Survey of medication for detained patients with a learning disability

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Summary

The Care Quality Commission (CQC) coordinates the provision of Second Opinion Appointed Doctors (SOADs), who visit people detained under the Mental Health Act. They consider clinical records and opinion from others, and decide whether medication to be prescribed for mental disorder is appropriate. As part of this process, the CQC receives information about the type and dose of medication prescribed, together with the patient's diagnosis

In light of concerns following events at Winterbourne View Hospital, CQC was asked to look at the information it had collected about prescribing for people with learning disabilities visited by SOADs. This report examines the information held by the CQC about 945 requests, which involved a patient with learning disabilities, submitted between October 2012 and August 2013. The requests were on behalf of 796 individual patients. This is because, in some cases, a provider clinician submitted more than one request for the same patient during that period.

The people with learning disabilities that the SOADs visited were detained in hospital under the Mental Health Act. It is likely, therefore, that they were those with more severe mental health problems and more severe forms of challenging behaviour.

Our main findings were that:

- For more than a half of the prescriptions, the patient did not have a diagnosis of a disorder for which that drug was a recognised indication. The research evidence base for prescribing for people with learning disabilities is limited. Manufacturers of medication often do not submit information on their use for people with learning disabilities when they apply for a product licence. As a consequence, many of the medications used in treating people with learning disabilities and considered professionally appropriate may not be specifically licensed for this population.

- Twenty-four per cent of patients were prescribed more than one different psychotropic drug to be given on a regular basis. When medication prescribed to be given 'as required' is included, 57% were prescribed more than one psychotropic drug; with 40% prescribed five or more drugs. A psychotropic drug is a one that is capable of affecting the mind, emotions or behaviour.

- Eighty-six per cent of patients were prescribed at least one antipsychotic drug to be given on a regular basis. Eighteen per cent were prescribed more than one antipsychotic drug to be given concurrently on a regular basis. An antipsychotic drug is one that is commonly used to treat a psychotic disorder such as schizophrenia.

- Six per cent of patients were prescribed a 'high dose' of a single type of antipsychotic medication to be given on a regular basis. Thirteen per cent were prescribed a 'high dose' by virtue of the additive effect of more than one type of antipsychotic medication. High dose is defined as a dose that is above the range recommended by the British National Formulary. The British National Formulary

is a guide, and may be departed from if there are sound reasons.

- Twenty-eight per cent of patients had an increased likelihood of being administered a combination of antipsychotic medication equating to a high dose because they were prescribed additional antipsychotic medication to be given ‘as required’. We do not know whether or how often this medication was administered.

- SOADs made changes to the overall treatment plan in some 25% of cases. However, many certified treatment plans still permitted the administration of multiple psychotropic medications and of high doses of antipsychotic medication.

We must be cautious in how we interpret these findings. The data are a by-product of the work of the SOAD service. They were not collected as part of a research study designed to answer the questions posed by the analysis. Although we are confident that the data on prescribing are correct, we are less confident that the information on diagnosis is fully accurate. With this in mind, we have been tentative in drawing conclusions. However, this analysis does raise issues and questions that might merit further exploration.

We do not know, from these results, the extent to which medication was prescribed as an attempt to manage behaviour as opposed to treat a mental disorder. If at least some of the prescribing was to control behaviour, this might be because staff either lacked the resources or skills to manage in other ways behaviour that they found challenging. The data were collected before the publication of the Department of Health’s policy document ‘Positive and Proactive Care: reducing the need for restrictive interventions’. This called for the widespread adoption of positive behavioural support planning to reduce the likelihood of staff resorting to restrictive interventions.

In 2012/13, when these data were collected, the SOADs certified many of the treatment plans as being appropriate. If staff in learning disability inpatient services are now using alternative, non-physical approaches to manage behaviours that challenge, it might be that SOADs can and should be more questioning of medication regimes that include prescriptions for multiple or high dose antipsychotic drugs.

Abstract

- It is estimated that 2% of the UK population have some form of learning disability and within this population there is a high rate of co-morbid mental disorder, estimated to be a prevalence of 30%. There have been concerns about high rates of psychotropic prescription for these groups, including the use of polypharmacy, whether medications are used outside of defined indications, the limited or lack of evidence for their efficacy, and the use of medication when there may be no clear diagnosis.
- This survey was conducted to contribute to actions arising from the Winterbourne View Concordat. It analysed 945 section 58 requests and 818 T3 reports, including 428 statements of reasons by SOADs, produced during a 10-month period in respect of medication prescribed to the learning disability population detained under the Mental Health Act.
- Patients were identified by meeting the criteria of being admitted to a learning disability specialist ward or having a diagnosis of either learning disability or autism.
- The programmes Checkbox and MHAdb were used to collect the data of 945 SOAD requests for patients with learning disabilities over a 10-month period between October 2012 and August 2013.
- Both medications prescribed by the Responsible Clinician and medications certified by the SOAD were surveyed. If ‘as required’ (commonly known as ‘prn’) medication was specified, this too was included.
- Quantitative analysis was undertaken with SPSS IBM 20. Thematic analysis was also undertaken on certificates which certified monotherapy (a single medication) and ≥8 medications.
- The sample was mostly male (66%) with a mean age of 34 years. Fifty-three per cent were patients being treated by an NHS care provider, and 47% treated by an independent care provider.
- The most common prescribed medication class, and the most common medication type about which there is polypharmacy concern, was antipsychotic medication (Table 1).

Table 1: request data – medication type and polypharmacy

Medication	Percentage of sample prescribed	Percentage featuring polypharmacy[1]
Antipsychotic	91	44
Antidepressant	34	4
Anxiolytic	82	28
Mood Stabiliser	48	24

- Independent care providers prescribed significantly more medications per person (4.3) compared to National Health Service (NHS) providers (3.6).[2]
- 63% of patients under the care of independent care providers were prescribed treatment plans featuring polypharmacy compared to the 51% of NHS cared patients. Overall, 57% of patients were prescribed polypharmacy.
- On average 57% of prescribed medications did not have a recorded diagnosis that matched the recognised indications for that medication – range was 38% to 88% (table 2).

Table 2: request data – match to recognised indications

Medication	Percentage prescribed 'regular' with no recognised indication	Percentage prescribed 'as required' with no recognised indication
Antipsychotic	48	53
Antidepressant	67	N/A
Anxiolytic	88	38
Mood Stabiliser	50	N/A

- High dosage rates were most prominent with antipsychotic medication. Where dosages were recorded, 28% of cases were prescribed antipsychotic high dosage medication. However, this rate dropped to 6% with 'regular' prescriptions for high dosage, after exclusion of 'as required'.
- 62% of cases were certified a medication regime featuring polypharmacy of CNS active medications (table 3).

[1] Polypharmacy included both regular and potential polypharmacy – that is to say medication which, being prn, was available to clinical teams to be given to the patient.
[2] Mean scores were used due to median scores being the same despite a statistically significant difference.

Table 3: SOAD certification – medication type and polypharmacy

Medication	Percentage of sample certified	Percentage featuring polypharmacy[3]
Antipsychotic	95	46
Antidepressant	38	4
Anxiolytic	85	14
Mood Stabiliser	49	18

- 67% of cases under the care of independent care providers were certified polypharmacy for CNS active medication. Fifty-six per cent of NHS cases certified polypharmacy. However, this survey acknowledges that the independent healthcare sector includes specialist services which would impact on the patient profile compared with NHS service users.
- Certificates provided for patients under the care of independent care providers were certified higher numbers of medication.
- Analysis of the SOADs' statements of reasons for certification showed there to be a link between presentation and treatment, though there was variable detail as to this.
- Further in-depth analysis was done on reports which certified eight or more medications, and monotherapy. Four themes emerged from these reports: symptoms, risks, progress, and treatment. Common symptoms cited included mood fluctuation and psychosis-related. Symptoms were commonly listed but rationale for treatment appeared to be more clearly linked to managing risk than alleviating symptoms. Risks included self-harm, physical and verbal aggression in both groups with roughly half of cases certified ≥8 medications being severe or persistent in nature.
- In conclusion, while rates of 'regular only' polypharmacy were relatively low at 21%, 57% of cases featured polypharmacy when potential and 'regular only' medication were combined. A significant rate of high dose medication, principally of antipsychotics, was also found.

[3] Polypharmacy included both regular and potential (prn) medication.

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1. Background

1.1 It has been estimated that 985,000 people, 2% of the general population in England, have a learning (or intellectual) disability (Emerson and Hatton, 2008). Reports have indicated that people with learning disabilities are more prone to physical and mental health problems compared to the general population (Alborz et al, 2005). Furthermore, it has been reported that over 30% of people with learning disabilities (LD) suffer from a co-morbid mental disorder (Cooper et al, 2007). However, due to communication difficulties often associated with this population, it is hard to diagnose through interview and to apply standard diagnostic criteria (Sovner and Hurly 1983; Levitas et al, 2004; Royal College of Psychiatrists, 2001). Challenging behaviour, which includes aggressive and sexually inappropriate behaviour, is often the primary cause of inpatient admission (Willner et al, 2013).

1.2 The purpose of this survey was to investigate the practice of prescribing for patients with learning disabilities detained under the Mental Health Act as one aspect of action number 45 of the Winterbourne View concordat. This action point noted a commitment to “explore with the Royal College of Psychiatrists and others whether there is a need to commission an audit of use of medication for this group. As the first stage of this, [the] Department of Health will commission by summer 2013 a wider review of the prescribing of antipsychotic and antidepressant medications for people with challenging behaviour”. This survey also covers aspects of action number 51 by investigating whether “medicines are used in a safe, appropriate and proportionate way and their use is optimised in the treatment of children and adults with learning disabilities. This should include a focus on the safe and appropriate use of antipsychotics and antidepressants”.

1.3 Various researchers have reported that 20-45% of the learning disability population receives psychotropic medication. Rates of mental illness in this population are higher than in the general population, while previous surveys have judged that 14-30% of the learning disability population receive psychotropic medication to treat or manage aggressive challenging behaviour (Clarke et al, 1990; Deb and Fraser, 1994; Deb et al, 2009). The term ‘challenging behaviour’ itself is descriptive not diagnostic, and does not indicate any understanding as to cause. Difficulties with communication, physical health problems and pain are considered to be common aetiological factors for aggression. In some patients aggression is linked with specific genetic or chromosomal conditions. The most influential conceptual framework for understanding such behaviours is that of Applied Behavioural Analysis (ABA). ABA proposes that such behaviours arise and are maintained through the response of others and that behaviours have a ‘function’. The likelihood of their occurrence may also be associated with specific internal or external setting conditions. These behaviours may be seen as demand avoidant or attention maintained and predominantly occurring in specific environmental circumstances. Within this context psychotropic medications are likely to have only a limited role, if any.

In contrast, Willner (2014) has proposed a theory behind the use of psychopharmacology for aggression: 'the neurochemistry of aggression links γ-aminobutyric acid (GABA), dopamine and serotonin (5-hydroxytryptamine: 5-HT), respectively, to appraisal of aggression-provoking cues, organisation of aggressive acts, and 'top-down' inhibition of aggressive behaviour via actions in the amygdala, nucleus accumbens and prefrontal cortex respectively. These relationships give rise to clear predictions for how medications interacting with these systems might be expected to influence aggressive behaviour, and if confirmed, would support the use of mood stabilisers (some of which are GABA agonists), neuroleptics (which are dopamine antagonists) and antidepressants (which potentiate 5HT) to control aggressive challenging behaviour'.

1.4 There are numerous studies which have reported high rates of antipsychotic prescription in the learning disability population, exceeding the rate of psychosis reported (Robertson et al, 2000). The estimated rate of schizophrenia in the learning disability population is 3% (Smiley, 2005) compared to the rates of antipsychotic prescriptions of up to 25-50% in NHS; 20-50% in community based services; and 10% in patients living with family (Branford, 1994).

Antipsychotic treatment for behavioural problems in the learning disability population is common practice and accounts for this discrepancy (Deb et al, 2014; Molyneaux et al, 2000; Branford 1994; Wressell et al, 1990). A consensus study reported on clinicians' not infrequent use of medication to manage behavioural difficulties (Unwin G., Deb S., 2008). Many studies argue that such behaviour results from communication difficulties often associated with this group as opposed to a mental disorder (Shroeder et al, 1997; Sigafoos, 2000; Chamberlain et al, 1993; Deb et al, 2009). Given that such behaviour is often persistent and lifelong (Emerson et al, 2001; Einfield and Tonge, 1996; Green et al, 2005) the proportion of patients with learning disabilities being prescribed psychotropic medication has been an area of concern. Common risks associated with newer generation antipsychotics include prolactin secretion (associated with erectile dysfunction), metabolic abnormalities for both lipid and glucose tolerance, and weight gain (Ucok and Gaebel, 2008). Interestingly Moss et al (2000) reported that the mental illness with the most marked association with challenging behaviour was depression.

However, the efficacy of antipsychotic medication for challenging aggressive behaviour in the absence of mental illness has also been scrutinised. Tyrer et al (2008) compared Risperidone, Haloperidol, and placebo for treatment of aggressive behaviour and found that the largest improvement was in the placebo group, with no evidence of a lesser therapeutic response compared to the antipsychotic treatments at any point, though all three led to decreased MOAS (modified overt aggression scale) scores. However, studies using larger doses reported that antipsychotic (Risperidone) was a superior alleviant for challenging behaviour compared to a placebo (Van den Borre et al 1993; Giagano et al, 2005). A meta-analysis conducted by Brylewski and Duggan (2004) concluded that there was no evidence of antipsychotic medication helping the reduction of challenging behaviour, though neither was there evidence of it causing harm.

1.5 Antidepressant use with learning disabilities has been less extensively investigated, though studies have examined its efficacy in the learning disability population. Sovner et al (1993) found antidepressants (specifically SSRIs) used with self-injurious behaviour and depressive symptoms. Bhaumik et al (2000) found that SSRIs improved depressive symptoms in patients with learning disabilities, but that increased maladaptive behaviour was a common side-effect.

1.6 Polypharmacy has no set definition, varying from the prescription of 2 or more medications, to more medications than clinically indicated (Alexandria, 2001; Hajjar et al, 2007). Polypharmacy is a widespread practice (Williams et al, 1999; Frye et al, 2000; Ghaemi, 2002). In terms of using more than one medication for the same problem, it is a recognised and valid approach in treating serious bipolar mood disorders, as it is noted that different medications have different efficacies in managing manic versus depressive episodes, or in reducing the frequency and severity of these episodes (Goodwin, 2009; NICE, 2014). In contrast, the use of multiple antipsychotic or benzodiazepine medications is considered to represent serious risk, without likely benefit.

However, there are clinically difficult situations where polypharmacy is a valuable option (Fleischhacker and Uchida, 2012), and where there is evidence supporting its use (Correll et al, 2009). There is however also increasing evidence of the dangers associated with polypharmacy (Taylor, 2010; Langan et al 2009; Tungaraza et al 2009; Essock et al, 2009). The few studies which have reported clinical benefits were lacking a control group and were of small sample size, while an increasing number of studies scrutinise the risks and costs of antipsychotic polypharmacy (Correll et al, 2004; Clark et al, 2002; Davies et al, 2004). Benzodiazepine polypharmacy has also been associated with increased mortality (Tiihonen et al, 2012; Baandrup et al, 2010; Tiihonen et al, 2009), and in the learning disability population the reported rate is 7% (Robertson et al, 2000). Bhaumik et al (2000) reported that 38% of their sample was treated with polypharmacy. Studies investigating polypharmacy have concluded that there is almost no attempt at rationalisation/reduction of the medication regime of patients with learning disabilities when they move out of inpatient care into the community (Nøttestad and Linaker, 2003).

Essock et al (2011) found that switching from polypharmacy to monotherapy (and maintaining on monotherapy thereafter) was successfully achieved with 69% of sample with no increase in hospitalization and an improvement in physical health (lowered BMI compared to an increased BMI for the polypharmacy group).This was supported by several studies (Branford, 1996; Fielding et al, 1980; Ahmed et al, 1997). Ahmed et al (2000) reported 52% of the experimental group, which utilised a phased reduction of their antipsychotic medication, none of whom were diagnosed with psychosis, were either on substantially reduced dosages or successfully withdrawn from the medication. Furthermore, there was no association with increase in maladaptive behaviours and drug reduction while activity engagement was significantly improved an important criterion for quality of life (Emerson and Hatton, 1994).

2. Underpinning statutory requirements

2.1 The second opinion appointed doctor (SOAD) service provides second opinions for treatment as required by section 58 of the Mental Health Act 1983 (as amended). A second opinion is required if a number of conditions are fulfilled. For the first three months of detention under sections of the Act to which the consent to treatment provisions apply (essentially the longer duration sections which have been instituted as a result of two medical recommendations), the doctor in charge of treatment (Responsible Clinician (RC)) may prescribe any medication for mental disorder they consider is appropriate, whether or not the patient is capable of giving consent and does so. It is thus possible for a patient to be given such medication during this first three months even if they refuse it or are not able to agree to it, and no certificate is required – this is referred to as the 'three-month rule'. It is of course good practice to obtain the patient's agreement during this period if possible. This 'rule' applies to medication; it is not possible for a capacitous patient to be given ECT against their will unless in a situation of urgency.

If after this three-month period, at any time while still detained, the patient's consent status is other than capacitous and consenting then a second opinion will be required. If the patient lacks capacity to consent to, or refuses, treatment, the RC is required to seek a statutory second opinion, the arrangements for which are coordinated via CQC. Similarly, if medication is being prescribed for the incapacitated or refusing patient on the basis of a second opinion certificate, and the RC wishes to change the medication type or dose beyond that authorised, then a fresh certificate will be needed. It is possible for the certificate to be time-limited by the SOAD or it may be withdrawn by CQC, and in such circumstances a further second opinion is likely to be necessary.

