

# Key issues in 2023

# Reflecting on the Shipman and Gosport inquiries and risks in current practice

Next year will mark 20 years since the publication of the final report of the Shipman Inquiry.

Since the reports were published, we have seen a significant shift in clinical and governance practices in relation to controlled drugs to support better care for patients both in the NHS and independent sector. Legislative changes, such as the 2006 and 2013 updated versions of the Safer Management of Controlled Drugs (Supervision and Use) Regulations, have also helped.

However, with capacity demands on the health and care system at an all-time high, it is important not to be complacent about the significance of the learning from this Inquiry, or from the events at <u>Gosport War Memorial Hospital</u>. In Gosport, poor culture, lack of clinical challenge and a failure to speak up meant that patients were placed on an end of life pathway indiscriminately and irrespective of their individual clinical needs.

Risks associated with controlled drugs are still present within health and care systems, which are constantly changing. Commissioning arrangements can also be complex and opportunities for communication and collaboration are sometimes reduced because of capacity constraints or incompatible digital systems. Closed cultures and clinical isolation can increase risks associated with the use of controlled drugs. We are also aware of the significant pressure on health and care staff, including those who are not registered with a professional regulator. This can lead to tragic outcomes for all involved, including the staff and the people they are caring for.

Within services, safer care can be promoted through a combination of a welcoming attitude towards professional challenge and speaking up, combined with the approach that the safer management of controlled drugs needs to be "everyone's business," – not just that of medicines or pharmacy teams.

In our 2022 report, we emphasised the importance of working collaboratively to improve the prescribing, managing and monitoring of controlled drugs, particularly through partnership working as part of local integrated care systems. The systems we now have in place should help us to identify concerning behaviour or practice sooner. It is vitally important to make the most of these systems, with collaborative working, effective communication and information sharing central to their effectiveness. This includes those organisations providing frontline health and care services, but also other local, regional and national level stakeholders, such as integrated care boards (ICBs), regulators, commissioners and professional bodies.

## Home Office licences

We continue to receive a number of questions about Home Office controlled drugs licences. Some services need these to enable them to treat people with essential medicines, including those used as painkillers, and for surgical procedures.

In last year's report, we recommended that providers allow enough time when applying for a licence. Working with the Home Office, we are producing guidance for providers when applying or re-applying for a Home Office licence.

# Legislation update

In December 2023, a range of amendments were made to the Misuse of Drugs Regulations 2001. These have an impact on which practitioners can prescribe controlled drugs.

Paramedic independent prescribers are now able to prescribe and administer 5 specified controlled drugs:

- morphine sulfate by oral administration or by injection
- diazepam by oral administration or by injection
- midazolam by oromucosal administration or by injection
- lorazepam by injection
- codeine phosphate by oral administration

Therapeutic radiographer independent prescribers are now able to prescribe and administer:

- tramadol by oral administration
- lorazepam by oral administration
- diazepam by oral administration
- morphine by oral administration or by injection
- oxycodone by oral administration
- codeine by oral administration

All prescribers must work within their scope of practice. Guidance from the <u>College of Paramedics</u> and <u>Society of Radiographers</u> is available to support registrants.

### Codeine: risks and re-classification

Codeine linctus has been re-classified from a pharmacy only medicine to a prescription only medicine due to the risk of dependence, addiction and overdose. This means that people will need to be prescribed codeine linctus and will not be able to buy it over the counter as previously without a prescription.

The Medicines and Healthcare products Regulatory Agency provides <u>information for</u> <u>healthcare professionals</u>, in relation to both the background review of the safety profile of codeine linctus, as well as useful advice for patients.

Risks around diversion of codeine are still current. For several years, we have heard about incidents of diversion involving codeine in services where it is held as a stock medicine. In some cases, providers have responded to risks by increasing auditing of stock and usage, or increasing recording requirements within their organisation, or a specific part of their organisation if risks are localised.

We also continue to hear about forged private prescriptions for codeine, both in linctus and tablet formulations. Although forgeries are becoming more elaborate, common issues on forged prescriptions may include:

- unclear or vague prescriber details
- mis-spellings
- unusually high quantities or doses
- out-of-area addresses (of the doctor, service and/or patient)

Incidents relating to forged prescriptions should be reported to the local NHS England CDAO and/or controlled drugs liaison officer (CDLO).

## Nitrous oxide reclassification

In November 2023, possession of nitrous oxide was made illegal if it is, or is likely to be, "wrongfully inhaled". It is now a Class C drug under the Misuse of Drugs Act 1971 and a Schedule 5 controlled drug under the Misuse of Drugs Regulations 2001.

