NHS SCOTLAND

National Therapeutic Indicators

2015/16

THERAPEUTICS BRANCH

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SCOTTISH GOVERNMENT

Acknowledgements

The National Therapeutic Indicators (NTIs) are developed and maintained by the Therapeutics Branch, Pharmacy and Medicines Division, Scottish Government. Mr Sean MacBride-Stewart provides pharmaceutical leadership, Dr Simon B Hurding provides clinical leadership and Mrs Rita Nogueira provides data analysis expertise. Consensus is provided by working with the NTI Reference Group.

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Thanks to all involved for their time, patience and expertise.

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Foreword

We are pleased to present the National Therapeutics Indicators Baseline Report for 2015-16, containing the data from the fourth quarter of the fiscal year 2014-15.

NHS Scotland has a history of delivering high quality care through its use of medication and remains committed to continual review and improvement in this area.

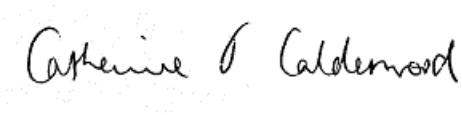
Boards should make use of this management information locally to identify areas for improvement and implement change to reduce unwarranted variation, waste and harm. NHS Scotland is striving for the goal of higher quality of care within an efficient environment: this report provides Boards with information towards the delivery of that agenda.

Though most of the National Therapeutic Indicators and Additional Prescribing Measures focus on single prescribing areas, they should be viewed in the context that most patients with long-term conditions have more than one and reviews should consider the recommendations in the *Polypharmacy Guidance 2015.* [1]

Colleagues should use the National Therapeutic Indicators to inform Board Prescribing Action Plans and consideration of the specific areas identified is recommended for the national focussed approach to medicines management.

We commend the information within this report to you.

Kind Regards



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26 November 2015

[1] Polypharmacy Guidance Second Edition, Scottish Government, March 2015

NATIONAL THERAPEUTIC INDICATORS 2015 to 2016

This report presents the fourth set of National Therapeutic Indicators (NTI) which are now developed and maintained by the Therapeutics Branch of the Scottish Government in collaboration with the NTI reference group. The aim of the NTIs is to help continue to improve all six dimensions of quality in prescribing: effectiveness, safety, efficiency, acceptability, equitability and timeliness. The exceptional work already achieved by prescribers and NHS Board medicines management teams is recognised.

Prescribing indicators have been used by NHS Boards to inform the quality, safety and efficiency of prescribing over the last ten to fifteen years. Early work was promoted and supported by the Audit Scotland report: *Supporting prescribing in general practice* [1] [2] in 1999. Many early indicators are still in use today. Audit Scotland's report: *Prescribing in general practice in Scotland* [3] (2013), supports the on-going use of the NTIs.

The Prescribing Information SysteM for Scotland (PRISMS) provides all of the data used for the NTIs. PRISMS is maintained by the Public Health Intelligence team (PHI) of NHS National Services Scotland (NSS) and allows access to the data collected by Practitioner Services Division (PSD),when processing each prescription dispensed for payment verification.

The NTIs 2015-16 have been developed with ongoing, detailed consultation with medicines management experts from all of the NHS Boards. The NTI reference group is a subgroup of the Scottish Prescribing Advisers Association (SPAA). Consideration of the Welsh National Prescribing Indicators (2015-16) [4] and the English Key Therapeutics Topics (2015) [5] is important to confirm the value of the National Prescribing Indicators. The NTIs are published as corporate reports in PRISMS.

New for 2015-16 is the inclusion of fourteen Additional Prescribing Measures (APMs). These are the first national indicators to use the Prescribing Information System (PIS). This dataset includes anonymised patient level data, which allows more sophisticated indicators. PIS relies on prescriptions dispensed having a Community Health Index (CHI) number. It is now considered that the CHI capture rate is high enough to use this data to address national prescribing priorities. The APMs are published as corporate reports in PIS.

The final list of twelve NTIs and fourteen APMs were presented as an advanced report to NHS Boards, at the SPAA national conference in October 2014, in order to inform Prescribing Action Plans for 2015-16. The early release was to ensure clear understanding of the areas of national importance. For future years it is proposed to use Q3 baseline data to allow earlier publication of this report.

Nani gigantum humeris insidentes

[1] *Supporting prescribing in general practice – a progress report* June 2003 ISBN 1 304651 05 4
[2] *Supporting prescribing in general practice September 1999* ISBN 0 906206 72 3
[3] P*rescribing in general practice in Scotland* January 2013 ISBN 978 1 907916 86 1
[4] All Wales Medicines Strategy Group. National Prescribing Indicators (2014-15) January 2014
[5] NICE. Key therapeutics topics – *Medicines management options for local implementation* (2013)

Contents

Key for enclosed graphs:

- Median – dark grey bar
- Interquartile range – grey box
- Maximum and minimum – whiskers, unless greater than 1.5 of interquartile range
- Outliers – (°) values of greater than 1.5 but less than 3.0 of interquartile range
- Extreme outliers – (•) values of greater than 3.0 of interquartile range

1. Proton Pump Inhibitors (PPI)

There is no current evidence suggesting improved efficacy of high-dose, high-cost PPIs when compared to low-dose, low-cost PPIs. There are increasing safety concerns about the long-term use of PPIs. The considerable drivers to prescribe PPIs and the difficulties of withdrawing treatment once commenced are recognised. **The aim is to encourage use of PPIs at the lowest and most cost-efficient dose and to minimise the potential risks of inappropriate long-term prescription.**

A PPI can be considered for gastroprotection for patients at **high risk** of gastro-intestinal complications with a NSAID.[1] **Gastroprotection must be used for patients on combined antiplatelet and oral anticoagulant**.

The most common use of PPIs in primary care is the management of dyspepsia. Around 25 to 40% of adults in the general population have dyspepsia at any one time and it accounts for up to 5% of GP consultations.[2]

The best empirical anti-secretory drug for treating uninvestigated dyspepsia remains unclear. (Note that uninvestigated dyspepsia would include patients with peptic ulcers; dyspepsia and gastro-oesophageal reflux). A recent review confirmed that PPIs are the most effective anti-secretory drug for treating uninvestigated gastro-oesophageal reflux.[3]

Despite the development of key guidelines,[4] [5] the management of uninvestigated dyspepsia remains controversial. In the absence of '*red flag'* features, two management strategies are recommended: empirical PPI or '*Test and Treat'* for *H* pylori. SIGN 68 *Dyspepsia* currently only recommends the latter approach.

NICE CG17 recommends as-required low-dose PPI (omeprazole 20 mg capsule or lansoprazole 15mg capsule) for uninvestigated dyspepsia. This should be reviewed at least annually. Where patients have uninvestigated 'reflux-like' symptoms regular high-dose PPI (omeprazole 40 mg capsule or lansoprazole 30mg capsule) may be required until symptoms are controlled. Then, as-required low-dose PPI should be considered.

The preference for as-required low-dose PPI with regular review is further reinforced by concerns around serious side effects. Chronic use of PPIs is associated with: community acquired pneumonia [6]; fragility fractures [7] and *Clostridium difficile* Infection (CDI).[8]

Patients prescribed PPIs should be reviewed at least annually and where appropriate continued use stopped. When it is not possible to stop the PPI then an 'as-required low-dose' agent should be used when clinically possible.

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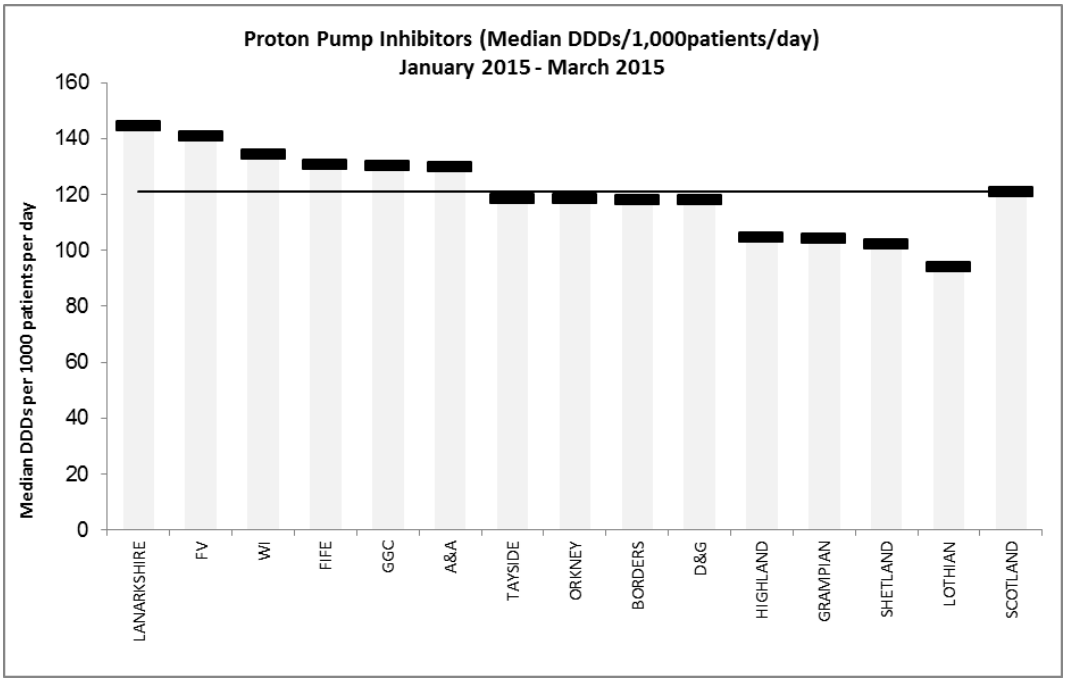
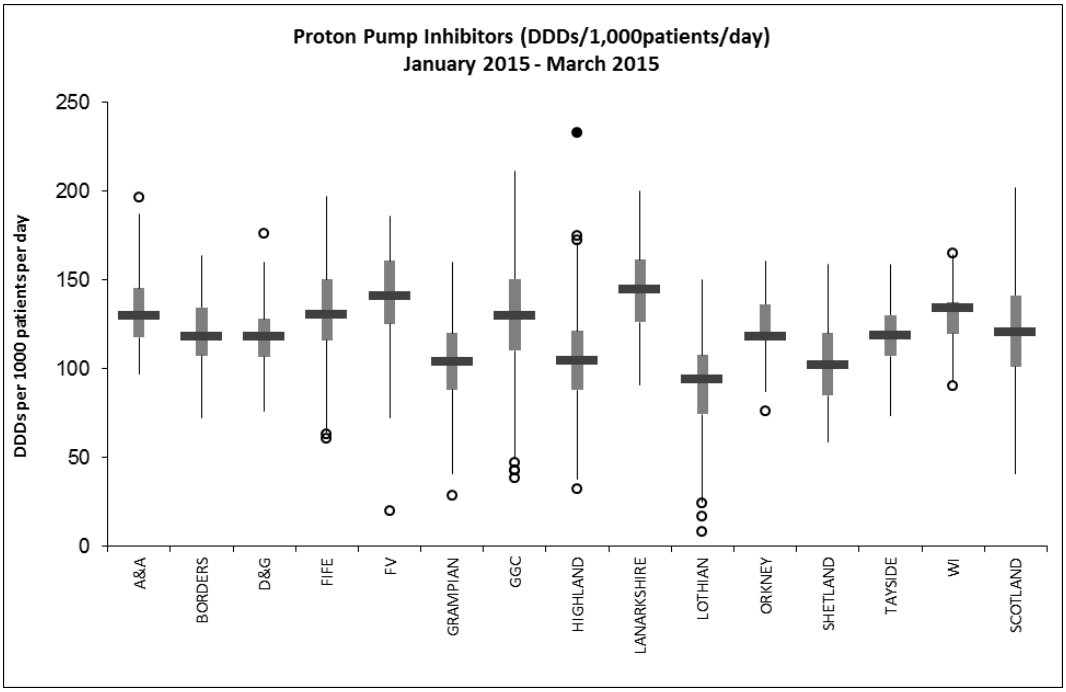
[1] Joint Formulary Committee. *British National Formulary.* Edition 69, March 2015
[2] Zagari RM, et al. *BMJ 2008*; **337**: a1400
[3] Van Pinxteren B, et al. *Cochrane Database of Systemic Reviews 2010,* Issue 11. Art. No. CD002095
[4] SIGN 68 Dyspepsia, March 2003 (Due for review in 2012 – overdue)
[5] NICE CG17 Dyspepsia, August 2004
[6] Laheij RJF, et al. *JAMA 2004*; **292** (16): 1955-60
[7] Kahlili H, et al. *BMJ 2012*; **344**: e372
[8] Howell MD, et al. *Arch Intern Med* 2010; **170**(9): 784-790

1.a Proton pump inhibitors (PPI): The amount of Proton pump inhibitor per 1,000 patients per day (DDD)

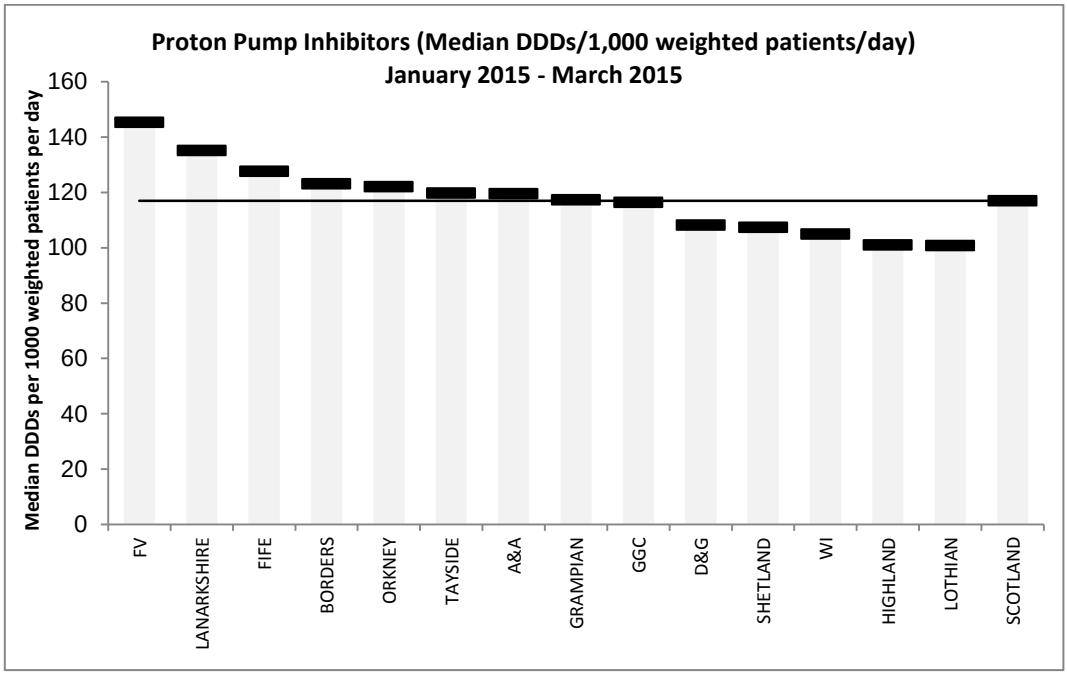
This NTI looks at the increased risk of community acquired pneumonia, fragility fractures and Clostridium difficile infection due to PPIs. Patients prescribed PPIs should be reviewed at least annually and where appropriate continued stopped. When it is not possible to stop then 'as required low-dose' PPI should be used. The measure looks at the amount of PPI (DDD) used per practice registered patient.

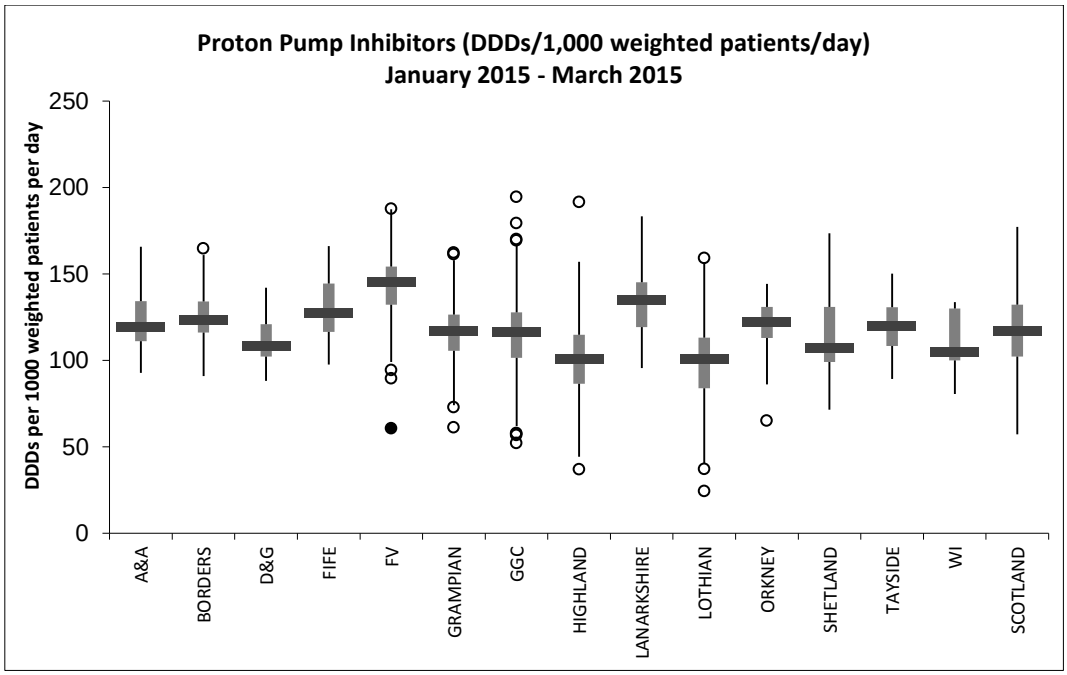




1.b Proton pump inhibitors (PPI): The amount of Proton pump inhibitor per 1,000 weighted patients per day (DDD)

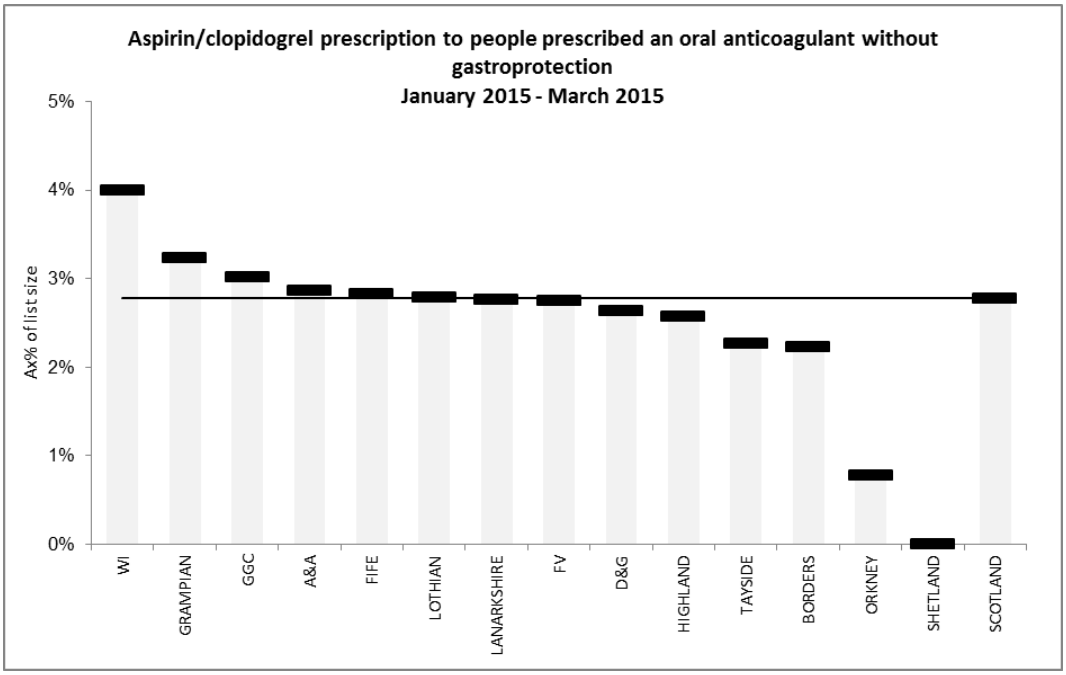
This NTI looks at the increased risk of community acquired pneumonia, fragility fractures and Clostridium difficile infection due to PPIs. Patients prescribed PPIs should be reviewed at least annually and where appropriate stopped. When it is not possible to stop then 'as required low-dose' PPI should be used. The measure looks at the amount of PPI (DDD) used per **weighted** practice registered patient.

