



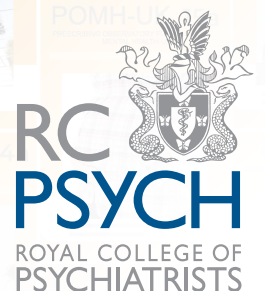
# POMH-UK

PRESCRIBING OBSERVATORY FOR MENTAL HEALTH-UK

The Prescribing Observatory for Mental Health

November 2020

# 15-YEAR REPORT



Authors:

**Professor Thomas R.E. Barnes and Carol Paton,  
Joint Heads of POMH**

Designed and typeset:

**Helen Greenwood**

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# Foreword

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**Professor  
Mike Crawford**

Director, CCQI

An overall aim of the College Centre for Quality Improvement (CCQI) at the Royal College of Psychiatrists is to help clinicians and patients make sense of mental health services. Through a range of initiatives that include facilitating educational initiatives, supporting the revalidation process, service accreditation schemes, national clinical audits and quality improvement (QI) projects, the CCQI provides support for psychiatrists and mental health providers and informs the patients they care for.

With respect to QI, the Prescribing Observatory for Mental Health (POMH), which started in 2005, is the longest-standing project within the CCQI and one of the very few that is sustained exclusively by membership subscriptions from mental health providers. Each of the POMH QI programmes focuses on prescribing practice relating to a particular illness and/or a particular medication or class of medication. By supporting the collection of reliable national data for each programme, POMH provides a wealth of information on the quality of prescribing practice thus allowing individual clinicians, multidisciplinary teams and service providers to compare the standard of evidence-based care they provide with that of other clinicians within their own service and other similar services nationally.

Almost all mental health Trusts are POMH members and the number that actively participate in each POMH QI programme is high. This long-term commitment by mental health services suggests that the POMH programmes are meeting a need and are valued.

NHS clinical staff now routinely receive QI training with the aim of promoting targeted local QI activity. Some impressive examples of such activity relating to participation in POMH QI programmes can be found in Trust Quality Accounts. As there is much to be gained by the most effective and safest use of currently available medicines, local multidisciplinary engagement to identify and work on areas for improvement is likely to lead to considerable benefits for patients.

# Introduction

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**Macbeth:**

Canst thou not minister to a mind diseas'd,  
Pluck from the memory a rooted sorrow,  
Raze out the written troubles of the brain,  
And with some sweet oblivious antidote  
Cleanse the stuff'd bosom of that perilous stuff  
Which weighs upon the heart?

**Doctor:**

Therein the patient  
Must minister to himself.

**Macbeth:**

Throw physic to the dogs,  
I'll none of it.

*Macbeth Act 5, scene 3, 40–47*

Thus, Shakespeare has the notion of psychopharmacological treatment roundly rejected. That was more than 400 years ago, but echoes of these negative sentiments are still commonly heard, despite the extensive scientific evidence that now supports the effectiveness of medication in the treatment of many psychiatric disorders. Nevertheless, such criticism highlights that there is a need to generate a greater awareness that optimal prescribing practice for psychotropic medication is actively promoted, informed by a constantly evolving evidence base and addressing the benefit-risk balance for each medication prescribed for each individual patient.

The key purpose of POMH over the last 15 years has been to support quality improvement (QI) in prescribing in UK mental health services, to help them achieve a safer and more effective use of the psychotropic medications currently available. POMH is managed within the Centre for Quality Improvement, in the Royal College of Psychiatrists. It was started in 2005 with a tapering grant from the Health Foundation, and since 2008 has been funded solely through subscriptions from member healthcare organisations (principally NHS Trusts); it remains independent of the pharmaceutical industry.

POMH invites mental health services to participate in audit-based QI programmes focussing on aspects of prescribing practice. For each QI programme, a relevant expert group is convened. Practice standards are agreed, usually derived from established evidence-based clinical guidelines, that will be accepted by clinicians as representing best practice and perceived as realistic and desirable to achieve in all patients to whom they apply. The POMH team then invites clinicians and clinical audit staff from member healthcare organisations to attend regional workshops, held across the country; contributions from delegates at these events are invaluable for the POMH process. These workshops provide an opportunity to discuss the practice standards and to refine and revise a bespoke data collection tool, which will be used to audit the performance of clinical services against the standards. The tool also collects demographic, diagnostic, and clinical service data and other relevant clinical information that provide clinicians with a context for interpretation of their prescribing practice. All the audit data to be collected are designed to support QI activity and would not be suitable for quality assurance or any formal ranking of services or healthcare organisations.

At the baseline clinical audit of a QI programme, data are collected by clinicians/clinical audit staff in each participating service and submitted online. The data are cleaned and analysed by the POMH team. Each participating Trust/healthcare organisation then receives a customised audit report that allows its performance against the practice standards to be compared with the total national sample and each of the other, anonymised, participating organisations, and allows the clinical teams in that organisation to be compared with each other. These reports are a QI intervention in that the benchmarked findings, when shared with the clinical teams involved, have the potential to prompt reflection on practice and inform local QI activity, targeted at the areas for improvement identified. Further, the identification of relevant patient or service variables can inform local strategies and systems to enable change. In addition, for many of the QI programmes a specific change intervention is developed, most commonly an appropriate decision support tool for clinicians.

The baseline audit is repeated 18 months to 2 years later by all member healthcare organisations that wish to participate. This re-audit similarly generates a customised report for each participating organisation, allowing services to assess the impact of their initial audit participation and any relevant local QI activity, specifically whether there has been any closing of the gap between the evidence-based standards and actual practice. Commonly, Trusts note their participation in a POMH QI programme in their annual quality account and in some cases identify the QI work prompted and informed by participation. In a small number of cases, such QI activity has been reported in published scientific papers. Several examples of such local QI work are described in this report.

The natural history of POMH QI programmes varies. For some, supplementary audits are conducted over several years, often at the request of member Trusts that wish to evaluate their progress following local, directed QI interventions, but also because, more generally, the early findings suggest that continuing to repeat the audit cycle could lead to further improvement. Other programmes are more short-lived, sometimes because the findings have only limited or relatively specific implications for practice and the value of further audits and feedback is judged to be uncertain.

POMH data have been shared with clinical guideline development groups, providing them with a representative profile of prescribing practice in the area on which they are generating pharmacological treatment recommendations. POMH data have also been cited to support the rationales for several research projects, principally clinical trials of medication, that subsequently obtained funding. Examples of this wider use of POMH data are also provided in this report.

The vast majority of Trusts with mental health services in the UK are POMH members, which potentially enhances the national impact of the QI programmes on the use of psychotropic medication in routine clinical practice. While the degree of dissemination and penetration of the data in the bespoke reports undoubtedly varies between individual Trusts/healthcare services, the improvement seen over the years in several of the programmes is testimony to the commitment to POMH-supported QI endeavours in many clinical services.

# QI work in member healthcare services

For each QI programme, the customised POMH reports allow Trusts to see their local performance in absolute terms against the audit standards, and also relative to other participating services. A key element of these programmes is that Trusts reflect on both their absolute and relative performance to prompt and inform local QI actions and initiatives.

Feedback of the audit findings to clinical teams serves as a reminder of the recommendations in clinical guidelines and the evidence-based practice standards and identifies local gaps. This is an essential first step in QI but in itself such feedback is unlikely to lead directly to major changes in clinical practice. The delivery of healthcare is complex as there may be multiple local systems and workarounds and a heavy reliance on staff remembering to do the right thing. It may therefore not always be straightforward to determine exactly what type of local intervention would be most helpful in supporting improvements in the quality of prescribing. The requirement that healthcare providers should produce annual quality accounts has allowed us to collate examples of local QI initiatives that have been prompted by participation in POMH programmes. A broad description of these initiatives can be found below and more detailed examples, specific to individual QI programmes, can be found in the relevant sections of this report. While it is not recorded how effective any of these QI strategies turned out to be, those interested in planning QI work to improve prescribing practice may find the summary descriptions of these initiatives below informative and helpful.

## Clinical audit



Some Trusts reported developing further, focussed local audits to better understand the nature and extent of the gaps in practice. For example, **Somerset NHS Foundation Trust (2018/19)** reviewed all patients identified in the baseline audit of clozapine prescribing as not having had a general physical health check in the last 12 months. **Berkshire Healthcare NHS Foundation Trust (2017/18)** reported that a nurse and a psychiatric trainee would be undertaking monthly audits on the use of the alcohol screening questionnaire and attending the MDT on each ward to discuss compliance with the local alcohol detoxification policy. **Avon & Wiltshire Mental Health Partnership NHS Trust (2017/18)** and **Cornwall Partnership NHS Foundation Trust (2018/19)** both reported participation in the Reducing Restrictive Practice programme, part of a wider Mental Health Safety Improvement Programme (MHSIP) which was established by NHS Improvement (NHSI) in partnership with the Care Quality Commission (CQC).



## Provision of equipment



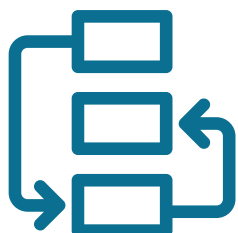
Lack of the necessary equipment is sometimes identified as a barrier to best practice. **Birmingham and Solihull Mental Health NHS Foundation Trust (2017/18)** reported moving existing ECG monitors to the locations that needed them and purchasing further monitors so that all patients receiving maintenance treatment with long-acting injectable antipsychotic medication could have an ECG where clinically indicated. **Sussex Partnership NHS Foundation Trust (2018/19)** reported moving clozapine suppliers to increase the number of near patient testing machines to facilitate access to monitoring and review for patients treated with clozapine who were under the care of community teams.

## Educational materials



Some Trusts described in their Quality Accounts the dissemination of educational materials such as the POMH 'ready reckoner' that raises awareness of the licensed maximum doses of antipsychotic medication and the effect on total antipsychotic 'dose' if such medications are prescribed in combination (**Cambridgeshire and Peterborough NHS Foundation Trust, 2017/18**) and the POMH change intervention leaflet that draws attention to strategies that could help minimise off-label prescribing of antipsychotic medication for people with a personality disorder (**Derbyshire Healthcare NHS Foundation Trust, 2015/16**). The development of local, targeted training delivered through bespoke e-learning packages was described for rapid tranquillisation (**Norfolk and Suffolk NHS Foundation Trust, 2016/17**) and alcohol detoxification (**Bradford District Care NHS Foundation Trust, 2015/16**). The rapid tranquillisation training at Norfolk and Suffolk was made available through their ESR. **Cambridgeshire and Peterborough NHS Foundation Trust (2017/18)** also described the implementation of training on the use of breathalysers so that patients could be assessed more fully for alcohol-related problems on admission to acute psychiatric wards.

## Clinical Policies and Procedures



Practice in individual Trusts is usually underpinned by local policies and in some cases these policies have been revised to clarify the actions needed to move practice closer to the standards. **Leeds and York Partnership NHS Foundation Trust (2017/18)** introduced a new RT policy that promoted the use of 'stat' rather than 'PRN' doses of antipsychotic medication, with the aim of reducing the number of prescriptions for potentially high-dose antipsychotic medication. **Oxford Health NHS Foundation Trust (2016/17)** reported managing all patients with dementia who are prescribed antipsychotic medication under CPA, with review of such medication being included in care plans.

## Clinical documents



Local forms have also been changed in order to support evidence-based practice. Examples include the addition of serum calcium to the standard laboratory request form used by lithium clinics (**Worcestershire Health and Care NHS Trust, 2017/18**) and the development of standard clinic letters for people with a learning disability who are prescribed antipsychotic medication, to prompt the appropriate monitoring of side effects as specified in NICE guidelines or documentation that such monitoring has been requested through primary care (**Derbyshire Healthcare NHS Foundation Trust, 2015/16**). **Oxleas NHS Foundation Trust (2016/17)** reported changing their inpatient prescription template for alcohol detoxification to include parenteral thiamine as a standard treatment, as a prompt to the prescriber to follow best practice; not prescribing thiamine would involve deliberately deleting it from the template.

## Clinical roles



Some Trusts reported work they had undertaken to clarify the responsibilities of clinical staff undertaking specific roles. For example, **Barnet, Enfield and Haringey Mental Health NHS Trust (2018/19)** allocated to staff in wellbeing clinics the task of liaising with primary care if clozapine was not visible on the summary care record of patients prescribed this medication. **North Staffordshire Combined Healthcare NHS Trust (2018/19)** assigned to the member of staff who completed the incident form following an episode of rapid tranquillisation the task of contacting the patient's clinical team to prompt a review of the care plan.

## Reminders and alerts



Patient-specific reminders to clinicians relating to actions that need to be taken are known to drive changes in practice. High-dose warning stickers have been attached to inpatient prescription charts to draw attention to any prescription for antipsychotic medication that exceeded the maximum licensed dose (**Norfolk and Suffolk NHS Foundation Trust 2015/16; Cambridgeshire and Peterborough NHS Foundation Trust, 2017/18**). At Norfolk and Suffolk doctors also acknowledge the use of high-dose warning stickers by signing. **The South London and Maudsley NHS Foundation Trust (2018/19)** reported checking, at the point of dispensing, that women of child-bearing age prescribed valproate were enrolled in the pregnancy prevention programme and if they were not, the prescriber was contacted.

