The safer management of controlled drugs: Annual update 2021

Annual update 2021

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Introduction

We are responsible for making sure that health and adult social care providers, and other regulators, maintain a safe environment for the management and use of controlled drugs in England. We do this under the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

As part of our responsibilities under the regulations, we report annually on what we find through our oversight. Based on this information, we also make recommendations to help ensure the continuing effectiveness of the arrangements for managing controlled drugs safely in England.

Our findings are important for:

- all controlled drugs accountable officers (CDAOs) in England and their support teams
- organisations that manage controlled drugs
- health and care professionals with an interest or remit in controlled drugs
- commissioners of health and care services
- professional healthcare and regulatory bodies

The data in this annual update relates to the calendar year 2021, but we also include relevant information for the first half of 2022.

Our oversight activity in 2021

Register of controlled drugs accountable officers

We maintain and publish an online register of controlled drugs accountable officers (CDAOs) across England for those organisations that are registered with us and are required under the 2013 Regulations as amended to have one. These organisations are defined as designated bodies under the regulations and are required to notify CQC of their CDAO appointment. We update this register monthly and, at the time of publishing, there were 980 CDAOs listed on the register.

We also provide other helpful information for CDAOs.

NHS England regional teams and controlled drug local intelligence networks

NHS England controlled drugs accountable officers (CDAOs) worked effectively and collaboratively during 2021. They held regular meetings that have resulted in more consistent messaging to members of local intelligence networks (LINs) – both nationally and regionally.

There were 70 local intelligence network meetings across England in 2021, with each LIN meeting virtually at least twice, and several regions holding a dedicated controlled drug learning event. We attended 65 of those network meetings along with other designated bodies and responsible bodies.

Local intelligence network meetings continue to be an effective way to raise concerns and share intelligence and learning, as well as providing valuable networking opportunities for members. Throughout the year, members shared case studies and discussed the continued pressures they and their organisation faced as a result of the continuing impact of the COVID-19 pandemic. We summarise the key themes that we hear at LINs, below:

Concerns discussed at CDLIN meetings

- People registering as temporary residents with GPs to obtain controlled drugs inappropriately and/or obtaining additional supplies of controlled drugs from multiple sources, including through online services.

- Difficulties experienced by community pharmacies in establishing whether people are properly authorised to collect controlled drugs on behalf of a patient.

- Inappropriate prescribing by both medical and non-medical prescribers either for themselves, or someone close to them.

- Keeping temporary staff up to date with changes to local controlled drugs policies and procedures and making all staff aware of how often to complete controlled drugs balance checks.

- Storing controlled drugs and paper prescriptions safely and securely, and the associated risks of potential diversion.

- Training staff on systems for electronic prescribing and administration and alerting about recent system updates.

- Determining who can carry out an accuracy check when administering controlled drugs.

- Incidents associated with home delivery services.

- Incidents associated with pregabalin and gabapentin, often because of their ‘sound alike look alike’ names.

- The safest and most effective way to manage patients' own controlled drugs in hospital settings.

Although we do hear about concerns raised in LINs, we also hear about some excellent improvement and innovative work from teams working across health and care to make the use of controlled drugs safer for patients. Hearing about these examples at LINs is a valuable way of sharing good practice across different types of health and care providers.

Many NHS England regional CDAO teams published controlled drug newsletters as a way of sharing information and maintaining contact with members between the network meetings.

NHS England CDAOs have continued to proactively follow up designated bodies that have not engaged with the local intelligence network either by not attending the meetings or delaying submitting their quarterly controlled drug occurrence reports. We strongly encourage those designated bodies to participate fully in the network meetings.

Other activities from NHS England in 2021 included:

- Further developing the national controlled drug electronic reporting tool to improve the way health and care organisations report controlled drug incidents and to provide a more convenient way to request authorised witnesses for destruction of controlled drugs.

- Updating and publishing a Single Operating Procedure aimed at improving consistency in operations.

Controlled Drugs National Group

CQC leads the Controlled Drugs National Group, which met in March, June and November 2021. Membership comprises government departments, key regulators and

agencies with a controlled drug remit in England, Scotland, Wales, Northern Ireland, Ireland and the Channel Islands.

Key discussion topics and issues of shared interest between our cross-border members included:

- ongoing issues arising from the pandemic
- diversion of controlled drugs
- cannabis-based products for medicinal use (CBPMs).

A separate summary of activity from the past year shows how member organisations contributed to the overall safer management of controlled drugs. If you would like a copy of this summary, email medicines.enquiries@cqc.org.uk.

Sub-group

The operational sub-group to the National Group also met regularly during 2021. Membership comprised:

- NHS England lead CDAOs
- specialist pharmacists and medication safety officers
- NHS Business Services Authority
- chief pharmacists
- clinical commissioning group (CCG) prescribing leads
- other government bodies.

Where it was appropriate, we also invited other healthcare professionals with relevant expertise. Our National Group newsletter includes all the information from the sub-group, and now has a readership of around 16,000. You can subscribe to this newsletter.

Key issues and concerns in 2021

Governance of controlled drugs

Last year, we recommended that services focus on improving their governance processes as it is crucial in supporting the safer use and management of controlled drugs. However, we still find that governance is not as robust as it should be. Examples include where changes have been made to how services are provided because of the pandemic, but the policies and procedures do not reflect this. We have heard about other issues, including:

- Poor procedures or lack of balance checks being carried out for controlled drugs. Balance checks are an important step in helping to identify the misuse, including the diversion of controlled drugs. Procedures for balance checks need to be fit for purpose for each service. For example, a hospice that regularly uses large quantities of controlled drugs may balance check at the end of each shift, whereas a small care home that stores a very small quantity of controlled drugs may balance check once a week. It is also important that staff have the opportunity to carry out these checks according to the procedures.

- Poor and inappropriate reporting and reviewing of controlled drug incidents – both within organisations and to relevant external organisations (such as NHS England and CQC).

- Lack of an appropriate risk assessment that results in unrestricted access to controlled drugs.