When a request has been received by CQC, this will be by way of a number of pieces of information supplied by the provider in response to specific questions. These include the RC's proposed treatment plan and a rationale to explain the reasons for the treatment plan requested.

A SOAD is allocated to the case and makes arrangements to conduct a second opinion assessment. Sometimes a request is cancelled before the SOAD visits. For example, the detained patient may be discharged, meaning not all requests are followed up. During a SOAD visit there will be an interview with the patient, assuming they agree to be interviewed, together with two professional consultees (for inpatients, one a nurse and the second a non-medical, non-nurse member of the team, who have been concerned in the patient's care), and a perusal of any case notes available. Discussion with these consultees, and the broad nature of their professional background, is a statutory requirement. There may be additional discussion with other members of the team, but this will not necessarily occur. With all the evidence collated the SOAD will decide whether the patient has capacity to consent to the treatment, and if the treatment proposed is appropriate to be given. If the SOAD considers

that the originally proposed treatment plan should be changed, whether slightly or significantly, they can effect these changes since at the conclusion of their deliberations they issue a statutory certificate detailing the treatment that is authorised to be given. That certificate is in a prescribed format. Depending upon the patient's consent status, whether the treatment is ECT or medication and the patient's age, the certificate varies slightly in its format but all are collectively referred to as the 'T' forms. The certificate of second opinion for medication is a Form T3. Where it is found that the patient can and does consent, then this consent is usually certified by the RC, while alternatively the SOAD may do so, in either case it is recorded on a Form T2. The SOAD also provides a statement of reasons, the basis of which is set out in case law, which should give what he reasonably regards as the substantive points on which he formed his clinical judgement.

The documentation flowing from a completed second opinion will therefore include the certificate detailing the treatments authorised together with a statement of reasons and the SOAD report form, a document summarising key elements of the assessment. This information, in conjunction with the provider clinician's original request submission, forms the core material for this survey.

Of importance is that the certificate records the treatments which may be given, and their maximum doses – it does not imply that all of the medication authorised will be prescribed at any point in time, nor that the doses will be at the maximum authorised.

The Mental Health Act 1983 applies to England and Wales; Scotland has different legislation. In Wales, however, the second opinion service is administered by Health Inspectorate Wales, not by CQC. Consequently, only data from England were available for the purposes of this survey.

Finally, it is important to emphasise that all of these provisions relate only to medication for mental disorder. Treatment prescribed to patients which is for physical disorders – for example, antibiotics, statins, drugs for high blood pressure or for stomach ulcers – are not covered by the provisions within the Mental Health Act, cannot be compulsorily given using that Act, and consequently are excluded from this survey.

Further explanatory detail on these matters can be found in the Mental Health Act Code of Practice (Department of Health, 2015).

Within the Mental Health Act 1983 (as amended in 2007), there is a clear requirement regarding the detention of a person suffering from learning disability. Detention of such a person which is justified solely on the basis of learning disability, that is to say without an additional mental disorder, must demonstrate that there is an association between the learning disability and either abnormally aggressive or seriously irresponsible conduct, or both.

3. Introduction to survey

3.1 Areas of particular interest for this survey included; (1) the frequency of prescription and SOAD certification of certain psychotropic medications to patients with learning disabilities, in particular the rates of antipsychotic, antidepressant, and anxiolytic prescription; (2) the frequency of prescribed/certified polypharmacy in this population; (3) the appropriateness of prescribed medications against the accepted indications as detailed in the BNF (*British National Formulary*). Analysis was conducted to identify the correlation between medications prescribed and certified, and the recording of diagnoses to justify their use. In addition there was analysis of the medication dosage. Finally, the survey concurrently investigated whether the medication prescribed was for a 'recognised indication' by examining the qualitative data featured in the proposed treatment rationale.

3.2 The second opinion doctor service covers all healthcare providers in England. This provides an opportunity for a comparison of the rates of prescription or certification (and requests by provider) for psychotropic medications between NHS and independent health care providers. Other aspects of interest included demographic variables including age and gender. The latter was viewed as potentially relevant since studies such as Seeman (2004) noted that antipsychotic optimal dosages differ between men and women due to a number of factors, the most obvious of which is higher prolactin levels in women; it was considered potentially useful to discover if gender variations occur in prescribing for the learning disability population.

3.3 Within the literature a study similar to this survey, conducted by Harrington et al (2002) examined prescribing practices for antipsychotics in the 'general' service user population who accessed mental health services. They found that large portions of the sample were prescribed more than one antipsychotic drug (48%) and, to a lesser extent, high dosage (20%).

This report has several limitations. As the data collection was retrospective, this impacts on the conclusions which can be made. The nature of the SOAD certificate, a legal document, is not intended to provide detailed information about the actual dosages the patient is prescribed; commonly it specifies a maximum dose limit rather than a specific dose. Furthermore, not all medication certified will necessarily be used by the Responsible Clinician. Discussions can and do take place between the Responsible Clinician and the SOAD, at the time of the latter's visit, which can explore treatment options and justification, together with additional information in the case notes that would not have been available in the data analysed for this report. Finally, the survey only included that group of patients with learning disabilities who required a second opinion.

4. Method and definitions

4.1 Data were taken from CQC databases, and completed second opinion assessment requests and corresponding SOAD reports, for a 10-month period (October 2012 to August 2013). The data collected were organised into tables detailing multiple aspects both of the request form and of the SOAD certificate. Patients were identified within the sample by analysing diagnosis and ward location.

The diagnosis field on the request form is a free-text box, and therefore the terminology used by an individual clinician may not precisely accord with terms others use. For the purposes of this survey, therefore, diagnosis was determined by analysing all the cases and matching patients who were recorded, on the SOAD request form, as having any form of learning or developmental disability which would reasonably be recognised by either the ICD or the DSM classification systems (DSM 5 was not in use during the time period covered by the survey), including any Autistic Spectrum Disorder (ASD).

Patients were also assigned a dichotomous 'diagnosis type', which was split into two categories; 'developmental' and 'acquired'. Patients assigned to the developmental category had any combination of: ADHD, personality disorder, learning disability, autism, or ASD listed in their diagnosis, these conditions being defined as pervasive disorders which develop in childhood/adolescence and continue into adulthood. Any patient whose diagnosis featured any mental disorder outside of these diagnoses was assigned to the acquired group. This diagnosis grouping was not applied to the analysis of 'recognised indications', as this would be of limited utility. Indeed, it is recognised that this may be an artificial dichotomy of limited clinical applicability – it was not done with the intention of applying it clinically. Because the study was retrospective, it drew upon data which were not designed for analysis of this nature, as a purpose-designed prospective research study might be, but rather to facilitate the separate analysis of a number of conditions not classically recognised as having symptoms more usually found in other mental disorders, for example, psychosis. These latter disorders are a more heterogeneous group of conditions. It is important to emphasise that arising from this artificial differentiation, there is no implication that clinically any particular condition is 'acquired', that is, not present from birth; it was done purely for the purpose of the analysis so as to provide a means of separating conditions that might reasonably be expected to be treated with different pharmacological approaches.

'Ward type' was identified using an internal database within CQC, any ward that was listed as a specialist learning disability ward was included in the survey, even if the patient did not carry a formal learning disability diagnosis, since it was assumed that any patient not having a learning disability should not be placed on such a ward.

4.2 Patients who were had been the subject of certificates authorising medication were assigned to a 'medication category', which was separated into five distinct

groups based on what was certified; these groups were identified and agreed by the expert panel:

(1) The patient is on one or two medicines and doses do not appear high;

(2) The patient is on more than two and less than five medicines and the doses do not appear high;

(3) The patient is on more than five medicines, and although the doses do not appear high, together they should lead to questions about polypharmacy;

(4) The patient is on polypharmacy (defined in 1.15 below) of one or more BNF categories of drug;

(5) The patient is on a large number (more than five) of medicines and polypharmacy.

Further qualitative enquiry in the form of thematic analysis was conducted on certificates which authorised monotherapy (a single medication certified on a T3), and those which authorised eight or more medications.

4.3 For the purposes of this survey polypharmacy was defined as any BNF drug class for which the patient was authorised to receive more than one medication. Sub-categories of this definition are polypharmacy relating to regular medication, and potential polypharmacy, where there is the possibility of polypharmacy by virtue of the combination of regular and 'as required' (prn) medication.

High-dose medication was defined within this study as either the prescription or certification of a medication above the maximum limits noted within the BNF, or any multiple drugs within a BNF drug class which, prescribed or authorised, in numeric combination amount to above 100% BNF dose of the equivalent of one drug. This could arise either through combinations of regular medication, or through regular and 'as required' medication combined. Finally, polypharmacy was defined as the multiple prescribing of CNS active medications for the treatment of mental disorder.

4.4 It was necessary to make assumptions about the category into which, for the purposes of this survey, Clonazepam and Midazolam should be recorded. It was decided that both should be classed as anxiolytics on the basis of several factors. However it should be noted that this must be viewed as inconclusive categorisation. Both drugs have been, within the survey, included in the list of medications for a mental disorder (rather than medication for a physical disorder). This is based on the fact of finding T3 forms including these drugs, thus indicating that their use for the patient in question was not for physical disorder – had that been so, one would expect that the SOAD would not have certified them since medication for physical disorder cannot be authorised within section 58 of the Mental Health Act. For physical disorder they can both be used in the treatment of epilepsy, and clonazepam for myoclonus in addition; these conditions are not uncommon in people with learning disability. Furthermore, several studies have reported clonazepam's efficacy in the treatment of anxiety based disorders including social phobia (Otto et al, 2000),

panic disorder (Rosenbaum et al, 1997) and generalised anxiety disorder (Baldwin et al, 2014). There is evidence for its use for the treatment of anxiety in mental health outpatient services (Siddartha et al, 2013). During the period covered by this study there was a national shortage of intramuscular (IM) lorazepam, and midazolam was being used as an alternative (BMJ, 2011). Midazolam has also been reported to have effective anxiolytic action (Nobay et al, 2004).

4.5 Medications of interest were defined as antipsychotics, anxiolytics, mood stabilisers, antidepressants and CNS stimulants. Where any such medication was recorded as a prescribed medication on the form requesting the second opinion, it was coded according to BNF chapter code and by agent name.

4.6 Clinical problems reported in relation to patients were, wherever possible, identified and linked to a corresponding ICD-10 code. Challenging behaviour (for which there is no satisfactory code) was noted separately. For psychiatric diagnoses this survey included only diagnoses recorded in the 'diagnosis' field of the request form. In respect of challenging behaviour and epilepsy, these were recorded where reported either in the diagnosis field or where reported in other fields.

4.7 Each medication requested was assessed for 'appropriateness' according to the diagnoses stated in each SOAD request. Where the review data specified doses for medications, daily doses were calculated and compared with the maximum daily dose as specified by the BNF. The number of agents requested in each class which were individually stated to be above recommended BNF maximum dose were also recorded and defined as 'high dose' agents. For the prescribed medications listed in each SOAD request, within each class of agents a BNF maximum equivalent was calculated, by summing the daily doses expressed as percentages of the maximum recommended dose (referred to as combined total dose). The outcome of the SOAD assessment with respect to whether changes were made, were compared with the above findings.

4.8 Episodically within this report, medication is referred to as being 'off-licence'. This refers to the product licence granted to the manufacturer to authorise the marketing of the drug. Commonly a pharmaceutical company will develop, or sell, a drug for a specific purpose, for example as an antiepileptic for the treatment of people suffering from epilepsy. While the drug is being used, it may become apparent that it has another, notionally entirely different, use – in this antiepileptics example, many such drugs are also found to be effective mood stabilisers. However, the gaining of a product licence is a costly process. Manufacturers will take a commercial decision on whether they consider it worthwhile to seek an additional product licence for the secondary use of a drug, as described above. If they do not, then any doctor prescribing that drug for its secondary purpose will be prescribing outside of the product licence – this is known as 'off-licence', 'off-label', or 'unlicensed' prescribing and usage. The key point of difference between this and prescribing within the licence is that to prescribe outside of the marketing authorisation is likely to increase the prescriber's professional responsibility and personal liability. Such an action is

not necessarily poor practice, and the use of the drug in this manner is not necessarily inappropriate. Indeed, it may be entirely appropriate and good practice. However, such usage is something the prescriber must be aware of, and must be able to justify.

4.9 Furthermore, manufacturers of medication often do not submit information on their use for people with usage in learning disabilities when they apply for a product licence. As a consequence many of the medications used in learning disability and considered professionally appropriate may not be specifically licensed for this population. This means that the indications described in the BNF may not cover their use with this group of patients.

5. Request cases data

Table 4

Total number of second opinion requests submitted in timeframe	9,757
Total number of second opinion requests for patients with learning disability	945
Sample size of unique patients	796

Demographic data

Table 5[4]

Age	
Mean age	34.5
Range	12-89
	Gender
Males	532
Females	264
	Ethnicity
White British	590
Asian	24
Black or Black British	53
Mixed	17
Other	11
Not specified	101

[4] Table 1.2 is based on 796 patients who were seen only once during the survey period.

Table 6

Number of cases	Number of patients
1	672
2	106
3	12
4	5
5	1
Total	**796**

5.1 All tables sourced data from section 58 requests. There were a total of 9,757 second opinion requests, for the population of England, made in the 10 month timeframe of the survey. Within this, 945 were identified as requests for patients with a learning disability. 834 of these requests went on to be assessed by a SOAD, and 818 featured medication. The differences between these figures arises because it is not uncommon for a request for a SOAD visit to be made, then cancelled prior to the visit because either the patient has been discharged from liability to detention, or been assessed as capable of and willing to consent to the treatment.

5.2 796 unique patients within the data set were seen once during the period and formed the demographic data (see table 5). 154 requests were for individuals already seen by a SOAD during the sample period and were therefore excluded from the demographic data, leaving 796. While there was a mean age of 34¾ years (standard deviation of 13.9) there was a large age range and a breakdown of age groups is represented in figure 1 below. For a flow chart of the data filtering please see appendix 2. 42 second opinion requests did not provide a MHA status[5]. 37 requests did not have ethnicity recorded. 21 did not have their medication consent status recorded.

[5] 36 were on a CTO, 6 had 'unknown' recorded as the section

Figure 1

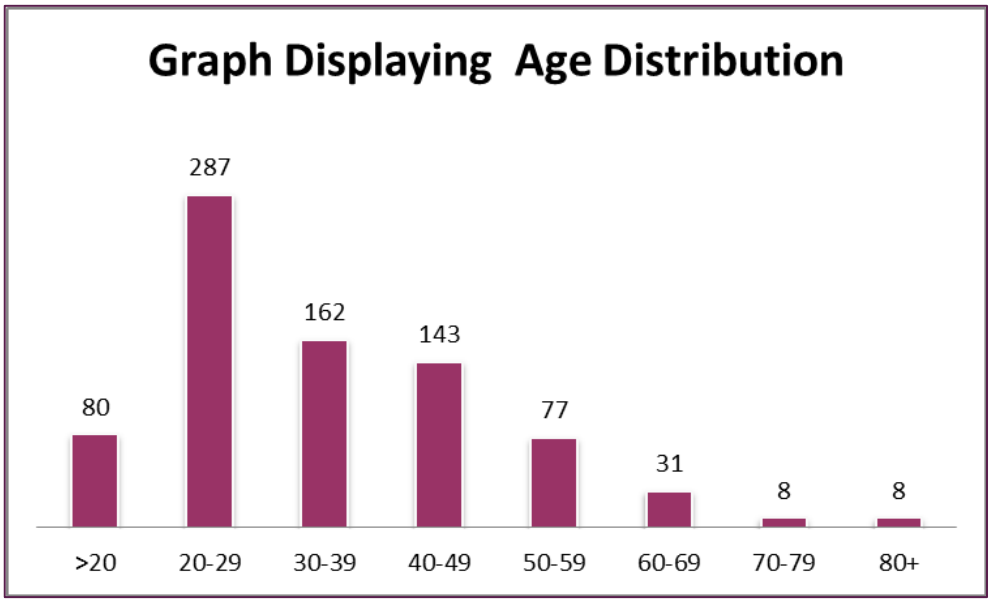

Table 7

Learning disability severity	
Mild	398
Moderate	132
Severe	33
Unspecified	382
Total	945

5.3 Learning disability severity was identified by analysing all requests to find any request that specified the severity of the patient's learning disability, even if psychometrics such as IQ tests were not cited. This is because the diagnosis of learning disability relates not just to IQ but also to measures such as social impairment. When measures of intelligence are used, the typical definition of learning disability severity is mild (IQ of 50-70), moderate (35-50), severe (20-35). Forty per cent of this sample (n=382) did not specify the severity of the patient's learning disability.

5.4 Of 945 requests, 701 (74.2%) were detained under a section 3, 80 (8.5%) on a section 37, with smaller proportions on section 2, section 38, section 47 and section 36. 91 (9.6%) are unknown.

Request – prescribed medications

5.5 Establishing diagnoses in people with learning disability is often far from simple; the rationale for prescribing, to some extent, includes what can reasonably be described as therapeutic trials. By this is meant the empirically-based use of a specific drug in an individual patient, to see whether there are benefits that outweigh any disadvantages that may be encountered. This is considered further in the discussion of the limitations of this study. In addition to this empirical approach, there is an available responsible body of opinion in respect of prescribing for people with learning disability, this being referred to as the Frith criteria (Bhaumik and Branford, 2005). The scope of this study is limited to the reporting of findings, and reference to these criteria is recommended for more detailed discussion of the issues.

