

Introducing a Systematic Approach to Clozapine Monitoring in a Community (Adult) Mental Health Service

AUTHOR(S)

Izu Nwachukwu

CITATION

Nwachukwu, Izu (2012): Introducing a Systematic Approach to Clozapine Monitoring in a Community (Adult) Mental Health Service. Royal College of Surgeons in Ireland. Thesis.
<https://doi.org/10.25419/rcsi.10811516.v1>

DOI

[10.25419/rcsi.10811516.v1](https://doi.org/10.25419/rcsi.10811516.v1)

LICENCE

CC BY-NC-SA 3.0

This work is made available under the above open licence by RCSI and has been printed from <https://repository.rcsi.com>. For more information please contact repository@rcsi.com

URL

https://repository.rcsi.com/articles/thesis/Introducing_a_Systematic_Approach_to_Clozapine_Monitoring_in_a_Community_Adult_Mental_Health_Service/10811516/1



Introducing a Systematic Approach to Clozapine Monitoring in a Community (Adult) Mental Health Service

A Dissertation submitted in part fulfilment of the degree of

MSc in Healthcare Management

Institute of Leadership

Royal College of Surgeons in Ireland

Dublin, 2012

Student ID: 09108319

Submission Date: 10th May, 2012

Word Count: 13,136

Facilitator: Philippa Withero



Ireland

RCSI Reservoir House,
Ballymoss Road,
Sandyford,
Dublin 18,
Ireland.

Bahrain

PO Box 15503,
Building No. 2441,
Road 2835,
Busaiteen 436,
Kingdom of Bahrain.

Dubai

4th Floor A/P25,
Dubai Healthcare City,
Dubai,
PO Box 505095,
United Arab Emirates

Declaration

"I hereby certify that this material, which I now submit for assessment for the Project Dissertation
Module on the MSc in Healthcare Management, is entirely my own work and has not been
submitted as an exercise for assessment at this or any other University."

Student's Signature(s): Dr Izu Nwachukwu

Date: 10th May, 2012

Student's Number : 09108319

Acknowledgements

I would like to acknowledge all those who contributed their time and expertise to the successful completion of this change management project – my work colleagues, fellow students and facilitators.

My special appreciation goes to all who suffer with severe and enduring mental illness, particularly schizophrenia. The courage with which you bear the burden of your illness provides the most potent inspiration for my continued personal and professional development as I strive to better understand and meet your needs.

Finally, my heart goes to my family only whom understand the human cost of my completing this Masters programme, and my endless endeavour to be a good doctor.

Dedication

EUNICE CHINYERE NWACHUKWU

(1940 – 2005)

Friend, inspiration, confidant and beloved mother

“To live in hearts we leave behind is not to die”

ABSTRACT

Change management is now considered a core managerial competency. Under the fiscal and regulatory environment that currently applies, healthcare managers and professionals must be competent in initiating, guiding and managing change to drive efficient and effective delivery of care.

This dissertation describes a successful journey through a planned change effort. An evidence-based approach to monitoring adverse effects of clozapine was implemented in a Community (Adult) Mental health Team. Clozapine has the sole license for treatment-resistant schizophrenia, but has been associated with several potentially life-threatening adverse effects. Accumulating evidence suggests that not enough attention is paid to recognising and addressing these adverse effects, a finding replicated in an internal audit of practice within this service. Additional external regulatory imperatives provided further impetus for change.

The change was implemented using the HSE change model as a guiding tool. A range of qualitative and quantitative tools that were used to evaluate the change revealed successful attainment of set objectives, and also identified early signs for long term sustenance and continuous quality improvements.

On reflection, the challenges encountered during this project have had considerable formative impact on the learning and practice of the author. It is hoped that future service evaluations will confirm attainment of its intended long term impact, while also providing objective bases for further continuous quality improvement initiatives.

Table of Contents

	Page
1. CHAPTER 1: INTRODUCTION	
1.1. Introduction	1
1.2. Background	1
1.3. Organisational context	3
1.4. The change project	5
1.5. Rational for selecting the change	6
1.6. Expected organisational impact	6
1.7. Summary	7
 2. CHAPTER 2: LITERATURE REVIEW	 7
2.1. Introduction	7
2.2. Literature Search	8
2.2.1. <i>Schizophrenia and treatment resistance</i>	8
2.2.2. <i>The role of clozapine</i>	10
2.3. Psychopharmacology of clozapine	11
2.3.1. <i>Pharmacodynamics</i>	11
2.3.2. <i>Pharmacokinetics</i>	12
2.4. Adverse effects of clozapine	12
2.4.1. <i>Clozapine and metabolic disorders</i>	13
2.4.2. <i>Haematological adverse effects</i>	15
2.4.3. <i>Other adverse effects</i>	15
2.5. Clozapine monitoring	16

2.5.1. <i>Practice guidelines and quality in healthcare</i>	16
2.5.2. <i>Recommended practice</i>	17
2.5.3. <i>Current practice</i>	18
2.6. Summary	19
3. CHAPTER 3: METHODS	
3.1. Introduction	19
3.2. Organisational change	20
3.3. Change management	21
3.4. Change models	21
3.4.1. <i>Lewin's change model</i>	22
3.4.2. <i>Kotter's change model</i>	22
3.4.3. <i>HSE change model</i>	23
3.5. The change process	24
3.5.1. <i>Initiation</i>	24
3.5.2. <i>Planning</i>	32
3.5.3. <i>Implementation</i>	40
3.5.4. <i>Mainstreaming</i>	42
3.5.4.1. <i>Embedding the change</i>	43
3.5.4.2. <i>Evaluation and learning</i>	44
3.6. Summary	45
4. CHAPTER 4: EVALUATION	
4.1. Introduction	46
4.2. Evaluation tools	46

4.3. Evaluation of project	48
4.3.1. <i>Qualitative methods</i>	48
4.3.1.1. <i>Focus groups</i>	48
4.3.1.2. <i>Interviews</i>	50
4.3.2. <i>Quantitative methods</i>	50
4.3.2.1. <i>Questionnaires</i>	51
4.3.2.2. <i>Retrospective chart reviews</i>	52
4.4. Summary	52
 5. CHAPTER 5: DISCUSSION	
5.1. Introduction	54
5.2. Strengths of the project	54
5.3. Limitations of the project	56
5.4. Recommendations for future improvements	58
5.5. Reflections	59
5.6. Summary	61
 References	62 - 71
 Appendices	72 - 82

1. CHAPTER 1: INTRODUCTION

1.1. Introduction

Change is a constant feature of life. It has assumed a particular strategic significance in the continuously evolving health and social care environment of modern times. In this dissertation, the author describes the assessment, planning, implementation and evaluation of an initiative aimed at improving the routine monitoring and management of physical health consequences of clozapine, a medication used for the treatment of schizophrenia. This first chapter introduces the concept of organisational change. A discussion follows on the change project, the rationale for the project, the aims and objectives and the organisational context in which the change was implemented. The expected organisational impact is outlined and the chapter concludes by setting out the broad layout for the remainder of this dissertation.

1.2. Background

Recent decades have witnessed tremendous advances in the scope and quality of care across all medical and allied health disciplines. Perhaps the most exponential of these advances have occurred in the field of mental health with the seismic transition from institutionalisation to community-based care (Wright, 1997). Other significant advances include unprecedented reforms in mental health legislations (Kelly, 2008); novel insights into brain neuroplasticity (Pascual-Leone et al, 2005) and the consequent advent of safer and more effective investigative and therapeutic agents. These reforms have resulted in safer practice and improved quality of care. They have

been underpinned by change, made by people within organisations.

From a clinical standpoint, one of the significant advances in contemporary psychiatric practice has been the greater attention paid to the interface between psychiatry and medical disorders (Mangtani et al, 2005; Whyte et al, 2007; Roberts et al, 2007). It is now widely recognised that people with major mental illnesses have a greater propensity to suffer with medical disorders, and that they tend to have worse outcomes from treatment (Mitchell, 2012; Connolly & Kelly, 2005). Their psychiatric illness, its treatment and the lifestyle choices they make have all been found to contribute to this excess morbidity and mortality (Malhi et al, 2010; Connolly & Kelly, 2005).

Psychiatry has long been renowned for its holistic approach to care planning and delivery (Angyal, 1948). Within this context, psychiatrists must take adequate care to recognise, prevent and address adverse effects associated with the therapeutic interventions that they implement (UEMS, 2009). They must also remain vigilant to medical conditions that may be incidental, contributory or consequential to mental illness and its treatment. Also, because co-morbidity is commonplace in psychiatry, the psychiatrist has a duty to actively collaborate with other specialists at various interfaces, including at primary and secondary care levels to minimise overall illness burden and enhance recovery (UEMS, 2009).

There is growing concern that current practices deviate considerably from the tenets espoused above, particularly in regard to the physical health care of psychiatric patients (Mitchell et al, 2012). Evidence now abounds on the association between

clozapine, the only medication licensed for treatment resistant schizophrenia, and several adverse physical health consequences (Malhi et al, 2010; Mortimer, 2011; Bolton, 2011). Several authors have commented on widespread shortfalls in care provision for patients on clozapine treatment (Bolton, 2011, Mitchell et al, 2012; Kohen, 2005). It was therefore considered prudent to examine how this mental health service compared with international standards and practices in this area.

1.3. Organisational Context

This project was carried out within a Community Mental Health Service (CMHS) that provides specialist assessment and treatment for adults of working age who suffer with major mental illness. The service is state-funded, providing outpatient and day services for a predominantly rural population catchment area of 35,000. Referrals are almost exclusively from local General Practitioners (GPs) who are self-employed contractors to the health service.

The main hub of the service is a community-based acute day hospital from where a multi-disciplinary team (MDT) of mental health professionals operate. The MDT comprises one Consultant Psychiatrist (the author), one Psychiatric Registrar, six Clinical Nurse Specialists, 2 Community Mental Health Nurses, and one each of Clinical Psychologist, Mental Health Social Worker, Occupational Therapist, Addiction Counsellor and Family Therapist. The team is supported by 3 administrative and secretarial staff. A subset of the team comprising 5 members from different disciplines (including the author) constitutes the Sector Management Team.

Team leadership is provided by the Consultant Psychiatrist (author) who is also a member of the Senior Management Team of the County Mental Health Service.

Cases referred to the team fall within the broad range of common psychiatric illnesses that typically present to an adult mental health service. These include psychotic disorders, mood disorders, anxiety disorders, alcohol and substance misuse as well as personality disorders. In line with best practice, the burden of ongoing clinical responsibility is shared with patients' GPs, including during the acute phase of their treatment, with regular updates on clinical progress and changes in treatment regimen. Insofar as is possible and appropriate, efforts are made to involve families and carers in the planning and delivery of care.

Patients on Clozapine were seen regularly in a dedicated Nurse-led clozapine clinic for regular full blood count monitoring as stipulated by the product license. Under strict governance protocol for the clinical use of clozapine, patients attend weekly for the first 18 weeks, then fortnightly for up to one year and monthly thereafter. The focus of this clinic was the detection and management of agranulocytosis, a rare but potentially fatal adverse effect of clozapine. Monitoring was carried out by two nursing staff that had received specialist training for the purpose. The team coordinator - an Assistant Director of Nursing (ADON) and the Clinical Nurse Manager for the Day Hospital provided nursing supervision. Patients were also assessed for blood pressure, pulse, glucose, lipids, liver function and weight. However, these other assessments were *ad hoc* as there were no guidelines and protocols in place for the monitoring of these parameters; nor were there standards or procedures for follow-up in the event that abnormalities were detected.

1.4. The Change Project

The change involved the development and introduction of a structured and systematic approach to monitoring and managing the adverse effects of clozapine. Clozapine is the only antipsychotic medication licensed for treatment-resistant schizophrenia. Unfortunately, it has a number of problematic and sometimes life threatening adverse effects that necessitate long term monitoring (Metzer, 2010; Mortimer, 2011). The most notorious of these, agranulocytosis, already has a robust and effective monitoring service currently provided by the drug manufacturer in line with the product license (Norvatis, 2010).

The scope of this change initiative therefore was to introduce a structured mechanism for monitoring and managing those various other adverse effects that contribute to the excess morbidity and mortality associated with the use of clozapine. This involved developing and implementing a local practice guideline on clozapine monitoring, enhancing the knowledge and attitude of staff to the safe clinical use of clozapine and facilitating active participation of patients in their own physical healthcare through improved awareness of modifiable risk factors. The change also involved the development of a structured proforma for documenting relevant clinical parameters; and a standardised letter for communicating any identified abnormalities to GPs with a view to ensuring prompt and effective interventions when necessary. There was also the introduction of medical back-up to the previously nurse-led clozapine clinic.

1.5. Rationale for selecting the change

The 2010 guidelines on schizophrenia from the National Institute for Health and Clinical Excellence (NICE) acknowledged the wide range of adverse effects associated with clozapine, and stipulated evidence-based guidelines for the physical health care of these patients (NICE, 2010). It was against this gold standard that the author previously compared the current practice of this mental health service as part of an audit cycle. The main finding of this continuous quality improvement initiative was a breach of international best practice in this area of clinical care. In addition, the whole area of care planning and delivery also come into focus following an unannounced visitation by the inspectorate division of the Irish Mental Health Commission (MHC) within the previous year. The service was therefore keen to improve its work in relation to clinical care pathways prior to the next visit by the commission.