Local intelligence networks and occurrence reporting

Under the Controlled Drugs (Supervision of Management and Use) Regulations 2013, the NHS England Accountable Officer must establish a controlled drug local intelligence network (CDLIN) to share information and intelligence about the misuse and safe use of

controlled drugs. A range of organisations attend LINs. Attendance across the country is generally very good, although some organisations do not engage with the network.

Some providers are also required to submit quarterly occurrence reports of errors involving controlled drugs in their organisation to NHS England CDAOs. Many providers send this information promptly, but we continue to hear about a small minority that do not.

Not engaging with a LIN or failing to submit quarterly occurrence reports is a concern. It may also indicate that these organisations are not giving appropriate priority to controlled drugs. We regularly engage with NHS England about providers that do not submit their quarterly occurrence reports. Where our intelligence suggests there are risks in a service, we will follow this up with the appropriate regulatory response.

Prevention of Future Death reports

After an inquest, a coroner can write a Prevention of Future Death Report, sometimes called a ‘Regulation 28 Report’. They do this when a coroner believes that more avoidable deaths could happen if no action is taken to mitigate a recurrence. The report is sent to the person and/or organisation(s) that the coroner believes has the power to take the preventative action. They must then respond within 56 days showing how they have made changes according to the coroner’s recommendations, or how they intend to, where relevant. Most reports are published on the Judiciary website.

Prevention of Future Death reports are an important source of information about controlled drug-related deaths. We have reviewed all reports that were listed on the judiciary website between 2017 and 2021 to present some of the key findings and learning in relation to controlled drugs.

Examples of controlled drugs related themes raised in these reports over the last five years include:

- **Poor communication between health and social care providers in local systems.** This included when patients moved between services. In one example, medical professionals treating a young person had not told a community pharmacy about a safety plan. The plan was in place because a young person had a mental health condition that put them at risk of deliberate overdose. Because the pharmacy was not aware of the safety plan, this meant that the pharmacy supplied medicines directly to this person when it was not safe to do so. Other examples included poor interoperability between different digital systems that providers in a locality used. This meant that healthcare professionals working in one organisation assumed that those working in another could view patients' notes and care plans, when in practice this was not the case, placing patients at risk.

- **Poor monitoring of patients in primary care.** This included GP services not monitoring patients who were taking dependence forming controlled drugs, or where a combination of controlled drugs was prescribed that are known to increase the risk of over-sedation or other side effects. Lack of processes or checks and balances where patients order controlled drugs on repeat prescriptions too often was also highlighted as a risk. Another case involved transferring a person at risk of deliberate overdose from a 7-day prescription to a monthly prescription without any risk assessment.

- **Patients deliberately accessing multiple prescribers for controlled drugs, including online services.** Several examples from reports demonstrated that patients were able to access different GPs, and other services such as out-of-hours and online services, to obtain harmful quantities of controlled drugs.

- **Collecting controlled drugs from community pharmacies.** In one example, a pharmacy had allowed multiple different patients to collect each other's prescriptions interchangeably. The coroner raised the concern that this meant people could stockpile medicines, which would lead to a raised risk of harm and/or death.

- **Patient education on risks of overdose.** When a person takes opioid-based medicines they develop tolerance to them, which means they are able to take higher doses than when they first started taking these medicines. When they stop taking opioids, their tolerance is reduced. One coroner highlighted the tragic outcome for a person who abstained from taking their medicines for a period but re-started taking them at the most recently prescribed dose, which was too high for them to tolerate.

- **Independent providers of healthcare and access to NHS care records.** Concerns have been raised in relation to how care providers in the independent and NHS sectors are digitally isolated from each other, specifically in relation to medicines that are prescribed to patients. One report we reviewed showed that this information gap enabled a patient to obtain duplicate prescriptions and to misuse the controlled drugs that eventually contributed to their death.

- **Weaknesses in electronic prescribing systems.** There is a range of electronic prescribing systems in use across both primary and secondary care. Reports highlighted that vulnerabilities in these systems were a risk to patient safety. It is vital that when health and care staff identify problems with these systems, they report them to the relevant electronic system provider for escalation. Providers of these systems must also ensure that any reported risks are mitigated effectively.

Although Prevention of Future Death reports are sent to specific individuals or organisations, the valuable information in them about controlled drugs risks should be used to support learning and change across both individual organisations and local health and care systems.

Controlled drugs in secondary care

During 2021, our Medicines Optimisation team reviewed medication safety in 95% of England’s NHS trusts, having discussions with medication safety officers and pharmacy and trust leaders in NHS acute, community, mental health, and ambulance services.

Governance

We found that arrangements for controlled drug governance across trusts were varied, often in response to the needs of the organisation and the people they serve. Incidents reported in trusts were reviewed by a range of teams, and these were then raised and reviewed further if needed, by various medication safety committees. Many trusts had a controlled drug oversight group (or similar) whose purpose was to review all controlled drug incident reports, including those associated with palliative care.

Auditing of controlled drugs varied significantly – both in terms of the level of scrutiny and how often they were carried out. It is important that services and organisations assure themselves that their controlled drug audits are fit for purpose and would identify risks and issues promptly. Lack of time and resources was cited as barrier to carrying out both audits and wider incident investigations.

Many trusts reported that their controlled drugs accountable officer (CDAO) also acted as the medication safety officer and these roles were viewed as complementary to one another. Crucially, CDAOs must have access to a trust's board to be able to raise any concerns to the appropriate level – we found this was the case across the trusts we spoke with.

Good board-level engagement is an essential element of ensuring the safer management of controlled drugs. Some trusts told us that their boards were well-engaged and proactive about controlled drug concerns, often inviting the CDAO to give regular updates. But in other trusts, we heard that the board was less willing to engage with controlled drug issues. This is a concern – any issues relating to controlled drugs that have been raised with boards must be taken seriously, so they can be reviewed, and a plan of action put in place to address them.

Trusts' pharmacy and medicines optimisation teams, which often include the CDAO function, had worked hard to strengthen controlled drugs governance arrangements, even throughout the challenges of the pandemic. One trust told us it had strengthened its governance by introducing dashboards for each hospital site, which incorporated

controlled drugs audits. As a result, the trust now has clear reporting on the performance of each hospital site.

