accessible informational tools and guidelines • Though need formal Evidence on discrete reduction of procedures

USA	3	3	2	4 Active 5 Passive	• Cost Sharing with Patients by mean of Bundled Payments • Value Based Insurance Design • Choosing Wisely (Bottom-up educational approach)	• Reduces overall health care use, although both high and low value • Bottom-up approaches have been shown to reduce elective care through shared decision making, with little risk of adverse consequences	• Imposing financial penalties on patients (cost-sharing) means patients are required to choose between high and low value, often reducing high value care. • Patient health and technology literacy required. • Challenging benefits design packages. • Grassroots initiatives - patient and provider involvement	• Successfully shown to encourage Effective Care • Technology integrated solutions. • Financial savings have been attained, although only marginal given the extent of health budget used
Canada	1	3	2	3 Active 4 Passive	• Bottom-Up passive mechanisms (e.g., Choosing Wisely, STARS Approach) • Risk Sharing with Patients (EMPOWER study) • Review of Incumbent Practices	• Positive Clinician and to a certain extent Patient reception • Preserves Physician Autonomy • Decision aids provided to patients demonstrated a reduction in elective procedures with little adverse risk through shared decision making	• Progress is slow • Requires Patient to take Ownership through Education and Understanding of Treatments and Technology • Labour Intensive Review of Incumbent Practices without obvious Evidence to support Change.	• Financial savings demonstrable • Involvement of Students to incorporate into their practice when graduated to clinicians. • Policy changes to fee schedule and insured services supported by government, political adherance
Other European Initiatives	0	4	6	4 Active 7 Passive	• International supportive across Health System Movement (EuroScan) • Medicine / Pharmaceutical Review that resulted in Delisting of several medications (HAS transparency review) • Proactive Disinvestment Process Case Study from Gemelli University	• Multiple Stakeholder Engagement • Respects Autonomy of Providers • Allows Different Approaches to be learned from • France's Prescrire achieved great success	• Patient and corporation opposition to disinvestment • Public confusion • Primarily medicines / Pharmaceutical focused, with limited consideration of Surgical Interventions, which are often more costly and higher risk • Passive dissemination of evidence	• Successful Cross Country Planning • Effective de-listing of several Medications HAS Success features: 322 drugs of insufficient real medical value delisted. Challenges: • *Prescrire* has been in effect for 30 years, therefore has gathered support from

					• Supply Side Authorisation from the Netherland's DFUMC project.		• Similar drawback of Passive Education Approaches • Changing political agenda delayed reassessment and delisting. • Entrenched stakeholder positions against delisting in some cases of high utilization • Surgeons inherently not wanting to change practice from their well-established habits	Stakeholders – although impact is minimal.

This scoping review has provided an insight into current methods that have been employed to address the concern of low value care. It both demonstrates the international concern of low value interventions but also the challenge in addressing it. The wide disparity in mechanisms to address the problem demonstrates that there is no easy solution.

The role of Health technology appraisal differs widely across countries, particularly with view to incumbent practices. England practices proactive HTA but does not employ it to de-adopt procedures in contrast to the United States that does not have a confluent HTA process in place at all; with inherent belief that the use of cost-effectiveness in appraisals for new technology and pharmaceuticals should not influence the decision to reimburse treatment, let alone disinvest. (97)

Yet there have been some successful ventures by HTA agencies. The mirroring behaviour in the role of HTA from Australia, France and Canada who seek to employ a program with established methodology that reviews incumbent practices with view to de-listing procedures / treatments / medications (e.g., Australian MBS review, France's HAS review, Canada's CADTH review) have all had positive results. However, this is labour and time intensive and may become victim of changing political landscapes, as in the case of the French 'Transparency Review'. Furthermore, one cannot ignore the dynamic nature of medicine, there are often times when an antiquated practice comes back into favour, and a delisted treatment may require re-listing. Given the time that is taken to review interventions it may be that in the life cycle of assessment the review is already out of date. Further criticism at this approach has been that it encounters only 'low hanging fruit,' that is procedures that are obviously antiquated and do not carry a significant financial burden. Beyond this is the clinical heterogeneity that is present in the use of various technologies, whereby there are procedures that are high value when used on some patients and low value when used on others. This is particularly true in the field of surgery, whereby classic approaches to well-known problems must remain in the armoury of the providers – it is here where blanket delisting may be challenging. This challenge has been recognised by the English Based Interventions Program, that have identified ‘exceptional circumstances’ when de-listed interventions may be used.

Other financial active methods that have been incorporated include pay for performance schemes USA, or England QOF framework. These strategies have been successful in priority setting, whereby financial incentives can be used to encourage providers to focus on most harmful or costly forms of inappropriate care. However, this requires precise measurement and monitoring, to ensure that the system is not incorrectly rewarding reduction of effective care in cases where interventions are appropriate. Bundled payments in USA offer a cost sharing approach to promoting disinvestment; here providers are encouraged to consider the value of services delivered, because of extra financial exposure for costs incurred. Positively this preserves clinician autonomy, though reliance on clinicians to change practice is a slow process. Cost sharing with patients is another method noted, however is not without challenge, evidence has demonstrated that charging patients (even a nominal fee) results in the reduction of both high and low value care. This is because patients are not able to discriminate between effective and low value care, which is potentially harmful for vulnerable groups.

The much published Choosing Wisely movement that has proliferated throughout several countries founded by the American Board of Internal Medicine emphasises resource stewardship within the health system. This represents various methods of clinician education as a passive lever to invite reduction of low value care. Clinician decision support systems, education and feedback have all demonstrated positive movement towards high value care. It also carries the advantages of respecting autonomy of provider stakeholder, yet success often depends on the intensity of education provided and therefore can be labour intensive. Reviewing disinvestment initiatives internationally places great importance on stakeholder involvement early, without motivated providers and policy creators any controversial decision will fail. The role of choosing wisely then becomes important, as it provides the opportunity for the clinicians that are key stakeholders to influence this process.

Positively there has been work performed across national boundaries to establish learning from other nations with similar problems (Euroscan). Such activities are valuable when gaining political support to prioritise Low Value Care as an important agenda. Furthermore, it offers early stakeholder engagement at multiple levels in the health system; this appears to be a key lesson learned from various interventions from all nations that is important for positive reception of a change, examples include the changing political agenda encountered by the Haute Autorite de Sante of France; when the Transparency Commission de-listed treatments from its formulary without acceptance of both patients and clinicians the result was local objection and the re-listing of 31% of its treatments.

The case study of Gemelli University perfectly illustrates the problem. Although this single institution was able to identify an economic issue caused by significant local variation in the use of surgical meshes, it found difficulty in addressing it. Requests for change were met with resistance due to senior members of the department not willing to change incumbent practice, a general resistance to policy adjustment and structural inertia that limited impact. Lessons learned from such case studies include the importance of understanding surgical habit, aversion of risk in cases where a new device (in this case surgical mesh for hernia repair) was provided. In this event the surgeons' preferences were taken on board, and clinicians engaged themselves where they perceived a patient benefit. It was also beneficial to have a transparent process, so that the surgeons were involved in all levels of the decision tree. Therefore, although a significant change in mesh use was noted - wholesale change was not present. This may reflect time needed for individuals to change practice because trust in new technology is required. These issues may be multiplied when considering low value interventions at a national scale, and then further multiplied when considering these procedures at an international scale.

Limitations on Narrative Review

The nature of the subject that was reviewed did not offer the opportunity to perform a systematic evaluation of literature, this is because the scientific literature did not provide valuable policy information. Most understanding that was attained and involved was from policy documents and non- academic searches. Furthermore, to review international de-adoption behaviour successfully systematically would be too great a task for said project. Therefore, one cannot be sure that further valuable pieces of information have not been identified – to include in the formulation of the narrative review. Initially attempts were made to include primarily interventions that affected surgical therapies, although there is only scant information within published literature on this subject. Beyond this there is also the flaw of publication bias. In addition to this, most interventions deal with low value care are in their infancy, and confident reporting of outcomes is limited.

Although not exhaustive the narrative review has provided a brief glimpse into the international approaches to inappropriate treatments. National, regional and local levers have been employed with differing levels of success. Similar tools to address these interventions have been used in different ways and differing success. Therefore, there is unlikely to be a ‘one size fits all approach’ to de-adopting low value interventions. Yet learning from these experiences a recognised pattern of addressing low value care emerges.

One may categorise existing levers based on the method of implementation; active (financial) or passive (educational), and their level of stakeholder involvement (micro, meso and macro). This has provided a critical perspective for evaluating strengths and weaknesses of disinvestment techniques. This will be explored in greater detail in Chapter 3 whereby these principles have been used to generate a framework that may offer a solution to tackle low value care. This framework is by no means an exhaustive fail-safe tool that one may use to change clinical care delivery, but it is a well-informed logic framed process by which the method of disinvestment may be conducted.

Chapter 3

Functional Framework to Guide the De-adoption of Low Value Interventions

Introduction

Universal health coverage should be an objective of every health system; to offer high value care which ensures that all people have access to the needed promotive, preventative, curative and rehabilitative services of appropriate quality to be effective whilst ensuring people do not suffer financial hardship (133). Therein a fundamental economic and ethical challenge arises, in the presence of persistently overused low value interventions will a health system be able to achieve high value care for all? Resources are often invested in interventions which do not maximise health outcomes per population. In turn, making the disinvestment of low value health care pertinent to all.

Evidence from the presented review of high-income countries has shown the most successful disinvestment approaches have involved multi-level (macro, meso and micro) collaboration with both active and passive tools. However, most interventions have focused on a single subset or aspect rather than creating a holistic strategy to maximise gains. It is here where an opportunity for improvement remains and lessons may be learnt from experience described in chapter 2.

Methods

For this reason, a conceptual framework for low value care that is evidence based, and logic orientated which addresses the practical methods of disinvesting wasteful interventions is presented. Previous strategies for disinvestment have been categorised and evaluated from a selection of high-income countries across Europe, North America and Australia. These have been used in identifying potential candidates for reform and learning from strategies which have been less successful in the previous review. In turn, this has influenced a holistic framework which encompasses these multiple recurring elements that are continuously involved in the lifecycle of disinvestment.

The objective of this framework and accompanying scoping review (Chapter 2) is to highlight the importance of disinvestment and identify ways in which it can be improved going forward.

The initial framework was presented in a formal seminar at the international Congress Health Technology Assessment International 2019 in Cologne, discussion was invited from a panel of stakeholders from within the health system including policy experts, Industry representatives, Patients, Health Economists as well as clinicians : (Prof. Elias Mossialos, Policy Expert, [LSE School of Health Policy], Dr Alicia Granados, Head of Global HTA Strategy, [Sanofi], Durhane Wong-Rieger, President and CEO [Canadian Organization for Rare Disorders – Patient view], Ruth Lopert, Consultant in Global Health and Pharmaceutical Policy [Organization for Economic Co-operation and Development, OECD] and Dr Aoife Molloy, Clinical Lead of Evidence-based Interventions [NHS England]. With a conglomeration of professional opinions, the framework was refined to a general consensus which has been provided. (Figure 4)

Said framework may serve as a benchmark for future disinvestment campaigns to prioritize, identify, implement and evaluate their likelihood for success. It may be considered a tool from which further activity can be guided as it lays the foundation for basic disinvestment opportunities that may be applied to health systems. Prior to explaining the framework lessons learned from the scoping review will be considered; in order to distil the critical thinking that has led to the formation of said framework.

Lessons Learnt from the Scoping Review

Previous efforts at conceptualising strategies towards disinvestment have included categorising interventions into those that affect patients, (demand side) and those that affect providers, that is clinicians and decision makers (supply side.) (14) This can be further categorised into active interventions (e.g., financial incentives) and passive (e.g., educational interventions, decision supportive tools etc.)

The ideas that were identified and summarised in Table 8, have now been further simplified into distinct concepts below (Table 9). This serves as a point of thinking where the implementation of changes may be made. The process of categorisation illustrates a step in critical thinking before formulation of the disinvestment framework: it permits one to take an overall view to see the tools which have been used and a rudimentary idea of success or failure.

Displaying the levers of disinvestment as in Table 9 also allows for the understanding of common strengths and limitations of each tool. For example, passive approaches such as shared decision making and clinician education both have the strength of being welcomed by providers, respecting clinician autonomy. Yet the end point of achieving de-adoption of low value interventions will be delayed, due to the process of education, clinician acceptance and change. Similarly active movements such as cost sharing and pay for performance initiatives will achieve comparatively rapid reduction in use of low value interventions. They are also similarly flawed - as evidence has demonstrated that such initiatives affect both low value and high value interventions with clinical heterogeneity meaning such approaches are unable to distil the detail required to determine when an intervention is high value in one case and low value in another.(14)

Furthermore, a major lesson learned from chapter 2 is the importance of multi-level stakeholder involvement within the health system. This is required for both political will to move an agenda forward as well as ensuring decisions made from the 'top down' are welcomed for progress. By analysing the health system at *macro* (policy), *meso* (healthcare organization, community), and *micro* (patient / clinician interaction) levels it provides greater clarity for effective engagement of stakeholders and operational challenges at each tier of the system.

From these ideas further conceptualisation of these tools into a practical framework has been performed and presented (Figure 4).

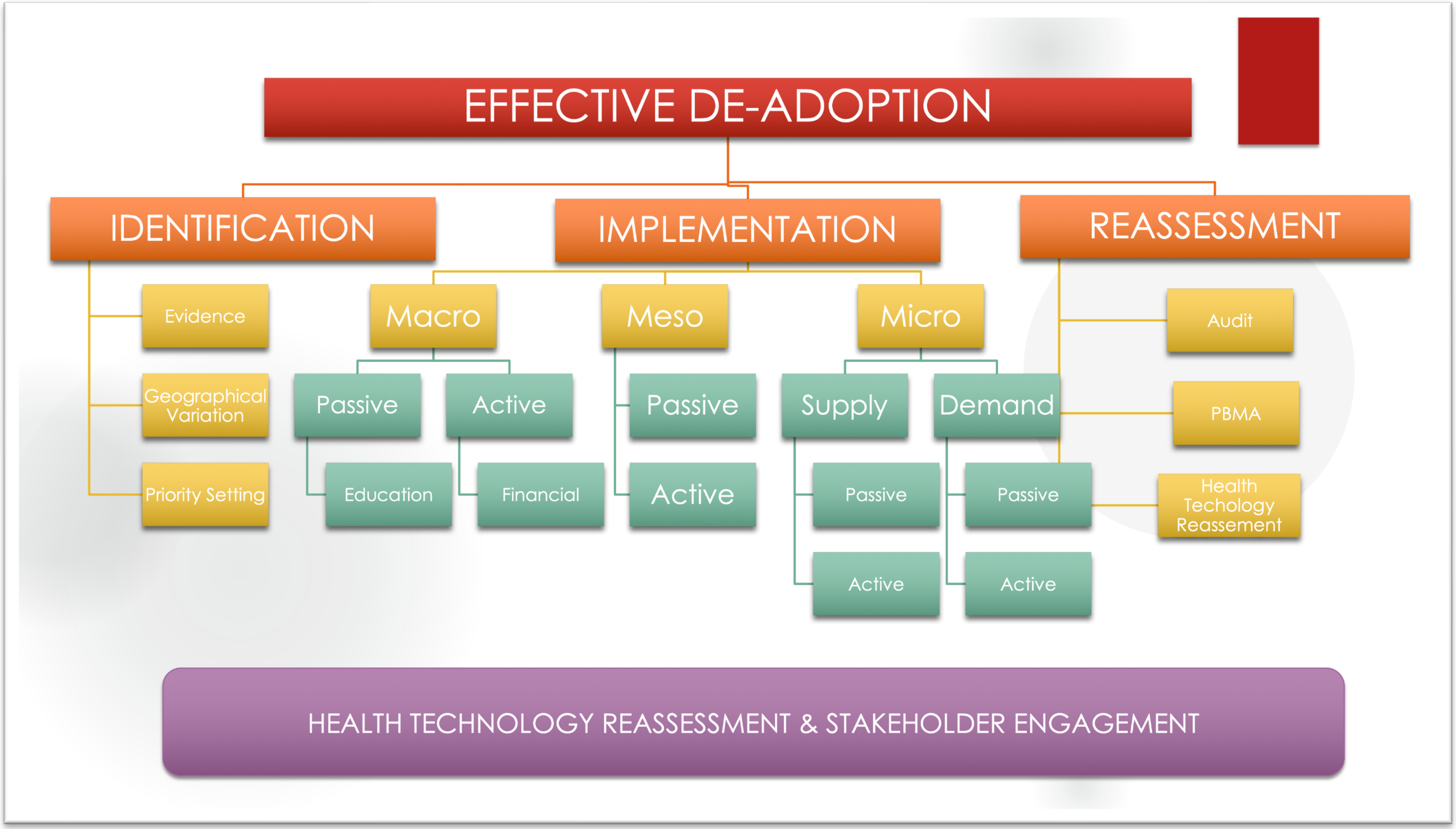
Table 9 – Conceptualised Approaches to De-adopt Low Value Care

Demand Side Interventions	
Passive	Active
• Educational interventions (public awareness campaigns, and patient information leaflets) – Strong Evidence of success • Shared-decision making between patients and clinicians – Mixed Evidence of success • Public reporting of variation in provision of low-care between healthcare providers – Weak Evidence of success	• Cost-sharing for low-value health technologies and treatments (co-payments, deductibles, and co-insurance) – Strong Evidence of success • Removal of low-value health technologies and treatments from a benefits package (ie delisting or negative lists) – Strong Evidence of success • Reference pricing to improve generic prescribing – Strong Evidence of success
Supply Side Interventions	
Passive	Active
• Clinical decision support tools (embedded in health information technology systems, patient pathways, and policies) – Strong Evidence of success • Educational interventions (awareness campaigns, continuing professional development) – Mixed Evidence of success • Feedback to providers (cycles of audit and feedback, individual feedback to prescribers) – Mixed Evidence of success	• Pay-for-performance (financial incentives to reduce provision of low-value health technologies and treatments) – Strong Evidence of success • Penalties or fines for overprescribing or providing unnecessary care – Weak Evidence of success • Payer restrictions (through gatekeeping, or prior approval mechanisms) – Strong Evidence of success • Risk sharing (through capitation or global budgets) – Mixed Evidence of success

Creating the Framework

The following conceptual model for disinvestment of low value care includes three main stages: first ***identification*** and prioritization of low value interventions through literature review and variation, followed by ***implementation*** of methods at macro, meso and micro levels to stimulate disinvestment. Finally, ***reassessment*** of the use of low value interventions to objectively assess the success or failure of the implementation. It should be stressed that this model is continuous, as healthcare is a dynamic field, where interventions are superseded by innovations regularly and similarly innovations are found to be flawed resulting in exnovation (Figure 4).

Figure 4 - Functional Framework for Effective De-adoption



Identification

Identification of procedures that are of low value is often controversial and challenging. As medical technology and data analysis advances certain antiquated methods and procedures become obsolete, unsafe, or cost-ineffective. Various approaches to identify these interventions have been tried.

Exploring Published Evidence

A common approach is exploring peer-reviewed literature. Search strategies that review the evidence base systematically to identify low value procedures routinely performed in health care have been reported (112). Many OECD countries including UK, Australia and Canada have utilized this approach. The searches include a multi-platform method where peer-reviewed work is examined alongside databases such as the Cochrane Library, using strict inclusion and exclusion criteria, to produce lists of procedures that the evidence base has identified to be of low or lower value. (This process is described in detail in Chapter 4)

Even when searches identify procedures that are of low value, translating the evidence into practice is challenging. Cost-effectiveness is assessed by guideline producing bodies - however this does not take in to account the resource impact or affordability of the recommendations. For example, the BMJ Rapid Recommendations series focuses on systematic literature searches combined with economic evaluations to develop recommendations that aim to translate evidence into practice. The recommendations focus on evidence that will change practice, and as such often focus on reducing low value interventions .(134) The NICE "do not do" database aimed to identify recommendations on what not to do from NICE guidance through automated searches and clinical approval of recommendations. The database failed to identify sufficient saving opportunities (1).

Variation

Another approach to identify candidates for disinvestment is to analyse administrative healthcare data. This can provide information on volume, variation and feasibility. Substantial variation may either demonstrate inequity of care (underuse of high value intervention) or inappropriate use of resources (overuse of low value interventions). Therefore, broad geographical variation implies inappropriate care, and whether it is overuse or underuse requires further assessment. Low volumes of an ineffective procedure suggest that disinvestment is feasible, that best practice is being achieved and learning can be shared with areas that are not achieving low volumes. Whereas high volumes suggest an area of high resource use. (135) This may represent overuse of a service; where there is regular use of a treatment to those patients who lie beyond the population to whom it is truly beneficial: the so-called 'indication creep'.

Challenges with data availability and suitability are common. Despite limitations due to coding errors that hamper robust analysis, patterns of variation can identify areas and interventions of priority. Identifying the threshold for intervention remains contentious, what represents ideal use is unknown, particularly when trying to account for the nuanced differences in local population. Ultimately identifying the optimal use of intervention where it is disinvested if overused and adopted if underused is a dynamic equilibrium that is difficult to achieve.

The Evidence Based Interventions (EBI) Programme within England's NHS produces statutory guidance and tariff changes on procedures that are inappropriate or only appropriate in certain circumstances. This is following identification of interventions both through rigorous evidence searches as well as variation in practice. Getting It Right First Time (GIRFT) and Rightcare also use data on geographical variation to benchmark health care providers and inspire high quality and high value care (136).

Prioritisation of interventions for disinvestment

The next step from identification (although contained within this arm of the model for simplicity) is the prioritisation of identified interventions. Previous efforts at disinvestment have often been hampered by the lack of systematic priority setting. In England local efforts to prioritise procedures for disinvestment are common. These typically include an evidence review and a local resource impact assessment; for example, local policies in CCGs listing Procedures of Limited Clinical Effectiveness (POLCE) or Procedures of Limited Clinical Value (PLCV). While local approaches mean that the needs and views of the local population are considered, variation and inequity can occur as the approach is not standardised and cannot cater for rare cases due to small numbers, lack of capacity and advocacy.

Therefore, public, patient and health system engagement in prioritisation of procedures for disinvestment is important for successful implementation. (137) However, prioritisation decisions should be informed by robust evidence and the impact on health care quality and resources. The evidence reviews mentioned previously provide rigorous appraisals of available evidence, and economic and cost impact reports can illustrate resource impact. However, it is imperative data analysis should support prioritisation decisions.

Implementation

Following identification, implementation of disinvestment efforts requires analysis of the environment and necessary stakeholders for adoption. Conceptualising the implementation stage into tiers allows greater emphasis of the multidimensional attributes within the healthcare setting to facilitate integration, crucial when selecting the optimal strategy.

By analysing the health system at *macro* (policy), *meso* (healthcare organization, community), and *micro* (patient / clinician interaction) levels it provides greater clarity for effective engagement of stakeholders and operational challenges at each tier of the system (10). Strategies for disinvestment can be further classified as *passive*; education driven providing information for decision makers, providers and patients, or *active*; financial rewards or other regulatory tools levied at each level to incentivize behaviour change and stakeholder compliance.

Macro Level Approaches

Passive Mechanisms

An analysis of past educational efforts aimed at reducing low-value care at the macro level have included Choosing Wisely (138), EuroScan (127), Spain's Guidelines for Not Funding Technologies (GuNFT) (114), and the UK's Atlases of Variation (18, 135, 139). Each initiative has focused on improving system level adherence and education through information, top-down policy levers and international collaboration.

The Atlases of Variation has stimulated efforts to passively inform providers at all levels on their underuse / overuse of specific medical care. Variation identifies outliers in practice, creating an opportunity for discussion at every level. The English NHS' Atlases of variation are supported by outcome benchmarking knowledge packs as well as commissioning for value information in order to impact meso and micro level decision makers and stimulate change. Thereby educating commissioners and clinicians to provide a breadth of understanding to the problem at hand. Italy similarly has provided target diagrams so policy makers can interpret and act on them accordingly. (18)

Macro level education campaigns require strong governmental support as most disinvestment efforts to date have been government led. Education has proven ineffective at stimulating change in silo, integration with financial tools and multi-tier engagement may lend well to an effective solution with high likelihood for success.

Active Mechanisms

A recent innovation within healthcare financing has been the use of insurance schemes to incentivize patient selection against wasteful treatment with co-payments and deductibles – termed value-based care. (23) (140). This has been popularized within health insurers in the United States through reference pricing for pharmaceuticals within multi-tier medicine formularies. This supply side innovation aims to align financial incentives to the quality, efficiency and value of care delivered to the patient. Alternative payment models such as accountable care organizations, bundle payment models and value-based purchasing focus on reimbursing providers for high value care, concurrently de-adopting low value interventions. Not only does this encourage patients to improve health literacy in the healthcare goods they consume but also increase involvement of treatment decisions. However, till date the success of pay-for performance has been limited; postulated to be due to limitations of design and difficulties at implementing incentives.

In addition to value payment schemes, accountable care organizations (ACO) have gained importance in providing integrated care. ACOs have prioritised coordination attempting to bring quality of care to the foreground adjacent to cost. In theory, the transfer of financial risk from the health care system to the ACO aligns financial incentives to reduce the use of wasteful interventions.(141)

The role of systematic priority setting has now become a prerequisite for nations to provide high quality care. Internationally, HTA is routinely recognised as a method to successfully make decisions on resource allocation that is both cost and clinically effective (with the notable exception of the USA). However, HTA is often limited by its focus on new and emerging technology, without the capacity to reassess previous antiquated ingrained interventions as in England: NICE's Cost Saving Guidance aims to address the real world context of guideline implementation and identify resource saving opportunities (142). Health technology reassessment (HTR) should similarly direct decisions on exnovation, that is the process of removal of innovations that do not improve organizational performance – at the end of the innovation cycle. (143)

Macro barriers

Overcoming inertia is a prerequisite to successful policy change and implementation. System level inertia at the macro level can include government bodies and organizations with that may be resistant to change. Any reform in status quo is likely to encounter opposition. Therefore, significant importance must be given to stakeholder consultations when framing the policy objective. Engaging key stakeholders within the implementation phase can help to address the challenge of appropriateness, feasibility, and relevance within context specific applications.

Meso Level Approaches

Passive Mechanisms

The role of primary care in delivering high value healthcare has been demonstrated (144). International comparisons of health outcomes in various health-care systems have shown the importance of primary care for delivering the correct care to the correct individual. Therefore, high quality primary health care may bolster the calls for increased shared decision making and a coordination of integrated care.

Healthcare facilities are the mid-point along the continuum between providers and national levers and can help facilitate provider adherence through local campaigns, policies and mandatory educational sessions tailored to the intended audience.

Active Mechanisms

Financial mechanisms have relied on health technology through electronic medical records (EMRs), assessment of existing health technology tools, and financially incentivized guidelines to increase provider adherence. Disinvestment initiatives have included the PriTec prioritization tool in Spain, the ETHAN program in the US, and Getting it Right the First Time (GIRFT) in the UK. Financial tools have been the favoured approach at the meso level with results positively indicating use as an effective method of eliciting behaviour change and compliance.

In England Clinical Commisioning Groups (CCGs) act as local level priority setting taskforces. They have employed the use of evidence review and a local resource impact assessment in order to instigate change. As described previously, CCGs have listed Procedures of Limited Clinical Effectiveness (POLCE) or Procedures of Limited Clinical Value (PLCV) that are only commissioned when strict criteria are met. (145) Although this has been met this with clinical disapproval. While local approaches mean that the needs and views of the local population are considered, variation and inequity can occur as the approach is not standardised and cannot cater for rare cases due to small numbers, lack of capacity and advocacy.

Meso barriers

In addition to system inertia common at the macro level it also remains a challenge at a meso level. Local change through CCGs, ACOs, insurance providers and healthcare facilities are easier to stimulate through grassroots motivated initiatives. By encouraging participation at the meso levels the initiative can receive local feedback which can improve transferability at the macro and micro levels. Overcoming inertia requires a combination of passive (education of local practices and organizations) and active (financial incentives tied to compliance) measures to inform and motivate change from low to high value healthcare.

Micro Level Approaches

Passive Mechanisms (Supply Side)

Clinical practice should be process driven and delivered according to evidence-based guidance, thus attempting to give clinicians safety for their decision making. Hence reference to clinical practice guidance has become routine to today's physician. Evidence suggests that establishing and advertising clinical guidance does improve both process and outcomes, yet the magnitude of change is variable. The lack of diffusion of these ideas often means that the time taken for a meaningful impact to take place results in delayed effects.

Furthermore, the nature of clinical medicine opens itself to over diagnosis and overtreatment, particularly in nations where health delivery is fee for service, an element of supplier induced demand. In order to combat this national bodies have recommended that strict definitions of disease diagnosis and treatment algorithms must be established.

Physician led grassroots initiatives have shown to increase compliance as evidenced by the multi-national Choosing Wisely campaigns which have focused on educating clinicians. However Choosing Wisely's effect has been limited, often by defensive decision making and the inability to prioritise high impact interventions.

Active Mechanisms (Supply Side)

Awareness and impact of cost has become more prominent among the physician cohort. The endorsement of financial incentives and restructuring of payment rules to support high value care is becoming more prevalent, particularly in the US. Dis-incentivizing low-value care through financial reimbursement has increased in importance with attempts to integrate pay-for-performance to engage providers in risk sharing. For example, the US institute of Medicines review of cancer care recommended that Medicare and other insurers recognise and compensate providers that follow the Choosing Wisely protocols.(146) Alternatively, France had minimal success administering financial penalties for providers who did not routinely align their practice with national guidance. For obvious reasons the physician body did not respond well to this innovation in healthcare delivery. Adjusting compensation to increase physician accountability and internalize behaviour impacts financial motivation and can be used as a carrot or stick reward respective of performance. Pay-for-performance mechanisms have limitations in practice but can be used as a steppingstone towards enabling providers to be more aware of their contribution to the budgetary constraints of the health system.

Passive Mechanisms (Demand Side)

Patient centred care and shared decision making have received continued advocacy as information on treatment and diagnosis have become more accessible to patients. Incentivizing accountability through financial penalties and education programs are two ways of engaging patients in the evolving shared decision-making process. (147, 148)

Patient involvement is not only an inherent ethical necessity when making decisions about healthcare, but it is also an important tool for change. Their involvement not only legitimises efforts to reduce healthcare costs without ‘rationing’ care but also play an indirect role at controlling demand for inappropriate and antiquated care. It is therefore important to provide these consumers with the correct information, and comprehensible knowledge in order for them to make appropriate decisions on services which are appropriate. The absence of accurate knowledge fuels expectations from uninformed, or misinformed individuals that results in clinicians obliging and providing low value care.