The choice to carry out this change project was therefore not a difficult one. Firstly, there was a genuine need for change, at service level, from both operational and strategic perspectives. Secondly, it was expected that the change would be cost neutral in that the *efficiency* and *utilisation* of existing resources might only require to be optimised. Thirdly, the author was in a vantage position of influence with favourable expert and position powers (French & Raven, 1959).

1.6. Expected Organisational Impact

On successful completion, this project was expected to have a wide range of positive effects across all stakeholders. Patients were expected to experience improved quality of care that would hopefully translate to considerably enhanced quality of life. With increased awareness of their modifiable risk factors, they would become active participants in their own healthcare and well being. Staff would be empowered with new skills, enhanced professional confidence, job satisfaction and career progression. With established compliance with best practice guidelines, the service was expected to become less susceptible to complaints, clinical incidents and litigations.

1.7. Summary

This chapter has provided an overview of what this change project entailed and the context within which it was initiated and completed. The goal of planned change is to improve operational and managerial effectiveness. In this regard, the potential benefits not only for the patient but also for the staff and entire organisation as a whole has been outlined. The next chapter will provide a literature review on the clinical use of clozapine while the subsequent chapters will focus on the method of change implementation, evaluation of the project and a discussion on the highlights of the project.

2. CHAPTER 2: LITERATURE REVIEW

2.1. Introduction

This chapter will explore the evidence base for the use of clozapine in treatment resistant schizophrenia. It will outline the mechanisms by which clozapine exerts its clinical effects, both therapeutic and harmful. A detailed discussion will follow on the adverse effects of clozapine and the recommended monitoring mechanisms aimed at improving the safety profile of the drug. The chapter concludes by highlighting the gaps in current service provision that formed the basis for this quality improvement initiative.

2.2. Literature Search

A comprehensive literature search was conducted on electronic databases including Pubmed, PsycINFO, Cochrane Library as well as the Psychology and Behavioural Science Collections. Further search was carried out using Google web search and Google Books. Relevant articles were filtered and reference lists were reviewed for supplementary sources. The following key words ‘clozapine’, ‘monitoring’, ‘metabolic syndrome’, ‘schizophrenia’ and ‘physical health’ were included in the search both singly and in various combinations. Furthermore, international and national policy documents (in English Language) were searched for relevant information on the subject. Overall, there was considerable amount of relevant peer-reviewed articles published on clozapine and its clinical effects, both therapeutic and adverse.

2.2.1. Schizophrenia and Treatment Resistance

The term schizophrenia was coined by Eugene Bleuler in 1911. Prior to this, reports of people suffering from symptoms suggestive of the illness had been recorded as far back as the second millennium BC (Bleuler, 1911). Schizophrenia is a severe mental illness which affects one percent of people at some point in their lives (DSM-IV, 1994). In an Irish context, this prevalence rate approximates the number of people required to fill the capacity of Aviva Stadium™. Schizophrenia is a complex illness with a wide variety of symptoms, of which any particular person may only show a selection. These symptoms fall within two broad categories – positive and negative (DSM-IV, 1994; Sims, 2002).

Positive symptoms of schizophrenia include delusions (strange beliefs that cannot be shaken by logic or reason), hallucinations (usually in auditory modality, where the person hears voices that are not there), paranoia (in which the person believes people, etc are plotting against them), and thought disorder (abnormalities of the way thoughts are linked together as expressed in speech or writing) (Sims, 2002). These symptoms generally respond well to treatment although they can be quite dramatic and frightening for both sufferers and their carers.

Negative symptoms develop more slowly and later in the course of the illness (Sims, 2002; Velligan & Alphas, 2008). They include social withdrawal, difficulties in communicating, lack of motivation and inability to cope with demands of everyday life like washing and dressing. Unfortunately, negative

symptoms do not respond as well to treatment (Smith *et al*, 2010); and can cause significant distress for both sufferers and their families who become frustrated by their lack of spontaneity and emotional response.

The mainstay of treatment for schizophrenia is antipsychotic medications; usually as part of a holistic treatment plan (NICE, 2010). About 25% of people recover fully over a few months; a further 50% recover somewhat, albeit with recurring episodes of illness for the remainder of their lives while the final 25% do not respond to conventional medical treatment and would suffer with enduring mental distress (Schizophrenia Ireland). This last group of patients are said to exhibit treatment resistance, defined as failure to respond to at least two conventional antipsychotic medications prescribed at appropriate doses over an appropriate duration (NICE, 2010). Due to problematic adverse effects associated with clozapine, the license for its clinical use has been restricted to this last cohort of sufferers (NICE, 2010).

2.2.2. *Role of Clozapine*

Clozapine was first developed by Sandoz® in 1961 but was introduced in clinical practice in 1972 (Crilly, 2007). Three years later it was voluntarily withdrawn by the manufacturers after the drug was conclusively linked with incidents of agranulocytosis which was unfortunately fatal in some of the patients that received the drug (Healy, 2004). However following robust evidence of its superior efficacy in treatment-resistant schizophrenia (McEvoy

et al, 2006; Lewis, 2006), clozapine received a restricted license specifically for patients who experienced treatment resistance. The caveat for this license was that a strict process be maintained for ongoing monitoring of the haematological profile of patients, with particular attention to the potentially fatal agranulocytosis (FDA, 2005).

Within the class of atypical antipsychotic agents, clozapine is unique with its superior efficacy for both positive and negative symptoms in resistant schizophrenia (Chandrasekaran, 2008). It has also been shown to reduce suicidality, tendency to substance misuse as well as violence and aggression. For example, a Cochrane review of 29 studies involving 2490 participants confirmed a comparatively favourable response to clozapine in measures of symptom reduction, number of relapses, treatment discontinuation and overall satisfaction (McGrath, 1999).

2.3. Psychopharmacology of Clozapine

2.3.1. *Pharmacodynamics*

Despite its unique clinical effects, clozapine shares its chemical structure quite closely with four other antipsychotics namely Olanzapine, Loxapine, Zotepine and Quetiapine (Stahl, 2000). Although it is primarily a 5HT_{2A} – D2 antagonist, clozapine has one of the most complex profiles in psychopharmacology with a myriad of receptor affinity and binding properties. This explains, at least in part, its unique clinical profile particularly

with regard to its broad range of adverse effects (Malhi, 2010). While its Serotonin-Dopamine antagonist properties are responsible for most of its antipsychotic effects, majority of its adverse effects are caused by its antihistaminic and anticholinergics properties. For example, clozapine induced weight gain is due mainly to its antihistaminic binding properties, made worse by concomitant Serotonin-2C antagonist actions (Stahl, 2000).

2.3.2. Pharmacokinetics

Clozapine is readily absorbed after oral administration with peak plasma concentration achieved after about 2.5hrs following an oral dose (Stahl, 2000). It is extensively metabolised by the liver to Norclozapine, which itself is pharmacologically active. Because it is subject to significant *first pass effects* in the liver, induction of metabolism such as occurs with smoking means that smokers do require considerably higher doses of clozapine to attain the same plasma concentration as non-smokers (Stahl, 2000). This has significant implications in terms of incidence and prevalence of adverse effects which have been shown to correlate with administered doses (Melkersson, 2004).

2.4. Adverse Effects of Clozapine

Evidence now abounds that people with schizophrenia die prematurely (Browne, 2000; Osby et al, 2000; Hennekens et al, 2005; Capassa et al, 2008; Metzger, 2010). They have a two to fourfold increased relative risk of premature death; with majority dying at least 10 years earlier than age matched controls (Brown, 1997; Joukamaa et al, 2001). For these patients, their illness, its treatment and their lifestyle choices all

contribute to this excess morbidity and mortality, two-thirds of which has been attributed to physical causes such as cardiovascular disease, respiratory disease and diabetes. Lifestyle choices such as poor diets, low rates of physical activity and increased likelihood to smoke cigarettes have also been shown to be significantly contributory (McCreadie 2003). In addition, of critical importance in the causation of their excess morbidity and mortality remains the role of antipsychotic medications, particularly Clozapine (Newcomer, 2005; Bolton, 2011).

2.4.1. Clozapine and Metabolic Disorders

Antipsychotic-related weight gain was first reported in the late 1950s (Baptista, 2008). Excessive body weight substantially increases the risk of morbidity from a number of physical illnesses (Rummel-Kluge, 2010). Weight gain, especially of the central obesity variety, is one of the cluster of risk factors (central obesity, hyperglycaemia, hypertension and dyslipidaemia) that, when present together, constitute Metabolic Syndrome (MS) (Malhi, 2010). When present, MS has been shown to result in a two to three-fold increase in cardiovascular disease mortality; five-fold increased risk to develop type 2 diabetes and a two-fold increase in overall mortality (Lakka et al, 2002; Dekker et al, 2005; Eckel et al, 2005).

Clozapine has the greatest efficacy of all antipsychotic medications for the treatment of schizophrenia (Malhi, 2010; Chandrasekaran, 2008). However, it induces the worst metabolic adverse effects (Metzer, 2010), and has been

associated with significantly higher rates of metabolic syndrome compared to conventional antipsychotics (Mitchell, 2012). For example, in a meta-analysis of 80 studies that examined antipsychotic-induced weight gain, clozapine treatment was associated with a typical weight gain of about 4.5kg over 10weeks, the most of any antipsychotic drug (Connolly & Kelly, 2005). In a 5year naturalistic study on the metabolic consequences of clozapine, Henderson and colleagues (2000) found that up to one third of patients on clozapine developed diabetes after 5 years of treatment. Similarly, Newcomer et al (2002) studied the abnormalities in glucose regulation during antipsychotic treatment of schizophrenia. They found that clozapine was more likely than conventional antipsychotics to increase plasma glucose and insulin following an oral glucose challenge. Other researchers have found that this increase in plasma insulin correlates closely with the plasma clozapine level, which is in itself closely related to clozapine dose (Melkersson, 2004). This high prevalence of diabetes in people receiving clozapine makes routine screening a necessity (Lamberti, 2005). Clozapine has also been associated with considerable increases in plasma lipid levels, with mean triglyceride levels doubled and mean cholesterol levels increased by 10% after 5 years of treatment (Henderson et al, 2000). Clozapine induced dyslipidaemia is treatable and early intervention has been shown to reduce morbidity and mortality (Durrington, 2003).

To put the above in context, Fontaine and colleagues (2001) estimated the consequences of antipsychotic-induced weight gain and found that while clozapine saved 492 schizophrenic patients from suicide per 100,000

clozapine-patient-years; clozapine induced metabolic syndrome killed 416 patients over the same period. Clozapine-induced metabolic syndrome is therefore a serious iatrogenic disease for which the clinician must take full responsibility.

2.4.2. *Haematological Adverse Effects*

Clozapine is a somewhat toxic drug that carries a box warning mainly in relation to its propensity to cause agranulocytosis (Munro, 1999). When agranulocytosis occurs, the body's ability to make the white blood cells that fight infection is greatly reduced with the result that an infection as simple as a sore throat can become life-threatening. Fortunately, agranulocytosis is rare with the risk of death reported in the UK as 1 in 100 000 patients exposed to clozapine (Taylor, 2009). This risk is well recognised and currently well managed by several approved clozapine-monitoring systems designed specifically for the purpose (Norvatis, 2010)

2.4.3. *Other Adverse Effects*

Clozapine has several other adverse effects (Appendix 1). A vast majority of these are idiosyncratic and tend to occur early in the course of treatment. Careful monitoring of these is a crucial aspect of good clinical care, especially as most can be treated or favourably modified by dose adjustment or other simple measures (Mortimer, 2011).

Without underestimating the suffering caused by schizophrenia, and following from the above descriptions, the intolerability and adverse effects of Clozapine poses a considerable challenge to the quality of life of those who have to take it. Fortunately, most of these adverse effects are easily detectable and completely reversible especially if robust mechanisms are put in place to ensure their early detection and prompt institution of appropriate interventions when necessary (Mortimer, 2011).

2.5. Clozapine Monitoring

2.5.1. Practice guidelines and quality in healthcare

Since the 2000s, there has been a proliferation of national guidelines for the medical care of people with major mental illness (De Hert, 2011). The effectiveness of these guidelines in improving clinical care standards has however escaped scientific scrutiny until recently (Tosh, 2010). There have been concerns that existing guidelines are generally devoid of clear mandatory recommendations (Pincus, 2007). Reports suggest that routine medical care for psychiatric patients remain often overlooked (Gul, 2006; Mitchell, 2012), with only modest improvement following the recent surge of best practice guidelines (Grol, 2001; Sheldon, 2004; Pincus, 2010). A large British study conducted one year after the NICE guidelines revealed a high prevalence of undetected and untreated metabolic risk factors - in their study of 1966 patients, Barnes and colleagues (2007) found that screening rates were very low (for every one person with diabetes, one was missed; for every case of dyslipidaemia, seven were missed while for hypertension, four were missed).

Several barriers to guideline-concordant, evidence-based care have been described, including inadequate organisational support, clinicians' reluctance to change and lack of clear lines of responsibility (Francke, 2008; Forsner, 2010).

2.5.2. *Recommended Practice on Clozapine Monitoring*

The Clozaril[®] Patient Monitoring Service (CPMS) is a 24hr a day, 7days a week service provided by Novartis[™] with the aim of optimising the safety of all patients receiving the drug in UK and Ireland (Novartis, 2010). This ISO 2000 certified service has its primary focus on the detection and management of agranulocytosis in patients receiving clozapine and has led to a 30% reduction in deaths due to this adverse effect alone (Novartis, 2010). Other Pharmaceutical companies that produce the clozapine are obliged by the drug license to provide a similar monitoring service.