## Use of IT



Electronic systems have been used to build registers of patients who require specific monitoring, such as those with a learning disability who are prescribed antipsychotic medication (**Cambridgeshire and Peterborough NHS Foundation Trust, 2015/16**). EMPA and pharmacy systems have also been used to identify women of child-bearing age who are prescribed valproate to help confirm annual risk assessments are carried out (**Birmingham and Solihull Mental Health NHS Foundation Trust 2018/19**). Apps have been used to improve lithium monitoring (**Avon and Wiltshire Mental Health Partnership NHS Trust 2017/18**) and the monitoring of physical health following rapid tranquilisation by prompting staff about the observations that are due (**Birmingham and Solihull Mental Health NHS Foundation Trust 2018/19**). **Berkshire Healthcare NHS Foundation Trust (2018/19)** reported the use of a valproate screensaver ('Stop, Think') highlighting a link to relevant pharmacy resources on all Trust computers. In addition, the Berkshire electronic prescribing system was customised to include a 'treatment reason' field that allowed plans for reducing and stopping valproate to be captured. At **St Andrew's Healthcare (2017/18)** medication templates have been built into electronic prescribing systems with links and guidance regarding prescribing and side effects, mandatory treatment duration and indications for specific medicines.

## Interface with primary care



The vast majority of patients under the care of mental health services live in the community and, for many, continuing medication is provided via primary care. Poor communication between these clinical services may result in gaps in care, as each service may assume the other is responsible for reviewing a patient's medication. Some Trusts have recorded examples of initiatives aimed at closer working with primary care. For example, **South West London and St George's Mental Health NHS Trust (2015/16)** reported acquiring access to local GP electronic patient summary records, to improve the links between primary care and mental health staff. **Sussex Partnership NHS Foundation Trust (2017/18)** reported updating their GP resource pack (reducing antipsychotic use in patients living with dementia) and noted that an audit of the use of antipsychotic medication by local GPs was also being completed. **Midlands Partnership NHS Foundation Trust (2017/18)** reported streamlining their pathology contracts to provide easier access to pathology results for clinicians, thus supporting lithium monitoring.

# Selected POMH QI programmes

## Alcohol detoxification (medically assisted withdrawal) on acute adult psychiatric wards

### Background

**NICE guidelines set out a series of recommendations for best practice in diagnosing, assessing and managing alcohol use disorders (NICE 2011a, 2011b) and it is from these guidelines that the standards for this QI programme were drawn.**

Alcohol use disorders span a wide spectrum of severity from hazardous and harmful drinking through to severe and complex alcohol dependence. Together, these disorders are the leading preventable cause of morbidity and mortality in working age adults (Schuckit, 2009; NICE, 2011a, 2011b). Many patients admitted to mental health wards have an alcohol use disorder, usually as a secondary problem, and admission presents an opportunity to intervene, potentially preventing alcohol-related morbidity and mortality.

Acute alcohol withdrawal, if untreated or sub-optimally managed, can be a life-threatening condition. Further, in the absence of adequate prophylaxis with parenteral thiamine, there is a risk of Wernicke's encephalopathy developing and this may lead to permanent brain damage in the form of Korsakoff syndrome. Relapse into problem drinking may be reduced when the patient is supported by a specialist community alcohol team. Relapse-prevention medication such as acamprosate can also be helpful.

### Data from the POMH QI programme

In both audits there was no documented alcohol history taken during the initial assessment for one in five patients admitted to acute adult psychiatric wards, raising the possibility that alcohol use disorders may go undetected and therefore untreated in people with mental illness. The delivery of a 'brief intervention', when a healthcare professional delivers a patient-specific message regarding the harms that alcohol has caused or has the potential to cause, increased from 42% at baseline to 58% at re-audit; there is evidence that this intervention reduces alcohol use in some people and failure to deliver this simple intervention is an opportunity missed.

Baseline audit  
**2014**

Re-audit  
**2016**

Both audits  
had data  
submitted  
for over **1000**  
cases

But perhaps the most striking finding from this POMH QI programme was that a number of evidence-based interventions were much more likely to be provided for patients who were seen by a specialist in addictions psychiatry than for those whose care was provided exclusively by an adult mental health team. The proportion of patients whose care was provided by an addictions specialist reduced from 29% at baseline to 21% at re-audit and some key elements of practice moved away from the audit standards as follows.

- Addictions specialists prescribed parenteral thiamine in 78% of medically assisted withdrawals at baseline and this proportion was similar at re-audit (76%) while non-specialists prescribed parenteral thiamine in 50% of cases at baseline and this proportion reduced to 42% at re-audit
- Addictions specialists prescribed medication for the prevention of relapse into harmful drinking for 49% of patients at baseline and this proportion reduced slightly to 43% at re-audit. The respective figures for non-specialists were 15% and 14%.
- At discharge, a referral was made to a specialist community alcohol service in 79% of cases at baseline and this proportion reduced to 66% at re-audit. As might be expected, far fewer referrals were made by non-specialists.

Evidence-based interventions were much **more likely** to be provided for patients who were seen by a specialist in addictions psychiatry

## Change intervention

In collaboration with our expert advisors for this QI programme, the POMH team developed a BNF-sized summary of 12 factors (**see Page 11**) to consider when assessing and managing alcohol use disorders. A brief explanation of the clinical rationale for each factor was provided to facilitate understanding by non-specialists.

## Challenges for QI

A recent report from the Royal College of Psychiatrists (RCPsych, 2020) raises concerns relating to the under-funding of addictions services, the lack of addictions training in the UK curriculum for psychiatry and the reducing number of higher training posts in addiction psychiatry (down almost 60% in the last 8 years). These are all systems barriers that will impede efforts to improve care for patients with alcohol use disorders who are cared for by mental health services.

In 2021 POMH plans to conduct a further supplementary audit addressing the quality of medically assisted withdrawal in acute adult psychiatric wards.

## Alcohol detoxification/medically assisted withdrawal: 12 clinical factors to consider

1. **Measuring breath alcohol:** The absolute breath alcohol level does not inform the decision whether or not to undertake medically-assisted withdrawal – but the level should be falling before such withdrawal begins (take 2 samples at least 15mins apart). Note that a very high breath alcohol level with minimal apparent impairment may suggest a high level of tolerance to alcohol and habitual heavy drinking. Similarly, the presence of withdrawal symptoms requiring treatment may occur with high breath alcohol levels in habitual heavy drinkers. The absolute level is not a measure of the severity of dependence. For reference, the legal limit for driving is 35 micrograms of alcohol per 100 millilitres of breath.
2. **Taking a drinking history:** This should include the number of units consumed each day and the duration of excess alcohol consumption. 1L of 1% alcohol is 1 unit (500mls of 4% alcohol is 2 units, 700mls of 40% alcohol is 28 units, etc.).
3. **Screening tools** such as the SADQ (Severity of Alcohol Dependence Questionnaire) can determine the level of alcohol dependence. Patients who score 16 or more have at least moderate dependence and medical-assisted detoxification is indicated. If the score is 10-15, further observation may be warranted, particularly in patients who have conditions that increase the risk of withdrawal complications (for example, anorexia). If the score is <10, medically-assisted detoxification is unlikely to be indicated.
4. **Conducting a thorough physical examination:** Be as thorough as you would if admitting a patient to an acute medical ward. It is essential that the physical examination includes assessment for signs and symptoms of Wernicke's encephalopathy and liver damage. Wernicke's encephalopathy is characterised by ophthalmoplegia (lateral nystagmus), ataxia and confusion; note that not all of these features need to be present for a diagnosis to be made (only around 10% of people with Wernicke's exhibit all three features). Liver damage may manifest as jaundice, enlarged liver, ascites, spider naevus, vomiting blood or blood in stool, liver palms, etc.
5. **Taking routine bloods:** Key investigations include LFTs (with GGT) and a FBC (with MCV). Such tests are helpful in identifying previously undetected serious physical pathology. If ALT or AST are >2.5 times the upper limit of normal, advice should be sought from a physician. A raised GGT indicated induction of this enzyme by alcohol (although this is not the sole reason for such a finding); on stopping drinking, GGT takes 2-3 months to recover. A raised MCV is common in heavy drinkers. The results of these tests should be shared with the patient; explaining the implications is one way of delivering a brief intervention. The patient's GP should be informed of the test results and repeating these tests will inform discussion with the patient about the progress they are making in cutting down their alcohol consumption.
6. **Prescribing a medically-assisted withdrawal regimen:** If there are no signs or symptoms of liver disease, a suitable regimen would include a reducing dose of chlordiazepoxide; if signs or symptoms of liver disease are present, a reducing dose of a shorter-acting benzodiazepine such as oxazepam is more appropriate.
7. **Ensuring it is safe to initiate medically assisted withdrawal:** Repeat the breath alcohol measurement; do not administer chlordiazepoxide (or any other benzodiazepine or sedative drug) until the breath alcohol measurement starts to fall. Administering benzodiazepines (which are sedative) when the blood alcohol concentration is still rising can lead to life-threatening respiratory and CNS depression.
8. **Protecting against the development of Wernicke's encephalopathy:** If there are no signs or symptoms of Wernicke's encephalopathy, prescribe Pabrinex (IM thiamine) one pair of ampoules daily for 3-5 consecutive days. If there is any suspicion that Wernicke's is present, an urgent medical opinion is indicated to inform the treatment plan, including the dose of parenteral thiamine.
9. **Monitoring response to the reducing chlordiazepoxide regimen:** Rating scales such as the CIWA-Ar (Clinical Institute Withdrawal Assessment Scale of Alcohol, revised) quantify how well symptoms of withdrawal are being controlled by the prescribed detoxification regimen. For example, a score of 15 or more predicts increased risk for severe alcohol withdrawal although complications can still occur in patients with much lower scores. The CIWA-Ar score should fall as detoxification progresses. As an absolute minimum, vital signs should be recorded on a MEWS (Modified Early Warning Score) chart.
10. **Reviewing the results of blood tests for evidence of clinically significant liver damage:** If present, seek advice from a physician and review the drug and dose prescribed to assist detoxification to ensure that the best balance is achieved by controlling withdrawal symptoms without over-sedating the patient (note that long half-life benzodiazepines such as chlordiazepoxide will accumulate, particularly in those whose capacity to metabolise is impaired).
11. **Delivering a brief intervention:** This can be done as soon as the patient feels more comfortable and is receptive to discussion; see point 5 above.
12. **Referring the patient on to specialist services for on-going help and support:** Where a patient is willing to consider stopping drinking alcohol or reducing consumption, consider referral to a specialist service. Discuss with the accepting service whether medication to maintain abstinence (e.g. acamprosate, disulfiram, naltrexone) or reduce alcohol consumption (e.g. nalmefene) should be initiated.

# Prescribing for people with a personality disorder

## Background

People with personality disorder have long-standing, pervasive patterns of thinking, feeling and relating to others that lead to social dysfunction and poor mental health. The most common type of personality disorder under the care of mental health services is emotionally unstable personality disorder (EUPD), which is characterised by affective instability, impulsivity and anger, transient psychotic or dissociative symptoms and intense, unstable relationships. Our study in 2011 (Crawford et al. 2011) found that, despite the weak evidence base for the pharmacological treatment of personality disorder and a lack of consensus in guideline recommendations, medication was widely used for people with personality disorder in the UK.

## Data from the POMH QI programme

The most common comorbid mental illness was an affective disorder, followed by schizophrenia, with more than half the sample (59%) having at least one comorbid mental illness. The personality disorder subtype was EUPD in over two-thirds (68%), and almost all these patients were prescribed psychotropic medication, most commonly an antidepressant or antipsychotic medication, principally reported to be for the treatment of the symptoms and behaviours that characterise EUPD. Prescribing patterns were similar in those who had a diagnosed comorbid mental illness and those who had EUPD alone, although patients in the latter group were less likely to have had their medication reviewed over the previous year, particularly with respect to tolerability (Paton et al. 2015).

## Clinical implications

The findings revealed that the prescription of psychotropic medication in EUPD is largely outside the licensed indications and treatment may be continued long-term by default. In any individual patient, whether the symptoms being targeted with medication are considered to be intrinsic symptoms of EUPD or symptoms of comorbid mental illness may depend on the prescribing clinician's diagnostic threshold. Compared with prescribing for patients with EUPD where there was judged to be a comorbid mental illness, the use of off-label medication for those with EUPD alone was less systematically reviewed and monitored, so opportunities for learning may have been lost

## Baseline audit 2012

**41** mental health Trusts submitted data on the treatment of **2600** patients

**59%** of patients had at least one comorbid mental illness

## POMH data in the context of wider initiatives

We reported the findings of the POMH baseline audit in a paper published in the Journal of Clinical Psychiatry (Paton et al. 2015). This was accompanied by three commentaries by clinical experts in this area, who reflected on the wider implications for the treatment of personality disorder, particularly in the USA. Paris (2015) considered that it was unsatisfactory that patients with severe personality disorders received almost routine polypharmacy and that this situation would only be remedied if specialised psychotherapy were made more readily available.

Silk (2015) was also concerned about the widespread use of a variety of medications and medication combinations for a disorder where the role and impact of medication was uncertain. In relation to borderline personality disorder (BPD), which was assumed to be equivalent to EUPD, there was a need to educate clinicians on management, with the judicious and systematic use of medication. Further, he cautioned that the enduring unhappiness, loneliness and emptiness of BPD, for which there is little evidence of response to psychopharmacology, should not be mistaken for major depression. Ingenhoven (2015) discussed the conflicting views on pharmacotherapy for personality disorder in international guidelines. He interpreted the POMH findings as showing that in the absence of consistent pharmacotherapeutic recommendations, the treatment of patients with BPD can reflect the arbitrary preferences of individual clinicians. However, he noted that any revision of international guidelines would have to rely on a limited and controversial evidence base with regard to both efficacy and tolerability.

