The prescribing and management of Gabapentin and Pregabalin in HM Prisons and Immigration Removal Centres in England

Collaborative Audit Report
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# Table of contents

<table>
<thead>
<tr>
<th>Executive Summary</th>
<th>Introduction and overview</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes Summary:</td>
<td>Section 1: Overall Patterns of prescribing, underpinning prescribing policies and costs</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Section 2: Patient Specific Outcomes</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Section 3: Incident reporting and medical and pharmacy workforce</td>
<td>7</td>
</tr>
<tr>
<td>Conclusion and recommendations</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td><strong>Main Report</strong></td>
<td>Introduction and overview of method and results</td>
<td>11</td>
</tr>
<tr>
<td>Section 1: Overall Patterns of prescribing</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>underpinning prescribing policies and costs</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>1.1 Amount of prescribing and financial analysis</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>1.1.1 Financial analysis</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>1.2 % of patients who have a documented indication for prescribing</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>1.3 What indications are gabapentin and pregabalin being used for?</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>1.4 The dose ranges and frequencies prescribed</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>1.5 The number of establishments who have and use a prescribing formulary or guidelines in place which explicitly include or excludes pregabalin/gabapentin</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Section 2: Patient Specific Outcomes:</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>2.1 Where gabapentin and pregabalin were initiated and when</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>2.2 The incidence and frequency of medication review</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>2.3 The % of in-possession vs. supervised consumption of these medicines and adherence to IP policy</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>2.3.1 The practical impact of in-possession</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>2.4 History of substance misuse and co-prescribing with opioids and tricyclic antidepressants</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>Section 3: Safety and Workforce</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>3.1 Medication Incidents involving Gabapentin and Pregabalin and Medication-related Security Incident Reports (SIRs).</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>3.2 Analysis of Pharmacy and Medical Workforce</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>3.2.1 Pharmacy workforce patterns</td>
<td>39</td>
<td></td>
</tr>
<tr>
<td>3.2.2 Medical workforce</td>
<td>39</td>
<td></td>
</tr>
<tr>
<td>Conclusion and recommendations</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td>References</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Appendix 1: Audit and Survey outcomes and standards</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Appendix 2: Glossary</td>
<td>45</td>
<td></td>
</tr>
</tbody>
</table>
Executive Summary

This collaborative audit and survey was developed to explore the prescribing and handling of gabapentin and pregabalin across prisons and immigration removal centres (IRCs) in England. Both these medicines are known anecdotally and via some published evidence to be highly sought after by patients attending healthcare for their own use or for trading\(^6\). These medicines are licensed for neuropathic pain, epilepsy and generalised anxiety disorder (GAD) and there is NICE guidance for each of these conditions\(^7\)\(^-\)\(^9\). In addition, the survey explored the medical and pharmacy workforce available at each site to provide a picture of this workforce and whether the use of locum medical staff and access to in-site pharmacy staff influences the prescribing pattern for these medicines.

The audit and survey were designed to provide comprehensive medicines use data for comparative purposes across prisons and IRCs for these medicines and to provide a tested process for replication in the future locally or nationally when analysis of prescribing of other medicines is needed.

Outcomes

94 prisons and 3 IRCs took part. There was no prescribing of gabapentin or pregabalin in the IRCs and no prescribing in 8 of the prisons. The outcomes have been separated into three sections to provide key messages and italicised actions summarised from the more detailed analysis of prescribing and handling available in the main report. Hyperlinks to relevant figures in the main report are included where these illustrate the points raised (N.B. once you look at the figure then by pressing the "alt" key + left arrow \(\leftarrow\) this will bring you back to where you were in the outcomes summary).

Section 1: Patterns of prescribing, underpinning prescribing policies and costs

These outcomes describe the overall prescribing picture and cost of gabapentin and pregabalin along with the prescribing formularies used and the reason these medicines have been prescribed (i.e. their indication).

1.1 Amount of prescribing and financial analysis

- 1819 prisoners are prescribed gabapentin or pregabalin in 86 of the 97 sites. There was no prescribing in IRCs. Figure 1 shows the level of prescribing in each site by site category with Figure 2 showing the actual number of prisoners taking gabapentin and pregabalin in each site.

- Prescribing of gabapentin/pregabalin occurs in 2.82\% of the prison population. This is about twice that of prescribing in the community. This raises the question about whether the prevalence of neuropathic pain, generalised anxiety disorder and epilepsy is higher in prisoners than in the general population to justify this difference.

- Prescribing is statistically highest in training prisons compared with local prisons with Cat A prisons showing higher rates than other prison categories. YOI prescribing is statistically lower than other categories of prison.

- Gabapentin and pregabalin costs the prison health system approximately £1.4m per year. There is potential for significant cost savings and cost avoidance if
prescribing patterns are changed to show similar patterns of prescribing to the community and optimised using formulary or QIPP initiatives.

1.2 What are pregabalin and gabapentin being prescribed for and is this within licensed indications

- 84.4% of prisoners prescribed gabapentin/pregabalin have a documented indication for this medicine. One in six prisoners have no indication recorded.
- Over half of prescribing is for neuropathic pain with a significant amount (22%) of unlicensed (i.e. off-label) prescribing mainly for other pain indications as shown in Figure 4.
- *Further work is needed to establish whether diagnosis of neuropathic pain is more or less robust than in the community or whether prevalence is higher in prisons*
- *Off-label indications for gabapentin and pregabalin should be examined and compared to national pain management guidelines. Off-label use of these medicines should be reviewed and minimised where this is not included in national guidance.*
- *Most prescribing (97%) is within the therapeutic range and usual dose frequency. However doses outside these should be reviewed to ensure clinical outcomes are being achieved.*

1.3 Are formularies in place and are they being used in practice

- Three quarters of sites have a prison, organisationally ratified formulary or guidelines to inform the prescribing of gabapentin and pregabalin. However up to 21% of these sites do not follow their prescribing policy.
- Of the 74 prisons that have a policy on the place in therapy (i.e. 1st, 2nd and 3rd line) for gabapentin and pregabalin, only 9 prisons seem to be following their policies. This may be due to the difficulties in identifying previous treatments in the records meaning that the policy can only be adhered to for new diagnoses
- *National guidance recommends the use of gabapentin and pregabalin only when another therapy has already been tried and failed. However, 23 sites (16 gabapentin; 7 pregabalin) include them as first line therapy.*

**Section 2: Individual Patient Outcomes**

This section covers the outcomes associated with the 1819 individual prisoner records audited in the 86 prisons where prescribing was present. These include:

- Where the medicine was initiated and when
- How often should they have a review and when was the last review completed
- A study of in-possession status for these medicines:
  - Do they have these medicines in their possession (IP) and does this reflect the prison’s IP policy.
  - What impact does the amount of non-possession (NIP) for the prisoner and the prison regime?
Is a history of substance misuse common in prisoners prescribed these medicines? Are they also taking opioids or tricyclic antidepressants that may increase risks in using gabapentin and pregabalin or suggest combination prescribing for similar indications?

2.1 Where are gabapentin and pregabalin first prescribed and when

- Two thirds of prisoners have gabapentin or pregabalin initiated in prison (see Figure 6 with more of these recorded as prison initiated in training prisons (75%) than in local prisons (46%). This goes against claims that training prisons inherit prescribing for their prisoners that has been initiated in local prisons. One in six having no record of where these medicines were initiated.

- Limitations to the data exist where prisoners have been moved around the prison estate and tracking initiation dates becomes more difficult or where primary care records were unobtainable during the first few days in prison.

- A third of prisoners have been taking gabapentin or pregabalin for less than 9 months with a further third taking these for up to 3 years. This outcome needs to be considered alongside the fact that the average time spent in prison is about 18 months so longer durations of therapy will be less common in prison clinical records.

2.2 How often are these medicines reviewed and are local review policies being followed.

- A high proportion of prison policies (87%) and actual prisoners (82%) taking pregabalin and gabapentin show medication reviews happening at least every 6 months or less.

- Only 39% of prisons follow their review policy for all prisoners with 61% of prisons have an average of 11 prisoners per prison where medication review is completed less frequently than their local policies.

- Prisons should locally review their system in place to:
  - Agree a medication review period that is achievable within the establishment and ideally within 6 months
  - Identify and prioritise medication reviews that are due for gabapentin and pregabalin which are subsequently completed and documented. This will reduce the number of prisoners not meeting their local policy.

2.3 In possession policy, policy adherence and operational implications for gabapentin and pregabalin

In-possession (IP) medicines are medicines that are stored and self administered by prisoners after healthcare completes a risk assessment. If a medicine is not held in-possession then this means that each dose must be given directly by healthcare staff under supervision. The level of in-possession seen in prisons is usually based on local in-possession policies which exclude the possession of specific medicines considered high risk for diversion or misuse.

- There is wide variation across prisons on the policy to hold gabapentin and pregabalin in their possession:
Medicines Use and Safety

2.1 Gaba
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lth Audit Report – June 2013 (DF)

- 21 (22%) prisons specify that prisoners can have gabapentin and pregabalin medicines in their possession by default (28-day or weekly possession)
- 43 (45%) do not allow them IP at all and
- 32 (33%) use individual assessment only to determine possession levels.

Supervised dose policies for these medicines are more common in local prisons (72%) than in trainer prisons (36.3%) or Young Offender Institutes (45.4).

- This variation is also reflected in the actual numbers receiving gabapentin and pregabalin in-possession where some level of in-possession occurs in 46% of prisoners (see Figure 10 (overall pie chart) and Figure 11 possession within sites).

