Key issues in 2022

Prescribing controlled drugs without the right patient information

During our inspections in 2022, we found evidence of clinicians prescribing controlled drugs to patients without the relevant medical and medication history. We have seen examples where private prescribing services have not requested these details from the person's NHS GP or secondary care provider before issuing prescriptions, as well as examples of GP services that don't supply these details in an appropriate way when asked.

In 2021, the General Medical Council updated its prescribing guidance. This clarified that, unless in exceptional circumstances, doctors must have access to relevant information from the patient's medical records. If they do not, they cannot prescribe:

- controlled drugs or medicines that are liable to abuse, overuse or misuse
- when there is a risk of addiction and monitoring is important.

Substance misuse services

Instalment prescribing

Prescribing controlled drugs in instalments is currently only available on paper prescriptions. There is a significant need to progress this to electronic format through the Electronic Prescription Service (EPS). This would help to prevent avoidable harm and provide more seamless care for patients by avoiding delays or missed doses of medicines if prescriptions have been lost, delayed in transit or as a result of miscommunication between different care providers.

Good practice

During 2022, we have seen some examples of good practice in substance misuse services. These include how services involve people's families and carers for safer use of controlled drugs in the home environment. The following example highlights risk assessments and targeted interventions to reduce fatal opioid overdoses:

The provider of this service was leading a study to identify risk factors associated with opiate overdose. The study aimed to enable staff to:

- improve risk assessment and planning by helping them to screen clients for risk factors
- offer more targeted interventions to reduce the risk of a fatal opioid overdose.

Staff were still involved in piloting this work, and when we inspected, all clients in the service had a specific risk assessment around overdose. Staff had additional tools to help them deliver more targeted interventions with clients to reduce risk.

Calderdale Recovery

We also saw examples of services working collaboratively with community pharmacies to promote better patient outcomes, as in this example:

Staff had built and maintained good relationships with the local pharmacy. When a client did not collect their prescriptions the pharmacy would contact the service, which would trigger a follow-up. In situations where the client could not be reached, escalation processes would be implemented such as contacting their next-of-kin or the police, where necessary. This also enabled recovery workers to consider the person's treatment plan and review prescribing at the next visit, especially in light of any relapse or other potential risks.

York Drug and Alcohol Service

Paramedic requisitions for controlled drugs

NHS England CDAOs monitor controlled drugs that have been requisitioned in their area across all professions. When ordering controlled drugs, paramedics should use a unique PIN number on the mandatory requisition form (FP10CDF). However, we have recently heard about paramedics requisitioning controlled drugs without using a PIN – either because they were not aware they had to, or because they did not know where to obtain a PIN.

We encourage paramedics who need a PIN to contact their local NHS England CDAOs. See our list of CDAOs for their contact details.

DBS checks for staff working with controlled drugs who have no contact with patients

Employers use Disclosure and Barring Service (DBS) checks to find out whether potential or current employees have a criminal record. These are required when employees will have direct contact with patients and people in more vulnerable circumstances.

We have been alerted to an issue that could cause risks in relation to controlled drugs. In some regulated services, the medicines preparation units are located on sites where patients are not permitted. This means that staff working exclusively on these sites will not be able to access an enhanced DBS check. Whilst DBS checks are not the only way of undertaking employment checks, this can make it more difficult for employers to ensure that staff who have contact with medicines that include controlled drugs are suitable to be employed in that position.

Clinical staff collecting controlled drugs from pharmacies

The risk of diversion increases when there are poor governance processes to monitor medicines that are delivered directly to patients rather than as part of a 'regular' delivery round.

We have heard examples where clinical staff have prescribed lower schedule-controlled drugs on paper forms, taken the prescription to a pharmacy for dispensing but have then delivered a lower quantity of medicine to the patient. There is additional risk with paper prescriptions, as there are no electronic records on EPS.

Non-registered staff and diversion of controlled drugs

In our 2020 annual update we raised awareness of the cross-sector issue of non-registered staff (those who are not on a professional register) diverting controlled drugs. We still hear examples of cases where staff have been dismissed from employment and incidents have not been reported to the police or NHS England CDAOs.