## Top 10 Tips for prescribing for people with a personality disorder



Some people with personality disorder (PD) have past experiences of being let down or ignored by others and may jump to the conclusion that if you do not prescribe medication this is because you do not think that their problems are important.



Offering something other than medication, such as clear information about a follow-up appointment or details of how to access another service, may help the patient accept that you have taken them seriously.



Be open with patients – evidence from studies and clinical experience are that medication is generally not a helpful approach to improving the mental health of people with personality disorder and can cause side effects. Refer service users and carers to national guidelines such as those developed by National Institute for Health and Care Excellence: <http://guidance.nice.org.uk/CG78/PublicInfo/doc/English>



While people with PD may experience high levels of emotional distress, the feelings of sadness and despair that people may have do not respond well to antidepressant medication (unless the person also has a mood disorder).



Service users may benefit from having a joint crisis plan that helps them and others manage at times of crisis. This crisis plan should, when possible, make specific mention of medication at such times.



If medication is judged to be required, consider short term use of a drug with few side effects which is relatively safe in overdose should be considered – such as short-term use of a sedative antihistamine for those who experience poor sleep at times of crisis.



When antipsychotic medication is used make it clear to the patient that this will be for short term use.



Whatever medication is used, make a time to review it and stop it unless there is clear evidence of benefit.



Check your own feelings before you prescribe medication. Are you experiencing the patients' anxiety that something must be done, or feeling frustrated that nothing is good enough and you need to do something to end the session?



While available evidence suggests that medication is over-prescribed for people with personality disorder, people with PD can develop depression or psychosis and comorbid conditions should be treated according to appropriate guidelines.



# Prescribing for depression in adult mental health services

## Background

The standards for this QI programme were derived from the NICE and BAP guidelines for depression.

Depression is a common illness, affecting 3% of the adult population at any point in time. The vast majority of people with depression are treated in primary care and the main treatment strategies used in this setting are antidepressant medication and low-intensity psychological interventions. Where the illness is complex, severe, treatment-refractory or associated with risk to the patient or to others, NICE recommends referral to mental health services (NICE, 2009) where specialist assessment will inform further treatment strategies that may be pharmacological, psychological, physical or a combination of one or more of these options. Both the NICE (2009) and British Association for Psychopharmacology (Cleare et al. 2015) guidelines make recommendations relating to pharmacological treatments where the illness has failed to respond to SSRI antidepressants, supporting strategies such as the use of combined antidepressants, and adding lithium or an antipsychotic medication to existing antidepressant treatment. There is evidence that outcomes for people with depression can be optimised if a systematic approach is taken to assessment and the sequencing of treatment (Bauer et al. 2019).

### Data from the POMH QI programme

With respect to those patients who had a short episode of care from a CMHT, more than four-fifths met one or more of the NICE criteria for referral to mental health services, suggesting that primary care manage the vast majority of more straightforward cases.

The data revealed that those patients with moderate or severe depression who remained under the care of a community mental health team for longer than a year were clinically complex in that more than half had a comorbid psychiatric diagnosis and the vast majority was prescribed antidepressant medication, often in combination with other psychotropic medications. Three-quarters of these patients had a care/crisis plan that identified factors that could adversely affect their mental health, but for those who did not, this limited the ability of the clinical team to recognise these triggers and put a mitigation plan in place.

Over four-fifths had a documented clinical assessment addressing the symptoms and severity of their depression but formal rating scales were rarely used. A comprehensive treatment history was available for only half of the cases and some evidence-based treatment options such as lithium were infrequently used. The majority, but not all patients had a review in the last year that addressed response to medication, adherence and side effects (see **Figure**).

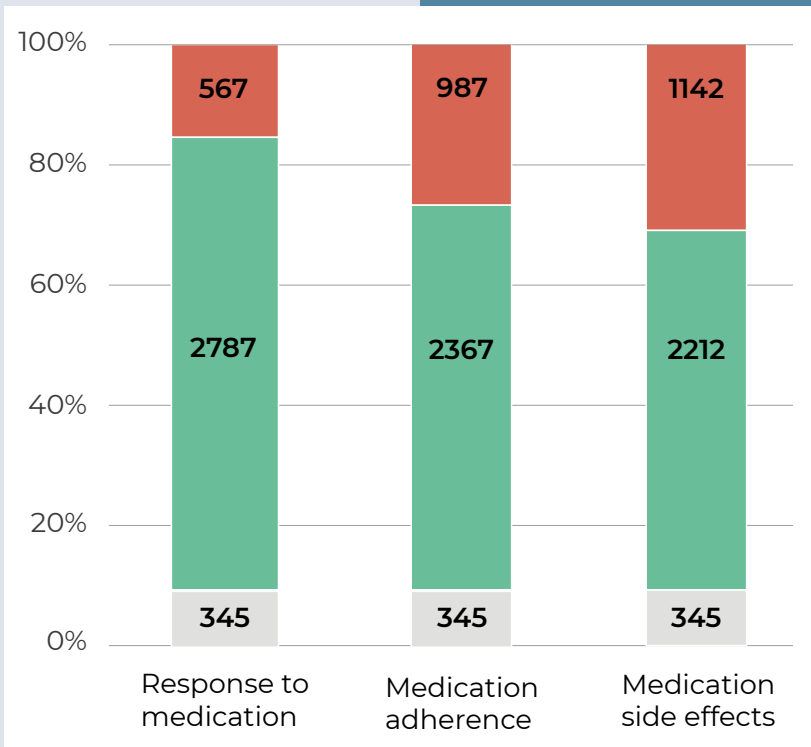
Baseline audit  
**2019**

**58** mental health Trusts submitted data on the treatment of **4843** patients

The re-audit is planned for **2021**.

Proportion of patients with depression under the care of a longer-term CMHT who had a documented review in the last year addressing response to medication, side effects and adherence: total national subsample (n=3699, 2019 baseline audit).

- No documented assessment
- Documented assessment
- No antidepressant medication prescribed



## Clinical implications (Paton et al. 2020)

- Care planning for patients with complex, severe and treatment refractory depression who are under the long-term care of a CMHT is compromised if there is no medication history available that outlines strategies that have been tried previously and whether or not these were effective, the side effects were tolerable and the medication was taken.
- Response to medication, adherence and side effects were not assessed in the previous year in some patients, limiting the quality of information that can be added to the patient's medication history.
- Some evidence-based pharmacological interventions may be under-used in patients with difficult-to-treat depression and this may compromise discharge to primary care for some.

A medication history is a critical component of care plans

Evidence-based interventions may be under-used for some patients

# Prescribing clozapine

## Background

**The data collected principally related to performance against practice standards for clozapine treatment, derived from NICE guideline 178 (NICE 2014).**

Compared with other antipsychotic medications, clozapine demonstrates superior efficacy in treatment-resistant schizophrenia, that is, schizophrenia that has failed to respond to adequate trials of at least two standard antipsychotic medications (Rubio & Kane, 2020). The response rate for such refractory illness is around 40% (Siskind et al. 2017), although there is emerging evidence that the longer treatment with clozapine is delayed, the lower the likelihood of response when it is tried (Yoshimura et al. 2017). In addition to mandatory haematological monitoring, treatment guidelines recommend routine monitoring of adverse effects and physical health in patients prescribed clozapine. Clozapine treatment is associated with a host of adverse effects including weight gain, dyslipidaemia and the development of diabetes, as well as cardiovascular effects such as hypotension, tachycardia, cardiac arrhythmias, myocarditis and cardiomyopathy (Citrome et al. 2016).

## Data from the POMH QI programme and clinical implications

A QI programme focussing on clozapine use in UK mental health services was initiated in 2018. 63 NHS Trusts/healthcare organisations participated in the baseline audit, submitting data for 6948 patients prescribed clozapine (POMH, 2019).

### Antipsychotic prescribing before starting clozapine

Information on the antipsychotic medication regularly prescribed immediately before starting clozapine was collected for a subsample of 481 patients who had been treated with clozapine for up to 18 weeks: 21% were prescribed combined antipsychotic medications and 6% a single antipsychotic in high dose.

- Immediately before starting clozapine, more than a quarter of patients had been prescribed antipsychotic regimens with a limited evidence base for their benefit-risk balance in treatment-resistant schizophrenia. The time spent testing such strategies may delay the initiation of clozapine treatment, potentially lowering the probability of a positive therapeutic response.

Baseline audit  
**2018**

**63**  
organisations  
submitted  
data on the  
treatment of  
**6948** patients

Clozapine  
treatment  
was often  
delayed while  
patients were  
prescribed  
high-dose or  
combined  
antipsychotic  
medication

## Clozapine dosage: sex differences

In 499 patients established on clozapine for less than a year, a daily dose greater than 400mg was twice as likely to be prescribed for men (16%) than women (9%). Three months after starting clozapine, the mean daily dose was 294mg for women and 324mg for men.

- The difference in mean daily clozapine dose between men and women in the early stages of treatment was less than might be warranted, given the known sex differences in the relationship between dose and plasma level (Rostami-Hodjegan et al. 2004). These findings suggest the possibility of reducing the clozapine dosage in some women without compromising efficacy.

## Pre-clozapine treatment screening and on-treatment side effect monitoring

There was documented pre-treatment screening of blood pressure, heart rate and ECG in at least 90%, and body weight, plasma lipids, plasma glucose/HbA1c and physical examination in approximately 80%. During the first two weeks of clozapine treatment there was documented daily measurement of both heart rate and blood pressure in 82% and body temperature in 77%.

411 patients had been treated for at least a month but less than 18 weeks. Of the 72% who had weekly side effect assessments documented in the first month of treatment, a structured assessment tool had been used in 29%.

In the 5908 patients prescribed clozapine for at least a year, blood pressure and body weight/BMI were documented in at least 80%, plasma lipids in 78% and plasma glucose in 73%, with an ECG in 55%.

- If some generalisation of these findings is warranted, they suggest that for most patients treated with clozapine in UK mental health services, physical health screening and side effect monitoring are in line with recommended practice. However, there was only limited use of structured side effect assessment tools, which allow adverse effects to be elicited more systematically and comprehensively (Yusufi et al. 2007; Hynes et al. 2015).

## Monitoring of cardiac side effects/myocarditis

Treatment monitoring for the 481 patients treated with clozapine for up to 18 weeks included an ECG in 90%, C-reactive protein (CRP) or creatine kinase in 42%, and troponin or B-type natriuretic peptide (BNP) in 29%.

- Monitoring for clozapine-induced myocarditis during the early risk period, using markers of inflammation such as CRP, and cardiac damage such as troponin and BNP, was not consistent. This may partly reflect the variation in the guideline recommendations for monitoring for myocarditis (Knoph et al. 2018) and partly that such tests tend not to be used routinely but rather when prompted by the emergence of cardiac symptoms.

Clozapine dosage could be lowered for some women without affecting treatment efficacy

Physical health checks and side effect monitoring for most patients were in line with recommended practice

There was variation in the monitoring for cardiac side effects/myocarditis

### Co-prescription with clozapine

Of the 5908 patients prescribed clozapine for at least a year, approximately two-thirds were also prescribed a psychotropic medication other than a second antipsychotic, two-thirds were prescribed medication to manage side effects of clozapine and almost a third of those with a diagnosis of schizophrenia were prescribed a second antipsychotic medication.

- The relatively common co-prescription of medications for most of the patients prescribed longer-term clozapine treatment may be associated with a greater side effect burden and increased physical health risks, reinforcing the need for continuing, systematic monitoring.

### Change in smoking habit and implications for plasma clozapine levels

Seventy-seven patients in the audit sample had been discharged from a smoke-free ward. In 52 (68%), the impact of the potential change in smoking status on clozapine dose/plasma levels and the implications for monitoring and/or dosage change had not been considered in their care plans.

- The failure to anticipate the consequences of a change in smoking status when discharged from hospital, as found in two-thirds of relevant cases in this audit, could lead to an increased possibility of sub-therapeutic plasma clozapine levels and thus a greater risk of relapse (Rostami-Hodjegan et al. 2004; Qurashi et al. 2019).

### Clozapine treatment and the primary care Summary Care Record (SCR)

For 3902 patients, prescribed clozapine for at least a year and under the care of a community mental health team, information was submitted about the documentation of their prescribed medications in the primary care Summary Care Record (SCR). In 42% of these cases, clozapine was not included in the SCR prescribing summary.

- For patient safety, the SCR should list all currently prescribed medications. If an SCR that failed to include a patient's clozapine prescription were to be used by a hospital doctor to inform acute treatment plans, clinical symptoms indicative of serious clozapine-related adverse effects such as agranulocytosis, myocarditis or severe constipation could be missed or an interacting medicine inadvertently prescribed.

Co-prescription with other medications was relatively common

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More consideration of the possible consequences of changing smoking habits on plasma clozapine levels is warranted in care planning

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Summary Care Records should list all currently prescribed medications

# Medicine related safety issues

## Valproate prescribing for women of childbearing age

### Background

The data collected were in relation to evidence-based practice standards (derived from NICE CG185) for the initiation of valproate treatment as well as its longer-term review and monitoring.

The POMH team has had a long-standing interest in the safety of valproate prescribing for women of child-bearing age. Our early work (James et al. 2007, 2009) attempted to evaluate the knowledge and practice of consultant psychiatrists with respect to the teratogenic effects of valproate. The findings suggested that these risks were not widely understood and valproate was often used in women of child-bearing age without appropriate safeguards being in place.

