Medicines in health and adult social care

Learning from risks and sharing good practice for better outcomes



The Care Quality Commission

Our purpose

The Care Quality Commission is the independent regulator of health and adult social care in England. We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

- We register health and adult social care providers.
- We monitor and inspect services to see whether they are safe, effective, caring, responsive and well-led, and we publish what we find, including quality ratings.
- We use our legal powers to take action where we identify poor care.
- We speak independently, publishing regional and national views of the major quality issues in health and social care, and encouraging improvement by highlighting good practice.

Our values

Excellence – being a high-performing organisation

Caring – treating everyone with dignity and respect

Integrity – doing the right thing

Teamwork – learning from each other to be the best we can

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Foreword from the Chief Inspector

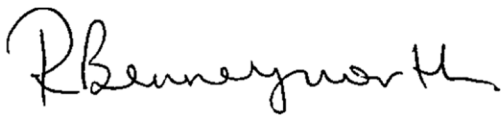
Across all health and care services, CQC's inspections shine a light on quality and enable the public to have confidence in the services they use. We celebrate good and outstanding care and share this so that all services can learn from it and improve; we also highlight where services need to improve where we find poor or unsafe care.

This report brings together what we have learned through our regulatory activity about the risks from medicines. It raises important issues for everybody involved with medicines in all health and adult social care settings. We know that there has been a lot of work to ensure safer use of medicines across services, but there are still areas that can be improved. We are keen that all health and care providers understand the risks, and are able to apply learning from these to enable better outcomes for people using services.

Providers often tell us that examples of good practice are a useful tool to help them get thinking about the improvements they can make in their own services. That's why we share some good practice and innovative ways of working in this report, as one aspect of our role is to help and encourage continuous improvement.

Through our regulatory work in health and care services, we have seen an increased risk of poorer experiences and outcomes when people's care is transferred between services. At this critical time, communication can break down around prescribing and supplying medicines, which means people may not always get the right medicines quickly enough, and this can lead to harm.

We therefore ask care providers, commissioners and other local stakeholders to reflect on this report: be aware of the risks, learn from the examples and think about the actions to use medicines safely, effectively and for the most optimal outcomes.



Dr Rosie Benneyworth BM BS BMedSci MRCGP
Chief Inspector of Primary Medical Services and Integrated Care

CQC's role in improving medicines optimisation

When CQC inspects health and care services we assess how well they meet people's needs. As part of this, we look at how people's medicines are optimised. Medicines optimisation is the safe and effective use of medicines to enable the best possible outcomes for people. It also looks at the value that medicines deliver, making sure that they are both clinically and cost effective, and that people get the right choice of medicines, at the right time, with clinicians engaging them in the process.

To do this, CQC has a national Medicines Optimisation Team of pharmacy professionals who take ownership for all aspects of medicines in the regulatory context. Our team works across the country providing specialist advice on the use of medicines in all settings. This includes being on site at inspections, as part of CQC's wider inspection team, and being integral to decisions on enforcement. We work with CQC's policy teams, ensuring that medicines are high on the agenda and are included in any changes to the way we inspect.

Our team has a strong focus on driving improvement through our extensive engagement programme with national partners, care providers and external stakeholders. We have produced a range of resources to help providers make sense of regulations and best practice guidance concerning medicines. These are all on our website, including information for primary medical services, dental services, and information on medicines for adult social care services. We also publish brief guides for our inspectors in mental health care settings.

Through this report, we want to encourage improvement by sharing what we have found through inspections – both sector-specific and cross-sector risks around medicines and examples of good practice that all providers can learn from.

We also highlight the urgent need for collaborative working to improve how medicines are managed when people are transferred between different health and care settings.

Pharmacy professionals should play a central role in facilitating this, by promoting the safe and effective use of medicines across all sectors.

Sarah Billington
Head of Medicines Optimisation at CQC

Summary: the common medicines issues across health and care

Medicines are used in almost every health and social care setting to improve people's health and wellbeing. The use of medicines ranges from GPs prescribing for long-term conditions such as diabetes to delivering complex chemotherapy regimes in acute hospital settings.

We know that people's physical and mental health outcomes improve when medicines are used in the best or optimal way and that, when not prescribed or administered correctly, they can cause harm. Applying the principles of medicines optimisation and good medicines management is therefore vital across all services.

Many of the services that CQC regulates have a role in managing medicines. Through inspection, we have seen that medicines present a clear risk to people when not used properly. Our State of Care report for 2017/18 highlighted that, of the five key questions that we ask on inspections, performance for the safe key question is poorest, and this commonly affects overall ratings for all types of provider across all sectors. A significant part of our assessment of the safe key question looks at how services manage medicines.

Reducing harm from medicines is a key national and international priority, and both the Department of Health and Social Care and the World Health Organization (WHO) have committed to this. This report aligns with both initiatives and provides additional context for services in England.

As the independent regulator, our role is to help providers of health and care services to understand the common areas of risk and where services need to improve how they use medicines.

From our analysis of inspection reports, notifications of incidents and enforcement notices, we have categorised the most common areas of risk with medicines across regulated health and adult social care services. This did not include providers of online consultations over the internet or by other remote means, as we have previously reported on these services.

These six common areas are summarised as follows.

Figure 1: The six most common areas of risk with medicines across health and care



Prescribing, monitoring and reviewing

Guidance from the General Medical Council is clear that professionals are responsible for the prescriptions they sign and for their decisions and actions when supplying and administering medicines, or authorising or instructing others to do so.[1] Prescribers and pharmacists supplying medicines have a responsibility to keep patients safe and to tell them about any risks in using a medicine. Carrying out timely medicines reviews is also key to ensuring that people's medicines remain both safe and effective.

Monitoring patients is an essential component of the prescribing process. This covers the initial prescribing to how people's medicines are monitored over the long term to ensure that they remain safe and effective. We found examples of risk and unsafe practice across a range of health and social care settings.

In general practice, there are risks for patients taking high-risk medicines such as insulin for diabetes, ACE inhibitors for hypertension, anticoagulants such as warfarin, methotrexate for arthritis and lithium for mental health conditions, as these were not always monitored routinely.

The use of high-risk medicines in acute hospital settings also presents risks for patients. For example, anticoagulant medicines to prevent blood clots were not always prescribed or supplied to patients in a timely way, which increased people's risk of deep vein thromboses (DVTs); doses of antibiotics were not reviewed frequently and adjusted following the results of blood tests; and a lack of familiarity and knowledge among ward staff around insulin resulted in mistakes.

It is equally important to monitor medicines in mental health settings. We found examples of poor monitoring of higher doses of antipsychotic medicines used to treat schizophrenia, and that staff were not always aware of the correct processes for injecting medicines to reduce people's agitation (rapid tranquillisation) and monitoring their physical health afterwards.

Administration

Risks associated with administering medicines were present across all sectors. Our analysis highlighted issues including missed and incorrect doses of medicines (including inadvertent repeated doses) and poorly managed covert and 'when required' administration, which results in poorer outcomes. We also saw problems when people self-administered their medicines when it was not appropriate to do so. Conversely, we found that people were not always supported to self-administer when they were able to. Issues with administration were commonly linked to poor record keeping, which included incorrectly transcribed medicines administration records and failure to record administration.

Transfer of care

People who use medicines may follow a pathway of care that can involve both health and social care services. The overall effectiveness of such a pathway can often depend on where they live, the range of local care services and how well these services work together to provide joined-up and person-centred care.

It is important that medicines are not considered in isolation, but as an integral part of the pathway, and at each step. For example, a person may be admitted from the care of GP and community health services to an acute hospital and then discharged to a care home under the care of a different GP.

Problems with the supply of medicines and how information is transferred put people at increased risk of harm when they change from one healthcare setting to another. We highlighted this in our report *Beyond barriers*, which looked at how well services work together to support and care for people aged 65 and over with complex and long-term care needs. These risks are ongoing against a backdrop of pressures on systems and the changing nature of how health care is provided, as seen through Integrated Care Systems and Sustainability and Transformation Partnerships.

In our analysis, we found examples where people's safety was put at risk when they had been discharged from hospital to care homes, or to their own home, without any guidance on how to take medicines, or without a supply of medicines at all. We also saw examples of unsafe care when information about changes to medicines was either not transferred soon enough, not accurate or not transferred at all.

Reporting and learning from incidents

Reporting incidents and near misses, and sharing the learning from them, is crucial to reduce the risk of a similar event happening again. Our analysis showed that medicines incidents were not always recorded, and low recording rates were sometimes associated with a culture of fear within organisations about reporting mistakes. We also found examples of providers who lacked the insight to investigate and share learning within their organisations.

Supply, storage and disposal

Problems with the supply of medicines could be linked to both prescribing and to problems with stock ordering and control. We found that a wide range of medicines were not always stored appropriately, including intravenous fluids and controlled drugs. We also found that some medicines were not stored at the manufacturer's recommended temperature, which can compromise their effectiveness and pose a risk to patient safety.

Staff competence and workforce capacity

Our analysis showed that staff were not always trained and assessed as competent to carry out aspects of their roles. This applied to both health and social care settings. In some examples, there were not enough competent staff in both domiciliary home care and residential care home settings to administer medicines to people. In acute hospitals there were examples of staff who were not competency assessed to operate syringe drivers. The concept of ongoing monitoring and assessing competency, particularly after medicines administration errors, was not implemented in some organisations. Our analysis also provided examples of services that did not have enough staff to carry out basic duties, such as essential monitoring after administering certain medicines, and carrying out medicines reconciliation.

The analysis also highlighted other common areas that contribute to risks, which affect medicines optimisation as a whole across all sectors. For example, having good governance (effective audit, policy and procedures, and incident reporting) and keeping clear and accurate records. It also highlighted some major concerns that were unique to each sector which we describe in further detail in the specific chapters.

Antimicrobial stewardship

As well as the common cross-sector issues, we also identified concerns around antimicrobial stewardship. Antimicrobial resistance is the ability of a microorganism (such as bacteria, viruses, and some parasites) to stop an antimicrobial (such as antibiotics, antivirals and anti-malarials) from working against it. Antimicrobial stewardship is everyone's business, as inappropriate prescribing and administration can lead to antibiotic resistance, and poorer outcomes for patients.

The O'Neill report on antimicrobial resistance described the challenges of prescribing antibiotics and recommended limiting overall prescribing. In January 2019, the Government announced its five-year action plan for antimicrobial resistance 2019-2024 and it's 20-year vision, which builds on the previous strategy calling for clinicians to keep up to date with emerging evidence on resistance and appropriate antibiotic use. Inspection reports and statutory notifications included examples where poor practice around antibiotics resulted in harm to patients.

Although we do not detail risks with antimicrobial stewardship in each sector chapter of this report, this issue spanned prescribing, monitoring and administration of medicines. Inspection reports and notifications detailed examples where antimicrobials were:

- not prescribed on time for people with suspected sepsis or meningitis
- not prescribed correctly
- not administered correctly, including at the correct intervals and ensuring that the patient completed the prescribed course.