The term "wrongful inhalation" means inhalation that is not for medical or dental purposes, nor accidental inhalation of nitrous oxide that has been released into the atmosphere (such as in industrial processes).

Services need to be aware of the risks of theft and diversion from areas where medical gases are used and/or stored. This can include static as well as mobile storage areas, such as doctors' and paramedics' cars and ambulances.

## **Nitazenes**

<u>Nitazenes</u> are synthetic opioids. They have been identified previously in the UK, but their use has been more common in the USA. They are psychoactive and their potency and toxicity may be similar to, or more than fentanyl. For context, fentanyl is in turn about 100 times more potent than morphine.

Nitazenes are often mixed with other street drugs and their use can be fatal. They are also sometimes found to be present in counterfeit medicines. An investigation by the Advisory Council on the Misuse of Drugs (ACMD) found that one nitazene, isotonitazene, was responsible for 24 fatalities in the UK in 2021. This particular nitazene is 500 times more potent than morphine.

Although nitazenes are illicit substances, we have chosen to include them in this report as we have received questions from healthcare services about where to find guidance on treating people for nitazene exposure or overdose. In July 2023, the Office for Health Improvement and Disparities issued a <u>useful alert relating to staff awareness of synthetic opioids</u>, and the treatment of overdose. This alert is important for organisations where staff may encounter people who use drugs and those who provide emergency care for opioid overdose.

# Overseas prescribing of controlled drugs

Prescribing of controlled drugs from outside England continues to be an issue that is raised with us. Practitioners who can legally produce a prescription in their European Economic Area (EEA) home country for controlled drugs in Schedules 4 and 5 can also legally prescribe these for someone in England. This is not a reciprocal agreement with the EEA.

As a result of this regulatory gap, people have accessed a range of inappropriately prescribed medicines, including controlled drugs, and continue to do so. This includes large quantities of Schedule 4 and 5 controlled drugs, which have resulted in both harm and death.

There are important considerations in relation to people visiting England who require continuity of treatment, and legitimately use this avenue of care. However, we also need to consider how the risks associated with this open avenue for inappropriate prescribing practices can be minimised.

# Designated bodies

The role of the controlled drugs accountable officer

Visibility of the controlled drugs accountable officer (CDAO) is important because it can help to encourage both proactive conversations about making the use of controlled drugs safer as well as an open reporting culture. We have seen some good examples of CDAOs making time to promote their role and visibility within their organisation. This is especially helpful in larger organisations with multiple locations, where it might not always be easy to identify and locate the CDAO.

As pressures in the healthcare sector continue, we are hearing that not all CDAOs have access to the resources they need. This is a crucial role, and the Controlled Drugs (Supervision of management and use) Regulations 2013 are clear that designated bodies must provide the funds and resources necessary to enable the CDAO to effectively discharge their <u>responsibilities</u>.

#### Board-level oversight of controlled drugs

The function of a CDAO is often viewed as a 'pharmacy team responsibility' within designated bodies such as NHS trusts and independent hospitals. Over the last year, we have heard about a range of incidences where employees of designated bodies at director level – including those who sit on boards – have not been proactively engaged with CDAOs who have raised controlled drugs concerns with them.

CQC expects that issues and concerns raised by the CDAO are discussed at board level and that these will be prioritised and scrutinised as appropriate for the specific circumstances.

It is also important that other leaders working in designated bodies engage effectively with the CDAO – including the chief nurse and medical director. Where NHS trusts take the view that 'controlled drugs are everyone's business', we often observe a much more open approach to raising concerns and problem solving.

# Resourcing of controlled drugs liaison officers

Each police force has a controlled drugs liaison officer (CDLO). This role was created by the 2006 Health Act and provides an important link between the police and partner agencies, and with stakeholders such as health and social care providers, regulators and NHS England. Their work is focused on the safe management of controlled drugs and can involve preventing or even prosecuting offences in relation to them. CDLOs are important members of controlled drug local intelligence networks (CDLINs) and will share information and intelligence, where appropriate, with partners.

CDLOs provide organisations with invaluable advice on the safe management and use of controlled drugs. They can also provide basic advice on security and more sophisticated law enforcement and intelligence gathering techniques. Although the criminal justice system is vitally important, most CDLOs will adopt a problem-solving approach to the issues and challenges facing healthcare providers.

