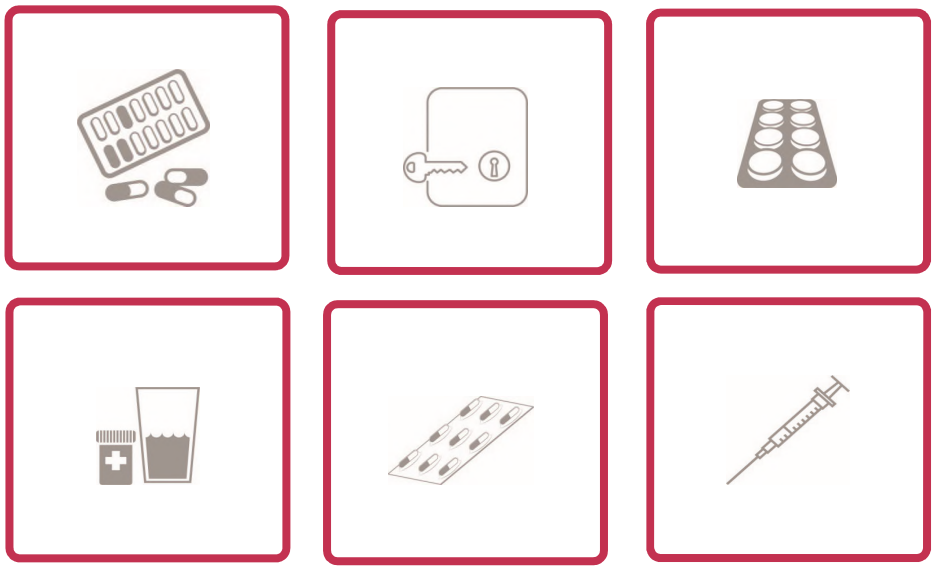
The safer management of controlled drugs

Annual update 2018

July 2019



The Care Quality Commission

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.

We also have a statutory duty to oversee the safe management arrangements for controlled drugs in England.

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.

Contents

Introduction

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

As part of our responsibilities under the regulations, we report annually on what we find through our oversight and make recommendations to help ensure the continuing effectiveness of the arrangements for managing controlled drugs in England. Our findings are important for all controlled drugs accountable officers (CDAOs) in England and their support teams, as well as organisations that handle controlled drugs, health and care professionals with an interest or remit in controlled drugs, commissioners of healthcare services and professional healthcare and regulatory bodies.

Data in this update is for the calendar year 2018, but we also include relevant information for the first half of 2019.

Key issues in this update

Opioid medicines: Our controlled drugs activity focused more on this area in 2018 and the first half of 2019 following reports of overprescribing leading to dependence and deaths in the USA, some European countries and parts of the UK. Levels of opioid prescribing are now being monitored more closely, for example by NHS England CDAOs, clinical commissioning groups and providers, and a range of organisations are developing tools and guidance to support prescribers.

Gosport Independent Panel report: In November 2018, the government published its response to the report of the Gosport Independent Panel into the deaths of patients through opioids prescribed 'without medical justification' at Gosport War Memorial Hospital. The response sets out the measures that have been put in place since the events described in the report, as well as actions for other bodies. It is vital that all organisations and individuals involved in health and care continue to reflect on these to avoid similar situations in the future.

Cannabis-based products: Towards the end of 2018, we saw the scheduling of cannabis-based products for medicinal use, although currently there is no licensed preparation available in the UK. The legislation also set out that these products can only be prescribed by a clinician on the GMC specialist register or be used in clinical trials. The prescribing of cannabis-based products for medicinal use is currently minimal but is growing, and is likely to increase over time as more clinics and specialist centres are established. It is therefore important for us all to remain vigilant in ensuring that these unlicensed products are only prescribed for unmet need by appropriately qualified specialists. Until a licensed product becomes available, NHS England procurement holds a list of specialist importers, as the products need to be imported through a company that holds the appropriate licences.

Unaccounted for losses of controlled drugs: For the first time, we have been able to share intelligence gathered through the NHS England national occurrence reporting tool. We have chosen to highlight the issue of mislaid controlled drugs as reported at controlled drug local intelligence network (CDLIN) meetings. We also share some national prescribing trends.

Recommendations

We make five recommendations to further strengthen the arrangements for the safe management and use of controlled drugs. This year, these focus on the importance of having oversight of the use of controlled drugs and the need to speak up where there are concerns.

Recommendation 1: NHS England	NHS England should review the resourcing of their lead CDAOs and support functions as part of restructuring arrangements to enable them to fulfil their statutory responsibilities effectively.
Recommendation 2: NHS England CDAOs	NHS England CDAOs need to determine what information they all need from their local intelligence network members and request it in a consistent way.
Recommendation 3: All CDAOs	CDAOs and nominated controlled drug leads must have oversight of the use of controlled drugs and follow up any unusual use to assure themselves that the arrangements for controlled drugs in their organisation are safe. This should include timely audits and considering treating controlled drugs as high-risk medicines.
Recommendation 4: All CDAOs	CDAOs and nominated controlled drug leads need to share controlled drug-related concerns about health and care professionals with their NHS England CDAO. Although it is important to be aware of GDPR requirements, these do not remove this responsibility in the interest of patient and public safety.
Recommendation 5: All healthcare professionals	All healthcare professionals need to remember their responsibility to speak up on areas of concern that might negatively affect patient safety, including prescribing, administering, dispensing, supplying and disposing of controlled drugs.

Progress on our recommendations

In last year's report on activity during 2017, we made four recommendations to improve the management of controlled drugs. The following table sets out the progress on these to date.

Recommendation	Progress
1. Prescribers should ask patients about their existing prescriptions and current medicines when prescribing controlled drugs. Where possible, prescribers should also inform the patient's GP to make them aware of treatment to minimise the risk of overprescribing that could lead to harm.	All NHS England CDAOs include this as an agenda item at their CDLIN meetings to remind members of the importance of notifying GPs about any medicines from other prescribers for their patients. CQC has made particular progress in relation to online prescribing where services are registered with us. We also emphasise this on inspections and have raised awareness in our controlled drug newsletters.
2. Commissioners of health and care services should include the governance and reporting of concerns around controlled drugs as part of the commissioning and contracting arrangements so that these are not overlooked.	This has been raised among NHS England CDLINs. However, action needs to continue and become embedded into commissioning arrangements.
3. Healthcare professionals should keep their personal identification badges and passwords secure and report any losses as soon as possible to enable organisations to take the necessary action.	We continue to raise this through NHS England CDLINs and in our controlled drug newsletters. However, it remains an issue and we must all continue to be vigilant as the diversion of controlled drugs is becoming increasingly sophisticated.
4. Health and care staff should consider regular monitoring and auditing arrangements for controlled drugs in the lower schedules, such as Schedules 4 and 5, to identify and take swift action on diversion.	Diversion and misuse of lower schedule controlled drugs are still a concern and we continue to encourage localised monitoring where appropriate.

CQC's oversight activity in 2018

Register of controlled drug accountable officers

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

Throughout 2018, there was an average of 982 organisations on our CDAO register. Of these, 726 CDAOs were from independent healthcare organisations, 228 were from NHS organisations and the others from organisations such as social care providers that fall within the designated body status.

To keep the CDAO register up to date, it is important that organisations tell us about any changes to their CDAOs' details. If an organisation re-registers with CQC, it needs to submit a new CDAO notification. In 2018, we received approximately 27 notifications each month. Notifications can be made using the online webform. Changes to contact details such as email address or phone numbers can be emailed to CDAORegisterData@cqc.org.uk.

We grant exemptions for the need to have a CDAO where it is disproportionate to appoint one in independent healthcare organisations that have more than 10 employees but have a low use of controlled drugs. Organisations with fewer than 10 employees are automatically exempted. The uptake of the exemption by eligible organisations continues to remain low, and in 2018 we received and approved six CDAO notification exemptions.

A very small number of organisations are registered solely with the Human Fertilisation and Embryology Authority (HFEA), and not with CQC. HFEA maintains a register of CDAOs.

We also provide other information for CDAOs on our website.

NHS England area teams and controlled drug local intelligence networks

During 2018, NHS England began its integration with NHS Improvement and move to seven regions. The transition of both organisations is continuing throughout 2019, which means we do not yet know the full implications on the structure of the NHS England CDAO teams or the resources available to them. This has caused increasing uncertainty for the future arrangements for NHS England CDAOs and their teams to identify and mitigate risks. Going forward, the current restructure is an opportunity to review the way in which the NHS England CDAO role is delivered across England. However, to enable the NHSE England CDAOs to deliver their responsibilities effectively, sufficient resource needs to be provided.

As well as this, we have found there is a need for a central co-ordination role that will bring all NHS England CDAOs together and enhance lines of communication.

Recommendation 1: NHS England	NHS England should review the resourcing of their lead CDAOs and support functions as part of restructuring arrangements to enable them to fulfil their statutory responsibilities effectively.

Over the year, NHS England CDAOs have worked more collaboratively, meeting together as an overall group and in smaller working groups that concentrate on specific tasks. They have also established systems for sharing intelligence such as patient alerts, national and local related news and guidance, which has led to more consistent messages at all controlled drug local intelligence network (CDLIN) meetings. However, allocation of local resources across the country is inconsistent, as some NHS England CDAOs have only minimal support. We have also noted that, although a national controlled drug reporting tool is now in use, it is currently being used in varying ways which make it more difficult to see the overall national picture.

NHS England CDAOs maintain a register of risks and challenges to the CDAO function and attempt to implement system-wide approaches to addressing these challenges. By attending these meetings, we have highlighted key areas from the register where the risks are thought to be the highest.

As well as the role of CDAOs in the new structure and lack of central and regional resources, risks also include the uncertainty surrounding the continuation of The Controlled Drug (Supervision and Management of Use) Regulations 2013, which have a statutory expiry date or 'sunset clause' of 31 March 2020. Additionally, the outdated Misuse of Drugs Regulations 2001 and the Safe Custody Regulations (1973) make interpretation difficult in a fast-changing health and care landscape. However, we are aware that these pieces of legislation are being revised by the relevant Government departments.