### Data from the POMH QI programme

The baseline audit in 2015 (POMH, 2016) part of the POMH QI programme addressing prescribing practice for adults with a diagnosis of bipolar disorder found that over a third (36%) of adults under the care of adult services were prescribed valproate. Valproate was more commonly used than lithium, which was prescribed for a quarter (25%) of patients in the sample.

Regarding the prescription of valproate to women of child-bearing potential (defined as being 50 years of age or younger) of the 2,364 women in that age range, a quarter (24%) were prescribed valproate. The respective figure for men was 43%. Of the 74 women younger than 50 years of age, who had started valproate in the preceding six months, there was documentation in the clinical records of a discussion about the potential benefits and side effects of the newly initiated valproate in two-thirds (66%) and the need for contraception in just over half (55%). In a similar proportion (50%), there was evidence that they had been informed specifically about the potential teratogenic effects of this medication and, in just under a quarter (24%), the woman had been informed of the implications for the longer-term cognitive development of the child (for example, neuro-development delay, autistic spectrum disorders) when valproate is taken during pregnancy.

Baseline audit  
**2015**

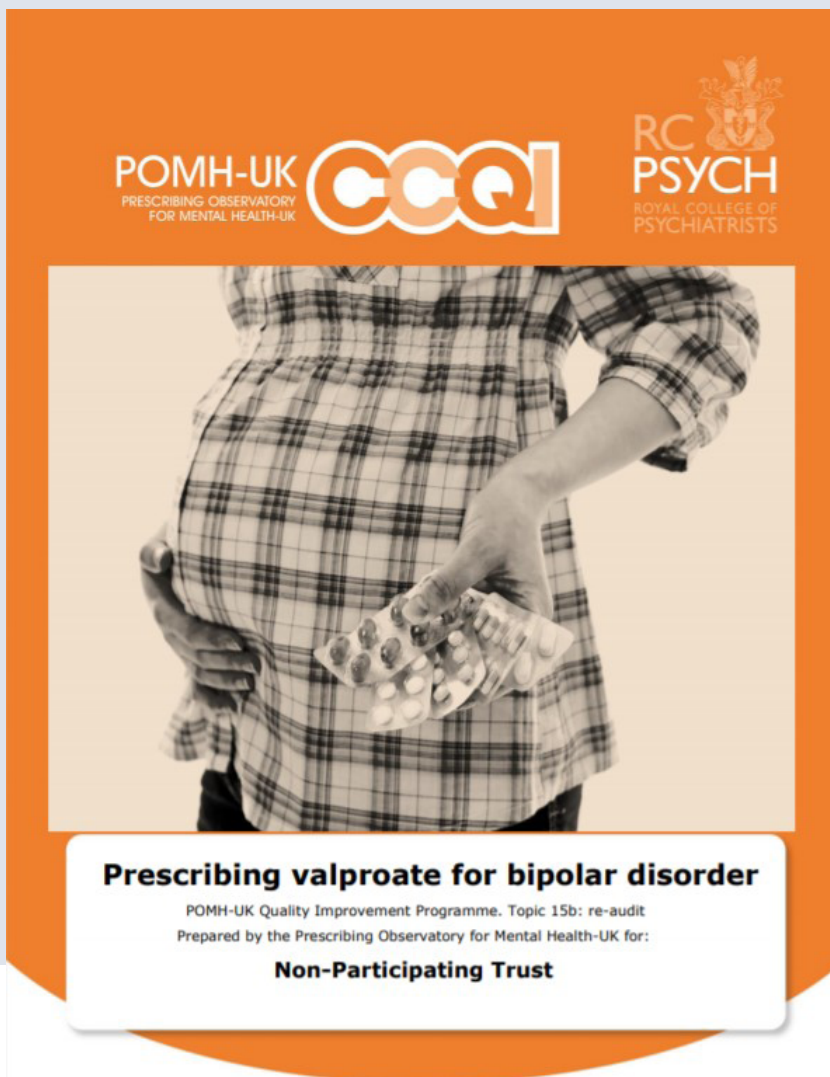
**55** mental health Trusts submitted data on the treatment of **6705** adults with a diagnosis of bipolar disorder

The re-audit in 2017 (POMH, 2018) found there were 63 women younger than 50 years who had started valproate treatment within the last six months. The proportion with whom the benefits and risks had been discussed was almost the same (68%) as at baseline, but a higher proportion had documented consideration of the need for contraception (70%) and there was a modest increase in the proportion with whom the teratogenic effects had been discussed (54%) and for whom information about neurodevelopmental implications for the child had been provided (33%) (Paton et al. 2018).

## Re-audit 2017

**56** mental health Trusts submitted data on the treatment of **6025** adults

The proportion of women under 50 years of age informed of the benefits and risks **remained similar** from the baseline audit to re-audit but the proportion informed about the need for contraception increased from **55% to 70%**



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PSYCHIATRISTS

**Prescribing valproate for bipolar disorder**

POMH-UK Quality Improvement Programme. Topic 15b: re-audit  
Prepared by the Prescribing Observatory for Mental Health-UK for:  
**Non-Participating Trust**

## QI work in individual mental health services

The 2018/2019 Quality Report from the South London and Maudsley NHS Foundation Trust highlighted the POMH data showing the performance of the Trust against the practice standards relating to the use of valproate for bipolar disorder. Consequently, clinicians had been informed of the results as well as the MHRA requirements for valproate use in women of childbearing age, including enrolment in the pregnancy prevention programme (PPP). Prescribers were to be advised of any women who had not been enrolled in the PPP.

## Wider impact **Regulatory measures**

In 2018, there was an invitation to present the POMH data to inform the Commission on Human Medicines, Sodium Valproate Expert Working Group, which was considering regulatory measures related to the risks associated with valproate use in pregnancy, including a formal pregnancy prevention programme. Similarly, there was an invitation to attend MHRA Valproate Stakeholder Network Subgroups, which provided views on the implementation of a strengthened regulatory position for valproate, including the proposed pregnancy prevention plan.

Subsequently, the European Medicines Agency recommended that valproate should not be used in pregnant girls or women with mental illness or migraine and only prescribed to pregnant women who suffer from a severe form of epilepsy that has not responded to other drugs; in any non-pregnant women of childbearing potential, valproate should only be prescribed with the implementation of a pregnancy prevention programme (European Medicines Agency, 2018). These recommendations were approved by the European Commission and all European Countries in 2018. The Medicines Health Care Products Regulatory Agency (2018a, 2018b) in the UK supported these requirements with a programme to raise awareness among clinicians and patients and introduce measures to ensure adherence to the new regulations.

In late 2020, POMH plans to run a new QI programme on valproate use in adult mental health services across all clinical indications, which will include assessment of compliance with the pregnancy prevention programme in this clinical setting.

### **Royal College of Psychiatrists' position statement**

A position statement from the Royal College of Psychiatrists (2018) addressed the withdrawal of valproate and alternative treatments in women of child-bearing age with bipolar disorder. This referred to the POMH clinical audit data, as evidence of current valproate prescribing practice (Paton et al. 2018, Baldwin & Amaro, 2020).

### **Independent Medicines and Medical Devices Safety Review**

An Independent Medicines and Medical Devices Safety Review (2020) addressed three medical interventions where there was concern about people suffering avoidable harm. One of these interventions was treatment with sodium valproate (the other two were Primodos, a hormone-based pregnancy test, and pelvic mesh). Considering the use of valproate in psychiatric services, the POMH audit in 2018 was cited as evidence that many women of childbearing age for whom valproate was prescribed for bipolar disorder had not been fully informed about the risks to the unborn child. The wide-ranging recommendations in the review included the appointment of a Patient Safety Commissioner and the establishment of a new, independent Redress Agency for those harmed by medicines and medical devices. The review also listed 'actions for improvement', which included the encouragement by hospitals of clinical audit and robust systems for monitoring and assuring quality. One of the actions for improvement specifically related to the use of valproate was that 'clinicians should continue to follow guidance regarding prescribing of valproate and alternatives for all indications'.



# The quality of biochemical monitoring for patients prescribed lithium

## Background

The use of lithium in bipolar illness and in unipolar depression is supported by evidence-based treatment guidelines (NICE, 2014; Goodwin et al. 2016; NICE, 2009). Lithium has a narrow therapeutic range and established adverse effects on the kidneys, thyroid and parathyroid and for these reasons, regular biochemical monitoring is required for all patients who are prescribed this medication (NICE, 2014). The quality of this monitoring has been the focus of a POMH QI programme.

## Data

At the baseline audit in 2008, data were submitted for more than 3,000 patients receiving lithium treatment. In the last year, two or more monitoring tests of kidney function, thyroid function and plasma lithium level had been conducted in 54%, 49% and 69% of cases, respectively (Collins et al. 2010). Partly in response to the findings from this audit and partly in response to reported patient safety incidents related to lithium, the National Patient Safety Agency issued a Patient Safety Alert with actions requiring that primary care, mental health and acute Trusts, along with hospital pathology services ensure systems are put in place to support the required monitoring (NPSA, 2009).

## Patient-held lithium pack

In collaboration with the NPSA and the National Reporting and Learning Service, POMH developed a patient-held lithium pack that contained a booklet with information about lithium treatment including the monitoring requirements, a record book for blood test results, and a lithium alert card. Raynor (2013) described the procedures followed in the development of this lithium pack as an example of good practice that could potentially benefit any future process for patient medication information in the USA.

Several hundred thousand of these packs have been distributed to patients via mental health services and primary care. The timing of these interventions meant that they could have had little influence on the POMH re-audit conducted in 2010 and, indeed, the re-audit findings were almost identical to baseline. But by the supplementary audit in 2011, the proportions of patients who had received the required number of monitoring tests of kidney function, thyroid function and plasma lithium level had increased to 70%, 66% and 80% (Paton et al. 2013), suggesting that these interventions prompted improvements in clinical practice. While these initial improvements have been maintained in the three subsequent supplementary audits conducted in 2013, 2016 and 2019, no further gains have been made, suggesting that a ceiling effect has been reached with the systems currently in place.

Baseline audit  
**2008**

Re-audits in  
**2010, 2011,  
2013, 2016  
and 2019**



Following publication of the patient-held lithium pack, improvements in monitoring were observed

## POMH data in the context of wider initiatives

A paper by authors from the National Patient Safety Agency and POMH (Gerrett et al. 2010) highlighted problems with monitoring of lithium blood concentrations and other mandated blood tests in routine clinical practice in the UK, referring to findings from the baseline audit of the POMH (2009) QI programme addressing such practice. Bulteau et al. (2016) conducted a retrospective pharmacoepidemiological study of lithium monitoring in France and concluded that their findings confirmed the observations of Gerrett et al. (2010), identifying a similar gap between guideline recommendations and actual clinical practice.

In 2019, the Pharmaceutical Services Negotiating Committee announced an incentive scheme for community pharmacy that includes payment for meeting quality criteria relating to ensuring the required lithium monitoring has been completed (PSNC, 2019). This has the potential to improve monitoring in those patients who have their medication supplied through a community pharmacy.

A further promising systems intervention for improving the quality of monitoring is the introduction of local lithium databases (Kirkham et al. 2013; Elliott, 2014). While there is no nationally endorsed system, the pharmacy team at TEWV NHS Foundation Trust have very kindly shared the excellent lithium register they developed: an Excel document that can be tailored locally as required. This has been made available to download via the members' area of the POMH website, along with a guide to implementation.

## Prescribing antipsychotic medication for people with dementia

### Background

The behavioural and psychological symptoms of dementia (BPSD), such as agitation, aggression, psychosis, wandering and sleep disturbance, are a legitimate target for treatment. The underlying causes of BPSD include psychotic experiences, discomfort and pain due to physical illness, or a person's basic needs (such as hunger, thirst, and social contact) failing to be met. Where the underlying cause is unidentified or unclear, custom and practice had been to use antipsychotic medication, although the risk-benefit balance of such treatment in this context had long been considered to be unfavourable.

In 2008, the Minister of State commissioned a review of the use of antipsychotic medication in people with dementia. The subsequent report, entitled 'Time for Action' (Banerjee, 2009), clearly outlined that the risks of such treatment were likely to outweigh the benefits in the majority of cases and this prompted a number of national initiatives to reduce the use of antipsychotic medications for BPSD.

## Data from the POMH QI programme

A baseline clinical audit was conducted as part of a POMH QI programme addressing prescribing practice for people with dementia under the care of mental health services (POMH, 2011). Fifty-four mental health Trusts submitted data on 10,199 patients. Of those without a comorbid psychotic illness, 1,620 (16%) were prescribed an antipsychotic medication, most commonly for BPSD symptoms such as agitation, psychotic symptoms, aggression and distress. The clinical variables predicting the use of antipsychotic medication included younger age, a care home or inpatient setting, and greater severity of dementia. Three-quarters of the patients on longer-term antipsychotic medication had a documented review of their therapeutic response in the previous 6 months (Barnes et al. 2012).

A re-audit was conducted in 2012 (POMH, 2012) and a supplementary audit in 2016 (POMH, 2016), with data submitted on the treatment of 12,790 and 10,199 people with a diagnosis of dementia, respectively. Focusing on the prescribing of antipsychotic medication for BPSD, and taking into account differences in the clinical characteristics between the three audit samples, the findings indicated that the prevalence of antipsychotic use decreased between 2011 and 2012 (by 23%) and that this decrease was maintained in 2016 (19% down from 2011). In 2016, in those people who were prescribed antipsychotic medication, underlying causes of BPSD had been considered in nearly three-quarters of cases and a non-pharmacological intervention had been tried prior to starting antipsychotic medication in two-thirds of cases.