Request – medication statistical analysis

Key findings

- 3,947 medications were currently prescribed across 945 requests.
- Independent care providers prescribed significantly more medication (mean of 4.3 medications) compared to NHS (mean of 3.6 medications) at the time of request (P≤ 0.001) with a moderate effect size (d= .36).
- Cases of polypharmacy:
    - Total number of 534 (57%) cases.
    - Total number of 250 (24%) for regular polypharmacy cases.
    - 51% (NHS) vs 63% (Independent).
    - 58% (LD specialised) vs 55% (Non-LD specialised).
- Prescriptions for five or more medications:
    - Total number of 376 (40%).
    - 31 % (NHS) vs 49% (Independent).
    - 40% (LD specialised) vs 40% (Non-LD specialised).
- There was no significant difference in the number of medications prescribed between the two recorded genders (P≤ 0.06).
- There was no significant difference between specialised learning disability and non-specialised learning disability placements in respect of the number of medications prescribed (P≤ 0.72).
- There was no significant difference between patients of different ethnicity in relation to the number of medications prescribed in a single treatment plan (P≤ 0.001).

5.6 Statistical analysis was conducted with SPSS. There were 945 cases analysed for the section 58 data. Double counting of individuals necessarily occurred. Though each request is unique, individuals might feature more than once in the survey because they had been the subject of an additional request for a second opinion during the survey period - perhaps because of a perceived need to change treatment previously authorised; these were included in the analysis. Average numbers of medications will be based on the median score unless specified as mean scores.

5.7 At the time of request there was no significant difference between males and females in respect of the number of medications currently prescribed. However, independent care providers prescribed significantly more medications compared to those in the NHS at the time of request (mean of 4.3 vs 3.6, t=

5.6, df= 943, P≤ 0.001) with a moderate effect size (d= .36). Furthermore, independent providers had significantly more occurrences, 280 (63%), of treatment plans featuring polypharmacy compared to the 254 (51%) NHS cases (chi square = 15.2, df =1, P≤ .0001) though there was only a small effect size (v= .127). Overall, 47% (443 cases) were treated by independent care providers with the balance of 53% (502) being treated by NHS providers.

5.8 No differences were found between specialised learning disability wards and non-LD wards in relation to the number of medications prescribed (t = .35, df= 1, P≤ 0.72). Similarly, there was no significant difference (chi square = .83, df = 943, P≤ .199) between learning disability ward with 255 (58%) cases and non-LD cases with 279 (55%) cases prescribing treatment plans featuring polypharmacy. Only 63 (6.6%) of prescribed treatment plans were not utilising polypharmacy.

5.9 The data relating to the national high secure service for people with learning disabilities at Rampton Hospital were separately analysed. There were 10 cases. The average number of medications prescribed was three (compared to the overall average of four) with only one case having ≥5 medications prescribed. Only one case from high secure hospitals was currently prescribed polypharmacy (antipsychotic) at the time of request. Four cases were currently prescribed an antipsychotic depot.

A total of 43 adolescent request cases were also analysed. On average, adolescents were prescribed four medications. However 18 (42%) were prescribed ≥5 medications. Polypharmacy was prescribed to 22 (51%) cases of which 21 (95%) was antipsychotics.

Patients subject to a CTO were a minority, with only 52 cases, but were separately considered for analysis. The average number of medications prescribed was two, lower than the overall average (three) with only six cases receiving ≥5 medications in their treatment. There was a rate of 10 (21%) polypharmacy for CTO patients.

Request – antipsychotic data

5.10 Ninety-one per cent (858 of the 945 requests) were prescribed at least one antipsychotic6 at the time of request. Within this group, 379 (44%) were prescribed antipsychotic polypharmacy though only 172 (20%) had polypharmacy as a component of 'regular' treatment. 814 (86%) had antipsychotics prescribed on a regular basis.

Table 8

Total number of antipsychotic agents currently prescribed	Frequency	%	Cumulative percentage
0	87	9.2%	9.2%
1	479	50.7%	59.9%
2	324	34.3%	94.2%
3	48	5.1%	99.3%
4	7	0.7%	100%
Total	945	100	

Total number of regular antipsychotic agents prescribed	Frequency	%	Cumulative percentage
0	131	14.0 %	14.0 %
1	641	67.8%	81.8%
2	161	17.0%	98.8%
3	12	1.2%	100%
Total	945	100	

Please refer to appendices for full table.

[6] Antipsychotics were classed as any medication within BNF category 4.2.1 or 4.2.2. Refer to appendix 21 for a complete list of agents included.

Antipsychotics and diagnoses within reviews:

5.11 780 of the reviews included at least one prescription for the regular administration of a named antipsychotic. Twenty per cent (153) of these proposed two named antipsychotic agents and 1% (8), three. Fifty-two per cent of these reviews (406) reported that the patient had at least one of the diagnoses for which antipsychotics are normally indicated.

5.12 Challenging behaviour is not a licensed indication for prescribing antipsychotic medication on a **regular** basis; the management of **acute** behavioural crises is discussed below. The exception to this is Risperidone, which is licensed for use in severe aggression associated with autism in children. Of the 374 reviews where no diagnosis was recorded in relation to which antipsychotics are normally indicated, 20% (75) were for Risperidone alone and, in all these, challenging behaviour was noted. Autism was not necessarily documented clearly, and it is therefore not possible to be certain as to how many of these fell within this indication. However, only five of the second opinion reviews in this survey were for children (those under 18 years), and it is therefore not feasible to suggest that the use of Risperidone in these circumstances is accounted for by childhood autism. Had all 75 been children – which they were not – then that would reduce from 48% to 37% the proportion of requests for regular administration of an antipsychotic, for which no licensed diagnostic indication was offered. These figures are provided because it is conceivable that clinicians were utilising this specific drug, in the over-18s, for severe aggression, and while this would still not be a licensed indication it is an identifiable probable usage, which if correct would mean that 37% of the prescriptions for regular antipsychotics were for unidentified purposes or purposes for which there was no correspondence with a licenced indication.

‘As required’ antipsychotics:

5.13 380 reviews included at least one request to prescribe a named antipsychotic ‘as required’. 20 of these requested two antipsychotic agents on this basis and one requested three. The table of indications for ‘as required’ administration of antipsychotics shows those drugs for which management of acute behavioural disturbance is a recognised indication. This survey assumed that these disturbances may and do occur in psychoses, including affective psychoses, and may also arise with patients reported as having challenging behaviour. In 47% of these reviews a psychiatric condition was recorded which could be seen as ‘relevant’ according to these licenced indications, with challenging behaviour being noted in 66% of these. In a further 35% challenging behaviour was noted but without there being any mention of an associated psychiatric condition. In 18% (69 reviews) neither type of indication was reported.

‘Regular’ high doses:

5.14 For antipsychotics prescribed for regular administration, full dosage regimes were specified in 96% of cases where one compound was prescribed and 87%

and 75% respectively where two or three compounds were prescribed. In 6% (46 of the 747) of reviews in which all relevant details were available at least one antipsychotic was requested in a high dose (above its prescribed maximum). This was more common in patients prescribed two or three antipsychotics (13.5%, chi square = 16.2, df=1, p<.0001).

‘Regular’ combined doses:

5.15 Thirteen per cent (97) of reviews included prescriptions for antipsychotics to be administered regularly and authorised a combined total antipsychotic dose exceeding 100% of the BNF recommended limits. There was no association between whether a patient was noted as having challenging behaviour, and high regular combined total antipsychotic dose.

‘Any’ antipsychotic (‘regular’ and/or ‘as required’ administration) – high doses of a single agent:

5.16 784 requests identified named antipsychotics where dosing information was given for administration on a regular and/or an ‘as required’ basis. It is not possible to determine how frequently medicines prescribed ‘as required’ would have been administered. However, such a prescription is in addition to the regularly administered medications proposed. On this basis, for any single compound, the sum of the regular and ‘as required’ doses is taken as the total potential antipsychotic load, since it is reasonable to assume that the patient could receive such a dose total, at least on occasion. On this basis, the number of requests where authorisation was sought for at least one potentially high dose antipsychotic increased to 72 (9%).

‘Any’ antipsychotic (‘regular’ and / or ‘as required’ administration) – high doses arising from combined doses of multiple agents:

5.17 Of these 784 requests for antipsychotics, where dosing information was available 28% (216) involved a combined total antipsychotic dose exceeding 100% of the BNF recommended limit.

Request – antidepressant data

5.18 318 (34%) of the 945 requests identified the patient as being prescribed at least one antidepressant[7] at the time of request. Fourteen (1.5%) of these request cases featured antidepressant polypharmacy prescribed; none included potential antidepressant polypharmacy – that is to say polypharmacy which might arise, like those with antipsychotics, by combination of regular medication combined with 'as required'. Two cases of 'as required' antidepressants were included; such an occurrence was thought to be unusual and raised a question as to data quality. However after checking these were included.

Table 9

Total number of antidepressant agents currently prescribed	Frequency	%	Cumulative percentage
0	627	66.3%	66.3%
1	304	32.2%	98.5%
2	14	1.5%	100%
Total	945	100	

Total number of regular antidepressant agents prescribed	Frequency	%	Cumulative percentage
0	629	66.5%	66.5%
1	302	32.1%	98.5%
2	14	1.5%	100%
Total	945	100	

Please refer to appendices for full table.

Antidepressants and diagnoses

5.19 298 reviews included at least one prescription for regular administration of a named antidepressant. 13 (4%) of these proposed two named antidepressant agents. 97 (33%) of cases reported that the patient had at least one recognised indication.

[7] Antidepressants were classed as any medication within BNF category 4.3

5.20 Autism is not a recognised indication for prescribing antidepressants, according to the British National Formulary. However, it is one for which they are widely used according to the national institute of mental health, although evidence for efficacy is limited (Williams et al, 2013). Autism appeared to be a distinct reason for their use in these patients, as the proportion of reviews in which autism was noted was significantly higher in those where no other relevant psychiatric diagnosis was reported (38%) than in those where there were other diagnoses mentioned (22%, chi square = 8.2, df=1, p<.005).

Regular high doses of a single agent:

5.21 For antidepressants prescribed for regular administration, dosage regimes were specified as being within BNF limits in 95% of cases where one compound was prescribed and 92% of cases where two compounds were prescribed. In 2% (six of the 284) reviews in which all relevant details were available, at least one antidepressant was requested in a dose above its BNF recommended maximum.

Regular combined doses of multiple agents:

5.22 Five per cent (15) of the reviews which included prescriptions for ‘regular’ antidepressants authorised a combined total antidepressant dose of over 100% of the BNF recommended limits.

Request – mood stabiliser data

5.23 449 (48%) of the 945 requests currently prescribed a mood stabiliser[8] at the time of request. 106 (24%) mood stabiliser prescriptions utilised polypharmacy, with 72 (16%) utilising polypharmacy for regular treatment.

Table 10

Total number of mood stabiliser agents currently prescribed	Frequency	%	Cumulative percent
0	496	52.5%	52.5%
1	343	36.3%	88.8%
2	86	9.1%	97.9%
3	20	2.1%	100.%
Total	945	100	

Total number of regular mood stabiliser agents prescribed	Frequency	%	Cumulative percent
0	499	52.8%	52.8%
1	374	39.6%	92.4%
2	64	6.8%	98.2%
3	8	0.8%	100%
Total	945	100	

Please refer to appendices for full table.

Mood stabilisers and diagnoses:

5.24 405 reviews included at least one prescription for regular administration of a named mood stabiliser. 69 (17%) of these proposed two named mood stabilizer agents and five (1%) proposed three. 213 of these 405 reviews (53%) reported

[8] Mood stabilisers were classed as any medication within BNF category 4.2.3 or 4.8.1 specifically Carbamazepine, Lamotrigine and Sodium Valproate.

that the patient had at least one of the diagnoses for which mood stabilisers are normally indicated.

Regular high doses of a single agent:

5.25 For mood stabilisers prescribed for regular administration, dosage regimes were specified in 89% of cases where one compound was prescribed, 74% of cases where two and 57% of cases where three compounds were prescribed. In 12 of the 382 (3%) reviews in which all relevant details were available at least one mood stabiliser was requested in a high dose (above its specified maximum).

Regular combined doses of multiple agents:

5.26 42 (11%) reviews including prescriptions for mood stabilisers administered regularly authorised a combined total mood stabilizer dose of over 100% of the BNF recommended limits. This does not necessarily equate to inappropriate practice – leading affective disorder researchers often recommend combinations of mood stabiliser and there is evidence for increased efficacy, unlike most cases of antipsychotic polypharmacy. (Goodwin, 2009; Taylor 2015)

Request – anxiolytic data

5.27 776 (82%) of the 945 requests currently prescribed at least one anxiolytic[9] at the time of request. 220 (28%) of cases featuring an anxiolytic utilised anxiolytic polypharmacy but only 8 (1%) proposed polypharmacy for regular treatment. Off-license anxiolytic was utilised in 123 (16%) cases.

Table 11

Total number of anxiolytic agents currently prescribed	Frequency	%	Cumulative percentage
0	169	17.8%	17.8%
1	556	58.8%	76.6%
2	206	21.8%	98.4%
3	14	1.6%	100%
Total	945	100	

Total number of regular anxiolytic agents prescribed	Frequency	%	Cumulative percentage
0	661	69.9%	69.9%
1	276	29.2%	99.1%
2	8	0.9%	100%
Total	945	100	

Please refer to appendices for full table.

Anxiolytics, benzodiazepine anticonvulsants and diagnoses:

5.28 This survey has included the entire benzodiazepine group here for two reasons. First, particularly with diazepam, reasons for usage can be for both anxiolytic and anticonvulsant purposes. Second – pharmacologically the action of anticonvulsant and anxiolytic benzodiazepines is similar, so they need to be considered together in evaluating combined total dosage.

[9] Anxiolytics were classed as any medication within BNF category 4.1.2. Specifically these were Chlordiazepoxide, Diazepam and Lorazepam. Clobazam was also included as it is also indicated for short term use in anxiety. Clonazepam and Midazolam have been included where explicitly specified for completeness.

‘Regular’ anxiolytics:

5.29 171 reviews included at least one prescription for regular administration of a named anxiolytic agent (not including clonazepam); four (2%) of these proposed two. Twenty (12%) reported that the patient had at least one of the diagnoses for which anxiolytics are normally indicated, 88% did not.

5.30 Clonazepam is licensed as an anticonvulsant not an anxiolytic. 109 reviews included a prescription for this compound. Of these, 28 (26%) reported a diagnosis for which it is normally indicated.

‘As required’ anxiolytics:

5.31 655 reviews included at least one prescription for a named anxiolytic ‘as required’. In addition to the diagnoses for which anxiolytics are normally indicated, and (where appropriate) epilepsy, this survey included conditions where acute behavioural disturbance is likely (psychoses, including affective psychoses) as indications for those compounds where management of this is a recognised use. This survey also looked at the recording of challenging behaviour in relation to these compounds. 404 (62%) of the 655 reviews reported a normal psychiatric indication with 237 (59%) of these also reporting challenging behaviour. 183 (28% of the 655) recorded challenging behaviour but no other indication and 68 (10%) recorded neither. Some benzodiazepines may be prescribed for insomnia; this did not appear as a recorded indication in the data.

5.32 Both clonazepam and buccal midazolam are used in epilepsy, the latter in acute situations. Clonazepam is also used for its calming or sedative properties in acute psychosis, though not licensed for this purpose. Similarly, buccal midazolam is used unlicensed in the management of acute behavioural disturbance. 38 reviews included a prescription for ‘as required’ clonazepam. Of these, eight reviews (21%) reported a diagnosis for which clonazepam is normally indicated. 13 reviews included a prescription for ‘as required’ midazolam. Eleven of these (85%) reported a diagnosis for which midazolam is normally indicated.

‘Regular’ high doses of a single agent:

5.33 Full dosage information was provided for anxiolytics for regular administration in 150 (90%) cases where one compound was prescribed and three (75%) where two compounds were prescribed. Only one of the 153 reviews (1%) in which all relevant details were available included an anxiolytic prescribed in a high dose.

‘Regular’ combined doses of multiple agents:

5.34 Two (1%) reviews including prescriptions for anxiolytics administered regularly authorised a combined total anxiolytic dose of over 100% of the BNF recommended limits.

‘Any’ anxiolytic (‘regular’ and/or ‘as required’ administration) – high doses:

5.35 560 reviews requesting named anxiolytics given for administration on a regular and/or an ‘as required’ basis had full dosage information. It is not possible to determine how frequently medicines prescribed ‘as required’ would have been administered. However, it is reasonable to assume that the prescriber was authorising the use of ‘as required’ doses in addition to the regularly administered medications requested. On this basis, for any single compound, the sum of the regular and ‘as required’ doses can be taken as the anticipated total anxiolytic load, at least on occasions. The number of reviews where at least one compound in this class was prescribed in a potentially high dose was 21 (4%).

‘Any’ anxiolytic (regular and/or ‘as required’ administration) – combined doses:

5.36 Of these 560 reviews where doses for anxiolytics were stated (regular and/or ‘as required’ administration), 78 (14%) involved a potential total combined anxiolytic dose exceeding 100% of the BNF recommended limits.

Request – miscellaneous medication data

5.37 0.3% (n=3) of the 945 requests were not being prescribed any medication at the point the request was made.

Table 12

Miscellaneous medication	
Hypnotic/Sedative antihistamine (4.1.1/3.4.1)	256/945
CNS Stimulants (4.4)	39/945
Antimuscarinic (4.9.2)	327/945

'As required'	
Treatments with 'as required' prescribed	840
Treatments without 'as required' prescribed	105

CNS stimulants and diagnoses:

5.38 39 reviews included at least one prescription for regular administration of a named CNS stimulant. One (3%) of these proposed two named CNS stimulant agents. 26 of these 39 reviews (67%) reported that the patient had a diagnosis for which CNS stimulants are normally indicated.