This can result in several consequences:

- Diversion is concealed from a future employer as it will not show up on a Disclosure and Barring Service check.
- The person could therefore gain employment at another organisation in a role that requires them to handle controlled drugs.
- People who misuse these medicines personally, or who access them through an illegal chain may be harmed.

This highlights the importance of sharing information in an appropriate and timely way. Your local NHSE CDAO can provide advice on the best way forward if you have concerns in relation to this issue.

We also provide guidance on employment checks as a useful reference.

Home office licences

Applying for a licence

We often receive queries from services that need a controlled drugs licence. We are not responsible for issuing of licenses – this responsibility sits with the Home Office.

Organisations must ensure that they plan ahead if they anticipate the need for a Home Office licence. This includes services that are either newly-registered with CQC or those that gain registration as a result of a sale. It is also crucial to consider Home Office licences when making planned changes to current services. In practice, this means allocating sufficient time to complete the full application process, which can include responding to queries and the need to supply additional information.

Services also need to factor in time for a compliance site visit from the licensing team, as well as undertaking the correct DBS checks. These need to be enhanced DBS checks completed by the Home Office's preferred provider. At the time of writing this report, it takes 16 weeks from the point when an application is accepted as being validly made (without omissions or errors) to booking a compliance visit. In practical terms compliance visits have a lead-time, and when a service declines the date offered for a visit this could lead to additional delays in the application process. These considerations are crucial – a possible consequence is that services are left without a licence and are unable to provide services or treatment for people.

'Self-sourcing' of controlled drugs

A growing number of organisations are asking their employees to supply their own controlled drugs when on clinical duties to avoid the need for a Home Office controlled drugs licence. This is happening more often for out-of-hours services, community first responders and independent ambulance services. Given the risks of diversion and storing controlled drugs in employees' own homes, this service model should be the exception, rather than the rule.

Where services ask employees to supply their own controlled drugs, it is crucial to have appropriate governance processes so that there is assurance that medicines:

- have been obtained legally
- are stored appropriately
- are of an acceptable nature and quality.

Controlled drugs legislation and current practice

Applications for a Home Office licence are determined on a case-by-case basis. However, there are instances where the need to have a licence to comply with this legislation can appear disproportionate to the size of the service and the very small quantities of the controlled drugs required. It would be helpful for a review of the circumstances in which controlled drugs legislation enables possession of controlled drugs without a licence in certain health and social care environments. This could prove beneficial if it helped to clarify and reflect current practice and potentially reduce burden on providers.

Complex commissioning

As health and care systems work towards better integration of services, we are seeing examples of increasingly complex commissioning where controlled drugs are involved. In practice, this can sometimes mean several different services providing various aspects of care for people in a particular location. Where this happens, it is important that the roles and responsibilities in relation to controlled drugs are clearly set out, understood and agreed by all parties involved so that people receive safe care.

This is particularly the case where different providers prescribe and administer controlled drugs. It is also important to agree who is responsible for consistently reporting controlled drugs incidents to the NHS England lead CDAO. Services also need to consider how they will share learning with each other in relation to any incidents or near-misses.

Private prescribing of controlled drugs

Schedules 4 and 5

In our last annual update, we reported on the lack of national oversight of prescribing Schedule 4 and 5 controlled drugs by providers in the independent sector. Private prescriptions for controlled drugs in these schedules do not use standardised forms and cannot be monitored. This also means that it is much easier to forge prescriptions for dispensing. This can result in personal misuse, onward diversion, or both. We also see that prescriptions are being taken out of the area to be dispensed to avoid raising suspicion with the supplying pharmacy.

This lack of oversight means that we don't know the true scale of the issue – we rely on anecdotal evidence from those who report these incidents and from Coroners through Prevention of Future Death letters. A review of the impact of the way the current system operates would be helpful to determine the changes needed to make it safer and more effective for prescribers, patients, supplying pharmacists and organisations who need to have oversight.

Schedules 2 and 3

Private prescribers only need to declare the main organisation in which they undertake their prescribing when applying for private prescription forms (FP10PCDs).

This means that a prescriber can work across multiple different clinics, using the same prescribing pad, but the resulting data collected will show all prescriptions with the same organisation address. This is inaccurate and is a missed opportunity for better oversight of controlled drug prescribing practices in the independent sector.

