

## **Safer Management of controlled drugs Diversion & abuse, prescribing and use.**



*Robert Allan – CQC's National Controlled Drugs Officer,  
Medicines Optimisation Team*

## What we will be covering:

- Maintaining a safe environment for managing controlled drugs assessing and overseeing how health and social care providers manage them.
- Controlled Drugs self assessment tools.
- Cannabis-based products and the role of the CDAO for monitoring, and the implication of changes to pregabalin and gabapentin.
- findings from the latest CQC Annual Report “Safer Management of Controlled Drugs” including current trends.
- Findings from the 2019 Controlled Drug Local Intelligence Network Effectiveness Survey.

# Controlled Drugs Safe Use, Prescribing and Management



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



- We report annually to Government on what we find through our oversight and make recommendations.
- Our findings are important for all controlled drugs accountable officers (CDAOs) in England and their support teams including:
  - All 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.

# Controlled Drugs Safe Use, Prescribing and Management



In our latest 2018 update we reported on:



- the increase in opioid prescribing across the UK,
  - measures put in place following the Gosport Independent Panel report,
  - our continuing concerns regarding lower schedule controlled drugs,
  - the introduction of legislation for cannabis based medicinal products.
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- We made five recommendations to further strengthen the arrangements for the safe management and use of CDs.
  - We shared key issues raised by NHS England (NHSE) CDAOs including examples of issues raised at their local area networks.
  - We continued to provide data on overall prescribing trends for CDs in 2018.
  - **New for 2018**
    - we included data from the NHSE [CD Reporting Tool](#) on unaccounted-for losses of CDs by NHSE area.
    - we showed the prescribing picture for opioids in Schedules 2 to 5 prescribed in combination with benzodiazepines, pregabalin or gabapentin across CCG areas of England, based on primary care prescription data.

# Controlled Drugs Safe Use, Prescribing and Management



## **NHS England**

1. 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.

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

## **All CDAOs**

3. 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.

4. 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.

## **All healthcare professionals**

5. 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.

We also reported on:





- Register of Controlled Drugs Accountable Officers (CDAOs) across England.
- Controlled Drugs National Group.
- Controlled Drugs National Group – four Sub-groups
  - *Outputs are in the form of a newsletter*
- Controlled Drugs National and Cross-Border Groups.
- Shared examples of issues raised through local intelligence networks.



# Controlled Drugs Safe Use, Prescribing and Management




## Some examples of the topics discussed at local intelligence networks:

- Monitoring of prescriptions. 
- Governance issues.
- Sharing reported incidents.
- Sharing the learning from incidents.
- Sharing information on individuals of concern. 
- Sharing incidents where theft has taken place, including where staff members were involved.
- Promotion of relevant information including updates to legislation, guidance and policies.



## Some examples of issues found on inspection:

- Lack of understanding of when a Home Office licence is required and for what schedules.
- Confusion between the CD register and CD record books in wards and departments.
- Controlled drugs storage issues; wooden cupboards still in use, contents not matching register entries.
- Access to keys and cupboards. 
- Lack of audits.
- Out of date policies including standard operating procedures.





## Our resources:

- CD Self Assessment tools
- FAQs
- Newsletters
- Annual Report



## Cannabis based products for medicinal use (CBPM)



- Epidyolex manufactured by GW Pharmaceuticals.

- Epidyolex, a cannabidiol (CBD)-based medicine for severe epilepsy has been given marketing approval by the European Medicines Agency.



- Approved as an adjuvant treatment for seizures associated with Lennox Gastaut syndrome or Dravet syndrome in patients aged two years or over. It is to be used alongside clobazam.

- NICE guidance (NG144) covers prescribing of cannabis-based medicinal products for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy.