Stopping over-medication of people with a learning disability, autism or both (STOMP)

STOMP is national project to stop the over-use of psychotropic medicines in people with a learning disability, autism or both. These medicines influence how the brain works and can be prescribed for conditions such as depression, psychosis, anxiety and epilepsy. While they are appropriate for some people, Public Health England estimates that between 30-35,000 adults with a learning disability take psychotropic medicines even though they do not have a medical condition that requires these medicines. STOMP aims to improve people's health and quality of life by encouraging regular medicines check-ups, ensuring that health professionals involve people, families and support workers in decisions about medicines, and by raising awareness of other non-medicine interventions and support to reduce the need for medicines.

We include some examples of STOMP in practice in this report to raise awareness of the project. NHS England has a range of resources for providers of health and social care, and for people and their families. In December 2018, STOMP-STAMP (Supporting Treatment and Appropriate Medication in Paediatrics) was also launched, aimed at improving support for children and young people with a learning disability, autism or both. This also looks at how psychotropic medicines are prescribed and aims to ensure that children and young people are prescribed medicines for the "right reason, the right amount and for as short a time as possible."

What all providers can do to improve

We know that providers across **all health and care settings** are working to ensure safe, high-quality care, often in challenging circumstances. But incidents involving medicines are common. To make sure that individual people receive their medicines safely, there are some areas that all providers can consider:

1. Pharmacy professionals play a vital role in improving the safe and effective use of medicines. We have seen the benefits to people when pharmacy staff are closely involved in services – either by having face-to-face contact with people or by strengthening systems by training staff and implementing technology.

- All types of health and care provider should consider how to include pharmacy staffing into the overall skill mix for their service.
- Providers need to find ways to work collaboratively with community pharmacies, who can act as partners to improve medicines safety.

2. There is an immediate need to improve how medicines are managed when people are transferred between different health and care settings:
   - Commissioners and providers of services need to work together to understand where there are local challenges in the system, improve communication and reduce risks to people at this important time.
   - Care providers should have a systematic process to both receive and discharge people from their services, so that their medicines are managed safely and effectively. Referring to summary care records could support this, with input from pharmacy professionals.

3. It is essential to have appropriate policies and processes for all medicines-related activities. However, having a policy itself does not change people's behaviour.
   - Policies need to be central to everyday practice, easy for staff to understand and readily accessible.
   - These need to be reviewed regularly to make sure they align with best practice guidance, including NICE guidance for medicines reconciliation, patient-centred care plans and accurate recording.

4. The processes for reporting medicines incidents, and learning from them, need to be strengthened.
   - Providers should make sure that staff know how to report incidents, including those that meet the threshold for reporting to CQC as a statutory notification.
   - This involves promoting and encouraging a culture of safety and a 'just culture' approach to reporting incidents.
   - Sharing learning from incidents across different organisations will help to raise awareness of risks and actions to mitigate them.

5. Medicines for mental health conditions are sometimes managed poorly in acute hospital services; conversely, we found that people's physical health is not always well looked after in mental health settings.
   - More effective collaboration between providers can reduce disparity and improve people's physical and mental health outcomes wherever they receive care.

6. Local authorities and commissioners can provide leadership around medicines optimisation by working collaboratively with their providers. Holding regular forums with care providers can raise awareness of the importance of the safe and effective use of medicines. By collecting and sharing local knowledge and practice, and the challenges around medicines, joint action and improvement plans can be developed.

7. Although not all providers currently have access to electronic systems for prescribing and/or administration, those that do should consider the best way to use them to support safe use of medicines. For example, in mental health settings this could extend to linking information about prescribing and Mental Health Act requirements for a person, and provide better information to community teams administering people's medicines.

Our analysis also identified some areas of risk that are specific to each health and care sector:

- mental health services
- primary care services
- adult social care services
- acute hospital services.

In each chapter in this report, we suggest some actions that providers can consider implementing to reduce these risks in their own services.

What CQC will do

We expect all services to provide safe and effective care. Our inspections have highlighted some worrying examples where poor practice has resulted in people receiving poor or unsafe care.

- We will continue to look closely at the safety of medicines in all sectors and target our specialist medicines team inspectors where we identify high-risk services or situations.
- We are clear in our assessments that we expect providers to audit key issues and areas of risk and we will look at the results and the action the provider has taken to address them.
- We will continue our programme of engagement to help drive improvement in medicines optimisation across the health and social care landscape.

The online healthcare services sector continues to grow, enabling people to remotely receive treatment for a range of medical conditions. In many cases, when these providers issue a prescription, it is dispensed by a pharmacy and delivered directly to the patient. CQC registers and regulates medical prescribers as part of a healthcare service, while pharmacies and pharmacists are registered with and regulated by the General Pharmaceutical Council (GPhC).

All providers have obligations to protect the people who use their services, and their individual doctors and clinicians need to be aware of their professional responsibilities.

We will continue to work with our UK regulatory partners, including the GPhC, Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health and Social Care to ensure the safety of patients.

Introduction

Medicines are a commonly used intervention in health care to prevent, treat and manage illness, and are found in almost every health and social care setting. The use of medicines ranges from those prescribed by GPs, for example to treat long-term conditions such as diabetes and asthma, which can be administered in adult social care settings, to those medicines used in delivering complex chemotherapy regimes in acute hospital settings.

When used optimally, we know that medicines improve people's mental and physical health outcomes. Medicines optimisation is a well-established, patient-centred concept involving the safe and effective use of medicines to enable the best possible outcomes. It uses an evidence-based multidisciplinary approach, looking at the value that medicines deliver, making sure that they are both clinically and cost effective, and that people get the right choice of medicines, at the right time, with clinicians engaging them in the process.

NHS England states that the goal of medicines optimisation is to help patients to:

- improve their outcomes
- take their medicines correctly
- avoid taking unnecessary medicines
- reduce wastage of medicines
- and improve medicines safety.[2]

We know that not adhering to the principles of medicines optimisation can result in poorer outcomes for people and additional cost to the healthcare system. In our regulatory work, safety is our main concern in all health and care services and performance for the safe key question is poorest across all sectors. Within this, the safety of medicines is a long-established concern.

A recent study estimated that 237 million medication errors occur in England each year. Avoidable drug reactions and medication errors have an obvious human cost and are estimated to result in significant financial burden.[3]

In 2017, the World Health Organization launched its Third Global Patient Safety Challenge, *Medication Without Harm*, which aims to reduce severe avoidable medicines-related harm by 50% over the next five years.[4] The fourth objective of the challenge is to engage key stakeholders to raise awareness of the importance of safety in medicines.

In this report, we aim to support this objective by sharing what we have found through our regulatory work to highlight the common risks with the use of medicines in health and adult social care services, and what some providers have done to reduce these risks.

Our report, *Opening the door to change: NHS safety culture and the need for transformation,* found that too many people are being injured or suffering unnecessary harm because NHS staff are not supported by sufficient training, and because the complexity of the current patient safety system makes it difficult for staff to ensure that safety is an integral part of everything they do.[5] The report made recommendations to support a change in approach from all parts of the healthcare system.

How CQC inspects the use of medicines

During an inspection, we look at how the provider ensures the proper and safe use of medicines. This is in line with Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

To do this, we use the key lines of enquiry (KLOEs) in our assessment frameworks for healthcare settings and for adult social care settings. Each KLOE has a tailored subset of prompts, which help our inspectors to answer the five key questions: is the service safe, effective, caring, responsive and well-led? Some aspects of medicines optimisation are common across the different sectors and types of care services. The KLOE relating to medicines (S4: How does the provider ensure the proper and safe use of medicines, where the service is responsible?) has some common prompts that cover aspects such as:

- prescribing, administering and monitoring medicines safely and effectively
- making sure that staff are trained and competent in their roles with medicines
- reviewing people's medicines regularly and appropriately
- ordering, transporting, storing, and disposing of medicines safely and securely in ways that meet current and relevant regulations and guidance
- managing people's medicines well when their care is transferred between services
- ensuring that people's behaviour is not controlled by excessive or inappropriate use of medicines.

When we inspect, we focus on the most relevant aspects of medicines optimisation for that particular type of setting and provider. We publish relevant information in inspection reports, as well as details of any enforcement action we have taken where we have told providers to improve how they manage people's medicines.

CQC also receives statutory notifications from providers about incidents involving medicines that are known to have caused harm, or possibly death, and where there is abuse or allegation of abuse of an incident reported to or investigated by the police.

This report

This report brings together findings from CQC's regulatory activity in relation to incidents involving medicines in regulated health and adult social care services. It presents a cross-sector picture in England of the risks associated with medicines in the different types of services.

We carried out qualitative and quantitative analysis of over 200 inspection reports of NHS and independent providers where we knew there were medicines-related issues, 100 enforcement notices (such as Warning Notices) and 1,500 National Reporting and Learning System (NRLS) and statutory notifications from providers between 2015 and 2018. The analysis did not include providers of online consultations over the internet or by other remote means, as we have previously reported on these services.[6]

In this report we present the different aspects of how these risks appear in the separate chapters for: mental health services, primary care, adult social care and acute hospital services.

Our Medicines Optimisation team have highlighted some examples of good practice and innovative ways of working that relate to medicines. These examples are from published inspection reports for services in all sectors. We share these to enable all providers to learn and adapt this to their own services.

Based on the findings of our analysis, we also recommend specific actions that providers can take to reduce risks and improve outcomes for people.

Medicines in mental health services

CQC regulates both NHS and independent mental health services. We analysed 50 inspection reports, eight enforcement notices and a sample of 600 notifications to the National Reporting and Learning System (NRLS). The sample included all notifications of death and severe harm and represented adult, older adult, forensic, learning disabilities, substance misuse and child and adolescent mental health services (CAMHS) specialties.

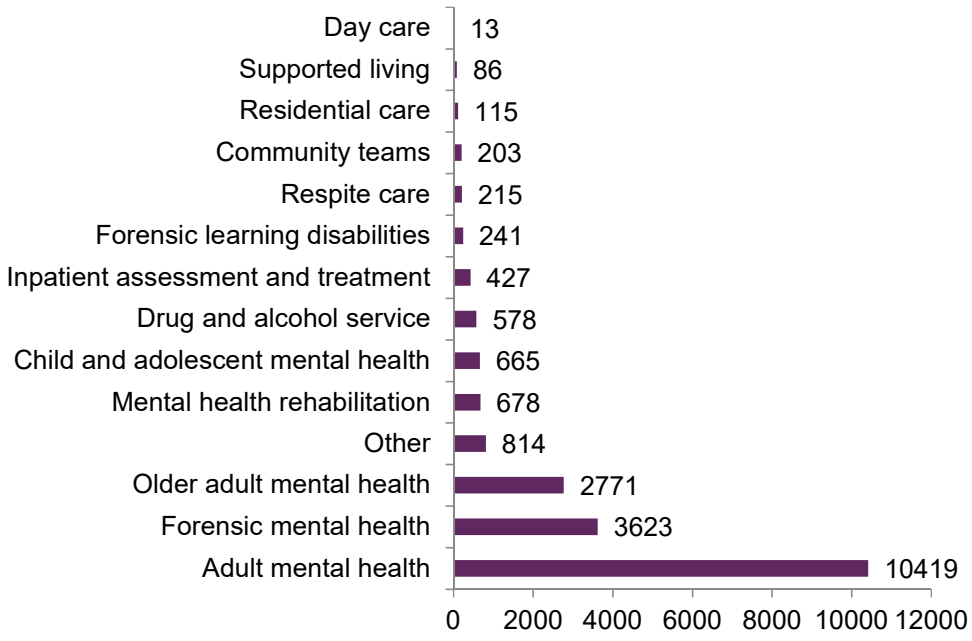
Key themes

In our analysis we identified several key themes pertinent to providers of mental health services, including rapid tranquillisation and the prescribing and monitoring of high-dose antipsychotics.