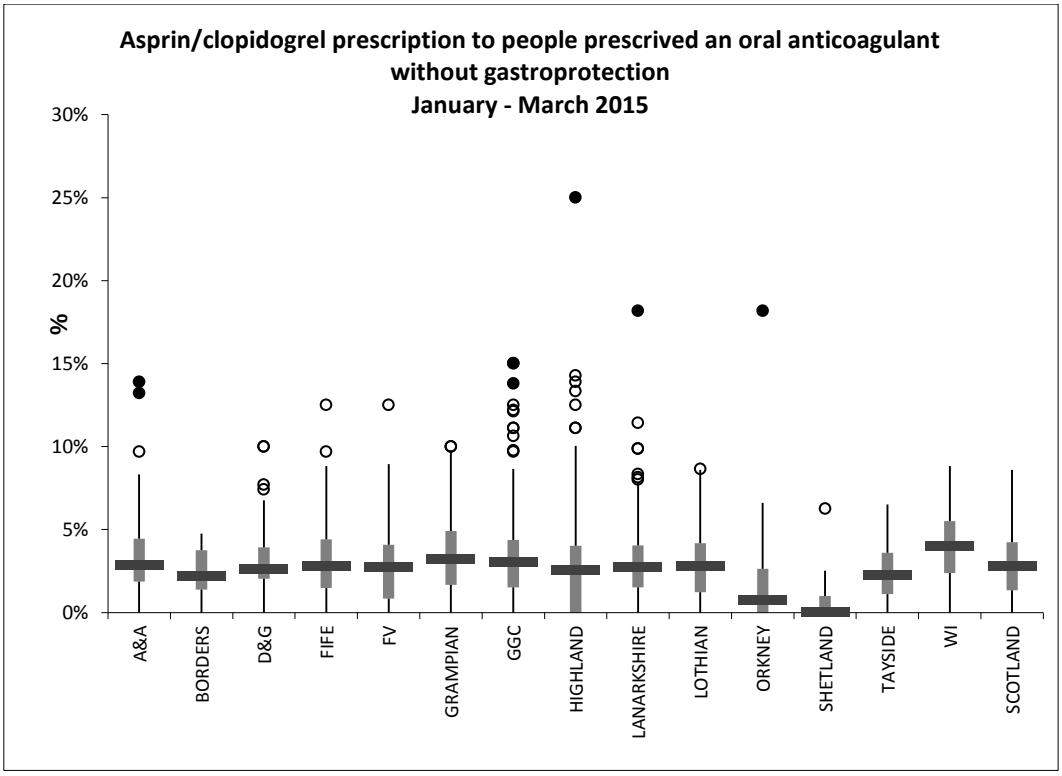




1.c Additional prescribing measure (APM): People prescribed an oral anticoagulant plus aspirin and/or clopidogrel without adequate prescribed gastroprotection

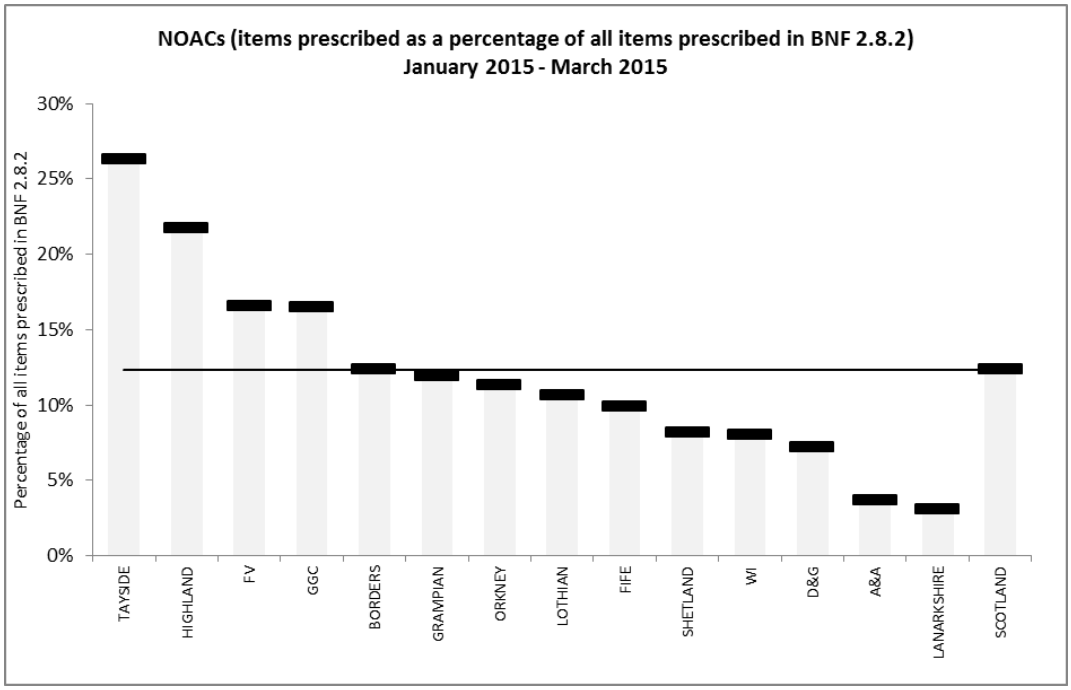
This additional prescribing measure (APM) looks at the **lack** of gastroprotective treatment for patients at high risk of gastrointestinal bleed due to combined antiplatelet and oral anticoagulation therapy. The patients in this category are identified as a percentage of practice registered patients.

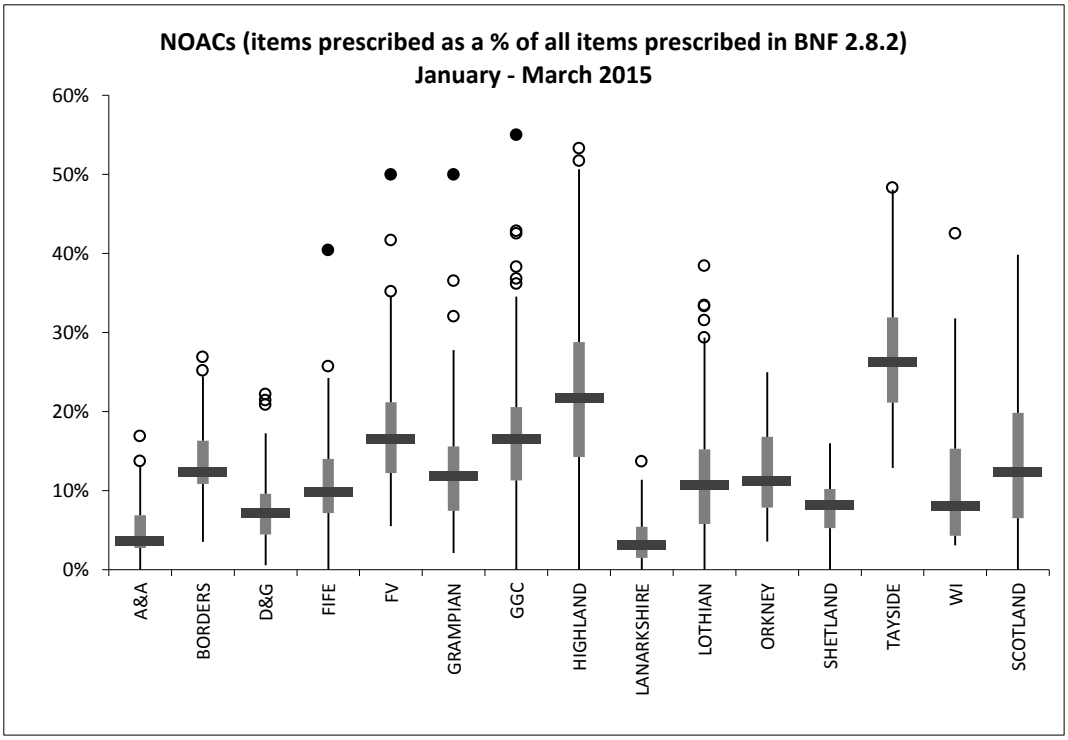




2. Novel oral anticoagulants (NOAC)

This additional prescribing measure (APM) looks at the use of the novel oral anticoagulants (apixaban, dabigatran and rivaroxaban). The measure looks at the percentage of NOAC prescribed as a percentage of all oral anticoagulants (BNF 020802) (items).





3. High Strength Inhaled Corticosteroids

This NTI focuses on the safety concerns regarding the inappropriate use of high strength corticosteroid inhalers and the importance of ensuring that the patient's steroid load is kept to the minimum level, whilst effectively treating symptoms. It is recognised that some patients will require treatment with high-dose ICS.

Standard-dose ICS* (200 to ≤ 800 micrograms/day in adults; 100 to ≤ 400 micrograms/day in children 5 to 12 years) should be prescribed for patients who require use of their short-acting $beta_2$ agonist more than twice a week, or if symptoms disturb sleep more than once a week, or if they have suffered exacerbations in the last two years requiring systemic corticosteroids or nebulised bronchodilator, (Step 2 BTS).[1] [2]

High-dose ICS* (>800 to 2000 micrograms/day in adults; >400 to 800 micrograms/day in children 5 to 12 years) should be prescribed for patients who respond only partially to standard-dose ICS with a long-acting $beta_2$ agonist or another long-acting bronchodilator, (Step 4 BTS).[1] [2] High-dose should be continued if there is clear benefit over standard-dose.

It is recommended that all patients taking high-dose ICS carry a steroid card.

There are recognised, potentially serious, systemic side effects from ICS. The most concerning is adrenal suppression, but others include: growth failure; reduced bone density; cataracts and glaucoma; anxiety and depression; and diabetes mellitus.[1] Marked adrenal suppression can occur with doses greater than 1,500 micrograms beclometasone per day (375 micrograms fluticasone proprionate per day in children).

Of particular concern is the use of high-dose ICS in children. A UK observational study found that high-dose ICS prescribing occurred in 5.6% of the under 5s and 10% of the 5 to 11 year olds.[3] In addition very high-dose ICS (> 800 micrograms beclometasone or equivalent) was prescribed to 3.9% of the under 5s and 4.9% of the 5 to 11 year olds.

Current advice for children on ICS can be summarised: [2]

- Regular growth monitoring (unreliable indicator of adrenal suppression)
- High-dose ICS should be used only under the care of a specialist paediatrician
- Adrenal insufficiency should be considered in any child with shock and/or reduced consciousness who is maintained on ICS

Patients should be maintained at the lowest possible dose of ICS. This is a dynamic process requiring **stepping down therapy.** Reductions in dose of ICS should be considered every three months, reducing the dose by 25 to 50% every time.[2]

This indicator is unable to measure the high-dose use of moderate or low strength corticosteroid inhalers.

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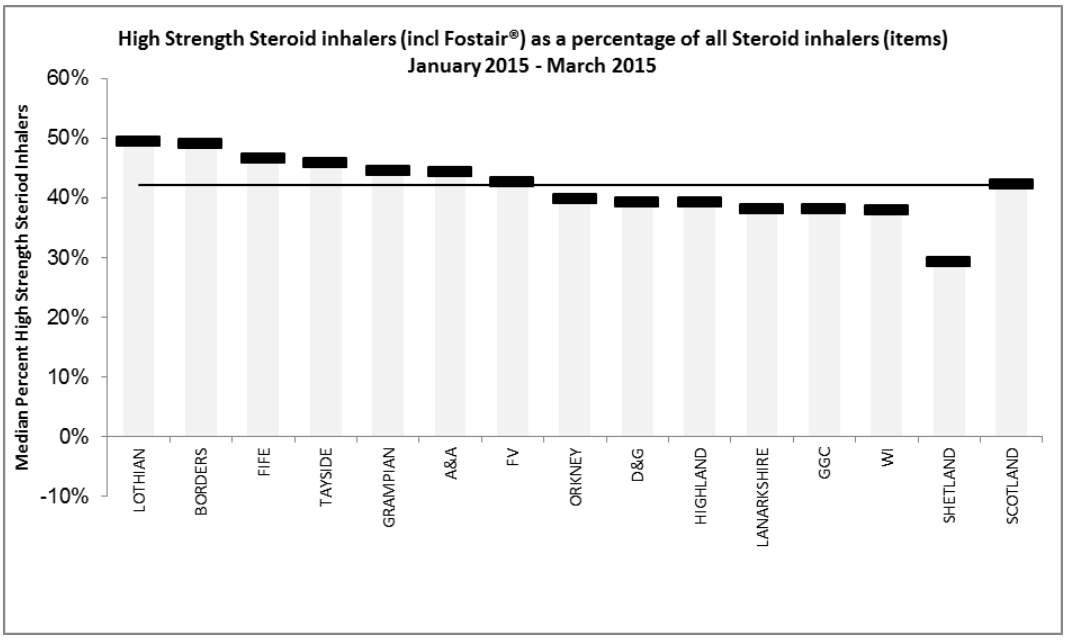
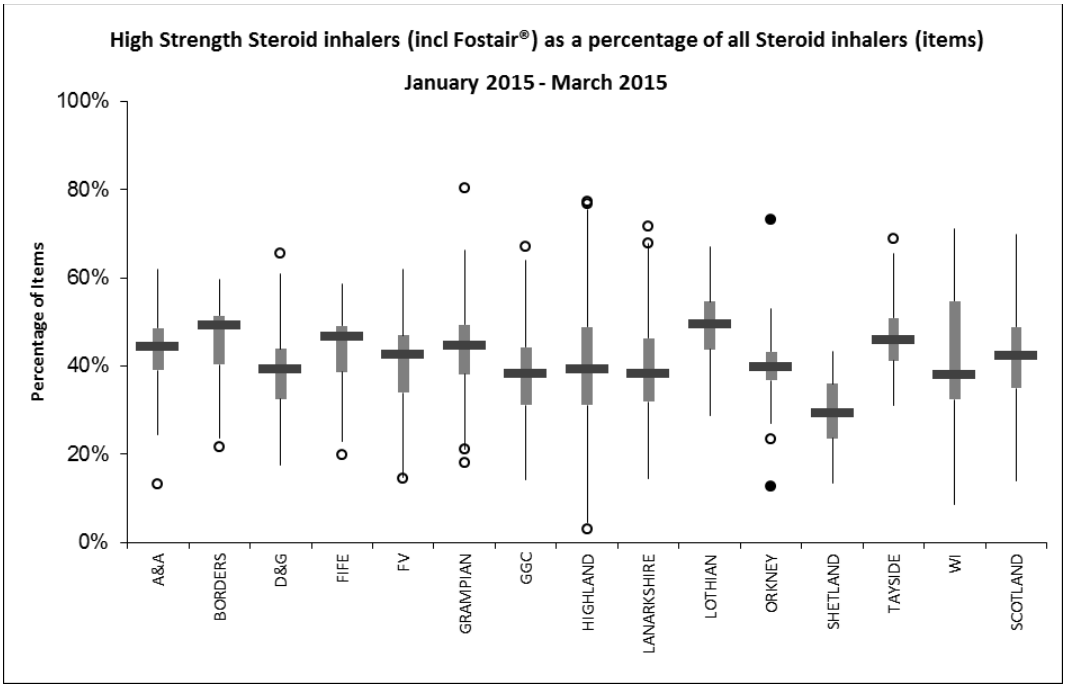
[1] Joint Formulary Committee. *British National Formulary.* Edition 69. March 2015
[2] Sign/BTS British guideline on the management of asthma, May 2008 (revised May 2011)
[3] Thomas M et al. *Br J Gen Pract 2006*; 56: 788-90

3.a High strength corticosteroid inhalers: The total high strength corticosteroid inhalers (including Fostair®) as a percentage of all corticosteroid inhalers (items)

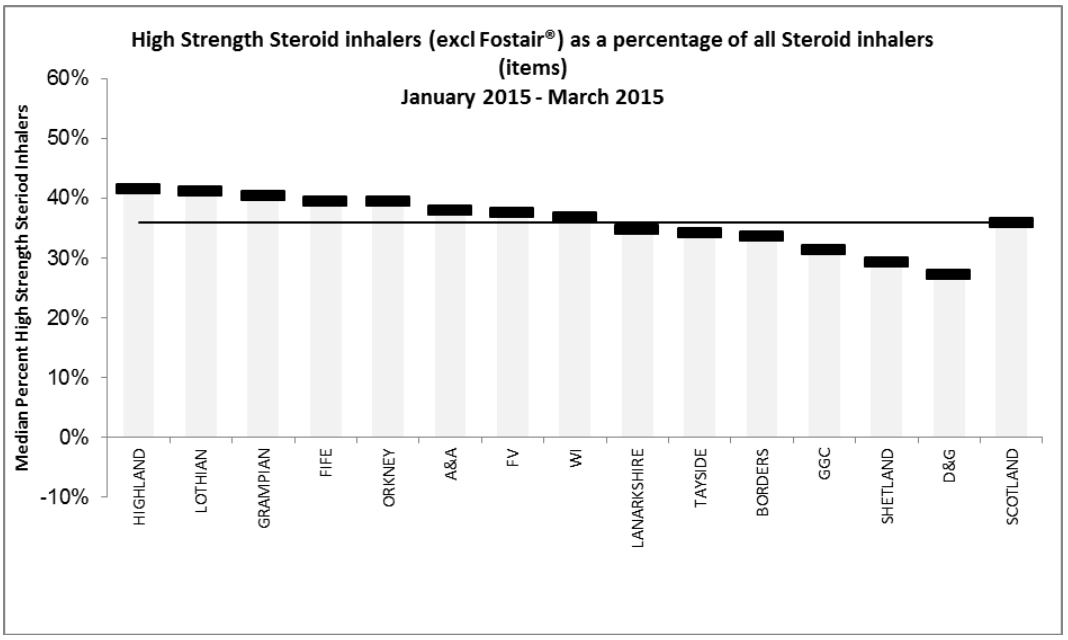
This NTI looks at the safety concerns regarding the inappropriate use of high-dose ICS and the importance of ensuring that the patient's steroid load is kept to the minimum level, whilst effectively treating symptoms. The measure looks at the amount (items) of high strength corticosteroid inhalers prescribed as a percentage of all corticosteroid inhalers. **The measure cannot identify the high-dose use of moderate or low strength corticosteroid inhalers.**

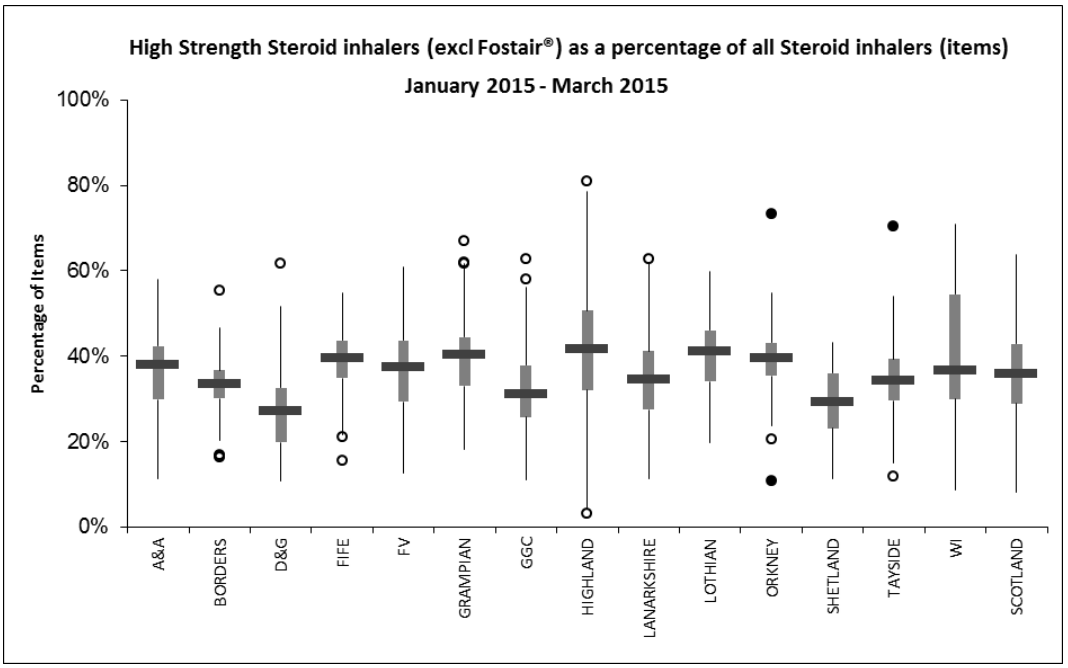




3.b High strength corticosteroid inhalers: The total high strength corticosteroid inhalers (excluding Fostair®) as a percentage of all corticosteroid inhalers (items)

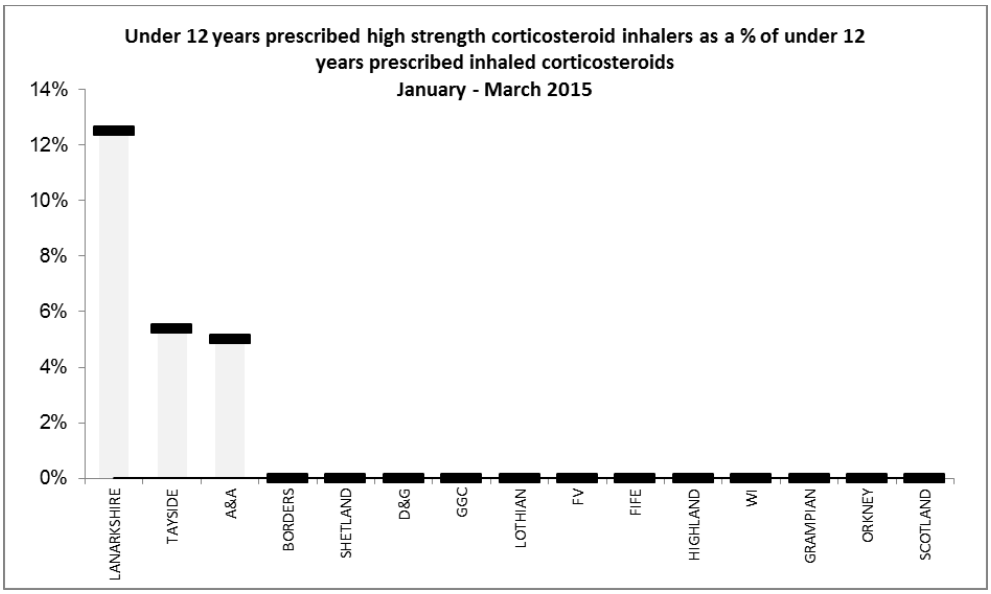
This NTI looks at the safety concerns regarding the inappropriate use of high-dose ICS and the importance of ensuring that the patient's steroid load is kept to the minimum level, whilst effectively treating symptoms. The measure looks at the amount (items) of high strength corticosteroid inhalers prescribed as a percentage of all corticosteroid inhalers. **The measure cannot identify the high-dose use of moderate or low strength corticosteroid inhalers.**

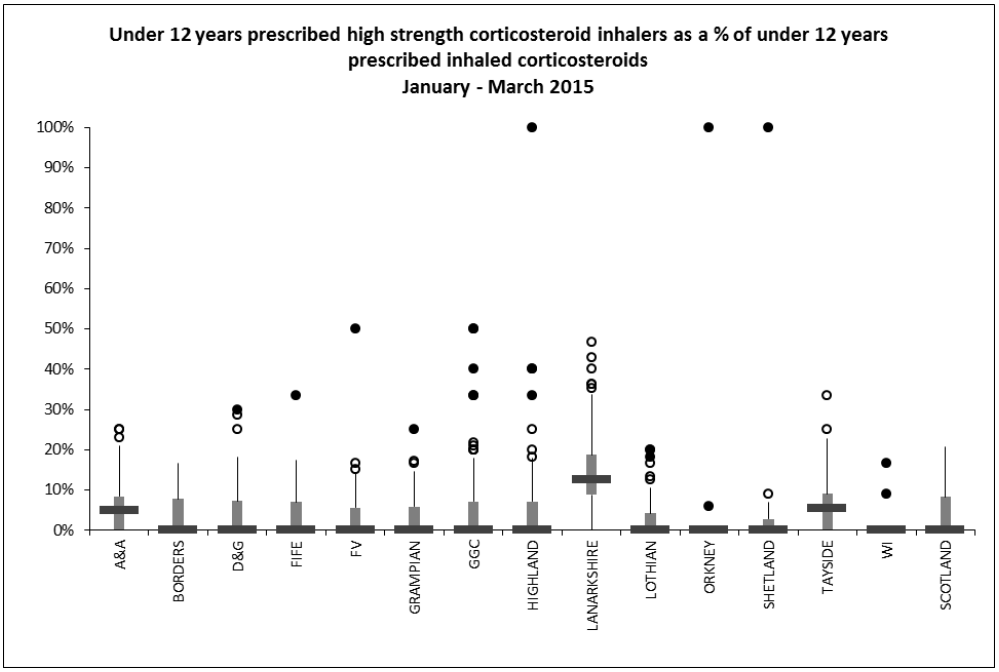




3.c Additional prescribing measure (APM): The number of under 12 year olds prescribed a high strength corticosteroid inhaler as a percentage of under 12 year olds prescribed a corticosteroid inhaler.