'Regular' high doses of a single agent:

5.39 For CNS stimulants prescribed, dosage regimes were specified in 97% (n=37) of cases where one compound was prescribed and in the only case where two compounds were prescribed. In 3 of the 38 (8%) reviews in which all relevant details were available a CNS stimulant was requested in a high dose (above its prescribed maximum).

‘Regular’ combined doses of multiple agents:

5.40 Four (11%) reviews including prescriptions for CNS stimulants authorised a combined total CNS stimulant dose of over 100% of the BNF recommended limits.

Prescribed medication matrix

Drug group	Antipsychotic	Antimanic/ mood stabiliser	Antidepressant	Anxiolytic	Hypnotic	Other CNS	Antimuscarinic
Antipsychotic	**33**	**355**	**233**	**536**	**179**	**31**	**251**
Antimanic/ mood stabiliser	**355**	**3**	**103**	**262**	**110**	**13**	**136**
Antidepressant	**233**	**103**	**3**	**189**	**71**	**6**	**90**
Anxiolytic	**536**	**262**	**189**	**15**	**132**	**25**	**186**
Hypnotic	**179**	**110**	**71**	**132**	**1**	**8**	**64**
Other CNS	**31**	**13**	**6**	**25**	**8**	**0**	**8**
Antimuscarinic	**251**	**136**	**80**	**186**	**64**	**8**	**0**

5.41 The medication matrix provides a quick reference for the prescribed medication combinations. For example, of the 945 section 58 request forms, 536 prescribed at least one antipsychotic and one anxiolytic at the time of request. Numbers in black boxes represent treatment plans which feature only that one type of psychotropic medication.

6. Certified medication statistical analysis

Key findings

- 3,791 medications were certified across 818 certificates.
- Females were certified, on average, more medications than males though the effect size was small.
- Patients treated by independent care providers were certified, on average, more medications (five vs four).
- Certifications for polypharmacy:
  - Total number of 508 (62%) cases.
  - 57% (NHS) vs 68% (independent).
  - 62% (LD specialised wards) vs 61% (other psychiatric wards).
- Certifications high dose medication:
  - Total number of 385 (47%) cases.
  - 43% (NHS) vs 51% (independent).
  - 47% (LD specialised wards) vs 47% (other psychiatric wards).
- Certifications for ≥5 medications:
  - Overall rate of 51% (n= 416) across all cases.
  - 43% (NHS) vs 58% (independent).
  - 49% (LD specialised wards) vs 52% (other psychiatric wards).

6.1 In total 818 SOAD certificates featuring medication were analysed. Missing or removed data in the SOAD section included 12 which were certificates for ECT only. Four SOADs did not issue a T3 (two issued a T2; one found the T3 at the time covered the proposed treatment; one reported that the patient required more time to prepare for assessment). The medication averages are based on the median score unless specified as mean scores.

Statistical analysis was carried out with SPSS. There were 818 data points analysed from the SOAD data. Double counting of individuals occurred due to each certification being unique therefore individuals featuring more than once in the survey were included in the analysis. There was a significant difference between gender and the provider type. Females were certified, on average, higher numbers of medications compared to males ($t = -2.68$, $df = 816$, $P \leq 0.007$) though the effect size was small ($d=0.18$). However there was not a significant difference between gender and high dosage certification (chi square = .08, df = 1, $P > 0.05$). There were more certified medications on an individual T3 for patients treated within independent trusts compared to NHS (5 vs 4 respectively, $t = 4.67$, $df = 816$, $P \leq 0.0001$). Patients certified more than eight

medications on T3 were slightly more common in independent care providers with 54% (n=25) against 46% (n=21) for NHS settings. There was no significant difference between a patient's ethnicity and the number of the medications certified, nor was there a significant difference between ethnicity and high dose medication dosage. However the disproportionate sample size between groups affects the significance greatly.

Table 13

Diagnosis type	
'Developmental'	343/818
'Acquired'	475/818

There was no significant difference in the number of certified medications between acquired and developmental diagnosis patients. There was no interaction between diagnosis type and the medication category a patient was in. Medication category was defined into five distinctive categories; (1) The patient is on one or two medicines and dosage do not appear high (11% of patients were in this category); (2) The patient is on more than two and less than five medicines but not on high dosage (21% of patients were in this category); (3) The patient is on more than five medicines but not on high dosage or polypharmacy (6% of patients were in this category); (4) The patient is on polypharmacy of one or more category (17% of patients were in this category); (5) The patient is on a large number of medicines and polypharmacy. (45% of patients were in this category). However, 56% of certificates for patients with a 'developmental' diagnosis were in category 4/5, compared to 66% of certificates for patients with an 'acquired' disorder. Only 3.3% (n=27) of total treatment plans did not utilise polypharmacy.

6.2 However, there was a significant difference between NHS and independent care providers with regard to the certification of a polypharmacy regime. Patients with learning disabilities under independent care were more likely to be in a higher medication group (group three or higher) with 74% of independent patients compared to 64% of NHS patients in this range. Overall, 68% of patients in independent care as opposed to 57% of NHS patients were certified polypharmacy with an overall mean of 62% (n=508). There was a significant difference between NHS (43%) and independent (56%) patients with regard to being certified high dose medication (chi square = 4.19, df = 1, $P \leq 0.04$; v= 0.72). However caution is advised in respect of this result as any certificate which included multiple medications within the same category, each being within their own BNF limit, was considered high dose medication as this would be considered within the T3 overall limits (for example, two antipsychotics each within their BNF limits potentially allows up to 200% of BNF dose limit). Furthermore, it should be emphasised that of the 257 certificates in the category 4/5 group only 91 were certified regular psychotropics only.

There was a significant difference between diagnosis type (acquired or developmental) and high dose certification, with 40% of patients with a 'developmental' disorder being certified high dosage compared to the 52% of 'acquired' disorders (chi square = 17.96, df= 1, P≤0.0001).

There was no significant difference between the type of ward (specialised for patients with learning disabilities vs non-specialised) and the number of certifications featuring polypharmacy (t = .10, df = 816, P> 0.05). 61% of patients on non-LD specialist wards were certified polypharmacy, while 62% were certified on learning disability specialised wards. Both specialist and non-specialist wards had 47% of patients certified high dose medication. Finally, 49% of certificates for patients on a learning disability specialised ward had patients certified 5+ medications compared to the 52% of non-specialist wards.

It should be noted that there was a discrepancy between the rate of medication polypharmacy certification (n= 549) and polypharmacy certification for patients (n= 508). This can be accounted by the fact that 32 patient cases had multiple instances of polypharmacy certified on their T3 e.g. 2 antipsychotics and 2 anxiolytics - while this represents two cases of medication polypharmacy, it is still only a single second opinion case.

6.3 The data from the high secure hospital sample were also isolated and analysed. There were eight cases, due to two requests being cancelled. The average number of medications certified was three, with only two cases having five or more medications prescribed. Three cases from high secure hospital were certified polypharmacy (all antipsychotic) by a SOAD. Five cases were certified an antipsychotic depot medication.

6.4 A total of 43 adolescent cases were analysed as a sub-group of interest. The average number of medications certified was five, though 28 cases were certified five or more medications in their treatment plan. There was a high rate of polypharmacy with 65% (n=28) of cases featuring this, of which 81% (n=21) was polypharmacy via regular medication. Forty-two per cent (n=18) of certified treatments also featured high dosage medication.

6.5 Of the 52 CTO requests 42 went on to be assessed by a SOAD. The mean number of medications certified was three (as opposed to the average of two prescribed). 24% (10) of CTO patients were certified treatment plans featuring polypharmacy, all being based upon 'regular' medication rather than 'as required'. Finally, 16% (a total of seven) certificates featured high dosage medication.

Certified antipsychotic data

6.6 A total of 780 (95%) of the 818 T3s certified at least one antipsychotic[10] and 362 (46%) were certified potential antipsychotic polypharmacy. Within this group 233 (30%) were certified high dosage, this included any certificates featuring two or more antipsychotics each within their BNF limit which could potentially both be used up to their separate respective limits. A total of 562 (72%) of antipsychotic certifications were for regular use and 218 (28%) were certified specifically as 'as required'. Seven (n=56) of T3s certified clozapine therapy, of these 50 (89%) included at least one additional antipsychotic.

Only 398 (51%) certificates were diagnosed with some form of psychosis; 313 with a psychotic diagnosis, 85 with a diagnosis of bipolar disorder and 317 cases referenced psychotic symptoms in the diagnosis/rationale/SOAD report). Of the 480 patients who had a reference of aggressive challenging behaviour at any point of the second opinion process (diagnosis/rationale/statutory statement) 455 (94%) were certified an antipsychotic equating to 58% of the total antipsychotic certifications. Finally, 167 (21%) of patients were certified a depot, of whom 47 (38%) were certified a depot with no other antipsychotic medication.

Table 14

Total number of antipsychotic agents certified	Frequency	%	Cumulative percentage
0	38	4.7%	4.7%
1	418	51.1%	55.8%
2	338	41.3%	97.1%
3	24	2.9%	100%
Total	818	100	

[10] Antipsychotics were classed as any medication within BNF 4.2.1 or 4.2.2

Total number of antipsychotic agents certified for regular use	Frequency	%	Cumulative percentage
0	256	31.3%	31.3%
1	352	43.0%	74.3%
2	197	24.1%	98.4%
3	13	1.6%	100%
Total	818	100	

Please refer to appendices for a more detailed breakdown of numbers.

Table 15

Total number of Depot agents certified	Total number of other agents (regular and 'as required') certified in conjunction with Depot
167 Certified a Depot	Depot + 0 = 12
	Depot + 1 = 11
	Depot + 2 = 12
	Depot + 3 = 37
	Depot + 4 = 38
	Depot + 5 = 31
	Depot + 6 = 15
	Depot + 7 = 7
	Depot + 8 = 4
	Total= 167

The table above displays the medication combinations with depot medication.

6.7 Of the 684 requests for antipsychotics administered regularly, and where assessment outcome data were available, the SOAD made a slight or significant change in 146 (21%). There was no association between this and whether a recognised indication was reported (23% with recorded indication present, 19%, chi square = 1.47, df=1, P> 0.05). Changes were made in 75 out of the 336 assessments (22%) where 'as required' antipsychotics were prescribed. If anything, changes were made more commonly where a recognised indication was recorded, though the difference was not statistically

significant (19% with indication absent, 26% with indication recorded, chi square = 2.63, df=1, P> 0.05).

6.8 SOADs made changes more commonly where high doses were prescribed. This was apparent both for regular administration (high dose – 39% made change, no high dose – 20%, chi square = 7.8, df=1, p0.005) and for ‘any’ antipsychotic (regular and/or ‘as required’ administration) (high dose – 37% made change, no high dose – 21%, chi square = 8.45, df=1, p<.005). A similar pattern was seen for SOADs’ responses to high combined total doses. This was unsurprising since in many cases the high total dose arose from a single compound. They made changes in 40% of cases where the combined total dose of regularly prescribed antipsychotics exceeded 100% of BNF maximum but only 19% where it did not (chi square = 18.5, df=1, p<.0001) For high combined total doses of antipsychotics for regular and/or ‘as required’ administration, changes were made in 33% of cases where the total dose was high compared to 18% of cases where it was not (chi square = 18.94, df=1, p<.0001).

Certified antidepressant data

6.9 The survey found 307 (38%) of the 818 T3s certified at least one antidepressant.[11] The vast majority, 302 (98%) were certified an antidepressant on a regular basis. Twelve (4%) patients certified antidepressant polypharmacy all of which was regular medication polypharmacy. A total of 44 (14%) patients were certified at least one antidepressant specifically in the context of a depressive illness. However, 120 (39%) patients did not have a diagnosis of depression or bipolar but some form of autism and consequently certified at least one antidepressant, making 36% of the total number of patients with autistic spectrum disorder (n=332) being certified an antidepressant in this context. Finally, 142 (46%) were certified at least one antidepressant for other diagnoses outside of the previous two groups, common diagnoses including schizophrenia and personality disorder.

Table 16

Total number of antidepressant agents certified	Frequency	%	Cumulative percentage
0	511	62.5%	62.5%
1	295	36.0%	98.5%
2	12	1.5%	100%
Total	818	100	

Total number of antidepressant agents certified for regular use	Frequency	%	Cumulative percentage
0	512	62.5%	62.5%
1	295	36.0%	98.5%
2	12	1.5%	100%
Total	818	100	

Please refer to appendices for full table.

6.10 In 54 (21%) of the 258 requests where the assessment outcome was known and for antidepressants administered regularly the SOAD made a slight or significant change. There was no association between this and whether a recognised indication was reported (recognised indication absent – 23%

[11] Antidepressants were classed as any medication as or within BNF category 4.3

recommended slight or significant change, indication present – 16%, chi square = 1.69, df=1, P> 0.05). Dosage information was available in 51 of these cases. There was no association between whether a high dose antidepressant was prescribed and the review conclusion (high dose – 17% made change, no high dose – 21%, chi square = 0.07, df=1, P> 0.05).

6.11 A similar pattern was apparent for SOADs' response to combined high doses. The SOAD made changes in 21% of cases where the combined total dose of regularly prescribed antidepressants exceeded 100% of BNF maximum and 21% where it did not (chi square = 0.003, df=1, P> 0.05).

Certified mood stabiliser data

6.12 Of the 818 T3s 405 (49%) had certified at least one mood stabiliser.[12] Within this 16 (3%) T3s allowed the certified mood stabiliser to be above BNF limits for a single drug. A total of 75 (18%) patients were certified mood stabiliser polypharmacy. Finally, 171 (42%) of mood stabiliser certifications were on a regular basis with 235 (58%) certified as 'as required'.

Table 17

Total number of mood stabiliser agents certified	Frequency	%	Cumulative percentage
0	412	50.4%	50.4%
1	331	40.5%	90.9%
2	69	8.4%	99.3%
3	5	0.6%	99.9%
4	1	0.1%	100%
Total	818	100	

Total number of mood stabiliser agents certified for regular use	Frequency	%	Cumulative percentage
0	648	79.2%	79.2%
1	133	16.3%	95.5%
2	34	4.2%	99.7%
3	3	0.2%	99.9%
4	1	0.1%	100%
Total	818	100	

Please refer to appendices for full table.

6.13 The SOAD made a slight or significant change in 80 (21%) of the 373 requests where the assessment outcome was known and where mood stabilisers were administered regularly. There was no association between this and whether a recognised indication was reported (recognised indication absent – 26% made

[12] Mood stabilisers were classed as any medication as BNF category 4.2.3 or 4.8.1

slight or significant change, indication present – 17%, chi square = 3.62, df=1, P> 0.05).

6.14 The SOAD made a slight or significant change in 77 (23%) of the 336 requests for mood stabilisers administered regularly where the outcome of the review was known and where doses were specified. There was no association between this and whether a high dose mood stabilizer was prescribed (high dose – 20% made change, no high dose – 23%, chi square = 0.05, df=1, P> 0.05).

6.15 A similar pattern was apparent for SOADs' responses to combined high doses. The SOAD made a slight or significant change in 13% of requests where the total combined dose of regularly prescribed mood stabilisers exceeded 100% of BNF maximum, and 24% where it did not (chi square = 2.31, df=1, P> 0.05), of the cases where the assessment outcome was known.

Certified anxiolytic data

6.16 A total of 694 (85%) of the 818 T3s certified at least one anxiolytic[13]. Patients who were certified anxiolytic polypharmacy were 14% (100) of that number. However only 4% (27) of these cases were certified for anxiolytic polypharmacy on a regular basis. No T3 time-limited anxiolytic certification. 336 (48%) of anxiolytic certifications were as regular medications. 40 reports had a beta-blocker certified as an off-licence anxiolytic. However, these were not included in the table or factored into polypharmacy rates.

Table 18

Total number of anxiolytic agents certified	Frequency	%	Cumulative percentage
0	124	15.2%	15.2%
1	594	72.6%	87.8%
2	96	11.7%	99.5%
3	4	0.5%	100%
Total	818	100	

Total number of anxiolytic agents certified for regular use	Frequency	%	Cumulative percentage
0	481	58.8%	58.8%
1	310	37.9%	96.7%
2	27	3.3%	100%
Total	818	100	

Please refer to appendices for full table.

6.17 The SOAD made a slight or significant change in 37 (25%) of the 150 requests for anxiolytics administered regularly and where the outcome of the review was known. There was no association between this and whether a recognised indication was reported (change made in 12% where a recognised indication was present, 26% where absent; chi square = 1.72, df=1, P> 0.05). Changes were made in 127 out of the 578 cases (22%) where ‘as required’ anxiolytics

[13] Anxiolytics were classed as any medication listed as BNF 4.1.2. If specified, Clobazam was also included as it is also indicated for short term use in anxiety. Clonazepam and Midazolam have been included where explicitly specified for completeness.

were prescribed and the outcome of the review was known. This was also not significantly associated with the presence or absence of indications as reported above (change made in 22% without indication, 22% with indication).

6.18 Slight or significant changes were made in 34 (25%) of the 135 requests for anxiolytics administered regularly where doses were specified and the assessment outcome was known. None of these 34 cases included a high dose anxiolytic prescription. Of the 495 cases where ‘any’ anxiolytic was prescribed for regular and/or ‘as required’ use and doses and assessment outcomes were recorded, the SOAD made a slight or significant change in 111 (22%). There was no association between this and whether a high dose anxiolytic was prescribed (change made in 38% without a high dose and 22% with a high dose; chi square = 2.16, df=1, P> 0.05).