The landmark Clinical Antipsychotic Trials in Intervention Effectiveness (CATIE) study in the United States identified significant deficiencies in the detection and management of metabolic risk factors in these patients (Nasrallah, 2006). In order to address the safety concerns relating to the metabolic effects of clozapine, the 2006 NICE guidelines for schizophrenia recommended that these patients receive appropriate physical healthcare, with regular monitoring of their relevant metabolic parameters.

According to NICE (2006), the monitoring requirements for patients who have been stabilised on clozapine are as follows:

- In the first year of treatment:
 - Blood Pressure, Pulse, Temperature to be assessed at least on a weekly basis
 - Weight, Body Mass Index (BMI), Waist Circumference, Fasting Lipids, Fasting Glucose and/or HBA_{1c} to be carried checked at baseline, 1month, 3months, 6months and 12months
 - Liver Function Tests (LFTs) to be carried out at baseline 6 months
- After the first year of established clozapine treatment:
 - Blood Pressure, Pulse, Weight, Waist circumference to be monitored at monthly visits
 - LFTs, Lipids, Glucose, Urea & Electrolytes to be monitored 6 monthly

Of note, the greater intensity of monitoring in the first year reflects the increased incidence of problems in the first compared to subsequent years of treatment.

2.5.3. *Current Practice*

An internal audit previously carried out by the author as a proactive quality improvement initiative revealed an absence of local policy and practice guidelines on clozapine monitoring. The study also found that when tests were carried out, the practice was *ad hoc* and opportunistic and there was no standard procedure to ensure that abnormal findings were adequately followed-up and addressed. Staff were unfamiliar with best practice guidelines on the subject area, and expressed uncertainty regarding the share of responsibility between psychiatry and primary care in relation to monitoring and managing adverse effects of psychotropic medications in general. On a positive note, staff were enthusiastic for supportive guidelines and infrastructure towards the optimal care of this vulnerable group of patients. However, as can be seen from the above, the mere introduction of guidelines is hardly sufficient to influence a change of practice. Thus the need for this managed change effort.

2.6. Summary

This chapter has provided an overview of the evidence base behind the clinical use of clozapine. The gap between best practice principles and current local practice has also been highlighted. Because of its unique position in the treatment of schizophrenia, the adverse effects of clozapine deserve more than a cursory acknowledgement of their existence. The next chapter will therefore focus on the concept of change and its management. It will also provide a description of how modern change management principles were applied in implementing evidence-based practice in relation to the clinical use of clozapine within this mental health service.

3. CHAPTER 3: METHODS

3.1. Introduction

This chapter provides an overview of change from an organisational perspective. It discusses the concept of change management, and gives some insight into external and internal dynamics that can be of importance at times of organisational change. A critical appraisal of the various change models is followed by an explanation of the rationale behind the choice of the HSE change model to guide this project. The change process carried out is then described in detail using the HSE change model as a guiding tool. The chapter concludes with a summary of its highlights.

3.2. Organisational Change

The Oxford English Dictionary defines change as ‘an act or process through which something becomes different’. From an organisational point of view, Jones (2001) defined change as a process by which an organisation moves from its current position to some future position for the purpose of increasing its overall effectiveness. Three points stand out from Jones’ definition. Firstly, organisational change is goal directed; secondly it is future oriented and thirdly it is aimed at enhancing effectiveness and efficiency. Consequently, organisational change can be considered inseparable from organisational strategy, and vice versa, (Burnes, 2004; Rieley & Clarkson, 2001).

Kotter and Schlesinger (2008) studied reactions to change and found that people’s emotional responses fall along a continuum from aggressive resistance to sincere embrace. According to Crozier & Friedberg (1980), resistance is a reasonable and legitimate expression of the risks which change entails for all who are affected by it.

Having said this, resistance is only one of the many challenges encountered in change. According to Senge et al (1999), these challenges come under three broad categories namely: (i) challenges of initiating change; (ii) challenges of sustaining momentum; and, (iii) challenges of system wide redesign and rethinking.

3.3. Change Management

Change management involves the ability to successfully guide change and is often the ultimate test of effective leadership. According to Todd (1999), it entails a structured and systematic approach to achieving sustainable change in human behaviour within an organisation. It can also be described as the planning, initialising, control and stabilising of change processes at both personal and organisational levels (Carnall, 2003). Change management is a core managerial competency (Senior, 2002). Graetz (2000) took an even stricter view on this by suggesting that the primary task of management in contemporary times is the leadership of organisational change.

3.4. Change Models

Several change management models have been described, all acknowledging change as a multi-step process. Although certain essential steps appear to be common across models, change is not predictable and hardly follows the exact steps that change management models suggest. The choice of model is therefore a matter of personal preference, but must take full cognisance of the context in which the change is to occur.

Examples of change models described in literature include Kurt Lewin's model (Lewin, 1951); Kotter's change model (Kotter, 1995); Young's model (Young, 2009) and the Health Service Executive (HSE) change model (HSE, 2008). Some of these are discussed in more detail below.

3.4.1. Lewin's Change Model

Kurt Lewin (1890 – 1947) is credited for some of the earliest systematic studies on planned change, especially from a group or organisational perspective. Two of his hypotheses remain relevant to current thinking on organisational change: the idea that organisational or group processes are maintained at a state of equilibrium by a forcefield consisting of opposing forces; and the conceptualisation of change as a three-stage process namely unfreezing, change and refreezing (Lewin, 1951). Lewin also emphasised the contextual nature of change as well as the impact of group dynamics on individual responses to change. More recently, however, Lewin's work has received criticism for its simplicity and linearity (Dawson, 1994); its greater applicability to incremental rather than transformational change (Dunphy and Stace, 1992); its heavy top-down, management-driven approach (Wilson, 1992; Dawson, 1994); its limited attention to the influence of power and politics (Wilson, 1992; Dawson, 1994) and its lack of dynamism (Kanter et al, 1992). However, some have argued that these criticisms are based on a rather narrow interpretation of Lewin's work (Hendry, 1996; Ritchie, 2006; Longo, 2011).

3.4.2. *Kotter's Change Model*

John P. Kotter, a professor at Harvard Business School, proposed an 8-step iterative process for implementing successful change (Kotter, 1995). Kotter's model is not radically different from that of Lewin described above. Rather, the 8 steps arguably represent an elucidation of the nuanced elements in Lewin's model, merely making these more explicit. These range from "creating a sense of urgency" (Unfreezing) to "anchoring" the changes (Refreezing). While Kotter's model has been hailed for breaking up change to small manageable steps, others have argued that it is overly prescriptive and does not allow for the often necessary between-step flexibility within the change management process (Sidorko, 2008).

3.4.3. *HSE Change Model*

The Irish Health Service Executive (HSE) recognises change as a constant feature of health and social care service delivery (HSE, 2008). The HSE change model (Figure 1) was thus developed, in 2008, with the aim of improving the experience of patients and service users by facilitating a consistent and effective approach to change across the entire system (HSE, 2008). Key attributes of this model include its basis on an organisation development approach, and its emphasis on the people aspects of change. It combines elements of project management to instil structure and discipline to the change process. It also places a strong value on active collaboration with stakeholders at every stage of the change process (HSE, 2008). The HSE model was selected to guide this change project because it was originally

developed with due consideration to the HSE organisational framework of which this Community Mental Health Service is part. By approaching change as a cyclical and iterative process with between-steps flexibility, the HSE model easily lends itself as an invaluable tool for inculcating an ethos of continuous quality improvement.



Fig. 1: HSE Change Model (HSE, 2008)

3.5. The Change Process

The four stages of the HSE change model include

- Initiation
- Planning
- Implementation
- Mainstreaming

The application of these steps to the change management process is now described in more detail.

3.5.1. *Initiation*

The key task here was preparing to lead the change. The focus was on putting forward a considered case for change; assessing and optimising readiness; establishing a sense of shared responsibility and building a solid foundation to drive and sustain the change effort (HSE, 2008). Personal and collective capacities for change were assessed and optimised by careful attention to factors that could potentially aid or impede the change effort. Similarly, an analysis of the people or groups that were likely to be impacted on by the process helped in creating a business case for change.

Forces at play – drivers and resistors

The initial stimulus for this change initiative was the author's special interest in the interface between psychiatry and medical disorders, and particularly their empathic disposition to the adverse effects of psychiatric medications. This interest was further enhanced by an unannounced visit by the MHC inspectorate division in the previous year when the service came under criticism in relation to clinical care pathways, especially in the areas of physical examinations and general health promotion. Because a revisit of the inspectors was envisaged within the coming year, the synergistic effect of an external policy environment and an internal need to improve the work of the service in this subject area became a potent driver for change. Other notable driving forces included the position and expert power of the author, the healthy team dynamics within the service and the existence of other parallel but supportive change initiatives that were ongoing as part of a wider reconfiguration of the service model. Opposing factors (resistors), on the other

hand, included the potential for change fatigue, the perceived fear of increased work-load and the potentially paradoxical effect of the position and expert power of the author.

Identification of Stakeholders

Health service organisations are notorious for their complex structural frameworks, multi-cultural dispositions and delicate group dynamics. To this is added the equally diverse and complex external environment (community) within which a typical service operates. It was therefore considered essential to map out the key stakeholders from both within and outside the organisation; and to determine the opportunities and potential concerns that the change effort might bring to them.

A stakeholders' analysis (Polonsky & Scott, 2005, HSE, 2008) was carried out in which stakeholders were mapped into internal and external groups on the basis of their relative influence and interest in the change. The essence of this exercise was to form an objective basis for the development of a comprehensive strategy for effective reach-out and communication; and to ensure receptive reaction and sustained commitment over the course of the proposed change (HSE, 2008).

For example, using the resulting power-interest grid (Appendix 2), the hospital senior management team, consultant psychiatrists, nursing management and local GPs were identified as the key stakeholders that required to be managed

closely. On this basis, the following communication channels were developed and sustained throughout the course of the change:

- Progress report was placed as a recurring item on the agenda of the monthly Senior Management Team meeting (which the author/change leader was a member). Of note, the Director of Nursing was also a member of this team.
- Progress report placed as a recurring item on the agenda of the monthly consultants' Peer Review meetings (also attended by the author/change leader).
- Regular feedback sessions to GPs at the monthly Primary Care Liaison meetings usually attended by the author/change leader and the Assistant Director of Nursing (also member of change team).
- Progress report on the project was also scheduled as a regular item on the weekly MDT meeting agenda.

Readiness and Capacity for change

Readiness and capacity for change are similar and related concepts. An understanding of both is essential in identifying appropriate ways to support people through change (HSE, 2008). Readiness is a measure of openness to embrace change and is closely aligned to organisational culture, interpersonal relationships and intra-group dynamics. Capacity on the other hand relates closely to the organisational commitment to resource the change both at individual and corporate levels (HSE, 2008).

The change leader rated key stakeholders for readiness and capacity using the Readiness-Capacity Assessment Chart (Beckhard & Harris, 1987). A high

rating was recorded in most areas of capacity for change while a medium rating was recorded for readiness for change. Much of the deficits in readiness arose from perceived lack of knowledge, and staff's reluctance to leave their 'comfort zone' (Kotter, 1996). Because readiness pre-empts potential resistance, this finding provided an invaluable basis to recognise targets for extra motivation and support, especially at the outset, but also throughout the course of the change process.

SWOT Analysis

This is a useful tool for operational and strategic planning. It enables an evaluation of the Strengths, Weaknesses, Opportunities and Threats that are involved in an organisational venture; thereby crystallising the internal and external factors that may be favourable or unfavourable to achieving set objectives (Panagiotou, 2003). Used correctly, this tool helps with the identification of competitive advantage for any organisation (Jyothi et al, 2008). At the second interactive group meeting, a SWOT analysis carried out by the team (Appendix 3) contributed immensely to developing a robust project implementation plan.

Cultural and Political factors

Cultural and political factors can significantly impact on the process and outcome of change (McAuliffe & Van Vaerenbergh, 2006; HSE, 2008). Understanding and managing organisational culture has a key role in formulating strategy or planning change (HSE, 2008). Culture can often be difficult to discern, both from within and from without the organisation. This

is due in part to the iceberg phenomenon described by Schein (1964), but can also be due to the high prevalence of subcultures that lie alongside the dominant culture within any organisation.

In descriptive terms, the prevailing culture at this mental health service conformed to 'role' culture as described by Handy (1985) or 'networked' culture of Geoffee & Jones (1996) both of which are typically found in healthcare organisations. In practical terms however, there was a culture of trust and openness within groups, although territorial behaviour remained prevalent, especially between doctors and nurses. A lot of socialisation took place during work hours so avenues such as tea or smoking breaks were utilised by the change leader as opportunities to exert influence. Also, because group loyalty to key figures was prevalent; the change leader developed a good relationship with key line managers and this was used effectively in promoting change.