## Cannabis based products for medicinal use (CBPM)

- CBPMs moved to become Schedule 2 controlled drugs from 1 November 2018.
- Only doctors on the GMC specialist register can prescribe them, not GPs.
- Responsibility sitting with the prescribing clinician.
- Intended for unmet clinical need on a named patient basis.
- NHS England lead CDAOs are exploring options for national data collection on prescribing of CBPMs for medicinal use in the NHS and private sector.

## Food grade CBD oil products

- Cannabis oil products containing less than 0.2% THC can be purchased over the counter in the UK as a food supplement
- Products sold as health food supplements are regulated under the Food Standards Agency and cannot make health / medicinal claims.
- Where patients bring in food grade CBD oil for their own or a relative's use in a service, it is for the service to undertake their own risk assessment.



## Unregulated CBD oil products, i.e. of unknown origin

- Uncertainty about dosage in unlicensed or illegal products is a key concern.
- Dosage and bio-availability will vary according to inhalation or ingestion, as well as strength and purity of the product.

## Pregabalin and gabapentin

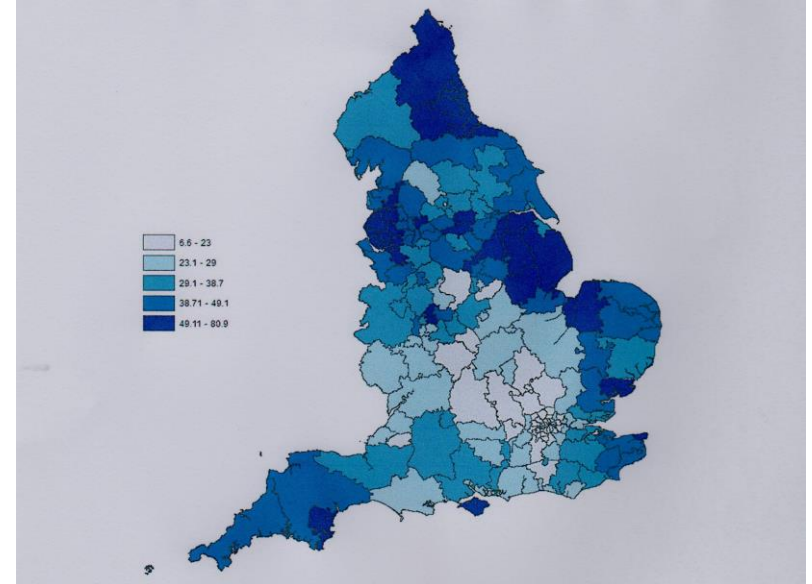
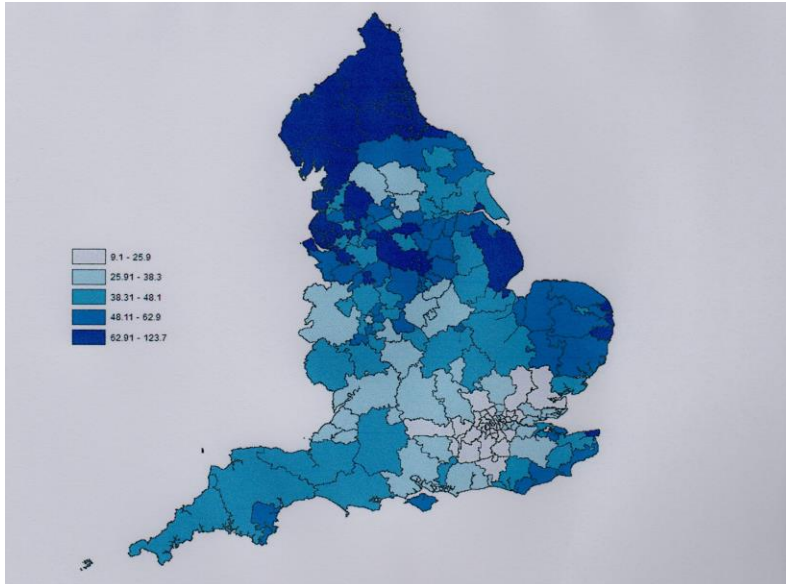
- Pregabalin and gabapentin were reclassified as class C controlled substances (Schedule 3 CD exempt from safe custody) from 1<sup>st</sup> April 2019.
- The change in law means the drugs are still available for legitimate use on prescription, but there will be stronger controls in place to ensure accountability and minimise the chances of pregabalin and gabapentin falling into the wrong hands or being stockpiled by patients.
- Doctors will now need to physically sign prescriptions, rather than electronic copies being accepted by pharmacists.