This additional prescribing measure (APM) looks at the use of high strength (> 400 micrograms a day of beclometasone or equivalent) corticosteroid inhalers in children under the age of 12 years. Children requiring high-dose treatment are at greatest risk of growth retardation and adrenal suppression and should be managed under specialist care. **This measure is unable to identify high-dose use of moderate or low strength corticosteroid inhalers.**





4. Hypnotics

This NTI focuses on the use of benzodiazepines and 'Z drugs' (non-benzodiazepine hypnotics). It is recognised that differing drug-maintenance and drug-withdrawal policies between Boards can act as confounders to using this measure for comparative data.

Hypnotic use in all ages is linked with tolerance, dependence, rebound insomnia and abuse. In the elderly, hypnotic use is associated with falls, cognitive impairment and fatigue.[1]

Before a hypnotic is prescribed the cause of the insomnia should be established. It is important to recognise that some patients have unrealistic sleep expectations. Others underestimate their alcohol consumption, which may be the cause of the insomnia. It is a common problem and 30% of the population have insomnia at any one time.[2]

88% of cases are secondary and treatment of the underlying cause should be sought: depression and/or anxiety (50%); physical illness affecting sleep (43%); restless leg syndrome (22%); sleep apnoea (9%); delayed sleep phase syndrome (2%).[3]

For primary insomnia, 30% of cases improve with 'sleep hygiene'. 'Bed-time restriction' has also shown to be a beneficial treatment. [2] Hypnotics are not actually effective at treating insomnia and have a high potential to cause harm. For 13 people taking a hypnotic for one week, only one person will experience sleep improvement (NNT13) and two patients will experience an adverse event (NNH6).[4]

There is clear evidence demonstrating the link between benzodiazepine use and an increased risk of developing dementia.[5]

A Norwegian study found that taking a hypnotic increased the risk of having a road traffic accident four-fold.[6] This finding has been confirmed by a more recent French study.[7] Data from the USA show that there is also an association with hip fracture rate.[8] The risk of hip fracture is highest in the first two weeks.

'Z drugs' offer no therapeutic advantages over benzodiazepines.[9] Reported prescribing practices were often at variance with the licence indication for short-term use.

Hypnotics should not be prescribed indiscriminately and should be reserved for short courses in the acutely distressed. Tolerance to their effects develops within 3 to 14 days of continuous use. Withdrawal after long term use can cause rebound insomnia and withdrawal symptoms.

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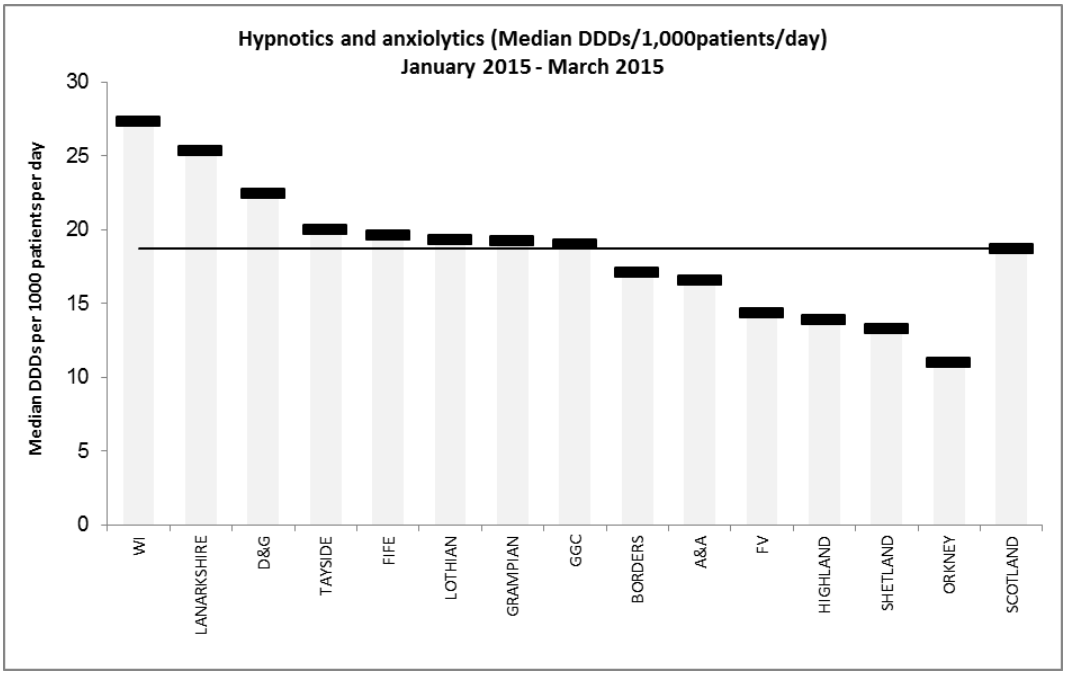
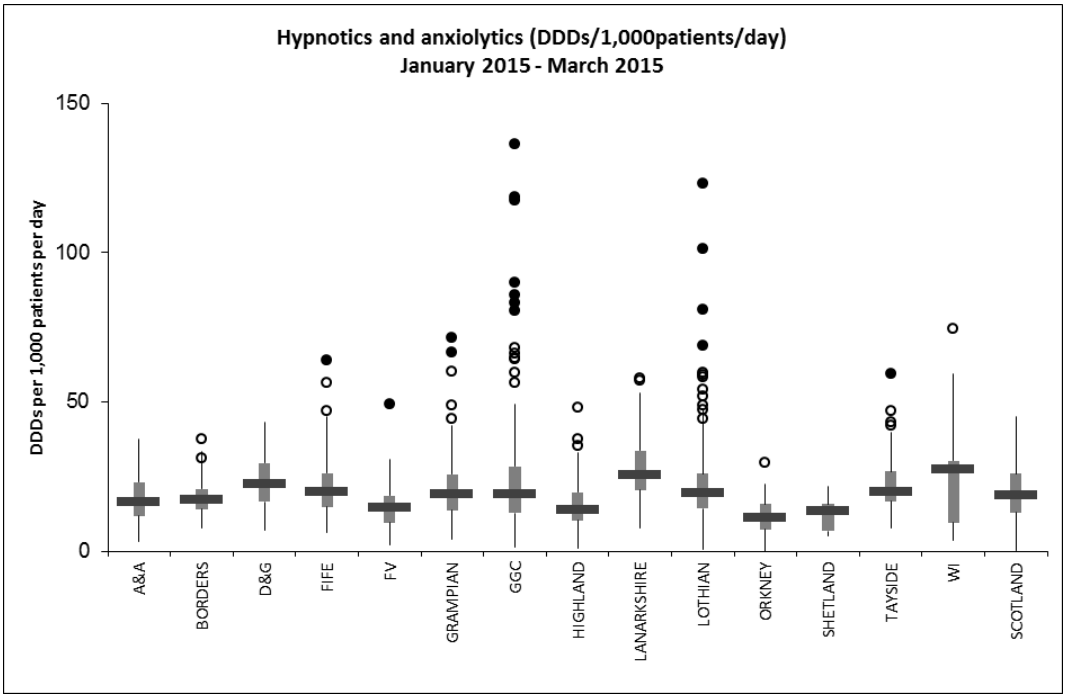
[1] Joint Formulary Committee. *British National Formulary.* Edition 69, March 2015
[2] Faloon K et al. *BMJ2011;* **342:** d2899
[3] Arroll, et al. *BJGP2012;* ***62****: e99-e103(5)*
[4] Glass J et al. *BMJ2005;* **331:** 1169
[5] Billoti de Gage S, et al. *BMJ2012;* **345:** e6231
[6] Gustavsen I, et al. *Sleep Med2008;* **9:** 818-22
[7] Orriols L, et al. *Clinical Pharmacology and Therapeutics.* 2011; **89**(4): 595-601
[8] Wagner AK, et al. *Arch Intem Med 2004*; **164:** 1567-72
[9] Siriwardena AN, et al. *BJGP 2008*; **58**: 417-22

4.a Hypnotics and anxiolytics: The amount of hypnotics and anxiolytics used per 1,000 patients per day (DDD)

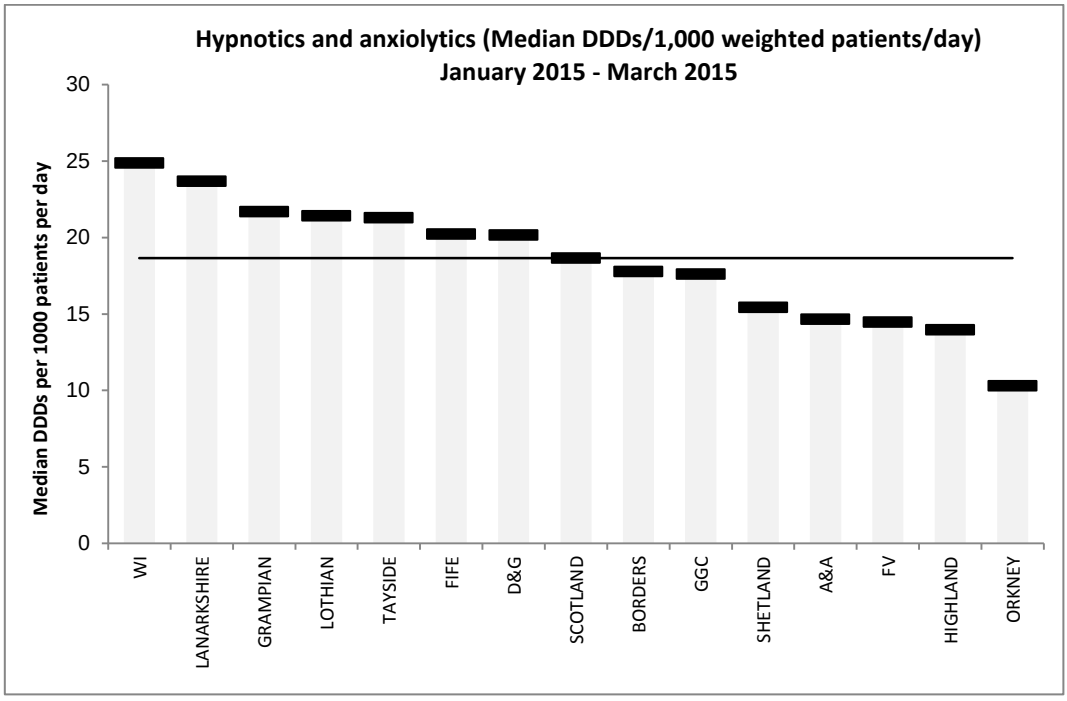
This NTI looks at the inappropriate use of hypnotics and anxiolytics. Use in all ages is clearly linked with tolerance, dependence, rebound insomnia and abuse. In the elderly population hypnotic use is also associated with falls, cognitive impairment and fatigue. The measure looks at the amount (DDD) of hypnotics prescribed per 1,000 patients per day. **The measure may be confounded by local drug misuse management policies.**

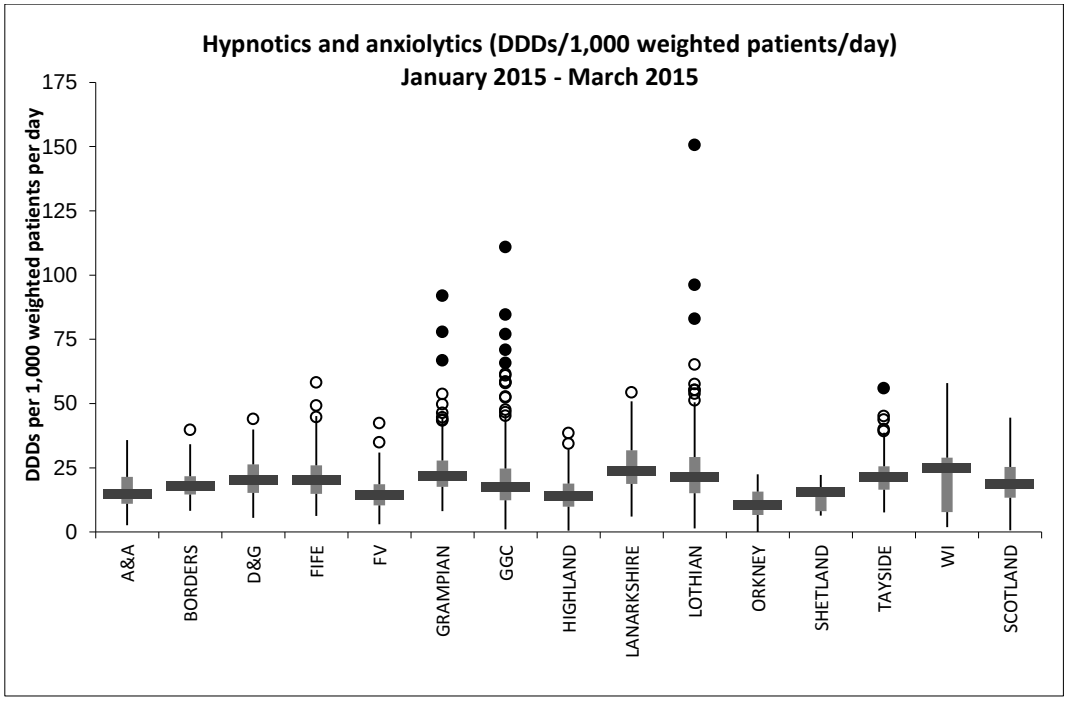




4.b Hypnotics and anxiolytics: The amount of hypnotics and anxiolytics prescribed per 1,000 weighted patients per day (DDD)

This NTI looks at the inappropriate use of hypnotics and anxiolytics. Use in all ages is clearly linked with tolerance, dependence, rebound insomnia and abuse. In the elderly population hypnotic use is also associated with falls, cognitive impairment and fatigue. The measure looks at the amount (DDD) of hypnotics prescribed per 1,000 **weighted** patients per day. **The measure may be confounded by local drug misuse management policies**.





5. Opioid Analgesics

This NTI focusses on the use of opioid analgesics in the management of chronic non-cancer pain. This condition affects 18% of the population and presents a major clinical challenge.[1] Most patients are managed in primary care and there is evidence of wide variation in clinical practice and resource provision. Best practice would include: supported self-management; pharmacological management; psychological based interventions and physical therapies.

First-line pharmacological management is with paracetamol and /or non-steroidal anti-inflammatory drugs, but, published data shows a continual increase in the volume of prescribed opioids to manage moderate to severe, chronic non-cancer pain.[2]

Comparison of opioid analgesics for chronic non-cancer pain (arthritis) with placebo or no treatment shows that the small benefit is outweighed by the large increase in adverse events.[3] A 2010 Cochrane review of long term use of opioids to manage chronic non-cancer pain concluded that the evidence for pain relief was weak and that the effect on quality of life or functional improvement was inconclusive.[4]

The challenges of managing chronic pain are reflected in patients' experiences of the condition.[5] Common themes include: a struggle to maintain a sense of worth, while feeling misunderstood and not believed; a diagnosis is highly valued; negotiation of the healthcare system is complex. The recommendation is to recognise that the patient with chronic non-cancer pain is someone who's life has deeply changed.

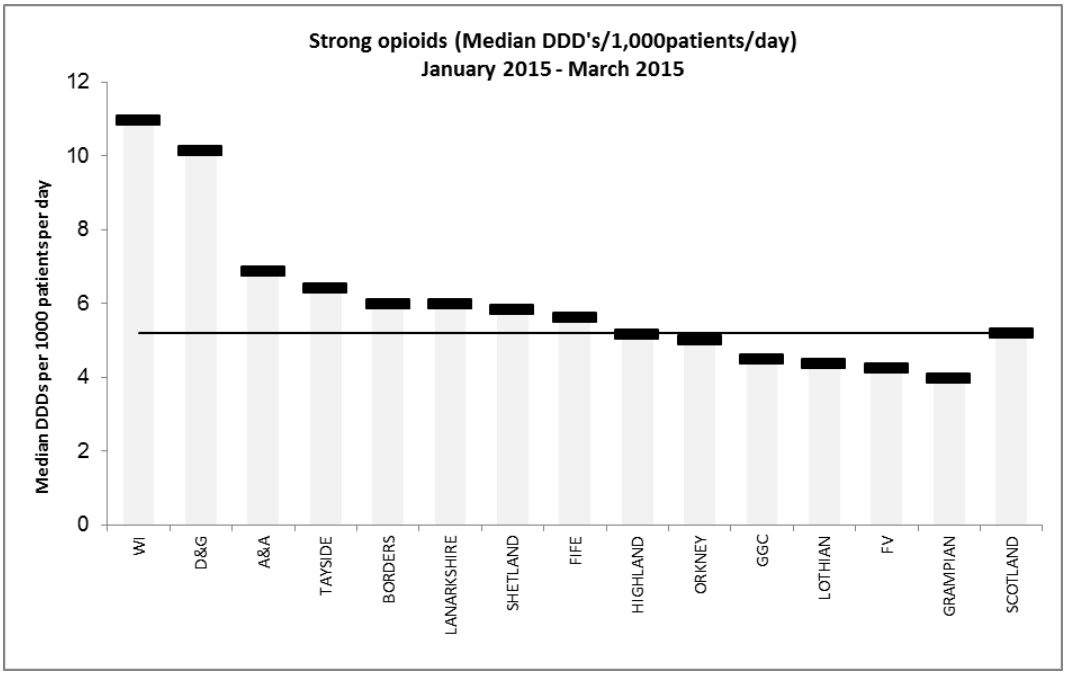
A 2013 BMJ paper suggests that we should adopt a novel approach to pharmacological management of chronic non-cancer pain.[6] The key concept is to recognise that individual response to analgesia is bimodal, so pain relief is either good (above 50%) or poor (below 15%). Responders should achieve good (above 50%) pain relief and improvements in fatigue, depression and sleep interference without side effects. Non-responders (below 15%) will be apparent after two to four weeks, and treatment should be stopped.

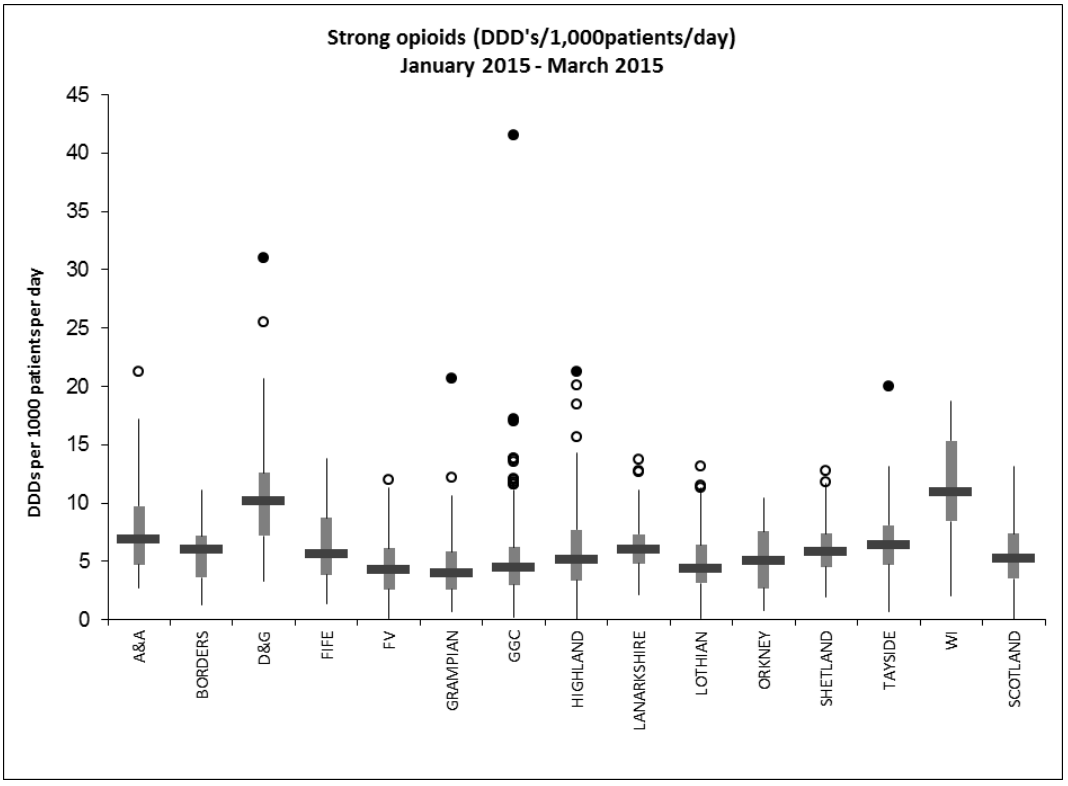
The standard way to assess medicine efficacy is to measure the average response of a population, as used in clinical trials. This approach does not work well in pain management due to the bimodal response discussed. Focussing on the individual response instead changes the standard medicine management approach. '*Clinically this means expecting failure, assessing pain, and understanding options for stopping and switching'* [7]. Individuals respond to different medicines in the same class and in different classes. This suggests that an extended formulary for management of chronic non-cancer pain is required. This should allow greater flexibility in identifying individual responders, the support to stop treatment for non-responders, and may reduce the use of opioid analgesics.

[1] SIGN 136 Chronic pain
[2] Freynhagen R, et al. BMJ 2013; 346:f2937
[3] Nuesch et al. *Cochrane Database Syst Rev* 2009;(40):CD003115
[4] Noble et al. *Cochrane Database Syst Rev* 2010;(1):CD006605
[5] BJGP 2013:63:641
[6] Moore A, et al. *BMJ* 2013;346:f2690

5.a Opioid analgesics: The amount of strong opioids prescribed per 1,000 patients per day (DDD)

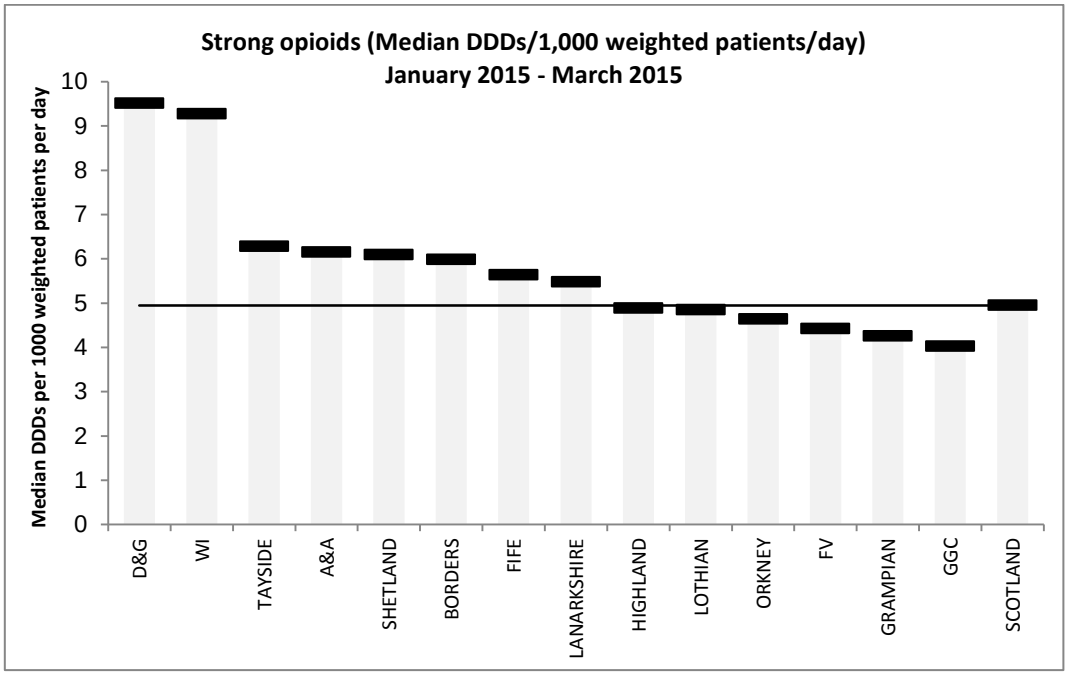
Opioids are well established in the management of acute pain and pain associated with terminal illness. Opioids can also provide symptomatic benefits for chronic non-cancer pain, however, repeated administration may cause problems of tolerance, dependence and addiction. The measure looks at the amount (DDD) of strong opioids (all opioids except codeine, dihydrocodeine and tramadol) prescribed per 1,000 patients per day.

