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An evaluation of the impact of a data driven, individualised, diabetes specific, structured information delivered by mail to people with diabetes.
The WICKED (Wolverhampton Interface Care-Knowledge Empowered Diabetes) Project.

A Thesis submitted to The University of Warwick for the degree of Doctor of Medicine

By

Dr Syed Muhammad Rizwan Gillani

[redacted]

Postgraduate Institute Warwick Medical School

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This work is dedicated to my family

who always believed in me and supported me.

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I would like to thank my family, specially my wife Erum, my daughters Shehreen and Aaminah, for their endless support and patience and my parents for their prayers.

Publications References

Some parts of my thesis have already been published in peer reviewed journals and I am listing those publications with complete references. I have included full publications at the end of my thesis.

1. Gillani SMR, AU Nayak, K Thiruvenkatasamy, V Baskar, BM Singh, A Viswanath. A method to validate the accuracy of a centralised district diabetes register. Practical Diabetes 2013;30:224–8.
2. Gillani SMR, Holland M, Sidhu M, Singh BM. A case control study of use of the Failed Access Score for determination of failed access to structured diabetes care: the WICKED project; Practical Diabetes 2014; 31(3): 107-110
3. Gillani SMR, Singh BM. A simple method for introducing care planning into specialist diabetes clinics. The WICKED Project; Practical Diabetes 2014; 31(8): 337-41.
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6. Gillani SMR, Nevill A, Singh BM. A randomised controlled trail in diabetes demonstrating the positive outcomes of a patient activation strategy systematically implemented across a whole health economy: The WICKED project. (Under review process)

Abstract Presentations

An evaluation of the impact of individualised, structured information delivered by mail to people with diabetes. The WICKED (Wolverhampton Interface Care-Knowledge Empowered Diabetes) Project; A7, APC DUK 2016

Gillani SMR, Singh BM. Findings of a patient survey to assess usefulness of structured diabetes care processes report delivery to the patients-The WICKED Project, P321 DUK APC 2015

Gillani SMR, Singh BM, A data integration methodology for targeting people with diabetes with key adverse outcomes. The WICKED project, P462, DUK APC 2014

Singh BM, Gillani SMR, The introduction of patient centric, patient driven, care planning consultations in specialist hospital clinics: The WICKED Project, P465, DUK APC 2014

Gillani SMR, Singh BM, Development of a care planning tool to facilitate structured, informed, patient empowered and led diabetes care. The WICKED Project, P464, DUK APC 2014

Gillani SR, Sidhu M, Singh BM, Audit of factors affecting access of patients to primary care diabetes services, Poster Number P540, DUK APC 2013

Award Nominations

The WICKED project has been nominated for following awards.

- Winner of “Blue Sky” award of outstanding research presentation, University of Warwick, May 2015.

- “Highly Commended-Best initiative supporting self-care” Quality in Care (QIC) Diabetes award 2015.

- Nominee for Patient Education and Self Care Award, annual professional conference DUK 2015.

- Nominee for Primary Care poster presentation award, annual professional conference DUK 2015.

- Nominee for Primary Care poster presentation award, annual professional conference DUK 2013.

Abstract

Background

Does promoting patient activation improve outcomes? We tested the hypothesis that provision of structured and personalised information can activate patients, promote self-care, and improve outcomes.

Methods

We recruited all eligible people with diabetes in Wolverhampton CCG (n= 14,559), randomizing them into two groups. The active group was mailed their "My diabetes, My information, My plan" report at baseline, 3 and 6 months; the control group received standard care for first 3 months, then a single mailing. We compared a Failed Process Score (FPS = completion of nine processes; zero = full attainment) and HbA1c. A patient feedback survey was sent to 1000 randomly selected patients from the active cohort to assess the qualitative impact of this individualised report.

Results

At three months, the FPS score (1.25 ± 1.87 vs. 1.35 ± 1.97, $P < 0.01$) and the change in FPS score (0.48 ± 1.55 vs. 0.42 ± 1.49, $P < 0.02$) were significantly better in the active group. At 12 months FPS score between group differences just failed overall significance ($F=3.459$, $p=0.06$). However, in those with lower baseline activation (FPS of ≥2), FPS was significantly better ($F=4.369$, $p=0.037$, 3 month ($p<0.01$), 12 month ($p=0.01$)) in the multi mailed and their likelihood of achieving the good attainment category (12 month FPS ≤1) with mailing was 1.15 (95% CI 1.02 – 1.29, $p=0.022$). Considering baseline HbA1c% categories as ≤7.5, 7.6-8.4 and ≥8.5, and adjusting for variables in univariate analysis ($r2=0.39$, $p<0.001$; age $p<0.001$, gender (ns), ethnicity (ns), IMD score (ns), type of diabetes (ns)), the impact of being mailed multiple times was significant ($F= 6.2$, $p=0.013$).In the patient feedback survey, patients found this report useful (89%), a source of knowledge (78%) and confidence (74%) and it helped them in understanding their diabetes (78%).

Conclusion

The provision of structured and individualized information to people with diabetes can positively influence the level of patient activation, promote better engagement and open the potential to improve other crucial diabetes outcomes.

Abbreviations

NICE	National Institute of Clinical Excellence
WHO	World Health Organisation
GPwSI	General Practitioner with Special Interest
DESG	Diabetes Education Study Group
NSF	National Service Framework
QOF	Quality Outcomes Framework
HMO	Health Maintenance Organisation
KP	Kaiser Permanente
DOH	Department of Health
BDA	British Diabetes Association
NSTS	NHS Strategic Tracing Service
DBS	Diabetes Batch Service
WDDR	Wolverhampton District Diabetes Register
CAS	Composite Access Score
FAS	Failed Access Score
FPS	Failed Process Score
PA	Patient Activation

Chapter 1: Introduction

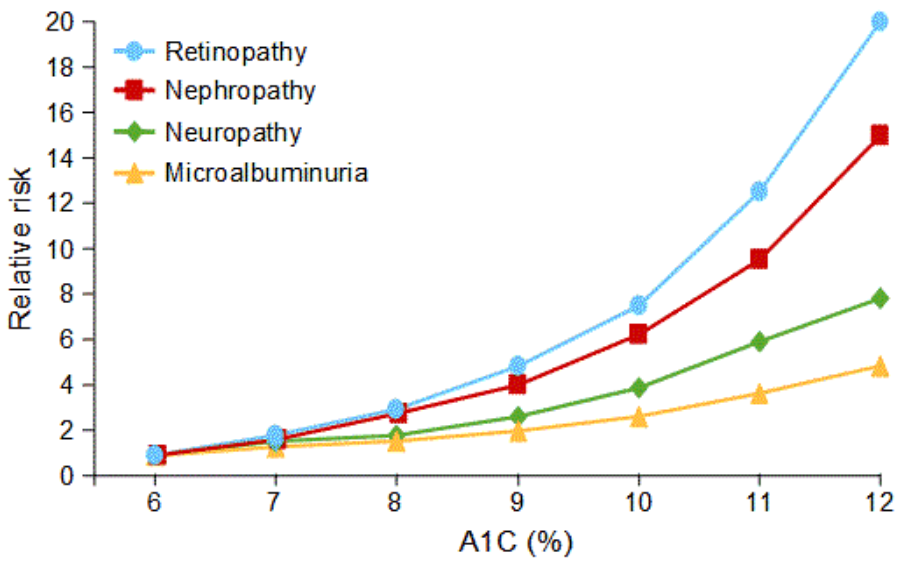
Diabetes

Diabetes is a common chronic disease that is described as a metabolic abnormality of carbohydrate, fat and protein metabolism resulting in high blood sugar levels due to total or relevant insulin deficiency (1). Insulin is a hormone that is produced by pancreatic beta cells in response to carbohydrate and protein in ingested food (2). Hyperglycaemia in turn causes long term micro and macro vascular complications affecting multiple organs in the body (3). Diabetes is widely divided into Type 1 and Type 2 diabetes. Other common types include gestational diabetes and terms like impaired fasting glycaemia and impaired glucose tolerance are used to describe early abnormalities in carbohydrate metabolism (1). Other rare form of diabetes include genetic defect in beta cell function, genetic defect in insulin action, disease of exocrine pancreas, endocrinopathies, drug or chemical induced, infections and idiopathic diabetes (4). Diagnosis is made on the basis of presenting symptoms and fasting blood tests, according to the World Health Organisation (WHO) criteria (5). There are different treatment options available based on type of diabetes, severity of disease at presentation, complications and other patient related factors that dictate the best suitable treatment option for the individual with diabetes. Over the last 15 years, diabetes treatment has progressed rapidly to provide multiple drug modalities to treat this disease. In the United Kingdom, the National Institute of Clinical Excellence (NICE) produces guidelines for treatment of diabetes and its complications through a continuous process of evaluation of the latest evidence around drug treatments and best practice across the world (6-8). It guides clinicians to perform at a set standard to facilitate the uniformity of care across the country.

Complications of Diabetes

Complications in diabetes are multifactorial, most importantly hyperglycaemia induced advanced glycation end products that trigger multiple enzymatic and non-enzymatic pathways resulting in tissue specific secondary responses (9). This results in micro and macro vascular end organ damage resulting in retinopathy, neuropathy, nephropathy, possible secondary cardiovascular disease and peripheral vascular disease (Fig 1.1) (10). This results in blindness, amputations, renal failure, myocardial infarction and cerebrovascular accidents leading to significant mortality and morbidity (11) as well as huge social and financial implications to the health economy (12). It is now well established that if we treat diabetes early and effectively, these complications can be delayed or avoided (13).

Fig. 1.1: HbA1C level and risk of micro vascular complications



Adapted from DCCT, Diabetes 1995; 44:968-43

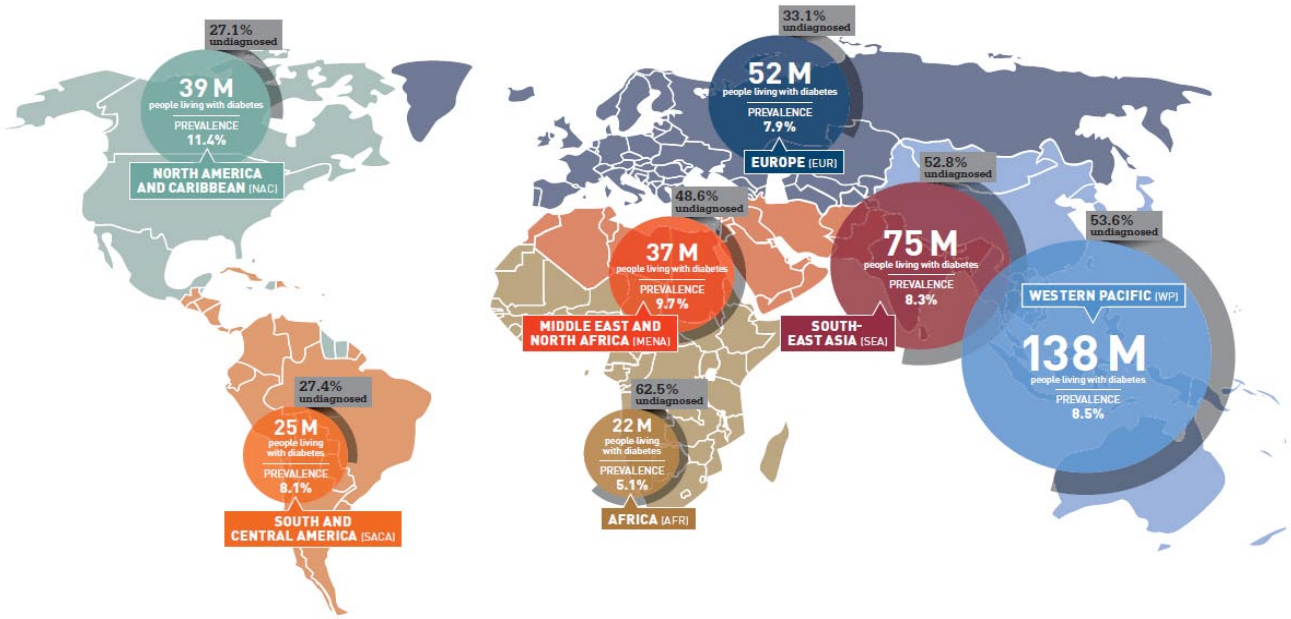
Treatment options for Diabetes

Treatment for diabetes was revolutionised through the discovery of Insulin in 1921 (14). Early oral hypoglycaemic agents like Sulphonylureas and Biguanides were the mainstay of oral treatment of diabetes until the last decade of 20th century. Since then there has been an explosion of new treatment options made available to people with diabetes, namely Glitazones, Gliptins, GLP-1 agonists and SGLT2 inhibitors, and many more are in the pipeline. A variety of treatment regimen have been trialled and tested and overall, diabetes treatment has been completely revolutionized in the last 20 years. In the United Kingdom, the National Institute of Clinical Excellence (NICE) produces evidence based best practice guidelines to ensure uniformity of diabetes care. However, despite standardised guidelines, the diabetes treatment optimisation remains suboptimal and patchy across the country. This may be due to the fact that diabetes, like any other chronic condition, requires an integrated care delivery needing individualised and tailored treatment to suit the needs of every individual patient, rather than adapting to a standard guideline. This integration needs to be patient facing, robust, governed and flexible to accommodate the variety of needs of people to enhance compliance and concordance with the treatment to optimise medical management of the disease.

Diabetes Epidemic

Diabetes is a silent epidemic that has slowly risen in prevalence from 2% in 1970 to 3.5% in 1990 (15). Since then there has been a steep rise in diabetes worldwide rising from 4% in 1995 (16) to 9% in 2014 among people aged over 18 years (Fig 1.2) (17). This is projected to affect 439 million adults worldwide by 2030. Between 2010 and 2030, there will be an estimated 69% increase in the numbers of adults with diabetes in developing countries and a 20% increase in developed countries (18). Diabetes has resulted in 1.5 million deaths worldwide in 2012 (19). It is estimated that diabetes will be the 7th leading cause of death worldwide by 2030 (20).

Fig. 1.2: Worldwide Diabetes Prevalence

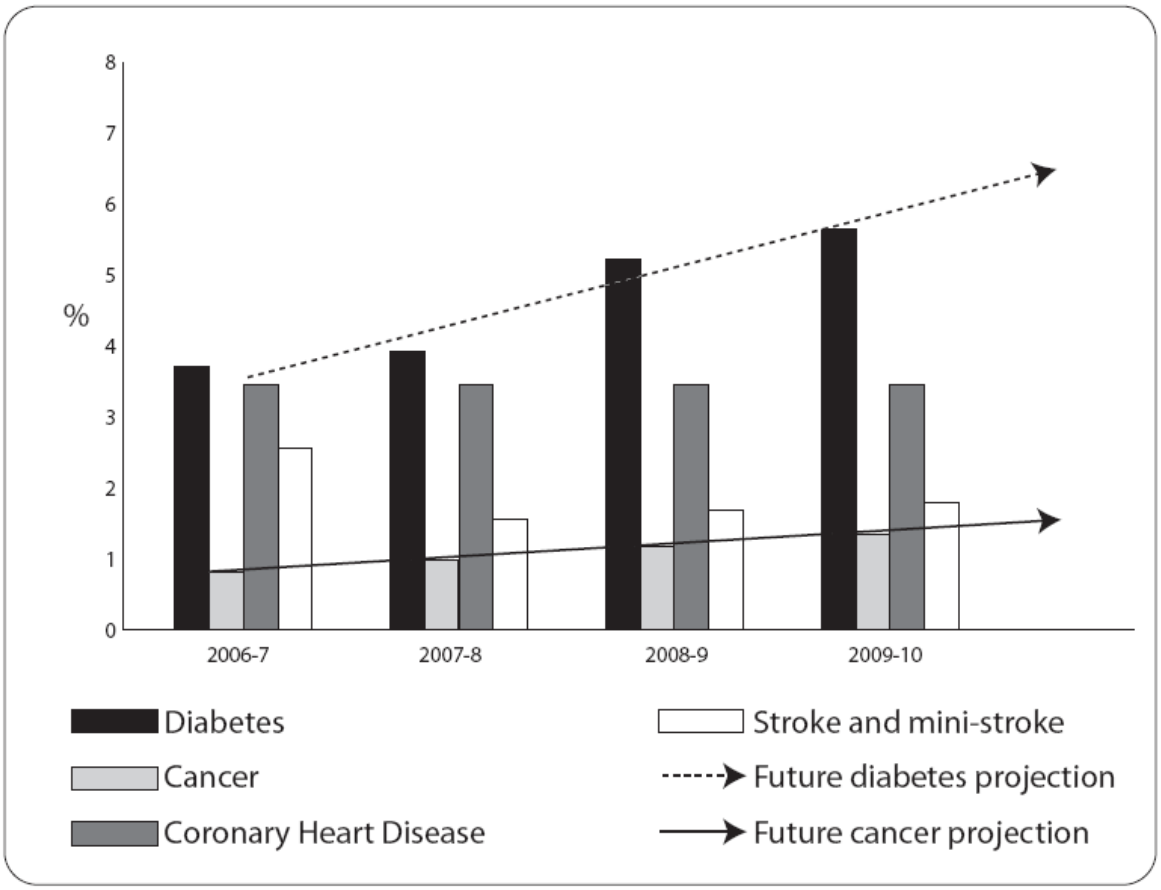


Used with permission IDF Diabetes Atlas Sixth Edition, 2014 update.

State of the Nation

In the UK, Diabetes prevalence has shown a steady rise from 2.8 in 1996 (21) to nearly 6% in 2014. An estimated 9.6 million people in England are at high risk of developing diabetes (22) and a predicted 4 million people in England will have Diabetes by 2025 (23). This disease causes around 20,000 early deaths/year, 100 amputations/week (24), a leading cause of preventable sight loss in working age group and is a major cause of renal failure, ischemic heart disease and strokes (Fig 1.3) (25). It costs the NHS £10 billion per year, which equates to 10% of the total NHS budget and about 80% of that is spent on complications (26), most of which can be prevented by timely and appropriate interventions. The total direct and indirect cost associated with diabetes in the UK is currently estimated at 23.7 billion and this figure is predicted to rise to 39.8 billion by 2035 (27). Many people with diabetes across UK are not receiving standard diabetes care, reflected by huge geographical variations among different Clinical Commissioning Group (CCG) areas (28). Despite National Service Framework (NSF) for diabetes and Quality Outcomes Framework (QOF) in primary care this variation is disappointing. There are multiple factors identified for these variations but despite all conventional frameworks to improve care we have not yet achieved desired outcomes in diabetes care delivery. This reflects on the gravity of situation and necessitates the exploration of new ways to resource effective delivery of diabetes care at the highest standard. The present project is around the development of a new model of diabetes care delivery that addresses the needs of people with diabetes in a resource constrained NHS. There is a huge gap in evidence base around diabetes care delivery in the UK, and my aim is to test parts of my model in a robust research framework to provide high quality evidence in this difficult arena.

Fig. 1.3: Prevalence of Diabetes compared with prevalence of Cancer, Coronary Heart Disease and Stroke by Year



Diabetes Care Delivery in 20th century in the United Kingdom

It is clear that a disease of this scale need to be dealt with by exercising great caution and a robust strategy is required to deliver care to people who suffer from this illness. It requires a framework of care delivery that is structured, efficient, governed, needs driven and able to cope with the rising demand of the disease burden. In order to understand modern diabetes care delivery in the UK, it is important to understand the evolution of diabetes care since the discovery of insulin.

Historically, with the advent of insulin in 1921 (14), diabetes became a specialist disease that requires specific skills. Initially, diabetes care delivery was restricted to specialist hospital clinics that were solely responsible for the diagnosis, management, patient education, record keeping, follow up and complication management. The first Diabetes centre in the UK was established in 1923 at King's college hospital and this progressed to a network of diabetes clinics across England and Wales by 1950. After coping with the disease burden for nearly 3 decades, the capacity of the hospital clinics was overloaded by the rising number and needs of people with diabetes. This correlated with a steady rise in diabetes prevalence and increasing awareness of the disease and its complications. It further resulted in overcrowded diabetes clinics with increasing patient's dissatisfaction.

In 1953, the capacity issue was addressed through a trial involving trained health visitors in diabetes care. Their role was to liaise with specialist clinics, general practitioners and public health departments in order to provide patient education and monitor the treatment in newly diagnosed people with diabetes (29). This was perhaps the start of community and domiciliary diabetes care. The role of these health visitors, considering them being first step in the evolution of diabetes specialist nurses, varied widely from monitoring people who are newly diagnosed with diabetes, during inter-current illnesses, pre-gangrenous foot infections as well as looking after hypoglycaemia and injection sites monitoring. Their scope was further extended to children with diabetes to liaise among their homes, school, family practitioners and specialist diabetes clinics. Although a very useful addition to the workforce, there was still a major gap in care delivery outside specialised hospital clinics.

Like any other chronic diseases, people with diabetes require on-going help on a routine basis. A steady rise in the prevalence of diabetes made it obvious that no specialised clinic in

the world can provide care to the number of people being diagnosed with this disease. Until this time diabetes care was relatively unstructured and different clinicians had different treatment targets and thresholds for the management of disease and its complications (30). Overall this resulted in increasing clinician's dissatisfaction as workload in clinics were becoming unmanageable and standards of care were more routine rather than expert reviews (31).

To overcome this growing problem, the role of general practitioners was deemed paramount. Malins wrote that "most physicians who run diabetic clinics would be glad to know of any satisfactory method by which patients could be returned to the care of their own doctors" (31). There were several factors that undermined the role of general practitioners in the management of uncomplicated diabetes. One reason was the availability of diabetes clinics in most areas where such clinics were by default considered responsible for the delivery of care to the local population. Another reason was that GPs trained before the advent of these diabetes clinics had learned little about management of this condition and were not very skilled or confident in taking over the responsibility. Last but not the least was the maintenance of competencies, because on a standard GP list, there will be only 8-10 people with diabetes that make it difficult for GPs to acquire and retain skills (32).

There were three possible ways in which the role of GPs could be explored to include them as effective partners in the care delivery of diabetes. One approach was to support GPs by providing them with a structure of care and encourage them to set aside one full clinic once or twice a month dedicated for diabetes reviews. The main emphasis was that the GPs will need a structure of care to follow with the help and support of their local diabetes clinics until the level when they achieved competencies to manage uncomplicated diabetes by themselves. This concept of structured diabetes clinics was rolled out in Wolverhampton in 1970 by Pat Thorne, and known as the Mini-clinics in General Practice (33). Every new patient regardless of their type of diabetes that was once seen by the specialist hospital clinic and deemed suitable to be looked after in primary care was discharged back to his or her GP with a management plan. This was followed up by structured input from specialists in the form of a management plan that navigated a treatment strategy to the GPs to define the most likely course of disease in next 6-12 months and how to manage it in the

community. If required, the person could be referred back to the hospital at any given point for further advice on management and to review the plan. GP practices choose to dedicate one clinician to develop an interest in looking after people with diabetes. They were supported by the hospital specialists in variety of ways including case based discussion sessions, informal and formal remote patient enquiries as well as by offering them to sit in diabetes clinics with specialist to acquire more knowledge and skills to manage complexities of diabetes. An annual visit to the surgeries by specialists was also arranged and was found to be very welcoming. All this was underpinned by the principles of co-working of clinicians and a uniform structure to deliver care to people with diabetes. As these clinics were running successfully, the need for motivation and enthusiasm of clinicians and structural organisation and governance in standardised care delivery of diabetes was considered to be of utmost importance (34). A 10 year audit of Mini-Clinics showed that there was no significant difference in diabetes control between people who were under specialist care, as compared with those who were looked after by their GPs in structured and well organised primary care clinics (35). This was a retrospective audit to assess service delivery that was not rolled out in a research framework, and there could be many confounding factors and bias, especially enthusiasm of the clinicians involved in Mini-clinics, that can make a huge difference in the outcomes of such initiatives. There can also be a selection bias, as despite matching the demographic details of the patient, the extent of disease and its complications managed in hospital clinic versus Mini clinics can make this judgment difficult. Despite this weakness, this was the first evidence available to compare the outcomes of people with diabetes under the community diabetes care against hospital clinics, and the results were very re-assuring. This idea of mini clinics was implemented at other sites in the UK and produced similar outcomes (36).

Another strategy was to explore the potential of active involvement of GPs in diabetes care delivery in shared care settings. A community diabetes service was set up by involving GPs to work in close collaboration with hospital clinics. An agreed education programme was launched to keep GPs up to date with advances in diabetes treatment. Hospital laboratory access was extended to GPs to facilitate 2 hours blood sugar monitoring tests in order to evaluate their patients in the community. An effective way of communicating between hospital and GP surgeries was established to seek support and ensure patient safety (37).

The outcomes of this whole process were assessed from patients', GPs' and the hospital's viewpoints. It was found that people liked to be looked after by their own GP due to more personalised care, less waiting time and continuity of care delivered to people who are essentially have no complex care needs. This has eased off the burden on the diabetes clinics, which can concentrate more on complex care needs of people who have uncontrolled or complicated diabetes. Although initially, GPs felt an increased workload in their day to day practice, many were keen to continue to provide care to their patient and found it challenging but rewarding (37). This is again a service development and shows mainly soft outcomes based on questionnaires to assess impact of this new service provision on the patients, their GPs and specialists. There was neither a control group, nor any before and after comparison on hard outcomes such as blood sugar control. However, one should not undermine the positive impact of perception of co-working in a patient centric way that emerged from this service development. Key outstanding questions from this shared care strategy were whether this strategy will continue to provide favourable results in the long term, how much care should be shared, and to what extent real sharing will take place. The economic evaluation of such strategy was required to assess the cost effectiveness of this approach.

Another strategy was to ask GPs to take responsibility for the care of their patients without any structure of support in place. This means that individual GPs have to assess their own needs for knowledge, skills and support to ensure adequate delivery of care to people with diabetes registered in their practice. People can be arbitrarily discharged from specialist care to their GP care without any close communication or any agreement with their GPs. This was subject to a 5 year follow up randomised control trial to compare primary care outcomes against specialised hospital clinics. Unsurprisingly, the results were found to be in favour of specialist care, and people under the so called "routine GP care" showed worsening glycaemic control and higher complication rates (38). This was a single centred trial with a relatively small sample size, and most of the confounding factors were related to lack of organisational governance, rather than the ability of the clinician to manage diabetes. For example, a major constraint was the lack of facilities and resources available to GPs to effectively deliver diabetes care in their practices. These included the non-availability of dietary advice, podiatry and access to lab services to monitor blood glucose. This trial

may have been designed to assess the specialism of generalists against the specialists of a disease and hence outcomes should not be surprising. The authors acknowledged that in other areas where mini-clinics or shared care proved to be successful there was significant organisation around these clinics in primary care. No similar trial was conducted either at the same place or within a different health economy to validate these findings and to address issues around possible bias of lack of facilities in this particular area against the clinician's ability to manage diabetes. This trial posed a great challenge to primary care physicians who were seeking to establish their role in long-term care delivery of diabetes.

Hence by comparing these three strategies over a period of about 2 decades it was clear that in order to cope with increasing workload of management of diabetes, primary care had to play an important role. Although motivation and enthusiasm of GPs played an important role in care delivery of diabetes it required a structural, organisational, educational and clinical governance frameworks to enhance the efficiency of the system and to achieve comparable outcomes of disease regardless of its place and mode of delivery (34). Several factors such as care being closer to home, more personalised care, holistic approach to deal with multi morbidity, continuity of care and its ability to influence lifestyle modifications made a strong case for the involvement of primary car in long term condition management, such as diabetes.

One of the important care processes in routine diabetes care that primary care was unable to deliver in the community was the detection of retinopathy. The role of ophthalmic opticians in screening for diabetes retinopathy, as well as diagnosing people with diabetes, was well recognised by the mid 1980s (39). The importance of retinal screening was further evaluated by Buxton et al, who compare different methods of screening by primary care, specialist clinics and ophthalmic opticians (40). It was obvious that this particular care process require a specialised retinal screening service regardless of place of care delivery. Therefore, in order to deliver structured diabetes care, the availability of specialised resources like retinal screening and perhaps podiatry and dietetic has to be shared between primary and specialist care. As the rest of routine diabetes service was deliverable in primary care, clinicians have shown both intent and commitment to acquire knowledge by engaging with educational programmes (41) and to take responsibility for their patients.

Nonetheless, delivering structured care in general practice led to a debate on how much specialisation is required in primary care, and where the boundary of care delivery should lie between primary and specialist care. On the question of specialisation, there were two schools of thoughts. One was in favour of one person in a practice acquiring knowledge and skills to deliver diabetes care. This latter concept evolved in the idea of GP with special interest (GPwSI). The benefits of this were higher skill level, continuity of care and facilitated primary and specialist care communication with one nominated person. Another school of thought was in favour of up skilling whole primary care, so that each individual GP should be able to provide standard diabetes care to whole population. The benefit of this approach is to expand your work force significantly, as well as holistic care delivery to all people at a set standard. The overlap of care between primary and specialist care services can be variable, and its existence in different shapes and forms like shared care, mini clinics and sole GP care has already been discussed. At the beginning of 1990, the new GP contract urged general practitioners to take more responsibility for looking after people with diabetes, and although the confidence to manage diabetes as well as other services like dietetic and podiatry were inadequate, there was significant interest and enthusiasm expressed by the GPs in taking diabetes care to primary care settings (42).

Diabetes care delivery in shared care or primary care settings in the 1990s was extensively reviewed, first by Greenhalgh (43) and then by Griffin (5). The most important findings demonstrated that effective, efficient and safe diabetes care to people with diabetes can be delivered regardless of the geography of primary and specialist services by extensive planning that assesses the best way to deliver care according to local needs and in consensus with primary and specialist services. This delivery is also enabled by written and agreed guidelines or care pathways, a systematic call recall system, involvement of motivated GPs with interest in diabetes, supported by enthusiastic specialist liaise on team, effective outreach team led by a specialist nurse to provide support to primary care, and by risk stratifying people with diabetes to transfer them to primary or specialist care in a rolling framework of audit and outcomes assessment.

Patient Education

Despite this evolution and the improvement in the medical management of diabetes in the last century the overall quality of diabetes care remain suboptimal. Like any other chronic disease, a large proportion of diabetes management has to be carried out by the person with the disease. Poor understanding of this concept of patient participation in their own care, for which they need to be educated to take control of several aspects of their disease, was one of the key reasons for the failure to improve diabetes care. Although there was a very early recognition of the importance of patient education by pioneers of diabetes like E.P Joslin who created a diabetes teaching clinic in Boston in 1929 and R.D Lawrence who founded the British Diabetes Association in 1934, the benefits of patient education took nearly 5 decades to get acknowledged and understood. To understand the importance of this highly important, yet very simple aspect of care, we need to look at the variety of issues related to the metabolic manifestations of diabetes. It swings from the extremes of glycaemia; severe hypoglycaemia to hyperglycaemic states like diabetic ketoacidosis; from mild numbness in the limbs to the total loss of sensation with the serious risks of foot ulcers; from mild visual symptoms to complete blindness; from minor circulation issues to gangrene and amputation and from likely reversible micro-albuminurea to end stage renal failure. Other key aspects that play a significant role in the metabolic control of this disease include patient's nutritional status, lifestyle habits, psychological constitution, familial, professional and social factors to name but a few.