In a typical 'role' culture, formal lines of communication are maintained and job descriptions rather than individual skills and abilities are sacrosanct. Also, strict adherence to principles and procedures rather than pragmatism or inventory is valued and rewarded (Handy, 1985). Careful attention was paid to these factors. Firstly, efforts were made to reinforce the rigid lines of communication by ensuring that social avenues were exploited for exchanging information and exerting influence. In this regard, caution was exercised on the position and expert powers (French & Raven, 1959) of the change leader. Secondly, there was a realisation of the need to enshrine the new standards and

procedures within the performance appraisal and supervision process of all staff involved in running the clozapine clinic. This was expected to help stabilise change in the long term.

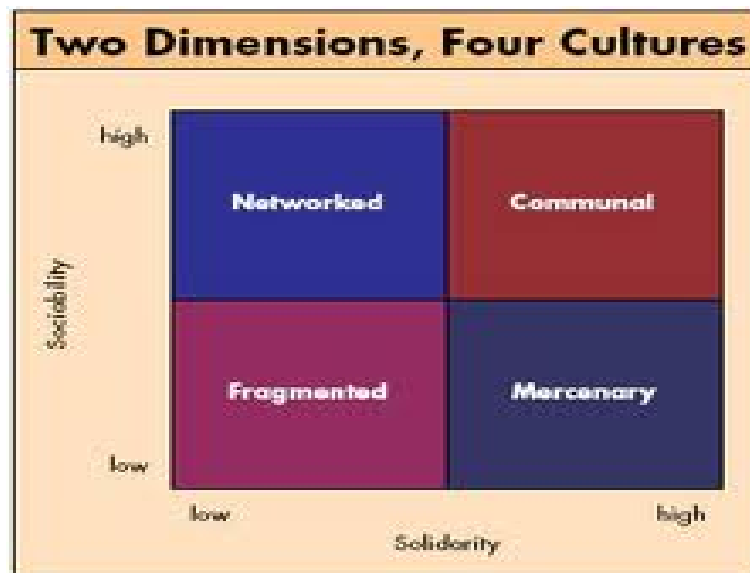


Fig 2: Geoffee & Jones Matrix (Google Images)

Assessment of Change Impact

An initial assessment of the potential impact of the change was carried out at an organisational level. This exercise provided further insight into the relative amount of attention, planning and resources that the change will require, and what aspects of the organisation that will be impacted by the change. From this exercise, a project impact statement was generated (Appendix 4).

Objectives and Outcomes

Objectives are specific statements of outcomes. They represent a clear and concise vision of what the change portends and must be communicated effectively if the change process is to succeed. They help to give direction to the change process, enhance the sense of urgency and promote cohesiveness amongst the guiding coalition or change team (HSE, 2008). Initial objectives and intended outcomes for this change project were derived by the change team from the project impact statement. These were further streamlined and fine-tuned by the group to make them SMART (Specific, Measurable, Achievable, Realistic and Timely) and easy to communicate. The specific objectives of the project were as follows:

- To develop a local policy guideline on clozapine monitoring that will be consistent with international best practice guidelines
- To implement ongoing compliance of the service with evidence-based practice in relation to clozapine monitoring
- To enhance the knowledge, attitude and practice of staff in relation of clozapine monitoring

Business case for change

The activities carried out in this *initiation* phase were synthesised into a business case for change. The essence of this exercise was to provide an objective basis and a compelling argument for a broad-based approval and support for the change. It also provided a reference document for tracking progress during the course of the change project (HSE, 2008). Careful consideration was given to the content and delivery of the business case to

ensure that stakeholders were clear on their roles, interests and potential challenges during the course of the change.

3.5.2. *Planning*

In this phase, specific details of the change were determined and communicated with a view to garnering support for the process. Creating this support ensured that people were carried along with a harmonised view of the new future for the organisation (HSE, 2008). This phase ushered in the first visible actions regarding the change initiative. Commitment was established on an organisation-wide basis; initial momentum was generated and capacity for change was optimised. The 7s model (Figure 3) conceptualised by Waters and Peterman (1982) enabled due consideration to be given to the various elements of the organisational framework during the planning and implementation of the change. The model provided an invaluable frame of reference for establishing a baseline and adopting a whole-organisation approach in managing the change process. Every change process has its complexities and challenges. The cornerstone for success in this phase was communication - there could never have been too much of it. The phase entailed three iterative steps, namely (HSE, 2008):

- Building commitment
- Determining the details of the change, and
- Developing the project implementation plan

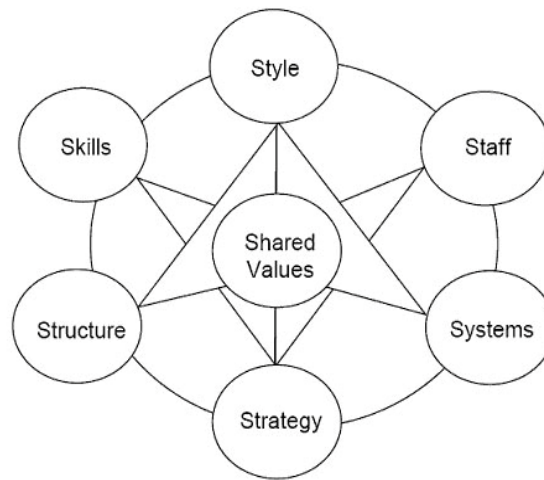


Fig. 3: The McKinsey's 7s Model (Waters & Peterman, 1982)

Building Commitment

Lewin (1951) was passionate about the role of group dynamics in organisational change. He believed that group procedures for changing attitudes or behaviours were effective because people tended to respond as group members rather than follow their own individual preferences. He hypothesised that “it is usually easier to change individuals formed into a group than to change any one of them separately” (Lewin, 1951). The HSE change model (HSE, 2008) also acknowledged group dynamics within its ethos of an organisational development approach and its focus on the people and cultural aspects of change.

Interactive group meetings are effective in changing behaviour; with their degree of interactivity correlating well with effectiveness in changing behaviour (NICE, 2007). While conferences and lectures raise awareness about desired change, they are often less effective in making change happen (NICE, 2007). It was in these contexts that the change leader adopted a group-

based approach in dealing with the change team especially during this early part of the project.

In building commitment, the key task was to inspire an appetite for change by clearly communicating the vision and demonstrating that change was underway. The change leader commenced this process by presenting the results of the internal audit to members of the MDT initially and subsequently in more detail to staff of the clozapine clinic. The emphasis on the clozapine clinic staff was because they were the people that were to be most affected by the change.

Awareness and conviction on what needs to change, and why, are crucial first steps in enabling change to occur. Healthcare professionals often lack awareness of, and/or familiarity with latest evidence-based guidelines. When they do, they may be unaware of what needs to change to bring their practice to compliance with these guidelines (NICE, 2007). The author observed that discussing the findings of the internal audit with the team in an interactive and non-coercive manner inspired an intrinsic desire for change, going by the spoken and unspoken comments and gestures evident at the end of the meeting. Thus, the earliest foundations for commitment to change were laid.

The audit findings were subsequently presented to the Senior Management (of which the change leader is member) at their next sitting. The presentation took cognisance of the broader contexts of the recent visit and findings of the MHC inspectorate and the implications for the service of their imminent revisit to

assess progress on identified failings. A business case for change was proffered and unanimously adopted by the group. The group became the guiding coalition for the change.

Determining the Detail of the Change

This step involved assessing the current situation, determining the finer elements of the change that needed to occur and outlining what available resources will support the change process (HSE, 2008). A further meeting was held with the MDT to communicate the ratification of the change initiative and to determine the specific next steps. A small-group, problem-solving approach was adopted for the meeting. Details of the audit findings turned out a very useful resource in terms of clarifying the status quo.

Brainstorming

A broad-based brainstorming session involving all MDT members, administrative staff and a representative of a patient's advocacy group instilled rigour to the planning process. One advantage of brainstorming is that participants can bounce ideas off each other, and further develop and refine these (NICE, 2007). Besides providing a means of developing creative solutions to the potential challenges ahead, brainstorming also facilitated active participation of team members in the formative stages, thereby fostering a sense of ownership of the process.

Journal Clubs

Following from the above; the change leader reflected on the process and outcome of the interactive, problem-based group meetings and undertook self-directed learning to fill gaps in personal knowledge that became apparent from questions and opinions expressed by staff during the meetings. Subsequently, four (weekly) journal clubs were facilitated for the team by the change leader with the aim of appraising recent literature and evidence-base on international best practice in the area. The value of evidence-based journal clubs in facilitating postgraduate learning has been well documented (Ebbert, 2001). These journal clubs were therefore chosen as the primary approach towards enhancing the knowledge of staff in relation to the safe clinical use of clozapine, as set out in the study objectives.

Process mapping

Visual descriptions of the flow of activities at the clozapine clinic were designed; for both the current practice and the desired future practice (Appendix 5). The variance between the two maps helped to crystallise the work that needed to be done to effect successful change. Process mapping is a powerful tool that can be used for determining the underlying causes of performance problems and identifying performance improvement needs. Once a process is mapped, it is easy to spot omissions, redundancies, insufficient work support, ineffective communication and all other obstacles that may impede effectiveness and efficiency (West, 1997; Marrelli, 1998).

The change team

It was during this phase that the change team was agreed. The change team comprised of a Consultant Psychiatrist (author, change leader); Psychiatric Registrar, two nursing staff from the clozapine clinic, Clinical Nurse Manager of Day Hospital (where clozapine clinic is based) and the Assistant Director of Nursing (ADON).

Proforma development

The next task undertaken was the development of proforma for documenting the findings of physical examinations and laboratory investigations conducted at clozapine clinic visits. It was considered that a single document that highlighted the relevant parameters would be most ideal. As there was no such document available from literature search, the team developed one *de novo*, with due reference to current evidence-base, during one of their interactive sessions. This draft was presented by the author to peers at the February 2012 Action Learning Set (ALS) where it received positive feedback. There was however advice to provide space for the signature of assessor, and also to consider printing the form on coloured paper to enhance its visibility within the often bulky patient medical records. These suggestions were unanimously adopted by the change team as reflected in the final version of the proforma (Appendix 6).

A standardised letter format was also developed to serve as a clear and concise way to promptly communicate any identified abnormalities to the patient's GP (Appendix 7). The initial draft of this received good feedback from peers at

the 2nd ALS and was also unanimously endorsed by GPs when it was presented to them during a primary care liaison meeting.

Developing the Implementation Plan

More detailed design of the change was undertaken at this phase, with careful attention paid to specific details of the process. The broad-based interdisciplinary group referred to above were once again consulted. Details of the objectives, process and potential impact of the project on all stakeholders were revised. People were encouraged to voice their fears and concerns and gentle reassurance and support were provided where necessary. The change leader remained cognisant of Cartwright and Baldwin's (2007) view that the change agent's ability to communicate, their skills of negotiation and the expert power they possess all play a crucial role in the success or otherwise of any change effort.

Scope of the change

The start date (01/03/2012) and implementation time frame (six weeks) was agreed and communicated widely. It was also agreed that the change will be focused on adverse effects of metabolic syndrome, albeit with attention to the various other idiosyncratic effects of clozapine. All documents containing clinical information on patients taking clozapine were to be amalgamated into the main patient medical record. Abnormal findings were to be communicated to patients' GPs using the standardised letter described above. It was also agreed at this point that the change team would meet for a quarter of an hour after the weekly MDT meetings throughout the course of the change. This was

with a view to ensuring regular updates, feedback and support during the change.

Sequence of change steps

It was agreed that all existing patients on clozapine (n = 32) would be invited for initial physical examination and laboratory tests to serve as baseline parameters for future reference. Eight patients were to be reviewed per week, with all expected to be seen over four a four week period. Subsequently, the monitoring exercise was to be carried out in compliance with the NICE (2006) guidelines described above. Development of a local policy on the monitoring of patients on clozapine was scheduled to be done serially during the weekly meetings of the change team. Post change evaluation was scheduled to take place at the end of the 6th week.

Resource requirements

Structural changes were resource neutral as existing staff and equipment were utilised within their effective capacity. Two new tapes for measuring abdominal and waist circumferences were procured while the existing BP measuring apparatus, weight/height measuring scale and clinical thermometer were examined to ensure good functional state.

3.5.3. Implementation

The focus of this step was to apply the agreed changes to the structure and process of care, paying careful attention to the factors that will promote

favourable outcomes and long term sustainability. Residual resistance often becomes apparent during this step. According to Armstrong (2001), the shock of the 'new' way may cause insecurities in people who are afraid to lose their familiarity and sense of belonging. In this regard, the change leader ensured relentless communication with the change team and other key stakeholders with a view to sustaining momentum and keeping focus on the vision and goals of the change.

The team kept to the agreed commencement date and the response of the first batch of patients for physical health screening was quite encouraging. One of the clozapine clinic nurses expressed unease about the mildly "invasive" nature of some of the physical examination procedures including measurement of the waist/hip ratio using a measuring tape. This concern was successfully addressed through reassurance and support from both the change leader and at peer level. Abnormal findings were uncovered in three out of the first eight patients and these were further reviewed by the consultant psychiatrist (change leader). Of these, two patients required further attention by their GPs and were referred accordingly using the standardised letter developed for the purpose (Appendix 7).