6.19 Of the 135 requests for anxiolytics administered regularly where doses were specified, only one requested a high combined total dose. In this case the SOAD did not make any change. In the 495 cases where ‘any’ (for regular and/or ‘as required’ administration) anxiolytics or benzodiazepine anticonvulsants were proposed a SOAD made changes in 111 (22%). This was more common where the combined dose was high, change was made in 35% of cases where the combined total of regularly and ‘as required’ doses exceeded 100% of BNF maximum but only 21% where it did not (chi square = 6.76, df=1, p=0.009).

Certified miscellaneous medication data

6.20 Only 14 (2%) patients seen by a SOAD were not certified any medication, and 422 (51%) were certified a medication for side-effects (4.9.2/4.6/2.4). Category 2.4 presents a problem – it is the category for beta-blockers, drugs that have licenced indication usage both for anxiety and also to address cardiac-related issues, including tachycardia (raised pulse rate), which can sometimes be seen as a side-effect of other medications for mental disorder. It was not possible reliably to differentiate these two uses within the data available for this survey. For this reason it is included in the ‘miscellaneous’ category.

Table 19

Miscellaneous medication	
Hypnotic and sedative antihistamine (4.1.1/3.4.1)	289/818
CNS Stimulants (4.4)	48/818
Antimuscarinic (4.9.2)	391/818

‘As required’	
T3s with specified ‘as required’	362
T3s without specified ‘as required’	456

Treatment approval data[14]	
Approved without change	658
Treatment slightly changed	144
Treatment significantly changed	29
Treatment not approved	4
N/A (cancelled)	110
Treatments with medication above BNF limit for a single drug	268

[14] See figure 3 in appendix 1 for display of the proportions of treatment approval.

6.21 In three (9%) of the 35 requests for CNS stimulants where the assessment outcome was known the SOAD made a slight or significant change. There was no association between this and whether a recognised indication was reported (recognised indication absent – 18% made slight or significant change, indication present – 4%, chi square = 1.89, df=1, P> 0.05).

6.22 The SOAD made a slight or significant change in three (9%) of the 34 requests where the assessment outcome was known and for CNS stimulants administered regularly where doses were specified. No changes were made in the three cases where a CNS stimulant was requested in a high dose.

6.23 A similar pattern was apparent for the SOADs' responses to combined high doses. No changes were made to the four cases where the combined total CNS stimulant dose was over 100% of BNF recommended limits.

Certified medication matrix

Drug group	Antipsychotic	Antimanic/ Mood Stabiliser	Antidepressant	Anxiolytic	Hypnotic	Other CNS	Antimuscarinic
Antipsychotic	**20**	**281**	**170**	**465**	**46**	**39**	**391**
Antimanic/ Mood Stabiliser	**281**	**1**	**65**	**175**	**71**	**15**	**42**
Antidepressant	**170**	**65**	**1**	**248**	**91**	**10**	**119**
Anxiolytic	**465**	**175**	**248**	**8**	**216**	**40**	**325**
Hypnotic	**46**	**71**	**91**	**216**	**0**	**19**	**134**
Other CNS	**39**	**15**	**10**	**40**	**19**	**0**	**19**
Antimuscarinic	**391**	**42**	**119**	**325**	**134**	**19**	**0**

6.24 The medication matrix provides a quick reference for the certified medication combinations. For example, of the 818 T3s, 465 included both at least one antipsychotic and one anxiolytic. Numbers in black boxes represent treatment plans which feature only that single type of psychotropic medication. A total of 3791 medications were certified between 818 patients.

7. Discussion

7.1 The results of this survey were consistent with previous research. Of the sample, 68% (534) was male and 74% (590) were white, which is consistent with previous research on the receipt of psychotropics (Lelliott et al, 2002), although that study was of adults in general psychiatric settings thus not directly comparable. There was no significant difference between the mean number of medications certified for patients on specialised learning disability wards and those on non-specialised learning disability wards.

A wide range of psychotropic medications were involved. Where antipsychotics were prescribed for regular administration, within-group polypharmacy was seen in 21% of cases. Doses above recommended BNF maxima were prescribed in 9% of cases for 'any' single antipsychotic (administered regularly and/or 'as required') but high combined total antipsychotic loads were much more common (28%). Roughly half of the patients for whom antipsychotics were prescribed had no recorded diagnosis of a psychiatric condition for which antipsychotics would be viewed as indicated by the BNF. Data from a national audit study by Paton et al (2011) showed that 12% of their sample had received one or more antipsychotic with no co-morbid psychiatric diagnosis in addition to learning disability. However, it was also noted that 60% of that cohort did not have a recorded psychotic illness. This indicates that the findings of this survey are broadly in line with that national audit. In this survey, high doses were much less frequently used in classes of medication other than antipsychotics, and there was similarly a limited correspondence between the diagnoses recorded for these patients and the diagnostic indications for which these drugs would normally be expected to be prescribed.

While gender differences were not apparent in prescribing, females were on average certified more medications within their approved treatment plan. The findings of the learning disability census reported that females were proportionately more likely to experience events including self-harm, an accident, physical assault on the service user, hands-on restraint or seclusion, during the three months preceding the census compared to males. These issues may lay behind this finding of an average higher number of certified medications in females than their male counterparts.

7.2 At the time of request 91% (858) were prescribed at least one antipsychotic. A large proportion of T3 forms certified an antipsychotic with 95% (780) featuring at least one antipsychotic. In total, 51% (398) of the patients certified an antipsychotic had a formal diagnosis of either psychosis or bipolar affective disorder. Aggressive challenging behaviour was featured in 58% (545) of cases and was commonly described in proposed treatment rationales, some offering it as a diagnostic label. This level is slightly higher than the rates cited in literature, which range from 16% to 50% depending on the definition of aggressive challenging behaviour (2008; Smith et al, 1996; McGrother et al, 2007; Deb and Hunter, 1991). Furthermore, 43% (339) were prescribed an antipsychotic for the challenging behaviour without there being any reference to a formal diagnosis of psychosis, despite the paucity of evidence to support this treatment (Tyrer et al, 2008; Brylewski and Duggan, 2004). It could be argued that the high rates were certified on an 'as required' basis however this is

questionable given that only 27% of T3s authorised antipsychotic medication ‘as required’. In addition, 94% of cases (814 of 858), who were prescribed an antipsychotic, were prescribed this on a regular basis. The Learning Disabilities Census Report reported that 68% (2,220) of service users had been given antipsychotic drugs leading up to the census day, and of these, 93% (2,064) had been given them on a regular basis.

7.3 A total of 32% (301) were prescribed an antidepressant at the time of request. Of the 818 cases assessed by a SOAD 39% (306) of certifications included an antidepressant. The rates of receipt in this survey are higher than those reported previously (Robertson et al, 2000). 14% (44) of patients were certified at least one antidepressant specifically in the context of a depressive illness. 39% (120) did not have a diagnosis of an affective disorder but were recorded as having some form of autism, and were certified at least one antidepressant. A few reports (six) that certified an antidepressant described poor food and fluid intake, which previous studies have reported as an indication of a mood disorder in the population with a more severe learning disability (Hurly, 2006), and other studies have supported its use in the learning disability population (Fraser et al, 1998). There is evidence supporting the use of antidepressant polypharmacy for patients with learning disabilities (Licht and Qvitzau, 2002; Shelton, 2003; Trivedi et al, 2006).

7.4 In the survey, 82% (776) of the 945 cases were prescribed an anxiolytic at the time of request. Of the sample for whom SOAD visits were made, 85% (694) were certified at least one anxiolytic. While anxiety disorders are a well-recognised and prevalent issue within the learning disability population (Coory and Bakala, 2005; Bailey and Andrews, 2003) this rate of certification is high. Five per cent (40) were certified a beta-blocker as an anxiolytic. While effective in reducing the physical aspects of anxiety, the benefits for the emotional and cognitive aspects of anxiety are not as great (Bystritsky et al, 2013). It is however possible that the prescriber, being unable to deal immediately with the emotional and cognitive aspects of anxiety since these require longer term interventions, is nevertheless prescribing an appropriate agent for one of the distressing aspects of anxiety.

7.5 A common risk factor associated with anxiolytics, in particular benzodiazepines, is increased falls (McMahon et al, 2014). Given the evidence of gait and mobility issues associated with developmental disabilities, in particular Autism and Asperger’s (Jansiewicz et al, 2006), there is a possible increased risk to this population arising from benzodiazepine use. This study did not, however, have scope to explore physical health issues.

7.6 The rate of mood stabiliser use was proportionately consistent between request and certification, with 48% (451) of cases prescribed at least one mood stabiliser medication at the time of request and 49% (405) of those seen by a SOAD being certified at least one mood stabiliser.

7.7 It is recognised that there is a high prevalence of epilepsy within the learning disability population, with studies reporting a rate up to 50% depending on the type and degree of learning disability (Lhatoo and Sander, 2001). However, only

3% (32) of the 945 request cases included epilepsy in the patient diagnosis; this is perhaps not surprising, given that the second opinion process is specifically for medication relating to a mental disorder and also because the predominant level of learning disabilities for detained patients is likely to be mild. Epilepsy is classed in the ICD-10 as a disease of the nervous system rather than a mental or behavioural disorder, and one might therefore not expect providers to give detail of physical disorders in a 'diagnosis' field on a form specifically for mental disorder. Nevertheless, it is known that the presence of epilepsy can influence the manifestations of some psychiatric conditions, and it may also impact upon the appropriateness and dosage of medication for mental disorder in the light of drug-drug interactions. The position is further complicated by the fact that many antiepileptic drugs have use as mood stabilisers – not all are licensed for this usage. However there is widespread recognition of their utility. It is therefore possible that some patients are receiving a drug for their epilepsy which, as a by-product, has action in stabilising their mood. The nature of the data collection for this survey was such that it was not possible to separate out these potential different uses of the same drug. Pragmatically, therefore, it was decided that if antiepileptic medication formed part of the request from a provider, or was certified by a SOAD, this would be viewed as having been for its mood stabilisation action.

7.8 Overall, 57% (534) of the sample population were prescribed and 62% (508) certified treatment plans featured polypharmacy. It was found that independent care providers had a larger proportion of patients, both 280 (68%) prescribed and 268 (67%) certified polypharmacy compared with the NHS where the comparable figures were 254 (51%) prescribed and 240 (57%) certified treatment plans featuring polypharmacy.

7.9 The independent healthcare sector includes specialist services which may be the placement of choice for those with multiple or complex needs, or those individuals with more long-term or severe challenging behaviours. Anecdotal evidence suggests that these are commonly the placements chosen by NHS commissioners for patients in these categories, and there are very many independent providers offering such a service – perhaps a greater number than in the NHS. Such placement decisions would impact on the patient profile compared with NHS service users, thus potentially affecting treatment plan issues such as polypharmacy use across the population. It was not possible to discern from this study whether the differences in prescribing practice related to differences in clinical practice, or arose from commissioners referring different diagnostic and prognostic groups to different provider types. It is also of note that of the group with a 'developmental' disorder 56% (197) were certified polypharmacy regimes, and 71% (140) high dosage medication. In comparison 65% (309) of patients with an 'acquired' disorder were certified polypharmacy, and 79% (246) with high dose medication. Antipsychotic polypharmacy (more than two antipsychotics) rates were consistent with results from a similar study (Harrington et al, 2002) which conducted a medication survey of all psychiatric patients, finding that 48% were prescribed more than one antipsychotic, compared to the 46% in this sample. However, the focus of that study was on prescriptions, not treatments certified – the latter may not result in a patient actually receiving any or all of the certified medications. An important

consideration, particularly for antipsychotics, is the use of polypharmacy for cross-titration though only 12 certificates specified this. Cross-titration is the planned crossover from one prescribed drug to another; there are some drugs, and conditions, where rather than stopping one and then starting the other, it is preferable gradually to reduce the dose of one drug while introducing its planned replacement and slowly increasing the dose of the latter. For a defined period, therefore, two drugs will be part of the prescription with the ultimate aim of reduction back to one. An additional, appropriate, use of polypharmacy is the augmentation of one drug with another, a strategy recognised as good practice in some specifically defined circumstances (Taylor, 2015).

Unlike previous studies (Kreyenbuhl et al, 2013; Jaffe and Levine, 2002; Weissman, 2002) this survey did not find age to be an influence upon the likelihood of receiving polypharmacy. However the uneven distribution of age groups may account for this. A finding consistent with current literature was that antimuscarinic medication was more likely to be certified to patients receiving polypharmacy (Kreyenbuhl et al, 2013; Procyshyn and Thompson, 2004; Covell et al, 2002) with 69% (224) of prescribed antimuscarinic medication and 73% (287) of certified antimuscarinic medication seen to occur in treatment plans featuring polypharmacy. Of the 508 cases who were certified polypharmacy, only 39% (198) did not have any specified ‘as required’ medication on the T3 and of that group 35% (179) had ‘as required’ listed on the medication request form. Fourteen per cent (100) of cases were certified anxiolytic polypharmacy. Studies have reported a significantly increased risk of mortality associated with anxiolytic polypharmacy (Tiihonen et al, 2012; Baandrup et al, 2010). Three per cent (12) of patients were certified antidepressant polypharmacy.

A finding of this study is the use of high total dose of combined multiple antipsychotic medications, with 28% of cases prescribed regular and/or ‘as required’ antipsychotics, reducing to 13% when considering only ‘regular’ antipsychotic administration, and a total of 30% of cases being certified antipsychotic medication in high doses. These rates are divergent from previous studies, where Harrington et al (2002) reported 20% of patients on high dose medication antipsychotic dosage. However as previously noted this is not necessarily a comparable group since the study population was not people with learning disabilities. There can be much more confidence in the findings that relate to high doses of medications administered regularly, since it is less likely that the medications administered on an ‘as required’ basis are actually given each day. Concern regarding use of high dose medication is one of patient safety and whether the risks have been properly assessed on an individual patient basis. A possible link has been described between antipsychotic drugs and acute major cardiovascular events. On this basis, the Royal College of Psychiatrists’ working group consensus statement (2006) suggested that “on the basis of current evidence, high-dose prescribing, either with a single agent or combined antipsychotics, should rarely be used and then only for a time-limited trial in treatment-resistant schizophrenia after all evidence-based approaches have been shown to be unsuccessful or inappropriate”. In their recommendations they observed: “Current evidence does not justify the routine use of high-dose antipsychotic medication in general adult mental health

services, either with a single agent or combined antipsychotics." They were silent as to the use of antipsychotics in learning disability.

There were 47% (386) of cases certified for high dosage medication. However this rate is potentially an overestimate since on the statutory certificate, Form T2 or T3, it is usual for there to be no specific dosage given; rather the total permitted maximum is certified by reference to the maximum percentage of the BNF allowed. As has previously been explained, the T form is permissive, not necessarily prescriptive – the prescribing clinician can give any medication(s) listed on the T form or listed in the categories described on the T form, within the maximum specified doses. Therefore, the fact that a T form may permit an above BNF dose does not equate to a conclusion that this is the dose a patient will actually receive.

Certification rates of high dosage antipsychotics were higher (30%) compared with previous studies that found rates of 20% (Lelliott et al, 2002). However the sample size was comparatively low (818 for this survey vs 3576 for Lelliott et al). In addition, it is important again to note that the larger 2002 survey was of a group of patients with totally different problems who were cared for in totally different settings.

7.10 Deb et al (2014) conducted a study investigating prescription trends of a sample of 100 community based patients with learning disabilities over a six-month period. There are comparable results with those from this survey, when only CTO patients from this survey were used as comparators (52 at request; 42 certified). Deb et al reported that 90% of the patients were on some form of psychotropic compared to the 100% in this survey (both prescribed and certified). Six per cent of the sample from Deb et al was on a depot compared to the 36% prescribed at request and 47% certified. Polypharmacy rates for CTO patients were noticeably higher with 21% prescribed polypharmacy at the time of request, and 23% certified polypharmacy by a SOAD compared to the 9% of the Deb et al sample. However, the sample size of CTO patients was very low, accounting for only 5% of the sample. Also, the sample in Deb et al may not have been detained under the Mental Health Act, potentially affecting the comparisons that can be made. Rationales for the proposed treatment plans which requested multiple antipsychotics provided little rationale for polypharmacy.

7.11 There were 43 adolescent patients (age 17 or under), 58% (25) of these cases were prescribed treatments featuring polypharmacy at the time of request; however 16% (4) were of polypharmacy based upon 'regular' medication. The number of cases which had evidence of certified polypharmacy increased to 65% (28) of which 75% (21) was in relation to regular medication. This is a higher proportion compared with the 35% reported by Spencer et al (2013). However, the sample size reported here is very small (43 for this survey vs 33,565 from Spencer et al). However earlier studies estimated prevalence of polypharmacy ranging between only 10-20% in this population (Rosenberg et al, 2010; Gerhard et al, 2009; Murray et al, 2013). Though the sample for Spencer et al was specifically autistic spectrum disorder, 72% (31) of the survey sample had some form of autism and the rate of polypharmacy remained

consistent at 67%. Other studies have reported increasing rates of polypharmacy in children (McIntyre and Jerrell, 2009; Constantine et al, 2010; Comer et al, 2010). Ten SOAD reports relating to adolescents were analysed; in these, polypharmacy appears generally to have been certified in the context of severe aggressive behaviour directed towards others, or the patient had shown a notable reduction in such behaviour in apparent response to such medication ongoing prior to the request for a SOAD. For these adolescents, rationales were of higher quality providing an explanation of the proposed medication regime, and more likely to give an account of plans to reduce or phase out medication.