We again emphasise the importance of knowing the identity of your CDAO and CDLO. It is always better to make early contact with your CDLO. Unless the matter is an emergency, this is preferable to calling the police directly, as CDLOs have the time, experience and knowledge to more effectively assist health and care providers.

CDLOs and partner organisations have raised concerns with us regarding the lack of national coverage of CDLOs across the country. Some CDLOs have a number of other roles and a few forces have long-term vacancies, which reduces the service provided to health and care providers. This issue is being addressed at a national level with the National Police Chiefs' Council (NPCC).

## Prescriber identification numbers

The current system for issuing prescriber identification numbers (PINs) for private prescribing and requisitioning of controlled drugs would benefit from a review. This could potentially help achieve better national oversight of prescribing and manage areas of risk.

There is currently no expiry date for PINs and practitioners are only required to provide one main address of work, even when they may also practise in a wide range of settings.

Not all practitioners requesting PINs will be required to be registered with CQC to undertake their work. This might be because they are an independent medical practitioner or a non-medical prescriber, such as a pharmacist, and may therefore fall outside CQC's scope of registration. This means they are not subject to the regulations we enforce and our assessment processes, and we therefore cannot check the quality of service being provided to people.

During the year, we have also seen that prescribers sometimes write private prescriptions using another prescriber's ready-printed pad, and they don't correct the PIN number or details to accurately reflect who actually prescribed the controlled drug.

There has been debate around whether the PIN application process is purely an administrative one, as prescribing privileges are from professional registration. However, checks by NHS England CDAO teams as part of prescriber PIN applications have previously identified governance risks that may not otherwise have been recognised, which demonstrates the value of the process. This is especially important in cases where the prescriber or service offered does not fall into scope of CQC registration.

Trends in recent years also show that prescribing of controlled drugs by non-medical prescribers is increasing, and any review of the PIN process should take account of this.

# Learning from incidents

When we speak with organisations about medicines incidents, we focus on understanding the circumstances surrounding them and what has been done to investigate, follow up and reduce the chance of future recurrence.

Over the last year, we have heard about a range of cases that relate to 2 particular medicines: alfentanil and morphine. We share some of the learning from these incidents here.

#### Alfentanil medication errors

We have seen a recent increase in incidents relating to the incorrect selection of alfentanil – either in terms of prescribing or physically selecting a vial for administration. Alfentanil is a potent injectable opioid with a range of uses, including during anaesthesia and for some patients receiving palliative care. It is available as 500 micrograms/ml strength and 5 milligrams/ml strength (sometimes referred to as 'intensive care' or 'high' strength). The cases we have heard about involved wrongly selecting the 'high' strength.

Contributory factors have included poor knowledge and awareness of higher strengths, the competency of staff when making dose calculations, and storage of the high strength preparation on wards where it is not commonly needed or used.

#### Organisations have shared the following points of learning:

- It is important to make staff aware of the existence of a higher strength.
- Pharmacy teams and ward leaders should have oversight of where alfentanil is needed, used and stocked, and should query requests for stock from wards where it is not normally used.
- Risk assessments of the use of alfentanil can be useful, especially as it helps services to develop ways of mitigating risks of mis-selection or incorrect prescribing.
- Some services remove the higher strength from the ward when it is not needed.

## Morphine sulfate – infant overdose

We are also aware of tragic circumstances surrounding overdoses of morphine in infants. In one example, morphine sulfate oral solution was administered at a dose 20 times higher than the intended dose. This happened because the infant's parents were supplied with a 10 milligrams/5ml oral solution after discharge from the hospital, and not a 100 micrograms/ml solution. NHS England North East and North Yorkshire has produced a helpful case study with details of the causative factors and learning points to reduce the risk of future occurrences.

#### **Points of learning included:**

- Making morphine a 'red' drug in paediatrics so that responsibility for a
  prescription cannot be transferred to the community. This means supply
  would come from hospitals and specialist centres only.
- Discharge summaries should contain the full name of the drug, formulation, strength, and clear dose instructions with consideration of daily maximum doses for PRN (when required) medication.
- The importance of speaking directly to the prescriber for medication queries with high-risk drugs, and/or patients with complex conditions.
- When counselling, ask patients to summarise and recall main points back to you to check their understanding.

# Remote prescribing of controlled drugs

Remote consultations resulting in the prescribing of controlled drugs are becoming more common, both across NHS and private settings. The pandemic triggered more widespread prescribing in this way, and we have seen this expand further over the last few years. When undertaken appropriately, remote prescribing can be convenient for people who need treatment and can enable prescribing clinicians to offer treatment in a timely way.