The remaining three weekly sessions of baseline tests were completed uneventfully. Staff had become more confident and appeared to be coping reasonably well with the demands of the new practice. Fourteen other patients required referral to eight different GPs for further assessment and treatment. These referrals were followed up by their key workers who remained in close

liaison with the GPs to ensure adequate follow-through and information sharing on their treatment. Seven of the GPs accepted their new roles without expressing concerns. Indeed, one of them wrote a letter expressing delight at the improved information sharing on the physical health of their patients who were under shared care with the mental health team. This positive feedback, along with several others from patients and their carers were acknowledged as short term gains and were used by the change leader to promote and sustain momentum on the change. However, one of the GPs was reluctant to take up the new responsibility, citing increased workload as his concern. Strong resistance to change is often rooted in deeply conditioned or historically reinforced feelings. This underscores the need for patience and tolerance in helping people in these situations to see things differently and to embrace new approaches. This act of resistance was successfully addressed by the change leader by engaging the GP in one-to-one sessions and providing him with more information and support.

The ADON oversaw the printing of proforma on coloured paper as agreed. The new proforma were properly filed, by the team administrative staff, within the patient case notes in line with HSE policy and guidelines on proper keeping of patients' medical records. Regular feedback on the change process was provided to the Senior Management Team, Consultants' peer review meetings and the weekly MDT meeting at the Day Hospital.

Because change involves a series of iterative events, sustaining momentum and energy is essential. With this in mind, the change leader engaged staff,

using a wide range of avenues, both on an individual and group basis. This was aimed at providing support, acknowledging challenges and encouraging expressions of alternative opinions where available. All reactions; positive or negative, verbal or non-verbal were given due consideration. Negative reactions were quite minor, and were merely around uncertainties regarding the proper filling of the monitoring proforma. These were addressed by information sharing, encouragement and support. Positive feedbacks however were plentiful, coming mainly from patients and their families, but also from GPs, change team and wider MDT members. These were highlighted as short term gains and served to inspire greater commitment to the cause.

3.5.4. *Mainstreaming*

Here, the focus was on integrating and sustaining the new practice; evaluating the change process and promoting continuous improvements. Ensuring that new practices and behaviours are rooted in social norms and shared values ensures that they do not regress as soon as the pressure for change is removed (HSE, 2008). Similarly, evaluating the project facilitates active learning from the process, while providing an objective basis for further service development initiatives, within the true spirit of change as a continuous and cyclical process.

3.5.4.1. *Embedding the change*

To make the new practice “the way we do our business” (HSE, 2008), the change leader adopted two approaches namely:

- Linking new work practices to improved performance, and

- Making adherence to new work practices relevant to regular performance reviews

Under the first approach, efforts were made to demonstrate to key stakeholders how the new work practices were linked to ongoing compliance with best practice guidelines and reduced susceptibility of the service to complaints and litigations. Helping people to establish such links is expected to have several positive effects, including:

- Promoting a sense of ownership of the new process and its outcomes
- Instilling a feeling of responsibility for ensuring the long term sustenance of the new work practice
- Making it explicit how individual behaviours can be linked with any deterioration of standards in the future
- Making people more open to change in the future

The second measure was an attempt to ensure that the next generation of decision makers are people who embody the new approach and are open to continuous improvements. If the requirements for career progression do not change, renewal rarely lasts and old ways of doing things quickly re-emerge (HSE, 2008). Although this could be easily dismissed as a “stick” approach, it remains relevant that “what gets measured gets done” (Drucker, 1954). Consequently, the change leader successfully negotiated with the nursing hierarchy to institute adherence to the new practice as part of the regular performance review and appraisal system for nurses towards their continued

professional development. The same was also agreed with the Clinical Tutor and Clinical Director in relation to the Psychiatric Registrar and Consultant Psychiatrist (change leader) both of whom would provide ongoing medical back-up to the clozapine clinic. The success of this approach depended somewhat on the formal, bureaucratic role culture (Handy, 1999) of the HSE of which this service is a part. Of note, the nursing staff welcomed this idea citing formal recognition of their personal efforts as a potentially strong motivating factor for future commitment to the cause.

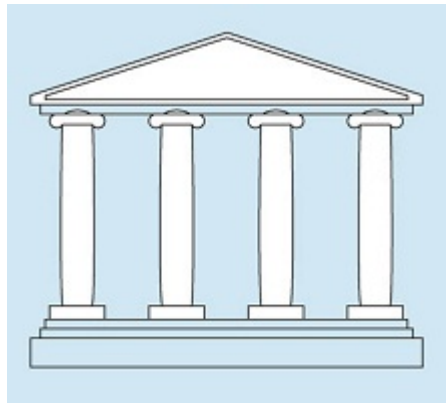


Fig 4: Handy's Role Culture – designed after the Greek Temple for Apollo

3.5.4.2. *Evaluating and Learning*

To further embed the new work practice, it was essential to review the design and implementation of the change process. The primary goals of evaluation were to facilitate any necessary adaptations of the ongoing process towards improved outcomes, and to identify learning points that will inform the conduct of future change programmes. In choosing evaluation tools and approaches, due consideration was given

to their validity and reliability, and efforts were made to ensure that the project objectives were properly aligned with evaluation outcomes.

Evaluation as referred to here was conducted in its broadest context, including not only of the structure, process and outcome of the change, but also on a personal level by way of critical reflection. For ease of reference, further details of the evaluation and reflection aspects of this dissertation will be provided in the relevant chapters below.

3.6. Summary

Having first provided an overview of the extensive literature available on change and its management, this chapter has described the successful journey through a planned change effort using the HSE change model as a guide. Future evaluations that have already been scheduled as part of this change project will hopefully confirm the long-term sustainability of the new work practice, while also providing objective bases for continuous quality improvements.

4. CHAPTER 4: EVALUATION

4.1. Introduction

Evaluation is a systematic and structured process of reviewing an experience with the aim of determining its value and deciding what could be done differently (HSE, 2008). According to Lazenbatt (2002), it provides a means of measuring the extent to which a set of actions have achieved their objectives. Peter Drucker (1954) captured the strong correlation between evaluation and motivation in his now famous hypothesis that “what gets measured gets done”. Even though it is listed as a separate step within the HSE framework, the model recognises evaluation as vital to every aspect of the change process (HSE, 2008). This approach of *evaluating in action* not only has a strong formative impact on individual and organisational learning, it also allows for adaptations to be made at every point in the change process. Such adaptability and flexibility provided for within the framework of the HSE change model made it an easy choice for this project.

The primary concern of evaluation is to determine the achievement of pre-defined goals. Rather than assume that implemented change is working, it is important that specific performance targets and measures are used to track and stabilise change (Moran, 2000). Two concepts are relevant here. The first is efficiency, a measure of the extent to which aims and objectives have been attained; and the second is effectiveness, a measure of the extent to which objectives have led to desired outcomes (Lazenbatt, 2002).

This chapter will address the evaluation of the change project in relation to its process and outcome. The tools and approaches chosen for the evaluation will be described along with the rationale behind their selection. It is important to note that at the time of writing this dissertation, the change cycle remained ongoing. However, significant and measurable achievements were already evident and making these explicit was considered essential to promoting and embedding the new approach.

4.2. Evaluation Tools

Various tools and approaches are available for the purpose of evaluation. In making choices between these, it is essential that due consideration is given to what is being measured and the context in which the measurement is to take place. Broadly speaking, evaluation can be approached from two distinct perspectives, namely qualitative and quantitative (Burns, 2000). Qualitative approaches are generally exploratory in nature and aim to provide insights, generate hypotheses or develop initial understandings on a subject. Sample sizes are usually small and data is collected using unstructured or semi-structured techniques including focus groups, individual interviews, etc. Analysis is on a non-statistical basis and reports are presented in descriptive terms. Quantitative approaches on the other hand are used to quantify data and generalise results from large samples. Data is collected using structured techniques such as questionnaires and checklists. Conclusive findings made from statistical analysis of such data may be used to recommend a final course of action. This project was evaluated using a combination of qualitative (focus groups, interviews) and quantitative (pre- and post change questionnaires, retrospective chart review) methods.

4.3. Evaluation of Project

4.3.1. Qualitative Methods

4.3.1.1. Focus Groups

Focus groups involve an explicit use of group interaction to produce data and insights that would be less accessible without the interaction generated in a group setting (NICE, 2007). Typically, it involves a facilitator using a range of stimuli to generate discussion in an interactive, non-coercive group setting (NICE, 2007). The use of focus groups in this project had a powerful formative impact on its progress, and also contributed to the summative evaluation of its outcome.

Three focus groups were facilitated altogether by the change leader during the course of the project – one at the initiation phase, the second at the planning phase and the last at the evaluation phase. The groups comprised of six members of the change team on the three occasions. The sessions were used to gain insights into the perceptions, opinions, attitudes and beliefs of team members on the various aspects of the change programme. Pre- and post- questionnaires were distributed at the end of the first and last sessions. These will be described in more detail under quantitative evaluation. The main value of the first two focus group sessions was in their formative effects on the change process, while the last session was weighted towards a summative appraisal of the process. A summary of findings of the last session is presented below.

Vision

There was a shared agreement that the vision was valid, clear and coherently articulated. Members felt that it was reasonably easy to buy into and develop their own personal sense of ownership of the vision.

Communication

Every member of the team felt that communication was adequate. There was a shared appreciation of the use of both formal and informal avenues of communication by the change leader. In particular, one team member highlighted the importance of the “walking the talk” attitude adopted by the change leader.

Team work

There was a general appreciation of the consistent involvement of the group at every stage of the project. Members felt that their contributions, opinions and concerns were acknowledged and that they felt empowered and supported to take measured risks as part of learning their new roles.

Cultural factors

There was consensus that both inter-group and intra-group sensitivities were well handled especially in relation to the usual tensions that usually exist between the various professions due to their differing cultural orientations. However, one team member regretted that

hierarchical sensitivities were aroused during one of the sessions when some aspects of the process were challenged.

Alignment of process with expected outcomes

Staff generally agreed that the project implementation plan was appropriately designed to achieve the project goals. There was also a consensus that project timelines were realistic and adhered to through the course of the project.

4.3.1.2. Interviews

Interviews aim to elicit the responder's perspectives by asking open-ended questions, listening to and recording answers in an iterative and goal-directed fashion (Kvale, 1996). Here, the change leader conducted informal interviews with local GPs (n=8) and patients (n=32) to assess their perceptions of and satisfaction with the change process and its outcomes. GPs were contacted largely by telephone (n=6), with the remainder (n=2) interviewed on a face-to-face basis. Patients on the other hand were interviewed during their routine clinical visits. The vast majority of respondents expressed satisfaction with the process and outcome of the change. While the views of GPs can be taken on its *prima facie* value, the change leader remained cognisant that the responses of patients must be interpreted with caution as the power differential between patients and their doctors, especially in a mental health context, can lead to false positive responses and assumptions.

4.3.2. *Quantitative Methods*

Pre- and post implementation questionnaires and a retrospective case note review constituted the quantitative evaluation tools used for this project. Questionnaires are useful for measuring whether a programme intervention has met its objectives. They allow for anonymity and can be used to collect vast amounts of data over a reasonably quick space of time. In addition, questions are standardised and can be easily analysed (Burns, 2000). A retrospective case note review, on the other hand, allowed for the measurement of the success or otherwise of the project to achieve its objective in relation to ensuring compliance with best practice guidelines for the monitoring of clozapine.

4.3.2.1. *Questionnaires*

An anonymous, self administered questionnaire was developed by the change leader based on literature review and in line with the project objectives. This questionnaire (Appendix 8) used five closed-ended questions with three set-response options to elicit the respondents' opinions on their own knowledge, attitudes and practices in relation to monitoring adverse effects of clozapine. There was also a question regarding their interest and commitment to continuous quality improvements on this aspect of their practice. The questionnaires were distributed to team members at the beginning of the first and last focus group sessions, and were returned by being dropped anonymously into a box provided for the purpose at the end of the sessions. The response

rate of 100% was not surprising giving the small size and collegial nature of the sampled group and the influence conferred by the position power of the change leader. Details of findings are provided in Appendix 9. In summary, there were significant improvements in all parameters that were measured. Of particular importance was the very high rating on “commitment to continuous quality improvement” which can be interpreted as an *early* sign of long term sustenance.

4.3.2.2. *Retrospective Chart Reviews*

Retrospective studies use existing data that would usually have been recorded for reasons other than research to measure specific outcomes (Dean, 2004). From a healthcare perspective, they are often referred to as *chart reviews* because the primary data source is invariably patient medical records. One of the objectives of this project was to implement compliance with best practice guidelines in relation to clozapine monitoring. A retrospective chart review was chosen to evaluate this because of its objectivity, as patients’ medical records were expected to provide reliable documentary evidence of clinical care.

In this exercise, the medical charts of all patients on clozapine treatment (n=32) were retrospectively reviewed to assess whether or not they contained the proforma that was developed as part of this project, and whether these had been properly completed to reflect evidence-based practice. Data was collected using a checklist method, and analysed with descriptive statistics. The result of a 100%

compliance rate was, again, unsurprising giving the small sample size and the commitment of the team to the objectives of the study.

4.4. Summary

This chapter has provided an overview of the concept of evaluation from a healthcare management perspective. It has described the evaluation of the change project in terms of its process and outcomes using a range of tools and approaches. The findings which were consistently positive from across the range of tools became potent secondary drivers for stabilising the new practice and setting the tone for continuous quality improvements. Inferences drawn from these evaluations will form the basis for the discussion and reflection aspects of this dissertation in the following chapter.