This complex spectrum of acute and chronic complications of the disease requires the education and training of patients to cope with the daily individualised demands of the disease burden. If we review the history of patient education in clinical practice, one of the earliest contributions was by E.P Joslin in the form of a book called "A Diabetic Manual" published in 1919 (44). This book was written for clinicians to guide them on how to educate their patients to deal with diabetes. With the discovery of Insulin, and after early failures of treatment of some of his patients on insulin, Joslin stated that "*it is a waste of time and money unless the patient was thoroughly instructed to manage his own case*" (45). In order to implement this concept of patient education and training, in the 1920s he introduced the concept of a diabetes nurse educator and diabetes wandering nurse to deliver diabetes education programme in the hospital and community respectively (46).

In the meantime, in 1941, R.D Lawrence edited a manual entitled "The Diabetic Life: Its Control by Diet and Insulin. A Concise Practical Manual for Practitioners and Patients"(47). In its introduction, he wrote *"it is the object of this book to bring modern treatment of diabetes by diet and insulin within the scope of general practitioner and the understanding of patients whose intelligent co-operation is necessary for the best results".* This manual essentially laid down the foundations of patient education and training as an active participant in their own care to achieve success in medical treatment. However it is very surprising that despite this excellent initial work, this idea was not widely accepted among the healthcare professional's community of diabetes in the UK up until the 1970s. Increasing evidence in favour of patient education and its relation to better outcomes by the work of Miller (48), Davidson (49) and Moffitt (50) in the late 70s looking at reduction in acute hospital admissions, cost effectiveness, bed occupancy and improved outpatient outcomes attracted the attention of the world to understand and accept the importance of the diabetes teaching programmes in reducing metabolic variability and improving short and long term clinical outcomes. Thereafter, there was a wider acknowledgment of this highly important aspect of care, and the American Diabetes Association and the European Association rolled out two huge initiatives in the form of setting up of American Association of Diabetes Educators and the Diabetes Education Study Group (DESG) respectively in 1979. This group produced a Europe wide report to identify confounding factors in implementing patient education in daily clinical practice. Key factors were a) poor patient motivation, b) lack of specific training for patient education, c) organisational difficulties to integrate patient education in routine diabetes care, d) lack of data and methodologies to assess effectiveness of such programmes (51). The suggestions were implemented across the Europe during 80s by organising 100 workshops to raise awareness and provide training, attended by around 1000 doctors and 1000 nurses. A huge impact was created by a series of teaching letters on about 20 different topics of interest in 25 different languages (52). Since then, diabetes education started to become an integral part of the care delivery of diabetes. Various different methods including individual and group teaching, as well as innovative educational tools like computer based programmes (53),(54), were introduced in the last decade of 20th century. An increasing awareness of people and growing will to gain as much independence as possible motivated people to take up such programmes and maximise

their benefits. Increasing acceptance by healthcare professionals also played a key role in integrating patient education in routine diabetes care delivery. At the end of the last century most interventions to improve the diabetes care tried in primary care, outpatient and community settings showed that patient education, effective call and recall system, exchange of patient information among healthcare professionals and use of multidisciplinary team in the community can be beneficial to various patient related outcomes (55). Overall the landscape of the NHS diabetes care delivery changed when Primary care took on increasing responsibilities for the care of their patients and GPs were willing to improve their skills and expertise in chronic disease management in the community (56).

Diabetes Care Delivery in 21st Century

At the beginning of this century, it was generally understood that care for people with diabetes was challenging, and by examining the evolutionary process of care delivery, it seems clear that in order to meet the needs of people with diabetes, both primary and specialist care had to play a vital role and needed to work in collaboration with each other. It was also well recognised by that time that patient education and involvement in their own care had a pivotal role to achieve desired short and long term clinical outcomes. As diabetes care expanded from the hospital to primary care to the community there was a need to ensure that a standardised service be provided to all people regardless of their portal of care delivery. This led to the introduction of the National Service Framework (NSF) for Diabetes in 2001. This document delineated 12 set standards to deliver a high quality diabetes care to children, young people and adults across the bounds of the NHS (57). NSF set standards of care around prevention, early diagnosis, people empowerment and shared decision making to facilitate self-management, optimisation of clinical management, clinical care of children and young people with diabetes, management of diabetic emergencies, hospital admission and stay, pregnancy in diabetes and detection and management of long term complications. After the initial reluctance to accept NSF by the primary care (58), it was found to be of great value in achieving the required standards of care with the introduction of financially incentivised Quality and Outcomes Framework (QOF) for primary care, launched in 2004 with the new primary care contract (59). Practices were provided with an opportunity to receive financial rewards to deliver quality care at a very high standard. In the QOF that was initially launched for 12 chronic diseases including diabetes, most clinical quality indicators were derived directly from NSF for diabetes. Organisation standards such as keeping a register for all people with diabetes and maintaining their record and medicine management further enhanced the ability to evaluate the standard of care that was delivered by the primary care to their patients. Patient experience and additional services were also incorporated in QOF to facilitate good quality care delivery to people's satisfaction. After embedding QOF as an integral part of primary care delivery in the UK for few years it was evaluated and showed an improvement in quality of care in terms of process completion as well as clinical outcomes (60). This was a systematic review that found 5 suitable comparator studies against QOF. All these studies were cross sectional

surveys, and demonstrated that financial incentive scheme of QOF has shown improvement in documentation and recording of diabetes care processes and although an improvement in intermediate outcomes is seen, long term morbidity and mortality outcomes were yet to be established. The limitations of QOF in delivering care to less organised practices and deprived areas (61), as well as meeting needs of specific group of people for example people with Type 1 diabetes and people with very poor glycaemic control (62), were observed in a retrospective cohort study. All this evidence suggests that there is a need to pursue the agenda of structured diabetes care in a standardised framework of practice in the UK to minimize geographical and other relevant variations in delivery of care by setting up minimum standards to meet the desired care delivery to all people with diabetes.

Models of Diabetes Care delivery

It is evident that any model of diabetes care delivery in 21st century that caries the notion of "Integrated Care" may be based on the fundamental principles of care delivery derived by the remarkable work done in the latter half of the last century as discussed above. Modern concepts of integrated care delivery models can be traced back to the concepts of mini clinics, shared care and co-working of primary and specialist care clinicians, as well as fundamental principles of patient education, empowerment and shared decision making. For any model of care delivery to be rigorous and sustainable, it should incorporate 5 fundamental pillars of governance that include clinical, structural, organisational, financial and data governance. The development of a district wide diabetes service in North Tyneside between 1979 and 1991 provided a detailed understanding of the evolution of such a model of diabetes care delivery that uses the principles of structured approach, patient empowerment, integration of care, performance management and team work to build a district wide diabetes service (63). This concept of multifaceted approach was further developed in the chronic care model (64) and was the foundation for the new house of care model for people living with long term conditions such as diabetes (65). This model evolved over years into its practical form in the "Year of Care" project. In this pilot project, which took place at three distinct sites in the UK, the importance of information provision to the service users to inform care planning process was assessed and found to be of benefit (66).

In the 21st century, the importance of patient engagement has been explored under different notions of enablement, empowerment, self-care, partnership working and patient activation. It is increasingly acknowledged that without promoting people to self-care for their diabetes, it can be difficult to achieve outcomes. In an extensive multicentre cross national study to examine psychological problems and barriers to improved diabetes management, it was found that the psychological wellbeing of the patients plays an important part to promote self-care and without understanding people's attitudes, needs and wishes, the achievement of optimal glycaemic control may not be easy to achieve (67). This was a large scale, multi methodology and diverse study, but has the potential bias to include better educated people, due to the study design and type of interviews used in the study. There can potentially be cultural and resource bias in the study, due to the involvement of multiple countries of varied sociocultural dynamics.

Different models of care have been trialled in the last 15 years in the UK. All of these models have used one or the other fundamental principles of chronic disease care delivery. Some of the models use categorical classifications to decide whether people are suitable to be looked after by the primary or specialist care teams. The Super Six model of Portsmouth (68) is a representative example of this approach, and has shown some benefits in terms of cost savings and increased patient satisfaction after 2 years (69). The outcomes reported from this initiative need to be looked at with caution as there is no control group to assess the impact of this new approach, and outcomes are based on a before and after analysis of multiple endpoints that are used as a marker of improved service delivery and better disease related soft outcomes without looking at defined hard endpoint clinical outcomes. One possible downside of such an approach is that it can demarcate the bounds of primary and specialist care based on the defined category, rather than needs of individual patient and referral across the categories will be clinician rather than need dependent. It can easily overlook complex cases of type 2 diabetes that may require highly specialised care, in order to prevent or halt complications. Leicester primary care also has a similar approach, although they have added an additional category of "people with complex needs" ("Super Seven") to address this issue.

A tiered system of care has also been reported in several places across the country. One way of developing a tiered approach is to develop an intermediate service run by the GP with special interest and takes the initial referral from the primary care and then to escalate it to specialist care as required. There is little published evidence available of such an approach in the form of an RCT to assess the effectiveness of this approach and results have shown no benefit when compared against the standard practice of direct referral to specialist care (70). This study used a cluster-randomised design, and only included people with type 2 diabetes. This is appropriate as most type 1 diabetes is already under specialist care. It was found that there was a slight improvement in HbA1C and cholesterol control, but less so in blood pressure in people looked after by intermediate care, although it was statistically non-significant. However, the role of intermediate care in patient education and improving skills among primary care might be more relevant than achieving hard clinical outcomes. This trial provided a valuable insight into the difficulties faced to conduct a real life, innovative, pragmatic and cluster randomised trial due to less than expected recruitment in the trial

and high numbers of loss to follow up. Another example of a tiered approach by up skilling of group of practices rather than individual GPs was tested in Blackpool, and although it showed some benefits, this model was decommissioned by the local clinical commissioning group after a short while and hence has not produced any quantifiable published outcomes.

Out of hospital specialist care by collaborative work of primary and specialist care clinicians as a subcontractor of the NHS within the framework of an independent organisation (private company) has been implemented in Derby (71). It constitutes 50% participation of primary and specialist care, integrated IT system and single budget to deliver outcomes. It has shown significant outcomes in terms of better glycaemic control, reduction in weight and insulin dose and cost effectiveness. These outcomes are not compared against a control group and some of them are based on before and after intervention analysis. This model is also in a sustainability crisis at present as this could be seen as duplication of those services by a third party provider that has already been commissioned to be delivered by the standard NHS organisations.

Another model of integrated care based on multi-agency collaboration is the Northwest London Integrated Care Project (ICP), which looks after people over 75 years or people with diabetes. It has multiple interventions, including an outpatient triage service as well as a facilitated discharge service to provide rehabilitation in the community. Early projected outcomes in terms of hospital admissions, bed days, cost savings and user satisfaction still need to be backed up by the real outcome data (72).

Information Technology is required to play a key role in the integration of services and the effectiveness of this tool has been valued in First Diabetes model of Derby (71) as well as Bradford diabetes services. By having a shared database between primary and specialist care, a whole new world of virtual integration can be explored with the potential for cost savings as well as providing a risk driven service without actual patient movement achieved by virtual consultations and sharing of expertise among clinicians (73).

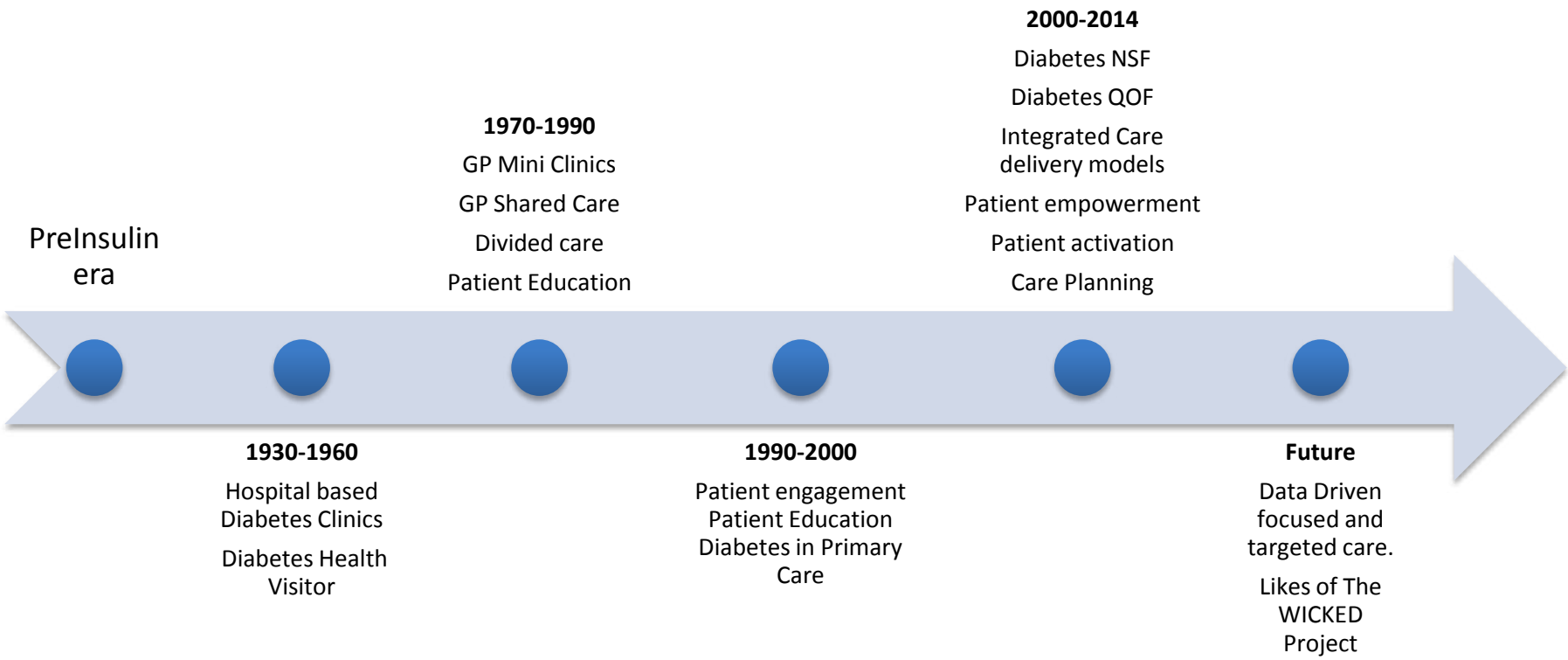
The co-working of primary and specialist clinicians in the community can easily be confused with the term community diabetes. This term is often used for the provision of care by a specialist outside the hospital at a different site, most often in a GP surgery. Community

diabetes remained a great area of interest in the last 15 years but in author's view, geography does not define the mode of care delivery to people. A specialist doing a clinic outside the hospital should not be taken as any different than doing a clinic in the hospital. Therefore, rather than dividing the care into community and hospital diabetes, care should be need driven and risk stratified regardless of its location, going back to the ethical principle of right care at right time by the right people (74). However, different co-working strategies have been tested, and one recent example is the Wakefield model of care. This is based on the principle of shared care, and is executed by specialists visiting the primary care physicians on a regular basis in order to address needs of people without necessarily referring them across the boundaries of the NHS (75). A similar integrated co-working model in community setting has been tested in Bolton and has shown a significant reduction in the number of hospital bed days per person (76) .This is a similar approach to that was used by P Thorn in his idea of mini clinics, where GP will be visited once a year by a specialist colleague to develop a mutual working relationship (33). Despite all these evolutionary changes spanning over a period of 7 decades, the fundamental question remains as to whether the NHS has developed a model of care delivery that has a firm evidence base in regards to its effectiveness, that fulfils the needs of people and is adaptable to the wider NHS to provide universal and standardised care.

Outside the UK diabetes care varies widely depending on the nature of the healthcare delivery system. Most of the world runs on insurance-based health services with priorities being dictated by a balance between ethical principles and financial incentives. It is a hard balance to maintain, but there are quite a few examples where health care delivery is guided by similar fundamental principles to those of the NHS. Two of these examples that are widely studied by the NHS are United States based Health Maintenance Organisations (HMO) called Kaiser Permanente (KP) and Medicare. KP, mainly based in California, serves both insurer and provider arms of the healthcare and hence has close resemblance to the modern NHS. It was found that both of these organisations has a better outcome data for their numbers of hospital admissions as well as length of stay in most chronic diseases including diabetes when compared against NHS (77) and although this report was criticised for not presenting the evidence to support that Kaiser's better bed utilisation is due to integration of care, active management, use of intermediate and self-care, and leadership

(78). It was also found in a randomised controlled trial within KP that one reason for reduced bed utilisation in diabetes was the introduction of a multidisciplinary integrated outpatient diabetes care management programme in the community that led to better integration across primary and specialist services (79). This trial excluded people over the age of 75 and those with well controlled diabetes, leading to potential selection bias. In this context, it is understandable that a significant improvement in glycaemic control was observed in this trial over a relatively short period of time. The question of whether the NHS can learn from KP was answered by suggesting that there is a huge potential in the NHS to implement a change of focus by promoting integration and ownership. This can be achieved by aligning the goals of clinical and managerial staffs, implementing risk stratification, case finding and management, encouraging accountability by peer review in order to manage standard of care, and more financial incentives to deliver high quality care by perhaps agreeing on standards at more local level rather than generalised implementation of agenda of care across the NHS (80). A summary of the evolution of diabetes care delivery in the UK is shown in Fig 1.4.

Fig. 1.4: The Evolution of Diabetes Care Delivery in UK-Past, Present and Future



Integration of Care

At present there is a huge drive in the NHS to move towards the notion of integrated care. This notion has several perspectives, and can be understood as an approach to improve the quality of care to the service users by collaboration of services to achieve a common goal of meeting clients and their carers' unmet and complex needs. The ageing population, increase in prevalence of chronic diseases and new and modern management options have made it increasingly difficult to provide high quality healthcare in a resource constrained NHS. In order to meet this challenge, the NHS has to change and adapt an innovative, efficient and effective approach to tackle issues like inefficiency, waste and poor productivity. The way forward is to provide integrated care according to the needs of people across system divides. Integration of care can be horizontal where all the services operating at one level and sometimes under one organisation work in collaboration, or vertical where services across different organisations or operating at different levels work together to provide all elements of care in a seamless continuum of care (81). Integration can also be real when all the services are operated under the umbrella of one organisation, for which HMO in US like KP is a powerful example (82).It has been tested in the NHS as a model of care for older people in Torbay where both health and social services demonstrated the effectiveness of a real horizontal and vertical integration in providing care to people with complex needs (83). This Integration can be "virtual", whereby multiple organisations can work together under an agreed framework of governance to provide multidisciplinary care to accommodate targeted population with complex needs that can be based on their multi morbidity but can also be based on individual parameters like age, or can be disease specific. One example of such integration is North West London ICP, where more than 100 general practices, 2 acute care trusts, 5 primary care trusts, 2 mental health care trusts, 3 community health trusts, 5 local authorities, and 2 voluntary sector organizations join together to serve over half a million population who was either more than 75 years of age or has diabetes (72), (84).

No matter what shape and form of integration is used, it needs to serve the purpose of delivering high value care in the context of increasing disease burden and difficult financial and organisational environment. Despite testing many model of care delivery no one model is found to be perfect, and there is an increasing understanding that organisational integration is neither necessary nor sufficient to deliver the benefits and it is clinical and

service level integration that is fundamental to produce desired outcomes (85). In an increasingly fragmented NHS, there are several barriers to achieving this integration: an NHS management culture that is permission based and risk averse; increasing primary and secondary care divides in the form of contracts, funding approaches and different priorities of service provision; lack of time and resources to support integrated care to sustain (86) and lack of research methodology applied to such projects in order to come to a meaningful conclusion; too much focus on organisational performance in comparison with performance across organisations and around patients, inability to develop a common framework to promote joint accountability for delivering patient centric services (87) and the absence of robust shared electronic patient records are key issues that require urgent attention (85).

Most recently, a comprehensive systematic review to assess the effectiveness of quality improvement strategies on the management of diabetes has been published (88). This review included strategies targeting healthcare systems, which include case finding and management, team changes, electronic patient registry, facilitated relay of information to the patients and continuous quality improvement (plan-do-study-act). Other strategies to target healthcare providers include audit and feedback, clinician education, clinician reminders and financial incentives and finally the strategies that target patients such as education of the patients, promotion of self-management and reminder system. All of these have been looked in both randomised and cluster randomised trial settings. The impact of these strategies was assessed not only on HbA1C but also on vascular risk profile. It was concluded that the strategies that have a pan system intervention strategies has a better impact on diabetes management and outcomes. Interventions that only target healthcare professionals are found to be significant only in those patients with poorer baseline Hba1C. The limitations of this study include varied baseline or standard care across various countries and selection bias of the trials published in English language only. Due to the large number of trials included there were inconsistencies in the defined outcomes of the trials hence made it difficult to assess the extent of secondary outcomes such as vascular risk and complications. Despite these weaknesses, the important message delivered in this trial is that non-pharmacological interventions can deliver both qualitative as well as quantitative benefits in clinical surrogate markers of diabetes. These benefits are modest with mean

HbA1C improvement of 0.3-0.4%, but they can be seen in the comparison of the benefit achieved by adding a 3rd line oral hypoglycaemic agent.

Regarding delivery of an integrated care, a recent mixed method case study used hospitalisation of people with diabetes as an index to assess the effectiveness of the healthcare delivery system across the bounds of primary and specialist services (89). This study is based on a 3 year long pilot project using a before-after design with control from adjacent geographical areas. This study concluded that investment in a separate community diabetes specialist service has not shown any benefit in rate of hospitalisation, but has increased fragmentation between primary and secondary care. Lack of clinical, financial and data governance were found to be the key issues led to the failure of the effective delivery of care. This study had a weak design, and there was lack of availability of complete dataset that might have an impact on the overall conclusion but unlikely to have changed it significantly.

Vision for the Future

The above discussion has highlighted the fact that diabetes care delivery is a complex subject. Over the course of more than half a century, remarkable improvements have been made in diabetes care delivery. We have moved from an era of unstructured, specialist led services to a structured, organised and system wide diabetes care. Despite several attempts to assess the effectiveness of various interventions the evidence in this arena is very limited. There is a need to explore various strategies by using the research with robust methodology to provide high quality evidence. The perception of the available evidence suggests that it is difficult to conduct research in this area, due to certain barriers such as multiple stakeholders' involvement, lack of differentiation between a service development and a research project as it seems easier to implement such initiatives as a service development. This loses the benefit of the control group in the assessment of the impact of such initiatives. Therefore, many reported improvements in outcomes could be due to temporal changes or confounding variables. As these interventions so far have only shown modest improvements, and in presence of a positive publication bias, there is a lack of encouragement in conducting such studies. Although available evidence does provide a valuable insight into what should be an effective healthcare delivery strategy should look like, there is a need to explore whether a data driven, risk stratified, needs based approach to diabetes care will allow efficiency in care delivery in a resource challenged NHS.

Based on this learning, there is a need to develop a model of diabetes care that should be based on the principles of corporate governance, should be ethical and principled, actively user centric and integrated at all levels of integration. It should address equality and equity in service access, process and outcome, be effective, efficient and appropriate by linkage to risk and modifiable risk. To deliver a resource efficient service in a finance restricted NHS we have to develop a model that can treat people according to their needs based on their risk profile. This means targeting people at higher risk with fully integrated services, while routine care is offered to those who are able to self-care even with little help and support. This type of focused care can only be developed if there is a risk stratification mechanism in place. Although in the past, risk based referral systems have been tested, above evidence suggests a suboptimal response to the needs of at risk group in a timely manner that can be influenced by the enthusiasm of clinicians involved in the care of the patient.

The introduction of QOF has facilitated data collection and electronic databases have become integral parts of all the services. QOF has shown great improvement in capturing the data around care processes and perhaps on intermediate outcomes but there is mixed evidence of any significant reduction in cost effectiveness, long-term morbidity and mortality (60, 90). Now there is an opportunity to use this available data to risk stratify the patient electronically based on their clinical parameters with less chances of getting lost in the system. This data can also be used to empower people by providing them with their personalised information in a structured format so that they can develop insight of their diabetes status and should be able to reflect how they can improve their care.

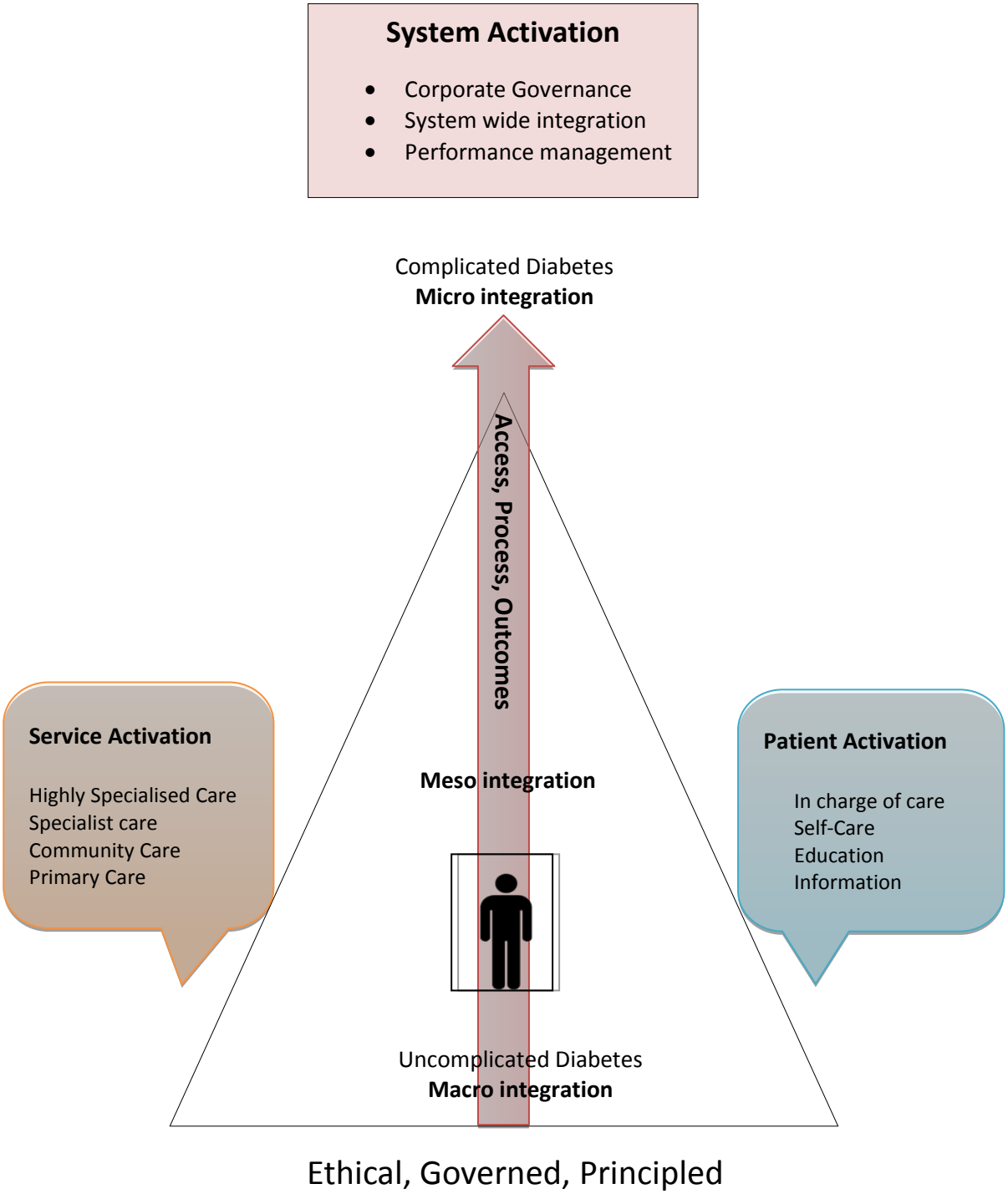
WICKED (Wolverhampton Interface Care-Knowledge Empowered Diabetes) is an initiative to re-design local diabetes care delivery across the local health economy in Wolverhampton. This model has 2 core components; Patient Activation and Service Activation. The "Patient Activation" arm aims to empower the patient by providing them with their diabetes specific individualised information in a structured format regardless of the patient's engagement with the service to promote self-care, and hence activate these patients in local diabetes care delivery. It is this arm of the model that has been tested in a cluster randomised control trial to assess the impact of this intervention of information provision to the completion of the nine key care processes in diabetes. In this trial, a structured A4 booklet containing individualised patient information is used as an intervention to encourage people to complete the key care processes that constitute standard diabetes care. The completion of the processes is the key element to inform local healthcare, and plays a vital role in risk stratification. This risk stratification strategy is the basis of "Service Activation" arm of the model that involves co-working between primary and specialist care around this cohort of people who are at higher risk of developing complications of diabetes. The whole model is thus based on the principle of equity in healthcare. In this model, all those people who can self-care can be managed without any pressing need to integrate resources around them but as the needs of the individuals increase, the model converge its resources to develop meso and micro integration among the services and people with diabetes to provide best possible care (Fig 1.5).

In order to execute such a project, there is a need to develop an understanding of the basic principles of the model as outlined above. A complete, live and validated database will serve as a core to the model and hence establishment and validation process of such a database will be crucial. To implement principle of equity in health care, it is important to develop an understanding around access to healthcare. A partnership working with activated patient will be key to success to develop a care plan and encourage patient to self-care therefore an attempt to test its implications in real life can provide a valuable insight. In the present thesis an attempt will be made to explore and develop an understanding around these principle areas of the WICKED model of diabetes care that include:

- Establishment and validation of an electronic centralised diabetes register-its importance and utilization in delivery of health care.
- Equity of access-understanding the barriers that affect Access to health care.
- Partnership working-How the care planning can be facilitated by knowledge empowered people.
- Impact of information provision to people with diabetes- Is it feasible? Will it be of any benefit? Can we find an evidence base?

Finally, the benefit of such integrated care delivery model should also show whether this has resulted in any improvements in outcomes. Such a system can then provide a toolkit for sustainability within the system as well as transportability to other regions.

Fig. 1.5: The WICKED escalator describing patient journey from uncomplicated low risk to complicated high risk diabetes.



Chapter 2: Establishment and validation of a centralised electronic diabetes register

Background

The burden of diabetes and related complications is increasing; the cost of newer medication is higher and the cost of high quality care is therefore increasing. Meanwhile, health care systems across the world are trying to cut costs, and providing high quality care at lower cost is not going to be easy in any health care systems. This requires innovative interventions to improve efficiency of the system and use of Information Technology (IT) can play a vital role in it. Electronic patient records have facilitated the use of data for various governance purposes, for example QOF and National Diabetes Audit. However this data has the potential to be used in more powerful way to drive direct clinical care of people with diabetes.