Another continuing issue reported by NHS England CDAOs is the lack of individual prescriber codes for dentists. Currently, all dentists in a local area use a single prescriber-controlled drug PIN code, rather than an individual prescriber code for each dentist as other private prescribers have. This makes it difficult for NHS England CDAOs to monitor individual dentist prescribers and follow up on any concerns on an individual basis. We acknowledge that the current area code does not provide sufficient information for monitoring purposes and will approach NHS Business Services Authority about issuing individual prescriber codes for all dentists as a future opportunity.

There were fewer CDLIN meetings during 2018 because of the re-alignment and merging of smaller neighbouring networks. In 2018, there were 33 NHS England CDLINs across the 14 NHS England areas, which met between two and four times during the year. Most meetings have included at least one area-wide CDAO training event. CQC attended around 75 CDLIN meetings and contributed a written meeting update when unable to send a representative.

CDLINs were attended by both designated and responsible bodies and they remain an effective way to share intelligence and learning in addition to providing valuable networking opportunities. Where attendance at meetings has slipped, NHS England CDAOs are now proactively following up with those organisations and re-engaging them in the process. For the larger CDLINs, the meetings have become a barrier for some members, who have either been more reluctant to share information within a larger group or have found a lack of opportunity to raise concerns. To address this, some NHS England CDAOs have introduced secure conference style apps that allow members to raise questions anonymously, and these have proved popular. As CDLINs grow in membership it is important that all members feel able to share concerns and contribute at the meetings.

Examples of issues raised through local intelligence networks

Issues raised	Actions taken, where required
Local monitoring of prescriptions has identified healthcare professionals writing prescriptions for themselves and getting them dispensed in a number of local community pharmacies.	Local reporting of concerns and sharing information identified 63 healthcare professionals. The healthcare professionals involved were investigated and supported throughout this process. Where appropriate, they were reported to their professional regulator.
Thefts of stationery items such as prescription pads and requisitions.	NHS England CDAOs alerted CDLIN members and community pharmacists to be extra vigilant and look out for anything unusual on a prescription or requisition.
Theft of identify card or badges from healthcare professionals	We highlighted this in our 2017 report. Unfortunately, this continues to be of concern and vigilance must continue to be a priority.
Inconsistency between CDLINs in reporting incidents using the reporting tool (information requested from members and how it is submitted).	NHS England CDAOs are aware of the issue and are addressing this through a working group.
Significant delays in submitting private controlled drug prescriptions to NHS BSA.	NHS England CDAOs reminded CDLIN members of the importance of timely submissions to enable accurate prescription monitoring.
Locum healthcare professionals unaware of legislation, guidance and local polices, leading to mistakes and errors.	NHS England CDAOs reminded CDLIN members of the importance of proper inductions for locum and temporary staff and giving them access to relevant national and local guidance, policies and support.

Issues raised	Actions taken, where required
Reluctance to share information about healthcare professionals of concern and personal identifiable information because of a fear of not complying with General Data Protection Regulations (GDPR).	NHS England CDAOs are reminding CDLIN members of their continued responsibility to share names to protect patients and prevent diversion.
A number of reported incidents of theft, diversion and misuse of lower schedule controlled drugs by health and care professionals and patients. Fewer controls for lower schedule controlled drugs mean they are targeted as they are easier to divert than those in the higher schedules.	NHS England CDAOs discussed with CDLIN members, the importance of risk-assessing arrangements and increasing monitoring where there are concerns. These medicines should also be kept out of easy reach in pharmacies as there have been reports of them being grabbed opportunistically over the counter or from easy to access shelving.
Ongoing loss of methadone prescriptions and methadone issued to the wrong patient.	These are both ongoing issues. NHS England CDAOs alerted CDLIN members and community pharmacists to remain alert and to inform the substance misuse service and NHS England CDAOs when there is an incident.
Drug testing at festivals: Police controlled drugs liaison officers (CDLOs) informed NHS England CDAOs of the growing use of psychoactive substances in their areas.	NHS England CDAOs have shared information with CDLIN members to raise awareness as services need to take this information into account when patients present for treatment. However, further work is needed to develop links with those organisations providing healthcare services at festivals.
Illicit substances brought on to healthcare premises.	CDLINs have shared learning, good practice and local polices.
A counterfeit Xanax preparation coming in from overseas.	NHS England CDAOs informed CDLIN members and raised awareness of its misuse. Controlled drugs liaison officers (CDLOs) were involved in monitoring this.
Poor record keeping in controlled drug registers.	NHS England CDAOs reminded CDLIN members of the legal obligations and importance of accurate and timely record keeping.

Although the controlled drug reporting tool is now being used by all 14 NHS England regions, there are inconsistencies in the way the tool is being used. Some regions only require incidents to be recorded while others require both incidents and occurrences.

This is causing concern and confusion for some organisations that cover several CDLINs as to what to report and in what format. Going forward, the difference between an incident and an occurrence, and what should be reported, needs to be clarified so that there can be greater consistency of reporting and an improved data set.

Recommendation 2: NHS England CDAOs	NHS England CDAOs need to determine what information they all need from their local intelligence network members and request it in a consistent way.

Unaccounted for losses of controlled drugs

Information now available through the controlled drug reporting tool has enabled us for the first time to present national data on the number of reported incidents to NHS England CDAOs. For this update, we have chosen to highlight the number of unaccounted for losses of controlled drugs by region in England.

During 2018/19, there were 2,899 unaccounted for losses of controlled drugs reported on the reporting tool. There was an average of eight daily unaccounted for losses recorded across England. The following figures set out the types of unaccounted for losses and their risk rating (as per the NHS England risk matrix in the occurrence reporting tool) by locality, and by controlled drug type.

Figure 1: Unaccounted for losses of controlled drugs by type of loss 2018/19 (by area)

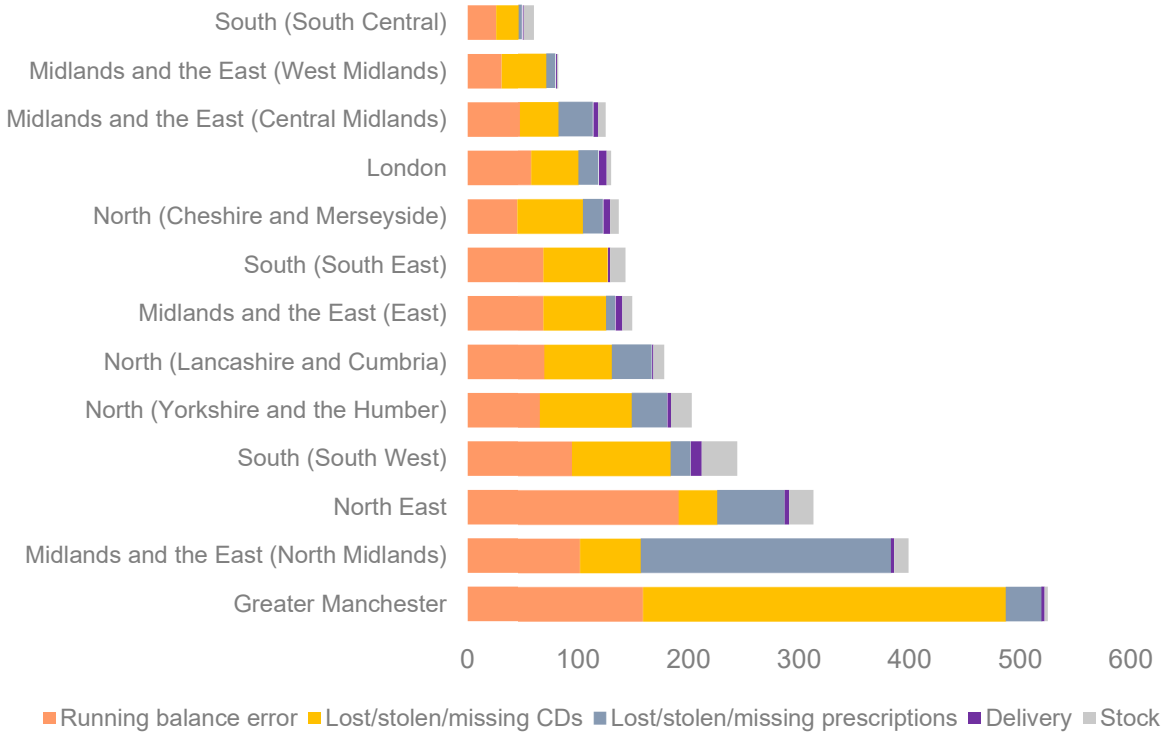


Figure 2: Unaccounted for losses of controlled drugs by level of risk 2018/19 (by area)

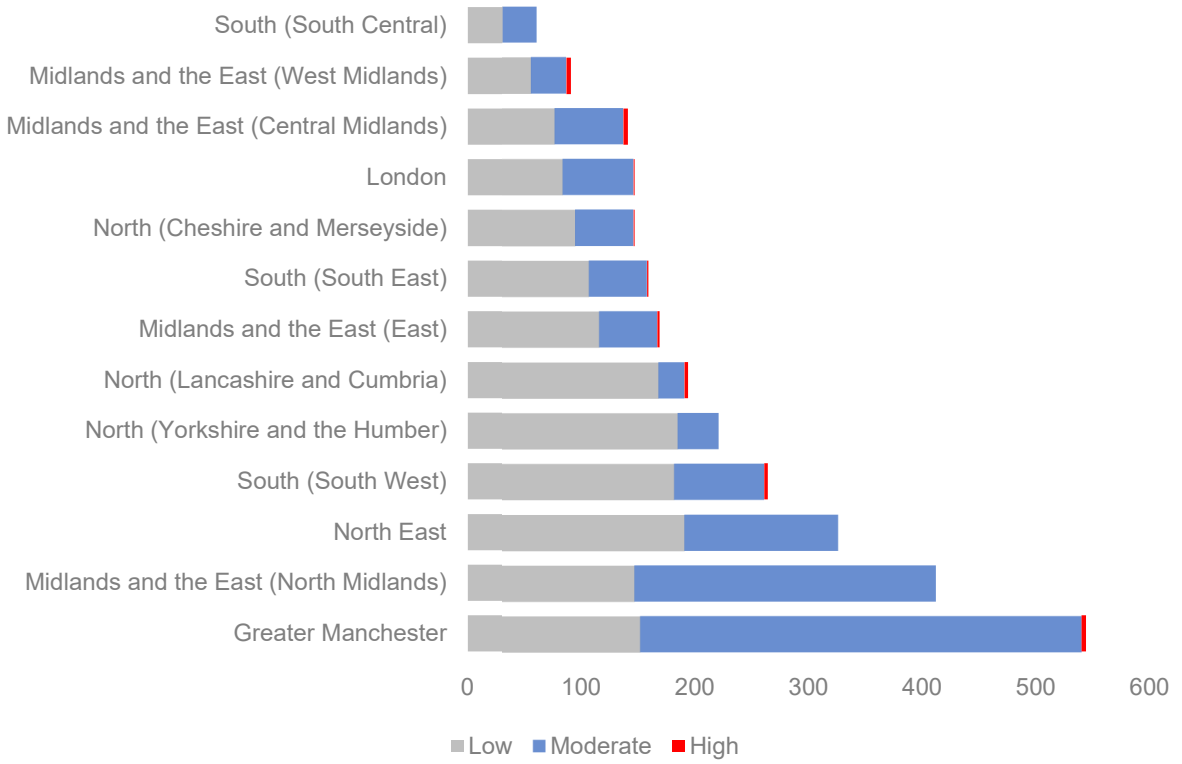


Figure 3: Unaccounted for losses of controlled drugs by type of drug 2018/19 (by area)