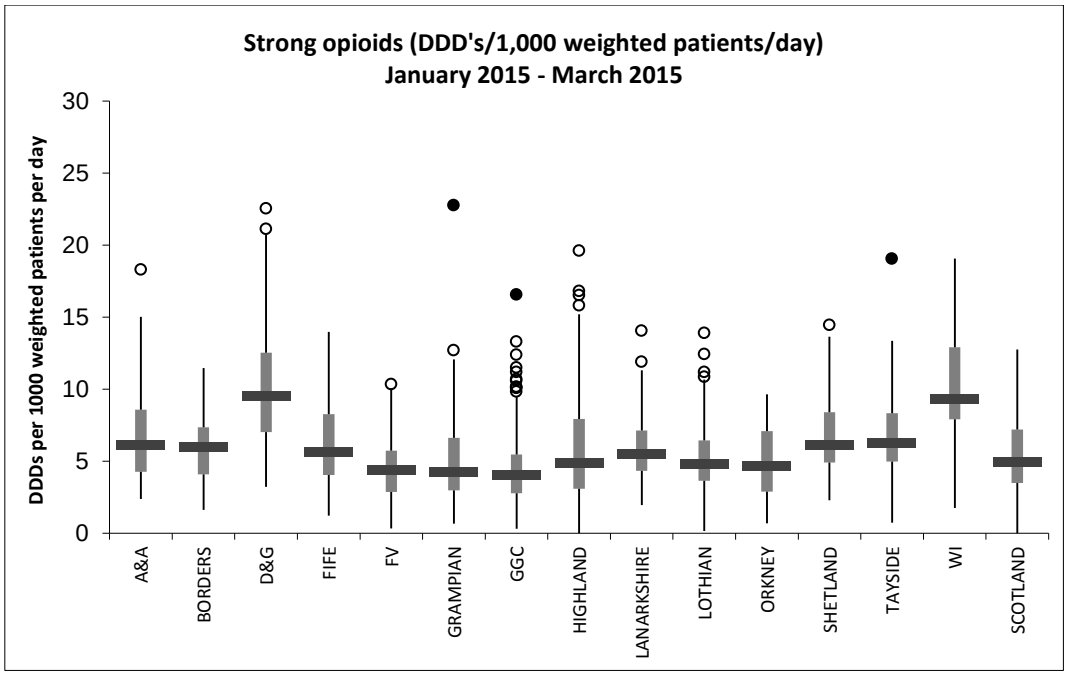




5.b Opioid analgesics: The amount of strong opioids prescribed per 1,000 weighted patients per day (DDD)

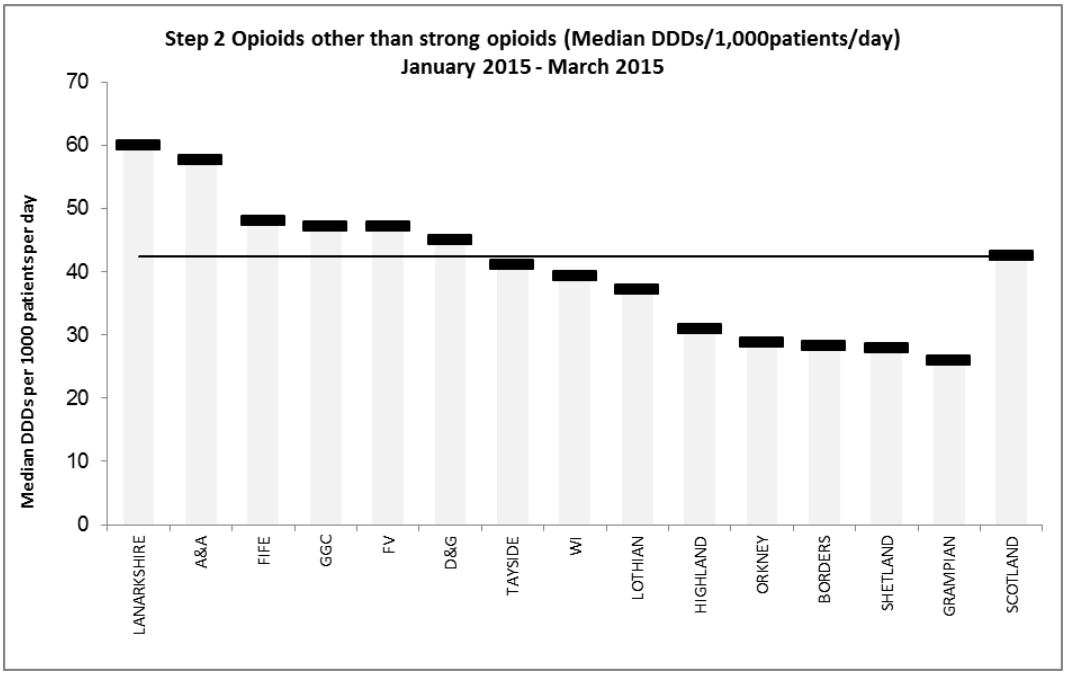
Opioids are well established in the management of acute pain and pain associated with terminal illness. Opioids can also provide symptomatic benefits for chronic non-cancer pain, however, repeated administration may cause problems of tolerance, dependence and addiction. The measure looks at the amount (DDD) of strong opioids (all opioids except codeine, dihydrocodeine and tramadol) prescribed per 1,000 **weighted** patients per day.

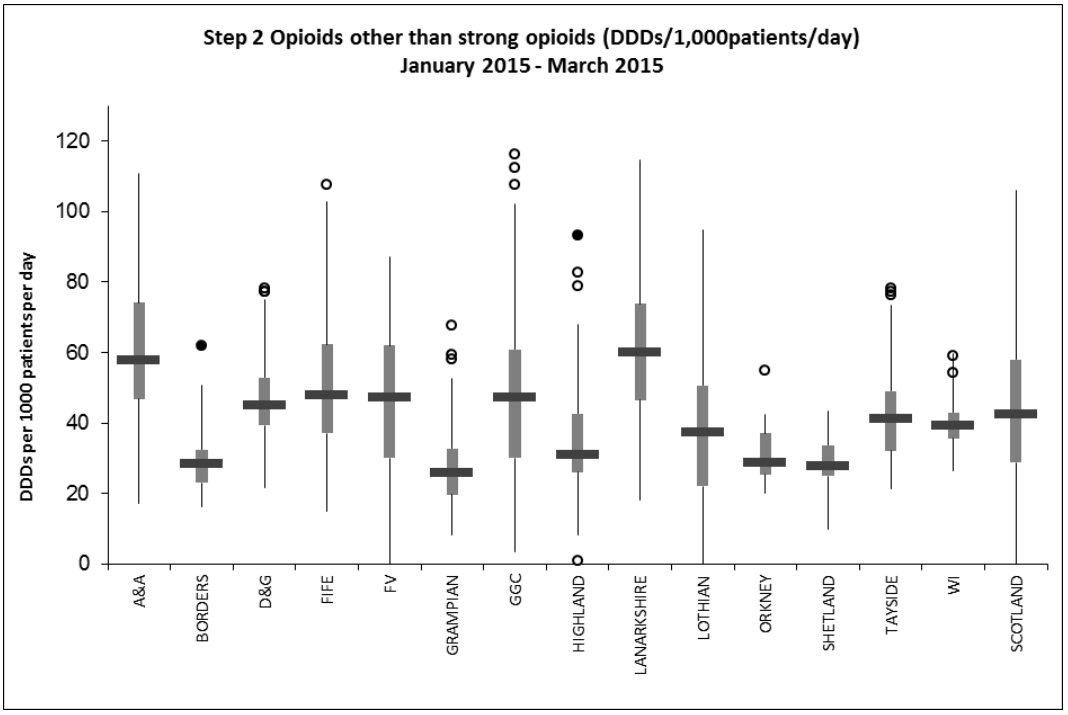




5.c Opioid analgesics: The amount of opioids other than strong opioids prescribed per 1,000 patients per day (DDD)

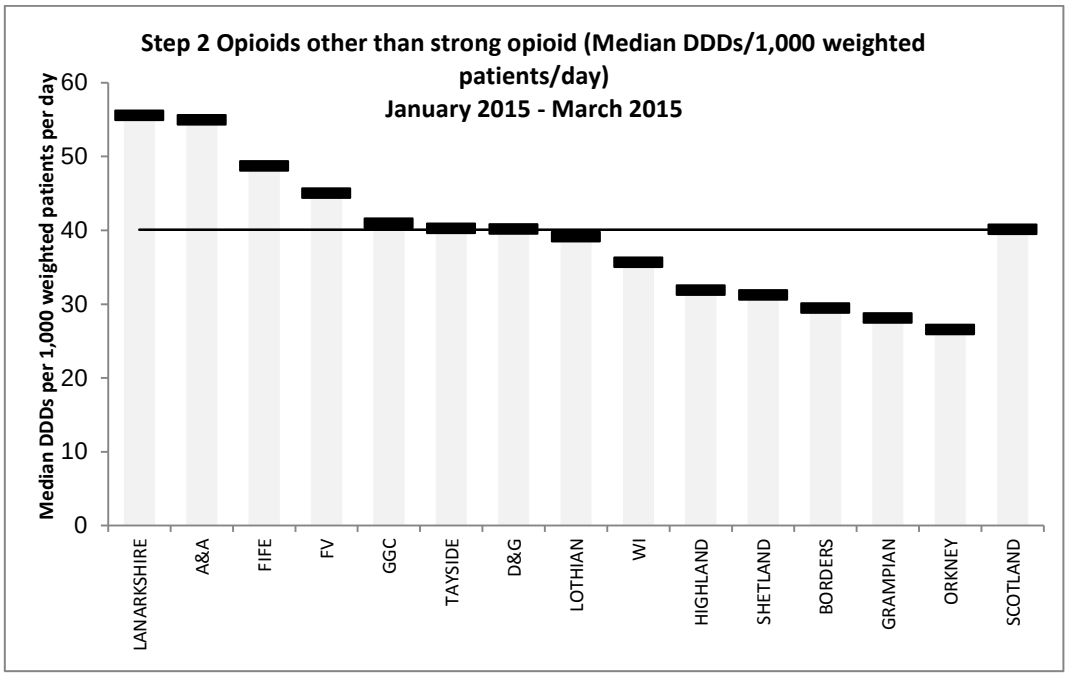
Opioids are well established in the management of acute pain and pain associated with terminal illness. Opioids can also provide symptomatic benefits for chronic non-cancer pain, however, repeated administration may cause problems of tolerance, dependence and addiction. The measure looks at the amount (DDD) of opioids, other than strong opioids (codeine, dihydrocodeine and tramadol) prescribed per 1,000 patients per day.

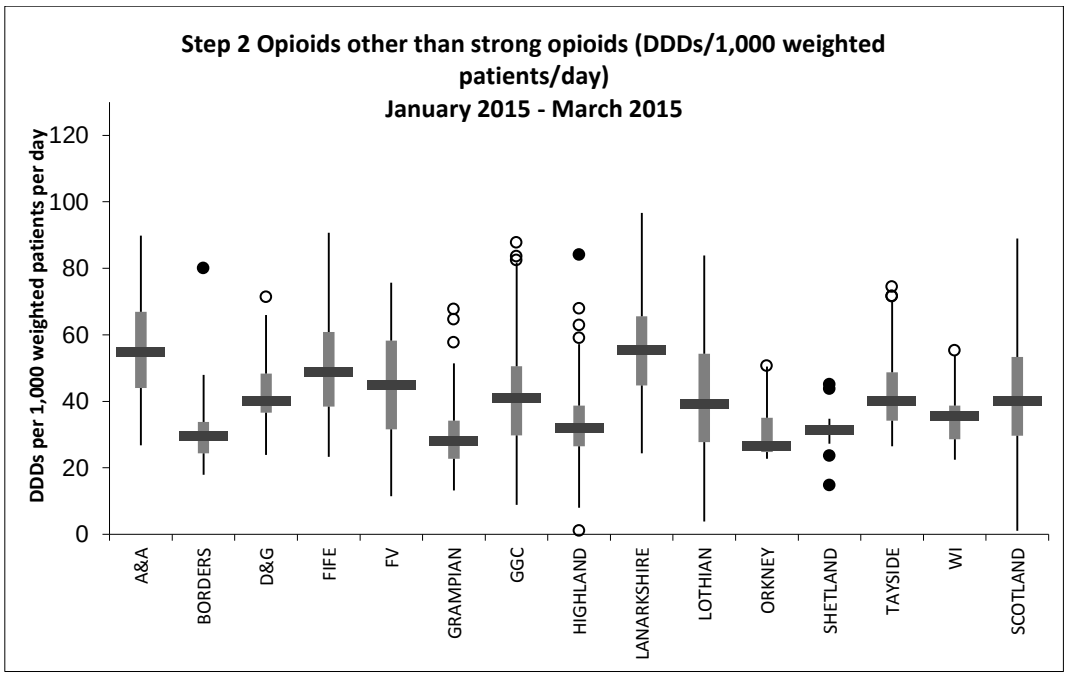




5.d Opioid analgesics: The amount of opioids, other than strong opioids, prescribed per 1,000 weighted patients per day

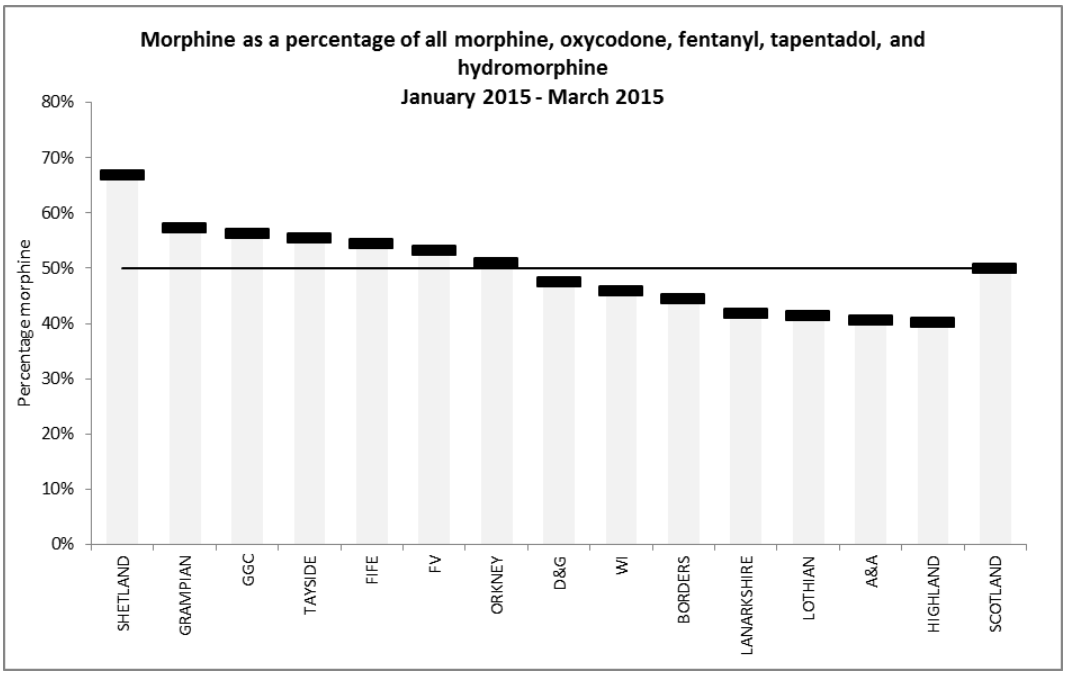
This NTI looks at the increasing use of opioids, other than strong opioids. Opioids are well established in the management of acute pain and pain associated with terminal illness. Opioids can also provide symptomatic benefits for chronic non-cancer pain, however, repeated administration may cause problems of tolerance, dependence and addiction. The measure looks at the amount (DDD) of opioids, other than strong opioids (codeine, dihydrocodeine and tramadol) prescribed per 1,000 **weighted** patients per day.

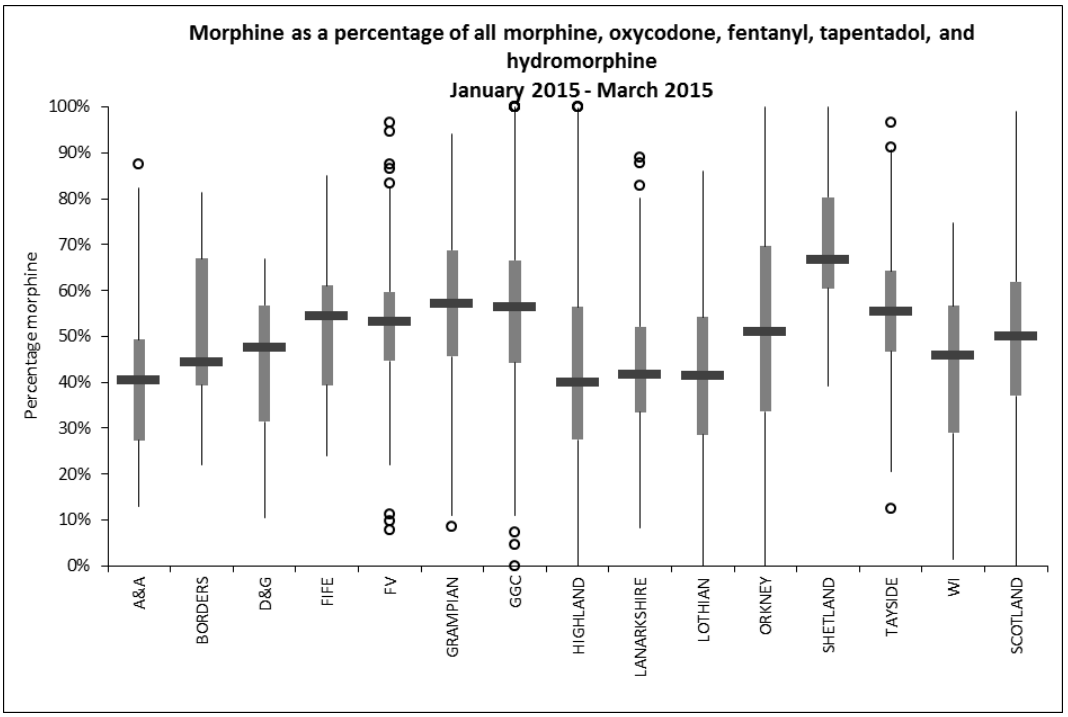




5.e Additional prescribing measure (APM): Morphine as a percentage of strong opioids (morphine, oxycodone, fentanyl, tapentadol and hydromorphine) (DDD)

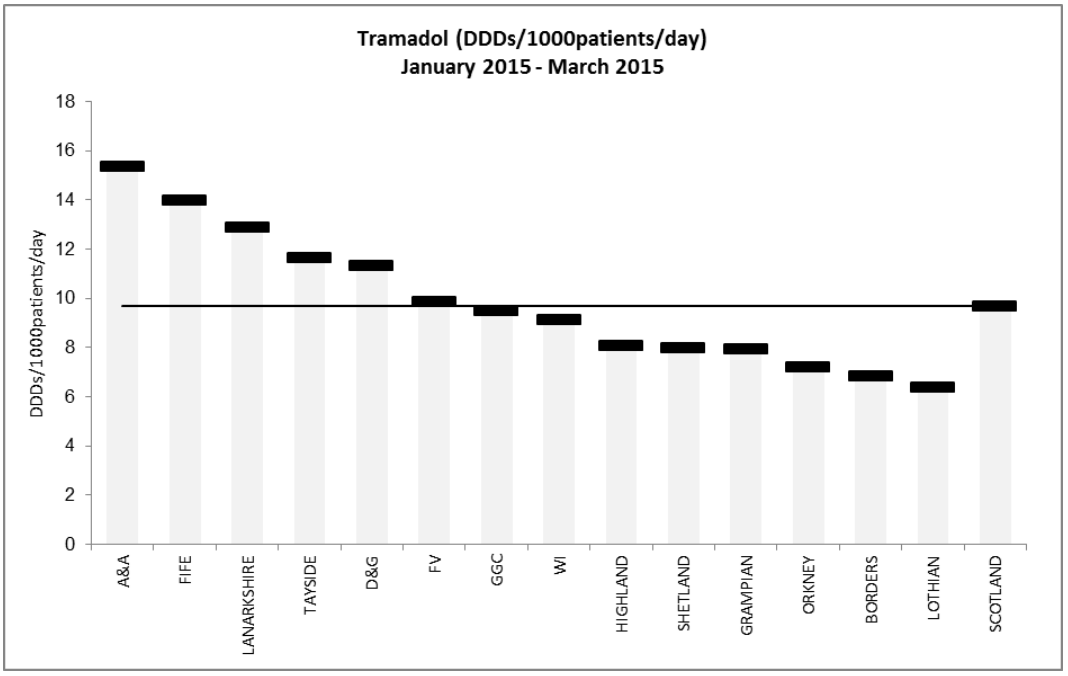
This additional prescribing measure (APM) looks at the first line recommended strong opioid morphine, as a percentage of all strong opioids. Morphine is the recommended first line strong opioid due to superior combined safety, effectiveness, and efficiency. The measure looks at the amount of morphine (DDD) as a percentage of all strong opioids.