In order to provide care to people with chronic diseases, it is a basic requirement that health services should know about people who are suffering from the illness (91). In diabetes health delivery, hospital clinics have used several ways to keep a record of people attending the clinic. This was either in the form of hospital outpatient records or hospital diabetes register containing details of all people with diabetes attending the hospital. With a better understanding of long term but for some preventable complications of the disease there was an increasing need to ensure that people who are having complex needs should be able to attend the clinics as required. In order to keep a track of these people, a call recall mechanism was desired that could not have been delivered without keeping an accurate record of demographics of these people. Due to the care division between primary and specialist care it was paramount to have a robust system of follow up in place with defined responsibilities of either service to ensure the arrangement of short or long term follow up (92). Keeping a practice register for all people who were discharged from the hospital and utilisation of very early punch card system was used both by primary and specialist care with a degree of success and that has provided the bases for most modern medical coding system (93, 94). Despite these efforts, follow up in diabetes remained suboptimal, resulting in preventable morbidity and mortality. In order to overcome this failure, there was an

increasing desire to find a robust method to establish and maintain a diabetes register. The St Vincent declaration (95) provided this platform to encourage health services to upgrade their systems in order to meet the targets of improvement in morbidity and mortality that was set in the declaration. In the first validation study by Coulter et al, diabetes was found to be the most accurately recorded chronic disease in the general practice register (91) but this was only done by the primary care prescription records matched with the diabetic register patients and match was found for 72% of people. In order to meet the recommendations of Department of Health (DOH) and British Diabetes Association (BDA), the establishment of a district diabetes register to facilitate the systematic population based assessment of care delivery outcomes, and to ensure effective, efficient and equitable health care services, was considered to be a fundamental requirement. However, in order to establish a district wide centralised diabetes register, there is a need to establish linkages in systems between primary and secondary care datasets. One of the earliest attempts made to link primary, secondary and pharmacy data showed that there were huge gaps among different datasets and this highlighted difficulties in establishing such register. It was found difficult to devise an effective strategy to overcome these data gaps, and hence makes it difficult to deliver effective health care in a local health economy (96). At the same time, significant improvements were observed in the delivery of structured diabetes care, with the establishment of a district diabetes register by either sharing primary and secondary care data or central linkages of record specific for diabetes and it was acknowledged that the establishment of such register was feasible and important (97, 98). Coding errors were found to be the most common cause of discrepancies in the datasets, possibly due to lack of training, insight or multi source input. However with improvements in the coding system and data capture facilitated by the information technology, the establishment of a robust diabetes register by establishing multiple database linkages was further explored in Scotland. In the DARTS (Diabetes Audit and Research in Tayside Scotland) study, a unique patient identifier was allocated to people with diabetes on GP register. Details of these individuals were cross checked against eight independent data sources, as follows: Diabetes prescriptions database generated by the Medicines Monitoring Unit; Four datasets from various hospital diabetes clinics; Data from a mobile diabetes eye unit; the regional biochemistry database; the Scottish morbidity record; and it has not only exposed gaps

among different data sources but also identified previously undiagnosed patients. This study proved that a robust centralised diabetes register can be established and used not only to plan and deliver health care but also to find people with diabetes who missed from mainstream registers (99). This was a large scale study that included mainline datasets in Scotland and provided a valuable insight into the utility of a centralised register. As the Scottish healthcare system is different from the English system, key question remained as to whether this study could be reproduced in any other parts of the UK.

Like any other service, maintaining an accurate register for an ever changing population can be tedious work that relies on the motivation and enthusiasm of the service providers. The main deterrents include poor data sharing between primary and secondary care, problems with case ascertainment, patient migration, and discrepancies resulting from multisource data input and acquisition. This issue of motivation was addressed by introducing QOF, with related financial incentives to maintain an accurate diabetes register of the practice (59). This showed significant improvement in data capture across all chronic diseases including diabetes and also helped in improving care process completion in diabetes (60). The quality of primary care diabetes registers has improved to such an extent that it is used as the most accurate database to provide information about people with diabetes to national retinal screening programme (100) as well as National Diabetes Audit (28).

However, despite all the progress made in this field, the fundamental concept of district diabetes register remained the source of demographic details of people with diabetes, although with the advancement in technology, it is perfectly possible that such a database can be used as a tool to plan and deliver health care pro-actively. It can be used to risk stratify people with diabetes and target care to those who needs it the most. Scotland has shown a significant improvement in this area by establishing a regional centralised electronic diabetes register containing information about all people with diabetes in Scotland (101). Unfortunately, due to increasing fragmentation in the English NHS and lack of management support, this type of data integration has not been observed anywhere in England and Wales.

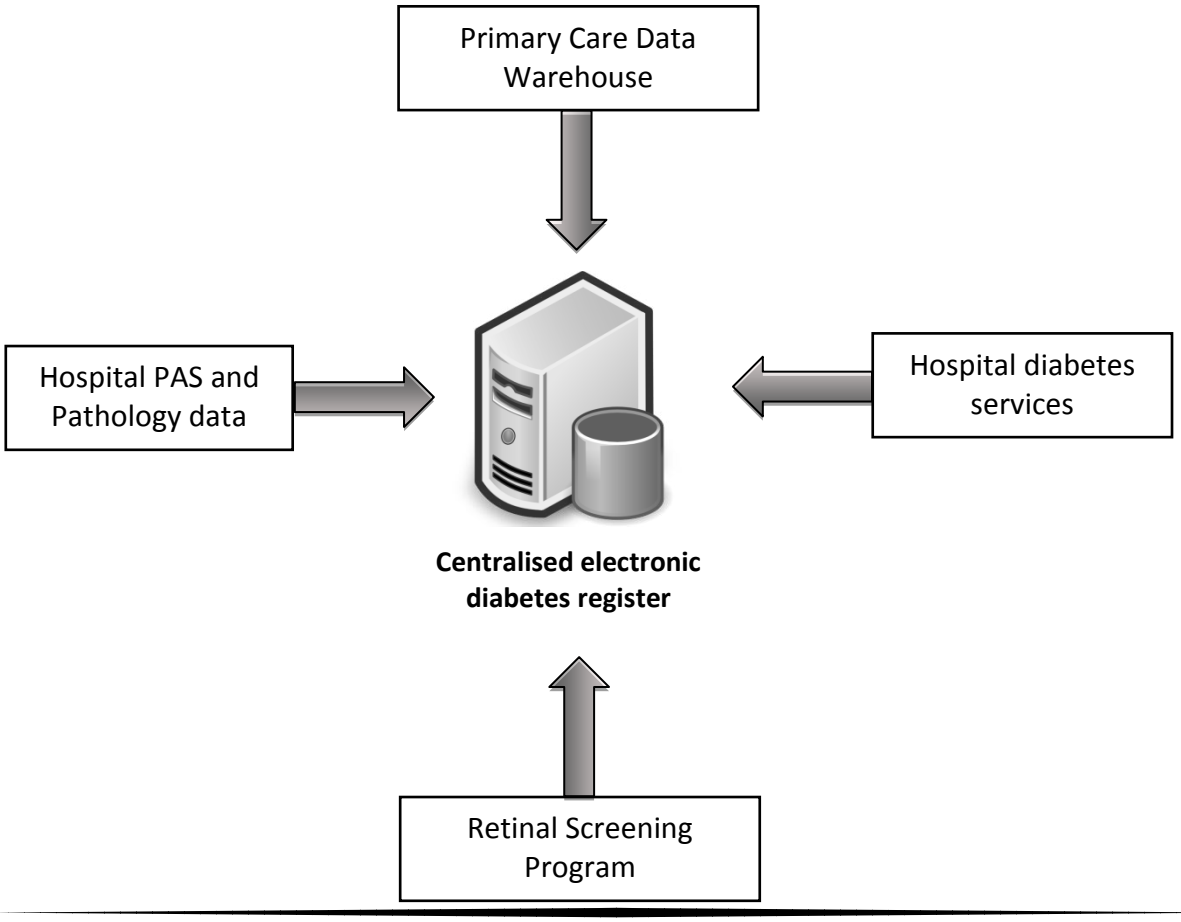
In Wolverhampton, we have tried to establish an electronic centralised diabetes register that is accurate, and able to capture all nine key care processes in diabetes across the whole

local health economy. We have also described a detailed method of how to validate such a database and it is a first demonstration of an algorithm that can be used to ascertain accuracy of a diabetes register on rolling bases.

Methodology of validation of the register

The Wolverhampton District Diabetes Register (WDDR) is a historic patient record system (dating back to 1990) for people with diabetes. It was incorporated into an electronic database based on the 'Diabeta3' system in year 2000. Since 2008, the diabetes retinal screening programme, and more recently the local foot screening programme, are all run through this database – thus so it is an integrated system that was strategically developed precisely to ensure integration of data. It links to the local hospital Patient Administration System and Pathology System, and its data accuracy is checked against the NHS strategic tracing service (NSTS), also known as Demographic Batch Service (DBS). Information from individual primary care practices is separately accrued into a central data warehouse that is used as our local Primary Care Database (Figure 2.1).

Fig. 2.1: Multiple data inputs in electronic centralised diabetes register.



To establish a centralised diabetes register, a starting point could be to merge data from both historic hospital diabetes register and primary care data set into one electronic register and then identify the data gaps between the two datasets. These gaps can then be investigated to produce a complete central dataset. Locally, to align the WDDR to the local Primary Care Database, demographic data on all alive patients coded as having diabetes from all 55 GP practices in the local area were extracted and uploaded into the WDDR in 2009. Individuals previously not known to the WDDR were subsequently registered. All live people registered in the WDDR who were not in the GP database were identified, and a questionnaire was sent to their GP practices to obtain information on diabetes diagnosis and demographics.

All GP practices responded to this questionnaire, and information obtained was updated on the WDDR. People who were not known to have diabetes in the GP database were subject to further biochemical cross checks (previous laboratory results) to verify the diagnosis of diabetes (according to WHO criteria). The WDDR was then updated, and GP practices were informed about any discrepancies for similar updating of their records (Figure 2.2). For non-identifiable patients, further demographic checks were undertaken with the DBS to confirm demographic details, after which a confirmatory check with the GP practice and/or the individual if necessary was made. The data were then updated in the WDDR. Finally, we designed a scoring system, termed the Composite Access Score (CAS), based on three key diabetes access parameters – HbA1c, urine ACR and retinal screening with a score of 1 being awarded for each item if done within the last 15 months. This CAS scoring was applied to the validated diabetes register to assess its utility in predicting whether an individual is in or out of the area, and this helped to develop a model for validating the WDDR post extraction of information from the GP database and DBS. A score of zero would indicate that the patient has either not been active in local diabetes care or has defaulted care (Figure 2.3).

After establishment and the initial validation process, in 2009, we acquired a complete demographic dataset. To make it useful, it was of the utmost importance to capture information of all nine key care processes in diabetes. After negotiating a data sharing agreement between primary and specialist care, the electronic database was enabled to capture this information from all available sources, as described above in November 2013. A

full set of revalidation process was repeated at this stage, to bring data to >95% accuracy. Once this data flow was established, the complete set of individualized diabetes specific parameters required to deliver structured diabetes care were captured in the database. This database was then used as basic prerequisite to develop a data driven modern healthcare delivery model-The WICKED Model of diabetes care.

Since November 2013, a quarterly cycle of revalidation process has taken place to monitor the entry into the diabetes register, such as new diagnosis and people who move in the area, while exits from the register, including deceased patients and people who move out of the area are updated regularly. This regular cycle of quality improvement helps to keep the errors to a minimum level and to establish a high quality validated database. All new people diagnosed with diabetes are uploaded on a monthly basis after cross validating their diagnosis against biochemical tests and those who don't fit the criteria are removed from the register and their GPs are informed. This enables the database to run at a high degree of accuracy.

Fig. 2.2: The process of cross checking GP Databases with a central diabetes register.

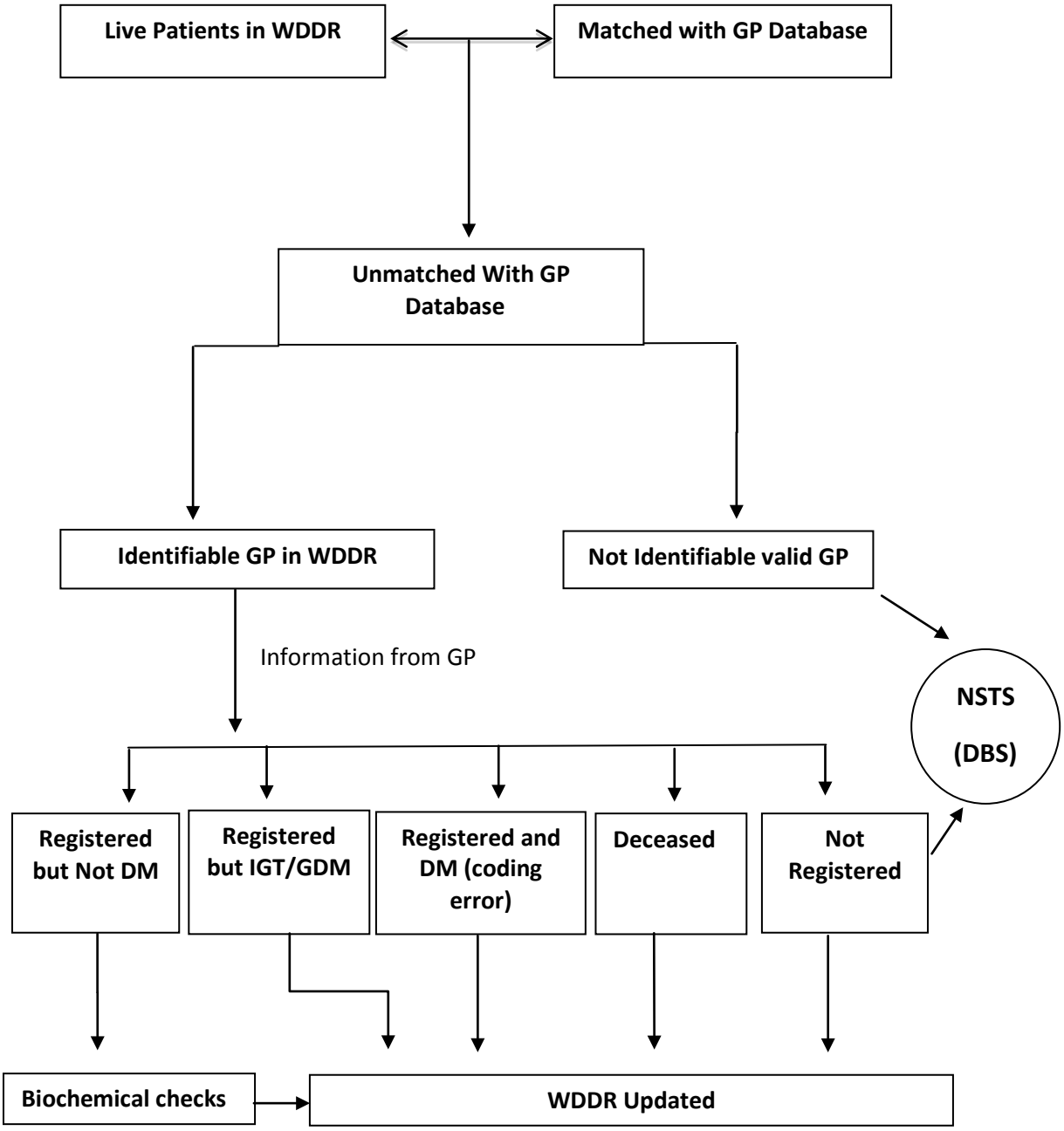
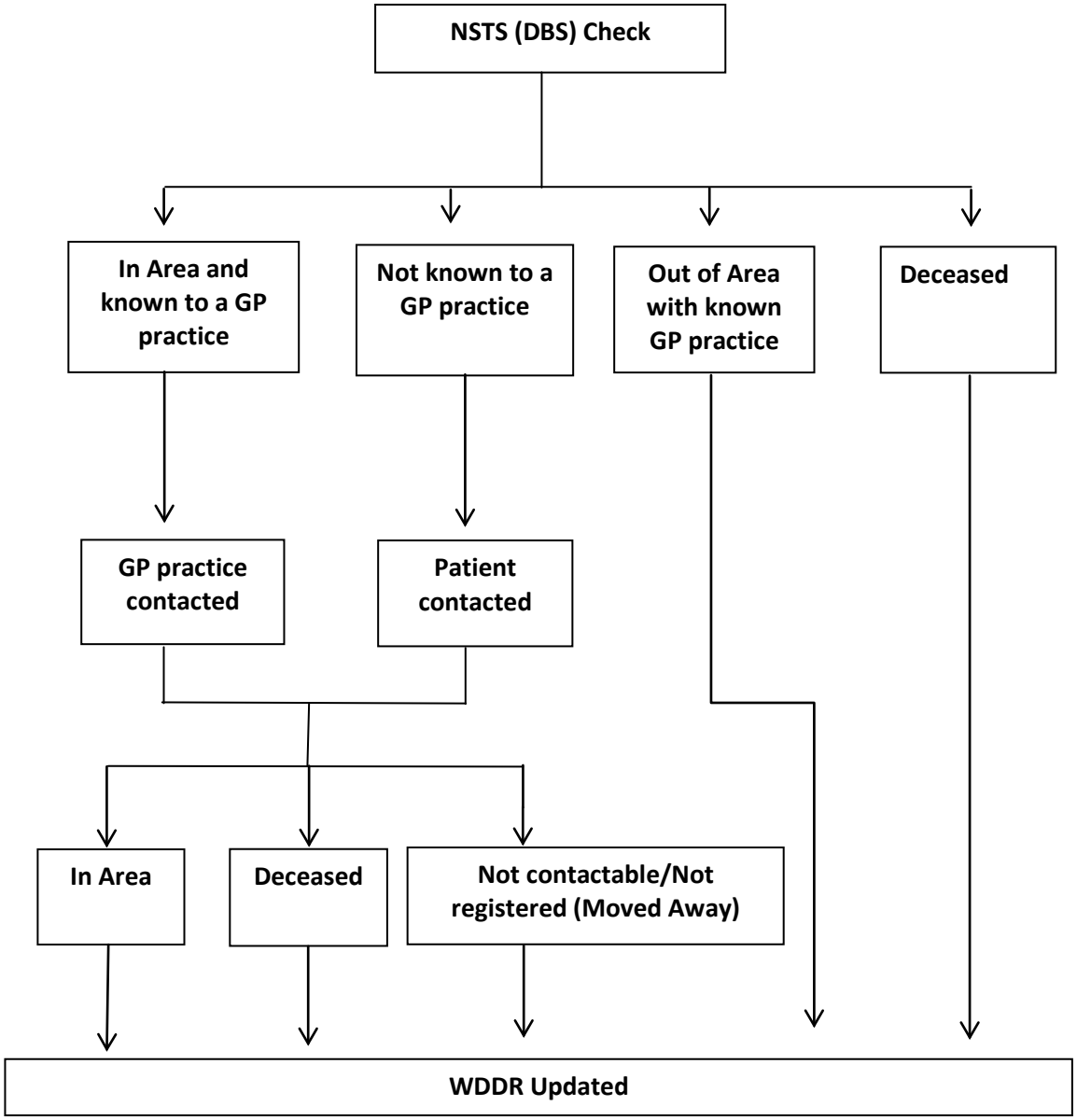


Fig. 2.3: The process of further demographic checks amongst people with diabetes not registered with local primary care.



Results

The results of the systematic process of validating the WDDR post data extraction from the GP database are summarised in Figures 1 and 2. The number of live patients with diabetes from the region in the WDDR and the GP extraction were 15 653 and 13 305 respectively. A total of 217 from GP databases were not known to the WDDR, and were subsequently registered.

In comparing the two registers (Figure 2.4), 13 088 individuals were in both databases; 2565 individuals in the WDDR were not identified in the GP database, in which further processes of validation were undertaken.

Of these 2565 patients in the WDDR who were not in the GP database, information on 2380 individuals was obtained by contacting their named GPs, all of whom responded. The response from GPs confirmed 1244 as being registered with them and having a diagnosis of diabetes. Their data were previously not transferred by the GP practices to WDDR data transfer, because of coding errors. These errors were identified, corrected and updated by locating breaks at multiple points of data transfer. There were 93 patients in GP databases who were correctly coded as either impaired glycaemia or gestational diabetes, and 61 patients were deceased. This information was updated in the WDDR.

There were 742 individuals with no identifiable GP. Biochemical checks on 240 people registered in the WDDR as having diabetes, but not confirmed by their GP, showed diabetes in 47 individuals and the GPs were informed. There was no suggestion of diabetes in 126 people, and 67 had either impaired glycaemia or previous gestational diabetes. These were updated in the WDDR. Thus, an initial 185 and a further 742 known to the WDDR had no identifiable GP. Therefore, altogether, 927 individuals with no identifiable GP practice were subject to DBS checks (Figure 2.5). A total of 237 were confirmed to be in the region but with a different GP practice, 422 with an identifiable GP out of area, 48 deceased and 220 had no identifiable GP practice. The 457 patients who were in the area were again approached via the GP and by direct patient contact, and this confirmed 238 in the area, 7 deceased, and 212 with no identifiable GP or had possibly moved away.

Overall, the WDDR numbers fell from 15 653 to 14 829 (n= 824: deceased -116; moved away -422; misdiagnosed -286) while the GP data rose from 13 088 to 14 617 (n= 1529: miscoded -1244; not known to GPs -285). Ultimately, only 212 of 14 829 (1.4%) on the central register were left unaccounted for, meaning we could not identify their GP or their status by any methodology. In this small group, we applied the CAS and found 99% had CAS=0 with only two individuals with a CAS of 1, essentially confirming their inactivity in local diabetes care provision.

Fig. 2.4: The results of cross checking GP Databases with a central diabetes register.

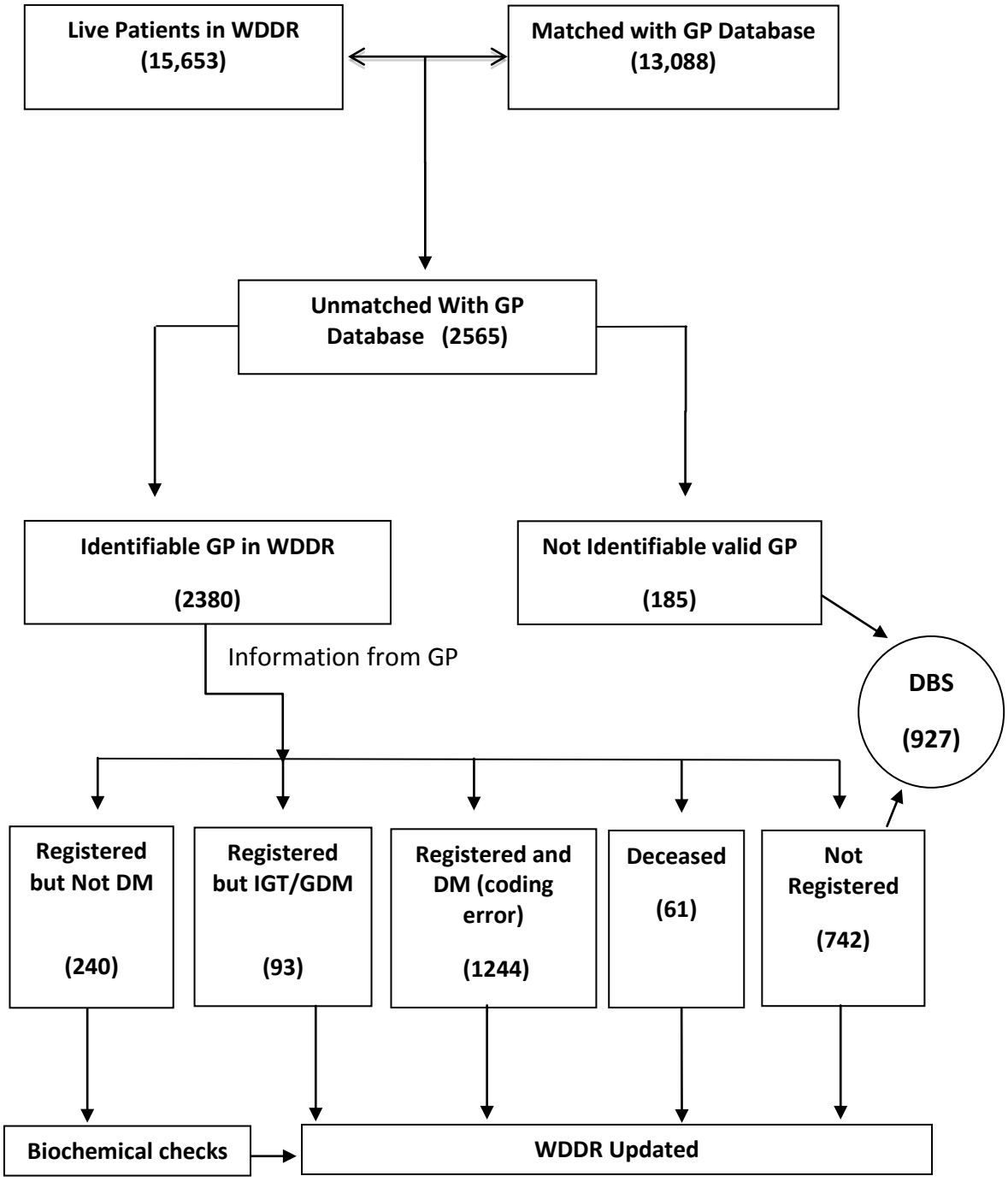
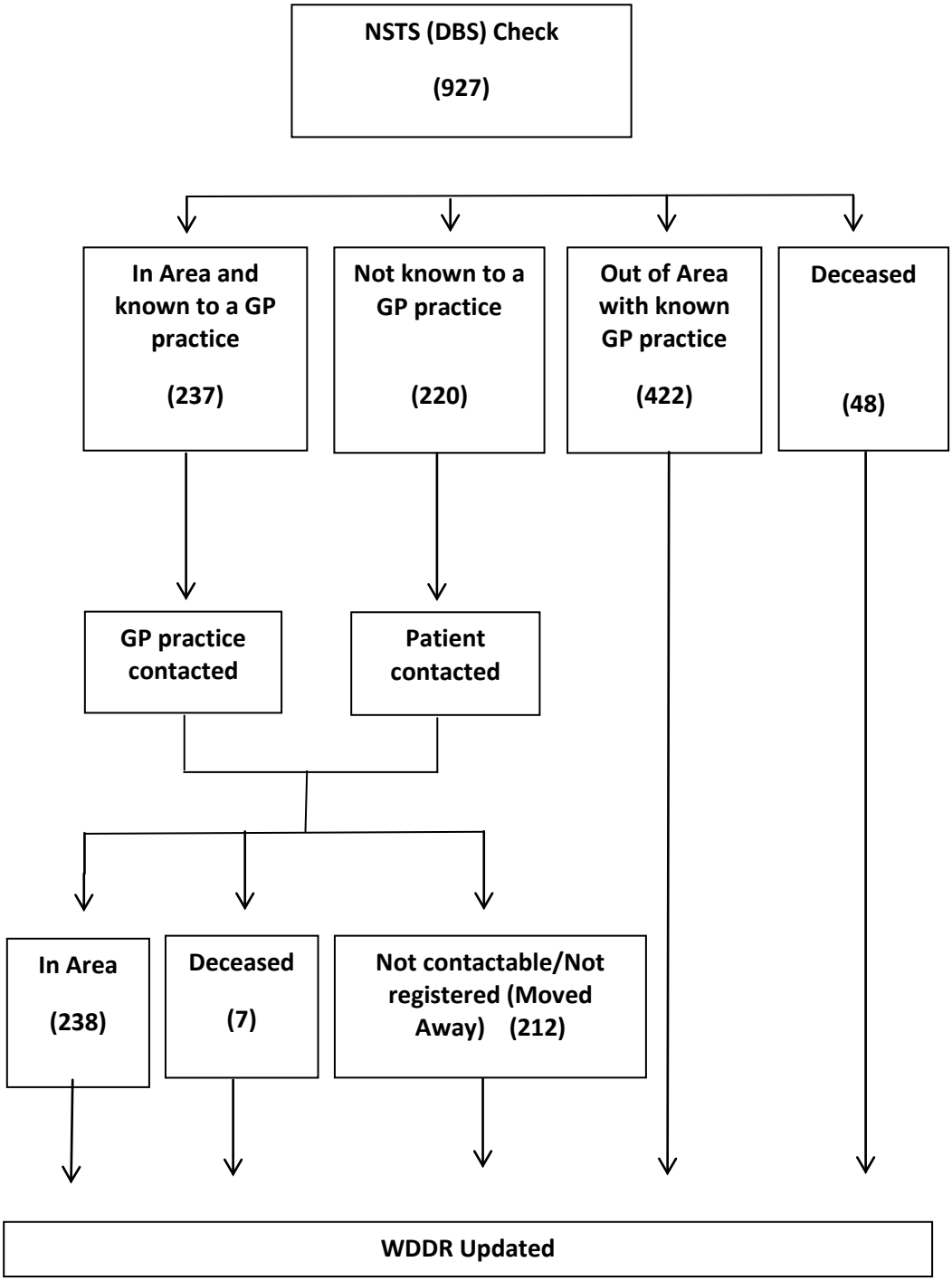


Fig. 2.5: Further demographic checks amongst people with diabetes not registered with local primary care.



After repeating the whole validation process in November 2013, there were 16,693 live patients in the Wolverhampton Clinical Commissioning Group (WCCG) area. The full results of this process are shown in (Figure 2.6). This was the baseline population recruited into the randomised control trial at the beginning of December 2013.

From November 2013 to November 2014, there were 1037 patients added in as newly diagnosed with diabetes. 954 were diabetic, and 86 were not diabetic and were subsequently removed. With repeated validation and database cleansing cycles, the number of people registered as having diabetes due to coding errors have reduced from 985 to 388, gestational diabetes and impaired glycaemic states reduced from 598 to 178 and 86 to 25 respectively. 388 people died during the year, and were removed from the register accordingly (Figure 2.7).

