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The Development of a Pharmaceutical Care Plan in the Scottish Mental Health Service

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Abstract

Background

Pharmaceutical care planning is increasingly seen as the most effective manner by which to deliver pharmaceutical care services to the patient. The role of the pharmacist, both specialist and generalist, is paramount, as much of the treatment in Mental Health is dependent on the effective management of the patients medication[(1)]. Consequently, there is a need for standardised pharmaceutical care planning within the speciality. In Scotland, the Mental Health Pharmacy Strategy Group (MHPSG) commissioned a project to develop and implement a care plan document that could be used at a national level. This project has taken on the recommendations from that study to re-design and validate a standardised document for pharmaceutical care planning in a psychiatric in-patient population.

Methods

Recommendations from the MHPSG's study and candidate care issues specific to mental health pharmacy were identified and incorporated into the re-design of the care plan document. A small field test was then conducted in NHS Lothian, where 12 care plans were completed by six pharmacists. Feedback from this study was used to re-develop a 2nd draft, which was subjected to peer review and assessment by focus group discussion. The focus group consisted of clinical mental health pharmacists from different health board areas who discussed the content, layout and general utility of the document. Findings from this discussion informed the re-development of a final version of the care plan document.

Results

A four page standardised document that will enable a uniform care planning approach within mental health pharmacy.

Conclusion

The development of a national care planning system is a labour intensive process. This project has managed to produce a care plan that may be used as a standard within mental health in-patients after further validation. Whilst the majority of pharmacists are aware of its benefits, several issues became apparent which may impede its implementation and use.

List of Abbreviations

ADR	Adverse Drug Reactions
BMI	Body Mass Index
BNF	British National Formula
CHI-number	Community Health Index number
CYP450	Cytochrome P450
DMP	Designated Medical Practitioner
DTP	Drug Therapy Problems
ECG	Electrocardiogram
EPS	Extrapyramidal side effect
GP	General Practitioner
ICP	Integrated Care Pathway
MAOI	Monoamine-oxidase inhibitor
MHA	Mental Health Act
MHPSG	Mental Health Pharmacy Strategy Group
MHT	Mental Health Trust
MWC	Mental Welfare Commission
NHS	National Health Scotland
NICE	National Institute of Clinical Excellence
OTC	Over The Counter
PRN	Pro re nata (As required medication)
REH	Royal Edinburgh Hospital
RMO	Responsible Medical Officer
SIGN	Scottish Intercollegiate Guidelines Network
SPMH	Scottish Pharmacy Mental Health
SSRI	Selective Serotonin Re-uptake Inhibitors
TCA	Tricyclic antidepressant
TDM	Therapeutic drug monitoring
UK	United Kingdom

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1. Introduction

"Mental health" and "mental illness" are not polar opposites, but may be thought of as points on a continuum[2].

Mental health is a state of successful performance of mental function, resulting in complete mental and social well-being in which the individual can cope with the normal stresses of life, deals with family and interpersonal relationships, and contribute to community or society. Mental health refers to the successful performance of mental functions in terms of thought, mood, and behaviour.[2, 3]

Mental illness is the term that refers collectively to all diagnosable mental disorders. It can be seen as a breakdown of the mental health, characterised by alterations in thinking, mood, or behaviour (or a combination of that) associated with distress and/or impaired functioning. Mental disorders are those health conditions in which alterations in mental functions are paramount.[2]

1.1. Magnitude of Mental Health Problems

Research suggests that about one in four people experience mental distress at any one time, with the most common problems being anxiety and depression. However, more serious conditions, such as schizophrenia, are also common, with one in every hundred people in the UK diagnosed with the condition. The UK spends about 10% of the total health budget on mental health.[4]

Mental health problems also often complicate other diseases and occur twice as often in people with physical illness as in the general population. Episodes of mental illness can come and go throughout a person's life and some people may experience their mental illness only once and then fully recover. Mental illness is a general term that refers to a group of illnesses that affect the brain, and can be mild or severe, temporary or prolonged, but are usually treatable. Recovery rates for mental health problems are between 70% and 80%.[5, 6]

Although as many as one in four people experience a mental health problem, and nearly three-quarters know someone who has been diagnosed with one, stigma has an important role within mental health practice. In spite of dramatic advances in our understanding and approach to mental ill health, some people still cling to the idea

that the straitjacket and the asylum are the norm. Stigma is often defined as ‘a mark of discredit or shame’. The shame of having a mental health problem is so high that many who develop a mental health problem do not want anybody to know about it. Stigma is manifested by bias, distrust, stereotyping, fear, embarrassment, anger, and/or avoidance. In 2001 an ‘SEE ME...’ campaign was initiated throughout Scotland to try and stop the stigma of mental illness. It has been a successful campaign, but as they have not met their goals yet, it is still running on its seventh year.[7, 8]

1.1.1 Mental health disorders

Definitions, assessments, and classifications of mental disorders can vary, but guideline criterion listed in the International Classification of Diseases (ICD10) and the (American Psychiatric Association) Diagnostic and Statistical Manual of Mental Disorders (DSM IV) are widely accepted by mental health professionals. Categories of diagnoses in these schemes may include mood disorders, anxiety disorders, psychotic disorders, eating disorders, developmental disorders and personality disorders. This text will give some more information on mood and psychotic disorders, as they make up the highest number of admissions to hospital. According to a survey done for adult psychiatric illness in England, depression and anxiety was the most common reason for hospital admission, accounting for 29.6% of all admissions, and schizophrenia and related psychoses came second as they accounted for 26.0% of the admissions[9].

1.1.1.1. Mood disorders

Mood disorders include depression, elation or a combination of the two. The primary affective disorders are classified as either unipolar or bipolar disorder. The exact aetiology is unknown, which is the case for most psychiatric disorders.[5]

Unipolar disorder includes subtypes like major depression, chronic mild depression (dysthymia) and postpartum depression. Depression is the most common of the affective disorders as 17% of the population suffers from depression some time in their life[6]. It is characterized by a low mood, loss of motivation, low self-esteem and diminished ability to experience pleasure.[6, 10]

Bipolar disorder appear in 1.3% of the population[6], and includes subtypes like bipolar I, bipolar II and cyclothymia. The disorder causes unusual shifts in a person's mood, energy, and ability to function, and is described by alternating periods of mania and depression. Bipolar I disorder is characterized by full manic episodes and major depressive episodes, while bipolar II has hypomanic and major depressive episodes. Cyclothymia is a milder form of bipolar disorder where the episodes of depression never meet the criteria for major depression. It is enough with only one manic episode to diagnose bipolar disorder, but depression is inevitable later in the course of the illness. The onset of mania is usually sudden and dramatic, and the patient often resists treatment because they don't recognize that they are ill. Episodes of illness are associated with distress and disruption, and a relatively high risk of suicide.[5, 6, 10]

1.1.1.2. Psychotic disorders

Psychotic disorders include schizophrenia and delusional disorder. Schizoaffective disorder is a category used for individuals showing aspects of both schizophrenia and affective (mood) disorders. Delusional disorder involves holding one or more non-bizarre delusions in the absence of any other significant signs or symptoms of mental illness (previously called paranoia).[6]

Schizophrenia is a chronic, severe and disabling brain disorder with a great range of symptoms. It is not to be mistaken with split personality. It affects about 1% of the population and is one of the most important forms of psychiatric illnesses, as it affects young people and is often chronic. The illness usually has positive symptoms like delusions, hallucinations and thought disorder; negative symptoms like apathy, social withdrawal and lack of drive; and cognitive symptoms which can be problems with attention, memory and ability to plan and organise.[6, 10-12]

The cause of schizophrenia is unclear, but the mode of action of antipsychotic drugs has led us to believe that it is caused by an alternation in the level of dopamine activity in the brain. Drugs that decrease the dopamine level seem to be effective, while drugs that increase the dopamine level can induce psychosis or exacerbate a schizophrenic illness[11].

1.1.2 Medication

For the purposes of this report, the main psychotropic drugs are discussed. These are: antidepressants, antipsychotics and mood stabilisers.

1.1.2.1. Antidepressant medication

Antidepressants are mostly used in patients that suffer from depression, and can be divided into tricyclic antidepressant (TCA), monoamine-oxidase inhibitors (MAOI) and selective serotonin re-uptake inhibitors (SSRI). According to systematic reviews and meta-analyses of studies undertaken in primary care and outpatient settings, all the different antidepressants have similar effectiveness in the majority of patients with major depressions[13]. SSRIs are better tolerated than older TCAs (which are associated with higher incidences of anticholinergic side-effects, sedation, weight gain and cardiovascular complications), are safer in overdose and are more likely to be prescribed at recommended doses for an adequate period. MAOIs are also associated with a lot of undesirable side effects, and are therefore reserved for resistant depression. Considerations to take into account when selecting an antidepressant is previous response, side-effects, contraindications, toxicity in overdose, patient preference and clinician familiarity. [6, 10, 11, 13]

In order to produce a full response the drugs are to be taken in adequate doses for about 4-6 weeks, and treatment should be continued for at least six months at full therapeutic dose before attempting withdrawal. Stopping and switching antidepressant can lead to ‘drug discontinuation syndrome’ if it’s not done gradually. Typical symptoms of antidepressant discontinuation syndrome include flu-like symptoms, insomnia, nausea, imbalance, sensory disturbances, and hyperarousal. These symptoms are usually mild, last one to two weeks, and are rapidly extinguished with reinstitution of antidepressant medication. Successful treatment with antidepressants should be reduced over a period of at least 4 weeks.[11, 13]

1.1.2.2. Antipsychotic medication

Antipsychotic drugs are a group of drugs commonly, but not exclusively, used to treat psychosis. Common conditions in which antipsychotics might be used include schizophrenia, bipolar disorder, mania and delusional disorder. The drugs are divided into the originally developed drugs, named *classical* or *typical* antipsychotics, and the more recently developed drugs, named *atypical* antipsychotics.

Patients may respond differently to different antipsychotic drugs, and often several drugs must be tried before the right one is found. This is mainly because of the wide range of side-effects that may occur. The antipsychotic potency of most antipsychotics is directly proportional to their ability to block dopamine receptors in the brain, although the exact mechanism is believed to be more complicated. Their selectivity for dopamine receptors varies a lot, and many also have significant effects on acetylcholine, norepinephrine, histamine and serotonin pathways. This gives the reason to expect a wide range of side-effects. The most common ones are; extrapyramidal side effects (EPS), such as rigidity, persistent muscle spasms, tremors, and restlessness; hyperprolactinaemia; reduced seizure threshold; postural hypotension; anticholinergic side-effects, such as dry mouth, blurred vision and constipation; weight gain and metabolic changes that is associated with an increased risk of developing hypertension, cardiovascular disease, type 2 diabetes and dyslipidaemia; and neuroleptic malignant syndrome (NMS), where the main symptoms are mild fever, fluctuating consciousness, muscular rigidity, autonomic instability and severe EPSEs [14].

The ‘atypical’ drugs have shown in clinical trials to have minimal potential for causing EPS. ‘Atypical’ drugs are therefore better tolerated in normal clinical doses than ‘typical’ drugs, and are recommended for first line use. [11, 15]

Clozapine was the first ‘atypical’ drug on the market and has shown to be very effective, but because of the significant risk of agranulocytosis is it largely reserved for use in treatment resistant patients. Agranulocytosis is an acute condition involving a severe and dangerous reduction in the number of white blood cells in the body. As the principal function of white cells is to combat infection, a decrease in the number of these cells can place patients at increased risk for infections. If the patient is on clozapine, a full blood count needs to be done weekly for 18 weeks, fortnightly until 52 weeks of treatment and then monthly thereafter if haematologically stable. To ensure that these tests are done, is clozapine only available through a distribution system, this means all results are authorised before medication is delivered/dispensed to the patient. [11, 12, 14]

Other commonly used atypical drugs are sulpiride, amisulpiride, risperidone, olanzapine and quetiapine, which do not have the risks of agranulocytosis, like

clozapine, or EPS, like the 'typical' drugs, but they can cause weight gain and metabolic changes [12].

1.1.2.3. Mood stabilizers

These agents are used to stabilise mood and so can be used to dampen an abnormally high mood (hypomania) or help to lift low mood (depression). Nevertheless, an antidepressant is often prescribed in addition to the mood stabilizer during depressive phases. This brings some risks as antidepressants can induce mania, psychosis, and other disturbing problems in bipolar patients - particularly when taken alone, but sometimes even when used with a mood stabilizer. [6, 11, 14]

The first mood stabiliser on the marked and still the one most commonly used is lithium**.** It acts to control mania as well as depression, but is mainly used prophylactically in bipolar disorder [16]. Its use in the treatment of acute mania is limited by the fact that it usually takes at least a week to achieve response because of its long plasma half-life. It can also be difficult to rapidly achieve therapeutic serum levels because of its narrow therapeutic window (approximately 0.6-1.0 mmol/L). If the plasma levels rise above 2.0 mmol/L, increased disorientation and seizures can occur, and that can progress to coma and death. This make monitoring essential, especially in the presence of a renal disease since lithium is excreted renally. The serum level should be measured after seven days, and then one week after each dose change until desired level has been achieved. Once the serum level is stable it should be checked every third month. Some studies have suggested a risk of birth defects in the new-born if a mother is taking lithium during her pregnancy. There is also evidence that sudden discontinuation of lithium increases the risk of a manic or hypomanic relapse, so if the treatment is to be stopped, it is advised to do it gradually.[6, 10, 11, 14, 16, 17]

Other commonly drugs used as mood stabilisers are sodium valproate and carbamazepine. Both were first used for the management of epilepsy, but they have also been found to offer benefits to many bipolar patients [18]. Sodium valproate has been found to be effective in patients who predominantly suffer with depression, whilst carbamazepine works less well in such cases [19]. Like lithium, they need to be monitored and blood tests may be necessary, although monitoring often does not

have to be as strict as in the case of lithium. They also present some risks during pregnancy.[6, 11, 14, 19]

1.2. Pharmaceutical care

The concept of pharmaceutical care was developed in the United States by Douglas Hepler and Linda Strand in 1990. They defined it as "*the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life*" [20]. This was subsequently refined by Strand and co-workers to "*a practice in which the practitioner takes responsibility for a patient's drug related needs and holds him or herself accountable for meeting these needs*" [21]. In order to achieve this, the practitioner needs to assess the patient to make sure the medicines taken is appropriate, safe and effective, and that the patient is able and willing to take the medication as intended. The practitioner also needs to develop a care plan for the patient and have a follow-up evaluation on a systematic basis. [21, 22] "*Pharmaceutical care reflects a systematic approach that makes sure that the patient gets the right medicines, in the right dose, at the right time and for the right reasons.*"[1]

Care plans enable the identification of a patient' pharmaceutical needs and allow these needs to be organised in a systematic manner to achieve goals of therapy. It is also a way of documenting the pharmacists work. A care plan is supposed to help see and resolve drug therapy problems and prevent new ones from developing. "*The key to a successful care plan is clear, measureable goals of therapy which include a parameter, desired value(s), and a timeframe for achieve them.*"[21] The care plan should include the care issues together with the desired output(s) and the action planned to achieve the output(s).[21, 23]

Having hospital pharmacists doing 'clinical work' has shown to identify and reduce important drug related problems, improve patient education and compliance, improve prescribing, 'clinical outcomes' and cost effectiveness, and to reduce rates of readmission and length of hospital stay. The presence of the clinical pharmacist on the ward is now generally welcomed as a source of information and advice by medical, nursing and other ward staff in Scotland; they are a part of a multidisciplinary health care team. The 'Framework for Practice'[24], published in

1996, recognises the need for pharmacists to participate fully as members of the team, and pharmacists in Scotland are now actively supporting drug and therapeutics committees, ward rounds, therapy review rounds, nurses' meetings, discharge planning meetings, case conferences, clinical meetings and unit meetings. [24] But the concept of pharmaceutical care has still much to offer, and there should always be room for improvements. It is recommended that the pharmacists should design protocols (local treatment guidelines), document problem solving and increase the level of teamwork and continuity of care to help improve the system they are working within. To achieve this they should improve their own personal level of practice by improving their knowledge as well as communications skills and attitudes to patients and teamwork.