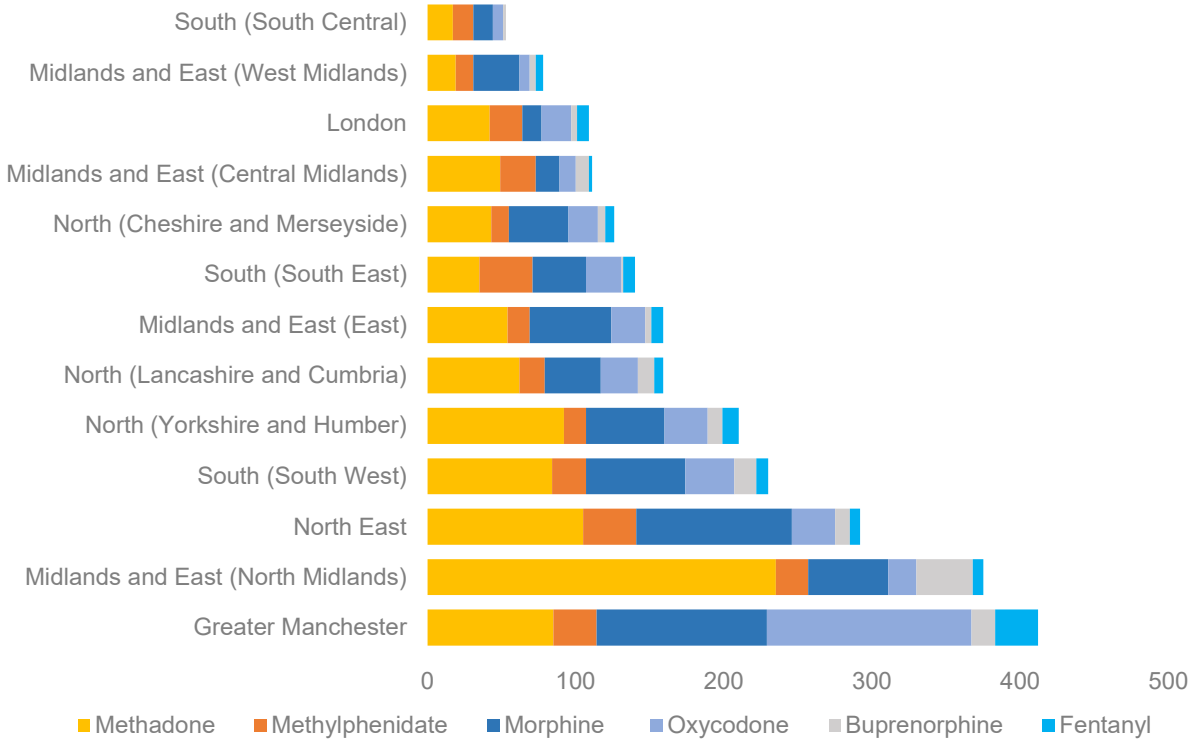
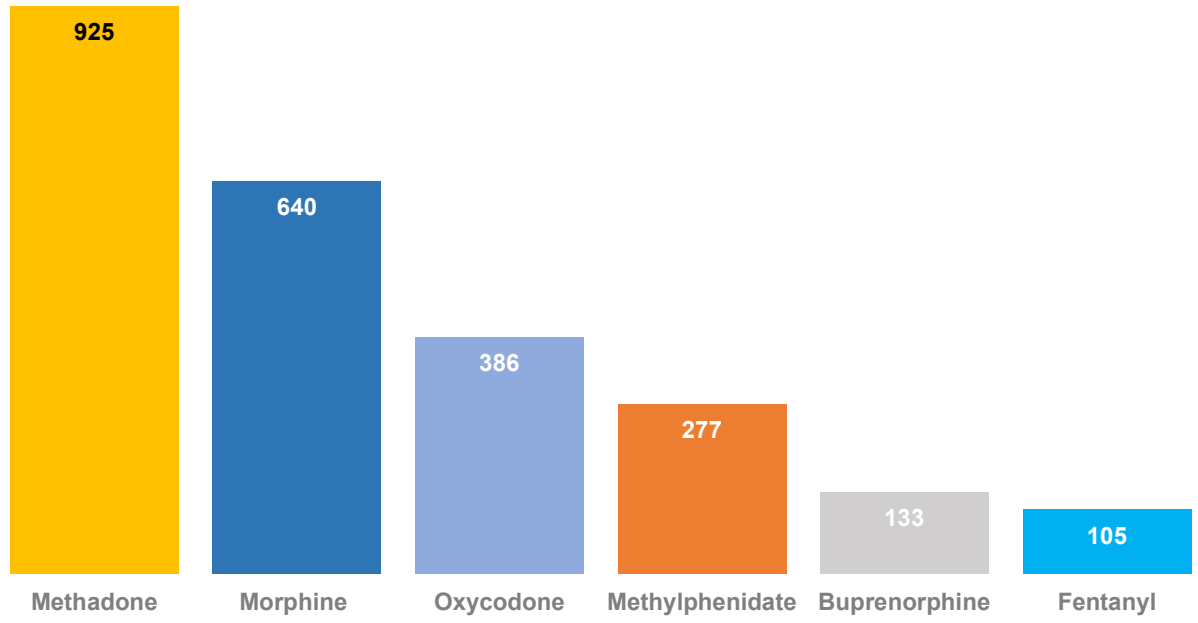


Figure 4: Unaccounted for losses of controlled drugs by type of drug 2018/19



It is important to note that because of the staggered roll-out of the reporting tool across NHS England regions, the data is subject to some variation in both the detail reported and the interpretation of risk by reporting organisations. The Greater Manchester team developed and started using the reporting tool in 2013, while some areas have only recently started to use it fully, and this explains their higher reporting figures. Although the North East area is not currently using the tool, it collates the same data as the other areas and provided data to contribute to the overall national picture.

The data currently available on the reporting tool has enabled 'persons and clinicians of concern' to be tracked and the relevant organisations notified to support these individuals. The next stage will be how NHS England interprets and disseminates the data and learning across the NHS England regions and local intelligence networks.

Controlled Drugs National Group

The CQC-led Controlled Drugs National Group comprises government departments, key regulators, and agencies with a controlled drugs remit. The group met three times in 2018 to share and discuss emerging issues and identify ways of working together to reach solutions. Following positive feedback, we continued to share summarised meeting notes with NHS England's CDAOs, to enable them to update members of CDLINs about developments and policy initiatives.

We have published a separate summary of activity from the past year showing how member organisations contribute to the overall safer management of controlled drugs.

Sub-groups

The four supporting sub groups to the Controlled Drugs National Group that focus on patient safety, thefts and frauds, prescribing and policy issues also met three times during 2018, either in person or by teleconference. Membership comprised stakeholders, including NHS England lead CDAOs, specialist pharmacists and medicine safety officers, other government bodies, NHS Business Services Authority, and chief pharmacists. Other healthcare professionals with relevant expertise were also invited as required.

CQC publishes a joint newsletter of the sub-groups using the GovDelivery system to over 8,000 subscribers with an interest in controlled drugs. These cover a variety of areas of interest. You can subscribe to CQC's newsletters relevant to your interests.

Cross-Border Group

The Cross-Border Group for safer management of controlled drugs in the devolved administrations met in March and September 2018. It included the Controlled Drugs Accountable Officers' Network Scotland, the Health and Social Care Board of Northern Ireland, NHS Wales and the Health Products Regulatory Authority of Ireland. The group provided a forum to discuss controlled drug matters at a strategic level and we have published a separate summary alongside this update of their major activities during 2018.

Main findings from inspections

We received positive feedback on our summary of issues found on inspection. As issues are broadly similar each year, please refer to the table in last year's update.

Updates on key themes from 2018

Opioid medicines

There was significant media interest in opioid painkillers during 2018 and the first half of 2019, with concerns raised about the number of prescriptions dispensed and the risk of dependence with this group of medicines. This follows concerns about the extent of prescribing and dependence currently seen in the USA, Canada, some European countries and Wales, and the implications this may have for England.

As a result, a range of organisations have been looking at measures to promote best practice and reduce overprescribing and dependence on controlled drugs. We share some key resources and guidance in development below.

National Institute for Health and Care Excellence (NICE)

NICE guideline	Committee recruitment	Draft scope consultation	Draft guideline consultation	Publication date
Chronic pain: assessment and management	7 Aug - 5 Sept 2019	7 Aug - 5 Sept 2019	21 Feb - 3 Apr 2020	19 Aug 2020
Safe prescribing and withdrawal management	7 Aug - 5 Sep 2019	7 Aug- 5 Sept 2019	28 May - 9 Jul 2021	27 Oct 2021

Public Health England

The then Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine, commissioned Public Health England to undertake a review of the scale and distribution of prescription drug dependence and withdrawal, and the optimal means of reducing it. See Prescribed medicines that may cause dependence or withdrawal.

Medicines and Healthcare products Regulatory Agency

MHRA convened an Opioid Expert Working Group in early 2019 to begin a review of the benefits and risks of opioid medicines, including dependence and addiction. One early recommendation from this group has been that all opioid medications must now carry clear warnings on labels highlighting the dangers of addiction and the risks of over-use.