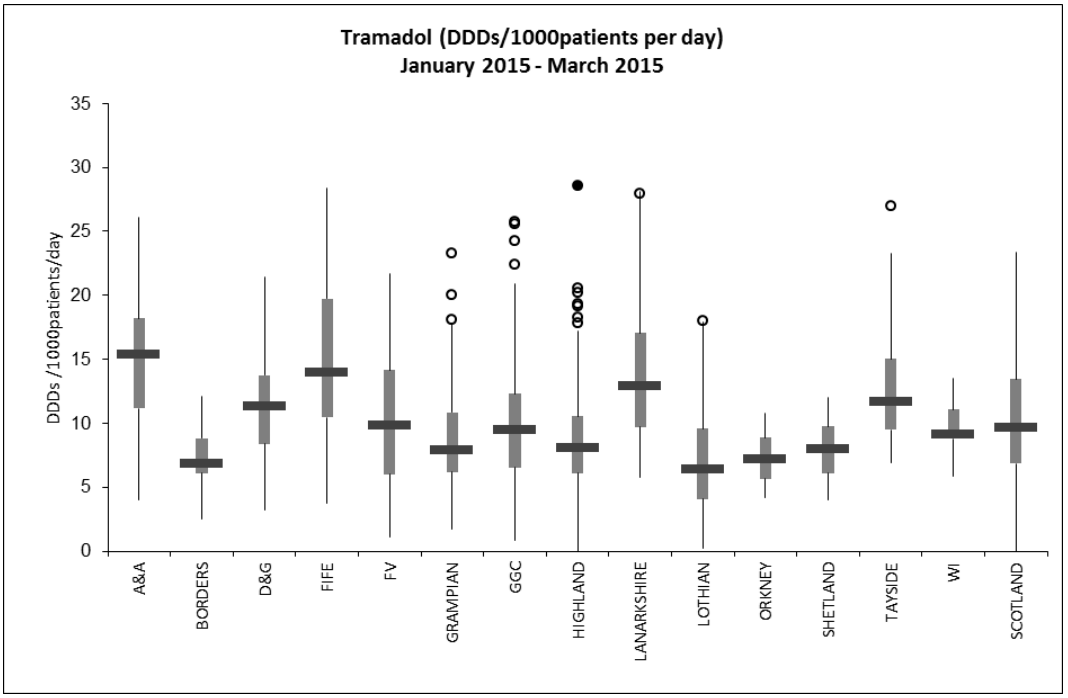




5.f Additional prescribing measure (APM): The amount of tramadol prescribed per 1,000 registered patients per day (DDD)

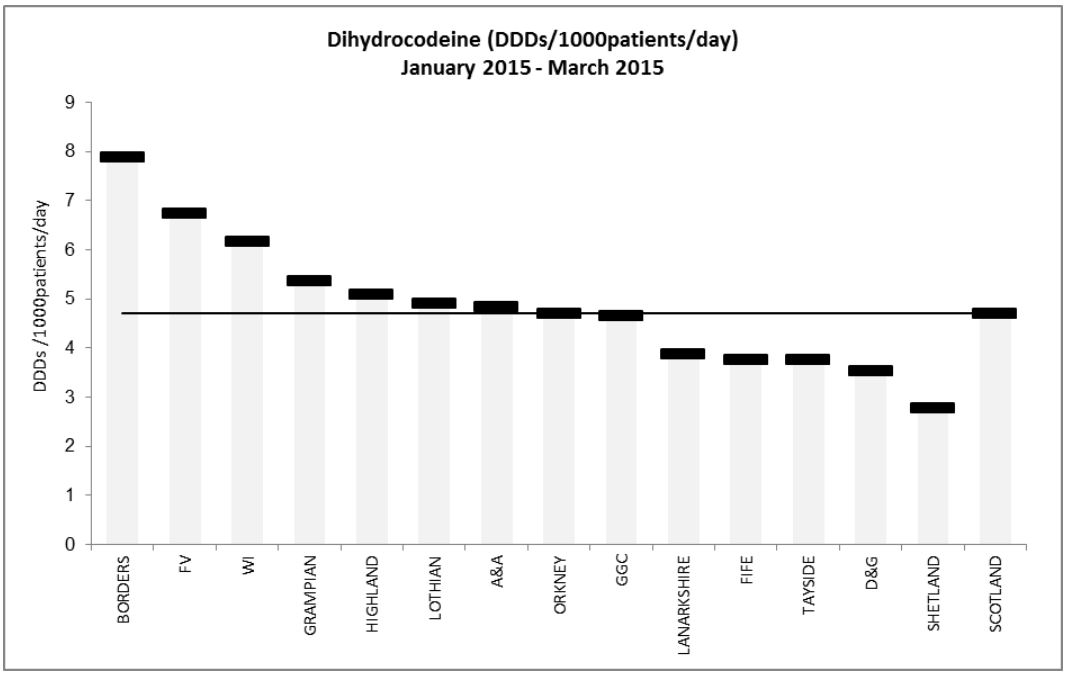
This additional prescribing measure (APM) looks at the comparative use of tramadol between the Boards. Tramadol is classified as a non-strong opioid and may be a suitable analgesic for some patients. Its use should take into consideration the variation in patient response and that dose equivalent for 50 mg tramadol varies between 4 to 10 mg of morphine.

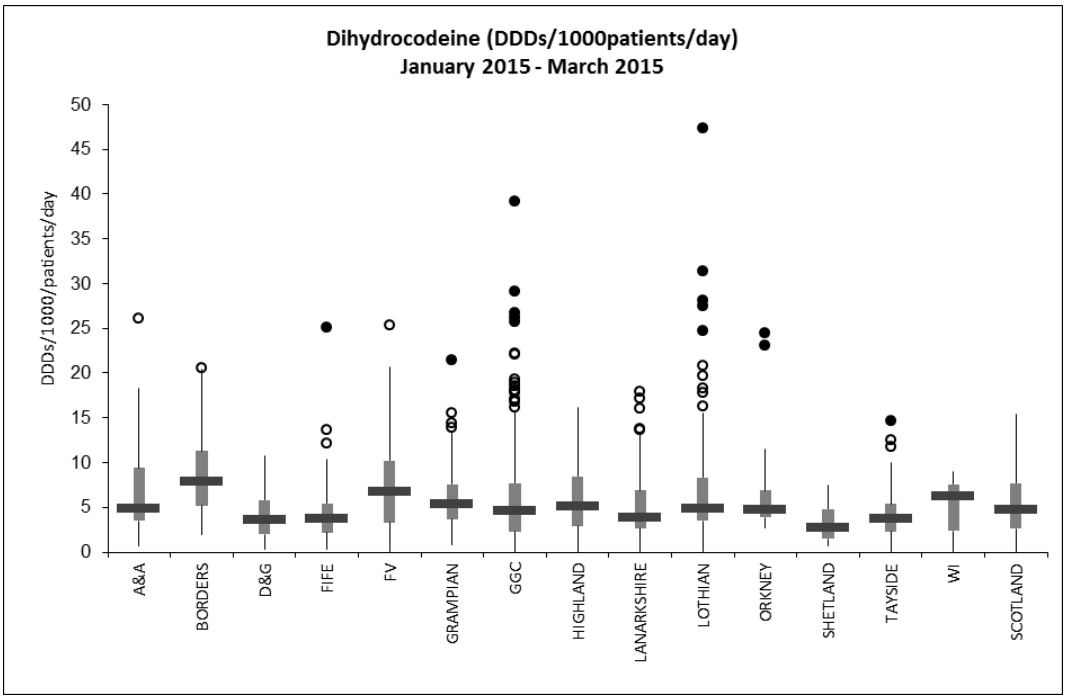




5.h Additional prescribing measure (APM): The amount of dihydrocodeine prescribed per 1,000 registered patients per day

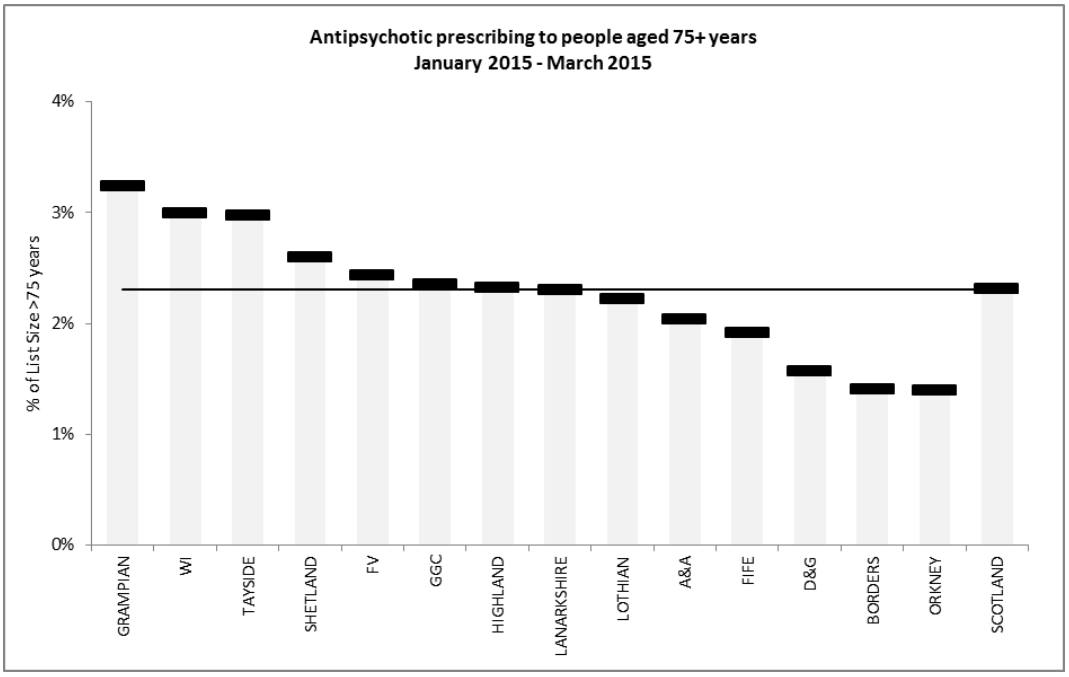
This additional prescribing measure looks at the comparative use of dihydrocodeine between NHS Boards. Dihydrocodeine is classified as a non-strong opioid and may be suitable for some patients in the management of chronic non-cancer pain.

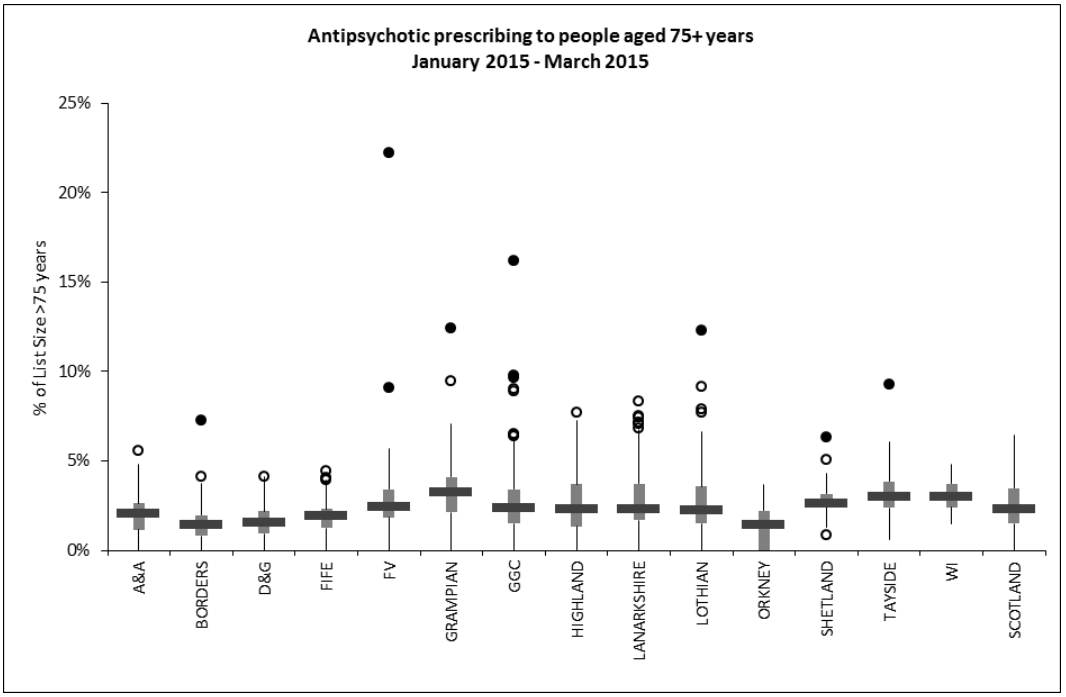




6. Use of antipsychotics in the over 75 year olds

This additional prescribing measure (APM) looks at the prescribing of antipsychotic medicines to patients over the age of 75 years. Antipsychotics have only limited benefit in treating behavioural and psychological symptoms of dementia and carry significant risk of harm. The percentage of patients over 75 years prescribed an antipsychotic drug is measured.





7. Antibiotics

This indicator is proposed and supported by the Scottish Antimicrobial Prescribing Group (SAPG).[1] Reductions in overall use of antibiotics is a key part of improving antimicrobial stewardship. The aim is to reduce antimicrobial resistance and reduce health-care associated infections in a safe manner that does not put patients at risk.

Evidence shows that antibiotic use in primary care drives bacterial antibiotic resistance for the individual and for the population.[2] [3] Higher levels of antibiotic resistance are associated with high use of antibiotics.[4]

The solution is not just to use fewer antibiotics: *'Our mission is not to prescribe as few antibiotics as possible, but to identify that small group of patients who really need antibiotic treatment and to explain, reassure and educate the large group of patients who don't.'*[5]

There are many clinical areas where antibiotic use clearly benefits an individual patient and the associated risks are outweighed. For example, pyelonephritis, cellulitis and community acquired pneumonia, are all infections that should **not** be targeted for a reduction in antibiotic use as the risk to the individual of not treating is too great.

However, 70% of antibiotics in primary care are used to treat self-limiting respiratory tract infections (acute sore throat, acute otitis media, acute rhinosinusitis and acute cough/bronchitis). The benefit of using antibiotics to treat these conditions in most patients is so marginal that it is outweighed by the risks to the individual and to society.[6]

The SAPG has produced a toolkit (ScRAP) to aid the process of using fewer antibiotics.[1] The Public Health England (PHE) template has been formally adopted for use in Scotland and gives clear guidance on the subgroups of patients that may benefit from use of antibiotics.[7]

The second antimicrobial NTI focuses on restricting the use of broad spectrum antibiotics. Use of the broad spectrum '4C antibiotics' (fluroquinolones, particularly ciprofloxacin, cephalosporins, co-amoxiclav and climamycin) is a well-recognised risk for *Clostridium difficile* infection (CDI),[8] MRSA and resistant UTIs in secondary care.[9] Evidence of the link between 4C antibiotics and CDI in primary care is emerging.

NHS Boards are required by Audit Scotland to report on what they are doing to reduce antibiotic use in primary care. This approach is further supported by the level 3 HEAT target to reduce total antibiotic use.

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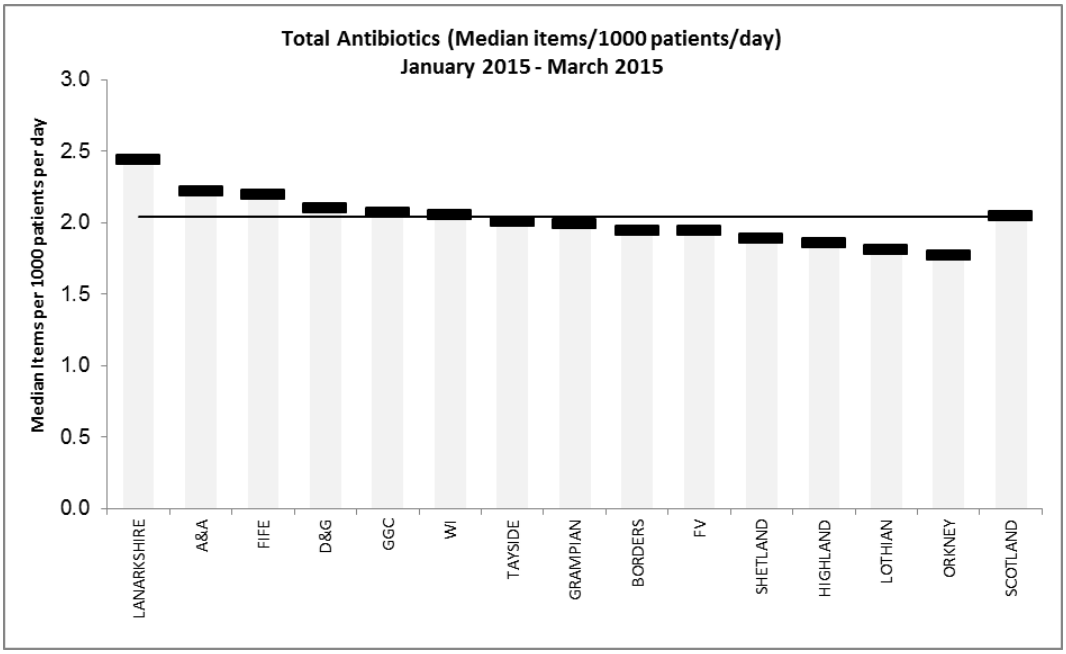
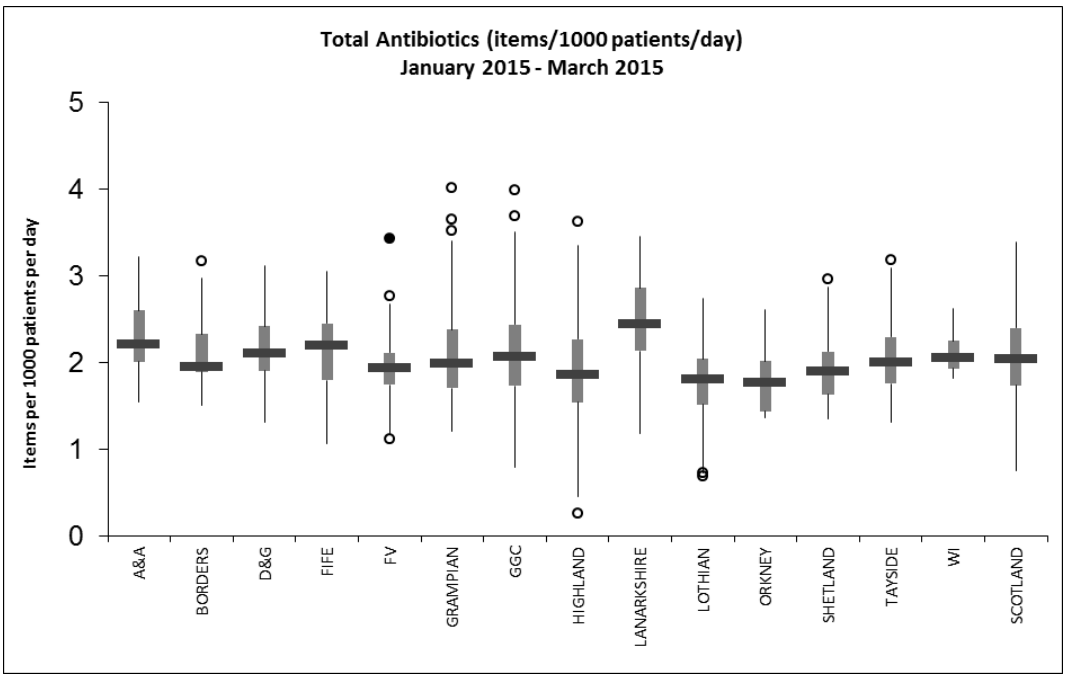
[1] The SAPG, Scottish Medicines Consortium, Delta House, 50 West Nile Street, Glasgow, G1 2NP
[2] Costelloe C, et al. BR Med J 2010; **340**: c2096
[3] Priest P, et al. BR Med J 2001; **323**: 1037-41
[4] European Antimicrobial Resistant Surveillance System (EARSS). Interactive Database
[5] Verheij TJM, Br J Gen Pract. 2009; **59**(567): 716-7
[6] NICE CG69 Respiratory Tract Infections, July 2008
[7] HPA *Management of infection guidance for primary care for consultation & local adoption, updated* July 2010
[8] Pepin J, et al. Clinical Infectious Diseases 2005; **41**(9): 1254-1260
[9] Davey P, et al. Emerging Infectious Diseases 2006; **12**(2): 211-216

7.a Antibiotics: The total amount of antibiotics prescribed per 1,000 patients per day (items)

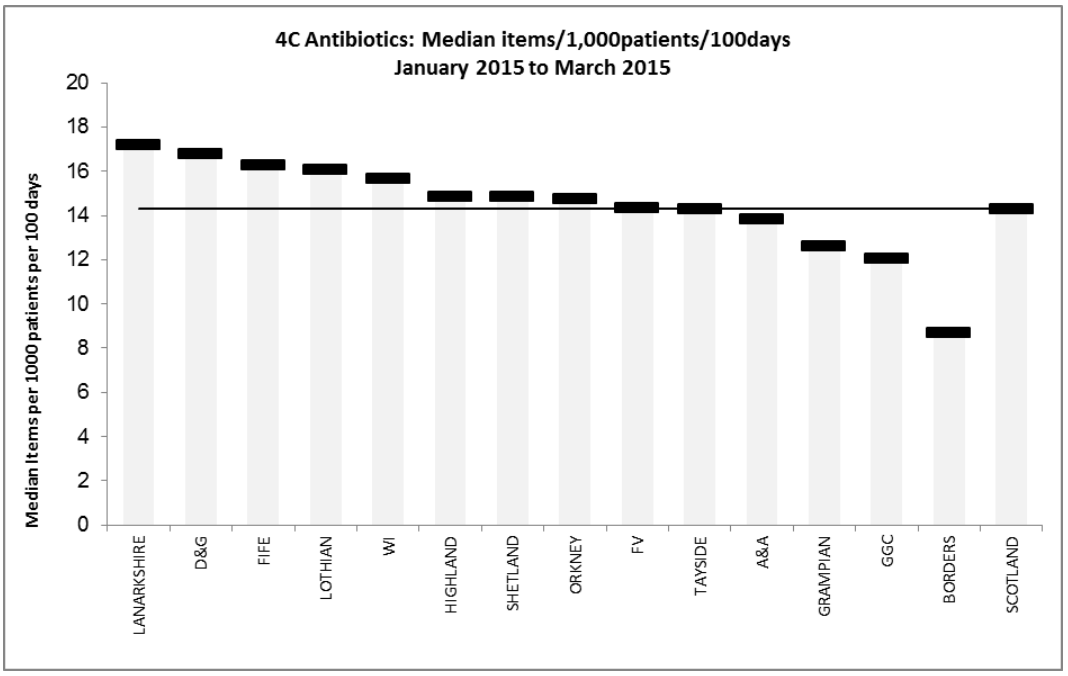
The Scottish Antimicrobial Prescribing Group (SAPG) agreed to use this NTI as a new national quality indicator for reduction of total antibiotics. It is now a key HAI Level 3 HEAT indicator. The measure will use January to March 2013 data as the baseline and to achieve the quality indicator, practices must either achieve a prescribing rate lower or equal to that of the Scottish 25th percentile or achieve an acceptable minimum reduction towards that level.