5. CHAPTER 5: DISCUSSION

5.1. Introduction

This change project set out to implement evidence-based practice in relation to the monitoring of patients treated with clozapine by a community mental health service. A review of relevant literature and an in-depth account of the journey through the planning, implementation and evaluation phases of this change have been outlined in the previous chapters. This chapter will highlight the strengths and limitations of the project. This will be followed by recommendations for future service development based on inferences drawn from the project evaluation. The chapter will conclude with a critical reflection on the author's experiences through the course of this project.

5.2. *Strengths of Project*

Scope of Change (within the core business of the service)

Clinical care pathways are central to the work of any health service organisation. Recognition that the desired change had huge significance within the context of the primary task of the service made it easier to secure and sustain the engagement of key stakeholders during the course of the project. It also meant that people were not taken far out of their *comfort zones*, one of the commonest causes of resistance to change.

Compelling Drivers for Change

With the increasing emphasis on healthcare regulation, evidence-based practice and continuous quality improvements have grown from desirable to

indispensable concepts. At service level, external policy requirements to comply with best practice guidelines increased the urgency and made the change somewhat inevitable. This type of scenario often arises in the organisational structure described by Henry Mintzberg (1994) as “Professional Bureaucracy” where external drivers, usually in the form of government or regulatory directives, provide the most potent drivers for change.

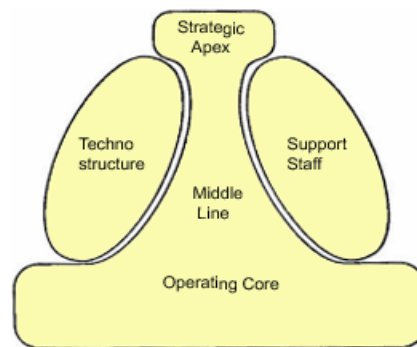


Fig 4: Mintzberg's model (after Sherwin, 2009)

Expert & Position Power of Change Leader

Raven and French (1959) described the potential influence conferred by expert knowledge and hierarchical position in organisational management. Again, this is particularly relevant in Professional Bureaucracies (Mintzberg, 1994). Cautious use was made of this potentially rich source of influence when the change leader bargained or negotiated with key stakeholders during the planning and implementation of the change.

SMART Objectives

Simple, Measurable, Achievable, Realistic and Timely (SMART) objectives are exactly what the acronym suggests. The concise and targeted nature of the

change objectives made it easier to carry people along and to maintain focus during the course of the change.

Resource Neutrality

This change required adaptations to the structure and process of care. In the current fiscal climate, cost-effectiveness can be both a reason for and an obstacle to change. In this project, care was taken to ensure that adaptations made were within the effective capacities of both personnel and equipments. In management parlance, the efficiency and utilisation of existing resources were merely optimised by adopting principles and tools of continuous quality improvement.

Parallel Change Initiatives (Supportive)

This change occurred in parallel with other quality improvement initiatives that formed part of a broader service reconfiguration programme. Some of these were particularly supportive, including ongoing introduction of individual care and treatment planning, integrated patient medical records and primary care liaison.

5.3. Limitations of Project

Small sample size

Though it may be harsh to judge the evaluation of this project with the strict rigour usually applied to systematic research, the power of the studies in detecting real change would be compromised by the relatively small sample

size arising from the small number of staff directly involved in the change process.

Expert & Position power of change leader

The expert and position powers of the change leader described above could paradoxically lead to superficial commitment and covert resistance with implications for long term sustainability of the change.

Time pressure

There was subjective pressure to achieve tangible milestones for the purpose of writing a meaningful dissertation. The need to submit this dissertation within a limited timeframe also meant that further evaluations that would be carried out to confirm stabilisation of the change will not be reported here.

Prior experience of managed change

There was no abundance of prior experience of managed change efforts both at personal and service levels. However, this potential weakness did not appear to have impacted to any material extent on the success of the effort.

Change fatigue

As stated above, there was a host of parallel change initiatives within the context of a wider reconfiguration of the service model. Confusion, despair, lowered organisational productivity and passive resistance can all arise in these contexts.

5.4. Recommendations for Future Improvements

The change described above has been implemented in one of four similar and adjacent geographically sectorised community mental health teams. On the basis of the success of this change effort, it would be prudent from both clinical and management perspectives to embark on a planned and carefully managed roll-out of the new approach to the entire mental health service. At the wider service level, adherence to best practice guidelines such as was introduced with this change will reduce exposure to complaints and litigations from service users and their carers, as well as the likelihood of censorship from the MHC inspectors at their inevitable future visits to the service.

In implementing the above recommendation, it is hoped that the service would benefit from the considerable experience gleaned by the staff involved in this project who have become a huge resource base as change champions. Incorporating elements of change management in the continued professional development curriculum of staff will provide a platform where the current change champions can share their learning and experience with their peers. Also, recognising and rewarding the achievements of current change champions will be an excellent way of implicitly and explicitly communicating what is valued; and in so doing help to embed the emergent culture of change.

From clinical and academic perspectives, data generated from implementing and evaluating this change could provide a useful basis for future formal research into the incidence and prevalence of metabolic disorders and other physical health disturbances that arise from, or are incidental to clozapine and other pharmacological

interventions. Such findings can inform the development of future evidence-based guidelines both locally and internationally. Indeed, the service can become a centre of excellence in the whole area of the interface between psychiatry and mental disorders by building on the special interest demonstrated by the author in this subject area

5.5. Reflection

Experiential learning is at the core of lifelong learning (Kolb, 1984; Rogers, 1969). It refers to the process of making meaning from one's direct experience. Here learning is constructed from experiences that arise in the context of work situations. It requires learners to focus on an experience; reflect upon it to understand it better; identify areas for further development; find solutions to new issues encountered and practice these solutions. Ultimately, the experiential learner is able to look back at an experience and its contexts in order to determine further action and reflection (Kolb, 1984).

Lifelong learning is no longer a choice for medical professionals; it is now both a necessity and an obligation. The skill of reflection is central to the twin concepts of experiential learning and lifelong learning. Reflection allows clinicians to use their day-to-day experiences to evolve and shape their practice. Reflective practice involves change. This change often derives from a discovery of; and adaptation to new knowledge. Both change and new knowledge can be painful. Emotional difficulties associated with critical reflection have been widely described (Brookfield, 1987; Mesirow 1990). These emotional difficulties arise because every change, even a change for the better, is accompanied by drawbacks and discomforts.

Challenging one's own underlying assumptions in these circumstances can be unsettling as I soon discovered during this project.

Looking back at this project, two particular factors had the most profound influence on the process and outcome of the change. The first was the conscious decision to adopt a group-based approach in dealing with the change team and entire MDT, particularly at the nascent stages of the change process. According to Lewin (1947), interactive, non-coercive group discussions where participants decide “among themselves” to adopt new behaviours are far more effective than expert lectures or one-to-one persuasion. Lewin argued that the reason why group procedures for changing attitudes and conducts are so effective is that people tend to respond as group members rather than on their individual preferences because of an inherent human desire to identify with group norms. In practical terms, this approach ensured an early buy-in by fostering a sense of ownership of the initiative, rather than it being perceived as imposed from above. To achieve this, it was important that I targeted both the “natural” and the “official” leaders within the group and maintained a cordial relationship with them to ensure that their influence was used positively during the course of the project.

The second factor was the careful attention that I paid to the pros and cons of my expert and position powers. While these can confer considerable potential to wield influence within organisations, they can also lead to superficial commitment and passive or covert resistance. As discussed above, this type of influence can be particularly helpful in the cultural and structural frameworks seen in healthcare organisations. A practical example is an earlier experience in which I attempted to

implement a similar change while working as a psychiatric trainee in another service. Despite cogent rationale and urgency for change in that situation, it was difficult to sustain investment, enthusiasm, and engagement on the project due to differing priorities as seen by the top hierarchy of that organisation.

At cognitive and emotional levels, my underlying attitudes of intellectual curiosity and openness to new experience became reinforced by the experience of this change project. Although my thoughts of carrying out this project were heralded with tremendous anxiety and trepidation, these feelings quickly gave way to excitement and enthusiasm as the prospects of turning the experience into a learning opportunity became more apparent. It must be said that this cognitive and emotional switch occurred in the context of the first Action Learning Set in January 2012 during which peer encouragement and support was facilitated by an expert in a non-coercive ambience.

5.6. Summary

This chapter has provided a discussion on the highlights of the change project, including the strengths and weaknesses of the project within the context in which it was implemented. The chapter has also provided a critical reflection on the author's experience and learning from the process, as well as recommendations on how the service could further benefit from the project. Undertaking this project has provided the author and the entire change team an invaluable learning experience on the whole concept of change and its management.

“Because things are the way they are, things will not stay the way they are”.

– Bertolt Brecht

References

- American Psychiatric Association. Diagnostic and statistical manual of mental disorders: DSM-IV, 4th Ed. Washington (DC): 1994. 886 pp.
- Angyal, A. (1948). The holistic approach in psychiatry. *Am J Psychiatry*. 105: 178 – 182
- Armstrong, M. (2001). *A handbook of Human Resources Management Practice*. 8th Edition. London: Kogan Page
- Baptista, T., Elfakih, Y., Uzcategui, E. Et al. (2008). Pharmacological management of atypical antipsychotic-induced weight gain. *CNS Drugs* 22 (6): 477 – 495
- Beckhard, R., Harris, R. (1987). *Organisational Transitions: Managing Complex Change*. Wokingham: Addison, Wesley
- Bleuler, E. (1911). *Dementia Praecox Oder Gruppe der schizophrenien*. Leipzig und Wien: F. Deuticke
- Bolton, P. J. (2011). Improving physical health monitoring in secondary care for patients on clozapine. *The Psychiatrist*. 35: 49-55
- Brookfield, S. D. (1987). *Developing Critical Thinkers*. Jossey-Bass, San Francisco
- Burnes, B. (2004). Kurt Lewin and the Planned Approach to Change: A Re-appraisal. *Journal of Management Studies* 41(6): 977-1002
- Burnes, B. (2004). *Managing change: A strategic approach to organisational dynamics*. 4th edition (Prentice Hall)
- Burns, R. B. (2000). *Introduction to Research Methods*. Sage, London
- Carnall, C. A. (1990). *Managing change in organisations*. London: Prentice Hall

- Carnall, C. A. (2003). Managing change in organisations. 4th edition. London (Prentice Hall)
- Cartwright, T., Baldwin, D. (2007). Seeing your way: Why leaders must communicate their visions. *Leadership in Action* 27(3), 15-24
- Chandrasekaran, P. K. (2008). Agranulocytosis monitoring with clozapine: to follow guidelines or to attempt therapeutic controversies? *Singapore Med J.* 49: 96 - 99
- Connolly, M., Kelly, C. (2005). Lifestyle and physical health in schizophrenia. *Adv Psych Tr.* 11:125 – 132
- Crilly, J. (2007). The history of clozapine and its emergence in the US market: a review and analysis. *History of Psychiatry* **18** (1): 39–60
- Dawson, P. (1994). Organizational change: A processual approach. London. Paul Chapman Publishing
- Dean, R. H. (2004). Retrospective studies and chart reviews. *Respir Care*; 49 (10): 1171–1174
- Decker, J., Girman, C., Rhodes, T. Et al. (2005). Metabolic syndrome and 10-year cardiovascular disease risk in the Hoorn Study. *Circulation.* 112: 666 – 673
- De Hert, M., Vancampfort, D., Correll, C. (2011). Guidelines for screening and monitoring of cardiovascular risk in schizophrenia: systematic review. *British Journal of Psychiatry.* 199: 99 – 105
- Drucker, F. (1954). The Practice of Management. New York: Harper & Row
- Dunphy, D., Stace, D. (1992). Under New Management. Sydney: McGraw-Hill
- Durrington, P. (2003). *Lancet.* 362:717 – 731

- Ebbert, J.O. (2001). The journal club in postgraduate medical education: a systematic review. *Med Teach*. **23**: 455 – 461
- Eckel, R., Grundy, S., Zimmet, P. et al. (2005). The metabolic syndrome. *Lancet* 365: 1415 – 1428
- European Board of Psychiatry. (2009). European Framework for Competencies in psychiatry. <http://www.uempsychiatry.org/board/boardreports.htm> (accessed 3rd May 2012)
- Food and Drug Administration (FDA), USA: accessed May 2012.
http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/019758s054ltr.pdf
- Forsner, T., Hansson, J., Brommels, M. et al. (2010). Implementing clinical guidelines for healthcare professionals: a qualitative study of facilitators and barriers. *BMC Psychiatry* 10:8
- Francke, A., Smit, M., de Veer, A. Et al. (2008). Factors influencing implementation of clinical guidelines for healthcare professionals: a systematic meta-review. *BMC Medical Informatics and Decision making*. 8: 38
- French, J., Raven, B. The bases of social power. In D. Cartwright & A. Zander. *Group Dynamics*. New York: Harper & Row, 1959
- Geoffee, R., Jones, G. (1996). What holds the modern company together? *Harvard Business Review*. 74 (6): 133 - 148
- Graetz, F. (2000). Strategic change leadership. *Management Decisions*. 38 (8): 550 - 562
- Grol, R. (2001). Success and failures in the implementation of evidence-based guidelines for clinical practice. *Medical Care*. 39: 1146 - 54