PrescQIPP prescribing support resources, metrics and tools

PrescQIPP (a national NHS-funded not-for-profit organisation supporting quality, optimised prescribing for patients) has produced a set of audit tools. These were developed by the NHS England East of England CDAO network to support practices and community pharmacists to review and tackle high dose opioid prescribing. The audits have been designed to help prescribers reflect on their prescribing. This is a simple and low cost intervention, with the potential for significant improvement of patient safety, with the key message being to treat high dose opioids like any other high-risk drug. See PrescQIPP High dose opioids audits.

Live well with pain

This resource has been developed by and for clinicians to help them support their patients towards better self-management of their long-term pain. It offers a range of knowledge, skills, tools and resources to help clinicians enable patients to become clearer about their needs, manage or cope with their pain well and make better use of the healthcare available to them. See Live Well with Pain.

Faculty of Pain Medicine in partnership with Public Health England

This opioids aware resource highlights good practice for healthcare professionals and patients to support prescribing of opioid medicines for pain. See Opioids aware.

NHS Business Services Authority

The updated metrics in the controlled drug prescribing portal enable detailed scrutiny of controlled drug prescribing at NHS England area, CCG and practice level and the follow up of outliers. See NHS BSA ePACT2 Dashboards Safer Management Controlled Drugs.

Open prescribing

Every month, the NHS in England publishes anonymised data about the prescribing by GPs. Openprescribing, produced by the Oxford Centre for Evidence Based Medicines, manages the data that makes it easier for GPs, managers and everyone to explore to support safer, more efficient prescribing. See OpenPrescribing.

Gosport War Memorial Hospital

The report of the independent panel into failings at Gosport War Memorial Hospital highlighted what went wrong when controlled drugs were prescribed inappropriately for patients at the end of their life in the Gosport area in the 1990s. At least 450 people, and possibly a further 200, had their lives shortened due to a culture of blanket prescribing of diamorphine painkiller and, ultimately, a disregard for life. There were other factors apart from the prescribing. For example, a poor culture where lack of clinical challenge and a failure to speak up played their part, but ultimately patients were put on an end of life pathway indiscriminately irrespective of their clinical need.

Although this happened from 1987 to 2001, there is no room for complacency. There are still some similar contextual issues, such as a fast-changing health and care landscape, complex commissioning arrangements, more patients choosing to remain at home at the end of their life and some areas of isolated practice. Health and care professionals must therefore consider their responsibilities to speak up and challenge any unusual prescribing of controlled drugs.

One area where work is already underway is how medicines are prescribed for end of life care. This has been put in the spotlight as a result of the Gosport Report. NHS England's national clinical director for end of life care is working with partners with a view to involving patients and family members to a much greater extent and ensuring an individualised approach to managing patients at the end of their life.

In the government's response to the Gosport Independent Panel report, NHS England lead CDAOs have committed to reviewing the effectiveness of their CDLINs to share information of concern. They asked CQC to conduct a survey on their behalf in our capacity of having national oversight of controlled drugs. We did this in April 2019, inviting all CDLIN members to take part, and received 481 complete responses.

We are currently analysing the survey results and will share them with NHS England during Summer 2019. This will contribute to an action plan, which will be shared with CDLIN members. Although the interim findings are generally positive, they also show that GDPR is cited as a barrier to the effective sharing of information, and we remind CDAOs and colleagues of the importance of speaking up and sharing information of concern to protect patients and the public.

We have also worked with NHS England CDAOs in supporting discussions about the events at Gosport at CDLIN meetings and other forums.

Recommendation 3: **All CDAOs**	CDAOs and nominated controlled drug leads must have oversight of the use of controlled drugs and follow up any unusual use to assure themselves that the arrangements for controlled drugs in their organisation are safe. This should include timely audits and considering treating controlled drugs as high-risk medicines.
Recommendation 4: **All CDAOs**	CDAOs and nominated controlled drug leads need to share controlled drug-related concerns about health and care professionals with their NHS England CDAO. Although it is important to be aware of GDPR requirements, these do not remove this responsibility in the interest of patient and public safety.
Recommendation 5: **All healthcare professionals**	All healthcare professionals need to remember their responsibility to speak up on areas of concern that might negatively affect patient safety, including prescribing, administering, dispensing, supplying and disposing of controlled drugs.

Primary medical services provided online

The last year has seen more opportunities for prescribing through a digital platform, both in the NHS and in the independent sector. This is often much more convenient for patients, as many online-only providers can issue a prescription, which is dispensed by a pharmacy and delivered directly to the patient. But there can also be greater risks associated with this modality, particularly with the privately-prescribed controlled drugs in lower schedules, for example co-codamol, co-dydramol, codeine and dihydrocodeine. This is because, like those in the higher schedules, they can lead to dependence, but also because of a lack of scrutiny and challenge as privately-prescribed prescriptions are not currently required to be submitted to the NHS Business Services Authority and therefore cannot be monitored.

CQC does not regulate pharmacy services as they are registered with and regulated by the General Pharmaceutical Council (GPhC), but 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. For further information about CQC's regulation of independent online services, please see our report The state of care in independent online primary medical services. The General Pharmaceutical Council has also published Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet.

Cannabis-based products for medicinal use

Cannabis-based products for medicinal use (CBPMs) received high-profile media coverage in 2018. On 1 November 2018, cannabis-based products for medicinal use were moved to Schedule 2 of the Misuse of Drugs Regulations 2001, which means unlicensed CBPMs can be lawfully prescribed by a doctor on the specialist register of the General Medical Council for patients with a specific unmet clinical need, without requiring a Home Office licence.

As there is currently no licensed product for use in the UK, products must be imported from other countries, predominantly Canada and The Netherlands.

Although the number of prescriptions is low, the Department of Health and Social Care (DHSC) is working closely with MHRA and NHS England to establish a supply. DHSC has shared with procurement pharmacists a list of products that are available through UK distributors, along with details of product composition and Good Manufacturing Practices (GMP) certification, where known. This information should help pharmacies if prescriptions are presented. Following consultation from 23 July to 20 August 2019, NICE will also publish guidance in October 2019 on Cannabis-based products for medicinal use.

NHS England lead controlled drug accountable officers (CDAOs) are exploring options for national data collection on prescribing of CBPMs in the NHS and private sector

Food grade CBD oil products

These products, sold as health food supplements, are regulated by the Food Standards Agency and cannot make health or medicinal claims. However, there is uncertainty regarding unlicensed or illegal food grade products, as dosage and bio-availability vary according to how the person uses them for example, by inhalation or ingestion, as well as strength and purity of the specific product.

Where people bring in food grade cannabidiol (CBD) oil for their own or a relative's use in a health or care service, we encourage the service to carry out its own risk assessment on an individual case-by-case basis.

Gabapentin and pregabalin

On 15 October 2018, the government announced that gabapentin and pregabalin were to be reclassified as Schedule 3 (class C) controlled substances from April 2019 following concerns about the exponential increase in prescribing, reports of misuse and diversion. This was to allow them to be more closely monitored but without the requirement for safe custody. This also means that they can no longer be prescribed online in Great Britain.

Legislation changes during 2018 and early 2019

Controlled Drugs (Supervision of Management and Use) Regulations 2013

The current regulations have a statutory expiry date ('sunset clause') of 31 March 2020. The Department of Health and Social Care is aware of the widespread support to maintain the current regulatory provisions and is working with the Scottish Government to remove the statutory expiry date from the regulations. However, this approach is subject to Ministerial agreement in both countries. Both governments will provide an update in due course.

Cannabis-based products for medicinal use

These are now in Schedule 2, but synthetic cannabinoids remain in Schedule 1, pending a longer-term review by the Advisory Council on the Misuse of Drugs. The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018.

The following are supporting resources:

- General Medical Council: Information for doctors on Cannabis-based products for medicinal use (CBPMs).
- The Home Office fact sheet: Drug Licensing Factsheet- Cannabis, CBD and other cannabinoids.
- Medicines and Healthcare products Regulatory Agency: Medicinal cannabis: information and resources and The supply, manufacture, importation and distribution of unlicensed cannabis-based products for medicinal use in humans 'specials'.
- NHS England and the Department of Health and Social Care: Cannabis-based products for medicinal use (October 2018). The supplementary information clarifies that the decision to prescribe is ultimately one for the prescribing clinician. This follows concerns raised after the British Paediatric Neurology Association and the Royal College of Physicians published their own guidance for prescribers, which some deemed to be too restrictive Supplementary guidance on cannabis based products for medicinal use (November 2018).
- NHS website: Medical cannabis (and cannabis oils)
- Royal College of General Practitioners: interim Guidance for GPs on cannabis-based medicines and products.
- Royal College of Physicians: Recommendations on cannabis-based products for medicinal use.
- British Paediatric Neurology Association (BPNA): Interim guidance on the use of cannabis-based products for medicinal use in children and young people with epilepsy.
- Association of British Neurologists: ABN Interim guidelines on use of cannabis-based products in neurology – December 2018.

Pregabalin and gabapentin

These are now classified as Schedule 3 (class C) controlled drugs (from 1 April 2019) The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) (England and Wales and Scotland) Regulations 2018.

Explanatory Memorandum and Advisory Council on the Misuse of Drugs advice.

Supporting resources:

- NHS England briefing note on the Rescheduling of Gabapentin and Pregabalin as Schedule 3 controlled drugs for community pharmacies and GP Practices in England.
- NHS England letter on the Handling of gabapentin and pregabalin as Schedule 3 controlled drugs in health and justice commissioned services.
- NHS England guidance with information on changes to the law relating to the reclassification of pregabalin and gabapentin.
- NHS England patient leaflet provides information on changes to the law relating to the reclassification of pregabalin and gabapentin.
- Health & Care Professionals Council (HCPC) and NHS England have issued a joint statement on the Reclassification of gabapentin and pregabalin giving details of which prescribers can issue prescriptions for controlled drugs. HCPC has guidance on the laws control the sale, supply, administration and prescribing of medicines.