- Pharmacists must dispense the drugs within 28 days of the prescription being written.

## Pregabalin and gabapentin

- Number of unique patients prescribed both gabapentin and an opioid concurrently in the same month per 1,000 patients in 2018
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# Controlled Drugs Safe Use, Prescribing and Management



National trends in the use and management of controlled drugs, key findings:

- Prescribing trends for controlled drugs in 2018 were broadly similar to 2017.
- NHS primary care services prescribed a total of 59,952,986
- 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.
- As in previous years, prescribing by non-medical prescribers increased, with nurse prescribing increasing by 10% and pharmacist prescribing by 56%.
- There was also more prescribing by physiotherapists and podiatrists, but numbers remain very small.

## Controlled Drugs Local Intelligence Networks (CDLINs) effectiveness survey:

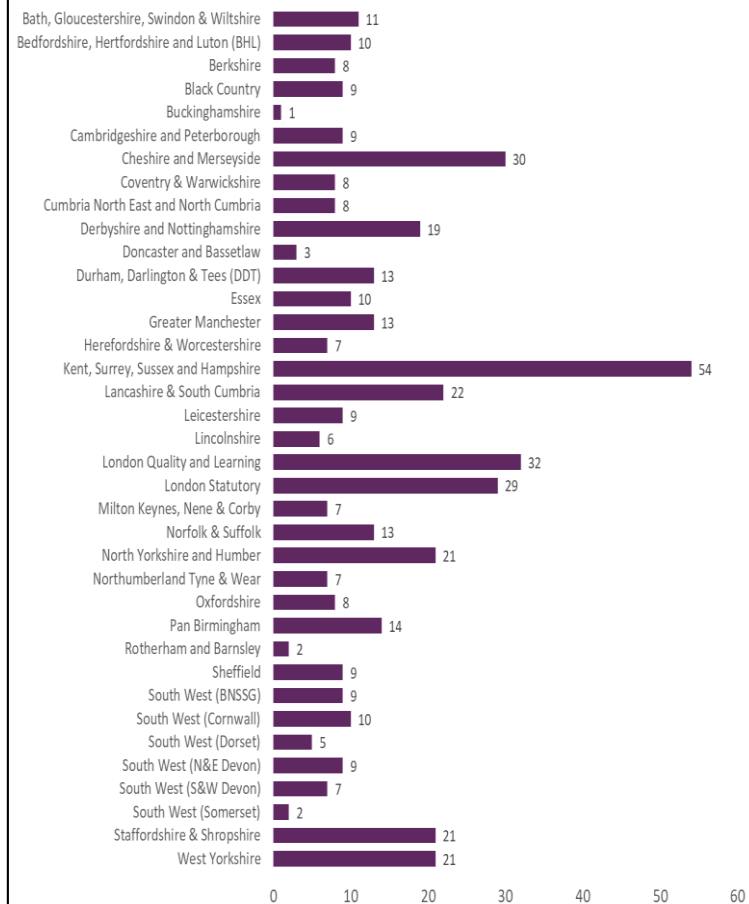
- Undertaken on behalf of NHS England to look at the effectiveness of their Controlled Drugs Local Intelligence Networks (CDLINs).
- Survey ran from 1<sup>st</sup> April until 7<sup>th</sup> May 2019.
- Received 481 complete anonymised survey responses.
- Formal response returned to NHS England in August 2019.