Incidents reported to the National Reporting and Learning System

NHS mental health trusts submitted a total of 20,865 medicines-related notifications of incidents from mental health and learning disability specialties to the National Reporting and Learning System (NRLS) in 2016/17. Most of these incidents resulted in low or no harm to people. One death was recorded as a result of a medicine incident, and moderate and severe harm accounted for 1.4% of all incidents. General deterioration in people's mental health was often reported as an outcome of incidents. The clear majority of incidents occurred in adult, older adult and forensic mental health inpatient services (figure 2).

Figure 2: Number of notifications to NRLS by specialty, 2016/17



Of the incidents in our sample of 600 NRLS notifications, two-thirds related to administration – largely medicines not being administered as prescribed. Most errors related to incorrect or missed doses, or wrong medicines. Examples include medicines given in the wrong form or at the wrong time, usually the result of human error, compounded by distractions and a lack of staff continuity.

Appropriate and safe rapid tranquillisation practices

Rapid tranquillisation (RT) is defined as "the use of medication by the parenteral route (i.e. injectable) where urgent sedation is needed."[7] Medicines must only be administered in this way if it is not possible or appropriate to give them orally.

Appropriate and safe RT practice is an important theme for providers of mental health services. It is essential to monitor patients' physical health, as there is a risk of adverse effects. Rapid tranquillisation was the largest single issue to emerge from the analysis of NHS trust inspection reports, but we also found it to be an issue for independent mental health services.

The main concerns raised around rapid tranquillisation were:

- lack of physical health monitoring, or records of monitoring, following administration, and lack of understanding among staff, with some not aware that what they were doing was classed as rapid tranquillisation and that there was a policy to follow
- under-reporting of incidents
- inappropriate use of rapid tranquillisation
- policies and guidance that were either out of date and/or lacked clarity.

Monitoring prescribing, and high-dose antipsychotic therapy

Monitoring patients is an essential component of the prescribing process. We found that people who were prescribed antipsychotic medicines were not always receiving the necessary health checks. A specific concern related to patients who were prescribed doses above the British National Formulary (BNF) recommended limit, often referred to as high-dose antipsychotic therapy (HDAT).

In some cases, patients were not monitored because there were no systems to support the process. In other cases, staff did not follow the trust's policy, sometimes because they were not trained, or because it was not clear who was responsible for the different aspects of monitoring people on HDAT. This was not just in NHS trusts, but extended to organisations in the wider healthcare system.

Monitoring was also an issue for people who were prescribed lithium and clozapine. In some cases, the required blood tests were not carried out in a timely way, which meant that prescriptions could not or should not have been collected. Prescribing, administration and monitoring of medicines for physical health conditions, such as insulin, was also a recurring theme in notifications.

Reviewing and monitoring prescribing practice was also a problem in substance misuse services. Our analysis found that some prescribers were re-issuing medicines without the recommended regular review, as well as not always linking to recovery plans when a patient relapsed.

Example of good practice: STOMP

Staff reviewed the effects of each patient's medication on their physical health according to guidance from NICE. The service had a STOMP lead. STOMP is a national project aimed at reducing the use of psychotropic medication for people with a learning disability or autism, or both. The lead devised STOMP care plans for the patients on their case load. They shared the positive outcomes for patients through reducing the use of psychotropic medication, which included increased mobility and a reduction in side-effects. The service facilitated regular STOMP meetings, which included a pharmacy overview.

Lincolnshire Partnership NHS Foundation Trust inspection evidence appendix, 2019

Consent to treatment and involvement in decisions

We found that issues with consent to treatment were common across providers in both the NHS and independent sector. Specifically, we identified problems with patients' treatment authorisation forms. Where people have the capacity to consent to treatment, staff use T2 forms, whereas T3 forms are used for people who lack capacity to consent. When completed correctly, these forms contain information about medicines that may be used as part of a patient's treatment plan. We found that important information about medicines was sometimes omitted, such as the maximum dose that can be prescribed. In some cases, there was also limited evidence of discussions between patients and their responsible clinicians about the medicines they were prescribed.

In some circumstances, staff are able to administer medicines to people covertly (without people's knowledge). This must be done on an individual basis, within the law and in the context of best practice frameworks. We found examples where this did not happen, and people were subject to a 'blanket restriction' where everyone is subject to the same treatment, even if it was not appropriate for them.

Example from inspection report: poor practice around covert administration

During one inspection, we found that staff were administering medicines covertly, without rationale, appropriate approval and regular review. This was considered routine practice on a particular ward. We also found that staff were crushing medicines that were not designed to be crushed, which could alter their clinical effectiveness. As well as this, the pestle and mortar used to crush medicines was not cleaned between each patient. This meant there was a risk of patients receiving traces of other patients' medicines, which could pose a problem if patients have allergies to medicines.

Example of good practice: involving patients in decisions about their care

When inspecting this substance misuse service, we found that staff gave information to patients to enable them to make informed choices about their medicines.

Patients told us they had the opportunity to discuss their medicines at their weekly ward round with their consultant psychiatrist, who listened to, and acted on their concerns. This meant that patients' medicines were optimised to treat their condition, while ensuring that any side-effects were minimised. We also saw that patients were well-supported towards recovery through a staged self-medication programme.

Turning point – Douglas House inspection report, 2016

Depot injections

Depot injections administer a slow-release, slow-acting form of medicines at regular, defined intervals (either weeks, or months). The medicine is injected by a clinician in a carrier liquid that releases it into the body slowly so that it lasts longer. The benefit of this is that people do not have to remember to take their medicine every day. However, our findings suggest that depot injections present one of the key risks for medicines in mental health services.

We found that depots were administered late, at the incorrect dose or to the wrong site on the body. Depot errors were more common in the community mental health services that we reviewed, often the result of poor communication between different healthcare providers. Issues arose between mental health teams and GP practices, where it was unclear who was responsible for administering the doses. Poor communication between teams when a person's care was transferred between services also meant that doses could be late or missed. Not maintaining clear, accurate records also played a part in depot errors, as mistakes in records were cited as a factor in the communication problems. Often categorised as 'moderate harm', the impact for patients included relapse or deterioration in their mental health.

Medicines for home leave

Notifications repeatedly reported incidents associated with people's medicines while they were on leave from inpatient care, at home. Mistakes were more common in child and adolescent services. For example, people's medicines were not always ready in time for their leave, were forgotten or not delivered. We also found an example where untrained staff were asked to dispense medicines for home leave. Mistakes were also made when staff prepared medicines in a hurry, which sometimes resulted in harm.

Patients themselves also made mistakes when taking their medicines while on home leave, often as a result of them, or their family or carers not having the appropriate knowledge or being given instructions from the service to help them understand how to take their medicines safely.

Some notifications described how the prescribed medicines resulted in adverse reactions or a deterioration in the patient's mental health. In some notifications, there were incidents that could have been avoided if staff had carried out medicines reconciliation.*

Example from a notification report: harm to a patient

In one notification, staff had dispensed incorrect emergency medicines for a young patient to take home with them. They felt under pressure to dispense, and that they could not wait for the usual medication to come from pharmacy. When the members of staff found that the patient's usual liquid medicine was missing, they found medicine in sachet form in the medicine cupboard and dispensed this as an alternative. However, the next day, the patient came back to the hospital complaining of abdominal pain and loose stools, and had an episode of fainting and low blood pressure.

After staff identified the error, the stock of medicine was removed from the cupboard and all staff, the patient and their family received information about the incident.

Clinical input from pharmacy professionals

Inspection reports highlighted the valuable input of pharmacy staff and how they help to ensure safe practices around medicines. However, limited capacity of small teams and insufficient pharmacy resource was a consistent theme in inspection reports analysed for NHS mental health trusts. This meant that pharmacists were not participating in multidisciplinary team meetings and that in some trusts, there was no pharmacy input or support into high-risk clinical areas. In some cases, community-based mental health teams had no medicines management support allocated to them.

Example of good practice: communication for patients and staff

During an inspection, we noted that pharmacy technicians had written advice on a standard pharmacy advice note and attached this to the front of a patient's prescription chart. This ensured that ward staff would see this important information. The pharmacy department also provided a monthly newsletter for clinical staff, which promoted safe and effective use of medicines. The trust's pharmacy team had also developed a bespoke monitoring tool for the side effects of anti-psychotics, which staff used on the wards.

Dudley and Walsall Mental Health Partnership Trust inspection report, 2017

* Medicines reconciliation is the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies and documenting any changes for a complete list of medicines, accurately communicated. 'Medicines' includes over-the-counter or complementary medicines. The process varies depending on the care setting.

Medicines reconciliation is important to ensure that people are prescribed and/or administered the correct medicines. In some places, medicines reconciliation wasn't taking place at all, in others it wasn't completed within the recommended 24 hours of admission. This could be directly linked to the lack of pharmacy resources.

We noted that some providers had improved in response to concerns about inconsistent medicines optimisation following a previous inspection. They did this by increasing the capacity of their pharmacy teams with additional pharmacists and pharmacy technicians, and training and deploying pharmacists as non-medical prescribers.

Some reports indicated that when the pharmacy team was integrated on the wards, it led to positive outcomes for people. In a pressurised environment, a shortage of staff and resources can contribute to medicines incidents. However, we have seen through inspections that even the simplest of changes can help to make improvements.

Example of good practice: integrated pharmacy services

When inspecting the trust, we found that each ward had dedicated pharmacy support. The input of the team helped ensure that prescribing practice met national guidance and good practice standards. The integration of pharmacy services on the wards also meant that staff could respond quickly to any issues around medication. In a case where this had happened, a patient's medication needed to be changed to liquid rather than tablet and the pharmacist was able to change the prescription quickly, which meant the patient did not miss any medication.

The trust had introduced a medicines optimisation needs assessment. Staff recorded details in a document that enabled them to:

- audit medicines reconciliation on admission
- check that side effects were monitored
- check the drug history
- check that relevant documentation and plans were in place
- check that specific medicines were monitored appropriately, including high dose antipsychotic, clozapine and lithium medication therapies.

Northumberland, Tyne and Wear NHS Foundation Trust inspection report, 2018

Administration errors and record keeping

The most common form of medicines errors was missed doses, across both NHS and independent mental health care providers. Reasons for these errors included: medicines being out-of-stock; poor records of administration, meaning it was unclear whether people had received their medicines; and inaccurate records. Miscommunication or transcribing errors also resulted in people either missing their medicine or receiving the wrong dose. Poor handover processes were also cited as a reason for these types of errors.

Some of the themes related to errors were linked to staffing pressures, lack of training and staff continuity.