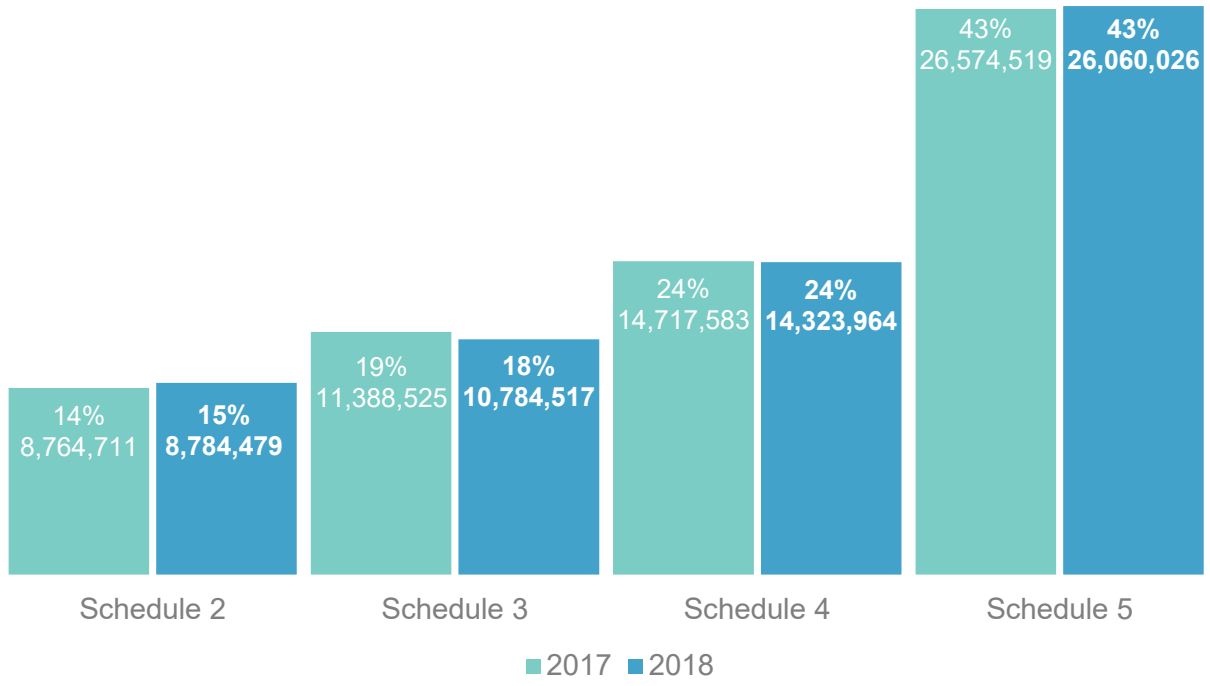
National trends in the use and management of controlled drugs

Prescribing trends for controlled drugs in 2018 were broadly similar to 2017.[a] NHS primary care services prescribed a total of 59,952,986 controlled drug items, which was a decrease of 2% compared with 2017. The cost of this was £466,002,352.43, a decrease of 6% on the previous year. Hospital prescribing (on FP10HP prescription forms that can be dispensed in a community pharmacy) was also broadly in line with that for 2017, with 1,039, 934 controlled drug items across Schedules 2 to 5 prescribed in hospital using an FP10(HNC) or FP10SS form.

As in previous years, prescribing by non-medical prescribers increased, with nurse prescribing increasing by 10% and pharmacist prescribing by 56%. This is most likely explained by multidisciplinary team working in primary care to address the rise in demand from patients on GPs, and also shows the value of pharmacists in new ways of working.

There was also more prescribing by physiotherapists and podiatrists, but numbers remain very small.

Figure 5: Controlled drug FP10 prescribing - items by schedule 2017 v 2018



a. The data used in this section has been extracted from the ePACT2 online system held by NHS Prescription Services. This system continuously updates its data, which means figures for 2017 published in last year's report may differ slightly from the figures for 2017 featured in this report.

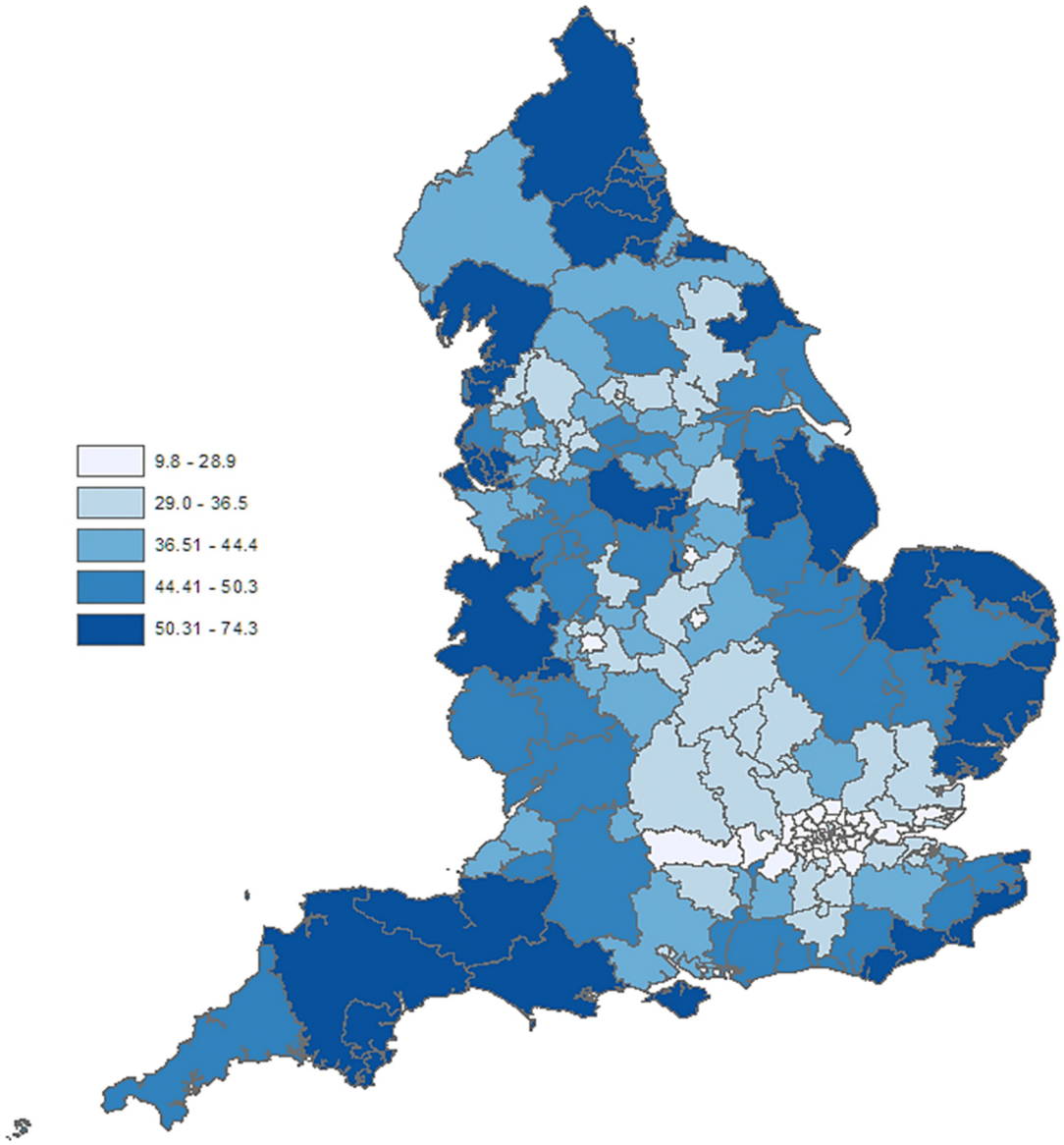
This year, we have set out the prescribing picture for opioids in Schedules 2 to 5 prescribed in combination with benzodiazepines, pregabalin or gabapentin across the geography of England. This is because there is a greater risk of dependence when patients are prescribed an opioid in combination with these medicines. We carried out analysis to try to identify the reason for such a variance in co-prescribing of these controlled drugs across England. We considered levels of deprivation in geographical locations and age of residents (see figures 9 and 10), along with age bands.

Our analysis did not identify a single factor that might explain the variation but it may be possible to detect some association with areas that have both higher levels of deprivation (figure 9) and a higher proportion of people aged over 65 (figure 10), particularly where these are more remote coastal areas.

The 10 clinical commissioning group (CCG) areas with the highest prescribing are identified in tables below each of the following three maps (figures 6, 7 and 8). It is important to note that the maps illustrate prescribing for end of life care and drug and alcohol misuse services, as well as prescribing for pain, and some of the areas of high prescribing may be explained by the fact that some CCGs continue to hold the budgets for drug and alcohol misuse services. Please also note that a number of CCGs have since merged to form a combined CCG.[b]