Another trust reported that it had carried out a quality improvement project to improve how controlled drugs are recorded in emergency departments. The outcome was a change in the format of the controlled drugs register and embedding a new recording system with further spot checks. Controlled drug incidents in the emergency department have since reduced.

Sharing learning

Sharing learning and insights from incidents is a priority to help reduce the risk of similar incidences occurring again. Clinical staff received this information in a range of ways, such as regular newsletters on medicines safety, patient safety groups, screen savers on computers, ‘check cards’ on lanyards for staff badges, and through internal and external medicines safety officer forum networks. Some trusts said it was easy to share controlled drug incidents and associated learning through the NHS England CDAO Regional Controlled Drugs Accountable Officer teams and local intelligence network. Some reflected that it would be helpful if other networks were as effective for non-controlled drug medication incidents.

Controlled drugs and medication safety

We found many trusts had worked hard to make improvements in the safer use of controlled drugs.

One type of incident that we continue to hear about is when morphine oral liquid is injected into patients, instead of being administered by mouth. Administering medicine through the wrong route is defined as a ‘never event’ in the NHS. A never event is a serious patient safety incident that is preventable. One trust shared the learning and actions it took to mitigate this type of incident. The trust had introduced purple bungs for all stock of this medicine on wards as well as liquid measuring aids to act as a visual reminder that the medicine is for oral administration only.

Other examples of the improvement work in trusts included:

- reducing the risk of selecting the wrong product or strength of a controlled drug by clearly separating them in the controlled drugs cupboard

- working towards safer discharge for patients, particularly for people taking benzodiazepines or opioids, by ensuring discharge information is accurate and provides advice for GPs and community pharmacies on reducing doses

- better training for staff on how to use a medicine that reverses the effects of a benzodiazepine overdose

- using digital incident recording systems to facilitate better investigation of controlled drug audits and learning from them.

Some trusts had previously expected staff to complete a ‘second accuracy check’ for administering controlled drugs without being trained or assessed as competent. These trusts had identified this as an issue and were implementing a plan of action to address this. We also found that having mixed paper and digital prescribing and administration systems, either within a provider or at transfer of care, were cited as a contributory factor towards controlled drug incidents.

Controlled drugs in adult social care services

Two of the most common controlled drug issues we still see in adult social care settings relate to:

- Using transdermal patches. We sometimes find that transdermal patches are not rotated to prevent skin damage and checked regularly to ensure they are still in place and old patches removed. We have also seen cases where people have not had adequate pain relief because their patch has fallen off.

- Reporting controlled drug errors to the right organisations. We often find that adult social care providers do not know who their local NHS England controlled drugs accountable officer (CDAO) is. Staff in social care organisations that do not have their own CDAO should report incidents to their local accountable officer at NHS England through the controlled drugs reporting website.

We have also seen increasing problems where controlled drugs are either not destroyed promptly or in the right way. In some cases, this has happened where services made changes because of the pandemic.

Our guidance on controlled drugs in care homes provides information for providers to address these issues.

We also encourage adult social care providers to ask for support from a relevant pharmacy professional. The shift towards integration and better working as a local system is a key opportunity to ensure that adult social care is considered an equal and crucial partner in ensuring the safe and effective use of medicines for people.

Controlled drugs in prisons and secure settings

There are challenges around the use and management of controlled drugs in prisons. We sometimes find that when people are transferred in and out of prisons, they do not always receive the correct medicines promptly resulting in delayed or omitted doses. For example, when people who are receiving treatment for substance misuse are released from prison, they do not receive medicines such as methadone or buprenorphine in a timely way.

At the heart of these issues is lack of effective communication and synchronisation of health and care service providers, such as between the prison, substance misuse services, community pharmacies and acute hospital services. This is often exacerbated when different providers use different clinical systems that have poor or no ability to connect and exchange information with one another.

We continue to hear about incidents that relate to instalment prescribing of medicines for substance misuse, both when people are released from secure settings, and across other services. In primary care electronic prescribing is available for non-instalment Schedule 2 and 3 controlled drug prescriptions. But electronic instalment prescribing is still not available. This presents a missed opportunity to provide safer experiences when care is transferred for people who need instalment prescriptions, as well as the benefits of electronic prescribing – better prescription security, and efficiency – to patients and providers more widely.

Remote prescribing and diversion of controlled drugs in NHS services

The COVID-19 pandemic inevitably called for new ways of working – one of which has resulted in a growth in remote prescribing by NHS providers, such as GPs. In many cases, this works well for both patients and practitioners. However, we are beginning to hear how some new ways of working have provided increased opportunities for fraudulent activity by patients seeking supplies of controlled drugs inappropriately.

An example is people impersonating the genuine patient on telephone consultations for controlled drugs. In some cases, this has also involved the impersonator claiming that they are the only person who can offer translation or interpreting services for the patient. In other cases, those seeking controlled drugs fraudulently have asked for their prescriptions to be sent to different community pharmacies to avoid raising questions or suspicion. Temporary systems to support remote clinics as a result of the pandemic need to be reviewed to ensure they have the correct safeguards and governance arrangements. Guidance on remote consultations and prescribing is available from the General Medical Council and the General Pharmaceutical Council.

Home deliveries of controlled drugs

Throughout 2021 we continued to hear about problems with home deliveries. This includes controlled drugs going missing, lack of training for delivery drivers, and the absence of an end-to-end audit trail that would help to identify any problems. It is also

essential to make the relevant employment checks, and ensure that staff are competent for their roles.

Controlled drugs in slimming clinics

A number of independent health clinics are registered to provide weight reduction services under the regulated activity of Services in slimming clinics. For many years, most clinics have prescribed the Schedule 3 controlled drugs diethylproprion and phentermine for the purposes of weight reduction. These are unlicensed, carry certain health risks and have very limited evidence of effectiveness. Over the last year, we have seen a shift away from prescribing these medicines in favour of licensed treatments, as well as the introduction of a more holistic approach to include services such as cognitive behavioural therapy.