Public reporting campaigns, Choosing Wisely, and the EMPOWER trial in Canada have prioritized educating patients to increase their understanding of low-value care so they can lead conversations and understanding information when accessing healthcare services. However, educational efforts must look to overcome the health literacy barrier that can lead to disproportionate outcomes for individuals with little education. (149)

Shared decision making is another movement gaining ground. Evidence supports shared decision making and has been considered a route to high value care. Additionally, it improves adherence to medication, reduces hospital admission and surgical interventions (150, 151). Internationally approaches to shared decision making are beginning to implement these improvements but policy recommendations must support the culture and behavioural change needed to achieve high value care (151). A 2011 Cochrane review showed that well informed patients are less likely to choose to undergo surgery, in favour of less invasive procedures. (150, 152). Although this is not always the case – even if ultimate reduction in care is not the end-point patient education remains a necessity.

Active Mechanisms (Demand Side)

Cost sharing in the patient-provider relationship has been used from the supply and demand-side to make patients internalise inefficient behaviour and increase accountability in healthcare decisions. The introduction of co-payments, deductibles and co-insurance has been leveraged by insurers in the US to guide patients when selecting treatment options. Low-value care services are priced with a higher co-payment than the high-value counterpart. However incentivising patients to choose care based on value is difficult. When often well-versed health practitioners cannot decipher between high and low value care – how can we realistically expects patients to understand the implications of cost and outcome?

The greatest barrier to implementation at the micro level is aversion to change (termed “loss aversion”). It remains a consequential challenge for both agents of the patient-provider relationship. Patients believe they are losing medical care due to cost saving measures. Providers believe they are told they have been incorrectly providing medical advice. (153)

Engaging providers in decision making is central to a successful intervention. Using passive (academic detailing, patient focused education campaigns) grassroots initiatives led by local change makers can help to develop robust guidelines, reduce evidence gaps, and encourage adoption ultimately stimulating the transition from low to high value healthcare (17). Active (financially incentivized) measures such as risk and cost sharing can force compliance from patients and providers but are far from cooperative in decision making.

Innovators are faced with a decision matrix, whether to educate or financially motivate, and what level of the health system to address. Decision makers can choose to integrate active and passive initiatives while targeting multiple tiers of the healthcare system to stimulate system wide change with high likelihood for success. (14) An alternative approach may include tailored interventions to a specific level of the health system with a direct focus on passive or active tools to emphasize greater clarity with a specified objective. Ultimately experience till date has not elucidated a failsafe approach, and it is likely one does not exist.

However, learning barriers from international experience may aid to optimise efforts at disinvestment.

Evaluation

With any health reform transformation cannot be complete until it has been re-evaluated in the face of existing change. It is imperative that the field of healthcare is recognised as a continuum. Therefore, once measures have been implemented it is important to evaluate the impact of these levers of change and address any failures that have occurred. The nature of technology and innovation means that a procedure or innovation may rapidly become antiquated given the current pace of research. In this situation the role of health technology reassessment is vital.

Methods for Re-evaluation – HTR, PBMA, Audit

Multiple evaluation tools including health technology reassessment, program budgeting marginal analysis, and evidence-based practice are highly applicable to interpreting performance outcomes on disinvestment. Evidence based decision making integrates information and implementation to achieve high level performance. Program budgeting and marginal analysis is not in favour of complete disinvestment as it is often unachievable and may result in inefficient behaviours. Rather, partial disinvestment based on opportunity cost (equating marginal benefit to marginal cost of services) results in an equitable, allocatively efficient distribution of services and health outcomes. The disinvestment of one service enables reinvestment of the accrued savings in another part of the health sector, achieving the "optimal balance of services in light of resource constraints" (154).

The use of HTR in the re-evaluation phase is critical to analyze the interventions ability to meet predefined objectives by assessing data, effectiveness and efficacy. Analysis of existing clinical practice is essential for disinvestment and increasing system wide efficiency. HTR is a subsequent analysis which follows previous HTA. HTR determines the efficacy and effectiveness of technology throughout the lifecycle of use. What differs HTR from HTA is the point in the lifecycle of technology the assessment is performed, and the intention of the assessment. HTA is intended for approval of new services, medical devices, and innovative practices whereas HTR performs reviews of existing services to determine those that are still optimal being both clinically and cost effective. HTR is intrinsically dynamic which allows it to be utilized at all stages of development and measurement. Therefore HTR can be considered as the ”continued management of technologies at any point in their lifecycle” (133).It can lend well to change the narrative on disinvestment from passive and slow to active and integrated . (155)

As a result of the importance in defining low value care, the complex interaction with stakeholders and re-evaluation of existing technology, it is necessary to integrate HTR as a cross-cutting dimension of the framework. HTR is a central element to define candidate technologies and medical services for disinvestment (identification and prioritization), is required to engage clinical and political stakeholders to determine the accuracy of services identified (implementation) and is necessary when evaluating the performance and measurable outcome of results (evaluation).

The final component of re-evaluation includes auditing performance. Following implementation, the disinvestment strategy must be audited through data collected from performance measurement to identify success, limitations and potential for improvement. Routine audit’s and HTRs encourage compliance and high performance as evaluation is no longer a static endpoint but a fluid ongoing process.

Stakeholder engagement

In addition to HTR, engagement of stakeholders is another cross-cutting dimension interacting with identification, implementation and evaluation. Successful disinvestment requires input from physicians, payers and patients who are likely to be affected by proposed changes.

Targeting patient adherence requires dedicated strategies focused on the micro-level of the health system through cost sharing or education. Improving patient acceptance requires education on the flaws of current medical practices for low-value care and the detrimental impact they can have on health outcomes and the broader system. Without education patients are likely to rely on the predominant belief that more is better in medicine (146). Financial mechanisms such as cost sharing can force patient acceptance without the need for education but may result in opposition and adverse behaviour. Increasing information on low-value care can support autonomous decision making and increase their skill and competence in making high quality health decisions about their choice of care.

Using evidence-based practice to inform implementation provides strong reasoning when devising strategies aimed at engaging stakeholders. To successfully engage providers a disinvestment initiative must frame the physician's responsibility in defining and reducing low-value care when providing patient consultations. Physicians should be consulted early as they have a central role in decision making which can affect the patient, health organization, and national policy agenda. Solutions should opt for active disinvestment to engage providers with the use of health technology and defined agenda setting (136). Contrary to existing theoretical stage models, active evaluation mechanisms which encourage provider feedback during the implementation phase utilizing health technology have the potential to encourage provider acceptance and communication – leading to increased compliance and improvements in implementation. Integrating stakeholders within ongoing decision making adjacent to HTR prioritizes that the candidates selected for disinvestment are relevant and feasible.

Barriers for HTR & stakeholder engagement

Clinical inertia and resistance from physicians represent a common barrier to implementation. Therefore, it requires diverse support from stakeholders at the micro, meso, and macro levels of the health system to encourage uptake of recommendations with the objective to reduce medical waste. These barriers to change represent significant challenges that must be addressed and integrated within solutions to achieve consensus and support for disinvestment whether partial or complete. In addition to aligning involvement of stakeholders and HTR at each stage of the model, further success can be achieved with an increase in education on HTR alongside capacity building of key stakeholders (3).

Technology

Health technology including EMRs, the PriTec tool and more local initiatives such as the ETHAN program have beneficial results in encouraging ongoing evaluation of process guidelines. It provides a simplistic approach for all levels of implementation (macro, meso and micro) to be engaged with. Integrated reminders can stimulate conversations on low-value care between patients and providers and serve as a tool for education and financial motivation. The growth of health technology has enabled patients to create and access their medical information once restricted to medical procedures and tests, ultimately promoting greater participation in the care consultation (54)

Table 10 - Examples of Interventions in the De-adoption Framework

System Level	Feature	Country	Intervention	Description
MACRO	Active	Australia	Comprehensive Management Framework	156 of 5209 services in the Medicare Benefits Schedule were reviewed and identified as potentially low value.
			Pharmaceutical Benefits Advisory Committee	Post-market review and selective disinvestment (40% price reduction for some Alzheimer's drugs) of medicines. Restricted access for certain drugs based on patient criteria.
		Canada	Ontario Reassessment Framework	Removal of insured services and amendment of fee schedules. Produced CAD $59M in savings.
		England	NHS Pilot Disinvestment program	Pilot program to identify interventions that would save £1M yearly. Following this guidelines and recommendations ("do not do" lists) were produced.
			QIPP	Reduced six low value care interventions within the first year. Aim to produce quality improvements and £20B in savings by 2020/2021.
		France	Transparency Commission	Disinvestment for 860 of 1675 drugs in the reimbursable list. Further reassessment of new drugs after initial five years.

		United States	R-SCAN	Online tool facilitating radiologist and physician cooperation in improving image utilization. Financial support from the Centers for Medicare and Medicaid Services' Transforming Clinical Practices Initiative
	Passive	Multiple	Choosing Wisely	International campaigns encouraging provider and patient engagement through low-value care lists. Participation from over 19 countries.
		Multiple	Euroscan	European partnership between governments, international organizations and research institutes. Sharing evidence and resources on emerging health technology.
		Australia	Life Saving Drugs Program Review	Determined if effective criteria were in place for reasonable access and cost-effectiveness. Proposed an additional review of listed medicines after 24 months.
			National Medicines Policy	In response to the WHO's conference on appropriate drug prescribing. National program to identify low-value services.

		England	Atlases of Variation	Interactive atlases published on unwarranted variation used to stimulate investment in high-value care.
			Evidence-Based Interventions program	Joint effort by five national organizations (NHSE, NHS Improvement, NICE, NHS Clinical Commissioners and the Academy of Royal Medical Colleges). Identified 17 low-value care interventions; 4 to be used in exceptional circumstances and 13 if prior conditions met.
			Reducing overprescribing ineffective medicines in primary care	Identified 18 medicines which should not be regularly prescribed. Estimated cost savings of £141M yearly.
		France	Prescrire	Monthly reviews of new drugs and yearly “drugs to avoid” lists.
		Spain	GuNFT	Identified ineffective medical technologies and measured patient preferences. Findings published in online reports.
		Sweden	Uncertainties and Disinvestment project	Health technology assessments performed without sufficient evidence. Produced a database and report on evidence-based practice and decision making.

MESO	*Active*	Canada	North York General Hospital	Reduced 10 low-value interventions through integrated recommendations in order entry systems, screensavers, blogs and social media. First year produced CAD $157K in savings.
		England	GIRFT	Pilot program to reduce variation in orthopedic surgery. Produced £30M in savings for 2014/2015 with potential for £1.5B in yearly savings .
		Italy	Gemelli Case Study	Reduced use of high weight surgical meshes by 65%.
		Spain	PriTec Prioritization Tool	Online program evaluating up to 50 simultaneous medical technologies for redundancy.
		United States	University of Southern California Medical Center	Reduced unnecessary preoperative consultations by 64% and wait times by 181 days (median). USD $1.2K savings per patient.

	Passive	Australia	ASTUTE Health Study	Multidisciplinary committee commissioned to develop a protocol for transparent decision making in assessing safety, cost and clinical effectiveness
		Canada	Alberta Health Services	Changed order forms and increased education reduced low value testing by 92% within 9 months saving CAD $1.5M.
			STARS	Grassroots led student initiative with participation from all Canadian medical schools. Let to similar campaigns in the Netherlands and United States.
		United States	Case Study Competition	Led by the Hospital of Society Medicine and Choosing Wisely. Prizes were awarded for best pediatric and adult low-value care recommendations.
			ETHAN	Ambulance teleconsultations reducing inappropriate emergency department admissions 6.7% saving USD $1M. Patients received instant referral to appropriate care.
MICRO	Active	United States	Cost-sharing	Insurance plans using coinsurance, copayments and deductibles in addition to value-based insurance design.

	Passive	Canada	The EMPOWER Cluster Randomized Trial	62% of participants engaged their provider in conversations on stopping benzodiazepine therapy. Post six months 27% ceased use.

Abbrieviations:

(Eliminating Medications Through Patient Ownership of End Results) EMPOWER
(ETHAN) Emergency Telehealth and Navigation Program
(GIRFT) Getting It Right First Time
(GuNFT) Guidelines for Not Funding Health Technology
(NHS) National Health Service
(NHSE) National Health Service England
(QIPP) The Quality, Innovation, Productivity and Prevention program
(STARS) Students and Trainees Advocating for Resource Stewardship

Conclusion

While there is broad consensus that disinvestment in low value care is crucial to the financial sustainability of healthcare systems, there continues to be disagreement among relevant stakeholders how to identify potential candidates for disinvestment and what approaches should be utilised to encourage disinvestment. The complexity of these challenges is further compounded by uncertainties in defining in what circumstances specific health technologies or interventions may be considered low-value, and technical difficulties in the monitoring and evaluation of initiatives. These confused objectives have often led to differing levels of success and fractured relationships between policy makers, clinicians, and patients. One thing is clear, that no perfect mechanism of disinvestment has been identified till date - in essence representing the challenge of disinvestment in low-value care.

The conceptual framework paired with the earlier analysis (Chapter 2) serves to highlight strengths and weaknesses in the current agenda for disinvestment. This is meant as a guide for the broader community to lead and inform the discussion on low value care and to encourage further international collaboration. Although the present framework was refined following involvement of expert consensus opinion from HTAi 2019, where several stakeholders were invited to offer their thoughts on the best method of disinvestment, no formal methodology was used. Therefore, for further validity further research is required, a Delphi approach would be valuable in this regard.

Looking to the future we agree that lessons can be drawn from past experiences and approaches over the last two decades. It is difficult to determine whether any tier of the framework is more relevant than another, what is clear is that for wholesale change no individual tier or strategy will be successful alone. Disinvestment must be sensitive to the opinions of all stakeholders whom often drive persistent use of low value care; it must have a rigorous and transparent approach to the identification and prioritization of potential candidates for disinvestment; and implementation must draw upon multiple approaches that considers both demand and supply side perspectives. Implementation needs to be understood as a dynamic process that involves continual monitoring and evaluation and feedback to individual clinicians and healthcare providers.

Chapter 4

Identifying Low Value Care in General Surgery

Introduction

As already established given the pressure on national health care budgets worldwide, and the well-publicised expected funding gap finding efficiency savings in health care provision is paramount. This provides motivation to *identify* and reduce the use of health care interventions that deliver only marginal benefits, be it through overuse, misuse or waste, that could be substituted by less costly alternatives without affecting safety and quality of care. As has been described earlier (Chapter 2 and 3) the first stage of de-adoption is the identification of candidates that do not confer high value benefit to the patient, provider and population. It is important to note that the objective should not be to implement cost-cutting strategies, but rather strategies that improve value (i.e. health outcomes achieved per unit cost spent) in health care delivery by avoiding the opportunity cost of investing in low-value services. It has been recommended that to align the objectives of all stakeholders, i.e. clinicians, patients and providers, a greater emphasis on value is key and achieving high value for patients must become the goal of health care delivery. Thereby reducing costs, improving health of the population and improving care experience (15, 156, 157).

Efficiency gains and value can be achieved if resources are re-allocated from low-value services towards equally (or more) effective, but less costly approaches. England's National Institute for Health and Clinical Excellence (NICE) commenced a formal agenda in this area in 2006 to address the issue of disinvesting in low-value care/procedure/practice (113). Consequently, NICE has published recommendation reminders reiterating existing guidance. Furthermore, following the launch of the Department of Health's QIPP programme (quality, productivity and prevention programme), NICE reviewed its disinvestment programme and the 'do not do' recommendations contained in NICE service guidance were issued. (113)

The public health commissioning network and NHS Atlas of Variation (158) have identified unacceptable variation in care surgical care commissioning by PCTs often perceived to be due to inconsistent approaches to commissioning of surgical procedures. There was also a significant difference between the language of the commissioners and the surgeons themselves, a conflict between quality versus value and populations benefits. This discrepancy led to inefficient governance of surgical procedures, highlighting it as an important genre in which to assess value of practice.

In this context, an initial step is to establish a systematic and transparent strategy to identify potential low value clinical services for review, with reference to general surgery. Aiming to highlight potential low value services which may provide opportunity for withdrawal; thus, improving the presence of high value services under the greater auspices of opportunity cost. The goal of this project is not however to produce an exhaustive list of ineffective practices but highlight possible avenues for debate to stimulate discussion with the overarching goal of reducing ineffective low value care.

Previous published methods of literature review have identified difficulties in performing an exhaustive search, commonly a broad literature search will identify a vast number of citations with only a few papers of realistic relevance. (159) Thus some groups have limited search to individual journals or have identified practices through highly cited journal articles only. Furthermore, only one example excluded pharmaceutical interventions, with medical interventions dominating previous findings. (53, 153) In contrast we focus on general surgical interventions and classify those interventions in terms of sources of potential disinvestment possibilities. A further step was then taken to evaluate the impact on the health budget by estimating the monetary value of these low value interventions

Methods

A combined method of identifying low value services was undertaken; this included a peer-reviewed literature search, a targeted database search and opportunistic sampling. With intention to identify general surgical procedures or interventions that are currently employed due to time honoured practice or previously published guidance; yet newer published research has identified these interventions to be ineffective with the previously identified outcome improvements found to be overestimated, or incorrect (53) .

A recognised difficulty with research in the field of disinvestment is the lack of regular terminology used to describe low value procedures. (6, 159) . Therefore an extensive list of keywords were required to perform an encompassing literature evaluation. The method used presently was similar to published approaches (112). However when this process was used it identified a vast number of articles through its broad literature review, which was too great a number to evaluate (159 858 citations after limitations were applied), thus only a fraction of the citations were reviewed (1500 papers.) Given this, strict limitation were employed, thus gathering the maximum number of papers with relevance, in order to accumulate a manageable number of citations which could be systematically evaluated to identify low value procedures.

Literature Review

A Medline search strategy using the Pubmed interface was employed using the keywords and medical subject heading (MeSH) strings (Figure 5) across the bibliographic databases in order to identify surgical services which were of low value and potential candidates for de-adoption. Choice of search terms was influenced by previous search strategies. (112) Filters were applied to identify citations published between 2000 and 2015, publication type (only meta analysis and systematic review were considered), English language articles and those with available abstracts. The inclusion of only high level evidence is due to clinician perspectives that for a change in current practice 'compelling' evidence is required, thus to make our results more relevant for potential de-adoption only meta-analyses and systematic reviews were included in the broad literature review. This had the additional benefit of narrowing the search finding citation number to a manageable volume. Exclusion criteria were applied to screens of titles, abstracts and full text articles. These are illustrated in Figure 2 Ultimately using this method of identification 6,680 citations were reviewed.

Targeted Database Search

All reports from the Cochrane library were considered, after standard filters (humans, English language, surgery) were applied. Similarly, all reports from the NICE 'do not do' recommendations were reviewed. Reasoning for reviewing these databases stems from the validity of high quality systematic reviews and expert opinion in establishing health policy respectively. Both offer valuable sources of high level evidence to identify areas of current overuse and low value practices. Therein a further 1345 and 1000 citations were reviewed from this search method.

Choosing Wisely

All currently published recommendations from the Choosing Wisely movements of USA, Canada, Japan, Australia and the Netherlands were reviewed. These are based on consensus opinion of established medical literature with the target of identifying services to de-adopt, thus are a relevant source of guidance on low value practices.

Opportunistic Sampling

This included reports identified following review of full text article citations; that is bibliographies of identified key articles were hand searched for any other relevant articles.

Following the three search strategies a master list of services was compiled. All citations were assessed by means of relevance, that is whether they addressed a clinical general surgical practice or diagnostic test and evaluated it against current practice. If no comparison was made, or no clinically relevant outcome was measured, and superiority / inferiority demonstrated then the article was excluded as value was not assessed. Any articles concerning novel insights into pathophysiology or novel molecular basis of disease were excluded. When practice information could not be identified by abstract alone then full texts were reviewed. Full details of exclusion criteria are demonstrated in Figure 7. Studies that reported the value of a procedure or service as inferior or similar to current strategies were included. Subsequently a final complete list was compiled.

Further estimation of the impact of each identified low value intervention was performed by evaluating cost and calculating potential savings. This was done by assessing both the cost of intervention and the incidence per annum in the UK. The frequency of procedure performed was included where available from the procedure's explorer tool on the Royal College of Surgeons' website for the year 2014. This information is derived from the Hospital Episode Statistic (HES) dataset, developed through a collaborative project between the RCS Surgical Specialty Associations, NHS England and Right Care (160). If frequency information was not available through this method, then a literature search was performed to identify relevant epidemiology. Costing information was taken directly from the National Schedule of Reference Costs Year : 2014 – 15 (6). Each intervention was costed according to its relevant healthcare resource group (HRG) ; which is a reimbursement tariff of the average unit cost to the NHS of providing a defined service in a given financial year (161). Any costs of an intervention beyond the associated healthcare resource group such as the cost of specialised high cost devices or costs of specific diagnostic imaging per procedure (the so-called 'unbundled HRGs') were not accounted for as they are often not consistently used for a given intervention. (161) Furthermore assumptions that the interventions were outpatients and did not involve any co-morbidities were made in order to make the most conservative estimate possible. (160) Note that this was a crude measure of costing, only taking into account the cost of the intervention as defined by reference costs HRGs : without performing a formal economic evaluation. Any excess costs involving the non-use of intervention were also not considered. Similarly, if costing information was not available through this method, then a literature search was performed in order to identify relevant information.

To categorise the results further services were segregated according to quartile with respect to cost (Quartile 4 where costs ≥£800.58, Quartile 3 where costs ≥£113, Quartile 2 where costs ≥ £3.20) . They were further categorised according to calculated median frequency (n=10 058). Thus, those interventions which were performed more commonly than the median were categorised into the high frequency group. Those interventions where volume activity information was not available (often due to the intervention being experimental in nature, or not in routine use as is against current clinical orthodoxy) were automatically considered low frequency. Quartiles were not used to describe frequency due to the skew created by the significant number of absent results. This then permits one to consider those services which have the highest impact (higher quartiles and high frequency) in comparison to the lower impact interventions (lower quartiles and low frequency).

Figure 5 - Literature Review Search Keywords

Keywords :

String 1: Safety

(Unsafe OR Danger OR Adverse Events OR poor Outcome OR (Low Quality) OR (poor Quality OR Harm OR Contraindication OR

OR

String 2 : Effectiveness

Ineffective OR Irrelevant OR Supersede OR Outdated OR new evidence OR Overused OR Unproven OR Inappropriate OR Equivocal OR uncertainty"[MeSH Terms] OR "uncertain" OR Obsolete OR Inferior OR Superior OR

OR

String 3 : Policy Solutions

Disinvestment OR CED OR coverage with Evidence development OR "development" OR AED OR Access with Evidence development OR growth and development OR development

NOT

String 5 : Pharmaexclusion

("Drug Therapy"[Mesh] OR "Drug Industry"[Mesh]) OR "Pharmaceutical Services"[Mesh]) OR "Pharmaceutical Preparations"[Mesh]) OR "Pharmacogenetics"[Mesh]) OR "Technology, Pharmaceutical"[Mesh]) OR "Pharmacoepidemiology"[Mesh]

AND

String 4 : Surgery

General Surgery"[Mesh] OR "Colorectal Surgery"[Mesh]) OR "Digestive System Surgical Procedures"[Mesh]

AND

String 6 : Evidence Level

"Review"[Publication Type] OR "Meta-Analysis"[Publication Type])

Figure 6 - Search Process Flow Diagram

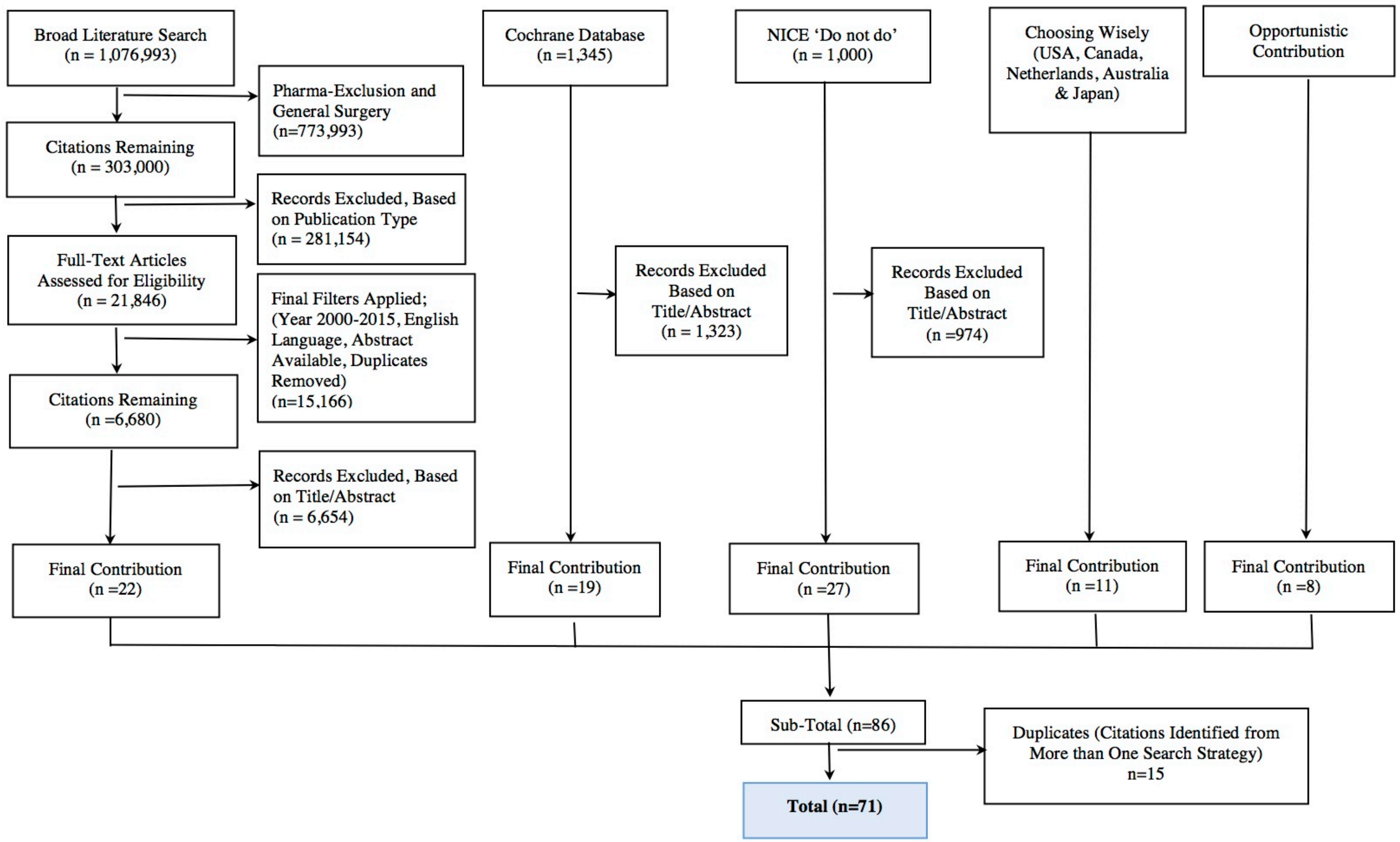


Figure 7 - Exclusion Criteria

1. No procedure / relevant service identified in article
2. Studies which did not relate the procedure to current strategy
3. No clinical relevant outcome measures; thus not identifying superiority or inferiority
4. Studies of low quality evidence
5. No abstract to evaluate
6. Citations which were considered irrelevant, not applicable to General Surgical field.

Results

A multi-platform search strategy identified 71 low value services, as detailed in the attached Appendix (Appendix 1). The literature review yielded a final contribution of 22 such services; with the Cochrane database review identifying 19; the NICE 'Do not do' lists identifying 27 recommendations; the Choosing Wisely published guidance identifying 11 services and an opportunistic review identifying a further 8. Following the subtraction of duplicate low value services (those that had been identified through more than one search strategy) a final list of was compiled. This list was then further stratified according to impact, by defining the relative cost per intervention and frequency of use. This then identified 2 services in cost quartile 4, high frequency group (highest impact); and 16 services in the first cost quartile low frequency group (lowest impact.) See Table 11.

Tables 12-15 identifies selected services from each group.

Services in cost quartile 4 and high frequency procedures represent those services that have the highest impact and therefore greatest burden on the current health economy. Unsurprisingly these relate to common interventions such as inguinal hernia repair in the minimially symptomatic individual, whose management options include watchful waiting or surgical intervention. Surgical orthodoxy dictates the need for offering surgery to prevent hernia strangulation, which carries significant morbidity and mortality. However, the two referenced randomised control trials highlight the safety of watchful waiting, indicating that the rate of hernia accident is 0.11% in over 65s. (9) This shows that surgical hernia repair is a low value procedure. However, the North American hernia trial's long term follow-up indicated that there was notable cross over between the two study cohorts, as those patients who presented initially with minimal symptoms may have developed worsening symptoms enough to warrant intervention and thus requested an operation, estimated at up to 68%. On the other hand, Kaplan Meier estimates found that 32% of patients after 10 years would still be suitably treated with watchful waiting. Furthermore, O'Dwyer et al. demonstrated that there was no significant quality of life years gained between the two groups, noting that outcomes were not altered between those managed conservatively vs those managed surgically (65, 162, 163) . Given that there were 54 894 hernia operations performed in 2014 at a cost of £1612 per patient, potentially 17 566 procedures may be considered low value with £28 316 521 of efficiency savings.

Similarly, in cost quartile 3 CT scanning for appendicitis is performed with excess cost since it has been demonstrated that alternatives such as ultrasound and clinical assessment offer improved value. This is particularly true in paediatrics where a CT study in a 5-year-old child shows that the lifetime risk of radiation-induced cancer would be 26.1 per 100 000 in female and 20.4 per 100 000 in male patients (164, 165), therefore a potential for harm. In 2014 throughout the UK there were 32 387 adult and 304 paediatric CT scans for appendicitis, accruing potential excess costs of £3 796 716.