1.2.1 Pharmaceutical care in mental health

The role of a hospital pharmacist has since the 1960's changed from being a dispensary based supply and support role to a primary ward/team based role. The mental health trusts (MHTs) have however suffered from a number of mistaken assumptions on how they don't need to develop their own specialist pharmacy service. It has been thought that the generic acute trusts would provide this expertise and that developments from acute trusts can be directly transferable to MHTs. MHTs however support people over a longer period of time and covers a larger geographical area with small units. The magnitude of medicines management may also differ since medication within mental health is more emotive and complex, with risks including inappropriate dosing, poly-prescribing and inadequate patient monitoring. In order to reverse these assumptions, "*The new ways of working for pharmacists and other pharmacy staff programme" [25],* were developed in 2001. This programme has amongst many other things shown that the presence of a pharmacist in the clinical/ward/community team is likely to improve relationships, improve medicines management and lead to better outcomes for service users. It has been a vital part of the transition from pharmacy being a neglected area to highlighting the need for it to be a key clinical service.[25-27]

Mental health is now one of the Scottish Executive's health priority areas alongside cancer and heart disease [28]. In 2002 the Scottish Executive (now referred to as the Scottish Government) published "*The Right Medicine: A Strategy for Pharmaceutical Care in Scotland" [1]*. Some priority areas were discussed and mental health was one

of them. The document highlighted the contribution pharmacists can give to the management of psychiatric and other medicines, and how they can help promote patient compliance. To ensure that high quality pharmaceutical care was provided across Scotland, the document endorsed development of "*an integrated pharmacy record and decision-support system*"[1].

Last year the Health Care Commission published a report "*Talking about medicines; the management of medicines in trusts providing mental health services"* [26], were a review of medicines management in 42 trusts (out of 83), that provided specialist mental health services in England and Wales, were carried out. It was released at the same time as "*The best medicine: the management of medicines in acute and specialist trusts*."[29] The same methodology was used in both the mental health and acute trust reports, and results were compared. This comparison shows that the level of medicines management support were less within mental health than those found in acute trusts. It also shows that about 67% of suggestions made by pharmacy staff was acted on in mental health trusts and that pharmaceutical interventions reduce harm for one in every 29 patients (compared to one in every 26 in acute trusts). Medical reviews showed that 46% of the patients did not take their medicines appropriately (compared to 12% in acute trusts) "Talking about medicines..." includes a checklist of recommendations to the MHTs on how to improve medicines management and how trusts should aim to deliver the same standards of care. This checklist is displayed in table 1 below. The Health Care Commission recommends that trusts review their strategy and leadership in relation to medicines management according to this checklist, and implement action plans to improve their performance.[26, 29]

The definition on medicines management in the UK Audit Commissions report from 2001, "*A spoonful of sugar*" follows; "*Medicines management in hospitals encompasses the entire way that medicines are selected, produced, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to produce informed and desired outcomes of patient care*"[30]

Table 1: Ten focus areas for medicines management within mental health

Ten focus areas for medicines management
1. Involving people in decisions and management of their medicines
2. Ensuring appropriate and effective use of medicines in people's care
3. Efficiently and effectively providing and administering medicines
4. Promoting multi-disciplinary team working to provide seamless care
5. Coordinating care with other service providers
6. Governing use of medicines
7. Choosing and prescribing medicines
8. Ensuring staff are competent to work with medicines
9. Accurately recording and reporting on use of medicines
10. Supplying and managing medicines in the trust

Mental health services are also a key theme in the NHS Quality Improvement Scotland (NHS QIS) work programme, and different approaches towards improvements have been taken over the years. In order to improve service effectiveness and quality, and to be able to routinely measure outcomes of this, they want to implement Integrated Care Pathways (ICPs) to the mental health trusts, based on shared planning and meeting individuals needs. "*An ICP is a multidisciplinary outline of anticipated care, placed in an appropriate timeframe, to help a patient with a specific condition or set of symptoms move progressively through a clinical experience to positive outcomes*" [31]. Their use as a tool in healthcare is well developed and has shown to have many benefits. An ICP can reduce duplication of work, improve communication, and clarify who does what, where and when. Individual wards in some trusts have started to introduce ICP, but many still have a long way to go. [28, 31] While waiting for, or as a way towards, the

implementation of ICPs, Scotland can benefit from a national standard in ways of working for pharmacists.

1.2.2. The development of standardised pharmaceutical care plans

Since 2002, work on a national system of care plans has begun in priority areas [4]. In 2003, Macintyre *et. al.* developed and tested a documentation system (care plan) for cancer patients receiving chemotherapy [27]. They concluded that the development of the pharmaceutical care plan has standardised the provision of pharmaceutical care to patient receiving chemotherapy for cancer in Scotland. Krska *et. al.* analysed a study in which pharmaceutical care were delivered to elderly patients on multiple therapy in 2001[32]. This showed that pharmaceutical care planning encouraged interaction with both patients and the multi-disciplinary team.

The Mental Health Pharmacy Strategy Group (MHPSG) is a national interest group which aims to improve the mental wellbeing of the population by providing strategic direction to NHS Scotland for the planning and development of pharmaceutical care in mental health.

The MHPSG designed and developed, over a two year period, a generic care plan document which they envisaged could be used at a national level to facilitate pharmaceutical care planning [4]. The generic pharmaceutical care plan comprised two sections: the Longitudinal information sheet, which was one page, intended to be completed once for each patient, and the Cross-sectional admission, which was six pages intended to be completed on each admission. The plan is laid out in appendix 1a and 1b. The necessity to develop and introduce such a care plan Scotland-wide was encouraged by a series of national reports; Scottish Executive 2006 [33], 2002 [1], 1999 [34] and 1997 [35].

In late 2006, NHS Greater Glasgow & Clyde Research & Development Directorate funded a project which allowed the newly developed care plan document to be field tested within the mental health pharmacy service during a two month period. Sixty three pharmacists from all eleven Health Boards and The State Hospital, Carstairs, were recruited. The care plan was used on 241 adults, 70 elderly and 16 forensic mental health patients from Scotland, in total 327 patients.

The aim of the project was to understand how a standardised generic pharmaceutical care plan could facilitate the practice of pharmaceutical care planning in mental health across Scotland. The research questions can be seen in appendix 2. To address the research questions, the participants completed a questionnaire and diary. The completed sections on the generic care plan were counted, and existing care plans in current use (11 in total ranging from 2 to 38 pages in length) were compared.

Results from this study were positive but several issues in relation to the layout and content were identified which had to be addressed before it could be implemented as a standardised national document. Comments on the generic plan can be divided in three major groups:

1. Content

   The sections dealing with current medication and care issues were found to be difficult to use and labour intensive. Other criticism concerned the lack of space for recording relevant information on the patient, and that the sequence of sections needed to be changed for the document to flow better.

2. Layout and length

   Dividing the plan into two separate parts was not well received, and complaints were made about too much paperwork and duplications. Complaints on duplications were mainly centred around the frequent need to enter patient details and between the generic care plan and information held elsewhere. At seven pages the document was found to be too lengthy.

3. Risk assessment and multi-disciplinary working;

   There was a desire for the care plan document to be adaptable to suit local and national developments within the service, most notably the introduction of Integrated Care Pathways (ICPs) and risk assessments.

The report unmasks the different ways pharmacists practice clinical pharmacy in Scotland. This project therefore aims to re-develop a standardised care plan document that can be used as a national tool for mental health pharmacists. [4]

1.3 Pharmaceutical care issues within mental health

There are a lot of potential care issues regarding mentally ill patients; this section will highlight some of the most important issues to be aware of.

1.3.1 Co-morbidity

Co-morbidity is when two or more psychiatric or physical illnesses are present in the same individual. Psychiatry and physical co-morbidity is common amongst people with a mental illness. [(2)]

Dickey *et. al.* conducted a study in 2002 where they examined whether certain medical disorders are more prevalent among adults with severe mental illness, and whether a co-morbid substance use disorder increases prevalence beyond the effect of severe mental illness alone[(36)]. The study showed that adults with mental illness have a higher risk of medical disorders than those without mental illness, and that those with a co-morbid substance use disorder had the highest risk for five of the disorders considered in the study.

There are several factors that increase the risk of medical disorders that are known to be directly associated with mental illness. These are amongst other[(36)]:

- use of medication with side effects such as weight gain, which are associated with diabetes and hypertension;
- high rates of smoking, which contributes to asthma, acute respiratory disease, heart disease and lung cancer;
- poor attention to personal hygiene, which is associated with skin infections;
- reduced physical activity and fitness, which contributes to hypertension and heart disease.
- Some medications used are also known to give adverse gastrointestinal effects.

Mental illness and substance use have a poor influence upon each other, and co-morbidity between these is unfortunately very common. It reflects both a high risk for drug use in subjects with mental illness and a high frequency of psychopathology triggered by drug use. People with concurrent disorders often fall through the cracks

in the health care system, as mental health services may refuse treatment to a person with an active drug or alcohol addiction, while addiction professionals may believe that a person cannot recover from problem substance use until the mental disorder is treated. [36]

1.3.2. Patient Monitoring

Individuals with a chronic mental illness are more likely to suffer from poor physical health, also since some of the medication used can contribute to physical health complications. To maintain the best care for the patient, monitoring of physical health and the drugs given are necessary.

1.3.2.1. Clinical Monitoring

Clinical monitoring is the term used for monitoring the physical health of the patient. Before starting a patient on antipsychotics, baseline tests are required and taken throughout the duration of treatment. [14] Tests undertaken are;

- urea and electrolytes, especially amisulpiride and sulpiride since they are excreted renally;
- full blood count, were clozapine need continuous checks because of the risk for agranulocytosis;
- blood lipids, weight and plasma glucose, which is associated with dyslipidaemia, cardiovascular diseases and diabetes type 2;
- ECG which among other is mandatory for haloperidol; blood pressure, because of the association with postural hypotension with clozapine, chlorpromazine and quetiapine;
- prolactin, as some drugs can cause hyperprolactinaemia;
- liver function tests, especially clozapine and chlorpromazine as they are associated with hepatic failure; and
- creatinine phosphokinase because of the risk for neuroleptic malignant syndrome.

Before prescribing lithium, cardiac (ECG), renal (serum creatinine and U&Es) and thyroid function (TFT) should be checked. U&Es and TFTs should be checked every 6 months. Since lithium has a narrow therapeutic window and is excreted renally, renal failure can cause serious toxic effects. (14)

1.3.2.2. Therapeutic Drug Monitoring (TDM)

TDM is the technical term for measuring the concentration of drug in the blood (plasma) to ensure that appropriate/therapeutic levels of drug are achieved/ maintained. A certain amount of a drug must always be present in the body to be effective. The range of drug concentrations that will safely achieve this result is known as the "therapeutic window." If the drug concentration falls below this range it will not have any effect, and if the drug level rises above the recommended therapeutic window, toxic side effects might result. Lithium is a drug with a narrow therapeutic window (0.6-1.0 mmol/l) and therefore need to be closely monitored. [14]

TDM is mostly used to check if therapeutic plasma levels have been achieved, but it can also be useful to detect non-compliance or predict or confirm toxicity.

1.3.2.3. Monitoring High Dose antipsychotic prescribing

According to the British council report "*Consensus statement on high-dose antipsychotic medication*" [37] from 2006, are up to a quarter of psychiatric in-patients prescribed a high dose of antipsychotic medication even though there is no firm evidence that high doses are any more effective than standard doses [14, 37].

The Consensus Working Group agreed to take the following as a definition of high dose: *"A total daily dose of a single antipsychotic which exceeds the upper limit stated in the summary of product characteristics or BNF and a total daily dose of two or more antipsychotics which exceeds the summary of product characteristics or BNF maximum using the percentage method."* [38] The percentage method is carried out by converting the dose of each drug into a percentage of the BNF maximum dose for that drug and adding these together (where a cumulative dose of more than 100% is a 'high dose').[37]

Antipsychotics in general have a wide margin of safety. However, there is a suspected association between high-dose prescription and sudden death. High

doses of antipsychotics can affect the cardiac muscle conduction, causing elongation of the QTc interval, which can predispose to cardiac arrythmia and is therefore associated with an increased risk of sudden death. High doses may also cause central nervous system depression, respiratory depression, hypoxemia and seizures. Dose-related side effects e.g. parkinsonism, dystonia and akathisia are more problematic at high doses, and there is an increased risk of tardive dyskinesia. The prescriber, along with the pharmacist and nurse, assumes responsibility for any harm to the patient. Monitoring of high dose prescribing consist of three monthly blood tests, measuring urea and electrolytes, and ECG to exclude abnormalities in cardiac function. Target symptoms should be assessed after six weeks and three months and if insufficient improvement in these symptoms has occurred, the dose should be decreased to the normal range.[14, 37]

1.3.3. Interactions

A drug interaction can be defined as an interaction between a drug and another substance that prevents the drug from performing as expected. This definition applies to interactions of drugs with other drugs (drug-drug interactions), as well as drugs with food (drug-food interactions) and other substances. An interaction is a kind of action that occurs as two or more objects have an effect upon one another. Drugs can interact with each other in two different ways; pharmacokinetic or pharmacodynamic.