Record keeping was also poor in relation to monitoring medicines, carrying out health checks, documentation regarding the Mental Health Act (for example, capacity to consent), the controlled drugs register, and people's allergies.

These types of errors meant that the doses of people's medicines needed to be amended (re-titration) to prevent the risk of overdose.

Example from inspection report: staffing issues

On an inspection, we learned that before the provider changed the staffing rota, the reliance on temporary staff to cover shifts resulted in inconsistent care and treatment for patients. This led to repeated errors in recording patients' medication and staff told inspectors that some agency staff were poor at sharing information. This put patients at risk because serious risks were not shared with senior staff. When we checked, we found that there was no process to ensure that an agency nurse was competent in the management and administration of medication, and they had not received an adequate induction to lead the shift.

Self-harm and intentional overdose

Overdose was a clear theme in incidents reported by mental health care providers. Occasionally, overdoses were accidental. More commonly, notifications described patients who had intentionally taken an overdose in an attempt to self-harm or to take their own lives. These were more common in community mental health services and sometimes involved alcohol and illegal drugs. We also saw examples where people had taken an overdose of medicines when they were on home leave from an inpatient setting. Other incidents were linked to poor practice at the service, such as poor storage of medicines, as the incidents involved medicines kept in stock or where old medicines had been hoarded in community settings.

Transfer of care

Several of the notifications we looked at occurred at the point when people were discharged or transferred to the care of another service. Unclear records of prescribing and administration was a common problem, which can lead to harm. For example, in some cases, transcribing was incorrect and administration was not always recorded accurately so it was unclear if people had taken their medicines.

Problems also arose when medicines records were not transferred, resulting in missed doses. Complex titration plans were sometimes unclear or the new care provider could not understand them. In other cases, GPs made prescribing errors as a direct result of incorrect discharge summaries. There were also examples where people went home without their medicines, either because they were not ready for discharge, they forgot about them, or the delivery of medicines to their home or next place of care did not happen.

Those who reported incidents articulated the need for better communication between wards and teams. The crucial role of medicines reconciliation was clear in notifications involving transfers of care; these highlighted where this was not being carried out robustly.

Example of good collaboration across sectors

At this mental health trust, we observed an innovative project designed to improve the wellbeing of people living with dementia in care homes. Trust staff were involved in training and supporting care home staff, as well as the design of a tool to measure the anticholinergic effect of a range of medicines. These medicines can have a negative effect on people with dementia, further impairing cognition. The information from this tool was then used to a support the review and reduction of prescriptions for these medicines.

South London and Maudsley NHS Foundation Trust inspection report, 2018

Reporting medicines incidents

In mental health care services, we had concerns about a low level of reporting incidents involving people missing their medicines (because of supply or prescribing issues) and rapid tranquillisation. In the inspection reports analysed, inspectors attributed low reporting rates to a lack of knowledge among staff around what constitutes a medicines incident. This was often the case for rapid tranquillisation, which supports the view that the policies for this are unclear. In one NHS trust, staff attributed their low reporting rate to "a 'fear culture' around medicine incidents, which discouraged individuals from reporting." Lack of learning from incidents was also a consistent theme from our analysis of inspection reports.

We have seen examples of incident reporting systems that enable staff to track the development and outcome of their incident report in real time. This approach strengthens supervision in pharmacy departments, as it enables staff to identify learning needs and strengthens a culture of 'just blame'.

Medication safety officers

The role of medication safety officer (MSO) was created in 2014 in response to a Patient Safety Alert from NHS England, which called for large healthcare organisations to have a named person responsible for medicines and medical device safety. The role is central to working towards safer use of medicines in a range of different organisations, including mental health trusts. It is essential to build capacity into the system to ensure this role can be well established. Key responsibilities for MSOs include ownership of reporting medicines incidents, including raising reporting rates and promoting learning. MSOs work as a member of the medication safety committees and are active in a National Medication Safety Network.

Example of the medication safety officer role in practice

Medicines incidents at the trust were reported through an electronic recording system. Two senior members of the pharmacy team were MSOs. With lead pharmacists, the MSOs automatically received and reviewed notifications of medicine incidents. A multi-disciplinary team at the medicines safety and governance group reviewed these incidents and acted on them.

Oxford Health NHS Foundation Trust inspection report, 2018

Governance and risk management

The analysis of inspection reports showed that providers were not always carrying out regular and consistent audits to monitor and improve quality. This was particularly the case for rapid tranquillisation. When audits identified issues, they were not always followed up with good quality action plans that included targets and timeframes to respond effectively.

Audits were one aspect of a wider theme around identifying and learning from problems. There were similar issues with the use of risk registers. Although there were some concerns with medication risks not being identified, the bigger problem was that in cases where risks were identified, not enough learning or strategies were implemented to minimise the risks.

In substance misuse services, poor security for prescription pads, and lost or missing prescriptions, mainly for methadone, were reported, which led to patients missing doses.

Example of good governance and risk management

The trust had an internal audit programme for pharmacy management, which included checks on controlled drug audits and pharmacist intervention audits. The majority of ward and unit-based audits were successfully transferred with wards themselves completing them rather than pharmacy, with pharmacy retaining an oversight of the audits. This is outstanding practice for wards to have ownership of the first-level audits; in most trusts this is pharmacy-led at this level.

The medicines optimisation team was represented on the medicines optimisation committee and clinical effectiveness group. The chief pharmacists were line managed by the medical director, which enabled communication directly to the board.

Sussex Partnership Trust inspection report, 2018

Example of good governance and risk management

The importance of the safety of medicines was effectively integrated into this trust's governance structure. The medical director was the lead director responsible for medicines optimisation and pharmaceutical services. The trust also had a medicines management committee, which reported to the performance and quality assurance committee. The trust gained assurance through monitoring performance targets and carrying out audits. A safer use of medicines group reviewed medicines incidents and identified the learning from them. These were included in the pharmacy department's regular newsletter for staff, which also included clinical guidance.

Oxleas NHS Foundation Trust inspection report, 2019

Actions for mental health care providers

Based on the risks identified with medicines use in mental health care settings, we encourage providers to take the following action to ensure that medicines are managed safely:

1. Procedures for rapid tranquillisation by injection need to be strengthened. Importantly, staff need to be trained to recognise the need for this, to deliver rapid tranquillisation safely and to monitor people's physical health appropriately.

2. There is a need to focus on improving how high doses of antipsychotic medicines are prescribed and monitored.

3. Audit processes and governance structures should enable staff to challenge prescribing and administration that is not in line with national guidance, or a person's consent to treatment.

4. Good physical health monitoring, including the side-effects and effectiveness of the prescribed medicines, must be considered central to everyday practice.

5. The role of medication safety officer is crucial to the oversight and responsibility for safety in mental health settings. This role should have higher recognition at board level. By providing updates on areas of concern from a medicines safety officer, a trust's board can be aware of issues and track progress on medicines safety.

Medicines in primary care services

CQC regulates NHS and independent primary medical care services, including: GP practices, out-of-hours or mobile doctor services, walk-in centres, minor injuries units, urgent care centres, and dental practices. We also regulate independent providers offering online-only consultations with a clinician, but did not include this type of provider in the analysis, as we published findings relating to medicines in these services in our report of March 2018.[6] Our inspections focus on the evidence-based use of medicines, hypnotics and antimicrobial stewardship.

Key themes

In our analysis, we identified several key themes pertinent to providers of primary care services, which included prescribing, monitoring and reviewing high-risk medicines and managing emergency medicines.

These findings are based on an analysis of 30 inspection reports from a mix of services as described above, 30 enforcement notices and 34 statutory notifications to CQC that involved a medicines concern submitted between 1 April 2017 and 31 March 2018.

In the analysis of risks in primary care services, the widest range of issues relating to medicines were found in GP practices, most likely because of their diverse scope of practice. Every year, NHS GPs carry out over 300 million consultations[8] and over a billion prescription items are dispensed in the community.[9] Issues in dental practices, urgent care centres and out-of-hours GP services were slightly less wide-ranging, and mostly focused around administration, recording and storage issues.

Notifications of medicines incidents

Between 1 April 2017 and 31 March 2018, we received 278 statutory notifications of serious injury and abuse, of which, 34 related to a medicines incident. The level of incidents reported in primary medical services was low compared with other sectors, and few related to incidents involving medicines. The majority of these related to GP practices. Analysis of the notifications indicated risks such as staff administering incorrect doses, wrong medicines and failing to give medicines altogether.

Prescribing, monitoring and reviewing high-risk medicines

A key theme identified in inspection reports was the importance of appropriately monitoring and reviewing patients' prescriptions for high-risk medicines. Some medicines are considered 'high-risk' because of the possible adverse side-effects, so patients require frequent tests (blood or other tests) and reviews, and doses may need to be adjusted to ensure they do not cause harm. Common examples of high-risk medicines include warfarin, lithium, methotrexate, azathioprine and leflunomide. Inspection reports gave examples of how providers did not always meet these requirements.

Infrequent medicine reviews led to problems with repeat prescriptions, as providers continued to authorise prescriptions of high-risk medicines, putting people at risk of harm. The General Medical Council's guidance *Good practice in Prescribing and Managing Medicines and Devices* states the need to ensure appropriate monitoring when people are prescribed medicines.[10] In practice, this would extend to ensuring that the appropriate monitoring and review has taken place to ensure that it is safe to issue a repeat prescription.

We saw many examples where this did not happen.

Example from inspection report: poor monitoring of high-risk medicines

On the inspection of a GP surgery, we saw that policies did not always match practice. For example, the policy stated that methotrexate (a medicine used to treat a range of conditions, including arthritis) would only be prescribed with regular blood tests. Regular blood tests are important to ensure that patients do not experience side-effects that can result in harm. When inspectors checked records at this practice, they found that blood tests were either not carried out consistently or the results checked before repeat prescriptions were authorised. Inspectors also found inconsistencies in prescribing three other high-risk medicines, including for one patient who had not had blood tests recorded for 12 months and others who had no blood tests recorded at all.

This theme was also reflected in enforcement notices, where people had been issued prescriptions for high-risk medicines, such as azathioprine, without being monitored appropriately.

We found that repeat medicines were not always reviewed at appropriate intervals before prescriptions were issued to patients. Our analysis also indicated that prescribing was not always correct and that lack of information on medicines resulted in patients taking them incorrectly. Absence of appropriate audit meant that poor prescribing practices were not always challenged. We also saw examples where patients had not been informed that they had been prescribed unlicensed medicines, and the associated risks of this.

Example of improved medicines reviews in a GP practice

Medicines reviews are a key part of medicines optimisation, ensuring that people can achieve the maximum benefit from their medicines, with the minimum side effects.

At a follow-up inspection of the practice, we found it had improved the process for medicines reviews. To make sure that patients had a regular review of their medicines, the practice had implemented a new one-stop system, which centred around the month of the patient's birthday. Part of the initial review was carried out by the nursing team followed by a medicine review with a GP. This new system was designed to reduce the need for multiple visits and appointments.

Sleaford Medical Group inspection report, 2018

Practices with effective systems that monitor high-risk medicines well often have good administrative support, together with timely input from clinicians. For example, they carry out regular searches on electronic prescribing systems to proactively identify patients who are prescribed high-risk medicines, and when they need a review, including any that may be overdue and when their blood (or other) tests are due. Software packages can help to mitigate risk and improve safety by highlighting relevant factors.