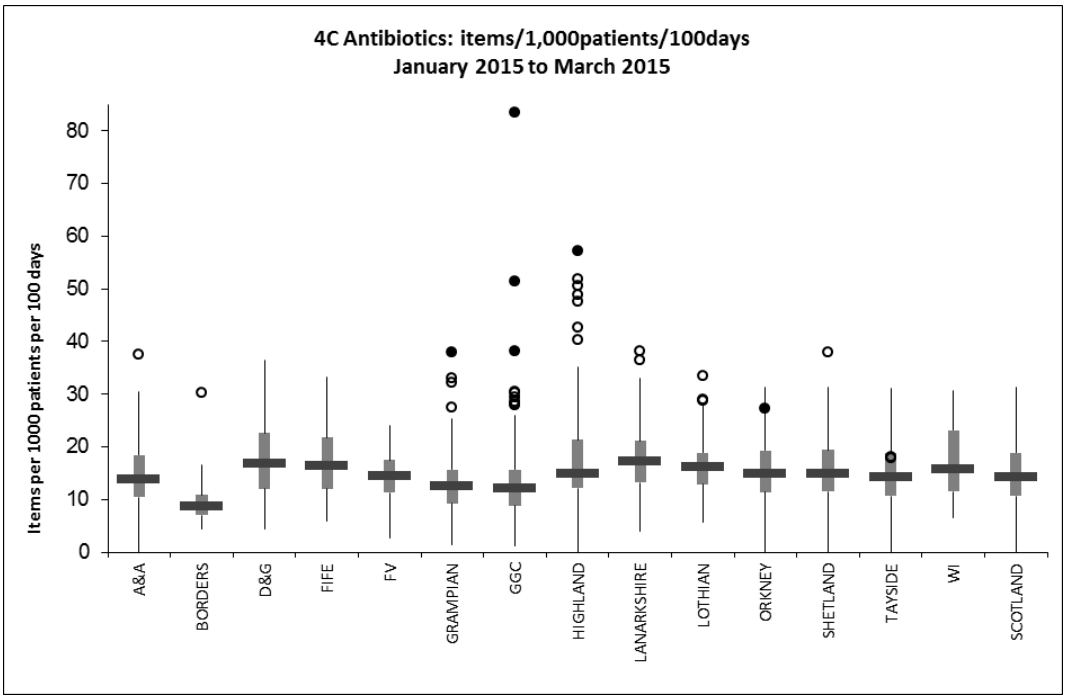




7.b Antibiotics: The amount of broad spectrum 4C antibiotics prescribed per 1,000 registered patients per 100 days (items)

This NTI looks at the comparative use of broad spectrum 4C antibiotics. The risks of healthcare associated infection (MRSA, CDI and ESBL) is far higher with broad spectrum antibiotics and their use should be reserved for a limited range of conditions.





8. Antidiabetic Drugs

This NTI has been developed with support from the national Diabetes Managed Clinical Network. The main rationale for its use is that metformin remains the only hypoglycaemic agent for which we have clear positive patient orientated outcomes.[1]

The importance of lipid lowering and blood pressure control over blood glucose control for type two diabetics is highlighted. Antidiabetic drugs should be used to augment the effect of diet and exercise, not replace it.[2]

The QOF HbA1c target has increased to 59mmol/L (7.5%). The *Cardiff UK GPRD Study* was a retrospective cohort study that showed a HbA1c of 59mmol/L (7.5%) was the lowest risk for all-cause mortality.[3] Increase above or decrease below this level is associated with an increased risk of all-cause mortality.

A meta-analysis looked at the effects of intensive glucose lowering on all-cause mortality, cardiovascular death and micro-vascular complications.[4] Intensive treatment had **no** significant effect on all-cause mortality or cardiovascular death, although risk of non-fatal myocardial infarction (NNT=117) and developing microalbuminuria (NNT=32) was reduced. However, the risk of severe hypoglycaemia was doubled (NNH=15).

The result of this meta-analysis should also be put into the context of the relationship between reductions in cholesterol, blood pressure and HbA1c with improvements in coronary heart disease and cardiovascular outcomes.[5] It has been calculated that the absolute reduction in cardiovascular events prevented by the different interventions per 1,000 patients per one year of treatment are:

- Lowering HbA1c by 1% = 3 events prevented
- Lowering LDL by 1 mmol/L = 8 events prevented
- Lowering BP by 10/5mmHg – 12 events prevented [6]

'the emphasis in type 2 diabetes should remain on tight control of lipids and blood pressure with reasonable but not exaggerated attempts to control glycaemia.'

The management of type 2 diabetes should emphasise the importance of weight reducing diet and increased activity. Lipid lowering and BP control should be managed optimally when such treatment is required. Metformin should be the first line agent. Sulphonylureas, pioglitazone, DPP4 inhibitors, GLP1 agonists and SGLT2s should be considered as second and/or third line agents with unique merits and weaknesses, and in the context of the risks of intensive HbA1c lowering.

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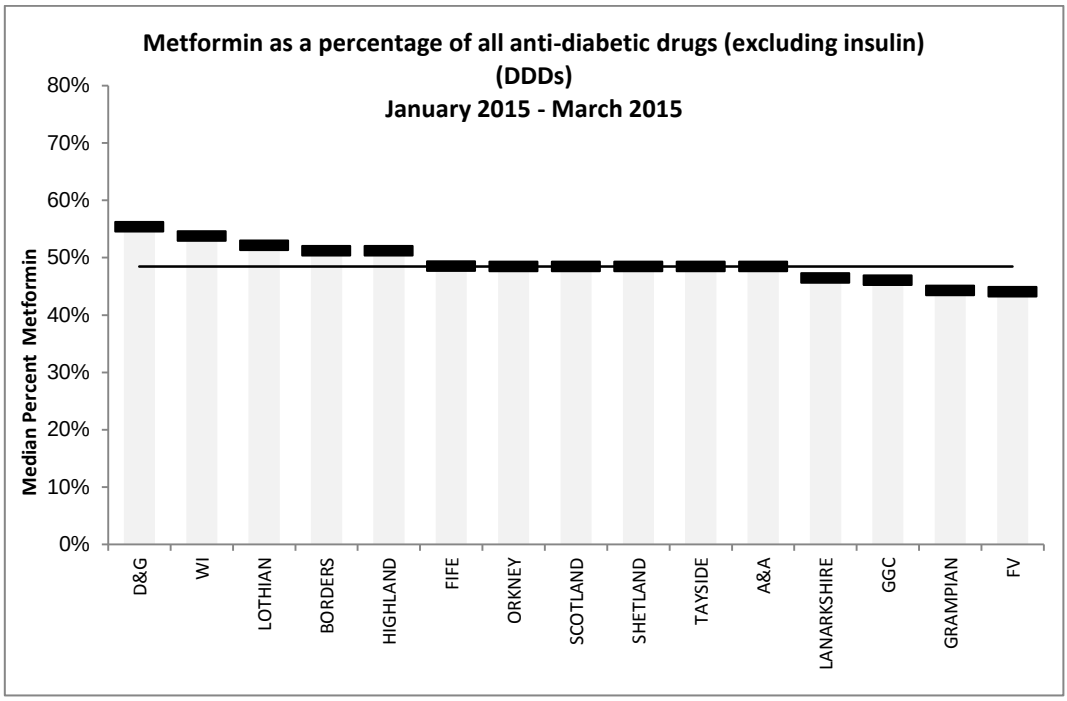
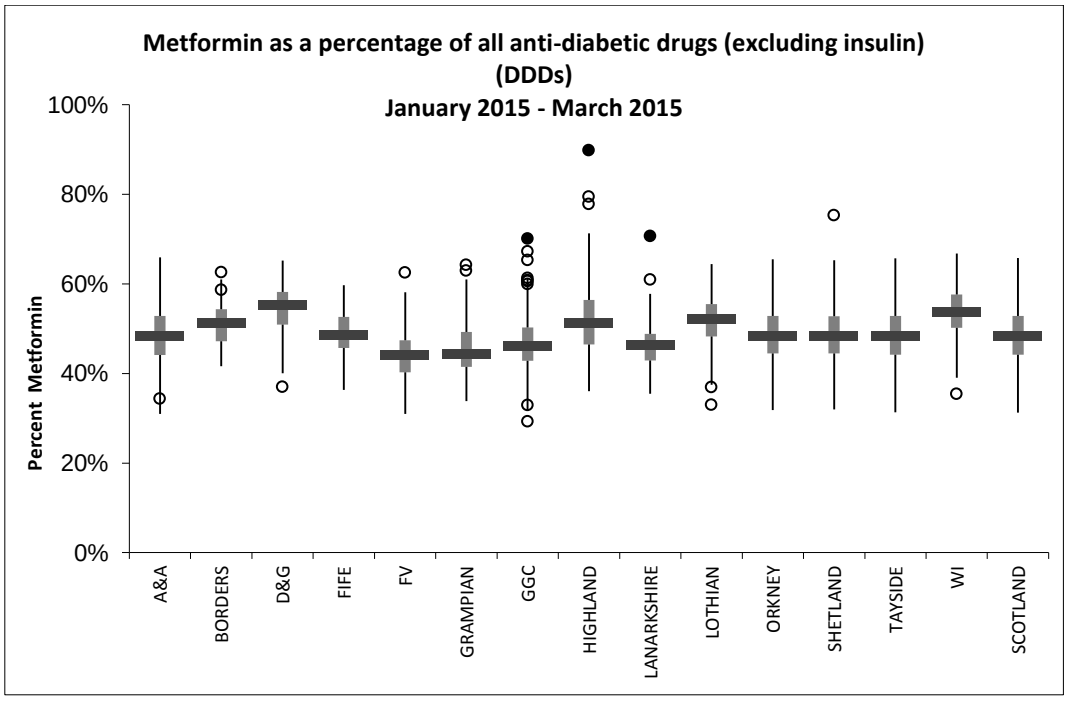
[1] Holman RR, et al. *N Engl J Med 2008*; **359**: 1577-89
[2] Joint Formulary Committee. *British National Formulary*. Edition 69. March 2015
[3] Boussageon R, et al. *BMJ2011;* **343:** d4169
[4] Yudkin JS, et al. *Diabetologia 2010;* **53:** 2079-85
[5] Preiss D, et al. *BMJ2011;* **343:** d4243
[6] Opie LH. *Lancet 2011;* **378**(9713): 103

8.a Antidiabetic Drugs: The amount of metformin prescribed as percentage of all anti-diabetic drugs (excluding insulins) (DDDs)

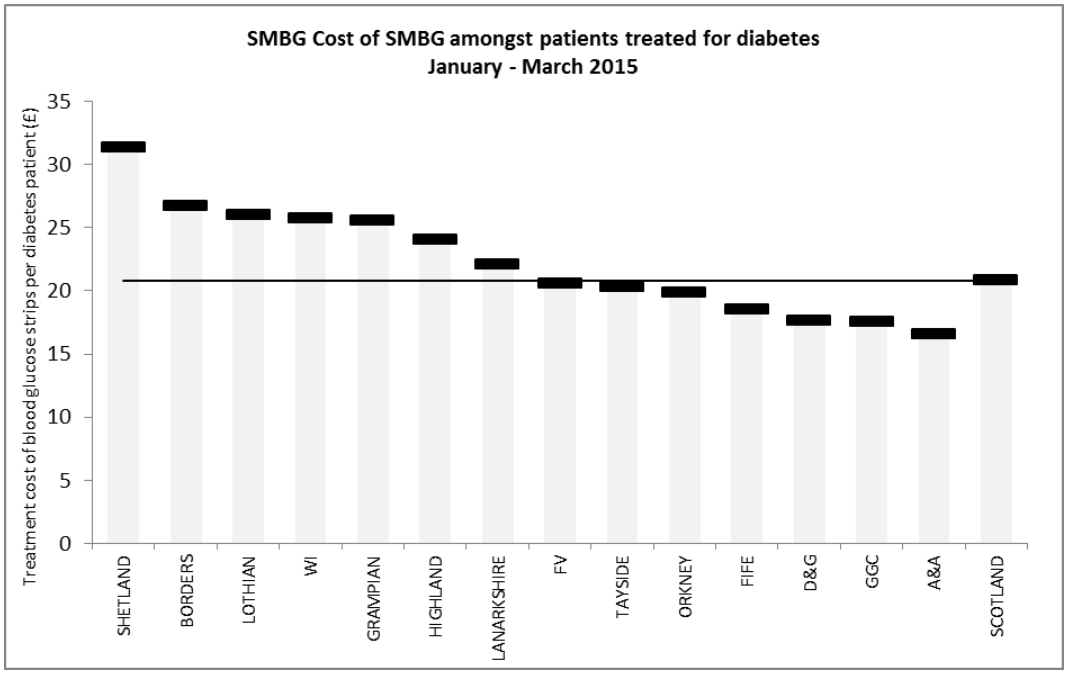
The management of type 2 diabetes should emphasise the importance of weight reducing diet, increased activity, lipid lowering and BP control before antidiabetic therapy. This NTI promotes the first line use of metformin when antidiabetic therapy is required. Sulphonylureas, pioglitazone, DPP4 inhibitors, GLP1 agents and SGLT2s should be considered as second or third line agents with unique merits and weaknesses, and, in the context of the risks of intensive HbA1c lowering.

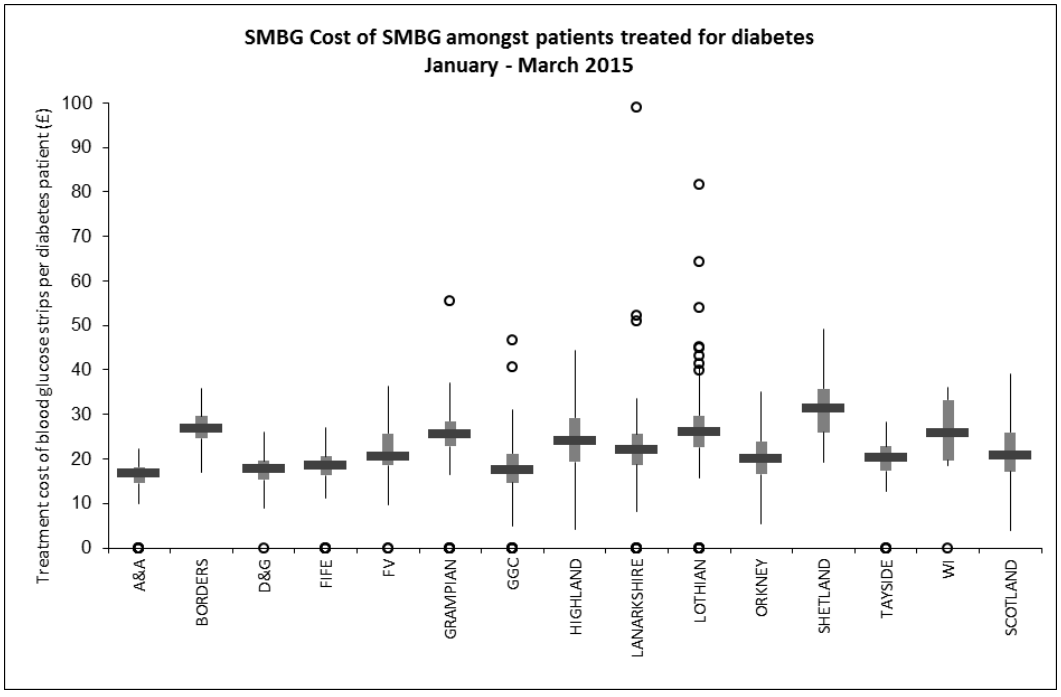




8.b Additional prescribing measure (APM): The cost of self-monitoring blood-glucose (SMBG) per patient treated for diabetes.

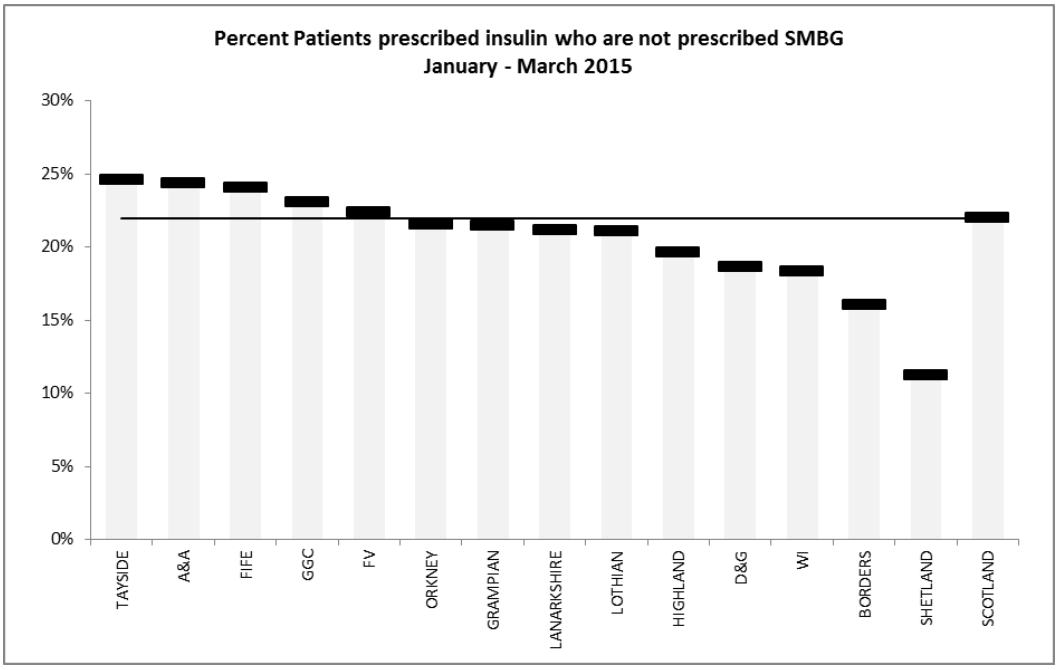
This additional prescribing measure (APM) aims to identify the inappropriate use of self-monitoring of blood-glucose. SMBG should only be used for patients treated with insulin and at risk of hypoglycaemia, particularly before activities like driving. They can be used **short-term** after changes to management. The measure looks at the cost of SMBG per patient prescribed a drug used in diabetes (BNF 6.1) in a given quarter.

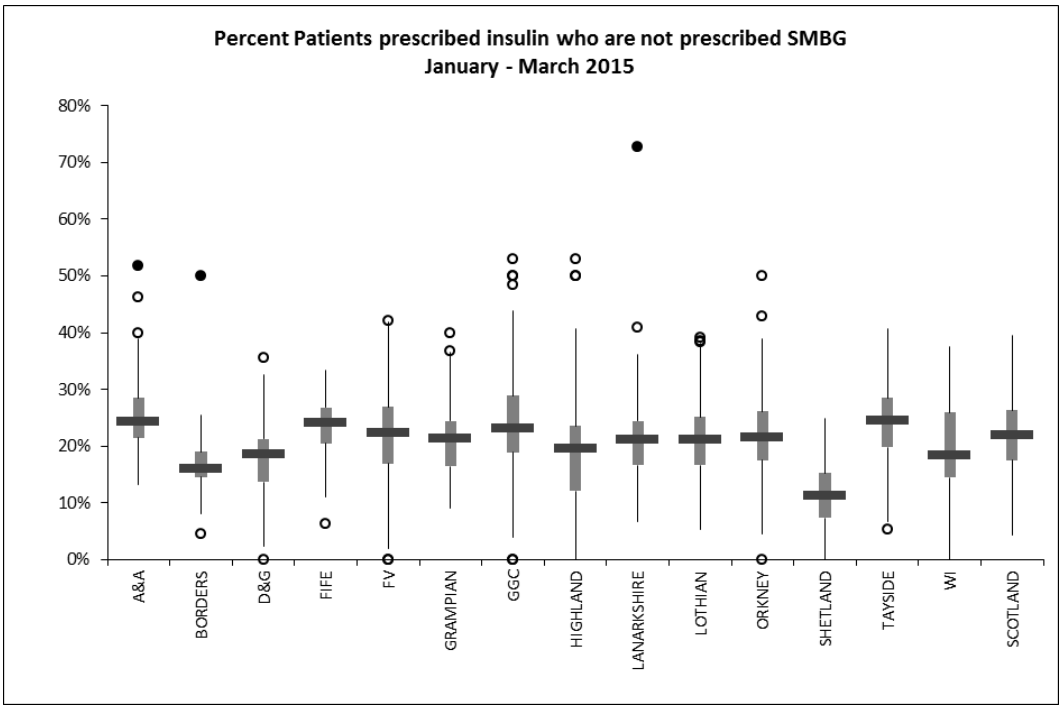




8.c Additional prescribing measures (APM): The percentage of patients prescribed insulin who were not prescribed self-monitoring blood-glucose strips in the same quarter.

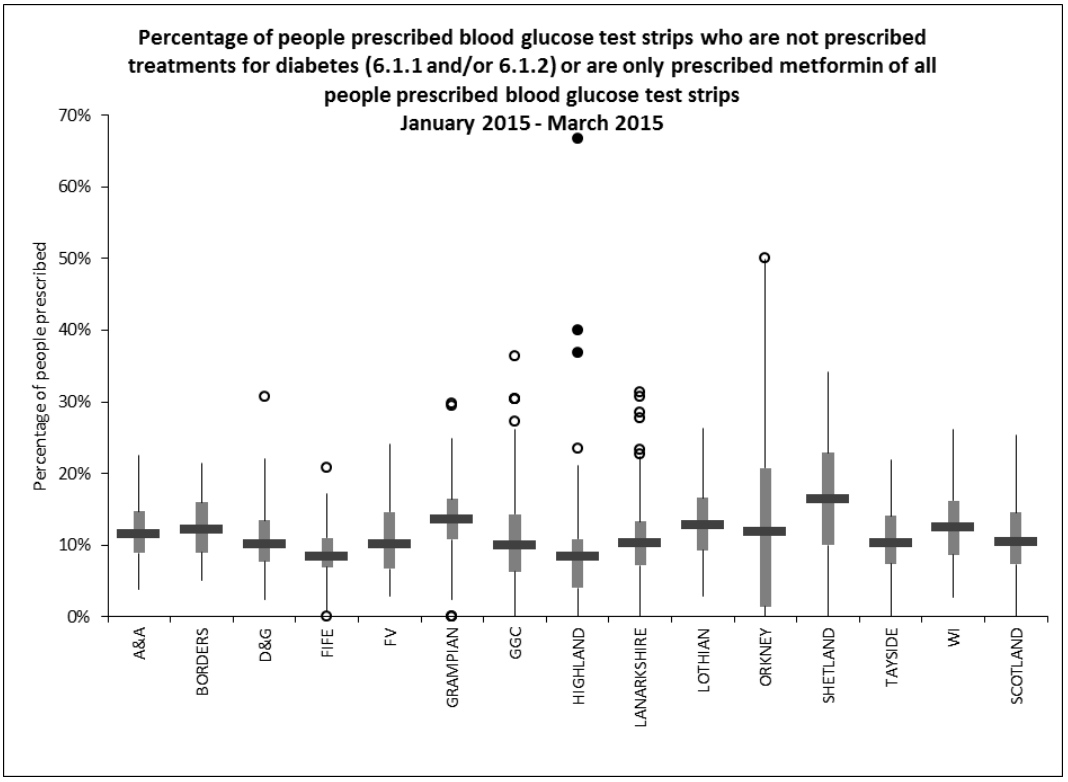
This additional prescribing measure (APM) aims to identify the under use of self-monitoring of blood-glucose by patients on insulin. SMBG should be used by all patients treated with insulin. The measure looks at the number of patients prescribed insulin but no SMBG as a percentage of all patients prescribed an insulin (BNF 6.1.1) in a given quarter.