1.3.3.1. Pharmacokinetic interactions

These are where one drug interferes with the absorption, distribution, metabolism or elimination of another drug. Drugs that inhibit or induce hepatic cytochrome P450 isoenzymes are the major reason for these kinds of interactions. The most important isoenzymes for mentally illnesses are shown in table 2 (note that its contents are not exhaustive).[11, 14, 21]

The potential for drug interactions is high for the majority of drugs used to treat mentally ill patients. Most antipsychotic drugs and SSRIs are metabolized by the CYP450 system, which can make co-prescribing difficult.

Nicotine can increase the clearance of many antipsychotics by as much as 10 - 50%, specially clozapine and olanzapine. The majority of mentally ill patients do smoke,

and although pharmacists should be advising the benefits of quitting, they should be aware of the potential rise in plasma levels. Interactions involving Hypericum are also potentially problematic as it is an inducer of CYP3A4. Hypericum, also known as St John's wort, is an herbal product which can be bought over the counter (OTC) from a variety of health food shops and some pharmacies. It is reputed to be effective in the treatment of mild depression. Many people regard herbal remedies as "natural" and therefore harmless. They are not aware of its potential to cause side effects or interactions with other drugs. This makes it important to address OTCs while taking drug history for a patient. [14]

Table 2: Substrates, Inhibitors and Inducers for selected cytochrome P450 isoenzymes [14]

Isoenzyme	Substrate	Inhibitors	Inducers
CYP1A2	Clozapine(major) Olanzapine	Cimetidine Ciprofloxacin Disulfiram Grapefruitjuice Omeprazole	Caffeine Cigarette smoke Cannabis Rifampicin
CYP2C9/10/19	Clozapine (minor)	Cimitidine Omeprazole	Carbamazepine
CYP2D6	Clozapine(minor) Olanzapine (partly) Risperidone Haloperidole Chlorpromazine	Cimetidine Fluoxetine/norfluoxetine Paroxetine TCA's Methadone	Carbamazepine (weak) Phenytoin (weak)
CYP3A4	Clozapine(major) Haloperidol Quetiapine	Cannabinoids Fluconazole Itraconazole Macrolides SSRI's Grapefruit juice	Barbiturates Carbamazepine Omeprazole Phenytoin Prednisolone St John's wort

1.3.3.2. Pharmacodynamic interactions

These are where the concurrent administration of drugs has the same or opposing pharmacologic actions and alteration of the sensitivity or the responsiveness of the tissues to one drug by another. Many of these interactions can be predicted from knowledge of the pharmacology of each drug. [11, 14, 21]

MAOI interactions with food containing tyramine (e.g. cheese, meat, certain wines), and with other drugs, are well established. It can lead to monoamine overload and hypertensive crisis. Patients on these drugs need to be advised on how to avoid tyramine-containing foods and the possibility of drug interactions. [14]

Valproate is highly protein-bound (up to 94%) so other drugs that are highly protein-bound may displace valproate from albumin and precipitate toxicity (e.g. aspirin). Other, less strongly protein-bound drugs, can be displaced by valproate, leading to increased therapeutic effect or toxicity (e.g. warfarin).[14]

1.3.4. Patient compliance

Compliance can be defined as the ability and willingness of a patient to adhere to a pharmacotherapeutic regimen agreed upon between patient and practitioner [21]. Noncompliance occurs when a patient is unable or unwilling to take the drug therapy as intended. Due to the nature of psychiatric illnesses and their subsequent effect on rationale thinking, noncompliance is often a problem amongst people with mental health problems; especially those detained under the Mental Health Act legalisation (see section 1.3.5.). However, patients should always be offered the opportunity of discussing their medication with a specialist involved in their care. It is a fundamental right to have access to information regarding treatment given. That allows the patient to make an informed decision based on careful evaluation of the benefits and risks involved.[11, 21]

Noncompliance amongst mentally ill patients can be attributed to [11, 12, 21] :

- *The illness*; if their thinking is too disorganised, they may not remember to take their medicine or to order repeat prescriptions etc. It is also common that they stop taking their medication because they have a lack of motivation, their concentration is poor or because there has been a long time since a relapse and they feel they have managed the illness.

- *Patient specific factors*; they may have a lack of insight where they do not realise that any experience or feeling they may have are actually symptoms of an illness and that treatment is required to relieve the symptoms/illness. They may not have enough knowledge, may be afraid to be addicted, get tired of all the monitoring tests or they just don't trust the doctors or the explained

benefits of the treatment. Another issue may be frightens of stigmatising in relations to family and friends.

- *Medication specific factors*; some side effects can be so unpleasant that they just quit without discussing it with the doctor. The medication can have a low efficacy, delayed onset of action on symptoms, or they may not like the formulation, like e.g. the taste of the drugs.

- *Doctor specific factors*; Drugs may be prescribed without regards to patients wishes. Explanation on the importance of continually treatment and the danger with sudden discontinuation has been left out.

When a practitioner discovers that a patient is noncompliant, he/she must be certain that the patient's medication regimen is therapeutically indicated, effective and safe.

There are many strategies to help people with mental illnesses improve their compliance. One can try to improve tolerability/minimise side effects by checking if minimum effective dose is used, if an alternative agent is available or if the side effects can be treated. One can also try to simplify the dosing regimen; some medications are available in long-acting, injectable forms, which eliminate the need to take a pill every day. Medication calendars or pillboxes labeled with the days of the week can both help patients remember to take their medications and let caregivers know whether medication has been taken. Electronic timers on clocks or watches can be programmed to beep when people need to take their pills, and pairing medication with routine daily events, like meals, can help patients adhere to dosing schedules. Stigma can be minimised by raising awareness of mental health problems with the public and improving patient and carer information. [12, 13, 21]

1.3.5. Consent to treatment plans

Mental health legislation (Mental Health (Care and Treatment) (Scotland) Act 2003) applies to people with a 'mental disorder', a term used to cover mental health problems, personality disorders and learning disabilities. It covers issues to when a patient can be taken into hospital against his/her will, given treatment against his/her will, what the patients' rights are, and safeguards to make sure his/hers rights are protected.

To make sure that prescribing is appropriate for those patients detained under the Mental Health Act, it needs to be documented in consent to treatment plans. [39, 40]

When a patient is detained under the Act there are certain circumstances and situations when treatment can be given without their consent, table 3 set out the safeguards and requirements for specific treatments. [38]

Table 3: Requirement of the 2003 Act for consent to treatment(38)

The Act allows the practitioner appointed as the responsible medical officer (RMO) to treat a patient with a mental disorder without consent for two months when the patient is detained. If the patient still will not consent after that, the Mental Welfare

Treatment	Capable and consents	Capable and refuses	Incapable, but does not resist or object	Incapable and resist or object
Neurosurgery and deep brain stimulation	Needs DMP opinion and lay opinions from MWC	Cannot be given	Needs DMP opinion and lay opinions from MWC. Must then be authorised by Court of Session	Cannot be given
Electroconvulsive therapy, vagal nerve stimulation and transcranial electromagnetic stimulation	Written consent and certification on form T2	Cannot be given	Needs DMP opinion on form T3 and can be given if in the person's best interests	Needs DMP opinion on form T3 and can be given to save life, prevent serious deterioration or alleviate serious suffering
Drug treatment for more than 2 months and medication to reduce sex drive and artificial nutrition	Written consent and certification on form T2	DMP opinion on form T3 with statement as to why treatment should be given	Needs DMP opinion on form T3 and can be given if in the person's best interests	Needs DMP opinion on form T3 and can be given if in the person's best interests
Other treatments (Section 242) e.g. medication within first 2 months, psychological therapies	Written consent	Best interests test – RMO records reasons for treatment in writing, with reasons for giving treatment in spite of refusal	Best interests test – RMO records reasons for treatment in writing	Best interests test – RMO records reasons for treatment in writing

Commission will appoint an independent specialist, called a designated medical practitioner (DMP), to assess the patient and confirm that the treatment is necessary. If the patient still does not agree, all prescribed medication must be detailed on a T3 form. If the patient agrees to take the medication, the medication needs to be detailed on a T2 form. The pharmacist has additional responsibility to make sure a patient detained under the Act is treated according to the law. [38-40]

2. Aim and objectives

2.1 Aim

Design and validate a documentation system that can be used for mental health pharmaceutical care planning in a Scottish in-patient population.

2.2 Objectives

1. Generate a list of candidate care issues/guideline standards relevant to mental health pharmaceutical care based upon a review of the relevant literature and authorised specialist reports.

2. Identify (a) data fields and (b) common care issues to be included in a care plan from recommendations made by a report to the MHPSG.

3. Re-design (a) the care plan document and (b) a set of guidelines of how to use the care planning documentation in light of recommendations from the report to MHPSG.

4. Field-test the draft documentation by conducting a survey in one or more samples of patients.

5. Validate a draft care plan and the guidelines by receiving feedback from SPMH members and practising Mental Health clinical pharmacists.

3. Subject and settings

3.1 Subject

A research group comprising the researcher, Mona Skarsaune, and the project supervisors, Ms Gazala Akram and Professor Stephen Hudson was formed. Miss Marianne Van de'Lisle, principal pharmacist at the REH, was also consulted but was not a member of the research group.

3.2. Settings

3.2.1. Field testing

The document was field tested within NHS Lothian at the Royal Edinburgh Hospital (REH) and the State Hospital in Lanarkshire from January 9th to January 25th 2008.

The REH provides acute psychiatric and mental health services, including treatment for learning disabilities and dementia. Its specialist services include centres for the treatment of eating disorders, alcohol problems and young people's mental health.

The State Hospital is one of four high secure hospitals in the UK, where assessment, treatment and care are provided in conditions of special security for individuals with mental disorder who, because of their dangerous, violent or criminal propensities, cannot be cared for in any other setting.

3.2.2. Focus group interview

A focus group interview was held at a Scottish Mental Health Pharmacy (SPMH) clinical meeting on the 21st February 2008, at the Park Hotel in Falkirk, Central Scotland. The group consisted of six pharmacists who all worked in different hospitals and in various specialities including General Adult, Rehab and the Elderly. Five health Board Areas were represented: NHS Greater Glasgow & Clyde; Highland; Tayside; Lanarkshire and Forth Valley.

SPMH is an interest group, providing a rich meetings program and contact group for pharmacists working within the psychiatric field in Scotland. The mission statement for SPMH is: 'to encourage, develop and promote the delivery of quality pharmaceutical care within mental health.'

4. Methods

4.1 Literature search

An extensive literature search using PubMed, Medline and Embase was conducted to locate literature detailing the current status on documenting pharmaceutical care within mental health. The search terms used were; *care planning*, *mental health*, *mental health* AND *pharmacists*, *mental health* AND *pharmaceutical care*, *mental health* AND *pharmacists and documentation*.

4.2 Generating candidate care issues and data fields

A list of candidate care issues and data fields were conducted by;

- Searching in existing online guidelines such as the Scottish Intercollegiate Guidelines Network (SIGN) and the National Institute of Clinical Excellence (NICE).
- Consulting The Maudsley Prescribing Guidelines, 9th Edition which is an recognised well respected resource for mental health clinicians with respect to prescribing
- The recommendations from the previous project by the Mental Health Pharmacy Sub Group (MHPSG)
- Getting familiar with the clinical practice of pharmacy within mental health. This was achieved by visiting different wards, with different clinical pharmacist at the Royal Edinburgh Hospital (REH), and at The State Hospital.
- Looking through projects previously undertaken by other specialities

All data fields from the REH current care plan, previous projects and the MHPSG generic care plan was taken under consideration. In addition NICE guidelines and The Maudsley prescribing guidelines were consulted.

The research group, consisting of the researcher and the supervisors Ms Gazala Akram and Professor Steve Hudson, had a meeting in the beginning of December where additional care issues and data fields were generated and unnecessary or inappropriate ones were removed.

4.3 Re-design of the prototype care plan

The researcher re-designed a draft care plan by incorporating the data fields and care issues generated by the researcher. The format chosen was drawn on previous care plans designed for use at the REH and in other patient groups [41]. Guidance on how to use the care plan was also designed together with an example care plan.

A very early draft was discussed at a research meeting in the beginning of December where suggestions for improvement were sought after. Another draft was developed and peer reviewed in the second week in December. This was achieved by sending the revised care plan, with guidance on how to complete it and an example care plan document by e-mail to all the supervisors, including Mrs Marianne Van-De-L'isle. Suggestions for improvements to the document were requested before the Christmas holiday. Minor adjustments were made, in late December and in the beginning of January, to form a prototype care plan.

4.4 Field-testing

The care plan was field tested for two and a half week by clinical pharmacists at the REH and the State Hospital from January 9th to January 25th 2008

Before the field testing, an e-mail with the prototype care plan, guidance and example care plan was sent out to all clinical pharmacists at the Royal Edinburgh Hospital, including the Principal pharmacist at the State Hospital. On the morning of January 9th the care plan was discussed amongst the pharmacists and the researcher at a clinical staff meeting to make sure all the participants understood what was required and how to complete the care plan document. The aim of this field testing was to see if the care plan could be used in daily clinical work and to gauge its utility as a standardised document. The inclusion criterion for the study was all new admissions to the wards during the two and a half week study period.

The pharmacists were asked to contact the researcher if they had a new admission so that she may observe and try to complete the care plan herself. Comments on the documents were to be sent to the researcher by e-mail.

After the field testing the researcher had another meeting with the pharmacists to feedback their comments and discuss any planned changes.

4.5 Validation of the care plan document

A focus group consisting of mental health clinical pharmacists from different parts of the country was considered the optimal means by which to validate the care plan document.

4.5.1 Focus group methodology

Focus groups are a method of generating qualitative research data, and consist of a group of people discussing a common theme or topic. It normally consists of four to 12 people and lasts for about one or two hours. It is often defined as a group interview, but aims to be more like a discussion rather than an interview. Questions should be unstructured, unbiased, non-threatening, and simple.