- Adherence to local IP policy is generally positive with only 6 prisons appearing not to follow their own policy.

- 981 prisoners (54%) receive gabapentin/pregabalin under supervision. 95% of these have to attend treatment sessions 2 or 3 times a day. This adds an average of 30 minutes to treatment times for these medicines alone.

- The number of prisoners in the treatment queue collecting supervised doses of gabapentin and pregabalin at each prison is between 1 and 48 with the average number being 14 (see Figure 12). These medicines contribute highly to the significant burden of supervised administration of high risk medicines in prisons.

- The impact of the in-possession status of gabapentin and pregabalin needs to be factored in to other policy decisions including formulary selection & implementation and substance misuse/drug strategy. This will ensure the operational impact to treatment sessions both for healthcare and prison staff are fully accounted for.

2.4 History of substance misuse and co-prescribing with opioids and tricyclic antidepressants in prisoners prescribed gabapentin and pregabalin

There is published evidence that both gabapentin and pregabalin are subject to abuse and dependency. Both medicines have known psychiatric side effects including euphoria and hallucinations.

Co-prescribing with opioids was examined as these are also highly sought after in prisons, and known to be diverted and abused. This outcome also provides an overview of where gabapentin and pregabalin are being prescribed alongside methadone and buprenorphine, medicines usually used for substance misuse treatment. There are known interactions between gabapentin and morphine and caution advised for co-administering pregabalin with other medicines acting on the central nervous system (which includes opioids).

Tricyclic antidepressant prescribing was audited as amitriptyline and duloxetine are included in NICE guidance for neuropathic pain as first line with combination therapy with pregabalin being second line.
Well over half of prisoners prescribed gabapentin and pregabalin also have a history of substance misuse. 47% are currently taking opioid substitution medication (methadone or buprenorphine).

49% of prisoners were also taking an opioid and 5% of these were taking more than one opioid.

35% of prisoners co-prescribed an opioid are taking tramadol with 18% taking other opioids used for pain relief (see Figure 16).

The level of substance misuse in prisoners receiving gabapentin and pregabalin is higher than expected given the risks of diversion and abuse of these medicines.

As methadone and buprenorphine can cause respiratory depression (the risk of which are increased by gabapentin and pregabalin), these medicines should be used with caution in these patients.

Co-prescribing of opiate analgesics should be reviewed given the main indications for gabapentin and NICE guidance for neuropathic pain.

The low use of combination therapy may indicate a reluctance to use low dose tricyclic antidepressants for neuropathic pain in prisons. This should be re-examined in the light of the RCGP guidance as diversion risks of these are lower.

Section 3: Safety and Workforce:

This section shows the data related to reported medication safety incidents for gabapentin and pregabalin against a backdrop of Security Incident Reports (SIRs) for all medicines and medical and pharmacy workforce analysis.

3.1 Medication Incidents involving Gabapentin and Pregabalin and Medication-related Security Incident Reports (SIRs).

The survey completed by participants recorded the number of healthcare medication safety incidents between April and September 2012 (6 months) involving gabapentin and pregabalin and also the number of medication-related SIRs.

318 medication safety incidents were reported by healthcare teams with most prisons (36%) reporting between 1 and 10 medication incidents over the 6 month period. 42% of sites had no reported medication incidents for the medicines which could indicate significant under-reporting.

Gabapentin and pregabalin medication safety incidents occur at a reported rate of one incident for every 17 prisoners prescribed them.

Nearly half of these healthcare based incidents are security related with a further 28% happening at the point of administration or supply to the prisoner (see Figure 17).

Medication SIRs are a backdrop for the extent of prescribed medication incidents identified by prison staff outside of healthcare. These SIRs occur at a rate of one SIR in every 25 prisoners but as 1 in 4 prisons reported zero medication SIRs this figure is likely to be an under-estimate. SIRs do not usually specify the medication involved.
There is wide variation in the reporting of healthcare and SIR medication incidents. Reporting should be encouraged and increased via policy levers such as the NHS Outcomes Framework (Domain 5) and prison service delivery outcomes (e.g. HMIP expectations).

Sharing of SIR data with healthcare was reported as problematic for one in seven participants. This aligns with the concerns raised in the recent review of unclassified deaths in custody report published in May 2012. Improvements in SIR/medication incident reporting could be made if medication SIR data is routinely reported via prison medicines management structures along with healthcare medication error reports. This will provide the prison and healthcare with a full overview of medication safety issues.

3.2 Analysis of Pharmacy and Medical Workforce and the possible impact of this on gabapentin and pregabalin prescribing policy and practice

In prisons and IRCs there are a variety of arrangements for the provision of pharmaceutical and medical services. There is a perception that the availability of on-site pharmacy teams and regular rather than locum medical staff have an impact on the prescribing patterns and governance of medicines.

As part of the survey completed by participants information about the amount of on-site pharmacist and pharmacy technician workforce and the use of locum GPs to deliver medical consultation sessions was collated and then linked to prescribing of gabapentin and pregabalin. This information would also provide a unique opportunity to gain a snapshot of the pharmacy and workforce patterns in prison and IRCs.

One in five prisons/IRCs do not have access to any pharmacy staff on-site with just over half (56%) having an on-site pharmacist.

Where on-site support is available this is a mainly a result of the prison having an on-site dispensing pharmacy where pharmacy staff is mandated. Only one in four prisons/IRCs without a pharmacy have access to on-site pharmacist support.

Most (67%) prisons/IRCs use non-locum GPs or have the same regular locum delivering medical care.

The use of formularies is greater with on-site pharmacy staff support and there is a trend towards lower prescribing rates of gabapentin and pregabalin for sites with pharmacy staff too, but this did not reach statistical significance.

The use of locum GPs vs. non-locum GPs showed no difference in prescribing rates for gabapentin or pregabalin.

Further health and justices sector research is needed to explore the benefits of on-site pharmacy staff support in influencing prescribing patterns and safe medicines use.
Conclusions and Recommendations for action

The audit and survey has provided a comprehensive analysis of a snapshot of prescribing of gabapentin and pregabalin in IRCs and prisons. The inclusion of over 70% of prisons in England suggests that the outcomes are representative across the prison estate. The outcomes have verified anecdotal information on the higher use of these medicines in prisons than in primary care and the high level of co-prescription of opioid analgesics and opioids used for substance misuse treatment. The policy infrastructure and implementation for the use of gabapentin and pregabalin in prisons does not consistently follow licensed indications or best practice that reduces the risk of harm or diversion.

The audit and survey outcomes, including their variation between sites, demonstrate the need for a concerted effort between all clinicians and prison staff to minimise the risk of misuse and harm from gabapentin and pregabalin by improving the implementation of NICE guidance and prison-based guidance on the prescribing and handling of these medicines. This will require strategies for handling high risk medicines in secure environments and developing robust, valued and inclusive ways of sharing best practice with the new NHS structures and partnership working with the Ministry of Justice National Offender Managers. Significant cost savings could result from a combined strategic and local approach.

**Recommendation 1: Commissioners** should include clinical audit of gabapentin and pregabalin use and key performance indicators as part of contract monitoring processes. This encourages the use of these medicines appropriately within formularies using licensed indications and within NICE guidance.

**Recommendation 2: Providers** should implement more robustly the policies they have or develop these for prescribing and handling gabapentin and pregabalin. This should be supported by better networking of clinicians using established networks and sharing of successful strategies, care pathways and best practice between providers and commissioners.

The impact of a high proportion of supervised (see to take) administration of these medicines, a fraction of the total supervised administration workload, highlights the challenges of supplying and administering medicines safely against the constraints of the prison regime which limits the time and security available for this essential function. It is also worthy of note that the recent benchmarking exercise completed in prisons could alter the capacity for prison officers to support the security aspects of medicines administration. If this capacity is reduced this would add extra pressure and risk of diversion of high risk medicines including gabapentin and pregabalin.

**Recommendation 3: National Offender Managers, Prison Governors/IRC Directors** should work in partnership with healthcare to ensure in-possession policies are developed and implemented to minimise the risk of diversion of gabapentin and pregabalin and other high risk medicines. This requires the routine delivery of the secure oversight of and appropriate time allocations for medicines administration (treatment times).

Access to an on-site pharmacy workforce has been shown to clearly benefit the medicines handling in other healthcare settings in primary and secondary care. It is also acknowledged that the involvement of pharmacists in delivering safe medicines handling is key to the safety of medicines use which has increased in national focus and
priority and scrutiny\textsuperscript{25,26,27}. It is a concern therefore that there are a significant proportion of sites that have no access to on-site pharmacist and pharmacy technician support.

**Recommendation 4: Commissioners** need to develop further levers within the commissioning cycle to increase on-site pharmacy staff to lead and support safe medicines use and evidence the contribution pharmacy staff make to the handling of medicines in secure environments.

This audit and survey method could be used to provide future analysis of other medicines but it is time consuming as many prisons rely on hand-written prescription charts. The secure environment sector lacks the access to centralised prescribing data available for primary care via the NHS Business Services Authority (i.e. ePACT data). Increased use of e-prescribing via the prison-wide clinical IT system (expected once the new prescribing module is released during 2013/14) could facilitate development of a more efficient centralised mechanism for analysing the use of medicines in prisons. This has already been achieved in primary care for use by commissioners and providers.

**Recommendation 5: Commissioners/NHS England** should explore the feasibility of introducing anonymised clinical data collection systems similar to those available in primary care that enable central and local analysis of prescribing data. This will facilitate future monitoring, understanding and influencing of the prescribing patterns in secure environments.