However, we have heard of examples where healthcare professionals are not adhering to safe practices when prescribing remotely, including non-medical prescribers.

When services contract healthcare professionals to undertake prescribing, including for controlled drugs, they must be assured that this is happening in a safe and effective way. This includes those employed as a member of staff or as a locum or independent contractor.

Services must ensure that those prescribers:

- are working within their scope of practice
- have enough time to undertake consultations
- have appropriate access to medical histories of patients they are prescribing for
- are able to assure themselves that they can fulfil any monitoring requirements for people during ongoing periods of treatment and prescribing
- effectively communicate relevant information with other health and care providers, such as GPs, as appropriate.

Professional regulators such as the <u>General Medical Council</u>, <u>General Pharmaceutical</u> <u>Council</u> and <u>Nursing and Midwifery Council</u> issue professional guidance for their prescribers.

# Cannabis-based products for medicinal use

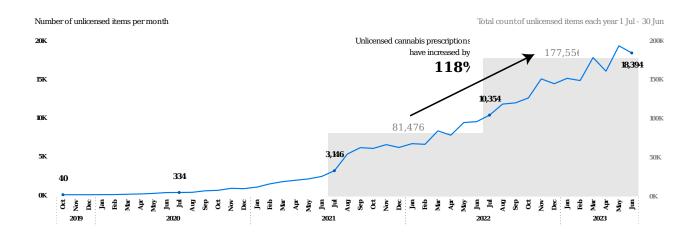
Cannabis-based products for medicinal use (CBPMs) are Schedule 2 controlled drugs under the Misuse of Drugs Regulations 2001. They can be prescribed by, or under the direction of, a doctor who is on the specialist register of the General Medical Council to treat patients on a case-by-case basis to meet an unmet clinical need.

During 2023, we continued to register clinics in the independent sector that provide treatment with CBPMs. At the time of publishing, 22 providers that prescribe unlicensed CBPMs were registered with CQC.

Over the last year we have seen instances where providers have not always communicated treatment plans and information on prescribed products in a timely way with other healthcare professionals involved in a person's care. It is vitally important to share information effectively with people's regular prescribers (normally their GP) to keep them safe. In some cases, this may also include liaising with secondary care and other independent services.

As in previous years, almost all prescribing continues to be for unlicensed CBPMs in the independent sector (figure 1).

Figure 1: Private unlicensed CBPM prescribing in England, October 2019 to June 2023



Note: Figure 1 does not include data before October 2019 because of low numbers.

Prescriptions for CBPMs are processed manually because CBPMs are not included in the <u>Dictionary of medicines and devices</u>. This means there is a time lag in the prescribing data available to present day. The most current available prescribing data for independent services has shown an increase of 118% across the following periods:

- 1 July 2021 to 30 June 2022: 81,476 items dispensed
- 1 July 2022 to 30 June 2023: 177,566 items dispensed.

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

Some non-medical prescribers can prescribe CBPMs under the direction of the specialist doctor. We have seen that most of the non-medical prescribing for CBPMs is undertaken by pharmacist independent prescribers, who work in clinics in the capacity of shared care with specialist doctors.

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 breach patient confidentiality.

It has been over 5 years since the change in legislation that permitted the prescribing of CBPMs. This change allows specialist clinicians to prescribe unlicensed CBPMs on a case-by-case basis, to meet an unmet clinical need. We have since seen a significant increase in prescribing to treat a wide range of medical conditions, as well as changing models of care, including those involving non-medical prescribers. People can also find it difficult to access joined-up care from all their healthcare providers. The number of unlicensed CBPMs prescribed each year continues to increase by at least 100% annually. A multiagency review of the impact of this change would be beneficial.

Administration of CBPMs in health and social care settings

The number of enquiries we receive about supporting the administration of unlicensed CBPMs in health and social care settings is increasing. CBPMs must have been prescribed for an unmet clinical need. They come in a range of preparations including oils, capsules and flowers that are vaped and it is illegal for these products to be smoked.

To help support staff when caring for patients prescribed CBPMs, providers' policies and processes should consider:

- ensuring the product has been prescribed
- how to support patients with ongoing supplies, if required
- safe storage, records and appropriate authorised access, as with other Schedule 2 controlled drugs
- appropriate training for staff if they are required to support with administration
- the position on vaping, and the possible need to obtain prescribed alternatives where people are not able to vape
- whether a risk assessment is required

# Storage of prescription stationery

We have seen during inspections that some services are not following guidance when managing prescription stationery (prescription forms) – this includes green FP10 forms and pink FP10PCD forms for private prescribing.