Classical treatment of cholecystitis involves antimicrobials for the initial inflammatory response followed by surgery at a delay. However, improved patient outcomes have been demonstrated with early cholecystectomy. Therefore, delayed cholecystectomy is low value, with a cost of £1114 per re-admission between initial presentation and eventual cholecystectomy (166). There were 72 572 admissions with right upper quadrant pain, with a 30-day readmission rate of 16.75%, which amounts to a total cost of £13 546 200. Further, savings of £820 per patient with index cholecystectomy have been estimated (8). (Caution must be taken here given the cited study is a German RCT and costs were calculated on the basis of Diagnosis Related Group classification of Germany in 2010). Thus, with 72 572 non-operative admissions with right upper quadrant pain even if 80% of these patients were operated on acutely (a conservative estimate of operative suitability given in the previously cited trial of the 642 patients only 15 were excluded due to unsuitability to acute intervention) then potentially £47 607 232 could be saved. Furthermore, it has been demonstrated that the QALYs of laparoscopic cholecystectomy performed within three days of admission, beyond three days but in the same admission, and electively in a subsequent admission were 0.888, 0.888 and 0.884 respectively, indicating that outcomes are not improved with different treatment strategies. (167)

It is generally accepted that following an episode of acute diverticulitis patients should have endoscopic evaluation to rule out colorectal malignancy. However, recent evidence has called this into question, with de Vries et al.'s systematic review finding that rates of CRC and advanced adenomas in patients with uncomplicated diverticulitis are equal or even less than the rates encountered in asymptomatic individuals (168, 169, 170, 171). Therefore, the performance of endoscopy following a radiological diagnosis can be postulated to be low value. There were 33 175 cases of non-operative diverticulitis admitted in the year 2014 in the UK. If each of these patients went on to have outpatient a flexible sigmoidoscopic assessment as dictated by surgical teaching, then a cost of £7 364 850 would be created.

A recent meta-analysis from Italy which examined the appropriateness of referrals for gastroscopy, suggested that 22% of appointments were not in line with guidance from the American society of gastroenterology, signifying evidence of diagnostic overuse. With 552 078 procedures performed in 2014, this represents a burden of overuse of £35 640 330 (172).

Within the high cost (quartile 3 & 4) low frequency group is the use of early ERCP in acute gallstone pancreatitis which was recommended by the 2005 UK pancreatitis guidelines (173,

174) . However, subsequent evidence including the Cochrane review and other meta-analyses, have shown that there may not be benefit to early ERCP in the absence of cholangitis (175, 176). This is an example of newer evidence changing a practice from 2005 when early ERCP was recommended, to subsequently, five years later found not to improve outcomes. The incidence of acute pancreatitis is 30 per 100 000, of which 36.9 are of gallstone aetiology. (177) This is a potential 7095 candidates for early ERCP (a low value procedure) of which 48% had acute ERCP in 2002 (178) of which only a small proportion (circa. 4% citing Uy et al.'s rate of cholangitis) would benefit from early ERCP, with potentially 3122 low value ERCPs being performed and potential savings of £5 614 845.

Further interventions in the cost quartiles 3 & 4 , low frequency group includes those interventions which involve new technologies (5 interventions), procedures applied to rare diseases (4 interventions) and those procedures not performed commonly due to alignment with current surgical practice (14 interventions), (Appendix 1) Protease inhibitors in ERCP (179) and robotic surgery (178, 180, 181, 182, 183, 184, 185) are examples of new technologies which are not used due to limited availability. In the case of robotic surgery there is evidence of moderate improvement in outcomes at a considerable cost - calculated to be £1105 per robotic operation, the high cost reduces the value of said procedures (184, 185). Literature review also identified different management pathways as being of low value, including the use of a second look gastroscopy after endoscopic mucosal dissection, (172) the benefit of oesophageal stenting prior to neo-adjuvant chemotherapy, (186) as well as the avoidance of risk reducing surgery in those with limited life expectancy (187). These services reflect management pathways which have been instituted following a growing body of evidence and are often not in current practice. Although this group's overall economic burden is difficult to assess as individually it may be minimal, cumulatively they will have significant impact upon the health budget.

Highlighted high frequency interventions in cost quartiles 1 & 2 include the use of bowel preparation prior to open general surgery (188, 189, 190), the use of surgical facemasks (191) and the benefits of antibiotic prophylaxis prior to surgery (192, 193). All are reliant on aged data, with newly published evidence suggesting contrary. A recent review of practice of antibiotic prophylaxis during operative hernia repair in London and South East England showed that 84% of surgeons believe that antibiotics are of high value signifying high rates of use of peri-operative antibiotics (193). The cost of a single dose of Co-Amoxiclav is £2.62, and with 54 894 cases of hernia repair performed in 2014, if each of the patients received antimicrobials this would reflect a sum cost of £143 822. Lastly, the group of low cost low frequency procedures reflect those procedures which are rare, often with anecdotal evidence justifying *current* practice.

Table 11 - Category Segregation for Low Value Interventions

Quartile	*High Frequency (number of services)*	*Low Frequency (number of services)*
4	2	12
3	3	8
2	9	10
1	11	16

Quartile 1 (>£0 <£3.20), Quartile 2 (>£3.20 < £113) , Quartile 3 (>£113 <£800.58), Quartile 4 (>£800.58 < £6868)

High frequency procedures were those more commonly performed then the calculated median (n=10 058)

Table 12 – Highest Impact (Quartile 3 & 4, High frequency)

Low Value Service	Citation and Level of Evidence	Issue Identified by Citation	Frequency	Unit Cost	Total Estimated Burden
Quartile 4					
Repair of minimally symptomatic inguinal hernia is low value	Fitzgibbons RJ, et al., O'Dwyer PJ, et al. (Evidence Level 1b)	Evidence demonstrates that minimally symptomatic inguinal hernia can be managed with watchful waiting for up to 2 years after assessment safely, with an incidence of hernia accident (the traditional reasoning of hernia repair) at a rate of 0.11% in the over 65 aged patients. Therefore Conservative management should be considered in appropriately selected patients.	54 894 cases in 2014 Given the Kaplan Meier estimates from O'Dwyer et al. of 32% being suitable for watchful waiting after 10 years: 17 566 low value procedures	£1612 (50)	£28 316 521

Delayed cholecystectomy is low value	da Costa et al., 2015 Wu et al., 2015, Hartwig and Buchler, 2014 Gurusamy, Davidson et al. 2013, Gurusamy, Koti et al. 2013, Gurusamy, Nagendran et al. 2013, Gutt, Encke et al. 2013, Wu, Tian et al. 2015 (Evidence Level 1a, 1b)	Compared with delayed cholecystectomy, early cholecystectomy reduced the rate of recurrent gallstone-related complications in patients with mild gallstone pancreatitis, with a very low risk of cholecystectomy-related complications	Non-operative gallstone admissions 72 572 12 155 Readmissions (within 30 days)	£820 (35) £1114.18 (34)	£59 509 040 £13 546 200 (Readmissions)
Quartile 3					
CT abdomen as first line for diagnosis of appendicitis is a low value scan	Frush DP et al. 2009, Schok et al., 2014, Bachur et al., 2015, Verma et al., 2015, Kotagal et al., 2015, Frush DP et al. 2009, Garcia K et al. 2009, Kharbanda AB. 2012, Krishnamoorthi et al. 2011, Rosen MP, et al 2011, Saito JM, et al. 2013, Wan MJ et al. 2009 (Evidence Level 1a , 1b)	When using computed tomographic scanning in the diagnosis of appendicitis, the percentage of negative appendectomies remains similar to that performed in the absence of investigations. CT imaging itself does not alter the end point of appendicitis.	Adult – 32 387 Paediatric – 304	£116 (50) £131 (50)	£ 3 796 716
Routine endoscopic assessment following CT diagnosed diverticulitis is low value	Ou et al., 2015, Sharma et al., 2014, de Vries et al., 2014, Agarwal et al., 2014 (Evidence level 1a /1b)	The risk of malignancy after a radiologically proven episode of acute uncomplicated diverticulitis is low. Advice is to offer endoscopic evaluation when CT imaging is concerning.	33 175 CT diagnosed diverticulitis	£222 (50)	£7 364 850

Inappropriate indication for upper endoscopy	Di Giulio, E., C. Hassan, et al. (2010) Evidence level 1a	For inappropriate EGD, the very low likelihood of cancer argues against endoscopic referral, whereas the low specificity substantially reduces the predictive value of an appropriate indication for both cancer and relevant endoscopic findings.	Without biopsy – 190 827 With biopsy – 361 251 According to cited reference 22% are inappropriate (overuse of diagnostics)	£286 (50) £297 (50)	£35 610 975

Table 13 - High Cost (Quartile 3&$): Low Frequency

Service and Indication	Citation and Level of Evidence	Issue Identified by Citation	Frequency	Unit Cost	Total Cost Burden
Quartile 4					
Early endoscopic retrograde cholangiopancreatiography in acute gallstone pancreatitis in the absecnce of cholangitis is low value	Uy et al. 2009 , Tse et al. 2012 (Evidence level 1a)	There is a trend towards more mortality from early ERCP with or without sphincterotomy in the setting of acute gallstone pancreatitis without cholangitis.	7095 candidates for early ERCP of which 48% had acute ERCP in 2002 (n=3405)(12) of which only a small proportion (circa. 4% citing Uy et al.'s rate of cholangitis) would be benefit for early ERCP. Potentially 3122 low value ERCPs being performed	£1649 (50)	£5 614 845
Outcomes following robotic surgery are comparable to those following laparoscopic surgery, therefore can use be truly justified	Szold et al., 2015, Bertani et al., 2013, Zong et al., 2014, Toro et al., 2015 Level 1A conference consensus opinion	To date, in the vast majority of clinical settings, there is little or no advantage in using robotic systems in general surgery in terms of clinical outcome.	** Unable to determine UK frequency of use as not commonly used	Across a full range of 20 types of surgical procedures that the additional variable cost of using a robot was about $1600 / £1105. When the amortised cost of the robot itself was included, the additional cost of using a robot in a procedure rose to about $3200 / £2211	Unclear

The use of Emergency Colorectal stenting for Obstruction (then elective operation) seems to have no advantage over Emergency Surgery in terms of long term outcomes (Single emergency surgery vs emergency stenting and then elective surgery)	Sagar et al. Level 1A	The use of colonic stent in malignant colorectal obstruction seems to have no advantage over emergency surgery and then elective resection. The clinical success rate was statistically higher in emergency surgery group. However, use of colorectal stents seems to be as safe in the malignant colorectal obstruction as the emergency surgery with no statistically significant difference in the mortality and morbidity. Colorectal stents are associated with acceptable stent perforation, migration and obstruction rates. The advantages of colorectal stent includes shorter hospital stay and procedure time and less blood loss.	143	£1522.75 (for procedure of stenting but is not in comparison to cost of operation) (6)	£217, 753.25
Quartile 3					
Second-look endoscopy after endoscopic submucosal dissection for gastric neoplasms	(194) Level 1A	There were no significant differences between second-look endoscopy and no second-look endoscopy with regard to large tumor size (>20 mm). This systematic review and meta-analysis showed that second-look endoscopy had no advantage for the prevention of post-Endoscopic Submucosal Dissection bleeding in patients without a high risk of bleeding.	Unclear , <1172 (Therapeutic Endoscopic Upper Gastrointestinal Tract Procedures) (National)	£286	< £335 192

Table 14 Low Cost (Quartile 1&2): High Frequency interventions

Service and Indication	Citation	Issue Identified by Citation	Frequency	Unit Cost	Total Cost Burden
Quartile 2					
Mechanical bowel preparation has few benefits for preventing Infection intraoperatively and therefore is a low value treatment	Arnold et al. 2015, Güenaga et al., 2011 NICE Cochrane Review Level 1A	Evidence from high-quality trials reports no or few benefits from MBP or rectal enema across surgical specialties. There is no benefit of mechanical bowel preparation prior to blective colorectal surgery.	Potentially all colorectal operations – 10,058	£9.07 per Case	£91 226
Routine versus no drain placement after elective laparoscopic cholecystectomy	Level 1A	The possible clinical benefit of routine use of abdominal drainage in uncomplicated laparoscopic cholecystectomies requires larger study populations. The approach is however not encouraged on the basis of the present analysis, as it results in increased postoperative pain and overall morbidity.	24482 (Methods)	£6.90	£168 925.80
Quartile 1					
Single dose antibiotics controlled post-operative wound infection – in hernia repair (clean surgery)	Sanchez-Manuel et al., 2012 Level 1A	Based on the results of this systematic review the administration of antibiotic prophylaxis for elective inguinal hernia repair cannot be universally recommended.	54 894 cases in 2014	Cost £2.62 per dose	£143 822

Role of the surgical facemask for protection of patient / surgeon is historical and supported only by historical data	Da Zhou et al., 2015 Lipp and Edwards, 2014	However, overall there is a lack of substantial evidence to support claims that facemasks protect either patient or surgeon from infectious contamination,	Potentially all [circa. 1.95 million cases in 2014]	£7.79 for pack of 100	£151 905

Table 15 Low Cost (Quartile 1&2) : Low Frequency

Service and Indication	Citation	Issue Identified by Citation	Frequency	Unit Cost	Total Cost Burden
Quartile 2					
Uncomplicated diverticulosis should and can be managed in the community i.e. primary care – Thus referral to secondary care for investigation is low / no value	Almerie and Simpson, 2015 (65) Evidence level 1a	Patients with suspected uncomplicated acute diverticulitis should be assessed according to their level of pain and associated systemic features of sepsis. In those where pain is controlled and there are no signs of systemic sepsis or multiple comorbidities, the patient may be treated in primary care.	**Unable to determine In line with clinical orthodoxy	£108	**Unclear
Abdominal drainage versus no drainage post gastrectomy for gastric cancer	Wang et al., 2011 Evidence level 1a	We found no convincing evidence to support routine drain use after gastrectomy for gastric cancer.	1766 Gastrectomies in UK (NOGCA audit 2013)	£6.90	£12 185
Quartile 1					
People undergoing anal sphincter repair Should not receive Constipating Agents in the Post op Period and should be allowed to eat and Drink ASAP	Faecal incontinence (CG49) NICE 'Do Not Do' Lists	Harm created by offering constipating agents following anal sphincter repair	All Incontinence Operations 1453 (methods)	£2.97 (Cost of course of Codeine)	£4315.41

Discussion

The importance of identification of low value interventions has been stressed in earlier chapters of the present study. It provides a platform from where disinvestment activities may begin. The challenge arises when confidently trying to identify candidates for disinvestment. This systematic review has followed a strict methodology which has provided opportunity to positively identify de-adoption candidates; and serves to offer a methodology which may be extrapolated to other fields.

This systematic review has identified 71 low-value general surgery interventions. The five with highest impact (with greatest clinical and economic burden) were: inguinal hernia repair in patients with minimal symptoms, delayed cholecystectomy, inappropriate gastroscopy, CT to diagnose appendicitis, and routine endoscopy in those who have had imaging-confirmed diverticulitis. Estimated potential opportunity savings to the NHS of stopping these procedures are £134 597 973 per annum. With five general surgical procedures carrying a burden of £135 million, the Audit Commission's previous estimate of £500 million per annum for all healthcare is likely to be conservative. (195)

Hence the identification and stopping of low-value interventions represents a significantly greater opportunity for efficiency savings than thought previously. Furthermore, the assessment used conservative assumptions – that all procedures were performed where possible as an outpatient (in the case of endoscopy, ERCP, hernia repair) and in individuals without co-morbidities.

Priority setting has also attracted debate previously. It is important those interventions which have significant opportunity cost be considered. For instance, although a high-impact procedure such as early laparoscopic cholecystectomy may offer savings of £59 million per annum, a reduction in the use of mechanical bowel preparation, a low-impact procedure, will confer annual maximum savings of less than £100 000. Although it may be easier to reduce the use of a cost quartile 1, high frequency intervention (e.g. use of surgical facemasks) it is unlikely to make a dent in the national budget. Similarly the cost quartile 3/4 novel interventions with low frequency of use may confer only similar limited cost reduction (e.e. colonic stenting). It is therefore important that clinicians and providers focus debate on the potential reduction of high-impact services. The method of categorising low value interventions into order of priority according to the economic burden is a simple method that may offer opportunity to policy makers to concentrate on the 'highest' hanging fruit, in contrast to the 'low hanging fruit' which is a regular criticism faced by previous de-adoption movements.(196)

There are pitfalls with labelling a procedure as low value, as clinical context dictates value.(197, 198) A prime example is inguinal hernia repair in the minimally symptomatic individual. Although the two cited RCTs both found watch-and-wait therapy to be equivalent to surgical repair in the short term, long-term follow-up identified a preference for surgical treatment. Thus, for patients whose symptoms worsened, the procedure would have been of high value. Therefore, an intervention is only low value when applied in the correct clinical context, and stopping these procedures will not be without problems. Complete cessation of elective inguinal hernia repair would result in the reduction of uncomplicated day-case operations with optimal outcomes, to an increase in emergency surgery where further complications such as bowel resection may ensue (9, 199).

Similarly, stopping CT for the diagnosis of appendicitis may result in incorrect or delayed treatment and subsequently patient harm. Although CT should be considered low value, it may well be that the expertise for accurate ultrasonography, which is heavily operator dependent, is not readily available (particularly out of hours). Furthermore, the cost of negative laparoscopy and its inherent risks needs to be considered.

Endoscopy following a radiological diagnosis of diverticulitis has been presented as low value here. Yet stopping it may result in missing an early colorectal cancer. Endoscopy should still be considered in patients who have a high risk of colorectal cancer, such as those with a family history.

It is important that stopping low-value interventions happens only in correct clinical populations where the intervention is of little benefit. The challenge lies in identifying patients for whom the clinical context dictates the intervention as low value. Thus, the classical surgical adage of careful patient selection proves true to both economic and surgical objectives.

This study has several limitations. First, the list is not exhaustive, as it focuses solely on high-level evidence (meta-analysis, RCT or systematic review) over a 5-year interval. It is possible that citations that may be relevant have fallen outside the search criteria.

Another challenge is the limitation of the administrative data sets used. For example, when reviewing the use of flexible sigmoidoscopy after CT diagnosis of diverticular disease, or early ERCP in gallstone pancreatitis, although the volume of each procedure was recorded, the indication was not. It is not possible to identify the number of inappropriate procedures performed nationally . Although the number of flexible sigmoidoscopies performed is known, the number of procedures that followed uncomplicated diverticular disease is not. Similarly, the number of early ERCPs performed in gallstone pancreatitis in the absence of cholangitis is unclear. Therefore, assumptions have been made based on potentially outdated literature, or indeed by assuming that surgical orthodoxy will result in all patients with CT-confirmed diverticulitis having flexible sigmoidoscopy. In the case of interval cholecystectomy, costs have been estimated from literature not based in the UK, as the cited study is a German RCT and costs therefore were calculated on the basis of German Diagnosis Related Group classification, using data from 2010. Although using these referenced papers has the advantage of taking into account cost of complications from early operation in the acute setting. It may be incorrect to extrapolate findings from another country and assume similar rates of non-adherence to guidance in the UK.

Accurately estimating the volume activity of the high-cost, low-frequency procedures has proven difficult. This is often due to the experimental nature of these therapies (for example, robotic and single-incision surgery, protease inhibitor use in ERCP, tetrastarch for fluid resuscitation, and heated carbon dioxide during laparoscopy), as well as the fact that this group deals with disease of rarity. This part of the list often describes procedures that are not performed routinely because current surgical practice is aligned with published guidelines. Examples including avoiding treating varicosities in pregnancy, avoiding routinely offering a defunctioning stoma in operations for anal incontinence, and not offering risk-reducing surgery where there is limited life expectancy. Such services were often found through NICE's 'Do not do' database, highlighting how many of their recommendations are already in line with current practice – the 'low hanging fruit.'

The literature search has highlighted a number of novel technologies, in particular the robotic technique and single-incision approaches. When compared with conventional techniques, outcomes are improved only marginally. Thus, they must be considered low value and a potential candidate for disinvestment. The European Association for Endoscopic Surgery cautions that the benefits of a robotic approach have not been measured, but that it could offer great ‘potential with sophisticated electromechanical systems’(180). There is a global acceptance that robotic surgery is likely to be common in operating theatres of the future, although the costs currently remain high. This may the representation of a novel technology – that initially the high costs limit their value, however with time and the introduction of competitors in the marketplace costs reduce and it can be considered a higher value intervention (200). Moreover, there are costs beyond strict patient outcomes, the considerations of optimal surgeon ergonomics and reduced occupational injury mean that there are some outcomes which have not been considered that may improve the value of robotic surgery.

This paper should serve as a stimulus for discussion among surgeons, patients and commissioners. It highlights that, in the surgical sphere, there are a number of low-value services that could be stopped, with significant savings.

Furthermore this demonstrates the first stage of the de-adoption cycle. The identification of low value interventions based upon peer reviewed published evidence. There 71 low value interventions identified through this route with a major impact on the economic burden from general surgery. With extrapolation of such methodology, that is a detailed exploration of peer reviewed literature identification of further low value interventions will be found, particularly in the surgical fields where expensive instruments and treatment strategies are commonplace.

Chapter 5

Evaluating Trends in Use of Early and Delayed Laparoscopic Cholecystectomy

Introduction

Previously presented work has identified several low value interventions in General Surgery. The objective of this chapter is to take a granular view of the passive behaviour of clinicians in England in response to new evidence. This present chapter thus addresses the idea of optimizing value with aim directed at the de-adoption of interval cholecystectomy and adoption of index cholecystectomy(7). Therefore, a retrospective observational study was performed from hospital administrative data to evaluate the primary the rate of adoption of early cholecystectomy and concurrent de-adoption of delayed cholecystectomy in response to a progressively more persuasive evidence base. The subject of said evaluation of cholecystectomy is not cross-sectional variation in use – which is likely to be evident. Of more interest is the longitudinal behaviour of surgeons, whether variation exists over an extended period of time and whether suppliers demonstrate differences in behaviour towards a more persuasive evidence base in the choice of treatment that is offered.

Cross Sectional Variation

Rates of common surgical procedures are known to have small area geographical variations. In 1938 Glover identified that rates of tonsillectomy varied significantly within English districts at rates that could ‘defy any explanation, save that of variation of medical opinion on the indication for the operation.’(201) It was postulated that the patient’s therapeutic needs provided only a limited bearing on the decision for offering treatment. This is fundamentally the concept that rings true to low-value interventions, where the indication for treatment is criticised and that within a community of surgeons there will be many alternating opinions on the correct strategy of treatment. At the time a study from the Medical Research Council identified that there was no evidence for wholesale tonsillectomy, yet there was a ‘tendency for the operation to be performed as routine prophylactic ritual for no particular reason and no particular result.’ (202) Thereby beginning to suggest the concepts of *supplier induced demand* and *surgeon-oriented decision making*. The most recent study of tonsillectomy rates still found a sevenfold difference in the rates of tonsillectomy in English regions, which could not simply be explained by small number of outliers.(203)

There was then a plethora of studies in the 1960s and 1970s which proceeded to document unexplained variation.(204, 205, 206) This led to refined methods of assessment with the Dartmouth Health Atlas leading the way in describing small area variations to identify implied clinical uncertainties. The objective of examining small area variations is to identify discretionary differences in the use of resources between neighbouring areas be they supplier induced or a matter of patient preference. Wennberg et al. have identified that when there is good evidence and professional consensus for an intervention being effective, there tends to be minimal variation in clinical practice - examples include hip fractures surgery and appendicectomy. However clinical practice varies notably where weak evidence exists – often associated with professional uncertainty. While there may be uncertainty at a group level it does not necessarily mean that individual surgeons are uncertain. They are confident in their decision's being correct however are not supported by the wider community (207).

International variation has also been studied by the Organization for Economic Cooperation and development (208). The OECD has demonstrated international variation in the rates of appendicectomies. The pattern of age specific intervention is virtually the same for men and women across OECD countries - illustrating how an appendicectomy is a high value intervention with international consensus on decision-making. The notable exception was

Germany particularly in young females aged 15-19. A young woman in Germany is 4.7 times more likely to have an appendicectomy than a young lady in the United States or England. A full understanding for the reasons and consequences of different utilization rates was not offered. Particularly as the diagnosis in USA is fully radiological, compared to UK where clinical acumen plays a significant part. (19, 208) Ultimately a more detailed understanding of patterns of illness and patient preferences was considered to be required.

The presence of cross-sectional variation cannot be ignored, the challenge remains in attempting to identify what proportions of variation are 'good' or warranted and which are 'bad' or unwarranted – that is which populations are receiving appropriate care and which populations are receiving inappropriate care. There are numerous possible factors which could explain healthcare variations, including, for example, the way treatment is funded and financed. In England the government aims to allocate resources equitably to populations, in contrast to the USA where healthcare spending emerges from fees paid to doctors and charges to hospitals. Therefore, the supplier has a financial incentive to provide more care and may result in variation. Despite this unwarranted variation continue to exist in UK. (209)

The Dartmouth group has described three categories of care. The first being *effective* care-where a strong evidence base exists and services that are offered are appropriate and the minimal variations that exist are due to clinical heterogeneity between geographical regions. The second is *preference sensitive* care, where treatment decisions are based on a subjective assessment of risks and benefits. This is often the case in a surgical intervention, whereby there is no correct decision, and the preference of a patient depends on their understanding on the risk:benefit ration and more importantly their understanding of it. It is for this reason and this group of treatment that shared decision making his most effective. The final category includes *supply sensitive* care where the supply of resources such as a hospital bed or endoscopy department results in increased used of an intervention. Crudely if a resource is available then it is clearly more likely to be used. (207, 210, 211)

Another challenge in dealing with variation is establishing the correct threshold for treatment. After demonstrating variation in care it becomes evident that outliers at both ends of the spectrum demonstrate inequity of treatment. There may overuse of a low value intervention, that results in harm to patients whom may be managed without an intervention, here the patient may be subjected to harm. At the opposite end of the spectrum there may be underuse of a high value intervention , due to the absence of appropriate expertise / equipment resulting in inquity of care and the so-called postcode lottery of treatment. (212)

These concepts are well studied and supported. The subject of said evaluation of cholecystectomy is not cross-sectional variation in use – which is likely to be evident. Of more interest is the longitudinal behaviour of surgeons, whether variation exists over an extended period of time and whether suppliers demonstrate differences in behaviour towards a more persuasive evidence base in the choice of treatment that is offered.

Diffusion of Innovation

The concepts of innovation diffusion have already been explained in detail. Most distinctly is Everett Rogers' 'Diffusion of innovations' philosophy which describes the 'S-shaped curve' after reviewing farming practices in Iowa.(36) The curve represents an initial slow rate of adoption in turn giving way to an exponential uptake of the idea after the intervention has achieved consensus, followed ultimately by another slow phase where few non-adopters remain. Initially an Innovation was regarded as an idea or practice and adopters were the individual practitioners. Beyond this an innovation has been conceptualized to be a movement that behaves as a 'product' which is judged in a cost: benefit circumstance in order to make decisions on adoption. (37)

With the emergence of a new technology that illustrates superiority over current practice, it is the requirement of medical practice to remain at the 'cutting edge', thus instigating change to the novel superior intervention. In practice, the implementation of a superior technology will require both a change in attitude as well as an organizational / institutional alteration. In the absence of either it may be that the innovation is abandoned, thus the innovation is exnovated. Exnovation is defined as the removal of novel innovations that are not effective in improving organizational performance, this may be because they disrupt routine management or do not fit with routine organizational strategy. (68)This organizational response is to ensure adequate 'absorptive capacity' within the provider organization to permit use. Thus, if an innovation is deemed to be incompatible with both the provider's capabilities as well as obstruct a provider in meeting external demands it is ultimately removed from routine use.

It is posited that in a dynamic healthcare system with multiple providers there will be exnovator providers who influence the global rate of adoption. Therefore, by identifying and understanding the provider attributes that result in exnovation one can provide better policy to support and adopt a high value intervention.

Exnovation differs from 'de-implementation', 'rejection' and 'de-adoption' in that these terms reflect the scaling back on any incumbent procedure whereas exnovation focuses on removal of innovative procedures specifically. The limited literature in this field reflects the inconsistency of nomenclature within this discipline. (52, 53)

This notion of innovation adoption may also be framed within the incentive of an organization; often the objective of a provider may be to maximize profits by maximizing volume of intervention. Thereby satisfying an ever-stretching demand from the community. An efficient profitable intervention will be regarded as superior and adopted whilst an unproductive intervention will be abandoned. Yet in the absence of improved outcomes maximizing volume may be dangerous, as the incentive is not on quality, safety and outcomes for the patient but simply number of patients treated. Therefore, with a better focus on health care 'value' adoption of high value interventions becomes an essential subject of study.

Thus with a new movement towards maximizing value to the patient, commonly defined as ratio of outcomes and costs, the de-adoption of low value , ineffective interventions will require similar incentives to be recognised.(15) This gives motivation to the present study where the adoption and exnovation of a high value intervention has been evaluated.

A priority innovative intervention in general surgery is the use of early cholecystectomy (EC) for both acute cholecystitis and gallstone pancreatitis. (7)

Early Cholecystectomy in Acute Cholecystitis (AC)

The current gold standard treatment for gallstone cholecystitis is laparoscopic cholecystectomy, it is the timing of surgery which has attracted debate. In the era of open surgery it was recommended that an operation within seven days of onset of symptoms (early cholecystectomy) had no increased morbidity over delayed surgery (interval cholecystectomy)) (213). With the onset of laparoscopic approaches concerns developed that in the early setting acute inflammation would result in a suboptimal view of Calot's triangle which may result in complications including conversion to open and bile duct injury which in itself carries associated co-morbidity. (214, 215, 216, 217, 218) Recent evidence has questioned the approach of delayed surgery, with the argument that fibrotic adhesions which are encountered after an interval may result in similar complications (219, 220). Furthermore, delayed surgery increases the risk of further gallstone related complications which result may result in recurrent admissions – these in themselves carry a burden of excessive morbidity and cost with 30-day readmission rate of 16.75% in the UK. (12)

Medical literature has attempted to address this issue with a progressive support of early cholecystectomy. The first trials which questioned this approach were from the Far East in 1998 since then there is a growing volume of evidence to question the need for interval cholecystectomy. (219, 221). Most recently the National Institute for Health Care and Excellence (NICE) has issued guidance that cholecystectomy should be offered within one week of diagnosis of acute cholecystitis in December 2015.(222) The first Cochrane review to assess this was published in 2006 which identified that early laparoscopic cholecystectomy appeared safe and prevented further admissions in the 'interval' resulting in reduced total hospital days. (223) Further iterations have continued to reinforce the safety of early cholecystectomy with the added conclusion that the relevant complications of bile leak were rare, such that to power a trial to appropriately assess this would require circa. 50 000 patients which in itself is not feasible (224, 225). Thus, suggesting that the evidence level is currently as strong as is reasonably going to be available. This is mirrored by other international groups such as the Japanese Tokyo guidance collective who recommend the use of early cholecystectomy for mild acute cholecystitis and consider delayed cholecystectomy for severe cases according to the decision of the treating clinician. This was first published in 2007 and then iterated in 2013. (226)

The time until cholecystectomy has also been reflected to be an indicator of care quality, with recent literature suggesting that a 75% rate of early cholecystectomy as feasible. (227)

Beyond clinical efficacy a cost-utility analyses both from within the NHS and abroad have illustrated the superiority of index procedure; thus demonstrating the value of early surgery. (228, 229)

Cholecystectomy in Gallstone Pancreatitis (GSP)

Cholecystectomy is also definitive treatment for gallstone pancreatitis, therefore preventing further episodes of disease. The optimal timing for said intervention has similarly earnt some discussion. In the period of open cholecystectomy Ranson concluded that the timing of biliary surgery to offer definitive correction of 'cholethiasis should be carried out as soon as evidence of acute pancreatitis has resolved'. (230) Similar to cholecystectomy for cholecystitis the introduction of laparoscopic surgery has called this view into questions suggesting that patients with mild gallstone pancreatitis (which compromises 80-90% of all patients with gallstone pancreatitis) may be better served with earlier intervention. (231)

The British Society of Gastroenterology published guidance in 2005 stating that anyone with gallstone-related pancreatitis should have cholecystectomy within the index hospital admission, unless arrangements have been made for definitive treatment within the two weeks (232). However, the evidence for such guidance has been referred to as incomplete. (233) Further studies (Ito 2008, Wilson 2010, Falor 2012) have all provided evidence in support of index cholecystectomy (234, 235, 236). A Cochrane review published in 2013 concluded that there is 'no evidence of increased risk of complications after early laparoscopic cholecystectomy,' and that early cholecystectomy may 'shorten the total hospital stay' in mild acute pancreatitis. (233) This evidence suggests that there should be a movement towards de-adoption of interval cholecystectomy for patients who suffer from acute gallstone pancreatitis, particularly as it is been iterated to be inferior to index cholecystectomy.