A consensus statement on the pharmacological treatment of dementia from the British Association for Psychopharmacology (2017) notes that alternatives to antipsychotic medication should be considered for BPSD because of side effects such as parkinsonism as well as concerns over cerebrovascular adverse events and increased mortality (MHRA, 2014). The National Institute for Health and Care Excellence clinical guideline for the management of dementia (NICE, 2018) recommends that antipsychotic medication should only be offered to people living with dementia if they are 'at risk of harming themselves or others' or 'experiencing agitation, hallucinations or delusions that are causing them severe distress'. The recommendations for the use of antipsychotic medication included using the 'lowest effective dose' for the 'shortest possible time', with reassessment of the person at least every 6 weeks, to check whether continued medication was still required.

Baseline audit  
**2011**

**54** mental health Trusts submitted data on the treatment of **10199** people with dementia

Re-audit  
**2012**

Data on on the treatment of **12790** people with dementia

Supplementary audit in **2016**

Data on **10199** people with dementia

Prevalence of antipsychotic medication use **decreased** between 2011 and 2012 by **23%** and the decrease was maintained in 2016

## QI work in individual mental health services

As part of a POMH audit, Wightman et al. (2011) reviewed the treatment of 67 patients in the Cambridgeshire area who had a diagnosis of dementia. They considered that the data collected suggested that antipsychotic medication was being used appropriately in their local services. It was generally prescribed for a short time and reviewed, and had enabled patients with distressing and difficult behaviour to remain at home. Areas for improvement included documentation of a discussion of risk in the clinical records and ensuring that underlying causes of BPSD had been explored.

## POMH QI programmes in the context of wider initiatives

### Department of Health

In 2010, the National Clinical Director for Dementia at the Department of Health led the development of a National Dementia Strategy for England and, as part of this initiative, set up a small working group to focus on developing an action plan to reduce the number of prescriptions for antipsychotic medication for people with dementia. POMH was invited to join this working group and share the national data from the POMH baseline audit. The findings of the subsequent POMH re-audit and supplementary audit were also shared with the National Clinical Director for Dementia, who spoke about the use of antipsychotic medication in people with dementia at the POMH 10-year conference in 2016.

### Consensus practice guideline

Experts in the UK, Norway, and the Netherlands collaborated on the generation of a consensus practice guideline on the prescription of antipsychotic medication for people with dementia living in care homes (Zuidema et al. 2015). The audit findings from the POMH QI programme on the use of antipsychotic medication in people with dementia were cited with regard to the variation in the prevalence of such prescribing between countries and the relatively common continuation of treatment for more than six months.

### National Institute for Health and Care Excellence

In 2015, NICE identified POMH as 'a prescribing data, metrics or supporting resource' in relation to the treatment of people with dementia with antipsychotic medication.

In 2016, POMH shared the national data from the QI programme with the NICE guideline development group updating the guideline on the assessment and management of dementia (NICE, 2018).

# The use of antipsychotic medication in people with a learning disability

## Background

Although the use of antipsychotic medication for psychotic and related illnesses in people with a learning disability (LD) is supported by clinical guidelines, the common off-label use of these medicines for the management of behavioural problems unrelated to diagnosed mental illness has always been controversial. The difficulties faced by psychiatrists in trying to balance the risks and benefits of pharmacological strategies when managing challenging behaviour in people with LD prompted the development of a good practice guideline by a group of experts in this field (Deb et al. 2006). A POMH QI programme addressing the quality of prescribing of antipsychotic medication in people with LD was initiated in 2009.

**The standards were drawn from the recommendations in this expert consensus guideline and related to the need to clearly document target symptoms and behaviours for antipsychotic treatment and regularly and carefully review the efficacy of such treatment and any associated side effects.**

## POMH QI programme on the use of antipsychotic medication for people with LD

At the baseline audit, data were submitted by 39 Trusts for over 2300 patients, just over half of whom had a diagnosis of either a schizophrenia spectrum disorder (ICD-10 F20-29) or an affective disorder (F30-39). Adherence to the audit standard relating to the documentation of the clinical reasons for prescribing was high (93%) and for most patients who did not have a psychotic or affective disorder this was one or more of agitation/anxiety, overt aggression, threatening behaviour or self-harm (Paton et al. 2011). Side effect assessments were less assiduous with documented assessment of EPS, body weight, lipids or glucose in the last year in only three-fifths of cases. At re-audit 18 months later there had been a modest improvement in the quality of side effect assessments with documented measures of body weight, lipids and glucose in almost three-quarters of cases (POMH, 2011).

Baseline audit  
**2009**

**39** Trusts submitted data on the treatment of over **2300** patients

Re-audit  
**2011**


**40** Trusts submitted data on the treatment of **2387** patients

## POMH data in the context of wider initiatives

In 2012, a report into the quality of care at Winterbourne View Hospital (DoH, 2012) was published further raising concerns regarding the over-use of psychotropic medication in people with LD. This report recommended that services should have systems and policies in place to ensure that prescriptions for psychotropic medications are regularly reviewed and that regular audits of prescribing are conducted. In 2015, NICE published a guideline addressing the management of challenging behaviour in people with a learning disability (NICE, 2015) that clearly outlined target symptoms and behaviours that may be legitimate targets for antipsychotic medication (violence, aggression or self-injury). These developments prompted a change to the eligibility criteria for the POMH supplementary audit conducted in 2015: all patients with LD could be included and this allowed for the prevalence of prescribing of antipsychotic medications to be determined. In addition, data were collected relating to whether antipsychotic treatment was limited to the target behaviours outlined by NICE.

In this supplementary audit, almost two-thirds of the national sample of 5654 people with LD were prescribed antipsychotic medication of whom just over half had a schizophrenia spectrum or affective disorder, and a further third exhibited behaviours recognised by NICE as potentially legitimate targets for such medication (violence, aggression or self-injury; NICE, 2015). These data do not support the claim that antipsychotic medications are widely used outside their licensed and/or evidence-based indications in people with LD, at least in those patients who are under the care of mental health services in the UK. But as at baseline and re-audit, there was room for improvement regarding the monitoring of side effects (Paton et al. 2016). These findings are in contrast with large studies of prescribing practice in primary care; for example, Glover & Williams (2015) who reported that the reasons for prescribing antipsychotic medication were documented in only two-fifths of cases

In 2015 following reports from Public Health England, NHS Improving Quality and the Care Quality Commission that raised concerns relating to high rates of prescribing of psychotropic medicines for people with a learning disability, NHS England led a 'call to action' (<https://www.england.nhs.uk/learning-disabilities/improving-health/stomp/research/>) and launched the STOMP campaign (Stopping overmedication of people with a learning disability, autism or both) in partnership with the Royal Colleges of Nursing, Psychiatry and General Practice, the Royal Pharmaceutical Society and the British Psychological Society. A large number of resources both educational and practical have been developed under this initiative and these are freely available on the STOMP website (<https://www.england.nhs.uk/learning-disabilities/improving-health/stomp/>).



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**Antipsychotic prescribing in people with a learning disability under the care of mental health services**

POMH-UK Quality Improvement Programme. Second supplementary audit, Topic 9d.  
Prepared by the Prescribing Observatory for Mental Health-UK for:

**Non-participating Trust**

POMH is conducting a second supplementary audit in 2020 and on this occasion a new standard has been added relating to the quality of the guidance provided by the LD team to primary care in cases where the GP has been asked to provide repeat prescriptions. This may help inform discussions regarding the following:

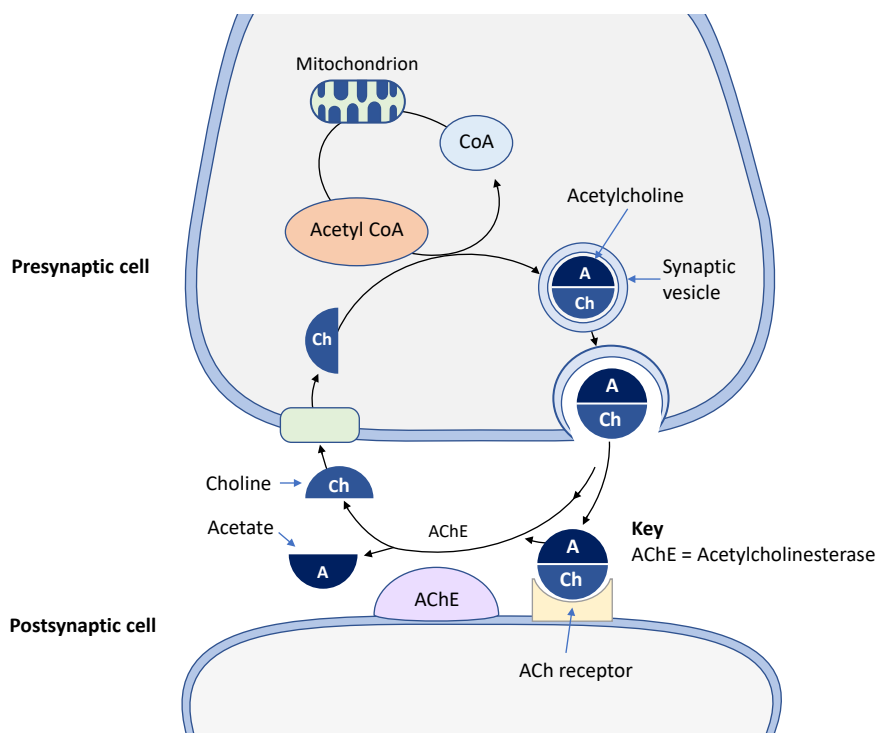
1. Why the clinical reasons for antipsychotic treatment are often absent from primary care records when they are clearly documented in secondary care clinical records in the vast majority of cases
2. Whether the responsibility for the review of a patient's antipsychotic medication, including side effect assessment, remains with the mental health services or has been clearly handed over to primary care.

# Informing treatment guidelines

## Prescribing for people with dementia: anticholinergic burden

### Background

All currently licensed anti-dementia medications, with the exception of memantine, exert their effect by preventing the breakdown of the neurotransmitter acetylcholine by the enzyme acetylcholinesterase in the brain: collectively, these medicines are called cholinesterase inhibitors.



Following signalling, acetylcholine is released from the receptors and then broken down by the acetylcholinesterase enzyme and recycled

Many medicines used to treat other conditions have anticholinergic actions, that is they prevent cholinergic pathways working as they should. These medicines not only block the actions of cholinesterase inhibitors but can cause problems with memory and concentration in their own right.



## Data from the POMH QI programme

In the benchmarking audit in 2007, 6% of the patients who were prescribed anti-dementia medication were also prescribed medication with clinically significant anticholinergic properties. At re-audit in 2013, this proportion was very similar at 7%. On both occasions, medicines used in the management of urinary incontinence were among the most commonly prescribed anticholinergic medicines. These medicines are often initiated by urologists or in primary care and clinicians in mental health services may be reluctant to change medicines that were started by doctors in other specialties.

Baseline audit  
2007

Re-audit  
2013

## POMH data in the context of wider initiatives

These national data were shared first with the guideline development group that was revising the NICE guideline for dementia, and then with the guideline development group that was revising the NICE guideline for urinary incontinence and pelvic organ prolapse in women. Both updated guidelines contain **new recommendations** about the use of anticholinergic medicines as follows:

### Dementia: assessment, management and support for people living with dementia and their carers - NICE guideline [NG97] June 2018

#### Section 1.6

Medicines that can cause cognitive impairment

- Be aware that some commonly prescribed medicines are associated with increased anticholinergic burden, and therefore cognitive impairment.
- Consider minimising the use of medicines associated with increased anticholinergic burden, and look if possible for alternatives:
  - When assessing whether to refer a person with suspected dementia for diagnosis
  - During medication reviews for people living with dementia
- Be aware that there are validated tools for assessing anticholinergic burden, but there is insufficient evidence to recommend one over the others.

### Urinary incontinence and pelvic organ prolapse in women: management - NICE guideline [NG123] April 2019

#### Recommendation 1.4.25

Before starting treatment with a medicine for over-active bladder, explain to the woman:

- that the long-term effects of anticholinergic medicines on cognitive function are uncertain.

These new recommendations raise awareness of the adverse effects of anticholinergic medicines on cognition and should prompt the following:

- Urologists, geriatricians and GPs to discuss these effects with patients before starting such medicines
- Psychiatrists, geriatricians and GPs to review established treatment with these medicines in patients with suspected or established cognitive impairment

## High dose and combined antipsychotic medication

### Data from POMH QI programmes

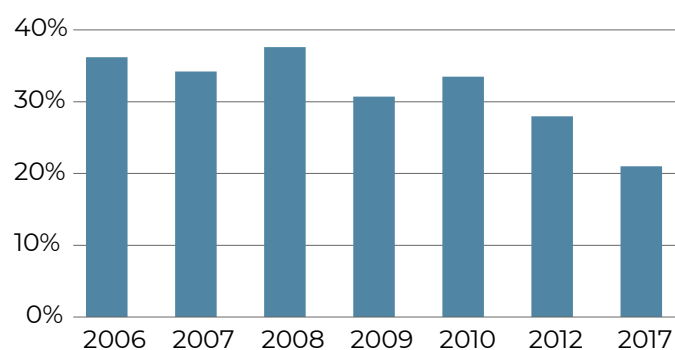
The QI programme addressing the use of high-dose and combined antipsychotic medications (antipsychotic polypharmacy) was the first one developed by POMH. While initially focusing on prescribing for patients on adult acute and psychiatric intensive care wards, it later broadened to include patients on forensic wards and under the care of rehabilitation/complex needs services. Between 2006 to 2017, seven national clinical audits were conducted against practice standards derived from recommendations in the NICE schizophrenia guideline, specifically that a single antipsychotic in a standard dose should be routinely used in clinical practice. The findings showed a steady but modest reduction over time in the proportion of patients prescribed high-dose (see **Figure**) and/or combined antipsychotic medication.