Fig. 2.6: Results of validation flow process in November 2013

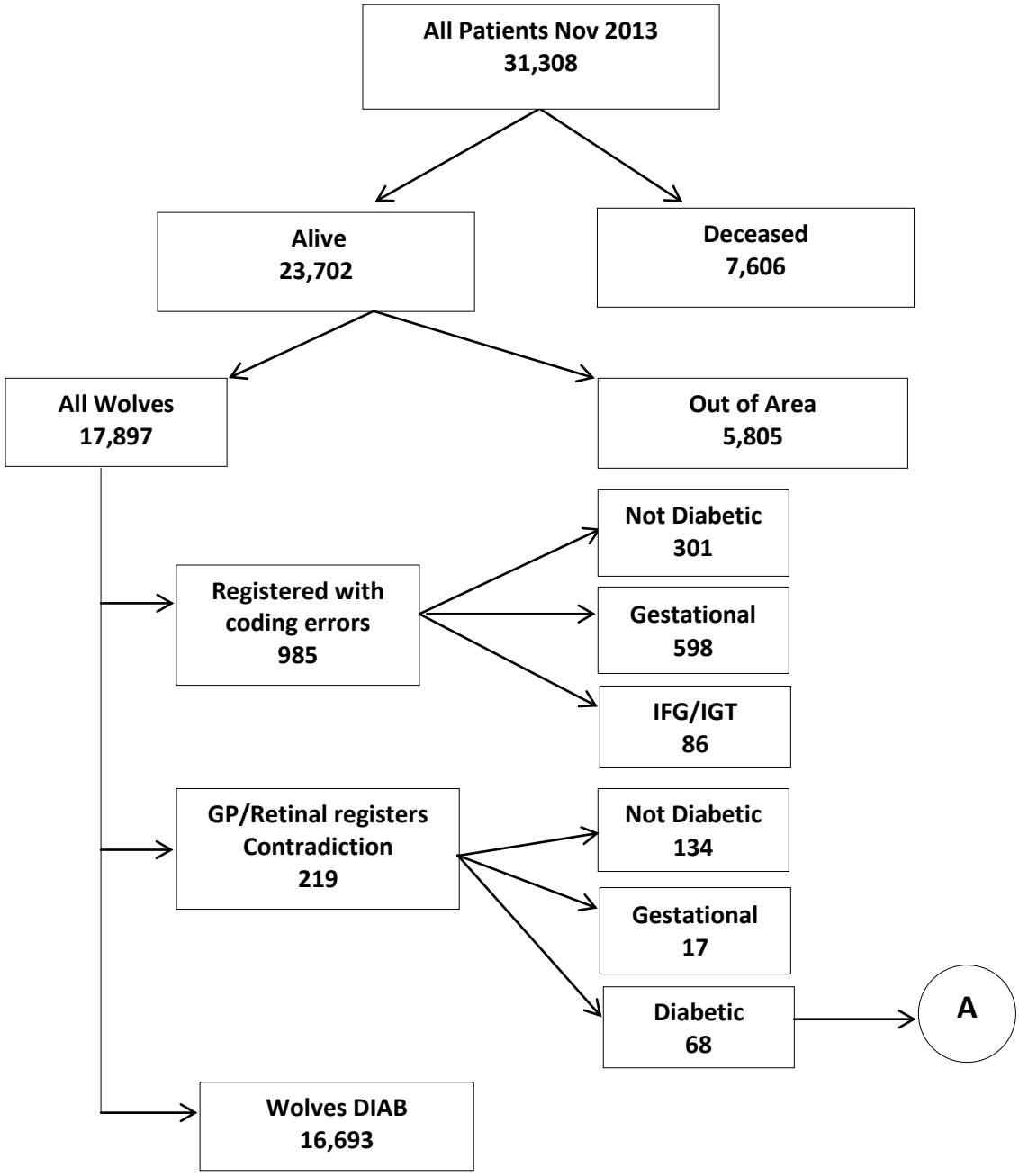
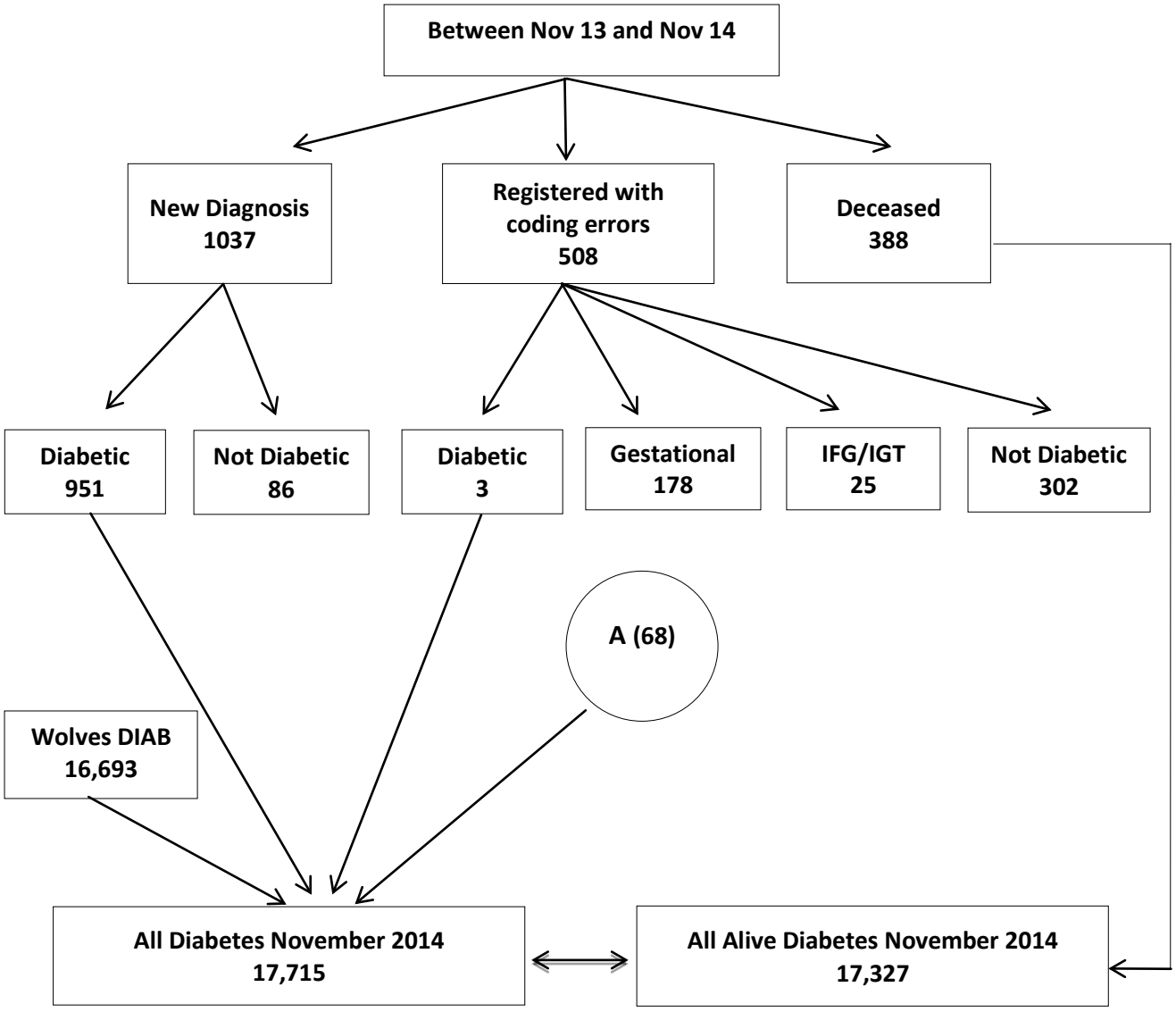


Fig. 2.7: 12 months' outcomes of continuous quarterly revalidation process of centralised diabetes register



Discussion

We have learned from this exercise that no single database can be fully accurate. It is difficult to maintain the accuracy of any database, due to the dynamic demographics of the population and limitations of electronic record sharing systems. The NHS Spine similarly faced several problems with its summary care record as a result of discrepancies, due to technical errors in patients' data uploads (102). However, since any such database can be crucial to service provision to the patients, we suggest that all local services should have a robust plan of validation that ensures a rolling mechanism of demographic cross checks from the DBS and GP databases at regular intervals, so as to reduce the number of discrepancies. This identifies people with diabetes who have either moved out of the area, or have moved from one GP practice to another, those who have died, those who are miscoded and those who do not have diabetes at all.

GP coding errors were found to be a major cause of discrepancy. This relates to the multiple Read Codes used by the GP clinical computer systems. The NHS Information Authority generates Read Codes regularly, but GP computer system providers can also use different Read Codes for the same condition (103). In our validation process, a significant proportion of the discrepancy in our central database was found to be due to coding errors in primary care systems. There are multiple points where coding errors can happen, including completeness of data at input (GP practice level) or extraction of data by software that does not recognise all possible codes. Some patients were coded as having diabetes in GP systems but not known to the WDDR. One reason was that on our first match, our list of codes was incomplete. A complete list of these codes can be updated at regular intervals to avoid these discrepancies. Other coding discrepancies were mainly impaired glucose tolerance (IGT) and gestational diabetes (GDM) against diabetes diagnosis. These were all cross checked (including confirmation of the biochemical diagnosis) and corrected. Some patients were known to the register (through its triangulation with other systems [diabetes retinal screening, hospital PAS and pathology]) and, again, all of these were individually reviewed. Wherever such discrepancies were found, miscoding in the prime GP system was the most common cause of error. Completeness and correctness of data also rely heavily on the enthusiasm of practices and individual GPs (104). In our experience, there were a significant number of people with diabetes in GP practices who were not identified at our

first GP contact, but when, after demographic checks, we wrote back to the GP practices they managed to identify these patients on their lists.

There is a need for standardisation of Read Codes so that all people with diabetes can be identified in the electronic record system to construct and maintain a valid diabetes register, since the quality of diabetes care depends on correct identification of these patients. One such example is the retinal screening programme that extracts its data from the GP2DRS system and relies on GP databases to identify people with diabetes. To achieve national standards of retinal screening, a database that is validated from multiple sources on a regular basis is vital. A recent NHS diabetes report has concluded that 85–90% of primary care data on diabetes are fit for purpose, but there is room for improvement (105). These coding errors, once rectified, will improve the quality of data feed in both the WDDR and GP2DRS databases.

The Composite Access Score is a very useful tool to identify patient access to diabetes services. When applied to individuals who were not identifiable by GP database, DBS and direct contact, it had a strong predictive value in identifying people who had moved away. It can also be used to identify people with diabetes who are not engaged with the services. Three key elements of this score, namely HbA1c, urine ACR and retinal screening will incorporate all the process modalities (blood test, urine test and contact with screening programme) a patient should have as a part of their routine diabetes care. The National Diabetes Inpatient Audit (NaDIA 2010–2011) report suggested that failure to complete nine care processes could deprive people of timely intervention to prevent complications (28). By applying a CAS score to all patients on a district diabetes register, all non-engaged people can be identified, and a proactive approach can be adapted to get these patients involved in their diabetes care.

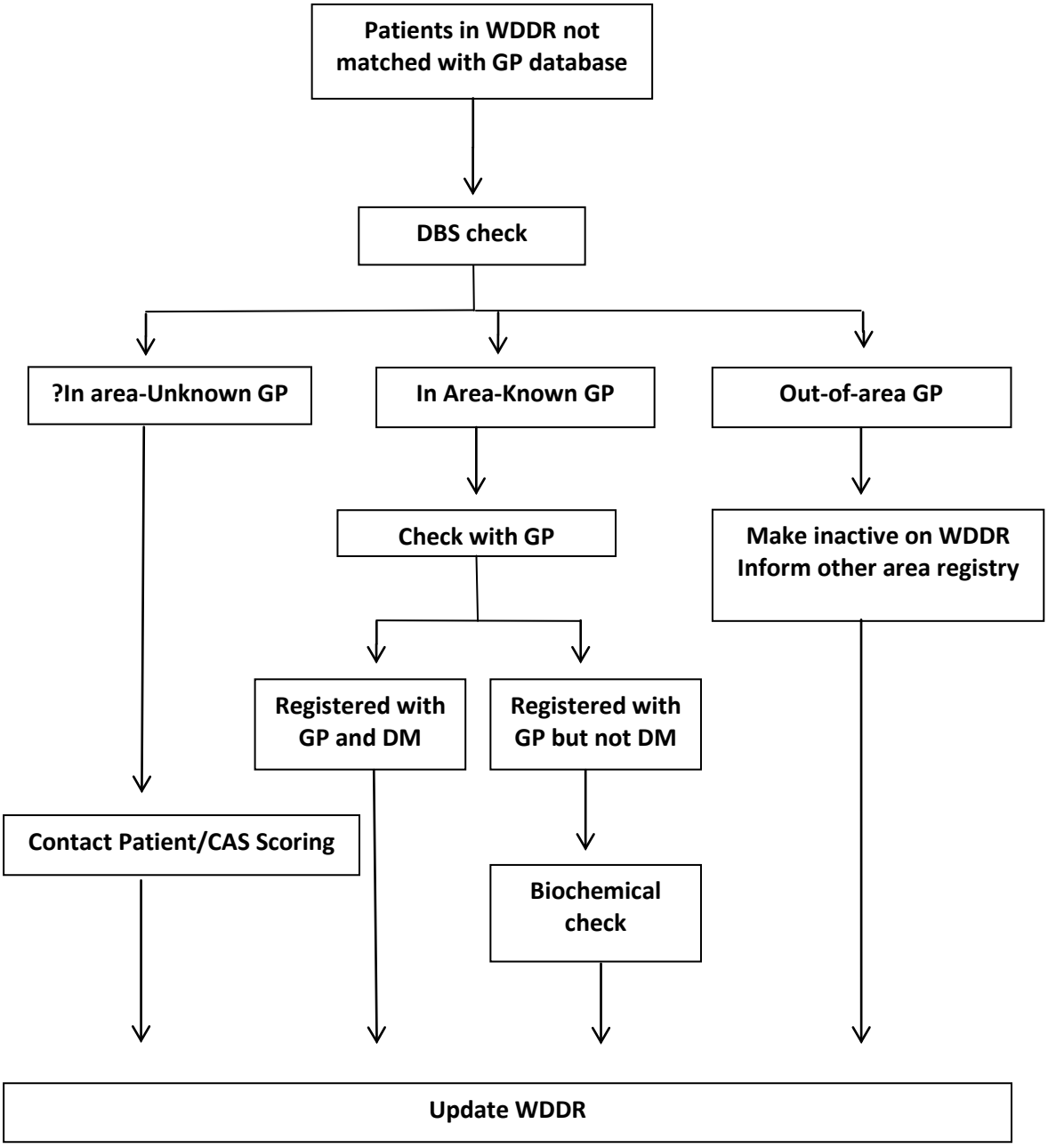
Biochemical checks could be utilised effectively to validate a database and to populate relevant registers such as the WDDR, IGT and GDM registers. This will help to identify accurately people to whom to offer correct management advice according to their status of diabetes or pre-diabetes. This failsafe process minimises the chances of inadvertently removing an individual from the register purely based on information available from GP data extraction that may not be always accurate (Figure 2.8).

This entire process of data validation is tedious and labour intensive, albeit worthwhile. Once a valid database is established after going through all of this hard work, it is easy to maintain it by cross checking details with other databases at regular intervals. Up until 2012, this database mainly held demographics, biochemical test results, retinal screening and partly foot screening details. Only those attending hospital diabetes clinic were recipients of their other processes (like weight, BMI, smoking status, vascular risk and foot risk) captured in this register, but those who were under their GP care were not included in the database. This lack of data integration was considered a key barrier in delivering integrated diabetes care across any local health economy (89). In 2013, we extended the data input to this register to include all key care processes data capture of all people with diabetes in Wolverhampton, regardless of the location of the care delivery. Hence, we now have the ability to acquire all the information in our accurate database updated on weekly basis with rolling cycles of validation at least quarterly. During each validation cycle all processes described above are carried out to a high standard of accuracy. All newly diagnosed patients are uploaded in the database on a weekly (80% of the practices) or monthly (20% of the practices) basis. Before their data entry into WDDR their diagnoses are cross checked against biochemical markers to ensure accuracy of the database. All discrepancies of diagnosis are then communicated back to the GPs to seek further clarification. The number of discrepancies in follow up checks has significantly reduced, making it a quick and cost effective process. This has not only improved the completeness of key care processes, including retinal and foot screening programmes, but has also helped us to plan our service delivery and resources according to the needs of the population. After this whole process of validation, we now have a >97% accurate district diabetes register in Wolverhampton.

This register can have wider implications in terms of assessing the severity of the diabetes epidemic. During the last year, despite adding over 1000 newly diagnosed patients the total size of the register didn't expand above 700 patients due to quality improvement processes in place for validation of this register. These processes of keeping the register updated are described above, and showed in figure 2.7. This equates to nearly 30% of the disease burden that may result in spuriously high disease prevalence and can potentially have direct implications on resource management and strategies to tackle this disease. National datasets like Health and Social Care Information Centre (HSCIC) show the prevalence of

diabetes based on the crude datasets from primary and perhaps specialist care, and without validating these datasets estimated diabetes prevalence in a specified area could be higher than actual prevalence. If we compare the expected prevalence range for our local health economy against HSCIC data sets, it would have been accurate if this work of validation of database would not have happened. There may be a need to address the accuracy of such national datasets that dictate national policies and direct resources by introducing such revalidation processes.

Fig. 2.8: Proposed Algorithm



Chapter 3: Access to Health Care

Background

No one would deny that even the most efficient healthcare delivery service in the world can only be successful if patients are actually accessing the service. Even with the best will in the world, there must be an interaction between the person with the disease and the health services, in order to initiate and support disease management. This concept of access should neither be confused with other issues such as default from care, nor considered the sole responsibility of person with the disease. It is, and should be taken as the joint responsibility of healthcare service, clinicians and patients to ensure that every one should be able to access the service to gain maximum benefit in their disease management. Therefore, the concept of access to health care should not only be well understood but also embedded as a fundamental necessity to ensure success of a healthcare delivery model.

The birth of the NHS was based on 3 core principles: that it meet the needs of everyone; that it be free at the point of delivery; that it be based on clinical need, not ability to pay. Nonetheless, health inequalities in United Kingdom were identified in the Black report in 1980. Key findings of this report showed that there were large differences in morbidity and mortality that favour higher social class and they were not addressed by health or social services (106). This report generated a major debate among health economics to try to define and explain the principles of equity and justice in health care. Over a period of time, several conflicting definitions of equity in healthcare have emerged that include “equality of expenditure per capita”, “distribution according to need”, “‘equality of access” and “equality of health” (107),(108, 109). Two of these definitions t based on the concept of “need” and “access” were explored in depth by Culyer and Wagstaff (110). Although it may seem to be a rather simple concept that healthcare should be distributed according to the needs of the patients, it has two different dimensions. Horizontal equity represent the equality of treatment for people in similar needs and vertical equity argue that people who have different needs should be treated differently (111). However, need can be judged either at the time of initial contact with the patient and people who are more ill than others should receive quicker treatment (112, 113), or it can be judged on the principal of capacity to benefit (114). A judgment regarding this capacity to benefit needs to be made very

carefully by keeping the holistic approach to balance the benefit against resources and capacity of health care system.

The concept of access to healthcare is also important to understand, as it can sometime be coupled with the concept of need; that people who have different needs should have different level of access to healthcare and this will again bring the horizontal and vertical versions of access similar to that of equity as described above. Access means that people should be able to avail themselves of a facility when they need it or want it. It is sometimes used with the term utilization (115, 116) but others consider that access can be taken as a forgone utility or a cost incurred in receiving healthcare (107) or maximum attainable consumption (117).

Justice in healthcare may be explained under four fundamental principles. “Need principles”, are most widely discussed, as evident from the above discussion, and advocate treatment of patients based on their needs. According to “Maximising Principles”, justice in health requires that care should be distributed to achieve best possible consequences. A key issue with this approach is that how can we quantify and predict the maximum benefit during the course of an illness or wellbeing of people. Reduction in inequalities of healthcare to the least advantaged people can be used as a single point of focus if we follow “Egalitarian Principles” although to utilise its maximum benefit one might want to use them in combination with maximising principles. Finally, all these principles can be used in combination to elaborate “Combination Principles” to apply various components of all other principles in a structured manner. However, the biggest issue would be how to maintain a balance when applying the combination principles and one way to deal with this is to keep a primary principle as a core strategy backed up by the second principle when first one fails to yield the answer (118).

Despite all efforts to eliminate inequalities from healthcare the findings of 10 years follow up of Black report (119) showed that these inequalities still existed. Therefore, it deemed necessary for the NHS to formulate a shared ethical code for everybody in health care to follow. This resulted in the emergence of a draft of ethical principles known as the Tavistock principles in 1997. This consisted of 5 fundamental principles that should govern the healthcare system (120). They were as follows:

1. *Health care is a human right*
2. *The care of individuals is at the centre of healthcare delivery but must be viewed and practised within the overall context of continuing work to generate the greatest possible health gains for groups and populations.*
3. *The responsibilities of the healthcare delivery system include the prevention of illness and the alleviation of disability.*
4. *Cooperation with each other and those served is imperative for those working within the healthcare delivery system.*
5. *All individuals and groups involved in health care, whether providing access or services, have the continuing responsibility to help improve its quality.*

These principles generated a debate about rights, balance, comprehensiveness, co-operation, improvement, safety and openness across the world (121) and elicited a degree of criticism (122). Eventually, after refinement and implementation, these principles were widely accepted not only in the NHS but also worldwide. These principles set the tone for the healthcare system to take overall responsibility to ensure that people should be able to access a high quality service to prevent and treat their illness and strive to achieve excellence in care and health gains for the population.

Despite the introduction of NSF and QOF to improve and support the access to healthcare there are huge geographical variations in the attainment of key care processes in diabetes (26).

In order to further understand this concept of access, I undertook a case controlled study to determine factor that affect Access to healthcare.

There is no known validated tool to identify failed patient access to diabetes health care. Within the validation process of our local diabetes data set (123), a scoring system was used to assess the level of access of patients to diabetes services – predominantly as a mechanism to determine those who were or were not still active participants in local diabetes care in order to maintain the epidemiological accuracy of the local diabetes register. We undertook a case control study of patients with diabetes, identifying and comparing those with complete or incomplete access criteria according to a score that we

renamed, the Failed Access Score (FAS). The objective of this study was to determine whether this score identified access failure that can be attributed to identifiable factors among individuals with diabetes.

Aims

To determine what factors can affect patient access to diabetes care.

To determine whether a scoring system can be used to identify people who are failing access to diabetes care.

Hypothesis

By using a scoring system, failed access to diabetes care can be flagged and the barriers that results in poor patient engagement can be identified.

Methods

The Failed Access Score

The FAS consists of three key care processes in diabetes, these being HbA1c, urinary albumin:creatinine ratio (ACR) and retinal screening. This maps to all domains of diabetes care processes in the form of: a blood test (HbA1c) – meaning that all blood tests could have been done; a urine test (ACR) – meaning that the patient attended a clinical appointment so that all clinical measures could have been completed; and a retinal screening test – confirming that the patients are in receipt of communication and able to engage in self-care. Each of these parameters is universally captured in the central database wherever undertaken, whereas others may not be (e.g. weight, blood pressure etc). Completion of all three processes is indicative that the patient has access to the service and engaged to the extent that sufficient opportunity exists for health services to complete all nine key care processes in diabetes. The failure of any one parameter over the preceding 15 months was scored 1. A score of zero meant that all three parameters were completed, while a score of 3 meant maximal failure of access such that none of the three parameters were completed and there was no access to the service.

Study sample

The study was undertaken in a single, large inner city GP practice. A retrospective case control study was undertaken on all the patients in this practice who failed more than one FAS parameter in the last 15 months, meaning they had a FAS of 2 or 3. They were compared to those with no access failure (FAS = 0) matched for age, gender, ethnicity and

type of diabetes as controls. All data were extracted from EMIS-Web primary care computer system. All identified factors were categorised either as patient or service related. Patient related factors were further subdivided thus: those related to non-attendance, care refusal or unavailability (moved away); or clinical and social issues that were a barrier to the patient attending (palliative care, house bound, mental health issues, multiple comorbidities, language barrier). Service related factors simply represent pure service failure in otherwise attending patients.

Whole population analysis

Further analysis of FAS was undertaken on the whole district population using data in our local integrated diabetes register. This analysis is served to highlight the fact that failed access can potentially be identified by using this score and we may take this small sample of the pilot study to speculate numbers of people in various categories of failed access to healthcare. However, this did not contain sufficient detail to drill down to constraints identifiable at the individual level as identified in the single practice survey. This can potentially be a full project in its own right, to identify and further explore the barriers to access.

The English Indices of Deprivation provides a relative measure of deprivation based on a group of 10 different indices that all measure different aspects of deprivation. The most widely used of these indices is the Index of Multiple Deprivation (IMD) which is a combination of a number of the other indices to give an overall score for the relative level of multiple deprivation experienced in every neighbourhood in England. It involves complex calculation methodology but a report based on small areas in England is produced regularly by the Department of Communities and Local Government.

Results

From a practice size of 6322, there were 478 registered with diabetes (prevalence 7.6%) of whom 51 were identified with partial or complete access failure by a FAS score of 2 or 3 (n=43 [84%] and n=8 [16%] respectively).

Of the 51 cases: ACR was missing in 72%; HbA1c in 42%; retinal screening in 34%. The demographic characteristics of the cohorts are presented in Table 3.1. The groups were matched for all a-priori selected demographic criteria but in post-hoc analysis the failed access group had a higher deprivation score. Reasons for access failure are given in Table 3.2. The service failed to complete the processes of diabetes in those who were regularly attending in 12 patients (24%). Eighteen (35%) patients had not attended despite documented multiple recall communications or had moved away, and we judged the practice could not have done more about these. However, 21 (41%) patients were constrained from access because of poor mobility, mental health issues, palliative or end of life care or comorbidities. Excluding those where service failure caused access failure (n=12), among 39 patients compared to controls, there was a significant difference in the proportional distribution of those constraints (χ^2=49.9, p<0.001) with a greater number of those house bound, with mental health issues, or in palliative care, although multiple morbidity in its own right was not associated with access failure. In the whole local health economy (Wolverhampton Clinical Commissioning Group), there were 16 644 registered patients with diabetes and their demographic and other data are given in Table 3.3. With increasing FAS, there were significant rises in age, male gender and deprivation score and a decrease in the prevalence of type 2 diabetes or, conversely, an increase in the prevalence of type 1 diabetes. Ethnicity data were incompletely recorded, but where known the association with increasing failures of access was nevertheless significant, and the prevalence of non-Caucasian ethnicity rose to 36% with a FAS of 3 from a baseline of 18% in those with a FAS of zero and/or in the whole population. In regression analysis, these factors were all significantly associated with the FAS (χ^2=303.9, p<0.001) but they explained very little of the variance in FAS – about 2% (r2=0.018) – such that the model was incapable of predicting individual access failure (<1% accuracy). In extrapolating the findings from a single practice to the 2362 patients across Wolverhampton with FAS of 2 or 3, there would

have been 567, 827, and 968 patients with access failure due to service failure, repeated non-attendance, or co-existing clinical or social issues, respectively.

Table 3.1

The demographics characteristics of cases with failed access to diabetes care compared to those matched controls with full access (mean ± SD or number (%)).

		Cases	**Controls**	**P**
		51	51	
Age	years	62 ± 17	61 ± 16	Ns
Gender	males	31 (61%)	31 (61%)	Ns
Ethnicity	Caucasian	20 (39%)	21 (41%)	Ns
	Asian	23 (45%)	26 (51%)	
	Black	6 (12%)	4 (8%)	
	Unknown	2 (4%)	0	
Duration Diabetes	years	11 ± 8	11 ± 7	Ns
Type Diabetes	type 2	48	48	Ns
Insulin use		15	16	Ns
Deprivation Score		40 ± 15	31 ± 16	0.009

Table 3.2

Constraints to access to diabetes care identified in cases and control groups (number (%))

		No constraint	Process failure	Non responder	Moved	Language barrier	House bound	Multi-morbidity	Mental health	Palliative care
Controls	51	39 (77)	0	0	0	0	2 (4)	7 (14)	3 (6)	0
Cases	51	0	12 (24)	11 (22)	5 (10)	1 (2)	6 (12)	1 (2)	8 (16)	5 (10)
Service Failure	12 (24)	0	12 (100)	0	0	0	0	0	0	0
Non-service modifiable	18 (35)	0	0	13 (72)	5 (28)	0	0	0	0	0
Service modifiable	21 (41)	0	0	0	0	1 (5)	6 (28)	1 (5)	8 (38)	5 (24)

Table 3.3

Whole district analysis of factors associated with the Failed Access Score (FAS).

	All	FAS= 0	FAS= 1	FAS= 2	FAS= 3	
	16644	10171(61%)	3999 (24%)	1547 (9%)	815 (5%)	
Age	64±15	65±14	63±16	61±18	58±17	F=84.5 p<0.001
Male	9030 (54)	5558 (54%)	2121 (53%)	815 (53%)	475(58%)	χ^2=43.8 p<0.001
Ethnicity **White,** **Asian,** **Black,** **Other** **Unknown**	 4475 (27%) 2104 (13%) 699 (4%) 216 (1%) 9150 (55%)	 2879 (28%) 1307 (13%) 427 (4%) 49 (1%) 5505 (54%)	 1069 (27%) 456 (11%) 147 (4%) 37 (1%) 2290 (57%)	 367 (24%) 186 (12%) 76 (5%) 41 (3%) 877 (57%)	 160 (20%) 155 (19%) 49 (6%) 89 (11%) 362 (44%)	 χ^2=748.8 p<0.001
Type 2 diabetes	15575(94%)	9620 (95%)	3746 (94%)	1454 (94%)	755 (93%)	χ^2=8.5 p<0.05
Deprivation score	35±16	34±16	35±16	37±16	37±16	F=26.7 p<0.001
HbA1c missing	1838 (11%)	0	286 (7%)	737 (48%)	815 (100%)	χ^2=9939.7 p<0.001
ACR missing	4616 (27%)	0	2372 (59%)	1492 (92%)	815 (100%)	χ^2=11195.2 p<0.001
Retinal Screening missing	3084 (18%)	0	1341 (34%)	928 (60%)	815 (100%)	χ^2=8211.4 p<0.001

Discussion

We have demonstrated that readily available data can be easily used to identify people with diabetes who have failed access to structured diabetes care. Having flagged this risk, we have proposed a framework for the categorising the primary factors leading to access failure: service failure, non-attendance and patient related clinical and social issues. In the latter category, a further classification substructure emerges that indicates the prime reasons that might well require a specific individualised care plan. Therefore, access is complex, but one of the founding principles of any healthcare delivery model. Access however should not be confused with or use as a synonym of "default" or "loss to follow up". It has been shown that people can default from care due to several reasons. This can be a simple misunderstanding in terms of seeking medical help when deemed necessary as compared to the need for monitoring to help prevent complications (124). Attitudes towards the disease as well as clinic, obesity, young age and type of treatment were also found to be important factors in defaulters (125). There is a particular stigma attached to these terms that leads to a sense of unease and a bias in the minds of healthcare professionals, as the burden of default lies with the patient and considered as a hallmark of non-serious behaviour or disengagement from the service.

However it is extremely important to separate an informed dissent from care to multifactorial issues that put people at a disadvantage in complying with scheduled care. Therefore a broader concept of access to healthcare needs to be understood in the context of needs that can be broader than those that are related to a particular illness. Mostly patient related factors are considered to be the main reason for default, the specific nature of the influence of the factors that were identified is often elusive. Considering that younger people are more likely to default but whether it is because they just do not care, or whether it is related to their affordability to take time off from work or school to attend the clinic or they do not like paternalistic attitude of clinicians in the clinic resulted in dissatisfaction and appear as waste of time. People experiencing stress and anxiety related to their disease (126) as well as those who lack basic resources like a telephone or a car are more likely to default (127). Prolonged waiting times, increasing parking costs, inability to book or afford child care are also found to be considerable confounding factors in promoting nonattendance (127). Considering such a diversity of factors relating to default tailor made

individualised approaches needs to be taken to address the concerns and needs of patients. In order to understand the concept of access, there is a need of effective communication, patient centricity, a review of health –system factors such as operational hours, distance to the clinic and waiting times, and as further research to elaborate other factors resulting in default from care is needed to understand the concept of access (128).

In our study, we proposed a data driven method to identify people with failed access that may require specific and individualised method of care delivery to meet the needs of these people at disadvantage. Executing this process requires a model of care that is integrated across NHS providers, and organisational and care pathway divides. The WICKED (Wolverhampton Interface Care, Knowledge Empowered Diabetes) project aspires to be a system of structured diabetes care that is patient centric (129). This shifts the notion of integration of care provision from between services to integration around the patient (71, 73, 130).Crucial to this is data integration and the effective use of those data to target patients at risk. Achieving access is a key objective (131). In simplistic terms, process and outcome cannot be delivered without access. Access failure may relate to service structure, capacity, accessibility, availability and efficiency, or a number of patient related factors such as language, culture, social capital, social status and deprivation as well as physical and mental health (132-134). What is clear is that it is not easy to predict access failure (135). Yet failure of access is clearly associated with adverse outcomes (136), although whether enhancing access improves outcome is not clear. As a single measure, we demonstrate that the FAS can be used to identify and target actual access failure. This allows access attainment to become a hard outcome that can be subject to review, audit, governance and performance management. A further simple data drill down can determine those in whom service failures have occurred and those who do not wish to access the service (137). Regarding the latter, it is the choice of an informed and competent adult as to whether to engage or disengage with health care services. This choice may be influenced by many factors, but any such choice should be respected. We emphasise that a health care service must ensure that a person is fully aware of the consequences of disengagement before labelling them as having informed disengagement, and that it is not the intention of the FAS to simply identify those who are to be exempted from care. The FAS can identify such patients and help get beyond the simple concept of ‘default’. The FAS particularly applies to

those identified with associated social and medical problems. Mental health problems were found to be the most common of these constraints as is well known (132, 138). Other important groups were the house bound, those with comorbidities or those in palliative care. It was interesting to note that, when compared with the control group, comorbidities alone did not affect access until it was associated with dependency (139), and it is clear that such patients require an individualised care plan (140).