Hence, interval cholecystectomy is a low value intervention and should not be offered to patients routinely. Despite this index cholecystectomy is not the choice treatment for most patients with cholecystitis with only 20% of surgeons habitually performing this intervention in 2003 (237). Consequently, the de-adoption of interval cholecystectomy and the adoption of interval cholecystectomy in response to published high evidence literature should be evaluated; whether change in behaviour follows and indeed whether it follows the pattern of diffusion as expressed by Rogers et al. Furthermore, this present study aims to describe a model of exnovation, if the behaviour of exnovator providers is the mirror opposite to adopters that Rogers has demonstrated.

The advantage of evaluating index vs interval cholecystectomy to represent de-adoption / adoption of an antiquated / innovative intervention is that change in practice does not require surgical training or need for new equipment. It represents a change in policy and culture that will more appropriately reflect the practice of the surgical community – who pride themselves on being ‘at the cutting edge’ to institute optimal therapy based on best evidence.

Further review of supply side variables that may contribute to rapid adoption of relevant interventions, may provide evidence to guide policy towards providing optimal environs for rapid engagement and active change in practice. Several processes have been hypothesized to influence a surgeon’s decision to alter practice, most commonly thought to be in response to a convincing wealth of published evidence or indeed didactic guidance. The familiarity of clinicians with opinion leaders and change agents (the ‘early innovators’ within the S-shaped curve) is also thought to influence de-adoption. (67, 238) Thus, we hypothesize that academic institutions who have a dense concentration of 'opinion leaders' and 'change agents' are more open to adoption of superior technology.

Structural processes will also influence the ability of a provider to permit adoption of innovative practices in response to clinical opinions. It was hypothesized that providers considered to be efficient, that is those who optimise the use of resources are more likely to adopt optimal care. Efficiency may be considered in terms of both technical and allocative efficiency, technically efficiency providers offer optimal outputs from a given volume whereas allocative efficiency offers the best combination of outputs from a given area of services. Ideally to make stronger conclusions allocative efficiency would be considered yet in the absence of an accurate formulation that could be measured technical efficiency was considered.

In order to assess this a retrospective observational study was performed from longitudinal administrative data to evaluate the primary the rate of adoption of index cholecystectomy in response to a progressively more persuasive evidence base.

Methods

Study Design

A retrospective observational study was performed using a longitudinal dataset extracted from the administrative database: Hospital Episodes Statistics (HES). This is an administrative record that has collected patient-level data from all English NHS trusts since 1987. (212) The units of observation were individual operations, when they were performed in relation to inpatient admission, coded diagnosis and the trust (acute care provider) where the case was performed.

HES registers information entered by clinical coders reviewing case notes of hospitalized patients upon discharge, thus recording information on all patients who are treated within the public sector across England as well as some private NHS Institutions. The primary unit within the database is the finished consultant episode; this is a defined continuous period of admitted patient care under a consultant within an NHS provider. Each record contains geographic, demographic, diagnostic and procedural data pertaining to an individual patient admission to English hospitals. Each entry contains up to 20 diagnosis codes categorized according to the International Classification of Diseases (ICD-10). There are 24 procedure fields which are populated with codes from the Office of Population Consensus and Surveys Classification of Surgical Operations and Procedures (OPCS-4.)

Patient Selection

All adult patients resident in England undergoing a cholecystectomy between 1st April 2006 and 31st March 2014 were identified according to the OPCS codes in Table 13. A longitudinal time frame was employed in attempt to model change in practice. At the time of study more this was the most recent data available within Hospital Episode Statistics database at the time of study. (Appendix 2 for details of data access agreement.) For these patients, all emergency inpatient admissions to an acute NHS hospital in England with a diagnosis of acute cholecystitis or gallstone pancreatitis prior to the date of their cholecystectomy were identified using the ICD-10 codes in Table 14. Only coded diagnoses were considered, thereby not including non-specific descriptions of abdominal pain or of cholethiasis in the absence of cholecystitis / biliary pancreatitis

Due to the longitudinal nature of the dataset an individual provider trust code may reflect multiple sites because of mergers, therefore hospital trusts where mergers were present were treated as single trust for the duration of the study period.

An Index Cholecystectomy was defined as an operation that occurred within 14 days of emergency admission with primary diagnosis of acute cholecystitis or gallstone pancreatitis. This includes operations recorded as non-elective procedures as well as those who were discharged and re-admitted as an elective procedure within the two-week time period, in accordance with the criteria described by NICE (239). An Interval cholecystectomy was defined as any emergency presentation with diagnostic codes of gallstone pancreatitis or cholecystitis followed by a cholecystectomy within one year of emergency admission, and not within 14 days of admission.

For each patient, the time period from their first emergency inpatient admission with a diagnosis of cholecystitis or gallstone pancreatitis to a cholecystectomy determined the duration to surgery, and therefore whether a procedure was defined as ‘index’ or ‘interval for that patient. Intervening admissions between the first presentation and surgery did not alter this timescale. It should be noted that only procedures which were preceded with an emergency admission were considered – if there was no emergency presentation (in the case of a patient referred from primary care for example) the patient did not meet the selection criteria. The rationale being that if a patient was not operated on within a year of admission then there may well be other comorbidities which would make surgery inappropriate, that is if an operation was not performed in a year it may be that an operation was not deemed gold standard management in that case and conservative treatment may have been sought (e.g. patients of old age, or with multiple comorbidities precluding an anaesthetic, multiple previous surgeries which would make further surgery high risk.)

It should be noted that only procedures which were preceded with an emergency admission were considered – if there was no emergency presentation (in the case of a patient referred from primary care for example) the patient did not meet the selection criteria. This was in order to limit study to patients whom required hospital admission, therefore meet the eligibility criteria for early operation.

Only patients aged over 18 years of age were included.

Variables

Primary Outcomes

The primary outcome measured was the relative change in proportion of early cholecystectomies performed per year within the sample period by each provider. Other outcome measures included the change in behaviour of a provider trust between two time periods – that is the difference in proportions of EC performed before and after April 2010 within the sample period. The choice of April 2010 was made because it was a point where published evidence became prominent. (234, 235)

Explanatory Variables

Patient and institutional characteristics which may influence provider's ability to change practice and de-adopt DC were evaluated.

Classical diffusion studies have demonstrated that education is a proponent of adoption and de-adoption. (240) Our hypothesis from previous diffusion models is that academic institutions, which are providers populated with academically active surgeons would be more likely to adapt their practice based on knowledge of published evidence.(241) Therefore, the independent variables considered were type of and size of hospital, as well as the presence of a specialized hepato-biliary unit.

Those providers with a higher proportion of cholecystectomy as general surgical workload are also likely to be familiar with published evidence, therefore more likely to adopt index cholecystectomy (242). Previous work has also demonstrated increased surgical quality with increased volume, therefore we further hypothesized that those providers that have a high proportion of gall bladder pathology will also be familiar with published evidence and are more likely to adopt high value surgery.(243)

Patient variables were used to adjust for case mix. This included age on admission, deprivation index and level of co-morbidity indicated by the Charlson Comorbidity Index (CCI). Age was treated as a continuous variable. The CCI was derived from the secondary diagnosis codes on index presentation and weightings applied were those as defined by Quan et al. from 2011. (244) Those patients with a score of 0 were considered to have 'low' co-morbidity, those with a score of 1 were considered to have 'medium' co-morbidity and those with a score of >1 were considered to have 'high' co-morbidity. The Index of Multiple deprivation (IMD) scores are assigned to the patient's postcode and areas were ranked from least to most deprived. Thenceforth for each procedure patients were assigned to a relevant quintile on the basis of their ranking, with the first quintile being least deprived.

Other outcomes were measured to determine quality, which in this setting is optimal health outcomes that in turn describes value. These include total length of stay and admissions per patient. Total length of stay is defined as provider admission bed days inclusive of any readmissions, pre-operatively, peri-operatively and post-operatively within 30 days. If a patient was transferred to another hospital for procedure, they were not classified as being discharged, it was considered a continuous inpatient stay. The number of admissions per patient is defined as the number of times a patient attended the hospital following initial diagnosis up until their operation, be it early or delayed. Adjustment for case mix was performed to account for age on admission, comorbidity and deprivation, whereby a standardized index of multiple deprivation was used.

Statistical Analysis

The number and proportion of early cholecystectomies before and after April 2010 were identified for each hospital. For each trust a 2x2 contingency table was generated in order to determine both relative change in the proportion of early versus delayed cholecystectomy (represented as odds ratio) with significance determined by Fisher's exact test. This parameter serves as a measure for a provider's ability to change behaviour and move towards index cholecystectomy, thus an individual provider's adoption behaviour. Using both odds ratio and p-value we were able to stratify trusts into 'static' ($p>0.05$), 'innovator' ($p<0.05$ and odds ratio >1) and 'exnovator' ($p<0.05$ and odds ratio <1).

To investigate the association between use of delayed cholecystectomy and provider characteristics we performed a multivariate linear regression model with the dependant variable being the relative change in proportion of early cholecystectomy whilst controlling for the pre-2010 covariates of institutional characteristics (size of provider, nature of provider (academic / non-academic institution), presence of specialist hepato-biliary units and proportion of gall bladder pathology as surgical workload) and patient characteristics (age and co-morbidity). The theoretical basis for this was to identify a possible institutional characteristic which may act as a predictor of future adoption behaviour. Ultimately the status of a provider as a hepato-biliary specialist centre was not included due to its co-linearity with teaching hospital status.

Residuals were normally distributed as assessed by visual inspection of a normal probability plot.

It was also hypothesised that providers considered to be technically efficient, that is those who optimise the use of resources would be more likely to de-adopt inappropriate care. Proxy measures for technical efficiency used were mean total length of stay (LOS) and the number of admissions per patient. This was then compared between the two time periods (pre and post 2010) to see if there has been any change in the different adopter categories. In turn a Spearman's rank order correlation was run to assess the relationship between the relative change in the proportion of early versus delayed cholecystectomy (represented as odds ratio) and ratio of number of admissions pre/post 2010. Preliminary analyses showed a linear relationship with normally distributed variables.

In turn a regression model was created to predict the effect of adopter odds ratio of early cholecystectomy against the number of admissions. This model similarly was also adjusted for patient (age and co-morbidity) and institution (size of provider, nature of provider, surgical workload etc.) characteristics. Similar analyses were then performed for total length of stay.

Each analysis was implemented for both acute cholecystitis and gallstone pancreatitis.

Data extraction and statistical analyses were performed using Python and STATA 15.

Table 16 -Procedure Codes

Procedure Description	OPCS-4 Code
Total Cholecystectomy and excision of surrounding tissue	J18.1
Total Cholecystectomy and exploration of Common bile duct	J18.2
Total Cholecystectomy NEC (Not elsewhere classified)	J18.3
Partial Cholecystectomy and exploration of common bile duct	J18.4
Partial Cholecystectomy NEC	J18.5

Table 17 - Diagnosis Codes

Diagnosis	ICD-10 (International Classification of Disease – 10) Code
Cholecystitis	K81
Acute Cholecystitis	K81.0
Chronic Cholecystitis	K81.1
Other Cholecystitis	K81.8
Cholecystitis, unspecified	K81.9
Biliary Acute Pancreatitis	K85.1
Other Acute Pancreatitis	K85.8
Acute Pancreatitis, unspecified	K85.9
Cholelithiasis	K80
Calculus of the Gallbladder with acute Cholecystitis	K80.0
Calculus of the Gallbladder with other cholecystitis	K80.1
Calculus of the bile duct with cholecystitis	K80.4

Results

The dataset delivered contained a total of n=6 651 899 patient episodes. Between January 2006 and December 2014, the total number of cholecystectomies included in the study was n=80 812 (n=35 336 for AC and n=45 476 for GSP); these were operations which were preceded by an admission with a formal diagnosis of gallstone pancreatitis or acute cholecystitis respectively. Those cases that were not coded with a formal diagnosis of either gallstone pancreatitis or acute cholecystitis or presented via GP to clinic, or even presented only to the emergency department without formal admission were excluded.

Acute Cholecystitis

Between January 2006 and December 2014, the total number of cholecystectomies included in the study was n=35 336.

The number of cholecystectomies performed annually increased from n=3633 (2006/7) compared with n=4411 (2014/15), an increase of 17.64%. There was no overall adoption of early cholecystectomy with proportion of early cholecystectomies remaining similar throughout the period (36.58% in 2006/7 and 32.64% in 2014/15). The mean proportion of EC was 32.67%, as shown in Figure 8.

Figure 9 displays the variation in rates of adoption of index cholecystectomy for AC by means of a volcano scatter plot, with significance from Fisher's exact test [-log(pvalue) - y axis) plotted against relative change in the proportion of index versus interval cholecystectomy [logoddsratio - x axis). 61.87% of trusts are in the 'static' provider category, n=88, with fewest in the 'adopter' category (n=18, 12.95%) and a quarter of all trusts in the exnovators group, (n=35, 25.18%). The patterns of adoption of early and late cholecystectomy over time are illustrated in figure 10.

Figure 10 provides a visual representation of the longitudinal behaviour of different adopter categories. The ‘adopter’ providers appear to demonstrate a behaviour similar to that described by Rogers – with a shallow initial phase, followed by exponential then flattening out. In contrast the ‘exnovators’ appear to display the opposite behaviour.

This is geographically represented in a cartogram (figure 11) where the odds ratio of adopting early cholecystectomy is represented by colour, and volume of procedures represented by size of sphere. There is significant geographical variation in the relative change between trusts, which in turn demonstrates the dynamic nature of change within a vast organisation such as the English National Health Service. Even within a single city there is significant variation between trust behaviour in terms of innovation and adoption (figure 12).

Figure 8 – Number of Cholecystectomies over time

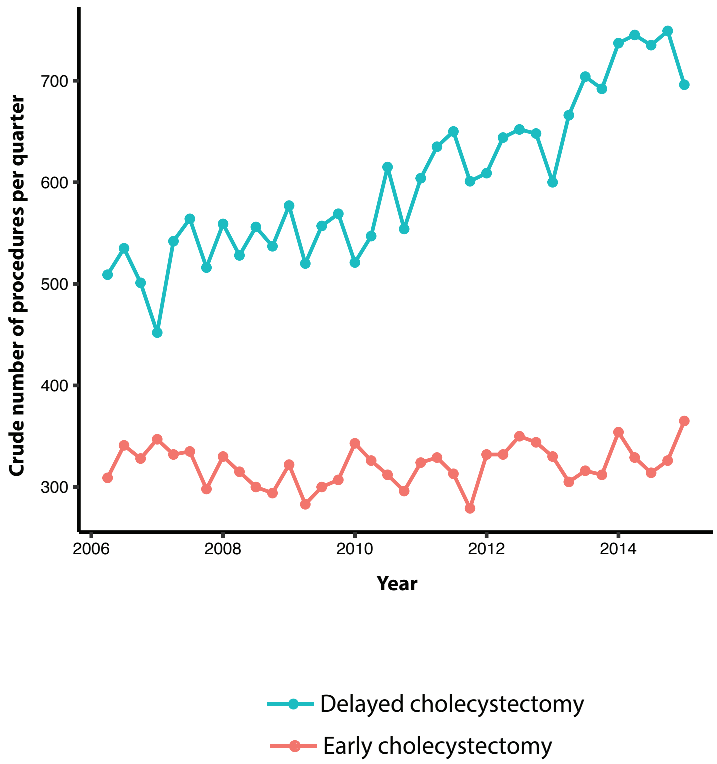


Figure 9 - Volcano Plot demonstrating different Adopter Categories

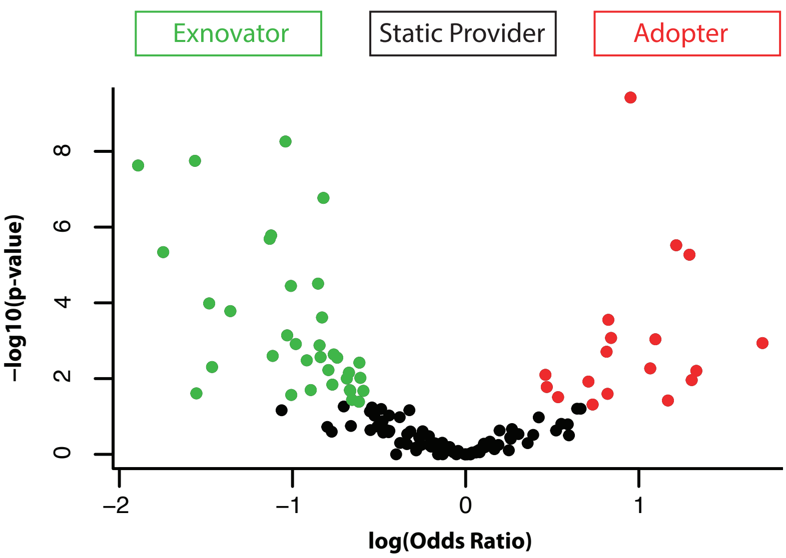


Figure 10– Patterns of Adoption within each behaviour Category

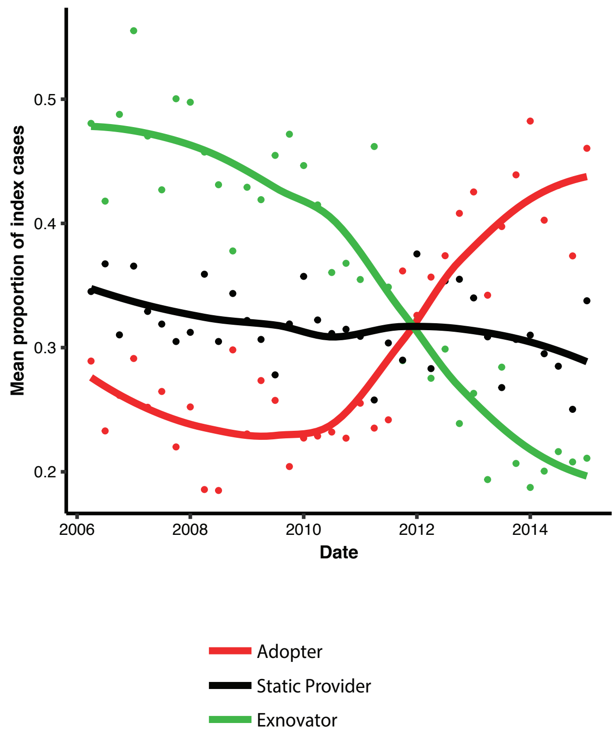
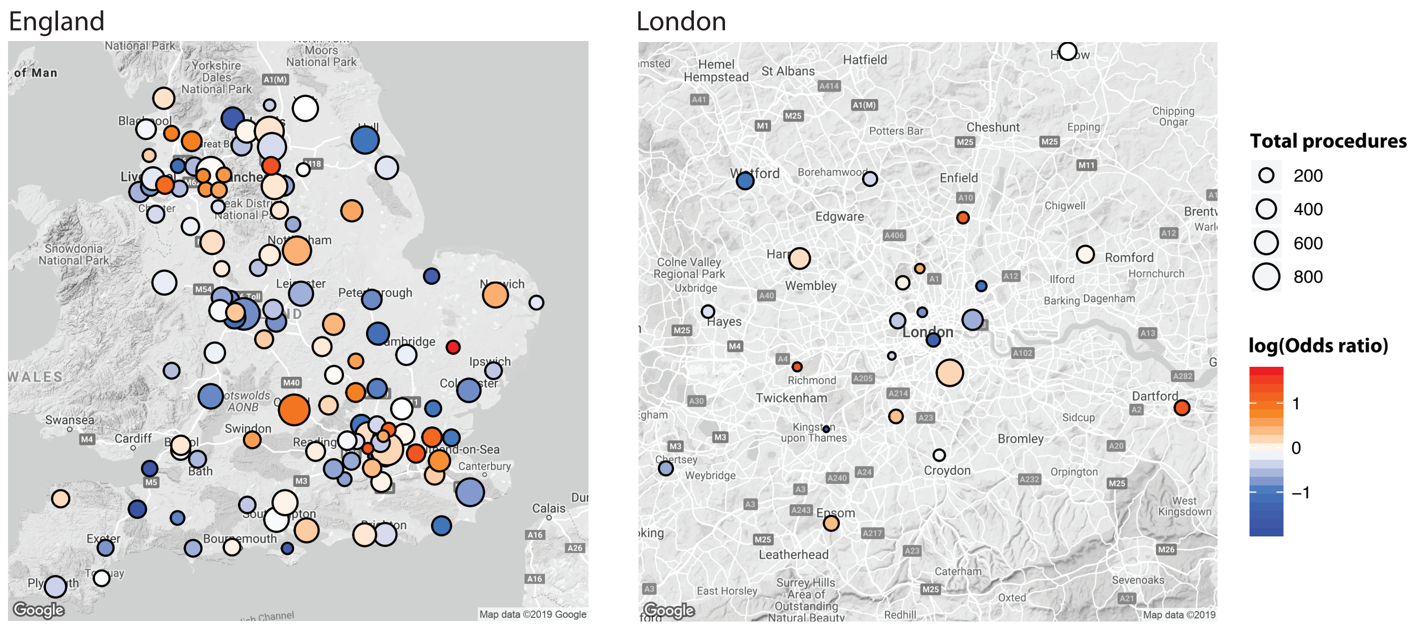


Figure 11 & 12 Variation Cartograms of Adopter Behaviour in England & London



Descriptive Statistics

Within the exnovators group there were 7 (20%) small providers, 13 (37%) medium providers, 7 (20%) large providers and 8 (22%) teaching hospitals. The ‘static’ group had a 24 (28%), 19 (22%), 27 (31%) and 16 (19%) hospitals that were small, medium, large and teaching hospitals respectively. The ‘adopter’ providers contained 5 (28%) small, 4 (22%) medium, 2 (11%) large and 6 (33%) teaching hospitals.

The ‘exnovator’ group were responsible for 26.7% of cholecystectomies (n=10 114), the ‘static’ group 59.58% of cases (n=22 606) and the ‘adopters’ were responsible for 13.77% of cases (n=5 224). Patient characteristics in terms of age and co-morbidity were similarly distributed between adopter categories. (Table 18 –Descriptive Statistics)

The ‘exnovator’ providers performed 32.56% (n=2 530) EC cases before 2010 and 19.16% (n=1146) EC cases after 2010. This is a difference of -13.4%. The ‘static’ providers performed 57.57% (n=4474) and 62.19% (n=3719) EC before and after 2010 respectively; with a difference of 4.62%. The ‘adopter’ providers performed 9.87% (n=767) and 18.65% (n=1115) before and after 2010 respectively, an increase of 8.78%.

Table 18– AC Descriptive Statistics, Identifying the difference in activities between adopter providers

	Adopters	Exnovators	Static	Overall
Cases (%)	5224 (13.77)	10 114 (26.66)	22 606 (59.58)	35336
Number of Trusts (%)	18 (12.95)	35 (25.18)	86 (61.87)	139

Early Cholecystectomy (In each provider Category)	Adopters	Exnovators	Static	Overall
Pre 2010	767	2530	4474	7771
Post 2010	1115	1146	3719	5980
Total Early Cases	1882	3676	8193	13751

Delayed Cholecystectomy (In each provider Category)	Adopters	Exnovators	Static	Overall
Pre 2010	2034	3107	7594	12735
Post 2010	1308	3331	6819	11458
Total Delayed Cases	3342	6438	14413	24193
Relative Change in Rate of Index Cholecystectomy before and after 2010 (Mean Odds Ratio)	2.79	0.39	0.96	

Patient Characteristics (In each provider Category)	Adopters	Exnovators	Static	Overall
Mean Age (years)	53.4 +/- 17.2	53.4 +/- 17.2	54.6 +/- 17.2	

Co-Morbidity (CCI) (In each provider Category)	Adopters	Exnovators	Static	Overall
Proportion Low (%) Score = 0	78.49	76.45	78.20	77.71
Proportion Medium (%) Score = 1	14.52	14.55	13.79	14.29
Proportion High (%) Score = >1	6.99	8.99	7.99	7.99

Provider Characteristics (In each provider Category)	Adopters	Exnovators	Static	Overall
Number of Hospitals (%)	37 (27)	80 (58)	22 (16)	139

Size (In each provider Category)	Adopters	Exnovators	Static	Overall
Small (%)	8 (21.62)	22 (27.5)	6 (27.3)	36 (25.9)
Medium (%)	16 (43.24)	14 (17.5)	6 (27.3)	36 (25.9)
Large (%)	7 (18.92)	26 (32.5)	4 (18.2)	37 (26.6)
Teaching (%)	6 (16.22)	18 (22.5)	6 (27.3)	30 (21.6)
HPB Centres (%)	5 (13.51)	19 (23.75)	4 (19.1)	28 (20.1)
Proportion of Total General Surgical Volume (%)	5.86 (5.82 to 5.90)	5.554 (5.552 to 5.557)	5.60 (5.54 to 5.67)	5.64 (5.61 to 5.65)

Multivariate Regression Analysis

A multivariate regression was run to predict adopter odds ratio from institution and patient characteristics. The model statistically significantly predicted odds ratio; $F(8,129)$ 2.274, p value <0.05. R2 for the overall model was 12.6% with an adjusted R2 of 6.9%, a moderate-weak sized effect.

Exnovator behaviour was significantly associated with higher mean patient age, higher proportion of cholecystectomy (of total general surgical workload) and larger providers (Figure 4).Those trusts who have older, unhealthy patients are more likely to do delayed operations. We identified a non-significant trend between HPB centre status and innovator behaviour (p=0.104).

Regression coefficients and Standard errors can be found in table 19. That is those hospitals who perform increasing volumes of cholecystectomy as their workload, with older patients were more likely to reduce the number of early operations, and therefore less likely to innovate.

Table 19 –Summary of Multiple Regression Analysis (Adopter Odds Ratio and Institution Characteristics)

Variable	ß	SE β	P value
Intercept	6.039	1.659	<0.05*
Patient Characteristics			
Age on Admission	-0.072	0.029	<0.05*
Co-Morbidity (CCI group)	-0.586	0.503	0.245
Institution Characteristics			
HPB Centre presence	0.272	0.203	0.18
General Surgical Volume	<0.001	<0.001	0.58
Proportion of Total General Surgical Volume Cholecystectomies	-8.631	3.83	<0.05*
Provider Size (Compared to Small)			
Medium	-0.542	0.200	<0.05*
Large	-0.581	0.237	<0.05*
Teaching	-0.501	0.257	0.053

Note – β = Standardized regression coefficient, SE β = Standard error of the coefficient. * denotes significance.

Secondary (Quality) Outcome Measures

Admissions

Early cholecystectomy resulted in a statistically significant ($p < 0.0001$) reduction in the mean number of admissions throughout the adopter categories, with the largest difference in the exnovator trusts (0.992 admissions). This is in keeping with previously published papers that early cholecystectomy results in fewer admissions. (as detailed in Table 20 & Figure 13)

There was also a significant difference between the mean number of admissions before and after 2010 in all adopter categories, with the largest difference being in the exnovators; who had an increased number of admissions (+0.281 admissions, $p< 0.0001$). In contrast the adopter provider trusts had a decrease in the mean number of admissions (-0.060 admissions, $p<0.001$). The static providers had a similar increase in the mean number of admissions of -0.129 admissions, $p<0.001$), as detailed in table 21 and figure 14. Therefore an exnovator provider will have to accommodate another 343 admissions for every 100 patients whom are diagnosed with acute cholecystitis whilst waiting for a delayed operation when compared to the adopter providers.