In the 2017 audit, 57 Trusts submitted data on 5159 patients from acute/PICU clinical teams, 38 Trusts submitted data on 1350 patients from rehabilitation/complex needs clinical teams, and 46 Trusts submitted data on 3563 patients from forensic clinical teams. In the total national sample (n= 10072), regular high-dose antipsychotic medication was prescribed for 10% of patients overall, only a third of whom had the high-dose prescription acknowledged in their care plan. Physical health monitoring was generally good for the patients on regular, high-dose antipsychotic medication, but an assessment over the past year for antipsychotic-induced movement disorder had not been documented for about a third.

The data revealed that the reduction in the prevalence of use of combined antipsychotic medications over time could be largely attributed to fewer prescriptions for PRN antipsychotic medication. The most common clinical reasons for prescribing regular combined antipsychotic medication differed across the clinical settings. For inpatients in acute adult ward/PICU settings, the most common reasons were a poor response to antipsychotic monotherapy or the overlap period while switching from one antipsychotic to another. For patients in forensic and rehabilitation/complex needs services, the most common reason was the augmentation of clozapine with a second antipsychotic; in three-quarters of such cases, the augmenting antipsychotic was amisulpride or aripiprazole.

Proportion of patients in each audit sample (2006-2017) under the care of acute adult/PICU teams for whom the total daily prescribed dose of antipsychotic medication (including PRN) was high dose (above the British National Formulary maximum licensed dose)

■ Proportion prescribed high-dose antipsychotic medication (including PRN)



Seven audits conducted between 2006 and 2017

Findings show a steady but modest **reduction over time** in proportion of patients prescribed a high-dose and/or combined antipsychotic medication.

The reduction can be partly attributed to **fewer prescriptions of PRN** antipsychotic medications

## QI work in individual mental health services

Informed by participation in the 2006 POMH audit, Mace and Taylor (2015) conducted a quality improvement programme in the South London and Maudsley NHS Foundation Trust. The aim was to reduce the prescribing of high-dose and combined antipsychotic medication for adult inpatients, including those on psychiatric intensive care units (PICUs). The interventions included restrictions and guidance to clinicians on the use of 'as required' (PRN) medications and the identification and review by pharmacy staff of all inpatient prescriptions for high dose and combined antipsychotic medications. Over the six years of this targeted improvement programme, there was a significant and sustained reduction in such prescribing.

The data collection tool used for clinical audit within the POMH QI programme was adapted by Prajapati et al. (2017) to collect data within Norfolk and Suffolk NHS Foundation Trust, as part of a multi-professional QI strategy, led by the clinical pharmacy team, to reduce the prescribing of high-dose and combined antipsychotic medications. The initiative also included a POMH change intervention: the distribution and display of an evidence-based poster on such prescribing. They compared their local clinical audit findings with those of the relevant POMH (2012) national audits and also noted significant improvements in local prescribing practice.

## POMH data in the context of wider initiatives

### Royal College of Psychiatrists' consensus statement on high-dose antipsychotic medication

The Royal College of Psychiatrists (2014) consensus statement on high-dose medication cited POMH publications (Paton et al. 2008; Barnes & Paton, 2011) to support the following points:

- Clinical factors associated with the prescription of high-dose antipsychotic medication include younger age, a longer duration of illness, a history of violence and aggression, and being male, although other variables, such as the severity and nature of the symptoms, the degree of medication adherence, the level of carer support and other psychosocial factors might potentially have some influence in individual cases.
- The clinical reasons for prescribing combined antipsychotic medications include attempting to enhance or speed up the therapeutic effect, managing challenging symptoms such as behavioural disturbance and aggression or targeting a particular symptom or symptom domain such as affective instability.
- Co-prescription of more than one antipsychotic is a risk factor for high-dose prescription. POMH data suggested that patients prescribed combined antipsychotics are more than 20 times more likely to be prescribed a high dose than those prescribed antipsychotic monotherapy.
- No clear relationship between the dosage of antipsychotic medication prescribed and ethnicity has emerged in UK studies.

## British Association for Psychopharmacology guidelines for the pharmacological treatment of schizophrenia

The updated version of the British Association for Psychopharmacology evidence-based guidelines for the pharmacological treatment of schizophrenia (Barnes et al. 2020), similarly cited POMH publications to support key points and recommendations, as follows:

- High-dose and combined antipsychotic regimens remain common and widespread strategies for treatment-refractory schizophrenia despite a lack of robust evidence regarding both their efficacy and safety for this indication.
- The use of combined antipsychotic medications is associated with a greater burden of side effects such as EPS, cognitive impairment, hyperprolactinaemia, sedation, sexual dysfunction, and metabolic symptoms.

## Rapid tranquillisation (RT)

### Background

Episodes of acute behavioural disturbance\* usually driven by mental illness, substance misuse or personality disorder are common in mental health settings and place both patients and staff at risk. Where de-escalation and other patient-specific interventions have failed to calm the situation and ensure the immediate safety of the patient, other patients and staff, parenteral (usually intramuscular) medication (RT) may be required (NICE, 2015); such medication is sedative. Given that patients who are acutely behaviourally disturbed are likely to be physiologically compromised, it is important that physical health observations are conducted after RT. Selected key recommendations made by NICE to guide medication choice and post-RT physical health monitoring are shown below:

### Violence and aggression: short-term management in mental health, health and community settings: NICE guideline [NG10] May 2015

#### 1.4.5

Use a restrictive intervention only if de-escalation and other preventive strategies, including p.r.n. medication, have failed and there is potential for harm to the service user or other people if no action is taken.

#### 1.4.37

Use either intramuscular lorazepam on its own or intramuscular haloperidol combined with intramuscular promethazine for rapid tranquillisation in adults.

#### 1.4.45

After rapid tranquillisation, monitor side effects and the service user's pulse, blood pressure, respiratory rate, temperature, level of hydration and level of consciousness at least every hour until there are no further concerns about their physical health status. Monitor every 15 minutes if the BNF maximum dose has been exceeded or the service user:

- appears to be asleep or sedated
- has taken illicit drugs or alcohol
- has a pre-existing physical health problem

\*See Addendum, page 59

## Data from the POMH QI programme

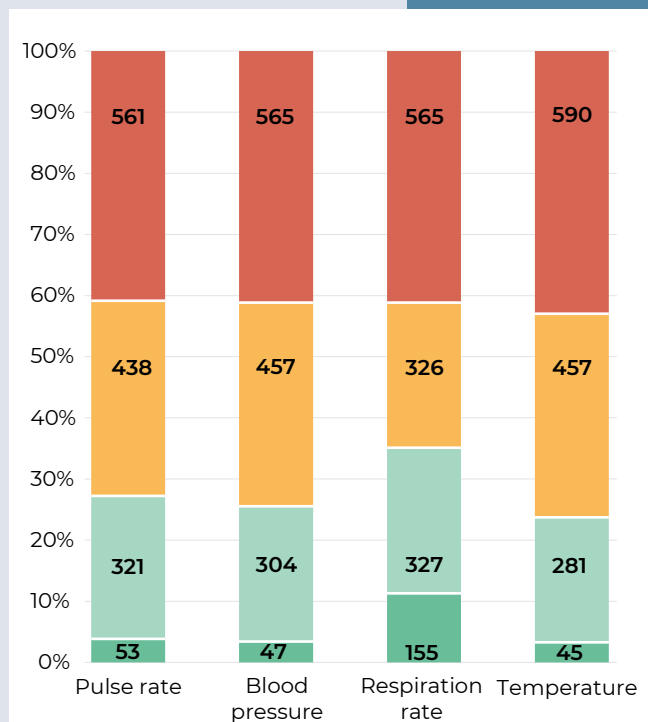
With respect to the monitoring of physical health immediately after RT, there were clear gaps between the standard and clinical practice with little change between baseline and re-audit (see **Figure**).

These data and their clinical implications were presented at the NAPICU annual conference in 2019 and shared with the expert group that developed the joint British Association for Psychopharmacology and National Association of Psychiatric Intensive Care Units (BAP/ NAPICU) guidelines for the clinical management of acute behavioural disturbance (Patel et al. 2018).

Further analyses of the wider data collected as part of this QI programme have facilitated understanding of who receives RT and why (see **Box 1**) and the challenges faced with respect to undertaking post-RT physical health monitoring (see **Box 2**).

Proportion of episodes in which IM medication was administered for which each of the four physical health measures (pulse rate, blood pressure, respiration rate and temperature) were recorded in the hour after RT (n=1373), at re-audit

- Proportion of episodes for which there was no documented evidence of any tests
- Proportion of episodes for which there was no documented test but refusal of a test was documented
- Proportion of episodes for which there was at least one documented test (with or without other test refusals)
- Proportion of episodes in which all four tests were documented for the measure



### Box 1: The pharmacological management of acute behavioural disturbance: data from a clinical audit conducted in UK mental health services\* (Paton et al. 2019a)

- Where medication was administered, this was by the intra-muscular route (RT) in half of cases. Those who received RT were more behaviourally disturbed (almost two-thirds required restraint) and more often detained in hospital under mental health legislation than those who received oral medication.
- The target behaviours for RT differed in men and women, with the former more likely to exhibit violence towards others and the latter self-harm. Initiatives to reduce the need for, and therefore use of, RT may be more successful if they are gender-specific.
- A benzodiazepine alone was administered in two-fifths of RT episodes while haloperidol combined with promethazine was used in fewer than one in thirty. The combination of haloperidol and lorazepam which has long been established clinical practice was used in almost a quarter of cases and targeted to those clinical situations that involved violence towards others, suggesting that in high-risk situations clinicians used a strategy that they are familiar with. A randomised clinical trial comparing a haloperidol/lorazepam combination with a haloperidol/promethazine combination is needed.
- One patient in four remained at least 'extremely or continuously active' in the hour after RT was administered. There is very limited evidence on which to base the choice of next-step pharmacological strategies in these circumstances.

\*Data relate to the baseline audit conducted in 2016; 1081 episodes of RT

### Box 2: Physical health monitoring after rapid tranquilisation: clinical practice in UK mental health settings\* (Paton et al. 2019b)

- The NICE-recommended minimum level of post-RT physical health monitoring was documented in less than a quarter of RT episodes and was not targeted towards those patients who may be at higher risk of physical health complications post-RT such as those who were known/suspected to have used substances around the time of the episode, had received high-dose antipsychotic medication or fallen asleep soon after intramuscular medication was administered. These data suggest that the risks associated with medication used for RT may not be fully understood by all clinical staff.
- Patients were more likely to be monitored if the episode involved actual or threatened self-harm and less likely to be monitored if the episode occurred in the evening or overnight. This suggests that more immediate risks to the patient and practical considerations such as staffing levels have a greater influence on whether recommended monitoring is done.
- It is possible that clinicians consider the recommended post-RT physical health monitoring to be too demanding to implement in routine clinical practice and/or not appropriate in every clinical situation. For example, checking blood pressure requires direct physical contact with a patient and this intrusion may be counter-productive if RT has failed to calm the patient (POMH data suggest it does in a quarter of cases).
- Post-RT monitoring practice could be improved by the implementation of guidance that integrated and refined the currently separate systems for undertaking and recording physical health observations post-RT, determining nursing observation schedules and detecting acute deterioration in physical health. The effectiveness and clinical utility of such an approach would be worth testing.

\*Data relating to a total of 2454 episodes of RT (combined baseline and re-audit) were submitted by 66 mental health services

# Cardiometabolic risk factors in people on continuing antipsychotic medication

## Background

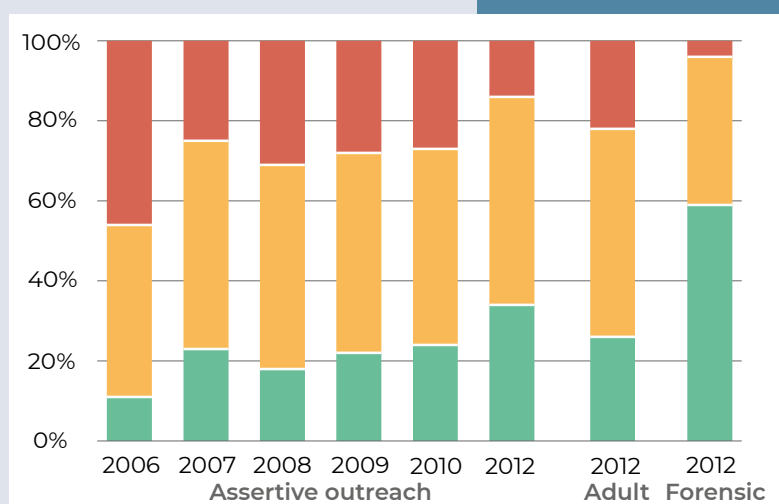
People with schizophrenia have an elevated mortality risk, two to three times that of the general population. This may be partly explained by lifestyle factors such as smoking, poor diet and limited physical exercise, but continuing antipsychotic medication can have metabolic side effects that contribute to this risk. Approximately a third of people on such medication long-term will have evidence of the metabolic syndrome. This a cluster of features (hypertension, central obesity, glucose intolerance/insulin resistance, dyslipidaemia) that is predictive of both type-2 diabetes and cardiovascular disease. Reviews of the association between psychotic illness, the metabolic syndrome, diabetes and antipsychotic medication have concluded that there is a need for active, routine physical health monitoring of all patients treated with such medication, with active management of any cardiometabolic risk factors identified (Cooper et al. 2016; Barnes et al. 2020).