Examples of using IT systems to promote safe prescribing

The practice had a medicines management team, which was a sub-team within the quality and performance team. They ensured that prescribing at the practice was clinically safe and budget-aware by using the IT system to run regular searches specific to prescribing at the practice. For example, the GPs received a quarterly update on their use of antibiotic medicines.

Wellway Medical Group inspection report, 2016

This practice had a comprehensive system to keep patients safe when taking high-risk medicines such as warfarin, methotrexate and other disease modifying drugs, which included regular monitoring in accordance with national guidance. The prescribing team ensured that when the prescription was ready to be signed, they printed off relevant monitoring checks, such as the patient's latest blood test result. The IT system alerted staff when a patient required a blood test and the patient was able to use the drop-in nursing service to have their test while still in the practice. One of the GP partners also carried out a monthly review of these patients as an additional check.

Frome Medical Practice inspection report, 2015

Patients were harmed because prescribers had not checked their medical history and notes, and had prescribed or administered a medicine that led to harm – particularly in the case of allergies. For example, in a dental surgery a patient was given anaesthetic that they were allergic to, even though this had previously been documented. This caused an allergic reaction that resulted in the patient being admitted to hospital.

Most prescribing in general practice is good, and we also saw examples of positive practice that helped to optimise people's medicines. This included using deprescribing tools to discontinue unnecessary medicines with the aim of improving outcomes of people taking multiple medicines. We saw examples where GPs visited care homes to review people's medicines, with positive outcomes recorded.

Example of effective GP input in care homes

GPs at the practice carried out a weekly ward round at the local hospital and regularly reviewed all the care plans for patients who were registered with the practice and who resided in the local nursing home. Staff at the nursing home confirmed that care plans are individualised and regularly reviewed, and that medicines were also reviewed regularly with a pharmacist, the GP, the nursing home team and the patient. This contributed to a significant decrease in hospital admissions.

Combe Down Surgery inspection report, 2016

Pharmacists in GP practices are sometimes deployed to undertake medicines reviews for patients who have recently been discharged from another healthcare provider. Some practices give the patient a print-out of their monitoring results along with an explanation of the results, information about their medicines and why they need to take them, as well as lifestyle advice. Others add specific information about people's medicines to the prescription form, so that this is included on the pharmacy dispensing label. This can be helpful to some patients who take multiple medicines.

Example of pharmacist involvement in GP practices

This practice had developed the role of lead pharmacist, which had a positive outcome for patients and promoted safer practice and management of medicines across each of the practice locations.

For example, the medicines management team carried out regular medicines audits to ensure prescribing was in line with best practice guidelines for safe prescribing. An administrative team also worked with the practice pharmacist to review patients who had recently been discharged from hospital, to ensure that they were taking the correct medicines, and that the practice's records were up to date.

Brownlow Group Practice inspection report, 2017

Example of optimising prescribing for older people

This GP practice used national guidance and findings to improve services. For example, NICE KTT7 highlights the potential harm and limited benefits of prescribing low-dose antipsychotics to treat dementia. In response, the practice started to implement the STOPP protocol (Screening Tool of Older Persons' potentially inappropriate prescriptions). It is a validated tool to reduce risk associated with polypharmacy.

The practice implemented this protocol in all three care homes in the practice area, which resulted in tangible benefits for patients. In the 12 months after implementing, prescribing of low-dose antipsychotics had almost halved and continues to be monitored.

Springbank Surgery, York inspection report, 2016

Emergency medicines

In the analysis, we found that management of emergency medicines was sometimes poor, including oxygen and those medicines in vehicles as part of out-of-hours and urgent care services. In these cases, we found that emergency medicines were:

- not available
- out of date
- stored inappropriately.

When medicines were not available, this was either because of poor stock control, or because providers did not make a risk assessment of what medicines they needed to keep in relation to the activities carried out at the location. Having out-of-date medicines in emergency kits puts people at risk as the effectiveness of medicines may be reduced.

The issues with emergency medicines can be linked to a lack of procedures or systems, and an ineffective system of checks.

Storing emergency medicines inappropriately was also a concern, mainly because it resulted in medicines being inaccessible. In some cases, emergency medicines were not stored on site, or were accessible only through a code that not all staff knew, which could create delays to treatment in an emergency. It is also essential that relevant staff are trained in the use of emergency medicines, including the treatment of anaphylaxis. CQC's website provides useful information for providers about emergency medicines in general practice and dental services.

Example of good practice in emergency medicines for sepsis

A GP at the practice had attended a one-day workshop on managing sepsis in primary care. By reflecting on cases that had happened at the practice, they led the implementation of a system, process and training programme to keep patients safe. A specific 'sepsis grab bag' was available as well as the emergency equipment trolley and emergency visit bag to ensure staff could access all the correct equipment and medicines to treat sepsis easily and without delay.

Harleston Medical Practice inspection report, 2019

Controlled drugs

Some providers did not keep accurate records in a controlled drugs register, which meant that they did not comply with relevant legislation.

We also found that providers did not always carry out regular balance checks of controlled drugs, which increased the risk of a delay in identifying discrepancies of stock control, and is not in line with good practice guidance.

Denaturing kits for disposing of controlled drugs were not always available. This was sometimes because the provider was unaware of the regulations, which suggests a lack of training may be a factor.

Cold chain and vaccines

Many vaccines need to be stored between 2 and 8ºC. Storage outside the manufacturer's recommended temperature ranges could result in vaccines being rendered inactive. The potential consequence is that if administered to a patient, the vaccine may not be effective. We found that providers did not always store vaccines correctly, in line with guidance from Public Health England. There is also guidance on this on CQC's website.

Medicines and device safety alerts

Safety alerts about medicines and devices, such as those from the Medicines and Healthcare products Regulatory Agency (MHRA), are a crucial source of information on the safety of individual products. Other alerts may also detail required changes to clinical advice. Failure to acknowledge and act on these could result in unsafe prescribing, or people being supplied with, or administered medicines that are not safe to use. Ineffective systems to act on these types of alerts put people at risk of harm across the different primary medical service types.

We found that some GP practices were only able to show evidence of part of this process, such as receiving the alert, but had not taken any action in response. Additionally, we also found that some GP practices failed to identify people who needed follow-up in response to these alerts.

Administration of medicines

Although administering medicines to patients in primary medical services may not be as common a task as in other settings such as in hospitals or care homes, we still identified areas of risk. For example, we found that medicines had been administered to the wrong people, with presumed identity sometimes a factor, as the following example from a notification shows.

Example from a notification: anaesthetic administration incident in a dental surgery

Two patients were booked in for treatment with different dentists; both patients had the same surname. When the nurse from surgery room 1 called their patient from the waiting room, one of the patients was in the toilet, so the other patient went with the surgery room 1 nurse. However, the nurse did not realise that it was the wrong patient.

The patient's name was confirmed in surgery room 1, where anaesthetic was injected and an occlusal cavity made in their tooth. The nurse from surgery room 2 then went to call her patient in the waiting room. Once in surgery room 2, the dentist recognised that this was not the right patient.

This type of error could be prevented by making the appropriate checks, which the provider should have in place. Other risks around administering medicines extended to vaccinations in the wrong arm or site, and failing to replace needles in a systematic way. Some of these cases resulted in avoidable injuries to patients. In one instance, the inaccurate injection of local anaesthetic during a dental procedure resulted in ongoing nerve damage.

Conscious sedation for dental surgery

Conscious sedation is a process in which a combination of medicines is used to help a patient to relax (a sedative) and to block pain (an anaesthetic). When used during dental procedures the patient remains awake during the whole procedure. The Intercollegiate Advisory Committee on Sedation in Dentistry has published best practice guidance for this.[11]

We found some examples of poor practice in inspection reports, such as poor governance, lack of staff competency, lack of personalised prescribing and administration, and poorly maintained equipment.

Example of poor practice in conscious sedation

At one inspection, we found a range of problems in how the practice carried out sedation, which put patients at risk of harm. Medicines for sedation were administered at the same dose to all patients, regardless of age or weight. Staff who delivered sedation did not have the appropriate qualifications, training, competence, skills and experience to do so safely. Inspectors also found that there was little documented evidence of discussion with patients about other strategies to reduce anxiety, pre-operative checks, monitoring of patients' vital signs, and post-operative checks before patients left the service. There was also no evidence that the anaesthetic machine had been maintained, serviced or calibrated to ensure it was safe to use.

Prescription stationery

The NHS Counter Fraud Authority has issued guidance on the security of prescription stationery.[12] We found that prescription stationery was not always stored in line with this guidance.

In some cases, inspectors found blank prescription forms left loose on top of printers and worktops. There were not always systems to monitor the serial numbers of issued prescriptions and in one instance these were stamped and signed before being written. This does not safeguard against the potential misuse of prescription stationery.

Patient group directions

Patient group directions (PGDs) are written instructions that allow specified health professionals to supply and/or administer a medicine directly to a patient with an identified clinical condition without the need for a prescription or an instruction from a prescriber. PGDs cover groups of patients who may not be individually identified before they present for treatment.

Our analysis identified that not all staff using PGDs had been authorised to do so. The health professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD, such as when nurses administer vaccines to patients. It is essential that those working with PGDs are trained, competent and agree to practise within the requirements of the PGD. This means that people will receive medicines only if it is safe and appropriate for them to do so. Our website provides useful information for providers about PGDs.

Training

Our analysis of inspection reports found that not all staff who administered, prescribed, reviewed and dispensed medicines were competent to do so or supervised appropriately. There were examples that suggested nurses or health care assistants had not received specific up-to-date training to administer or authorise certain treatments safely and effectively for certain medical conditions. In one example, nurses and reception staff in a dental surgery provided antibiotics and pain relief for patients when the dentist was off site.

It is also important that staff understand how to correctly record patient reviews on electronic systems. This is especially relevant to the differences between medicines reviews and other reviews so that they do not inadvertently record that a medicines review has been undertaken, when it has not.

Example of training and support for a prescribing team

One of the GP partners at the practice worked with a group of reception and administration staff to provide additional training to form a prescribing team. Staff were provided with a detailed medicines management handbook and standard operating procedures to follow. The prescribing team was overseen by one of the lead GPs.

Since establishing the team, the practice noted a reduced workload for GPs, better communication and improvements in following up patients with long-term conditions.

Dr Wilkinson and Partners inspection evidence, 2019

Recording and learning from medicines incidents

In cases where we took enforcement action, the key themes described in enforcement notices included not recording medicines incidents properly, failing to show evidence of actions taken in response, and not sharing learning to prevent them happening again.

One example involved a provider that had failed to document eight significant events, which included medicines going missing and being administered to the wrong people. In this particular case, there was a failure to record, investigate and review errors, and it demonstrated a lack of understanding. This gives an insight into lack of awareness of how such cases should be recorded and suggested that more effective training may be needed.

Examples of learning from medicines incidents

In this practice, lessons were learned and shared widely in response to a significant event where a patient was prescribed medicines above the recommended dose. The practice carried out a clinical audit of repeat opioid prescriptions, revised the policy and devised a controlled drug checklist, which was shared with the local clinical commissioning group at a medicines management meeting.