**Recommendation 6: NHS England** at both national and within area teams should use emerging and current clinical networks to identify and resource strategic and local pharmaceutical and medicines commissioning support expertise to enable the delivery of these recommendations.

**Acknowledgements**
The East and South East Specialist Pharmacy Services would like to thank all the participating project leads based in each site who completed and submitted their data. We are grateful to Dawn Denison for providing the data analysis and project support for this audit and Professor David Wright for the statistical analysis. In addition we would like to thank the members of the stakeholder group who developed the audit and survey:

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Main Report

Introduction

Prescribing patterns across prisons and immigration removal centres (IRCs) is unknown with no standard method for collecting benchmarking collaborative data. It is well recognised that certain medicines are sought after in prisons and misused via trading and bullying mainly for their psychotropic effects. The publication of prescribing guidance in prisons by the Royal College of GPs in 2011\(^1\) highlighted the most common medications misused within prisons and rated them for their general suitability for use within a secure environment. Advice is also given on the safe prescribing of these medicines in terms of documented and appropriate use of licensed indications.

The routine analysis of prescribing trends and medicines audit is a requirement in the Prison Health Performance and Quality Indicators (2011-2013)\(^2\). The recommendation\(^3\) for prisons to have a medicines management committee to oversee the safe handling of medicines provides a multi-disciplinary opportunity to manage key levers that minimise the risks from trading or misuse of medicines. These include handling medication safety incidents that take place in healthcare and within the wider prison, developing a robust in-possession policy\(^4\) that excludes the possession by prisoners of known medicines at high risk of abuse and developing a formulary that takes account of specific prison guidance.

Recent evidence from an analysis of unclassified deaths in custody\(^5\) suggested that the medicines governance and in particular the sharing of information between healthcare and the wider prison about medicines issues had contributed to the harm of prisoners.

This collaborative audit and survey was developed to explore the prescribing and handling of gabapentin and pregabalin across prisons and immigration removal centres (IRCs) in England. Both these medicines are known anecdotally and via some published evidence to be highly sought after by patients attending healthcare for their own use or for trading\(^6\). These medicines are licensed for neuropathic pain (the main indication for their use), epilepsy and generalised anxiety disorder (GAD) and there is NICE guidance for each of these conditions\(^7\)\(^-\)\(^9\). In addition, the survey included aspects that explored the medical and pharmacy workforce available at each site as this would provide a picture of this workforce and whether the use of locum medical staff and access to on-site pharmacy staff influences the prescribing pattern for these medicines.

The audit and survey were designed to provide comprehensive medicines use data for comparative purposes across prisons and IRCs for these medicines and to provide a tested process for replication in the future locally or nationally when analysis of prescribing of other medicines is needed.
Method

A set of survey outcomes and audit standards were agreed by a multidisciplinary project steering group of healthcare and prison service membership. These outcomes are shown in appendix 1 and are based on prison specific guidance[^1-^4], national prescribing and medication review guidance[^10]. All prisons and IRCs in England were invited to participate.

The data was collected via completion of a web-based questionnaire by each site and a detailed spreadsheet with 16 criteria for each patient prescribed gabapentin or pregabalin. The survey and spreadsheet along with a copy of the information sent to participating sites is available here ([link](#)). In order to minimise the risk of patient duplication due to prisoner transfer, the data was collected during a specified 7 day period. The information was returned and analysed centrally against the agreed outcomes and standards. Some statistical analysis on specific outcomes was completed with support from the School of Pharmacy University of East Anglia.

Analysis of the data was completed to enable comparison between prison categories (A to D male prisons; prisons for females; Young Offenders Institutes (YOI) and IRCs); prison types (local, training prisons and IRCs) and prisons within each sub-region of NHS England[^11]. Definitions of these along with other relevant definitions used in this audit/survey are shown in the glossary in appendix 2.

Results

97 sites (3 IRCs and 94 prisons) completed the audit and survey with all sites submitting both the survey and the prescribing spreadsheet. No prescribing of gabapentin or pregabalin was present in the IRCs and there was no prescribing in 8 of the prisons surveyed. The analysis takes into account that certain prison policies are agreed on a prison cluster basis as they are overseen by one healthcare provider.

All the data presented is anonymised with selected representation of the data displayed for either site type or category. A full suite of all graphs produced showing the comparisons between site types, category and sub-region will be available separately ([to have link to suite of graphs for use](#)). The results have been split into three sections that explore different aspects of the audit and survey outcomes with key messages given for each sub-section:

**Section 1:** Patterns of prescribing, underpinning prescribing policies and costs. This section looks at the overall prescribing picture and cost of gabapentin and pregabalin along with the formularies used and the reason these medicines have been prescribed (i.e. their indication).

**Section 2:** Patient Specific Outcomes: This section covers the outcomes associated with the individual patient prescribing information in the prisons where prescribing was present. It also examines the in-possession handling of these medicines and the impact this has on the prisoner, healthcare and prison staff.

**Section 3:** Safety and Workforce: This section shows the data related to reported medication safety incidents for gabapentin and pregabalin against a backdrop of Security Incident Reports (SIRs) for all medicines and medical and pharmacy workforce analysis.
Section 1: Patterns of prescribing, underpinning prescribing policies and costs

This section looks at the overall prescribing picture of gabapentin and pregabalin from the 97 sites that participated. This includes:

- How much prescribing there is and how this varies between sites and between secure settings and the wider community
- Information on the annual cost of prescribing pregabalin and gabapentin along with some potential cost savings or cost avoidance should prescribing be aligned with primary care including primary care QIPP initiatives for these medicines.
- Whether prescribing is within licensed, documented indications and within expected dose ranges
- Whether formularies are in place to support the prescribing and handling of gabapentin and pregabalin and how the policies are actually reflected in actual prescribing from the individual clinical data reported.

1.1 Amount of prescribing and financial analysis

In the 97 secure sites audited, 1819 prisoners were prescribed either gabapentin or pregabalin with an average prescribing rate for both medicines across the detained population of 2.82%. Use of pregabalin is generally lower than gabapentin except for sites in the North West, South West and Yorkshire & Humberside sub-regions (see Table 1).

The prescribing rates in primary care for these medicines has been estimated based on national ePACT data for July to September 2012 and using ONS adult population statistics. This shows that the overall prescribing rate is between 1 and 2% with rates for gabapentin being between 0.7% and 1.4% and pregabalin between 0.3 and 0.5% of the adult population. Prison prescribing overall for both medicines is thus about twice as much as in the community with this difference being dominated by the extra prescribing of pregabalin (about 3 times as much as in the community) rather than gabapentin (about 1.5 times as much).

The differences in prescribing rates between prison types are shown in table 2. There is no prescribing in IRCs and a statistically significant lower rate of prescribing in YOI sites (Local vs. YOI and Trainer vs. YOI both p<0.001, Mann Whitney-U test).

The lower rate in local prisons compared to trainer prisons is also statistically significant (p=0.005, Mann Whitney-U test). This could be accounted for by the fact that local prisons hold both remand and sentenced prisoners, whereas trainer prisons only hold sentenced prisoners where demand for gabapentin and pregabalin may be higher due to longer custody periods.
Table 1: Prescribing rates of gabapentin and pregabaline by NHS sub-regions

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<thead>
<tr>
<th>Sub Region (no. of sites audited)</th>
<th>Number Prescribed Gabapentin</th>
<th>Number Prescribed Pregabaline</th>
<th>Total</th>
<th>% Gabapentin</th>
<th>% Pregabaline</th>
<th>% Prison Population Prescribed Gabapentin &amp; Pregabaline</th>
</tr>
</thead>
<tbody>
<tr>
<td>East of England (16)</td>
<td>173</td>
<td>157</td>
<td>330</td>
<td>1.95%</td>
<td>1.77%</td>
<td>3.71%</td>
</tr>
<tr>
<td>East Midlands (15)</td>
<td>214</td>
<td>130</td>
<td>344</td>
<td>2.14%</td>
<td>1.30%</td>
<td>3.45%</td>
</tr>
<tr>
<td>London (13)</td>
<td>86</td>
<td>76</td>
<td>162</td>
<td>0.85%</td>
<td>0.75%</td>
<td>1.59%</td>
</tr>
<tr>
<td>North East (7)</td>
<td>58</td>
<td>57</td>
<td>115</td>
<td>1.23%</td>
<td>1.20%</td>
<td>2.43%</td>
</tr>
<tr>
<td>North West (4)</td>
<td>46</td>
<td>53</td>
<td>99</td>
<td>0.98%</td>
<td>1.12%</td>
<td>2.10%</td>
</tr>
<tr>
<td>South Central (12)</td>
<td>113</td>
<td>64</td>
<td>177</td>
<td>2.06%</td>
<td>1.17%</td>
<td>3.22%</td>
</tr>
<tr>
<td>South East (6)</td>
<td>82</td>
<td>55</td>
<td>137</td>
<td>2.04%</td>
<td>1.37%</td>
<td>3.41%</td>
</tr>
<tr>
<td>South West (8)</td>
<td>31</td>
<td>69</td>
<td>100</td>
<td>0.84%</td>
<td>1.88%</td>
<td>2.72%</td>
</tr>
<tr>
<td>West Midlands (10)</td>
<td>98</td>
<td>82</td>
<td>180</td>
<td>1.41%</td>
<td>1.18%</td>
<td>2.60%</td>
</tr>
<tr>
<td>Yorkshire &amp; Humberside (6)</td>
<td>79</td>
<td>96</td>
<td>175</td>
<td>1.69%</td>
<td>2.06%</td>
<td>3.75%</td>
</tr>
<tr>
<td>Total</td>
<td>980</td>
<td>839</td>
<td>1819</td>
<td>1.53%</td>
<td>1.31%</td>
<td>2.82%</td>
</tr>
</tbody>
</table>