The Spearman rank-order correlation demonstrated a significant negative correlation between the relative change of proportion of early cholecystectomy (represented as log(odds ratio)) and the ratio of admissions pre/post 2010, (rho = -0.76, $p<1 \times 10^{15}$). Univariate and multivariate regression models statistically predicted admissions $F(8, 129)$ 25.63 p value <0.0001. R^2 being 61.38% and adjusted R^2 of 59.00% - highly significant. The model remained significant when covariates of patient and institution characteristics were included. (Figure 15)

Figure 13- Difference in mean number of admissions within Adopter Categories

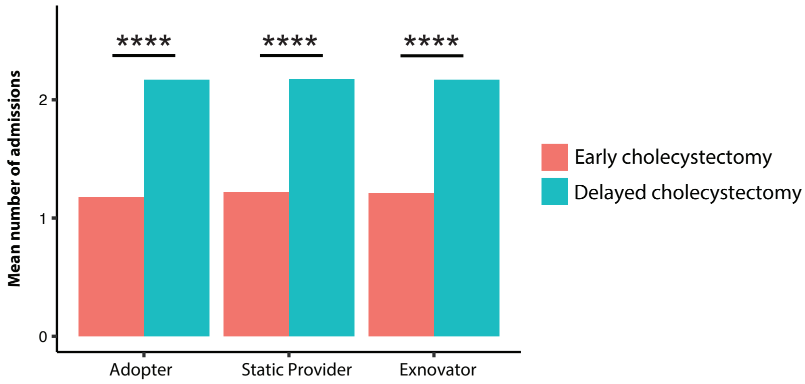


Figure 14– Difference in Mean Number of admissions before and after 2010

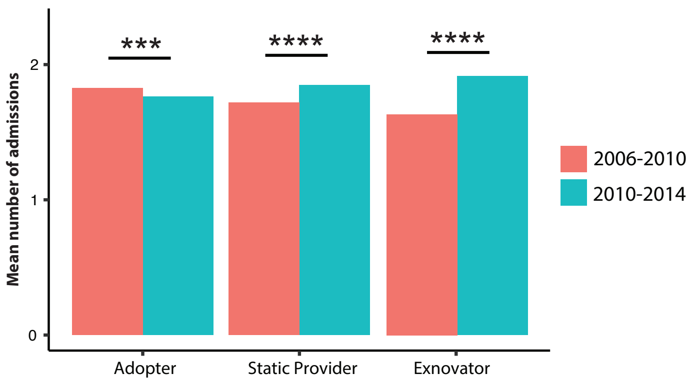


Figure 15– Correlation of Relative Change of proportion of Early Cholecystectomy [log(odds ratio)] and ratio of admissions before and after 2010

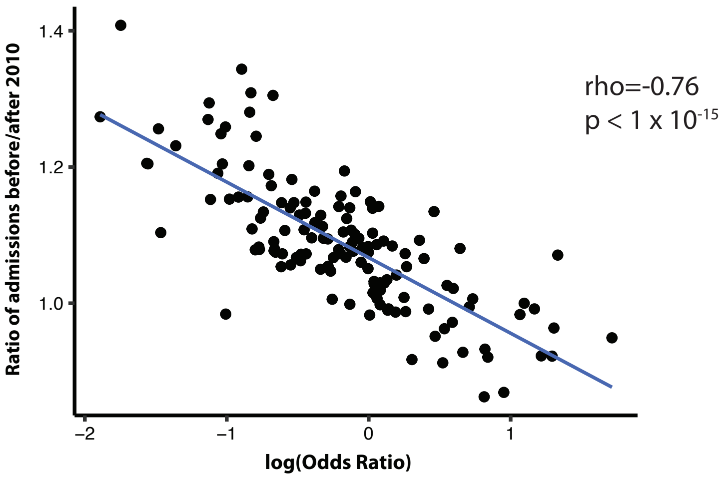


Table 20 - Descriptive Statistics of Mean Number of Admissions and Total length of Stay

Type of cholecystectomy	*Adopter Category*	*Admissions (mean)*	*Total Length of Stay (mean)*
Early	Adopter	1.167	9.159
Late	Adopter	2.123	10.624
Early	Static Provider	1.158	9.802
Late	Static Provider	2.122	10.804
Early	Exnovator	1.138	9.214
Late	Exnovator	2.130	10.358

Difference between adoptor Categories	Adopter	-0.955 ($P < 0.0001$)	-1.465, ($P < 0.0001$)
	Static	-0.964 ($P < 0.0001$)	-1.003 ($P < 0.0001$)
	Exnovator	-0.992 ($P < 0.0001$)	-1.145 ($P < 0.0001$)

Table 21– Mean Admissions and Length of Stay per Time Period

Time Period	*Adopter Category*	*Admissions (Mean number)*	*Total Length of Stay (Mean days)*
Before 2010	Adopter	1.825	10.401
	Exnovator	1.634	10.123
	Static Provider	1.721	10.803
After 2010	Adopter	1.765	9.879
	Exnovator	1.915	9.751
	Static Provider	1.849	10.180

Difference Per Category before and after 2010	Adopter	-0.060, (p<0.001)	-0.522 (no significance)
	Exnovator	0.281, (p<0.0001)	-0.371 (p<0.0001)
	Static	0.129, (p<0.0001)	-0.622 (no significance)

Table 22–Summary of Multiple Regression Analysis (Adopter Odds Ratio and Mean Number of Admissions)

Variable	ß	SE *ß*	P value
Intercept	1.079	0.019	<0.001*
Log(odds ratio)	-1.133	0.008	<0.001*
Patient Characteristics			
Age on Admission	<0.0092	<0.001	0.2801
Co-Morbidity (CCI group)	-0.039	0.0031	0.2033
Institution Characteristics			
HPB Centre presence	0.028	0.019	0.07
General Surgical Volume	<0.001	<0.001	0.58
Proportion of Total General Surgical Volume Cholecystectomies	<0.001	<0.001	0.77
Provider Size (Compared to Small)			
Medium	-0.014	0.015	0.34
Large	-0.025	0.018	0.17
Teaching	-0.014	0.-19	0.47

Note – *ß* = Standardized regression coefficient, SE *ß* = Standard error of the coefficient. * denotes significance.

Total Length of Stay

There was a significant reduction in length of stay in all provider categories when early cholecystectomy was employed, again like previously published work. The difference in length of stay was largest in the exnovator group (-1.465 days, $p<0.0001$) and smallest in the static group (- 1.003 days, $p<0.0001$). It should be noted that this is total length of stay for said disease not simply for the operation, hence an adopter provider that operates on index admission will avoid multiple presentations and subsequently reduce total length of stay.

There was a reduction in the overall total length of stay in all adopter categories; although findings were non-significant within the adopter and exnovator categories. This was a difference of 0.371 days, $p<0.0001$. Suggesting that all trusts have been able to improve total length of stay over time. (as detailed in tables 17 & 18)

Furthermore the Spearman rank-order correlation did not demonstrate a significant correlation between the relative change of proportion of early cholecystectomy (represented as log(odds ratio)) and the ratio of admissions pre/post 2010, (rho = -0.07, p =0.45).

Figure 16 - Reduction in Total Length of Stay between Provider Categories

Figure 17– Reduced Total Length of Stay in all Provider Categories

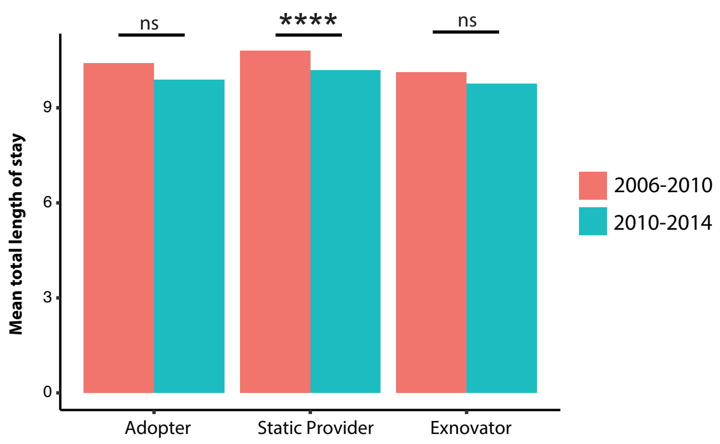


Figure 18 - Spearman rank-order Correlation of relative change of proportion of Earl Cholecystectomy and ration of Total Length of Stay (LOS) before and after 2010

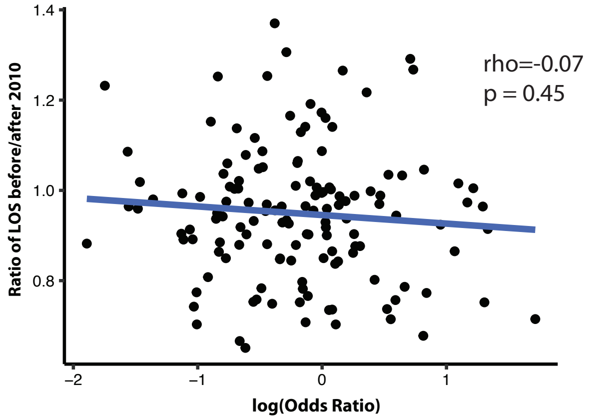


Table 23–Summary of Multivariate Regression Analysis (Adopter Odds Ratio and Mean LOS)

Variable	ß	SE *ß*	P value
Intercept			<0.001*
Log(odds ratio)	-1.133	0.008	<0.001*
Patient Characteristics			
Age on Admission	<0.0092	<0.001	0.2801
Co-Morbidity (CCI group)	-0.039	0.0031	0.2033
Institution Characteristics			
HPB Centre presence	0.028	0.019	0.07
General Surgical Volume	<0.001	<0.001	0.58
Proportion of Total General Surgical Volume Cholecystectomies	<0.001	<0.001	0.77
Provider Size (Compared to Small)			
Medium	-0.014	0.015	0.34
Large	-0.025	0.018	0.17
Teaching	-0.014	0.-19	0.47

Note – *ß* = Standardized regression coefficient, SE *ß* = Standard error of the coefficient. * denotes significance.

Gallstone Pancreatitis

Between January 2006 and December 2014, the total number of cholecystectomies included in the study was n=45 476 these were operations which were preceded by an admission with a formal diagnosis of gallstone pancreatitis. Those cases that were not coded with a formal diagnosis of either gallstone pancreatitis or acute cholecystitis or presented via GP to clinic, or even presented only to the emergency department without formal admission were excluded.

The number of cholecystectomies performed for GSP in 2006/7 was n=4431. This increased to n=5780 in 2014/15, an increase of 23.34%. The proportion of index cholecystectomies increased slightly from 13.13% in 2006/7 to 19.84% in 2014/15. The mean rate of index cholecystectomies was 15.62% (sd 1.922, min 13.13% max 19.84%). As evidenced in figure 19.

Variation in provider behaviour is demonstrated by means of a volcano scatter plot (Figure 20), with significance from Fisher's exact test [-log(pvalue) - y axis) plotted against relative change in the proportion of index versus interval cholecystectomy [logoddsratio - x axis). 66.19% of trusts are in the 'static' provider category, n=92, with fewest in the 'exnovator' category (n=12, 8.63%) and a quarter of trusts in the 'adopter' group, (n=35, 25.18%)

Figure 21 demonstrates the longitudinal behaviour of different adopter categories. The 'adopter' providers appear to demonstrate a behaviour similar to that described by Rogers – with a shallow initial phase, followed by exponential then flattening out. In contrast the 'exnovators' appear to display the mirror opposite behaviour. There appears to be a significant upstroke at the beginning of the time period followed by exnovation behaviour that is certainly more prevalent then when compared to the AC graphs.

This is illustrated geographically by means of a heat map (figure 22) where the difference in odds ratio of adopting early cholecystectomy is represented by the colour, and volume of procedures represented by size of sphere. There is noticeable geographical variation in the relative change between trusts, without any geographic continuity. Even within a single city there is wide variation between trust behaviour in terms of exnovation and adoption (figure 23). It forms a similar distribution to that demonstrated with Acute Cholecystitis.

Figure 19 – Rates of Early and Delayed Cholecystectomy for Gallstone Pancreatitis

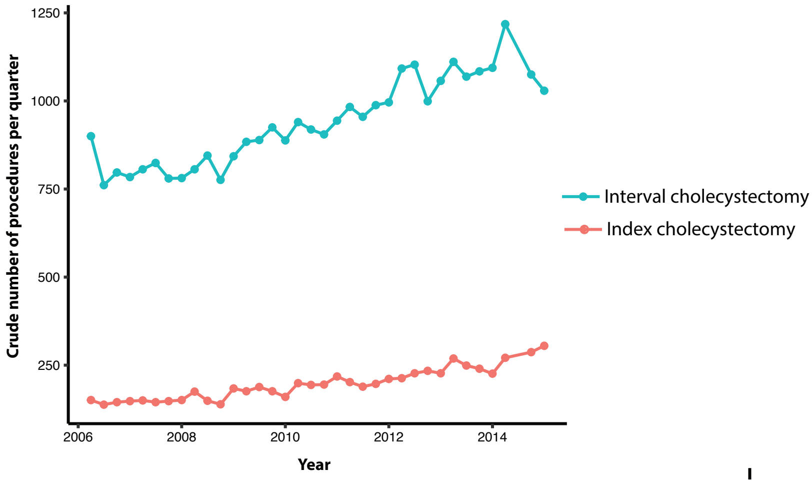


Figure 20 – Volcano plot of behaviour plot

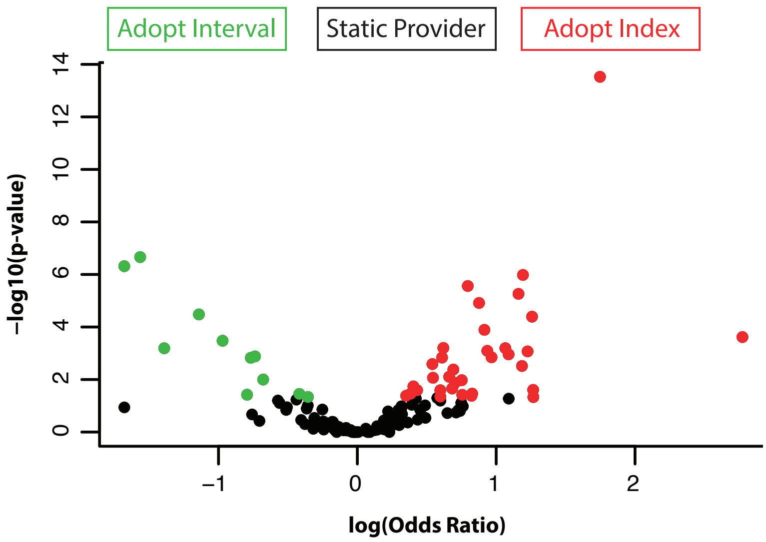


Figure 21 – Longitudinal Behaviour of Providers offering Early and Delayed Cholecystectomy in GSP

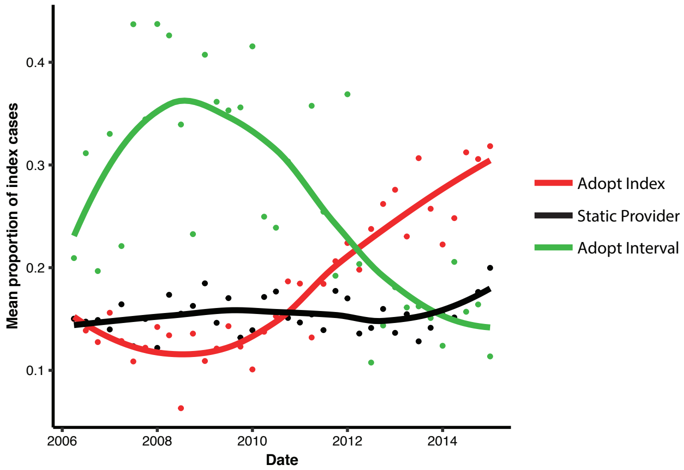
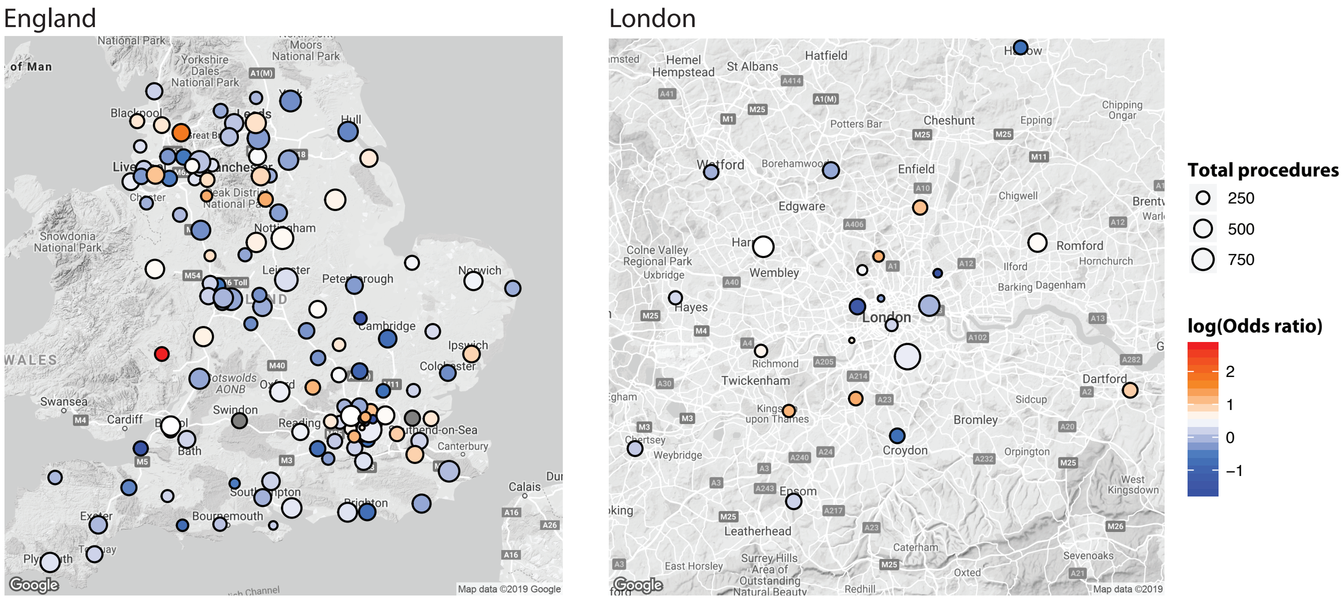


Figure 22 & 23– Variation in the Adoption of Early Cholecystectomy in England & London



Descriptive Statistics

The static group contained n=24 (26.09%) , n=25 (27.17%), n=25 (27.17%) and n=17 (18.48%) small, medium, large and academic providers respectively. A quarter of all providers were ‘adopters’ whom had n=8 (22.86%) small, n=8 (25.71%) medium, n=9 (25.71%) large and n=9 (25.71%) teaching hospitals. The remaining 12 trusts were found to be exnovators, with n=4 (33.33%) small, n=2 (16.67%) medium, n=2 (16.67%) large and n=4 (33.33%)academic centres.

The ‘exnovator’ group were responsible for 7.80% of cases (n=4 150), the ‘static’ group 64.22% of cases (n=34 160) and the ‘adopters’ were responsible for 27.98% of cases (n=14 885). Patient characteristics in terms of age and co-morbidity were similarly distributed between adopter categories. (Table 21 - Descriptive Statistics)

Before 2010 there were n=5 104 and n=22 007 early and delayed cholecystectomies performed respectively, at a rate of 23.19%. After 2010 there were n=5 556 and n=20 528 ealry and delayed cholecystectomies performed respectively at a rate of 27.06%.

The ‘exnovator’ providers performed 34.18% (n=708) early cholecystectomies before 2010 and 20.48% (n=425) early cases after 2010, a change of -13.74%. The ‘static’ providers performed 17.80% (n=3 092) and 18.14%(n=3 055) early cholecystectomies before and after 2010 respectively, a difference of 0.3%. The ‘adopter’ providers performed 16.9% (n=1304) and 28.96% (n=2 076), an increase in 12.06%.

Multivariate regression modelling was performed in attempt to identify institutional and patient characteristics statistically significantly predicted differences in rates of index cholecystectomy pre and post 2010, $F(7, 130) = 4.70$, $p < 0.001$. However no variables were found to have statistically significant predictive value odds ratio of adopter behaviour. This was the same when only significant adopters and exnovators were considered. (Table 24)

Table 24– Descriptive Statistics GSP

	Exnovators	*Static*	*Adopters*	*Overall*
Cases (%)	4159 (7.80)	34160 (64.22)	14 885 (27.98)	53195
Number of Trusts	12 (8.63)	92 (66.19)	35 (25.18)	139
Early Cholecystectomy				
Pre 2010	708	3092	1304	5104
Post 2010	364	2133	974	5556
Total	1133	6147	3380	10660
Delayed Cholecystectomy				
Pre 2010	1363	14231	6413	22007
Post 2010	1654	13782	5092	20528
Total	3017	28013	11505	42535
Proportion of Early Cholecystectomy				
Pre-2010 (%)	34.19	17.85	16.90	18.83
Post-2010 (%)	20.44	18.14	28.96	21.30
Proportion of Total General Surgical Volume (%)	6.22 (5.37 to 7.07)	6.89 (6.59 to 7.18)	6.59 (6.03 to 7.14)	6.80 (6.79 to 6.81)
Patient Characteristics				
Mean Age [sd.](95% CI)	54.07 [17.34] (53.66 to 54.48)	54.60 [17.19] (54.33 to 54.85)	53.88 [17.09] (53.32 to 54.42)	54.37 [17.22] (54.16 to 54.57)

Charlson				
Proportion Low (%)	76.72	74.64	76.75	76.04
Proportion Medium (%)	15.65	15.48	14.71	15.28
Proportion High (%)	7.63	9.89	8.54	8.69
Provider Characteristics				
Number of Hospitals (%)	15 (10.8)	97 (70.2)	26 (18.8)	138
Size				
Small (%)	5 (33)	23 (23.7)	8 (30.8)	36 (26.1)
Medium (%)	4 (27)	25 (25.8)	7 (26.9)	36 (26.1)
Large (%)	2 (13)	28 (28.9)	6 (23.1)	36 (26.1)
Teaching (%)	4 (27)	21 (21.7)	5 (19.2)	30 (21.7)
HPB Centres (%)	3 (20)	21 (21.7)	4 (15.4)	28 (20.3)

Table 25 - Multivariate Regression Analysis of Change in Proportion of Index Cholecystectomy before and after 2010 for GSP

		Model A	*Model B*
Variable		Coefficient (multivariable)	Coefficient (multivariable)
HPB Centre	No	-	-
	Yes	-0.20 (-0.99 to 0.58, p=0.605)	-0.51 (-3.15 to 2.12, p=0.697)
Surgery Volume (N)		0.00 (-0.00 to 0.00, p=0.886)	0.00 (-0.00 to 0.00, p=0.609)
Provider Type	1	-	-
	2	-0.51 (-1.26 to 0.24, p=0.184)	-0.99 (-3.31 to 1.33, p=0.394)
	3	-0.47 (-1.35 to 0.42, p=0.300)	-1.47 (-4.16 to 1.22, p=0.276)
	4	-0.44 (-1.44 to 0.55, p=0.382)	-1.94 (-5.05 to 1.18, p=0.216)
Mean Charlson Score		1.46 (-1.95 to 4.86, p=0.399)	6.89 (-4.13 to 17.91, p=0.213)
Mean Age		0.01 (-0.10 to 0.12, p=0.876)	-0.03 (-0.44 to 0.38, p=0.885)
Proportion Cholecystectomies		1.40 (-13.24 to 16.04, p=0.850)	6.92 (-42.96 to 56.79, p=0.780)

Model A is the Multivariate Regression containing all providers, Model B represents results including only significant providers (that is excluding static providers)

Secondary (Quality) Outcome Measures

Admissions

There was a statistically significant reduction (p>0.0001) in the mean number of admissions throughout the adopter categories when early cholecystectomy was used. The change was similar throughout the provider categories; 0.923, 0.910, 0.915 admissions (p<0.001) , in the adopter, static and exnovators categories significantly. This is in keeping with previously published work.

Similar to AC, there was a significant difference between the mean number of admissions before and after 2010, most notably in the adopter providers whom demonstrated a reduction of 0.037 admissions, p<0.0001 compared with the exnovator providers whom had an increase of 0.235 admissions, p<0.0001 between the two time periods. Therefore the exnovator provider will have at least 270 more admissions per 1000 patients whilst waiting for an operation when compared to the adopter providers. (As detailed in tables 23-24 and figures 24 - 26)

The spearman rank-order correlation demonstrated a statistically significant negative correlation between the relative change of proportion of early cholecystectomy [log(oddsratio)] and ratio of admissions before and after 2010, rho=.-0.66, $P<1x10^{15}$.

Figure 24 – Effect of Early Cholecystectomy on Mean Number of Admissions

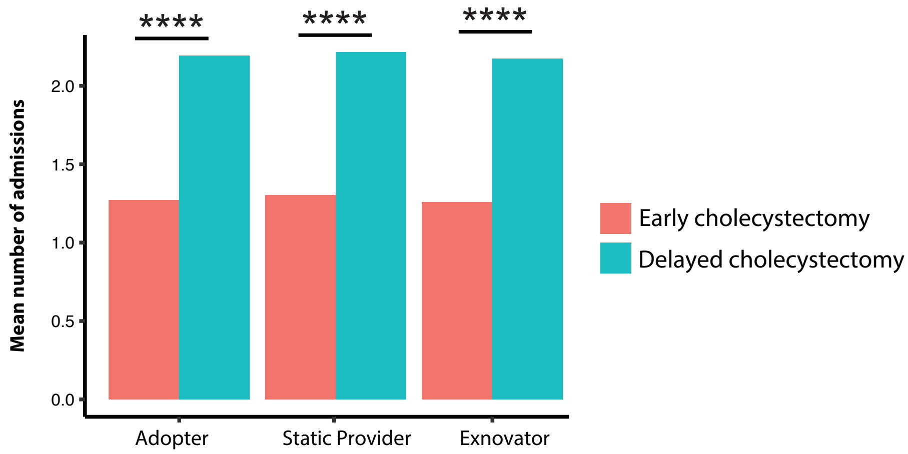


Figure 25 - Mean Number Admissions in Different Time Periods between Provider Categories

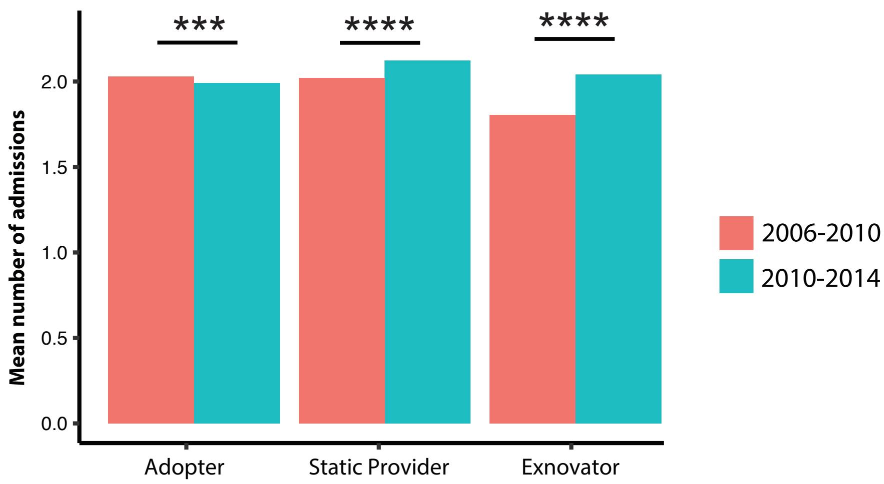
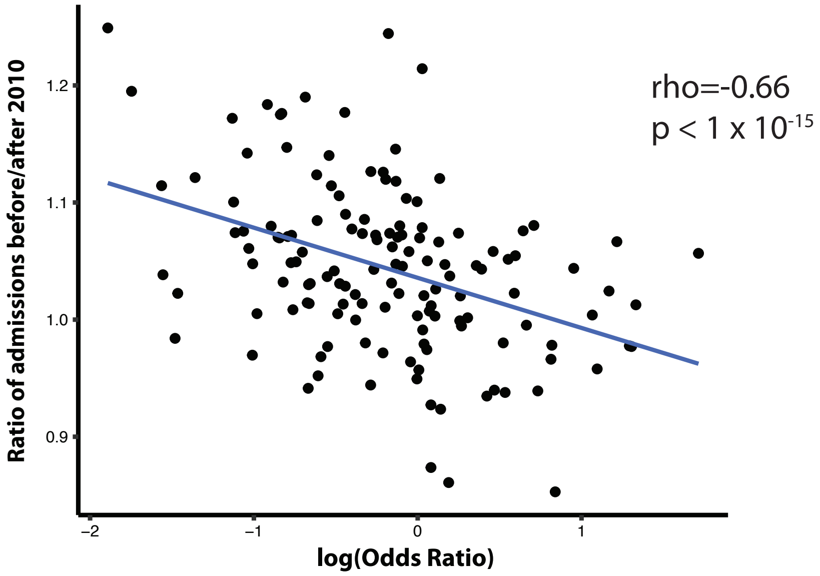


Figure 26 – Spearman rank-order correlation of relative change of proportion of Early vs Delayed Cholecystectomy against ratio of admissions before/after 2010



Total Length of Stay

There was a significant increase in the total length of stay when delayed cholecystectomy was used. The largest increase in total length of stay was in the exnovator providers (3.934 days, $p<0.0001$) with similar results in the static and adopter groups, (3.398 and 3.875 days, respectively. Also, in alignment with previously published reports. (Figure 27)

There was a significant reduction in the total length of stay in all provider categories before and after 2010, with a mean reduction of 3.875, 3.398 and 3.934 days ($p<0.0001$) within the adopter, exnovator and static providers respectively. There appears to be no effect on provider type on LOS, as all the groups were able to significantly reduce it over time. (Figure 28)

Spearman rank order correlation did not demonstrate significant effect, rho=-0.08, p=0.37. (Figure 29)

Figure 27– Reduction in Total Length of Stay between Provider Categories – GSP

Figure 28 – Reduced Total Length of Stay in all Provider Categories - GSP

Figure 29– Spearman rank-order Correlation of realative change of proportion of Earl Cholecystectomy and ration of Total Length of Stay (LOS) before and after 2010

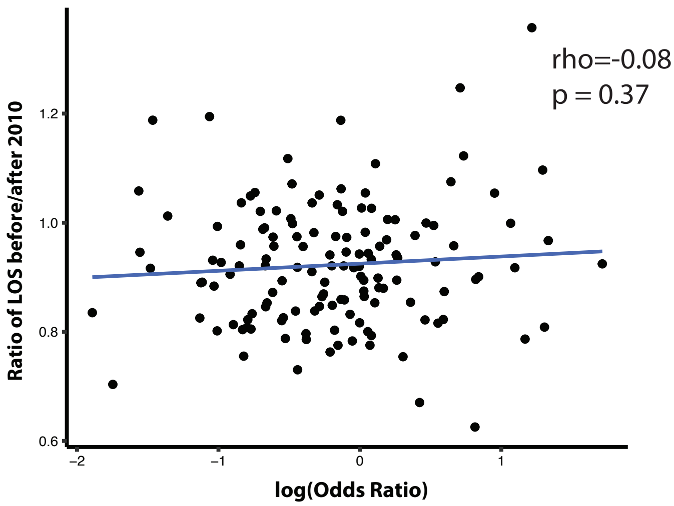


Table 26 – Descriptive Statistics of Mean Number of Admissions and Total length of Stay

Type of Cholecystectomy	*Adopter Category*	*Admissions (mean)*	*Total Length of Stay (mean)*
Early	Adopter	1.270	9.645
Late	Adopter	2.193	13.520
Early	Static Provider	1.304	10.121
Late	Static Provider	2.214	13.519
Early	Exnovator	1.257	10.055
Late	Exnovator	2.172	13.989

Difference in Mean No of Admissons	Adopter	0.923	3.875
	Static	0.910	3.398
	Exnovator	0.915	3.934

Table 27– Mean Admissions and Length of Stay per Time Period

Time	*Provider Type*	*Admissions (Mean Number)*	*Total Length of Stay (Mean Days)*
Before 2010	Adopter	2.028	13.309
	Exnovator	1.805	14.238
	Static Provider	2.022	13.598
After 2010	Adopter	1.991	12.285
	Exnovator	2.041	12.044
	Static Provider	2.122	12.543

Difference Per Provider Category before and after 2010	Adopter	-0.037, (p<0.0001)	-1.024, (p<0.0001)
	Exnovator	0.235, (p<0.0001)	-2.194, (p<0.0001)
	Static	0.100, (p<0.0001)	-1.055, (p<0.0001)

Table 28–Summary of Multiple Regression Analysis (Adopter Odds Ratio and Mean Number of Admissions) – GSP

Variable	ß	SE *ß*	P value
Intercept	$1.088\text{x}10^0$	$1.785\ \text{x}10^2$	<0.001**
Log(odds ratio)	$-6.86\text{x}10^2$	$7.323\ \text{x}10^3$	<0.001**
Patient Characteristics			
Age on Admission	$7.863\ \text{x}10^5$	$5.96\ \text{x}10^5$	0.189
Co-Morbidity (CCI group)	$-3.036\ \text{x}10^2$	$3.431\ \text{x}10^2$	0.377
Institution Characteristics			
HPB Centre presence	$2.211\ \text{x}10^2$	$1.364\ \text{x}10^2$	1.620
Proportion of Total General Surgical Volume Cholecystectomies	$-8.471\ \text{x}10^6$	$3.206\ \text{x}10^6$	<0.01*
Provider Size (Compared to Small)			
Medium	$4.613\ \text{x}10^3$	$1.331\ \text{x}10^2$	0.729
Large	$-2.310\ \text{x}10^3$	$1.582\ \text{x}10^2$	0.883
Teaching	$1.593\ \text{x}10^2$	$1.692\ \text{x}10^2$	0.348

Note – *ß* = Standardized regression coefficient, SE *ß* = Standard error of the coefficient. * denotes significance.