Controlled drugs in adult social care services

Medicines errors

Each year, we ask registered adult social care providers to provide information about whether they administer controlled drugs, and if so, how many controlled drug-related medicines errors occurred in the service in the previous 12 months.

We analysed the information from those that responded and found that:

- 67% (13,501) of services (20,184) administered controlled drugs
- of the services that administer controlled drugs, 17% (2,248) reported controlled drugs incidents in the previous 12 months
- 39% (7,846) of services (20,122) reported no medicines errors at all.

Reporting incidents and near misses in services and having a good process to review these is where a 'just culture' is important. This enables support for staff to be open about errors and to learn from them. This is crucial to reduce the risk of a similar event happening again.

Our guidance on medicines errors in care homes offers information for providers to help with best practice in this area. Incidents related to controlled drugs (including loss or theft) should be reported to the local NHSE Controlled Drugs Accountable Officer (CDAO). Their contact details are on our CDAO register.

Application of transdermal (skin) patches

We continue to see varied processes and procedures in relation to applying patches containing controlled drugs and have heard about harm because of inadequate risk assessments and monitoring. We provide guidance on this, and a new guide from the Specialist Pharmacy Service was also published last year, which may also be helpful when designing and monitoring processes around patch administration.

STOMP guidance

During some of our inspections of adult social care this year, we have found examples of good awareness of the principles and application of STOMP guidance (stopping over-medication of people with a learning disability, autism or both). Some medicines that STOMP guidance refers to are controlled drugs, such as benzodiazepines or Z-drugs.

One of the key aspects of this guidance is ensuring that prescribing and administration of these medicines is appropriate and, where possible, that non-drug options are available so that people's behaviour is not controlled by using these medicines. The following example shows this.

> Staff in the care home were exceptionally skilled in enabling people to express their views and wishes. For example, one person was unsettled and required medicines to help them remain calm. Staff spoke with the person's family and discovered they had a passion for art. So, they obtained an easel, canvas and oil paints to enable the person to paint and staff arranged for them to display their art at an in-house exhibition. The person settled in the service and spoke about the meaning behind their artwork, and no longer required their calming medicines.
>
> Greensleeves Care Home

Controlled drugs in secondary care

During 2022, our Medicines Optimisation team reviewed medication safety in over 90% of England's NHS trusts. We held discussions with CDAOs and senior pharmacy leaders in NHS acute, community, mental health, and ambulance services. This was to help us understand how NHS services in secondary care were managing controlled drugs safely in the context of pressures on the system.

The key themes that we found through our conversations were:

- **Role of the CDAO:** Some CDAOs had access to training for the role, while others did not. There were also significant differences between the time and support for some CDAOs to undertake their role, with some stating they were concerned they did not have enough time to complete the required work effectively. The CDAO role was often performed alongside other roles, such as Medication Safety Officer, which also increased time and workload pressures.
- **Governance:** Most trusts reported that their board was accessible and any concerns raised with them were taken seriously. How trusts chose to manage their governance varied in response to their needs as a provider, and we saw some inventive methods of collecting data to help provide assurances that controlled drugs were being managed safely.

  For example, one told us it had changed the audit template to an electronic survey, which automatically generates a report that can be sent to the ward manager. This trust also has a dashboard that enables staff to focus on any areas of concern and helps to analyse data.

  However, we did find examples where incidents that should have been raised at board level were only discussed there as part of an annual report on controlled drugs, which meant that action to address issues was delayed. We also heard about instances where learning was not shared within trusts.
- **Diversion:** This was a concern, especially in surgical and busy areas. Lower schedule controlled drugs were a particular concern and diversion sometimes involved staff.
- **Reporting incidents:** We found that reporting cultures varied at different sites, even within the same trust. CDAOs and their supporting teams sometimes found it difficult to manage the volume of reported incidents. Where staff reported all incidents diligently, this contributed to large overall volumes, and although this increased the workload for CDAOs, they did not want to discourage a good reporting culture.