- Gul, M., Nihgam, A., Broughton, N. (2006). Clinical monitoring of patients on clozapine. JPPS. 3:2
- Handy, C.B. (1999) [1976] Understanding organizations, London, Penguin
- Health Service Executive. (2008). Improving our services: A users guide to managing change in the Health Service Executive. Dublin: HSE National Organisation Development and Design Directorate
- Healy, D. (2004). The Creation of Psychopharmacology. Cambridge: Harvard University Press. pp. 238–42
- Henderson, D. C. et al. (2000). Clozapine, diabetes mellitus, weight gain and lipid abnormalities: a five year naturalistic study. Am J Psychiatry. 157:975- 981
- Hendry, C. (1996). Understanding and creating whole organisational change through learning theory. Human Relations. 48 (5): 621 - 641
- Jones, G. R. (2001). *Organisational theory*: Prentice Hall International Inc.
- Jyothi, B., Babu, G., Krishna, I. (2008). Object oriented and multi-scale image analysis: Strengths, Weaknesses, Opportunities and Threats - A review. Journal of Computer Science. 4(9): 706-712
- Kanter, R., Stein, B., Jick, T. (1992). The challenge of organisational change. New York: Free Press
- Kelly, B. D. (2008). The mental treatment act 1945 in Ireland: an historical enquiry. History of Psychiatry. 19 (1): 047 - 067
- Kohen, D. (2005). Physical health in mental illness: psychiatry's shared responsibility. Adv Psych Tr. 11: 457 – 458

- Kolb, D. (1984). *Experiential learning: Experience as the source of learning and development*. Englewood Cliffs, NJ: Prentice-Hall
- Kotter, J. P. (1995). *Leading Change: Why transformation efforts fail*. Harvard Business Review (March – April)
- Kotter, J. P. (1996). *Leading change*. Boston, M. A: Harvard Business School Press
- Kotter, J., Schlesinger, L. (2008). *Choosing Strategies for change*. Harvard Business Review. 130-139
- Kvale, S. (1996). *Interviews: An Introduction to Qualitative Research Interviewing*. London: Sage Publications
- Lakka, H., Laaksonen, D., Lakka, T. et al. The metabolic syndrome and total cardiovascular disease mortality in middle-aged men. *Journal of the American Medical Association*. 288: 2709 – 2716
- Lamberti, J. et al (2005). Diabetes mellitus among outpatients receiving clozapine: prevalence and clinical-demographic correlates. *J Clinical Psychiatry*. 66:900 – 906
- Lazenbatt, A. (2002). *The evaluation handbook for health professionals*. London: Routledge
- Lewin, K. (1951). *Field theory in social science*, New York, Harper and Row
- Lewis, S. et al. (2006). Randomised control trial of effect of prescription of clozapine versus other second-generation antipsychotic drugs in resistant schizophrenia. *Schizophr Bull* 32:715 – 723
- Longo, R. (2011). *Is Lewin’s change management model still valid?* HR Professionals (online)

- Macdonald, E., Herman, P., Hinds, P., Crowe, J. and McDonald, P. (2002). Beyond interdisciplinary boundaries: views of consumers, carers and non-government organisations on teamwork. *Australian Psychiatry*, 10(2), pp.125-129
- Malhi, G., Adams, D., Plain, J. et al (2010). Clozapine and cardio-metabolic health in chronic schizophrenia: correlations and consequences in a clinical context. *Australasian Psychiatry*. Vol 18, No 1.
- Mangtani, P., Breeze, E., Kovats, S. et al. (2005). Inequalities in influenza vaccine uptake among people aged 74 years in Britain. *Preventative Medicine*. 41: 543 - 553
- Marrelli, A. (1998). *Guide to managing process performance improvement projects*. El Segundo, CA: Hughes Space and Communications Company
- McAuliffe, E. & Van Vaerenbergh, C. (2006). *Guiding Change in the Irish Health System*. Kells, Co Meath: HSE National Organisation Development and Design Directorate
- McEvoy, J. et al. (2006). Effectiveness of clozapine versus olanzapine, quetiapine and Risperidone in patients with chronic schizophrenia who did not respond to prior atypical antipsychotic treatment. *Am J Psychiatry*. 163:600-610
- McGrath, J. (1999). New antipsychotic medications. *Aust Prescr*. 22: 81 - 83
- Melkersson, K. (2004). Clozapine and olanzapine, but not conventional antipsychotics, increase insulin release in vitro. *Eur Neuropsychopharmacology*. 14: 115 119
- Mesirow, J. (1990). *Fostering critical reflection in adulthood: A guide to transformative and emancipatory learning*. San Francisco: Jossey-Bass

- Metzer, H., Bobo, W., Lee, M. (2010). A randomised trial comparing clozapine and typical Neuroleptic drugs in non-treatment resistant schizophrenia. *Psychiatry Research*. 177:286 – 293.
- Mintzberg, H. (1994). *The rise and fall of strategic planning*. New Jersey, USA. Prentice Hall
- Mitchell, A.J., Delaffon, V., Lord, O. (2012). Let's get physical: improving the medical care of people with severe mental illness. *Adv Psych Tr*. 18:216-225
- Mortimer, A. (2011). Using clozapine in clinical practice. *Adv Psych Tr*. 17:256-265
- Munro, J. et al. (1999). Active monitoring of 12760 clozapine recipients in the UK and Ireland. *Br J Psychiatry*. 175:576-580
- National Institute for Health and Clinical Excellence. (2010). *Schizophrenia. Guideline on core interventions in the treatment and management of schizophrenia in adults in primary and secondary care.*
<http://www.nice.org.uk/nicemedia/pdf/CG82FullGuideline.pdf> (accessed 3rd May 2012)
- National Institute for Health and Clinical Excellence. (2007). *How to change practice: understand, identify and overcome barriers for change.*
<http://www.nice.org.uk/media/D33/8D/Howtochangepractice1.pdf> (accessed 07.May 2012)
- Newcomer, J. (2002). Abnormalities of glucose regulation during antipsychotic treatment of schizophrenia. *Arch Gen Psychiatry*. 59:337 – 345
- Newcomer, J. (2005). Second-generation (atypical) antipsychotics and metabolic effects: a comprehensive literature review. *CNS Drugs* 19: 1 – 93

- Norvatis (2010). Clozaril 25mg and 100mg tablets. The electronic medicines compendium (<http://www.medicines.org.uk/emc/document.aspx?documentid=1277>)
- Panagiotou, G. (2003). Bringing SWOT into Focus. *Business Strategy Review*, 14, 8-10
- Pascual-Leone, A., Amedi, A., Fregni, F., Merabet, L., (2005). The plastic human brain cortex. *Annual Review of Neuroscience*. 28: 377 – 401
- Pincus, H. (2010). From PORT to policy to patient outcomes: crossing the quality chasm. *Schizophrenia Bulletin* 36: 109 - 111
- Pincus, H. Page, A., Druss, B. Et al. (2007). Can psychiatry cross the quality chasm? Improving the quality of healthcare for mental and substance use conditions. *American Journal of Psychiatry* 164: 712 – 719
- Polonsky, M., Scott, D. (2005). An empirical examination of the stakeholder strategy mix. *European Journal of Marketing*. 39 (9/10): 1199-1215
- Ritchie, B. (2006). Lewin's change management model: Understanding the three stages of change <http://www.new-paradigm.co.uk/Culture%20&%20Complexity.doc> (accessed 5th May, 2012)
- Rieley, J., Clarkson, I. (2001). The impact of change on performance. *Journal of Change management*. 2(2): 160 - 172
- Roberts, L., Roalfe, A., Wilson, S. et al. (2007). Physical health care of people with schizophrenia in primary care: a comparative study. *Family Practice*. 24: 34 – 40
- Rogers, C. (1969). *Freedom to learn: a view of what education might become*. Columbus, OH, Charles E. Merrill

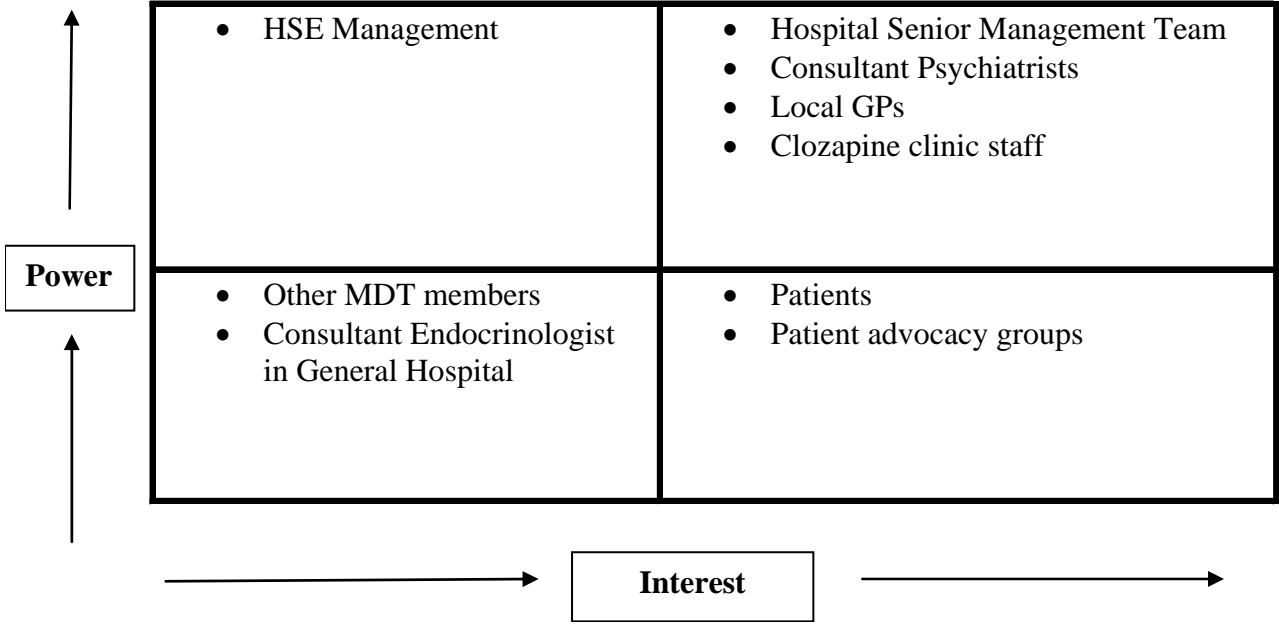
- Rummel-Kluge, C., Komosa, K., Schwarz, S., et al. (2010). Head-to-head comparisons of metabolic side effects of second generation antipsychotics in the treatment of schizophrenia: a systematic review and meta-analysis. *Schizophrenia Research*. 123: 225 – 233
- Schein, E. (1992). *Organizational Culture and Leadership: A Dynamic View*. San Francisco, CA: Jossey-Bass.
- Schizophrenia Ireland. Understanding Clozaril Treatment: handbook for patients and carers. www.sirl.ie
- Senge, P., Kleiner, A., Roberts, C. et al. *The Dance of change: The challenges of sustaining momentum in Learning Organisations*. New York: Doubleday/currency
- Senior, B. (2002). *Organisational change*. 2nd edition. London (Prentice Hall)
- Sheldon, T., Cullum, N., Dawson, D. Et al. (2004). What's the evidence that NICE guidelines have been implemented? Results from a national evaluation using time series analysis, audits of patients' notes and interviews. *BMJ* 329: 999 – 1004
- Sidorko, P. E. (2008). Transforming library and higher education support services: can change models help? *Library Management*, 29 (4/5): 307 - 318
- Sims, A. *Symptoms in the mind: an introduction to descriptive psychopathology*. Philadelphia: W. B. Saunders; 2002. ISBN 0 – 7020 – 2627 – 1
- Smith, T., Weston, C., Lieberman, J. (2010). Schizophrenia (maintenance treatment). *Am Fam Physician*. 82 (4): 338 – 339
- Stahl, S. M. (2000). *Essential Psychopharmacology. Neuroscientific Basis and Practical Applications*. 2nd Edition. Cambridge University Press

- Taylor, D., Paton, C., Kapur, S. (2009). The Maudsley prescribing guidelines. Informa healthcare. London. Pg 66
- Todd, A. (1999). Managing radical change. Long range planning. 32 (2): 237 - 244
- Tosh, G., Clifton, A., Mala, S. et al (2010). Physical health care monitoring for people with serious mental illness. Cochrane Database of Systematic Reviews. (issue 3): CD008298
- Velligan, D., Alphas, L. (2008). Negative symptoms in schizophrenia: the importance of identification and treatment. Psychiatric Times. 25 (3)
- West, J. (1997). Managing performance in the white spaces. In G. Rummler (Ed.), Performance improvement pathfinders: Models for organizational learning systems (pp. 108-123). Silver Spring, MD: International Society for Performance Improvement
- Whyte, S., Penny, C., Phelan, M. Et al. (2007). Quality of diabetes care in patients with schizophrenia and bipolar disorder: cross sectional study. Diabetic Medicine 24: 1442 – 1448
- Wilson, D. C. (1992). A strategy of change. London: Routledge
- Wright, D. (1997) getting out of the asylum: understanding the confinement of the insane in the nineteenth century. Soc Hist Med. 10 (1): 137 - 155
- Young, M. (2009). A meta model of change. Journal of Organizational Change Management, 22, 524-548

Appendix 1: Table showing adverse effects of clozapine

	Common	Uncommon/Unusual	Serious/Life Threatening
1.	Sedation	Colitis	Agranulocytosis
2	Hypersalivation	Delirium	Thromboembolism
3	Constipation	Eosinophilia	Cardiomyopathy
4	Hypotension	Heat stroke	Myocarditis
5	Hypertension	Hepatic failure	
6	Tachycardia	Ocular pigmentation	
7	Weight gain	Pancreatitis	
8	Fever	Pericardial effusion	
9	Seizures	Pneumonia	
10	Nausea	Thrombocytopenia	
11	Nocturnal enuresis	Vasculitis	