7.12 Patients in high secure hospital settings were both prescribed and certified fewer medications compared to the overall trend of the data. Several factors may perhaps explain this difference. Thompson (2000) reported that a high proportion of patients detained in high secure hospitals have a primary diagnosis of personality disorder and considered that the training for staff in such settings is aimed to prevent or de-escalate violent episodes. It may thus be the case that medication usage is less in this group. Moreover, patients in high secure settings are detained for significantly longer periods compared with those placed on generic acute mental health wards; during a prolonged period there may be a greater opportunity to optimise the patient's medication, thus potentially allowing an improved mental state on a relatively low dosage and number of medications. What may also be relevant is that there has been previous criticism of high secure hospitals and high dose medication, such that there has been significant scrutiny of the issue resulting from the views of the Royal College of Psychiatrists and others, while they also have available to them a clinical pharmacy service which many providers lack.

7.13 As mentioned in the methods section, the survey has many limitations. It was both opportunistic and retrospective. The opportunistic nature of the study means that one cannot draw firm conclusions from the data about the appropriateness of the types and doses of the medications prescribed. This would have required a research study that ascertained diagnoses and problem types using standardised assessment tools. It would also have required a detailed analysis of the history of prescribing and the extent to which alternatives to prescribing had been tried and evaluated for each individual patient. Another consideration is the fact that 17% (165) of the sample were diagnosed with moderate or severe learning disability, a population for which the ICD-10 has limited clinical utility (Smiley, 2005).

The retrospective nature of the survey resulted in incomplete data that affect the validity of any conclusions which can be made. Whilst the number of medications, including 'as required', and the numbers which could potentially be receiving polypharmacy, were identified, the individual actual dose being administered was not captured because the T3 only authorises a maximum limit. To capture these data would have required the locating, correlating, and analysis of all of the individual patients' medication administration record charts ("drug cards"), a task that could not feasibly be undertaken retrospectively. Certification of medication simply gives authorisation for what could be given, it does not equate to a patient receiving it. Whilst a patient may not receive any medication additional to or different from that specified on the T3 certificate,

they will not necessarily receive all of the medication which the T3 would theoretically permit to be used.

Another consequence of the retrospective nature of the study was that those completing the SOADs' statements of reasons for certification had not been asked to submit information in a structured form to support analysis. SOADs have more information available to them other than that recorded in the forms. This is because they are required to discuss the cases with key staff and to explore the available documentation. However, although this information informs the decision they take, SOADs are not required to record all of this detail on the form.

Notwithstanding all of these caveats, this study of prescribed medication as deduced from proxy data, found high rates of psychotropic prescription and polypharmacy as have earlier audits and studies (Deb et al, 2014; Robertson et al, 2000). The population which this survey investigated was patients detained under the Mental Health Act who required a second opinion for either medication or ECT (with only medication T3s being analysed), further limiting the scope of the results.

There is no recognised ideal method for estimating total medication load where two or more compounds of a single class are given together. A Royal College of Psychiatrists' working group (2006) proposed two approaches in the context of reviewing total antipsychotic doses. One is dependent upon identifying dosage equivalents by reference to a representative drug in the class (in the case of antipsychotics, the reference drug is chlorpromazine). The other method converts the dosage of each agent into a percentage of the BNF recommended maximum and arithmetically totals these separate figures to arrive at a total maximum equivalent. The second percentage method was chosen for this study, as the aim was to explore dosage issues in several classes of drugs; dose-equivalent tables for the purpose of the first method, similar to that described in the Royal College of Psychiatrists' report, have seemingly only been reported for antipsychotics (Gardner et al, 2010). The percentage method is also that used by SOADs in calculating any limitations that they impose upon total drug dosage.

A limitation of the approach used is that it does not allow for situations where different compounds in the same drug class as defined here have some differences in their mechanisms of action. This may mean that either the therapeutic or the side-effects of combinations are not simply additive. Dose maxima vary between jurisdictions, and can be a function not of toxicity but of the total maximum which the manufacturer sought at the time they chose to make an application to the relevant regulatory authority, thus the recommended maxima can vary between countries.

The approach to assessing whether medications were being prescribed in response to recognised and licenced indications also had limitations. Establishing diagnoses in people with learning disability may be difficult particularly when their use of spoken language is limited or absent. Therapeutic trials of possibly helpful drugs may be used partly to clarify diagnoses (Fraser,

1999). There were a small number of assessments where this type of rationale was recorded.

Diagnostic statements varied in their clarity. Some diagnoses were, in effect, recorded indirectly in the 'treatment' component of the referral form, but not in 'diagnosis'. This is easily explained and should not be taken as criticism of providers in this regard – the referral request form instructs providers to detail all treatments, whether for mental or physical conditions, since it is important for the SOAD to be aware of the totality of medication being prescribed or suggested so that they can take into account the overall pharmacological impact, and any interactions, in deciding upon appropriateness. Since their focus is on mental disorder, not physical conditions, there is less need for the latter to be recorded on the request form at the point of submission.

For challenging behaviour, since this is a symptom not a diagnosis, the approach taken in this survey was to include any indications that could be found. For psychiatric diagnoses there was greater restriction, with the inclusion only of diagnoses recorded in the diagnosis field. The identification of which compounds were appropriate to which clinical indications may have been over-inclusive; were that to be the case it might suggest the findings of this survey could be understated.

Transforming Care (2012) highlighted 'deep concerns about over use of antipsychotic and antidepressant medicines'. It recommended involvement of pharmacists as well as doctors and nurses in assessing and reviewing patients' medication. Whilst nurses are a necessary statutory part of the SOAD process, pharmacists are not, though they can be involved as an additional consultee. SOADs are required to speak with a second statutory consultee, and in circumstances where complex or contentious medication is proposed they commonly endeavour to utilise a pharmacist as that second consultee. The availability of this professional resource is however patchy.

Although the records indicate whether or not the SOAD made any change to the Responsible Clinician's (RC) treatment plan, they do not necessarily record the nature of the changes made. Whilst it was noted that changes were most commonly made in association with prescriptions incorporating high doses, it was not possible to establish whether the changes were made specifically to the doses of the medications prescribed in these assessments. A reason for this is that there are, deliberately, no definitions applied to whether the changes are 'slight' or 'significant' – codification of this would be virtually impossible since it is entirely a matter for individual clinical judgment in the circumstances of the specific case – what is a slight change given the context of one patient's case will be a significant change in the context of a second, different, patient.

7.14 Taking into account these limitations, the main conclusions of this study are that:

In many cases, patients with learning disabilities who lack the capacity to consent to medication, detained under the Mental Health Act, have prescriptions with limited diagnostic rationale from the RC included in the

information comprising the second opinion request. The proportion of prescriptions for which there appears to be no recognised indication for that drug, by which is meant an indication for which the drug is question appears not to be licensed, appear consistent with current literature. A study by Lowe-Ponsford and Baldwin (2000) investigated the rate of 'off-label' prescribing of psychotropic medication within the NHS and concluded that 65% of doctors issued such prescriptions. Haw and Stubbs (2007) reported that over 50% of benzodiazepines were prescribed without indication (this rate rises to >90% when factoring in that time-limit recommendations were commonly not complied with). Ornstein et al (2000) found that roughly 40% of prescribed antidepressants were not for mood disorders. Other studies have reported the more frequent favouring of Sodium Valproate for aggression (Sugarman et al, 2013).

Within-class polypharmacy, generally considered not to be good therapeutic practice, is seen, though not widely when 'regular only' polypharmacy was considered (21% of cases prescribing named antipsychotics for regular administration, 4% for named antidepressants and 2% for named anxiolytics). Rates do increase noticeably when 'potential' polypharmacy is considered. Certified medication followed similar patterns.

Prescription of drugs in doses above recommended BNF limits is mainly confined to antipsychotics. In this drug class combined doses above 100% of BNF limits were seen in 28% of cases where regular and / or 'as required' antipsychotics were prescribed. This was also a consistent trend with certified antipsychotics which saw a rate of 30%.

This survey was able to identify four possible factors for the lack of connection between diagnoses and prescribing. Firstly, a diagnosis that justified prescribing but was not mentioned. The qualitative data provided limited explanation for this discrepancy, typically rationalising anxiolytic and antimuscarinic medication, but no major diagnosis was detailed in the treatment rationale which was omitted from the diagnosis field. Nearly half of antipsychotic prescriptions for regular administration were agreed to by the SOAD with there being limited diagnostic reason recorded in the material available to us. In some cases, explanations in terms of problem behaviour were given as rationale particularly for high doses. However, recognising the difficulty of the situation does not alter the lack of evidence of efficacy of the proposed medications.

Secondly, there may be a general assumption among clinicians that medication has value in the control of challenging behaviour. Challenging behaviour was referenced in 480 (51%) cases when combined with the basic link between treatment and diagnosis. Brylewski and Duggan (2009) in their review considered that many clinicians are likely to base practice on clinical experience due to the absence of evidence behind pharmacological treatment for challenging behaviour; this would account for the limited evidence provided.

Thirdly, current medication was prescribed due to an historical diagnosis which is currently in remission. However the medication is continued in order to prevent deterioration. While there were cases which did note stability in

conditions, these were still listed in the diagnosis field and thus viewed within this survey as being current conditions.

Finally, there could be unspoken factors influencing prescribing. One possibility is subtle pressure to use medication to control aggression, by virtue of its ready availability and the relative ease of prescribing within inpatient settings, whereas other interventions such as improved staffing or environmental adaptations are issues for the medium-term or longer, and do not address an immediate difficulty of risk or patient distress which may present itself to staff.

This latter possibility may also have an impact on the use of high dosage, as there can be a pressure to maintain or increase the dose of medication when a patient is currently aggressive, a practice which has been reported previously (Fielding et al, 1980; Briggs, 1989). Thereafter, there can be understandable reluctance to then reduce the dose, for fear of what the possible consequences may be - there can thus be a ‘dose creep’ upwards. A further consideration may be that the patient is not happy about reducing their medication either through the comfort of routine or fear as to the consequence on their stability.

If at least some of the prescribing was to control behaviour, this might be because staff either lacked the resources or skills to manage in other ways behaviour that they found challenging. The data were collected before the publication of the Department of Health’s policy document ‘Positive and Proactive Care: reducing the need for restrictive interventions’ (Department of Health, 2014). This called for the widespread adoption of positive behavioural support planning to reduce the likelihood of staff resorting to restrictive interventions.

In 2012/13, when these data were collected, the SOADs certified many of the treatment plans as being appropriate. If staff in learning disability inpatient services are now using alternative, non-physical approaches to manage behaviours that challenge, it might be that SOADs can and should be more questioning of medication regimes that include prescriptions for multiple or high dose antipsychotic drugs.

What is clear is that this group of patients have difficulties which require skilled intervention to help them. Medication is likely to play a part in this. However there is as yet no commonly applied clinical consensus as to what types of medication, if any, should be given, at what doses, and for what indications.

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Appendices

Appendix 1: Graphs of demographic characteristics

Figure 2

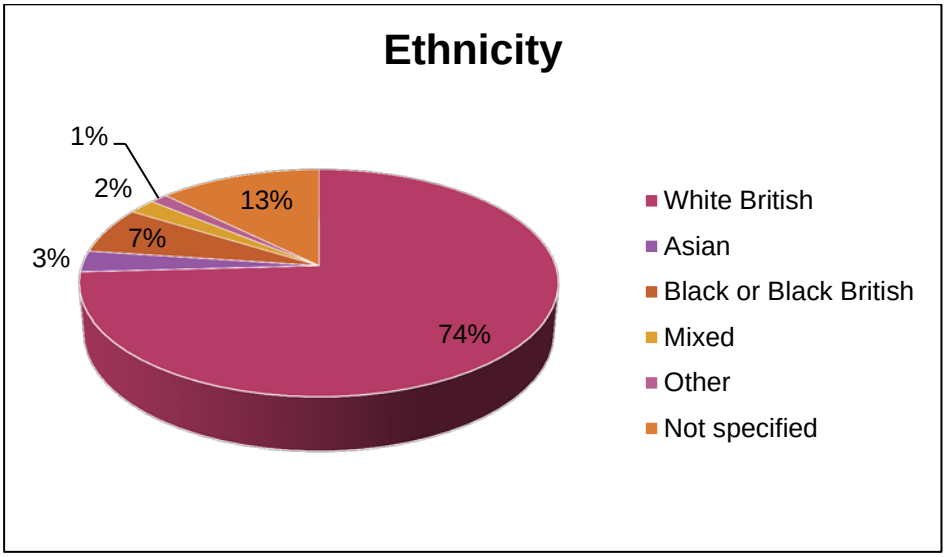


Figure 2 (above) shows the percentages of ethnic groups within the sample. White British was the most common ethnicity making 74% of the sample population.

Figure 3

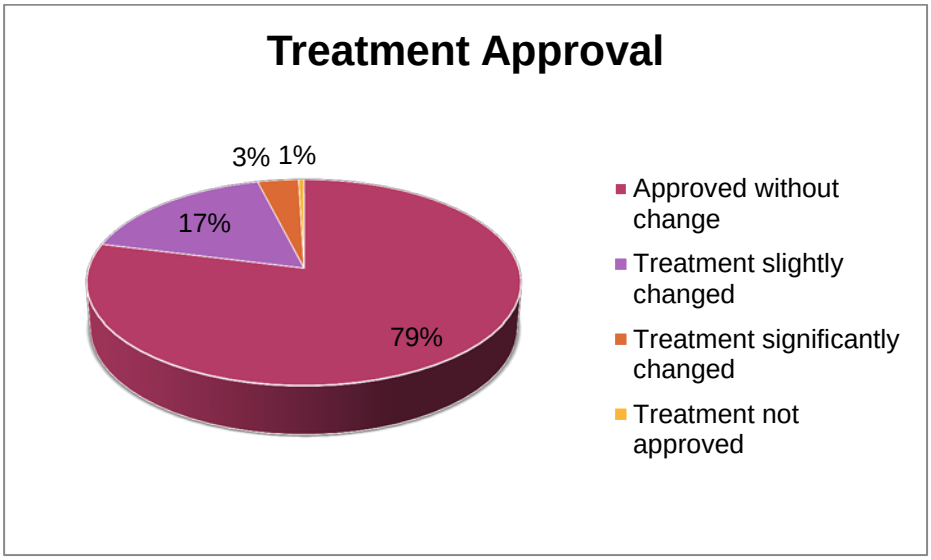
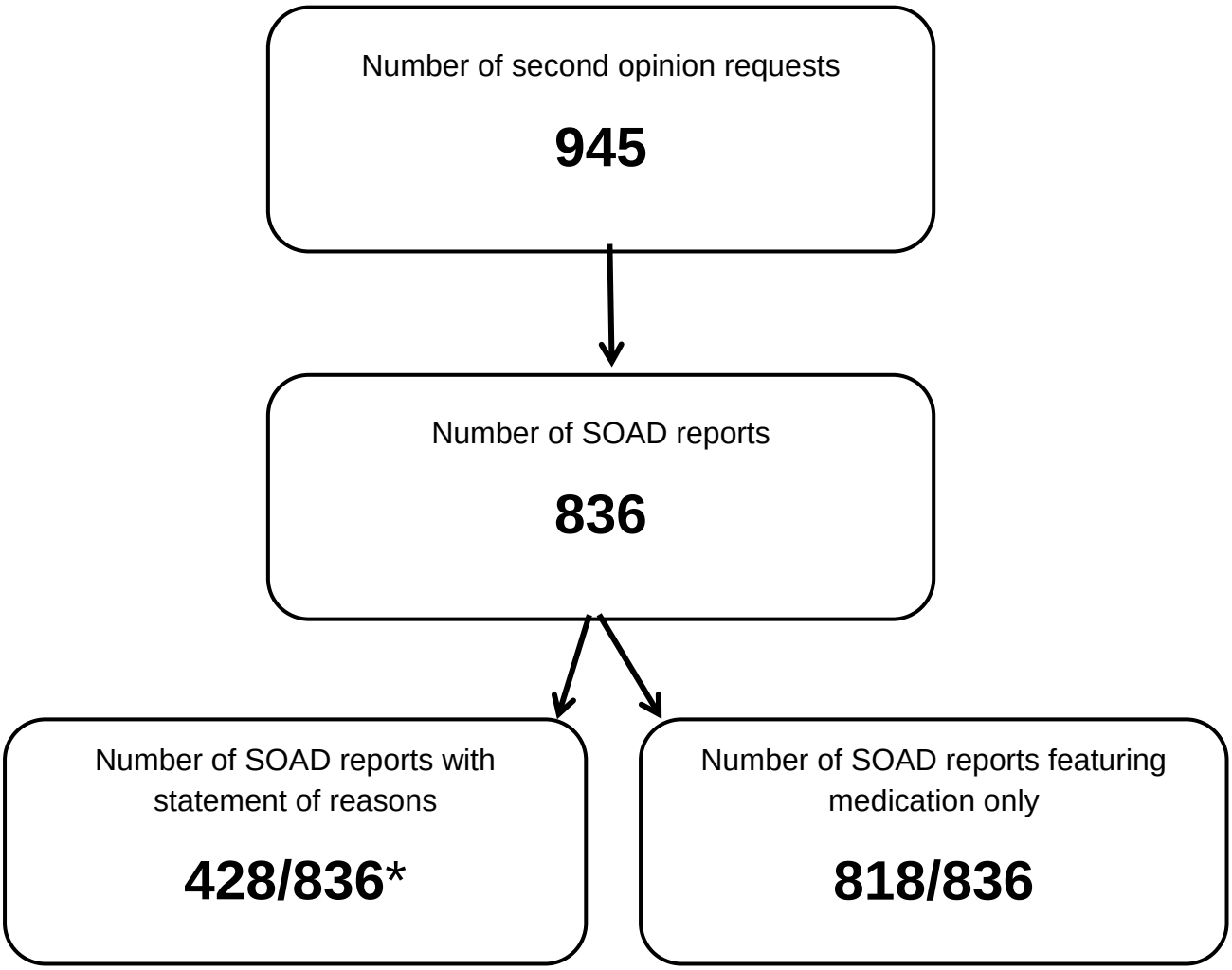


Figure 3 (above) displays the percentages of treatment modifications made by SOADs within the sample. Treatments approved without change was the largest category with 79%. This graph has excluded cases which were cancelled.