The idea is that the participants get engaged in a discussion amongst each other instead of directing their comments solely to the moderator. The moderator is the person who's running the focus group by leading the discussion or indulging in some 'structured eavesdropping'. [42]

The moderator should encourage participation from all, keep the discussion on track, and basically act as a facilitator. There can be considerable advantages by having a second person involved in the running of the group, especially if there is a lack of experience with running it. The second person can help by taking notes and observe body langue, themes, enthusiasm, mood of discussion etc., and can give feedback on the moderator's performance. [42, 43]

4.5.1.1. Advantages and disadvantages with using Focus Group methodology

There are many advantages to using focus groups. These include;

- Time effectiveness; as it allow the researcher to get the opinion of a number of people at the same time,
- Relatively inexpensive; by neither needing a lot of time or equipment,
- Greater flexibility, as it offers a wider opportunity to probe into issues

Other advantages are that focus groups can work well for people who may have limited education, modest verbal skills or other specific difficulties. A discussion also gives the participants the chance to make comments in their own words, while being

stimulated by thoughts and comments from the other persons in the group. By being empowered of their role in the group, people often express views they might never expressed in other settings. At the same time people often tend to check and correct each other, and that gives sort of a natural quality control on the data collection by

Disadvantages with focus groups are that it can be difficult to get people to participate; you don't want to pay them to come, because that can lead to bias as the paid respondents may try to say what the researcher wants to hear, and you also need to find a time that is convenient for all the participants. Some may find the focus group situation intimidating or off-putting, and if the moderator don't do a good job it can lead to having one or two people dominating the group, and the other participants may feel under pressure to agree with the dominate view. If a disagreement and an irrelevant discussion arise, it can distract the discussion from the main focus. Another disadvantage is the limited number of questions covered. It is not recommended to have more than ten questions within an hour, preferably less. The data collection may also often be difficult to analyse, and you cannot generalise the results as the participants are not randomly sampled. [42, 44]

Most researchers recommend aiming for homogeneity within each group in order to capitalise on people's shared experiences. However, it can also be advantageous to bring together a diverse group, for example, from a range of professions, to maximise exploration of different perspectives within a group setting, but it is then important to be aware of how hierarchy within the group may affect the data; a nursing auxiliary, for example, is likely to be inhibited by the presence of a consultant from the same hospital. [42, 44, 45]

4.5.2. Validation of care plan document by peer consensus using a focus group approach

Participants for the focus group were to be recruited from members of Scottish Pharmacy in Mental Health (SPMH). On November 27th the researcher attend a SPMH clinical meeting to inform members about the project, and to encourage their participation for the Focus Group discussion. The Focus Group discussion was scheduled for the lunch recess at the next clinical meeting on the 21st February 2008. The meeting was held at the Park Hotel, Falkirk, Central Scotland.

A week before the meeting on February 14th, an e-mail with the care plan and guidance text was sent out to all the members of the SPMH, asking for their comments via email to the research team, email to the SPMH chairman, or by volunteering to take part in the group discussion. Inclusion criteria for participating were that the pharmacist should be regularly using care plan documentation.

The objective for hosting this group was to find views on how the clinical pharmacists, as a group, felt about the care plan document. A topic guide (appendix 3) was developed to make sure all the themes were covered. The main purpose was to find out if this document could be implemented in their day to day practice, and if not, what changes could be made to make it easier to use.

To help with data analysis the discussion was audio recorded with participants' permission and the tape was subsequently transcribed for analysis.

5. Results

5.1 Literature search

The literature search did not identify any published material within the field of pharmaceutical care planning in mental health thereby confirming the need for such a venture.

5.2 Candidate care issues and data fields

5.2.1. Candidate care issues

A number of care issues within mental health were identified, Table 4 lists what the research group identified as most important to the practice of mental health pharmacy.

Table 4: Pharmaceutical care issues

No	Pharmaceutical care issues
Drug History	
1	Confirm medical and psychiatric history
2	Confirm history of non-compliance
3	Confirm history adverse drug reaction or non responsive therapy
4	Confirm any problems with drug interactions
Polypharmacy	
5	Simplify dosing regime
6	Check if patient gets unnecessary treatment
7	Check therapeutic benefit
8	Check treatment of avoidable adverse drug reactions
9	Switching drugs – check the need for wash out period / titrations
Guidelines	
10	Conformity to guidelines
Monitoring	
11	Check frequency and results
12	Check if drugs with a small therapeutic window

Interactions

13 Particularly with CYP 450 for antipsychotics

Adverse drug reactions

14 Check if minimum effective dose is used

15 Check if there are alternative agents

16 Address different ADR's for individual patients

17 Check treatment – use of anticolinergic drug should be reviewed every 3 – 6 months

High dose antipsychotics

18 Check if necessary

19 Monitor urea, electrolytes and ECG – QTc at baseline and thereafter three monthly.

***Mental Health Act (MHA)* T2 / T3**

20 Check if appropriate according to law

21 Check if all treatment is given in accordance with MHA legislation

Compliance

22 Confirm ability to self-medicate

Patient understanding

23 Patient awareness of indication for antipsychotic drug therapy

24 Patient awareness of what action to take if missed dose

25 Patient awareness of adverse drug reactions

26 Patient awareness of interactions with other drugs (incl. OTC), food, alcohol etc.

27 Patient awareness importance of compliance

28 Patient knowledge of signs of intoxication of some drugs (e.g. Lithium)

5.2.2. Patient data fields

The patient data fields generated by the researcher are listed in table 5 below. Data fields the researcher did not want to include, but that more than one of the sources found important, is written in italics. A small explanation on why it was not included can be found under comments.

Table 5: Patient data fields

No	Data fields	Comments
	Patient Details	
1	Name	
2	*Preferred forename*	Slightly used anymore
3	Local ID / *CHI number*	ID number is much more used
4	Address	
5	Age / Date of birth (DOB)	
6	Gender (male / female)	
7	Height (m)	
8	Weight (kg)	
9	BMI	
10	Social history	With alternatives to tick
11	Family history	
12	Drug use	Including all illicit substances
13	Alcohol consumption	
14	Smoking status	With alternatives to tick
15	Carer	With number and address
16	Named person	With number and address
17	General Practitioner (GP)	With number and address
18	Community Psychiatric nurse	
19	Community Pharmacy	With number and address
	Admission details	
20	Date of admission	
21	Source of admission	
22	Pharmacy log date	
23	Consultant	
24	Clinical Pharmacist	
25	Legal status code	
26	Key worker	
27	Hospital	
28	Location / Ward	
29	*Working diagnosis*	Merge together to become only
30	*Confirmed diagnosis*	‘diagnosis’

31	Presenting compliant	
32	Self medication	
33	Compliant	
	History	
34	Relevant medical history	
35	Relevant drug history	
36	Relevant psychiatric history	
37	Adverse event history	ADR's, drug sensitivities, interactions
	Current	
38	Current medication incl. OTC	
39	As required medication (PRN)	
40	Depot injections	
41	Stat doses (one offs)	Requested to give as separate section
42	Medicines if T2 or T3	
	Monitoring / investigations	
43	High dose antipsychotic prescribing	
44	Therapeutic drug monitoring	
45	Weight	
46	Blood pressure	
47	Pulse	
48	Renal function	U&E's
49	Liver function tests	ALT, GGT, Bilirubin
50	Blood count	FBC, WBC, MCV, *PLT, Neutro*
52	Plasma glucose	
53	Hb	
54	Blood lipids	Cholesterol, triglycerides
55	Creatinine phosphokinase (CPK)	
56	Thyroid function	THS, Free T4
57	Prolactin	
58	ECG – OTc	
59	EEG	

References:(4, 14, 41) , Lothian's current care plan. (Parameter-abbreviations is shown in appendix 4)

5.3 Re-design of the prototype care plan

The researcher re-designed a prototype care plan by incorporating the candidate care issues and patient data fields listed in 5.2.1. and 5.2.2. The format for the care plan was similar to the one already in use at the Royal Edinburgh Hospital, and the care plan recently developed for diabetes patients [41]. The first draft care plan is given in appendix 5, were the main themes of the care plan can be divided into six;

- *General demographic data*: Which includes patient details such as name, address, date of birth, BMI, gender etc.; general comments which can be social and family history; addresses of important people involved with the patient, e.g. carer/named person and GP, as well as drug sensitivities, smoking status and substance misuse.

- *Admission details*: This included why, when and where the patient were admitted, as well as diagnose, legal status and hospital staff involved. It also had a suggestion to record if the patient were on any drugs that needed close monitoring.

- *Patient history*: A section meant to record any relevant medical, psychiatric and drug history including adverse advent history

- *Monitoring*: a sheet to record laboratory tests, divided into care episodes where the pharmacist could record the date reviewed, as well as the date the test was taken. Therapeutic drug monitoring and monitoring of high dose antipsychotic prescriptions were placed right above the care issue recording as it also was thought to be recorded more specific there.

- *Current medication*: divided into regular-, depot- and as required medication. Made administration times for pharmacist to tick and an ‘other’ if none of the times fitted.

- *Care issues*: a care issue check list was not included in the first draft. The issues were discussed during a research meeting later. However, it was decided that all the care issues concerning treatment changes were to be recorded separately from the rest of the care issues e.g. educational needs and therapeutic plan checks.

A meeting with the research group was held on December 3rd to discuss and validate the care plan. The pharmaceutical care issues associated with mental health problems were categorised into ten main issues; drug history, polypharmacy, guidelines, drug therapy problem (DTP) risk, interactions, adverse drug reactions, high dose antipsychotic, Mental Health Act (MHA) T2/T3, compliance and patient understanding. These main issues were to be standard care issue checks, as a prompt to the pharmacists, to make sure they have thought through all main the issues that can arise with a mentally unwell inpatient. Appendix 6 shows the issues raised by the research group and suggestions followed. The draft care plan was then suitably modified to form a prototype care plan (shown in appendix 7).

To meet all the recommendations from the original MHPSH report, several changes were made to the original generic pharmaceutical care plan. Table 6 summarises the changes made to the original care plan to form the new prototype care plan.

Table 6: Changes made to the original generic pharmaceutical care plan

No	CHANGES MADE ACCORDING TO THE MHPSG-REPORT
Deletions made to the care plan	
1	duplications
2	changes to patient details
3	own discharge box
4	care issue check levels
5	summary of progress made during admission
6	investigations
Additional space to record all relevant information;	
7	contact details
8	family and social history
9	weight/height and BMI
10	drug sensitivities to top of first page
11	smoking status
12	substance misuse

13 history of non-compliance together with ‘relevant medical history’

14 relevant drug history (incl. adverse or non responsive therapy)

15 pharmacists monitoring reviews – (date and sign)

16 clinical monitoring

17 monitoring of high dose antipsychotic prescribing

18 if patient is self medicating or not,

19 if the patient is under T2 or T3

20 depot injections separately

21 as required medication

22 standard care issue checks

To increase logicality

23 changed the layout

24 made it possible to use patient label

25 made lager space for some of the data fields

26 changed the current medication sheet completely (because it was said to be messy & difficult to reed, time consuming & cumbersome)

27 changed the care issue section completely (because no one understood it);

28 → made standard care issue checks and moved them to the top of the individualised care issues.

29 → based upon the method previously used and validated in care plan documentation for patients with type 2 diabetes mellitus (41).

Increase efficiency

30 compressed the two documents to be only one document

31 deleted several sections

32 changed patient details on the top of each page, to just CHI number on every second page (as it will be printed in double pages)

Duplications

33 combined the Longitudinal information sheet with the Cross-sectional sheet

34 deleted patient details on top of every page

5.4. Field testing

Field testing of this new version of the care plan was conducted over 16 days at the Royal Edinburgh Hospital and the State Hospital. Twelve care plan documents were completed by six pharmacists.

At the pre-meeting before the field testing, the discussion with the clinical pharmacists at the Royal Edinburgh Hospital was mainly centered on how to use the care issue section. After the test-period, feedback from the participants was received by e-mail, and a second meeting was held to summarise the resistance towards the care plan and the suggestions for improvements. The feedback in general, together with changes made according to suggestions, is shown in table 7 below.

Table 7: Feedback in general after the field-testing

General feedback with changes to the care plan
Not enough space to write in; *"have to be a very neat writer to get things into spaces provided"* • Made more space for addresses and care issues • Merged social- and family history to be one comment box • Added version nr on top of front page
Results/clinical monitoring should be moved; *"better after the prescription sheet, and possibly after care issue section for reference"* • No changes made (see discussion for argument)
Clinical monitoring are missing some parameters; *"If we are ticking and dating to say we've checked them, then surely we should just record any abnormalities that we are following up on?"* • Changed to clinical monitoring abnormalities • Removed all biochemical references, and left ten lines open to fill in relevant information.
Don't like the individual care issues, or the abbreviations; *"Dislike some of the abbreviations, particularly DTP risk, and I can't quite get the hang of splitting the care issues"* • Changed the guidelines • Changed drug therapy problems (DTP) risk to co-morbidity.

5.6 Validation of care plan document by peer consensus using a focus group approach.

The focus group consisted of six pharmacists who all worked in different hospitals and in various specialities including General Adult, Rehab and the Elderly. Five health Board Areas were represented: NHS Greater Glasgow & Clyde; Highland; Tayside; Lanarkshire and Forth Valley.

Since time was limited, as the focus group was scheduled during lunch and had to be completed in 45 min, it was decided that the discussion should follow a semi structured format that would be primarily led by the facilitator.

Several issues were raised in relation to the layout and content of the care plan document and appear to be largely related to issues of:

a) Layout of the document

b) Recording of Monitoring Parameters

c) Medication/prescription writing

d) Recording of the Care Issues

5.6.1 Comments on the care plan from the focus group

Some of the pharmacists were more familiar with smaller care planning documentation, and found this document too time consuming. The relevance of recording patient history was not seen, as that information can be found in the medical records. The impression was that if any specific issues about the patient history appeared then they would record these under the care issues section.

" I'm used to a lot simpler versions, they tend to be more one sheet..."

"I would say that if I had to fill in one of these for all of my patients, it would be difficult to fit in all my other ward commitments."

a) Layout of the document

The majority thought the document was too lengthy but did eventually agree that most of the information detailed on the front page was necessary. Some gaps in patient admission details were identified, in particular for patients with repeated admissions.

> *"The admission has no room for changes if the patient is readmitted, maybe you could make a box for previous admissions?"*

A request for space to record the care manager were made, and it was suggested to make room for recording "other people" relevant for the patients care. A suggestion to add compliance aid so the pharmacists can know if the patient needs blisters etc. on discharge was made as well.