Appendix 2: Stakeholders' Analysis



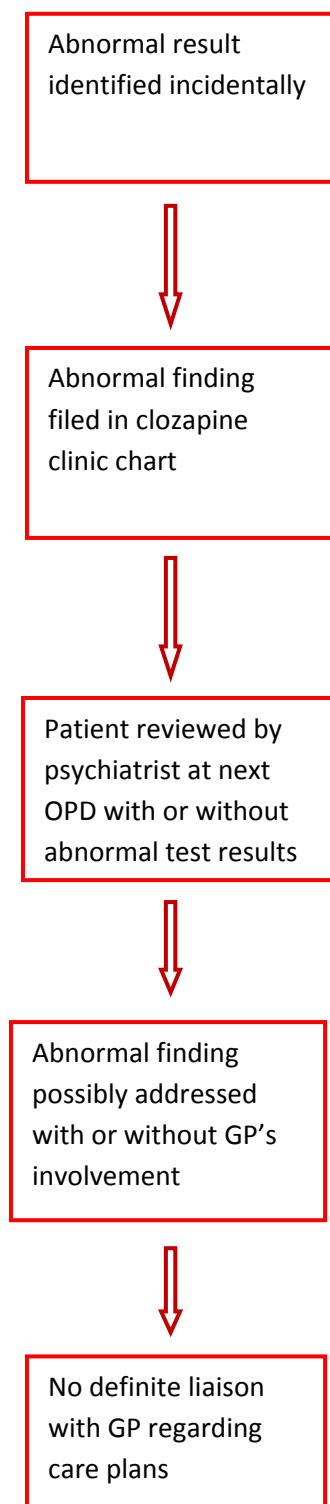
Appendix 3: SWOT Analysis

<p>STRENGTHS</p> <ul style="list-style-type: none"> • Good early buy-in • Expert and position power of change leader (author) • External policy environment • Internal need to improve practice • Cost effectiveness of project • Strong interest and commitment by team 	<p>OPPORTUNITIES</p> <ul style="list-style-type: none"> • Parallel development of individualised care and treatment planning • Recently increasing emphasis on service-user involvement • Ongoing Primary Care Liaison project • Completion of Masters Degree!
<p>WEAKNESSES</p> <ul style="list-style-type: none"> • Prevailing low staff morale in HSE and public service • Fear of increased workload by nursing staff • ‘Role’ culture within the organisation 	<p>THREATS</p> <ul style="list-style-type: none"> • Recruitment embargo - unstable staffing levels • Precarious relationship with some local GPs • Change fatigue – ongoing parallel changes due to broader service reconfiguration agenda • Potentially heightened awareness of patients to claims and litigations

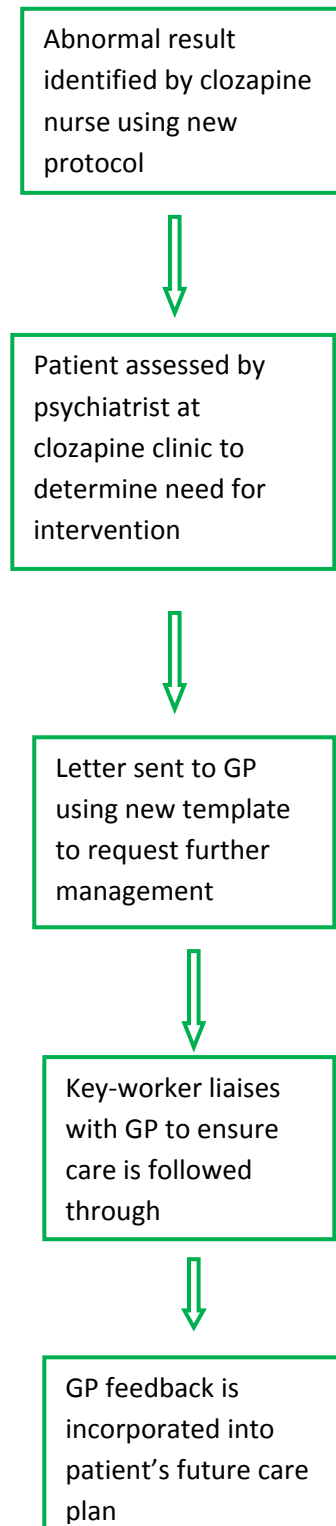
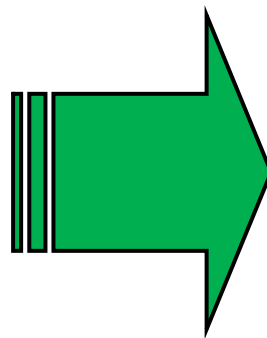
Appendix 4: Project Impact Statement

	How things are done now	How things would be following this project
Behaviour	<p>The physical health of patients on clozapine is not receiving evidence-based attention.</p> <p>Physical examinations and laboratory investigations are not systematic .</p> <p>Abnormal results are not effectively followed through.</p> <p>There is no coordination of care with GPs for the management of adverse effects.</p>	<p>The attitude and practice of staff in relation to clozapine monitoring will come in line with best practice guidelines.</p> <p>Comprehensive surveillance of relevant physical parameters will be carried out on an ongoing basis.</p> <p>Findings will be shared collaboratively with patients and their GPs and continuity of care between the psychiatry and primary will be optimised.</p>
Structural	<p>There are no procedures or guidelines with regard to the monitoring of patients on clozapine.</p> <p>There is no protocol for the follow up of abnormal laboratory or physical examination findings.</p>	<p>An evidence based proforma will be in place to guide clozapine monitoring.</p> <p>Policies and procedures will be in place for the coordination of care between the service, the patients and their General Practitioners.</p>
Personal	<p>I have long maintained a special interest in the interface between psychiatry and medical disorders.</p> <p>I have a particular interest in psychopharmacology, and an empathic disposition towards the adverse effects of medications.</p>	<p>Through participating in this project, I will enhance my knowledge, attitude and practice in relation to the physical health of the patients under my care.</p> <p>I will strive to continually improve my practice in the area during my career.</p>
Cultural	<p>Attention to the physical health of patients on clozapine has at best been casual and opportunistic.</p> <p>Staff have approached this role with only a superficial awareness of the ethical and evidence-based considerations that underlie such practice.</p>	<p>Staff will become accustomed with the ethical considerations that underlie the safe clinical practices in relation to the adverse consequences of prescribed medications.</p> <p>The structured and systematic approach used in introducing the change will help embed the revised care process and pathway within the cultural fabric of the organisation.</p>

APPENDIX 5: Process maps of old and new care pathways



Flow Chart 1: Old care pathway



Flow Chart 2: New care pathway

Appendix 6: New Proforma for clozapine monitoring

PATIENT'S NAME:	DOB:	DIAGNOSIS:	SMOKER: <input type="checkbox"/> YES <input type="checkbox"/> NO
	SEX: <input type="checkbox"/> M <input type="checkbox"/> F	CO-MORBID DIAGNOSIS:	DATE CLOZAPINE COMMENCED:

PHYSICAL PARAMETERS	DATE			
CURRENT DOSE				
WEIGHT (kg)				
WAIST CIRCUMF (cm)				
BP (mmHg)				
PULSE (b/pm)				
TEMP (°C)				

LAB INVESTIGATIONS	
GLUCOSE	
HBA1c	
U/E/Cr	
LIPID PROFILE	
LFT	
FBC	
REMARKS (including signature of assessor)	

Appendix 7: Standardised letter format for communicating abnormal findings to GPs

North Sector
County Mental Health Service
Ireland

Date

Dr.....
GP Practice Address
City Centre
Ireland

Re: **Patient Name, DOB**
 Address
 Diagnosis
 Current Medications

Dear Dr.....

Routine physical evaluation performed on the above named patient has revealed the following abnormalities:

-
-
-
-
-

Please be advised that these findings may be associated with the antipsychotic medication – clozapine. Your urgent attention to this matter would be most appreciated.

Yours sincerely,

Consultant Psychiatrist

Appendix 8: Pre and Post Implementation Questionnaire (Staff)

Dear Colleague,

Please kindly take a few moments to answer these questions in relation to the routine monitoring of patients on clozapine.

1. How would you rate your knowledge in relation to the adverse effects of clozapine treatment?
 - a. Poor
 - b. Adequate
 - c. Very good
2. How would you rate your own current practice in relation to the monitoring of the adverse effects of clozapine treatment?
 - a. Poor
 - b. Adequate
 - c. Very good
3. How would you rate your attitude in relation to the monitoring of the adverse effects of clozapine treatment?
 - a. Poor
 - b. Adequate
 - c. Very good
4. How would you rate your satisfaction with the current practice of this service in relation to the monitoring of patients on clozapine treatment?
 - a. Poor
 - b. Adequate
 - c. Very good
5. How would you rate your interest in improving the monitoring of patients on clozapine treatment within this service?
 - a. Poor
 - b. Adequate
 - c. Very good

Thank you for taking time to complete this questionnaire.

Post-implementation questionnaire (Staff)

Dear Colleague,

Please kindly take a few moments to answer these questions in relation to the recent change to the monitoring of patients on clozapine.

1. How would you rate your knowledge in relation to the adverse effects of clozapine treatment?
 - a. Poor
 - b. Adequate
 - c. Very good
2. How would you rate your own current practice in relation to the monitoring of adverse effects of clozapine treatment?
 - a. Poor
 - b. Adequate
 - c. Very good
3. How would you rate your attitude in relation to the monitoring of the adverse effects of clozapine treatment?
 - a. Poor
 - b. Adequate
 - c. Very good
4. How would you rate your satisfaction with the current practice of this service in relation to the monitoring of patients on clozapine treatment?
 - a. Poor
 - b. Adequate
 - c. Very good
5. How would you rate your commitment to continually improving the monitoring of patients on clozapine treatment within this service?
 - a. Poor
 - b. Adequate
 - c. Very good

Thank you for taking time to complete this questionnaire

Appendix 9: Evaluation Findings

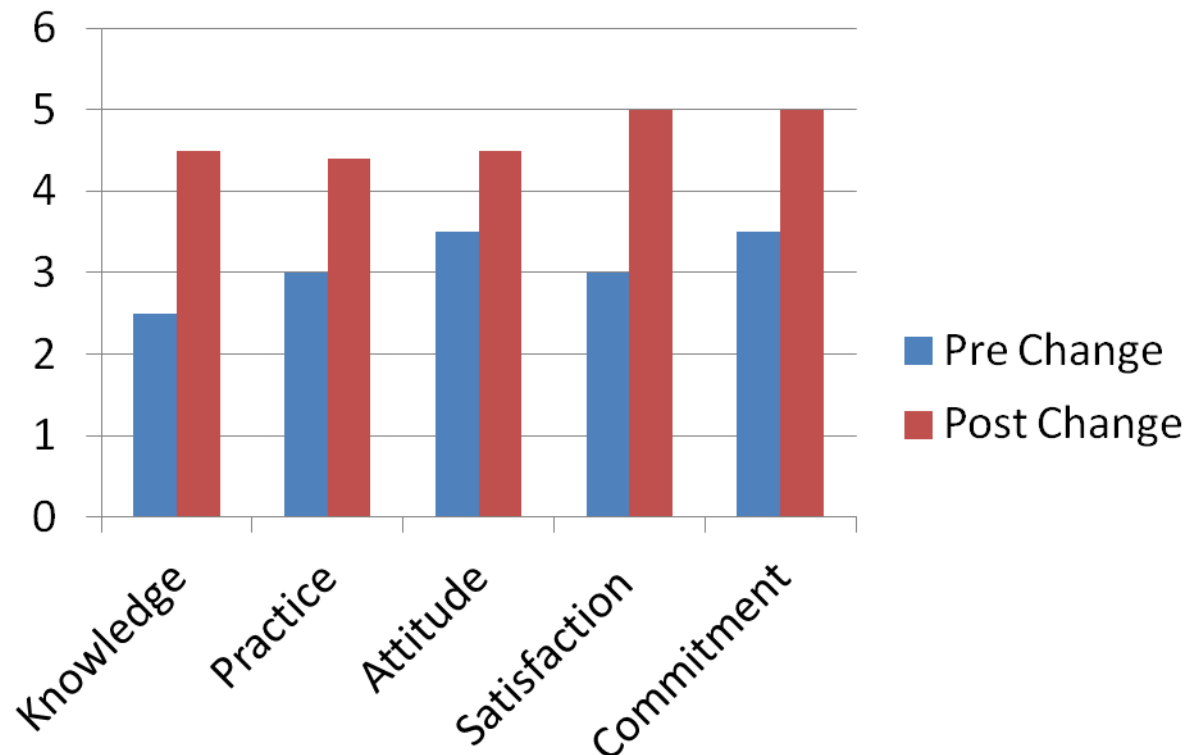


Fig. 1: Graph showing responses of staff to pre and post change questionnaires. In the survey, staff were requested to rate their own knowledge, attitude and Practice in relation to monitoring the side effects of clozapine. They were also asked to rate their satisfaction with the practice at service level, and their commitment to continued quality improvements.

Appendix 10: Project Poster