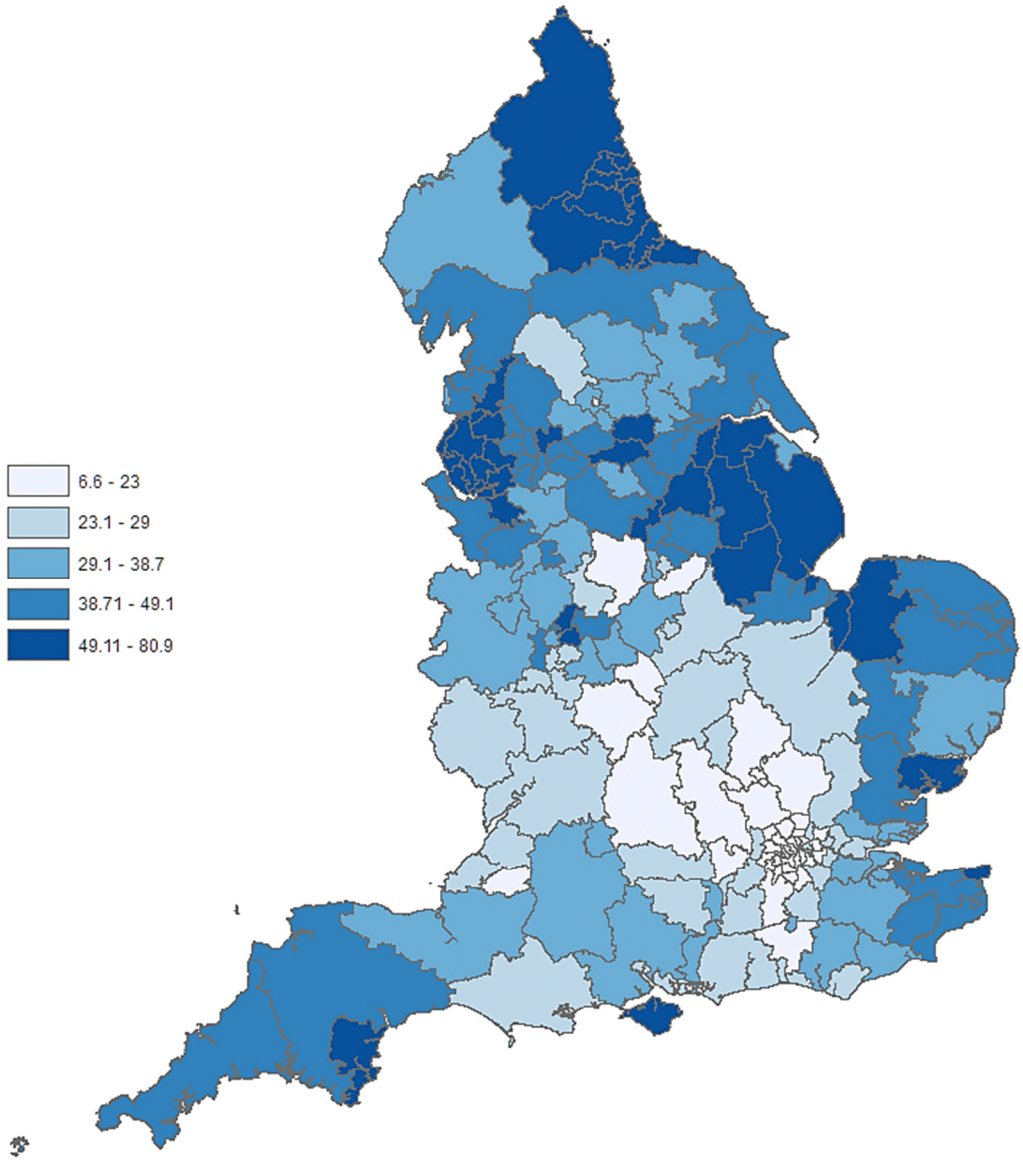
b. See https://www.england.nhs.uk/ccg-details/ for details of merged CCGs

Figure 6: Number of unique patients prescribed both a benzodiazepine and an opioid concurrently in the same month per 1,000 patients in 2018



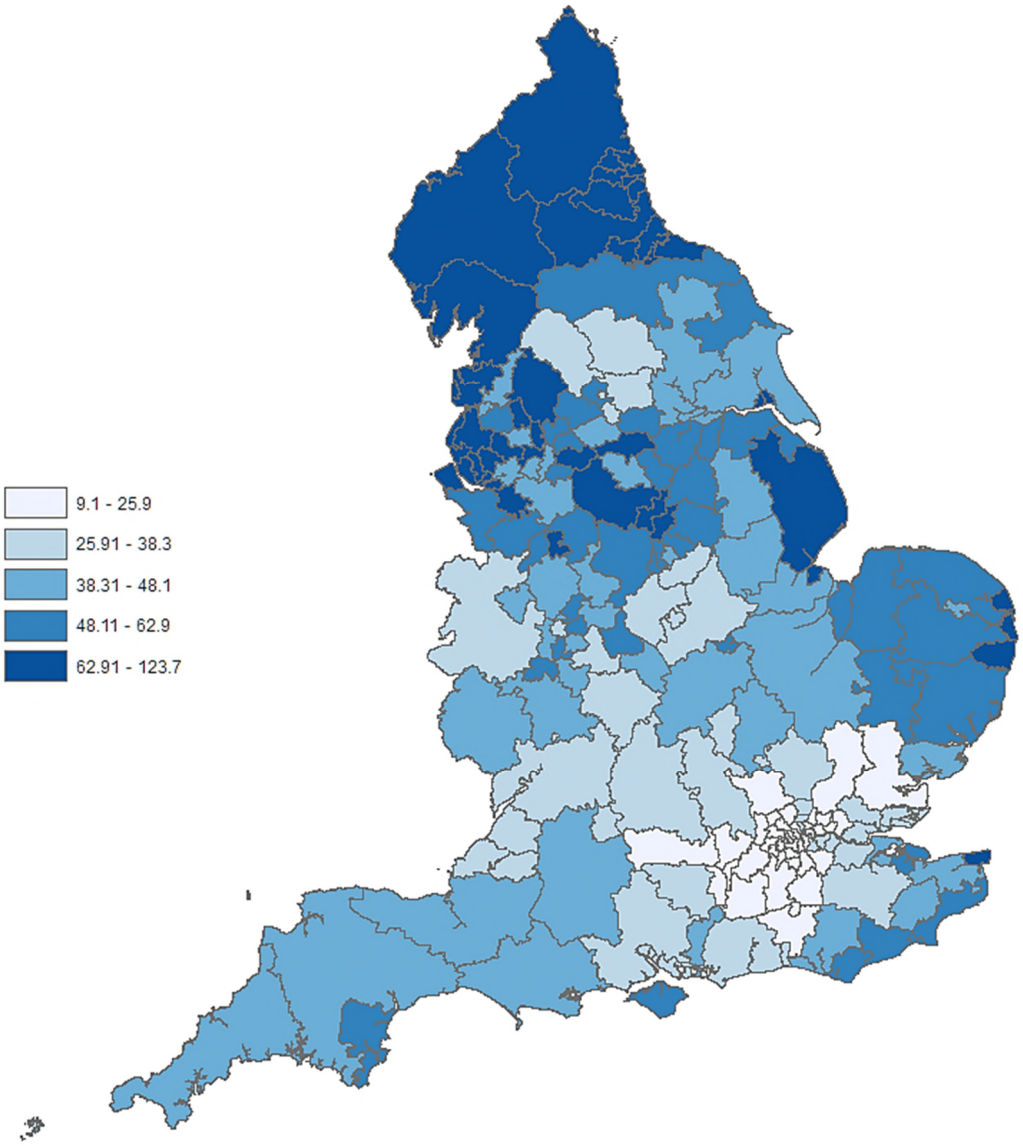
10 highest prescribing CCGs in 2018	Number of unique patients per 1,000 patients
Isle of Wight CCG	74
Thanet CCG	71
St Helens CCG	71
Hastings & Rother CCG	69
North Derbyshire CCG	68
South Devon And Torbay CCG	66
Hardwick CCG	66
Wirral CCG	65
North East Essex CCG	65
West Norfolk CCG	64

Figure 7: Number of unique patients prescribed both pregabalin and an opioid concurrently in the same month per 1,000 patients in 2018



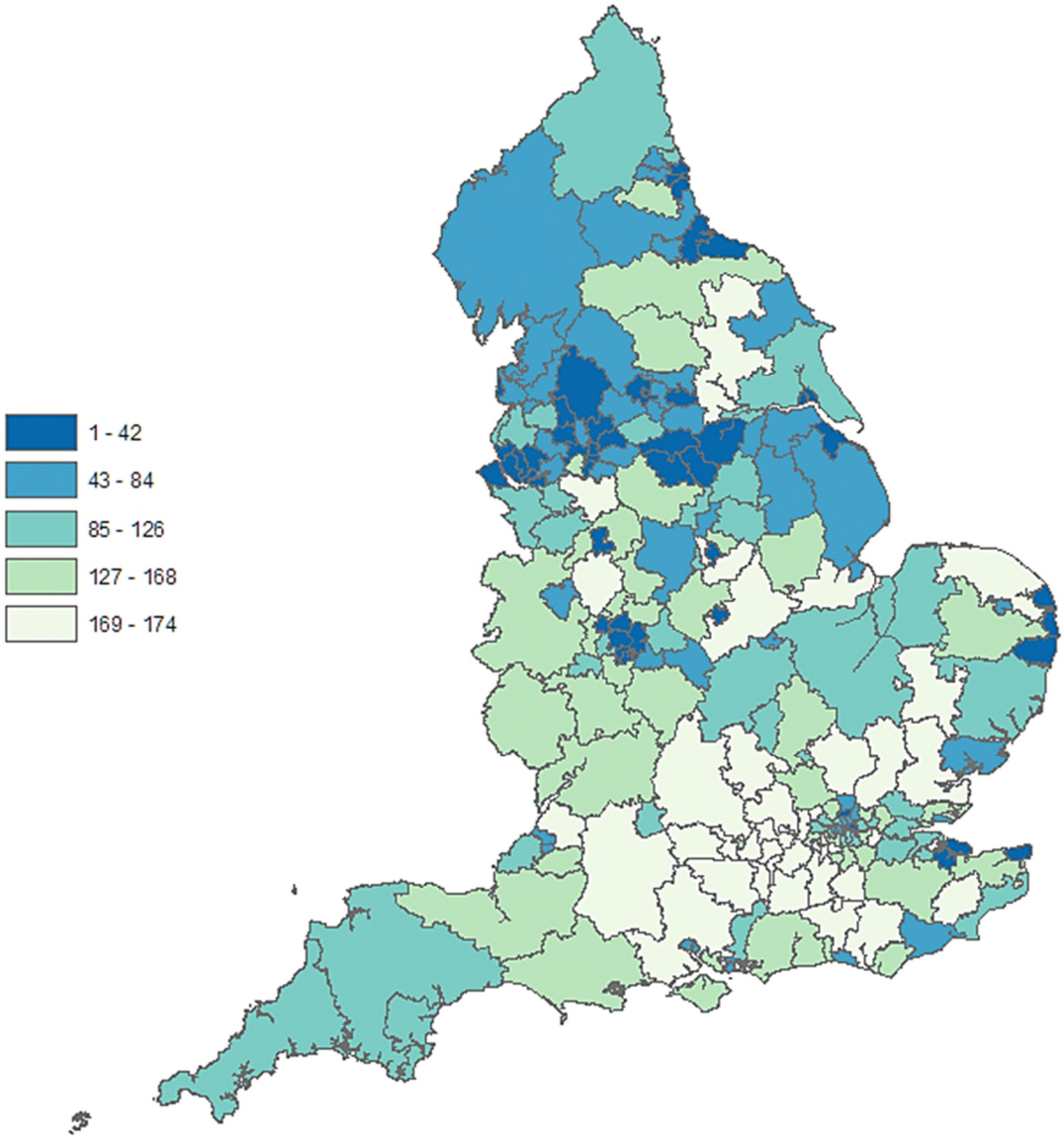
10 highest prescribing CCGs in 2018	Number of unique patients per 1,000 patients
Knowsley CCG	81
South Tees CCG	80
St Helens CCG	77
Lincolnshire East CCG	75
Halton CCG	74
Durham Dales, Easington & Sedgefield CCG	69
South Sefton CCG	67
Newcastle Gateshead CCG	66
Hartlepool And Stockton-On-Tees CCG	66
West Norfolk CCG	66