Discussion

This study has demonstrated that despite best evidence there has been limited national adjustment in the practice of offering a low value surgical procedure. This finding is consistent with other studies who have similarly looked at rates of early cholecystectomy for gallstone pathologies. (245, 246, 247)

We have identified substantial longitudinal variation in the approach of acute gallstone pathologies, and it is likely that the burden from ‘exnovator’ providers will continue to prevent nationwide adoption of index cholecystectomy unless the motivations of exnovation are addressed. Despite the efforts of some innovative providers who have taken positive steps to change practice to ally themselves with current evidence (12.95% and 25.18% of providers for the AC and GSP respectively), exnovators that represent 25.18% and 8.63% of all providers for AC and GSP respectively will prevent wholesale change. The effect of exnovation on the use of high value procedures is more significant when considering many providers displayed no net increase in index cholecystectomy use (61.87% and 66.19% of providers for AC and GSP respectively.)

The similarity in the approach to AC and GSP is unsurprising as both pathologies provide surgeons with similar clinical problems, and it is likely that similar expertise, knowledge and experience will contribute to comparable decision making. Furthermore, structural constraints that are present will impact on both pathologies within the same provider trust. Interestingly figure 21 may suggest an improved behaviour towards the use of Index Cholecystectomy when dealing with GSP as there are fewer exnovator providers (12 (8.63%) vs 35 (25.18%) in GSP and AC respectively) and a greater number of adopters (26 (25.18%) vs 18 (12.95%) in GSP and AC respectively), although the differences are not statistically significant (p=

0.59 and p= 0.19 for exnovators and adopters respectively). This may be in response to the didactic guidance that was issued in 2005 by the British Society of Gastroenterology implying the importance of index cholecystectomy in GSP. The guidance issued by NICE with regards to AC in 2015 will not affect the studied cohort and therefore its impact has cannot be assessed.

There was also notable cross-sectional variation. Cartograms for both AC and GSP display significant difference in the performance of early cholecystectomy. This is in keeping with previous findings that variation is ubiquitous and persistent. (212) This indicates the nature of the decision for early cholecystectomy, there is unlikely to be any overall consensus as to it being the best treatment algorithm that may be offered. Therefore, in the environs of preference-sensitive interventions the risk averse surgeons may see the intervention as having a poor benefit to risk ratio and therefore influence patients into opting for delayed surgery, influencing supply side factors. Furthermore this may be due to the supply sensitive nature of said intervention, that the structural constraints that prevent the options to perform early cholecystectomy will persist to cause underuse of this high value intervention .Therefore early cholecystectomy would be described as both preference and supply sensitive when described by the Dartmouth group.(207)

The rate of uptake of early cholecystectomy within the adopter categories in both AC and GSP display a similarity to sigmoidal S-shaped curve defined by Rogers in classical diffusion studies, although there is no obvious exponential central phase that indicates rapid adoption of novel operative approach. It may be that the exponential phase of adoption of EC has not been reached, and lag phase is still continuing, thus suggesting overall there is no consensus amongst English surgeons that the standard of care should be an early operation; that is despite best evidence there has not been a wholesale acceptance of change in clinical treatment – also contributing to its cross sectional variation in use. The period of study may in itself reflect the early lag phase with only ‘early adopters’ and ‘early majority’ providers making use of index cholecystectomy.

The exnovator behaviour line graphs appear to be the mirror opposite of Roger’s S shaped innovation curve. There appears to be an early majority of exnovators followed by a central phase of more rapid exnovation followed ultimately by flattening out towards the end of the study period, more pronounced in GSP. Although it is difficult to make firm conclusions about the nature of exnovator individuals we may suggest that exnovation activity is similar to innovation activity, and that within a large provider cohort such as the English National Health Service there will be dynamic changes where both adoption and exnovation is occurring consistently, the challenge lies in attempting to identify providers whom are most at risk of exnovating high value treatment strategies and providing incentives through policy nationally and at a local level in order to minimise their impact, thereby promoting widespread adoption of optimal treatments. This is one of the first studies to attempt to model de-adoption in surgery.

An alternate hypothesis is that the ‘exnovators’ and ‘adopters’ are at different points in the innovation cycle. The ‘adopter’ providers may represent those institutions in the ‘early majority’ phase of the innovation cycle, who are continuing to expand their use of the innovative high value care pathway in contrast the ‘exnovators’ are those providers who initially adopted (Ie. ‘early adopters’) and have now exnovated on the realisation that providing this service is not sustainable, financially and structurally. This may be due to absent incentives which policy is obliged to address. (40, 240)

Other theoretical models of abandonment identify ‘laggards’ (the last group of practitioners to innovate) as the first to exnovate. (36) However others have speculated that in the complex clinical environment new evidence regularly questions incumbent practices, thereby resulting in exnovation and so called medical ‘reversals’ that the ‘early innovators’ are also those providers within the ‘early majority innovators’ being both the first to innovate and the first to exnovate in response to updated evidence.(26, 67).

This study’s results are comparable to other healthcare examples. Previous publications have demonstrated how implementation of novel treatment pathways is difficult often obstructed by present medical practices that are well supported by the active physician community such as the persistent use of costly ineffective antibiotics to manage middle ear infections in children. (248) This may reflect the nature and actions of the majority of physicians who have an aversion to risk and loss in response to innovation: moving away from well versed incumbent practices that have offered safety to patients for several years requires a particular surgical appetite that may not be widespread. It would be interesting to define the individual surgeons who may choose to alter practice. Published studies have indicated that surgeons with more experience and who may be less concerned with managing complications associated with change in practice are more likely to de-adopt low value interventions. (67) Unfortunately our dataset does not offer clinician information, simple measures such as age, experience and specialty of practicing surgeon is likely to contribute to the ability to take on a novel treatment strategy.

The multivariate regression model for AC demonstrated a significant impact of biliary operations as proportion of surgical volume on adoption of early cholecystectomy, with an adjusted coefficient of ß= -8.63. This is contrary to the hypothesis, that those centres where cholecystectomy is common would readily align themselves with best practice, in fact they are more likely to be exnovator providers. Similarly, medium and large providers also have negative coefficients, ß= -0.54, and ß =-0.58 respectively. Unlike previous work there was no relative increase in adoption performance of academic institutions that were equally spread throughout adopter categories. (247) A possible explanation for these findings is the in-built inertia set within these providers. Those centres with high rates of cholecystectomy are likely to have well versed mechanisms to offer this service, particularly in medium and large providers. There remains a supply sensitive element to the variation described. However, when a systematic change is required structural and administrative barriers that cannot be easily overcome provide obstacles. This is less so in the smaller hospitals where there are less impediments to overcome, or indeed teaching hospitals where there may be more of an appetite to embrace innovation.

Interestingly although the multivariate model for GSP identified that institutional and patient characteristics statistically significantly predicted differences in rates of index cholecystectomy pre and post 2010, no variables were found to have statistically significant predictive value odds ratio of adopter behaviour unlike AC.

Failure of innovation may also be a reflection on the structural constraints within certain hospitals. This has been highlighted previously, with a lack of radiological or endoscopic support, denying the surgeon opportunity to provide early operation. (246, 247, 249) Such constraints are less prevalent in fee-for-service systems, where financial rewards and competition provide a necessity for a provider to change. Although a lack of institutional inertia may explain delayed innovation, it does not explain the equal action of exnovators. The regression from optimal treatment strategies is not caused by structural constraints that prevent innovation but by external influences not rewarding diligence. This is the underlying issue that requires attention.

Of real concern for English patients are the relative rates of early cholecystectomy from other developed nations. Population studies have demonstrated rates of early cholecystectomy in USA at 52.7%, and 54% in Switzerland for acute gallstone pathologies (246, 250). An explanation for this difference may be the nature of the health service, whereby a fee-for-service structure promotes innovation and single payer managed care stifles innovation. Financial incentives and competition provide the surgeon with more encouragement to align with 'cutting edge' practice and innovate; even in a culture of greater litigation. Certainly, there will be less inherent institutional barriers to overcome. Mobley et al. have demonstrated that rates of high value colonoscopy were higher in fee-for-service regions then those with managed care in Medicare populations.(251) Similarly, it may be observed that in health systems with financial constraints such as England innovation such as the routine use of early cholecystectomy is delayed, ultimately meaning that English patients are not being routinely offered optimal care. The counter example to this argument is the rates of EC being performed in Canada, a population study demonstrated rates of EC in Ontario of 58%. (252) Similar to the English system the operate offer a 'single-payer' system.

Early surgical intervention resulted in reduced mean number of admissions, both for AC and GSP, in all provider categories. Furthermore, there is also a reduced total length of stay. This is in keeping with previously published papers (223, 225).

However, the difference between number of admissions when reviewed within provider categories over time varies significantly. Adopter providers have reduced the mean number of admissions by 0.060 in AC, and 0.037 in GSP. This is in contrast to the exnovator providers whom had an increase in mean number of admissions of 0.281 in AC and 0.235 in GSP. Therefore, an exnovator provider will have to accommodate another 341 admissions for every 1000 patients whom are diagnosed with acute cholecystitis whilst waiting for a delayed operation when compared to the adopter providers. Similarly, an exnovator provider will have to accommodate an extra 272 admissions for every 1000 patients whom are admitted with GSP whilst waiting for a delayed operation in comparison to adopter providers. These numbers will have notable implications for workload of surgical departments, cost as well as poor quality care for patients. From the value perspective, they can only be regarded as comparatively low. This is further reiterated by the significant negative correlation of relative change in proportion of EC use and ratio of admissions before and after 2010.

Although one must be weary that a decrease in admissions does not always indicate progress. There is an assumption that the increase in early cholecystectomy would reduce admissions. Yet this may not be the only reason, they would also decrease if providers do not have capacity to admit symptomatic patients and a decision is taken to avoid admission by discharging the patient for delayed surgical intervention. Fewer admissions may also be the result of more proactive primary care, whereby patients bypass the emergency department entirely. This is likely to have become more prominent with time in alignment with the modern vogue toward increased day case surgery and reduced hospital admissions for care in medicine in general, particularly in the elderly population.

Interestingly similar significant changes were not evident when studying total length of stay in both AC and GSP. Although we demonstrated a reduction of total length of stay within each provider categories, there were no significant difference between the provider types over time. It is likely that this represents an overall improvement for care of patients undergoing cholecystectomy and a movement towards day case treatment which coincides with our longitudinal analysis. Another objective of surgical care over this period.

This study demonstrates that changing clinical practice is difficult. Particularly amongst surgeons, who have developed reputations as creatures of habit with resistance to change; more so when the objective is to ‘unlearn’ an incumbent practice. This process by which individuals and institutions acknowledge and release prior ingrained knowledge in order to incorporate new behaviours becomes central to the target of successful de-implementation (253). Without a culture willing to unlearn and its counterpart innovate will not result. Previous qualitative studies have demonstrated that practice change disturbs the status quo, which results in a new equilibrium that is uncomfortable for the surgeons. (254, 255) This may reflect the nature and actions of the majority of doctors who have an aversion to risk in response to innovation.

It would be interesting to define the individual clinician characteristics who may choose to alter practice; published studies have indicated that surgeons with more experience and who may be less concerned with managing complications associated with change in practice are more likely to de-adopt low value interventions. (67) Unfortunately this dataset did not offer clinician information.

Methods to address these issues include the Royal College of Surgeons’ “Cholecystectomy Quality Improvement Collaborative (Chole-QuIC)” initiative in order to empower clinicians to bring about change in their local hospital.(256) Similarly the “Getting it Right First Time” (GIRFT) report in General surgery has identified the need for hospitals to have better capacity planning with the allocation of operating theatres matched to the emergency surgery workload. (246) This needs to be supported by institutional leadership with goals of high rates of early cholecystectomy. Dedicated emergency surgical centres who offer a specialist led cholecystectomy service have demonstrated feasibility in terms of outcomes, and perhaps this may offer a sustainable option of offering optimal care.(257, 258)

Limitations

There are a number of limitations to the present study which limit the extent to which firm conclusions that can be made. Firstly, there are the inherent concerns of performing an observational study relying on administrative data sets that are known to contain coding inconsistencies. Furthermore, incomplete coding of key fields (Admission age) limits the assessments that may be performed. However, HES data has been used to monitor selected outcomes nationally and quality of administrative data has improved over time. (259, 260) Unmeasured confounders and differences in patient disease severity cannot be accounted for with this data. We excluded those patients who were coded as having gallstone disease, cholelithiasis as the national guidance that is applicable relates to acute cholecystitis. It is likely however there is overlap between the true formal diagnosis and what is coded, therefore the complete cohort of patients may have not been captured due to our exclusion criteria. The absence of clinician related factors significantly effects the ability for firm conclusions to be made about the decisions to choose to perform early or late cholecystectomy. Furthermore, organisational determinants of exnovation whether strategic die to management decisions, implementation failure due to structural constraints, leadership turnover may all contribute to the exnovation behaviour of individual procedures. These distinct causes of exnovation may well be the reason why few statistically significant predictors of exnovation were identified in multivariate models. For further study advances in measuring exnovation behaviour, and an attempt at identifying the role of clinicians and managers in such behaviour would be interesting.

Conclusion

Exnovation is a process that is occurring simultaneously with adoption of innovative procedures. Till date little academic interest has been given to exnovation, and it is crucial to identify and address the providers that are exnovators, in order to understand the mechanism that stimulates de-adoption of a novel intervention. Nationally diffusion of innovations will continue to be slow unless exnovation is directly addressed. Health policy should control exnovation in order to limit its effect, thereby permitting wholesale change. When the English National Health Service's performance is compared internationally rates of early cholecystectomy are lacking. It may be that fee for service systems exhibit superiority for innovation as the competition and financial incentives may motivate a clinician to change practice. This needs to be considered, otherwise English patients will continue to receive sub-optimal care.

Chapter 6 –

Discussion

Discussion

Thesis Review

Background Summary

The overwhelming motivation of the thesis is to highlight the importance and relevance of low value care particularly in surgery, thereby stimulating discussion in English surgical health policy. It should be reiterated that patient care is the key objective not cost saving as has previously been described. Therein a conceptual framework and established understanding have been offered to supply policy makers with evidence to make decisions along the value paradigm.

The initial concepts originate with the definition of value. The idea of high value care itself stems from the theoretical models of maximal quality of care - optimal health services for individuals and populations. This requires adequate 'structure'; suitable 'process' between patients and providers which in turn will impact on ideal 'outcomes' – that represent the recovery, the restoration of function of both individual patients and in turn populations. The focus is thus on highly effective quality care and not volume.

Yet in the auspices of struggling health budgets and an aging population focusing on quality alone without knowledge of the financial constraints becomes single-minded. Therefore, in order to represent a holistic response to problems at hand the business case needs attention, hence the notion of 'value' in health care. Here the ratio of outcomes (the 'ultimate validators of the effectiveness and quality of medical care' (20)) to cost becomes relevant.

Therefore, by reducing interventions which are low value one may reduce health budgets, improve efficiency and improve overall care. Furthermore, under the auspices of opportunity cost one may be able to provide therapies that were considered to be beyond reach, as well as support innovation.

Innovation in health care has been studied extensively and summated in Rogers' elegant 'S-shaped' sigmoid curve, where there are early innovators, followed by exponential increase and ultimately laggards whom are the last individuals to accept an innovation.

Service transformation is a common ambition, whether within healthcare or the wider study of industry - a company is rewarded by its ability to seek a new avenue of practice fuelled by research with the objective of disrupting the landscape of incumbent practice. It is for this reason much research and energy has been focused on this very change – adopting 'the new.' However, innovations and their promotion are often insufficient for replacing established activities that are often still economically functioning. These antiquated practices should be progressively removed from practice yet often they persevere to prevent dynamic movements of a system forward. Therefore, the focus on innovation should be complemented by due attention to abandoning practice– 'the old.'

An understanding of the conceptual nuances of de-adopting a practice should be considered. Till date the literature has a number of terms to describe this process of removing 'the old' these include 'de-aoption', 'disinvestment', 'exnovation' 'deimplementation' and at least 39 others (52, 53), reflecting the nature of this topic. No regular definition exists at it is still being understood. It is important to devise a conceptual understanding of the different descriptions of such activities in order to accurately apply the correct terminology and attempt to orchestrate these nuanced differences into a conceptual framework.

Furthermore, it has been argued that the language used to describe these approaches has a certain impact. ‘Disinvestment’ and ‘decommissioning’ are received poorly by patient populations in contrast to ‘de-adoption’ which although is received better does not encompass the full meaning of actions associated with it. As a result another ambition of this project was to model the behaviour of de-adoption, try to arrive at an understanding of how it may be effected more succinctly.

Synopsis of Findings

The first requirement was to study the process of de-adoption; in order to understand previous international with disinvestment. Therefore, a scoping narrative review was presented to demonstrate the performance of higher income nations in dealing with low value procedures.

To date most programs have been led at the national level supported by ‘carrot and stick’ financial incentives with little measurable success. However, the depth and recency of these programs has been limited with significant political opposition and inertia from clinicians and patients, one of the largest obstacles to change. The notable discrepancy in approaches to address the problem demonstrates that there is no simple solution. The Italian case study from Gemelli University perfectly illustrates the problem. At a micro level individual clinicians were able to recognise an inadequacy to their current treatment processes in mesh repair of hernia (a routine surgical procedure. Following identification, the team aimed to educate colleagues and subsequently implement change by demonstrating non-inferiority of incumbent mesh use (often associated with higher cost). Yet requests for change were met with resistance due to a general resistance to local policy adjustment and structural inertia that limited impact. These issues are of course increased exponentially when considering low value interventions at a national scale, and then further multiplied when considering these procedures at an international scale, particularly when different motivations and financial re-imbursement systems underpin the health budget.

Tools of controlling de-adoption are also used with different degrees of efficacy. HTA is a good example : England practices proactive HTA but does not employ it to de-adopt incumbent practices; Australia has embarked on an ambitious project to reassess all of the current re-imbursed treatments along the value ratio (Medicare Benefits Schedule Review) and the United States does not have a confluent HTA process in place at all; with inherent belief that the use of cost-effectiveness in appraisals for new technology and pharmaceuticals should not influence the decision to reimburse treatment. (84) Reviewing the different approaches to the same problem and also reviewing the different uses of different tools provides valuable insights when addressing low value interventions.

In order to rationalise international efforts to low value care a framework was formulated. There appeared to be three distinct stages that are required in the de-adoption cycle. Firstly *identification* and prioritization of low value interventions, followed by *implementation* of methods at *macro*, *meso* and *micro* levels in order to stimulate disinvestment.
Finally, *reassessment* of the use of low value interventions to objectively assess the success or failure of the implementation. It should be stressed that this model is to be continued, as healthcare is a dynamic field, where interventions are superseded by innovations regularly and similarly innovations are found to be flawed resulting in exnovation – it is an endless cycle.

Identification requires a detailed analysis of current literature and variation in practice, as has been performed within many health systems including those from USA, Canada and Australia. From which point prioritisation for disinvestment can be assessed. Priority setting is a key step in the de-adoption process as a common criticism of disvestment programmes are that they only cater for 'low hanging fruit'. *Implementation* is often context specific involving challenges with resource constraints, provider adherence and dissemination of guidelines. This requires education and financial components to achieve sustainable change and redefine practice norms. System level inertia from providers and policy makers present frequent barriers to change and obstacles for disinvestment, thus requiring continuous involvement of stakeholders. Although we have learned significant amounts from implementation science the challenge is scaling back treatment not up-scaling treatment (the topic of interest for most of implementation study.) It is critical for *evaluation* to comprise of health technology reassessment (HTR), program budgeting marginal analysis (PBMA) and audit. Health technology reassessment and stakeholder engagement are two cross-cutting dimensions within the framework. This requires careful consideration within all three stages of the model; identification, implementation and evaluation, to reform practice behaviour and enable successful disinvestment. (Figure 4)

This framework serves as a benchmark for future disinvestment campaigns to prioritize, identify, implement and evaluate their likelihood for success. Additionally, it aims to develop an informed mechanism on the process of successful change and a guideline to functional disinvestment. It may be considered a tool from which further activity can be guided as it lays the foundation for basic disinvestment opportunities that may be applied to health systems locally and internationally.

Having learned a method for disinvestment the next target was to identify candidates for de-adoption in England from a detailed literature review; and concurrently evaluate their burden on the health system. As medical technology and data analysis advances certain antiquated methods and procedures become obsolete, unsafe or cost-ineffective. Various approaches to identify these interventions have been tried. In the present study a systematic review of interventions in general surgery was performed in order to establish a transparent strategy to identify potential low value clinical services for review with reference to general surgery – the author's area of expertise. A combined method of identifying low value services was undertaken; this included a peer-reviewed literature search, a targeted database search and opportunistic sampling. With intention to identify general surgical procedures or interventions that are currently employed due to time honoured practice or previously published guidance; yet newer published research has identified these interventions to be ineffective with the previously identified outcome improvements found to be overestimated, or incorrect.

The search strategy identified 71 low value interventions detailed in Appendix 1. The list was further stratified according to impact in order to aid priority setting – there were 5 services in the high frequency and high cost brackets (highest impact); 22 services in the high cost low frequency group, 23 services in the low cost and high frequency group, with 21 in the low cost low frequency group (lowest impact.) See Table 8. The five with highest impact (with greatest clinical and economic burden) were: inguinal hernia repair in patients with minimal symptoms, delayed cholecystectomy, inappropriate gastroscopy, CT to diagnose appendicitis, and routine endoscopy in those who have had imaging-confirmed diverticulitis. Estimated potential opportunity savings to the NHS of stopping these procedures are £134 597 973 per annum. With five general surgical procedures carrying a burden of £135 million, the Audit

Commission's previous estimate of £500 million per annum for all healthcare is likely to be conservative. (195)

Priority setting has also attracted debate previously. It is important those interventions which have significant opportunity cost be considered. For instance, although a high-impact procedure such as early laparoscopic cholecystectomy may offer savings of £59 million per annum, a reduction in the use of mechanical bowel preparation, a low-impact procedure, will confer annual maximum savings of less than £100 000. It is therefore important that clinicians and providers focus debate on the potential reduction of high-impact services. The method of categorising low value interventions into order of priority according to the economic burden is a simple method that may offer opportunity to policy makers to concentrate on the 'highest' hanging fruit.

With candidate interventions for de-adoption these may then be presented to policy-makers to offer options along the previously described de-adoption framework. Yet without a true understanding of the behaviour of de-adoption recommendations cannot be made. Therefore, a granular review of a low value intervention (delayed cholecystectomy) which should be replaced by the (high value) early cholecystectomy was performed.

Relying on administrative data sets a retrospective observational study was performed from longitudinal administrative data to evaluate the primary the rate of adoption of index cholecystectomy in response to a progressively more persuasive evidence base. It was hypothesised that alongside the ubiquitous geographical cross-sectional variation there would also be longitudinal variation in the behaviour adopting high value early cholecystectomy and de-adopting low value delayed cholecystectomy for acute gallstone pathologies. With another objective of this chapter attempting to model the de-adoption of low value – to evaluate whether behaviour of abandoning a procedure mirrored adoption.

A further conceptual nuance here is that the abandonment of an intervention in this scenario may be defined as exnovation – which is perceived to occur at the end of innovation cycle

The initial findings from said chapter were that despite a more convincing evidence base, that has become prominent and incontestable circa. 2010 there was imperfect national adherence to adopt early cholecystectomy and that the antiquated procedure of delayed cholecystectomy is the dominant force; there has been a failure of innovation. (Figures 8 & 19)

Of greater concern was the presence of exnovator providers, those whom previously offered early cholecystectomy had now regressed to offer delayed intervention, essentially abandoning best practice and adhering to old fashioned treatment, thereby offering low value care to their patients. Despite the efforts of some innovative providers who have taken positive steps to change practice in order to ally themselves with current evidence (12.95% and 25.18% of providers for the AC and GSP respectively), exnovators that represent 25.18% and 8.63% of all providers for AC and GSP respectively will prevent wholesale change. The effect of exnovation on the use of high value procedures is more significant when considering the majority of providers displayed no net increase in index cholecystectomy use (61.87% and 66.19% of providers for AC and GSP respectively.)

An attempt to model the behaviour of exnovators and adopters was then performed. The line graphs of the innovators bears resemblance to Rogers' sigmoid S shaped curve of innovation, with a shallow initial phase followed by an exponential period. Neither graph demonstrates any evidence of flattening out of the curve. Of particular interest and novel finding is the behaviour of the exnovator providers, here the line graph may be described as having the opposite behaviour, initially shallow then a rapid decrease in response to the similar evidence base. (Figures 10 & 21). Although it is difficult to make firm conclusions from this single study one may tentatively hypothesise that the behaviour of de-adoption is the opposite to adoption. However further study in this field is required to make more confident conclusions.

When reviewing the cross-sectional behaviour of offering early cholecystectomy there was notable variation as demonstrated in the cartograms (Figures 11, 12, 22 and 23). This reflects the preference sensitive nature of decision making, that those providers whom do not believe in the most recent evidence and have relied on decades of experience to keep their patients safe were not willing to take on new treatment strategies that they do not trust. Furthermore, this may also reflect the supply sensitive nature of EC. that indeed structural inertia that is already present within established NHS providers cannot be easily altered.

Multivariate regression modelling was used to predict effect of biliary operations as proportion of surgical volume on adoption of EC, this had a negative coefficient in the case of AC. This is contrary to the hypothesis, that those centres where cholecystectomy is common would readily align themselves with best practice, in fact they are more likely to be exnovator providers. Similarly, medium and large providers also have negative coefficients, ß= -0.54, and ß =-0.58 respectively. Unlike previous work there was no relative increase in adoption performance of academic institutions that were equally spread throughout adopter categories. (247) A possible explanation for these findings is the in-built inertia set within these providers. Those centres with high rates of cholecystectomy are likely to have well versed mechanisms to offer this service, particularly in medium and large providers. There remains a supply sensitive element to the variation described.

EC resulted in reduced number of admission when reviewed within all provider categories. Adopter providers have reduced the mean number of admissions by 0.060 in AC, and 0.037 in GSP. This is in contrast to the exnovator providers whom had an increase in mean number of admissions of 0.281 in AC and 0.235 in GSP. Therefore, an exnovator provider will have to accommodate another 341 admissions for every 1000 patients whom are diagnosed with acute cholecystitis whilst waiting for a delayed operation when compared to the adopter providers. Similarly, an exnovator provider will have to accommodate an extra 272 admissions for every 1000 patients whom are admitted with GSP whilst waiting for a delayed operation in comparison to adopter providers. Naturally this will be associated with increased cost to the provider which may easily be avoided, and furthermore re-emphasises how delayed surgery is a low value intervention.

Clinical transformation remains a challenge, particularly in a surgical sphere. Surgeons have developed reputations as creatures of habit whom are resistance to change, unsurprising as each time they operate they are required to take on risks that cannot be measured in a data driven analysis. However, the process of 'unlearn(ing)' is something that does not come naturally and may be a topic of future study.

Addressing the Study Objectives and Novel Findings

This thesis proposed to stimulate discussion on low value care in the surgical sphere. It aimed to identify candidates for disinvestment and offer a method from which to help inform policy makers to reduce unwarranted variation with the primary objective of better care for patients and populations and secondary objectives of efficiency gains.

The current study has provided a novel, well-informed conceptual model along which policy makers may apply the actions of de-adoption. The target would be to use said framework not as an exhaustive fail-safe approach but as an aid when attempting to disinvest. It is the first such model that has been created after learning lessons from international experience in the field of de-adoption. Although there have been previous methods published for de-adopting low value care this conceptual model is innovative in that it attempts to gather any successful previous campaigns and combines them to offer a holistic model. It is the understanding of the authors that the holistic multi-tiered approach that incorporates stakeholder engagement at every step of the process that will provide superior efficacy in the de-adoption agenda. The true test is when such framework is incorporated into the de-adoption policy agenda. It should also be noted that the concepts presented are those that exist in an ideal setting, time pressures and practicalities of funding may mean that it is simply not possible to combine all tiers of the framework into a single de-adoption programme and this may be why a comprehensive plan has been difficult to implement till date.

The present thesis has also offered a number of candidates for de-adoption, from the detailed literature review performed in Chapter 4. 71 low value procedures in General surgery were identified – furthermore the burden from only five of these interventions was valued at £135 million per annum. Publication of these novel findings received significant attention from both the clinical community as well as wider political community, receiving headline attention in multiple news outlets.

Initial reaction from clinicians was not welcoming, criticism was levied against ‘economic reductionism’ in the leader article in the journal where the findings were published. (145) Although the paper was received antagonistically by some it was found to be thought provoking and stimulated significant debate in the surgical sphere. Despite this objection, the methodology was accepted and adhered to by teams within NHS England, such that it has stimulated policy action and has resulted in the author being involved in the Evidence Based Interventions programme that is currently underfoot.