Dr Langridge and Partners inspection report, 2016

Following a significant event, this practice carried out an audit on the use of monitored dosage systems for patients who take multiple medicines, to ensure that they were appropriate for the patients. This led to a 14.5% reduction in the use of these systems by patients for whom they may have been unsafe.

Caldbeck Surgery inspection report, 2018

Actions for primary care providers

Based on the risks identified with medicines use in primary medical settings, we encourage providers to take the following action to ensure that medicines are managed safely:

1. A programme of monitoring helps to ensure safe, high-quality prescribing by all prescribers. This should include reviewing practice processes to monitor medicines, particularly high-risk medicines, regularly auditing adherence to national guidance such as NICE guidelines, and updating prescribing following national patient safety alerts. Using prescribing software effectively can facilitate these activities.

2. Internal systems and processes need to enable accurate and timely changes to prescriptions for example, when patients are discharged from hospital and after regular medicines reviews for patients with long-term conditions.

3. It is important to make a comprehensive assessment of what constitutes an appropriate stock of emergency medicines for your location. Stocks of medicines on site and those for home visits need to be checked regularly to ensure they are in date and readily accessible in an emergency.

4. There is great benefit in GP practices working more closely with pharmacy professionals to focus on medicines optimisation, as using their expertise can reduce pressure on their practice. All primary care providers can benefit from the skill mix of community pharmacists, practice pharmacists and pharmacy technicians.

5. To learn from medicines incidents in general practice, they need to be reported consistently with statutory notifications made when appropriate. Having a good process to review and discuss significant events helps people to understand and share learning.

Medicines in adult social care

Over 20,000 adult social care services are registered with CQC, including care homes (with or without nursing care), home care services and shared lives schemes. Each type of service supports people with their medicines differently, depending on their needs. For example, in a domiciliary home care setting, this could involve providing medicines support for a person who has several long-term conditions, whereas care homes that provide nursing care may well deliver complex end of life care involving many medicines with specialised equipment, such as syringe pumps.

Key themes

In our analysis we identified several key themes pertinent to providers of adult social care, which included errors in medicines administration and record keeping, and managing 'when required' (PRN) medicines.*

These findings are based on an analysis of 55 inspection reports (including a mix of care homes, care homes with nursing and domiciliary home care services for older people and people with a learning disability), 50 enforcement notices and 405 statutory notifications that CQC received.

Notifications of medicines incidents

CQC received at least 5,059 medicines-related statutory notifications from adult social care locations between 1 April 2017 and 31 March 2018. We analysed a sample of 405 statutory notifications of serious injury and abuse that mentioned medicines. As well as errors with administration and 'when required' medicines, incidents included intentional overdose by individuals and errors linked to what community pharmacies had supplied to the care services.

Medicines administration errors

Administering an incorrect dose of medication was the most commonly-reported error in statutory notifications from adult social care services. This sometimes happened when members of staff did not check the medicines administration record (MAR) chart before administering the medicine. A number of incidents described staff administering a second dose of medicine in error, as the original dose had not been signed as being administered on the MAR chart.

People also missed doses of their medicines. This was sometimes a result of changes in the timing of medicines rounds in care homes, incomplete MAR charts or simply when staff had forgotten to administer. Sometimes people's medicines were not available for them to take; this was sometimes because staff had not ordered from the GP practice in time. However, we have also seen examples where GP practices do not supply prescriptions or medicines in a timely way.

* PRN is a Latin term that stands for 'pro re nata', which means 'as the thing is needed'.

Staffing levels were found to affect the timing of medicine administration. In the analysis of inspection reports for domiciliary care services, there were examples of staff arriving late to home visits and subsequently administering medicines at the wrong time.

When we identified that incorrect doses had been administered, these tended to be related to temporary changes to prescriptions that were implemented incorrectly. In our analysis of notifications, distractions were also cited as a cause of administration errors.

Transdermal patches (a medicated adhesive patch placed on the skin to deliver a specific dose of medicine through the skin and into the bloodstream) can be used to treat a range of medical conditions, from pain to Parkinson's disease. Administration errors relating to transdermal patches were common. People were placed at risk when patches had not been removed, when more than one was in place at the same time, when they were changed at incorrect intervals and when there was a failure to apply a patch at all.

Record keeping

The key contributing factor for administration errors was poor record keeping. We saw that MARs were either not completed, or not completed accurately. Discontinued medicines and incorrect strengths of medicines were sometimes found on MAR charts. These types of errors were more likely when MAR charts were hand-written or included additional hand-written medicines. Where MARs were hand-written in care homes, they had not always been second checked to ensure they were accurate.

Incomplete records of administration also applied to topical preparations and transdermal patches. Sometimes there weren't any corresponding records to indicate where or when the preparations were to be applied.

'When required' (PRN) medicines

Medicines designated as 'when required' (PRN) are those that people take only when they need them – such as pain relief, or asthma reliever inhalers. Staff in adult social care services did not always have enough information to ensure they were able to support people with PRN medicines. This was particularly the case with how and when they need to be administered, and when staff needed to ask for additional help, such as from a GP. Problems with PRN medicines were common across all service types.

PRN medicines are sometimes prescribed to support people who display behaviour described as challenging, such as anxiety or agitation. Medicines should not be used as a first line option. Our key lines of enquiry specifically direct our inspections to examine how well these types of medicines are managed, to ensure that people's behaviour is not being inappropriately controlled.

Analysis of inspection reports highlighted poor record-keeping in relation to PRN medicines, including those prescribed for agitation or behaviour described as challenging. We found examples where providers did not keep clear records of why medicines had been administered or what other actions had been taken to help de-escalate the situation before administering a medicine.

Example of poor practice in the use of PRN medicines

In our analysis, we found examples of how poor practices around PRN medicines could adversely affect people's quality of life. On one inspection, we saw that medicine protocols for pain relief were not person-centred and lacked sufficient detail for staff to know if the person needed their medicine. Where people could not communicate to let staff know if they were in pain, there were insufficient guidelines in place for staff to provide consistent treatment.

Analysis also highlighted examples where providers had thought carefully about how to ensure people's PRN medicines were managed safely, effectively and in a person-centred way.

Example of good practice in the use of psychotropic PRN medicines

At one care home, inspectors found that psychotropic medicines (medicines that affect how the brain works) were prescribed for use on a PRN basis. Although staff knew that they could use these medicines for symptoms of high anxiety or distress, the PRN protocols guided them in techniques to try with people before giving these medicines. This approach helped to reduce the over-use of these types of medicines.

One person said they had been reviewed and taken off medicines, "I finished taking tablets altogether". The registered manager explained to us that this was part of the organisation's goals for improvements. They were working within the STOMP (Stopping Over Medication of People with a Learning Disability, Autism or Both) initiative.

Dimensions East Anglia inspection report, 2017

Storage and disposal of medicines

Inspection reports described medicine trolleys being left unattended and medicines being stored in places that people could gain access to. This included thickening powder, which is used to thicken food and drink for people with swallowing difficulties. This is significant because there is a risk of death from asphyxiation if it is ingested accidentally.[13]

Storing medicines correctly helps to ensure that they remain fit for use, and that only the appropriate people can access them. We sometimes found that medicines were not stored at the correct temperature. When temperatures deviate from the safe range, staff need to take proportionate action to ensure that the medicines are still safe to use.

Covert administration and mental capacity

Covert administration is when medicines are administered in a disguised way, without the knowledge or consent of the person receiving them. As a result, the person is unknowingly taking a medicine.

Covert administration is only likely to be necessary or appropriate when a person actively refuses to take their medicines, which are deemed essential to their health and wellbeing. They must also have been judged not to have capacity to understand the consequences of their refusal as determined by the Mental Capacity Act 2005. Changing the format of medicines (such as crushing) so that they can be administered covertly can alter how they function. Staff in care homes need to take appropriate advice on this.

We found that providers did not always comply with the Mental Capacity Act, or act on guidance on how to alter medicines safely. This included medicines for older people and people with learning disabilities who were using services in care homes and from domiciliary care services. Mental capacity and best interest assessments had not always been carried out for people who were receiving medication covertly, and in some cases, we found no evidence of a best interests meeting or involvement of a pharmacist.

We also found some excellent examples of steps taken to reduce repeated refusals of medicines, which prevented the need for medicines to be administered covertly. There were also examples where staff had thought very carefully about how they could best support people they cared for when administering medicines. For example, it is important for people with Parkinson's to take medicines at regular intervals otherwise their mobility is reduced; but where they also have dementia, they may become distressed if they cannot remember taking it. In one example, staff in a care home developed a simple, person-centred reminder system based on a resident's love of animals. They used stickers to remind them that they had taken their medicines, which meant the resident was less distressed, missed fewer medicines and their Parkinson's was better managed, which led to an improvement in quality of life.

Staff training

NICE guidance states that staff should have an annual review of their skills and competency.[14, 15] We found that some providers were not carrying out competency assessments or regular competency checks. This meant they were unable to demonstrate that their staff were competent to administer medicines safely. Some staff reported that they had not received any formal medicines training. One inspection report in our analysis highlighted that several medicines incidents had occurred, and staff training and competency not been reviewed.

These concerns also extended to registered managers who did not maintain an up-to-date understanding of the latest legislation and best practice guidelines for medicines optimisation.

Policy, procedures and audit

NICE guidance recommends that providers should have a medicines policy, which is based on current legislation and the best available evidence. We found that some providers did not have a policy at all. In other cases, policies were not up to date and did not reflect best practice guidelines.

Inspectors also noted that staff did not always follow policies. For example, staff did not provide the right support for people to help with their medicines, in line with what was documented in care plans. In other cases, MAR charts were signed before people had received their medicines or were signed by staff who had not administered the medicines.

Other common themes in adult social care settings were ineffective systems to monitor quality and drive improvement. Many inspection reports mention that providers' audits did not identify the concerns and errors that inspectors saw, such as those outlined previously, which suggests poor auditing practice.

We did find examples of providers that could demonstrate a positive impact by emphasising the safe use of medicines, such as having a designated person or 'medicine champion' to take ownership of all aspects of medicines optimisation in a service.

Self-administration of medicines

People should be able to choose to look after and take their own medicines, unless a risk assessment suggests otherwise.[16]

We found examples of people having self-administered the wrong medicine in error as well as examples where family carers had made administration errors. Notifications from some domiciliary care services suggested that the responsibility for who administers medicines was unclear, which meant there was confusion if the person or their family had already administered the medicine.

A considerable number of statutory notifications related to intentional overdose, although this was specific to care homes caring for young adults with a mental health condition. In most cases, people self-administered an overdose of over-the-counter medicine, particularly paracetamol, which they had obtained off-site. In some instances, these overdoses also involved alcohol or people's own prescription medicines.

Example of promoting self-administration of medicines

This service was motivated to work with people to help them become fully independent in managing their medicines. We found an example of a person who was unable to manage their own medicines when they first moved to the service and relied heavily on staff to support them. This person's risk assessment was updated monthly and provided a detailed audit trail of how the staff team encouraged and supported them to reach their goal of managing and administering their own medicines.

