

Evaluating the Pharmacist Provision of Clozapine Services

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This study was designed as research for public benefit and aimed to evaluate the input of a pharmacist in the monitoring of people who were taking clozapine for treatment-resistant schizophrenia.

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1. Background to the study

1.1 Schizophrenia

Schizophrenia the most common psychotic disorder in the United Kingdom. It is a chronic, enduring, disabling mental illness affecting 1% of the population. Following diagnosis, 20% of patients will recover and 20% will not, with the majority returning to some level of health but never to pre-diagnosis state. Of all patients with schizophrenia 20-40% will attempt suicide at some point and of these 10% will succeed.⁽¹⁾ Schizophrenia is therefore a chronic, relapsing, long-term condition for the majority of people receiving that diagnosis.⁽¹⁾

Schizophrenia has significant public health implications. People who suffer with the condition are at greater risk of developing diabetes⁽²⁾ and cardiovascular disease than those in the general population: they are more likely to smoke, drink alcohol to excess, and lead a sedentary lifestyle as well as having a treatment-independent higher risk of metabolic syndrome. In addition, most antipsychotics are associated with an increased risk of weight gain and direct and indirect cardiovascular effects.⁽³⁾

1.2 Schizophrenia and clozapine

People with schizophrenia will generally need to take medication for the rest of their lives in order to prevent relapse and re-admissions to hospital. Treatment is usually with antipsychotic drugs. Side effects of such medication include movement disorders, akathisia (inner and motor restlessness), weight gain, sedation, worsening of the negative symptoms of schizophrenia (social withdrawal and/or apathy) and changes in sexual function⁽⁴⁾ and consequently, achieving patient adherence is a challenge.

For about 20% of patients their schizophrenia is refractory to at least two different antipsychotics. In principle, these patients are regarded as having Treatment Resistant Schizophrenia (TRS) and are eligible for treatment with clozapine. Positive public health outcomes associated with the successful use of clozapine include prevention of suicide, relapse and hospital admissions, improved patient satisfaction, gainful employment and increased socialisation.⁽⁴⁾⁽⁵⁾

However, although clozapine can be an effective agent to treat the symptoms of schizophrenia, it is associated with side effects that are potentially fatal. Clozapine-associated agranulocytosis led to voluntary withdrawal from the market by the manufacturer of clozapine in the mid-1970s but it was re-introduced about 20 years ago for treatment-resistant schizophrenia. The accompanying risk-management plan to manage the agranulocytosis risk has resulted in treatment initiation in a hospital setting and regular associated blood tests with monitoring of mental and physical health. Generally, in the hospital setting, pharmacy departments tend to be in charge of monitoring the weekly or fortnightly blood results before dispensing the medication.

1.3 Clozapine services and the role of pharmacists

Historically clozapine services have been situated on-site within an NHS mental health Trust, and, for those holding down jobs, regular trips to hospital for blood tests and monitoring are not only inconvenient, but they also provide a continual reminder of the stigma and isolation surrounding the treatment of schizophrenia. Given that the vast majority of people with a mental health condition are treated and cared for within their local community, it could be considered that under certain conditions it might be possible to situate clozapine services in the community rather than on a hospital site.⁽⁶⁾ Potentially, pharmacists could contribute to ensuring such conditions are met for instance by playing a role in treatment adherence as well as side effect monitoring.

1.4 Cost of schizophrenia and clozapine

Schizophrenia is costly in terms of total treatment services. Although clozapine is a relatively expensive antipsychotic compared to some (approximately £110.90 per 28 day-period at 450mg daily), expenditure on medicines in the treatment of schizophrenia is a relatively small proportion of the total cost. This is because inpatient care in the acute stages of schizophrenia can be for 3

to 6 months at a cost of about £270 per bed per day. Costs to society must also be considered: approximately 80% of people with the condition remain unemployed, and some may become involved in criminal behaviour. This, in turn, places a high burden on family carers.⁽⁷⁾ Clozapine is considered to be cost effective both from the National Health Service (NHS) perspective and from a societal perspective. It may be that changing the care model such that clozapine services are delivered away from the clinic sites reduces the treatment-associated costs further and it may be that pharmacists can contribute to this.

1.5 Exploring the Pharmacists Role

Pharmacists have expert knowledge of medication and they are able to identify how the negative effects of the medication may adversely impinge on adherence and patient health outcomes. Some pharmacists now have the training to conduct clinical assessments of patients and to make treatment and prescribing decisions without referral to a medical practitioner. If these extended skills are used effectively then this may have a beneficial impact on patient care and it may be that pharmacists could play an important role in delivering clozapine services in the community. Before any such changes can be proposed however, it is necessary to make a thorough evaluation of clozapine service provision with particular reference to the role of the pharmacist.

There is little evidence in the literature that identifies the potential contribution of the pharmacist in this area. In theory, pharmacists are well placed to identify signs and symptoms of possible relapse and noncompliance to prevent a possible downward spiral into uncontrolled disease and relapse. A key focus of this study was to identify the specific roles of pharmacists in clozapine services as well as any health economic implications.

1.6 Study setting

The study was carried out in an NHS Trust in the south-west of the United Kingdom. The Trust delivered its clozapine services from clinics based in the offices of community mental health teams or from outpatient clinics at the local hospital. There were 7 clinics in total and there had been a recent drive to include a pharmacist in each of these clinics, to improve the quality and safety of prescribing. This resulted in 3 of the 7 clinics including a pharmacist in the multi-professional team. Each clinic had a different configuration of professionals providing the service; this included phlebotomists, rotational junior doctors, rotational psychiatrists, community psychiatric nurses and pharmacists and allowed an evaluation of different configurations for the effective supply of clozapine services.

2. Aims of the research

The aim of the study was to evaluate alternative models for the delivery of clozapine services and compare patient outcomes and costs when different teams of professionals (pharmacist, nurse, hospital or general practice doctor) are involved in delivering the care. Between the time of grant application and the study start date, staffing configurations in some of the clinics changed. As a consequence, pharmacist-led clinics were no longer available for separate evaluation and we had to modify the study objectives accordingly.

The final study objectives were to:

1. Identify and describe different models for the delivery of clozapine to people with TRS.
2. Evaluate the association between different staff configurations and the experiences and health outcomes of service users.
3. Explore the views of professionals about different team configurations.
4. Examine the roles and responsibilities of pharmacists in each team, and explore the factors that enable pharmacists to contribute most effectively to successful outcomes from care.
5. Investigate the resource implications, costs and value for money of the different service delivery approaches.

3. Research methods

The setting for this study was one large NHS mental health Trust within seven community clozapine services for people with TRS.

A mixed methods in-depth comparative case study design was used to collect information on participant characteristics, experiences of service utilisation, and the pharmacist contribution. The methodology drew on the multidisciplinary skills and experience of the research team, and benefited from the active involvement of a patient and carer advisory group. The theoretical basis for the study was the structure-process-outcome framework for assessing quality of care.⁽⁸⁾ This provided a framework to explore whether the structure (e.g. an individual clinic or clinic model) was associated with participant outcomes (e.g. satisfaction or wellbeing) as a result of a clinic process (e.g. lack of appointment system). As there were 7 case study sites each with a different staffing configuration it was important to highlight any differences, where possible, between those clinics with pharmacist input and those clinics without. Clinic model configurations are shown in table 1.

3.1 Patient and carer advisory group

Before gaining ethical approval we sought input from people and carers of people who were taking clozapine. This was to ensure we explored areas that were important to those using the services routinely and to guide us in developing the measurement and evaluation tools over the duration of this study.

3.2. Ethical approval

NHS Ethical approval was granted for the study (Ref. 08/WSE03/52) and this included identification of suitable participants in terms of vulnerability and capacity to consent. The study adhered to regulations laid down in the Data Protection Act 1998.

4. Data collection and analysis

4.1 Data

Data from multiple sources were collected and triangulated to provide a full 'picture' of how different clinics deliver services, and to evaluate the role of pharmacists:

- (i) Site visits, observation, interviews with key informants, documentary review to describe the sites and identify the models of service delivery; (see section 5)
- (ii) Questionnaire survey of the service users at each site to obtain information on their characteristics, wellbeing and functional status, views on quality of care and self-reported utilisation of other health and social care services; (see section 6)
- (iii) Questionnaire survey of health care professionals working in the clozapine clinics
- (iv) Semi structured interviews to obtain views of staff about team configurations and roles;
- (v) Direct observation of service provision and interviews with users to obtain further insight into the patient experience.
- (vi) Record reviews to obtain further information about users and their service utilisation.