Another interesting finding is that there was no significant difference between ethnicities unlike many other studies that shows significant difference in ethnicities (141). This may be due to the small scale of this study, which means that this issue is hidden. On the other hand, it may be reflective of a real change, where with the passage of time, the diversity and evolution of local population has improved awareness in ethnic minorities to seek help and to look after their chronic diseases equally well as compared to Caucasians.

The strength of this pilot study is the highly matched control population and a standardised approach to data collection from one practice only, which will limit practice management and organisational bias. The limitations of the study are that it is small scale and only used 3 out of nine key care processes to compile FAS. However, since we conducted this study and upgraded our database to the capability to acquire information about all nine key care processes, we used the Failed Process Score (FPS) as a marker to measure patient access in our randomised controlled trial as described in forthcoming chapters. As FAS is a novel tool that has not been validated previously, it was difficult to estimate its accuracy to identify failed access.

There is a scope for a future qualitative study not only to validate FAS, but also as to gain a deeper understanding of the barriers to access to health care. In this regard there is a need to identify people at a disadvantage by using data effectively but in order to meet their needs there should be a better understanding of the perspective of these groups to define what strategies could work best with the different categories of people to deliver an equitable health care service in the modern NHS.

As demonstrated by this study, a database can be used in a variety of ways to help improve diabetes care delivery and one aspect of it to identify access failure to inform healthcare systems to take steps to improve patient access. There are other potential arenas to utilise this database in a meaningful way to improve direct patient care. Therefore, there is a need to further explore impact of incorporating a data driven patient empowerment strategy to increase active involvement of the patient in their care, for example, care planning consultations.

Chapter 4: Patient Activation and Care Planning

Background

"Patient activation" is a relatively new concept that has been studied extensively in last 2 decades (142). This terminology is better understood in the United States, where a lot of work has been done to explore the potentials of patient activation. However, the notion of patient activation has been synonymised in various terminologies like patient empowerment, patient enablement, self-care, patient engagement and patient centricity; across UK and has a longer history of understanding than the terminology itself. All these terms embrace the fundamental principle of active patient involvement in disease management. No one would deny that the patient who lives with chronic diseases has to execute their management plans on day to day basis. It is understandable that it can only be achieved effectively if the patients are active in their own disease management strategy. Therefore, in order to better understand this concept, we need to go through the underpinning principles and their evolution in the history of healthcare.

The concept of patient involvement in diabetes is not new, and as discussed in the first chapter, very earlier pioneers in diabetes care like E. Joslin (44) and R D Lawrence (47) have acknowledged that effective healthcare cannot be achieved without the intelligent co-operation of people suffering from the disease. However, this type of patient engagement requires a behavioural change from both parties i.e. patients and clinicians, in the consultation process (143). Traditionally, clinicians are trained on a medical model that focuses on the treatment of the disease, and can potentially overlook the holistic needs of an individual, and hence conflict with the notion of patient empowerment (144). This was based on the idea that the clinician knows best, and the patient's part in the consultation was to follow whatever has been told as an obligation. The benefit of compliance would outweigh the quality of life matters for the patients. This approach in chronic disease care delivery such as diabetes did not work, and despite all advancement in medical treatments, achievement of optimal control remains well below expectations (145-147).

Due to the evolution of information technology, people with chronic diseases have started to gain more information from multiple sources and growing evidence suggests that

people's involvement in their own care results in better outcomes (148). This has pushed healthcare systems to adapt this notion of active patient involvement in the healthcare delivery processes. This shifts the balance of healthcare consultation from a compliance model to a collaborative model of care, whereby a consultation is called a meeting between experts (149). This approach focused on three key aspects of disease management; choice, control and consequences. People living with diabetes have to make a choice in their day to day decision making in order to control glycaemic variability. These choices need to be informed, and a person should be able to exercise control in making these choices. Patients have control to execute their management plan in whatever way they wish to do so and as they are directly affected by the consequences of their choices and control, they should have active involvement in designing their individualised management plans (150).

This type of physician patient interaction has been evaluated from various aspects of improvement in hard clinical outcomes, behavioural change as well as patient satisfaction (148, 151-154) and was found to be effective. On the contrary, studies have shown that a patient empowerment approach may require a sustained length of time to show any benefits that can be as long as 6 years (155), and this may not be enough to produce a behaviour change (156). This empowerment may show an improvement in patient's confidence, due to acquired diabetes knowledge, but may not be translated into either psychological (self-care, satisfaction) or physiological benefits (157, 158). However all these studies have focused on the outcomes of interventions in which patient were empowered by the healthcare professionals and facilitation came from them, rather than patient's own initiatives or learning from information.

The simple fact of prevalence dictates that without empowering people to self-care for themselves, no system in the world would be able to meet the resources required to meet the needs of this slow epidemic. Therefore, this concept of patient empowerment that is defined as *"[a] process whereby patients have the knowledge, skills, attitudes and self-awareness necessary to influence their own behaviour and that of others in order to improve the quality of their lives"* (159) flourished further, to enhance people's ability to self-care. In the NHS the terminology of "Expert patient" was embraced by primary care long before (149) it was introduced in the specialist care (160, 161). The Department of Health (DOH)

proposed implementation of this concept, which should encourage people to take a key role in the decision making of their care process and will promote self-care; across all chronic diseases by 2007. At the same time, user-led self-management requires a cultural change that was anticipated to be difficult to implement. In the USA, Kaiser Permanente had a legacy to promote this cultural change, to the extent that vast majority of their people with diabetes are self-caring and the resources are diverted to either shared care for people who are at intermediate risk and specialised care for people who are at high risk of complications to justify the equity of healthcare without undermining the quality of care needed for the whole epidemiologic base (162). In the NHS, this concept of expert patient has met with mixed views. Those who are in favour of this policy see it as an opportunity to allow clinicians to build a rapport with their patients and a shared decision making will also facilitate the sharing of responsibilities and risks associated with the choices made in partnership with the patients themselves (163). It is also seen as a collaboration between users and providers where both are aware of their responsibilities and utilise this partnership to achieve best possible heath in given resources at hand (164). Others see it as a risk to the NHS, as the literal meaning of expert patient will provoke a conflict between healthcare professionals and the patients who can demand and argue for the things that are unsuitable, unproven or expensive, resulting in a breakdown of the patient-doctor relationship (165). This terminology has been criticised for lack of clarity, leading to misconceptions, with limited explanations of rights and responsibilities and a lacking of a strategy to challenge professionals' assumptions towards chronic diseases (166).

Patient activation is a relatively new term that incorporates six fundamental domains of self-efficacy, engagement in health maintenance, involvement in management of disease, collaboration with healthcare providers, choose and access the appropriate services and ability to navigate the healthcare system towards improvement. Thus, Patient Activation (PA) is a behavioural concept that can be defined as "'an individual's knowledge, skill, and confidence for managing their health and health care" (167, 168). One of the earliest demonstrations that patient activation improves diabetes related outcomes was reported in the form of an RCT at patient discharge from the hospital, which showed that people who are activated had better functional status after discharge (142). This was a short scale study, which looked at functional status in people who were trained to self-care after discharge. In

its own right, this only explored one of the six main domains of patient activation. However, this along with other concepts of people empowerment helped to develop a better understanding of PA in future.

This concept was further developed by Judith Hibbard in the USA, and to evaluate its impact, a comprehensive Patient Activation Measure (PAM) was developed in 2004 by adapting a robust methodology of literature review, expert consensus and piloting different phases of the scale (167). According to Hibbard et al., there are 4 levels of patient activation. At level 1, people with chronic illness tend to be passive in management of their own condition. This may well be due to lack of understanding of their role in the process of care. At level 2, with more activation, these people start to develop an understanding of their illness but lack knowledge and confidence to actively participate in their own care. At level 3, by providing them with knowledge and information these people develop confidence to start making day to day decisions for managing their condition, but they may still not be fully independent in making these assessments. At level 4, with the time and support, these people can eventually gain maximum confidence to act in an appropriate way to manage them, but at this stage, the issue is whether this level of functional capability can be maintained in the long run, and any level of stress can derail this level of patient activation (169). People with higher level of activation see PA as being in control and in charge of their own health (169) and these people have shown benefits in term of less use of emergency care and hospitalization(170) , better hard clinical outcomes markers like HbA1C and Lipids (171), better health related behaviours and less Primary care services utilizations (172). Nonetheless, fewer data are available about its cost effectiveness (173).

A meeting between an activated patient and a healthcare professional is supposed to be very productive and should produce a comprehensive management plan for the long term illness such as diabetes. This information can be captured in a written plan of care like “minutes of a meeting” as a care plan that can be taken as a written and mutually agreed agreement of care to guide future management plan of individual patient. Since the beginning of the 21st century, the DOH has promoted this concept of care planning to be incorporated as a routine process in all long-term conditions, including diabetes, with the vision that every one of the 15 million people with at least one long-term condition to have

an agreed care plan (174). At initial stages of implementation care plans were used as means to record a consultation and an agreed agenda that may help primary healthcare providers and patients to recall their last consultation but it was not very commonly used in multidisciplinary care provision (175) and its impact on diabetes outcomes were uncertain (176) but most of this evidence was from outside UK and was of small scale audits.

In the UK, care planning in diabetes was incorporated as a standard of care in diabetes NSF (57) and in collaboration with Diabetes UK; one of the leading charity of people with diabetes; a care planning in diabetes document was produced in 2006 (177). This document guided the principles of care planning in long term conditions in general, but focused mainly on diabetes. It incorporated many national DOH initiatives of people's involvement in self-care like "Our health, Our care, Our say "(178) and "Supporting people with long term conditions to self-care: a guide to developing local strategies and good practice" (179). In this report, it was acknowledged that to promote care planning a change in behaviour will be required from healthcare professionals as well as patients, the care planning process is a two way communication, negotiations and joint decision making underpinned by the fundamental principles of patient centeredness and partnership working. To execute these principles successfully, the "Disease-illness model" was proposed to be implemented when looking after people with chronic diseases (180). This model encourages clinicians not only to look at a disease from illness view point, but also to try to develop an understanding of the individual's experiences of that condition. This requires paying attention to patient's "Ideas, Concerns and Expectations" (181); a term very well known to primary care clinicians but not so well to specialist services. However a systematic review in 2009 to assess the impact of personalised care planning in diabetes showed that there is lack of evidence that the process of care planning was either implemented in its true sense or showed any benefits in diabetes outcomes (140).

In order to implement a comprehensive care planning process "Year of Care" pilot project was launched (130) across three sites in England. Key drivers of this projects was to develop a care planning strategy that can implement a personalised and tailored care plan that identify an individual's needs, issues, concerns, goals and actions, and can manage the tension between what the health care professional and the person with diabetes may view

as good outcomes while ensuring a supportive organisational framework is in place to support the whole process. Over 3 years this project has shown an improvement in number of care planning consultations, training of HCPs, improved experience, knowledge and skills of people with diabetes and has provided a platform to implement care planning process across the wider NHS (66).

However, despite these efforts, the implementation of care planning is patchy and can be a cause for concern for many HCPs. In practice, it might require an organisational change, shifts in attitudes and behaviours, large-scale education and training, extensive research, audit, evaluation and governance and, not least, funding. Sceptics may allude to this process as a 'tick-box exercise'. For specialists, it may be considered something best left to primary care, who in turn may think they have enough on their diabetes agenda. As part of a modernising agenda in our local WICKED model of diabetes care, incorporating a further shift to patient centricity, we determined the feasibility of introducing a care planning process into our routine specialist diabetes clinics. This pilot also assessed utilization of a patient information provision tool to the patient to promote patient activation, as well as role of this tool in care planning process for future implementations.

Aims

To establish that people with diabetes can understand a structured document mapped against all 9 key care processes in diabetes and can use it as a template in their consultation with healthcare professionals

To establish that a structured document can assist healthcare professionals to standardize their consultation and enable them to do care planning and generate a care plan at the end of the consultation.

Hypothesis

A simple but structured document containing key care processes in diabetes provided to the patients before their clinic appointment can align the patients and healthcare professionals to participate in a care planning consultation with a view to generate a mutually agreed care plan.

Methods

A structured document was designed to facilitate a care planning process. A design group was established, including lay patient representatives, clinicians, a medical illustration expert, and a trained diabetes education facilitator (Expert Programme). National Health Service guidance for patient information materials was used to set design standards (All these processes are discussed in depth in the methodology chapter). The finalised document constituted a simple diabetes care planner mapped against all core diabetes care processes incorporating an adult reflective learning approach (182) driving a 'Do, Review, Learn, Apply' process focused on promoting understanding. It emphasised engagement, enablement and empowerment, with the intention of facilitating patient driven care. At this stage, the document did not contain individualised patient level information (such as their weight, HbA1c etc). This finalised document was piloted in 50 patients consecutively attending a general specialist diabetes clinic for acceptability.

Following the results of this evaluation, the document (Table 4.1) was used in structured care planning, which was agreed and introduced into all of our routine diabetes clinics. The care planning document was given to 148 consecutive patients and a total of 12 clinicians participated in this one-week-long trial. All clinicians were consulted and orientated in the

process, and perceived challenges relating to alterations in routine consultation were highlighted and discussed with the intention of standardising the whole process. Every patient was given a copy of the document on arrival, and while waiting for their appointment, they were asked to read it and to reflect and comment on each parameter. There was no training or orientation. The completed document was used to structure the clinical consultation. In this consultation, each domain was mutually reviewed, discussed and a plan agreed. This was summarised into the dictated clinic letter addressed to the patient, in the first person, in the presence of the patient. A copy of this letter was sent to their general practitioner and other health care professionals as needed (the intention being that all aspects of the management were overt to the patient, no matter how complex, challenging or controversial). Hence, this clinic letter served as documentation of the care planning process, as the written care plan and as the communication of that plan to all other relevant heath care professionals. After the consultation, every patient was asked to complete a questionnaire to assess satisfaction, consultation alignment, productivity, engagement, patient–doctor relationship, and mutual learning and understanding. Each participating clinician was given a questionnaire to summarise their views at the end of the one-week pilot.

Fig. 4.1: Final structured care planning document

Dear Patient

Please look at your diabetes information overleaf. Please prepare yourself for your consultation with your nurse or doctor. Have a look at the various headings in the table and work out whether you think your position is good, borderline or is of concern. If so think about what you would like to improve and what you might do to improve it. Please show this letter and information to the doctor or nurse that you see and be sure that your concerns are discussed and dealt with in the consultation.

My Diabetes Plan		
Where do I stand?	**Where do I want to be?**	**How do I get there?**
My Lifestyle (Diet, exercise, smoking) Good , Borderline , Of Concern		
My BMI (Weight) Good , Borderline , Of Concern		
My Blood Pressure Good , Borderline , Of Concern		
My Cholesterol Good , Borderline , Of Concern		
My Circulation Risk Low, medium, High		
My Eyes Good , Borderline , Of Concern		
My Kidneys Good , Borderline , Of Concern		
My Feet Good , Borderline , Of Concern		
My HbA1C (sugar control) Good , Borderline , Of Concern		
My Hypo risk (risk of low blood sugars) Low, medium, High		
My Medication Good , Borderline , Of Concern		
My Diabetes Knowhow Good , Borderline , Of Concern		
My Well-being Good , Borderline , Of Concern		
My Comments: ◯ Clinic staff to circle if unable to use forms in English.		

Results

Patients' views of the care planning consultation

We surveyed all 148 consecutive patients attending our routine diabetes clinics in one week, of whom 101 completed the form and responded to the questionnaire (Table 4.1), while others used the form, engaged in the process but did not return the associated questionnaire. Thus, we only captured the demographics of the 101 respondents (55 male, age 60±12 years, duration of diabetes 12±9 years, 67 on insulin, 3 new and 98 review patients; 63% were Caucasian, 14% Asian, 4% Afro Caribbean and 19% unknown ethnicity).

Patients scored the process 'good' or 'very good' at around 80% for each question. Almost all patients (98% of those who replied to the final two questions) were happy with the behaviour and attitude of the doctor, and/or would be happy to see the same doctor again.

Clinicians' views of the care planning consultation

All 12 doctors responded to the questionnaire (Table 4.2): six consultants, five middle grades, and one GP hospital practitioner. They generally rated the structured, patient-driven consultation process as 'good' or 'very good', reporting increased patient engagement, shared decision making, and better communication; they felt it was more time consuming though worthwhile. Crucially, this increased their insight into the patient's needs. Another important point was that most clinicians felt that this was a learning opportunity that improved their consultation.

Table 4.1

Outcome of a patient satisfaction questionnaire of the care planning consultation (undertaken as described) using the structured care planning document within a defined standardised process (n = 101 respondents of 148 surveyed with 8 questions against a 4 point scale: poor; satisfactory; good; very good).

Questions	**Good or Very Good** Of 101 respondents
Do you feel the consultation covered your medical problems?	81
Were your concerns and questions addressed?	76
Did you receive a clear explanation of your medical care?	81
Were you given a clear explanation of what will happen next?	79
General opinion about the care planning process?	77
How did you find the overall attitude and behaviour of the doctor?	82
Would you be happy to see this Doctor again?	81

Table 4.2

The outcome of a survey of clinician undertaking (as described) a standardised structured care planning consultation (n = 12 surveyed with 13 questions against a 4 point scale: definitely not; maybe not; yes maybe; yes definitely).

Question	**Yes (N, %) (definitely or may be)**
Does the care planning document facilitate the consultation?	10 (83)
Did you find patients were more engaged with the consultation?	10 (83)
After the patient had done some reflection with the help of this document, do you feel that the document helped align the patient's agenda and the clinician's agenda?	9 (75)
Do you feel you had a better understanding of the patient's concerns?	9 (75)
Do you feel this document helped you to structure your consultation to address the concerns and needs of the patient?	10 (83)
Did the patient's document enable you to do care planning and generate the clinic letter in a structured way?	9 (75)
Do you think your clinic care planning letter to the patient will enable the patient to recall and reflect on the consultation at a later date in a positive way?	11 (92)
Do you think it is appropriate to write to the patient cc GP with this sort of information (rather than write to the GP with or without cc patient)?	9 (75)
Does this type of consultation require more time than usual?	7 (58)
Does dictation of a structured letter consume more time than usual?	9 (75)
Assuming more time was felt to be required - do you feel that it would be worth it?	9 (75)
Do you feel it is a good idea to incorporate this process into routine diabetes consultations?	9 (75)
It is hoped that the process is also a learning opportunity for the professional. As a reflective practitioner, did the process increase your insight into the patients' needs and there by improve your own consultation skills?	9 (75)

Discussion

As a principle, it is important to understand the difference between a care plan and care planning (177). A care plan is a document. Care planning, however, is a process. The implementation of care planning into practice is a new experience for both patients and clinicians, and it is ill defined. With the shift to concordance models of care that respect and incorporate the patient's views into day-to-day practice (183), the struggle is to know how to make the fundamental principles of patient centeredness, enablement and empowerment a reality (159). Care planning is a crucial tool that is intended to align the needs and agendas of patients and clinicians alike into a joint consultation, to facilitate meaningful, shared diabetes management planning, and in order to promote better care and outcomes.

The risk, however, is that a care plan will be drawn up by a knowledgeable and trained professional 'for' a patient who lacks knowledge, information and an understanding of their diabetes or the process. To mitigate this risk, it is necessary for a patient to understand their diabetes and their role and rights within the intended process, and for the intended process to be well defined. Conventionally, it is considered that education is the means by which patients acquire this knowledge, and become more expert. Education aside, the biggest failure within current ways of working may be that patients do not have specific information about their own diabetes in order to make assessments or decisions and this has been evidenced, as has been the impact of information provision (184). In this process, we did not provide generic diabetes education to patients, nor any specific training on how to use the document or on how to engage in the process, and the document did not contain specific patient-level information. The contention was that within a structured framework of judging or assessing themselves, patients would be able to reflect on and express their own perceived position on various domains of diabetes care, however accurate or inaccurate, and that this could be used as a platform for a constructive dialogue. In relationship to that dialogue, a key challenge was the need to ensure that the consultation behaviours of clinicians were calibrated to the needs of the care planning process: to value and use the completed document; to be respectful and be receptive to the views expressed by patients in that document; to engage in a structured and systematic way in a formative dialogue in each domain outlined; to agree and not impose a plan of action; and to ensure the

documentation and communication of the agreed plan were in partnership with the patient. This did not require any major effort, but a short simple orientation – focusing on an awareness of their role and responsibilities in a patient-centric and patient-driven care process leaving them to adapt their personal style to facilitate such consultations.

It was, however, useful for clinicians to be aware of notions of patient activation and the positive impact of motivational interviewing on self-management, psychological and glycaemic outcomes (185) although it can be influenced by participant and delivery factors of these types of motivational interventions (186). However such interventions may help them to engage their patients at a constructive level of partnership working, tailored to that individual. There is evidence that effective physician– patient communication results in better health outcomes (154), and short duration training in this context has been found to be as equally effective as long-term tariff training (187). Thus, this was not an extensive, taught process, but an expectation for modified or learned behaviour. All of this was done in less than 1 hour in one of our standing educational meetings, with about 1 hour of preceding awareness raising and orientating information provision by email.

Thus, from what might have been a very difficult process, underpinned by a number of complex underlying principles, this translated into a simple mechanism – a simply structured systematic document based on a reflective model; completed by patients with no orientation or training (while waiting); encouraging patients to self-assess their diabetes (agnostic to their attitudes, aptitudes or knowledge); formulate a potential plan; be free and comfortable in expressing their concerns; setting an expectation that these will be respected and addressed; defining for clinicians the nature of that expectation; establishing a standardised process by which the transaction might be executed.

The outcome was positive from both the patients' and the clinicians' perspectives. Clinicians had the perception of increased time allocation; however, this process has not had any effect on either the number of consultations/clinics or the 30 minute waiting time target and, since this pilot, the care planning process has been incorporated in all of our routine diabetes clinics without any additional time allocation. Evidence suggests that such consultations might not take more time, but rather, are more balanced and more focused (188), although others have suggested the potential of a negative impact (130). Thus, based

on the principles outlined, and from a patient and clinician perspective, we believe this to be the first published evaluation of the framework methodology for the implementation of a diabetes-specific care planning process, although in a controlled study others implemented a similar process to find positive outcomes in the content and structure of the resulting consultation (188).

The principles and philosophies underpinning the 'Year of Care' project are common to those outlined here, and authors have published on the development of their process and qualitative analysis of the perceptions of patients and professionals, although we are not aware of quantitative outcomes.

We conclude that worthwhile care planning can be introduced into specialist diabetes clinics with little effort or no expense. Based on the findings of this pilot study, we planned to conduct a large-scale, randomised controlled trial to examine in detail the effectiveness of a care planning tool that empower people by providing them with their individualised diabetes information, on the quality of care in diabetes and its related outcomes.

Chapter 5: Wolverhampton Interface Care, Knowledge Empowered Diabetes-The WICKED Project

Based on the learning gained from the historic and current models of care delivery across UK, we have restructured our diabetes care delivery in a new model of integration in Wolverhampton called "Wolverhampton Interface Care-Knowledge Empowered Diabetes" (WICKED). So far, all the models of care delivery have incorporated one or the other facets of integration and have explored that facet well but we aimed to develop a model that can embrace all aspects of integration not only among the services but also integrate active, informed and empowered people within the service delivery model of care. This is an attempt to shift the focus from a service centred approach to a people centred approach of care delivery. In previous chapters it is discussed that all these models of care delivery were perhaps rolled out as a service development, hence the lack of evidence around their outcomes. Therefore, it is important that every model of care should have fundamental principles embedded in the delivery of care backed by a research framework to extract robust evidence in order to implement the benefits of such a model to the wider NHS community. Our model is based on eight fundamental principles discussed below.

The principles of WICKED model

That the model has Corporate Governance

Clinical Governance is well defined in the new NHS, which imposes statutory duty on all healthcare organisations in the NHS to ensure quality improvement (189). Key components of clinical governance are well described (190, 191) as the mechanism to ensure improving quality in health care delivery as defined by the WHO. It is divided into four aspects of professional performance, resource used, risk management and patient satisfaction with the service provided (192). Most clinicians generally understand its attributes, and strive to achieve best quality of care.

Yet within a fragmented NHS attempting to operate a complex care long term condition such as diabetes across variously commissioned internal boundaries without wider corporate governance (193), clinical governance often feels like a futile pursuit. In order to deliver effective clinical governance, those accountable and responsible for any model of

health care delivery must consider the following aspects: Organisational governance, so that the requirements of the model are formally agreed to be implemented within and, most especially, between relevant organisations; Structural Governance, so that the resources and infrastructure are in place and can be managed to deliver that which has been agreed to be delivered; Financial governance, so that funding is in place and properly managed and effectively utilised and, perhaps of most vital importance, Data Governance without which there is no potential for informed decision making on the basis of evidence.

That the model is Ethical and Principled

In the UK it is an obligation of the NHS that every person has a right of health care regardless of geographical, social, cultural or ethnic boundaries. The core principles are well understood (118). They are embraced in the Tavistock Principles (194) of rights, balance, comprehensiveness, co-operation, improvement, safety and openness and extended to notions of effectiveness, appropriateness and rationing, in Justice for Health (118).

That the model is actively User Centric

It has almost become passé to claim that service delivery is patient or user centric, but all too often, this is a service centric notion of customer care. In service design terms, however, this feeds into the concepts of equality and equity of access (195), effective and appropriate care, risk driven care and the potential to impart benefit without causing harm. Thus it drives care in relationship to Need, and then requirement for capacity management and prioritisation (if rationing is too emotive a term). It changes the aspirational notions of integrated care to a practical out turn impacting at the patient and service interfaces and at the inter service boundary.

Further, the model links in a somewhat more abstract or intangible way to concepts of patient empowerment, engagement and activation (196) and it means that these become necessary outcomes of the proposed model in their own right, without which the power dynamics cannot shift from compliance to concordance or from a hierarchical relationship to one of partnership, as now needs to be epitomised in modern concepts of care planning with a modern understanding of roles and responsibilities (140, 197).

That there is Equality and Equity in service Access, Process and Outcome

Care cannot be provided to those who do not or cannot access it, and when they do access it the provision of care may be partial or incomplete in terms of process, and clinical outcomes cannot be delivered without process. The final delivery of good and appropriate outcomes requires further variation according to "Need" and the "potential to benefit". Even then, the attainment of good outcomes may not be the governed and performance managed end point of effective access and process provision.

Equality of "Access" to healthcare can be taken at face value at the level of geography, availability, acceptability, meaning an equal or fair opportunity to access a defined provision of care (110, 131) but it must also be about quality. Equity in healthcare is the practical corollary of the relationship between "Access" and "Need" to provide the same services to people with equal need and varying ability to access it (Horizontal Equity) and different services to those in different, worsening or escalating health care need scenarios again with variable access constraints (Vertical Equity). Equity is the notion by which, for example, a person with diabetes and severe psychiatric illness would receive effective care to prevent end stage diabetes morbidity that an equal provision of funding, resource and services would simply not attain. Equality extends to equity when resources and services are flexed (and thus become unequal) to attain equal access, process and outcome. Thus the attainment and measurement of equity is complex and difficult to either execute or evaluate (198). The huge geographical variations in delivery of diabetes care and in hard end point clinical outcomes across the UK despite national frameworks of structured and audited care delivery manifestly reflect the failure to execute equality and equity (26).

That the model is Effective, Efficient and Appropriate by linkage to Risk and Modifiable Risk

The concept of Need is diverse, and all too often the key driver, but it can be moderated and simplified by applying the principle of "capacity to benefit" (199) which in turn relates to concepts of risk and modifiable risk. Interventions that can modify risk are amenable to analysis of related benefit and harm. Whilst this involves a judgment of benefit, it can be

informed and justified on the basis of available quality clinical evidence and cost benefit analysis (118).

Orientation and Integration at the Interface

Orientation

True user centricity drives model design away from service centricity. A conventional service centric model is often depicted as being 2 tiers (primary and secondary care) or maybe 3 tiers (primary, intermediary, and secondary). In such models, the patient is often an invisible commodity. Their ownership is with organisations that have discrete boundaries and internal corporate, financial and clinical governance agendas which may become territorially and competitively counterproductive. Meanwhile, the worthiness of community care is relegated to notions of geography and organisational positioning (e.g. none acute), and the value of specialised care according to specific need is lost.

In WICKED, the patient is depicted centrally, in the context of their friends and family, and set within their community. This provides a formal framework to contextualise the relevant needs of the patient and their community. Thus, Community Diabetes becomes that form of specialised care that meets the needs of people whose diabetes presents additional difficulty in their community context to a degree that they lose equity in diabetes health care and are thus disadvantaged. This may be because of social isolation, immobility, dependency, multi morbidity, dementia, psychiatric illness, end of life care needs or it may be in the context of work or schooling. A crucial example of this is a community start-up of insulin therapy, which may simply be in an NHS environment out of a hospital but this geographical shift should not be taken anything more meaningful than just being more convenient. It would not however qualify as a community start of insulin within WICKED, which is about additional and significant risks imparted in their personal and community context such as social factors, the home environment, the setting within their family, dependency and care needs, work or school based problems not to mention attitude, aptitude, vision, dexterity, and hypoglycaemia risk. The patient, with their various levels of complexity, interfaces with the NHS (and vice versa) in 2 blocks, primary care and specialist care (and this is not simply specialist diabetes services) and these 2 care blocks interface

with each other. These are not organisational boundaries, but relate to care needs being self-care in the context of their community, primary health care and specialised health care.

Integration

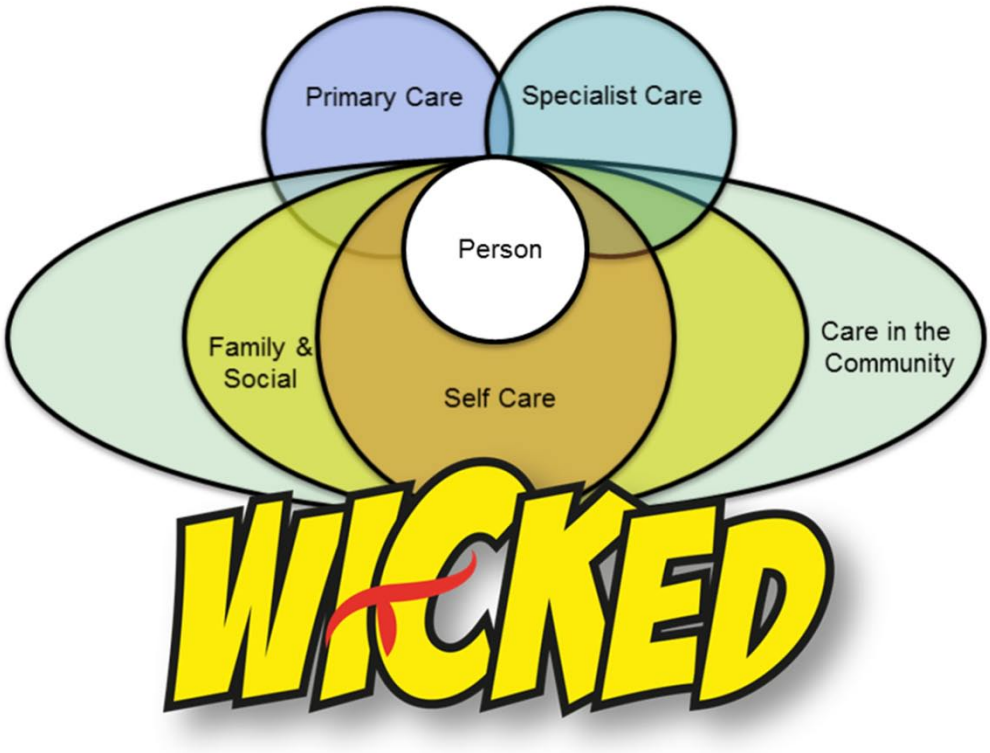
Faced with growing demands, an ageing population and an increased prevalence of diabetes, fragmented service provision in the NHS will result in wasted resources and poor outcomes. Accordingly there is a desire to move to integration of services to extract efficiency benefits (85). Although often discussed, the implementation of integrated care is still sporadic and often local to individual health economies and anecdotal. Added to this is the lack of evidence base to determine its effectiveness and sustainability in the wider NHS (200). Various UK models of diabetes care have tested different components of integration, but there is little outcome data available (66, 69, 71, 73, 75, 201), largely because they relate to service redesign implemented without the research methodology needed to provide evidence. Not only may it be difficult to achieve but it remains poorly understood. For true integration, health organisations need to work together at various levels.