Figure 8: Number of unique patients prescribed both gabapentin and an opioid concurrently in the same month per 1,000 patients in 2018



10 highest prescribing CCGs in 2018	Number of unique patients per 1,000 patients
Hardwick CCG	124
Durham Dales, Easington & Sedgefield CCG	123
Blackpool CCG	114
Northumberland CCG	107
North Durham CCG	107
Hartlepool And Stockton-On-Tees CCG	106
Sunderland CCG	104
Great Yarmouth & Waveney CCG	99
South Tyneside CCG	93
South Tees CCG	89

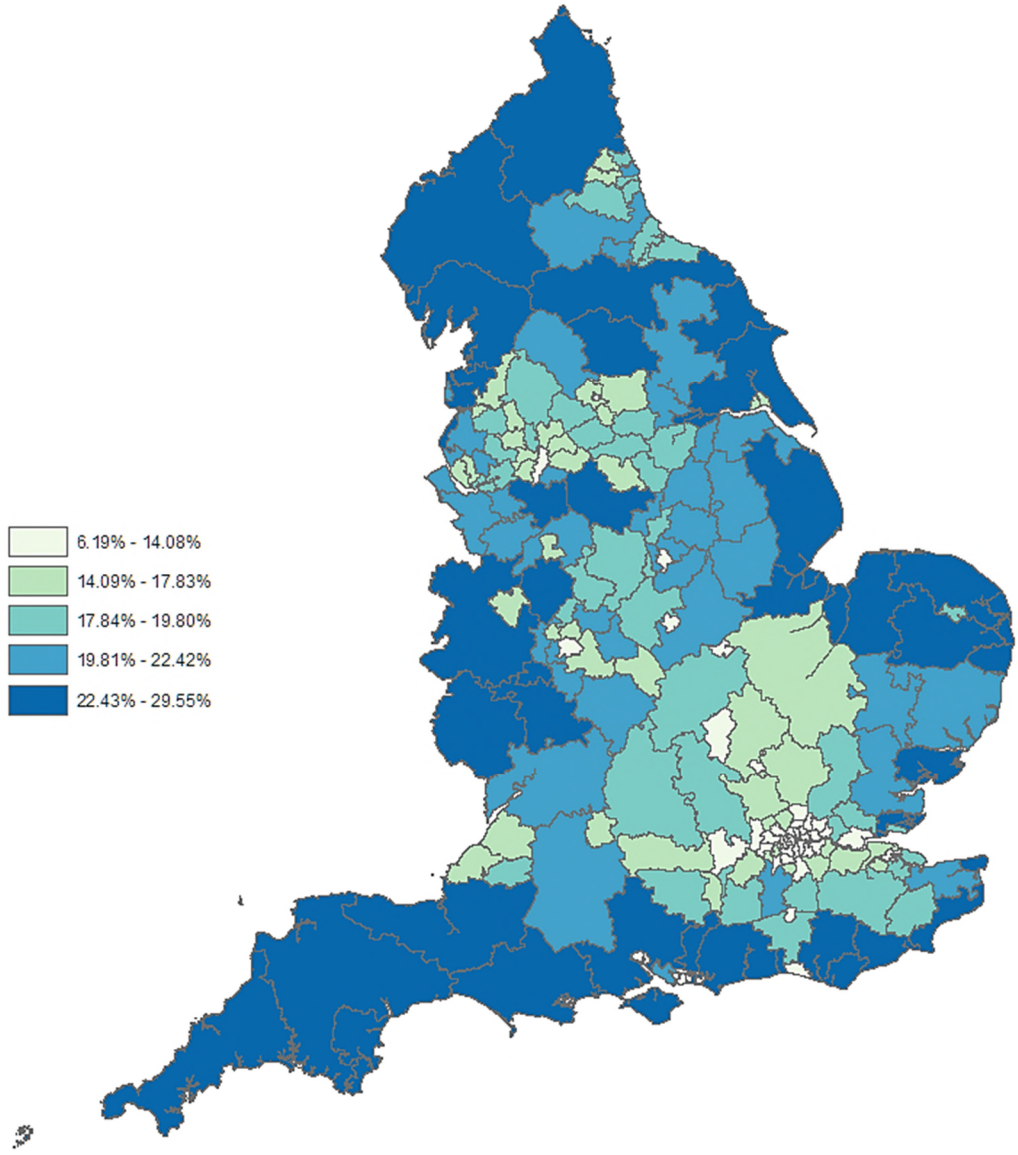
Figure 9: Level of deprivation by clinical commissioning group in 2015 (1 = most deprived)



Source: Index of Multiple Deprivation 2015.

Note: the data here relates to 2015, as this was the most up-to-date information available.

Figure 10: Percentage of the population aged 65 or over by clinical commissioning group in 2017



Source: Office for National Statistics: Mid-2017 Population Estimates.

We have also looked at national prescribing by age band of the patient in more detail for oxycodone[c] and morphine[d] in Schedule 2 (figures 11 and 12).

Figure 11: Schedule 2 morphine items by age group per 100,000 population in 2018

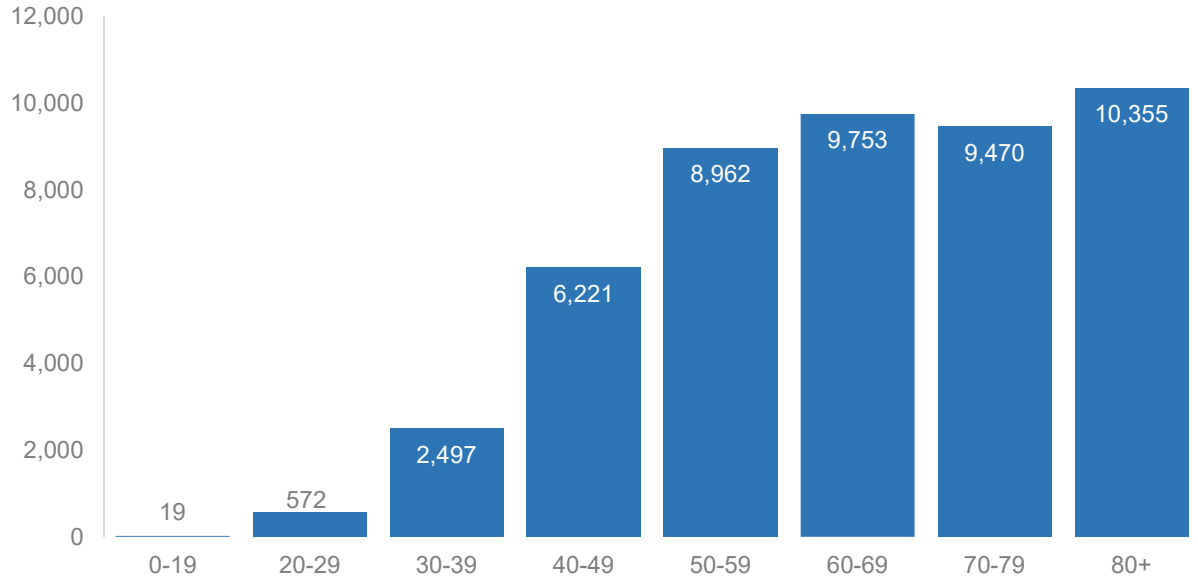
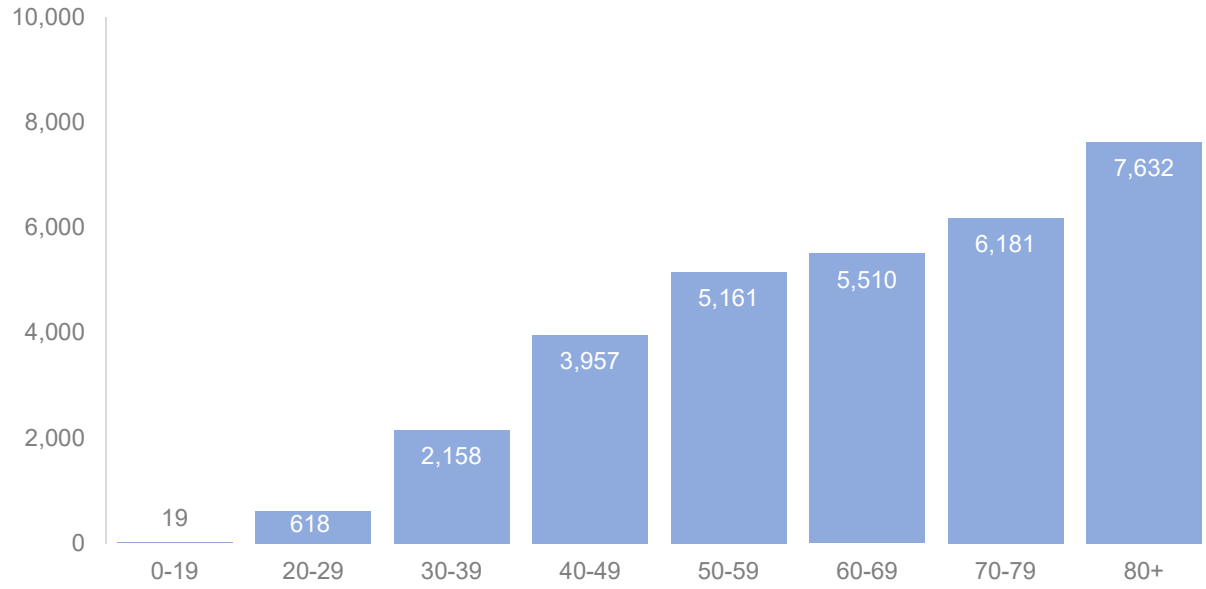


Figure 12: Schedule 2 oxycodone items by age group per 100,000 population in 2018