Table 2: Prescribing rates in different site types

<table>
<thead>
<tr>
<th>Type</th>
<th>Number Prescribed Gabapentin</th>
<th>Number Prescribed Pregabaline</th>
<th>Total</th>
<th>% Gabapentin</th>
<th>% Pregabaline</th>
<th>% Prison Population Prescribed Gabapentin &amp; Pregabaline</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRC</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Local</td>
<td>302</td>
<td>341</td>
<td>643</td>
<td>1.10%</td>
<td>1.25%</td>
<td>2.35%</td>
</tr>
<tr>
<td>Trainer</td>
<td>637</td>
<td>456</td>
<td>1093</td>
<td>2.17%</td>
<td>1.55%</td>
<td>3.73%</td>
</tr>
<tr>
<td>YOI</td>
<td>41</td>
<td>42</td>
<td>83</td>
<td>0.62%</td>
<td>0.64%</td>
<td>1.26%</td>
</tr>
<tr>
<td>Total</td>
<td>980</td>
<td>839</td>
<td>1819</td>
<td>1.53%</td>
<td>1.31%</td>
<td>2.82%</td>
</tr>
</tbody>
</table>

Figure 1 shows the rates of prescribing between different prison categories. This shows the highest rate of prescribing is in Category A prisons (average 4.5%) where sentences tend to be longer than other prison categories.

To put the prescribing rates into patient context and provide information in the variation of prescribing across the sites, Figure 2 shows the number of prisoners prescribed gabapentin/pregabaline in each site organised by prison category. 11 sites showed no prescribing of either medicine.
Prescribing rates of pregabalin and gabapentin between different prison categories:
Figure 2 Number of patients prescribed gabapentin/pregabalin in each prison/IRC by category
1.1.1. Financial Analysis

The annual cost of prescribing gabapentin and pregabalin was estimated based on the individual patient data submitted by each site and using the January 2013 Drug Tariff\textsuperscript{13}.

The calculations show a total cost of £945,000 across the 94 prisons (extrapolated to £1.4m across the 127 England prisons). This is an estimate but the figures suggest that:

- Gabapentin prescribing costs £257,000 annually for 980 prisoners which if extrapolated to all prisons in England would be £356,944.
- Pregabalin prescribing costs £755,550 annually for 837 prisoners which if extrapolated to all prisons in England would be £1,050,000.
- Dose optimisation of pregabalin doses where these are prescribed three times a day but where the same total daily dose could be given twice daily would save £60,000 in the participating prisons (8% of pregabalin costs). This is because all strengths of pregabalin tablets cost the same and it can be given twice or three times daily with no difference in clinical outcome\textsuperscript{14}.
- Reducing the rate of prescribing of both gabapentin and pregabalin to community prescribing rates would reduce costs to £500,000 for pregabalin and £170,000 for gabapentin in the participating prisons. This represents a possible saving of £400k (30%) across all prisons in England.
- If pregabalin was removed from formularies for neuropathic pain and replaced with gabapentin and the ratio of gabapentin vs. pregabalin prescribing shifted to 80:20, then this would reduce costs by £600k across the participating prisons (63% saving) which extrapolates to a saving of circa £882k across prisons in England.

Key messages:

- 1819 prisoners are prescribed gabapentin or pregabalin in 86 of the 97 sites. There was no prescribing in IRCs.

- Prescribing of gabapentin/pregabalin occurs in 2.82% of the prison population. This is about twice that of prescribing in the community. This raises the question about whether the prevalence of neuropathic pain, generalised anxiety disorder and epilepsy is higher in prisoners than in the general population to justify this difference.

- Prescribing is statistically highest in training prisons compared with local prisons with Cat A prisons showing higher rates than other prison categories.

- Gabapentin and pregabalin costs the prison health system approximately £1.4m per year. There is potential for significant cost savings and cost avoidance if prescribing patterns changed to show similar patterns of prescribing to the community and optimised using formulary or QIPP initiatives.
1.2 % of patients who have a documented indication for prescribing

The audit standard for this outcome is that 100% of prescriptions should have a documented indication (reason why the medicine has been prescribed) in the clinical records. The audit showed that 84.4% of prisoners prescribed gabapentin or pregabalin had a documented indication in their clinical record.

Figure 3 shows the percentage of prisoners taking gabapentin/pregabalin where an indication has not been recorded. Sites showing 0% on this chart meet the audit standard (i.e. all of their prisoners have a documented indication for prescribed gabapentin/pregabalin). An average of 16.1% of prisoners in each prison do not have a recorded indication (1 in 6).

Figure 3: Number of prisoners in each prison with no documented indication

1.3 What indications are gabapentin and pregabalin being used for?

The audit standard is that 100% of pregabalin/gabapentin use should be for licensed indications. These are: Neuropathic pain, epilepsy and generalised anxiety disorder (pregabalin only).

The pie chart in Figure 4 shows the range of indications documented, neuropathic pain being the most common (55%).

399 (22%) of prisoners are being prescribed gabapentin or pregabalin for unlicensed indications. These indications were for other types of pain (including migraine, sciatica, arthritis) with 79 (19.7%) being prescribed for back pain. Unusual indications recorded included methadone reduction, diabetes management, chest pain and buying from the wing!
Figure 4: Range of indications for pregabalin and gabapentin

Key messages:

- 84.4% of prisoners prescribed gabapentin/pregabalin have a documented indication for this medicine. One in six prisoners have no indication recorded.

- Over half of prescribing is for neuropathic pain with a significant amount (22%) of unlicensed (i.e. off-label) prescribing mainly for other pain indications.

- Further work is needed to establish whether diagnosis of neuropathic pain is more or less robust than in the community or whether prevalence is higher in prisons.

- Off-label indications for gabapentin and pregabalin should be examined and compared to national pain management guidelines. Off-label use of these medicines should be reviewed and minimised where this is not included in national guidance.
1.4 The dose ranges and dose frequencies prescribed

The audit standard is that 100% of prescribing should be within the licensed dose ranges. The table below shows the proportion of prescribing within stated dose ranges for pregabalin and gabapentin:

Table 3: Dose ranges for pregabalin and gabapentin

<table>
<thead>
<tr>
<th>Gabapentin</th>
<th>Number of prisoners</th>
<th>% of total prescribed</th>
<th>Pregabalin</th>
<th>Number of prisoners</th>
<th>% of total prescribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 300mg*</td>
<td>20</td>
<td>2.0%</td>
<td>&lt;150mg*</td>
<td>38</td>
<td>4.5%</td>
</tr>
<tr>
<td>300mg - 600mg</td>
<td>165</td>
<td>16.8%</td>
<td>151mg - 300mg</td>
<td>267</td>
<td>31.8%</td>
</tr>
<tr>
<td>601mg - 1200mg</td>
<td>366</td>
<td>37.3%</td>
<td>301mg - 600mg</td>
<td>520</td>
<td>62.0%</td>
</tr>
<tr>
<td>1201mg-2400mg</td>
<td>316</td>
<td>32.2%</td>
<td>&gt; 600mg*</td>
<td>14</td>
<td>1.7%</td>
</tr>
<tr>
<td>2401mg-3600mg</td>
<td>111</td>
<td>11.3%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 3600mg*</td>
<td>1</td>
<td>0.1%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0.1%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Doses outside therapeutic ranges

Overall 96% prisoners were receiving doses within the expected range. There were 14 prisoners on high doses of pregabalin (>600mg) and one prisoner on >3600mg of gabapentin.

Dose frequencies for pregabalin and gabapentin were mainly twice (882/48%) and three times daily (833/46%) with daily (48/3%) and four times daily (52/3%) being less common. Four prisoners were taking variable doses and annotation from auditors showed that this was used where gradual dose reductions were being implemented. The dose frequencies stated in the Summary of Product Characteristics (SPC) for both medicines\(^\text{15,16}\) show a two or three times a day frequency based on their pharmacokinetics. This only needs to be reduced to once a day dosing in severe renal impairment. It is therefore possible that the once daily doses are resulting in periods of sub-therapeutic treatment, and the four times a day doses could be resulting in too short a gap between doses and raising the peak plasma concentration or increasing accumulation.

Key messages:

- **Most prescribing is within the therapeutic range and usual dose frequency. However doses outside these should be reviewed to ensure clinical outcomes are being achieved.**

1.5 The number of establishments who have and use a prescribing formulary or guidelines in place which explicitly include or exclude pregabalin/gabapentin

Each site submitted information about whether they used a prison formulary or guidelines, a formulary or guidelines ratified by another organisation (e.g. the PCT) or whether they used national guidelines.