- **Pain relief for end-of-life care:** We heard good examples of multi-agency working to support good medicines optimisation for patients at the end of their lives. Some trusts raised the issue of accountability for controlled drugs in patients' own homes when several different providers of care are involved.
- **Wet signatures:** The need to have 'wet' or written signatures for controlled drugs often led to delays in the supply of medicines for patients and prevented healthcare settings from being able to make best use of their digital systems.
- **Prescribing:** We heard some good examples of monitoring prescribing of controlled drugs, including some de-prescribing programmes for opioids, z-drugs and benzodiazepines. Some of this work was shared with the local integrated care system (ICS), as in the following example:

"As part of our efforts to make sure that patients are not inappropriately prescribed long-term opioids, hypnotics and other medicines we've got a specialist pharmacist who works with our chronic pain team leading work on de-prescribing opioids across the city. We've shared that work with the ICS. We've also got a consultant pharmacist for older people working in our city, who is leading a wider piece of work around de-prescribing. De-prescribing is embedded into our clinical practice in relation to how we review patients' medicines at discharge. This ensures that medicines intended for short-term use while in hospital are reviewed at discharge and discontinued if appropriate."

- **Improvement projects:** We heard about a wide range of projects aimed at improving patient care. Staff had worked hard to develop them and were proud of the outcomes. The following are some examples of initiatives that staff told us about:
    - Where appropriate, switching prescribing from a liquid oral opioid to an oro-dispersible tablet (which dissolves in the mouth) to reduce risks around unintentional overdosing.
    - Following a review of discharge prescriptions, prescribers in the surgery and anaesthetics departments improving the clarity of instructions for GPs.
    - Working with police to carry out risk assessments of controlled drugs and electronic drug cabinets to look for further benefits of using automated processes to manage controlled drugs.
    - Developing an information leaflet for patients on 'managing your controlled drugs in your home'.
    - Using innovative ways to share messages across teams, such as a video on how to second check controlled drugs safely. This enables busy staff to engage and support the policy through short learning sessions.

Shared care

In last year's annual update, one of our recommendations was that “Health and care staff need to make sure they provide shared care in line with best practice guidance”.

However, we still have concerns in this area, particularly where care is shared between NHS providers and those in the independent sector. Monitoring patients is a key concern, especially when they need tests at certain intervals.

Private prescribing of medicines licensed for attention deficit hyperactivity disorder (ADHD) is one area of concern where shared care can be ineffective. Prescribing of these medicines by private health providers again increased between 2021 and 2022, driven by increased awareness of these medical conditions and poorer access to NHS mental health services. Detailed prescribing data is available in the next section of our report. Figures 1 and 2, also show the increased prescribing of these medicines over the last 5 years. Although prescribing has increased in both the NHS and independent sector, the increase in private prescribing during the pandemic is steeper.

Where private health providers wish to share care with an NHS GP, it is crucial that they investigate whether this will be a possibility – both practically and in line with guidance from the Department of Health and Social Care. Patients must be assessed for this at the outset of treatment: if NHS treatments cannot be provided as part of the shared care, any tests such as blood tests are likely to incur additional costs.

Figure 1: Private prescribing of methylphenidate, lisdexamfetamine and dexamfetamine (2017-2022)