- Macro-integration is the alignment of commissioning and service providers to deliver the healthcare needs of an entire population and, whilst it is considered effective, and has been successfully achieved in various USA HMO models in the USA (202-205) it seems almost impossible to implement it in the current NHS governance model.
- Meso-integration is the inter or intra organisational delivery of health to particular groups or categories of patients, often encapsulated within care pathways (206-209)
- Micro integration focuses care provision to individual patients (210, 211).

Micro Integration, Model Integration and Integration at the Interface

Understanding of patient interfaces is vital to develop a patient focused model of care and to integrate services according to the needs of the people. The figure below (Fig 5.1) highlights those interfaces that a person with diabetes will have in their daily life. These interfaces are unique for each individual depending on their social circumstances, care needs and disease specific needs. Therefore, these interfaces are fluid in nature, and can significantly change in proportion over a period of time and hence a model of care should be aware of these interfaces and tailor the delivery of care to meet the ever changing needs of the patients and their interfaces.

Fig. 5.1: Ideology of patient centric interface care



Whilst macro and meso integration are vital, it is at the point of micro integration, at the level of the patient, which failure of care manifests, is most readily measured and is so depressingly destructive. It may not be inter organisational integration that will address that failure. Thus, an obligation for services to integrate should not be confused with the need for the governance of a model of care to be integrated in order to identify those at various risks and drive care. To address that risk, the requirement may be for the responsible service to deliver more effectively (patient / service interface), for services to co-work, or for transfer of care provision between services (inter service interface). Indeed, integration may become counterproductive when its execution generates further potential for failure (e.g. failure to identify those at need, referral based systems that fail), or where accountability and responsibility becomes confused and as such these interfaces are known to be the most likely point of breakdown of effective care and communication (212). Complexities in integration extend even further, such that a patient on retinopathy, foot, renal, glycaemia and hypertension pathways may not receive effective inter care pathway integrated care. The model should thus be effective in delivering equity of access to appropriate and effective care through model driven patient centric integrated service provision, and, in this context, integration has a broad remit.

Thus, in our model of care, the aspiration is for a commissioned framework, with both corporate governance and clinical governance, with clear ethical principles, based on user centricity (with activation, empowerment, and enablement), with an imperative to deliver equity of access to appropriate and effective care that through model driven patient centric integrated service to drive service provision.

The Structure of the WICKED model

A model that covers the whole epidemiological base works on the basis of push and pull. It endeavours to "Push" people to self-care by promoting information, knowledge, empowerment and building confidence to promote shared decision making-a notion called patient activation. It "Pulls" people who are at higher risk identified by data governance and streamlined by risk stratification into a seamless integrated primary and specialist services framework to break clinical inertia-a notion called service activation.

Patient Activation

Although patient activation is a term that has been in use for last 2 decades, it is not clear what activate the patients. There is a wide spectrum of interventions from education to consultation to care planning and partnership working that can potentially activate patients. In the WICKED model, we used information provision as an intervention to activate the patients. We believe that all individuals have the capacity to learn from the information. When such information is provided in a simple yet structured format, it starts a thought process and urges people to explore further information. According to the theory of change, a person needs to be dissatisfied about a situation and should be able to visualise a better future, and combining with the first step taken towards change exceeds the resistance to change, the change happens (213). We believe that information provided in a structured way can act as a catalyst for dissatisfaction, and can provide an insight into how the future might look like. Furthermore, the encouragement to reflect and set personalised agenda to take first step towards the change can be the key. The current project is based on the hypothesis that information provision used as an intervention can activate people to change by completing their key care processes as a first step in their diabetes care delivery. In the next chapter, it is explained how this hypothesis of patient activation was tested in a large scale RCT.

In the WICKED model, activated patients are supposed to self-care as well as informed and empowered patients will be able to set personalised goals and develop an individualised care plan by working in partnership with their healthcare professionals.

Other facets of patient activation include the provision of tailored education according to the needs of the patients based on actual or perceived benefits to the individuals rather than adapting a blanket approach to provide structured education to everybody that may not be the requirement of that very individual, and hence a waste of valuable resource. It is evident that the uptake of such structured programs is sub optimal across the country, despite being in place for over 10 years (26).

Therefore, we believe that patient activation is a core component of the WICKED model that enables the concept of patient centricity and allows users to integrate at a level of service-user interface that permits them to drive services according to individual needs, rather than in direction of service directed pathways.

Service Activation

Service activation is a new term used as a part of the WICKED model of care. To understand the concept of service activation, it is important to provide a brief overview of patient's journey through different care pathways in a standard NHS health economy.

Most patients come into direct contact with their primary care physicians who are responsible for providing both acute and chronic disease management to the patients usually for a long period of time. Primary care clinicians manage most of conditions themselves and if further help is required, then the referrals are made to multiple providers of community and specialist care. For a person with diabetes, diagnosis is usually established by their GP except in the case of type 1 diabetes, which can present direct to hospital via Accident and Emergency (A&E) department in the form of a medical emergency called Diabetic Ketoacidosis (DKA). GPs manage the diabetes based on the NSF, QOF and standard nine key care processes up until the point when patients need specialist treatment, usually in the form of injectable therapies or complications related input. Community services such as podiatry also require referral from the GP to review people with diabetes related foot problems. Most of these pathways are referral dependent, and require a healthcare professional to trigger a pathway to let people access the services they need.

Clinical inertia in diabetes is now well recognised, and is defined as "failure of healthcare providers to initiate or intensify therapy when indicated" (214). Significant delays in intensifying the treatment in people with diabetes results in poorer outcomes (215, 216). This inertia not only exists in primary care (217), but also in specialist services (218), as well as during hospitalisation (219, 220). It is a complex issue, with multiple factors contributing to it such as poor patient concordance and adherence to the treatment (221), healthcare system related barriers and impaired perception about responsibility among clinicians (222). One key enabler to overcome this issue of clinical inertia can be pan systems, data driven risk stratification of people based on their clinical parameters regardless of their care settings. Hence integrated co-working informed by effective data governance to overcome clinical inertia is a core principle of the service activation limb of the WICKED model of care.

In WICKED, we use referral free, data driven risk stratification to inform both primary and specialist care services to focus people who are at higher risk of diabetes outcomes to provide integrated services to meet the needs of those people. In this process, the Wolverhampton is divided into six clusters that comprise of a group of GP practices, their named consultant, named diabetes specialist nurse and an allocated prescribing advisor. By using the database, all people with higher clinical risks based on three parameters including HbA1C, BP and Cholesterol levels are identified virtually (Table 5.3). Lists of these people are forwarded to each GP practice, and their named diabetes consultant and DSN for review prior to arrange a face to face meeting of the team to discuss all those patients to devise an action plan. These meetings are arranged by mutual agreement between primary and specialist care team, and are attended by the practice nurse, lead GP and diabetes consultant and specialist nurse. All patients are virtually reviewed for their access constraints, risks, diabetes care processes and long term outcomes. This whole process is repeated after 6 months to monitor the progress and to continue with the action planning to target high risk people.

This approach results in an interface care development, whereby primary and specialist services operated independently yet coming together as an overlap to create an interface for the high risk patients to be managed in a timely and adequate way hence addressing failures of referral pathways as well as issues around clinical inertia (Fig 1.5). This is what we call service activation across NHS bounds. We believe that it is very hard to deliver a standardised service to every person with diabetes, and principles of equity and equality in care should be observed when trying to utilise resources in a most efficient way.

Table 5.1: Data driven risk categorisation of the whole population including failed processes.

Parameter	Any result n =17323	15 months	Value (Any)	Higher risk levels	Failed Outcome Clinical Risk Tier 1	Failed Outcome Clinical Risk Tier 2
HbA1c	16736 (96%)	15598 (90%)	7.6 ± 1.65 %	≥7.5, 6553 (38%) ≥8.5, 3701, (21%) ≥9.0, 2665, (15%)	Any of HbA1c ≥ 8.5, SBP ≥ 160, Chol ≥ 6 4807 (28%)	Any of HbA1c ≥ 9, SBP ≥ 160, Chol ≥ 6 3777 (22%)
SBP	16446 (95%)	15750 (91%)	133 ± 15.3 mmHg	≥140, 4249 (25%) ≥160, 864 (5%)		
Cholesterol	16670 (96%)	15322 (88%)	3.8 ± 1.4 mmol/l	≥5.0, 2777 (16%) ≥6.0, 1020, (6%)		
Smoking status *	15848 (91%)	15848 (91%)	Never, 9086 (53%)	Current, 2143 (12%)		
Vascular status *	17323 (100%)	17323 (100%)	Primary 13319 (77%),	Secondary, 4004 (23%)		
1^{O} CHD Risk Score*	12094 (91%)	12094 (91%)	14 ± 8 % over 10 years	≥15%, 5019 (29%) ≥30%, 582 (3%)		
Any Macrovascular	1^{O} CHD Risk Score >=30% or Secondary			4586 (27%)	1382 (29%)	1125 (30%)
Retinopathy	16197 (93%)	14321 (83%)	None, 9701 (56%)	Any retinopathy, 6496 (38%) Vision threatening, 1712 (10%)	2332 (49%) 802 (17%)	1835 (49%) 633 (17%)
Creatinine	16795 (97%)	15762 (91%)	90 ± 47 umol/l	≥120, 1743 (10%) ≥150, 735 (4%)	552 (11%) 264 (6%)	457 (12%) 229 (6%)
E GFR*	16795 (97%)	16795 (97%)	77 ± 23 ml/min	≤60, 3809 (22%) ≤30, 466 (3%)	1035 (25%) 177 (4%)	818 (22%) 160 (4%)
ACR	16187 (93%)	13938 (81%)	10.0 ± 46.0 ug /umol	≥10, 1047 (6%) ≥30, 899 (5%)	801 (16%) 399 (8%)	679 (18%) 343 (9%)
Any Renal	Creatinine > 120 or e-GFR ≤60 or ACR≥30			4206 (24%)	1235 (26%)	989 (26%)
Any Retinal or Renal	As above + any Retinopathy			8793 (51%)	2862 (60%)	2250 (60%)
Any Vascular	As above + any Macrovascular			10463 (60%)	3272 (68%)	2594 (69%)
Foot	15105 (87%)	11965 (69%)	Low risk, 6724 (39%)	High risk, 3123 (18%)	873 (18%)	704 (19%)
BMI	14558 (84%)	14266 (82%)	30.8+-6.3 kg/m^2	>30, 7255 (42%) >40, 1201 (7%)		
Failed Access & Process		5506 (32%)			Either 8594 (50%) Access, 3787 (22%) Risk, 3088 (18%) Both, 1719 (10%)	Either 7927 (46%) Access, 4150 (24%) Risk, 2421 (14%) Both 1356 (8%)

Project Plan

Aims and Objectives

1. To confirm that full data acquisition from multiple data sources into a centralised diabetes register can be attained and validated regularly within a fragmented English NHS.
2. To establish that delivery of a structured report reflecting process and key outcomes in diabetes individualised to each patient is possible despite the above barriers.
3. To determine whether people with diabetes can utilise such a structured report based on key diabetes parameters relating to diabetes care processes in a way which drives objective improvement in their processes completion rate.

PICO of Project

Population

All people with diabetes over the age of 18, both male and female, with all types of diabetes diagnosis, and registered in Wolverhampton Clinical Commissioning Group (WCCG) area, were recruited in the trial.

Intervention

Delivery of an individualised structured diabetes care process and outcomes report in the form of a printed A4 size booklet via postal mail to the population described above. The active group will receive this booklet at 0, 3 and 6 months intervals and will be compared against a control group that will receive this document once at 3 month.

Comparison

At 3 months' time point, active group who received one mailing will be compared against a control group with no mailing. At 12 months active group who received multiple mailings (n=3) will be compared against a control group who has only received one mailing.

Outcomes

Primary

1. To determine that such a structured and personalised information booklet can be established and mail delivered to a large population covering the whole epidemiological base in a local health economy.
2. To observe any change in the completion rates of nine key care processes in diabetes reflective of patient activation induced by the intervention.

Secondary

1. To determine whether people with diabetes like to receive such information and can utilise it to activate themselves to self-care.

Study Registration:

The study was registered in the UK national research database (UK CRN ref: DRN 795, available at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=14324) and US clinical trials database (Clinical Trials Registration: NCT02200965).

Funding:

British Medical Association (BMA) Joan Dawkins Grant 2012 partly funded this project but has no role in either execution of the project or writing of this thesis.

Ethical Approval:

Ethical permission was obtained from NHS Health Research Authority, NRES Committee North East-York; REC Ref 13/NE/0052; IRAS project ID 117977 (See Appendix 3). Further clarification was obtained from National Information Governance Board as per REC recommendations.

Research Methodology

Establishment of the database

Establishment and validation of an electronic district diabetes register has been discussed in detail in Chapter 3.

To instigate this project, a functional and up to date database was of the utmost importance. Before the project could be executed, we established both clinical and demographic feeds into the database that was getting updated as a complete dataset at least once a month. Our multisource feed included data from the primary care data warehouse, retinal screening programme, hospital Patient Administration System (PAS), local pathology lab and direct data entry from our paperless inpatient and outpatient diabetes specialist services. This database was subject to a rolling process of revalidation against hospital coding system and against NSTS on a quarterly basis, to ensure the accuracy of the information that is consistently found to be more than 95% accurate. Patient movements in and out of the area, updating new diagnosis and deceased patient status were a few challenges that were faced in the day to day maintenance of this database. All people who were alive on 30/10/2013 were downloaded and included as a baseline population for the project.

Development of Project Intervention

This project is based on the provision of information about nine care processes directly to people with diabetes. To execute this information provision we needed to develop a highly structured yet simple tool that could not only deliver the desired information to the people in an understandable way, but could also encourage them to take the necessary action to make the required change where applicable. To develop this tool, a research focus group was established that included 4 lay people with diabetes, representing 2 local public diabetes networks, a local diabetes structured education programme trainer (EXPERT Program), 3 clinicians (2 GPs and 1 hospital consultant) and a graphic designer from the medical illustrations department of a local hospital.

During the first meeting, the agenda was to develop a tool that can serve the purpose of information delivery to the patients. After agreeing on the basic domains to be included in

the tool, the task to develop a document to reflect those domains was allocated to the author. A questionnaire with guidance notes and reflective plans was developed, and subject to discussion in the second meeting. The agenda of this meeting was to discuss the purpose, comprehension, utility, centricity, value, relation to diabetes management, and novelty of this report. The layout, design and colour scheme were also discussed. We further discussed the development of a patient questionnaire that could assess all the above mentioned aspects of this report.

After the second meeting, a document was designed with the help of local medical illustrations department. A detailed structured questionnaire consisting of 16 questions was designed to inquire about all above mentioned domains, and was given to the focus group for review by e-mail. After seeking approval from the group, this document was given to 50 consecutive patients attending the diabetes centre clinic over a period of 2 days. The structured questionnaire was used to receive their anonymised feedback. The results of this pilot are available in the results section of this chapter.

The outcomes of this pilot were presented to the research focus group and based on the outcomes, final amendments were made to develop the final booklet that was edited accordingly and was resent to all members of the group to seek final approval. After these 3 cycles of development, a final project intervention document was created (See appendix 1).

Project Intervention Tool "My Diabetes, My Information, My Plan" booklet

The project intervention tool is size A4 booklet named "My Diabetes, My Information, My Plan" (Attached as appendix I). This booklet complies with standard NHS written information provision guidelines. It is printed in a yellow colour with dark black text that has the most visibility for people with impaired vision and colour blindness. All text meets minimum requirements of readability in terms of font size, and scored 6 on Flesch-Kincaid Grade level readability test. This document is based on the fundamental principles of adult model of learning "Do, Review, Learn, Apply", which maintain that all adults can learn from the information provided to them in an easy and understandable way, and once they are empowered by the knowledge of this information, they have the ability to reflect and act so as to achieve better self-care and diabetes outcomes.

In this document, the first page introduces the document to the recipient. It navigates the person to read the detailed guidance of how to use this document and further available guidance on the back page. It also allows them to ring on a phone number in case they have any questions around the utility of this document or to inform us if there is any change in their circumstances.

The middle 2 pages of this booklet contain all the information. Page 2 is called “My Diabetes Information”. This page has individualised information mapped against nine key care processes in diabetes with a brief one word clinical comment; Good, Borderline or Of Concern, so as to provide the reader with some help to make sense of this information. Only information of preceding 15 months (in line with QOF guidance at that time) was included in this page, and if any information was older than this or was not completed previously, it was marked as “Needs Doing”, to prompt patients to think about getting that test or measure done as soon as was practical for them.

Page 3 is called “My Plan”. This page is mapped against all the information given on page 2 and has 3 columns. The first column, “Where am I”, encourages patients to write about their thoughts after knowing about their information related to their diabetes. The second column, “Where I want to be”, prompts patients to reflect on their own status of diabetes care and to set a personalised goal to achieve for their diabetes. The last column, “How I will get there”, prompts them to make an action plan to achieve those targets that are set by them and to work out ways and means of how to achieve them. As these are patient’s own targets, we presume that people will make an individualised plan to achieve these targets, and wherever they feel that help from healthcare professionals is required, they will seek this help appropriately, as explained in the guidance notes on page 4. This tool can also inform carers and significant others of the diabetes status of the patients, since they sometime have a major responsibility to manage the diabetes of their loved ones or people under their care, and hence may activate the patient’s environment by activating family, friends and community.

Cluster Randomisation Process

In 2010, Wolverhampton was ranked as the 20th most deprived of 326 English local authorities according to the English Indices of Multiple Deprivation (IMD) (223). It has a total population of around 265,000, of which nearly 17,000 people have diabetes. It is divided into 3 geographical regions within WCCG, and each region is divided into 3 subsectors to make 9 health subsectors of varying sizes and demographic makeup. The subsectors, and thus clients belonging to primary care practices within each of them, were cluster randomised by sub sector into 2 groups intended to be matched for age, gender, ethnicity, type of diabetes and baseline FPS, utilising pilot processes based on information gathered over the preceding 15 months. This meant that all clients belonging to any individual primary care practice and all practices within these individual subsector clusters were randomised in blocks, so that no practice had a mixture of mailed or non-mailed individuals, thus minimising any impact of care-providing professionals or practice specific process on the outcomes. Sub-sectors were placed in descending order of size, and were then paired with the nearest sub-sector according to size. The top two subsectors were allocated to active or control group by the toss of the coin, and each pair was then randomly allocated to either active intervention group or the non-recipient control group, thus creating cluster-randomised practices (and their patients) accordingly. The last subsector was included in the active group to increase the sample size as we believed that this intervention will be of benefit, and we wanted a maximum number of people to receive that benefit. After the randomisation process, baseline data was further cross validated for patient movements and death status excluding another 105 patients from the baseline group (both active and control groups). All the people alive and in the area on 30/11/2013 were finally recruited in the study (Fig 5.2).

According to the study protocol, both groups should have been matched in their baseline FPS. Despite this cluster randomisation process, by hap chance, there was a mismatch in the baseline (pre-intervention) level of the key intended outcome variable, the full 9 parameter Failed Process Score (FPS), with a significantly better FPS in the intervention group. This was thus moderated by the removal of the 3 lowest scoring primary care practices from the non-intervention group accounting for 1,871 control subjects so that the 2 groups were fully matched for all relevant variables at baseline prior to the intervention. Subsequently, after

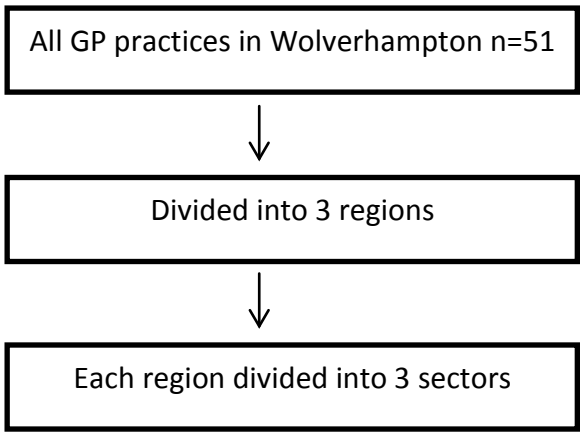
randomisation and the mailing intervention, a further 263 patients had died or moved away by the 3 month analysis point and they were also excluded, leaving a final cohort of 14,559 with 8374 (57%) in the active group versus 6185 (43%) controls at 3 month analysis point (Table 5.2).

The 2 groups were allocated to either receive the document, which was an active intervention, or not. The document was mailed within the same week to the active group. Updated data were re-examined at 3 and then 12 months after this randomisation and intervention. The core analysis related to the 9 key diabetes processes that inform UK NHS diabetes health care delivery – HbA1c, BMI, blood pressure, urine ACR, serum creatinine, serum cholesterol, recorded smoking status, digital retinal photography and foot examination. Each item was scored as 1 if missing and 0 if completed within a 15 month period and each individual thus had a summative score calculated to assess the accrued process failure – the Failed Process Score (FPS). This ranged between 0 - 9 equating to a spectrum from complete process attainment (FPS =0) to complete process failure (FPS =9). It is this parameter and its derivatives that were subject to analysis. Data were analysed on SPSS version 22 with statistical tests taken as significant at $p<0.05$. The significance of difference between means was tested by Student's T test, of differences between proportions by the Chi square test. Binary logistic regression analysis to derived likelihood ratios adjusted for relevant factors was carried out with the help of Prof Alan Nevill (Editor in Chief JSS, University of Wolverhampton, Faculty of Education, Health and Wellbeing) and discussed with Nick Parson (Statistician from University of Warwick).

This is a pragmatic, real life trial conducted on a large population base across bounds of NHS within a local health economy and it has been carried out with the best possible methodological rigour. For a trial of this magnitude and nature, there can be potential limitations or weaknesses in the trial design that need to be looked at in the given context.

We used a process of cluster randomisation of the patients by their GP practices. Wolverhampton is a large geographical area that is divided into 3 sectors, with each sector being further subdivided into 3 sub sectors for the provision of healthcare by WCCG. As is the case with any other geographical location, it includes areas of higher and lower deprivation, a mixture of small and large size practices, variable availability of services within each practice and other population demographics that tend to vary from one part of the city to the other. The purpose of randomisation in a trial is to remove bias. In this type of pragmatic design, we need to be aware not only of demographic geographic variations, but also keep in mind that motivation, practice size and the structure of individual GP practices can influence the outcomes significantly. One of the markers that can be used for randomisation is the deprivation score. As deprivation score follows the patients and not GP practices and patients are free to register with any practice in any part of the city. We cannot calculate the deprivation index of the GP practices and hence cannot use this as an index for randomisation. Similarly individual patient randomisation is not desired in this study design, and we cannot afford to have a small number of patients in the same GP practice that are in the active group and others in control group. This will result in contamination and clinician's bias. Therefore, we used the cluster size order to list all 9 subsectors, and then paired them to the next sub sector for the cluster randomisation of the GP practices and hence their patients that created 2 equal size groups that will have a complete mix of GP practices and their patients without any issues around demographics or GP practice quality biases. In order to ensure that our randomisation process was effective, we compared all the demographic and care process parameters of the two groups and despite ensuring randomisation, we ended up with a very small differences between two groups that was a matter of pure chance, due to unknown or un identifiable reasons. As FPS was the main indicator to evaluate our intervention, the difference of FPS between the groups was moderated by the a-priori removal of 3 worst FPS practices from the control group according to study protocol.

Fig. 5.2: Flow chart of Cluster Randomisation Process



Nine Sectors arranged in descending size order shown as numbers of patients in each sector

No	3178	
	2201	Yes
	2112	Yes
No	1965	
No	1699	
	1636	Yes
	1468	Yes
No	1246	
	1030	Yes

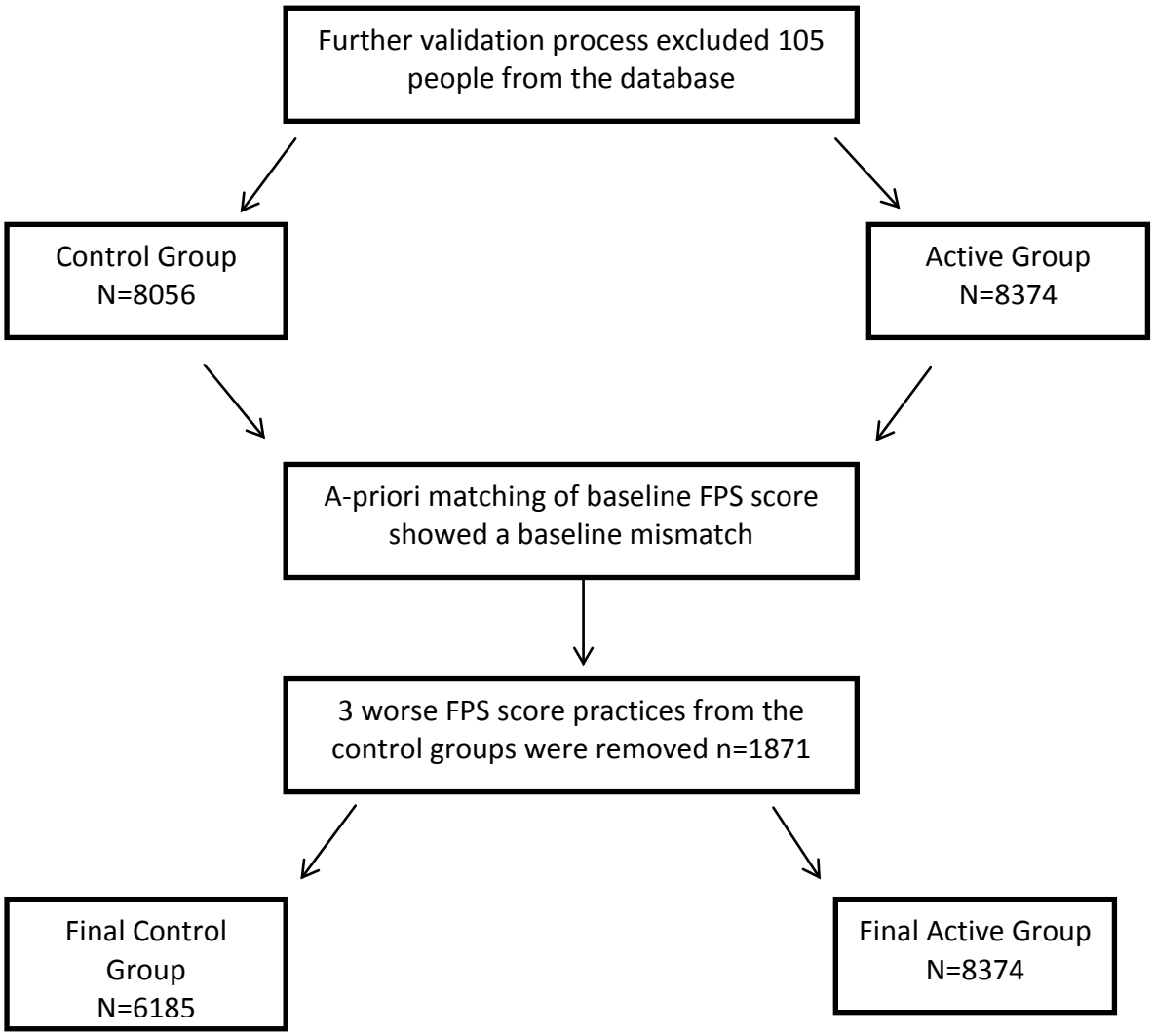

Further validation process excluded 105 people from the database
Control Group N=8056
Active Group N=8374
A-priori matching of baseline FPS score showed a baseline mismatch
3 worse FPS score practices from the control groups were removed n=1871
Final Control Group N=6185
Final Active Group N=8374

Table 5.2

The baseline characteristics of the 2 groups after a-priori matching based on FPS score.

	Whole group	Not mailed Control group	Mailed Active group	p value
Group size	14559	6185 (43%)	8374 (57%)	
	Demographics			
Age years	64.0 ± 14.6	63.8 ± 14.6	64.1 ± 14.6	ns
Gender (male)	7960 (55%)	3425 (55%)	4535 (54%)	ns
Ethnicity (Caucasian)	10124 (70%)	4351 (70%)	5773 (69%)	ns
Type of diabetes (type 2)	13412 (94%)	5688 (93%)	7724 (94%)	ns
Duration of diabetes (years)	10.5 ± 8.6	10.5 ± 8.7	10.5 ± 8.4	ns
Deprivation score	35.5 ± 16.1	35.8 ± 16.6	35.2 ± 15.8	p<0.05
	Process measures (n= 9) Showing process attainment and outcome			
Failed Process Score	1.74 ± 1.84	1.77 ± 1.88	1.73 ± 1.82	ns
Failed Process Score category (Good)	8336 (57%)	3526 (57%)	4810 (57%)	ns
HbA1c **Outcome (% glycated)**	12522 (86%) 7.8 ± 1.7	5387 (87%) 7.8 ± 1.7	7135 (85%) 7.8 ± 1.7	ns
Retinal status **Outcome (no retinopathy)**	12000 (82%) 6986 (58%)	5087 (82%) 2964 (58%)	6913 (82%) 4022 (58%)	ns
Urine ACR **Outcome (umol / mmol)**	10100 (70%) 9.0 ± 39.3	4309 (70%) 9.1 ± 44.6	5791 (69%) 8.9 ± 34.8	ns
Serum Creatinine **Outcome(umol/l)**	12696 (87%) 88.6 ± 44.3	5373 (87%) 89.1 ± 46.3	7323 (87%) 88.3 ± 42.3	ns
Foot status **Outcome (low risk)**	10629 (73%) 6091 (57%)	4508 (73%) 2586 (57%)	6121 (73%) 3505 (57%)	ns
Smoking status **Outcome (non-smoker)**	11664 (80%) 9935 (85%)	4836 (78%) 4074 (84%)	6828 (82%) 5861 (86%)	p<0.05
Systolic Blood Pressure **Outcome (mmHg)**	12946 (89%) 134 ± 16	5459 (88%) 133 ± 16	7487 (89%) 135 ± 16	p<0.001
Serum Cholesterol **Outcome (mmol / l)**	12043 (83%) 4.4 ± 1.1	5151 (83%) 4.3 ± 1.1	6892 (82%) 4.4 ± 1.1	p<0.01
Body Mass Index **Outcome (kg/m2)**	11027 (76%) 31.0 ± 6.3	4620 (75%) 31.0 ± 6.2	6407 (77%) 30.9 ± 6.3	ns

Extension of the intervention to both arms at 3 months

At the end of 3 months, all people in the control group also received the booklet for the first and only time, and people in the active group received the booklet for the second time. The active group received the third and final mailings at the end of 6 months, and both groups were followed up for 12 months in total (Fig 5.3). We continue to capture the data on a monthly basis as our routine data upload, but it was only analysed at 3 and 12 months intervals. A complete log of all failed deliveries returned back to the department and all phone calls received were kept for the record maintenance, but was not analysed, as it was less than 1% and unlikely to be of any meaningful significance, and thus, beyond the remit of the project. Therefore, the final analysis will look at a comparison of multiple mailings (n=3, Active group) vs. single mailing (Control group) at 12 months of first intervention.