When we spoke to the person, they said, "When I first moved here I had no confidence at all, I didn't understand why I needed to take my meds, but the staff have worked with me and educated me to why I need my meds. I am now in the position where I am confident to manage my own meds, this has been a massive achievement for me."

Mary and Joseph House inspection report, 2016

Transfer of care

Throughout the analysis, we found that issues around transfer of care were often related to the dynamic between adult social care and secondary care services.

Notifications from care homes described people being discharged from hospital with missing medicines and amended prescriptions, which were poorly communicated. We identified that some medicines errors in care homes happened because of a disparity in the medicines that were supplied and the information in the discharge summary. In some cases, care home staff also misinterpreted instructions on discharge summaries.

Actions that hospitals requested regarding changes to people's medicines were not always undertaken. We also identified how medicines were managed between a person's own home and their family, carers or day centres as an area of risk. Examples showed that this led to missed doses as a result of people's medicines being forgotten or going missing.

Example of promoting safety at transfer of care

The nursing home provided support in line with the enhanced models of care, which were piloted through NHS England's vanguards initiative. The home had introduced the local authority's integrated red bag scheme. These bags included ready prepared documentation about a person's medical needs, their prescribed medicines, Do Not Attempt Cardio-pulmonary Resuscitation (DNAR) status, and information relating to their mental capacity. This meant that if and when required, this information was ready to be passed on immediately to ambulance crews and medical staff to help them determine the treatment a person needed if they needed to be admitted to hospital in an emergency.

The White House Nursing Home Limited, Surrey inspection report, 2018

Actions for adult social care providers

Based on the risks identified with medicines use in adult social care settings, we encourage providers to take the following action to ensure that medicines are managed safely:

1. Adopting best practice guidance will improve safety and outcomes for people, specifically NICE guidance for managing medicines in care homes (SC1) and in the community (NG67). As well as care providers, this is also relevant for commissioners, GPs, pharmacy professionals and healthcare professionals.

2. Providers of adult social care should consider having an attached or named pharmacist to support staff with issues around the use of medicines. More specifically, closer working can help to implement guidance and training on administering medicines covertly, 'when required' (PRN) medicines, and those required as part of end of life care.

3. Training staff and assessing their competency in handling and administering medicines should be an ongoing priority. It should be clear who is responsible for training staff about medicines and that this training is kept up to date.

4. It should be made clear who has ongoing clinical responsibility and oversight of medicines. Expectations around responsibility should be clear in the contracts that local authorities and CCG commissioners issue to providers.

5. The new role of nursing associate may help to ease pressure on nursing staff in care homes, but providers must make sure that they are deployed safely and effectively, with the appropriate competencies and supervision when their work involves medicines.

6. Adopting NHS England initiatives such as Enhanced Health in Care Homes and Medicines Optimisation in Care Homes can help drive improvement by involving pharmacists and providing joined-up primary, community and secondary care to residents of care and nursing homes.

Medicines in acute hospital services

CQC regulates both NHS and independent acute hospital services. Clinical specialism and the use of medicines is especially broad in acute hospitals and can include complex combinations of medicines for chemotherapy and surgery, for very unwell babies and young children, and for people in intensive care. The use of high-risk medicines, such as anticoagulants (medicines used to treat or prevent blood clots) is also significant in acute hospital services.

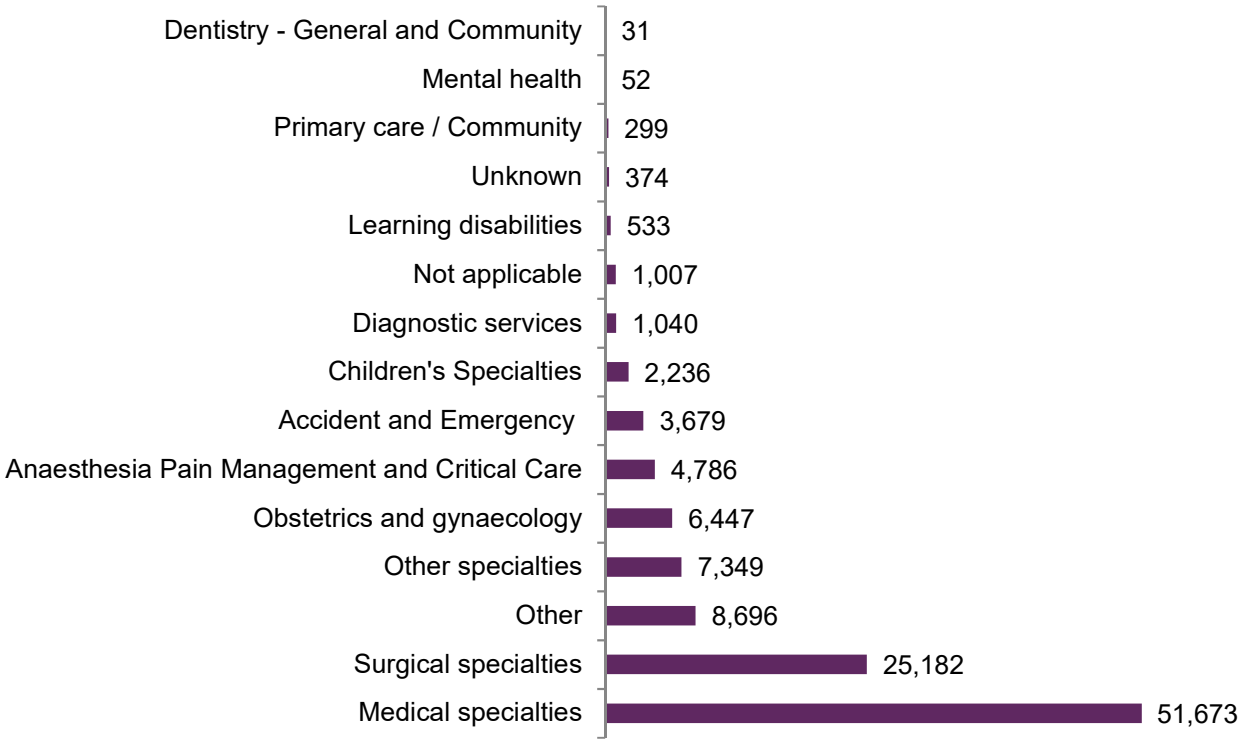
Key themes

In our analysis we identified several key themes pertinent to providers of acute hospital services, which included prescribing errors, capacity of pharmacy services and high-risk medicines such as anticoagulants and insulin. This is based on analysis of 80 inspection reports, 600 National Reporting and Learning System (NRLS) notifications and 17 enforcement notices.

Notifications of medicines incidents

Between 1 April 2017 and 31 March 2018, inpatient specialties in NHS acute trusts submitted 113,384 notifications from 15 inpatient specialties to NRLS categorised as a medicines incident (figure 3). The majority of these resulted in low or no harm to the patient. On average, NHS trusts reported 9,448 medicines incidents each month (311 each day) during this period. At least 11% of these resulted in some degree of harm to patients, 35 of which resulted in death.

Figure 3: Number of NRLS notifications by specialty 1 April 2017 to 31 March 2018



Many incidents related to prescribing and administration errors. The outcomes of these included injury, adverse reactions, increased length of stay in hospital, cancelled surgery, delayed discharge and re-admission. The risk factors for medicines errors included poor governance and record-keeping, staffing, equipment and ineffective communication.

Prescribing and administration errors

The single most common theme from our analysis of notifications was prescribing errors. Notifications consistently reported incidents where prescribers had made an error that resulted in patients receiving the wrong medicine, the wrong dose, medicines that interact with each another, or no medicines at all. Transcribing errors were often cited as a cause. Other causes included allergies not recorded on prescription charts, which resulted in people being given medicines they were allergic to, and body mass incorrectly estimated, or not considered by prescribers at all. The consequences of this ranged from people receiving toxic to suboptimal doses.

People did not always have their usual prescribed medicines with them when they were admitted to hospital, particularly when admitted as an emergency. Common examples were medicines for conditions such as epilepsy, diabetes and Parkinson's disease. This places patients at increased risk of adverse events – such as seizures and poor blood sugar control.

Poor writing or directions on prescription charts was sometimes compounded by no signature from the prescriber, which meant that nursing staff either could not administer or administered medicines incorrectly.

However, some providers introduced initiatives to minimise administration errors, as the following example shows.

Example of using pharmacists to administer medicines on the ward

As well as the ward nurses on Gwynne Holford Ward, the trust employed a pharmacist who had been trained in medicines administration. The pharmacist spent time talking to patients about their medicines when they administered them.

This reduced administration errors but also resulted in patients having better knowledge and access to information about their medicines to help them make decisions about their treatment; they were therefore more prepared and confident to start to self-administer their medicines.

St George's University Hospitals NHS Foundation Trust

We also found some good examples of using both simple, practical measures and more advanced technology to reduce medicines administration errors in acute trusts.

Example of a simple way of reducing missed doses of soluble medicines

When inspecting this trust, we saw that wards were using a green cup to highlight where patients were taking soluble medicines, which was a suggestion from a student nurse. All soluble medicines were prepared in green cups. This prevented other staff on the ward inadvertently throwing medicines away, when a patient had not taken the full dose.

West Suffolk NHS Foundation Trust, inspection report, 2018

Example of timely medicines administration in an acute trust

The trust carried out work to reduce delays in administering STAT (immediate) antibiotic doses. An innovative automated alerting system was implemented across the trust to communicate to front line staff when antibiotic doses are due. The administration of these antibiotics is monitored through the Quality Dashboard metrics. In October 2016, 79% of doses were administered within one hour of the target time. This has had a major impact on improving the management of patients with sepsis.

The trust had introduced a similar system for the timely administration of medicines to treat the symptoms of Parkinson's Disease. If this medicine is missed or delayed, a patient may experience loss of control of their symptoms. By implementing the alert system, the administration of these medicines within 30 minutes of the target time improved from 47% in 2015 to 70% in 2016.

Heart of England NHS Foundation Trust inspection report, 2017

High-risk medicines

Anticoagulation

High-risk medicines should be prescribed in line with best practice guidance (such as that issued by NICE) to prevent adverse events such as a deep vein thrombosis (DVT). Notifications showed cases where anticoagulation medicines to reduce the risk of blood clots were consistently not prescribed or administered following surgery or childbirth, even after assessments for venous thromboembolism (VTE). In some cases, the anticoagulation medicine had been stopped for surgery but not initiated again afterwards.

The following examples are from notifications to NRLS from NHS trusts, where errors with anticoagulation medicines resulted in re-admission to the hospital and harm to the patient.

Examples from NHS trusts of notifications involving anticoagulation

After a woman gave birth, her risk assessment for venous thromboembolism (VTE) was repeated. This showed that she was at high risk of VTE. Guidelines advise extending enoxaparin prophylaxis for 10 days, but this was not done.

In another example, a patient was admitted with a pleural effusion and chest infection, and oral anticoagulation (apixaban) was stopped to perform pleural aspiration. However, apixaban was not restarted on discharge.

By contrast to these examples, other notifications indicated that harm had occurred when two anticoagulants had been inappropriately prescribed together, resulting in excessive bleeding. Although we saw examples of prescribing anticoagulants without VTE risk assessments, we also found an example of proactive work to reduce risks with VTE and anticoagulants.