4.2 Economic evaluation

An economic evaluation was embedded in the study. This calculated the total and the average (per patient) costs of each clinic, and analysed the health and social care utilisation that was self-reported by participants in questionnaire returns.

Due to the diversity of the approaches, further details of the data collection and analysis are presented in conjunction with the findings.

4.3 Layout of results

This research used a mixed methods approach because the subject of interest was complex and it was felt that the research objectives could not be met by using one means of data collection

alone. In order to unravel how the clinics worked it was important to spend time observing and noting clinic processes in order to identify and describe the service delivery models. This is outlined in section 5. We then collected information from patients about how they felt physically and mentally at the time of completing the questionnaire and about their experiences of attending their clinic (section 6). This very factual information, however, only provided us with what the patients said actually happened to them in the clinics. To find out their feelings about what happened and to seek explanations for the results of the questionnaire we then spoke to patients and also followed them through a clinic visit making notes about the process and asking them how they felt about their consultations with HCPs. These results are shown in section 7. Finally, the picture would not have been complete without some input from the HCPs providing the care and services to patients. For this reason we asked staff how they felt about their jobs and the delivery of care to patients through both a questionnaire and face-to-face interviews (section 8).

5. Identification of the Service Delivery Models

Descriptive features (hours of operation, staffing, patient numbers, equipment) of the seven clinics in the study area were obtained from site visits, interviews and documentary review. These are summarised in table 1. The equipment present in each clinic was noted as the availability of the correct equipment to conduct specific clinical examinations and tests, may affect the quality of care provided to service users.

Table 1: The seven clozapine clinic sites and the two Clinic Models

CLINIC	Model 1 Clinics with Pharmacist Input			Model 2 Clinics without Pharmacist Input			
	1	2	3	4	5	6	7
Accommodation ¹	Dedicated	Shared	Shared	Shared	Shared	Shared	Shared
Clinic hours per week	3	2	2	3	2 hours per month	2	2
No. clozapine patients on list	62	45	18	21	12	20	11
No. patients attend per week	10	10-15	5	3-8	12	5-8	11
Doctor	Locum Psychiatrist	SHO, just takes blood	Locum Specialist Registrar	No routine medical support	No routine medical support	Staff grade Psychiatrist not routinely there	Staff grade Psychiatrist 30 minutes per month
Pharmacist	Clinical pharmacist	Senior mental health pharmacist	Clinical mental health pharmacist	No pharmacist in clinic	No pharmacist in clinic	No pharmacist in clinic	No pharmacist in clinic
Nurse	Band 7	No	CPN ²	Band 7	Band 7	Band 6 (CPN)	Band 6 (CPN)
Health Care Assistant	No	Yes	No	No	No	No	1 hour per week
Phlebotomist	Yes	No	No	No	No	No	No
Receptionist	No	2 Shared	1-2 Shared	2 Shared	1-2 Shared	1-2 Shared	1 Shared
Thermometer	Yes	Yes	Yes	No	Yes	Yes	Yes
BP machine	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Blood drawing kit	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near patient FBC testing kit	Yes	Yes	No	No	No	No	No
Weighing scales	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Electrocardiogram	No	No	No	No	No	No	No

Notes:

1. Shared clozapine clinic rooms means that they were used for other clinics at other times during the week
2. Community Psychiatric Nurses (n=10) rotate attendance

Two staffing models were identified. Clinics 1,2 and 3 had a doctor, pharmacist and nurse in attendance (Clinics with Pharmacist Input). Clinics 4, 5, 6 and 7 which were run by nurses did not have a doctor routinely present although a doctor could be contacted in cases of emergency. Patients attending the clozapine clinics for routine monitoring associated with clozapine also had regular hospital outpatient appointments with psychiatrists.

The number of clozapine patients registered at the clinics ranges from 11 in clinic 7 to 62 in 1. The clinics without a pharmacist tended to have smaller number of patients than clinics with pharmacist input (mean of 16 vs 42). All except clinic 1 (based in an abandoned office) shared their facilities, i.e. other patient groups were treated in them at other times of the week. All clinics opened weekly, except clinic 5 which was held once per month. The equipment available was similar across all clinics.

Blood samples were taken from patients at all clinics, but only the largest two clinics (1 and 2) had near patient testing technology (provides the results on site so that prescribing can proceed, or any problems can be picked up immediately). Near patient testing can reduce costs and offers advantages for the patients who do not have to return to collect medications on a separate occasion.⁽⁹⁾ For patients in the other five clinics, doctors reviewed the blood readings and issued prescriptions outside the clinic time (reported 3 minutes per test), when the results came back from the laboratory. The frequency of blood tests was clinically determined, but was usually every 2 weeks at first, extending to monthly after 12 months without problems.⁽¹⁰⁾

6. Results of the Patient Participant Questionnaire

Key findings from the patient participant questionnaire

1. **Participants in the clinics with a pharmacist reported no difference in health, wellbeing, self-efficacy and ability to manage their own health than clinics without pharmacist input.**
2. **Participants with higher scores of wellbeing were more likely to be satisfied with their clinic services (R= .34, p< .001, 95% CI= .19-.50)**
3. **The presence of co-morbid depression (R = -.43 , p< .01, 95% CI = -.73 to - .13) and use of recreational drugs (R = -.77, p<.05, 95% CI=-1.41 to – 0.13) were negatively correlated with wellbeing.**
4. **Clinics with a pharmacist were more expensive than clinics without. However, clinics with a pharmacist that had the highest patient throughput, had lower per patient costs because economies of scale could be realised.**
5. **Having a doctor at the clinic may reduce demands on outpatient psychiatric referrals and use of CPN services in the community, but this finding needs to be validated through further investigations. There was no difference in mean costs of service utilisation by clinic attendees across the two models**

6.1 Recruitment

Out of 185 clinic users, 66 agreed to take part in the first survey (Table 2) a response rate of 35%, range 11% (Clinic 3) to 70% (Clinic 6). The mean response rate at clinics without a pharmacist was higher than at the clinics with pharmacist input (44% vs 30%).

The patient recruitment process was slow and when the reasons for this were investigated feedback from clinic patients indicated that they may have some problems completing the questionnaire. For example some said that they were suspicious of unfamiliar documents, their concentration was poor, they had difficulty reading or felt completing the questionnaire could affect their clinic experience.

To help improve recruitment, when the research team visited each clinic site to collect descriptive data they made themselves available to support patient participants in completing their survey. As a result of this strategy recruitment rates increased sharply.

Informed written consent was always obtained. All interviews and the observation of patient participants' clinic journeys took place at the respective clinic site.

Table 2: Survey recruitment and response rates

Model	Clinic	Number of patients	Number of patients given questionnaires	Number responses	% of all patients responding
Pharmacist Input	1	62	62	17	27.4
	2	45	42	19	42.2
	3	18	18	2	11.1
Model total		125	122	38	30.4
No Pharmacist Input	4	21	21	8	38.1
	5	12	12	2	16.7
	6	20	20	14	70.0
	7	11	9	4	36.4
Model total		64	62	28	43.8
ALL		189	184	66	34.9

6.2 Results

The responses to the questionnaire were entered into SPSS (version 16) to generate descriptive, summary and inferential statistics. The table below shows the characteristics of participating patients and the comparison of clinic models. Although all of the results are summarised in this and the tables that follow only differences between participants and models that were statistically significant are discussed.

The statistical analyses were complicated by the fact that it was not possible to clearly identify the contribution of the pharmacist due to the presence of a doctor in all clinics with pharmacist input. Although the provision of care could be divided into two models – those with input from a pharmacist and those without, the clinics with a pharmacist also had the input from doctors whereas the clinics that had no formal pharmacist input were all run by nurses who, whilst they did not prescribe, took responsibility for some clinical aspects of patient care that might otherwise have been undertaken by doctors.

6.2.1 Comparison of clinic models: characteristics of service users

The data in table 3 show the characteristics of the patient participants in relation to the two models of service delivery.