Another conceptual idea that is truly novel and has not been explored previously in the field of health care is an attempt to model de-adoption. Much study and interest has been given to the diffusion of innovations and as such Rogers' initial model based on cattle rearing in America has been reproduced in several fields of business and industry, as well as healthcare. However, the mirror opposite, a study of de-adoption has not been modelled. This thesis is the first such academic activity which has attempted to identify and examine such behaviour – although difficult to make firm conclusions this study may offer options for further study in these field and provisional hypotheses. The importance of understanding de-adoption behaviour has been highlighted in this work, in order to achieve service transformation, the levers that one may impart to promote de-adoption of low value care and adoption of high value care is pertinent

The results and novel findings are presented in Table .

Limitations

There are a number of limitations to the present work. When attempting to assemble a well-informed conceptual framework for de-adoption a narrative review was performed. The methodology was not systematic; therefore, it cannot be assumed that key literature was not missed. The difficulty however is the nature of the topic for narrative review, the most valuable articles were policy documents and not in academic journals found through opportunistic sampling. Beyond this limitation in methodology is the flaw in publication bias that is present in all reviews, particularly when trying to evaluate success of previous de-adoption interventions. Failing interventions are not published by teams performing said interventions and journals alike. The real difficulty in this chapter when evaluating previous attempts at disinvestment is the infancy of current de-adoption agendas. It is too early to identify any gains both financial and in terms of health outcomes.

The identification of low value interventions which was performed through systematic review was also not without flaws. It is likely low value interventions were missed, given the methodology focussed on only high level evience (meta-analysis, RCT or systematic review) over a 5-year interval. It is likely that citations that may be relevant have fallen outside the search criteria. The use of administrative datasets is also challenging. In this chapter of study a problem was the absence of an understanding of indication for intervention. For example, when reviewing the use of flexible sigmoidoscopy after CT diagnosis of diverticular disease, or early ERCP in gallstone pancreatitis, although the volume of each procedure was recorded, the indication was not. Without knowledge of the indication it is not possible to identify the number of inappropriate procedures performed nationally. Although the number of flexible sigmoidoscopies performed is known, the number of procedures that followed uncomplicated diverticular disease is not. Similarly, the number of early ERCPs performed in gallstone pancreatitis in the absence of cholangitis is unclear. Therefore, assumptions have been made based on potentially outdated literature, or indeed by assuming that surgical orthodoxy will result in all patients with CT-confirmed diverticulitis having flexible sigmoidoscopy. Accurately estimating the volume activity of the high-cost, low-frequency procedures has proven difficult. This is often due to the experimental nature of these therapies (for example, robotic and single-incision surgery, protease inhibitor use in ERCP, tetrastarch for fluid resuscitation, and heated carbon dioxide during laparoscopy), as well as the fact that this group deals with disease of rarity. This part of the list often describes procedures that are not performed routinely because current surgical practice is aligned with published guidelines. Examples including avoiding treating varicosities in pregnancy, avoiding routinely offering a defunctioning stoma in operations for anal incontinence, and not offering risk-reducing surgery where there is limited life expectancy.

The use of Hospital Episode statistics when studying the behaviour of early and delayed cholecystectomy was also challenging due inherent errors of coding inconsistencies. Furthermore, incomplete coding of key fields (Admission age) limits the assessments that may be performed. However, HES data has been used to monitor selected outcomes nationally and quality of administrative data has improved over time. (259, 260) Unmeasured confounders and differences in patient disease severity cannot be accounted for with this data. We excluded those patients who were coded as having gallstone disease, cholelithiasis as the national guidance that is applicable relates to acute cholecystitis. It is likely however there is overlap between the true formal diagnosis and what is coded, therefore the complete cohort of patients may have not been captured due to our exclusion criteria. The absence of clinician related factors significantly effects the ability for firm conclusions to be made about the decisions to choose to perform early or late cholecystectomy. Furthermore, organisational determinants of exnovation whether strategic die to management decisions, implementation failure due to structural constraints, leadership turnover may all contribute to the exnovation behaviour of individual procedures. These distinct causes of exnovation may well be the reason why few statistically significant predictors of exnovation were identified in multivariate models.

Future Study and Policy Implications

It may be regarded as a successful achievement of this study that there has already been a change in national policy in response to the initial paper published from the thesis. Following publication of the first paper and subsequent national debate the author was invited to join a round table discussion on low value interventions that are presently in use in England. Subsequently a similar methodology was used to identify other candidates of low value for de-adoption. NHS England have subsequently established the 'Evidence Based Interventions' programme that has incorporated the concepts of low value interventions into day to day practice such that 'zero' tariffs have been appointed for a 17 interventions. This collaboration between Academy of Medical Royal Colleges, NHS Clinical Commissioners, the National Institute for Health and Care Excellence as well as NHS England and Improvement has recently instigated the zero tariffs for the low value interventions and we wait with enthusiasm to see whether the active attempts to limit financial renumeration has notable impact.

Therefore, certainly an interesting first point of study would be to evaluate the effects of this active lever on the use of low value interventions, particular those of a surgical nature that are high frequency and high cost, this may include carpal tunnel release and tonsillectomy. It would certainly be interesting to study the response from the surgical community particularly after initial publication of these concepts was not welcomed on social media. Beyond the simple evaluation of frequency of low value interventions would be the longitudinal measure of variation, defining which providers (both hospitals and individual medical practitioners) who were keen to adhere to new guidance and those whom were not. There would also be a opportunity to study active de-adoption and attempt to model said behaviour to see if there was truly a reflection of Rogers' curve.

In addition to this would be to assess if there were any unexpected consequences of the zero tarrifs, whether there is opportunity for clinical work to be focussed in a different area , whether there were more high value interventions that have been offered in the vacancies of reduced low value interventions. For example, if there is a reduction of carpal tunnel release operations will there be a concurrent increase in the number of joint replacements performed by the same operating team?

A notable absence from the thesis is a qualitative study involving patient opinions on the topic of low value care. It is prudent to involve the most important stakeholder in decisions about ‘rationing’ of care, therefore a patient involvement project that provides insights into the ideas, concerns and expectations of a patient when their care is being limited. Similarly a qualitative study that addresses the ideas of risk and loss aversion to the clinicians would be of significant value when attempting to organise further de-adoption frameworks and certainly provide more confidence of success.

Table 29 - Summary of Findings and Novel Ideas

Study Title	Objective of Study	Research Questions	Key Findings	'Added Value' Gap in the Literature	Further Research Opportunities
International Approaches to Low Value Care	To Gain an Understanding of the current health policy landscape in managing Low Value Care	How have various high-income nations addressed the problem of Low Value Care? Which Interventions have been Utilised? Have there been any Successful Interventions that may be learned?	De-adoption of Low Value Interventions has become an International priority in High Income Countries Wide Disparity in Methods to Address Inappropriate Care No Reliable Method of De-adoption	Demonstrates how different countries are using similar tools for different benefits, eg. Health Technology Assessment Case Studies of Failure at a Local Level vs. Grassroots Initiatives vs National Interventions Need to categorise de-adoption strategies into tiers	A more complete systematic review that assess behaviours of Low and Middle income countries whom are aiming to optimise value with limited budgets Furthermore an evaluation of the quantative impact of de-adoption measures
Functional Framework to Guide the De-adoption of Low Value Interventions	To Compose a Framework by which De-adoption of Low Value Interventions may be employed. This framework may serve as a benchmark for	Which Strategies may one employ in order to effectively De-adopt Procedures of Low Value ?	The Process of De-adoption is a dynamic cyclical event with constant reassessment. It passes through three stages: *identification* and prioritization of low value interventions through literature review and variation, followed by *implementation* of	Successful De-adoption requires a holistic approach with Stakeholder Engagement at every stage. Performing De-adoption at National (Macro), Regional (Meso) and Patient / Provider (Micro) Levels will maximise the chances of Success.	Attempt to implement the framework in order to see if it is successful

	future disinvestment campaigns to prioritize, identify, implement and evaluate their likelihood for success.		methods at macro, meso and micro levels in order to stimulate disinvestment. Finally, *reassessment* of the use of low value interventions to objectively assess the success or failure of the implementation.	Levers of De-adoption may be categorised into Active (with financial rewards or other regulatory tools) and Passive (Clinician and Patient Education) This framework serves as a benchmark for future disinvestment campaigns to prioritize, identify, implement and evaluate their likelihood for success.	
Identifying Low Value Care in General Surgery	To perform a systematic and transparent review that Identifies Potential Low Value Clinical Services for Review, with reference to General Surgery	Which General Surgical Interventions are Low Value? What is their Incidence and Monetary Burden?	71 Low Value Care Interventions were Identified in General Surgery. The list was further stratified according to impact in order to aid priority setting – there were 5 services in the high frequency and high cost brackets (highest impact); 22 services in the high cost low frequency group, 23 services in the low cost and high frequency group, with 21 in	Candidates for De-adoption in General Surgery An effective method to prioritise Interventions for focussed de-adopton; based on the frequency of use and the cost of the Intervention. A recognition that Clinical heterogeneity may often define value; with some individuals gaining from said procedure and others attaining no benefit. The key is offering	The findings have already been disseminated into current Policy practice (Evidence Based Interventions Program). A quantitative study to evaluate the impact of said program and the unintended side effects would also be beneficial

			the low cost low frequency group (lowest impact.) Of which the highest impact interventions (Both high cost and high frequency) carried a monetary burden of £135 million per annum	the correct procedure to the correct patient.	
Evaluating Trends in Use of Early [EC] (High Value) and Delayed [DC] (Low Value) Cholecysectomy for Acute Cholecystitis and Gallstone Pancreatitis	To perform a Granular Assessment of the Passive behaviour of Providers to an Established Evidenced Based Surgical Innovation which demonstrates Superiority over Incumbent Practices	Is there any Evidence of De-adoption of Delayed Cholecystectomy and Adoption of Early Cholecystectomy in England - Ie. Has there been a Change in Practice ? What are the Trends of De-adoption of DC ? Do Individual Provider Trusts	There was no evidence of change of practice despite a good evidence base. In fact, there were a number of provider trusts whom performed less high value EC over the study period (exnovators). There were 35 ‘exnovator’ providers, 86 ‘static’ providers and 18 ‘adopter’ providers in Acute cholecystitis. Therefore, there were twice as many providers abandoning the high value intervention as those adopting it over the study period.	Demonstrating the Number or EC and DC over time. Characterising individual hospital trusts as Adopters, Static or Exnovators. Creating a Model for the behaviour of De-adopter providers By identifying trusts by their Adopter Behaviour one can better understand and target the trusts that require support in order to optimise value of care. The identification of exnovation as a target for Health Policy Levers in order to aid rapid system transformation	Further characterisation of a de-adopter / exnovator provider needs to be performed : Do factors such as age, clinical experience, previous litigation affect decisions on adoption. Can this be managed ? How can policy directly address exnovator providers ? A deeper understanding of the process of ‘(un)learning and the behaviour of De-adoption’

		Display specific behavioural Characteristics? Are there any Characteristics that individual Providers Demonstrate which may result in their behaviour?	Exnovation of EC is occurring simultaneously as adoption of EC. Without addressing the exnovator providers adoption of innovation is impossible		

Concluding Remarks

The study of low value care in general surgery is unusual. It is a contentious and controversial topic amongst clinicians whom do not take criticism well, particularly when suggesting that their practice is imperfect and can be improved. Fear of litigation and unwarranted variation of complications will always influence the preference-sensitive supply.

The notion of value has become more prominent since during the period of study and better education of surgeons and trust providers may aid transformation. However, this thesis has demonstrated that there is a significant burden of low value care currently in use. Therefore, as surgeons we are not offering the best evidence-based care for our patients which should motivate practitioners to change.

Returning to the Hippocratic principle of non-maleficance, by offering low value interventions we are potentially offering harmful imperfect care, this is far from acceptable.

Appendix 1

Table 30 - Low Value Interventions in General Surgery

Literature Final Contribution - 22
Cochrane Database Final Contribution – 19
Nice Do not Do - 27
Choosing Wisely Contribution - 11
Opportunistic Contribution – 7
Sub-total - 86
Duplicates – 15
Total 71

Table 31 - Complete List of Low Value Interventions

Service and Indication	Citation	Issue Identified by Citaton	Level of Evidence	Cost	Population Applicable (Frequency per annum)	Reason for Low Value
High Cost High Volume						
Routine Endoscopic Assessment following CT diagnosed diverticulitis appeared unnecessary	(168, 169, 170, 171)	The risk of malignancy after a radiologically proven episode of acute uncomplicated diverticulitis is low. In the absence of other indications, routine colonoscopy may not be necessary. Patients with complicated diverticulitis still have a significant risk of colorectal cancer at subsequent colonic evaluation.	Level 1A	£222 (6)	Patients with Radiological Diagnosis of Uncomplicated Diverticulitis 33175 - CT Scan diagnosed Diverticular disease	Cost Ineffective
Delayed cholecystectomy is equal to or superior to interval cholecystectomy	(3) (4, 5, 8, 261, 262, 263)	Compared with delayed cholecystectomy, same-admission cholecystectomy reduced the rate of recurrent gallstone-related complications in patients with mild gallstone pancreatitis, with a very low risk of cholecystectomy-related complications	Level 1A/1B	£820 /case (166) £1114.18 /Readmission (8)	All Gallstone related admissions suitable for Cholecystectomy 72 572 Non-operative gallstone admissions 12 155 Readmissions (within 30 days)	Clinically Ineffective Cost Ineffective

Tension free repair for Minimally symptomatic inguinal hernia	(9, 10)	Primary outcomes similar at 2yrs for watchful-waiting and repair groups. Moreover, repair of asymptomatic inguinal hernia does not affect the rate of long-term chronic pain.	Level 1B	£1612 /case (6)	54 894 cases in 2014 (26) Given the Kaplan Meier estimates from O'Dwyer et al. of 32% being suitable for watchful waiting after 10 years: 17 566 low value procedures	Clinically Ineffective
CT abdomen not indicated as first line for diagnosis of Appendicitis; Imaging itself does not alter the end point of Appendicitis	(264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275)	When using imaging in the diagnosis of appendicitis, the percentage of negative appendectomies remains close to the percentage declared when CT is used for diagnosis. Although CT is accurate in the evaluation of suspected appendicitis in the pediatric population, ultrasound is the preferred initial consideration for imaging examination in children. If the results of the ultrasound exam are equivocal, it may be followed by CT. This approach is cost-effective, reduces potential radiation risks and has excellent accuracy, with reported sensitivity and	Level 1A	Adult £116, Paediatric £131 (276)	Young Patients with a Diagnosis of Appendicitis Adult – 32 387 Paediatric – 304	Risk of Harm > Benefit Clinically Ineffective

		specificity of 94 percent in experienced hands.				
Inappropriate indication for upper endoscopy	(172)	For inappropriate EGD, the very low likelihood of cancer argues against endoscopic referral	Level 1A	£286 (without biopsy), £297 (with biopsy) (6)	Without biopsy – 190 827 With biopsy – 361 251 According to cited reference 22% are inappropriate (overuse of diagnostics)	Cost Ineffective Overuse of Diagnostics
High Cost Low Volume						
Second-look endoscopy after endoscopic submucosal dissection for gastric neoplasms	(194)	There were no significant differences between second-look endoscopy and no second-look endoscopy with regard to large tumor size (>20 mm). This systematic review and meta-analysis showed that second-look endoscopy had no advantage for the prevention of post-Endoscopic Submucosal Dissection bleeding in patients without a high risk of bleeding.	Level 1A	£286 (6)	Post endoscopic submucosal dissection patients without risk factors of Secondary bleeding	Clinically Ineffective Cost Ineffective
Endoscopic retrograde cholangiopancrea-tiography in acute	(175, 176)	Seven RCTs were retrieved, but only two RCTs involving 177 treated patients and 163	Level 1A	£1649 (6)	All Gallstone Pancreatitis patients in the absence of Cholangitis	Clinically Ineffective

gallstone pancreatitis without cholangitis		control patients were included. A meta-analysis on morbidity was inconclusive (RR=0.95, 95% CI: 0.74-1.22). Meta-analysis on mortality only showed a trend in favor of conservative management (RR=1.92, 95% CI: 0.86-4.32) for both mild and severe pancreatitis. There is a trend towards more mortality from early ERCP with or without sphincterotomy in the setting of acute gallstone pancreatitis without cholangitis.			7095 candidates for early ERCP of which 48% had acute ERCP in 2002 (n=3405)(12) of which only a small proportion (circa. 4% citing Uy et al.'s rate of cholangitis) would be benefit for early ERCP. Potentially 3122 low value ERCPs being performed	
Should oesophageal stents be used before neo-adjuvant therapy to treat dysphagia in patients awaiting oesophagectomy?	(186)	Commonly associated with stent migration and chest discomfort, both of which may frequently result in the need for stent removal or replacement. There is additional evidence within the manuscripts reviewed to demonstrate that the use of oesophageal stents in the neoadjuvant setting can lead to significant complications in a small proportion of patients which can compromise opportunity for curative	Level 1A	£1270 (Mean HRG for Stent) (6)	All patients suffering dysphagia, undergoing neoadjuvant therapy that are being considered for surgical intervention	Risk of harm > benefit

		surgery. The use of stents in this situation cannot be recommended.				
Protease inhibitors for preventing complications associated with ERCP: an updated meta-analysis	(179)	At present, there is no solid evidence to support the use of protease inhibitors to prevent ERCP-associated complications. Although overall and ulinastatin subgroup analyses showed a small risk reduction for pancreatitis, it seems very possible that low-quality primary studies produced a veneer of efficacy.	Level 1A	£6868 (277)	All use of Protease Inhibitors in the prevention ERCP associated pancreatitis	Clinically Ineffective, Cost ineffective
Routine preoperative biliary drainage should not be carried out on Pancreatico-duodenectomy (PD) patients	(278)	This meta-analysis suggests that biliary drainage before PD increased postoperative infectious complication, wound infection, and DGE. PBD should not be routinely carried out in PD patients.	Level 1A	£1649 (6)	All PD patients who were considered for routine biliary drainage Potentially 1560 (No. of PD Cases); although not performed routinely	Risk of Harm > Benefit
Outcomes following Robotic Surgery are comparable to those following Laparoscopic Surgery, therefore can use be truly justified.	(180, 181, 182, 183)	To date, in the vast majority of clinical settings, there is little or no advantage in using robotic systems in general surgery in terms of clinical outcome. Due to the special economic environment in which robotic surgery is	Level 1A Conference Consensus Opinion	Circa. £1105 /case (184, 185)	All General Surgical Robotic Operations	Cost Ineffective, Non – Superior Outcomes

		currently employed special care should be taken in the decision making process when deciding on the purchase, use and training of robotic systems in general surgery.				
SILS Cholecystectomy is not superior to 4 Port Cholecystectomy and Conventional Laparoscopic Appendicectomy	(279, 280, 281, 282, 283, 284, 285, 286)	The equal length of hospitalization, patient quality of life and pain perception and the longer operative times, high likelihood of incisional hernia and surgical site infection call into question the utilization of single port surgery, as it does not seem to confer an advantage over classical laparoscopic cholecystectomy. Single Port Laparoscopic Appendicectomy shows no benefit over Conventional Laparoscopic Appendicectomy, including even parameters such as postoperative pain and cosmetic results, and, therefore, there is no indication to use this approach over standard laparoscopic appendectomy. Single Port Laparoscopic Appendicectomy does take longer to perform. Further studies are needed to	Level 1A/1B	£271 (287)	All SILS cholecystectomy	Cost Ineffective, Non-superior Outcomes

		confirm that the procedure is more costly. – ie minimal cosmetic benefit, longer operating time and increased costs				
Resection of asymptomatic primary tumour in patients with unresectable stage IV Cancer is not warranted	(288)	Resection of the primary tumour in ***asymptomatic*** patients with unresectable stage IV colorectal cancer who are managed with chemo/radiotherapy is not associated with a consistent improvement in overall survival. In addition, resection does not significantly reduce the risk of complications from the primary tumour (i.e. obstruction, perforation or bleeding). Yet there is enough doubt with regard to the published literature to justify further clinical trials in this area. The results from an ongoing high quality randomised controlled trial will help to answer this question	Level 1A	£786.87 (6)	All candidates with extensive disease being considered for resection	Risk of Harm > Benefit Clinically Ineffective
People undergoing anal sphincter repair should not Routinely receive Temporary	**Faecal incontinence** (CG49) NICE 'Do Not Do' Lists	One study randomised 27 patients with faecal incontinence requiring sphincter repair to additional	NICE 'Do Not Do' Lists	£2506.75 (6)	All those patients undergoing aphincter repair	Risk of Harm > benefit,

Defunctioning Colostomy	(289)	defunctioning stoma (n=13) or no stoma (n=14). There was no significant difference between groups in any of the outcomes measured, for example, the Cleveland Clinic Incontinence Score, complications, and hospital stay at a mean follow-up period of 34 months. People undergoing anal sphincter repair should not routinely receive a temporary defunctioning stoma.	Level 1B			Clinically Ineffective, Cost Ineffective
Do not offer Radiotherapy following mastectomy to patients with early invasive breast cancer at low risk of local recurrence	**Early and locally advanced breast cancer** (CG80) NICE 'Do Not Do' Lists	The effects of radiotherapy on overall survival were of less benefit for women with negative lymph nodes than those with positive lymph nodes. NICE Guidance: do not offer radiotherapy following mastectomy to patients with early invasive breast cancer who are at low risk of local recurrence (for example, most patients who are lymph node-negative).	NICE 'Do Not Do' Lists	£378 (6)	All women with negative lymph nodes in invasive breast cancer	Clinically Inefective, Cost ineffective

Do not give adjuvant tamoxifen after breast conserving treatment for DCIS unless high risk of invasive disease	**Early and locally advanced breast cancer** (CG80) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£415.10 (per annum) (290)	All patients who have been surgically treated for DCIS	Clinically Ineffective
Don't do GI Endoscopy for Malignancy of unknown Origin unless indicated	**Metastatic malignant disease of unknown primary origin** (CG104) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£369 (Colonos copy) (6)	All MUO patients	Cost Ineffective
Don't Do Risk Reducing Surgery for those with limited life Expectancy	**Familial breast cancer: NICE guidance** (CG164) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£2813.66 / Mastecto my (Ipsilater al) (6)	All patients with limited life expectancy	Clinically Ineffective
Don't offer EVLA in pregnant patients	**Varicose veins in the legs** (CG168) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£1170.50 (6)	All pregnant patients with Varicose veins	Clinically Ineffective

Measurement of alfa-fetoprotein in alpha-fetoprotein- producing gastric cancers	(291)	Preoperative serum AFP levels showed no correlation with tumour size, depth of invasion, disease stage or survival. Postoperative serum AFP level can help predict recurrence but a normal level does not mean absence of recurrence	Level 1A	**Unable to Determine	All gastric tumours for follow up	Lack of Evidence, Clinically Ineffective
Sentinel lymph node biopsy (SLNB) in patients with a preoperative diagnosis of ductal carcinoma in situ (DCIS).	NICE Guideline 80: Early and locally advanced breast cancer: diagnosis and treatment, 2009 NICE Do not Do	NICE recommendation: Do not perform sentinel lymph node biopsy (SLNB) routinely in patients with a preoperative diagnosis of ductal carcinoma in situ (DCIS) who are having breast conserving surgery, unless they are considered to be at a high risk of invasive disease	Level 1A	£1281.78 (6)	Patients with a preoperative diagnosis of ductal carcinoma in situ (DCIS) who are having breast conserving surgery, unless they are considered to be at a high risk of invasive disease	Lack of Evidence, Clinically Ineffective
Don't perform axillary lymph node dissection for clinical stages I and II breast cancer with clinically negative lymph nodes without attempting sentinel node biopsy.	(292, 293, 294, 295, 296)	Sentinel node biopsy is proven effective at staging the axilla for positive lymph nodes and is proven to have fewer short and long term side effects, and in particular is associated with a markedly lower risk of lymphedema (permanent arm swelling). When the sentinel lymph node(s) are negative for cancer, no axillary dissection	Level 1A	£800.58 + Costs to patient (6)	Ie. Axillary lymph node dissection in the absence of sentinel lymph node biopsy is a low value procedure	Clinically Ineffective

		should be performed. When one or two sentinel nodes are involved with cancer that is not extensive in the node, the patient received breast conserving surgery and is planning to receive whole breast radiation and stage appropriate systemic therapy, axillary node dissection should not be performed.				
Avoid the routine use of "whole-body" diagnostic computed tomography (CT) scanning in patients with minor or single system trauma.	(297, 298, 299, 300)	Aggressive use of "whole-body" CT scanning improves early diagnosis of injury and may even positively impact survival in polytrauma patients. However, the significance of radiation exposure with these studies must be considered, especially in patients with low energy mechanisms of injury and absent physical examination findings consistent with major trauma.	Level 1A	£132.00 (6)	All Single system trauma patients considered polytrauma 3514 (Ref Major Trauma in England, National Audit Office) [total trauma CT]	Overuse of diagnostics, Clinically ineffective

Avoid colorectal cancer screening tests on asymptomatic patients with a life expectancy of less than 10 years and no family or personal history of colorectal neoplasia.	(301, 302, 303) U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. preventive services task force recommendation statement. Ann Intern Med. 2008 Nov 4;149(9):627-37.	Screening for colorectal cancer has been shown to reduce the mortality associated with this common disease; colonoscopy provides the opportunity to detect and remove adenomatous polyps, the precursor lesion to many cancers, thereby reducing the incidence of the disease later in life. However, screening and surveillance modalities are inappropriate when the risks exceed the benefit. The risk of colonoscopy increases with increasing age and comorbidities. The risk/benefit ratio of colorectal cancer screening or surveillance for any patient should be individualized based on the results of previous screening examinations, family history, predicted risk of the intervention, life expectancy and patient preference.	Level 1A	£842.29 / Colonoscopy (6)	Low risk Colorectal Cancer patients with limited life expectancy	Overuse, Clinically Ineffective, Cost ineffective
Rubber band ligation versus excisional haemorrhoidectomy	(304)	Complete long-term remission of haemorrhoidal symptoms was better with surgical	Level 1A	£187 (In excess of delayed	All patients with Grade 3 or 4 haemorrhoids	Clinically Ineffective

for haemorrhoids for Grade 3 or 4	Shanmugam, V., L. Campbell Ken, et al. (2005) Rubber band ligation versus excisional haemorrhoidectomy for haemorrhoids. Cochrane Database of Systematic Reviews	excisional than rubber band ligation for grade III haemorrhoids.	Extra clinic appointments, wasted interventions, time	operation) (6)		
Do not do manual evacuation unless oral and rectal Treatment has failed	NICE Guideline 99: Constipation in children and young people: diagnosis and management of idiopathic childhood constipation in primary and secondary care, 2010 NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£451 (Cost of Minor Anal Procedure – Emergency) (6)	All Chronically Constipated patients	Clinically Ineffective
The use of Colorectal stenting seems to have no advantage over Surgery	(305)	The use of colonic stent in malignant colorectal obstruction seems to have no advantage over emergency surgery. The clinical success rate was statistically higher in emergency surgery group.	Level 1A	£1522.75 (for procedure of stenting but is not in	All patients suitable for Stenting prior to Resection of symptomatic colorectal tumour 143	Lack of Evidence

		However, use of colorectal stents seems to be as safe in the malignant colorectal obstruction as the emergency surgery with no statistically significant difference in the mortality and morbidity. Colorectal stents are associated with acceptable stent perforation, migration and obstruction rates. The advantages of colorectal stent includes shorter hospital stay and procedure time and less blood loss.		comparison to cost of operation) (6)		
Low Cost High Volume						
Mechanical Bowel preparation has few benefits for preventing Infection intraoperatively – I.e. is low value treatment	(189) (188, 190) **Surgical site infection** (CG74) NICE 'Do Not Do' Lists	Evidence from high-quality trials reports no or few benefits from MBP or rectal enema across surgical specialties. In the field of gynecologic surgery, high-quality evidence supports the view that MBP may be safely abandoned.	Level 1A	£9.07 (290)	All Elective Colorectal patients 10058	Clinically Ineffective,
Single dose Antibiotics controlled post-operative wound	(306)	Based on the results of this systematic review the administration of antibiotic prophylaxis for elective	Level 1A	£2.62 (290)	All Hernia repair Surgery 54894	Clinically ineffective

infection – in Hernia repair (Clean Surgery)		inguinal hernia repair cannot be universally recommended. Neither can the administration be recommended against when high rates of wound infection are observed.				
Routine versus no drain placement after elective laparoscopic cholecystectomy	(307)	The possible clinical benefit of routine use of abdominal drainage in uncomplicated laparoscopic cholecystectomies requires larger study populations. The approach is however not encouraged on the basis of the present analysis, as it results in increased postoperative pain and overall morbidity.	Level 1A	£6.90 (308)	All Routine Cholecystectomy 24482	Clinically Ineffective
NGT use in Abdominal Operations	(309)	Routine nasogastric decompression does not accomplish any of its intended goals and so should be abandoned in favour of selective use of the nasogastric tube.	Level 1A	£1.90 (308)	Potentially all Abdominal Operations - 737756 Emergency General Surgical Operations	Clinically Ineffective
Prophylactic Anastamotic Drainage in Colorectal Operations	(310)	There is insufficient evidence to show routine drainage of anastomosis prevents complications	Level 1A	**Unable to determine	10058 - Not in routine Use	Clinically Ineffective

No benefit of Plastic Adhesive Drapes to prevent SSIs	(311)	There was no evidence from the seven trials that plastic adhesive drapes reduce surgical site infection rates, and some evidence that they increase infection rates	Level 1A	£0.16 (per drape) (312)	Potentially all Operations 1950000	Clinically Ineffective, Lack of Evidence
No benefits of wearing surgical facemasks during clean surgery	(191)	From the limited results it is unclear whether the wearing of surgical face masks by members of the surgical team has any impact on surgical wound infection rates for patients undergoing clean surgery.	Level 1A	£0.77 (per facemask) (308)	Potentially all Operations 1950000	Clinically Ineffective, Lack of Evidence
Do not use Routine Skin Disinfection or topical Cefotaxime in Abdominal Surgery to Reduce SSI	**Surgical site infection** (CG74) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£0.49 (290)	Potentially all Operations 1950000	Clinically Ineffective, Lack of Evidence

Do not use Intracavity Lavage to Reduce the Risk of SSI	(313, 314, 315, 316, 317, 318) **Surgical site infection** (CG74) NICE 'Do Not Do' Lists	There is no evidence that intracavity lavage with antibiotics, other than a single small study of tetracycline lavage after contaminated surgery, reduces the incidence of SSI.	Level 1B NICE 'Do Not Do' Lists	<£9.08 per dressing (290)	Potentially all Operations 1950000	Clinically Ineffective, Lack of Evidence
Do not use topical antimicrobials for wounds healing by primary intention	**Surgical site infection** (CG74) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£0.97 / dose (290)	Potentially all Operations 1950000	Clinically Ineffective, Lack of Evidence
Do not use expensive dressings if gauze is sufficient.	(319, 320, 321)	A non-adhesive gauze dressing (coated in ointment or paraffin) is sufficient for many wounds, including post-operative incisions, lacerations, skin tears or bite wounds.	Level 1A NICE 'Do Not Do' Lists	<£9.08 per dressing (290)	Potentially all Operations 1950000	Clinically Ineffective, Lack of Evidence