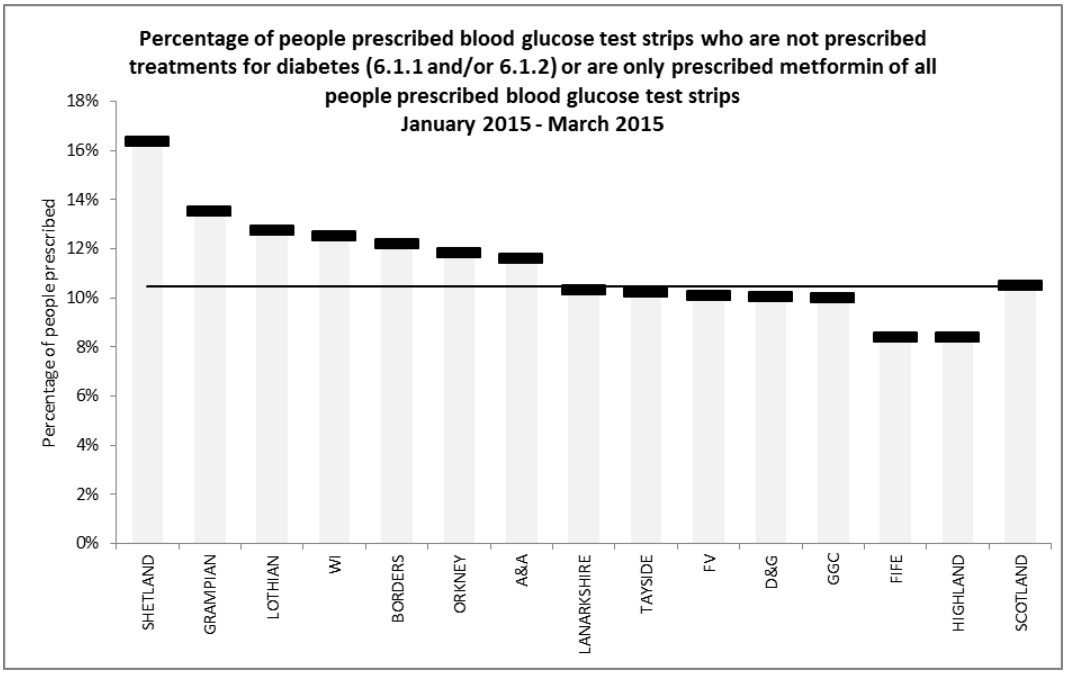




8.d Additional prescribing measure (APM): The percentage of people prescribed self-monitoring blood-glucose (SMBG) testing strips, yet have not been prescribed a treatment for diabetes, or are prescribed metformin alone.

This additional prescribing measure (APM) aims to identify the inappropriate use of self-monitoring of blood-glucose. It identities the number of patients being prescribed SMBG but no insulin (BNF 6.1.1) or antidiabetic (BNF 6.1.2), or, those patients on metformin alone, as a percentage of patients prescribed SMBG.





9. Non-steroidal anti-inflammatory drugs (NSAIDS) including Cox-2 inhibitors

This NTI looks at the use of NSAIDs in the management of acute and chronic non-cancer pain. They reduce the production of prostaglandins by inhibiting the enzyme cyclo-oxygenase.[1] Selectivity for inhibiting different types of cyclo-oxygenase varies. This and a number of other factors influences their susceptibility to produce gastrointestinal effects.

The use of NSAIDs in the management of chronic non-cancer pain is likely to be most successful when focussing on individual response. A responder can be defined as someone who experiences good (>50%) pain reduction and improvements in fatigue, depression and sleep disturbance without side effects.[2] [3]

In a systematic analysis NSAIDs improve pain relief and function when compared to placebo, but at the cost of significantly more side effects.[4] There is moderate evidence that NSAIDs are more effective than paracetamol, but again with increased risk of side effects. Evidence suggests that NSAIDs are not more effective than other drugs for acute low-back pain.

60% of people respond to any NSAID, and so a first-line agent should be selected with minimal risk of side effect. This will usually be ibuprofen or naproxen. Responders experience pain relief soon after taking the first dose, and full analgesic effect will usually be obtained within a week. Individual dose titration by responders, to balance pain relief with tolerable side effects, is likely to produce a better result.[5] Full anti-inflammatory effect with an NSAID will not be apparent for three weeks of regular treatment.

Non-responders to first-line NSAIDs may respond better to an alternative one. This possibility is not currently reflected in evidence-based clinical guidelines where the trend is to recommend a limited list of medicines, based on the assumption of a class effect, despite important differences in pharmacokinetics or drug interactions.

Gastrointestinal (GI) adverse effects with NSAIDs are well established. Greatest risk of serious upper GI events are with non-selective NSAIDS and those with a long half-life, including modified release preparations. Highest risk is with piroxicam, followed by naproxen, whereas COX-2 inhibitors are associated with the lowest risk.

Major vascular events are increased by a third with the use of diclofenac, celecoxib, entoricoxib and parecoxib. [6] This means an increase of three major coronary events, per 1,000 patients treated with the NSAID for twelve months. Diclofenac and the COX2-inhibitors are now contraindicated in patients with ischaemic heart disease, cerebrovascular disease, peripheral arterial disease and heart failure.

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[1] BNF 69 accessed 28.09.15

[2] Moore at al. *BMJ* 2013;346:f2690

[3] SIGN 136

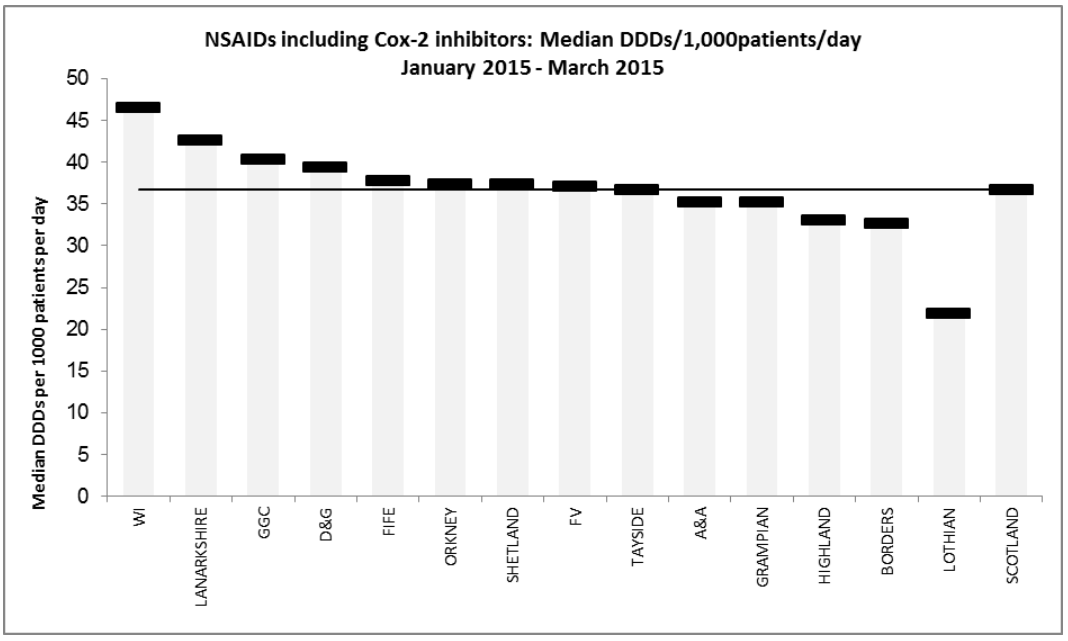
[4] Roelofs PD et al. *Cochrane Database of Systematic reviews* 2008, issue1

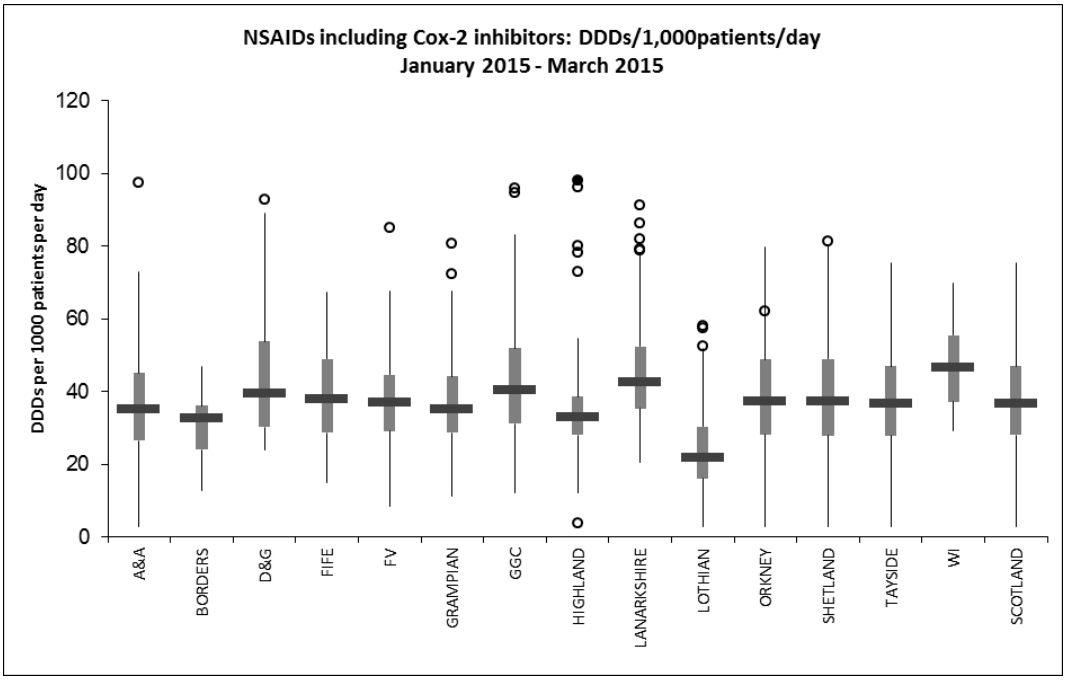
[5] Crofford LJ et al. *Pain* 2008;136:419-31

[6] Bhala N, et al. *Lancet* 2013;382(9894):769-79

9.a NSAIDS including Cox-2 inhibitors: The amount of NSAIDs prescribed per 1,000 registered patients per day (DDD)

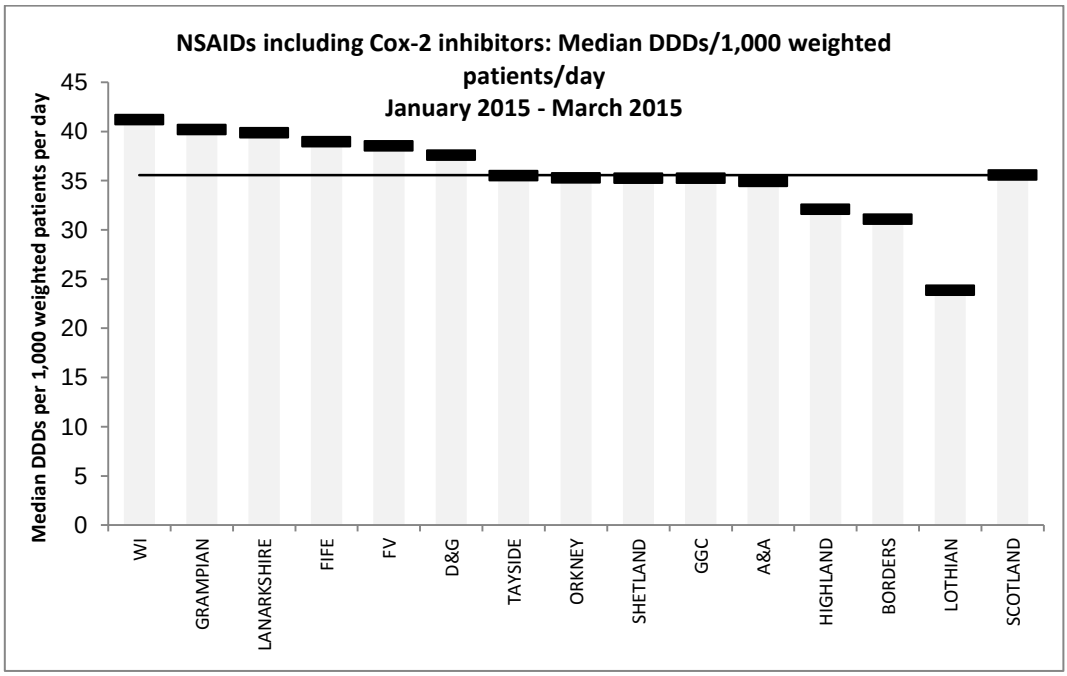
This NTI looks at the total use of non-steroidal anti-inflammatory drugs (NSAIDS). There is overwhelming evidence to reduce prescribing of NSAIDs, especially in the elderly, due to the risk of GI, cardiovascular and renal complications.

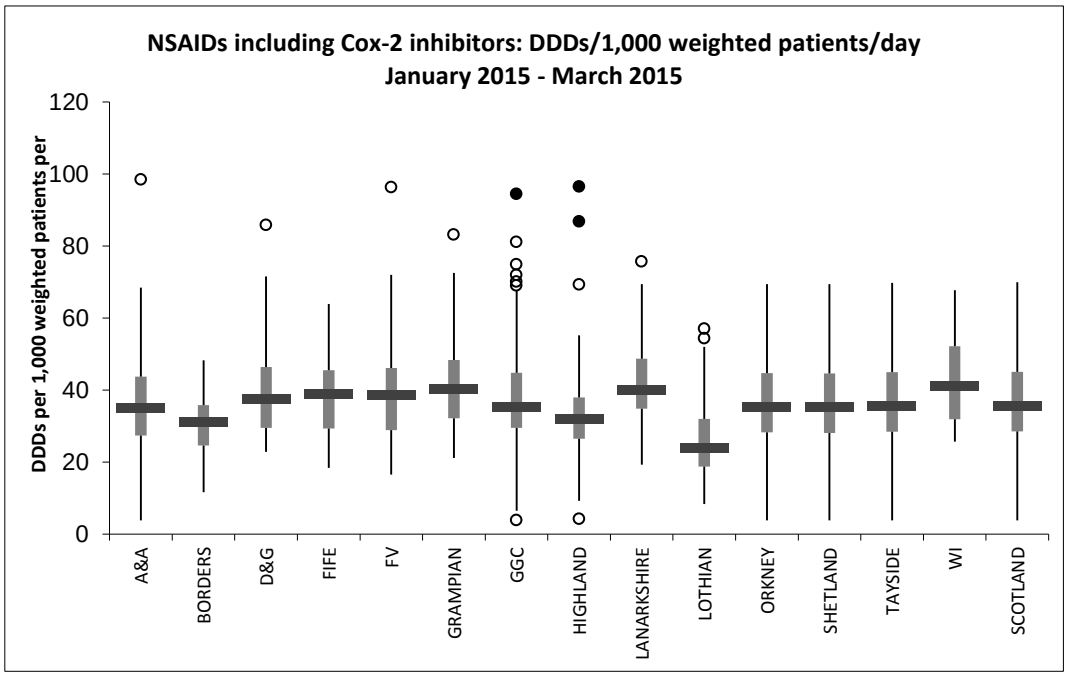




9.b NSAIDs including Cox-2 inhibitors: The amount of NSAIDS prescribed per 1,000 weighted registered patients per day (DDD)

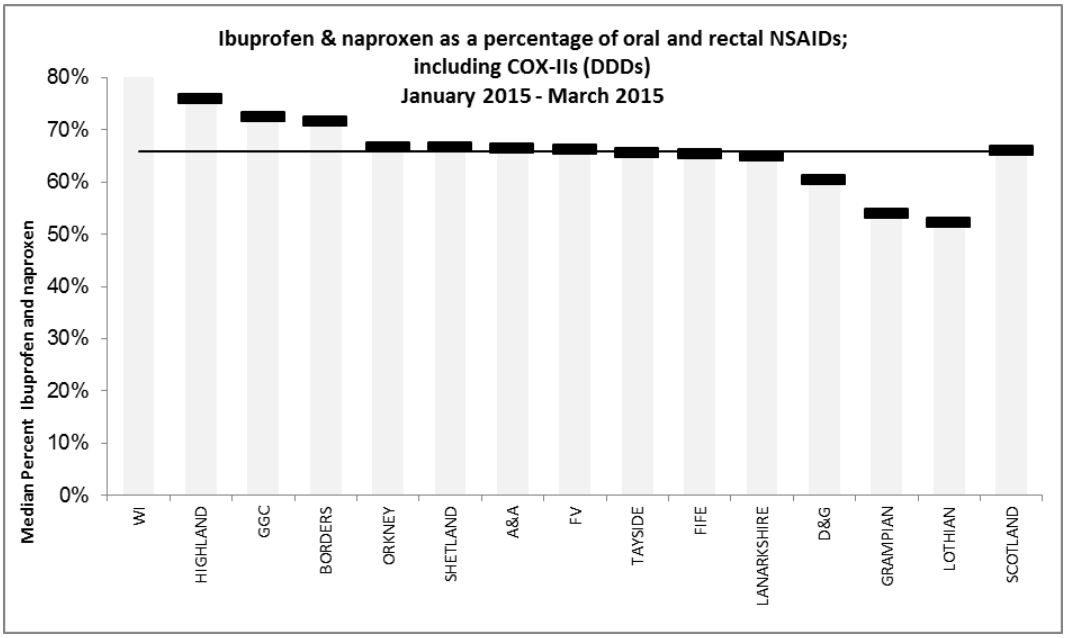
This NTI looks at the total use of non-steroidal anti-inflammatory drugs (NSAIDS). There is overwhelming evidence to reduce prescribing of NSAIDs, especially in the elderly, due to the risk of GI, cardiovascular and renal complications.

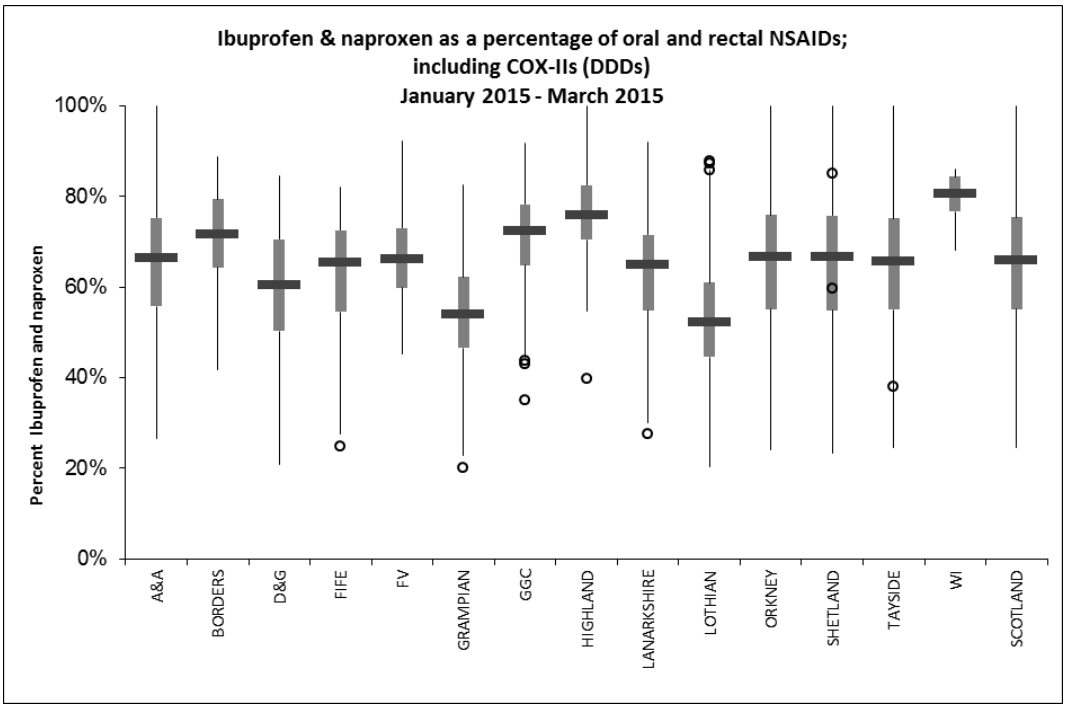




9.c NSAIDs including Cox-2 inhibitors: The amount of Ibuprofen and naproxen as a percentage of all NSAIDs (DDDs)

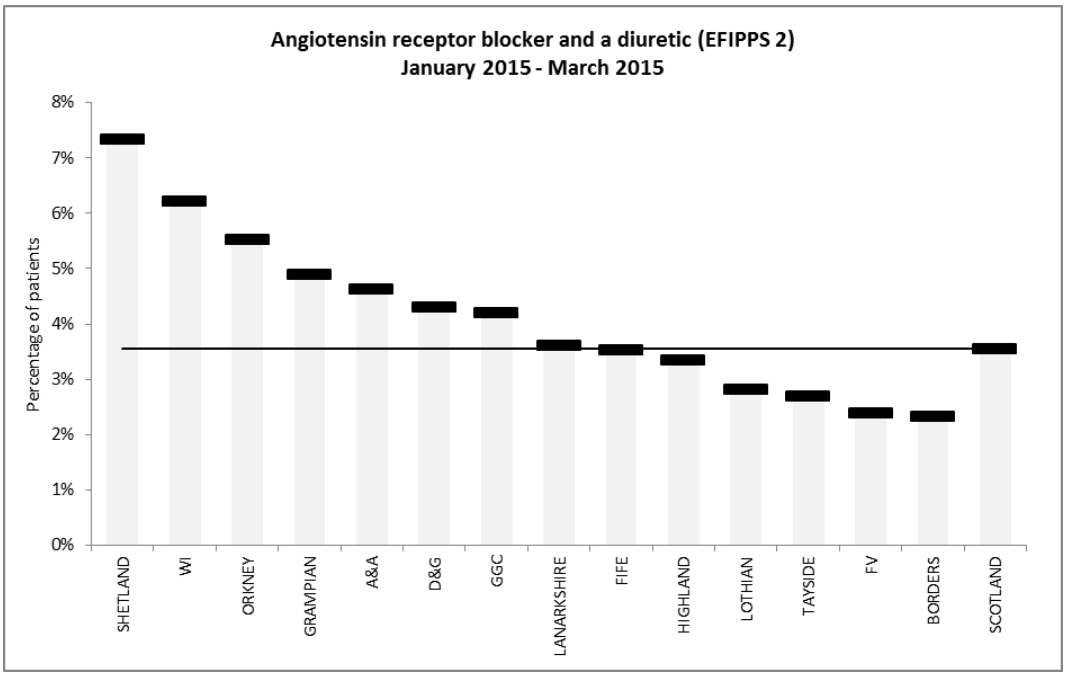
This indicator looks at the use of the recommended first-line NSAIDs, ibuprofen and naproxen. 60% of people are likely to respond to first-line NSAIDs, with a positive response being apparent soon after the first dose. Maximum analgesic effect is apparent after one week and anti-inflammatory effect after three weeks. Low dose ibuprofen and naproxen are considered to have the most favourable thrombotic cardiovascular safety profile.