Table 4 shows the responses and also includes whether gabapentin and/or pregabalin are included in the formulary and whether actual prescribing reflected these policies:
Table 4: Formulary use, inclusion of gabapentin and pregabalin

<table>
<thead>
<tr>
<th>Formulary Use</th>
<th>Number of sites</th>
<th>% of total sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisationally Ratified Prison Formulary</td>
<td>65</td>
<td>67.0%</td>
</tr>
<tr>
<td>Organisationally Ratified Prescribing Guidelines</td>
<td>9</td>
<td>9.3%</td>
</tr>
<tr>
<td>and NICE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only Externally Developed Guidance (i.e. NICE etc)</td>
<td>23</td>
<td>23.7%</td>
</tr>
<tr>
<td>Gabapentin &amp; Pregabalin on Formulary</td>
<td>71</td>
<td>73.2%</td>
</tr>
<tr>
<td>Gabapentin Only on Formulary</td>
<td>12</td>
<td>12.4%</td>
</tr>
<tr>
<td>Pregabalin Only on Formulary</td>
<td>4</td>
<td>4.1%</td>
</tr>
<tr>
<td>Neither on Formulary</td>
<td>10</td>
<td>10.3%</td>
</tr>
<tr>
<td>Number of prisons where prescribing is contrary to formulary status</td>
<td>20</td>
<td>20.6%</td>
</tr>
</tbody>
</table>

For the 20 sites where pregabalin and/or gabapentin were being prescribed outside their formulary, the number of prisoners being prescribed these medicines was between 1 and 27. There are usually two main reasons for this:

- It is usual practice for there to be exceptions to the formulary for any diagnosis, but these numbers would usually be low (i.e. <20%).
- Prisons may also use the formulary for new initiations only and only change non-formulary medication already being taken prior to admission as part of their medication review process for longer stay prisoners.

So there will always be a degree of non-compliance to a formulary and this analysis gives us an idea of how much of this exists for these medicines in the prisons that have a formulary in place.

Place in therapy was also investigated by asking whether gabapentin and pregabalin were used 1st, 2nd or 3rd line for neuropathic pain and generalised anxiety disorder (GAD) for those prisons using a ratified formulary/guideline (n=74). National guidance recommends the use of gabapentin and pregabalin only when another therapy has already been tried and failed\(^7\,^8\,^9\). Table 5 shows the overall place in therapy for gabapentin and pregabalin as a whole across the sites:

Table 5: Place in therapy for sites within formularies containing gabapentin and pregabalin

<table>
<thead>
<tr>
<th>Place in therapy*</th>
<th>Pregabalin</th>
<th>Gabapentin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Line</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>2nd Line</td>
<td>9</td>
<td>34</td>
</tr>
<tr>
<td>3rd Line</td>
<td>60</td>
<td>43</td>
</tr>
<tr>
<td>Non-formulary</td>
<td>20</td>
<td>15</td>
</tr>
</tbody>
</table>

* For one or more indications; some sites (n=74) stated more than one place in therapy (i.e. 2nd and 3rd line) and these have been included separately.

Figure 5 shows the actual place in therapy identified in clinical records for prisoners prescribed gabapentin and pregabalin in the participating sites grouped by prison category. 723 (40%) of prisoners clinical information did not clearly show whether other medicines had been tried prior to gabapentin or pregabalin. This is not surprising given that previous prescribing records, especially community-based records are generally not available to reference. This means that prescribers have only prison records and verbal information from the prisoner to support the choice of medicine.
Where a clear indication for therapy was given and a place in therapy discernible, it was possible to compare the prison’s policy on place in therapy compared to the actual place in therapy in the 74 prisons where a policy existed. The data showed that only 9 (12%) sites demonstrated policy adherence for place in therapy and 55 (74%) were clearly not adhering to their policy with the remaining 10 sites.

The audit standard is that 100% of patients should have tried a previous medicine first prior to being prescribed gabapentin/pregabalin. In NICE guidance, the place of gabapentin and pregabalin for neuropathic pain and GAD is not first line\(^8,9\). In prisons the use of tricyclic antidepressants in low doses as first line treatment for neuropathic pain is the preferred option in the RCGP Guidance\(^1\), so the use of either of gabapentin or pregabalin as first line is questionable given their potential for diversion or abuse.

**Key Messages:**

- Three quarters of sites have a prison or organisationally ratified formulary or guidelines to inform the prescribing of gabapentin and pregabalin. However up to 21% of these sites do not follow their prescribing policy.
- Of the 74 prisons who have a policy on the place in therapy for gabapentin and pregabalin, only 9 prisons seem to be following their 1\(^{st}\), 2\(^{nd}\) and 3\(^{rd}\) line policies. This may be due to the difficulties in identifying previous treatments in the records meaning that the policy can only be adhered to for new diagnoses.
- National guidance recommends the use of gabapentin and pregabalin only when another therapy has already been tried and failed. However, 23 sites (16 gabapentin; 7 pregabalin) include them as first line therapy.
Section 2: Prisoner Specific Outcomes

This section covers the outcomes associated with the 1819 individual prisoner records audited in the 86 prisons where prescribing was present. These include:

- Where the medicine was initiated and when
- How often should they have a review and when was the last review completed
- A study of in-possession status for these medicines:
  - Do they have these medicines in their possession (IP) and does this reflect the prison’s IP policy.
  - What impact does the amount of non-possession (NIP) for the prisoner and the prison regime?
- Is a history of substance misuse common in prisoners prescribed these medicines?
- Are they also taking opioids or tricyclic antidepressants that may increase risks in using gabapentin and pregabalin or are linked to similar indications?

2.1 Where gabapentin and pregabalin were initiated and when

Auditors were asked to identify whether the medicines were initiated in the community, hospital, another prison or their current prison. The pie chart below (Figure 6) shows the range of responses overall and Figure 7 shows the variation within the individual prisons:

Figure 6: Place of initiation of gabapentin and pregabalin
Gabapentin/pregabalin is being initiated in prisons for 63% of prisoners audited with more of these recorded as prison initiated in training prisons (75%) than in local prisons (46%). This goes against claims that training prisons inherit prescribing for their prisoners that has been initiated in local prisons. There may be limitations to this data due to the difficulties in establishing community-based medication histories, especially in training prisons where prisoners may have been moved around between several sites and a prison initiation could be incorrectly assumed. This may also account for the higher rate of community and unknown initiations seen in the local prisons.

**Duration of therapy**

Records for individual prisoners were explored to establish the duration of therapy and table 6 shows the range of outcomes for this:

**Table 6: Range of duration of therapy**

<table>
<thead>
<tr>
<th>Documented record of initiation</th>
<th>Number of prisoners</th>
</tr>
</thead>
<tbody>
<tr>
<td>During last 9 Months</td>
<td>560 (31%)</td>
</tr>
<tr>
<td>Between 1 - 3 years</td>
<td>621 (34%)</td>
</tr>
<tr>
<td>Greater than 3 Years</td>
<td>52 (2.3%)</td>
</tr>
<tr>
<td>Unknown/Unclear/No data Submitted</td>
<td>586 (32%)</td>
</tr>
</tbody>
</table>

There is a documented initiation date for just over two thirds of the prisoners prescribed these medicines with nearly all showing treatment duration of up to three years. This outcome needs to be considered alongside the fact that the average time spent in prison is about 18 months¹⁷ so longer durations of therapy will be less
commonly reported due to the lack of community information and the initiation rates of these medicines in prisons.

**Key Messages**

- **Two thirds of prisoners have gabapentin or pregabalin initiated in prison with more of these recorded as prison initiated in training prisons (75%) than in local prisons (46%).** This goes against claims that training prisons inherit prescribing for their prisoners that has been initiated in local prisons. One in six having no record of where these medicines were initiated.

- **Limitations to the data exist where prisoners have been moved around the prison estate and tracking initiation dates becomes more difficult or where primary care records were unobtainable during the first few days in prison.**

- **A third of prisoners have been taking gabapentin or pregabalin for less than 9 months with a further third taking these for up to 3 years.** This outcome needs to be considered alongside the fact that the average time spent in prison is about 18 months (Story of the Prison Population: 1993 – 2012 England and Wales January 2013) so longer durations of therapy will be less common.

### 2.2 The incidence and frequency of medication review

The frequency of medication review in prisons has in the main been aligned with national guidance for patients in the community. Regular medication review is cited in both the RCGP Prescribing in Prisons¹ and A Pharmacy Service for Prisoners³. Due to the variable average length of stay in prisons, the risk of abuse of gabapentin and pregabalin and their licensed indications, the audit standard for medication review of these medicines was agreed as 6 months in 100% of patients as a standard for this audit.

The sites submitted information on their medication review policy for gabapentin and pregabalin via the survey as well as identifying the actual date of the latest review of prisoners prescribed these medicines.

In policies, prisons and IRCs showed the medication review frequencies detailed in Table 7:

<table>
<thead>
<tr>
<th>Policy for Med Review Frequency</th>
<th>Number of sites (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly</td>
<td>8 (8.4)</td>
</tr>
<tr>
<td>Every 3 Months</td>
<td>47 (49.5)</td>
</tr>
<tr>
<td>6 Months</td>
<td>27 (28.4)</td>
</tr>
<tr>
<td>Annually</td>
<td>2 (2.1)</td>
</tr>
<tr>
<td>Not Stated in Policy</td>
<td>5 (5.3)</td>
</tr>
<tr>
<td>Decided by GP/Prescriber</td>
<td>4 (4.2)</td>
</tr>
<tr>
<td>Gaba/Pregaba Not Prescribed</td>
<td>4 (4.2)</td>
</tr>
</tbody>
</table>

This shows that 87% of sites expected medication reviews to be completed within the audit standard of 6 months.
The actual frequency of medication review for the 1819 prisoners prescribed gabapentin and pregabalin is shown in Figure 8:

Figure 8 Actual medication review period for prisoners prescribed gabapentin or pregabalin

Actual medication reviews were being completed within 6 months for 82% of prisoners. More detailed analysis showed that in the 86 prisons prescribing gabapentin or pregabalin, 59 of them (61%) had one or more prisoners where the review was not completed within the expected time-frame. The extent of this non-adherence to their policies is explained in Figure 9 which shows the number of prisoners having reviews less frequently than expected for the 59 prisons:

The 59 prisons had an average of 11 prisoners not receiving medication reviews in the expected timeframe.
Key messages:

- A high proportion of prison policies (87%) and actual prisoners (82%) taking pregabalin and gabapentin show medication reviews happening at least every 6 months or less.
- Only 39% of prisons follow their review policy for all prisoners with 61% of prisons have an average of 11 prisoners per prison where medication review is completed less frequently than their local policies.
- Prisons should locally review their system in place to:
  - Agree a medication review period that is achievable within the establishment and ideally within 6 months
  - Identify and prioritise medication reviews that are due for gabapentin and pregabalin which are subsequently completed and documented. This will reduce the number of prisoners not meeting their local policy.
2.3 The % of in-possession vs. supervised consumption of these medicines and adherence to IP policy

This section explores the level of in-possession of gabapentin and how this affects the prisons operationally. The information includes:

- How much gabapentin and pregabalin is held in-possession (IP),
- How does this compare to the policies in place
- What impact does non in-possession (NIP) have operationally?