Table 3: Characteristics of participating patients and comparison of clinic models

Variable	Units	Clinics with pharmacist input			Clinics without pharmacist input			Significance p *
		N	n	%	N	N	%	
Gender	Male	38	25	65.8	28	21	75	0.421
Ethnicity	White British	38	35	92.1	28	22	78.6	0.153 +
Education: age left full time education	<=16	37	19	51.3	28	15	53.6	0.673^
	17 - 18		7	18.9		7	25	
	Over 18		11	29.7		6	21.4	
Employment status	Full time	37	2	5.4	28	0	-	0.420
	Part time		6	16.2		2	7.14	
	Voluntary		7	13.5		4	14.3	
	Seeking		2	5.4		3	10.7	
Live alone	Yes	38	14	36.8	28	14	50	0.285
Live sheltered	Yes	36	8	22.2	28	2	7.14	0.165 +
Co-morbidities: self reports having:	Hypertension	38	10	26.3	28	2	7.14	0.046
	Coronary heart	38	3	7.9	28	0	-	0.256 +
	Diabetes	38	5	13.2	28	5	17.9	0.732+
	Asthma	38	7	18.4	28	6	21.4	0.761
	Alcohol/substance	38	8	21.1	28	1	3.6	0.067 +
	Depression	38	18	47.4	28	15	53.6	0.618
	Anxiety	38	20	52.6	28	12	42.9	0.432
	None	38	10	26.3	28	8	28.6	0.839
Weight change since clozapine	Increased	37	28	75.7	28	18	64.8	0.489^
	Stayed the same		5	13.5		7	25.0	
	Decreased		4	10.8		3	10.7	
Smoke	Yes	37	21	55.3	28	16	57.1	0.879
Recreational drugs	Yes	38	1	2.63	28	3	10.7	0.304+
Overweight / obese	BMI > 25	33	22	65.7	27	21	77.8	0.342
Exercise	< once per week	38	4	10.5	28	4	14.3	0.714+
Exceed weekly alcohol recommendations	Women:>14; Men: >21 units	38	3	7.9	27	5	18.5	0.260+
Sleep during day	Yes	38	16	42.1	28	11	39.3	0.818
Attendance: appointments	Number missed last 3 months	37	2	5.4	28	3	10.7	0.430^
Adherence: taking your clozapine	Ever vs never forget	38	12	31.6	28	11	39.3	0.600^
	Units	N	Mean	Std dev	N	Mean	Std dev	p*
Age	Years	38	44.92	12.428	28	38.71	11.065	0.040
Social support	1 (low) - 5	35	4.4	0.723	26	4.35	0.745	0.792
		N	Median	Range	N	Median	Range	p*
Years with mental illness	< 1y; 2-5y; 5-10y; 11-15y; >15y	38	11-15	<2-5 - >15	28	5-10	<2-5 - >15	0.102^
Years taking clozapine	1:<1y; 2:1-2y; 3:>2y	38	>2	<1 - >2	28	>2	1-2 - >2	0.642^
No of medicines including clozapine	1: 1; 2: 2 - 3; 3: 4 - 5; 4: >5	37	4-5	1- >5	28	4-5	1 - >5	0.411^

Key: *Chi square tests for categorical variables unless otherwise shown, i.e. + = Fishers Exact, ^Mann Whitney U.

The mean age of participants treated in the clinics with a pharmacist was significantly higher than that of patients in the clinics without pharmacist input that were nurse led ($p < 0.040$). This may be because the clinics with pharmacists had been established for longer and thus the patient population may have been older overall. However, the results show that there was no difference in the length of time patients attending any of the clinics had been taking clozapine so an alternative reason from the difference may be that that older patients are more likely to have co-morbidities and so attend clinics where there is a doctor present. When examining the results in terms of co-morbidities, it can be seen that a higher number of patients who attended clinics with pharmacist input reported having hypertension ($p < 0.046$).

6.2.2 Comparison of clinic models: quality of care

The reason for collecting data about participant characteristics was to allow a comparison to be made of the quality of care provided in the two models. For example, hypothetically, patients attending clinics with pharmacist input may report greater satisfaction with the clinic overall and this may be because there is a doctor present at each clinic visit. The implication of this might be that all clinics should have a doctor present in order to optimise patient satisfaction through improved quality of care. The table below shows the quality of care indicators that were measured by the questionnaire and that were used as comparators in the analyses.

Table 4: Comparison of clinic models by quality of care indicators

Variable	Units	Clinics with pharmacist input			Clinics without pharmacist input			Significance	
		N	Mean	Std dev	N	Mean	Std dev	P value	Test
WEMWBS (mean)	(Range 1 worst -5)	37	3.33	0.68	28	3.02	0.71	0.082	T test
Self-reported health	VAS: 1 - 10 (best)	38	7.43	2.060	27	6.43	1.974	0.052	T test
Self efficacy, mean of 3 scales (1 -10)	(Range 3 not - 30 totally confident)	38	6.75	2.20	28	5.85	2.13	0.097	T test
IADL 8 items mean	(Range 0-800best)	38	83.6	22.2	28	80.2	22.6	0.541	T test
VSSS-EU 16 item mean satisfaction	(Range 1 worst -5)	38	3.99	0.67	28	4.07	0.48	0.622	T test
VSSS-EU 3 item overall satisfaction mean	(Range 1 worst - 5)	38	4.06	0.69	28	4.23	0.58	0.309	T test
Waiting times in clinics	Minutes	38	32.37	24.62	28	12.59	11.29	0.0001	T test
Consultation times	Minutes	38	20.29	16.064	28	15.75	11.719	0.900	T test
			n	%		n	%		
Weight change since starting clozapine	Increased	37	28	75.7	28	18	64.8	0.489	ChiSq
	Stayed same		5	13.5		7	25		
	Decreased		4	10.8		3	10.7		
FBC	Tested vs`not	38	37	97.4	28	28	100	1.000	ChiSq
BP	Tested vs`not	38	38	100	28	27	96.4	0.424	ChiSq
Pulse	Tested vs`not	38	33	86.8	28	23	82.1	0.732	ChiSq
Weight	Tested vs`not	38	38	100	28	27	96.4	0.424	ChiSq
Temperature	Tested vs`not	38	35	92.1	28	19	67.9	0.021	ChiSq
ECG	Tested vs`not	38	31	81.6	27	14	51.9	0.015	ChiSq
Whether patients were asked about caffeine intake	Were not asked	38	33	86.8	28	22	78.6	0.373	ChiSq
			Median	Range		Median	Range	P value	
Appointment frequency ¹	Weekly/fortnightly/monthly	38	fortnightly	Weekly monthly	28	monthly	Weekly-monthly	0.008	M-W
Constipation	Range: Never - always suffer	38	sometimes	Never-always	28	sometimes	Never-always	0.398	M-W
Dribbling	Range: Never - always suffer	38	sometimes	Never-always	28	often	Never-always	0.037	M-W
Dry Mouth	Range: Never - always suffer	38	rarely	Never-always	27	never	Never-always	0.218	M-W

Key: M-W = Mann Whitney U test

Notes: 1. Clinic 5 (without pharmacist model) only opened once a month, whilst other clinics were weekly and this will influence the finding.

The table above shows those things that should be monitored in patients taking clozapine and would be expected to be provided by the clinic. Each of these aspects of care was examined in relation to the two models and although there were some significant differences between the two models causality cannot be ascertained as each clinic is individual.

Statistically significant differences were found between clinics with a pharmacist and clinics without in reported average waiting times (32 vs 13 minutes), appointment frequency (median fortnightly vs monthly, possibly reflecting the lower frequency of opening of Clinic 5), routine temperature taking vs not (92% vs 68%) and ECG testing vs not (82% vs 52%). Patients in clinics with pharmacist input were significantly more likely to report dribbling side effects. There was no significant difference between clinic models on the other quality of care variables (mean and overall satisfaction, consultation times, weight change, routine testing of FBC, BP, pulse and weight, reporting of constipation and dry mouth symptoms) (Table 4).