The history areas were proposed being without lines to have the ability to write in more than one line for one relevant episode, and more space to write in, in general, was desirable.

> *"…see the lines in it, do they need to be in it? – if you didn't have lines, you would fit more in."*

b) Recording of Monitoring Parameters

This section faced a lot of resistance. Participants wanted the therapeutic drug monitoring section to be similar to the clinical monitoring section. This would allow trends to be seen at a glance and omit the need for a new line for every new test on the same drug.

The area for recording monitoring of high dose prescribing was equally not well received. A general feeling was that this issue should be referred to in the care issues section and not be separated from it. For example, one participant said they would prefer a box to tick if reviewing was necessary. If there are any problems or issues with the prescribing they would record it as a care issue, and therefore found this process duplication.

"I would document that (high dose prescription) in my care issues and medical notes – I don't see why I would have to replicate it in a section here..."

There was also some debate as to who should be recording which parameters, and practice in this area is variable. Some participants voiced that the monitoring was the nurse's responsibility, and that the pharmacist job is to just to review if the patient still needs to be on a high dose antipsychotic, whereas others thought the pharmacists role should be more proactive.

"One thing I would say about high dose is; these monitoring are nurse responsibility – it isn't in our job prescription to make sure they do the TPR's and ECG's."

"...my only care issue is; is it still needed? .....would like a box that says reviewed, so that I could see if I've asked them"

c) Medication /Prescription Section

The separation of psychotropic medication from the non-psychotropic medication was well received. The overall view was that depots should be included in the psychotropic medication section. A few of the pharmacists wanted the recording of medication start and stop date to be closer or next to each other, with the argument that it would make it easier to see if the drug had been discontinued. They also wanted some indication of the level of self medication, and suggested that level-boxes be inserted at the top of the current medication sheet to reflect this.

"Psychotropic is psychotropic – don't need to separate out the depots."

"...in the kardex we use; it's not separated out anymore."

d) Recording of the Care Issues

The group was generally positive with the concept of standard checks, but wanted more blank spaces in case a care issue did not fit into any of those identified. They also suggested that there should be a prompt in the individualised care issues section where one could insert the corresponding standard check number, such as the date-column.

The format where the individualised care issues are separated into two columns raised a lot of negative comments. Participants generally found this section labour intensive and difficult to understand. There was little effort to try and see if it could work after appropriate training, and too much emphasis on that this was different from what they were used to.

"…maybe have a few blank checks' if the care issues you have don't match the standard ones?"

"...this is a bit more complicated than I am used to."

"It is not the way I work!"

"I'm not sure how I would have split into two columns.....I wouldn't separate it."

"I think I would get really frustrated with myself because I'm going to write it in the wrong column and then go; Oh no! – and I'm going to rewrite it, and then that's going to annoy me!"

To summarise the comments from the focus group, table 8 shows a synopsis of the general statements.

Table 8: Synopsis of the general statements from the focus group

To minimise effort;	Need some adjustments in the layout to make notes fit better. Take out the lines in all history boxes.
To be more logical;	Merge some of the boxes, e.g. depot section with psychotropic medication Change the therapeutic drug monitoring to see trends.
To include all the information necessary;	Need space for readmission. Need level of self medication.
Visionary statements;	To time consuming with the new way of recording individualised care issues. Duplicates with information held elsewhere (e.g. ICP).

5.6.2. Guidance text

Participants had little to say about the guidance document and seemed happy with its content and layout.

5.7 Changes to the care plan after focus group

All the comments and suggestions from the focus group meeting, together with the comments from the field testing, were closely considered when adjustments were done to complete the final version of the care plan document. Not all suggestions were followed but the rationale for this is mentioned in the discussion. Changes made to the document as a result of the focus group comments are listed in table 9.

Table 9: Changes to the prototype care plan, according to the focus group comments

Space
• The admission line was made bigger to make room for readmission • The table division line in the history boxes were deleted
Monitoring
• The therapeutic drug monitoring box was made a part of the clinical monitoring table, to that it would be easier to identify trends or patterns in results
Medical recording
• tick-boxes for level of self medication included on top of the current medication sheet • Merged depot section with psychotropic medication • Changed the guideline text by adding that one could draw a red line over the drug that has been discontinued to see more easily which drugs has been stopped
Care issues
Changed the “date”-column to “date and no” for recording standard checks, guidance changed to explain how to use that column.

The finalised version of the care plan is shown below, and the guidance text and example care plan can respectively be seen in appendix 8 and 9

PHARMACEUTICAL CARE PLAN - MENTAL HEALTH

Date / Clinical pharmacist; **Care plan No:**

(Patient label) **Name** **Preferred forename**	**CHI #** **Age /** **Date of birth**	**Gender** Male ☐ Female ☐	**General Comments (e.g. social & family history)**

Address **Postcode**	**Weight / kg**	**Height / m**	**Drug sensitivities**
	BMI		

General Practitioner **Address** **Tel**	**Community Pharmacy** **Address** **Tel**	**Carer / named person** **Address** **Tel**	**Smoking Status** Smoker Non-smoker Number/day	☐ ☐	**Substance misuse** Yes ☐ No ☐ **Specify**:

ADMISSION DETAILS

Admission; **Date and Source**			**Presenting Complaint**
Consultant	**Hospital**	**Date/ Legal Status**	
Key worker	**Ward**		
Discharge Date	**Advanced Statement Y** ☐ **N** ☐		**Diagnosis**

RELEVANT MEDICAL HISTORY (INCLUDING HISTORY OF NON-COMPLIANCE)

Date	**Description**	**Date**	**Description**

RELEVANT DRUG HISTORY (INCLUDING ADVERSE OR NON RESPONSIVE THERAPY)

Date	**Medication**	**Comments**	**Date**	**Medication**	**Comments**

OVER THE COUNTER MEDICATION / COMPLEMENTARY THERAPY

Name

RELEVANT PSYCHIATRIC HISTORY

Date	**Description**

PHARMACIST'S MONITORING REVIEWS												
Date												
Sign												

CLINICAL MONITORING ABNORMALITY											
Date											
Weight (kg)											
Blood pressure											
Creatinine (60–120) µmol/l											
Na (135-145)mmol/l											
K (3.6-5) mmol/l											
Ca (2.1-2.6)mmol/l											
Urea (2.5-6.6) mmol/l											
Blood glucose (3.5-5.8) mmol											
ALT (10-50) µ/l											
GGT (5-55) µ/l											
Bilirubin (3-16) mmol/l											
WCC (4-11) x 10^9/ l											
Neutrophils (2-7.5) x10^9/ l											
Platelets (150-350) x 10^9/ l											
Hb (11-18) g/dl											
Chol esterol (3.9-7.8) mmol/l											
HDL											
CPK (25-170) F IU/l (25-195) M IU/l											
TSH (age related)											
ECG											

THERAPEUTIC DRUG MONITORING											
Medication	Range	**Time & date of sample**	**Conc**	**Time & date of sample**	**Conc.**	**Time & date of sample**	**Conc.**	**Time & date of sample**	**Conc**	**Time & date of sample**	**Conc**

RECORD OF MONITORING FOR HIGH DOSE ANTIPSYCHOTIC PRESCRIBING								
Start Date	**Medication**	**Dose**	**BNF %**	**Confirmation of Monitoring Initial and date**				**Stop date**
				Baseline	**3 Months**	**6 Months**	**9 Months**	

Patients CHI-number:

CURRENT MEDICATION						Date: SELF MEDICATING Y ☐ N ☐ Level 1☐ 2☐ 3☐	
Start date	**Psychotropic Medication incl. depot's**	**Dose**	**Route**	**Administration times/frequency**	**Stop date**	**T2/T3 (if applicable)**	**Comments**

Start date	**Non- Psychotropic Medication**	**Dose**	**Route**	**Administration times/ frequency**	**Stop date**	**Comments**

AS REQUIRED MEDICATION

Start date	**Medication**	**Dose**	**Route**	**Indication**	**Frequency**	**Max dose in 24 hours**	**Stop date**	**Comments**

STANDARD CHECKS IDENTIFYING PROBLEMS WITH;				
1.Drug history ☐	**3**.Guidelines ☐	**5**.Interactions☐	**7**.HD antipsychotics ☐	**9**. Compliance ☐
2.Polypharmacy☐	**4**.Co-morbidity ☐	**6**.ADR's ☐	**8**.MHA T2/T3 ☐	**10**.Patient understanding ☐

INDIVIDUALISED CARE ISSUES			
Date & No	**Care Issue No.**	**Therapeutic Plan Checks + Documentation Changes + Patient Education**	**Therapeutic Plan Changes** (Individualisations/ Dosage Change/ Treatment Interruption/ Management of Co-morbidity)
	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		
	Specify		
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	Specify		
	Action		
	Output		

REGULAR CURRENT MEDICATION

Date

SELF MEDICATING Y ☐ N ☐

Level 1☐ 2☐ 3☐

Start date	Psychotropic Medication incl. depot's	Dose	Route	Administration times/frequency	Stop date	T2/T3 (if applicable)	Comments

Start date	Non- Psychotropic Medication	Dose	Route	Administration times/ frequency	Stop date	Comments

AS REQUIRED MEDICATION

Start date	Medication	Dose	Route	Indication	Frequency	Max dose in 24 hours	Stop date	Comments

6. Discussion

This has been a successful project in meeting the aims outlined in the protocol. The researcher has managed to produce a documentation system which with further validation and minor adjustments may be used to create an agreed future national standard within Scottish mental health in-patients. The combination of validation methods provided opinions from both practice and theory, and the desirable mixture of pharmacist participating in the focus group discussion was achieved.

The project also managed to meet many of the original MHPSG recommendations, such as improvements to the original generic pharmaceutical care plan through changes to individual sections, as well as changing the layout and making it more compact.

6.1 The need for the project

The literature search showed that it is a low amount of research done on pharmaceutical care in general, and that it is an obvious research area in the future for pharmacists worldwide. Documentation is necessary for quality assurance of what pharmacists do, including peer review where pharmacists can compare ideas of good practise. There was a definite lack of systems for documenting delivery processes and outcomes, but work on national systems of care plans has begun in priority areas (32, 41, 46). The cancer care plan project by Macintyre *et. al.* in 2003(46) shows that standardisation helped strategic decision making across Scotland. A national system within the different specialities will provide standardisation of patient care, as well as giving an opportunity to measure outcomes through statistics.

Improving mental health services in Scotland is a top priority for the Scottish Executive(28), and in their delivering plan for Mental Health(33), published in 2006, they expected to see arrangements for standardised joint assessments. They envisaged that this wide-ranging plan would change the way mental health services are delivered in the future, and one of the targets in this plan was to reduce the number of hospital re-admissions by 10 percent. As studies has shown that pharmacists help reduce rates of readmission and length of hospital stay(24),

pharmacists obviously need to be included in this plan. The Scottish Executive also highlighted the differences between the mental health services in large cities and those in remote and rural areas; they want to see that good standards of care and treatment are available regardless of the location(33). Developing a nationally agreed care planning system will definitely contribute to that.

6.2 Bringing a research approach into the team delivering the service

It is thought that the researcher, as a pharmacy student, would be more objective developing a national care plan than an experienced pharmacist with acquired ways of working. The researcher was not biased by an own care plan, and had to read all guidelines and necessary literature to make sure everything was included. Had an experienced pharmacist been assigned this project instead, he/she might have favoured an own care plan, and maybe trusted him- /herself more in knowing the literature and guidelines by heart. The project obviously needed experienced pharmacists opinions, but having an ‘outsider’ doing the ground work and final decisions might have been beneficial.

6.3 Familiarity with mental health clinical pharmacy practice

To get more familiar with mental health clinical pharmacy practice in Scotland, the researcher attended an introduction course in clinical pharmacy at the Strathclyde University. This course and the literature search, together with a visit to the State Hospital and different wards at the REH, made the researcher understand the need for this project. The researcher got a comprehension of the importance of documenting pharmaceutical work, and it became apparent that pharmacists have different approaches in meeting the patients need.

The time the researcher spent with mental health pharmacists, at the State Hospital and the REH, also gave an opportunity to discuss what they did and did not like about the previous care plan in person, as well as how they found their current care plans to work in practice.

The biggest resistance towards the original MHPSG care plan seemed to be the ’current medication’ and the ‘care issue levels’. The researcher found the ‘care issue

levels' understandable, and thought it made a good prompt, but saw the need of changing it based on the large and unanimous resistance towards it.

The Lothian care plan document had already received favourable comments in the previous report(4), and it appeared that the pharmacists at the REH and the State Hospital were quite happy with the document they were currently using as well. Favouritism of own care plans seems to be a trend throughout all of Scotland. Most of the pharmacists are happy with the way they work today, and are not too pleased about having to change it. This is a normal behaviour for all human beings: if they think they are doing a good job, why change it? Easy to understand, but as time goes by everybody should have an aim to improve themselves. There are always new research and medicines coming up in this field. Pharmacists cannot be timid in embracing change. If they are, they will soon become obsolete and less needed. This project is not to say that some do it right and some do it wrong, it is to make a good prompt for all the pharmacist to work after so that one can know that the patients gets the same quality of pharmaceutical care.

6.4. Design of the Care Plan

This project was a continuation of the project carried out by the MHPSG in 2006/2007(4), and can therefore be seen as a re-design of the original generic pharmaceutical care plan. This section will discuss the development of the final care plan in relation to the changes made to the original MHPSG care plan based on comments from the MHPSG report and the mental health pharmacists that participated in the validation process.

6.4.1. Additions

Duplication of effort was identified as a major problem, and changes were made to reflect this. An effective use of time and space could be achieved by using a sticky backed printed patient label for patient details, and CHI numbers on top of each page instead of full patients' details.

The patient details section was missing important details on physical characteristics such as weight, height and BMI. These were found relevant to include due to the risk of weight gain as a side effect of medications used to treat mental illnesses. Details

of smoking and substance misuse were also included in this section because of the interaction between cigarettes and certain medicines, especially the risk of an increased plasma concentration if the patient should suddenly quit smoking, and the bad influence substance misuse has on mentally ill patients. Substance misuse may also affect patient compliance as it can contribute to a feeling of not being ill and make it easier to forget to take prescribed medication.

An area for recording family- and social history were provided in the first draft of the document, but that was changed to be an area for general comments during the validation process due to lack of use. The segment for recording drug sensitivities were moved to the patient details section to increase logicality, and the areas for recording community cares, such as the GP, were increased to make room for addresses and telephone numbers.