These problems are more apparent where prescription forms are ordered centrally to be delivered to a provider's main office but they are not logged as received, not stored securely and not tracked when they are sent to prescribers. Unauthorised access to stationery and an inability to identify when prescription forms have been lost or stolen can and does lead to diversion of controlled drugs and harm to people. Where individual prescribers have access to prescription stationery in their own homes, they also have a responsibility to store these securely. Incidents of prescription stationery loss or theft should be reported to NHS Counter Fraud and NHS England CDAOs. Both NHS counter fraud and CQC provide guidance on prescription security.

# Managing unknown substances in services

More providers are asking us for advice about how to manage unknown substances that people hand in when they are using services, such as in a hospital setting.

Services need to have a clear policy and process to manage this issue and the risks associated with it, and there must be a robust documented audit trail. Unknown substances must be put into a secure, sealed container. Quantities that indicate personal use only can be destroyed locally as an unknown substance. Services should assess and manage the risk of exposure to unknown substances during the destruction process.

Larger quantities, which are indicative of supply (not for personal use), will need to be notified to the police. CDLOs are a good first point of contact for concerns in relation to this. Any trends should also be communicated to the NHS England CDAO so they can share the issue and any learning with the CDLIN.

It is important to note that dispensed supplies of cannabis-based products for medicinal use are legal to possess when they have been prescribed.

We have seen some good policies and learning points in relation to handling suspected unknown substances shared at CDLINs, so this could be a good starting point for services that are looking to develop or update their policies.

## Identity badges, cards and uniforms

We continue to hear about theft and/or misuse of ID badges and cards, and how these have been used after a member of staff has been dismissed from, or left a service, to access and illegally obtain controlled drugs. We have also heard about the theft or sales of genuine staff uniforms, which have been used to create a credible story for people to request access to controlled drugs. This underlines the importance of ensuring that ID cards and uniforms are returned, and that access cards are de-activated as quickly as possible when staff change roles or leave employment.

# Delays in submitting private controlled drug prescriptions to NHS Business Services Authority

We have been made aware of delays in sending private controlled drugs prescriptions to the NHS Business Services Authority (NHSBSA). This trend was highlighted in our annual update in 2019 but has again been raised with us. Any service, including community pharmacies, that dispenses Schedule 2 and 3 controlled drugs against private prescriptions must send these to the NHSBSA as soon as possible. See <u>information on the submission process on the NHSBSA website</u>. This also includes pharmacies that dispense against prescriptions for cannabis-based products for medicinal use.

# Keeping controlled drugs after someone has died

When a person dies, their medicines may need to be kept for 7 days in case the coroner requires them for an investigation. This may include a supply of controlled drugs, including those of a high strength, and in injectable form.

Over the last year, concerns have been raised about the risks associated with instructing bereaved relatives to keep these medicines, especially when healthcare professionals involved in care of the family have concerns that medicines could be used for self-harm. This is often made more complex when a range of different care providers have been involved in treating or caring for the person and their family members. We hear that healthcare professionals are also concerned about removing these medicines from people's homes, in terms of legality, creating records, considering where to take the medicines for safe destruction and what to do if a family member or carer refuses permission to remove them.

Clear professional guidance would be useful in this area in both reducing risks for people who may be storing these medicines, as well as for helping healthcare professionals and service providers to understand their role and remit in these circumstances.

# Incorrect use of controlled drugs disposal kits

When we inspect services, we sometimes see that controlled drugs disposal kits containing resin are not used properly. This results in a range of controlled drugs being left open to diversion. Examples of incorrect use include:

- Assuming the kits can be used more than once, by adding more medicines to the kit container after water has already been added and the resin has already set.
- Overfilling the kits, so that the resin does not set.
- Storing waste controlled drugs in the kit container on open shelves rather than locking away in a controlled drugs cabinet.

Each manufacturer has its own instructions, and we encourage services to read these before using the kits.

# Electronic controlled drugs registers and medicines storage

Electronic controlled drugs registers and electronic medicines storage solutions can offer many benefits to patients and providers in terms of safety, assurance and convenience. Over the last few years, more NHS trusts have contacted us about rolling out electronic registers and/or electronic controlled drugs storage. However, at the same time we had heard concerns about the risks of doing this and navigating the roll out process.