Diversion and misuse by staff

We continue to hear about instances where staff have diverted controlled drugs – either for their own use or for onward supply. The effects of the pandemic on the health and care workforce have been significant and ongoing, with people working longer hours and under exceptionally challenging circumstances. In some cases, we've heard that the stress associated with this has influenced people towards diversion and misuse where the opportunity arises, resulting in harm. Good governance, audits and oversight can help to reduce the opportunity for diversion or identify these activities at an earlier stage.

It has never been more crucial to support staff working in health and care. Support offered to staff is varied, not just in terms of the employing organisation, but also what is available across the different healthcare professions. Some professions have established support charities such as Pharmacist Support, which provides a range of services, including support for mental health and wellbeing. Other professions and staff who are not healthcare professionals may have varied access to support.

Shared care

During 2021, we have had a growing concern about people's care when it is shared between NHS providers and the independent sector, especially in relation to services that prescribe medicines for adults and children with conditions such as attention deficit hyperactivity disorder (ADHD). The primary care prescribing data in this year's report shows an increase in 2021 in prescribing of medicines licensed for ADHD by providers in the independent sector.

There are several concerns:

- Prescribing formularies in independent services are sometimes different to those in local NHS services. This means that patients can be initiated and stabilised on a medicine by an independent healthcare provider, but the medicine may not be prescribed locally in the NHS.

- Agreement on responsibilities between independent and NHS services are not always effective – such as problems in agreeing who undertakes patients' follow-up monitoring, and when.

- Communication between providers in independent and NHS services is not always quick enough or effective.

All these issues put patients at increased risk of harm. Any approaches to shared care, including any protocols, need to facilitate ongoing safe and effective care. They should take into consideration the increasing amount of service provision from independent providers, and any important factors that could affect the quality of care such as lack of access to certain NHS patient record systems.

Cannabis-based products for medicinal use

During 2021, we continued to register independent clinics that provide treatment with cannabis-based products for medicinal use (CBPMs). At publication of this report, 15

providers that offer prescribing of unlicensed CBPMs were registered, with more being assessed for registration.

CBPMs are Schedule 2 controlled drugs under the Misuse of Drugs Regulations 2001. They can be prescribed by, or under the direction of, a doctor who is on the specialist register of the General Medical Council to treat patients with a specific unmet clinical need.

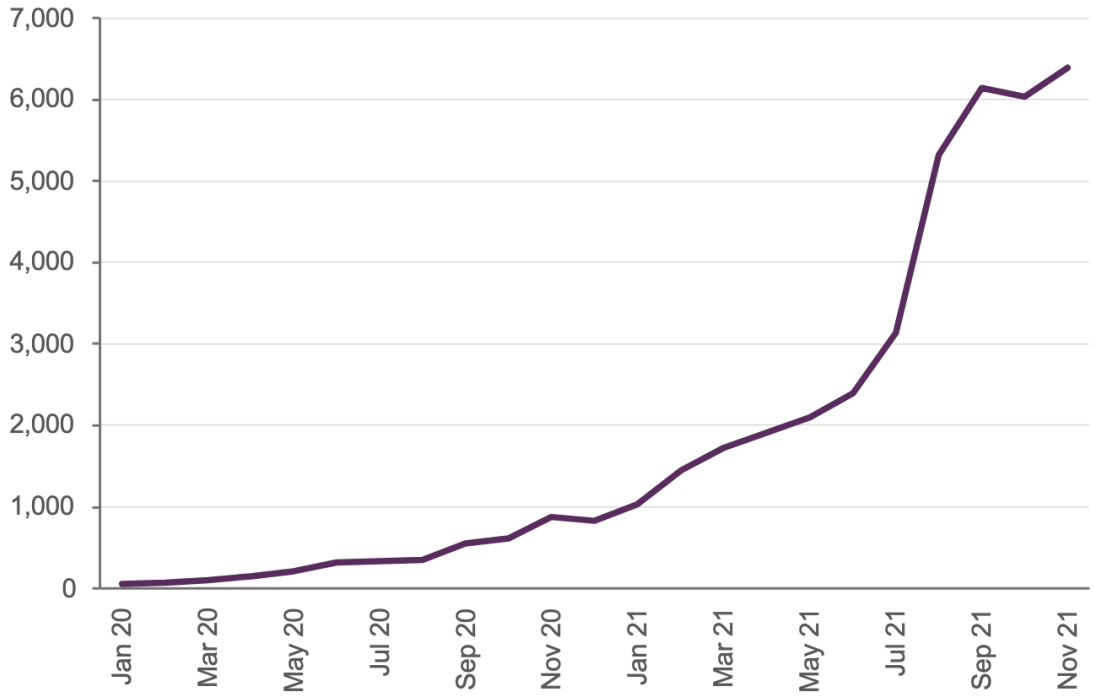
Every year, the substantial proportion of prescribing continues to be for unlicensed CBPMs within the independent sector. Prescribing of these medicines was made possible with legislation changes in 2018, and the sector continues to develop. The current prescribing data for independent health services has shown an increase over the past year:

- 3,636 items were prescribed between January and November 2020

- 37,634 items were prescribed between January and November 2021.

This represents an increase of 935% from 2020 to 2021.

Figure 1: Prescribing of cannabis-based products for medicinal use by independent unlicensed health services January 2020 to November 2021 by number of items



Source: NHS Business Services Authority data (June 2022)

We are not able to publish the data for NHS prescribing of unlicensed CBPMs. This is because the number of items prescribed within the NHS is so small that this could potentially affect patient confidentiality.

Through our regulatory activities in relation to these independent health clinics, we have found some innovative practice such as initiatives with a focus on international collaboration and learning, and a bespoke real-world data collection platform to systematically monitor patient outcomes.

But we have also seen some concerning practices primarily relating to:

- poor governance

- ineffective functioning of multidisciplinary team meetings, and associated record keeping

- determining unmet clinical needs

- which patient records are reviewed before prescribing, to ensure that it is safe to do so

- how well patients continue to be monitored and how information is shared with people's own GPs.