Several segments in the admission details section, such as presenting compliant and diagnosis, were increased to make room for all necessary notes. The legal status was increased to provide space to record any changes that may occur during a hospital stay, and the segment for the admission date and source was increased to make room for readmissions.

In order to get a good synopsis of the patient history, relevant drug history was added in addition to relevant medical and psychiatric history. The area was designed to also include ADR's and OTCs. Inclusion of OTC would serve as a prompt when taking drug history/current medication. Use of OTC medications may often be a relevant care issue in mentally ill patients, particularly with regards to the interaction between Hypericum (St John's Wort) and drugs metabolised through the CYP450 system. The medical history was re-designed to include any history of non-compliance that might have occurred in the past, so one if necessary can be extra aware in the future. All the history segments was made bare so the pharmacists would not feel restrained to only use one line to record any relevant history about the patient.

The monitoring areas in the original care plan were thought to be too small, and to be of no use as a prompt on what to record. A whole page was made available for recording: monitoring reviews, where the pharmacists only needs to write the date and sign if parameters have been reviewed; clinical monitoring abnormalities, where trends can be seen for any abnormal tests; monitoring for high dose prescribing,

where the pharmacists can insert date and sing when monitoring of the patient has been done according to guidelines; and therapeutic drug monitoring. Having an own area for recording if high dose prescribing have been monitored makes a good prompt in remembering to calculate the doses and making sure the monitoring is done according to guidelines.

Mentally ill patients are often exposed to comorbidities(36), and will therefore need to be monitored for other physical irregularities beside the “typical tests”. The clinical monitoring table was therefore made out with a few blank lines for recording any other tests that may be needed.

The top of the current medication sheet was arranged so boxes could be ticked if the patient is self medicated, and additional boxes were made to tick for the patient’s level of self medication. As the pharmacist has an additional responsibility making sure patients detained under the Mental Health Act are treated according to law, space was provided to record if medications are listed on a T2 or a T3 form.

6.4.2. Deletions

Several deletions were made in order to shorten down number of pages in the document. Both the areas for ‘discharge’ and the ‘summary of progress made during admission’ were deleted, and admission date and source were merged. The discharge information was mainly well received, except for the lower part on why the discharge did not go as planned, but it was believed that this information could manage with just a segment for ‘discharge date’ under admission details. If any pharmacological problems lead to a change in the planned discharge, the pharmacists have the opportunity to document that as a care issue under ‘individualised care issues’. This also applies to progress during admission; problems arising during admission should be documented with the outcome under ‘individual care issues’. The own area for adverse event history in the original MHPSG care plan was deleted to be a part of the drug history instead.

The current medication was one of the most criticised sections of the original care plan as the majority found it very difficult to use. The layout of this section was changed completely by making it look more resembling to prescription kardex’s used on the wards. In the process of changing it, the medications were divided into psychotropic, non-psychotropic, and ‘as required medication’. Depots were also

separated out in the first draft. The validation process indicated that there was no need for such a separation and since this division is no longer a standard in the new kardex's, it was merged with the psychotropics. This also gave more space for recording 'ordinary' psychotropic's if depots are not used.

The area for investigations was deleted to become clinical monitoring abnormalities instead, and the therapeutic drug monitoring (TDM) was changed to be a part of that table. This was a desire from the focus group participants as this would enable them to view the trends. In order to make the TDM fit, the medications start date and dose were deleted as that can be found under current medication anyway.

Since the care issue level section attracted so much criticism in the previous study, the redesign process was significantly concentrated in this area. A whole page was deleted, and instead standard care issue tick box checks were incorporated at the top of the individualised care issue sheet. The DTP-risk check, included in the prototype care plan, received some inferior comments during the field testing so it was replaced with comorbidity. DTP is an abbreviation for drug therapy problems, which is more likely to be a joint description of many different care issues, whilst comorbidity is a huge problem amongst mentally ill patients that often can lead to pharmaceutical care issues. The numbers of the care issues can be recorded with the specifications in the individualised care issue section. The standard checks are thought to act as a reminder of what problems to assess in each patient. It might also be a help to systematise all the care issues, so identification of specific care issues will be easier to perform and statistics over checks can be generated.

The care issue section in the original care plan was laid out somewhat different than the pharmacists were used to, and some of the comments in the report was that they would prefer to have the pharmaceutical care issue section divided into; care issue ; action; output, like they were used to. The new care plan arranged for this in addition to division into therapeutic plan changes and other issues, like therapeutic plan checks, documentation changes and patient education needs. This was based on a care plan developed in 2007 for patients with diabetes(41). The new layout of the individualised care issue section was found to be a good way to get a quick synopsis of the treatment changes during admission.

6.4.3. Changes not incorporated

Complaints about duplication were also made in relation to the recording of patient history. However, it was felt that this section should remain, as not all pharmacists have access to ward notes at any one time, and that searching through other notes may not be the most efficient use of time. The history sections received complaints on scarcity of space during the validation process. Taking the whole document under consideration, the areas were not increased. If understandable cues of relevant history are used, there should be enough space to write all necessary information. If further information is needed this will be available in the medical notes.

The area for monitoring high dose prescription also faced some resistance during the validation process, and was suggested to be removed due to duplication with the care issue section and lack of relevance. It is believed that this area makes a good clinical prompt so the area was not deleted. It is true that it is not the pharmacists job to make sure the nurses do their job, but it is however the pharmacists job to make sure the patient gets the right treatment, and that there will be no complications due to medication. This includes checking laboratory results for efficacy and safety of the medication given. If the monitoring has not been done, the pharmacist cannot confirm continuation of treatment. Having an own monitoring area for high dose prescribing will cause information to stay united, and make it easier to get a quick overview.

The monitoring sheet was suggested to be moved after the field testing, but as long as the monitoring sheet is facing the prescription sheet, it should not be a problem.

Some of the participants in the focus group wanted the start and stop dates to be next to each other on the current medication section to better see which drugs have been discontinued. As this will give the pharmacists a good opportunity to make mistakes, it was not incorporated. Instead the guideline was changed to explain that if a drug has been discontinued one could draw a red line over it.

It was also asked for some additional blanks with the ‘standard care issue checks’ if a care issue should not fit under any of the listed categories. This was not done due to lack of space, and the fact that these checks had been considered to be the standards. These checks may be used to generate statistics over frequency of ‘standard care issue checks’. If some health board areas needs to add additional

'care issue checks' to get the statistics they want, they can feel free to add a number for that under 'date and no' without it being the standard way of recording.

Splitting the care issues was not well received during the validation process. This is obviously a new way of recording, but with proper guidance and training it should not be too hard to get used to. All the resistance towards it may be due to unfamiliarity, and the fact that the pharmacists included in the validation process were not very open to changes. It was found to be a good way to get a quick synopsis of the treatment changes during admission, and should be tested out. The only change made was in the care plan guideline, to try and explain the application of the section in a more easy and understandable way. Other specialities, like diabetes, have also made this a part of their standardised care plan(41), why would it be so much more difficult for mental health pharmacists to use it? Maybe this is the future?

Some of the pharmacists were not used to very comprehensive care plans, and found this document too time consuming. But as all the literature and the MHPSG-report have been consulted, this amount of information was found necessary. If important information about the patient and his/hers care are recorded in sections, it would make it easier to get a synopsis of the most important issues. If the new care plan is compared with the original one, one can see that the new care plan has been merged to be only one booklet, and the number of pages has been decreased from seven to four (six if the extra page is added). The new care plan would therefore comprise all the necessary information in a much smaller and understandable document.

6.5 Pharmacists' contributions and reactions

Piloting the care plan at the REH and the State Hospital was well received by the clinical pharmacists working there. They were happy to try use to the care plan, although they were satisfied with the one they were using now, and understood the purpose of having a standardised care planning system.

However, findings from the focus group discussion suggest that the pharmacists were not very interested in using a new standardised care plan document. It appeared that there was a certain resistance and lack of interest towards the project.

They just kept comparing the new care plan with their own, as it seemed they thought that was the best way of recording pharmaceutical care. They did not see the intention of creating a new care plan as it is suppose to be a part of the ICP soon. Implementation of ICPs has been a plan for many years, but no one actually knows when it is going to happen. However, one of the commitments in the Scottish Executive's mental health delivery plan was that the NHS QIS would develop the standards for ICPs for schizophrenia, bi-polar disorder, depression, dementia and personality disorder by the end of 2007, and that NHS Board areas would develop and implement ICPs that would be accredited from 2008 onwards(33). The development of a nationally agreed template pharmaceutical care plan for use within mental health settings may be useful in the implementation of the ICPs.

Another interesting aspect was to see the differences in what the pharmacists found important to document. It seemed as one of the pharmacists could have managed with just the patients name and his/hers care issues, where others needed more information included. One did not want the monitoring- and history boxes, but needed an own box to tick what kind of self medicated level the patient is on. Looking at all the comments together, shows that tick boxes for level of self medication is thought to be more important to include in a standardised care plan than e.g. a synopsis of monitoring high dose antipsychotic prescribing. What is more important for the patient's well being? There is a suspected association between high-dose prescription and sudden death(14), whilst non-compliance can cause deterioration of the illness. The pharmacist obviously needs to make sure that the patient is able and willing to take the medication prescribed, but one will think that making sure that patients on high dose antipsychotics are being properly monitored should be just as important.

The pharmacists need to be able to see the importance of documenting the work they do. They should have an aim to try getting everybody to work more similarly and then eventually create a consistent standard of care. If pharmacists do not document what they are doing, they will have no proof that they have done their job if e.g. something goes wrong. One can see their point of having access to medical notes when it comes to patient history, but it is not the intention to copy all the information on to the care plan, just the history relevant to make sure the patient gets the right treatment. It

will make the job easier if they do not have to read through many pages of history every time they need some information.

Complaints on the amount of effort needed to complete the care plan seemed to be a return in all validation processes, which make one wonder if maybe the pharmacists have too many obligations. This new document is thought to include what is necessary to record for satisfactory care of a patient, if they do not have time for that a review of the workload should be conducted.

6.6. Design methods and their limitations

6.6.1. Field testing

The major limitation of the field testing was the short study period of just two and a half weeks, and the small number of care plans completed. This was mainly due to staff holidays and the lack of new admissions. The State Hospital returned even fewer completed care plans, but that was expected because of the nature of its admission/assessment periods. The care plan was only used within the REH and the State Hospital, and cannot be representative for all of Scotland, nor can it show the usefulness on long term hospital stays.

The clinical meeting before the field testing started was to make sure everybody understood all the sections in the care plan so they would be able to use it as intended. The discussion also dealt with the need for the pharmacists to be critical to the care plan during the evaluation, as their apprehension of being rude became an issue. They were asked to write down all the difficulties as they were encountered during the field testing. To get a practical feel for the care plan, the researcher asked to accompany the clinical pharmacists when a new patient was admitted, and it was agreed that they would notify the researcher if they could fit it into their time schedule. Since the researcher only got contacted by one clinical pharmacist, one can assume it was two very busy weeks, or that they just did not find it necessary to include the researcher.

6.6.2. Focus group

The researcher chose to host a focus group as a method to validate the care plan. An interaction between pharmacists from different parts of the country was considered to give a worthwhile discussion of the usefulness of the care plan as a standardised document within the mental health pharmacy departments in Scotland. The time limit on the project, and lack of founding also gave a good reason for choosing this time-effective and inexpensive method. Getting pharmacists to register for the focus group in advance became an issue, but a final request received six pharmacists from different health broads to agreeing to participate.

The findings from the focus group are restricted to the thoughts and views of six pharmacists. They therefore need to be viewed with a degree of caution. It is possible that if another cohort of pharmacists had been interviewed, completely different data could have been generated. However, the pharmacists were typical of those working in Mental Health pharmacy and so could be considered a fair representation of the workforce.

From the outset, it was difficult trying to make the pharmacists understand or appreciate the purpose of the care plan. They appeared to lack insight into its purpose as a standardised document. They were, as mentioned earlier, largely absorbed about their own care plans, and kept comparing the new one with their own. Since the group consisted of pharmacists from different parts of the country, none of them worked with similar care plans, and everybody had different ways of documenting their work. They made little room for changes in the way they work today, which made it difficult to talk about the new care plan. But as they were asked to try and see beyond their own care plans, the discussion went a little better.

The lack of preparation by the participants may have also hindered the discussion. It appeared that few if any had looked at the document before the meeting, so they may have been limited with their views. Some of the volunteers might not have wanted to take part but felt unable to decline when asked directly. This could have made some effect on the dynamics and flow of the group discussion. If the participants had volunteered in advance, and done proper preparations, the researcher would have known that they were sincerely interested in the project, and that most of their comments would have been carefully thought through. Another

reason the discussion did not flow as well as desired can be attributed to the way it was lead. Neither the researcher nor the co-assistant had any experience with being a moderator/facilitator; the co-assistant had however attended several focus group discussions in the past.

Reason for not having more than one volunteer in advance could maybe be caused by the researcher's way of inviting the pharmacists, although the purpose of the project was described two months ahead, and an information e-mail was sent out to the pharmacist participant weeks before the focus group took place.

6.7 Further recommendations

This project shows that the development of a national care plan document is a labour intensive process. The previous project piloted a care plan for two months, which gave an insight in what the majority of pharmacists wanted such a document to include. These comments were taken on in this project, but the pharmacists consulted during the process do still not fully agree with the usefulness of all sections included.

Since the methodology in this project was somewhat limited, it is recommended to challenge the collected opinions with further validation. The care plan should not be dismissed based on opinions from one single focus group. Conducting a few more carefully planned focus groups, hosted by an experienced facilitator, may be beneficial. If proper preparation from both the researcher and the participants in a focus group are executed, a dynamic group discussion is more likely to happen. Getting pharmacists to use their time on profoundly preparing, and participating in a focus group, can be difficult. A solution may be to host the focus group at a place easy to access for all participants, and by and with some incentive. Issues concerning bias if the participants get paid may be solved by enticing with a fancy meal instead. Pharmacists from all eleven health boards should be represented at some time in the different focus group discussions.

The care plan may also benefit from a new national field test over a longer period of time. That will need time and funding. Another way could be to implement the care plan as a national standard, after new focus groups and adjustments have been

made, and then have a review after maybe a half a year, to see if it has improved the care planning and that the pharmacists have been able to use it as intended.