Clinical monitoring

People with schizophrenia have increased cardiovascular risk factors both modifiable and/or non-modifiable. People taking clozapine should be monitored regularly with blood tests, blood pressure, pulse, weight, temperature and electrocardiogram [ECG] to ensure the safety of the medication. Findings suggest that participants were not routinely receiving ECGs. In addition, participants at Clinic 4 reported not having their temperature taken which is corroborated by the research team's observations that some clinics did not have a thermometer to enable measurement of temperature. An increase in temperature may indicate that the patient has an infection which may be an early indication of agranulocytosis.

Caffeine Intake

Clinic staff monitored the levels of smoking (which decreases blood levels of clozapine) but did not measure intake of caffeine-related products (which increases plasma levels of clozapine). This is important to ensure the individual does not experience adverse effects when their caffeine drinking habits change. In terms of side effects, 74% of participants suffered with constipation but only 31% of these received a prescribed medication for it. A further 91% suffered with hypersalivation but only 25% of these were prescribed medication to alleviate this.

The Warwick-Edinburgh Mental Wellbeing Scale –WEMWBS (a measure of wellbeing)

Individuals attending Clinic 6 most frequently reported the lowest levels of wellbeing and those attending Clinic 4 most frequently reported the highest levels of wellbeing. When the two models were compared those individuals attending clinics with a pharmacist tended to report higher levels of wellbeing however this difference was not statistically significant.

The overall WEMWBS score correlated positively ($p < 0.001$) with clinic attendee satisfaction score with their clinic. This meant if clinic attendees perceived they were more satisfied with clinic services overall and that they received the information they needed, their wellbeing scores were higher. Increasing years of education correlated negatively with wellbeing ($p < 0.05$, which meant the more educated a person was the less satisfied they reported they were with their clinic services); as did a diagnosis of co-morbid depression and use of recreational drugs.

Mental wellbeing was found to be associated with the self-efficacy item 2 which asked patients to indicate their perceived ability to manage their own mental health condition so as to reduce their need to see a health care professional. The clinic model with a pharmacist was associated with the highest overall scores of patients' '*reported ability to manage their mental health condition*' and this was explored in the face-to-face interviews with patient participants.

Instrumental activities of daily living (IADL) - a proxy measure of mental status

The IADL was used as a proxy measure of mental status and was completed by participants at the beginning of the study to allow us to identify at baseline (questionnaire time one) whether the patients attending each clinic differed in terms of their mental status as this could potentially explain any differences in findings between the clinics. If patient populations were similar in terms of mental health status then that would give confidence that any differences in, for example, patient satisfaction will be more likely to be 'real' rather than a result of underlying differences in patient characteristics. No significant differences were observed in IADL scores between clinics.

As well as measuring the mental status of individuals who attended the clinics, this study sort to identify what factors (lifestyle, health etc), if any, were related to better mental status scores. Multiple regression modelling found that the overall IADL mean score (range 0 -100, 100 representing good mental status) was significantly associated with: whether the person lived alone (those who lived alone were likely to have lower mean IADL scores than those who did not); years of education (being in full time education to over 18 years of age had a positive effect on IADL); having a diagnosis of diabetes (negative impact on IADL); having a diagnosis of asthma (positive impact on IADL) (see Table 5).

The Verona Service Satisfaction Scale – European Version (VSSS-EU)

Participants were asked to rate their satisfaction with the access, efficacy, the information, the types of intervention, the professional skills and behaviour and their general satisfaction of the clinic they attended. Multiple regression modelling showed that user satisfaction (Verona Service Satisfaction Scale- EU) was predicted by two factors: waiting time in minutes, and whether the person had an ECG test done when they attended their clozapine clinic. Clinic model attended (clinics with pharmacist input vs clinics without pharmacist input) was not a significant predictor of satisfaction. The full list of variables included in the modelling and the results of the parsimonious model are shown in Table 5. For every extra minute a person waited to be seen, their satisfaction with the clinic lowered by 0.008 points on the VSSS-EU (range 1-5). Patients who reported receiving ECG tests scored 0.370 points higher than those patients who had not had an ECG test. This model explains 17.6% of the variability in VSSS-EU. Further investigation revealed a strong positive association between self-reported wellbeing and service satisfaction.

Table 5:

Results of a reduced form regression models* that explored associations between patient reported satisfaction and mental status (dependent variables) and patient characteristics and clinic attended (independent variables) n=66

Dependent variable	N R ²	Predictors	Fitted parameter	95% C I	P*
VSSS-EU (Clinic satisfaction)	N = 65 R ² = 0.176	Constant	3.974	3.690 to 4.258	0.001
		Clinic waiting time	-.008	-.014 to -.002	0.009
		Have ECG (yes)	.370	.075 to .665	0.015
IADL (Mental status) Mean Score	N = 65 R ² = 0.324	Constant	101.512	84.628 to 118.397	0.001
		Live alone (yes)	-15.110	-24.793 to -5.427	0.003
		Educated > 18 yrs	16.584	5.502 to 27.667	0.004
		Diabetes (yes)	-17.889	-31.396 to -4.382	0.01
		Asthma (yes)	14.540	2.179 to 26.900	0.022

*Independent variables included in the first stage model were: age; gender; ethnicity; waiting time at clozapine clinic; frequency of clozapine clinic appointments; length of time on clozapine; length of time with mental illness; whether or not tests and procedures performed (FBC, BP, pulse, weight, temperature, ECG), clinic staff monitor caffeine, report constipation/hypersalivation/dry mouth side effects, sleep during day; number of missed appointment over last 3 months; frequency of forgetting to take clozapine; having (or not) hypertension, CHD, diabetes, asthma, alcohol or substance dependence, depression, anxiety; number of medications per day including clozapine; caffeine units per day; alcohol units per week; recreational drug use; smoking status; live alone (or with others); accommodation (private or sheltered); home help; in employment; age of leaving full time education. Sample sizes are reduced by missing data in some models. R² values show the proportion of variability in the dependent variable that is explained by the model.

6.2.3 Economic Evaluation

Analysis of clozapine services in one large NHS Mental Health Trust identified two service delivery models amongst seven community clinics: clinics with pharmacist input and clinics without (see Table 1). The mean age of patients registered in clinics with pharmacist input was higher than that of the patients seen at the clinics without pharmacist input, and they tended to report better health,

wellbeing and self-efficacy, but there were few other significant differences in the characteristics of the patients treated in the two types of clinic.

Clinics with a pharmacist tended to have larger patient loads than those clinics without pharmacist input (mean 42 vs 16), but there was considerable variability within models. The total costs of running clinics with a pharmacist that included input from other health care professionals (e.g. doctor, nurse, phlebotomist) was higher than that of clinics without pharmacist input that were mainly run by nurses, reflecting the expense of the larger team and more highly trained professionals in that model. The average cost per patient varied widely across clinics (£80 - £ 750) with economies of scale being realised by clinics serving larger numbers of patients.

Utilisation and cost of health and social services was similar in both models, except that patients in the clinics without pharmacist input reported significantly more use of community psychiatric nurses (outside the clozapine clinic). The reason for this is not known, but may reflect the referring practices of the nurses running the clozapine clinics. In addition, there was a tendency for patients in the clinics with pharmacist input to report less outpatient visits to psychiatrists, so it is possible that access to the doctor in the clozapine clinic substituted to some extent for specialist care. Patients attending clinics, at which pharmacists were present, reported similar access to pharmacists outside the clinic as patients who attended the clinics without pharmacist input.

6.2.4 Follow-up Questionnaire

The follow-up survey used a shorter questionnaire and was aimed at exploring the major patient-related outcomes of mental status, mental wellbeing, and satisfaction. The second questionnaire also included questions to explore what participants felt were the 'value added' aspects of having a pharmacist available to talk to. Each of the 66 initial respondents was sent a follow-up questionnaire approximately 3 months after their initial input. Of these, 31 completed questionnaires were returned (47% response rate).

A repeated measures ANOVA was carried out to test for changes in reports of satisfaction, wellbeing and mental status over time. No changes were observed between baseline and follow-up scores on the mental status (IADL) or wellbeing (WEMWBS) measures. However, when comparing the mean scores for the two questionnaires, participants' satisfaction with access to clozapine services (one of the things measured using the VSSS-EU) declined significantly over time ($F(1,27) = 5.08, p < 0.05$).