As with all services, where we see poor practice, we follow up with the most appropriate regulatory response. Our guidance about our expectations for providers of CBPMs includes what we look at when we register and inspect services.

Propofol

Propofol is a medicine used as an anaesthetic. It is not a controlled drug, but we have been hearing more frequently about how this medicine is both being diverted and misused. In some very tragic cases, this has involved healthcare professionals injecting themselves with it, which has resulted in their unintentional death. Services that hold stocks of this medicine must consider the risks and possibilities associated with the potential misuse and/or diversion of this medicine, including where it is stored and who has access to it.

ePACT2 data for controlled drugs

There are many electronic tools to help providers and commissioners understand more about prescribing trends and concerns around controlled drugs. One tool is ePACT2 – an online application that allows access to prescription data for authorised users. It enables users to look more closely at controlled drug prescribing, either through dashboards or bespoke reports.

In May 2022, a new Opioid Prescribing Comparators dashboard was released, which aims to help prescribers improve care and reduce harm for patients taking opioids to manage chronic non-cancer pain. The comparators were developed in partnership between NHS Business Services Authority, Wessex Academic Health Science Network (AHSN) and NHS England. It is the first dashboard to be split by gender and to make live electronic prescribing system (EPS) data available.

The dashboard will enable GPs, pharmacy professionals and other healthcare professionals to:

- identify problematic opioid prescribing issues in a locality
- understand more about these issues, including how many patients are taking opioids, enabling a more targeted response
- help measure the effectiveness of interventions
- use live data to help identify patients who have been on opioids for between three and six months to prevent acute use of opioids for non-cancer pain from turning into chronic use.
- analyse the data in more detail by selecting and comparing age group and gender, and several levels of the NHS organisation structure down to practice level.

See the primary care prescribing section for some snapshots of this data to demonstrate what outputs can be achieved.

We often find that providers and other stakeholders want to make more use of systems such as ePACT2. But we have found there is a not always enough time for staff to engage in training to support them to use these systems effectively, or even when they are trained, there isn't enough time to use the system because of other workplace

pressures. We encourage support to enable staff to use these systems effectively because of the potential benefits in relation to the safer management of controlled drugs and improved patient care.

Regulatory activities and developments

Oversight of controlled drugs across integrated care systems

The move towards integration of local health and care services presents an opportunity to develop more effective oversight of controlled drugs. While different systems will be at various stages in their journeys towards integration, it is important that they consider how they can achieve oversight of controlled drugs. This should include working towards good oversight of sectors that do not include designated bodies but that commonly use controlled drugs, such as care homes.

System-wide learning from controlled drugs incidents should form a key component of this. For the learning to be most effective, it is important that organisations report incidents that relate to transfer of care, including where the incident originated in a different service or sector. It is also crucial to consider social care providers, including home care services, as well as independent providers of healthcare and community pharmacies as part of any changes, procedures or communications.

Regulatory gaps and controlled drugs

We are still concerned about the regulatory gaps in relation to some services that prescribe controlled drugs. For example, some online services that are based outside England, but that offer services to patients in England, may be out of the scope of registration with CQC, so are currently not legally allowed to register in England. This means that where controlled drugs are supplied to patients in England in an unsafe way, we are unable to take regulatory enforcement action to prevent further supplies.

We are working with the Department of Health and Social Care and other national organisations to determine the best way to close these gaps and keep people safe.

Clinical system searches in GP providers

We have developed clinical searches that are often carried out as part of inspection activity, to support us to gather evidence about the quality of care in a GP practice. Searches of a practice's clinical system are part of understanding the clinical safety and effectiveness of care. They are based on national guidance, good practice and safety advice from the Medicines and Healthcare products Regulatory Agency (MHRA) and now include some controlled drugs, such as for gabapentinoids, z-drugs (such as zopiclone and zolpidem) and benzodiazepines. These searches will be available for all practices to access ahead of inspections. You can read more information and see search categories in searches in the clinical system.

Sharing policies and procedures

We are often asked whether providers can share their policies and procedures. Providers are free to do this as it can be a helpful way of reducing the burden on a provider of producing their own in isolation. Where providers have adopted aspects another organisation's policies and procedures, it is important that they are fit for purpose to support their own work safely and effectively.

Controlled drug issues found on inspection

The issues we find on inspections are broadly similar each year. This is also true of many of the themes discussed in local intelligence network meetings. We are developing new controlled drugs resources that describe these common issues and provide some advice and suggestions to improve. These will be available later in 2022.

National trends in the prescribing of controlled drugs

Prescribing trends in primary care

Note on data: Data on prescribing is collected by ePACT2 – an online application that provides authorised users with access to prescription data held by NHS Business Services Authority. For prescribing in the NHS, including hospitals and dental services, we have extracted data from this application for the the years 2020 and 2021 to provide overall figures and trend analysis. For non-medical prescribing, the NHS Community Pharmacist Consultation Service, and requisitions and prescribing in independent primary care, the data for 2021 was supplied directly by NHS Business Services Authority. We have not updated the data for 2020 published in our 2021 annual report. There may be changes to overall figures as ePACT2 may be updated over time.

In this section, we highlight prescribing trends of the most commonly-prescribed controlled drugs. In 2021, we have seen marked increases in prescribing volumes of medicines that are licensed to treat attention deficit hyperactivity disorder (ADHD), such as dexamfetamine, lisdexamfetamine and methylphenidate. We have also seen an increase in prescribing of unlicensed cannabis-based products for medicinal use (CBPMs) as the market continues to develop.

During 2021, NHS primary care services prescribed a total of 73,807,554 controlled drug items, which was a reduction of 1% compared with 2020 (74,238,158 items). However, the cost of this was £575,120,712, an increase of 2% compared with the previous year (£565,906,712).