	Surgical site infection (CG74) NICE 'Do Not Do' Lists	Additional absorbent dressings may be used if the wound is draining fluid. A hydrocolloid dressing (to keep the wound moist) or foil is best for wounds resulting from skin transplants.				
Don't irrigate wounds to prevent SSI	**Surgical site infection** (CG74) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£0.97 (500ml sterile saline) (290)	Potentially all Operations 1950000	Clinically Ineffective, Lack of Evidence
Do not use diathermy for surgical incision to reduce the risk of surgical site infection	**Surgical site infection** (CG74) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	nil	Potentially all Operations 1950000	Clinically Ineffective, Lack of Evidence
Don't do AXR for assessment of Constipation (Paediatrics)	NICE Guideline 99: Constipation in children and young people: diagnosis and management of idiopathic childhood constipation in primary	The evidence shows that the plain abdominal radiography has little or no value to either confirm or refute a diagnosis of idiopathic constipation. One systematic review [EL=III] of six studies found conflicting	Level 1A	£25 (6)	All Constipated paediatric patients	Clinically Ineffective Risk of Radiation Harm in young patients

Don't do GI Endoscopy for constipation (Paediatrics)	and secondary care, 2010 NICE 'Do Not Do' Lists Lit Review	evidence for the association between a clinical diagnosis of constipation and a radiographic diagnosis of constipation. One case control study [EL=III] found that the Leech scoring method showed poor diagnostic accuracy and reproducibility. NICE Recommendation: Do not use a plain abdominal radiograph to make a diagnosis of idiopathic constipation in children and young people				
Don't give prophylactic Antibiotics for people with mild Acute Alcohol Related Pancreatitis unless otherwise indicated	**Alcohol-use disorders: physical complications** (CG100) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£39.30 (five day course of Co-Amoxiclav) (290)	All patients with Mild Alcoholic Pancreatitis	Clinically Ineffective
Don't give PPIs before endoscopy for patients with suspected Upper GI Bleeds	**Acute Upper GI bleeding** (CG141) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£6.01 (290)	All Patients	Clinically Ineffective

Don't give Antibiotics for Positive wound cultures without evidence of infection clinically	**<u>Pressure ulcers: NICE guideline</u>** (CG179) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£39.30 (Five day course of Co-Amoxiclav) (290)	All Patients with positive wound cultures and no clinical evidence of infection	Clinically Ineffective
Scalpel versus no-scalpel incision for vasectomy	(322)	The no-scalpel approach to the vas resulted in less bleeding, hematoma, infection, and pain as well as a shorter operation time than the traditional incision technique	Level 1A	nil	All Vasectomy patients	Clinically Inferior to alternative
Avoid admission or preoperative chest X-rays for ambulatory patients with unremarkable history and physical exam	(323, 324, 325, 326, 327) Amorosa JK, Bramwit MP, Mohammed TL, Reddy GP, Brown K, Dyer DS, et al. ACR appropriateness criteria® routine chest radiographs in ICU patients [Internet]. 2011 [cited 2014 Feb 22]. Available from: http://www.guideline.g	Performing routine admission or preoperative chest X-rays is not recommended for ambulatory patients without specific reasons suggested by the history and/or physical examination findings. Only 2 percent of such images lead to a change in management. Obtaining a chest radiograph is reasonable if acute cardiopulmonary disease is suspected or there is a history of chronic stable	Level 1A £20	£25 (6)	All elective ambulatory Patients	Clinically Ineffective

	ov/content.aspx?id=35151. Mohammed TL, Kirsch J, Amorosa JK, Brown K, Chung JH, Dyer DS, et al. ACR appropriateness criteria® routine admission and preoperative chest radiography [Internet]. 2011 [cited 2014 Feb 22]. Available from: http://www.guideline.gov/content.aspx?id=35150.	cardiopulmonary diseases in patients older than age 70 who have not had chest radiography within six months.				
Do not clean a wound with (sterile) saline solution.	(Schein, Gecelter et al. 1990) Choosing Wisely - Netherlands	Acute wounds only need to be cleansed when the wound is open and contaminated with dirt. In that case, it can be cleansed by rinsing it with lukewarm (potable) tap water.	Consensus Opinion (CW Netherlands)	£0.97 (290)	All wound irrigation	Cost Ineffective
Do not bandage a primary closure wound	(328, 329, 330, 331)	Covering a surgically closed wound with dressings after an incision does not lead to fewer	Level 1A	<£3.20 / bandage	All wounds	Cost and Clinically Ineffective

	Richtlijn acute wonden NVvH [Guideline for acute wounds, Association of Surgeons in the Netherlands]: http://www.heelkunde.nl/uploads/o1/hI/o1hIRR2oR4QDojTm5pGj-GA/Richtlijn-Wondzorg-final.pdf.	wound infections. Changing bandages that adhere to the wound may also be painful. Cover the wound only if it is leaking fluids, if it needs protection from abrasive clothing, or if the patient does not want to see the wound. 'Surgical site infection: prevention and treatment of surgical site infection.' NICE Clinical Guideline 74 (www.nice.org.uk/nicemedia/pdf/CG74NICEGuideline.pdf) 2008:86-90.		(290)		
Narrow band imaging (NBI) versus conventional white light colonoscopy (WLC) for the detection of colorectal polyps	(332)	We could not find convincing evidence that NBI is significantly better than high definition WLC for the detection of patients with colorectal polyps, or colorectal adenomas. We found evidence that NBI might be better than standard definition WLC and equal to high definition WLC for detection the patients with	Level 1A	**Unable to determine	All patients undergoing Colonoscopy Common procedure 154583 (unclear use of NBI)	Clinically Ineffective

		colorectal polyps, or colorectal adenomas.				
Low Cost Low Volume						
Wrapping of Omentum around anastomosis is not warranted in Pancreatic Surgery	(333)	On the basis of the literature available at present, we cannot recommend the use of wrapping with omentum in pancreatic surgery. Prospective randomized studies applying a systematic wrapping technique are needed in order to establish whether its use should be generalized.	Level 1A	Nil – Cost of extra operatin g time	All Pancreatic Surgery Uncommon disease (1560 cases / annum)	Lack of Evidence
Defunctioning Loop Ileostomy (LI) > Loop Colostomy (LC) in effectiveness	(334)	The results of this meta-analysis show that a defunctioning LI may be superior to LC with respect to a lower prevalence of surgical complications.	Level 1A	**unable to determin e, difficult to assess cost of complica tions of loop colostom y vs ileostom y	All cases for stoma Not in Routine Use	Clinically Ineffective (Inferior)

To evaluate the effect of bursectomy on overall survival, recurrence-free survival and safety of patients with gastric cancer by performing a meta-analysis	(335)	Gastrectomy with bursectomy is not superior to non-bursectomy in terms of survival. Bursectomy is not recommended as a routine procedure for the surgical treatment of gastric cancer.	Level 1A	Nil – Cost of extra operatin g time	All Gastrectomy Patients Uncommon disease (1766 cases / annum)	Lack of Evidence in Support
"Intra-abdominal drainage after pancreatic resection: is it really necessary? A meta-analysis of short-term outcomes	(336)	The meta-analysis shows that the presence of an intra-abdominal drainage does not improve the post-operative outcome after pancreatic resection.	Level 1A	£6.90 (308)	All Pancreatectomy Patients Uncommon disease (1560 cases / annum)	Lack of Evidence
Abdominal drainage versus no drainage post gastrectomy for gastric cancer	(337)	We found no convincing evidence to support routine drain use after gastrectomy for gastric cancer.	Level 1A	£6.90 (308)	All Gastrectomy Patients Uncommon disease (1766 cases / annu	Lack of Evidence in Support
Routine drainage for orthotopic liver transplantation	(338)	There is currently no evidence to conclude whether routine abdominal drainage is useful or harmful in patients undergoing orthotopic liver transplantation. Evidence from non-randomised studies of high risk of bias showed conflicting results on the impact of routine drainage in	Level 1A	£6.90 (308)	Uncommon Disease (274 cases / annum)	Lack of Evidence in Support

		orthotopic liver transplantation on serious adverse events, showing that this question is an important clinical research question. Well-designed randomised clinical trials with adequate sample size to decrease systematic errors and to decrease random errors are necessary.				
Vascular Occlusions in Elective Liver Surgery	(339)	Intermittent vascular occlusion seems safe in liver resection. However, it does not seem to decrease morbidity. More randomised trials seem to be needed.	Level 1A	**Unable to determine	All Liver Surgery Experimental	Lack of Evidence in Support
Interventions for Anal Canal intra-epithelial neoplasia (AIN 1 & 2)	(340)	No true value of the use of imiquimod in the treatment of Anal Intraepithelial Neoplasia	Level 1A	£113 (290)	Not in Routine Use - against clinical orthodoxy	Clinically Ineffective
People undergoing anal sphincter repair Should not receive Constipating Agents in the Post op Period and should be allowed to eat and Drink ASAP	Faecal incontinence (CG49)		NICE ‘Do Not Do’ Lists	£2.97 (Cost of course of Codeine)	All Sphincter Repair Patients All Incontinence Operations 1453 (methods)	Harm > Benefit

	NICE 'Do Not Do' Lists			(290)		
Total fundoplication for gastroesophageal reflux disease (vs partial fundoplication)	(341)	Total fundoplication resulted in a significantly higher incidence of postoperative dysphagia (odds ratio [OR], 1.82-3.93; P < .001), bloating (OR, 1.07-2.56; P = .02), and flatulence (OR, 1.66-3.96; P < .001). The reoperation rate was significantly higher after Total compared with Partial Fundoplication (OR, 1.13-3.95; P = .02).	Level 1A Minimal difference in cost between two procedures	Nil (Differen t intra-operative time)	All Anti-Reflux surgery 7577	Lack of Evidence to prove superirority
Limited surgery may be of use in benign Pancreatic Lesions vs Complete Pancreatico-duodenectomy	(342)	There is a high level of evidence from prospective controlled trials regarding the significant maintenance of exocrine and endocrine pancreatic functions after limited resection compared to complete pancreato-duodenectomy.	Level 1A	**unable to determin e	Patients suitable for limited resection Uncommon Pathology	Clinically ineffective
There is no evidence for the use of Cryotherapy for the treatment of Liver Metastases	(343)	On the basis of one randomised clinical trial with high risk of bias, there is insufficient evidence to conclude if in patients with liver metastases from various	Level 1A	**Unable to determin e	All patients considered candidates for cryotherapy treatment Not in routine use	Clinically Ineffective

		primary sites cryotherapy brings any significant benefit in terms of survival or recurrence compared with conventional surgery. In addition, there is no evidence for the effectiveness of cryotherapy when compared with no intervention. At present, cryotherapy cannot be recommended outside randomised clinical trials.				
There is insufficient evidence to support the use of Electro-coagulation for liver metastases	(344)	On the basis of one randomised trial which did not describe its methodology in sufficient detail to assess risk of bias and quality, excluded 27% of patients after randomisation due to various reasons, and is probably not free from selective outcome reporting bias, there is insufficient evidence to conclude that in patients with colonic cancer liver metastases, electro-coagulation alone brings any significant benefit in terms of survival or recurrence compared with the control. In addition, there is insufficient evidence for the effectiveness	Level 1A	**Unable to determine	All candidate for electro-coagulation Not in Routine use	Clinically Ineffective

		of adding allopurinol or dimethyl sulphoxide to electro-coagulation. The probability for selective outcome reporting bias in the trial is high. More randomised trials are needed in order to sufficiently validate electro-coagulation with or without co-interventions.				
Fecal occult blood screening for colorectal cancer	Special Report: Fecal DNA Analysis for Colon Cancer Screening. (2206) from http://www.bcbs.com/ blueres ources/tec/vols/21/21_ 06.ht ml	Fecal DNA screening sensitivity for cancer was 52% while FOBT screening sensitivity for cancer was 13%. Specificities for both tests were similar	Level 1A	**Unable to determin e	Patients who are candidates for Screening Programme	Clinically Ineffective (Inferior)
Uncomplicated Diverticulosis should and can be managed in the community Ie Primary Care – IE Referral to secondary care for investigation is low / no value	(345)	Patients with suspected uncomplicated acute diverticulitis should be assessed according to their level of pain and associated systemic features of sepsis. In those where pain is controlled and there are no signs of systemic sepsis or multiple	Level 1A	£108 (6)	All Patients with uncomplicated diverticulosis should not be referred to secondary care	Cost ineffective

		comorbidities, the patient may be treated in primary care				
Miniport Laparoscopic Cholecystectomy has no advantage over traditional 4 port Laparoscopic Cholecystectomy	(346)	Miniport laparoscopic cholecystectomy cannot be recommended routinely outside well-designed randomised clinical trials.	Level 1A	£100.78 (347)	All procedures with miniport use for cholecystectomy Eperimental	Cost Ineffective , fails to demonstrate superiority
Heated CO2 with or without humidification has minimal benefit on patient outcomes	(348)	The study offers evidence that during laparoscopic abdominal surgery, heated gas insufflation, with or without humidification, has minimal benefit on patient outcomes.	Level 1A	**Unable to Determin e	All procedures for laparoscopy where humidified CO2 is considered Experimental	Cost Ineffective, fails to demonstrate superiority
Do not use Tetrastarch for fluid resuscitation	Intravenous fluid therapy in adults in hospital: NICE guideline (CG174) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£15.31 / 500ml (290)	All instances where tetrastarch fluid is used for resuscitation	Cost and clinically Ineffective
Anal fistula surgery in patients with inflammatory bowel disease, Flap advancement is inferior to fistula plugs	(349)	Compared surgical flap advancement, closure of the primary fistula opening in patients with inflammatory bowel disease using a biologic anal fistula plug had improved healing. Given its low	Level 1B	**Unable to determin e	Anal fistula surgery where flap advancement is considered prior to use of a fistula plug	Clinically ineffective

		morbidity and relative simplicity, the anal fistula plug should be considered for treating high trans-sphincteric anal fistulas in patients with inflammatory bowel disease.				
For patients with hypovolaemia, there is no evidence that albumin reduces mortality or in burns / low albumin states	(350)	For patients with hypovolaemia, there is no evidence that albumin reduces mortality when compared with cheaper alternatives such as saline. There is no evidence that albumin reduces mortality in critically ill patients with burns and hypoalbuminaemia. The possibility that there may be highly selected populations of critically ill patients in which albumin may be indicated remains open to question.	Level 1A	£56.52 / 1000ml	Use of albumin in patients with hypovolaemia	Cost Ineffective, Evidence fails to demonstrate superiority
Do not do MMG for patients who have had mastectomy (ipsilateral)	Early and locally advanced breast cancer (CG80) NICE 'Do Not Do' Lists		NICE 'Do Not Do' Lists	£25	Post Mastectomy patients for Surveillance	Clinically and Cost Ineffective

Appendix 2

Application Summary and Additional Technical Detail

DARS-NIC-72318-M4W8J-v0.11

NHS Digital

Data Access Request Service (DARS) Application

1: General

Request Number	DARS-NIC-72318-M4W8J-v0.11
Request Title:	Evaluating the Rate of Deadoption of Interval Cholecystectomy, a Low Value Intervention, and Diffusion of Index Cholecystectomy, a High Value Intervention
DSA Start Date	05/07/2017
DSA End Date	05/07/2018

1a. Summary

Reason for Referral to Approval Group: Independent Review – For Recommendation

Agreement Type Application: New

Summary of data changes

1b: Data Controller(s)

- **Imperial College London**

Data Controller Imperial College London

Tanaka Building
South Kensington Campus
London
SW7 2AZ
England

Organisation Type: Academic

Data Controller Type: Sole Data Controller

HSCIC Framework Contract Reference:

Contract Expiry Date:

Security Assurances for Data Controller

Type: IG Toolkit

Version: 14

Date Completed: 30/03/2017

Comments:

Code - EE133887 - Imperial College London - Big Data and Analytical Unit

IGT Score: 100% - Reviewed grade satisfactory

IGT Reviewed Date:

Date Checked by HSCIC:

DPA Registration

DPA Registration Number: Z5940050

DPA Organisation Name: Imperial College

Expiry Date: 24/10/2017

DPA Checked On :

Activity Recorded:

Personal information is also processed in order to undertake research. The personal data processed for this purpose may include identifiable, sensitive, patient confidential information such as names, contact details, financial information and family information. The sensitive types of information processed may include physical or mental health information, racial or ethnic origin and religious or other beliefs.

1c: Data Processor(s)

- **Imperial College London**

Data Processor Area: England/Wales

Organisation Address: Tanaka Building
South Kensington Campus
London
SW7 2AZ
England

Security Assurances for Data Processor

Type: IG Toolkit

Version: 14

Date Completed: 30/03/2017

Comments:

Code - EE133887 - Imperial college London-Big Data And Analytical Unit

IGT Score: 100% - Reviewed grade satisfactory

IGT Reviewed Date: 12/05/2017

Date Checked by HSCIC: 02/06/2017

DPA Registration

DPA Registration Number: Z5940050

DPA Organisation Name: Imperial College London

Expiry Date: 24/10/2017

DPA Checked On: 05/06/2017

Activity Recorded:

Personal information is also processed in order to undertake research. The personal data processed for this purpose may include identifiable, sensitive, patient confidential information such as names, contact details, financial information and family information. The sensitive types of information processed may include physical or mental health information, racial or ethnic origin and religious or other beliefs.

2. Locations

2a. Processing Location(s)

Imperial College London ICT Data Centre

Location Area: England & Wales

Organisation Address: South Kensington Campus

London
SW7 2AZ
United Kingdom

2b. Storage Location(s)

Imperial College London

Location Area: England & Wales

Organisation Address: South Kensington Campus
London
SW7 2AZ
United Kingdom

2c. Territory of use

England/Wales

3. Datasets Held/Requested

3a. Data Access Already Given

Dataset	Extract Type	Identifiability	Sensitivity	Periods	Legal Basis for Dissemination	Frequency

3b. Additional Data Access Requested

Dataset	Extract Type	Identifiability	Sensitivity	Periods	Legal Basis for Dissemination	Frequency
Hospital Episode Statistics Admitted Patient Care	Extract	Pseudo/Anonymised	Non Sensitive	2006-2007 2007-2008 2008-2009 2009-2010 2010-2011 2011-2012 2012-2013 2013-2014 2014-2015 2015-2016	Health and Social Care Act 2012 – s261(1)	One-off
Data Minimisation						
20% of the APC fields requested. Data should be restricted to patients which have a procedure (OPERTN_4_NN) code of J181, J182, J183, J184, J185, J186, J187, J188, J189. The data has been minimised by requesting only the relevant fields required for each data year. Imperial College have requested only the fields required for the relevant years. Geographical region is required so no further reduction is except that we only require trust level (PROCODE3) and we would ask to restrict to only trusts which have 10 or more operations per year for the relevant procedure code above.						

3c. Patient objections

Patient Objections applied? No

This request is considered to be compliant with the ICO's "Anonymisation: managing data protection risk" code of practice.

4. Fair processing

Fair processing requirements do not apply as no identifiable data is being requested.

5. Purpose/Methods/Outputs

5a. Objective for processing:

Background

Finding efficiency savings in health care provision is paramount given the pressure on national health care budgets worldwide. This provides motivation to identify and reduce the use of interventions that deliver little benefit. A greater emphasis on value is key and achieving high value for patients must become the goal of health care delivery. A clinical definition of low value interventions has been established as care in the absence of a clear medical basis for use or when the benefit of therapy does not outweigh risks; this encompasses terms such as medical overuse and over-diagnosis. The importance of identifying and studying low value healthcare services is motivated by the concept of 'opportunity cost', i.e. that disinvestments in low value procedures and services from the healthcare budget leads to the opportunity for further investments in higher value services. That is, a reduction in low value service results in improved value of care overall.

Objective for processing

This application is for data as part of a PhD and this study aims to investigate the relationship between two interventions for the same condition. One of these interventions, interval cholecystectomy, is a low value intervention, while the other, index cholecystectomy is considered a high value intervention.
These two interventions would be analysed to inspect the patterns of deadoption and adoption respectively. Cost analysis will be used to compare the two interventions and this will take into account the impact of adverse events, readmissions and excess mortality to ensure that costs and impact are both analysed. These analysis will then inform output (see output section) which will be used to help change current practices and improve patient care.

5b. Processing activities:

Data Controller

The Big Data and Analytical Unit (BDAU) is part of Imperial College London. It is a multidiscipline team which collaborates with a large network of researchers across the college to ensure the maximum use, impact and dissemination of healthcare research data. Data access is strictly controlled by the BDAU through a robust dataset registration process. No one other than BDAU staff can authorise access to the data. Access will be restricted to Imperial College London researchers only with a valid requirement which aligns with the data sharing agreement.

Data flow

On approval of this data sharing agreement, hospital episode statistics admitted patient care data for 2006 - 2016 will be transferred into the BDAU Secure Environment (SE) using the secure transfer method provided by NHS Digital. This data will be held in an allocated unique dataset directory with an unique ID assigned to it which is tracked through the BDAU asset registry. Researchers who require access to this data will need to sign a user registration to gain access to the system where the data is held and an additional dataset registration to gain access to this dataset. Requirements for access when completing the dataset registration process will be assessed against the data sharing agreement to ensure compliance. No access will be given to raw/original data to anyone other than those with valid requirements against the data sharing agreement.

Data reduction

This data will be restricted to a subset of data from the above dataset based on only the two interventions. The restriction is described in the restriction section of this application.

Legal basis

All data will be pseudonymised data and therefore is being held under Section 261(1) of the Health and Social Care Act 2012. No attempt will be made at any time to re-identify any individuals held in the dataset. There will be no further linkage attempts to any data held by the BDAU or any researchers who have access to the data. The BDAU tracks all datasets held in the BDAU and who has access to them at any given time, this allows us to cross-reference and evaluate any other datasets which researchers may have access to. The BDAU SE is a remote access platform and data is not allowed to be transferred out of this environment unless it's anonymous aggregated data. No data will be transferred outside the BDAU SE without validating against this data sharing agreement.

Analysis

The raw data provided by NHS Digital will be analysed solely in the BDAU SE. Any further analysis done outside the BDAU SE will be done using anonymous aggregated data (usually for visualisation purposes for output). Data will be analysed to investigate the two interventions and associated cost, utilisation and outcome patterns. This will involve statistical analysis using standard and innovative statistical programmes inside the BDAU SE. Cost data will be integrated into the raw dataset on an intervention level and will not re-identify individuals. Results will graphed and compared at an aggregate level. Analysis will be performed only by the researchers who have valid requirements as per the data sharing agreement.

Dissemination

Anonymous aggregate data will be used to create output (see output section) which will then be used to help change current practices and improve patient care.

5c. Specific Outputs Expected, Including Target Date:

Output data

All data which is used for output will be anonymous summary aggregate data. All outputs will contain only aggregate level data with small numbers suppressed in line with the HES analysis guide. No raw data will be transferred outside the BDAU SE unless an amendment is submitted to the data sharing agreement and described clearly in the data flow in the processing section. Raw data will not be used for commercial purposes.

Models

Q3/2018 - A model for efficient de-adoption will be developed as part of this study

Publications

It is intended that this study will lead to the following peer-reviewed publications which will be targeted for Health Affairs, the Lancet and the BMJ:

Q3/2018 - Modelling of deadoption of low value procedures
Q3/2018 - Adoption of high value procedures and geographical network analysis of diffusion of innovation
Q3/2018 - Cost implications of non-deadoption of low value procedures

Presentations

It is intended that this study will lead to presentations at the following conferences:

Q2/2018 - The Association of Surgeons of Great Britain and Ireland - surgical conference
Q2/2018 - Health + Care, Commissioning in Healthcare - conferences directed at healthcare commissioners
Q3/2018 - The Association of Upper Gastrointestinal Surgeons - surgical conference
Q3/2018 - Road to Rightcare, Overuse Conferences, World Congress on Health Economics - academic meetings

Academic output

This study will contribute to a PhD thesis which will be published online.

Target audience

The outputs of this study are aimed at those who will make use of the findings to decide the best course of care for patients. This includes surgeons who would performing these operations, clinical commissioners who decide on priorities for funding and healthcare leads who can influence guidelines. This study is part of the Centre for Health Policy at Imperial College London which helps advise on global health policy, the Patient Safety Translational Research Centre which is one of 3 centres in the UK which translates research into clinical practice and the Global Health and Development Group which were formally part of NICE International which helped advise for local and global standards for clinical practice.

5d. Expected Measurable Benefits to Health and/or Social Care Including Target Date:

Cost savings

Savings of £820 per patient with index cholecystectomy have been estimated (Gutt CN et al. 2013); thus with 72,572 (http://www.rcseng.ac.uk/healthcare-bodies/nscc/data-tools) non-operative admissions with gallstone disease in 2014, savings of £59,509,040 exist. Therefore, the opportunity cost of reallocating resources towards higher value services is great; and although this work will not guarantee such efficiency savings it will contribute to beginning a conversation with policy makers and clinicians to optimise treatment and begin change management. This conversation requires more evidence which will be a direct product of this work.

System impact

This project would not only provide knowledge of the cost of persistent interval cholecystectomy but also an understanding of how best to promote a change to index cholecystectomy. By providing a novel model of efficient de-adoption (which would be a specific output of this research) potential benefits may be extended to other low value procedures, both surgical (e.g. arthroscopy in osteoarthritis) and non-surgical (e.g. use of antibiotics when not indicated.) Our aim with this work is to explore the practice, purpose and experience of deadoption and to develop new tools and insights to help guide those trying to navigate this space. We would expect that the papers would be published by October 2018, thereby impacting clinical activity by October 2019.

5e. Is the Purpose of this Application in Anyway Commercial?

No

6. Special Conditions

7. Approval Considerations

Materials Reviewed	Version	Date of Document	Date of Approval	Expiry / Review Date	Comments
Protocol					SD1
Protocol		07/07/2017			
Protocol	5.7a	07/07/2017			Latest copy which aligns with Section 5 for submission on 07/07/2017

8. Period and Funding

8a. Data Retention

Indicative Data Retention Period: 31/10/2020

Reason for this Period: The PhD with which this data application is linked ends in October 2019. Thus we plan to retain the data for a year beyond the planned end date of the study to allow for revisions or amendments of papers.

(Proposed) Agreement end Date: 31/05/2017

8b. Funding Sources

Type of Funding Source: Public

Awarding Institution: Imperial College London

EU/International programme:	
Reference and title of project/activity:	
Year of submission/award:	07/10/2015
Applicant or Partner:	Applicant
Funding evidence URL:	

9. ONS Users

10. Sub-licencing

Does sub-licensing apply?	No

11. Charges

Set up and first year service charge	£5,200.00
Annual Service Charge	£1,000.00

In the event that an audit or investigation by NHS Digital reveals that any organisation named within this agreement as data controller or processor (section 1) either hasn't complied with, or is not complying with, any of its obligations under the Data Sharing Framework Contract or Data Sharing Agreement, the audit fees of £15,000.00 will be chargeable to each data controller (section 1) named in this agreement.

14. Applicant Details

Applicant Name	Dalton Coker
Name of Applicant Organisation	Imperial College London
Organisation Type	Academic
Applicant Email	dalton.coker@imperial.ac.uk

Annex A: Additional technical information

1. Data to be received by HSCIC under this agreement

2. HSCIC data covered by this agreement

A summary of the datasets covered by this agreement are shown in section 3 above.

2a. Data already held

2b. Additional data provided under this agreement

- <u>Hospital Episode Statistics Admitted Patient Care</u>

Periods

2006-2007
2007-2008
2008-2009
2009-2010
2010-2011
2011-2012
2012-2013
2013-2014
2014-2015
2015-2016

Sensitive fields

Identifiable fields

Other fields

[ADMIAGE] Age on admission,
[ADMIDATE] Date of admission,
[ADMIMETH] Method of admission,
[ADMINCAT] Administrative category,
[ADMISORC] Source of admission,
[BEDYEAR] Bed days within the year,
[CDSVERSION] CDS version number,
[CLASSPAT] Patient classification,
[CURRWARD] Current electoral ward,
[DIAG_NN] All Diagnosis codes,
[DISDATE] Date of discharge,
[DISDEST] Destination on discharge,
[DISMETH] Method of discharge,
[ELECDATE] Date of decision to admit,
[ELECDUR] Waiting time,
[ENCRYPTED_HESID] Encrypted HESID,
[EPIDUR] Episode duration,
[EPIKEY] Record identifier,
[EPITYPE] Episode type,
[FAE] Finished Admission Episode,
[FAE_EMERGENCY] Finished Admission Episode, emergency classification,
[FCE] Finished Consultant Episode,
[IMD04] IMD Index of Multiple Deprivation,
[IMD04RK] IMD Overall Rank,
[INTMANIG] Intended management,
[MAINSPEF] Main specialty,
[OPDATE_NN] Date of operation,
[OPERSTAT] Operation status code,
[OPERTN_4_01] Primary Operative procedure codes 4 character,
[OPERTN_4_NN] All secondary Operative procedure codes 4 character,
[PROCODE3] Provider code - 3 character,
[PROTYPE] Provider type,
[PURCODE] Commissioner code,
[PURSTHA] Commissioner's Strategic Health Authority,
[STHATRET] Strategic Health Authority area of treatment,
[SUSCOREHRG] SUS generated Core Spell HRG,
[SUSHRG] SUS generated HRG,
[SUSHRGVERS] SUS generated HRG version number,
[SUSSPELLID] SUS generated spell id,
[TRETSPEF] Treatment specialty,
[WAITDAYS] Duration of elective wait

Filters/minimisation efforts

20% of the APC fields requested.
Data should be restricted to patients which have a procedure (OPERTN_4_NN) code of J181, J182, J183, J184, J185, J186, J187, J188, J189.
The data has been minimised by requesting only the relevant fields required for each data year.
Imperial College have requested only the fields required for the relevant years.
Geographical region is required so no further reduction is except that we only require trust level (PROCODE3) and we would ask to restrict to only trusts which have 10 or more operations per year for the relevant procedure code above.

Data Transfer Method

3. Additional Information

Recommended product(s)

List Clean	No
Patient Status	No
Patient Tracking	No

Additional Technical Detail

LEEDS DATA PRODUCTION

HES APC Extract 2005 - 16.
No filters required.

Customer requires month-year of Date of death.

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