Before any implementation can be done, the pharmacists will be likely to need convincing that more pages than present in their existing care plans are worthwhile. Workshops to allow all pharmacists to discuss how to use the care plan are likely to encourage a more favourable response, especially with a view to the new way of recording care issues. Future work will also benefit from implementation of the care plan to the Schools of Pharmacy as a part of the training of clinical pharmacists. It is important that the students learn how to document, and if they all get the same training independent of which school they attend, that will help standardisation of pharmaceutical care.

The optimal way of using a standardised care planning system would probably still be the use of a database instead of a paper document, which also would help avoid duplication.

7. Conclusion

Implementation of a standardised care planning system is a labour intensive process. This project has managed to produce a care plan document which with further validation and minor adjustments can be used as a standard document within the mental health area. It may be used as a prompt to ensure that all the relevant mental health issues are effectively captured, and may also be used as a training toolkit for staff new to Mental Health.

Findings from the validation process show that the pharmacists are not completely ready to take on this document as a standard, but it simultaneously shows that they need more convincing to take on any document as a standard. They need to understand how mental health patients in Scotland can benefit from a standardised care planning system.

It will obviously take some time for the pharmacist to adjust to a standardised way of working. Mandatory use of the new care plan document will therefore not be imposed on currently practising pharmacists, but it will be expected that they address all the issues contained in the standardised care plan document in their day to day practice.

The Mental Health Pharmacy Strategy Group, as a cohesive national group, should provide the means to achieve their aims of having a standardised care plan by using their ability to influence the health boards.

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8. Appendixes

Appendix 1: MHPSG original generic pharmaceutical care plan

Appendix 1a: Longitudinal sheet

Appendix 1b: Cross sectional sheet

Appendix 2: Research questions from the MHPSG project

Appendix 3: Focus group topic guide

Appendix 4: Parameter abbreviations

Appendix 5: First draft care plan

Appendix 6: Issues raised by research group, and suggestions followed

Appendix 7: Prototype care plan before field testing

Appendix 8: Care plan guidance text

Appendix 9: Example care plan

Appendix 1a

MHPSG original generic pharmaceutical care plan

Longitudinal sheet

NHS Scotland

Generic Pharmaceutical Care Plan
Longitudinal information

Patient Details

Surname	**Local ID**
Forename	**CHI number**
Preferred forename	**Date of Birth**
Sex Male Female	

Changes to patient details Score out, with a single line, any details which have changed and document new information in table below

Information type	New details	Information type	New details

Relevant medical history

Date (approximate)	Problem description

Relevant psychiatric history (include previous diagnoses and their drug treatments)

Adverse event history (Known Sensitivities, Allergies, ADRs)

Appendix 1b

MHPSG original generic pharmaceutical care plan

Cross sectional sheet

NHS Scotland

Generic Pharmaceutical Care Plan
Cross-sectional admission

Patient Details

Surname	**Local ID**
Forename	**CHI number**
Preferred forename	**Carer**
Sex Male Female	**Named person**
Date of Birth	**GP**
Does the person have an advanced statement Yes No Unknown **If yes** document any effect this has on pharmacy procedures	**CPN**
	Community Pharmacist

Admission Details

Date of admission	Consultant
Source of admission	Hospital
Pharmacy log date	Ward
Legal status	Named nurse/keyworker
Treatment Plan status	Clinical pharmacist
Presenting complaint	
Working diagnosis	Confirmed diagnosis

Discharge Information

Discharge date – planned	Discharge date – actual
If planned and actual date differ was there any pharmaceutical reason? Yes No If yes please give reason	

Summary of progress made during admission

Care Issues

Tick box if care issue has been considered, circle ticked box, if a problem has been identified ie ☑

Care Issues – level 1 – Treatment/dosage appropriate with respect to the following								
Date								
1 Diagnosis								
2 Physical state complications								
3 Adverse event history								

Care Issues – level 2	**Monitoring**							
Date								
4 Counselling/education								
5 Therapeutic drug monitoring								
6 Drug interaction								
7 MHA treatment plan								
8 Discharge planning								
9 Polytherapy								
10 High dose antipsychotic								
11 Side effect(s)								
12 Rationale for treatment change								
13 Concordance								
14 Renal function								
15 LFTs/Bilirubin								
16 FBC								
17 ECG – QTc								
18 Hyponatraemia								

Care Issues – Level 3						
	Date checked	Problem identified	Date checked	Problem identified	Date checked	Problem identified

Current medication including OTC

Surname	**Local ID**
Forename	**DOB**

							Comments – including any guidelines or protocols in use
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						

							Comments – including any guidelines or protocols in use
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						
Medication Route	Date						
start date stop date	Dosage						

Therapeutic drug monitoring

Medication	Date	Dose	Hours post dose	Concentration	Target Concentration	Comments

Investigations (record what the investigation was and the abnormal result)

Investigation	**Date**	Result	**Date**	Result	**Date**	Result

Care Issues

Surname	Local ID
Forename	DOB

All Care Issue (levels 1, 2 and 3) problems should be recorded here.

	Pharmaceutical Care Issue	Desired Outcome	Outcome achieved ❒
Date	Action to be taken/Recommendation/Progress		Request Action by ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team
	Pharmaceutical Care Issue	Desired Outcome	Outcome achieved ❒
Date	Action to be taken/Recommendation/Progress		Request Action by ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team
	Pharmaceutical Care Issue	Desired Outcome	Outcome achieved ❒
Date	Action to be taken/Recommendation/Progress		Request Action by ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team
	Pharmaceutical Care Issue	Desired Outcome	Outcome achieved ❒
Date	Action to be taken/Recommendation/Progress		Request Action by ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team
	Pharmaceutical Care Issue	Desired Outcome	Outcome achieved ❒
Date	Action to be taken/Recommendation/Progress		Request Action by ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team

	Pharmaceutical Care Issue	Desired Outcome	Outcome achieved ❒
Date	**Action to be taken/Recommendation/Progress**		**Request Action by** ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team
	Pharmaceutical Care Issue	**Desired Outcome**	**Outcome achieved ❒**
Date	**Action to be taken/Recommendation/Progress**		**Request Action by** ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team
	Pharmaceutical Care Issue	**Desired Outcome**	**Outcome achieved ❒**
Date	**Action to be taken/Recommendation/Progress**		**Request Action by** ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team
	Pharmaceutical Care Issue	**Desired Outcome**	**Outcome achieved ❒**
Date	**Action to be taken/Recommendation/Progress**		**Request Action by** ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team
	Pharmaceutical Care Issue	**Desired Outcome**	**Outcome achieved ❒**
Date	**Action to be taken/Recommendation/Progress**		**Request Action by** ❒ Medical ❒ Nursing ❒ Pharmacy ❒ Clinical Team

Appendix 2

Research questions from the MHPSG project

Research questions from the MHPSG project;

1. How completes the care plan?
2. When is the care plan completed, e.g. before, during or after MDT meetings?
3. Is it easy to use the documents?
4. Are the correct data being collected?
5. Does the document alter the way of working?
6. How useful do questionnaire respondents see that the Generic Care Plan is to other disciplines within the MDT?
7. How do the documents help in communicating information to Community Pharmacists/GPs?
8. What are the barriers to implementation of the document?
9. Is the pre-implementation training adequate?
10. What data are being collected by the Care Plan?

Appendix 3

Focus Group Topic Guide

Focus Group Topic Guide

How useful do you think this document will be?

Then talk them through the Sections;

- Personal info
- History sections
- Monitoring sheet
- P**r**escription sheet
- Checks
- Individualised care issues
- Possibility of adding an extra sheet
- The order of the pages

- **Resistance/ Barriers to its use**
- **Adjustments or changes they think it could benefit from**
- **Suggestions for improvements**

Also need to discuss the guidance document and if it's any help.

What are the problems with it?

How can it be improved?

Appendix 4

Parameter abbreviations

Parameter abbreviations

ALT	Alanine aminotransferase
Bili	Bilirubin
Ca	Calsium
Chol.	Cholesterol
Creat.	Creatinine
CPK	Creatinine Phosphokinase
ECG	Electrocardiogram
EEG	Electroencephalogram
FBG	Fasting blood glucose
Free T4	active form of thyroxin
GGT	Gamma glutamyl transferase
Hb	Hemoglobin
HDL	High-density lipoprotein
K	Potassium
LDL	Low-density lipoprotein
MCV	Mean corpuscular volume
Na	Sodium
Neutro	Neutrophils
PLT	Platelets
TFT	Thyroid function tests
TG	Triglyceride
THS	Thyroid-stimulating hormone
U&E	Urea and electrolytes
WBC	White blood cell count

Appendix 5

First draft Care Plan

PHARMACEUTICAL CARE PLAN: MENTAL HEALTH
PATIENT PROFILE

(Patient label) Name Preferred Forename	CHI #	Gender Male ☐ Female ☐	Social History Living alone ☐ Living with Partner/family ☐ Other: ☐	Family History
Address Postcode	Date of birth/ Age	Weight / kg | Height/m BMI	Smoking status: Smoker ☐ Number/day: Non-smoker ☐ Ex-smoker ☐ Since	Drug sensitivities
General practitioner Address Tel	Community Pharmacy Address Tel	Carer/named person Address Tel	Use of illicit drugs Y ☐ N ☐ What: Alcohol consumption Y ☐ N ☐ Units/week:	Comments

ADMISSION DETAILS			
Date of admission	Pharmacy log date	Legal Status	Presenting complaint
Source of admission	Hospital		
Consultant	Ward		
Key worker	Planned discharge	Diagnosis	
Clinical pharmacists	Actual discharge		

RELEVANT MEDICAL HISTORY			
Date (approximate)	Problem description	Date (approximate)	Problem description

RELEVANT DRUG HISTORY / ADVERSE EVENT HISTORY		
Date (approximate)	Medication	Comments

RELEVANT PSYCHIATRIC HISTORY

Date	Problem description

MONITORING/INVESTIGATIONS

EPISODES OF CARE	Care Episode 1 Date:		Care Episode 2 Date:		Care Episode 3 Date:		Care Episode 4 Date:		Care Episode 5 Date:		Care Episode 6 Date:	
	Values	Date	Values	Date	Values	Date	Values	Date	Values	Date	Values	Date
Weight (kg)												
Blood pressure												
Creat (55–120) µmol/l												
Na (135-145)mmol/l												
K (3.5-5) mmol/l												
Ca (2.12-2.65)mmol/l												
Urea (2.5-6.7) mmol/l												
ALT (5-35) µ/l												
GGT (7-33) F µ/l (11-51) M µ/l												
Bili (3-17) mmol/l												
FBC x 10^9/ l												
WCC (4-11) x 10^9/ l												
Hb (11,5-16) F g/dl (13,5-18)M g/dl												
Gluc (3.5-5.5) mmol/l												
Chol (3.9-7.8) mmol/l												
Tg (0.55-1.9) mmol/l												
CPK (25-170) F IU/l (25-195) M IU/l												
TSH (age related)												
Free T4 (9-22) pmol/l												
Prolactin <600 F U/l <450 M U/l												
ECG												

CURRENT MEDICATION

Start date	Regular medication	Dose	Route	Administration times					Stop date	Comments
				8	1	6	10	other		

Start date	Depot Injections	Dose	Frequency	Stop date	Comments

AS REQUIRED MEDICATION

Start date	Medication	Dose	Route	Indication	Frequency	Max dose 24 hours	Stop date	Comments

HIGH DOSE ANTIPSYHOTICS		
Date	**Percentage calculated from BNF**	**Drugs / Doses**

TERAPEUTIC DRUG MONITORING						
Medication	**Date**	**Dose**	**Hours post dose**	**Concentration**	**Target concentration**	**Comment**

Care issue check list?

INDIVIDUALISED CARE ISSUES			
Week No + Date	**Care Issue**	**Patient Education / Documentation Changes and Therapeutic Plan Checks**	**Therapeutic Plan Changes** (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		

	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
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	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		

Appendix 6

Changes to the first draft care plan;

Issues raised by research group and suggestions followed

Discussion point	Research group suggestions	Done
Lay out	Remove some of the data fields , to compress the care plan	✘
Patient details,	Leave Social history blank.	✘
	Remove number a day and ex-smoker from smoking status-box	✘
	Change “use of illicit drugs” to “substance misuse	✘
Admission details, remove some unimportant data fields , to compress the care plan	Merge date and source of admission	✘
	Move pharmacy log date and name of clinical pharmacist to the top of the sheet	✘
	Merge planned and actual discharge	✘
	Remove tick boxes for close monitoring drugs	✘
Relevant medical history	Add compliance	✘
	Decrease space for date	✘
Relevant drug history / ADR history	Split table in two identical sections	✘
	Add OTC / complementary needs in a box below	✘
Relevant psychiatric history	Lose five lines	✘
Monitoring / investigations	Divide lab-investigations into themes	✘
	Remove Care episodes	✘
	Change gluc to FBG (fasting blood glucose), and move it	✘
	Supply with HDL, LDL, and PLT and neutrophiles	✘
	Use REH reference range	✘
Current medication	Remove administration times	✘
	Add non-psychotropic- and psychotropic medication	✘
High dose antipsychotics	Change headings to date, dose, BNF %, and monitoring episodes	✘
Therapeutic drug monitoring	Change headings to date, medication, dose, time of sample, concentration measured and range	✘
	Split table in two identical sections	✘
Care issue check list	Make a table of care issue check words for the research group to agree on	✘
Individualised care issues	Remove week number	✘

Appendix 7

Prototype Care Plan

Before field testing

PHARMACEUTICAL CARE PLAN - MENTAL HEALTH
PATIENT MEDICATION PROFILE

(Patient label) Name Preferred forename	CHI # Age / Date of birth	Gender Male ☐ Female ☐	Family History		Social History
Address Postcode		Weight / kg	Height / m	Smoking Status Smoker ☐ Non-smoker ☐ Number/day	Drug Sensitivities
		BMI			
General Practitioner Address Tel	Community Pharmacy Address Tel	Carer / named person Address Tel		Substance misuse Yes ☐ No ☐ Specify:	Comments

ADMISSION DETAILS

Admission; Date and Source		Date/ Legal Status	Presenting Complaint
Consultant	Hospital		
Key worker	Ward		
Discharge Date	Advanced Statement Y ☐ N ☐		Diagnosis

RELEVANT MEDICAL HISTORY (INCLUDING HISTORY OF NON-COMPLIANCE)

Date	Description	Date	Description

RELEVANT DRUG HISTORY (INCLUDING ADVERSE OR NON RESPONSIVE THERAPY)