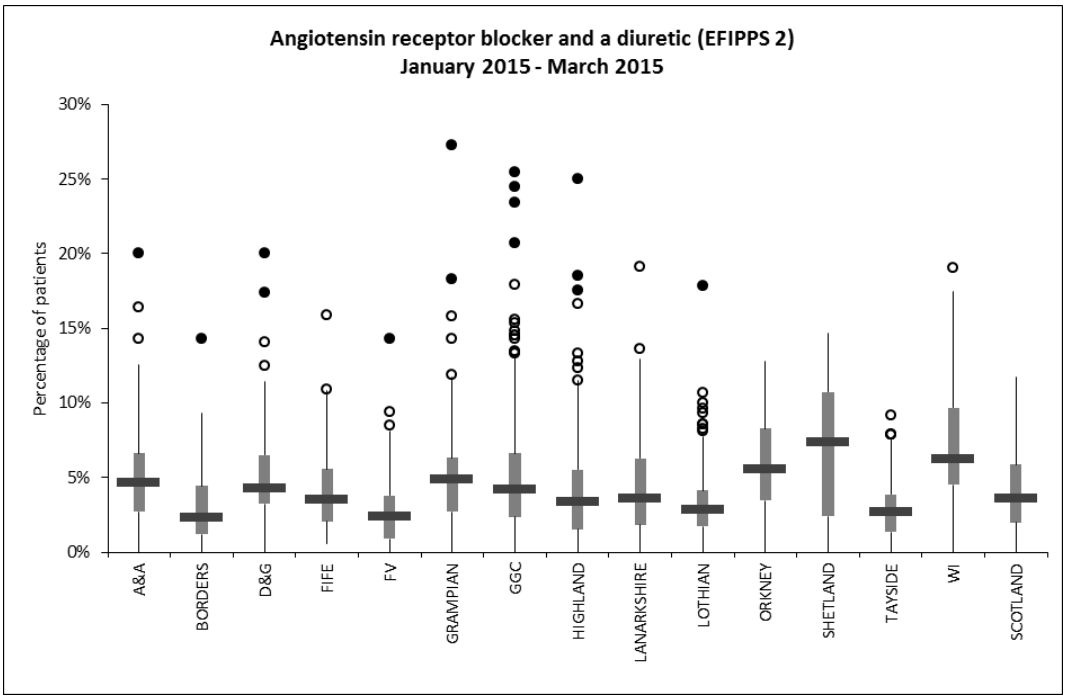




9.d Additional prescribing measure (APM): The percentage of people prescribed a NSAID in addition to an angiotensin-converting enzyme/angiotensin-2 receptor antagonist plus a diuretic over the age of 65 years

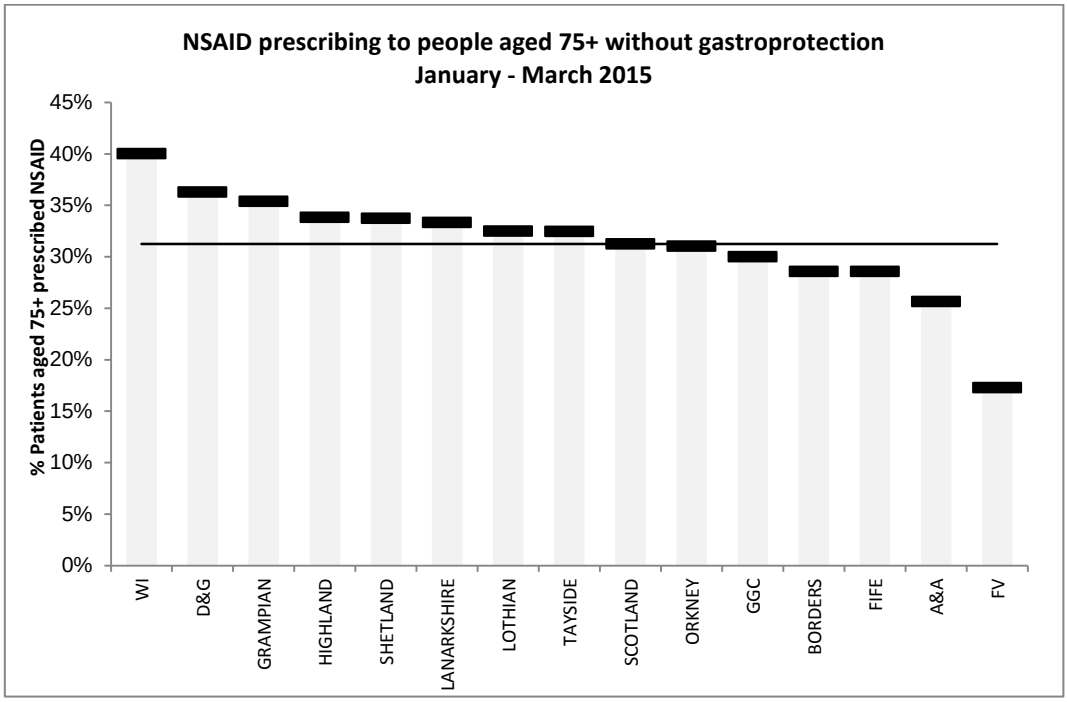
This additional prescribing measure (APM) looks at the combined use of a NSAID plus angiotensin-converting enzyme inhibitor or angiotensin-2 receptor antagonist plus a diuretic ('Triple Whammy') in people over the age of 65 years. The measure looks at the people over the age of 65 years who are prescribed an angiotensin-converting enzyme or angiotensin-2 receptor antagonist plus a diuretic, and the percentage of those also prescribing an NSAID.

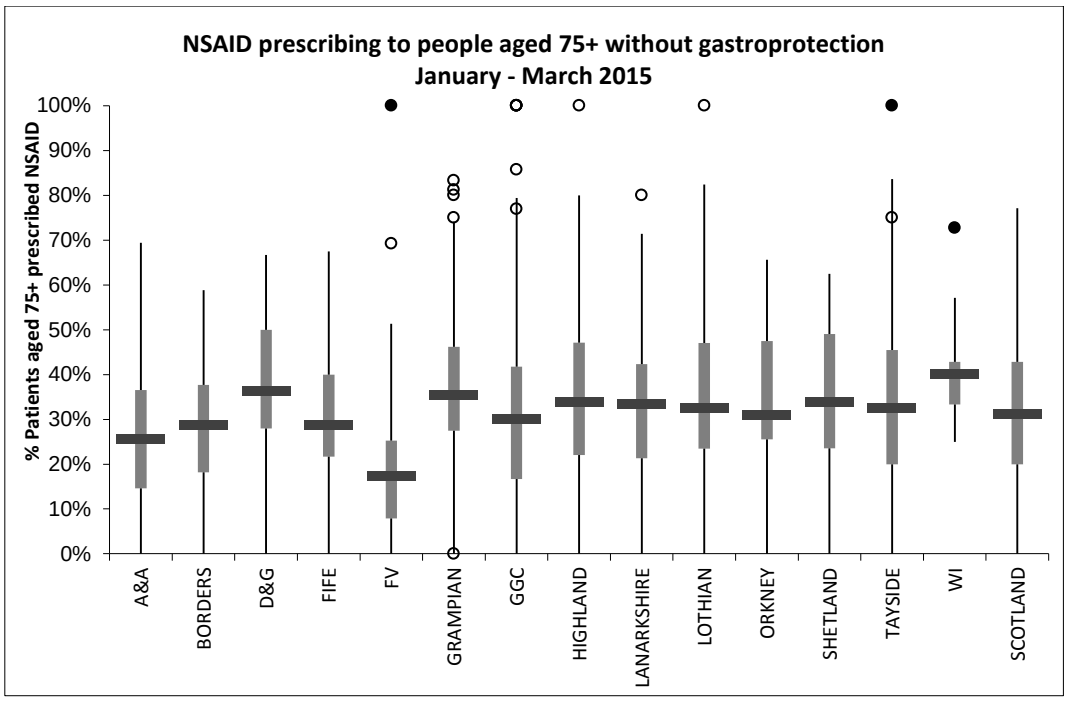




9.e Additional prescribing measure (APM): Percentage of people over 75 years who are prescribed an NSAID without gastroprotection.

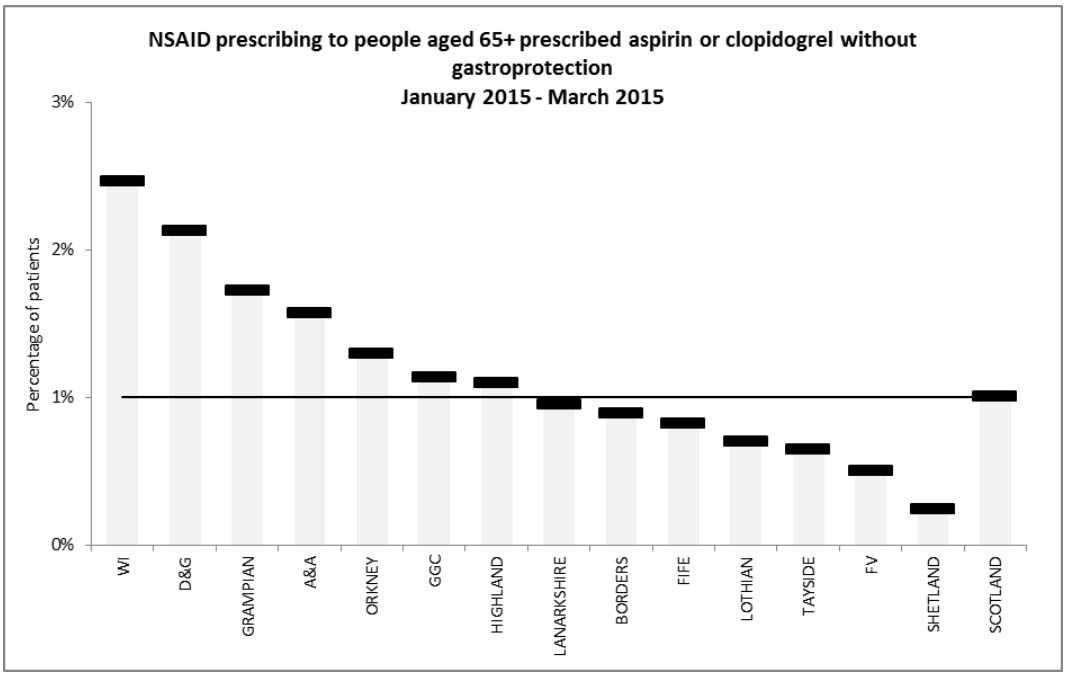
This additional prescribing measure (APM) focusses on the prescribing of NSAIDs to people over the age of 75 years, when there is no prescribed acid suppression. The measure looks at all those patients over the age of 75 years who are prescribed an NSAID and identifies the percentage of those not prescribed additional gastroprotection.

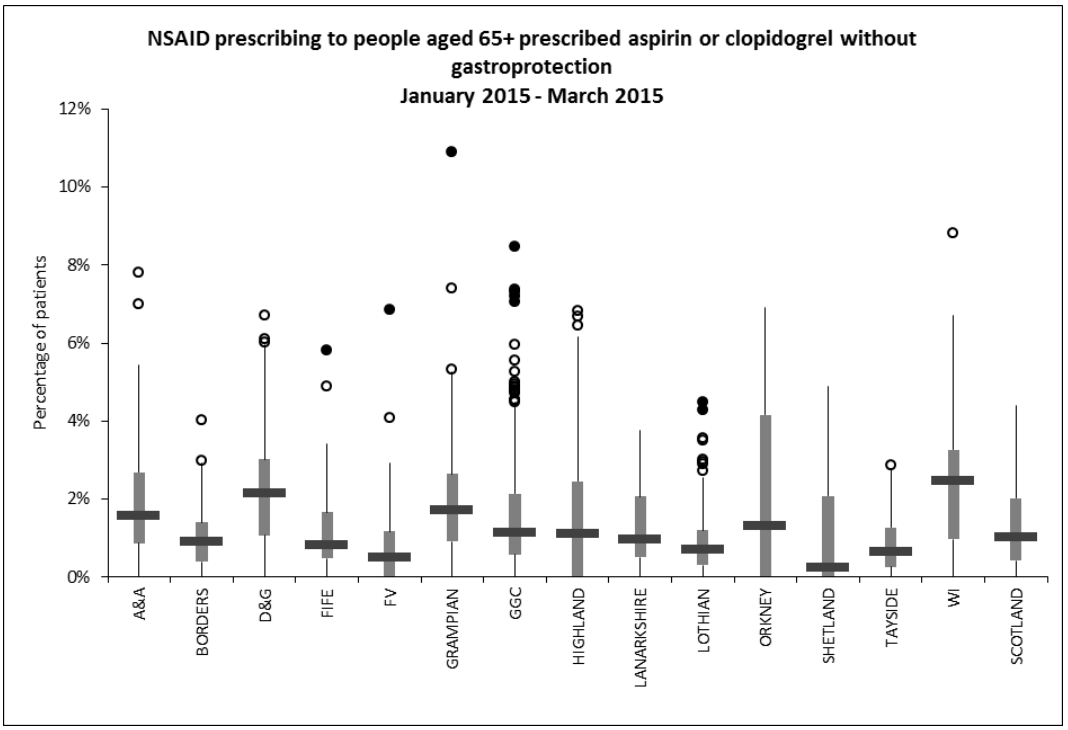




9.f Additional prescribing measure (APM): The number of patients over the age of 65 years who have been prescribed an NSAID plus aspirin and/or clopidogrel but without gastroprotection

This additional prescribing measure (APM) focusses on patients prescribed an NSAID, who are at increased risk of gastrointestinal side-effect due to age, concomitant prescribing of antiplatelet and no gastroprotection. The measure looks at all patients over the age of 65 years who are prescribed aspirin and/or clopidogrel and identifies the percentage of those who are also prescribed a NSAID, but no gastroprotection.





10. Antimicrobial Wound Dressings

The use of antimicrobial dressings has increased rapidly in recent years, despite the fact that the clinical and economic advice for the use of these agents remains poor. This indicator recognises that prescribing in this area is often nurse-led and highlights the need to engage nurses in the quality agenda. Support from the nursing profession at all levels will be required if change is to be achieved.

Spreading infection at the wound site requires treatment with systemic antibiotics.[1] An antimicrobial dressing may reduce bacteria at the wound surface but will not eliminate a spreading infection. If used, there should be regular review of the antimicrobial wound dressing and it should be stopped after two weeks if there is limited benefit.

A Cochrane Review looked at the use of topical silver for preventing wound infection.[2] The trials compared silver-containing products (dressings and creams) against products that did not contain silver. Most of the studies were small and of poor quality. The authors concluded that there was little evidence to support the use of silver-containing dressings.

Another Cochrane Review looked at the use of topical silver for treating infected wounds.[3] Three randomised controlled trials (RCTs) assessing the effectiveness of topical silver in the treatment of contaminated and infected acute or chronic wounds were identified. The review found that silver-containing foam dressings did not result in faster healing.

The VULCAN study was a non-blinded RCT and cost-effective analysis undertaken in the UK.[4] Patients (213) with venous leg ulcers (not necessarily infected) were randomised to silver or non-silver non-antimicrobial, low adherence dressings beneath compression. There was no difference between the groups in the proportion of patients achieving complete healing at 12 weeks, 6 months (RR 1.34; 95% CI 0.88 to 2.03) or at 12 months (RR 1.03; 95% CI 0.51 to 2.08). The authors concluded that there was little to support the use of silver dressings in the treatment of venous leg ulcers.

Healthcare Improvement Scotland recommends that, *Given the lack of clinical and cost effective evidence to support or refute the use of silver dressings to either prevent wound infection or completely heal wounds, it is suggested that their continued use should be supported only in the context of local research and audit examining their effectiveness in these key endpoints.*[5]

Current prescribing data strongly suggests that antimicrobial wound dressings are often used inappropriately. The poor evidence base should be recognised by all clinicians using these products. Only short-term use is recommended and clinical effect should be regularly reviewed.

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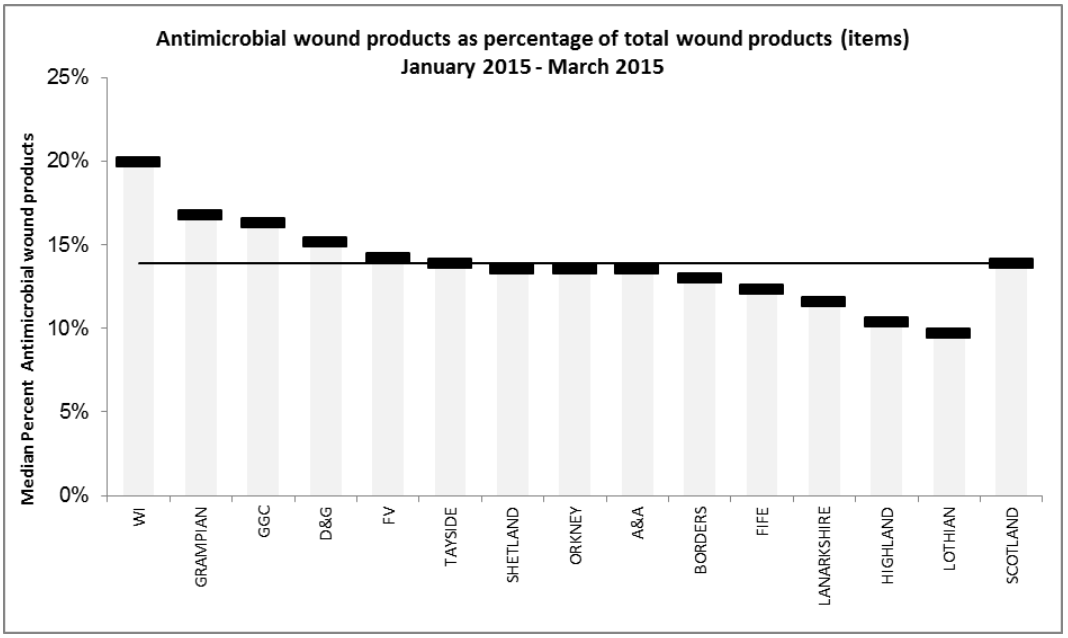
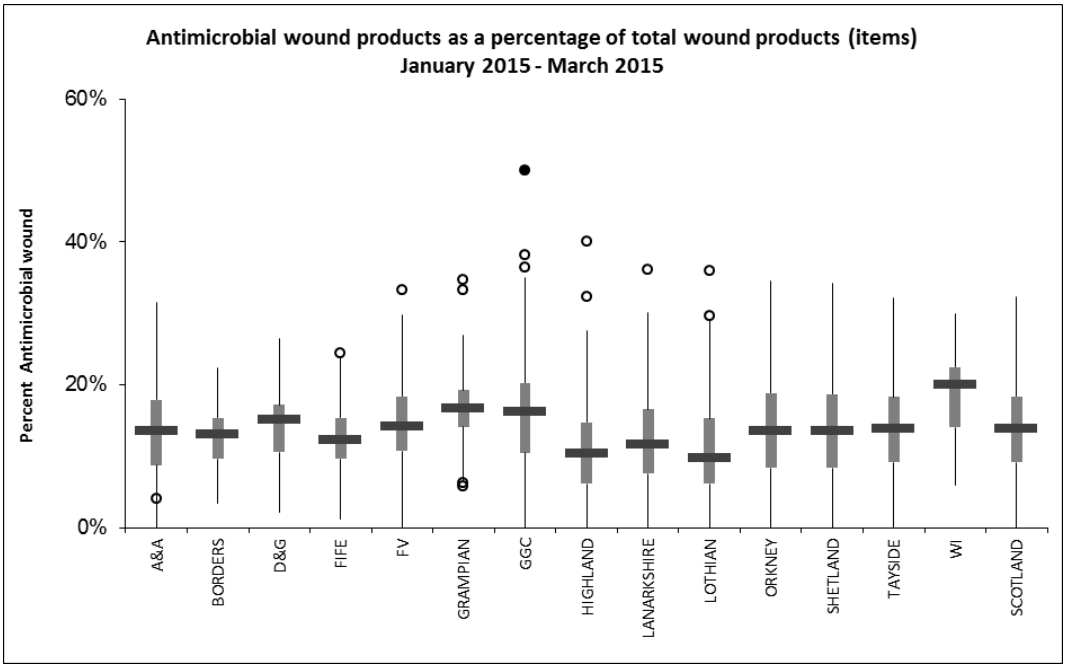
[1] Joint Formulary Committee. *British National Formulary.* Edition 69, September 2015
[2] Storm-Versloot MN, et al. *Cochrane Database of Systemic Reviews 2010,* Issue 3. Art. No: CD006478
[3] Vermeulen H, et al. *Cochrane Database of Systemic Reviews 2007*, Issue 1. Art. No: CD005486
[4] Michaels JA, et al. *Br J Surg 2009;* **96**: 1147-56
[5] Healthcare Improvement Scotland. Advice statement 001/13, January 2013

10.a Antimicrobial Wound Products: Antimicrobial wound products as percentage of total wound products (script items)

Antimicrobial wound dressings have a role to play in managing localised infection only in exceptional circumstances. Current prescribing data strongly suggests that these products are often used inappropriately. The lack of evidence for their use should be recognised by all clinicians using these products. Only short-term use is recommended and clinical effect should be regularly reviewed.





11. Black triangle medicines

This additional prescribing measure (APM) looks at the use of black triangle medicines. The measure looks at the volume of medicines prescribed for BNF chapters 1 to 7 and 9 to 13 and identifies the percentage of those that are black triangle medicines.