In February 2024, we held an online forum to discuss concerns and learning in relation to these issues. A range of trusts, including those that had successfully rolled out these systems and others that were scoping roll-out, kindly gave up their time to attend this forum. Although we recognise that the complexity of rolling out electronic registers and storage systems is different across organisations, we share the learning from this forum to benefit providers.

#### Learning from our forum

#### Good planning and engagement

It's important to engage early to successfully implement electronic systems. Staff need to feel ownership and be able to actively contribute – from planning to completion. This includes having representation from each staff group that would be using the systems.

One trust spoke about the importance of engaging and involving nurses throughout the planning and rollout phase, as they were the primary users. Most trusts emphasised the importance of not under-estimating the range of stakeholders that need to be involved in collaborative working to ensure success. For example, we heard about the need to work with colleagues in estates teams as electronic storage cabinets may need a room re-configuration to accommodate them, as well as IT teams to ensure sufficient WiFi connection or the right electronic connectivity.

Good working relationships were crucial to success. Project boards that bring stakeholders together regularly, including with IT development teams, had been valuable. These helped to co-ordinate planning and enabled different people to ask questions relevant to their department and governance systems.

One trust told us it holds a weekly forum for staff to share experiences of the electronic registers and storage systems, as well as fortnightly meetings with senior staff, including senior nurses, to escalate concerns and feedback.

Trusts told us in our forum that they would find it helpful to link in with other trusts more regularly, to pick up on best practice and learning from their engagement work and user groups.

#### Technical expertise and training

Several trusts told us about the benefits of providing training from technical experts ('superusers') from pharmacy teams to other departments on electronic registers. Training nurses as superusers had also worked well in some trusts, so that learning was facilitated by nurses, for nurses.

We heard that staff training is an ongoing process, especially following staff turnover or changes to electronic systems. Trusts also spoke about the importance of planning the optimal time to deliver training. This makes sure that superusers are available in roll-out phases to provide effective support to frontline staff, and that the training is not delivered too far in advance or too close to rollout.

#### Governance, system integration and risk management

It's important to have good governance systems in place before any rollout as governance can be more difficult to develop once systems are implemented. We heard that governance can and will change during the initial and subsequent installation phases of electronic registers and storage. This can affect medicines-related governance and policies as well as wider trust policies.

We also heard about the importance of completing physical checks and audits when needed – and that although technology is beneficial, it should not be relied on entirely.

Integrating electronic registers and storage into existing IT systems can sometimes be difficult, as it means having to run 2 systems concurrently. It also means assessing and managing the risks associated with this.

It is vital to have robust systems to handle IT failures. This includes ensuring a 'back-up of information from systems. Trusts told us they worked with IT teams to ensure they had robust back-up plans for both routine and unexpected events, which included considering which servers were used for different electronic systems.

It's also important to consider at the beginning of the design process who should be authorised to access electronic registers and how access can be removed as soon as possible, for example if people leave employment with the trust.

#### Additional learning points

- It's important to reflect on the success of each phase of rollout, to improve planning for the next phases.
- When developing an electronic controlled drugs register, as well as recording statutory information, it's important not to forget to routinely collect other information that is needed to manage controlled drugs safely.
   Many paper registers already do this.
- Electronic registers can restrict which people can investigate incidents and discrepancies, as each username can have different levels of authorisation for viewing and editing. This can stop any unauthorised editing of the register.
- Electronic registers and storage can provide new, more detailed information about the management of controlled drugs. This will require further consideration as to how to use the data in the best way to manage risk and encourage improvement.

#### What CQC expects

We are often asked about our expectations in relation to both electronic storage and registers. We understand the diversity among providers, including NHS trusts, in their size, how they work and the populations they serve. The general principles that we expect providers to consider are:

- The system should meet legal requirements.
- It should be fit for purpose for the provider's needs, which may involve bespoke elements to meet this. For example, it could mean additional data fields in registers.

- Systems should be covered by the provider's governance processes, including audits.
- Access to the systems should be assessed, appropriately restricted and monitored.
- Staff should be trained at the point of implementation, and on an ongoing basis, for example when there are system updates.
- There should be robust processes for back-up and/or IT failures.
- Ongoing use and development should be monitored and any emerging risks appropriately assessed and managed.

We understand that legislation governing safe custody of controlled drugs is 50 years old, and that there may be some circumstances in which new electronic storage systems do not meet the technical requirements of the legislation (such as where the storage is going to be sited). In these cases, we recommend a risk assessment combined with discussion and advice from local police controlled drugs liaison officers before implementation.

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