## Data from the POMH QI programme

The initial clinical audit in 2006 (Barnes et al. 2007) collected data on prescribing practice for a large sample of people under the care of UK mental health services prescribed antipsychotic medication. A relatively low level of annual monitoring of the four aspects of the metabolic syndrome (blood pressure, body weight/waist circumference, and plasma glucose and plasma lipid levels) was found; only approximately one in ten of these patients had documented evidence of all four measures in the past year in their clinical records. Over the six years of the programme (Barnes et al. 2008, 2015), in successive audits, this proportion rose to approximately one in three (see **Figure**). Over the same period, the proportion of patients with no evidence of any monitoring of any of the metabolic syndrome measures fell from almost a half to one in seven patients. Some targeting was found, with a known diagnosis of diabetes, dyslipidaemia, or hypertension being associated with a higher rate of monitoring for all aspects of the metabolic syndrome

Proportion of patients with documented screening for all four aspects of the metabolic syndrome (central obesity, hypertension, dyslipidaemia, raised blood glucose or HbA1c) in the audit samples under the care of assertive outreach (2006-2012), adult mental health (2012 only) and forensic (2012 only) teams

- No evidence of screening
- Some reference to screening
- All four aspects recorded



## Baseline audit 2006

Over 6 years the number of patients with documented evidence of all four metabolic syndrome measures **rose** from approx. **1 in 10 to 1 in 3**

## QI work in individual mental health services

Informed by the POMH data, a QI initiative in the Leicestershire Partnership NHS Trust (Gumber et al. 2010) addressed the effectiveness of monitoring metabolic profiles in patients prescribed continuing antipsychotic medication. Completion of a full audit cycle between 2006 and 2009 was associated with an improvement in monitoring as well as the communication of abnormal results to primary care services. The re-audit findings were compared with the national findings on the POMH audits.

A study in Scotland (Pearsall et al. 2019) investigated the level of screening for cardiometabolic disease and adverse health outcomes in adults with severe mental illness under the care of the Greater Glasgow and Clyde adult mental health services, using data from an electronic clinical information system. They compared their findings on physical health monitoring with those of the POMH baseline audit in 2006.

## POMH data in the context of wider initiatives

A systematic review and meta-analysis (Mitchell et al. 2012) examining the level of routine metabolic screening practices in those people prescribed antipsychotic medication included data from the 2008 POMH audit. The conclusion was that the general rate of such metabolic monitoring was sub-optimal. The POMH data have also been referred to in reviews addressing the rates of screening for cardiovascular risk factors (Baller et al. 2015) and interventions to address physical health risk (Papanastasiou et al. 2012; Cotes et al. 2015; McGinty et al. 2016), in people with severe mental illness. A guideline on metabolic monitoring (Firth et al. 2019) cited the POMH work to support the recommendation that people prescribed antipsychotic medication should have their blood pressure, body-mass index, blood glucose, and lipid profile checked at least every 6 months

### **BAP guidelines on the management of weight gain, metabolic disturbances and cardiovascular risk associated with psychosis and antipsychotic drug treatment**

These guidelines referred to the POMH audit findings as evidence of the extent to which physical health monitoring, particularly in relation to the metabolic syndrome, was not routinely carried out in people with schizophrenia on continuing antipsychotic medication, as well as the finding by the National Audit of Schizophrenia (Crawford et al. 2014) of a low level of appropriate intervention for risk factors detected by such monitoring.

The BAP guidelines also noted the barriers to such monitoring that had been identified in the initial POMH audit (Barnes et al. 2007), which could inform local QI activity. These barriers included uncertainty by members of a psychiatric clinical team as to whether the responsibility for physical health monitoring was theirs or a primary care clinician, a lack of confidence about interpreting abnormal monitoring results, and a widespread lack of availability of basic equipment such as a tape measure and weighing scales.



The 'Summary of literature review and recommendations' in these guidelines includes the following:

- Assessment of risk factors for metabolic disease and CVD is vital and should be carried out regularly. Evidence from national audit programmes in secondary care is that monitoring of such risk factors is inadequately carried out.
- Clinical commissioning groups and Trusts, working with clinicians in both primary and secondary care, need to ensure that appropriate agreements are in place with regard to who takes the lead responsibility for the monitoring and management of physical health for people with psychosis at the different stages of their care.

## Prescribing for bipolar disorder

### Data from POMH QI programme

The national data from several POMH QI programmes are relevant when considering the quality of prescribing practice for people with bipolar disorder. The following key points from these data were shared with the expert group that developed the most recent version of the British Association for Psychopharmacology guidelines for bipolar disorder (Goodwin et al. 2016).

#### Biochemical monitoring of lithium

Although practice has improved over the course of the POMH lithium QI programme, at least one patient in five who is prescribed this medication does not receive the minimum biochemical monitoring recommended by NICE (NICE, 2014). Over the 11-year course of the POMH QI programme addressing the biochemical monitoring of patients prescribed lithium, the proportions of patients who had received at least 2 tests of plasma lithium over the last year increased from 68% to 81%, two tests of renal function increased from 55% to 74% and two tests of thyroid function from 49% to 68% (POMH, 2019). While these improvements are clinically relevant, a gap remains between guideline recommendations and clinical practice.

#### Co-prescribing with lithium

The great majority of patients with bipolar disorder who are prescribed lithium are also prescribed other psychotropic medications, supporting the clinical experience of clinicians that bipolar disorder can be a difficult illness to treat. Further analyses of data from the POMH QI programme addressing lithium treatment revealed that prescribing patterns for people with bipolar disorder were relatively consistent over time. For patients prescribed lithium, 45–50% were also prescribed a second drug, about 30% a third, and 5% a fourth. Only 20% were prescribed lithium alone.

Two patients in every five with bipolar disorder who are prescribed lithium are also prescribed antidepressant medication (Paton et al. 2013). Thus, although continuing treatment with antidepressant medication is not supported by the available evidence it remains relatively common in clinical practice.

**Over 11 years** the biochemical **monitoring** of patients receiving lithium has **increased** but a **gap still remains** between guidelines and clinical practice

The **majority** of patients with bipolar disorder who are prescribed lithium are **also prescribed other psychotropic medications**

### Prescribing valproate in women of child-bearing age

Valproate was prescribed for a quarter of the women with bipolar disorder who were of childbearing age (Paton et al. 2018). There was documented evidence for only half of these women that they had been given information relating to the teratogenic and neurodevelopmental risks associated with valproate treatment.

### Monitoring for metabolic side effects in people prescribed antipsychotic medication

POMH audit data suggest that people with bipolar disorder who are prescribed antipsychotic medication are less likely to be monitored for metabolic side effects than people with schizophrenia prescribed these same medications. Further analyses of the national data collected for the QI programme addressing screening for the metabolic side effects of antipsychotic medication (POMH, 2012) revealed that all four measures of the metabolic syndrome (body weight, blood pressure, blood glucose and lipids) had been documented in the last year for 23% of patients with an affective disorder who were prescribed antipsychotic medication while 24% had received no screening at all. The respective figures for those with a diagnosis of a schizophrenia spectrum disorder were 36% and 15%. This is despite the fact that people with bipolar disorder are at increased cardiovascular risk in the same way as those with schizophrenia.

### Use of combined and high-dose antipsychotic medication in people with bipolar disorder

Patients with an affective disorder are commonly prescribed either high-dose or combined antipsychotic medication. Further analyses of the data collected for the POMH QI programme addressing the prescribing of high-dose and combined antipsychotic medication revealed that just over a third of patients with an affective disorder were prescribed either high-dose or combined antipsychotic medication. There is no evidence to support such prescribing practice.

**1 in 4** women of childbearing age were prescribed valproate but **only half** of these were informed of the associated risks

The level of monitoring for antipsychotic side effects is **lower** for bipolar disorder than schizophrenia

Just **over a third** of patients with an affective disorder were prescribed combined or high-dose antipsychotic medication

## Implications for QI initiatives in clinical practice

- A continuing focus of the biochemical monitoring of patients who are prescribed lithium is needed (see Safety section).
- Clinical studies exploring the use of continuing antidepressant treatment in people with bipolar disorder would usefully improve understanding of why this strategy is so widely used when the available evidence suggests that it is unlikely to be helpful in most cases.
- Continuing efforts to avoid exposure to valproate during pregnancy are necessary (see Safety section).
- Systems should be put in place to ensure that patients with bipolar disorder receive routine annual screening for cardiovascular risk factors in the same way as patients with established schizophrenia.
- It may be helpful to critically review, on a case-by-case basis, the use of high-dose and combined antipsychotic medications in people with bipolar disorder.

# Primary research: POMH data contributing to the rationales for funded trials

## The AMICUS study: Amisulpride augmentation in clozapine-unresponsive schizophrenia

The 2012 clinical audit conducted as part of the POMH QI programme addressing the use of high-dose and combined antipsychotic medication in acute inpatient services and forensic services included data on over 5,000 acute inpatients and over 3,000 forensic patients prescribed antipsychotic medication. Regular prescription of combined antipsychotic medications was documented in 14% and 17% respectively. A common reason given by clinical teams for prescribing such a combination was the failure of the illness to respond to treatment with a single antipsychotic medication. Just under 5% of prescriptions for combined antipsychotic medications in acute adult wards represented the augmentation of clozapine treatment with another antipsychotic medication, whereas in rehabilitation/complex needs services and forensic services the respective figures were in excess of 20%. This was despite the lack of a robust evidence base for the risks and benefits of such a pharmacological strategy for refractory schizophrenia. Amisulpride was the antipsychotic medication most commonly prescribed in combination with clozapine.

These data were used to support a successful grant application to the Health Technology Assessment Programme at the National Institute for Health Research. The resulting AMICUS study (Barnes et al. 2017, 2018) was a multicentre, double-blind, individually randomised, placebo-controlled trial, with follow-up at 12 weeks. The main aims were to test the benefits, costs and risks of augmenting clozapine treatment with a second antipsychotic medication, amisulpride, compared with placebo, for treatment-resistant schizophrenia that had also proved to be relatively unresponsive to clozapine. The main findings were first, no statistically significant differences were found between the amisulpride and placebo group on measures of mental health although a small numerical advantage was found for amisulpride at week 12. Secondly, a greater side effect burden was identified for the amisulpride-clozapine combination, including problems that could be cardiac in origin.

### Implications for clinical practice

The effectiveness of amisulpride augmentation of clozapine remains unproven in RCTs. If such a strategy is used in clinical practice it must always be in the context of an individual treatment trial with careful on-going assessment and monitoring of efficacy and tolerability, including vigilance for indicators of emerging cardiac abnormalities.

## The LABILE and CALMED studies: Exploring the effectiveness of lamotrigine and clozapine for people with emotionally unstable personality disorder

The 2012 audit conducted as part of the POMH QI programme addressing prescribing for people with a personality disorder collected data on 1776 people with emotionally unstable personality disorder (EUPD), of whom just over two-fifths had no other psychiatric diagnosis. Three-fifths of this group were prescribed an antipsychotic medication and a fifth a mood-stabilising medication to ameliorate symptoms and behaviours associated with EUPD, such as impulsivity and mood instability (Paton et al. 2015). No medication is currently licensed for the treatment of EUPD and, based largely on the lack of relevant clinical studies in people with this diagnosis, NICE (2008) recommends that psychotropic medication should not be routinely used to alleviate the intrinsic features of EUPD.

The POMH data were used to support two successful grant applications to the Health Technology Assessment Programme at the National Institute for Health Research, as follows.

**The LABILE study** (Crawford et al. 2018) was a multicentre, one-year, double-blind, individually randomised, placebo-controlled trial of lamotrigine in people with EUPD. Both the lamotrigine and placebo groups improved markedly in the first 12 weeks of the study (overall mental health was assessed using the Zanarini Rating Scale for Borderline Personality Disorder: ZAN-BPD) but there was no advantage for lamotrigine over placebo at this point nor at one year.

### Implications for clinical practice

The structure and support provided as part of participating in a clinical trial led to worthwhile improvements in the overall mental health of people with EUPD and, as lamotrigine does not add to the size of this effect, it should not be routinely prescribed to manage mood instability associated with EUPD.

**The CALMED study** aims to test whether, compared with placebo, clozapine improves mental health and quality of life of people with EUPD and reduces the amount of time they spend in hospital. This study is currently recruiting participants who have a history of repeated admission to adult acute services or who are currently under the care of forensic services.

## The ATLANTIS study: valproate augmentation for non-clozapine antipsychotic-resistant psychotic symptoms in schizophrenia

As part of a POMH QI programme addressing the quality of clozapine prescribing practice, 63 NHS Trusts/healthcare organisations submitted data for 6948 patients prescribed clozapine and in the subsample of 5633 patients treated with clozapine for over a year, 1000 (18%) were co-prescribed valproate. A further QI programme addressing the use of high-dose and combined antipsychotic medication in 2017 collected data on the treatment 10,072 patients prescribed antipsychotic medication, across acute adult, PICU, forensic and rehabilitation/complex needs settings. This audit yielded similar findings in that clozapine and valproate were commonly co-prescribed. It is likely that in at least a proportion of such cases in both QI programmes, the clinical indication for valproate was to provide prophylaxis against clozapine-induced seizures. However, in the latter QI programme, almost one patient in five was co-prescribed valproate with a non-clozapine antipsychotic medication. The vast majority of these prescriptions were likely to be off-label, with the most likely clinical reasons for the use of valproate being to stabilise mood, to treat impulsivity and aggression, or to augment antipsychotic medication where the symptoms of schizophrenia had shown an insufficient response to such medication alone. The limited objective data from randomised controlled trials preclude any confident judgement being made about the likely efficacy and tolerability of this strategy and fail to provide a strong justification for such widespread off-label use of valproate in patients with schizophrenia.