Appendix 2: Data count flow chart



[15] *Quantitative data (including medication requested and certified) include all 818 medication based cases. Only qualitative data were affected.

Appendix 3: Request antipsychotic data

Total number of cases that had an antipsychotic prescribed for the treatment of a mental disorder	Total number of cases that had an antipsychotic (regular or 'as required') prescribed in conjunction with other psychotropic medications for treatment
479 Prescribed 1 Antipsychotic	Antipsychotic + 0 = 33
	Antipsychotic + 1 = 81
	Antipsychotic + 2 = 121
	Antipsychotic + 3 = 109
	Antipsychotic + 4 = 78
	Antipsychotic + 5 = 37
	Antipsychotic + 6 = 12
	Antipsychotic + 7 = 7
	Antipsychotic + 8 = 1
	Total = 479
324 Prescribed 2 Antipsychotics	2 Antipsychotics + 0 = 14
	2 Antipsychotics + 1 = 30
	2 Antipsychotics + 2 = 81
	2 Antipsychotics + 3 = 79
	2 Antipsychotics + 4 = 65
	2 Antipsychotics + 5 = 39
	2 Antipsychotics + 6 = 12
	2 Antipsychotics + 7 = 2
	2 Antipsychotics + 8 = 2
	Total = 324
48 Prescribed 3 Antipsychotics	3 Antipsychotics + 0 = 0
	3 Antipsychotics + 1 = 6
	3 Antipsychotics + 2 = 8
	3 Antipsychotics + 3 = 16
	3 Antipsychotics + 4 = 9
	3 Antipsychotics + 5 = 5
	3 Antipsychotics + 6 = 3
	3 Antipsychotics + 7 = 1
	Total = 48
7 Utilised 4 Antipsychotics	4 Antipsychotics + 0 = 0
	4 Antipsychotics + 1 = 0
	4 Antipsychotics + 2 = 0
	4 Antipsychotics + 3 = 3
	4 Antipsychotics + 4 = 1
	4 Antipsychotics + 5 = 2
	4 Antipsychotics + 6 = 1
	Total = 7

Appendix 4: Request antidepressant data

Total number of cases that had an antidepressant prescribed for the treatment of a mental disorder	Total number of cases that had an antidepressant (regular or 'as required') prescribed in conjunction with other psychotropic medications for treatment
304 Prescribed 1 Antidepressant	Antidepressant + 0 = 4 Antidepressant + 1= 22 Antidepressant + 2= 48 Antidepressant + 3= 64 Antidepressant + 4= 64 Antidepressant + 5= 55 Antidepressant + 6= 28 Antidepressant + 7= 12 Antidepressant + 8= 5 Antidepressant + 9= 2
	Total = 304
14 Prescribed 2 Antidepressants	2 Antidepressants + 0= 1 2 Antidepressants + 1= 2 2 antidepressants + 2= 1 2 Antidepressants + 3= 3 2 Antidepressants +4= 1 2 Antidepressants +5= 3 2 Antidepressants +6= 2 2 Antidepressants +7= 1
	Total = 14

Appendix 5: Request mood stabiliser data

Total number of mood stabilisers prescribed for the treatment of the mental disorder	Total number of cases that had a mood stabiliser (regular or 'as required') prescribed in conjunction with other psychotropic medications certified for the patient
343 Prescribed 1 Mood Stabiliser	Mood stabiliser + 0 = 3
	Mood Stabiliser + 1 = 24
	Mood stabiliser + 2 = 34
	Mood Stabiliser + 3 = 85
	Mood Stabiliser + 4 = 85
	Mood Stabiliser + 5 = 64
	Mood Stabiliser + 6 = 34
	Mood Stabiliser + 7 = 9
	Mood Stabiliser + 8 = 4
	Mood Stabiliser + 9 = 1
	Total = 343
86 Prescribed 2 Mood Stabilisers	2 Mood Stabilisers + 0 = 0
	2 Mood Stabilisers + 1 = 3
	2 Mood stabilisers + 2 = 12
	2 Mood Stabilisers + 3 = 22
	2 Mood Stabilisers + 4 = 24
	2 Mood Stabilisers + 5 = 18
	2 Mood Stabilisers + 6 = 5
	2 Mood Stabilisers + 7 = 1
	2 Mood Stabilisers + 8 = 1
	Total = 86
20 Prescribed 3 Mood Stabilisers	3 Mood Stabilisers + 0 = 1
	3 Mood Stabilisers + 1 = 3
	3 Mood stabilisers + 2 = 1
	3 Mood Stabilisers + 3 = 5
	3 Mood Stabilisers + 4 = 3
	3 Mood Stabilisers + 5 = 5
	3 Mood Stabilisers + 6 = 1
	3 Mood Stabilisers + 7 = 1
	Total = 20

Appendix 6: Request anxiolytic data

Total number of cases that had an anxiolytic prescribed for the treatment of a mental disorder	Total number of cases that had an Anxiolytic (regular or 'as required') prescribed in conjunction with other psychotropic medications for treatment
556 Prescribed 1 Anxiolytic	Anxiolytic + 0 = 17
	Anxiolytic + 1 = 70
	Anxiolytic + 2 = 106
	Anxiolytic + 3 = 146
	Anxiolytic + 4 = 107
	Anxiolytic + 5 = 61
	Anxiolytic + 6 = 33
	Anxiolytic + 7 = 12
	Anxiolytic + 8 = 3
	Anxiolytic + 9 = 1
	Total = 556
206 Prescribed 2 Anxiolytics	2 Anxiolytics + 0 = 15
	2 Anxiolytics + 1 = 25
	2 Anxiolytics + 2 = 32
	2 Anxiolytics + 3 = 46
	2 Anxiolytics + 4 = 47
	2 Anxiolytics + 5 = 26
	2 Anxiolytics + 6 = 8
	2 Anxiolytics + 7 = 4
	2 Anxiolytics + 8 = 3
	Total = 206
14 Prescribed 3 Anxiolytics	3 Anxiolytics + 0 = 1
	3 Anxiolytics + 1 = 4
	3 Anxiolytics + 2 = 1
	3 Anxiolytics + 3 = 3
	3 Anxiolytics + 4 = 0
	3 Anxiolytics + 5 = 4
	3 Anxiolytics + 6 = 1
	Total = 14

Appendix 7: SPSS data outputs

Table 20 shows the SPSS output finding a significant difference (P ≤ 0.001) between NHS and independent care providers for the number of medications prescribed with a small effect size (d = .18). Table 21 shows the SPSS output representing a significant difference (P ≤ 0.001) between NHS and independent care providers for the number of psychotropics certified. There is a moderate effect size (D= .29).

Table 20

Group statistics

	ProviderType	N	Mean	Std. Deviation	Std. Error Mean
NumMeds	Independent	443	4.3	2.0	.10
	NHS	502	3.6	2.1	.09

Independent samples test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
NumMeds	Equal variances assumed	2.15	.14	5.60	943	.000	.75	.14	.49	1.02
	Equal variances not assumed			5.62	937	.000	.75	.13	.49	1.02

Table 21

Group statistics

	ProviderType	N	**Mean**	Std. Deviation	Std. Error Mean
N.O.Cert	NHS	423	**4.4**	1.8	.09
	Independent	395	**4.9**	1.7	.09

Independent samples test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	**Sig. (2-tailed)**	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
N.O.Cert	Equal variances assumed	1.87	.17	-4.27	816	**.000**	-.53	.12	-.77	-.28
	Equal variances not assumed			-4.28	816	**.000**	-.53	.12	-.77	-.28

Table 22 shows that there is a significant difference (P≤ 0.01); however the strength of association is low (Cramer's V = 0.16). The discrepancy between the 540 counts of polypharmacy vs the 506 in SPSS can be accounted for because a single count of polypharmacy in SPSS can include multiple counts in reality (for example, two antipsychotics and two antidepressants on a single T3 is two counts of polypharmacy but in SPSS it would count as one).

Table 22

Case processing summary

	Cases					
	Valid		Missing		Total	
	N	%	N	%	N	%
Medication Group * Provider Type	818	100%	0	0.0%	818	100%

MedicationGroup * ProviderType crosstabulation

			ProviderType		Total
			NHS	Independent	
Medication Group	Lowest Risk	Count	60	30	90
		Expected Count	47	445	90
	Low Risk	Count	103	70	173
		Expected Count	90	845	173
	Mild Risk	Count	20	27	47
		Expected Count	24	237	47
	Moderate Risk	Count	76	63	139
		Expected Count	72	67	139
	Highest Risk	Count	164	205	369
		Expected Count	191	178	369
Total		Count	423	395	818
		Expected Count	423	395	818

Chi-square tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	22.2[a]	4	.000
Likelihood Ratio	22.4	4	.000
Linear-by-Linear Association	17.9	1	.000
N of Valid Cases	818		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 22.70.

Symmetric measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	.17	.000
	Cramer's V	.17	.000
	Contingency Coefficient	.16	.000
N of Valid Cases		82	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Table 23 shows that there is a significant difference between high medication dosage certification with regard to provider type (P≤ 0.04). There is a strong association (Cramer's V= 0.72).

Table 23

Case processing summary

	Cases					
	Valid		Missing		Total	
	N	%	N	%	N	%
Provider Type *Above BNF	818	100%	0	0%	818	100%

ProviderType * AboveBNF crosstabulation

			AboveBNF		Total
			No	Yes	
Provider Type	NHS	Count	238	185	423
		Expected Count	223	200	423
	Independent	Count	194	201	395
		Expected Count	209	186	395
Total		Count	432	386	818
		Expected Count	432	386	818

Chi-square tests

	Value	df	**Asymp. Sig. (2-sided)**	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.19[a]	1	**.04**		
Continuity Correction[b]	3.9	1	.05		
Likelihood Ratio	4.19	1	.04		
Fisher's Exact Test				.04	.02
Linear-by-Linear Association	4.19	1	.04		
N of Valid Cases	818				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 186.4.

b. Computed only for a 2x2 table.

Table 24 shows that there is a significant difference in the certified medication size between genders (P≤ 0.01). However, there is only a small effect size (D= 0.2).

Table 24

Group Statistics

	Gender	N	Mean	Std. Deviation	Std. Error Mean
N.O.Cert	Male	566	4.5	1.78	.08
	Female	252	4.9	1.77	.11

Independent samples test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	**Sig. (2-tailed)**	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
N.O.Cert	Equal variances assumed	.04	.84	-2.68	816	**.007**	-.36	.13	-.62	-.10
	Equal variances not assumed			-2.69	484.1	.007	-.36	.13	-.62	-.10

Table 25 shows analysis of diagnosis type interacting with high medication dosage certification; there is a significant difference but a small effect size (V=.14).

Table 25

Case processing summary

	Cases					
	Valid		Missing		Total	
	N	%	N	%	N	%
AboveBNF * DiagnosisType	818	100%	0	0%	818	100%

AboveBNF * DiagnosisType crosstabulation

			DiagnosisType		Total
			Acquired	Developmental	
Above BNF	No	Count	221	211	432
		Expected Count	251	181	432
	Yes	Count	254	132	386
		Expected Count	224	162	386
Total		Count	475	343	818
		Expected Count	475	343	818

Chi-square tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	18.0[a]	1	.000		
Continuity Correction[b]	17.4	1	.000		
Likelihood Ratio	18.1	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	17.9	1	.000		
N of Valid Cases	818				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 161.86.
b. Computed only for a 2x2 table

Directional measures

			Value
Nominal by Interval	Eta	Above BNF Dependent	.15
		Diagnosis Type Dependent	.15

Symmetric measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	-.15	.000
	Cramer's V	.15	.000
	Contingency Coefficient	.15	.000
N of Valid Cases		818	

a. Not assuming the null hypothesis.
b. Using the asymptotic standard error assuming the null hypothesis.

Table 26 displays the SPSS output analysis of the interaction between diagnosis type and medication category. This was significant (P≤0.05) but a small effect size (V= .108).

Table 26

Case processing summary

	Cases					
	Valid		Missing		Total	
	N	%	N	%	N	%
Medication Group * Diagnosis Type	818	100%	0	0%	818	100%

Medication Group * Diagnosis Type crosstabulation

			DiagnosisType		Total
			Acquired	Developmental	
Medication Group	Lowest Risk	Count	47	43	90
		Expected Count	52	38	90
	Low Risk	Count	88	85	173
		Expected Count	101	73	173
	Mild Risk	Count	24	23	47
		Expected Count	27	20	47
	Moderate Risk	Count	86	53	139
		Expected Count	81	58	139
	Highest Risk	Count	230	139	369
		Expected Count	214	154	369
Total		Count	475	343	818
		Expected Count	475	343	818

Chi-square tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	9.5[a]	4	.05
Likelihood Ratio	9.4	4	.05
Linear-by-Linear Association	8.1	1	.004
N of Valid Cases	818		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 19.7.

Directional measures

			Value
Nominal by Interval	Eta	Medication Group Dependent	.10
		Diagnosis Type Dependent	.11

Symmetric measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	.11	.05
	Cramer's V	.11	.05
	Contingency Coefficient	.11	.05
N of Valid Cases		818	

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Table 27 displays the comparison of the mean number of medications between male and female patients. There was a significant difference with females having a higher number of medications. The effect size was small (D= 0.18).

Table 27

Group statistics

	Gender	N	Mean	Std. Deviation	Std. Error Mean
N.O.Cert	Male	566	4.5	1.78	.08
	Female	252	4.9	1.77	.11

Independent samples test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
N.O.Cert	Equal variances assumed	.04	.84	-2.68	816	.007	-.36	.13	-.62	-.10
	Equal variances not assumed			-2.69	484.1	.007	-.36	.13	-.62	-.10

Table 28 displays the X^2 analysis of high medication dosage certification and provider type. There was a significant difference (P≤0.04) and a large effect size (v=.72).

Table 28

Case processing summary

	Cases					
	Valid		Missing		Total	
	N	%	N	%	N	%
Above BNF * Provider Type	818	100%	0	0%	818	100%

AboveBNF * ProviderType crosstabulation

Count

		ProviderType		Total
		NHS	Independent	
Above BNF	No	238	194	432
	Yes	185	201	386
Total		423	395	818

Chi-square tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.19[a]	1	.04		
Continuity Correction[b]	3.91	1	.05		
Likelihood Ratio	4.19	1	.04		
Fisher's Exact Test				.04	.02
Linear-by-Linear Association	4.19	1	.04		
N of Valid Cases	818				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 186.
b. Computed only for a 2x2 table

Directional measures

			Value
Nominal by Interval	Eta	Above BNF Dependent	.07
		Provider Type Dependent	.07

Symmetric measures

		Value	Approx. Sig.
Nominal by Nominal	Phi	.07	.04
	Cramer's V	.07	.04
	Contingency Coefficient	.07	.04
N of Valid Cases		818	

a. Not assuming the null hypothesis.
b. Using the asymptotic standard error assuming the null hypothesis.

Table 29

Table 29 displays detail of the number of prescribed number of medications between ethnic groups.

Number of medications prescribed * ethnicity crosstabulation

			Ethnicity						Total
			Asian	Black	White	Mixed	Not Stated	Other	
Number of Medications prescribed	0	Count	3	6	63	3	4	1	80
		% within Ethnicity	9.7%	8.6%	9.1%	15.8%	3.4%	6.2%	8.5%
	1	Count	1	2	34	2	2	2	43
		% within Ethnicity	3.2%	2.9%	4.9%	10.5%	1.7%	12.5%	4.6%
	2	Count	2	8	68	4	17	4	103
		% within Ethnicity	6.5%	11.4%	9.8%	21.1%	14.5%	25.0%	10.9%
	3	Count	6	10	91	0	41	2	150
		% within Ethnicity	19.4%	14.3%	13.2%	0.0%	35.0%	12.5%	15.9%
	4	Count	7	10	131	1	41	3	193
		% within Ethnicity	22.6%	14.3%	18.9%	5.3%	35.0%	18.8%	20.4%
	5	Count	3	18	126	6	8	2	163
		% within Ethnicity	9.7%	25.7%	18.2%	31.6%	6.8%	12.5%	17.2%
	6	Count	5	8	99	2	1	1	116
		% within Ethnicity	16.1%	11.4%	14.3%	10.5%	0.9%	6.2%	12.3%
	7	Count	4	5	50	0	2	0	61
		% within Ethnicity	12.9%	7.1%	7.2%	0.0%	1.7%	0.0%	6.5%
	8	Count	0	3	18	1	1	1	24
		% within Ethnicity	0.0%	4.3%	2.6%	5.3%	0.9%	6.2%	2.5%
	9	Count	0	0	8	0	0	0	8
		% within Ethnicity	0.0%	0.0%	1.2%	0.0%	0.0%	0.0%	0.8%
	10	Count	0	0	4	0	0	0	4
		% within Ethnicity	0.0%	0.0%	0.6%	0.0%	0.0%	0.0%	0.4%
Total		Count	31	70	692	19	117	16	945
		% within Ethnicity	100%	100%	100%	100%	100%	100%	100%

Table 30

Table 30 displays detail of the number of certified number of medications between ethnic groups.