At the end of 12 months, a further 603 people deceased or moved away, resulting in 866 people in total who were lost to follow up (Deceased=453, Moved away=378 and not traceable=35), leaving a final cohort of 13,956 people that completed 12 months of the trial.

In an ideal world, we wanted to keep our control group for the whole 12 months duration of the intervention but due to governance issues with the WCCG as this intervention was supposed to benefit people, it was agreed that this intervention would be delivered to all people with diabetes in Wolverhampton within 3 months of the initiation of the project, and therefore we had to extend the intervention to control arm after 3 months. At this point, the data analysis was performed to compare the impact of mailing versus non mailing, but as the active group at baseline received 3 mailings in total, as compared to the control group that only received one mailing, the 12 months analysis will show the impact of one mailing versus multiple mailings between the two groups.

Fig. 5.3: Timeline of Open Label Extension Process

Active group

Booklet mailed Booklet Mailed Booklet Mailed

Baseline 3 Months 6 Months 12 Months

Data Collected Data Collected Data Collected

No Intervention Booklet Mailed

Control group

Power Calculation

Power calculations were not performed at the beginning of the trial, for several reasons. However a retrospective power calculation has been performed.

Power calculation is usually performed to determine the sample size of a study that is likely to detect the effect of intervention in a study. One of the main reasons for power calculation is to avoid type 2 statistical errors or false negatives. To calculate the power of a study, one need to know the effect size, sample size and alpha significance criterion. This is usually based on the results of a previous pilot project to determine an adequate sample size for the main study. In principle, power calculation is helpful when one is required to select a sample from an epidemiological population base.

This project involved recruiting the whole epidemiological base and hence no sample was taken out of this baseline population within a local health economy. There is no known clinical trial or pilot study that can be used to determine either the effect size or sample size. Although a pilot study could have been performed prior to this project, it was not done because the intervention was found to be easily implementable to the whole population from the outset of this project, without incurring any unusual financial cost, time constraints and without putting any patients at risk. However, in retrospect, if we presume that after doing a power calculation, given sample size would have been smaller than this, then the present project would have been adequately powered. On the other hand, even if a sample size of this magnitude is not adequately powered, then the recruitment for the present study could not have been extended outside the local health economy bounds. As this project involves a unique database use to execute the project and to our knowledge no health economy in England and Wales has such a database it was practically impossible for the researcher of this study to expand sample size to neighbouring health economies. One may argue that the entire diabetes population is larger than the single health economy and hence this can still be looked at as a sample of the diabetes population as a whole, unfortunately, this was the largest sample that we could recruit in this study. Therefore, in my view, power calculation may not be relevant to this study and if anyone wishes to re-perform this type of study in the future this project may serve as a pilot project to perform power calculation for such studies.

A further reason of not performing power calculation is that in this study we used a novel measure (FPS) to assess the impact of our intervention. This tool is not used or validated in any other studies, and there are no estimates of how much difference should we assume to set significance. There is much evidence to suggest that people who do not complete their care processes will have poorer outcomes in diabetes, yet a Failed Process Score to assess patient activation in self-care has never been tested before. Therefore, it was not possible to calculate the power of the study without any guide to estimate the magnitude of change to expect as a result of this intervention. However, if we perform retrospective power calculations to detect a 3% difference in FPS at alpha= 0.05 and Power= 0.8, the sample size required will be 3477 people in each arm, and thus, our study is proved to be adequately powered.

Patient satisfaction Survey

To evaluate the impact of this tool qualitatively, we used a patient satisfaction questionnaire, containing 14 questions that were derived from the questionnaire that we used in our pilot project in process of developing our project intervention tool "My Diabetes, My Information, My Plan". All the questions were re-evaluated by our research focus group, and the final questionnaire was designed by our medical illustration department in the form of 2 sided A4 sheet (See appendix 2). We did not use any standard validated diabetes questionnaire, as there was no such questionnaire available to assess the usefulness of our tool. To develop a validated questionnaire for this purpose is perhaps a project in its own rights, and hence deemed beyond the remit of this project.

The final questionnaire contained an introduction of the questionnaire and its relation to the evaluation of previously sent booklet to the patients on the front page. The second page had all 14 questions with a four scale answers to the most questions that include; "Yes definitely", "Yes May be", No May be and No definitely to allow people to express their thoughts about various domains of the booklet. Only one answer that was about the frequency of this booklet was divided into "Once a year", "Twice a year" and "No I don't want to have this information".

From the active group at baseline (n=8725) all people under the age of 75 were selected for this survey. From this cohort of people, 1000 were randomly selected for the survey by using MS Excel 2011 random number generation process. Sample size of 1000 was decided randomly. All people were mailed the questionnaire in the same week with a self-addressed reply envelop enclosed. All replies were collected and the questionnaire was re mailed to those who did not respond after 2 weeks. At the end of 4 weeks, the reply collection process was stopped and the survey was closed.

At this stage, we had the FPS outcomes at 3 months post active intervention and we hypothesized that people with low process attainment were less active in self-care and hence FPS can be used as a marker of patient activation. After receiving the response of the survey, the group was divided into "responders and "non-responders" and we hypothesized that people who did not respond to the questionnaire were less active in their diabetes care and hence response rate to the questionnaire can be used as a second marker of patient

activation. By using these 2 markers of patient activation, we compared the FPS score, clinical risks and hard endpoint outcomes between responders and non-responders of the survey to test the hypothesis that less active people are likely to be at higher risk to develop diabetes complications.

Using SPSS version 22, data were then analysed using the Student t-test or the Chi square test for the difference between means and proportions respectively with statistical significance taken at $p<0.05$.

Results

The results of the data validation process, assessment of patient access pilot and care planning in diabetes clinics pilot have been included in their corresponding chapters. This section presents the results of user acceptability pilot, 3 months outcomes of project intervention comparing the active and control group with one versus no mailing contact, 6 months patient satisfaction survey and 12 months analysis of project intervention with one mailing contact to the control group and 3 mailings contact to the active group.

User Acceptability Pilot

Of 50 patients, 37 responded (14 females, age 59±12 years, 7 type 1 diabetes, 23 on insulin, 29 Caucasians). More than 80 % positively reported this document to be understandable, informative and helpful, and it promoted being in control / charge of the diabetes. 90% had never had such information before; they wanted it again, and said they would use it in consultation with professionals. 91% people resolved to use this information to take better care for their diabetes. Detailed results against each question are shown in the table 5.3.

Table 5.3

Pilot user acceptability survey outcomes (n=37 out of 50).

Questions	**Yes definitely or Yes to some extent (%)**
Did you understand the purpose of this document and what it is meant to be used for?	92%
Were the contents of the report easy to read and understand and do they make sense to you?	92%
Was the information useful?	89%
Did this information give you more knowledge about your diabetes?	89%
Did this information help you to understand your diabetes better?	89%
Would this information help you to improve your diabetes?	86%
Would this information help you make changes in your diabetes?	78%
Will this information help you be more confident about your diabetes?	81%
Would this information help you feel more in charge or control of your diabetes?	78%
Would you take this information with you to your next diabetes appointment with a doctor or a nurse?	86%
Did you think this information will help in your next visit of diabetes review with a doctor or a nurse?	84%
Have you ever received information like this about your diabetes in the past?	76% **(Never)**
Would you like to receive information like this in the future?	84%
How often would you like to have this report with this sort of information about your diabetes?	81% **(once/twice a year)**
Overall, do you think it is a good idea for people with diabetes to have this sort of report?	92%
Overall, do you think people with diabetes will use this information to take better care of them?	84%

3 months outcomes comparing Mailed (Active) vs. Non-Mailed (Control) Groups

The groups were well matched on all a-priori demographic factors, although, post hoc, there were very minor differences in the measure of deprivation, smoking status outcome, systolic blood pressure, and serum cholesterol (Table 5.2).

At baseline, there was no significant difference in the Failed Process Score (FPS) whether measured as the numerical mean, the distribution in all 10 numerical categories (FPS 0 to 9), or the proportion with good attainment (GA, FPS ≤ 1) (Table 5.2).

At 3 months, the FPS score, the change in FPS score, and an improvement in FPS ≥1 were all significantly better in those mailed vs. controls (Table 5.4, Figure 5.4). At 3 months the association with GA categorisation was 74% in the mailed group versus 71% in controls (χ^2 =10.0, p<0.05). There was no impact of mailing in those with preceding GA (χ^2 = 1.05, ns) (in other words the retention of GA status), nor on the proportion deteriorating from GA to poorer attainment (PA), (mailed 10.0% vs. control 9.3%, χ^2 =1.0, ns). However, the impact of mailing on the attainment of GA in those with preceding PA was significant with the shift from PA (FPS ≥2) to GA (FPS ≤1) being greater in those who had received the document. Examining the difference in percentage attainment of the GA category at 3 months for the mailed group versus control by individual FPS score categories (0 through to 9, 10 categories) showed the differential percentage attainment with mailing to be positive in every category but with major changes in magnitude with a worsening baseline position (0=0.2%, 1=1.3%, 2=1.1%, 3=3.2%, 4=4.7%, 5=5.3%, 6=7.6%, 7=6.0%, 8=11.7% and 9=10% respectively, overall χ^2 = 10.0, p<0.05) although the numbers in the lower attainment categories were relatively small. The change in FPS at 3 months was recoded into deterioration, no change or improvement (2924 (20%), 5356 (37%) and 6279 (43%), (Figure 5.4) and, equating this to GA or PA categorisation attainment at 3 months showed significant differences (χ^2 = 10.0, p<0.05). With mailing, those with no change in FPS score were more likely to retain their GA status (82% vs. 80%, χ^2 = 5.6, p<0.02), those who improved FPS score were more likely to attain GA status (84% vs. 82%, χ^2 = 5.6, p<0.02) but those who deteriorated in FPS score were not affected by the mailing in their final attainment category.

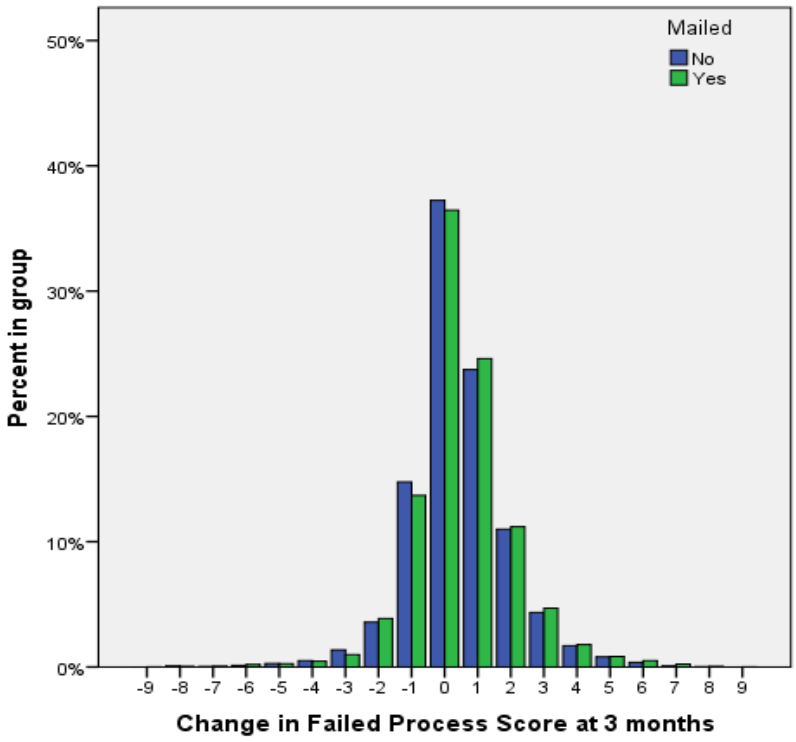
Binary logistic regression analysis was used to compare the relative effect of mailing compared to non-mailing whilst taking into account all demographic factors and the baseline FPS (Table 5.2). The relative likelihood, the odd ratio, of showing an improvement in FPS by ≥1 with mailing was 10% ($p<0.05$) with baseline FPS ($p<0.001$), age ($p<0.01$), deprivation score ($p<0.01$) and duration of diabetes ($p<0.01$) as significant co-variables; it was 14% ($p<0.01$) for the 3 month GA category (whether retention or attainment) with baseline FPS ($p<0.001$), age ($p<0.05$), and gender ($p<0.05$) significant co-variables, but was of greater magnitude at 18% ($p<0.01$) for attaining GA by moving from baseline PA with baseline FPS ($p<0.001$), age ($p<0.05$) and type of diabetes ($p<0.01$) significant co-variables.

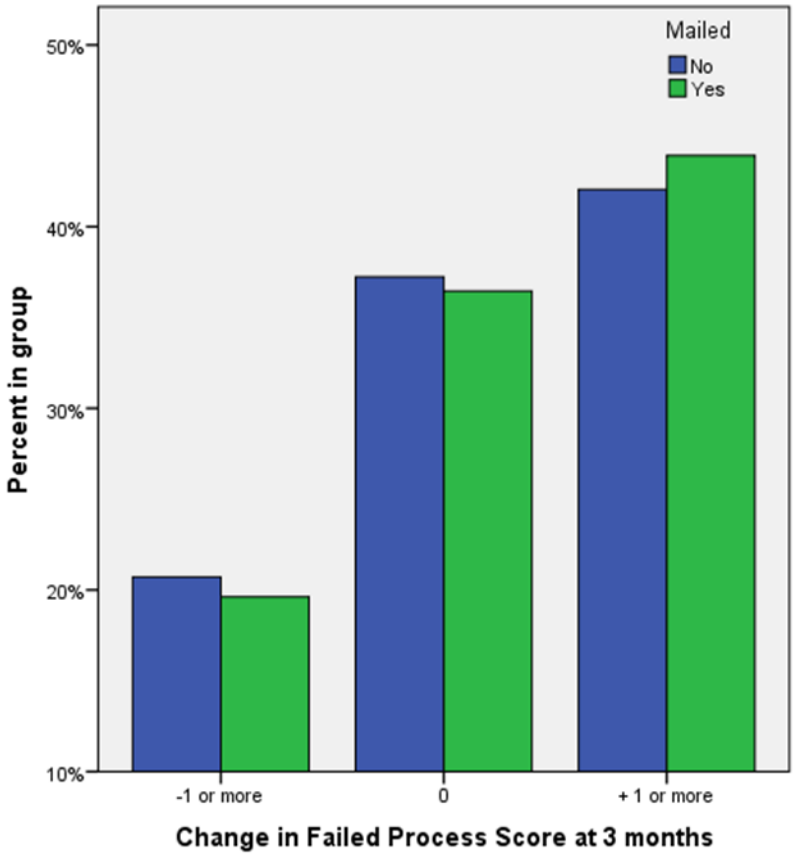
Table 5.4

The effect of receiving the personalised information booklet on 3 month diabetes process outcomes measured as the Failed Process Score (FPS, 0 = maximal attainment, 9 = complete failure of attainment). Good attainment, FPS ≤1; poorer attainment, FPS ≥2; OR = Odds ratio.

Variable	**Not Mailed vs. Mailed**	
	n=6072 vs. n=8224	
FPS at 3 months	1.35 ± 1.97 vs. 1.25 ± 1.87	p<0.01
Change in FPS from baseline	0.42 ± 1.49 vs. 0.48 ± 1.55	p<0.02
FPS improvement ≥1	42% vs. 44% OR 1.10 (95% CI 1.02-1.20)	p<0.05 p<0.05
Overall Good Attainment at 3 months	71% vs. 74%, OR 1.14 (95% CI 1.04 -1.25)	p<0.05 p<0.01
Shift from Poorer to Good Attainment	46% vs. 51% OR 1.18 (95% CI 1.05-1.33)	p<0.001 p<0.01
3 month attainment of the 9 individual processes		
HbA1c	5682 (91%) vs. 7608 (91%)	ns
Retinal status	5252 (85%) vs. 7149 (85%)	ns
Urine ACR	5138 (83%) vs. 6826 (82%)	p<0.05
Serum Creatinine	5708 (92%) vs. 7730 (92%)	ns
Foot status	4448 (72%) vs. 6157 (73%)	p<0.02
Smoking status	5006 (81%) vs. 6985 (83%)	p<0.001
Systolic Blood Pressure	5593 (90%) vs. 7769 (93%)	p<0.001
Serum Cholesterol	5580 (90%) vs. 7500 (90%)	ns
Body Mass Index	5068 (82%) vs. 7249 (87%)	p<0.001

Fig. 5.4: The change in the Failed Process Score at 3 months compared to baseline in the 2 groups either as crude data (top panel) or re categorised as described (bottom panel).





12 Months outcome comparing multiple mailings (Active) vs. single mailing (Control) Groups

Failed Process Score

The baseline FPS was not significantly different between groups, nor was there any significant difference in the distribution in FPS categories (Table 5.6).

There were point differences for the 3 month FPS (mailing versus non mailed p=0.024) as previously reported, and also at 12 months (single mailed vs. multiple mailed p<0.06) although, in analysis of variance, whilst the FPS score varied significantly within subjects over time (F=997.9, p<0.001), the between group intervention of multiple mailing just failed to have a significant impact on FPS (F=3.459, p=0.06) despite time point significances (Table 5.6, Fig 5.5).

However, considering the baseline status, those with a good baseline FPS of ≤1 had similar attainment between groups at 12 months (ns) whilst those with a poor baseline FPS of ≥2 were more likely to achieve good attainment at 12 months in the mailed group (Final FPS ≤1, 49.2% vs. 46.0%, $\chi 2$=6.09, p=0.014).

Thus, when considering the target group, those with lesser activation and a baseline FPS of ≥2, meaning the exclusion of those with a baseline FPS of ≤1, in analysis of variance there was significant between groups effect (F=4.369, p=0.037), in the active group the 3 month (p<0.01) and 12 month (p=0.01) FPS was significantly better, and their likelihood of achieving the good attainment category (12 month FPS ≤1) with mailing was 1.15 (95% CI 1.02 – 1.29, p=0.022).

HbA1c, Systolic Blood pressure and Cholesterol

We selected those who had both a baseline HbA1c measure and a repeat HbA1c at least 4 months after the initial mailing date (n= 10015, mailed 5637, not mailed 4378).

In the whole cohort HbA1c improved over the year (HbA1c% 7.8 ± 1.6 vs. 7.5 ± 1.6, p<0.001).

The crude end year HbA1c was not significantly different between groups (multi mailed 7.5 ± 1.6 vs. single mailed 7.6 ± 1.6, ns) but this masked an impact in sub groups.

Considering baseline HbA1c% categories as ≤7.5, 7.6-8.4 and ≥8.5, and adjusting for variables in univariate analysis (r^2=0.39, F=126.9, p<0.001; age p<0.001, gender (ns), ethnicity (ns), IMD score (ns), type of diabetes (ns)), the impact of being multi mailed was significant (F= 6.2, p=0.013).

The significant difference lay amongst those in the baseline HbA1c category ≤7.5 (mailed HbA1c% 6.7 ± 0.09 (mean ± SEM) vs. 7.1 ± 0.08, F=11.1, p<0.01) (Fig 5.6).

Analysis of the change between final and initial HbA1c values by HbA1c category showed this to be a small but significant avoidance of deterioration of HbA1c levels in those multi mailed (HbA1c% category ≤7.5, delta HbA1c% 0.31 ± 0.7 vs. 0.02 ± 0.6, F=10.3, p<0.01) whereas the other 2 categories showed an improvement, most marked in HbA1c category ≥8.5, which was unaffected by mailing.

There were no discernable differences between groups for blood pressure or cholesterol.

Table 5.5

Demographics and Clinical Parameters of final cohort at 12 months.

Active= Received 3 mailings

Control= Received 1 mailing.

Demographics	**Mailing** (Mean ± SD)		**P**
	Active = 8045	**Control = 5911**	
Age (Years)	63.9 ± 14.5	63.4 ± 14.4	NS
Sex (Male)	54%	55%	NS
Ethnicity (White)	69%	70%	NS
Deprivation Score	35.2 ± 15.7	35.9 ± 16.6	0.013
Type 2 Diabetes	94%	94%	NS
Duration of Diabetes	10.4 ± 8.4	10.5 ± 8.7	NS
Smoking (Never smoked)	60%	58%	0.015
Clinical Parameters			
BMI (kg/m^2)	30.9 ± 6.3	31.1 ± 6.3	0.05
BP(mm Hg)	135 ± 16	132 ± 16	<0.001
HbA1C (DCCT- %) (IFCC- mmol/mol)	7.8 ± 1.7 61.5 ± 18.1	7.8 ± 1.7 61.6 ± 18.3	NS NS
Urine ACR (mg/mmol)	8.7 ± 34.6	8.9 ± 43.9	NS
Creatinine (µmol/l)	88.3 ± 43.2	89.1 ± 46.4	NS
Chol/HDL Ratio	3.8 ± 1.4	3.8 ± 1.4	NS
Primary Risk	71%	69%	<0.003
Primary Risk Score (Framingham)	18.0 ± 7.5	17.8 ± 7.4	NS
Retinopathy	58%	57%	NS
Foot Risk	57%	57%	NS

Table 5.6

Comparison of FPS Score (Total and Dichotomised) between Active group (received 3 mailings) vs. Control group (Received 1 mailing)

Failed Process Score (FPS)	**Groups**		**P**
All 9 Processes	**Active** **n= 8045**	**Control** **n=5911**	
Baseline	1.70 ± 1.78	1.71 ± 1.80	0.631
3 Months	1.20 ± 1.81	1.27 ± 1.84	0.024
12 Months	1.65 ± 1.92	1.72 ± 1.94	0.057
Dichotomised FPS (FPS ≥2)	**n= 3380**	**n=2499**	
Baseline	3.35 ± 1.58	3.38 ± 1.60	0.508
3 Months	2.14 ± 2.26	2.27 ± 2.29	0.027
12 Months	2.25 ± 2.29	2.38 ± 2.28	0.034

Fig. 5.5: Pattern of Mean FPS change at 3 points (1=baseline, 2= 3 months and 3= 12 Months) between Active and Control Groups as Total FPS (Top Panel) and Dichotomised FPS (Bottom panel)

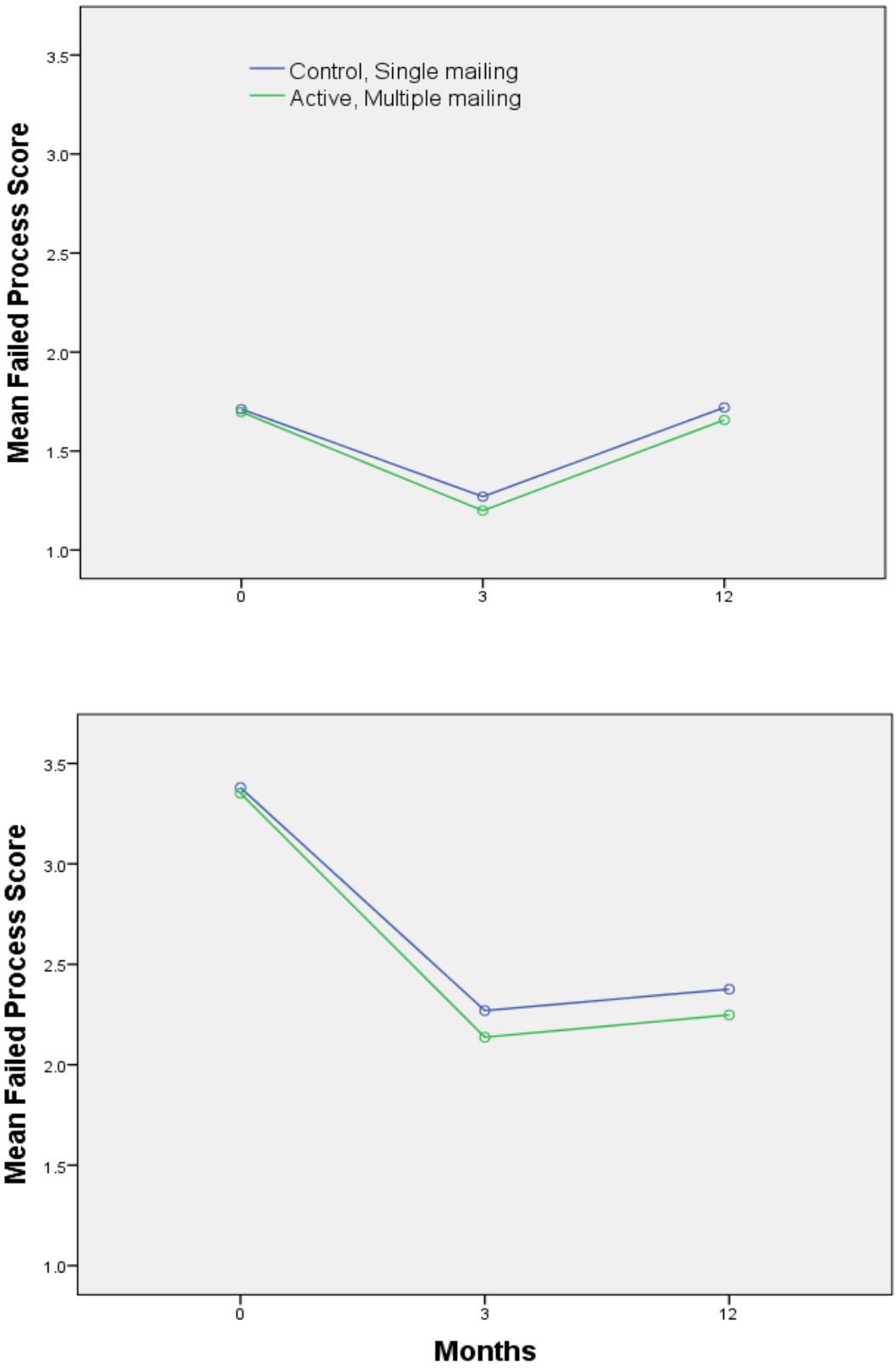
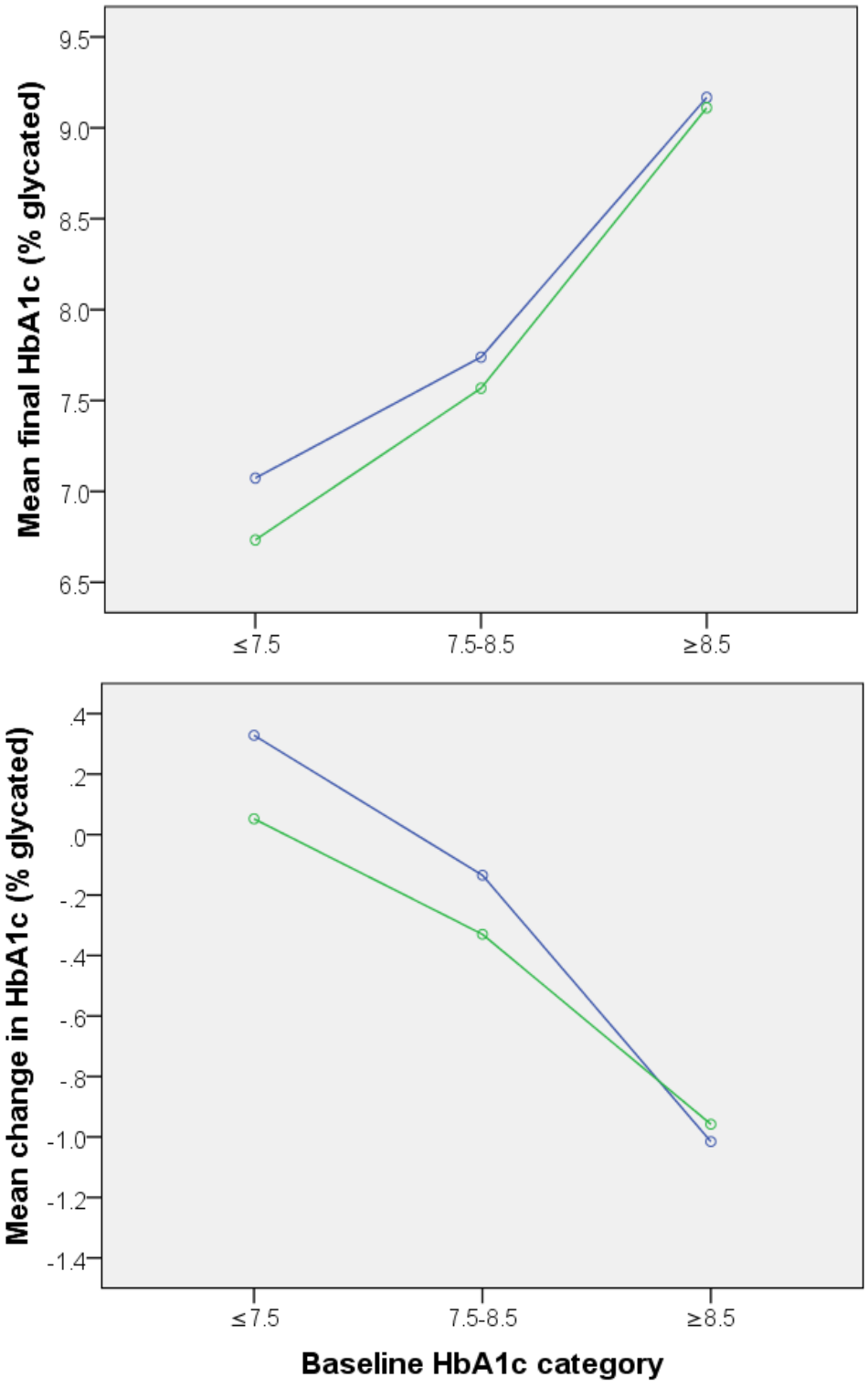


Fig. 5.6: The mean (top panel) and delta (bottom panel) HbA1c outcomes at the end of 12 months categorised by baseline HbA1c status in those receiving multiple versus single mailings.



Patient Survey Outcomes

The 1000 surveyed people were not significantly different in any demographic or other characteristics compared to those not surveyed (n= 5282, Table 5.9). Of the1000, 419 and 581 did or did not respond to the questionnaire respectively. Their demographic and clinical details are also given in Table 5.9. Non responders were younger and more likely to be of a non-white Caucasian background, but there was no significant difference in gender, their index of deprivation, or in type or duration of diabetes.

The results of the evaluation of "My Diabetes, My Information, My Plan" from the 419 respondents are presented in table 6 and a positive response was expressed to every question (Table 5.7).