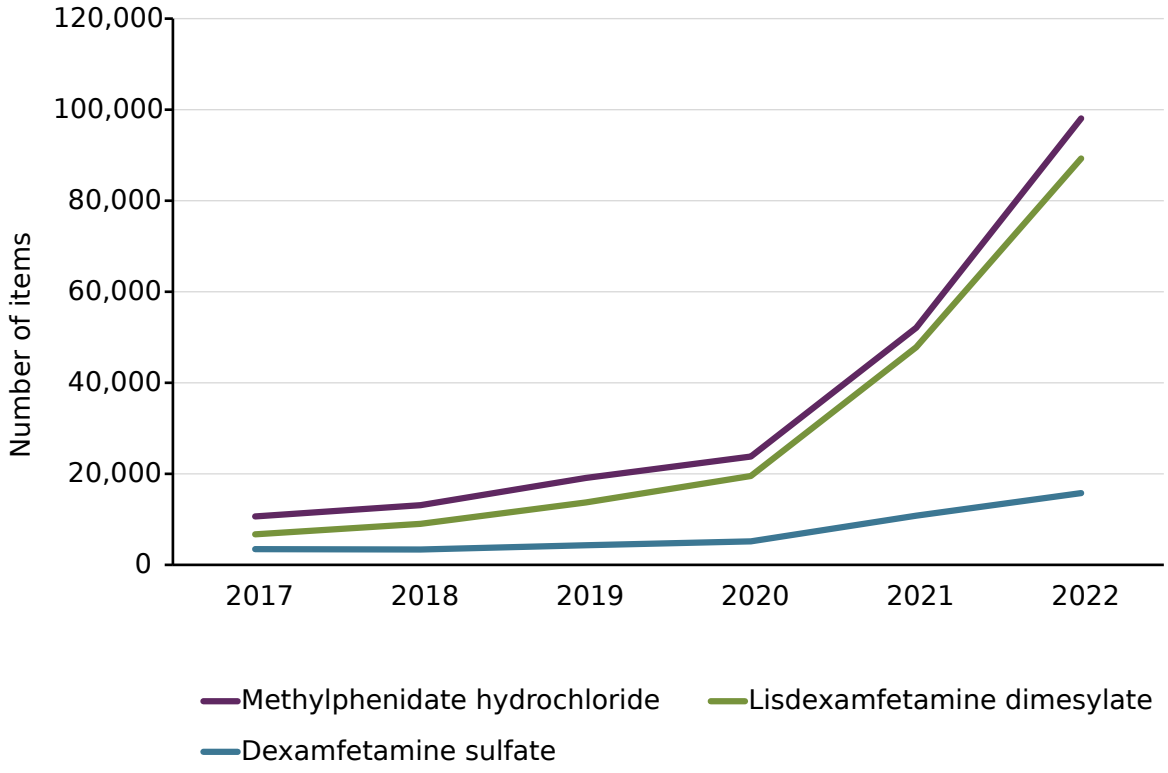
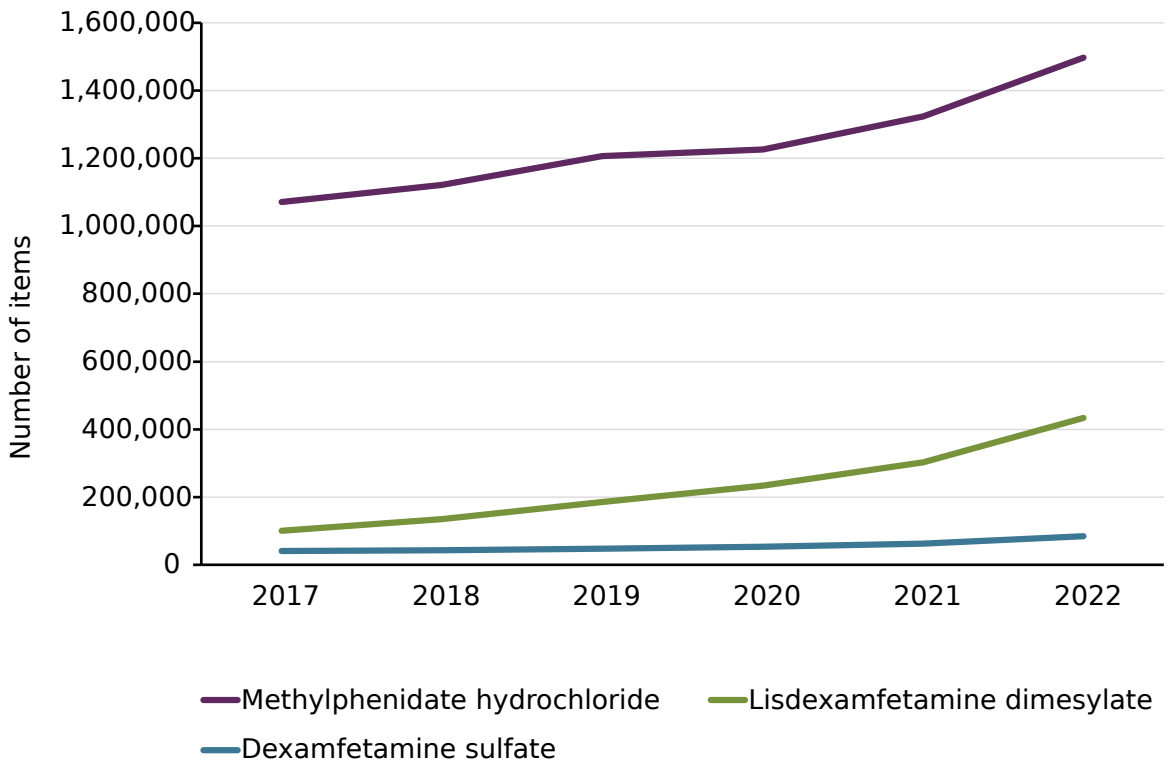