Value-added aspects of having a pharmacist available

Participants were asked whether there was a pharmacist at the clinic they attended and if so whether they saw them regularly and why. They were also asked whether they felt there were any benefits in seeing the pharmacist. Participants attending a clinic without a pharmacist were asked if they would like to see a pharmacist and if so why or why not.

The quotes below are taken from the hand written narratives that participants entered on their questionnaire.

Participants who said they would like to see a pharmacist in their clinic gave their reasons as: *"To talk to them about clozapine levels and dosage reduction"* (Patient 10); *"To answer questions about dosage/weight correlation.....questions about effective levels."* (Patient 11) and *"To know what my meds and explain side effects are"* (Patient 49)

One patient said they would not want to see a pharmacist because *"I currently have nothing to ask, my CPN is able to give good answers and I am happy with that"* (Patient 22).

Patients who attended a clinic with a pharmacist were asked whether they would like to see the pharmacist regularly and responses were mixed with one patient saying they would like more information about getting their medication changes. This patient only saw the pharmacist to collect their medication. Another patient said there was no need to see the pharmacist as they saw the doctor.

7. Findings from the in-depth tracking study

Key findings from the patient participant observation and face-to-face interviews

1. Communications within consultations were generally not patient-focussed and therefore did not elicit the problems individual patients had.
2. Privacy of consultations was often compromised.
3. Long waiting times were associated with reduced patient satisfaction.
4. The clozapine clinics' purpose and value were experienced differently by patient participants
5. Clozapine produced improved mental status for many which outweighed associated side effects that were experienced
6. Benefits included a sense of self and return of engagement with enjoyable social relationships and employment
7. Institutionalisation of clinic services provided impacted negatively on participants, who perceived that no-one was listening to their concerns

7.1 Process

The in-depth tracking study followed a patient participant's journey through their usual clinic attendance. The number of healthcare professionals seen at each visit varied and could include nurse, doctor, pharmacist, phlebotomist and/or healthcare assistant. A member of the research team entered the clinic with the participant and then timed and observed all activities. After each interaction with a healthcare professional (HCP) the patient participant was asked to rate their satisfaction with the consultation using a Consultation Satisfaction Tool which had 19 items.⁽¹¹⁾ These included statements such as *'this HCP was interested in me as a person, not just my illness'* and *'this HCP talked to me about my concerns.'*

While the consultation was taking place the researcher observed the behaviours of the HCP and the interactions with the participant in relation to communication skills and shared decision-making. This used a standardised observation tool incorporating 19 different communication behaviours. The patient participant was then given the option of taking part in an interview to explore their thoughts and feelings further on the services provided by the clinic.

7.2 Recruitment

In total 10 people consented to have their clinic visit observed and 9 consented to be interviewed. The consultation satisfaction and observation tools were scored according to published guidance and the interviews were transcribed verbatim and analysed using Interpretative Phenomenological Analysis.^(12, 13)

7.3 Results from consultation observations

The Consultation Satisfaction Tool asked participants to score their satisfaction with each HCP consultation using a scale where 1 = strongly agree, 3 = neutral and 5 = strongly disagree. The types of behaviours HCPs were rated on included whether they asked participants for their opinions about their treatment, whether the participant felt the HCP listened to them and talked to them about their concerns. The research team member observing the consultation also scored the HCP on their consultation skills. The skills scored by the researcher matched those that patient participants used to rate their satisfaction.

7.3.1 Consultation and communication skills

In terms of the most favourable behaviours (indicated by lower values), doctors scored favourably in 12 of the 19 areas, with nurses and pharmacists equal in 4 of 19 and phlebotomists 2 of the 19. Pharmacists demonstrated the least favourable consultation behaviours in 8 of the 19 areas, with nurses in 5 and doctors and phlebotomists in 4 of the 19. However when the scores across all 19 domains were averaged the findings demonstrated with greater clarity the participants' perception of the HCP communication skills within a consultation (Table 6).

Table 6: Participant satisfaction with Healthcare Professional Consultation Styles

Healthcare professional	Average Score (across 19 domains)	Range
Doctors	2.6	1.7 to 4
Nurses	2.7	1.4 to 4
Phlebotomists	2.8	1.8 to 4.3
Pharmacists	3.2	2 to 4.3

Lack of privacy for the patient was a key concern. It was observed that neither phlebotomists nor nurses closed the door to the consulting room to maintain privacy and confidentiality.

7.3.2 Researcher observations of consultations

Communication behaviours were marked from a score of 0 = not observed to 4 = observed and of a high standard. The scoring indicated that nurses seemed able to greet the participant well and elicit the problem the individual wanted help with. However although they scored highest in asking people what further information they needed to help with the problem, scores were low overall and ranged from 0.9 to 1.5. This indicates a low level of competency in this area for all the health care professionals working at these clinics.

Scores exploring professional behaviours involved with identifying and addressing problems which were important to the patient, ranged from 1.3 to 3.3 indicating a minimal to good display of the behaviour. Scores associated with shared decision-making ranged from 0.5 to 3.4, being very minimal to a good standard.

Waiting times ranged from zero to 150 minutes, with one doctor arriving two hours late for the clinic session. The duration of consultations ranged from 2 (with a phlebotomist) to 30 minutes (with a doctor) with the average being 8 minutes.

When the 19 behavioural scores were averaged for each professional group, doctors (average 2.5 range 0.9 to 3.9) and phlebotomists (2.5 range 0 to 4) scored equally, as did nurses (2.0 range 0.6 to 4) and pharmacists (2.0 range 0 to 4).

7.4 Results from patient participant interviews

Four key themes arose from the narratives of the patient participants. These were: clozapine clinics themselves, clozapine the medicine, sense of self and institutionalisation. The participants in the in-depth tracking exercise shared their experience of taking clozapine and attending a clozapine clinic regularly. Each associated theme seemed to have both negative and positive aspects for individual participants. Quotes are given below as examples of typical responses received from patient participants.

The clozapine clinics

The clinics were the place they had to attend in order to continue on clozapine. For some, each time they came to the clinic it reminded them they were seriously ill,

“it’s because this is like a reminder of being ill coming here yeah and yeah that is what it is you know that’s perhaps the biggest issue as a reminder of how things used to be you know.”

Patient Participant 10

For others it was a place in which they felt safe.

“Yeah oh this place has been an absolute godsend to me, absolute fantastic, I have been in other units Clinic X, Unit X, but this just beats them all, the staff are fantastic, my CPN is, I just can’t fault it.”
Patient Participant 4

Clozapine the medicine

Although clozapine is associated with many side effects and there is a need for regular blood tests, participants felt that on balance, it was a medicine they needed to keep taking. This patient could cope with the side effects because they were taking control.

“I started off, I mean all of the side effects you normally get saliva, dizziness, blurred vision but at the end of the day it was taking control of my symptoms so I always thought well I am not worried about the err side effects.”
Patient Participant 4

People attending clinics without a pharmacist found it difficult to get the treatment for their side effects dealt with whilst they were at their routine clinic appointment. Sometimes the nurse would have to ask the doctor to write a prescription and if there was no doctor on site this could take time.

“Well you know sometimes I’m kind of like, I get side effects so I have needed procyclidine but I come to NURSE X and I’ve said ‘look I need some procyclidine’ and I can’t get it there and then it has to, you know and NURSE X is helpful and NURSE X said I’ll see the doctor in a couple of days but you know it would be nice to sort the tablets you know.”
Patient Participant 10

Sense of self

Several participants talked about the side effects of this medicine but expressed views that treatment could be improved and suggested there was perhaps insufficient awareness hereof.

“You know if only the people who invent this stuff tried it themselves and they would think ‘oh this isn’t ideal, we can do better.’”
Patient Participant 5

On the other hand some patients recognised that there were beneficial effects including a renewed recognition of the ability to take care of themselves.

“I feel as fit now as I could possibly feel I have got no queries or anything, I eat well I have got a good appetite I go out to the gym and exercise and I feel very capable in every way.”
Patient Participant 16

Institutionalisation

Participants realised that there were more aspects to their wellbeing and quality of life than just clozapine and the mandatory requirements to attend a clozapine clinic in order to access it. They spoke of the need to be listened to and to receive a holistic approach to treatment which included medication, talking therapies at an advanced level and continuity of care by someone who was sensitive to their needs.