Example of integrated electronic VTE risk assessing and prescribing

The trust's pharmacy service has established an electronic VTE risk assessment pro-forma, which is integrated with the electronic prescribing and medicines administration (EPMA) system. This requires any registered doctor, nurse, pharmacist or pharmacy technician to complete the VTE and bleeding risk assessments before being able to access the patient's electronic drug chart for the first time. A re-assessment is then prompted 24 hours after admission.

Following the introduction of this facility, the proportion of VTE risk assessments that are completed within 24 hours of admission have consistently been above the national target of 95%.

The Chesterfield Royal Hospital NHS Foundation Trust inspection evidence appendix, 2018

Insulin

Insulin is a high-risk medicine, which some people with diabetes need to take to control their blood sugar levels. We found that errors associated with insulin were common among notifications. Administering the wrong dose and timing of insulin was an issue, especially when people did not have access to food, or were 'nil by mouth' (NBM) before an operation. Consequences of poorly-managed insulin were hypoglycaemia (low blood sugar) and unresponsiveness, and diabetic ketoacidosis (high ketones as a result of high blood sugar).

There is a growth in the range of products and complexity of insulins now in use, but a lack of familiarity and knowledge among ward staff of how to use them safely can contribute to mistakes. A national safety alert has also highlighted the risk of severe harm or death if insulin is drawn directly from pen devices or cartridges for administration. Notifications indicated that staff were not clear what they should do when there is an insulin error. Notifications also highlighted a general culture of reluctance to challenge or question unclear prescribing, as well as staff saying they were busy or tired as contributing factors.

Example of promoting safe use of insulin

The pharmacy department encouraged continuous improvement and innovation. Staff had received training in service improvement methods, and there was a quality improvement programme for six workstreams. The trust had appointed a safer diabetes care pharmacy fellow, who carried out research in collaboration with a local university to improve insulin and prescribing safety in hospital. This led to changes in the trust's policy, increases in pharmacy staffing to support people to self-administer insulin, and the development of e-learning to improve how to manage acute diabetes complications.

Sheffield Teaching Hospitals NHS Foundation Trust inspection evidence, 2018

Controlled drugs

In our analysis, errors associated with controlled drugs often related to missed doses, administering wrong doses or prescribing errors. In these cases, staff had not always followed safe prescribing guidelines.

In some reported incidents, patients had received an overdose of a controlled drug, which resulted in toxicity. Staff did not always recognise opiate toxicity promptly, with some examples indicating that staff were not always aware of drowsiness as a symptom of toxicity.

Some services had ineffective stock control, with controlled drugs going missing, and poor governance around controlled drugs, particularly in terms of audit and learning.

We also found examples where untrained staff were involved in administering controlled drugs, including those delivered through a syringe pump, as in the following example.

Example from inspection report

Sometimes there was only one trained nurse on duty. This meant that at night healthcare assistants could check the administration of controlled drugs, which would sometimes include syringe drivers. There was no evidence of healthcare assistants having competency assessments for checking controlled drugs or syringe drivers.

Gentamicin

Gentamicin is an antibiotic that needs to be reviewed frequently and the dose adjusted based on the results of blood tests. In some incidents, renal function, age and weight were not always taken into account when calculating dosages. We saw examples of poor outcomes for people as a result of incorrect doses, which included kidney and hearing damage.

Pharmacy staffing and medicines reconciliation

The capacity of pharmacy staffing is a crucial consideration for the acute setting; our analysis found insufficient pharmacy resource was a concern for both NHS and independent hospitals. In independent hospitals, pharmacy support was often split over different sites or not available out of normal hours. In NHS services, the vacancy rate sometimes meant there wasn't enough pharmacy resource to cover all departments. In other cases, pharmacists with specialist training were not available, such as paediatric pharmacists, or those trained in intensive care.

Poor pharmacy resources resulted in delays in supplying medicines, nursing staff being diverted to other tasks such as stock control and no pharmacy input into ward rounds.

Inspection reports also highlighted that lack of staffing capacity and high workload resulted in an inability to carry out medicines reconciliation after admission to hospital, either within the recommended 24-hour timeframe, or at all. This affected both NHS and independent services.

The inability to carry out medicines reconciliation was reflected in the incidents we analysed. For example, people's usual medicines were not prescribed, transcribing errors in records went unnoticed and medicine contra-indications and interactions were not identified in a timely way.

However, we have also found examples of providers that have invested in advanced training for their workforce or used digital systems to improve people's outcomes.

Example of investing in training for the workforce

A pharmacist was supported to develop their scope of practice by becoming an advanced practitioner. The pharmacist had their own caseload of patients with minor illnesses. In addition, they were also on hand to help provide advice about medicines to other staff working in the emergency department.

Dartford and Gravesham Trust inspection report, 2018

Example of using electronic patient record in medicines reconciliation

The electronic patient record held details of patients' prescriptions and could be accessed by the multidisciplinary ward team. If there were any issues with prescriptions it enabled the pharmacy team to communicate these to the multidisciplinary team on the wards electronically and provided an audit trail. It also meant they could prioritise the review of patients to meet the key performance indicator for medicines reconciliation.

Salford Royal NHS Foundation Trust inspection report, 2018

Non-pharmacy staff and skill mix

We found that the absence of appropriately trained nursing and medical staff on wards caused delays in receiving medicines. In some cases, there were not enough trained staff to administer or review medicines to ensure that people were kept safe. One notification suggested that certain medicines, such as gentamicin, should not be prescribed at certain times such as bank holidays because of the unavailability of doctors to review and act on blood tests.

The ongoing competency of staff to administer medicines was not always assessed, particularly following incidents. Staff had not always received specific training in specialised areas of administration, such as insulin, syringe drivers and using intravenous medicines and cannulas. This also applied to agency staff. Many trusts had a policy to run mandatory medicines management training for clinical staff. However, we sometimes found that, in practice, this did not happen.

Storing medicines

As well as unlocked cupboards or fridges, examples of poor storage in our analysis extended to processes for storing keys securely. In NHS settings, we found that security concerns often related to more general estates issues, such as broken doors or locks.

Injectable medicines were sometimes stored inappropriately. We also found examples when injectable medicines were prepared for people, and then left unattended and unlabelled in an open environment. Not only does this present risk around unrestricted access to medicines, but it could contribute to incorrectly administrating medicines to a patient. The Royal Pharmaceutical Society has produced national guidance for safe and secure handling of medicines in healthcare settings.[17]

Governance

Some providers either did not have appropriate policies and procedures or, if they did, these were not routinely reviewed and did not reflect best practice and national guidelines. When policies and procedures were in place, they were not always followed. As with primary care and mental health settings, we found that prescription pads were not always stored or tracked in line with national guidance.

As well as no policy for medicines management, our analysis highlighted other missing policies such as for safe administration of medicines, carrying out competency checks for staff and reporting incidents.

As with other sectors, acute hospital services did not always carry out effective audit to monitor and improve the quality of how medicines were managed.

Medication safety officers

The role of medication safety officer (MSO) is central to working towards safer use of medicines in a hospital. One of the key responsibilities for MSOs is ownership of reporting medicines incidents, which involves improving reporting rates and promoting learning among staff. MSOs work as a member of the medication safety committees and are active in a National Medication Safety Network.

Transfer of care

We identified that 108 out of the 600 incidents analysed (18%) occurred at the point when the patient was discharged or transferred to the care of another service. Timeliness of discharge medicines was a common problem; in some cases when medicines were not ready, the patient's discharge was delayed.

Problems were often linked to people not being prescribed their usual medicines and transcribing errors, some of which was linked to pharmacy resources. Mistakes or omissions were sometimes made in discharge letters to GPs. This meant that medicines were missed, given at an incorrect dose, or that follow-up appointments did not occur.

Anticoagulation was highlighted as a particular area of risk at transfer of care. In one example, a patient had a pacemaker fitted, but on discharge they received no information on the need to start an anticoagulation medicine, and this was not included in the summary letter to the GP. This person was re-admitted to hospital with a stroke.

We also saw that people became unwell because their medicines were not managed properly when they were waiting for transfer between hospitals. An important aspect of the discharge process is that people are appropriately assessed, to ensure they can safely take their own medicines. This did not always happen and resulted in re-admission to hospital.

Example of improving medicines safety at transfer of care

The trust actively used an electronic referral system to support 'at-risk' patients by timely communication of medicine-related information to the patient's usual community pharmacy on discharge. In the year to April 2018, the trust had made over 3,000 referrals and estimated that this had prevented at least 100 re-admissions.

The trust's medicines support team worked as part of the multidisciplinary integrated neighbourhood team within one of the local clinical commissioning groups to provide support for individual patients where there were medicines safety concerns. Referrals to the team came from a wide range of services including: GPs, social care services, voluntary services and community pharmacies.

East Lancashire Hospitals NHS Trust inspection report, 2019

Medicines for mental health in acute hospitals

Acute hospitals commonly provide treatment for people with mental health conditions. We looked specifically at notifications from the emergency department (A&E) setting to find out how people with mental health conditions were managed – particularly those who experienced a crisis.

Prescribing errors increased the risk of harm to patients. Patients treated for an overdose of paracetamol were sometimes found to have been subsequently prescribed additional paracetamol-based medicines in error, such as co-codamol. We also found the treatment for paracetamol overdose was stopped prematurely and doses were administered at the wrong strength or time, or were missed entirely.

Doctors in emergency departments did not always liaise with consultant psychiatrists or alcohol liaison teams about changing people's medicines. For example, the failure to consult with appropriate specialists led to a patient being prescribed too high a dose of an antipsychotic, without an appropriate staged reduction of their existing medicine. This practice could have led to harm.

When people experience a mental health crisis, other concurrent physical health problems may contribute to distress and significant discomfort. We saw examples of this in notifications and found that physical symptoms were not always treated in a timely way.

We also found that people who were at a high risk of another overdose had access to their own medicines, either through their own supply or through visitors to the ward.

The earlier chapter in this report on what we found in mental health services provides more detailed information on the use of rapid tranquillisation in mental health settings. Rapid tranquillisation is also used in emergency departments, where we found that it was not always administered or recorded appropriately when used, and was not always given in accordance with policy or best practice guidelines.

Actions for acute hospital providers

Based on the risks identified with medicines use in acute hospital settings, we encourage providers to take the following action to ensure that medicines are managed safely:

1. The role of medication safety officer is crucial to the oversight and responsibility for safety, particularly regarding prescribing, monitoring and administration of high-risk medicines, including insulin. This role should have higher recognition at board level. By providing updates on areas of concern from a medicines safety officer, a trust's board can be aware of issues and track progress on medicines safety.

2. To reduce the risk of drug allergy, prescription and medicines administration records (paper or electronic) should be standardised to allow easy recording of allergies and adverse drug reactions, in line with NICE guidance.

3. When patients are discharged from hospital electronic information systems need to transfer details relating to medicines accurately and in good time. Staff in hospitals and other services need to work collaboratively at this crucial stage to improve how information is transferred. There is an opportunity to share collective learning from errors and system failures.

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