Figure 2: NHS prescribing of methylphenidate, lisdexamfetamine and dexamfetamine (2017-2022)



Note: This includes both primary care prescribing (FP10 prescription forms) and hospital prescribing (FP10HP prescription forms).

Workload pressures in community pharmacy

There continues to be significant workload pressure for staff in the community pharmacy sector. Community pharmacies are a crucial part of our health and care system, providing services and support to a range of health and care providers. We have seen the knock-on effect of these pressures in services registered with CQC.

Examples include where substance misuse services have taken on supervised consumption of opioid substitution treatment because the local community pharmacy cannot provide the service. Services that issue instalment prescriptions should communicate closely with their local community pharmacies to ensure that supervised consumption services are available and advise patients accordingly.

We have also seen that people who have been issued a paper prescription, often out of normal hours, are not always able to get a supply of their medicine at their nearest pharmacy because of closures.

Cannabis-based products for medicinal use

During 2022, we continued to register clinics in the independent sector that provide treatment with cannabis-based products for medicinal use (CBPMs). At the time of publishing, 18 providers that prescribe unlicensed CBPMs were registered, with more currently being assessed for registration.

During 2022 we continued to monitor and inspect providers in line with our current regulatory approach. Although we found some providers had made improvements in various aspects of their service, a stronger focus on good governance was sometimes needed to ensure safe, high-quality care.

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.

As in previous years, almost all prescribing continues to be for unlicensed CBPMs in the independent sector. The most current available prescribing data for independent health services has shown an increase of 216% over the past year:

- from 1 January to 30 September 2021, 25,212 items were dispensed.
- from 1 January to 30 September 2022, 79,579 items were dispensed.

This data relates specifically to prescriptions that are dispensed in a community setting.

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

Access to medicines for care at the end of life

The pandemic brought into sharp focus the challenges associated with managing pain and symptom relief during end-of-life care. We hear from care home providers about the cost and lengthy process associated with obtaining a Home Office licence to hold a very small quantity of controlled drugs as anticipatory medicines. In practice, this means that many care homes don't hold any stock, so they need to use other routes to prescribe and supply controlled drugs to ensure that patients can access these medicines.

We know there is a great deal of excellent work in relation to anticipatory prescribing to ensure that people get the medicines they need at the right time. However, it is sometimes difficult to predict when a patient might be nearing the end of their life, which can mean the right medicines are unavailable both within the care home setting and when people choose to die at home.

In some cases, delays to treatment and additional work can be caused by issues such as:

- incorrectly written prescriptions or authorisations to administer
- unavailability of stock
- access to medicines out of normal hours.

This is especially relevant given the ongoing pressures on health and care staff after the pandemic.

Good symptom management is such a crucial part of end-of-life care, so it would be helpful to understand more about the scale of this issue. We also need to understand the possible risks and benefits around the ability for nursing home providers to hold a very small stock of controlled drugs as anticipatory medicines to treat patients at the end of life only.

Over-prescribing medicines that cause dependence and withdrawal

In both our 2019 and 2020 reports, we raised awareness of Public Health England's evidence review, 'Dependence and Withdrawal associated with some prescribed medicines'. This addressed opioid medicines for pain, the gabapentinoids, benzodiazepines and z drugs (medicines that act in a similar way to benzodiazepines), and antidepressants.

Since the 2019 report, we have seen improved awareness and more initiatives to address this type of prescribing to improve patient outcomes in NHS GP services, as the following examples show.