“Don’t get me wrong but sometimes I think what is going on up here (pointing to head), I need to see someone like you know psychiatrist, psychologist to deal with the issues going on in my mind you know.”
Patient Participant 4

I’m not asking them anymore I’ve asked them so many times over the years so many times it just don’t interest them, “the question about the suffering” I won’t ask them again they’re [pause] a waste of time.”
Patient Participant 3

If a healthcare professional cared about the patient this was recognized in their behaviour and stood out as being the exception.

"[Doctor X] is very good because she remembers you know, individual points about a patient and asks relevant questions and umm she is probably the best Doctor I have ever seen actually...It does (matter) because psychiatric services are the poor relation of health service and this particular Doctor [Doctor X] cares."

Patient Participant 5

There may be a perceived biomedical viewpoint that receiving a medication and attending a clinic is the complete answer to a serious illness, as suggested by comments from patient participant 3 below:

"Oh it's all these things that sort of are a part of my life that you know it's not like 'oh I come to the clinic, I take tablets' and everything is either really marvellous or you know."

8. Results from the healthcare professionals' questionnaire and interviews

Key findings from the healthcare professional's survey and face-to-face interviews

1. No significant differences in scores for job satisfaction or organisational climate for staff from clinics with or without a pharmacist
2. More than half of all staff reported that continuity of care was a barrier to care provision
3. 43% of all staff felt that their knowledge and skills were greater than those required to do their job
4. Care delivery for many patients was not individualised
5. There was confusion and disagreement about the skill mix required within the clinics
6. There was little understanding of the notion of a 'recovery model'
7. Pharmacists were reluctant to use their prescribing skills to the full

8.1 Questionnaire results

8.1.1 Response rates

In total 48 staff were approached to take part in the healthcare professional survey and 23 responded. Of these 18 were permanent members of staff who worked at the clozapine clinics each week; 14 returned a completed questionnaire. The remaining 30 members of staff (9 of whom returned a completed questionnaire) had other roles. These included individuals who helped run the clozapine services when permanent members of staff were on leave, managerial staff, members of medical staff who prescribed clozapine and/or whose patients attended the clozapine services. In order to improve response rates to the HCP survey, the questionnaire was shortened. Items relating to caseload, co-worker satisfaction, and hours of working were removed. Since there was some missing data from the later participants, results reported below include the appropriate total number of respondents who answered that particular item.

8.1.2 Job and co-worker satisfaction

There were no significant differences between the responses from staff in the two models of care for job satisfaction, but within the individual items there were interesting results. Eight out of 16

respondents who were asked about levels of friction in their organisation said there was either a great deal or some friction. When this was broken down into the two clinic models 5 out of 7 staff in clinics without a pharmacist reported friction compared to 3 out of 9 in clinics with a pharmacist. There were also interesting differences in the ways that the patient consultations were carried out.

8.1.3 Tasks performed at clozapine clinics

Respondents who conducted patient consultations (18 out of 23 of the HCPs who completed the questionnaire) were asked whether they asked patients about the following issues detailed in Table 7:

Table 7: Questions asked during the consultation

Patient asked about	Clinics with pharmacist input (n=9)				Clinics without a Pharmacist (n=9)			
	Yes	Yes and record in notes	No	N/A	Yes	Yes and record in notes	No	N/A
Symptom change	2	4	0	3	1	7	0	1
Side effects	1	5	0	3	2	6	0	1
Accommodation	1	3	2	3	3	4	1	1
Employment	2	4	0	3	3	5	0	1
Involvement in education or training	2	4	0	3	3	5	0	1
Family and social life	2	3	1	3	3	5	0	1

Note: Totals unequal where task not performed.

As can be seen in table 7 more staff in clinics without a pharmacist reported asking about these issues and recording them in the patients' notes. Table 8 below shows the actual numbers of pharmacists, nurses and doctors who reported asking these questions.

Table 8: Questions asked during consultation, comparing the different health care professionals

Patient asked about	Pharmacists (n=3)				Nurses (n=4)				Doctors (n=5)			
	Yes	Yes and record in notes	No	N/A	Yes	Yes and record in notes	No	N/A	Yes	Yes and record in notes	No	N/A
Symptom change	0	2	0	1	0	4	0	0	1	4	0	0
Side effects		2	0	1	0	4	0	0	2	3	0	0
Accommodation	1	1	0	1	0	4	0	0	3	0	2	0
Employment	1	1	0	1	0	4	0	0	3	2	0	0
Involvement in education or training	1	1	0	1	0	4	0	0	3	2	0	0
Family and social life	0	2	0	1	0	4	0	0		3	1	1

Although the numbers are small, from Table 8 pharmacists appear to ask patients less often regarding medicine-related issues as well as other aspects relevant to successful recovery from schizophrenia than other HCPs do.

In this phase of the research we identified service items that the healthcare professionals involved said they either did or were done by colleagues as part of clozapine monitoring. These have been

summarised in Table 9 below in three categories. These highlight the areas of care that the HCPs feel are important in the monitoring process and will be discussed in section 9.

Table 9: Identified service items

Clinical Examination Skills	Advisory and Communication Skills	Prescribing Skills
<ul style="list-style-type: none"> - Take bloods - Interpret blood results - Take blood pressure and/or pulse - Take temperature - Measure weight - Conduct ECG - Conduct Mental state exam 	<ul style="list-style-type: none"> - Advise on medication - Advise on control of symptoms of schizophrenia - Advise on side effects management - Advise on prevention of adverse drug reactions - Advise on smoking cessation - Advise on lifestyle and cardiovascular risk - Advise on reducing diabetic risk 	<ul style="list-style-type: none"> -Prescribe other medicines -Prescribe clozapine -Make home visits

8.2 Interview results

8.2.1 The philosophy of care delivery to service users

A philosophy of care refers to a concept of care which underpins an organisation’s service delivery. It helps provide focus for the organisation and individuals and teams of HCPs to promote a particular philosophy with which they present and deliver their care to individuals using the service. For example the New Horizons document sets out a vision of mental wellbeing for all to help improve recovery and re-integration into communities for all people.⁽¹⁴⁾ Throughout this phase of the research the researchers were looking for evidence of the philosophy of care in place in the organisation.

The quote from this nurse illustrates the underlying ethos. She was asked whether she felt the patients were satisfied with the care they received.

“I’ve never asked them that question and I think those that we have that come to clinic now are for whatever reason - whether it’s the fact that they’ve been improved mentally because I always think that people that are not satisfied with the service they wouldn’t come to it and they wouldn’t take the medication, the fact that they’re turning up regularly and we haven’t got to chase them for any reason..... but I would say they’ve never said that they’re not, we’ve had clients in the past who have voiced that but that was an indication of their mental state not being very stable rather than they didn’t like the actual service the clinic was providing that was more to do with an indication of their mental state. So I think they are I’ve never actually asked them just presumed the fact that they turn up all the time it indicates that they are”.

Nurse 13

8.2.2 Management of services to service users

The NHS has faced spending cuts and financial constraints which place an added burden on staff and resources that are already reported by staff to be over stretched. A number of participants talked about how there seemed to be no specific funding for the clozapine clinics and if there was, then no-one knew who held the budget and how much was in it. There was a sense of resignation that this was the way things were but in contrast, this nurse raised the important issue of being able to find ways of working within the financial constraints to provide the best service possible:

“I’ve got no funding I’ve got no budget so anything I want is a case of sort of asking for it and see if it happens, there’s no special budget to fund anything so it’s just a case of what I can do time-wise I’m on my own.... it’s trying to find ways with the constraints you’ve got to change it. But yeah on the whole things have got a hell of a lot better than they used to be”.

Nurse 8

8.2.3 Integrating pharmacist input into services

All of the pharmacists who had regular roles in the clinic were trained as non-medical prescribers and whilst they were happy to prescribe for the side effects of clozapine they were not willing to take responsibility for the prescribing of clozapine itself.