Number of Certifications * Ethnicity Cross-tabulation

			Ethnicity						
			Asian	Black	White	Mixed	Not Stated	Other	Total
Number of Certifications	1	Count	0	1	22	0	3	1	27
		% within Ethnicity	0.0%	1.9%	3.6%	0.0%	3.0%	7.7%	3.3%
	2	Count	2	3	48	1	10	3	67
		% within Ethnicity	6.7%	5.7%	7.9%	5.9%	10.0%	23.1%	8.2%
	3	Count	5	6	95	1	17	1	125
		% within Ethnicity	16.7%	11.3%	15.7%	5.9%	17.0%	7.7%	15.3%
	4	Count	7	12	135	3	20	3	180
		% within Ethnicity	23.3%	22.6%	22.3%	17.6%	20.0%	23.1%	22.0%
	5	Count	6	18	116	5	19	1	165
		% within Ethnicity	20.0%	34.0%	19.2%	29.4%	19.0%	7.7%	20.2%
	6	Count	5	7	100	4	14	3	133
		% within Ethnicity	16.7%	13.2%	16.5%	23.5%	14.0%	23.1%	16.3%
	7	Count	4	3	53	3	10	1	74
		% within Ethnicity	13.3%	5.7%	8.8%	17.6%	10.0%	7.7%	9.0%
	8	Count	1	3	23	0	4	0	31
		% within Ethnicity	3.3%	5.7%	3.8%	0.0%	4.0%	0.0%	3.8%
	9	Count	0	0	12	0	2	0	14
		% within Ethnicity	0.0%	0.0%	2.0%	0.0%	2.0%	0.0%	1.7%
	10	Count	0	0	1	0	1	0	2
		% within Ethnicity	0.0%	0.0%	.2%	0.0%	1.0%	0.0%	.2%
Total		Count	30	53	605	17	100	13	818
		% within Ethnicity	100	100%	100%	100%	100%	100%	100%

Appendix 8: Certified antipsychotic table full

Total number of SOAD certificates that certified antipsychotics for the treatment of a mental disorder	Total number of patients certified a regular antipsychotic in conjunction with other psychotropic medications certified for the patient
418 Certified 1 Antipsychotic	Antipsychotic + 0 = 19 Antipsychotic + 1 = 54 Antipsychotic + 2 = 93 Antipsychotic + 3 = 120 Antipsychotic + 4 = 82 Antipsychotic + 5 = 33 Antipsychotic + 6 = 13 Antipsychotic + 7 = 3 Antipsychotic + 8= 1
	Total = 418
338 Certified 2 Antipsychotics	2 Antipsychotics + 0 = 3 2 Antipsychotics + 1 = 18 2 Antipsychotics + 2 = 54 2 Antipsychotics + 3 = 78 2 Antipsychotics + 4 = 93 2 Antipsychotics + 5 = 55 2 Antipsychotics + 6 = 26 2 Antipsychotics + 7 = 10 2 Antipsychotics + 8= 1
	Total = 338
24 Certified 3 Antipsychotics	3 Antipsychotics + 0 = 0 3 Antipsychotics + 1 = 1 3 Antipsychotics + 2 = 5 3 Antipsychotics + 3 = 7 3 Antipsychotics + 4 = 6 3 Antipsychotics + 5 = 2 3 Antipsychotics + 6 = 2 3 Antipsychotics + 7= 1
	Total = 24

Appendix 9: Certified antidepressant table full

Total number of antidepressants certified for the treatment of the mental disorder	Total number of patients certified an antidepressant (regular or 'as required') in conjunction with other psychotropic medications certified for the patient
295 Certified 1 antidepressant	Antidepressant + 0 = 1 Antidepressant + 1= 4 Antidepressant + 2= 46 Antidepressant + 3= 60 Antidepressant + 4= 61 Antidepressant + 5= 66 Antidepressant + 6= 31 Antidepressant + 7= 13 Antidepressant + 8= 11 Antidepressant + 9= 2
	Total= 295
12 Certified 2 antidepressants	2 Antidepressants + 0= 0 2 Antidepressants + 1= 0 2 antidepressants + 2= 0 2 Antidepressants + 3= 2 2 Antidepressants +4= 2 2 Antidepressants +5= 3 2 Antidepressants +6= 0 2 Antidepressants +7= 3 2 Antidepressants +8= 2
	Total= 12

Appendix 10: certified mood stabiliser table full

Total number of mood stabilisers certified for the treatment of the mental disorder	Total number of patients certified a mood stabiliser (regular or 'as required') in conjunction with other psychotropic medications certified for the patient
330 Certified 1 mood stabiliser	Mood stabiliser + 0 = 1
	Mood Stabiliser + 1 = 11
	Mood stabiliser + 2 = 26
	Mood Stabiliser + 3 = 70
	Mood Stabiliser + 4 = 89
	Mood Stabiliser + 5 = 69
	Mood Stabiliser + 6 = 41
	Mood Stabiliser + 7 = 14
	Mood Stabiliser + 8 = 8
	Mood Stabiliser + 9 = 1
	Total = 330
69 Certified 2 mood stabilisers	2 Mood Stabilisers + 1 = 2
	2 Mood Stabilisers + 2 = 6
	2 Mood Stabilisers + 3 = 6
	2 Mood Stabilisers + 4 = 19
	2 Mood Stabilisers + 5 = 18
	2 Mood Stabilisers + 6 = 15
	2 Mood Stabilisers + 7 = 3
	Total = 69
5 Certified 3 mood stabilisers	3 Mood Stabilisers + 1 = 0
	3 Mood stabilisers + 2 = 1
	3 Mood Stabilisers + 3 = 2
	3 Mood Stabilisers + 4 = 1
	4 Mood Stabilisers + 5 = 0
	3 Mood Stabilisers + 6 = 1
	3 Mood Stabilisers + 7 = 0
	Total = 5
1 Certified 4 mood stabilisers	4 Mood Stabilisers + 1 = 0
	4 Mood stabilisers + 2 = 0
	4 Mood Stabilisers + 3 = 0
	4 Mood Stabilisers + 4 = 1
	Total = 1

Appendix 11: certified anxiolytic table full

Total number of Anxiolytics certified for the treatment of a mental disorder	Total number of patients certified an Anxiolytic (regular or 'as required') in conjunction with other and 'as required' drugs certified for the patient.
594 Certified 1 Anxiolytic	Anxiolytic + 0 = 6 Anxiolytic + 1 = 40 Anxiolytic + 2 = 90 Anxiolytic + 3 = 150 Anxiolytic + 4 = 131 Anxiolytic + 5 = 94 Anxiolytic + 6 = 55 Anxiolytic + 7 = 20 Anxiolytic + 8 8
	Total = 594
96 Certified 2 Anxiolytics	2 Anxiolytic + 0 = 0 2 Anxiolytics + 1 = 5 2 Anxiolytics + 2 = 11 2 Anxiolytics + 3 = 17 2 Anxiolytics + 4 = 30 2 Anxiolytics + 5 = 17 2 Anxiolytics + 6 = 10 2 Anxiolytics + 7 = 4 2 Anxiolytics + 8 = 2
	Total = 96
4 Certified 3 Anxiolytics	3 Anxiolytics + 0 = 0 3 Anxiolytics + 1 = 0 3 Anxiolytics + 2 = 0 3 Anxiolytics + 3 = 1 3 Anxiolytics + 4 = 0 3 Anxiolytics + 5 = 1 3 Anxiolytics + 6 = 2
	Total = 4

Appendix 12: qualitative analysis

Survey tool legend

Likert Scoring:

1. Strongly Disagree
2. Disagree
3. Neither Agree nor Disagree
4. Agree
5. Strongly Agree

Medication category legend

Patient category:

1. The patient is on one or two medicines and doses do not appear high
2. The patient is on more than 2 and less than 5 medicines and the doses do not appear high
3. The patient is on more than 5 medicines and although the doses do not appear as individual high doses, together they should lead to questions about polypharmacy
4. The patient is on high dose medication of one or more of the medicines
5. The patient is on a large number of medicines and high doses.

Appendix 13: ‘recognised indications’ accepted as justification for the request of a medication

ICD 10 code	ICD description
E51	Wernicke’s encephalopathy
F00	Dementia in Alzheimer’s disease
F01	Vascular dementia
F03	Unspecified dementia
F06	Other mental disorders due to brain damage and dysfunction and to physical disease
F07	Personality and behavioural disorders due to brain disease, damage and dysfunction
F10	Mental and behavioural disorders due to use of alcohol
F11-F19	Substance dependency / misuse
F19.5	Mental and behavioural disorders due to multiple drug use and other psychoactive substances
F20	Schizophrenia
F22	Delusional disorder
F23	Psychotic illness
F25	Schizoaffective disorders
F29	Psychosis
F30	Mania
F31	Bipolar
F32	Depression
F33	Recurrent depression
F39	Unspecified mood / affective disorder
F40	Phobic anxiety disorders
F41	Other anxiety disorders incl GAD
F41.2	Mixed anxiety and depressive disorder
F42	Obsessive compulsive disorder
F43	Acute stress reaction
F43.1	Post-traumatic stress disorder
F43.2	Adjustment disorders
F45	Hypochondriasis

F50	Eating disorder
F60	Personality disorder
F61	Mixed and other personality disorders
F63.1	Pyromania
F63.8	Other habit and impulse disorders
F65	Disorders of sexual preference
F70.0	Mild mental retardation
F70.1	Mild mental retardation with significant impairment of behaviour
F70.8	Mild mental retardation with other impairment of behaviour
F70.9	Mild mental retardation without mention of behaviour
F71.1	Moderate mental retardation with significant impairment of behaviour
F71.8	Moderate mental retardation with other impairment of behaviour
F71.9	Moderate mental retardation without mention of behaviour
F72.1	Severe mental retardation with significant impairment of behaviour
F72.9	Severe mental retardation without mention of behaviour
F79.1	Unspecified mental retardation with significant impairment of behaviour
F79.9	Unspecified mental retardation without mention of behaviour
F84	Autism
F84.5	Asperger's syndrome
F90	Hyperkinetic disorder
F92	Conduct disorder
F94	Attachment disorder
F95.2	Tourette's
F98	Stuttering
G40	Epilepsy

Appendix 14: ICD-10 codes considered justified for the use of antipsychotic agents for regular administration

		ICD 10 code										
		F20	F22	F23	F25	F29	F30	F31	F32 - F33 where psychotic symptoms mentioned	F41	F41.2	F65
Agent	AmisulprIde	x	x	x	x	x	X	x	x			
	Aripiprazole	x	x	x	x	x	X	x	x			
	Asenapine						X	x				
	Benperidol											x
	Chlorpromazine	x	x	x	x	x	X	x	x			
	Clozapine	x	x	x	x	x	X	x	x			
	Flupentixol	x	x	x	x	x	X	x	x		x	
	Flupentixol depot	x	x	x	x	x			x			
	Fluphenazine depot	x	x	x	x	x			x			
	Haloperidol	x	x	x	x	x	x	x	x	x	x	
	Haloperidol depot	x	x	x	x	x			x			
	Levomepromazine	x	x	x	x	x	x	x	x			
	Olanzapine	x	x	x	x	x	x	x	x			
	Olanzapine depot	x	x	x	x	x			x			
	Paliperidone	x	x	x	x	x	x	x	x			
	Pericyazine	x	x	x	x	x	x	x	x			
	Pipotiazine depot	x	x	x	x	x			x			

	Prochlorperazine	x	x	x	x	x	x	x	x	x	x	
	Promazine								x			
	Quetiapine	x	x	x	x	x	x	x	x			
	Risperidone	x	x	x	x	x	x	x	x			
	Risperidone depot	x	x	x	x	x			x			
	Sulpiride	x	x	x	x	x	x	x	x			
	Trifluoperazine	x	x	x	x	x	x	x	x	x	x	
	Zuclopentixol Dihydrochloride	x	x	x	x	x	x	x	x			
	Zuclopentixol acetate											
	Zuclopentixol depot	x	x	x	x	x			x			

Appendix 15: ICD-10 codes considered justified for the use of antipsychotic agents for as required administration

	ICD 10 code			
		F20 - F29	F30 - F31	F32 - F33 where psychotic symptoms mentioned
Agent	Amisulpride			
	Aripiprazole	x	x	x
	Asenapine			
	Benperidol			
	Chlorpromazine	x	x	x
	Clozapine			
	Flupentixol			
	Flupentixol depot			
	Fluphenazine depot			
	Haloperidol	x	x	x
	Haloperidol depot			
	Levomepromazine	x	x	x
	Olanzapine	x	x	x
	Olanzapine depot			
	Paliperidone			
	Pericyazine	x	x	x
	Pipotiazine depot			
	Prochlorperazine			
	Promazine			
	Quetiapine	x	x	x

	Risperidone	x	x	
	Risperidone depot			
	Sulpiride			
	Trifluoperazine	x	x	x
	Zuclopentixol Dihydrochloride			
	Zuclopentixol acetate	x	x	x
	Zuclopentixol depot			

Appendix 16: ICD-10 codes considered justified for the use of benzodiazepine anxiolytic agents for regular administration

		ICD-10 code							
		F10	F32	F33	F40	F41	F41.2	F43	G40
Agent	Chlordiazepoxide	x			x	x	x	x	
	Diazepam		X	X	x	x	x	x	
	Lorazepam		X	X	x	x	x	x	
	Clobazam				x	x	x	x	x
	Clonazepam								x

Appendix 17: ICD-10 codes considered justified for the use of benzodiazepine anxiolytic agents for as required administration

		ICD 10 code											
		F10	F20 - F29	F30 - F31	F32 - F33 where psychotic symptoms mentioned	F40	F41	F41.1	F41.2	F42	F43	F43.1	G40
Agent	Chlordiazepoxide	x				x	x	x	x	x	x	x	
	Diazepam		x	X	x	x	x	x	x	x	x	x	x
	Lorazepam		x	X	x	x	x	x	x	x	x	x	x
	Clobazam					x	x	x	x	x	x	x	

		F20 - F29	F30 - F31	F32 - F33 where psychotic symptoms mentioned	G40
Agent	Clonazepam				x
	Midazolam	x	x	X	x

Appendix 18: ICD-10 codes considered justified for the use of mood stabiliser agents

		ICD 10 code					
		F25	F30	F31	F33	F39	G40
Agent	Carbamazepine	x		X		x	x
	Lamotrigine	x		X		x	x
	Lithium	x	x	X	x	x	
	Sodium valproate	x		X		x	x
	Valproic acid	x		X		x	

Appendix 19: ICD-10 codes considered justified for the use of antidepressant agents

		ICD 10 code								
		F25	F31 – F39	F40	F41.1	F41.2	F42	F43	F43.1	F50
Agent	Agomelatine	x	x			x		x		
	Amitriptyline	x	x			x		x		
	Clomipramine	x	x	x		x	x	x		
	Dosulepin	x	x			x		x		
	Duloxetine	x	x		x	x		x		
	Escitalopram	x	x	x	x	x	x	x		
	Fluoxetine	x	x			x	x	x		x
	Fluvoxamine	x	x			x	x	x		
	Imipramine	x	x			x		x		
	Lofepramine	x	x			x		x		
	Mirtazapine	x	x			x		x		
	Moclobemide	x	x	x		x		x		
	Paroxetine	x	x	x	x	x	x	x	x	
	Sertraline	x	x	x		x	x	x	x	
	Trazodone	x	x	x	x	x		x		
	Venlafaxine	x	x		x	x		x		

Appendix 20: ICD-10 codes considered justified for the use of CNS stimulant agents

		ICD-10 code
		F90
Agent	Atomoxetine	x
	Dexamphetamine	x
	Methylphenidate	x
	Modafinil	x

Appendix 21: BNF maximum doses for agents specified in data used to assess high dose and cumulative doses

Dose limits are described as they were at the time the prescriptions were issued.

Agent	Daily maximum dose (mg)
Agomelatine	50
Amisulpride	1200
Amitriptyline	200
Aripiprazole	30
Asenapine	20
Atomoxetine	120
Benperidol	2
Buspirone	45
Carbamazepine	1600
Chlordiazepoxide	200
Chlorpromazine	300
Citalopram	60
Clobazam	60
Clomipramine	250
Clonazepam	8
Clozapine	900
Dexamphetamine	60
Diazepam	30
Dosulepin	150
Duloxetine	120
Escitalopram	20
Fluoxetine	60
Flupentixol	18
Flupentixol depot	21
Fluphenazine depot	7
Fluvoxamine	300
Haloperidol	30 oral, 18 im
Haloperidol depot	11
Imipramine	300
Lamotrigine	400
Levomepromazine	1000
Lithium carbonate	No maximum dose specified
Lithium citrate	No maximum dose specified
Lofepramine	210
Lorazepam	4
Methylphenidate	100
Midazolam	20
Mirtazapine	45
Modafinil	400
Olanzapine	20
Olanzapine injection	21
Paliperidone	12

Paliperidone depot	5
Paroxetine	60
Pericyazine	300
Pipotiazine depot	7
Prochlorperazine	100
Promazine	800
Quetiapine	800
Risperidone	16
Risperidone depot	4
Sertraline	200
Sodium valproate	2500
Sulpiride	2400
Trazodone	600
Trifluoperazine	No maximum dose specified
Valproic acid	2000
Venlafaxine	375
Zuclopentixol dihydrochloride	150
Zuclopentixol acetate	No maximum dose specified
Zuclopentixol depot	86

How to contact us

Call us on: **03000 616161**

Email us at: **enquiries@cqc.org.uk**

Look at our website: **www.cqc.org.uk**

Write to us at: Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Follow us on Twitter: **@CareQualityComm**