The in-possession status of medicines in prisons falls into four types: Daily, weekly and full (28-day) in possession or not in-possession (NIP). If a medicine is not held in-possession, then the prisoner has each dose administered individually under supervision (commonly known as “see to take”). The IP status is based on the prison’s IP policy which usually includes a list of medicines which have a specific level of IP as a default. The decision to restrict the level of IP for individual medicines is based on the risk of abuse and diversion of the medicine or the severity of harm in overdose. Commonly restricted medicines include schedule 2 and 3 controlled drugs (CDs), opioids, benzodiazepines, hypnotics, tramadol and gabapentin and pregabalin.

Possession status is also assessed for individual prisoners based on the mental health of the patient, the risk or history of self-harm or abuse of medicines and whether there are any physical or cognitive reasons which prevent the prisoner from independently taking their medicines. This individual risk assessment is usually completed on arrival at the prison and is reviewed at stated intervals or when a change in the patient’s safety is highlighted. More detailed information about in-possession and how this works is available in a publication by the National Prescribing Centre.

In offender health, there have been Prison Service Orders and Instructions that include specific advice on the in-possession of high risk medicines.

Before looking at the individual possession status of the prescribed gabapentin and pregabalin, the policy decisions about the IP status of these medicines will be examined. This policy information is taken from the survey responses given by 96 of the 97 participating sites and showed that:

- 21 (22%) prisons specify that prisoners can have gabapentin and pregabalin medicines in their possession by default
- 43 (45%) do not allow them IP at all and
- 32 (33%) use individual assessment only to determine possession levels.

Table 8 examines the difference in IP policy for gabapentin and pregabalin across site types:

<table>
<thead>
<tr>
<th>Prison type</th>
<th>% not allowing IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local</td>
<td>72.5%</td>
</tr>
<tr>
<td>Trainer</td>
<td>36.3%</td>
</tr>
<tr>
<td>YOI</td>
<td>45.4%</td>
</tr>
<tr>
<td>IRC</td>
<td>0%</td>
</tr>
</tbody>
</table>

Table 8: % of prisons not allowing possession of gabapentin or pregabalin
There is a clear difference (statistically significant P<0.001 Mann Whitney-U test) between the IP policies for local vs. trainer prisons and YOIs, with trainers and YOIs allowing a greater amount of IP than locals. This reflects the different population in local prisons where prisoners on remand or newly sentenced may be new to the prison and have an unknown security risk relating to medicines abuse and diversion.

Moving on to the actual possession of gabapentin and pregabalin prescribed by 86 out of the 97 sites, Figure 10 shows the overall picture of the actual possession status for prisoners receiving these medicines:

Figure 10: Type of in-possession for prescribed gabapentin and pregabalin

This shows that 46% of prisoners have gabapentin and pregabalin in-possession, with the remaining 54% (981) having to attend treatment sessions for supervised doses at least once a day.

To gain a sense of how possession of gabapentin and pregabalin looks across the prisons prescribing it, Figure 11 shows the in-possession status of prisoners within each of the sites prescribing gabapentin and pregabalin organised by prison category:

This shows a mixed picture of IP but with a tendency towards more in-possession in Cat C and D prisons. This makes sense as these categories are usually preparing prisoners for release and independence. They are also considered less of a security risk than Cat A, B and Young Offenders and this includes the risk of medicines abuse/diversion.
When compared to the local policies for in-possession, the data suggests that 11 (13%) prisons allow possession of gabapentin and pregabalin for one or more prisoners when the policy states these should not be held IP. In five of these prisons, the numbers are low enough to suggest that these are specific agreed exceptions rather than the policy not being adhered to.

2.3.1 The practical impact of supervised doses for gabapentin and pregabalin

Due to the richness of the data submitted, we were able to provide further information about the practical impact of supervised administration of gabapentin and pregabalin across the participating prisons. In order to receive a supervised dose, prisoners have to join a queue up to three or four times a day to receive their gabapentin or pregabalin usually at a specific time slot set aside for treatments each day. This queue will vary in length and treatment times can take over an hour to complete. The supply of the medicines is usually completed by nurses, pharmacy technicians and pharmacists, sometimes with an assistant to help them. The prison and healthcare services within them find the supply of medicines particularly challenging and the greater the amount of supervised (NIP) medicines the greater the pressure on the prison regime and healthcare/prison workforce capacity.

This audit has given us some insight into the impact of these two medicines alone on the medicines/treatment queue. The data was analysed to show the proportion of prisoners who have to attend treatment times for NIP gabapentin and pregabalin one, two, three or four times a day. Table 9 shows this distribution of attendance:

Table 9: No. of prisoners for each frequency of attendance for NIP gabapentin and pregabalin
This means that 935 (95%) prisoners having their doses supervised need to attend treatment times two or three times a day. For individual prisons, the data can be organised to show the supervised dose load for each prison for these medicines. Figure 12 shows the number of prisoners receiving supervised doses with these split into the different dose frequencies.

**Figure 12: Frequency of administration for prisoners receiving gabapentin and pregabalin NIP**

<table>
<thead>
<tr>
<th>Frequency Prescribed</th>
<th>Number of Supervised Prisoners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>31</td>
</tr>
<tr>
<td>Twice Daily</td>
<td>626</td>
</tr>
<tr>
<td>Three Times a Day</td>
<td>309</td>
</tr>
<tr>
<td>Four Times a Day</td>
<td>13</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
</tr>
</tbody>
</table>

The average number of prisoners needing supervised doses is 14 (range 1-48) with most of these attending two or three times a day. If it takes approximately two minutes to call, ID the prisoner, collect, prepare, supervise, supply and record the dose supplied, then gabapentin and pregabalin supervised doses take on average about 30 minutes of the treatment time in each prison.

**Key messages on In-possession of gabapentin and pregabalin.**

- There is wide variation across prisons on the policy status and number of prisoners able to hold gabapentin and pregabalin in their possession.
- Adherence to local IP policy is generally positive with only 6 prisons appearing not to follow their own policy.
- 981 prisoners (54%) receive gabapentin/pregabalin under supervision. 95% of these have to attend treatment sessions 2 or 3 times a day. This adds an average of 30 minutes to treatment times for these medicines alone.
The number of prisoners in the treatment queue collecting supervised doses of gabapentin and pregabalin at each prison is between 1 and 48 with the average number being 14. These medicines contribute highly to the significant burden of supervised administration of high risk medicines in prisons.

The impact of the in-possession status of gabapentin and pregabalin needs to be factored in to other policy decisions including formulary selection & implementation and substance misuse/drug strategy. This will ensure the operational impact to treatment sessions both for healthcare and prison staff are fully accounted for.

2.4: History of substance misuse and co-prescribing with opioids and tricyclic antidepressants

There is published evidence that both gabapentin and pregabalin are subject to abuse and dependency. Both medicines have known psychiatric side effects including euphoria and hallucinations. Reports to the MHRA via the yellow card system show 77 and 29 reports relating to abuse/dependence for pregabalin and gabapentin respectively. A literature review completed to support this audit reported that:

- The SPC (data sheet) for pregabalin states that cases of abuse have been reported. Caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of pregabalin abuse.
- Although pregabalin appears to have low potential for abuse, certain populations (e.g. those with a history of substance abuse) may be more liable to abuse or misuse it.
- Gabapentin dependence/abuse was generally related to withdrawal effects and syndromes rather than abuse directly although case reports of abuse in secure environments have been reported.
- Authors of the main article on gabapentin dependence suggest that: In practice, it is better to avoid exposing patients to these risks when the expected benefits are not properly documented. Healthcare professionals should take care to prevent and detect addiction to pregabalin or gabapentin.

Against this backdrop there are growing concerns in offender health about the abuse and diversion of gabapentin and pregabalin, so the prevalence of a history of substance misuse in offenders taking gabapentin and pregabalin was included within the scope of the audit.

The data collection included entries showing whether individual prisoners taking gabapentin and pregabalin had a documented history of substance misuse. The analysis showed that 56.1% of prisoners taking these medicines had this history. Figure 13 shows how this is spread across the sites prescribing these medicines while Figure 14 shows the number of prisoners having a history of substance misuse as a proportion of all prisoners prescribed gabapentin and pregabalin.
Figure 13: % of Prisoners prescribed gabapentin and pregabalin who have a history of substance misuse (organised by prison category)

These show a variable mix of substance misuse history across all prison categories.