Overall prescribing of controlled drugs in Schedules 2 to 5 in 2021

Figure 2: Prescribing of controlled drugs by schedule in 2021

	Total items in 2020	Total items in 2021	Change
Schedule 2	9,149,239	9,109,102	Down by less than 0.5%
Schedule 3	25,650,213	25,836,714	Up by 1%
Schedule 4	13,734,613	13,342,781	Down by 3%
Schedule 5	25,704,093	25,518,957	Down by 1%

Of all prescribing of controlled drugs in primary care:

- **Schedule 2** accounted for 12%

- **Schedule 3** accounted for 35%
- **Schedule 4** accounted for 18%
- **Schedule 5** accounted for 35%

Patterns of prescribing in NHS primary care

In 2021, of the most commonly-prescribed controlled drugs, there was a reduction in prescribing for a number of controlled drugs compared with 2020 (figure 3).

Figure 3: Reductions in prescribing of controlled drugs in 2021

	Total items in 2020	Total items in 2021	Change
Temazepam (Schedule 3)	805,607	720,110	Down by 11%
Fentanyl (Schedule 2)	962,824	879,786	Down by 9%
Co-dydramol (Schedule 5)	1,631,670	1,522,217	Down by 7%

Diazepam (Schedule 4)	4,617,195	4,448,994	Down by 4%
Zopiclone (Schedule 4)	5,023,725	4,872,068	Down by 3%
Morphine sulfate (Schedule 2)	2,894,713	2,811,960	Down by 3%
Dihydrocodeine (Schedule 5)	1,503,242	1,460,884	Down by 3%
Tramadol (Schedule 3)	5,922,921	5,787,434	Down by 2%
Lorazepam (Schedule 4)	1,085,693	1,063,924	Down by 2%

Zolpidem (Schedule 4)	613,050	601,151	Down by 2%
Methadone (Schedule 2)	1,848,675	1,836,787	Down by 1%
Co-codamol (Schedule 5)	15,068,506	14,992,328	Down by 0.5%
Gabapentin (Schedule 3)	7,385,338	7,382,097	Down by less than 0.5%
Morphine sulfate (oral solution 10mg/5ml) (Schedule 5)	2,285,548	2,283,039	Down by less than 0.5%

Other notable reductions in prescribing during 2021 include:

- **Diamorphine (Schedule 2):** down by 43% (25,402 total items in 2021, 44,637 total items in 2020). This is likely due to ongoing shortages of this drug.

- **Co-proxamol (Schedule 5):** down by 24% (7,833 total items in 2021, 10,286 total items in 2020)

- **Nitrazepam (Schedule 4):** down by 12% (335,309 total items in 2021, 382,208 total items in 2020)

Pethidine is a Schedule 2 controlled drug, now with limited indications in clinical practice. Over the last year we have heard about how pethidine continues to be inappropriately prescribed to patients in primary care or stocked as an emergency medicine when there is a limited need for it. During 2021 the prescribing was down by 28% compared with 2020. However, this still represents 8,123 total prescription items in NHS primary care compared with 11,274 in 2020. Where pethidine has been prescribed in primary care, particularly on an ongoing basis, it is important that this is reviewed by a suitably qualified clinician to ensure that it is remains clinically appropriate.

Of the most commonly-prescribed controlled drugs, there was an **increase in prescribing** in 2021, compared with 2020 for:

Figure 4: Increases in prescribing of controlled drugs in 2021

	Total items in 2020	Total items in 2021	Change
Methylphenidate (Schedule 2)	1,101,746	1,188,128	up by 8%

Pregabalin (Schedule 3)	7,819,255	8,243,352	Up by 5%
Codeine (Schedule 5)	5,084,563	5,139,012	Up by 1%
Buprenorphine (Schedule 3)	3,168,794	3,193,462	Up by 1%
Clonazepam (Schedule 4)	1,012,667	1,017,465	Up by 0.5%
Oxycodone (Schedule 2)	1,850,075	1,851,783	Up by less than 0.5%

Other notable increases in prescribing during 2021 include:

- **Lisdexamfetamine** (Schedule 2): up by 32% (266,918 total items in 2021, 201,611 total items in 2020)

- **Dexamfetamine** (Schedule 2): up by 19% (58,494 total items in 2021, 49,074 total items in 2020)

NHS Non-medical prescribing

Prescribing of controlled drugs by non-medical prescribers increased for all professional groups by 14% from 4,215,881 items prescribed in 2020 to 4,799,328 items in 2021. Prescribing by nurses (including nurse independent prescribers and community practitioner nurses) accounted for 51% of all non-medical prescribing in 2021 (2,427,897 items).

Pharmacist prescribers are increasingly working in GP practices and primary care networks. Pharmacist prescribing has increased by 20% and accounted for almost 49% of all non-medical prescribing in 2021 (2,361,921 items in 2021, 1,962,615 items in 2020). In 2017 pharmacists accounted for only 29% of non-medical prescribing (487,036 items). This trend of pharmacist prescribing is likely to continue as all newly-qualified pharmacists will be independent prescribers by 2026.

Figure 5: Increases in non-medical prescribing of controlled drugs in 2021

	Total items in 2020	Total items in 2021	Change
Paramedic prescribing	3,328	8,415	Up by 153%
Podiatrist prescribing	29	73	Up by 152%

Radiographer prescribing	15	36	Up by 140%
Physiotherapist prescribing	780	984	Up by 26%
Pharmacist prescribing	1,962,615	2,361,921	Up by 20%
Nurse prescribing	2,249,114	2,427,897	Up by 8%

NHS dental prescriptions for controlled drugs

Dentists working in the NHS can prescribe three controlled drugs on NHS dental prescription forms to patients: diazepam, temazepam and dihydrocodeine.

Dihydrocodeine was the most prescribed medicine, accounting for 86% of total dental prescribing in 2021. A total of 32,516 items were prescribed – a decrease of 13% from 37,251 items prescribed in 2020.

Diazepam and temazepam accounted for 14% of all dental prescribing in 2021. During 2020, prescribing of both medicines decreased (by 31% and 37% respectively) from 2019. But in 2021, prescribing increased by 39% for diazepam (4,397 total items

prescribed in 2021, 3,154 total items in 2020) and by 28% for temazepam (1,018 total items prescribed in 2021, 796 total items in 2020).