“I’m actually an independent prescriber now but umm for the past couple of years I’ve been supplementary prescribing umm just for the side-effects of medication so if they’ve got just things they might not ask the doctor. Yeah the patients often won’t tell the doctor that they’ve got something like constipation cause they don’t think it’s part of their illness, they don’t realise it’s linked [pause] to their medication but they will they will mention it to me so I’ve been prescribing for their side-effects”. Pharmacist 7

When this pharmacist was asked about their reluctance to prescribe clozapine the response was,

“I think I prefer not to do it at the time right now umm because I don’t actually talk to the patients about their mental state and they have always got access to the doctor and to be honest I don’t think I want that responsibility”. Pharmacist 7

One pharmacist spoke of how the service could be improved through better use of her skills as a prescriber:

“With the increasing numbers as well and you know I would like to interview patients as well obviously with my supplementary prescribing I could have more time with the patients as well so that would be really good [pause] umm you know sometimes they are just coming in and out quickly and yeah you could give them a better service but you know it’s the NHS [laughs]”. Pharmacist 5

The picture that emerges from the interviews with HCPs is predominantly one of a lack of overall organisation and leadership of the clinics. The result of this seems to be that the HCPs were trying to do their best with the resources they had within the service models that had developed, but were failing to see the effect this was having on patient care. There was some perception of the skill mix that is required to run a clozapine clinic but the individuals providing care did not seem to be working as a team.

“So I suppose you need someone to be able to take bloods, you need someone to be able to do mental state examinations and you need somebody who can prescribe and I suppose in this day ‘n’ age where you are blurring the boundaries between who can do that it is difficult to say, you know you just need people in those roles”. Doctor 2

The above quotation from the doctor sets out some of roles that they felt were an integral part of providing effective care but also indicates that the roles of staff may not be well defined. In spite of this participants reported that they were generally happy with their jobs and enjoyed their work in the clinics, although some perceived their caseload was too high. As far as the pharmacist’s role is concerned they seem to have taken on their roles in the clinics in an *ad hoc* way – taking on tasks simply because no-one else wanted to do them. For those who trained as independent prescribers there was little evidence that they were using this training to the full.

9. Discussion

This study highlights opportunities for improvement in clozapine services provided to patients with treatment resistant schizophrenia. In particular, in view of our original study aim of identifying the pharmacists’ role and opportunities to expand this role, it is clear both from the self-reported health care professionals’ behaviour and from patient questionnaires that the pharmacists’ role at present is unclear to patients, is underused in the view of some pharmacists, and more

responsibilities could be transferred to pharmacists in the clinic. A more detailed description of the study implications is provided below.

9.1 Identification and description of alternative service models

Although we were able to identify two models for the delivery of clozapine services the combination of staff in the clinics with a pharmacist made it impossible to identify the contribution made by pharmacists.

None of the clinics in this study were pharmacist-led; the smaller clinics were all run by nurses and had no pharmacist present whereas in the larger clinics it was assumed that physicians took the lead. However, this was not clear as none of the members of staff we spoke to knew who had overall responsibility for the clinics. Dispensing of medicines took place at the central pharmacy for the Trust and medicines were then sent to each clinic for collection by patients. In the clinics where a pharmacist was present they gave out the medication. There were differences between the clinics observed. Patient participants at the clinics without pharmacists were younger, reported slightly better wellbeing and self-efficacy than those in the larger clinics, but apart from that patient populations appeared to be reasonably comparable,

Pharmacists who participated in the study were pharmacist-prescribers who either did not prescribe at all (n=3) or in their prescribing they focused on pharmacological management of clozapine-related side effects such as constipation (n=3). Pharmacist participants were reluctant to prescribe clozapine themselves.

9.2 Different models of care and their association with experiences and outcomes of service users

Regression modeling of patient wellbeing, instrumental activities of daily living, compliance and self-efficacy revealed a number of patient characteristics that were significantly associated with these indicators of functionality, but whether clinics were nurse led or not, or had a pharmacist present or not, was not a relevant factor. People receiving clozapine for TRS receive interventions from a variety of different agencies as well as their social support networks and it would be difficult to identify how one element of care affected outcomes.⁽¹⁵⁾ Comparisons of clinics with a pharmacist and those without using a range of variables chosen to reflect quality of care, suggested that patients waited less time in the smaller clinics that were run by nurses, but that they were less likely to have some of the recommended routine tests taken (temperature and ECG). It is unclear whether these patients had their ECG taken elsewhere. As the patients attending clinics with a pharmacist received care from a doctor too it was not possible to distinguish between the role of the pharmacist and that of the physician when attributing these differences observed.

9.2.1 Patient satisfaction

Clinics with a pharmacist received the highest score for perceived efficacy of the clinic and the types of intervention offered. However, clinics without pharmacist input scored highest for satisfaction in the other 4 domains (satisfaction with information provided, satisfaction with access to the clozapine clinic, general satisfaction with the clozapine clinic and professional skills and behaviour). This may be because the clinics without a pharmacist were run by nurses and patients were treated by the same person at each visit. It is suggested that professional skills and behaviours were more easily perceived by patients as they were dealing with one person rather than a team. In the clinics without pharmacist input, where nurses took the lead, patients had greater opportunity to build a relationship with their care provider. The fact that clinics with a pharmacist scored more highly in satisfaction with efficacy of the clinic and type of intervention offered may be because the team approach adopted in those clinics provides patients with care from a number of HCPs. No evidence was found that this increase in satisfaction was due to the input from the pharmacist.

Findings from the face to face interviews with patients indicate that some patients were happy to take their medication and attend the clinics regularly as this meant that they stayed well. This in

itself is an indicator that for some patients at least clozapine was providing them with a sense of self and ability to live a more independent life.

9.2.2 Mental wellbeing

It might be suggested that improved functioning and quality of life are related to a sense of mental wellbeing. Participants attending clinics that had pharmacist input tended to report higher levels of wellbeing but again, these clinics also had input from a number of other healthcare professionals including doctors. Thus, the increase in wellbeing cannot be attributed to the pharmacists alone but may be a result of the team approach to care delivery in these clinics. When patients were asked about the contribution of the pharmacist (see section 6.2.4) their comments were mixed. Some were aware that the pharmacist was able to answer questions about their medication. Others did not feel there was any additional benefit and that their CPN provided for all aspects of their care. The fact that patients relate pharmacists with medication only indicates that in this setting the pharmacists are not taking advantage of their extra training in clinical skills.

The presence of co-morbid depression and the use of recreational drugs correlated negatively with mental wellbeing. Depression is common in people with a chronic illness of which schizophrenia is one and can occur in up to 50% of patients. It is unclear from these findings whether the co-morbid depression was actually being treated but it is accepted that untreated depression results in poorer physical and mental health outcomes than those people without it. ⁽⁸⁵⁾

9.2.3 Physical wellbeing

Maintaining health means maintaining appropriate individual blood levels of clozapine. Clinic staff were monitoring the levels of cigarette smoking which is known to decrease blood levels of clozapine but were not monitoring intake of caffeine related products which increase plasma levels of clozapine. These results indicate that better training in the monitoring of patients taking clozapine is required to maintain physical wellbeing as the apparent lack of awareness of the importance of this issue could result in harm to the patient.

The reduction of cardiovascular and diabetes risks are a key concern in the treatment of schizophrenia. The clinics were monitoring the physical elements of these risk factors such as weight, blood pressure and blood tests for glucose and lipids, which were completed on a regular basis. Although staff were making every attempt to monitor the health of the patients during observations of the patients' journeys the researchers noted that essential equipment was not always available. In particular in one of the clinics where care was provided by a nurse there was no thermometer available to take measure body temperature. Ensuring that all necessary equipment is available must in part be the responsibility of the staff carrying out the clinical checks. However, in the interviews with staff they spoke of the lack of a specific budget for the clozapine clinics and that none of the staff knew who in the organisation was responsible for this.

9.3 The roles, responsibilities and factors affecting service provision by pharmacists

People attending clinics with a pharmacist tended to report better health, wellbeing and self-efficacy, but there were few other significant differences in the participant characteristics. Participant utilisation and related cost of health and social services was similar in both models, except that participants attending clinics without a pharmacist reported significantly more use of community psychiatric nurses (outside the clozapine clinic). The reason for this is not known, but may reflect the referring practices of the professionals running these clinics. There was a tendency for participants in clinics with a pharmacist to report less outpatient visits to psychiatrists, so it is probable that easier access to the doctor in this clinic model substituted to some extent for routine specialist care.