In non-responders, the FPS was significantly worse as was attainment in every single one of the 9 subsidiary processes (Table 5.8). In those where outcomes were ascertainable who had process measures with the 15 month time frame, non-responders had a higher HbA1c, BMI, serum cholesterol and were more likely to be smokers but there were no significant differences in mean systolic blood pressure. The proportion of those with HbA1c >9%, a systolic blood pressure of >160 mmHg (borderline significance) and a serum cholesterol >6mmol/l was higher in non-responders. The 10 year primary CHD risk score was significantly worse in non-responders when adjusted for the 6 year mean age difference between the groups (Table 5.8, Figure 5.7). This effect between groups was independent of age ($F=22.2$, $p<0.001$). Despite the separation amongst middle age bands, the effect was not statistically different between groups within separate age bands. Overall this meant that an estimated 27 additional cardiovascular events might occur over the following 10 years in the non-responding group with current primary CHD risk. There were no significant differences in the crude prevalence of established microvascular disease (eye, foot or renal) or established secondary macrovascular disease.

Table 5.7

Patient Survey Outcomes

The responses to a questionnaire relating to an individualised diabetes information booklet which were categorised in a 4 point scale as: Yes definitely; Yes, to some extent; No, not really; No, definitely not.

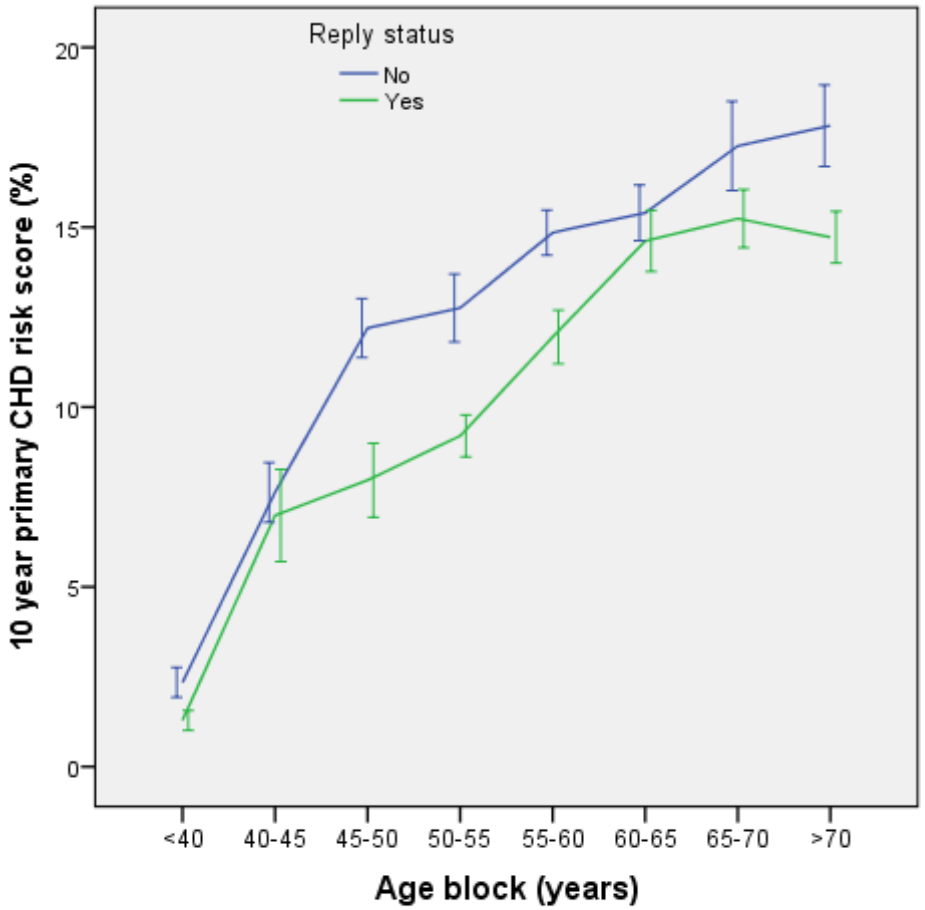
Questions	**Reponses received (n=419 of 1000)**	**Yes definitely or Yes to some extent (%)**
Did you understand the purpose of this document and what it is meant to be used for?	397	355 (85)
Were the contents of the report easy to read and understand and do they make sense to you?	404	354 (85)
Was the information useful?	414	368 (88)
Did this information give you more knowledge about your diabetes?	410	321 (77)
Did this information help you to understand your diabetes better?	406	302 (72)
Would this information help you to improve your diabetes?	408	317 (76)
Would this information help you make changes in your diabetes?	406	316 (76)
Would this information help you feel more in charge or control of your diabetes?	412	316 (76)
Would you take this information with you to your next diabetes appointment with a doctor or a nurse?	402	312 (74)
Did you think this information will help in your next visit of diabetes review with a doctor or a nurse?	408	325 (78)
Would you like to receive information like this in the future?	409	328 (78)
How often would you like to have this report with this sort of information about your diabetes?	406	358 (85)*
Overall, do you think it is a good idea for people with diabetes to have this sort of report?	413	377 (90)
Overall, do you think people with diabetes will use this information to take better care of them?	414	365 (87)

Table 5.8

The demographic and clinical parameters of those randomly selected to be surveyed (with p values comparing responders vs. non responders) and those not surveyed.

	Not Surveyed	Surveyed		P value
Demographics		Responders	Non responders	
Number	5282 (%)(± SD)	419 (%)(± SD)	581 (%)(± SD)	
Age (years)	58.5 ± 10	62 ± 10	56 ± 12	P< 0.001
Gender (male)	3012 (57)	246 (59)	318 (55)	ns
Ethnicity Caucasian, Asian, AFC, Mixed Other or Unknown	2868 (54) 1329 (25) 254 (5) 58 (1) 773 (15)	249 (59) 76 (18) 18 (4) 4 (1) 72 (17)	293 (50) 175 (30) 20 (3) 9 (2) 84 (15%)	P<0.001
IMD Score	35.5 ± 15.7	34.4 ± 15.8	36.3 ± 15.3	ns, (P=0.054)
Type of diabetes (type 2)	4881 (92)	389 (93)	537 (92)	ns
Duration of Diabetes (years)	9.7 ± 7.9	9.8 ± 8.2	9.4 ± 7.6	ns
Failed Processes				
Failed Process Score	1.3 ± 2.0	0.8 ± 1.1	1.7 ± 2.3	P< 0.001
HbA1c	517 (10)	19 (5)	76 (13)	P<0.001
BP	405 (8)	13 (3)	63 (11)	P<0.001
BMI	644 (12)	31 (7)	97 (17)	P<0.001
Cholesterol	581 (11)	31 (7)	87 (15)	P<0.001
Smoking status	846 (16)	47 (11)	112 (19)	P<0.001
Retinal screen	832 (16)	33 (8)	120 (20)	P<0.001
ACR	969 (18)	53 (13)	159 (27)	P<0.001
Creatinine	453 (9)	15 (4)	77 (13)	P<0.001
Foot examination	1343 (25)	83 (20)	167 (29)	P<0.01
Outcomes				
HbA1C	7.7 ± 1.7	7.5 ± 1.4	8.0 ± 1.9	P<0.001
BP Systolic	133 ± 15	133 ± 14	134 ± 16	ns
BMI	31.5 ± 7.2	30.6 ± 6.4	32.0 ± 6.7	P<0.01
Cholesterol	4.4 ± 1.1	4.3 ± 1.0	4.6 ± 1.2	P<0.001
Vascular Risk (Secondary)	1009 (19)	94 (22)	107 (18)	ns
$1^0$10 year CHD risk (numbers calculable) Age adjusted 1^0 10 year CHD risk (antilog)	13.3 ± 7.2 (661) 10.7 ± 2.1	12.4 ± 6.2 (288) 9.3 ± 1.8	13.3 ± 7.2 (373) 12.0 ± 1.8	ns, P<0.001
Current smoker	753 (14)	39 (9)	102 (18)	P<0.001
ACR	8.8 ± 33.8	7.5 ± 30.1	11.8 ± 44.4	ns
Creatinine	85 ± 41	85 ± 34	84 ± 55	ns
Retinal Risk Vision Threatening Background None	464 (10) 1384 (31) 2602 (59)	36 (9) 115 (30) 235 (61)	62 (13) 137 (30) 262 (57)	ns
Foot Risk High Intermediate Low	551 (14) 1113 (28) 2275 (58)	56 (17) 85 (25) 195 (58)	55 (13) 110 (27) 249 (60)	ns
HbA1c ≥ 9%	835 (16)	50 (12)	113 (19)	P<0.001
SBP ≥ 160 mmHg	240 (5)	18 (4)	40 (7)	ns, (P=0.054)
Cholesterol ≥ 6	280 (5)	12 (3)	39 (7)	P<0.01
Any	1182 (22)	75 (18)	168 (29)	P<0.001

Fig. 5.7: The mean ± SEM % Framingham 10 year primary CHD risk score in those who did or did not respond to the questionnaire.



Chapter 6: Discussion and Conclusion

No one would deny that giving good quality, reliable and comprehensive information to people with diabetes is not right and appropriate in principle, and there is evidence that they want it, expect it and value it (224-227), but is it of any demonstrable value to their diabetes care?

In this large scale, single health economy, randomised controlled trial we have demonstrated that the provision of structured information regarding all core diabetes care processes, with due consideration to its purpose, design and utility, had an overall positive affect on the complete / near complete attainment of those key care processes.

It should be noted that the intervention and the 3 month assessment occurred at a time when UK primary care teams put in maximal effort to achieve the completion of diabetes care processes for the end of financial year payment relating to the NHS primary care diabetes quality outcomes framework (QOF). It has been shown in multiple assessments that the introduction of QOF led to a significant improvement in the documentation and completion rates of care processes (61, 62). This QOF process would tend to mask any effect of the intervention, and the process was applicable to both groups. Therefore, any benefit of the mailed booklet with a single intervention, demonstrated over a short observation period, exactly coinciding with the time that primary-health care providers were actively trying to complete their contractual obligation (QOF) and thus attain their financial payment, is a surprisingly positive outcome.

On the face of it, the effect of multiple mailing had no significant impact on patient activation as measured by the accrual of key diabetes processes in the FPS score. Nor did it have any significant impact on the key clinical surrogate marker of risk, but this however should be considered in relationship to the potential to benefit, as well as the balance of the likely impact of patient activation versus the magnitude of service activation.

Nevertheless, mean numerical attainments or benefits might be considered to be moderate, or even marginal. This is because of the overall attainments related to impacts on specific sub groups. If patient activation is driven by this booklet and if attainment of the process is a marker of their engagement, then it is to be expected that those with pre-existing very good

attainment (FPS 0 or 1), who are de-facto already active and engaged, might not be further positively influenced. This indeed turned out to be the case. Thus, the target for benefit are people with poor engagement in poorer FPS groups, and we show that even those with much poorer attainment (including FPS 5 or more) seemed to show a continuum of benefit. In the whole cohort, almost 60% were already in a high attainment position and thus could not further benefit. When considering those with poorer attainment, the pattern of initial improvement was more marked, and they did not deteriorate to baseline, while in the active group the impact of single then repeat mailing was positive and significant, so that at the end of 12 months they were 15% relatively more likely to be in the higher attainment category. Thus the impact of single or multiple mailing may be seen to have achieved its objective of having a significant impact over and above that of maximal service activation, and to have separately benefited the intended target groups in lower attainment categories.

There was an interesting variation in the nature of this benefit across the cohort. This can be understood from the perspective of any diabetes model of care, including ours, and it is linked to the notion of patient activation. In WICKED, the notion of care provision is governed to be user centric, but in an increasingly fragmented NHS, it is almost impossible to attain integration between multiple providers (89). Thus, the focus is to set clear standards for care provision to providers, to permit access to quality health care to all people with diabetes within our health economy (horizontal integration) and to identify individuals according to their specific needs and risks and move fragmented services to integrate around them accordingly (vertical integration) through clinical governance and performance management (228).

Crucial to this is the fact that people with diabetes become the drivers of their own health care. It is conventionally felt that for people with diabetes to have a sufficiently expert understanding of their condition, they require training and education (160), but equally, they cannot be knowledgeable or seek learning if they have no information. People with diabetes bemoan the lack of specific information given to them about their diabetes by health-care professionals and organisations and there is evidence to show that such information is both valued and valuable (184). It is on this basis that the trial was designed to determine if information would lead to patient activation and enable them and empower

them to achieve the processes of diabetes care that health-care providers struggle to attain (28).

We have previously shown that those with increasing process failure very rarely "default" from care (229). Some simply have not been captured by the provision (15%), some are informed dissenters who may have made a choice not to access provision (30%), but most are those who wish to access care but cannot because of physical or psychiatric comorbidity or are house bound and immobile, and are thus constrained from becoming active in their own care. The booklet might not therefore have been expected to overcome such barriers, but it did appear to do so. We also note that in those who became activated during this period of time, such activation was further enhanced by the receipt of the document, such that not only did their score improve, but so too did their attainment of the targeted good attainment (GA) category. What we can also say, in relationship to worsening FPS outcomes, is that no harm appears to have been caused by this intervention. Hence, for example, in those in poorer attainment categories who might be dissenting from care, they might have been further discouraged, or others may have been falsely reassured and become more blasé, but there is no evidence of this, and thus no evidence of harm.

Whilst we have focused on the benefit to these measurable diabetes care-process outcomes, other outcomes might be excepted to improve, and we have shown, in previous pilot work, that the document was wanted, needed, valued and well evaluated by people with diabetes, but also that it had had a very positive effect on doctors in their relationship with the patient and the understanding of their care needs (230).

Then impact of HbA1c can be similarly considered. Our a-priori expectation was that if any differential impact were to have occurred, it would have been in those with poorer baseline glycaemic control, but the opposite result is perhaps predictable. As is well recognised, the focus of clinicians and services will be on poorly controlled patients (26), service inertia and delay is a crucial reason for poor attainment in such patients (216) and the propensity to improve is almost certainly dependent on service intervention through drug titration and, in many patients, escalation to injectable therapies (231). A patient in this category is unlikely to have been able to influence their own outcome over and above the impact of service interventions. However, in the better baseline HbA1c attainment cohort (HbA1c ≤7.5%), the

service would have been less focused on them as they were already at or below the UK HbA1c attainment target (6), there would have been no perception that drug therapies required modification, and patients would have been more likely to have been able to significantly modify their own already good attainment, perhaps by diet and life style interventions or by improved concordance. The group with multiple mailings essentially maintained their HbA1c whilst the group with single mailing deteriorated by 0.3 HbA1c%. This seems small, but roughly equates to size of effect of the addition of a second or third line oral hypoglycaemic agent in Type 2 diabetes (232).

The small size of any magnitude of effect can be further considered in the light of known evidence. In a recent Lancet metanalysis, non-pharmacological interventions were extensively reviewed (88). They can be categorised into 3 categories of quality improvement strategies targeting health systems, healthcare providers and people with diabetes. It was concluded in this review that patient focused and health system wide interventions are more likely to influence outcomes in low to intermediate HbA1C risk group. However those with high HbA1C get most benefit from strategies focusing healthcare providers. This can be interpreted in the context of service related clinical inertia, where a clinician dependent intervention will have more benefit both in pharmacological and non-pharmacological interventions. However, we must acknowledge the fact that all such interventions have only shown modest improvements in hard outcomes such as HbA1C, which has only shown a mean difference of 0.37 %. Data from UKPDS suggested that a 1% reduction in mean HbA1c results in 21% fewer deaths, 14% fewer myocardial infarctions, and a 37% decrease in microvascular complications at the population level (233). An HbA1C improvement of 0.3% by our intervention might translate to 7% fewer deaths, 5% fewer myocardial infarctions, and 12% fewer microvascular complications at the population level.

It is evident from the patient satisfaction survey that people with diabetes wished to have their individualised information in a structured format that is easy to understand and found it beneficial in a number of domains.

To the best of our knowledge the use of this booklet is the first example to demonstrate prospectively that an information tool (as an intervention) can be used to improve patient activation with its use resulting in a significant improvement in the completion of diabetes

process measured in the Failed Process Score (234). We demonstrate that non response to the survey, equating to potentially poorer patient activation, was not only significantly associated with a worse FPS as another marker of activation but also with adverse clinical risk, as reflected by HbA1c, BMI, Cholesterol, smoking and primary CHD risk. We did not use a validated patient activation measure tool (168), which was beyond the remit of our project, but we took FPS and a failure to respond to the survey as indirect measures of patient activation. We accept that these may be assumptions, but highlight the conundrum that formally measuring patient activation can only be undertaken in those that engage in care. The true potential bias is thus the erstwhile low response rate to the survey. The response rates to health surveys average around 60% (235) when using maximal techniques (236), and in surveys with 1 reminder a response rate of 40% is typical (237) and we emphasise that the selected population was a random sample that did not differ significantly in any regard from the wider cohort which minimises any potential bias linked to non-response. In retrospect, we could have selected a smaller sample size backed up by multiple reminders to enhance our response rate to more typical rate of around 60%.

A poor FPS score and low survey response may reflect poorer patient activation, which may in turn be associated with measurable increased risk. However, non-response does not mean that the information booklet is ineffective in modifying that risk. Our primary outcomes clearly demonstrated a greater impact on diabetes access and process measure outcomes in the poorer FPS categories. The potential therefore clearly exists, as a consequence of increased access and process attainment, that the adverse clinical profile may become modifiable through follow on service intervention.

We have not carries any cost benefit analysis of this intervention as a part of this project. However, once a functional database is established, the cost of mail merge, printing and mailing via post came to an accrued cost of <£1 per patient. If we map this cost against hard outcomes of the interventions i.e. HbA1C improvement of 0.3% and improved care process completion rate then it is highly likely that this intervention will prove cost effective. Further cost benefits can be extracted by targeting people with diabetes in high risk categories that will result in reduce mailings and hence less cost.

The limitations of the study are acknowledged to be the relatively small magnitude of change observed, the relatively short time frame to first assessment of mailed vs. non mailed group and the inability to assess longer term clinical outcomes within the time frame. It is possible that the observed benefit at 3 months could have been by chance or random finding but persistence of improvement at the end of 12 months has confirmed the benefits of intervention. The strengths of the study include its large size, minimal loss to follow up and cluster randomisation methodology used to provide robust evidence in this evidence deficient arena of diabetes care.

In summary, in a large randomised controlled trial, we have demonstrated that the provision of structured diabetes-specific clinical information, through a specifically designed booklet, led to significant improvements in diabetes process outcomes with no evidence of harm. People with diabetes are able to understand their most important diabetes related information when it is presented to them in a simple but structured format. The booklet is easy to generate, and is seemingly low tech, with the proviso that the enabling background complexities of data integration and quality assurance are at a very high and well governed standard. It should be easily reproducible in other health economies. It can be disseminated independent of health care professionals and systematically distributed across a whole population. It provides people with diabetes with an opportunity to reflect on their own status and take action and it does facilitate their consultation with healthcare professionals (230). It does promote patient activation even amongst those with a poorer baseline FPS scores (234). Indeed, this greatest impact seemed to be amongst those with poorer prior attainment in which the booklet enhanced their activation as determined by their improved FPS score and their attainment of the best outcome category. This effect appears to be independent of all demographic factors and the baseline marker of patient activation. This study can be used in future as a pilot to navigate the fundamental principles of a model of user centric, data driven diabetes care delivery. The service activation limb of this model is subject to another project to produce valuable information and to help designing better co-working strategies based on evidence that may facilitate adoption of the WICKED model as a widely accepted model of diabetes care delivery in the NHS.

Guidance Notes

My Diabetes Information Report

The report on page 2 has items of information about your diabetes.

Each item is a measure or test and has a description explaining what it is. It shows the latest result over last 15 months. Ideally they should be less than 12 months old. If a test hasn't been done or is out of date, please get it done as soon as possible, You may not be getting the correct care or treatment if out of date information is used.

It then gives you the guidance based on your results so you can work out if the situation is "Good", "Borderline" or " Of concern". You may already be aware of this and you may already be on the correct treatment plan. In any case, judge whether you understand what the result means and whether you need to do something about it.

If you are still not clear about the result, or feel action is needed, see your GP team for advice - ask for a routine appointment (not urgent) with your GP surgery.

My Diabetes Plan

Having worked through your information in "My Information" and having come to your own view about each item of diabetes care, please look at "My Plan".

Again there are a number of sections. Decide where you stand on each of them - mark down if it is "Good", "Borderline" or "Of concern".

Decide where you would like to be. For example - what level of diabetes glucose control or blood pressure control are you aiming for? Always think of what is best for you in your situation. Then think about what you might need to do to get there and try and make a plan. Use this plan to improve your diabetes care. Feel free to use it with your diabetes team to help them understand your worries and your needs.

You may have other items of concern - please make a list of them as needed. There is space for you to make further notes and comments if you wish.

Definitions

Good = the result is satisfactory and acceptable with no need to worry. Lower risk.

Borderline = should be better and adjustments need to be made. Medium risk

Of Concern = in definite need of improvement and further testing and must be kept under close review. Higher risk.

Designed and produced by The Department of Clinical Illustration & Graphic Design Mi 489612 03.04.13 V 0.5

The Royal Wolverhampton NHS
NHS Trust

Wolverhampton Diabetes Care

Mr Mickey Mouse
1 Hollywood Blvd
Hollywood
Los Angeles
LA1 A12

Dear Mr Mouse DOB 1/1/1900; Hosp No. A123456; NHS No.123 456 7891

My Diabetes, My Information, My Plan

We are writing to you on behalf of local NHS services delivering diabetes care in Wolverhampton.

This letter has important information about your diabetes.

Please use it to understand your diabetes and what you may need to do or to change in order improve your health.

You can also use it when you see your GP or practice nurse, the hospital diabetes service or other health professionals. Please feel free to ask them questions about things that concern you or that you don't understand. You can work through this report with them. Use it to raise any concerns or questions you have. You and your health care team will find this helpful in making the best plan for your health care, a plan that will more suit your needs.

That's why this is called "My Diabetes, My Information, My Plan".

On the following pages you will find:

- **Guidance notes (back page).**
- "My Diabetes Information" - a report covering all of your diabetes results and examinations (page 2).
- "My Diabetes Plan" - a plan maker to help you to assess or judge your own diabetes care and make a plan of action if it's needed (page 3).

If you do not have diabetes or you feel this letter should not have been sent to you, please kindly let us know by phoning on **01902 695629.**

My Diabetes Information Report

Symbols: “<” means “less than” and “>” means “more than”
The levels that are in keeping with “Good” or “Of concern” are shown

Measure or Result (Good, Of concern)	Value	Clinical Comment	What is it?
Weight	**73.4**	**See BMI**	Measure of weight in kilograms
BMI (<25, >30)	**32**	**Of concern**	Weight in relation to height
Blood pressure (<140, >160)	**167**	**Of concern**	Blood pressure (top number).
Cholesterol or Chol to HDL ratio (<4.5, >5.5)	**5.6**	**Borderline**	Blood test of cholesterol or Cholesterol corrected for “good” HDL Cholesterol if known
Smoker (Non-smoker)	**No**	**Good**	Question of smoking status
Blood vessel circulation risk Primary / Secondary	**Primary**	**Good**	Circulation risk. Primary means no circulation illness. Secondary means heart, stroke, leg or foot circulation problems.
Primary Risk Score (<15%, >30%)	**24%**	**Borderline**	Calculation of blood vessel circulation risk over 10 years.
Eye Exam	**No Changes**	**Good**	Test for diabetes changes at back of eye by photography.
ACR (< 3.5, >10)	**15.7**	**Of concern**	Urine protein test for early diabetes changes in kidneys.
Creatinine (<120, >150)	**138**	**Of concern**	Blood test of kidney function.
Foot exam	**Low risk**	**Good**	Test for nerve or circulation damage.
HbA1c DCCT (< 7.5%, >8.5%)	**7.2**	**Good**	Blood test of long term diabetes or “Sugar” control.
HbA1c IFCC (< 58, >70)	**55**	**Good**	Same as above but using new units of measure (as above).

My Diabetes Plan

My opinion Where do I stand? Circle your status in each box	**My Feelings Where do I want to be?**	**My Plan What steps should I take?**
My Lifestyle (Diet, exercise, smoking) Good, Borderline, Of Concern		
My BMI (Weight) Good, Borderline, Of Concern		
My Blood Pressure Good, Borderline, Of Concern		
My Cholesterol Good, Borderline, Of Concern		
My Circulation Risk Low, Medium, High		
My Eyes Good, Borderline, Of Concern		
My Kidneys Good, Borderline, Of Concern		
My Feet Good, Borderline, Of Concern		
My HbA1C (sugar control) Good, Borderline, Of Concern		
My Hypo Risk (risk of low blood sugars) Low, Medium, High		
My Medication Good, Borderline, Of Concern		
My Diabetes Know how Good, Borderline, Of Concern		
My Well-being Good, Borderline, Of Concern		
Other:		
Other:		

My Comments:

The Royal Wolverhampton NHS
NHS Trust

A questionnaire about the document "My Information, My Diabetes, My Plan"

PLEASE HELP

Dear PT NAME

DOB Hosp NHS

You recently received your "My Diabetes, My Information, My plan" document. We would like to know if it was helpful.

It would help us to understand whether the report, its instructions and the information contained was clear and useful.

Please take some time to answer all of the questions over leaf.

Read each question and circle the answer the box that most represents your view.

When you have finished, please send it back using the stamped addressed envelope provided.

Many thanks for your help.

Dr. B M Singh

Dr. Syed Gillani

GP and Clinical Research Fellow in Diabetes

New Cross Hospital Wolverhampton

CIRCLE JUST ONE ANSWER FOR EACH QUESTION

Did you understand the purpose of this document and what it is meant to be used for?

Yes definitely Yes to some extent No not really No definitely not

Were the contents of the report easy to read and understand and do they make sense to you?

Yes definitely Yes to some extent No not really No definitely not

Was the information useful?

Yes definitely Yes to some extent No not really No definitely not

Did this information give you more knowledge about your diabetes?

Yes definitely Yes to some extent No not really No definitely not

Did his information help you to understand your diabetes better?

Yes definitely Yes to some extent No not really No definitely not

Would this information help you to improve your diabetes?

Yes definitely Yes to some extent No not really No definitely not

Would this information help you make changes in your diabetes?

Yes definitely Yes to some extent No not really No definitely not

Would this information help you feel more in charge or control of your diabetes?

Yes definitely Yes to some extent No not really No definitely not

Would you take this information with you to your next diabetes appointment with a doctor or a Nurse?

Yes definitely Yes to some extent No not really No definitely not

Did you think this information will help in your next consultation with a doctor or a nurse?

Yes definitely Yes to some extent No not really No definitely not

Would you like to receive information like this in the future?

Yes definitely Yes to some extent No not really No definitely not

How often would you like to this sort of report with this sort of information about your diabetes?

Once a year twice a year I don't want to have this information

Overall, do you think it is a good idea for people with diabetes to have this sort of report?

Yes definitely Yes to some extent No not really No definitely not

Overall, do you think people with diabetes will use this information to take better care of themselves?

Yes definitely Yes to some extent No not really No definitely not

NHS
Health Research Authority

NRES Committee North East - York
Room 002
TEDCO Business Centre
Viking Business Park
Rolling Mill Road
Jarrow, Tyne & Wear
NE32 3DT

Telephone: 0191 428 3387
Facsimile: 0191 428 3432

08 February 2013

Dr Syed M R Gillani
Academic Fellow Diabetes
The Royal Wolverhampton NHS Trust
Wolverhampton Diabetes Centre
New Cross Hospital
Wednesfield Road
Wolverhampton
WV10 0QP

Dear Dr Gillani

Study title:	**The NHS Choice and Information Revolution - exploring the utilization of highquality clinical data governance processes to promote informed patient drivencare in a locally integrated English diabetes health economy.**
REC reference:	**13/NE/0052**
IRAS project ID:	**117977**

The Proportionate Review Sub-committee of the NRES Committee North East - York reviewed the above application on 08 February 2013.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Miss Hayley Jeffries, nrescommittee.northeast-york@nhs.net.

Ethical opinion

The Committee questioned whether it was research or service evaluation but felt that because controls were involved it should be considered as research.

Members queried whether the study was a cluster RCT and after discussion concluded it was similar to a simple cohort study.

Members considered confidentiality issues surrounding the posting of reports to participants because of the potential of it being incorrectly delivered to the wrong address. It was suggested that the participants GP could pass the information to the patient however it was felt this was not practical. The Committee felt there was no alternative to this as this is a risk when posting any sensitive information.

The members commented on whether all participants would have English as a first language or whether the report would be available in different languages.

The Committee felt the main ethical issue is the use of patient identifiable data without consent as referenced in A30-1 in the IRAS form. It was commented that the researchers already have the data and it is not being collected for research purposes. However it was noted that it would be impractical to get informed consent from 16,000 participants. The members suggested that the researchers contacted the NIGB regarding this.

Dr Singh confirmed that the NIGB had not been contacted yet but was happy to do so and will keep the Committee informed.

The members were concerned that the score forms could not be relied upon as measures and considered that the actions of recipients and their seeking support and advice could be influenced by confounding factors which were not related to the report.

Dr Singh responded that as agreed with the local health economy, the diabetes research that they do in hospital is not about endpoints and outcomes but it is about processes that they deliver to all 18,000 patients. There are 10 or 11 processes within which there are 3 key processes which measure access to services and this indicates engagement. The remaining processes are unaffected. Because the researchers are dealing with processes and not outcomes, it is that which measures the impact of the report.

The Committee noted that the report to be sent to participants was not included in the submission.

Dr Singh advised that he had requested this to be included in the initial submission and would provide this as soon as possible.

Decision

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

New Cross

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Additional Conditions Specified by the Committee

1. The Committee requested a copy of the "My Diabetes, My Information, My Plan" document for information only.

2. The Committee advised that the researchers contacted the NIGB to check whether their approval is required. (This is a recommendation not a stipulation).

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
GP/Consultant Information Sheets	GP letter, V1	
Investigator CV	Dr Syed Gillani CV, January 2013	
Other: Baldev Singh CV		
Protocol	Project Proposal V1, January 2013	
REC application	3.4	

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
information is available at National Research Ethics Service website > After Review

13/NE/0052	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

pp
Professor Peter Heasman
Chair

Email: nrescommittee.northeast-york@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers" SL-AR2

Copy to: *Mrs Yvonne Hague, The Royal Wolverhampton NHS Trust*
Mrs Lorraine Jacques, The Royal Wolverhampton NHS Trust

NRES Committee North East - York

Attendance at PRS Sub-Committee of the REC meeting on 08 February 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Malcolm G Harrison	Lay Member	Yes	
Professor Peter Heasman	Professor of Periodontology	Yes	
Mr Austin Wilcock	Clinical Governance Co-ordinator (Retired)	Yes	

Health Research Authority
NRES Committee North East - York
Room 002
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13 February 2013

Dr Syed M R Gillani
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Dear Dr Gillani

Study title: **The NHS Choice and Information Revolution - exploring the utilization of high quality clinical data governance processes to promote informed patient driven care in a locally integrated English diabetes health economy.**
REC reference: **13/NE/0052**
IRAS project ID: **117977**

Thank you for your email of 11th February 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 08 February 2013

Documents received

The documents received were as follows:

Document	***Version***	***Date***
Other: My Diabetes, My Information, My Plan		

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	***Version***	***Date***
GP/Consultant Information Sheets	GP letter, V1	
Investigator CV	Dr Syed Gillani CV, January 2013	
Other: Baldev Singh CV		

Other: My Diabetes, My Information, My Plan		
Protocol	Project Proposal V1, January 2013	
REC application	3.4	

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/NE/0052 **Please quote this number on all correspondence**

Yours sincerely

Hayley Jeffries
Committee Co-ordinator

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Copy to: Mrs Yvonne Hague, The Royal Wolverhamptom NHS Trust

Mrs Lorraine Jacques, The Royal Wolverhampton NHS Trust

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