These patterns could be related to the easing of public restrictions for the COVID-19 pandemic:

- Patients are likely to have experienced shorter delays for treatment and therefore are less likely to have needed pain relief for longer term home use.

- More appointments may have resulted in more prescribing of diazepam and temazepam for dental procedures.

NHS hospital prescribing for community pharmacy dispensing

In 2021, hospital prescribing (on FP10HP prescription forms that can be dispensed in a community pharmacy) was also broadly in line with 2020. There were 971,971 controlled drug items across Schedules 2 to 5 prescribed in hospital using an FP10(HNC) or FP10SS form. This is an increase of less than 0.5% from 2020 (969,481 total items), with a reduced cost of 5% (£15,735,985 in 2021, £16,518,641 in 2020).

Of all prescribing of controlled drugs in hospitals for dispensing in a community pharmacy:

- **Schedule 2** accounted for 53%

- **Schedule 3** accounted for 19%

- **Schedule 4** accounted for 20%

- **Schedule 5** accounted for 8%

Of the most commonly-prescribed controlled drugs, during 2021, pregabalin prescribing reduced by 6% (20,742 total items in 2021, 22,003 total items in 2020) and gabapentin prescribing reduced by 10% (5,080 total items in 2021) compared with 2020 (5,623 total items). There was also a 2% reduction in buprenorphine prescribing (143,238 total items in 2021, 146,321 total items in 2020) and a 6% reduction in methadone prescribing (330,620 total items in 2021, 350,908 total items in 2020).

Figure 6: Increases in hospital prescribing of controlled drugs for community pharmacy dispensing in 2021

	Total items in 2020	Total items in 2021	Change
Dihydrocodeine (Schedule 5)	2,654	3,341	Up by 26%
Co-codamol (Schedule 5)	28,905	35,447	Up by 23%
Morphine sulfate (Schedule 5)	11,702	13,355	Up by 14%
Codeine (Schedule 5)	23,050	26,162	Up by 14%

Lisdexamfetamine (Schedule 2)	32,219	35,747	Up by 11%
Dexamfetamine (Schedule 2)	3,956	4,359	Up by 10%
Methylphenidate (Schedule 2)	124,314	135,693	Up by 9%

NHS Community Pharmacist Consultation Service

The national NHS Community Pharmacist Consultation Service (CPCS) was launched in October 2019. It aims to reduce pressure on primary and urgent care services, including emergency departments and out-of-hours GP services, by referring people to community pharmacies for advice, treatment, and urgent repeat prescriptions. The service may supply certain controlled drugs in specific circumstances for a limited period. The most commonly-supplied controlled drugs were:

- **clonazepam** 500mcg tablets
- **co-codamol** (in a range of forms, including tablets and capsules) 30/500mg, 15/500mg and 8/500mg
- **codeine** 15mg and 30mg tablets
- **co-dydramol** 10/500mg tablets

- **diazepam** 2mg and 5mg tablets
- **dihydrocodeine** 30mg tablets
- **morphine sulphate** oral solution 10mg/5ml
- **zopiclone** 7.5mg tablets.

Optimising prescribing data to promote safer patient care

ePACT2 Opioid comparators dashboard

The new ePACT2 Opioid prescribing comparators dashboard has recently been released and is based on live unvalidated EPS data, which is designed to show a snapshot in time. Data will be refreshed every two weeks, with each refresh showing the latest 28 days of data. The validated data showing trends over time will also be available in the future. We highlight some of the reports in the dashboard to show how useful this can be in understanding more about local prescribing issues. The data in the following sections refers to the period from 15 April to 12 May 2022.

Note: NHS Business Services Authority data cannot be filtered to exclude patients who are diagnosed with cancer and are using an opioid to manage the pain that can be associated with malignant diseases, especially as part of care at the end of life. Therefore, when using the comparators to select patients for a structured medication review, users will need to triage the list of patients to exclude those using opioids to manage pain from cancer.

Multiple items of morphine sulfate 10mg/5ml oral solution

This comparator is important, given the risks and harm we sometimes see with using this medicine. In England, more than 10,000 patients have been prescribed three or more of these items in one month. Prescribing will be appropriate for some patients within this group, but there will also be others for whom alternatives may be more beneficial.

Figure 7: Prescribing of multiple items of morphine sulfate 10mg/5ml oral solution (15 April to 12 May 2022)

Number of items prescribed in one month	Number of patients (in England)
1	86,581
2	20,632
3	5,301
4	3,032
5 or more	2,151

A local view of opioid prescribing

Another useful aspect of the comparator dashboard is the ability to look at prescribing of opioids in a specific geographical area, enabling local users of ePACT2 to look more closely at prescribing in their area. The number of patients receiving opioid pain

medicines per 1,000 patients remains highest in the north of England, where we have seen higher prescribing in previous years.

Figure 8: Number of patients receiving opioid pain medicines per 1,000 patients by region (15 April to 12 May 2022)

Region	Number of patients receiving opioid pain medicines	Number of patients receiving opioid pain medicines per 1,000 patients
North East and Yorkshire	247,650	27
North West	175,924	23
Midlands	213,790	19
South West	109,391	18
East of England	102,356	14

South East	133,503	14
London	83,091	8

Patients receiving opioid pain medicines by duration

It is useful to know how long a patient has been taking an opioid medicine. The ePACT 2 opioid prescribing comparators can help to identify patients who have been prescribed opioids for between three and six months. This will enable interventions for patients before they develop problems associated with longer term opioid use. It can also enable prescribers to identify patients who have been taking these medicines longer term, who may therefore need a more intensive and careful approach to support tapering down of doses, where this is clinically justifiable.

Figure 9: Number of patients receiving opioid pain medicines by duration (15 April to 12 May 2022)

Duration of prescribing	Number of patients receiving opioids (in England)
1 to 84 days	156,464
85 to 168 days	68,856
169 days or more	840,401

Patients receiving high oral morphine equivalent

The meaning of the term ’oral morphine equivalent’ (OME) is complex, but it essentially provides a relatively standardised measure of opioid doses. This is an important indicator because higher doses of opioids are associated with an increased risk of overdose and death. The Faculty of Pain Medicine states that the risk of harm increases substantially at doses above an OME of 120mg per day but does not provide any extra benefit in the context of chronic, non-cancer pain relief.