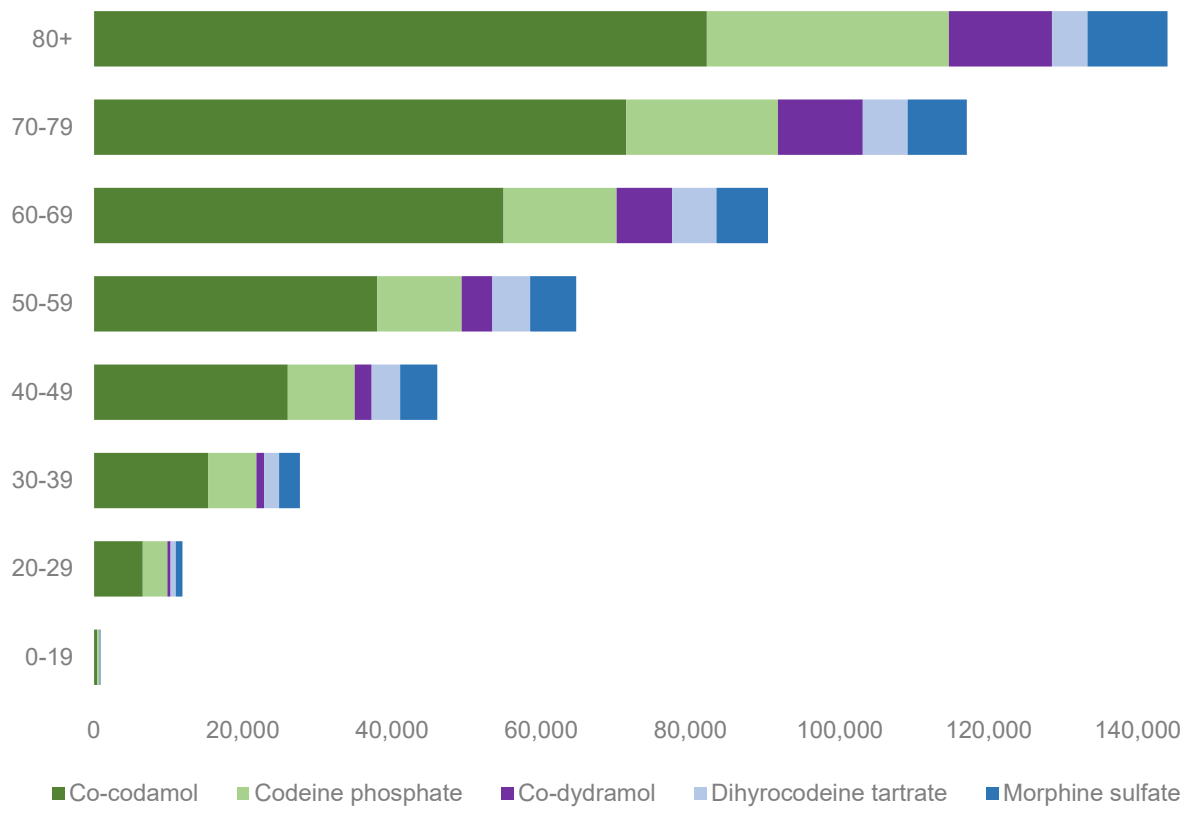
c. Oxycodone figures include the combination product Targinact (oxycodone and naloxone).

d. Morphine includes morphine hydrochloride, morphine sulfate, and morphine tartrate.

Figures 11 and 12 both show that the highest prescribing was in the older age group (people aged 80 years and over), rather than the 60-70 age group, which was not expected, given the availability of prescribing guidance.

Similarly, we have looked at prescribing of analgesics in Schedule 5 by age group (figure 13).

Figure 13: Schedule 5 analgesic items by age group per 100,000 population in 2018



Figures 14 and 15 on the next page show in more detail the prescribing of co-codamol and codeine phosphate, the two most prescribed Schedule 5 analgesics. Again, the highest prescribing was in the oldest age group, which poses the question as to whether this is the most appropriate prescribing for this age group given their side-effect profile and likely co-morbidities.

Figure 14: Schedule 5 co-codamol items per 100,000 population in 2018

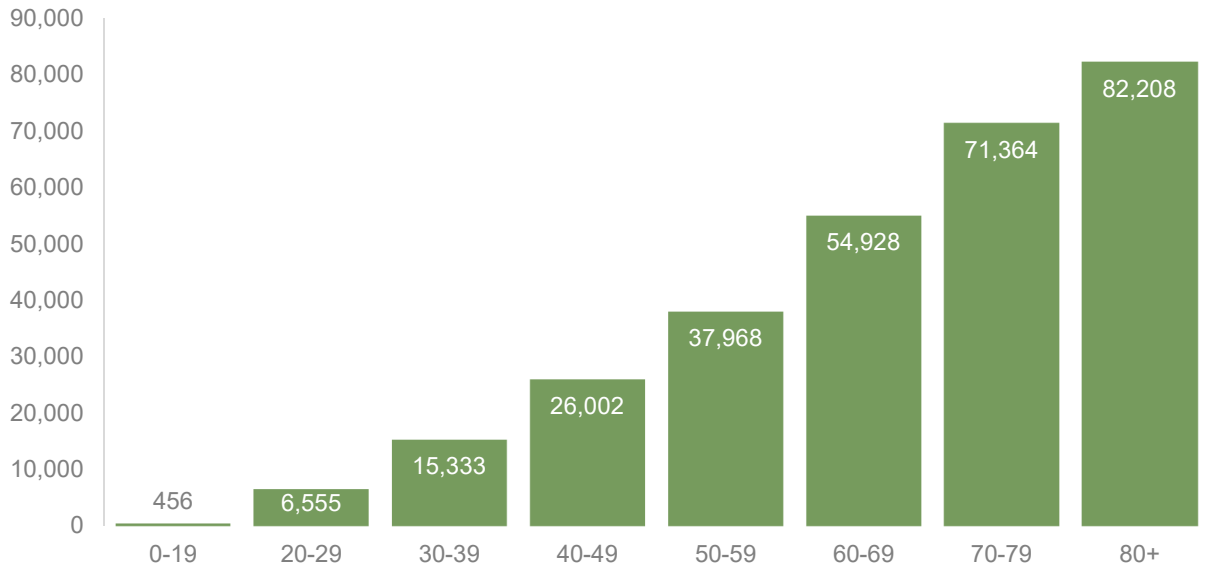
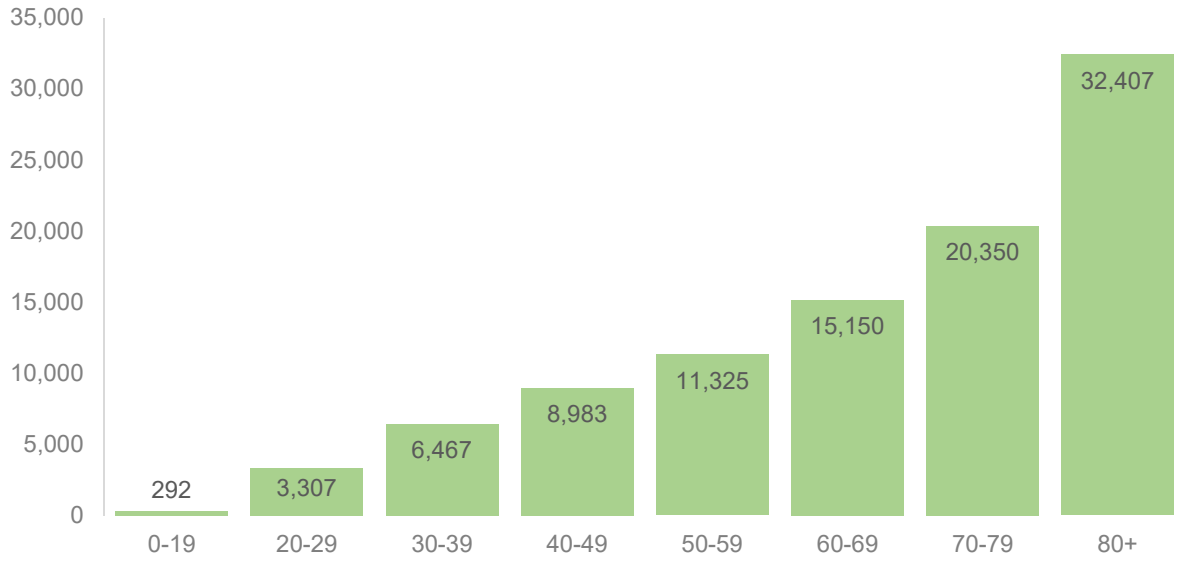


Figure 15: Schedule 5 codeine phosphate items per 100,000 population in 2018



It is important to note that this is not the complete picture. The trends presented above are derived from primary care prescription data and do not take account of those products available without a prescription, for example, over-the-counter codeine-containing products or private prescriptions for Schedules 4 and 5 controlled drugs. However, from the discussions at CDLIN meetings we are aware that the ready availability of these medicines, which can lead to dependence, is a cause for concern but is not easily monitored.

Conclusion

The remainder of 2019 is a period of consolidation where organisations reflect on their current practice and implement further improvement, so they can assure themselves that their arrangements for controlled drugs are safe. It is particularly important that organisations focus on their prescribing and monitoring using the support tools that are now available.

Although the prescribing of cannabis-based products for medicinal use is currently minimal, this is likely to increase over time as more clinics and specialist centres become established. It is important for us all to remain vigilant in ensuring that CBPM products are only prescribed for specific unmet need by appropriately qualified specialists and to continue to keep this under review as licensed products become available.

The rescheduling of gabapentin and pregabalin provides an opportunity for greater monitoring and scrutiny of these medicines so that we can assess whether the rescheduling has any impact on prescribing rates and related harm over the next year or so.

Meanwhile, the ongoing growth in online primary medical services and the lack of scrutiny of private prescriptions for lower schedule controlled drugs remains a matter of concern. It continues to be difficult for NHS England CDAOs to be assured that these medicines are being prescribed appropriately and further consideration needs to be given to this gap in oversight.

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How to contact us

Call us on:	03000 616161
Email us at:	enquiries@cqc.org.uk
Look at our website:	www.cqc.org.uk
Write to us at:	Care Quality Commission Citygate Gallowgate Newcastle upon Tyne NE1 4PA

Follow us on Twitter: @CareQualityComm

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