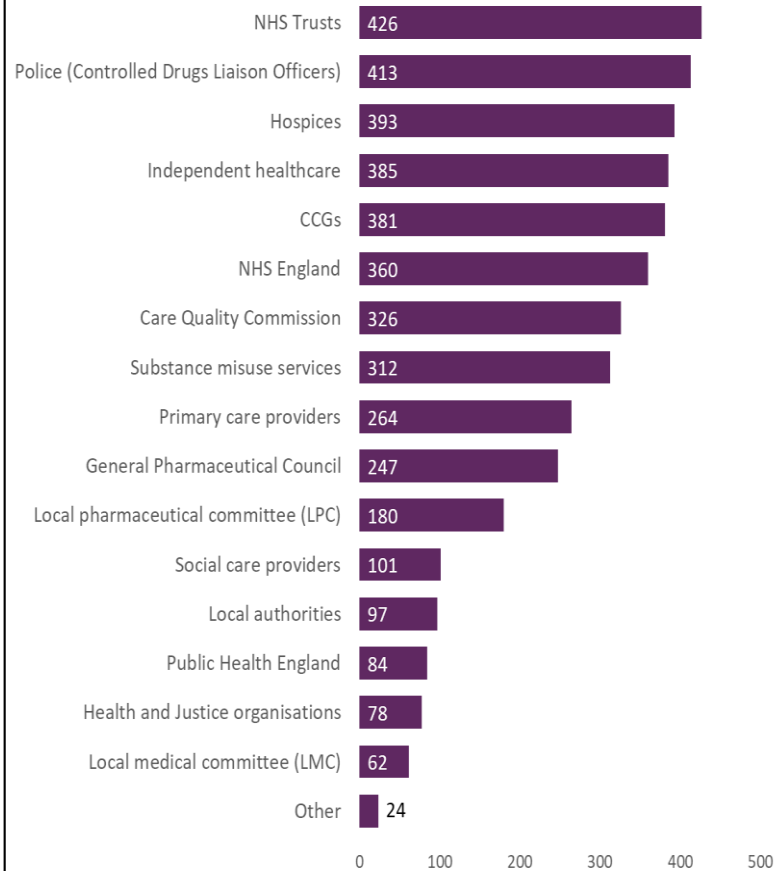
# Controlled Drugs Safe Use, Prescribing and Management



Which Local Intelligence Network are you a member of?



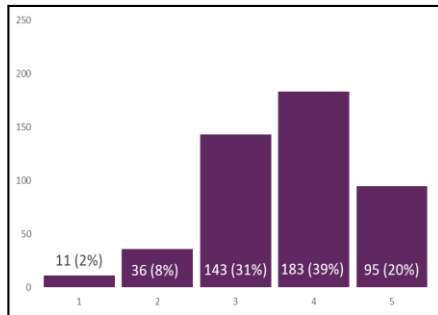
Which of the following organisations and/or types of organisation are you aware of attending the LIN? Tick all that apply



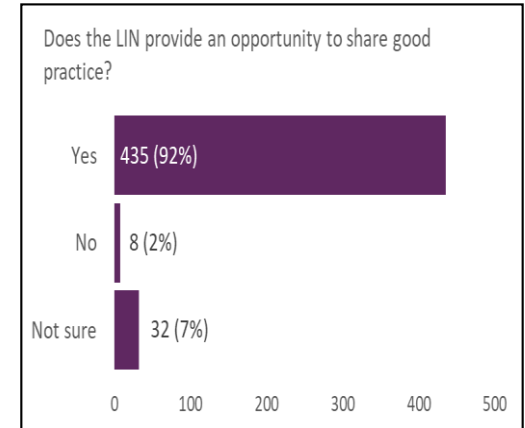
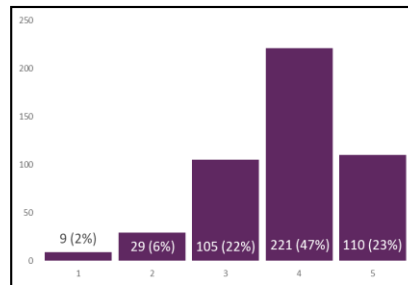
# Controlled Drugs Safe Use, Prescribing and Management