The National Institute of Health and Care Excellence (NICE) has also recently produced a patient resource to support this work.

> Following an audit to look at opioid prescribing, the practice found that 71 patients were on the maximum daily dose of these medicines. In response, the practice designed a pilot service in conjunction with the clinical commissioning group, the local hospital and Resolutions, a local drug and alcohol recovery service. A repeat audit at the end of the pilot showed that 31 patients had reduced the dose of these medicines.

Lea Vale Medical Practice

This practice had adopted the use of a medication risk stratification tool. This was designed to help identify any patients who are likely to be put at risk of harm from their medicines. The practice also used a pharmacist-led information technology intervention tool to help to reduce medication errors, and thereby improve medication safety.

Belvidere Medical Practice

In March 2023, NHS England released a Framework for action for integrated care boards (ICBs) and primary care to help support this ongoing priority. Actions at integrated care system level have the potential to provide leadership and improve local collaboration to benefit patients. Over the last year, we have heard about examples of this good work, including:

- A range of opioid reduction projects in the North East that include a campaign aimed at helping GP practices to review opioid prescribing in primary care. This includes videos of patients' lived experiences.
- The 'Living well with pain' programme in Gloucestershire, which uses a system-wide approach to help bring services together for effective patient care. This is an evidence-based programme, focused on exercise and improved access to mental health services, to help people with chronic pain live as well as possible.

Transitioning to electronic systems

During 2022, we have seen more examples of the benefits of digital systems, such as this example of collaborative working between a hospice and an NHS trust:

The service worked with the acute hospital trust to implement an electronic system to prescribe medicines and record their administration. This system was used across all NHS hospital services and adult hospice services in Cornwall.

This meant that information about people's medicines was more readily available when they transferred between services. These electronic records were complete and up-to-date, with clear recording of allergies and reasons if medicines were not given.

Mount Edgcumbe Hospice

As services progress towards greater use of electronic systems and recognise the benefits, they still need to consider possible risks that are different to paper records. Examples of issues that we have heard about this year include:

- people still being able to divert controlled drugs from electronic storage
- loss of vital data with no appropriate back-up procedures, for example in electronic controlled drug registers
- staff not being up-to-date with system updates, leading to medicines errors
- lack of staff training and understanding in relation to the wider functionality of the system, including how electronic audits work.

There are also growing concerns from those who work with patients around the delay in changes to legislation to permit the full use of electronic systems. Services are now transitioning their digital functionality at pace, and are concerned that the new systems are not reflected in legislation.

Our guidance for adult social care services explains about electronic medicines administration records (eMARs) and how keeping good digital record systems can help to achieve good outcomes for people using services.

Governance of controlled drugs

Good governance is central to the safe and effective management of controlled drugs. We have previously made recommendations in relation to this in our annual updates. When we see problems with controlled drugs on our inspections, it is often because governance is poor and not functioning effectively.

We publish self-assessment tools for primary and secondary care organisations. These tools help you to establish whether you have the right governance processes in place, or if you need to make further considerations. The tools are available to download without having to provide any contact details.

Partnership working: NHS England controlled drug accountable officers and police controlled drug liaison officers

Multi-agency partnership working is an essential part of helping to ensure that controlled drugs are managed safely across health and social care. Both NHS England CDAO teams and police controlled drug liaison officers (CDLOs) are highly knowledgeable and experienced in providing advice and support about a range of controlled drug issues and concerns – from medicines errors to suspected thefts and unaccounted losses.

We encourage services to make contact where they need support following an incident or concern. You do not have to be a designated body to contact CDAOs or CDLOs. The Association of Police Controlled Drug Liaison Officers website enables you to check the up-to-date contact details for your local CDLO and your local NHSE CDAO's details are on our CDAO register.

Local authorities as Responsible Bodies

Under the Controlled Drugs (Supervision of Management and Use) Regulations 2013 local authorities have a 'Responsible Body' status. This means that they can be a part of local intelligence networks (LIN). Even though local authorities are crucial system partners in relation to the safer management of controlled drugs, we rarely see them represented within LINs. Where not already linked into a LIN, we encourage the local authority medicines lead to make contact with their local NHS England CDAO to discuss the possibility of joining the LIN.