Figure 10: Number of patients receiving high oral morphine equivalent by duration (15 April to 12 May 2022)

Duration of prescribing	Number of patients with a total oral morphine equivalent volume of 120mg or more per day in the most recent 28-day period (in England)
1 to 84 days	874
85 to 168 days	1,332
169 days or more	63,024

Patients receiving high oral morphine equivalent in combination with z-drugs

Patients on a high OME dose are already at a higher risk of harm – this is increased further when they are also prescribed certain other medicines at the same time. These medicines include ‘z-drugs’ (zopiclone, zolpidem), benzodiazepines and gabapentinoids. The comparators dashboard provides further information on this type of concurrent prescribing – the following example shows the concurrent prescribing of z-drugs.

Figure 11: Number of patients receiving high oral morphine equivalent with z-drugs by duration (15 April to 12 May 2022)

Duration of concurrent prescribing	Number of patients receiving high oral morphine equivalent volume of opioids in combination with z-drugs (in England)
1 to 84 days	78
85 to 168 days	111
169 days or more	6,212

Controlled drug prescribing in independent (private) primary care

In 2021, a total of 131,999 items were prescribed across independent primary care services, which is an increase of 84% from 2020 (71,702 total items). Independent prescribing of Schedule 2 controlled drugs alone increased by 105% (117,431 total items prescribed in 2021, 57,326 total items in 2020). This figure does not include unlicensed cannabis-based products for medicinal use.

Independent prescribing of Schedule 2 controlled drugs

Looking specifically at all independently prescribed medicines in Schedule 2:

- **Methylphenidate** accounted for 44% (52,080 items) in 2021 (up by 118% compared with 2020, 23,857 total items prescribed)

- **Lisdexamfetamine** accounted for 41% (47,831 items) in 2021 (up by 145% compared with 2020, 19,517 total items prescribed)

- **Dexamfetamine** accounted for 9% (10,831 items) in 2021 (up by 109% compared with 2020, 5,184 total items prescribed).

This echoes the increased prescribing of these medicines that we see in the NHS prescribing data. Many independent services will also be undertaking shared care. Increased prescribing volumes, combined with the concerns we have highlighted about the safety and effectiveness of shared care, mean that this is an area of increased risk.

Prescribing for some Schedule 2 controlled drugs has reduced in 2021 compared with 2020.

Figure 12: Reductions in prescribing of Schedule 2 controlled drugs in 2021

	Total items in 2020	Total items in 2021	Change
Fentanyl	1,012	380	Down by 62%
Morphine sulfate	2,039	1,419	Down by 30%
Alfentanil	349	286	Down by 18%
Methadone	2,608	2,241	Down by 14%

Independent prescribing of Schedule 3 controlled drugs

Independent prescribing of Schedule 3 controlled drugs only increased by 2% over the previous year (14,022 total items prescribed in 2021, 13,779 total items in 2020). Pregabalin was the most prescribed drug in Schedule 3. This accounted for 56% of all Schedule 3 prescribed items (7,798 items) during 2021, which was up by 11% compared with 2020 (7,008 items).

Prescribing of some Schedule 3 controlled drugs has reduced in 2021 compared with 2020:

Figure 13: Reductions in prescribing of Schedule 3 controlled drugs in 2021

	Total items in 2020	Total items in 2021	Change
Midazolam	890	622	Down by 30%
Tramadol	1,593	1,293	Down by 19%

Requisitions

Requisitions are documents that allow the appropriate people to order medicines for use in their professional practice, such as ordering a stock of controlled drugs that are later administered to patients. There has been a 4% decrease in requisitions in 2021 as the total number of items requisitioned was 14,384 compared with 15,037 in 2020. In 2021, 59% of all requisitions were from NHS providers and 41% were from independent organisations.

The top 10 controlled drugs on requisition remain the same in 2021 as for 2020. The most commonly-requisitioned controlled drugs in 2021 were:

- **Pregabalin:** 13% of all requisitions (1,873 items in 2021)
- **Oxycodone:** 12% of all requisitions (1,739 items in 2021)
- **Morphine sulfate:** 11% of all requisitions (1,536 items in 2021)

- **Methylphenidate:** 10% of all requisitions (1,388 total items in 2021)
- **Midazolam:** 7% of all requisitions (1,054 total items in 2021)
- **Buprenorphine:** 6% of all requisitions (891 total items in 2021)
- **Gabapentin:** 6% of all requisitions (886 total items in 2021)
- **Fentanyl:** 5% of all requisitions (768 total items in 2021)
- **Tramadol:** 5% of all requisitions (655 total items in 2021)
- **Methadone:** 3% of all requisitions (439 total items in 2021)

Recommendations

From our analysis of prescribing data, feedback from controlled drug local intelligence networks, and our wider inspection and regulatory work, we make the following recommendations to drive improvement in the safer management of controlled drugs:

Providers need to ensure their governance of controlled drugs is up to date and fit for purpose. We continue to find areas that need to improve across health and social care. Good governance of controlled drugs will help services to improve the safety and quality of people's care and the minimise risk of diversion. Good board-level engagement in relevant organisations is an essential element of ensuring the safer management of controlled drugs.

Health and care staff need to make sure they provide shared care in line with best practice guidance. This helps people to receive safe care in a timely way, and that the safety and effectiveness of their medicines is monitored continually. Learning from incidents should be shared across local areas to support this work.

Providers should use the available data sources and tools to better understand prescribing risks and issues with controlled drugs. Once those risks and issues are identified, local collaboration can help to create action plans and interventions to promote safer care.

Designated bodies should fully engage with controlled drugs local intelligence network activities. Local intelligence networks are vital in sharing intelligence and valuable learning. To be effective, networks need the full co-operation and engagement of members. It is also important for designated bodies to ensure that quarterly controlled drug occurrence reports are returned promptly when requested by an NHS England CDAO.

We will continue to monitor progress against these recommendations throughout 2022.