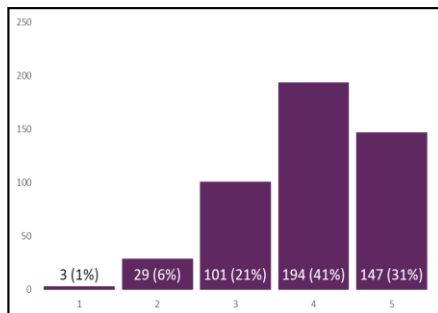
How effective do you consider the LIN is at taking action?



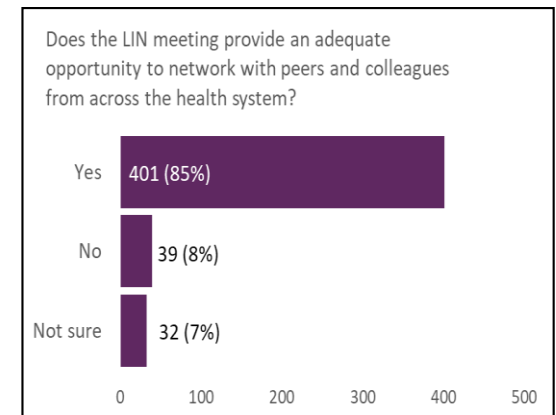
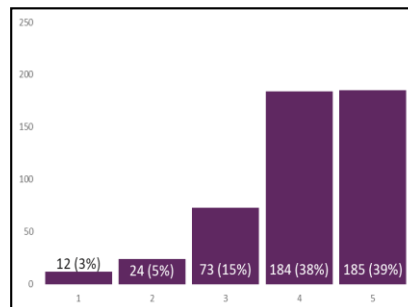
How effective do you consider the LIN is at facilitating the co-operation?



How beneficial do you consider the LIN in securing the safe management and use of controlled drugs?



How confident are you in sharing sensitive information with LIN members about concerns?



(1 being lowest 5 being highest).

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What could the LIN do differently, what should it stop doing and is there anything it should start doing?"  
*Summary of free text answers.*

## **CDLIN content**

- Include an element of education.
- Clear meeting objectives/outcomes.
- Better workload balance – all weighed on designated bodies.
- Focus on real issues of concern and not every CD incident.
- Be more pro-active about certain issues rather than re-active.
- Providing feedback and results from discussed investigations.
- Less time spent on public health issues.
- Hold organisations to account for their lack of systems and processes they have in place.
- Add a section for prior submitted questions that are answered at the LIN.
- It may be helpful to additionally receive feedback at the learning and sharing LIN meetings from CQC around CD issues and ongoing work from the CD working groups.
- More focus on Primary care prescribing and community management of CDs.

## **Membership**

- The effective LINs are smaller, so everyone feels free to speak.
- Inviting community service providers, pharmacy reps, GPs, and PCN Rep
- Perhaps the CDAOs for larger organisations would benefit from their MSOs attending as well/instead.
- Established providers with history.

## **Location**

- Local CDLNs for local organisations.
- Members to be able to attend other CDLNs outside their own.
- Too big a geography, trying to blend geographical areas together that have little in common re patient flow.

## **Reporting**

- Request meeting updates before CDLIN takes place.
- A consistent approach to which incidents to report.
- Need clarity at what level of risk to report to CDAO for the quarterly report.
- Don't see the point in submitting reports on line, should be able to access DATIX incident reports.
- Private sector providers do not share incident reports and when they do they tend to gloss over events, perhaps in case it proves commercially damaging.
- The reporting in occurrence reports is not presented in any consolidated view to identify signals.

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