The POMH data were used to support a successful grant application in 2019 to the Health Technology Assessment Programme at the National Institute for Health Research. ATLANTIS (Anticonvulsant Augmentation Trial in Schizophrenia) is a one-year randomised, placebo-controlled, double-blind study designed to assess the efficacy and cost-effectiveness of valproate as an augmentation agent for antipsychotic-resistant psychotic symptoms in patients with schizophrenia who are not prescribed clozapine. Recruitment to this study is planned to start in early 2021.

### Implications for clinical practice

The effectiveness of valproate augmentation of antipsychotic medication in people with schizophrenia is uncertain. Rather than continue to prescribe this off-label augmentation strategy as part of routine clinical care, clinicians may wish to support recruitment of eligible patients to the ATLANTIS study. But, if valproate is used in clinical practice to augment continuing antipsychotic medication, this should be in the context of an individual treatment trial with careful on-going assessment and monitoring of efficacy and tolerability/side effects.

In autumn 2020, the baseline audit is planned for a new POMH QI programme, addressing the quality of valproate prescribing across a range of clinical indications in mental health services.

## The PRIMROSE study: prediction and management of cardiovascular risk for people with severe mental illnesses

In 2006, POMH conducted the baseline audit in its QI programme addressing screening for the metabolic side effects of antipsychotic medications in patients treated by assertive outreach teams. Data on the clinical treatment of 1966 patients on antipsychotic medication under the care of UK assertive outreach teams revealed that only 26% had received screening for blood pressure, 17% for BMI/waist circumference, 28% for plasma glucose (or HbA1c) and 22% for plasma lipids. Results for all these four elements of the metabolic syndrome were documented in the clinical records for 11% of patients.

These baseline monitoring data from the POMH QI programme were cited in the successful application to the National Institute for Health Research, Programme Grants for Applied Research for the PRIMROSE (Prediction and management of cardiovascular risk for people with severe mental illnesses) study (Osborn et al. 2015, 2016, 2018, 2019; Zomer et al. 2017). This involved a research programme and trial in primary care in people with severe mental illness (SMI). The aims of the study were: to develop and validate risk models for predicting cardiovascular events and evaluate their cost-effectiveness; to develop an intervention to reduce levels of cholesterol and cardiovascular disease risk; and test the clinical effectiveness and cost-effectiveness of this new intervention in primary care.

The findings of the study were that the SMI-specific cardiovascular disease risk scores were better predictors of new cardiovascular disease if used to guide statin prescribing in people with SMI. No superiority was shown for the new intervention over treatment-as-usual, for level of cholesterol.

### Implications for clinical practice

The use of general population risk scores that rely largely on measures of blood pressure, body weight, glucose and lipids as well as age can underestimate cardiovascular disease risk in people with SMI. The PRIMROSE study generated a new, SMI-specific, cardiovascular risk prediction algorithm, with the potential to increase the awareness of cardiovascular risk in patients with SMI, which should be acceptable and easy to use (it does not involve blood tests) and may be helpful when deciding whether to prescribe statins to prevent cardiovascular disease.

# Afterword

## Professor Tim Kendall

National Clinical  
Director for  
Mental Health,  
NHS England

It is a pleasure to be asked to write this afterword for the 15-year report of the Prescribing Observatory for Mental Health (POMH). The report illustrates the beneficial value of the POMH QI programmes and medicines safety initiatives for mental health services and how the data collected have been useful for guideline development groups and have contributed to several successful research submissions.

An emerging theme from this report is how the POMH QI programmes and the data collected can have a positive impact on practice both locally and nationally. POMH QI programmes have had success in improving prescribing practice in line with best practice, although such changes may take time to become evident, usually a few years. POMH has influenced the prescribing of antipsychotic medication, both in its use for psychoses and in dementia, reducing harmful use in both contexts. They have covered all classes of medications used in mental health and engaged almost all NHS mental health provider organisations. The report outlines how the POMH data collected have been used within some individual mental health services to benchmark against practice standards, as subsequently described in their Trust Quality Accounts. These serve as positive examples of local systems improvements that can be made. Thus, I would urge those Trusts that are not already doing so, to consider adapting these published initiatives for use in their own services and to detail their own QI activity in their Quality Accounts. This would provide some assurance, to both commissioners and the wider public, of their commitment to best care relating to the use of medicines. Indeed, I am heartened to know that the vast majority of mental health Trusts have continued engagement with POMH programmes.

At a national level, I was particularly struck by how the large POMH datasets can usefully inform evidence-based treatment guidelines and ensure that recommendations are relevant to actual clinical practice. The datasets may also identify common prescribing practices that are not currently supported by an evidence base and for which primary research studies are needed to systematically explore benefits and harms. Lastly, the data also allow for an assessment of how fully certain key recommendations have been implemented in practice. For all of these reasons, I would like to see more systematic sharing of the key messages from the anonymised POMH national datasets with guideline development groups and clinical academics who are developing proposals for primary research studies. By working together in this way we can all contribute more effectively to initiatives that aim to improve the way medicines are used in our mental health services.

I hope that one day we will mirror the success seen in the national stroke register ([SNAPP](#)) which has proven how big data can provide crucial information to inform NICE guidance and improve outcomes for patients, creating a virtuous circle linking practice-based evidence to evidence-based practice. Similarly, we must make the case for using big data to inform prescribing in mental health. Crucially, this can only work if we continue to engage mental health providers and demonstrate that participation in national QI initiatives helps each of us to make positive changes in prescribing locally, while simultaneously moving the bar of high-quality prescribing upwards nationally. To these ends, POMH has shown us for 15 years how this can be done.



# Appendix A: POMH publications

## Prescribing high dose and combined antipsychotics on adult psychiatric wards

2011

Barnes TRE, Paton C. Antipsychotic polypharmacy in schizophrenia: benefits and risks. *CNS Drugs* 2011; 25: 383-399.

Shingleton-Smith A, Paton C, Barnes TRE. Antipsychotics: combined and high dose. In: Oakley C. et al. (eds) *101 Recipes for Audit in Psychiatry*. Cambridge: Cambridge University Press, 2011, pp.185-186.

2009

Barnes TRE, Shingleton-Smith A, Paton C. Antipsychotic long-acting injections: prescribing practice in the UK. *British Journal of Psychiatry* 2009; 195: 37-42.

2008

Paton C, Barnes TRE, Cavanagh MR, Taylor D, Lelliott P. High-dose and combination antipsychotic prescribing in acute adult wards in the UK: the challenges posed by PRN prescribing. *British Journal of Psychiatry* 2008; 192: 435-439.

## Screening for metabolic side effects of antipsychotic drugs

2015

Barnes TRE, Bhatti SF, Adroer R, Paton C. Screening for the metabolic side effects of antipsychotic medication: findings of a 6-year quality improvement programme in the UK. *BMJ Open* 2015; 5:e007633. doi: 10.1136/bmjopen-2015-007633

2008

Barnes TRE, Paton C, Hancock E, Cavanagh MR, Taylor D, Lelliott P, on behalf of the UK Prescribing Observatory for Mental Health. Screening for the metabolic syndrome in community psychiatric patients prescribed antipsychotics: a quality improvement programme. *Acta Psychiatr Scand* 2008; 118: 26-33.

2007

Barnes TRE, Paton C, Cavanagh M, Hancock E, Taylor DM. A UK audit of screening for the metabolic side effects of antipsychotics in community patients. *Schizophrenia Bulletin* 2007; 33: 1397-1403.

## Prescribing anti-dementia drugs

2012

Barnes TRE, Banerjee S, Collins N, Treloar A, McIntyre S, Paton C. Antipsychotics in dementia: prevalence and quality of antipsychotic drug prescribing in UK mental health services. *British Journal of Psychiatry* 2012; 201: 221-226.

2009

Perecherla S, Paton C, Shingleton-Smith A, Barnes TRE. Variations in prescribing patterns for anti-dementia drugs across PCT populations. *Progress in Neurology and Psychiatry* 2009; 13: 30-33.

## Monitoring of patients prescribed lithium

2014

Paton C, Barnes TRE. Undertaking clinical audit, with reference to a Prescribing Observatory for Mental Health audit of lithium monitoring. *The Psychiatric Bulletin* 2014; 38: 128-131.

2013

Paton C, Adroer R, Barnes TRE. Monitoring lithium therapy: the impact of a quality improvement programme in the UK. *Bipolar Disorders* 2013; 15: 865-875.

2010

Collins N, Barnes TR, Shingleton-Smith A, Gerrett D, Paton C. Standards of lithium monitoring in mental health Trusts in the UK. *BMC Psychiatry* 2010; 10: 80.

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## Medicines reconciliation

2011

Paton C, McIntyre S, Bhatti SF, Shingleton-Smith A, Gray R, Gerrett D, Barnes TRE. Medicines reconciliation on admission to inpatient psychiatric care; findings from a UK quality improvement programme. *Therapeutic Advances in Psychopharmacology* 2011; 4: 101-110.

## Antipsychotic prescribing in people with a learning disability

2016

Paton C, Bhatti S, Purandare K, Roy A, Barnes TRE. Quality of prescribing of antipsychotic medication for people with intellectual disability under the care of UK mental health services: a cross-sectional audit of clinical practice. *BMJ Open* 2016; 6: doi: 10.1136/bmjopen-2016-013116.

2011

Paton C, Flynn A, Shingleton-Smith A, McIntyre S, Bhaumik S, Rasmussen J, Hardy S, Barnes TRE. Nature and quality of antipsychotic prescribing practice in UK psychiatry of learning disability services: findings of a national audit. *Journal of Intellectual Disability Research*. 2011; 55: 665-674.

## Prescribing for people with personality disorder

2015

Paton C, Crawford MJ, Bhatti SF, Patel MX, Barnes TRE. The use of psychotropic medication in patients with emotionally unstable personality disorder under the care of UK mental health services. *Journal of Clinical Psychiatry* 2015; 76: e512-e518.

## Prescribing valproate for bipolar disorder

2018

Paton C, Cookson J, Ferrier IN, Bhatti SF, Fagan E, Barnes TRE. A UK clinical audit addressing the quality of prescribing of sodium valproate for bipolar disorder in women of child-bearing age. *BMJ Open* 2018; 8: e020450. doi:10.1136/bmjopen-2017-020450.

**Rapid  
Tranquilisation  
in the context of  
the  
pharmacological  
management  
of acutely  
disturbed  
behaviour**

**2019**

Paton C, Adams CE, Dye S, Delgado O, Okocha C, Barnes TRE. Physical health monitoring after rapid tranquillisation: clinical practice in UK mental health services. *Therapeutic Advances in Psychopharmacology* 2019; doi: 10.1177/2045125319895839.

**2018**

Paton C, Adams CE, Dye S, Fagan E, Okocha C, Barnes TRE. The pharmacological management of acute behavioural disturbance: Data from a clinical audit conducted in UK mental health services. *Journal of Psychopharmacology* 2018; doi: 10.1177/0269881118817170.

**Use of clozapine**

**2020**

Barnes TRE, MacCabe JH, Kane JM, Delgado O, Paton C. The physical health and side effect monitoring of patients prescribed clozapine: data from a clinical audit conducted in UK mental health services. *Therapeutic Advances in Psychopharmacology* 2020; 10: 1-10.

**Prescribing for  
depression in  
adult mental  
health services**

**2020**

Paton C, Anderson IM, Cowan PJ et al. Prescribing for moderate or severe unipolar depression in patients under the long-term care of UK adult mental health services. *Therapeutic Advances in Psychopharmacology* 2020; 10: 1-13.

**Additional**

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Barnes TRE, Paton C. Improving prescribing practice in psychiatry: The experience of the Prescribing Observatory for Mental Health (POMH). *International Review of Psychiatry* 2011; 23: 328-335.

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James L, Barnes TRE, Lelliott P, Taylor D, Paton C. Informing patients of the teratogenic potential of mood stabilizing drugs: a case note review of the practice of psychiatrists. *Journal of Psychopharmacology* 2007; 21: 815-819.

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# Appendix C: References

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### **The use of antipsychotic medication in people with a learning disability**

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## Informing treatment guidelines

### High dose and combined antipsychotic medication

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# Addendum

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The terms 'acute behavioural disturbance' and 'acutely disturbed behaviour' as used in this report are descriptive. They relate to a spectrum of agitated or disturbed behaviours and do not indicate a specific diagnosis. Guidance on the use of the terms 'Acute Behavioural Disturbance' (ABD) and 'Excited delirium' (ED) will be provided in a forthcoming College position statement.

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**Contact details:**

Prescribing Observatory for Mental Health, College Centre for Quality Improvement (CCQI)  
The Royal College of Psychiatrists, 21 Prescot Street, London E1 8BB  
Tel. 0208 618 4010, website: [www.rcpsych.ac.uk/pomh](http://www.rcpsych.ac.uk/pomh)

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