Date	Medication	Comments	Date	Medication	Comments

OVER THE COUNTER MEDICATION / COMPLEMENTARY THERAPY

Name

RELEVANT PSYCHIATRIC HISTORY

Date	Description

PHARMACIST'S MONITORING REVIEWS

Date													
Sign													

CLINICAL MONITORING

Date												
Weight (kg)												
Blood pressure												
Creat (60–120) µmol/l												
Na (135-145)mmol/l												
K (3.6-5) mmol/l												
Ca (2.1-2.6)mmol/l												
Urea (2.5-6.6) mmol/l												
FBG (3.5-5.8) mmol/l												
ALT (10-50) µ/l												
GGT (5-55) µ/l												
Bili (3-16) mmol/l												
WCC (4-11) x 10^9/ l												
Platelets (150-350) x 10^9/ l												
Neutrophils (2-7.5) x10^9/ l												
Hb (11-18) g/dl												
Chol (3.9-7.8) mmol/l												
HDL 0.9-1.4 mmol/l (M) 1.1-1.7 mmol/l (F)												
LDL 3.0-6.4 mmol/l (M) 2.8-6.1 mmol/l (F)												
TG (0.55-1.9) mmol/l												
CPK (25-170) F IU/l (25-195) M IU/l												
TSH (age related)												
Free T4 (9-22) pmol/l												
Prolactin <600 F U/l <450 M U/l												
ECG required undertaken												

RECORD OF MONITORING FOR HIGH DOSE ANTIPSYCHOTIC PRESCRIBING

Start Date	**Medication**	**Dose**	**BNF %**	**Evidence of Monitoring ✓ if performed**				**Stop date**
				Baseline	**3 Mthly**	**6 Mthly**	**9 Mthly**	

THERAPEUTIC DRUG MONITORING

Date	**Medication**	**Dose**	**Time & date of sample**	**Concn measured**	**Range**	**Date**	**Medication**	**Dose**	**Time & date of sample**	**Concn measured**	**Range**

CURRENT MEDICATION

SELF MEDICATING Date — Y ☐ N ☐

Start date	Psychotropic Medication	Dose	Route	Administration times/frequency	Stop date	T2/T3 (if applicable)	Comments

Start date	Non- Psychotropic Medication	Dose	Route	Administration times/ frequency	Stop date	Comments

Start date	Depot/long acting Injections	Dose	Frequency	Stop date	T2/T3(if applicable)	Comments

AS REQUIRED MEDICATION

Start date	Medication	Dose	Route	Indication	Frequ--ency	Maximum dose In 24 hours	Stop date	Comments

STANDARD CHECK'S IDENTIFYING PROBLEMS WITH;				
1.Drug history ☐	**3**.Guidelines ☐	**5**.Interactions ☐	**7**.HD antipsychotics ☐	**9**.Compliance ☐
2.Polypharmacy ☐	**4**.DTP risk ☐	**6**.ADR's ☐	**8**.MHA T2/T3 ☐	**10**.Patient understanding ☐

INDIVIDUALISED CARE ISSUES			
Date	**Care Issue**	**Therapeutic Plan Checks + Documentation Changes + Patient Education**	**Therapeutic Plan Changes** (Individualisations/ Dosage Change/ Treatment Interruption/ Management of Co-morbidity)
	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		
	Specify		
	Action		
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	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		

CURRENT MEDICATION

SELF MEDICATING Y ☐ N ☐ Date

Start date	Psychotropic Medication	Dose	Route	Administration times/frequency	Stop date	T2/T3 (if applicable)	Comments

Start date	Non- Psychotropic Medication	Dose	Route	Administration times/ frequency	Stop date	Comments

Start date	Depot/long acting Injections	Dose	Frequency	Stop date	T2/T3(if applicable)	Comments

AS REQUIRED MEDICATION

Start date	Medication	Dose	Route	Indication	Frequ--ency	Maximum dose In 24 hours	Stop date	Comments

Appendix 8

Care plan guidance text

Guidance for the completion of the Mental Health Pharmaceutical Care Plan

Patient details, admission details
Complete as soon as possible after admission.

- Note the patient's name, address, postcode, date of birth (age) and CHI number. If a patient label with all this information is available, it should be applied here.
- Provide the names and, if known, the addresses of the Carer, GP and community pharmacy. If you find that there are other community persons that are more important to record, feel free to change as you write.
- Note the general patient characteristics including gender, weight, height and BMI (if available)
- Note smoking status and substance misuse e.g. alcohol, illicit drugs (specify what is being misused)
- Record any known drug sensitivities.
- Use the general comment box to record other things you find important to have documented e.g. Patient's social- and family history

Relevant Medical History / Compliance
Note relevant medical history you find useful, e.g. diabetes, cardiovascular problems etc.
Include if the patient has a history of treatment/medication non-compliance.

Relevant Drug History / ADRs
Note patient response to any earlier treatments, if he/she had a satisfactory/ unsatisfactory response, had any unwanted/adverse effects from medication etc.

Purchased Medicines/ Complementary Treatments
Note any medicine that the patient takes without prescription i.e. Over The Counter medication, including herbs and vitamins of interest. E.g. St. Johns Wort (hypericum). Also any other treatments that might be considered complementary

Relevant Psychiatric History
Extract the key data, and record information you consider useful to have available at a glance - do not replicate a full psychiatric history.

Pharmacist Reviews
Note the date lab results were checked, and sign.

Clinical Monitoring Abnormality
Record any abnormal values of the relevant laboratory results and the dates they were taken. This will allow trends to be seen through treatment changes.

High Dose Antipsychotic Medication

- Note the date the antipsychotic prescribing became 'high dose'.
- Calculate and note the percentage (High) dose of each antipsychotic drug from the recommended daily dose as indicated in the BNF.

Confirm necessary monitoring has been performed as per High Dose prescribing Guidelines every 3 months by making a √ under evidence of monitoring preformed.

Therapeutic Drug Monitoring
Note time and date that the sample was taken. This will allow accurate calculation of plasma levels according to the number of hours post/pre dose.
Record the measured concentration and recommended plasma range of the drug.

Current Medication
Record regular psychotropic, including depot and other long acting injectable formulations, and non psychotropic medication separately. (Non psychotropic includes all medication that is NOT related to the mental condition of the patient). Also record 'as required' medication (prn) in the box provided. When a drug has been discontinued it might be a good idea to make a red line over it.
Fill in the administration times using whatever format you find most useful

Standard check's
Ten categories of standard check's are listed as a check procedure for the patient screening process. If a check has led to identification of an individualised care issue you should tick the box that best describes the care issue. Care issues should be numbered according to the standard check category.

Individualised Care Issues
Report Care Issues arising from the routine monitoring in the patient's individualised care plan. If the care issues has been numbered from the standard check's, the number should be recorded in the "date and no" column.
The column on the left is for all specific checks and all changes that are directed at correcting the patient records or addressing educational needs.
The column on the right is used to separate out the treatment changes. If a check leads immediately to a treatment change, the care issue should be documented in terms of the change. For example a check of creatinine leading (in the same care episode) to a change in dose should be recorded as a dose change plus explanation together in the right hand column. See example

Appendix 9

Example care plan

PHARMACEUTICAL CARE PLAN - MENTAL HEALTH
PATIENT MEDICATION PROFILE

(Patient label) Name	CHI #	Gender	Comments (e.g. Family and Social History)
Robert Smith **Preferred forename** Bob	2006549999 **Age /** 53 yr **Date of birth** 20.06.54	Male ☑ Female ☐	Lives with wife, no children

Address	Weight / kg	Height / m	Drug sensitivities
19/3 Forth Street Edinburgh **Postcode** EH1 3LE	80 kg **BMI** 24.7	180 m	

General Practitioner	Community Pharmacy	Carer / named person	Smoking Status		Substance misuse
Dr Smith **Address** The Surgery High Street **Tel** 111 1234	**Address** Main Road **Tel** 111 5678	Jane Smith **Address** **Tel**	Smoker Non-smoker Number/day	☐ ☑	Yes ☐ No ☐ **Specify**:

ADMISSION DETAILS

Admission; Date and Source	Consultant	Hospital	Key worker	Ward	Discharge Date	Advanced Statement	Date/ Legal Status	Presenting Complaint	Diagnosis
Arranged by CPN at 14.04.2006	Dr Deans	NTH	S/N Ross	12	16.05.2006	Y ☑ N ☐	14.04.06 / STDC	Hostile and aggressive, lacks insight that he is hypomanic	BPAD-hypomanic

RELEVANT MEDICAL HISTORY (INCLUDING HISTORY OF NON-COMPLIANCE)

Date	Description	Date	Description
Okt 2004	Diabetes type 2. Diet controlled		
June 2005	Hypertension		

RELEVANT DRUG HISTORY (INCLUDING ADVERSE OR NON RESPNSIVE THERAPY)

Date	Medication	Comments	Date	Medication	Comments
1991	Haloperidol	Acute dystonic reaction			
2002	Citalopram	Sexual dysfunction			
4/6–07	Valproate	Dose dependent tremor			
	Mirtazapine	Relapse episode			
	Phenelzine	Relapse episode			
	Reboxetine	Works			

OVER THE COUNTER MEDICATION / COMPLEMENTARY THERAPY

Name

RELEVANT PSYCHIATRIC HISTORY

Date	Description
1991	Psychotic illness – drug induced?
1993	BPAD – manic episode. Admission for 3/12.
Okt.1996	Anxiety disorder. 10 session input from psychologist
1999-2006	BPAD – hypomanic episodes in 1999, 2001, 2005 and 2006. Admitted for about 2/12 every time.
1999+ 2002	BPAD – depressive episodes. Change of treatment – mirtazapine switched to phenelzine

PHARMACIST'S MONITORING REVIEWS														
Date	15/4	21/4	29/4											
Sign	ms	ms	ms											

CLINICAL MONITORING ABRORMALITY													
Date	14/4	21/4	28/4										
Weight (kg)													
Blood pressure													
Creatinine (60–120) µmol/l													
Na (135-145)mmol/l													
K (3.6-5) mmol/l													
Ca (2.1-2.6)mmol/l													
Urea (2.5-6.6) mmol/l													
Blood glucose (3.5-5.8) mmol	11,1	6	4,2										
ALT (10-50) µ/l													
GGT (5-55) µ/l													
Bilirubin (3-16) mmol/l													
WCC (4-11) x 10^9/ l													
Neutrophils (2-7.5) x10^9/ l													
Platelets (150-350) x 10^9/ l													
Hb (11-18) g/dl													
Chol esterol (3.9-7.8) mmol/l													
HDL													
CPK (25-170) F IU/l (25-195) M IU/l													
TSH (age related)													
ECG													

RECORD OF MONITORING FOR HIGH DOSE ANTIPSYCHOTIC PRESCRIBING								
Start Date	**Medication**	**Dose**	**BNF %**	**Evidence of Monitoring ✓ if performed**				**Stop date**
				Baseline	**3 Mthly**	**6 Mthly**	**9 Mthly**	

THERAPEUTIC DRUG MONITORING											
Date	**Medication**	**Dose**	**Time & date of sample**	**Concn measured**	**Range**	**Date**	**Medication**	**Dose**	**Time & date of sample**	**Concn measured**	**Range**
25/4-06	Valproate	1g, bd	8 pm (12h post)	110 mg/l	50-100 mg/l						

CURRENT MEDICATION

SELF MEDICATING Y ☐ N ☐ **Date**

Start date	Psychotropic Medication	Dose	Route	Administration times/frequency	Stop date	T2/T3 (if applicable)	Comments
14/4-06	Lamotrigine	100 mg	O	OD			
14/4-06	Vaproate m/r	500 mg	O	Nocte	20/4-06		
20/4-06	Valporate m/r	1 g	O	Nocte	22/4-06		
22/4-06	Valporate m/r	700 mg	O	BD	24/4-06		
24/4-06	Valporate m/r	1 g	O	BD	26/4-06		
25/4-06	Quetiapine	50 mg	O	BD	26/4-06		Increase by 50 mg a day until 200 mg, BD
26/4-06	Valporate m/r	900 mg	O	BD			
28/4-06	Quetiapine	200 mg	O	BD			

Start date	Non- Psychotropic Medication	Dose	Route	Administration times/ frequency	Stop date	T2/T3(if applicable)	Comments
18/4-06	Lisinopril	20 mg	O	OD			

AS REQUIRED MEDICATION

Start date	Medication	Dose	Route	Indication	Frequ--ency	Maximum dose In 24 hours	Stop date	Comments
14/04-06	Haloperidol	5mg	O	agitation	1hour	30mg	18/4-06	

STANDARD CHECK'S IDENTIFYING PROBLEMS WITH;				
1.Drug history ☑	**3**.Guidelines ☐	**5**.Interactions ☑	**7**.HD antipsychotics ☐	**9**.Compliance ☐
2.Polypharmacy☐	**4**.Co-morbidity ☐	**6**.ADR's ☑	**8**.MHA T2/T3 ☐	**10**.Patient understanding ☐

INDIVIDUALISED CARE ISSUES			
Date and No	**Care Issue**	**Therapeutic Plan Checks + Documentation Changes + Patient Education**	**Therapeutic Plan Changes** (Individualisations/ Dosage Change/ Treatment Interruption/ Management of Co-morbidity)
15/4-2006	*Specify*		Risk of EPSE due to Haloperidol , (Patient has history of dystonic reaction)
No 6	*Action*		Need for Haloperidol prn to be discussed with prescriber
18/4-06	*Output*		Haloperidol discontinued, no further prn antipsychotic required
18/4-2006	*Specify*		Untreated hypertension
No 1	*Action*		Check with patient/ GP to restart usual treatment – lisinopril 20 mg
24/4-2006	*Output*		Patient is now normotensive
18/4-2006	*Specify*	Note interaction between valproate and lamotrigine. Lamotrigine levels may double, however been on this combination before admission.	
No 5	*Action*	Monitor for s/e particularly rash	
24/4-2006	*Output*	No evidence of lamotrigine dose related s/e	
25/4-2006	*Specify*		Patient c/o tremor. Related to valproate level
No 6	*Action*		Reduce dose slightly, and reassess tremor
28/4-2006	*Output*		Tremor has resolved
25/4-2006	*Specify*	Lack of progress on valproate monotherapy.	
	Action	Atypical antipsychotic options discussed. UKPPG leaflets provided.	Start on quetiapine
1/5-2006	*Output*	Patient agreed to quetiapine for hypomania, largely as a result of its evidence for use in bipolar depression (NICE)	Responding well to combination, continue treatment short term