The fact that the patients in clinics without pharmacists had fewer clinical tests and a greater incidence of the side effect of hypersalivation does not provide evidence that pharmacist input in

those clinics would make a difference to the results. What it does do is indicate an area where pharmacists with a specialist prescribing qualification could be expanding their role.

Each of the pharmacists in our study played a different role at the clinic they attended and since there was no clear job or role description for their input they did the tasks that they felt most comfortable with. From the results of the face-to-face interviews with HCPs it can be seen that although pharmacists would prescribe for side effects they did not want to prescribe for clozapine. One pharmacist said that this was because they did not want to take the responsibility for prescribing in this area. It might be suggested that the main reason for being a non-medical prescriber at a clozapine clinic is to do the prescribing and not self-selected parts of that role. All prescribers must work within their levels of competence and confidence but in this situation it seemed there was no training in place to ensure non-medical prescribers increased their confidence and competence in a structured and mentored fashion. Training needs should be identified by the individual as a part of their continuing professional development and the appropriate learning undertaken. It seems also that the professional responsibilities and accountability of each role within the clinic need to be outlined clearly in order to clarify any misconceptions about the prescribing of clozapine and to increase the confidence of pharmacist prescribers in prescribing clozapine. This has implications for the management of the clozapine services and clearly defined roles and responsibilities should be agreed with input from the staff working in the clinics. The service items defined in Table 9 combined with the opinions of clinicians (such as those reported in 8.2.3) should be a starting point for the improvement in services.

9.4 The potential ‘added value’ of pharmacists

Although we are unable to identify any added value of pharmacists in terms of cost due to the team approach employed in these clinics, we are able to suggest added value based on the results of patients’ and healthcare professionals’ narratives and on the tasks reported to have been performed in the clinics (Table 9).

In any role, the success or ‘added value’ of a pharmacist will be a balance of supporting professional skill mix, the venue and timing of the service delivery and a personal balance of professional responsibility and the requirements of the role (job) description.

In section 8.1.3 we identified the tasks being carried out by staff in the clinics. Based on the service items identified in Table 9 there are a number of areas where it is proposed that pharmacists could contribute further to the care of patients. These are shown in Table 10.

Table 10: Potential added value roles for pharmacists

The Added Value Roles
<ul style="list-style-type: none">- Contribute to the identification of new or changing symptoms which may have implications for patients’ mental state.- Recognition of the signs and symptoms of possible relapse,- Provide clarification of medicines management advice- Recognition of non-compliance with medication,- Proficiency in medicines management related issues,- As part of the consultation consider debt, accommodation, relationship or social problems (as these may affect patients’ ability to function and feel safe)- Follow-up of clinic non-attendees, and- Recording attendee status on their previous visit so a comparison could be made. (important for continuity of care)

9.5 The resource implications and costs of the alternative service delivery approaches

Regarding the economic analysis, the overall conclusions were that team configurations and patient throughput affect average (per patient) costs, and that having a doctor in the clinic may reduce demands on outpatient psychiatric referrals and use of CPN services in the community, but this finding needs to be validated through further investigations.

9.6 Philosophy of care

During the face-to-face interviews with staff participants were asked whether they felt that patients were satisfied with the care they received. One nurse suggested that if patients did complain then this was more an indication that their mental state was deteriorating than of any real understanding of their situation (see section 8.2.1).

The consultation observations suggested that the healthcare professionals seemed to be largely focussed on completing physical examinations and gathering information relevant to their regular clinic tasks. These physical checks were, of course, essential but some patients' concerns about social or welfare issues were overlooked.

As this study progressed it became apparent that there was no real philosophy of care underpinning service delivery. Without an understanding of the philosophy of care, staff cannot work together to achieve common goals that are embedded in that philosophy. Although such a philosophy should originate at the top with those responsible for service design, planning and delivery it should never be a one way process. Listening to the staff and patients' views and identifying concerns from both must be fed back up to senior level. If a philosophy of care is to be developed and implemented, staff must be trained to work within its framework and then to put that training into action to provide optimum benefits to patients. The majority of staff interviewed for this study wanted to do the best they could within the resources they had but that very lack of resources and their seeming inability to ask for more, was preventing them from improving the service they gave.

10. Study Limitations

The data used in the study were taken from the responses of patients to a single cross sectional questionnaire. The response rate was 35% and it is not known how representative the sample is of the whole population of patients attending the clozapine clinics in this study. This lower than expected response rate may have been due in part to the complexity of the survey tool and because of this some respondents were assisted in completing their questionnaires by the study researcher who attended clinics, and the quality of the data is believed to be high.

The relatively small sample sizes may have prevented differences between service delivery models from reaching significance, and a larger study would be required to ascertain if there is a clinic effect. Moreover, a longitudinal design is needed to capture outcomes from specific interventions. Even so, evaluations of complex systems of care, as in the mental healthcare delivery, are notoriously problematical.⁽¹⁶⁾

Due to the complexity of healthcare delivery in the models under study we have not been able to isolate and identify the value-added nature of adding a pharmacist to a clinic. Their contribution may be in the more effective use of medicines and the faster recognition and treatment of clozapine-related side effects, but this study was unable to find evidence of this. During this study the healthcare Trust involved was re-structured. Buildings (including clozapine clinics) were closed and services moved. To complicate things further the contract for the purchase of clozapine was changed during this study to another pharmaceutical company and associated monitoring processes and staff training required updating.

11. Implications for Delivery of Clozapine Services

The findings suggest that there is scope to review the team configurations needed to deliver community clozapine services in a cost-effective manner. The role and responsibilities held by doctors in some clinics are filled by nurses in other clinics where the patient characteristics are largely similar, and with minimal impact on quality of care (as perceived by users). Pharmacists in the study area played a supporting role to doctors, but might be able and willing to assume greater responsibility if working with individual patients at their pharmacies, or in clinic settings in tandem with nurses. Patients receiving clozapine monitoring and medication in community clinics continue to be reviewed by their hospital consultant on a regular basis, and the optimal means of organising care for this vulnerable patient group needs to be considered in the context of an overall integrated service that will allocate scarce resources effectively to maximise value-for-money. Evidence from this study suggests that access to doctors in medicines monitoring clinics may reduce demands on outpatient psychiatric referrals and use of CPN services in the community, and this finding needs to be validated through further investigations.

Further research to identify the optimal service delivery arrangements and skill mix for community clozapine services should include consideration of the role that pharmacists might play, within multi-disciplinary team configurations, in the monitoring of patients and prescribing and distribution of medication. One delivery model which could be investigated further for its suitability for TRS, is the 'hub and spoke' model described by Lee *et al* for emergency psychiatric services.⁽¹⁷⁾ This model has the 'hub' or central clinician (e.g. the psychiatrist with / without a nurse or pharmacist prescriber) linking to the 'spokes' which provide care and support (e.g. CMHTs and GPs). These alternative service delivery models should be based around the competencies and practice of community pharmacists, and other team members, with studies investigating the feasibility and acceptability of these arrangements to service commissioners, providers and users. The next stage would be to use robust research methods (such as a randomised controlled trial) to evaluate the effectiveness and cost – effectiveness of alternative models, and the independent contribution of pharmacists. Such studies should incorporate consideration of the optimal clinic size that will balance high quality, patient-centred care with the realisation of economies of scale and scope. In addition these studies should consider the overall impact of providing regular access to medical professionals in routine clozapine monitoring clinics on referrals to secondary care, use of community services, relapses, and costs.

12. Recommendations for practice

A summary of the recommendations for practice is given below.

Recommendations for Practice

1. The Philosophy of Care Delivery to Service Users

A philosophy of care should be implemented that places patient well-being and an individualised approach to care at the core of clozapine provision.

2. Management of Services to Service Users

Management structures should be clarified and include a budgetary framework, aims and objective and measurable outcomes of the service intervention. Each member of the team needs a clear role with transparent managerial links; appropriate training and equipment to deliver the aims of the service and clinical supervision.

3. Integrating Pharmacist Input to these Services

Consideration should be given to the better integration of pharmacy services and the use of pharmacists' expert skills and training.

4. Models for Delivering Clozapine

Alternative models of care for the delivery of clozapine services should be explored.

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