Gabapentin and Pregabalin Offender Health Audit report –June 2013 (DF)
Co-prescribing with opioids was examined as these are also highly sought after in prisons, and known to be diverted and abused. This data would also provide an overview of where gabapentin and pregabalin are being prescribed alongside methadone and buprenorphine. There are known interactions between gabapentin and morphine with caution advised for co-administering pregabalin with other CNS depressants (which includes opioids)\textsuperscript{15,16}.

Figure 15 shows the proportion of prisoners co-prescribed opioids in each site. 1004 (49\%) of prisoners were also taking an opiate and 58 (5\%) of these were taking more than one opiate. The data may reflect the fact that the main indication for gabapentin and pregabalin was neuropathic pain (57\%) with other pain indications accounting for 22\% where you might expect co-prescribing with other analgesics. NICE guidance for neuropathic pain\textsuperscript{8} states that “if gabapentin/pregabalin are unsuccessful Tramadol can be used instead or in combination with second line treatment but treatment should not be started with opioids (such as morphine or oxycodone) other than tramadol without an assessment by a specialist pain service or a condition-specific service”.

Figure 15: Number of prisoners on gabapentin or pregabalin co-prescribed an opioid

The actual opioids prescribed were also recorded and Figure 16 shows the breakdown of these.
Figure 16: Actual opioids prescribed with gabapentin and pregabalin

It is clear from Figure 16 that 47% of prisoners taking gabapentin or pregabalin are also receiving IDTS (substance misuse) treatment as this is the usual reason for methadone and buprenorphine prescribing. Tramadol is the most common opiate analgesic prescribed which is also well known for diversion and abuse in prisons.

Tricyclic antidepressant prescribing was audited as amitriptyline and duloxetine are included in NICE guidance for neuropathic pain as first line with combination therapy with pregabalin being second line. 159 prisoners (8.8%) were co-prescribed a tricyclic antidepressant. The low numbers may reflect the perceived risks of using tricyclic antidepressants in prisons due to the risk in overdose. However in the lower doses used for neuropathic pain the RCGP prison prescribing guidance does recommend their use.

Key messages

- Well over half of prisoners prescribed gabapentin and pregabalin also have a history of substance misuse. 47% are currently taking opioid substitution (IDTS) medication.
- 49% of prisoners were also taking an opioid and 5% of these were taking more than one opioid
- 35% of prisoners co-prescribed an opioid are taking tramadol with 18% taking other opioids used for pain relief.
- The level of substance misuse in prisoners receiving gabapentin and pregabalin is higher than expected given the risks of diversion and abuse of these medicines.
- As methadone and buprenorphine can cause respiratory depression (the risk of which are increased by gabapentin and pregabalin), these medicines should be used with caution in these patients.
- Co-prescribing of opiate analgesics should be reviewed given the main indications for gabapentin and NICE guidance for neuropathic pain.
- The low use of combination therapy may indicate a reluctance to use low dose tricyclic antidepressants for neuropathic pain in prisons. This should be re-examined in the light of the RCGP guidance as diversion risks of these are lower.
Section 3: Safety and Workforce

This section covers the safety and workforce links underpinning the outcomes in the previous sections.

Medication safety is a key part of Domain 5 of the NHS outcomes framework and incident reporting is an outcome measure\(^1\). Medication incident reporting is also included in HMIP expectations\(^2\) and the prison quality and performance indicators (2012)\(^2\).

To deliver safe medicines handling there needs to be a multidisciplinary clinical team that includes expertise in medicines optimisation. There is a perceived increase in the use of medical locums and a decrease in the provision of pharmacy staff and expertise on-site in prisons to support delivery of medicines governance which includes formulary adherence. We have taken the opportunity with this audit to examine the medical and pharmacy workforce picture and identify whether this affects the prescribing rates of gabapentin and pregabalin or the use of prison formularies.

Outcomes included in this section are:
- To identify the what kinds of medication/SIR incidents are being reported involving Gabapentin/Pregabalin
- To identify if the make up of the workforce has an impact on the handling of these medicines

3.1 Medication Incidents involving Gabapentin and Pregabalin and Medication-related Security Incident Reports (SIRs).

The survey completed by participants recorded the number of medication safety incidents between April and September 2012 (6 months) involving gabapentin and pregabalin.

318 medication safety incidents were reported by healthcare teams (a rate of 1 in every 17 prisoners prescribed it). The volume of incidents reported across the prisons is shown in Table 9. Figure 17 shows where in the medicines pathway the incidents took place which was completed for 303 out of the 318 incidents.

Table 9: Volume of incidents reported across the prisons

<table>
<thead>
<tr>
<th>Number of medication safety incidents involving gabapentin and pregabalin</th>
<th>Number of prisons reporting incidents within this range (n=97)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero</td>
<td>40 (42%)</td>
</tr>
<tr>
<td>1 to 10</td>
<td>35 (36%)</td>
</tr>
<tr>
<td>11 to 20</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>21 to 30</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>&gt;30</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>17 (18%)</td>
</tr>
</tbody>
</table>
Most prisons reported between 1 and 10 medication incidents involving gabapentin and pregabalin and the majority of these were either security related (49%) or happened at the point of administration or supply (28%). One in six prisons do not know whether medication incidents have been reported for these medicines.

Another source of incident reporting in prisons is Security Incident Reports (SIRs). These are a prison-specific incident form that is completed by prison staff and can also be completed by healthcare staff. Feedback from participants and the stakeholder group who developed the audit reported that SIRs do not mention the medication name in the majority of cases so only overall medication SIRs can be examined.

Participants were asked to find out how many medication related SIRs had been reported in the same 6 month period. This would provide a backdrop to the healthcare identified incidents involving gabapentin and pregabalin.

3171 medication related incidents were reported via SIRs between April and September 2012. This equates to about 1 SIR for every 25 prisoners based on a prison population 85,690 for September 2012. Table 10 shows the volume of SIRs reported across the sites:

<table>
<thead>
<tr>
<th>Number of medication SIRs reported</th>
<th>Number of prisons/IRCs (n=97)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero</td>
<td>27</td>
</tr>
<tr>
<td>1 to 10</td>
<td>18</td>
</tr>
<tr>
<td>11 to 25</td>
<td>9</td>
</tr>
<tr>
<td>26 to 40</td>
<td>2</td>
</tr>
<tr>
<td>41 to 60</td>
<td>11</td>
</tr>
<tr>
<td>61 to 100</td>
<td>7</td>
</tr>
<tr>
<td>&gt; 100</td>
<td>10</td>
</tr>
<tr>
<td>Unknown</td>
<td>13</td>
</tr>
</tbody>
</table>
There is clearly a variation in the level of medication SIR reporting across prisons and IRCs. One in 7 prisons/IRCs could not access the SIR data and over a quarter of prisons had no medication SIRs at all in this period, which suggests under-reporting.

**Key messages:**

- **Gabapentin and pregabalin medication safety incidents occur at a reported rate of one incident for every 17 prisoners prescribed them.**
- **Nearly half of these healthcare based incidents are security related with a further 28% happening at the point of administration or supply to the prisoner.**
- **Medication SIRs are a backdrop for the extent of prescribed medication incidents identified by prison staff outside of healthcare. These SIRs occur at a rate of one SIR for every 25 prisoners but 1 in 4 prisons reported zero medication SIRs so this figure is likely to be an under-estimate.**
- **There is wide variation in the reporting of healthcare and SIR medication incidents. Reporting should be encouraged and increased via policy levers such as the NHS Outcomes Framework (Domain 5) and prison service delivery outcomes (e.g. HMIP expectations)**
- **Sharing of SIR data with healthcare was reported as problematic for one in seven participants. This aligns with the concerns raised in the recent review of unclassified deaths in custody report published in May 2012. Improvements in SIR/medication incident reporting could be made if medication SIR data is routinely reported via prison medicines management structures along with healthcare medication error reports. This will provide the prison and healthcare with a full overview of medication safety issues.**

### 3.2 Analysis of Pharmacy and Medical Workforce

In prisons and IRCs there are a variety of arrangements for the provision of pharmaceutical services and medical services. There is a perception that the availability of on-site pharmacy teams and regular rather than locum medical staff have an impact on the prescribing patterns and governance of medicines.

As part of the survey completed by participants information about the amount of on-site pharmacist and pharmacy technician workforce and the use of locum GPs to deliver medical consultation sessions was collated and then linked to prescribing of gabapentin and pregabalin. This information would also provide a unique opportunity to gain a snapshot of the pharmacy and workforce patterns in prison and IRCs.

#### 3.2.1 Pharmacy Workforce patterns

20 (21%) of sites operate without any on-site pharmacy team at all, 44 (46%) have no on-site pharmacist support and 58 sites receive their medicines supplies from an externally based pharmacy service provider. Of the 52 sites with on-site pharmacists, 38 of these sites had on-site dispensing pharmacies which requires a pharmacist to be employed. This means that only 14 sites (25%) out of the 58 sites without a dispensary had access to on-site pharmacist support and these pharmacists were on site an average of 0.5wte (two and a half days a week).
Overall 70% of the pharmacy workforce (in 86 sites with pharmacy staff) are pharmacy technicians working an average of 1.7wte and 25 (26%) sites having only pharmacy technicians on-site. 49 sites have both on-site pharmacists and pharmacy technicians.

Figure 18 shows the spread of the pharmacy workforce across the sites (arranged by prison type) that have on-site support.

Figure 18: On-site Pharmacy workforce with working time equivalents (WTE)

This spread clearly shows that the level of pharmacy workforce is significantly higher in local prisons where the majority of the 38 on-site prison pharmacies are located. Many trainer prisons rely solely on pharmacy technicians for on-site support with external pharmaceutical suppliers.

Given the risks with prescribing and supply of medicines, including CDs in prisons, it is surprising that there is such a low pharmacy workforce in prison healthcare teams.

3.1.2 Medical Workforce

The survey explored the routine use of medical locums to deliver sessions in prisons and IRCs. The data shows that 32 sites (33%) use more than one locum GP to deliver their medical services. Thus two thirds of sites have regular employed GPs or used the same locum GP on a routine basis.
3.1.2 Impact of medical and pharmacy workforce on formulary use and Gabapentin/Pregabalin prescribing

The data was analysed to see whether on site pharmacy support increased the use of formularies. Statistical analysis using Fishers Exact Test showed there was a significant increased use of formularies in prisons that have an on-site pharmacist (p=0.002) and either on-site pharmacists or pharmacy technicians (p=0.007).

The amount of gabapentin and pregabalin prescribing was compared between sites with on-site pharmacy support against those without pharmacy staff on-site. This was calculated using the Mann Whitney U test and showed a p value of p=0.070. This means that there was a difference (where prescribing trends were lower where on-site pharmacy staff were available) but that this did not reach significance. This lack of significance may have been because the sample size of prisons/IRCs was too small to have the power to detect a significant difference.

Examination of the prescribing data relating to the use locum vs. regular GPs showed no difference in prescribing patterns (Mann Whitney U test p= 0.105). Again this was probably due to the low sample size and so the analysis did not have the power to detect small differences.

Key messages:

- One in five prisons/IRCs do not have access to any pharmacy staff on-site with just over half (56%) having an on-site pharmacist
- Where on-site support is available this is a mainly a result of the prison having an on-site dispensing pharmacy where pharmacy staff is mandated. Only one in four prisons/IRCs without a pharmacy have access to on-site pharmacist support.
- Most (67%) prisons/IRCs use non-locum GPs or have the same regular locum delivering medical care
- The use of formularies is greater with on-site pharmacy staff support and there is a trend towards lower prescribing rates of gabapentin and pregabalin for sites with pharmacy staff too, but this did not reach significance.
- The use of locum GPs vs. non-locum GPs showed no difference in prescribing rates for gabapentin or pregabalin.
- Further health and justices sector research is needed to explore the benefits of on-site pharmacy staff support in influencing prescribing patterns and safe medicines use.
Conclusions and Recommendations for action

The audit and survey has provided a comprehensive analysis of a snapshot of prescribing of gabapentin and pregabalin in IRCs and prisons. The inclusion of over 70% of prisons in England suggests that the outcomes are representative across the prison estate. The outcomes have verified anecdotal information on the higher use of these medicines in prisons than in primary care and the high level of co-prescription of opioid analgesics and opioids used for substance misuse treatment. The policy infrastructure and implementation for the use of gabapentin and pregabalin in prisons does not consistently follow licensed indications or best practice that reduces the risk of harm or diversion.

The audit and survey outcomes, including their variation between sites, demonstrate the need for a concerted effort between all clinicians and prison staff to minimise the risk of misuse and harm from gabapentin and pregabalin by improving the implementation of NICE guidance and prison-based guidance on the prescribing and handling of these medicines. This will require strategies for handling high risk medicines in secure environments and developing robust, valued and inclusive ways of sharing best practice with the new NHS structures and partnership working with the Ministry of Justice National Offender Managers. Significant cost savings could result from a combined strategic and local approach.

**Recommendation 1: Commissioners** should include clinical audit of gabapentin and pregabalin use and key performance indicators as part of contract monitoring processes. This encourages the use of these medicines appropriately within formularies and licensed indications and within NICE guidance.

**Recommendation 2: Providers** should implement more robustly the policies they have or develop these for prescribing and handling gabapentin and pregabalin. This should be supported by better networking of clinicians using established networks and sharing of successful strategies, care pathways and best practice between providers and commissioners.

The impact of a high proportion of supervised (see to take) administration of these medicines, a fraction of the total supervised administration workload, highlights the challenges of supplying and administering medicines safely against the constraints of the prison regime which limits the time and security available for this essential function. It is also worthy of note that the recent benchmarking exercise completed in prisons could alter the capacity for prison officers to support the security aspects of medicines administration. If this capacity is reduced this would add extra pressure and risk of diversion of high risk medicines including gabapentin and pregabalin.

**Recommendation 3: National Offender Managers, Prison Governors/IRC Directors** should work in partnership with healthcare to ensure in-possession policies are developed and implemented to minimise the risk of diversion of gabapentin and pregabalin and other high risk medicines. This requires the routine delivery of the secure oversight of and appropriate time allocations for medicines administration (treatment times).

Access to an on-site pharmacy workforce has been shown to clearly benefit the medicines handling in other healthcare settings in primary and secondary care. It is also acknowledged that the involvement of pharmacists in delivering safe medicines handling is key to the safety of medicines use which has increased in national focus and
priority and scrutiny. It is a concern therefore that there are a significant proportion of sites that have no access to on-site pharmacist and pharmacy technician support.

**Recommendation 4: Commissioners** need to develop further levers within the commissioning cycle to increase on-site pharmacy staff to lead and support safe medicines use and evidence the contribution pharmacy staff make to the handling of medicines in secure environments.

This audit and survey method could be used to provide future analysis of other medicines but it is time consuming as many prisons rely on hand-written prescription charts. The secure environment sector lacks the access to centralised prescribing data available for primary care via the NHS Business Services Authority (i.e. ePACT data). Increased use of e-prescribing via the prison-wide clinical IT system (expected once the new prescribing module is released during 2031/4) could facilitate development of a more efficient centralised mechanism for analysing the use of medicines in prisons. This has already been achieved in primary care for use by commissioners and providers.

**Recommendation 5: Commissioners/NHS England** should explore the feasibility of introducing anonymised clinical data collection systems similar to those available in primary care that enable central and local analysis of prescribing data. This will facilitate future monitoring, understanding and influencing of the prescribing patterns in secure environments.

**Recommendation 6: NHS England** at both national and within area teams should use emerging and current clinical networks to identify and resource strategic and local pharmaceutical and medicines commissioning support expertise to enable the delivery of these recommendations.

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Appendix 1: Audit and Survey outcomes and standards

The following outcomes and standards were agreed by the project steering group and were compared across the participating sites:

**Outcomes**

- To identify % of prison population (remand and sentenced) prescribed Gabapentin/Pregabalin and estimated cost
- To identify % of prison population have a documented indication for prescribing
- To identify % of those prescribed Gabapentin/Pregabalin who are co-prescribed opioids and/or tricyclic antidepressants.
- To quantify the number of establishments who have a prescribing formulary or guidelines in place which explicitly include or excludes pregabalin/gabapentin
- To quantify the % of in-possession vs. supervised consumption of these medicines
- To identify % of establishments where prescribing data suggests adherence to the formulary and IP policies
- To identify the dose ranges prescribed for prisoners
- To identify incidence and frequency of medication review
- To identify the what kinds of medication/SIR incidents are being reported involving Gabapentin/Pregabalin
- To identify if the make up of the workforce has an impact on the handling of these medicines
- To identify the duration of treatment based on documented initiation dates
- To establish the place in therapy (i.e. 1st/2nd/3rd line) of gabapentin and pregabalin within policy and actual prescribing data
- % of patients with a documented history of substance misuse

**Standards**

- 100% of prescriptions should be for licensed indications
- 100% of prescriptions should have a documented indication in the clinical records
- 100% of patients should have their medication reviewed at least every 6 months
- 100% of doses should be within the recommended range for the stated indication
- 100% of patients should have tried a previous medicine first prior to being prescribed gabapentin/pregabalin
Appendix 2: Glossary

IRC  Immigration Removal Centre: Immigration removal centres are holding centres for foreign nationals awaiting decisions on their asylum claims or awaiting deportation following a failed application.

Local prison  Local prison is a type of prison where a person is detained before a trial (i.e. on remand) or for about 3-4 weeks directly after a conviction (i.e. sentenced). They are usually local to the court where the trial takes place.

Trainer prison  Trainer or dispersal prisons is a type of prison where sentenced prisons are transferred to after conviction and a short stay in the local prison.

YOI  Young offender institutes: There are 39 young offenders institutes (YOIs) in England and Wales which house 15-21 year olds.

Prison Categories  A person who has been convicted of an offence and given a prison sentence is placed into one of four categories.

Category A (High Security) – offenders who are considered to be high risk of escape or a danger to the public
Category B – offenders who do not require maximum security but who are still considered to be of risk to the community
Category C – offenders who cannot be kept in an open prison but who are not likely to try and escape
Category D (Open) – offenders who can be trusted not to escape and be kept in an open prison

An offender’s category will be reviewed during the course of their sentence and may change as they serve their sentence. For example, someone serving a long sentence may begin as a category B offender but move to a category C after a period of time and then possibly category D as they near the end of their sentence. This will allow them to experience trust and to slowly reintegrate themselves into the community. An offender’s category may also go the opposite way if their behaviour merits it.

IDTS  Integrated Drug Treatment System is the substance misuse treatment pathway for prisoners. It aims to increase the volume and quality of treatment available to prisoners, with particular emphasis on early custody, and provides better integration between clinical and psychosocial services.

SIR  Security Incident Reports: These are a prison-specific incident form that is completed by prison staff and can also be completed by healthcare staff. They are collated and analysed by the prison and used to identify and manage security risks.

Opioids  These any of a group of substances that resemble morphine in their physiological or pharmacological effects, especially in their pain-relieving properties. Examples of medicines in this group are codeine, tramadol, oxycodone, buprenorphine, methadone.